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Doctor of Philosophy in Public Health

THESIS

EFFECT OF INSTITUTIONALISING COMMUNITY HEALTH SYSTEM VITAL SIGNS ON PREVENTABLE NEONATAL DEATHS IN MASHONALAND WEST PROVINCE, ZIMBABWE, 2020 - 2021: A MIXED METHODS APPROACH

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A thesis submitted in fulfilment for the degree of Doctor of Philosophy in Public Health (PhD) of the University of Lusaka, Zambia.

DECLARATION

I, Meggie Gabida, affirm that I have thoroughly read and comprehended the University of Lusaka's regulations concerning plagiarism for PhD Students. This thesis, therefore, represents my original research and has not been previously submitted for any professional or academic purposes. Additionally, I confirm that all sources from other authors, whether published works or grey literature, have been appropriately cited and acknowledged to the best of my knowledge. Parts of this work have been published or submitted for publication; these are listed under Publications Arising from this Thesis.

Signed …… Date……

PUBLICATIONS ARISING FROM THIS THESIS

The following publications have arisen from the research reported in this thesis. I am the lead and corresponding author of both and was responsible for the conceptualisation, data collection, analysis and drafting of each manuscript, with contributions from my co-authors as described in each publication.

1. Gabida, M., Kazonga, E., Bowa, K., Dhege, C. and Chiurunge, P. (2025) 'Predictive modelling and community health system factors for reducing preventable neonatal deaths in Mashonaland West Province, Zimbabwe, 2020–2021', *East African Scholars Multidisciplinary Bulletin*, 8(2), pp. 28–50. Available at: https://doi.org/10.36349/easjmb.2025.v08i02.003.

2. Gabida, M., Kazonga, E. and Bowa, K. 'A critical paradigm analysis of community health system strengthening to reduce neonatal mortality in rural Zimbabwe'. *East African Scholars Multidiscip Bull, 9(4), 80-84. Available at:* https://doi.org/10.36349/easjmb.2026.v09i04.003.

Publication 1 reports findings from the cluster-randomised controlled trial described in Chapters Four and Five. Tables 18, 19, 23–27, 34, 41 and 42, and Figures 12, 14 and 23 of this thesis therefore present data that also appear, in the same or a similar form, in that article, which is published open access under a Creative Commons Attribution-NonCommercial 4.0 International licence (CC BY-NC 4.0). Publication 2 draws on the theoretical framing presented in Chapter Three and the discussion in Chapter Six.

This thesis is the complete account of the study. Where results reported in the thesis differ from those in the publications, the thesis reflects the final analysis.

DEDICATION

I am grateful to the Almighty for granting me the strength, resilience, knowledge, and wisdom necessary to complete this thesis successfully.

To my late grandmother (Mrs Meggie Muzvariri Ndlovu), who taught me to be optimistic and praise the Almighty despite life's obstacles.

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TABLE OF CONTENTS

DECLARATION ii
PUBLICATIONS ARISING FROM THIS THESIS iii
DEDICATION iv
ACKNOWLEDGEMENTS v
LIST OF TABLES xiv
LIST OF FIGURES xvi
ACRONYMS AND OPERATIONAL DEFINITIONS OF TERMS xvii
ABSTRACT xx
CHAPTER ONE 1
BACKGROUND TO THE STUDY 1
1.1 Introduction 1
1.2 Background of the problem 2
1.2.1 Global trends in neonatal mortality 4
1.2.2 Global causes of mortality in children under five years old, 2015 5
1.2.3 Global trend accelerating progress on under-five mortality, 2016 5
1.2.5 Country context 6
1.2.6 Zimbabwean Health Sector 8
1.2.7 Community health system and preventable neonatal deaths in Zimbabwe 9
1.2.8 Health sector performance indicators 12
1.3 Statement of the problem 14
1.3.1 Trends in Neonatal Mortality, Zimbabwe, 1999–2024 15
1.4 Objectives 16
1.4.1 Broad objective 16
1.4.2 Specific objectives 18
1.5 Questions to be answered 18
1.6 Hypothesis 19
1.7 Significance of the study 20
1.8 Scope and delimitation 21
1.9 Study limitations 22
1.10 Key definitions used 22
1.11 The organisation of the rest of the report 28
CHAPTER TWO 31
LITERATURE REVIEW 31
2.1 Introduction 31

2.2 Global context: health systems, primary health care, and the neonatal mortality burden 33
2.2.1 The global neonatal mortality crisis 33
2.2.2 Historical trajectory of community health and its institutionalisation 35
2.2.3 The WHO health system building blocks: applications and limitations 35
2.2.4 The Socio-Ecological Model and neonatal survival 36
2.2.5 Global frameworks and paradigm shifts in community health systems 38
2.3 Successes and failures in using community health systems to improve neonatal outcomes 39
2.3.1 Ethiopia: Institutionalisation as a core state function 39
2.3.2 Brazil: Formal employment as the distinguishing variable 40
2.3.3 Rwanda: Democratic accountability and governance integration 40
2.3.4 China: The limits of community trust without formal institutionalisation 41
2.3.5 Comparative lessons: African regional programmes 42
2.3.6 Synthesis: Five conditions differentiating effective from ineffective community health systems 43
Table 2: Conditions differentiating effective from ineffective community health systems 44
2.4 Structural gaps in the institutionalisation of community health systems 46
2.4.1 Governance and policy fragmentation 47
2.4.2 Inadequate and unstable financing 47
2.4.3 Human resources and workforce challenges 47
2.4.4 Data and health information system deficits 47
2.4.5 Limited community participation and social accountability 48
2.4.6 Scarcity of rigorous system-wide evaluations 48
2.4.7 Sociocultural and contextual barriers 48
2.5 Community-based interventions and neonatal mortality reduction 49
2.5.1 Evidence of effectiveness 49
2.5.2 Mechanisms of impact 49
2.5.3 Contextual adaptation and system integration 50
2.5.4 Implications for Zimbabwe 50
2.6 Neonatal mortality in Zimbabwe: Context and challenges 50
2.6.1 National epidemiological profile 50
2.6.2 Mashonaland West Province: Sub-provincial context 51
2.6.3 Key contextual challenges 52
2.6.4 COVID-19 and the 2020–2021 study period 53
2.6.5 Zimbabwe's Policy Response: The National Community Health Strategy 2020–2025 54
2.7 Methodological landscape: predictive modelling in community health systems 55

2.7.1 Statistical and epidemiological modelling approaches 55
2.7.2 Systems-thinking and dynamic modelling approaches 56
2.7.3 Machine learning and predictive analytics 57
2.7.4 Methodological choice: Rationale for this study's approach 58
2.8 Research gap and study rationale 59
2.8.1 Convergence of evidence on the institutionalisation deficit 59
2.8.2 The specific evidence gap 60
2.8.3 Study rationale and contribution 61
2.9 Theoretical and conceptual synthesis: connecting literature to framework 61
2.9.1 Theoretical foundations 61
2.9.2 Conceptual framework 62
2.9.3 Connecting literature to design 65
CHAPTER THREE 66
THEORETICAL AND CONCEPTUAL FRAMEWORK 66
3.1 Introduction 66
3.2 Research paradigm: The critical paradigm 66
3.2.1 Framing of the critical paradigm 66
3.2.2 Ontological Position 67
3.2.3 Epistemological Position 67
3.2.4 Axiological Position 67
3.2.5 Methodological implications 68
3.2.6 Justification for the critical paradigm 68
3.3 Theoretical Framework 69
3.3.1 The Mosley and Chen Analytical Framework 70
3.3.2 The Socio-Ecological Model (SEM) 71
3.3.3 The Modified Tanahashi Health Service Coverage Model 71
3.3.4 Complementarity, integration and necessity of frameworks 74
3.3.5 Contextualisation and rationale for framework selection within Zimbabwe's Community Health System 75
3.3.6 Summary of Integration and Application 76
Table 4: Comparative Summary of Frameworks and Integration Benefits 77
3.4 Conceptual Framework 82
3.5. Integrated causal pathway for the effect of institutionalising community vital signs on neonatal death 85
3.6 Operationalisation of Concepts 89
3.6.1 Institutionalising Community Health (Composite Independent Variable) 89
3.6.2 Key Measurable Components and Indicators 89
3.7 Operationalisation of variables 92

3.7.1 Justification for Inclusion of Key Variables 92
3.7.2 Addressing multicollinearity and use of multilevel modelling 98
3.8 Summary 99
CHAPTER FOUR 101
METHODOLOGY 101
4.1 Introduction 101
4.2 Research Design 103
4.2.1 Trial Design 104
4.3 Research Context 113
4.4 Eligibility Criteria 115
4.4.1 Inclusion Criteria 115
4.4.2 Exclusion Criteria 115
4.4.3 Methods of Recruitment 115
4.5 Intervention and Comparator 115
4.5.1 Control Clusters 115
4.5.2 Intervention Clusters 116
4.6 Study participants follow-up 124
4.7 Outcome measures 124
4.7.1 Endpoints for the study and expected outcomes 126
4.7.2 Process evaluation 126
4.9 Sample Size Determination and Rationale 128
4.9.1 Quantitative component 128
4.9.3 Qualitative Sampling and Saturation 130
4.10 Interim Analyses and Stopping Guidelines 130
4.11 Randomization 131
4.11.1 Randomisation and allocation sequence generation 131
4.11.2 Type of randomisation and restriction 131
4.11.3 Allocation concealment 132
4.11.4 Implementation of randomisation 132
4.11.5 Blinding 133
4.11.6 Participant recruitment and flow 133
4.12 Qualitative component 134
4.13 Description of the research instruments 134
4.14 Description of the data collection procedures 136
4.14.1 Quantitative data collection to meet QUAN objectives 136
4.14.2 Data collection 137
4.14.3 Qualitative data collection to meet qualitative objectives 137

4.14.4 Bias mitigation strategies 138
4.15 Description of data analysis and presentation procedures 138
4.15.1 Primary data analysis 138
4.15.2 Primary analysis model 139
4.15.3 Secondary analyses 141
4.15.4 Machine learning and predictive modelling 142
4.15.5 Subgroup analysis 149
4.15.6 Missing data, sensitivity analysis and model assessment 150
4.16 Secondary data analysis: Qualitative methods 150
4.17 COVID-19 protocol adaptations and implications 151
4.17.1 Bias Analysis Framework 153
4.18 Ethical Considerations 153
4.19 Summary 155
CHAPTER FIVE 156
DATA ANALYSIS, PRESENTATION OF FINDINGS 156
5.1 Introduction 156
5.2 Presentation of the Findings 157
5.2.1 Baseline information during formative research 157
5.2.2 Characteristics of households at the initial assessment 158
5.2.3 Household characteristics at baseline 159
5.2.4 Baseline neonatal mortality characteristics 160
5.2.5 Baseline Balance Table 160
5.3 Prospective trial enrolment of pregnant women 161
5.3.1 Primary Outcome: Neonatal mortality at 28 days 162
5.3.2 Trial Profile 164
5.3.3 Characteristics of pregnant women: A demographic and socio-economic overview 165
5.3.4 Qualitative analysis - Insights from Key Informant Interviews 171
5.4 Intervention Fidelity Results 172
5.4.1 Overall Composite Fidelity Score 172
5.4.2 Contamination/Spillover Analysis 173
5.4.3 Temporal stability of fidelity 174
5.4.4 National scale-up demonstration 174
5.4.5 Separation of national vs. intervention components 175
5.5 Causes and time of neonatal deaths 175
5.5.1 Socioeconomic status and neonatal deaths 176
5.5.2 Community health system predictors that are independently associated with reducing neonatal deaths 177

5.5.3 Correlation Analysis 184
5.5.4 Multivariable community health system prediction model, for reducing preventable neonatal deaths 185
5.5.5 Feature Importance Analysis 188
5.5.6 Risk and Protective Factors in Neonatal Mortality 189
5.5.7 Community Health System Model Equation 189
5.6 Machine learning and predictive modelling for institutionalising the community health system in reducing neonatal deaths 192
5.6.1 Cross-Validated Model Performance 193
5.6.2 Out-of-Fold Performance Metrics 195
5.6.3 Confusion Matrix Analysis 196
5.6.4 Probability Calibration 199
5.6.5 Cox Regression Analysis of Neonatal Mortality Covariates 200
5.7 Effect of the community health system on neonatal deaths 202
5.7.1 Community System Strengthening Institutional Framework Components 203
5.7.2 Pathway of institutionalising community health systems to reduce preventable neonatal deaths. 206
5.7.3 Diagram of synergistic effects between community health system components 208
5.7.4 Multilevel Logistic Regression for predicting preventable neonatal deaths 211
5.8. Qualitative Analysis: Structured Thematic Findings from Key Informant Interviews and Focus Group Discussions 216
5.8.1 Theme 1: Understanding of Institutionalisation of the Community Health System 216
5.8.2 Theme 2: Availability Coverage of Community Health System Components 219
5.8.3 Theme 3: Accessibility of Community Health Services 221
5.8.4 Theme 4: Acceptability, Utilisation, and Effective Coverage 225
5.8.6 Cross-Thematic Matrix: Comparison Across Participant Strata 227
5.8.7 Mixed-Methods Integration: Synthesis of Qualitative and Quantitative Evidence 228
5.8.8 Note on Analytical Rigour and Reflexivity 229
5.9 Summary 230
CHAPTER SIX 232
DISCUSSION OF RESULTS 232
6.1 Introduction 232
6.1.1 The interpretive paradox 232
6.1.2 What this chapter argues 232
6.1.3 A note on interpretation 233
6.2 Interpretation of principal findings 234
6.2.1 Independent predictive associations of IV1, IV2, and IV3 234

6.2.2 Magnitude of Individual and Combined Predictive Effects (Objective Two) 238
6.2.3 Predictive modelling and simulation projections 241
6.2.4 Strongest Predictors and Policy Implications 242
6.3 The multivariable community health system prediction model 245
6.4 Machine learning findings: Random Forest and Decision Tree 247
6.5 Qualitative analysis: Mechanisms, meanings, and structural conditions 250
6.5.1 Overview of the qualitative strand 250
6.5.2 Analytical Argument One: Institutional path dependency as the structural Antecedent of governance non-functionality 251
6.5.3 Analytical Argument Two: From availability to effective coverage — The failure of one-off support 252
6.5.4 Analytical Argument Three: Cross-Level SEM Mechanisms in Geographic and Social Access 254
6.5.5 Analytical Argument Four: Community Governance as the Mechanism for Effective Coverage 257
6.5.6 The dose-dependent effect of IV3: A cross-thematic synthesis 259
6.5.7 Reflexivity, trustworthiness, and analytical integrity 260
6.6 Contribution to the Global and African evidence base 260
6.7 Policy, practice, and research implications 264
6.7.1 The central policy argument 264
6.7.2 Health system strengthening 265
6.7.3 Practice implications 266
6.7.4 Research priorities 267
6.8 Research Strengths and Limitations 268
6.8.1 Strengths 268
6.9.1 Summary of key findings 276
CHAPTER SEVEN 279
CONCLUSION AND RECOMMENDATIONS 279
7.1 Introduction 279
7.2 Conclusions 280
7.3 Novel Contributions 284
7.4 Concluding Remarks 287
7.5 Recommendations 288
7.5.1 Ministry of Health and Child Care (MOHCC): National Level 289
7.5.2 Provincial Health Directorates (Mashonaland West and comparable provinces) 291
7.5.3 District Health Management Teams (DHMTs) 291
7.5.4 Village Health Committees (VHCs) and Health Centre Committees (HCCs) 293
7.5.5 Village Health Workers (VHWs) 293

7.5.6 Ministry of Primary and Secondary Education and Intersectoral Partners 294
7.6 Recommendations for Further Research 296
REFERENCES 298
APPENDICES 421
Appendix 1: Using the Tanahashi Model lens to analyse coverage of health services and community health system strengthening. 422
Appendix 2: Summary of evidence from reviews on key interventions with an impact on neonatal mortality 424
Preventive and promotional interventions 424
Appendix 3: Equations 426
5.3.2 Verbal Autopsy Limitations 426
Appendix 4: Feature Importance Analysis 427
5.5.4 Community Health System Model Equation 427
UNILUS Ethical Approval 433
Appendix 2: Medical Research Council of Zimbabwe Approval 435
Appendix 3: Permission to conduct the Study, Mashonaland West Province 436
Appendix 4 437
INFORMED CONSENT FORM FOR PARENTAL CONSENT (English) (Adapted from the MRCZ Consent Form) 437
Appendix 5 444
TSAMBA YEMVUMO YEMUBEREKI (Shona) (Adapted from the MRCZ Parental Consent Form) 444
Appendix 6 449
Women of Childbearing Age Enumeration Form 449
Appendix 7 451
Household Questionnaire (Day 3, Day 7 and Day 28) 451
Appendix 8 463
Neonatal Community Verbal Autopsy (Adapted from International Standard Verbal Autopsy Questionnaires, (WHO, 2007) 463
Appendix 9 469
Key Informant Interviews: Questionnaire for District Community Health Supervisors 469

LIST OF TABLES

Table 1: Deaths in children below five years, 2021 5
Table 2: Conditions differentiating effective from ineffective community health systems 44
Table 3: Summary of the modelling approaches reviewed and their applicability to this study 59
Table 4: Comparative Summary of Frameworks and Integration Benefits 77
Table 5: Frameworks, Key Variables, and Analytic Methods 78
Table 6: Research Question-Variable-Indicator-Analytic Model Mapping 79
Table 7: Hypothesis Pathway Summary 81
Table 8: Variables utilised in the examination of influences on neonatal deaths 95
Table 9: Intervention Fidelity Measurement Framework 110
Table 10: Package of services for households 118
Table 11: Study endpoints and outcomes 125
Table 12: Prospective surveillance tools and content 135
Table 13: Summary of expected FGDs, IDIs and KIIs in Mashonaland West province 137
Table 14: Empirical intracluster correlation coefficients 140
Table 15: DAG Informed Covariate Selection Rules 142
Table 16: Algorithms evaluated, rationale for selection, and key references 144
Table 17: Pre-specified performance metrics, formulae, and rationale for inclusion ... 146
Table 18: Analysis of the initial population of women of reproductive age (15-49 years) surveyed between February and April 2020. 157
Table 19: Essential data regarding respondents 158
Table 20: Household characteristics at baseline 159
Table 21: Baseline neonatal mortality characteristics 160
Table 22: Baseline Characteristics by Trial Arm 161
Table 23: Household characteristics by intervention allocation for women of childbearing age, 2020-2021 (n=973 166
Table 24: Demographic characteristics of women of childbearing age by intervention allocation, 2020-2021 (N=973) 167
Table 25: Characteristics of neonate by intervention allocation, 2020-2021 (n=973 168
Table 26: Community Characteristics Based on Intervention Group Allocation, 2020-2021 (n=973) 169
Table 27: Service Delivery Features by Intervention Group Allocation, 2020-2021 (n=973) 170
Table 28: Summary of Focus Group Discussions and Key Informant Interviews in Mashonaland West Province 172
Table 29: NIH BCC Fidelity Framework by Trial Arm 173
Table 30: Exposure to intervention components in the control arm - Contamination/spillover analysis 174
Table 31: Critical program gaps and intervention boost 175
Table 32: Community health system predictors of neonatal deaths, Mashonaland West province, 2020-2021 180
Table 33: Multiple Testing Adjustment for Secondary Outcomes 184
Table 34: Predictive model using multiple logistic regression for community health systems aimed at reducing preventable neonatal deaths in Mashonaland West Province, 2020-2021. 187

Table 35: Leave-One-Cluster-Out cross-validated performance of four predictive models for preventable neonatal death (n = 973). 194
Table 36: Out-of-fold model performance on the full analytic sample (n = 973) under Leave-One-Cluster-Out cross-validation, with DeLong's ROC AUC estimates and calibration scores 196
Table 37: Confusion matrices and derived classification statistics for all four classifiers, aggregated from out-of-fold predictions under Leave-One-Cluster-Out cross-validation (n = 973) 198
Table 38: Hosmer -Lemeshow calibration test results for all four classifiers, applied to aggregated out-of-fold predicted probabilities (n = 973) 200
Table 39: Cox proportional hazards regression: community health system variables associated with neonatal mortality (n = 973; 68 events) 201
Table 40: Omnibus tests of model coefficients for the Cox community health system regression model 202
Table 41: Multilevel Logistic Regression for predicting preventable neonatal deaths through the community health system, Mashonaland West 213
Table 42: Weighted two and three-level random intercept logit model for predicting preventable neonatal deaths, Mashonaland West, 2020-2021 214
Table 43: Summary of Themes Emerging from Qualitative Analysis (NVivo-supported thematic content analysis) 216
Table 44: Qualitative availability indicators and quantitative findings, Mashonaland West, 2020-2021 219
Table 45: Cross-Thematic Matrix: Participant Strata Comparison (NVivo, Mashonaland West KIIs and FGDs, 2020–2021) 227
Table 46: Mixed-Methods Integration Matrix - Qualitative Themes and Quantitative Confirmation, Mashonaland West, 2020–2021 228
Table 47: Community health system model coefficients and variables 429

LIST OF FIGURES

Figure 1:"Levels of care in the health system in Zimbabwe" (Lassi, & Salam, 2025). 8
Figure 2: Relationship between institutional deliveries and under five mortality (Source: Zimbabwe Demographic Health Survey, 2015 13
Figure 3: Under five mortality and Neonatal Mortality in Zimbabwe. Adopted from MICS Report, 2019 13
Figure 4: Trend in neonatal mortality in Mashonaland West Province compared to the national average, 1999 – 2024 15
Figure 5: Map for Mashonaland West province 21
Figure 6: Global trend accelerating progress on under-five mortality, 2016 34
Figure 7: Bridging Neonatal Survival Gaps: SEM Levels and Community Health System Vital Signs 38
Figure 8: Illustration of the progression of neonatal mortality rates in Zimbabwe from 1990 through 2022 51
Figure 9: Theoretical Framework 73
Figure 10: Conceptual Framework on reducing neonatal deaths 87
Figure 11: Structure for testing the effect of institutionalising community vital signs on neonatal death 88
Figure 12: Modified women's and men's learning and action groups on community-led reduction in neonatal deaths 121
Figure 13: Key elements of the social accountability model 122
Figure 14: Trial Profile: Randomisation of study participants to intervention and control clusters 164
Figure 15: Reported Day of death for the 68 Neonatal Deaths, 2020-2021 176
Figure 16: Comparison of neonatal death by socio-economic status, Mashonaland West province, 2020-2021 177
Figure 17: Correlation heatmap of predictors of neonatal deaths, Mashonaland West province, 2020-2021 184
Figure 18: Feature Importance in Neonatal Death Prediction 188
Figure 19: Risk and protective factors in neonatal deaths – conceptual schematic 191
Figure 20: Temporal effect of the community health system on neonatal deaths, Mashonaland West province, 2020-2021 204
Figure 21: Community Health System Framework for Reducing Neonatal Deaths, Mashonaland West province 205
Figure 22: Pathway of institutionalising community health system for reducing preventable neonatal deaths, Mashonaland West province, 2020-2021 207
Figure 23: Diagram of synergistic effects between community health system components on reducing neonatal deaths, Mashonaland West Province, 2020 - 2021 210
Figure 24: Proposed Community-Based Implementation Strategy to Reduce Neonatal Deaths in Mashonaland West Province, 2020-2021 284
Figure 25: Proposed community-based conceptual framework for reducing neonatal deaths 287

ACRONYMS AND OPERATIONAL DEFINITIONS OF TERMS

ANMs	Auxiliary Nursing Midwives
APH	Antepartum Haemorrhage
ARI	Acute Respiratory Infections
ARSS	At Risk Surveillance System
ART	Antiretroviral Therapy
ASHA	Accredited Social Health Activists
ASM	*Animatrice de Sante Maternelle*
BCC	Behaviour Change Communication
BEmNOC	Basic Emergency Obstetric and Neonatal Care
CBPHC	Community-based primary health care
CDC	Centres for Disease Control and Prevention
CEHP	Community Essential Health Package
CEmNOC	Comprehensive Emergency Obstetric and Neonatal Care
CH	Community Health
CHA	Community Health Assistant
CH-CoP	Community Health Community of Practice
CHEW	Community Health Extension Worker
CHPS	Community-based Health Planning and Services
CHS	Community Health System
CHW	Community Health Worker
CPAP	Continuous Positive Airway Pressure
CPR	Contraceptive Prevalence Rate

CSO	Civil Society Organisation
CSS	Community Systems Strengthening
DOH	Department of Health
EBF	Exclusive Breastfeeding
ENAP	Every Newborn Action Plan
ENND	Early Neonatal Death
FSB	Fresh Stillbirths
HBB	Helping Babies Breathe
HBS	Helping Babies Survive
HDA	Health Development Army
HEP	Health Extension Program
HEWs	Health Extension Workers
HFA	Health Facility Assessment
HIV	Human Immunodeficiency Virus
iCCM	Integrated Community Case Management
IMNCI	Integrated Management of Neonatal and Childhood Illnesses
IMR	Infant Mortality Rate
IPTp	Intermittent Preventive Treatment of Malaria
ITNs	Insecticide Treated Nets
LBW	Low Birth Weight
KMC	Kangaroo Mother Care
NGO	Non-Governmental Organization
MICS	Multiple Cluster Indicator Survey
MOHCC	Ministry of Health and Child Care

MMR	Maternal Mortality Rate
NNM	Neonatal Mortality
NNMR	Neonatal Mortality Rate
ORS	Oral Rehydration Solution
PIH	Pregnancy Induced Hypertension
RCTs	Randomized Controlled Trials
rPNC	re-engineering primary health care
SAfH	Social Accountability for Health
SACE	Social Accountability and Community Engagement
SBCC	Social and Behavior Change Communication
SDOH	Social Determinants of Health
UHC	Universal Health Coverage
UN	United Nations
UN IGME	UN Inter-agency Group for Child Mortality Estimation
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
VHTs	Village Health Teams
VHWs	Village Health Workers
VVHWs	Volunteer Village Health Workers
WHO	World Health Organisation
ZDHS	Zimbabwe Demographic and Health Survey

ABSTRACT

Background: Preventable neonatal mortality remains a critical public-health challenge in Zimbabwe despite relatively high coverage of antenatal care and facility-based childbirth. This study evaluated whether institutionalising three core "vital signs" of the community health system (i) a trained and supported Village Health Worker (VHW) workforce, (ii) functional community governance through Village Health Committees, and (iii) modified Women's and Men's Learning and Action (WLA/MLA) groups could reduce neonatal mortality in rural communities in Mashonaland West Province, Zimbabwe.

Methods: An embedded quantitative–qualitative mixed-methods design was undertaken within a two-arm pragmatic cluster-randomised controlled trial comprising 52 ward-level clusters. Intervention clusters received an institutionalised package integrating the three community health-system vital signs, while control clusters continued standard Ministry of Health and Child Care community health service delivery. A total of 984 pregnant women were enrolled, with live-born infants followed through 28 days of life. The primary outcome was neonatal death from 0–28 days, used as the measurable outcome for preventable neonatal mortality. Deaths were identified through household surveillance and confirmed using verbal autopsy or facility records. The primary analysis followed the intention-to-treat principle and used a three-level mixed-effects log-binomial regression model, incorporating random intercepts for cluster and VHW catchment, to estimate adjusted risk ratios (ARRs) with 95% confidence intervals. A concurrent qualitative process evaluation, comprising in-depth interviews, focus group discussions and observation, explored implementation pathways and was analysed thematically before integration with the quantitative findings.

Results: Among 973 mother–infant pairs included in the analysis, 882 live births were recorded, including 446 in intervention clusters and 436 in control clusters. Neonatal mortality was 4.5% (20/446; 44.8 per 1,000 live births) in intervention clusters compared with 11.0% (48/436; 110.1 per 1,000 live births) in control clusters. The intervention package was associated with a substantially lower risk of neonatal death (ARR 0.43, 95% CI 0.26–0.70; $p < 0.001$), corresponding to a 57% relative reduction and a number needed to treat of 16 mother–infant pairs (95% CI 11–29). Low birthweight (<2,500 g) and lower levels of community women's literacy were the strongest baseline risk factors for neonatal death. Qualitative findings suggested that the intervention strengthened recognition of neonatal danger signs, timely care-seeking, referral and community-level support for maternal and newborn health.

Conclusion: Institutionalising three community health-system vital signs as an integrated package was associated with a substantial reduction in neonatal mortality in rural Mashonaland West Province during 2020–2021. The findings provide experimental evidence that strengthening community health-system capacity, governance and participatory action concurrently can improve neonatal survival. Because the components were delivered as a combined intervention, the trial establishes the effect of the package rather than individual components; component-specific estimates are therefore adjusted associations. These findings support consideration of

the integrated package within Zimbabwe's National Community Health Strategy and comparable resource-constrained rural settings.

Limitations: Interpretation is constrained by the 12-month follow-up period, relatively small number of neonatal deaths, disruption associated with the COVID-19 pandemic, potential contamination from concurrent national community-health programmes, and the single-province study setting, which may limit precision and external generalisability.

Keywords: Neonatal mortality; Community health systems; Village Health Workers; Community governance; Mixed-methods research

CHAPTER ONE

BACKGROUND TO THE STUDY

1.1 Introduction

Preventable neonatal deaths remain one of the most urgent and unresolved public health challenges of the 21st century. Despite decades of investment in facility-based care and global commitments to the Sustainable Development Goals (SDGs), neonatal mortality in Africa South of the Sahara, and in Zimbabwe specifically, has remained very high. This chapter defines the key constructs embedded in the research title, contextualises the problem of preventable neonatal deaths, and establishes the rationale for examining the institutionalisation of community health system vital signs as a predictor of neonatal survival. Four concepts are central to this thesis and require precise definition at the outset.

First, the Community Health System (CHS) refers to the networks of local actors, relationships, governance structures, and processes that promote health within communities and households, operating alongside but integrated with formal health structures (Schneider *et al.,* 2022). In Zimbabwe's context, the CHS is anchored on seven building blocks aligned to the WHO building blocks (Leadership/Governance, Health Financing, Health Workforce, Medical Products, Health Information, and Service Delivery) with a focus on three core vital signs: the community health workforce, community governance structures, and adapted learning and action groups.

Second, the vital signs of the community health system are the core, measurable drivers that determine whether it is functional and capable of producing health outcomes. Just as clinical vital signs indicate whether a patient is alive and stable, community health system vital signs indicate whether the system is active, accountable, and effective. In this study, the three vital signs are: (i) the village health workers (VHWs)/community health workforce, (ii) community governance, and (iii) adapted women's and men's learning and action groups.

Third, institutionalisation of the community health system refers to the deliberate process of embedding these vital signs into the routine structures, policies, and accountability mechanisms of the formal health system, ensuring their sustainability,

measurability, and integration with district-level health planning and reporting (Karim *et al.,* 2022).

Fourth, preventable neonatal deaths are deaths of live-born infants within the first 28 days of life that could have been averted through timely and appropriate care at the community or institutional level. In this study, the focus is specifically on deaths attributable to preterm birth complications and neonatal infections, which are the leading preventable causes in the Zimbabwean context (MOHCC, 2016; WHO, 2024).

The WHO (2016) identified a range of high-impact interventions to reduce neonatal mortality, spanning quality delivery care, care for small and vulnerable newborns, and management of sick newborns. Critically, the reach and effectiveness of these interventions at the household level depend on a functional community health system, making the institutionalisation of community health system vital signs central to their delivery. This study's outcome of interest is the preventable neonatal mortality rate per 1,000 live births. Postnatal visit coverage within 48–72 hours of birth, timely referral following detection of neonatal danger signs, care-seeking and community-level coverage of essential newborn care practices are process indicators on the hypothesised pathway between institutionalisation and neonatal survival; they are analysed as secondary and process outcomes and are not treated as equivalent to neonatal mortality. With these definitions established, this chapter traces the evolution from individual healthcare to organised community health movements for improving population well-being. The chapter examines historical trends in neonatal mortality from global, regional, and local perspectives, and contextualises preventable neonatal deaths in Mashonaland West Province, Zimbabwe (Mekonnen *et al.,* 2023).

This study explores the centrality of community empowerment in health and its influence on contemporary approaches to health care delivery, setting the stage for understanding how the institutionalisation of community health system vital signs can be modelled as a predictor of reduced preventable neonatal deaths.

1.2 Background of the problem

Community health, as an organised approach to population well-being, has evolved over several decades, shaped by the growing recognition that complex, interrelated factors extend well beyond the formal health sector (WHO, 2002; WHO, 2008; Solar

& Irwin, 2010). Persistent gaps between service provision and utilisation, compounded by a shifting disease burden, drove scholars and policymakers to acknowledge the social determinants of health as fundamental drivers of health outcomes.

This recognition brought community participation to the center of health discourse. Communities were acknowledged as possessing contextual knowledge of their own health challenges and viable local solutions, making their involvement essential to effective health system design (Montesanti, 2010; Lasker & Guidry, 2008; WHO and UNICEF, 2021). Chapter 2 examines the evolution of these social determinants and community health frameworks.

Persistent global health inequities culminated in the Alma-Ata Declaration of 1978, which proposed primary health care (PHC) as a model for health delivery centered on community participation, multisectoral collaboration, and equitable access (WHO, 1978). The Ottawa Charter of 1986 subsequently strengthened this framework by articulating the conditions necessary for community empowerment.

The commitment to PHC was reaffirmed at the regional level through the 2008 Ouagadougou Declaration, which called on African member states to institutionalise community health systems and strengthen accountability across all levels of the health system (WHO, 2008; Maly *et al.,* 2019). These priorities align with the six WHO health system building blocks, which provide the framework within which this study situates the institutionalisation of community health system vital signs (WHO, 2008; WHO, 2014). The detailed PHC policy trajectory and its relevance to community health system development are reviewed in Chapter 2.

Progress towards the SDGs by 2030 remains uneven across the African continent, with persistent epistemological and structural challenges that complicate the attainment of global health targets, particularly in maternal and neonatal health (United Nations, 2015; Moses, 2024). Despite ongoing efforts, under-five mortality in sub-Saharan Africa was estimated at 72 per 1,000 live births in 2022, almost three times the SDG target of 25 per 1,000 live births (UN IGME, 2024).

SDG target 3.2.2 calls for all nations to achieve a neonatal mortality rate (NMR) of no more than 12 per 1,000 live births by 2030 (Odimegwu & Adewoyin, 2022; Usman *et al.,* 2022). Maternal mortality also remains well above the SDG target, estimated at around 510 per 100,000 live births, compared with the 2030 target of 70 per 100,000

live births (United Nations, 2016). These figures underscore the urgency of community-level interventions to complement facility-based care.

Substantial evidence shows that community-led interventions can significantly improve outcomes for mothers, neonates, and children (Lassi *et al.,* 2016; Story *et al.,* 2017). However, community-based care remains the weakest component of health systems in many developing nations, even though approximately 97% of maternal, neonatal, and child mortality occurs in these settings (Saleem *et al.,* 2014; Bhutta *et al.,* 2017; Nwameme, Tabong & Adongo, 2018).

1.2.1 Global trends in neonatal mortality

The first 28 days after birth, known as the neonatal period, represent the most critical phase for a child's survival (Mitiku, 2021; Tamir, 2024). Infants are at the highest risk of dying during this period, with almost 75% of neonatal deaths occurring within the first seven days of life (WHO, 2024). In 2022, the global neonatal mortality rate was approximately 17 per 1,000 live births, and neonatal deaths accounted for close to half of all deaths among children under five (UN IGME, 2024).

The primary causes of neonatal death globally are preterm birth complications (35%), intrapartum complications including birth asphyxia (23%), and neonatal infections (15%), together accounting for over 75.8% of total neonatal deaths (Kananura *et al.,* 2016; WHO, 2024). In the early neonatal phase, preterm birth and intrapartum complications predominate, while infections such as neonatal sepsis, pneumonia, and meningitis are the leading contributors during the late neonatal period (Oza *et al.,* 2015; Getahun, 2024). Importantly, most of these deaths are preventable through targeted interventions.

1.2.2 Global causes of mortality in children under five years old, 2015

Table 1: Deaths in children below five years, 2021

Newborns deaths		**Deaths in children aged 1-59 months**	
Prematurity	17%	Lower respiratory tract infections	10.5%
Birth asphyxia	10.9%	Malaria	8.8%
Other neonatal deaths	4.9%	Diarrhoea	8.1%
Congenital anomalies	4.7%	Other communicable diseases	5.6%
Lower respiratory infections	3.7%	Injuries	5%
Sepsis	3.4%	Other NCDs	3.4%
Diarrhoea	0.6%	Congenital anomalies	3.3%
Injuries	0.3%	Tuberculosis	2.7%
Meningitis/ encephalitis	0.3%	Measles	2.2%
Tetanus	0.2%	Meningitis/ encephalitis	1.6%
		Prematurity	1.1%
		HIV/AIDS	0.9%
		Birth asphyxia/trauma	0.6%

Source: UNICEF Data Repository, 2021

Ending preventable child deaths by 2030 is a key target of SDG 3, with the goal that every child, regardless of the circumstances of birth, has an equal chance of survival (Hug *et al.,* 2019). Between 1990 and 2017, the global neonatal mortality rate declined by 51%, from an estimated 5 million to 2.5 million deaths annually (WHO, 2015; Hug *et al.,* 2019). NMRs vary widely across regions, with the highest rates recorded in Central Africa, West Africa, and South Asia in 2023 (UNICEF, 2023). Progress accelerated between 2000 and 2017 compared with the preceding decade (WHO, 2017).

1.2.3 Global trend accelerating progress on under-five mortality, 2016

At the current pace of progress, 27.8 million children are projected to die within the first 28 days of life by 2030 (UN IGME, 2019). Zimbabwe ranks among the 63 countries most likely to miss the SDG neonatal mortality target, requiring at least a two-fold acceleration of progress (WHO, 2017; Sharrow *et al.,* 2022; WHO, 2023). Chapter 2 presents the full epidemiological analysis and cause-of-death breakdown.

1.2.4 Neonatal mortality in sub-Saharan Africa

Sub-Saharan Africa experiences the highest risk of neonatal death within the first month of life and has made the least progress in reducing such mortality (Tura *et al.,* 2013). In 2022, the region recorded the highest neonatal mortality rate of any world region, approximately 27 deaths per 1,000 live births, against a global average of 17 and accounted for more than 40% of all neonatal deaths worldwide (UN IGME, 2024). The rate of decline in neonatal mortality has been slower than for older children, so that the neonatal share of under-five deaths continues to rise.

Achieving significant reductions in neonatal mortality requires substantial investment in resilient primary healthcare systems, both institutional and community-based, ensuring effective coverage, quality care during the antenatal period, labour, and childbirth, and targeted follow-up for small and sick newborns within the first seven days of life (Kruk *et al.,* 2024; WHO, 2022). Such investments also prevent long-term disability among surviving children (Bhutta *et al.,* 2014).

Various community-based and community-led health interventions and initiatives in countries such as Malawi, Ethiopia, and Rwanda have demonstrated significant success in "achieving key Millennium Development Goals (MDGs), specifically a two-thirds reduction in under-five mortality and a 75% decrease in maternal mortality by 2015 compared to 1990 levels" (Zimba *et al.,* 2012; Kananura *et al.,* 2016; Mengesha & Sahle, 2017; Ruducha *et al.,* 2017; Annan & Asiedu, 2018; Sharrow *et al.,* 2022). These approaches have also proven "effective and cost-efficient in improving child and maternal health outcomes across diverse settings" (Bjorkman & Svensson, 2009; Datiko & Lintjorn, 2010; Zulliger, 2012; Puett *et al.,* 2013; Neupane *et al.,* 2014; Gwacham-Anisiobi *et al.,* 2024).

1.2.5 Country context

Zimbabwe's population exceeds 16 million and is characterised by a predominantly youthful structure, with approximately 50% under the age of 18 (ZIMSTAT, 2018). Women constitute 52% of the population, with women of reproductive age accounting for 23.4% of the total (ZDHS, 2015). These demographic characteristics shape the demand for maternal and neonatal health services and are central to the study's context.

Zimbabwe has prioritised education as a driver of health improvement, achieving a near-universal adult literacy rate of 94%, with 73% of women aged 15–49 having attended or completed secondary school or higher (ZDHS, 2015; UNICEF, 2018). These gains support improved health-seeking behaviour, particularly among women of reproductive age.

1.2.5.1 Socio-economic situation

Zimbabwe's socio-economic environment directly shapes health outcomes, particularly for mothers and neonates. Following the near collapse of the health system in 2008, the economy partially recovered between 2009 and 2013, but fiscal space has remained constrained, with GDP per capita at approximately USD 1,008 in 2016 and more than 67% of the rural population living below the poverty line (ZDHS, 2015; Cuneo, Sollom & Beyrer, 2017). Gender inequality compounds these challenges: the community health workforce is over 80% female, yet national gender policies have not fully translated into equal economic opportunities for women, limiting their power in health decision-making (WHO, 2018; Idris *et al.,* 2023).

1.2.5.2 The pragmatic analysis of women's and children's situation in Zimbabwe

Only 41% of women are employed compared to 65% of men, limiting their power in health decision-making and care-seeking behaviour (ZDHS, 2015; WHO, 2018). Zimbabwe ranks among the 40 countries with the highest maternal mortality, with the MICS 2014 reporting 614 deaths per 100,000 live births, the majority from preventable causes (Family Health Department Annual Report, 2016). Despite 93% ANC coverage and 77% institutional delivery with a skilled birth attendant, women continue to die, predominantly within health facilities, pointing to quality-of-care deficits rather than access alone (ZDHS, 2015; MOHCC, 2016). Barriers to care include limited transportation, out-of-pocket costs, and low community awareness of danger signs; 42% of rural women still deliver at home (MICS, 2019). Neonatal mortality accounts for 44% of all under-five deaths in Zimbabwe, with birth asphyxia, prematurity, and neonatal infections as the leading preventable causes (ZDHS, 2015; MOHCC, 2015). A marked rural-urban divide persists, with neonatal mortality substantially higher in rural areas.

1.2.6 Zimbabwean Health Sector

Zimbabwe operates a five-tier health delivery system, adopted in line with the PHC approach in 1980, ranging from primary to quinary levels (Ray & Masuka, 2017). The community level is recognised but remains largely uninstitutionalised within this structure. No province has met the national target for health facility density, and an estimated 40% of the rural population lives more than 5 km from the nearest health facility, creating geographic barriers that community health systems are well-positioned to address (MOHCC, 2015; Dodzo & Mhloyi, 2017).

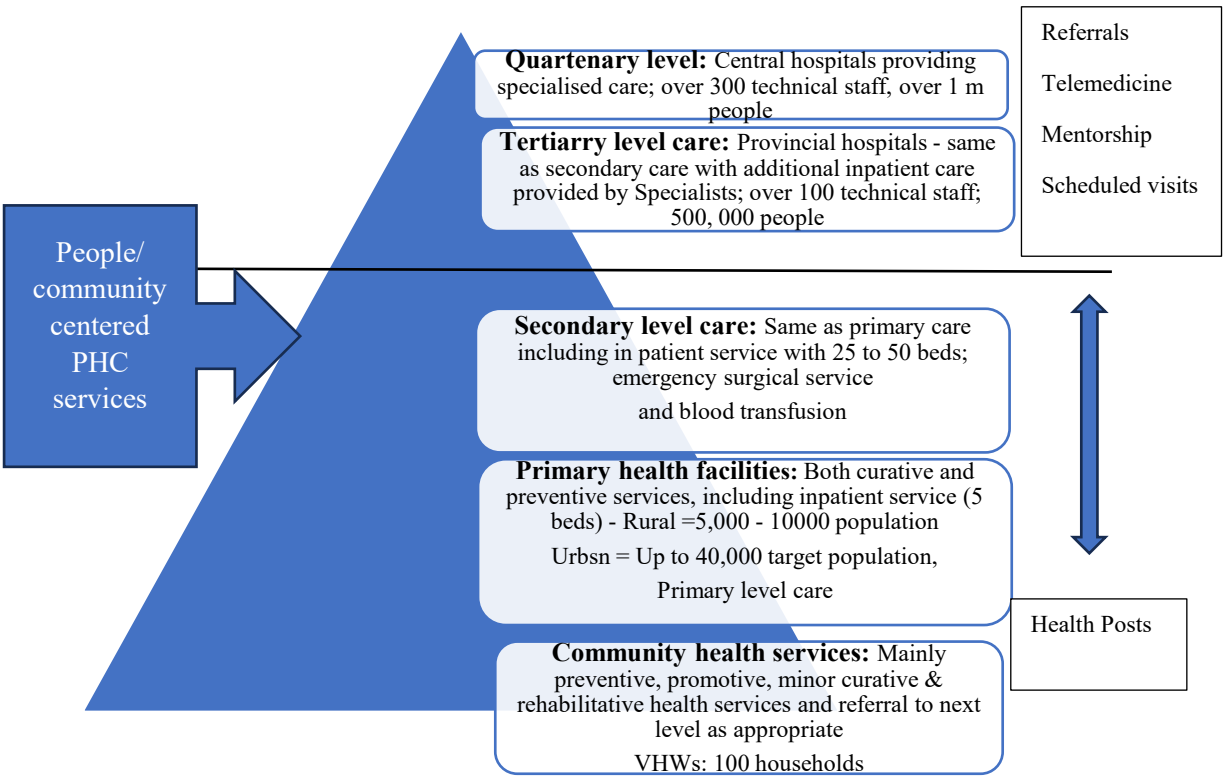


Figure 1:"Levels of care in the health system in Zimbabwe" (Lassi, & Salam, 2025).

1.2.7 Community health system and preventable neonatal deaths in Zimbabwe

Community health systems are widely documented as accelerators of progress towards the SDGs, and particularly towards universal health coverage, on the African continent (Oleribe *et al.,* 2019; Saviano *et al.,* 2019; Kieny *et al.,* 2017). Zimbabwe has committed to strengthening the primary health care approach and to building the community systems that underpin it. The development of the first National Community Health Strategy 2020–2025, together with the package of essential health services for the community level, marked the beginning of the road towards institutionalising community health services; the Ministry of Health and Child Care ratified the strategy in 2020.

Community health services include those delivered through community initiatives, outreach services and community health workers (CHWs). Historically, CHWs have contributed significantly to the fight against the top killers of women and children, responded to health emergencies and curbed the growing burden of non-communicable diseases (Bonita & Beaglehole, 2014). At the core of community health is providing basic health services to rural and urban communities, with full community participation and ownership, reaching every household (LeBan, Kok & Perry, 2021).

Recognised CHWs have existed in Zimbabwe since 1980, when the government established village health workers (VHWs) in line with the Alma-Ata Declaration (MOHCC, 2015; Kambarami *et al.,* 2016). Their work ranged from prevention and promotion services to treatment of minor ailments (Jongdeepaisal *et al.,* 2024). As the disease burden changed, VHWs were assigned more tasks, including community case management and Vitamin A supplementation. However, this was done with inadequate training, limited supportive supervision, limited geographical coverage, and limited involvement of local governance structures. Today, Zimbabwe has various typologies of community health workers, including "paid and unpaid individuals" who work within the health sector as volunteers **(**Kasteng *et al.,* 2016). VHWs make up the majority of community health workers, with over 23,400 distributed across the country, compared with the required 40,000 (Africa CDC & UNICEF, 2025). The VHWs are volunteers who receive a quarterly stipend and other non-financial incentives, including uniforms, bags, hats, tennis shoes, and bicycles (MOHCC, 2019).

Recognising the importance of the community health system, Zimbabwe is undergoing reforms to establish a cross-sectoral community health system that enshrines the principles of community participation and ownership. These reforms aim to address key system challenges, including the verticalisation and fragmentation of initiatives, limited geographic access, poor service quality, and insufficient community involvement in shared responsibility for health. The intended outcome is the formal recognition of the community level as the first tier of the health sector, institutionalised within the formal health system and accountable to district-level structures (MOHCC, 2020; van Niekerk *et al.,* 2023).

1.2.7.1 Linking institutionalisation to the WHO health system building blocks

To situate the three community health system vital signs within a wider health systems framework, each was mapped to the six WHO health system building blocks: service delivery, health workforce, health information systems, medical products and technology, health financing, and leadership and governance (WHO, 2007; WHO, 2014). This mapping shows that institutionalising CHS vital signs is not a standalone intervention but an integrated health systems strengthening strategy. Together, these building blocks support the early detection of neonatal danger signs, timely referral, sustained community governance, and evidence-based decision-making, each of which is hypothesised to reduce the three delays that drive preventable neonatal deaths (Bohren *et al.,* 2015; Lassi *et al.,* 2016; Prost *et al.,* 2019). The full indicator-level mapping and measurement framework is presented in Chapter 4 (Methodology).

1.2.7.2 National Community Health Strategy

Zimbabwe's inaugural National Community Health Strategy (NCHS) 2020–2025, developed between 2017 and 2019 through consultations with over 400 stakeholders, provides the strategic framework for institutionalising the community health system. Together with the Community Essential Health Package (CEHP) and the Investment Case for Community Health, the NCHS aims to establish an equitable, integrated, and sustainable community health system that delivers door-to-door services, promotes community ownership, and accelerates progress toward universal health coverage

(MOHCC, 2020; Gizaw, Astale & Kassie, 2022**). The strategy is structured around the following expanded health system building block**s:

1. Social Accountability and Community Engagement (SACE)
2. Community-based health services delivery
3. Community health development workforce
4. Community health information system (CHIS)
5. Community supply chain management
6. Community governance, leadership, and coordination
7. Financing for community health

The NCHS was launched in 2020 and is currently being implemented across all provinces in Zimbabwe. The detailed policy analysis of the NCHS is presented in Chapter 2.

1.2.7.3 Why these three vital signs

Of the seven building blocks of the National Community Health Strategy, three were selected as the study's intervention variables and are referred to as the community health system's vital signs. The selection rests on three criteria. First, theoretical centrality: in the Community Health Systems Framework (Schneider *et al.,* 2022) and the WHO building blocks, the workforce, governance and community participation are the components through which all other functions are delivered; a supply chain or information system has no effect on a household unless a worker, a committee and an engaged community act on it. Second, empirical support: the community health workforce (Lassi *et al.,* 2016), participatory women's groups (Prost *et al.,* 2013; Seward *et al.,* 2017) and functional community governance structures (Balabanova *et al.,* 2019) are the three community-level components for which systematic reviews and trials report a measurable association with neonatal survival. Third, manipulability at the cluster level: each of the three can be introduced, resourced and measured within a ward-level cluster during a trial period, whereas community supply chain management, the community health information system and financing for community health are

national and district-level enablers that could not be varied between trial arms and were therefore treated as contextual conditions common to both arms (Section 4.5). Social accountability and community engagement, the first building block, are not a separate vital sign in this study because they are the mechanism through which community governance (IV2) and the learning and action groups (IV3) operate.

The metaphor of vital signs is used deliberately. Clinical vital signs are a small set of routinely measured indicators that show whether a patient is alive and stable; the three community health system vital signs are the routinely measurable indicators of whether the community tier is present, functioning and accountable. Institutionalisation, as defined in Section 1.10.5, converts them from project inputs into permanent features of the health system.

1.2.8 Health sector performance indicators

There seems to be a relationship between low institutional delivery and "high under-five mortality in Zimbabwe", with provinces recording institutional deliveries of 80% or less having higher "under-five mortality of above 100 per 1,000 live births" (Musarandega *et al.,* 2022) (Figures 2 and 3). This is no coincidence, as neonatal mortality accounts for more than one-third of the under-five mortality rate, and newborn survival is closely linked to the health and survival of mothers (Noble *et al.,* 2022). There are also variations between provinces, with some provinces, such as Midlands, having slightly higher institutional delivery of 81% with high under-five mortality of 72 per 1000 live births (Musarandega *et al.,* 2022; Noble *et al.,2022;* Kamanga *et al.,* 2022), while others have low institutional delivery, with under-five mortality rates comparable to provinces with high institutional deliveries, such as Mat South. This reflects other interrelated factors beyond coverage alone. The country has made significant progress in reducing mortality in children; however, the progress is masked by the contribution of neonatal deaths, which constitute 44% of all under-five deaths (Choguya, 2015; Musarandega *et al.,* 2022; Noble *et al.,*2022; Kamanga *et al.,* 2022)**.**

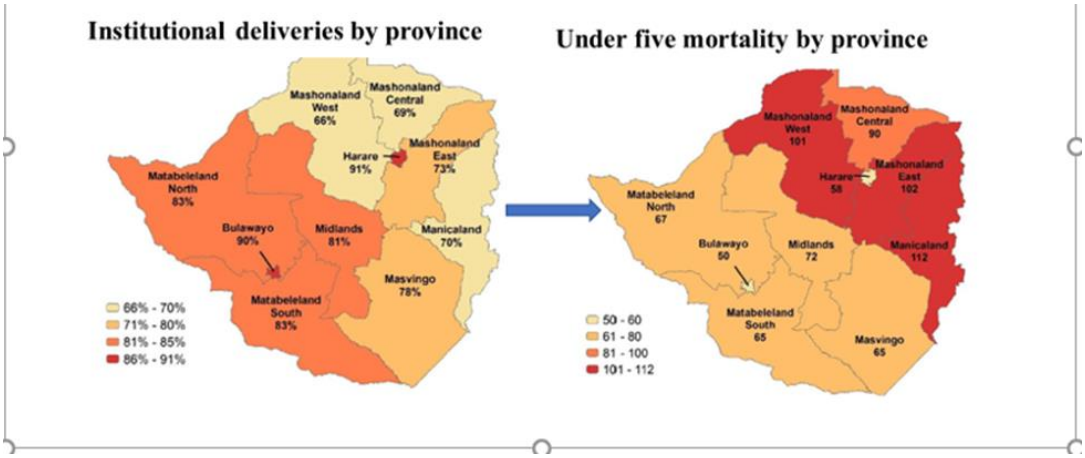


Figure 2: Relationship between institutional deliveries and under five mortality (Source: Zimbabwe Demographic Health Survey, 2015

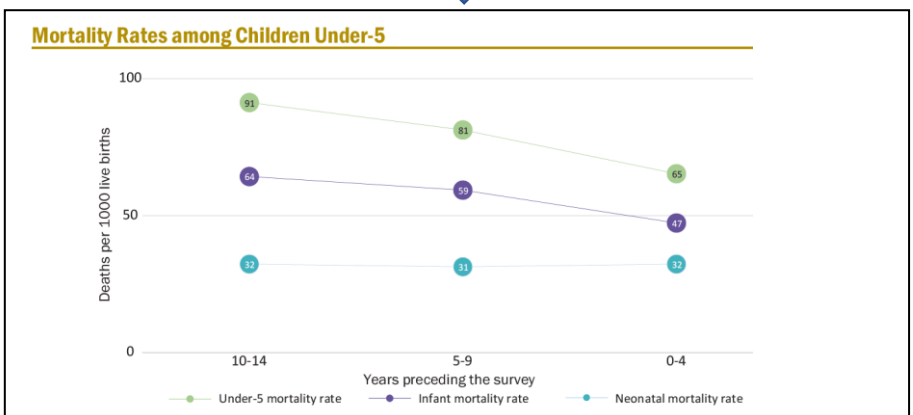


Figure 3: Under five mortality and Neonatal Mortality in Zimbabwe. Adopted from MICS Report, 2019

Zimbabwe has made deliberate efforts to reduce neonatal deaths through high-impact, low-cost interventions, including focused antenatal care, tetanus immunisation, skilled birth attendance, neonatal resuscitation, kangaroo mother care, and exclusive breastfeeding promotion (Foster *et al.,* 2017; MOHCC, 2017). However, systematic attention to community-based interventions for improving maternal, neonatal, and child health outcomes has remained limited. The Astana Declaration of 2018 renewed the global commitment to reposition community health as central to achieving universal

health coverage, signalling the need for a paradigm shift (Bassoumah, Adam & Adokiya, 2021).

Since the 2017 conference on institutionalising community health in South Africa, Zimbabwe has implemented reforms aligned with the proposed principles, including developing the NCHS as a first step toward formalising the community level as the first tier of care. Persistent challenges remain in human resources for health, recognition of cross-sectoral components, health infrastructure, and suboptimal health-seeking behaviour (Dussault & Dubois, 2003; Africa CDC & UNICEF, 2025).

1.3 Statement of the problem

Zimbabwe continues to record persistently high neonatal mortality rates despite significant investments in facility-based care. The national NMR stood at 32 per 1,000 live births in 2019, more than double the SDG 3.2 target of 12 per 1,000 live births by 2030, while Mashonaland West Province has consistently recorded among the highest rates in the country, at 46 per 1,000 live births in 2015 and 29 per 1,000 in 2019 (ZDHS, 2015; MICS, 2019; Musarandega *et al.,* 2022) (Figure 4). This persistent mortality burden, despite facility coverage indicators such as antenatal care and skilled birth attendance reaching 96%, signals that the problem lies not in facility-based care alone. Rather, it points to a deeper structural failure: the non-institutionalisation of the community health system as a functional, integrated layer capable of preventing neonatal deaths before and after facility contact.

The core problem this study addresses is therefore the non-institutionalisation of the community health system, specifically, the failure to systematically formalise and functionally integrate its three vital signs: the VHW/community health workforce (IV1), community governance structures such as Village Health Committees (IV2), and Women's and Men's Learning and Action groups (IV3) where the persistently high neonatal mortality rate is its measurable consequence. Available evidence suggests that facility-based improvements alone have not delivered the expected reductions in mortality. Comparisons such as Midlands Province (institutional delivery 81%, but U5MR 72/1,000) versus Masvingo Province (institutional delivery 78%, but lower

U5MR 65/1,000) show that higher facility use does not automatically translate into better neonatal survival (Yemane *et al.,* 2024).

National audits further show that the first and second delays in the Three Delays Model (the delay in deciding to seek care and the delay in reaching a facility) account for a disproportionate share of perinatal deaths, and that many women lack awareness of danger signs during pregnancy, delivery, and the neonatal period (MOHCC Maternal Death Audit Report, 2019; Muwema *et al.,* 2024; Tesfay *et al.,* 2025). This study proceeds from the hypothesis that these delays are, in substantial part, a consequence of the absence of a functional, institutionalised community health system, and that gaps in community-based newborn care therefore constitute the critical unresolved challenge; whether institutionalising that system reduces neonatal deaths is the question the study was designed to test. The MOHCC midterm review of the NHS 2016–2020 concluded that the country was off track to meet neonatal and under-five mortality targets (MOHCC, 2019).

1.3.1 Trends in Neonatal Mortality, Zimbabwe, 1999–2024

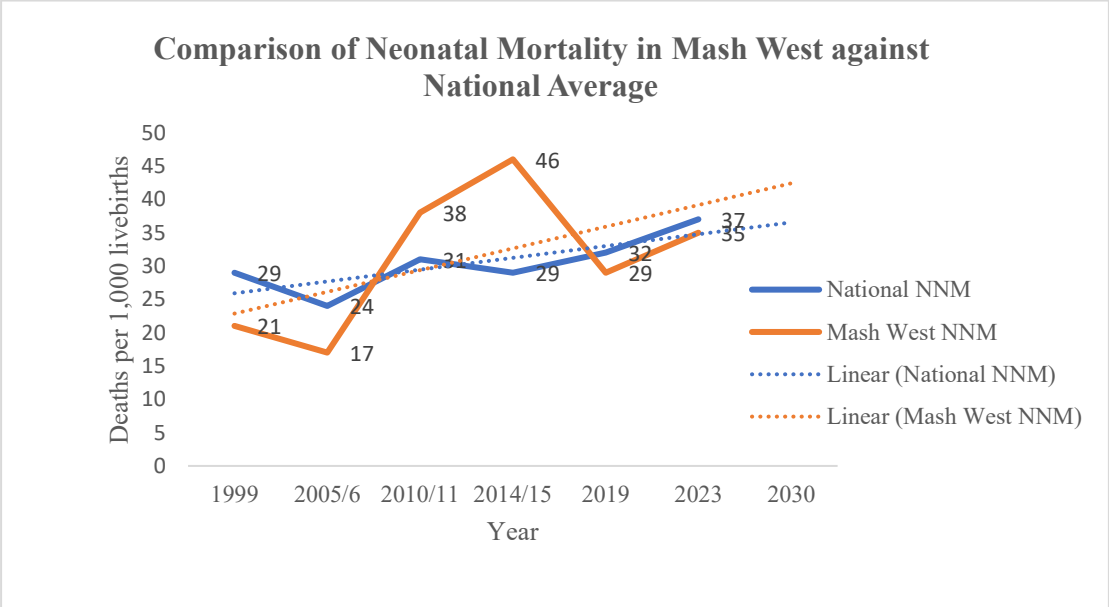


Figure 4: Trend in neonatal mortality in Mashonaland West Province compared to the national average, 1999 – 2024

Source: Multiple Indicator Cluster Survey 2019 and UN IGME 2024.

Despite growing global evidence that institutionalised community health systems can accelerate neonatal survival, three things remained unknown in Zimbabwe before this study. First, there was no randomised evidence on whether institutionalising the community tier as a package (VHW workforce, community governance and participatory groups together) reduces neonatal mortality; existing Zimbabwean studies were observational and examined single components, such as VHW effectiveness or discrete interventions, rather than the community health system as an integrated whole (Nhede & Catraio, 2021; Chasekwa *et al.,* 2022; Noble *et al.,* 2022). Second, the magnitude of any such effect, and the number of mother–infant pairs that would need to be reached to avert one neonatal death, had not been quantified in a high-burden rural province. Third, no study had established which of the three components is most strongly associated with neonatal survival, or how the effect changes under partial as opposed to full institutionalisation, information that the National Community Health Strategy 2020–2025 requires in order to sequence investment.

This study was therefore designed to address this gap by testing, in a cluster-randomised trial, whether and by how much institutionalising three community health system vital signs the Village Health Worker (VHW) / community health workforce (IV1), functional community governance structures/Village Health Committees (IV2), and modified Women's and Men's Learning and Action (WLA/MLA) groups (IV3) on preventable neonatal deaths due to preterm birth complications and neonatal infections) in Mashonaland West Province between 2020 and 2021. In doing so, it generates the evidence needed to guide the systematic institutionalisation of the community health system in Zimbabwe and, by extension, in comparable high-burden settings.

1.4 Objectives

1.4.1 Broad objective

The primary aim of this study was to evaluate the effect of institutionalising three community health system vital signs the Village Health Worker (VHW) / community health workforce (IV1), functional community governance structures/Village Health

Committees (IV2), and modified Women's and Men's Learning and Action (WLA/MLA) groups (IV3) compared to standard community health service delivery, on the rate of preventable neonatal deaths (per 1,000 live births) among neonates aged 0–28 days in Mashonaland West Province, measured as all-cause neonatal mortality with cause-specific mortality from preterm-birth complications and neonatal infections as a secondary outcome (Section 1.10.7), Zimbabwe, measured at 28 days of life over the 2020–2021 study period, using a two-arm randomised controlled trial design with predictive modelling and simulation.

In accordance with the ICH E9(R1) estimands framework, the trial objective is defined as follows: (i) Population: neonates (0–28 days) born to mothers residing in communities within Mashonaland West Province, Zimbabwe; (ii) Treatment condition: institutionalisation of IV1, IV2, and IV3 versus standard community health service delivery; (iii) Variable of interest: all-cause neonatal mortality rate per 1,000 live births at 28 days of life (with cause-specific mortality from preterm-birth complications and neonatal infections as a secondary variable); (iv) Population-level summary: difference in neonatal mortality rates between the intervention and control arms; (v) Intercurrent events: stillbirths are excluded from the live-birth denominator; participants lost to follow-up before day 28 are addressed using a missing-at-random assumption with multiple imputation; no cause-based exclusion is applied to the primary variable.

The study was anchored in the Mosley & Chen Framework, the Socio–Ecological Model, the Tanahashi Framework and Complex Adaptive Systems (CAS) theory, which together informed the prediction of neonatal health outcomes by community-level structural and participatory variables.

The hypothesised causal pathway is summarised as follows and illustrated in Figure 11 (Section 3.5): institutionalisation of the three vital signs (IV1–IV3) strengthens the community health system mechanisms of household contact, danger-sign recognition, referral and community accountability; these mechanisms increase timely access to, utilisation of and quality of antenatal, delivery and postnatal care (the Tanahashi coverage cascade) and improve household newborn-care practices; these in turn act on the proximate maternal and neonatal determinants identified by Mosley and Chen (birth spacing, thermal care, early breastfeeding, infection prevention and early management of preterm complications); and it is through these proximate determinants that

preventable neonatal deaths from preterm-birth complications and infection are averted. Each link in this chain is a hypothesis tested or examined in this study, not an assumption.

1.4.2 Specific objectives

The following four specific objectives operationalise the broad objective and culminate in a predictive model and its policy interpretation.

Specifically, to:

1.4.2.1 Determine the effect of institutionalising IV1, IV2 and IV3 on preventable neonatal deaths compared to standard community health service delivery in Mashonaland West Province.

1.4.2.2 Quantify the individual and combined predictive effect of IV1, IV2, and IV3 relative to the control arm on preventable neonatal deaths (per 1,000 live births at 28 days of life), including effect sizes with 95% confidence intervals.

1.4.2.3 Develop and simulate a predictive model to project neonatal mortality reduction under scenarios of full, partial, and non-institutionalisation of IV1, IV2, and IV3, handling intercurrent events via a hypothetical strategy and loss to follow-up via multiple imputation.

1.4.2.4 Assess the benefit–harm balance, unintended consequences and policy implications of institutionalising IV1, IV2 and IV3 within the community health system, drawing on the effect estimates and predictive model developed under Objectives 1.4.2.1–1.4.2.3.

1.5 Questions to be answered

The research questions were designed to directly address each specific objective and, collectively, to answer the broad objective of developing and simulating a predictive model of the effect of institutionalising the community health system vital signs,

specifically the VHW/community health workforce (IV1), community governance structures or Village Health Committees (IV2), and WLA/MLA groups (IV3) on the reduction of preventable neonatal deaths. It explored how policy direction, governance structure, practice, and processes for institutionalising these elements affect predictions of neonatal health outcomes.

1.5.1 Which of the three community health system variables, VHW/community health workforce (IV1), community governance structures/Village Health Committees (IV2), and WLA/MLA groups (IV3) is independently and significantly associated with a reduction in preventable neonatal deaths in Mashonaland West Province between 2020 and 2021? ***RQ1 (answering SO1)***

1.5.2 What is the magnitude of the individual and combined predictive effect of institutionalising community health system vital signs (IV1, IV2 & IV3) on preventable neonatal deaths (DV) in Mashonaland West Province between 2020 and 2021? ***RQ2 (answering SO2)***

1.5.3 What does the simulated predictive model project as the expected reduction in preventable neonatal deaths (DV) under scenarios of full, partial, and non-institutionalisation of IV1, IV2, and IV3 in Mashonaland West Province? ***RQ3 (answering SO3)***

1.5.4 What are the benefit–harm balance, unintended consequences and policy implications of institutionalising IV1, IV2 and IV3 within the community health system in Mashonaland West Province? RQ4 (answering SO4)

1.6 Hypothesis

1.6.1 Null Hypothesis (H_0): Institutionalising the community health system vital signs in Mashonaland West province of Zimbabwe has no effect on reducing neonatal deaths.

1.6.2 Alternative Hypothesis (H_1): Institutionalising the community health system vital signs in Mashonaland West province of Zimbabwe has an effect on reducing neonatal deaths.

1.7 Significance of the study

Neonatal mortality remains unacceptably high in sub-Saharan Africa, including Zimbabwe. In 2020, Zimbabwe reported an estimated 21 neonatal deaths per 1,000 live births, compared to the SDG 3.2 target of 12 per 1,000 live births by 2030 (WHO, 2021; UNICEF, 2022). Despite renewed global commitments to primary health care, such as the Astana Declaration (2018), and ongoing efforts to achieve Universal Health Coverage, the empirical contribution of institutionalised community health systems to neonatal survival remains underexplored, particularly in high-burden rural African settings (Walraven, 2019; Kraef & Kallestrup, 2019; Leydon *et al.,* 2021). This study addresses this gap and is significant in three key domains.

First, in the context of maternal, neonatal, and child health practice, this study provides empirical evidence regarding which community health system variables - the Village Health Worker/community health workforce (IV1), community governance structures (IV2), and WLA/MLA groups (IV3) - independently and collectively predict preventable neonatal deaths. In Zimbabwe, where 86% of births occur in health facilities (MICS, 2019), yet neonatal mortality remains high, these findings identify community-based structural gaps that facility-based care alone cannot address. The results offer actionable guidance for the Ministry of Health and Child Care (MoHCC) in strengthening the National Community Health Strategy, the VHW programme, and maternal and newborn health programming in Mashonaland West Province and similar rural settings (Lewycka, 2011; WHO, 2020; Bhutta *et al.,* 2014).

Second, in terms of research and knowledge generation, the existing literature has primarily focused on isolated components of community health, particularly community health worker (CHW) effectiveness, while overlooking the broader community health ecosystem and its combined predictive effect on neonatal outcomes (Nhede & Catraio, 2021; Chasekwa *et al.,* 2022; Noble *et al.,* 2022). No previous study in Zimbabwe has modelled the simultaneous, institutionalised effect of all three community health system vital signs on preventable neonatal deaths using a mixed-methods predictive design. This study addresses this gap by introducing the community health vital signs framework as a measurable and replicable predictive construct, representing a conceptual and methodological contribution relevant to future health

systems research, systematic reviews, and policy development in comparable low- and middle-income country (LMIC) settings (Bloland *et al.,* 2012; Lassi *et al.,* 2016; Koblinsky *et al.,* 2016).

1.8 Scope and delimitation

This research was conducted in Mashonaland West Province, a predominantly rural province comprising seven administrative districts: Chegutu, Hurungwe, Kariba, Makonde, Mhondoro-Ngezi, Sanyati, and Zvimba (see Figure 8). The province was selected on account of its notably high neonatal mortality rate. Formative research was conducted from February to April 2020, followed by prospective research from September 2020 to October 2021. A minimum sample size of 984 pregnant women of childbearing age (15–49 years) was recruited. Detailed study area characteristics are presented in the Methods chapter.

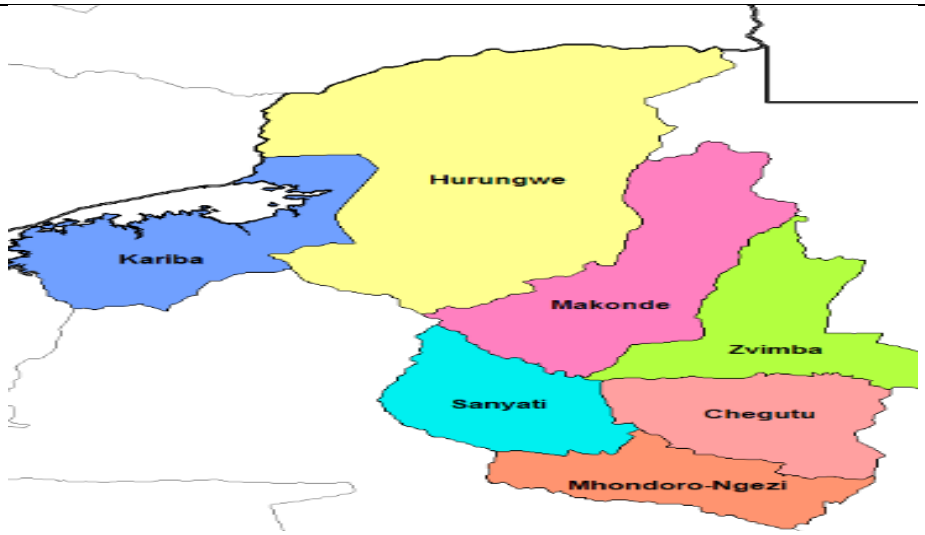


Figure 5: Map for Mashonaland West province

Source: Google Maps

The study participants included women of reproductive age, Community Gatekeepers (Village Heads, Opinion Leaders, Chiefs, Religious Leaders), CHWs, district health teams, and representatives of other local governance structures. These respondents were drawn from the sampled wards and villages, which are the smallest administrative units.

The study focused on community-led interventions on critical components of essential newborn care practices at home and related neonatal health outcomes. Specifically, the socio-economic status of mothers with newborn babies less than 28 days after birth was assessed, guided by the WHO-UNICEF guidelines on essential newborn care, which stipulate practices such as clean cord care, clean deliveries, drying and warming, early initiation and exclusive breastfeeding, among others, that are critical for neonatal survival (Lawn *et al.,* 2023). Mothers were followed up as soon as they were confirmed to be pregnant and continued through the postnatal period, with a focus on the 28 days following delivery (Lawn *et al.,* 2023; Guye *et al.,* 2025).

1.9 Study limitations

The limitations encountered in this study—availability of the target population and loss to follow-up, the impact of COVID-19 on household follow-up and the enabling environment for service delivery, and recall and social-desirability bias in the reporting of the timing of neonatal deaths—are discussed together with their implications for the interpretation of findings in Chapter Six, Section 6.8.2.

1.10 Key definitions used

1.10.1 Institutionalisation

Institutionalisation refers to the process of embedding practices, programmes, policies, and interventions into the routine operations and structures of a health system, ensuring their sustainability, ownership, and long-term impact (WHO, 2009; Atun *et al.,* 2010; Bulthuis *et al.,* 2020). In the context of this study, it specifically denotes the vertical scale-up of community health system vital signs through policy, legal action, and integration into formal district health planning, financing, and accountability mechanisms (de Savigny & Adam, 2009; van Niekerk *et al.,* 2023). See Section 1.1 and Chapter 2 for full contextualisation.

1.10.2 Community Health Community of Practice (CH-CoP)

A community of practice (CoP) is a group of individuals who share a common concern or interest and enhance their knowledge through continuous interaction (Kothari *et al.,* 2015). In this study, the CH-CoP refers to the collective learning structures, including women's and men's learning and action groups, through which community members develop and sustain healthy newborn care practices.

1.10.3 Community Health (CH)

Community health refers to the delivery of essential health services to all individuals within a defined geographic area, with active community participation. Unlike targeted demographic programmes, it addresses the full population within a locality, promoting health across the life course (Ministry of Health, Malawi, 2017; Republic of Zambia, 2017).

The term community health is also used interchangeably with community-based primary health care (CBPHC), which describes a collaborative process through which health programmes and communities work together to improve health outcomes. This approach promotes healthy behaviours at the household level, extends services beyond formal health facilities, and adopts a multi-sectoral strategy that addresses education, income, nutrition, living conditions, and empowerment (Story *et al.,* 2016; Gholipour *et al.,* 2023; Obi *et al.,* 2024; Petiwala *et al.,* 2021). Unlike formal health care systems, which tend to be clearly defined, community systems and structures often vary and are sometimes viewed as supplementary resources (Simmons, Fajans & Ghiron, 2007; Ludwick *et al.,* 2022).

1.10.4 Institutionalising Community Health

Institutionalising community health means engaging community members as key stakeholders in delivering locally specific, collaborative, and innovative community-focused health strategies that strengthen the existing primary health care system. This is achieved through the adaptation of health system structures, resource redistribution, and the extension of service delivery mechanisms to the community level for sustainable, community-led interventions, including home visitation, community action groups, and formal recognition of community health workers within the health system (Durrance-Bagale *et al.,* 2022; Dove *et al*., 2024).

1.10.5 Institutionalisation of Community Health System Vital Signs

In this study, institutionalising community "vital signs" refers to the deliberate and sustained integration of core, measurable drivers of the community health system into routine health system functions. These drivers encompass three complementary elements: village health workers and the broader community health workforce (VHWs/CHWs), community governance structures, and modified women's and men's learning and action groups. Institutionalisation encompasses the formalisation of role definitions, structured training and supervision, routine data collection and reporting, allocation of financial and non-financial resources, accountability and feedback mechanisms, and formal linkages with the district health system ensuring that community-level actions, performance, and outcomes, including neonatal survival, are routinely monitored, addressed, and sustained (Prost *et al.,* 2019; Kok *et al.,* 2023).

This thesis distinguishes institutionalisation from four related terms with which it is often conflated. Implementation is the delivery of an activity during a programme or project period; an activity can be fully implemented and still disappear when funding ends. Integration links a community activity to a facility or district process (for example, referral or reporting); it is one component of institutionalisation, but does not, by itself, secure resourcing or recognition. Participation is community members' involvement in an activity; it is a mechanism through which the vital signs act, not evidence of their institutionalisation. Routine programme delivery is the provision of standard services by existing structures without formal recognition, sustained resourcing or accountability. Institutionalisation, by contrast, is present only when a vital sign is formally recognised in policy, sustainably resourced, supervised and supported, embedded in routine information and accountability systems, and governed by structures that persist beyond any single programme.

Institutionalisation was measured for each vital sign at the cluster level using the input, process and output indicators described in the paragraphs below and operationalised in Section 3.6.2 and Section 4.5. Each cluster was scored on the proportion of indicators achieved and classified as fully institutionalised (all three vital signs at or above the 80% fidelity threshold), partially institutionalised (one or two vital signs at threshold) or not institutionalised; the composite index and its justification are given in Section 3.6.2.

The first vital sign concerns the community health workforce, specifically VHWs. At the input level, institutionalisation is evidenced by documented job descriptions, the number of individuals trained, and training completion rates. These inputs translate into assessable processes, including the frequency of supervisory visits, the strength of referral linkages to health facilities, and the coverage of routine home visits conducted during pregnancy and throughout the first 28 days postpartum (Lassi *et al.,* 2016; WHO, 2018). The resulting outputs and outcomes are assessed through the proportion of births receiving a postnatal visit within 72 hours, the rate of timely referrals for neonatal danger signs, and VHW/CHW retention rates, each serving as a proxy for the depth and durability of workforce integration (Baqui *et al.,* 2009; Gogia and Sachdev, 2010).

The second vital sign relates to community governance structures (Balabanova *et al.,* 2019). At the input level, institutionalisation is indicated by functional health committees, established terms of reference, and documented meeting schedules. At the process level, meeting minutes capture governance quality by recording community-facility planning and budget inputs, as well as the presence of community feedback and complaint mechanisms. The outputs and outcomes of effective community governance include documented community input into health planning and measurable reductions in referral decision-making delays, both of which reflect a governance structure genuinely embedded within the health system (Balabanova *et al.,* 2019; Teklu *et al.,* 2020).

The third vital sign encompasses modified women's and men's learning and action groups (Prost *et al.,* 2013; WHO, 2014). Inputs for this element include adapted curricula and modules focused on community participation and engagement. At the process level, this is measured by the frequency of group sessions, attendance records disaggregated by sex and age, and the degree to which group activities are formally linked to VHW follow-up (Rath *et al.,* 2010).

Intended outputs and outcomes include increased knowledge of neonatal danger signs, improved newborn care practices such as early breastfeeding initiation and thermal care, and faster care-seeking behaviour (Prost *et al.,* 2013; Seward *et al.,* 2017). These household- and community-level changes are central to reducing neonatal mortality, with meta-analyses reporting up to a 20% reduction in neonatal mortality where

women's groups practising participatory learning and action achieved adequate population coverage (Seward *et al.,* 2017).

1.10.6 Neonatal Mortality or specifically Neonatal Death

Neonatal death refers to the mortality of a live-born infant within the first 28 days after birth, defined by timing rather than clinical cause (WHO, 2020). Measurement is complicated by frequent misclassification with stillbirths, which underestimates the true burden. This study focuses specifically on deaths within the first complete 28 days, regardless of birth weight or gestational age (Spector & Daga, 2008; WHO, 2020).

1.10.7 Preventable Neonatal Death

A preventable neonatal death is the death of a liveborn infant within the first 28 days of life (the neonatal period, comprising early neonatal deaths at 0–6 days and late neonatal deaths at 7–27 days) that could have been averted through timely, appropriate and accessible care at the community or institutional level (Pathirana *et al.,* 2016; WHO, 2020). In this study the term denotes the conceptual outcome named in the title. The measured primary endpoint is all-cause neonatal mortality at 28 days, expressed as deaths per 1,000 live births, ascertained by household surveillance and confirmed by verbal autopsy or facility records (Section 4.14), and analysed by intention to treat. All-cause mortality was chosen as the primary endpoint for three reasons. First, cause-of-death assignment by verbal autopsy is imprecise, and a proportion of deaths in this trial lacked complete verbal-autopsy data (Section 5.5); restricting the primary endpoint to particular causes would introduce differential misclassification into the randomised comparison. Second, in this setting the leading causes of neonatal death (preterm-birth complications, neonatal infection and intrapartum-related events) are all amenable to the community-level actions the intervention delivers (early antenatal engagement, birth preparedness, danger-sign recognition, timely referral, thermal care, early breastfeeding and clean cord care), so the population of neonatal deaths is overwhelmingly preventable in principle. Third, all-cause neonatal mortality is the standard primary endpoint in community-based neonatal survival trials (Prost *et al.,* 2013; Lassi *et al.,* 2016). Cause-specific neonatal mortality (preterm-birth complications, neonatal infection, other) is analysed as a pre-specified secondary outcome (Sections 4.7 and 5.5). Care-seeking, referral, postnatal visits and service

utilisation are process indicators on the causal pathway and are not treated as outcomes equivalent to mortality.

The following clinical and epidemiological terms are used throughout the thesis. Full definitions are provided in the Glossary.

1.10.8 Community Health Systems (CHSs): Networks of local actors, relationships, and processes that promote health within communities and households, operating alongside but distinct from formal health structures (Schneider *et al.,* 2022).

1.11.9 Community Health Workers (CHWs): Members of the communities they serve, chosen by those communities, accountable to them, and supported by but not formally integrated into the health system's organisational structure (WHO, 2018).

1.10.10 Early Neonatal Death (END): Death of a live-born infant within the first seven days of life, per 1,000 live births (WHO, 2016).

1.10.11 Low Birth Weight (LBW): Birth weight of less than 2,500 grams, regardless of gestational age (WHO/UNICEF, 2023).

1.10.12 Late Neonatal Death (LND): Death of a newborn occurring after the first seven days but within the first 28 days of life (WHO, 2015).

1.10.13 Maternal Death: Death of a woman during pregnancy or within 42 days of termination of pregnancy from causes related to or aggravated by the pregnancy or its management (WHO, 2020).

1.10.14 Preterm Birth: Birth before 37 completed weeks of gestation (Blencowe *et al.,* 2013).

1.10.15 Primary Health Care (PHC): A comprehensive, society-wide approach to organising health systems to ensure accessible, equitable, and participatory health service delivery across the life course (WHO & UNICEF, 2018).

1.10.16 Small for Gestational Age (SGA): An infant below the 10th percentile of birth weight for gestational age (WHO, 2015).

1.10.17 Stillbirth: A baby born with no signs of life, weighing more than 1,000 g or at more than 28 completed weeks of gestation (Lawn *et al.,* 2010).

1.10.18 Universal Health Coverage (UHC): Ensuring that every individual has access to quality health services without financial hardship (WHO, 2019).

1.11 The organisation of the rest of the report

Chapter One: Background – This chapter provides a comprehensive outline of this research report, highlighting the critical role of institutionalising community health systems in addressing preventable neonatal deaths. An outline of the current global, regional and local statistics on neonatal mortality will be presented visually, emphasising the urgent need for effective intervention strategies to tackle the problem of increasing neonatal deaths. This chapter will set the stage for understanding how strengthening these systems can significantly reduce neonatal mortality rates, ultimately improving public health. The Methods chapter presents detailed facility density data and health system performance indicators under the Study Area section.

Chapter Two: Literature Review - This chapter examines the existing body of knowledge, foundational theories, and major studies that have shaped the discourse on the institutionalisation of community health systems, vital signs, and preventable neonatal deaths. This review considers contributions from other scholars to unpack the complexity and multidimensionality of the factors contributing to neonatal deaths. The critical analysis also uncovers unanswered questions and emphasises emerging areas requiring further enquiry and investigation, which this report aimed to address (Wong *et al*., 2022; Luft *et al.,* 2022).

Chapter Three: Outline of Theoretical and Conceptual Framework - This chapter articulates the key theories relevant to this study and the conceptual framework underpinning this research, and justifies these theories through critical analysis, applicability, limitations, and relevance. Building on the theoretical foundation, the Conceptual Framework will be presented visually to illustrate the key variables and their interrelationships. This chapter also details how the concepts within the framework will be measured and analysed, ensuring clarity in this research approach. Overall, it provides a coherent structure that connects existing literature to this study, ensuring that the exploration of community health systems institutionalisation and preventable neonatal deaths is grounded in established academic discourse.

Chapter Four: Methodology - Outlines the research methodology employed. This section provides a comprehensive overview of the research design and setting; the detailed target population; the sampling strategy employed; the methods used to collect data; the ethical considerations; and the methods of analysis used to explore the unanswered questions, including any limitations.

Chapter Five: Data Analysis and Results - This pivotal chapter takes a deeper dive into the foundational processes that transformed raw data into meaningful insights, it starts with outlining the methodologies employed for data collection and the rationale, the intricacies of data preparation, cleaning and techniques for data quality and usability. This chapter presents the statistical methods used to extract insights from the data. It serves not only as a methodological guide but also as a foundation for the subsequent findings and discussions presented in later chapters.

Chapter Six: Discussion of Findings - This chapter presents the key findings from the data analysis. The results will be systematically organised to highlight the most significant patterns, trends, and relationships identified. The chapter begins with a concise presentation of quantitative results, including statistical metrics, visualisations, and comparative analyses that elucidate the core insights. It then delves into qualitative findings that provide context and depth to the numerical data.

Chapter Seven: Conclusion and Recommendations – Synthesises the key findings of the study and their implications, drawing together the threads developed in the preceding results and discussion chapters. It distils the most significant contributions to knowledge on community health systems and the reduction of preventable neonatal deaths, and translates these into actionable recommendations for policy, practice, and future research. The chapter situates these conclusions within the wider discourse on a systems perspective of community health and its role in preventing newborn deaths (Mitiku, 2021; Nabila *et al.,* 2024).

References - The references are organised alphabetically by the first author's surname, in accordance with Harvard referencing style guidelines. They form a curated collection of works that provided the foundation for this research (Gogia & Sachdev, 2010; Memon et al., 2015; Egan & McGill, 2021).

Appendices – The appendices will be organised systematically, clearly labelled and referenced in the main text. These will include, but are not limited to, ethical approvals, consent forms, and research instruments.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Neonatal mortality remains a major global health challenge, particularly in low- and middle-income countries. Progress toward lowering neonatal deaths to 12 per 1,000 live births by 2030 has been uneven. In Zimbabwe, about 44% of under-five deaths are neonatal, with the national neonatal mortality rate at 32 per 1,000 live births in 2019. Mashonaland West Province reported 29 per 1,000 live births, still above global targets, down from 46 per 1,000 live births in 2015 (MICS, 2019). These numbers reflect problems in delivering proven interventions through community health platforms, rather than a lack of effective solutions.

This chapter reviews evidence to answer two key questions: How do health systems and their community counterparts affect neonatal mortality, and why has the institutionalisation of community health systems not led to sustained, scalable reductions in neonatal mortality? Rather than merely describing, this review analyses mechanisms, conditions for success or failure, and the specific institutionalisation deficit in Zimbabwe's community health system. The chapter's structure is outlined below to guide the review.

The review flows as follows: Section 2.2 sets the global context and outlines the history of community health and its impact on neonatal outcomes. Section 2.3 examines how health systems have succeeded or failed in reducing neonatal mortality, drawing on country comparisons. Section 2.4 identifies structural gaps in institutionalisation. Section 2.5 examines evidence for community-based interventions. Section 2.6 focuses on neonatal mortality in Zimbabwe, especially in Mashonaland West Province during the 2020–2021 study period. Section 2.7 describes methods for predictive modelling in community health, informing the study's analysis. Section 2.8 defines the research gap and rationale. Section 2.9 offers a theoretical and conceptual synthesis linking literature to the framework.

This review is based on systematic reviews, meta-analyses, program evaluations, and national health strategies published mainly in the last 15 years, along with key foundational works (Lewin *et al.,* 2010; WHO, 2010; Bhutta *et al.,* 2014). It follows a global-to-local focus, analysing how institutionalisation, or its absence, affects the effectiveness of community health systems in reducing neonatal mortality. Vital signs, such as pulse, temperature, blood pressure, and respiratory rate, are the most basic measurable indicators of systemic function. Analogously, in this context, 'vital signs' refer to the essential, measurable indicators of a functioning community health system. The absence or deterioration of these community health system vital signs predicts the system's inability to prevent neonatal deaths, paralleling how clinical vital sign deterioration signals patient decline.

The study focuses on three vital signs for community health systems:

1. Village Health Workers / Community Health Workers: This refers to staff numbers, training, pay, and integration into the system.
2. Community Governance Structures: These cover committees at the health centre, ward, and village. They show accountability, coordination, and representation.
3. Participatory Learning and Action Groups: These are organised community groups that solve problems together on perinatal and neonatal issues.

These three components function as interdependent indicators within a system rather than isolated elements. Each is necessary individually, but their collective effectiveness depends on institutionalisation within the broader health system. The study's central hypothesis is that the degree of institutionalisation of these three vital signs is the primary predictor of preventable neonatal deaths in Mashonaland West.

The selection of these three components, rather than the full set of seven building blocks in Zimbabwe’s National Community Health Strategy, follows the criteria set out in Section 1.2.7.3 and is supported by the evidence reviewed in this chapter. They are the three community-level components for which the international literature reports a measurable association with neonatal survival: the community health workforce (Lassi *et al.,* 2016; Perry *et al.,* 2017), participatory women’s groups (Prost *et al.,* 2013; Seward *et al.,* 2017) and community governance and accountability structures

(Balabanova *et al.,* 2019; Rifkin, 2018). Section 2.4 reviews community supply chains, community health information systems, and community health financing as structural enablers whose absence constrains all three vital signs, but they operate at the national and district levels and could not be varied between trial clusters; therefore, they are treated as contextual conditions rather than intervention variables. Social accountability and community engagement are the mechanisms through which governance structures and participatory groups act and are examined under those two vital signs.

2.2 Global context: health systems, primary health care, and the neonatal mortality burden

2.2.1 The global neonatal mortality crisis

The global burden of neonatal mortality is both a public health crisis and a health system failure (Lawn *et al.,* 2013; UNICEF, 2017). By 2016, neonatal deaths made up 46% of all under-five deaths globally. This was up from 37.4% in 1990 (Figure 6). This increase occurred because child survival improved more for older children. These improvements were driven by facility-based, disease-targeted interventions. The newborn period saw less improvement (Sharrow *et al.,* 2022; UNICEF, 2017). Most neonatal risks arise from birth practices, newborn care, and community health behaviours before contact with a healthcare facility (Darmstadt *et al.,* 2005; Ahmed *et al.,* 2022).

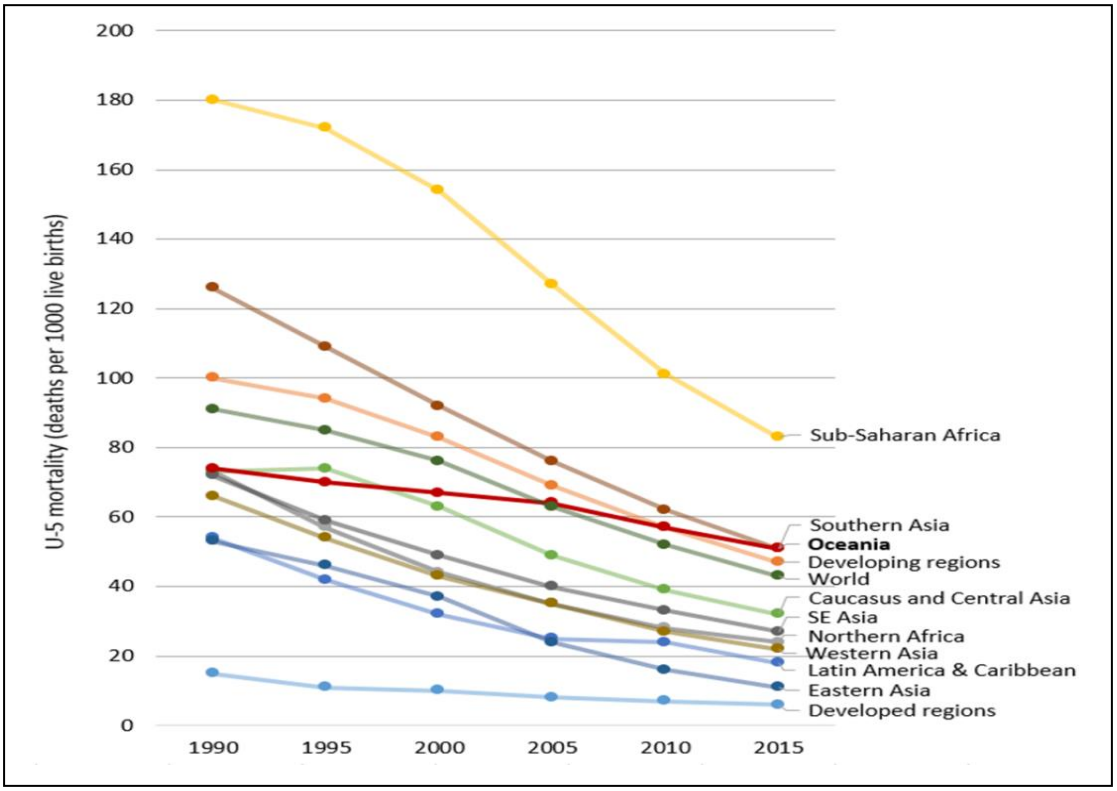


Figure 6: Global trend accelerating progress on under-five mortality, 2016

Source: UNICEF (2016)

The issue is not the effectiveness of interventions but the mechanisms by which health systems fail to deliver them systematically at the community level. Mechanisms such as inadequate workforce integration, weak governance structures, and insufficient or misaligned financing limit the scale and consistency of delivery. Institutionalisation, or its lack, shapes the pathways, including how workforce capability is developed, governance is enacted, and financing is channelled, through which proven models succeed or fail in practice. In sub-Saharan Africa, these breakdowns often prevent community-based strategies from reaching those in need, thereby slowing progress compared with other regions.

Research shows that community health workers and community-based care packages can reduce maternal and neonatal deaths when well supported (Lassi *et al.,* 2016; Kayentao *et al.,* 2023). But community health delivery is often the weakest and most fragmented part of the health system in LMICs. Community health has long been poorly

defined, underfunded, and undermanaged. This dates back to the Alma-Ata Declaration in 1978 (Perry *et al.,* 2017; LeBan, Kok & Perry, 2021).

2.2.2 Historical trajectory of community health and its institutionalisation

Community health has evolved for more than a century, and the 1978 Alma-Ata Declaration enshrined community participation as a key part of primary health care. In 2018, the Astana Declaration reaffirmed this commitment forty years later (Perry & Zulliger, 2012; Rifkin, 2018; WHO/UNICEF, 2018). This history does not show linear progress. Instead, it reveals recurring tension, as each global recommitment to community health is followed by selective, uneven, and politically contingent implementation at the country level.

The Alma-Ata vision of a bottom-up, community-based health system has often been replaced by top-down, facility-focused investments. This shift has affected neonatal survival. Different countries have taken very different paths to institutionalise community health. This has led to mixed results. In some settings, such as Nigeria, community health workers are unpaid volunteers without formal roles or training (Perry *et al.,* 2017; Kane *et al.,* 2021). In others, such as Ethiopia, Health Extension Workers are formal staff with salaries, career paths, training, and defined service packages (Perry *et al.,* 2015; Assefa *et al.,* 2019). This range reflects differences in political commitment and whether community health is treated as a core function or an add-on (Tseng *et al.,* 2019; Chen *et al.,* 2021).

Zimbabwe occupies the lower end of this spectrum. Its Village Health Workers remain volunteers. They are not integrated into the formal health system. They lack defined career structures and consistent supervision. Their number is about 21,600, short of the required 40,000 (Woldie *et al.,* 2018; MOHCC, 2021; Hobbs *et al.,* 2022). This position directly frames the institutionalisation deficit that the study investigates.

2.2.3 The WHO health system building blocks: applications and limitations

The main framework for health systems is the WHO's six building blocks: service delivery, workforce, “health information, medical products and technologies, financing, and leadership and governance” (WHO, 2010; Gebremeskel, Udenigwe &

Etowa, 2023). While useful, the framework has two key limitations for community health. First, it was made for facility-based care. Using it for community health can misrepresent local challenges with investment and planning (Sacks *et al.,* 2019). Second, the building blocks are static and linear. Community health systems, however, are complex, adaptive, and shaped by local context (Sacks *et al.,* 2019).

These limitations have practical consequences. Policymakers applying the building blocks to community health tend to focus on technical inputs, such as training and supply chains. They often neglect the governance, accountability, and social cohesion dimensions, which are equally important to the performance of community health systems (Sacks *et al.,* 2019; LeBan *et al.,* 2021). Social determinants, such as poverty, gender inequality, cultural norms, and education, shape health outcomes at the household and community levels. The building blocks framework lacks ways to capture and address these factors (Braveman & Gottlieb, 2014; Chelak & Chakole, 2023).

Despite these limitations, the building blocks framework provides a foundational organising structure for this review. The community health system vital signs operationalised in this study: VHWs/CHWs, community governance structures, and participatory learning/action groups map directly onto three of the six building blocks (workforce, governance, and service delivery) while addressing the community-level dimensions that the original framework underspecifies. This alignment enables the study's findings to speak directly to health system policy frameworks while advancing beyond their limitations.

2.2.4 The Socio-Ecological Model and neonatal survival

The Socio-Ecological Model (SEM), originally developed by Bronfenbrenner (1977) and adapted for public health by McLeroy *et al.* (1988), provides a complementary theoretical lens for understanding neonatal mortality. The SEM conceptualises health behaviours and outcomes as shaped by multiple nested levels of influence: individual, interpersonal, community, organisational, and policy. For neonatal survival, this model is particularly appropriate: birth practices, recognition of danger signs, and the decision to seek care are all shaped within household and community circles before any contact with a facility (Kruk *et al.,* 2018).

The WHO estimates that approximately 70% of all diseases are averted or addressed at the household and community level, reframing the community not as a peripheral delivery point but as the primary site of health production (Kruk *et al.,* 2018). The SEM explains why facility-based interventions alone are insufficient for neonatal survival: they address only organisational and policy-level influences, leaving individual, interpersonal, and community-level determinants unaddressed. Institutionalising community health system vital signs (VHWs, community governance, and participatory groups), operationalises the community and interpersonal levels of the SEM, providing the missing link between policy commitments and household-level outcomes. Figure 7 demonstrates that facility-based interventions primarily address organisational and policy levels of the SEM, leaving individual, interpersonal, and community determinants insufficiently addressed. Institutionalising community health system vital signs (VHWs, community governance, participatory groups) activates these inner SEM levels, bridging the gap from policy to improved household outcomes.

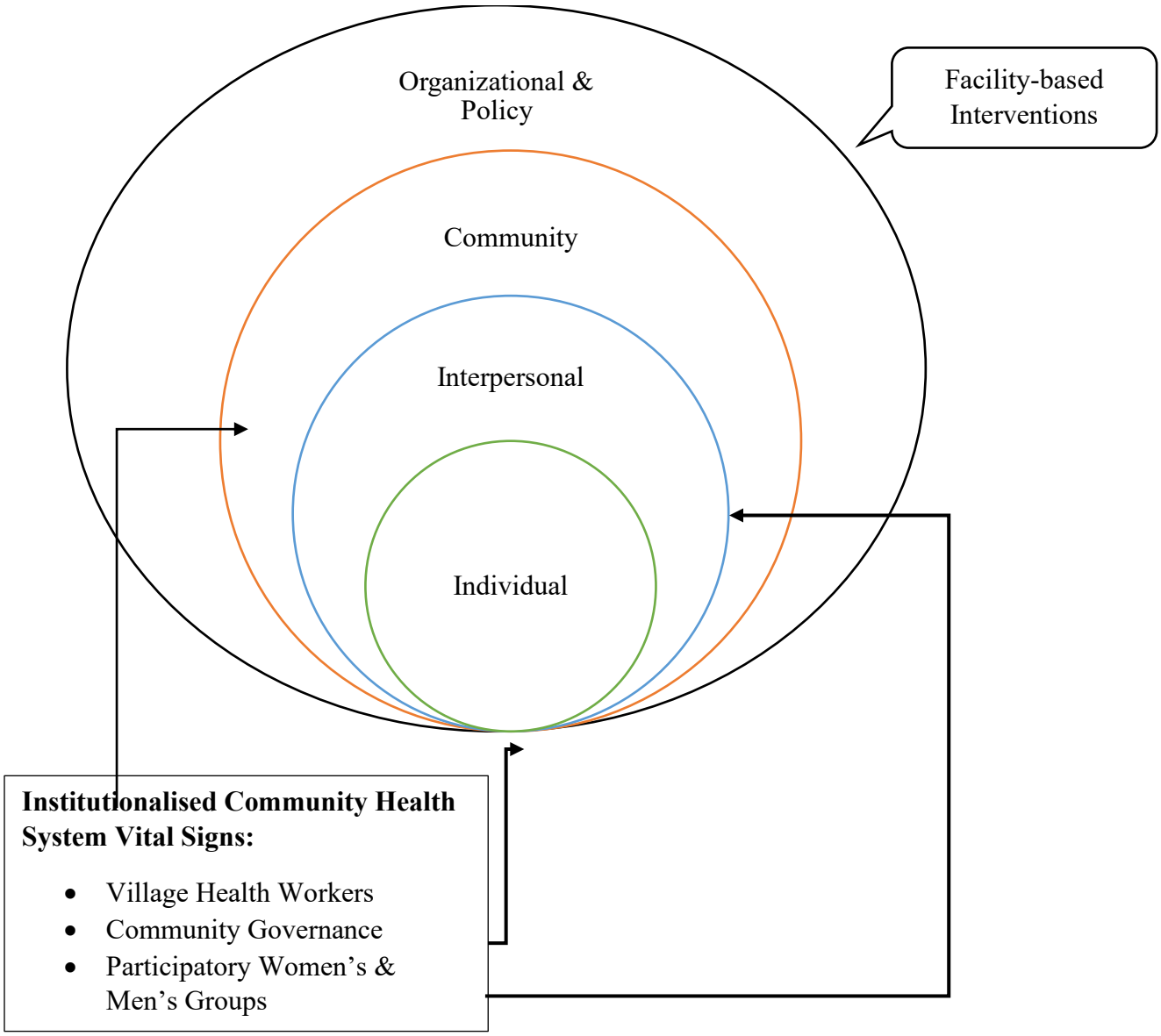


Figure 7: Bridging Neonatal Survival Gaps: SEM Levels and Community Health System Vital Signs

2.2.5 Global frameworks and paradigm shifts in community health systems

Multiple global frameworks, including People-Centred Health Systems, Every Woman Every Child, and the UN Global Strategy for Women's, Children's, and Adolescents' Health (2016–2030), have reiterated the centrality of communities in achieving neonatal survival (Brizuela & Tunçalp, 2017). The analytical question driving this section is not what these frameworks say, but why the four decades of global consensus have failed to translate into institutionalisation at the country level.

The WHO and UNICEF Every Newborn Action Plan (ENAP) explicitly recognises this gap: two of its five strategic objectives address community and family engagement directly, while the remaining three address the quality of facility care, financing, and health information systems (WHO-UNICEF, 2015). The analytical implication is clear: ENAP's community objectives cannot be achieved without an institutionalised community health system to operationalise them.

A critical paradigm shift in the evidence is the move from CHW-centred to systems-centred thinking. For decades, community health programmes focused narrowly on individual CHW roles, producing evidence of CHW effectiveness at a small scale but failing to achieve national-scale results because they neglected the broader system within which CHWs operate (Coles *et al.,* 2020; LeBan *et al.,* 2021). The emerging consensus, supported by Ethiopia, Rwanda, and Brazil, is that CHW programmes are sub-systems embedded within a broader community health system — one that includes community-based organisations, faith-based organisations, governance structures, social accountability mechanisms, and the formal health system itself (Wilson, Lavis & Guta, 2012; LeBan *et al.,* 2021). The performance of the entire system, not the individual CHW, determines whether neonatal mortality decreases. This insight underpins the present study's three-component vital signs approach.

2.3 Successes and failures in using community health systems to improve neonatal outcomes

2.3.1 Ethiopia: Institutionalisation as a core state function

Ethiopia is the most frequently cited African example of treating community health as a core state function, with salaried workers, defined career paths, and formal integration into the national health system, and its declines in under-five and neonatal mortality have been associated with this model (Wang *et al.,* 2016; Assefa *et al.,* 2019). The association is not a clean attribution: the same period saw rapid economic growth, expansion of facility-based obstetric care, road and education investment and large donor inflows, and the evaluations available are largely before-and-after or cross-sectional designs that cannot separate the Health Extension Programme from these concurrent changes (Assefa *et al.,* 2019; Kok *et al.,* 2015). The Health Extension

Programme deploys over 38,000 salaried Health Extension Workers, reinforced by the Health Development Army, a community volunteer network.

Enabling conditions include political commitment, standardised training, and formal system integration, not programme design alone. Remaining challenges, such as supervision quality, supply chain reliability, and urban adaptation, are themselves institutionalisation challenges, suggesting that the depth of integration, not merely its existence, is what matters for outcomes (Kok *et al.,* 2015; Muhammad *et al.,* 2023). Ethiopia's trajectory from fewer than 5,000 to over 38,000 HEWs demonstrates that rapid, government-financed scale-up is achievable when political will exists.

2.3.2 Brazil: Formal employment as the distinguishing variable

Brazil's Family Health Strategy (FHS), which embeds community health workers within multidisciplinary, municipally employed primary care teams rather than deploying them as standalone volunteers, is associated in municipal panel analyses with reductions in infant and neonatal mortality and avoidable hospitalisations, and with gains in equity (Johnson *et al.,* 2013; Macinko & Harris, 2015). These analyses adjust for municipal income, education, and sanitation, which strengthens the inference, but Brazil's conditional cash transfers, sanitation investment, and falling fertility over the same period mean the FHS contribution is a share of the decline, not the whole of it. CHWs are locally recruited, trained and municipally employed, and conduct monthly household visits regardless of demand.

The analytical lesson is that formal employment, accreditation, and sustainable government financing, rather than the community visit model itself, distinguish Brazil's outcomes from volunteer-based systems (LeBan, Kok & Perry, 2021). The FHS now covers approximately 265,000 CHWs serving a large share of Brazil's population. Sustainability remains contingent on continued political commitment, confirming that institutionalisation is a political achievement rather than a technical one.

2.3.3 Rwanda: Democratic accountability and governance integration

Rwanda offers the strongest African case for community-driven institutionalisation: CHWs are elected by their communities and formally recognised within national health

governance, and the country recorded a 60% reduction in maternal mortality and a 70% decline in under-five mortality between 2000 and 2021 with fewer than 1,000 doctors nationwide (Condo et al., 2014; UNICEF, 2021). Those declines coincided with near-universal community-based health insurance, performance-based facility financing, strong economic growth, and unusually centralised political accountability, so the CHW programme is best understood as one element of a coherent system reform rather than the sole cause of the mortality decline. The programme's multi-tiered structure includes pairs of CHWs (binomes) responsible for community health and nutrition, maternal health workers managing antenatal and postnatal care, and social affairs workers.

Following reforms in 2007 and 2012, the system was strengthened through clear role differentiation, structured supervision, and government coordination, deploying over 45,000 CHWs nationally (Nishimwe & Mchunu, 2021). Rwanda's outcomes are not attributable to CHW numbers alone but to the governance architecture (electoral accountability, defined roles, and formal government coordination) that makes those CHWs effective. This governance dimension is precisely what is absent in Zimbabwe's volunteer-based VHW system and what this study's community governance vital sign seeks to measure.

2.3.4 China: The limits of community trust without formal institutionalisation

China's experience reveals a recurring dynamic: initial gains from community-embedded, politically committed programmes are not self-sustaining unless formalised within the state system (Perry, Zulliger & Rogers, 2014). China's barefoot doctors, locally trained farmers with deep community embeddedness, are credited with contributing to large declines in infant mortality and infectious disease in the 1960s and 1970s (Zhang & Unschuld, 2008).

The analytically significant transition came in the 1980s: barefoot doctors were upgraded to formally examined, supervised village doctors, forming the backbone of China's primary health care system. The lesson is that community trust and coverage, however strong, do not produce durable institutionalisation without formal state recognition, examination standards, and supervision structures — a direct lesson for

Zimbabwe, where VHW community acceptance is not matched by formal system integration.

2.3.5 Comparative lessons: African regional programmes

2.3.5.1 Malawi

Malawi's Health Surveillance Assistants (HSAs) programme, operational since 1960 and formalised with salaried government employment from 1995, is one of the oldest institutionalised CHW systems in sub-Saharan Africa (Kok *et al.,* 2016; Chikaphupha *et al.,* 2016). Village health committees provide community accountability, while decentralised management through District Health Management Teams and examination-based certification sustain HSA performance. This represents a minimum standard of institutionalisation that Zimbabwe's volunteer-based VHW system has not consistently met; it is also a cautionary case, because Malawi's neonatal mortality has fallen more slowly than its under-five mortality despite six decades of a salaried cadre, indicating that workforce institutionalisation alone does not secure neonatal survival (Kok et al., 2016).

2.3.5.2 Kenya

Kenya organises CHWs into units serving approximately 1,000 households, with standardised training based on the Kenya Essential Package for Health (Aridi et al., 2014; Gupta & Khan, 2024). Kenya's analytical lesson lies in its effort to standardise CHW roles and competencies nationally — a step toward institutionalisation despite incomplete formalisation of employment. The limitation is that standardisation without remuneration and governance integration yields inconsistent results, which is directly instructive for Zimbabwe.

2.3.5.3 South Africa

South Africa's reconfigured primary health care (rPHC) introduced ward-based PHC outreach teams structurally resembling the institutionalisation model advocated here (Moosa, Derese & Peersman, 2017). However, practical implementation was suboptimal due to limited training, insufficient supervision, and uneven geographic coverage (Khuzwayo & Moshabela, 2017; Nelson & Madiba, 2020). Weak linkages between the community and facility services and limited financing further undermined effectiveness. South Africa exemplifies how structural definition without the integration of financing, supervision, and governance produces nominal institutionalisation without mortality reduction.

2.3.5.4 Nigeria

Nigeria's community health cadre evolved from volunteer Village Health Workers to a tiered structure that includes Community Health Officers and Extension Workers (Mbachu *et al.,* 2022; Gibson et al., 2023). Despite formal plans, institutionalisation failed in practice: VHWs remained volunteers, coverage was uneven, and targets were consistently unmet (Effiong *et al.,* 2025). Disease-specific focus on HIV/AIDS, TB, and malaria further limited comprehensive newborn care. Nigeria exemplifies how structural definition without financing, governance, and a comprehensive scope produces nominal institutionalisation without mortality reduction.

2.3.6 Synthesis: Five conditions differentiating effective from ineffective community health systems

Read together, the country cases point to five conditions that recur wherever community health systems have been associated with sustained reductions in neonatal mortality, and whose absence recurs where they have not (Table 2). The synthesis that follows the table sets out where the evidence agrees, where it conflicts, how context modifies the relationship, and what the evidence cannot show.

Table 2: Conditions differentiating effective from ineffective community health systems

Condition	Mechanism	Illustrative Evidence
1. Political Commitment and Formal Integration	High-performing countries treat CHWs as formal state employees within national health systems	Ethiopia, Rwanda, Brazil vs. Nigeria, Zimbabwe
2. Defined Scope and Structured Training	Effective programmes operate with clearly defined service packages, standardised training, and competency-based certification	Ethiopia's 16-package HEP; Brazil's Primary Care Teams
3. Supervision and Supportive Management	Sustained investment in management, supervision, and logistics is essential for quality at scale	South Africa's ward teams failed without supervision and support
4. Community Ownership and Embeddedness	Community-driven programmes demonstrate greater sustainability and reach beyond external support cycles	Rwanda's elected binomes; Ethiopia's Health Development Army
5. Remuneration as an Institutionalisation Imperative	Financial compensation is essential for sustained, full-time CHW engagement and equity of coverage	Volunteer reliance causes dropout, part-time work, and inequity

The most consistent correlate of community health system effectiveness in reducing neonatal mortality is the degree of institutionalisation across workforce, governance, accountability, and financing within the formal health sector (Croke, 2021; Mengistu *et al.,* 2025). Countries achieving this have shown reductions in neonatal and child mortality; those that do not have experienced persistently high neonatal mortality despite similar intervention designs (Rifkin, 2018; Hone, Macinko & Millett, 2018).

Where the evidence agrees: Every case in which a community cadre has been associated with mortality decline (Ethiopia, Brazil, Rwanda, Malawi) shares formal recognition, some form of remuneration, structured supervision and a defined link to the facility tier; every case of nominal institutionalisation without mortality gain (South Africa, Nigeria, and Kenya to a lesser degree) lacks at least two of these. This pattern is consistent across systematic reviews of CHW programmes (Lewin *et al.,* 2010; Perry *et al.,* 2017; Scott *et al.,* 2018) and across the participatory-group trials, where the effect

of women's groups was conditional on coverage and on the presence of a functioning workforce to act on the demand they generated (Prost *et al.,* 2013; Seward *et al.,* 2017).

Where the evidence conflicts: Three findings complicate a simple institutionalisation-equals-survival reading. First, formalisation can erode the community embeddedness that made a cadre effective: China's transition from barefoot doctors to examined village doctors improved standards but weakened household reach and trust (Perry, Zulliger & Rogers, 2014). Second, salaried status is not sufficient: Malawi's Health Surveillance Assistants have been government employees for decades, yet neonatal mortality has declined more slowly than under-five mortality (Kok *et al.,* 2016). Third, the size of the effect attributed to community platforms varies widely between the participatory-group meta-analysis (Prost *et al.,* 2013), the home-visit reviews (Lassi *et al.,* 2016) and the national programme evaluations, partly because these evaluate different things (a specific intervention delivered by a cadre versus the cadre itself) and partly because the national evaluations cannot separate the programme from secular trends.

How context modifies the relationship: The countries with the largest associated declines (Ethiopia, Rwanda) combined community health reform with strong central political commitment, facility expansion and financing reform; the countries where structure did not translate into outcomes (South Africa, Nigeria) had comparable or greater fiscal capacity but fragmented governance and disease-specific verticalisation. The mediating variable that recurs is governance: whether there is a structure at community and district level that holds the workforce accountable and links it to the facility tier. This is the reason governance is treated as a vital sign in its own right in this study rather than as a property of the workforce.

What the evidence cannot show: Almost all country-level evidence is observational, before-and-after or ecological; the participatory-group evidence is randomised but evaluates a single component; and there is no randomised evidence anywhere in sub-Saharan Africa on the effect of institutionalising workforce, governance and participatory groups together as a package. The claims that can be supported from the literature are therefore that these components are associated with neonatal survival and that governance appears to condition the effect of the workforce; the claim that

institutionalising them as a package causes a reduction in neonatal deaths is a hypothesis, and testing it is the purpose of this study.

Zimbabwe shares the structural profile of the latter group: human resource shortages, limited fiscal space, and a volunteer-dependent community workforce, and has only recently begun institutionalisation through its 2020–2025 National Community Health Strategy. The specific mechanisms required and evidence gaps around their combined effect on neonatal survival are detailed in Sections 2.4 and 2.8.

2.4 Structural gaps in the institutionalisation of community health systems

Despite clear evidence supporting the effectiveness of community health systems in reducing neonatal mortality, persistent structural gaps hinder their full institutionalisation in LMICs. These gaps span all six WHO building block domains and collectively undermine the scalability, sustainability, and impact of community-based neonatal interventions. Zimbabwe exhibits all five principal structural gaps simultaneously, making it an analytically significant case for studying institutionalisation reform.

The literature reviewed in Section 2.3 tends to equate institutionalisation with the formal employment, remuneration and training of the workforce. That reading is too narrow for this study. Drawing on the health-systems and institutional literature (North, 1990; Kok *et al.,* 2015; Scott *et al.,* 2018; Schneider *et al.,* 2022), institutionalisation is treated here as multidimensional, comprising six dimensions: (i) policy and legal recognition of the community tier and its actors; (ii) sustained public financing and remuneration; (iii) workforce training, supervision and career structure; (iv) governance and accountability structures that link community actors to district management; (v) inclusion of community-level data in routine health information systems; and (vi) institutionalised community participation through recognised structures. A community health system may be well advanced in one dimension (for example, a trained workforce) and absent in others (governance, financing); it is the combination that distinguishes institutionalisation from implementation, integration, participation, or routine delivery, as set out in Section 1.10.5. The seven gaps that follow are organised against these dimensions.

2.4.1 Governance and policy fragmentation

Weak and fragmented governance arrangements at national and subnational levels impede coherent policy implementation and integration of community health into broader health system architecture (Perry *et al.,* 2017; Scott *et al.,* 2018). In many contexts, including Zimbabwe, community health is treated as a donor-driven add-on rather than a core state function, leading to inconsistent political commitment and parallel systems that lack coordination, thereby reducing accountability and efficiency (Tseng *et al.,* 2019; Chen *et al.,* 2021).

2.4.2 Inadequate and unstable financing

Sustainable financing remains a critical structural gap. Heavy reliance on external donor funding exposes community health programmes to volatility, with interruptions adversely affecting workforce remuneration, commodity supply chains, and training (LeBan, Kok & Perry, 2021; Africa CDC & UNICEF, 2025). Fiscal limitations and competing priorities constrain domestic resource mobilisation, limiting long-term planning and institutional sustainability (Zimbabwe Ministry of Health, 2020).

2.4.3 Human resources and workforce challenges

The community health workforce often suffers from insufficient formal recognition, limited career progression pathways, inadequate training, and weak supervision (Kane *et al.,* 2021; Hobbs *et al.,* 2022). Zimbabwe's Village Health Workers face high attrition and variable motivation, compromising service continuity and quality. The absence of standardised competency frameworks and certification limits professionalisation and integration within health system hierarchies (Woldie *et al.,* 2018; Schaaf *et al.,* 2020).

2.4.4 Data and health information system deficits

Community-level data remain poorly integrated into national health information systems, limiting evidence-based decision-making, resource allocation, and adaptive management (Seward *et al.,* 2017; Zimbabwe Ministry of Health, 2020). Fragmented data flows and inadequate capacity for collection, analysis, and use at community and

district levels weaken monitoring of neonatal health outcomes and programme performance — a structural condition directly relevant to the modelling approach adopted in this study.

2.4.5 Limited community participation and social accountability

Structural barriers to meaningful community engagement persist, including weak mechanisms for community governance, planning participation, and accountability (Rifkin, 2018; Perry & Zulliger, 2012). The lack of community ownership reduces acceptability, responsiveness, and sustainability of interventions, particularly in contexts where trust in health workers is fragile. Social accountability mechanisms, such as health facility committees and community feedback forums, require formal recognition and resourcing to function effectively (Lodenstein *et al.,* 2017).

2.4.6 Scarcity of rigorous system-wide evaluations

While the literature extensively documents the components of community health systems and their theoretical impact on neonatal mortality, there is a notable scarcity of rigorous, system-wide evaluations that quantify the integrated effect of simultaneously institutionalising multiple components of community health systems. Most existing studies in high-burden, resource-constrained settings rely on cross-sectional or descriptive designs that cannot support causal inference or predictive modelling (Nishimwe, Mchunu & Mukamusoni, 2021). This gap limits applicability to policy formulation and programme scale-up, underscoring the need for comprehensive evaluations that model components as an interconnected system.

2.4.7 Sociocultural and contextual barriers

Socioeconomic vulnerabilities, gender norms, and cultural beliefs influence community acceptance, participation, and utilisation of community health services. These social determinants of health are insufficiently addressed in institutionalisation efforts, thereby reducing the effectiveness of interventions aimed at improving neonatal survival (Braveman & Gottlieb, 2014; Chelak & Chakole, 2023). For Zimbabwe and

Mashonaland West specifically, rural geographic barriers, female disempowerment, and traditional beliefs around birth practices compound the institutionalisation deficit.

2.5 Community-based interventions and neonatal mortality reduction

2.5.1 Evidence of effectiveness

Multiple systematic reviews and meta-analyses demonstrate that community-based approaches can reduce neonatal mortality by 20% to 45%, depending on the intervention package and coverage level (Prost *et al.,* 2013; Seward *et al.,* 2017). Participatory women's groups that employ learning-and-action cycles empower communities to identify and address perinatal challenges, consistently yielding significant reductions in mortality (Pulkki-Brännström *et al.,* 2021). Home visits by trained community health workers providing counselling and newborn care are also associated with reduced mortality, especially when integrated with facility-based services (Penfold *et al.,* 2014; Lassi *et al.,* 2016).

Key effective interventions include: early initiation of breastfeeding within the first hour after birth; clean cord care to prevent infections; thermal care (including kangaroo mother care) for low-birthweight and preterm infants; recognition of neonatal danger signs and timely referral; and promotion of antenatal care attendance and skilled birth attendance through community mobilisation (Lewycka *et al.,* 2010; Gope *et al.,* 2019). These interventions are delivered through home visits, women's groups, community education, and family engagement, which foster supportive environments.

2.5.2 Mechanisms of impact

Community-based approaches enhance neonatal survival by increasing knowledge, encouraging healthy behaviours, improving care-seeking, and strengthening community–facility linkages. Participatory women's groups facilitate social cohesion and collective problem-solving, challenge harmful cultural norms, and empower women (George & Branchini, 2017; Tavrow & Upadhyay, 2017). Home visits enable early identification of complications for prompt referral (Gogia & Sachdev, 2016). Social accountability mechanisms, health facility committees and community feedback

forums play a key role in empowering communities to hold providers accountable for service quality (Lodenstein *et al.,* 2017).

2.5.3 Contextual adaptation and system integration

The success of community-based interventions depends on adequate coverage, quality implementation, and tailoring to local contexts. The women's group approach has yielded variable outcomes across South Asia and Africa, underscoring the need for context-specific adaptation and robust programme support (Azad *et al.,* 2010; Prost *et al.,* 2013). Combining community-based interventions with facility-based care amplifies impact by addressing both supply- and demand-side barriers, ensuring continuity of care throughout the antenatal, intrapartum, and postnatal periods (Darmstadt *et al.,* 2005; Lassi *et al.,* 2016).

2.5.4 Implications for Zimbabwe

In Zimbabwe, where neonatal mortality remains high and community health systems are largely informal and volunteer-dependent, institutionalising community-based interventions is essential to maximise their potential (MOHCC, 2020; Hobbs *et al.,* 2022). This includes formalising VHWs, strengthening participatory women's groups, and enhancing community governance structures. The National Community Health Strategy (2020–2025) seeks to embed these interventions within the formal health system by emphasising sustainable financing, supervision, and integration of data systems. However, evidence on the effectiveness of these reforms in reducing neonatal mortality remains limited, and this study directly addresses this gap.

2.6 Neonatal mortality in Zimbabwe: Context and challenges

2.6.1 National epidemiological profile

Zimbabwe continues to experience persistently high neonatal mortality, particularly in rural provinces. The national NMR was 32 per 1,000 live births as of the 2019 Multiple Indicator Cluster Survey (MICS, 2019) and rose to 37 per 1,000 live births (national average) (ZDHS 2023-2024). Neonatal deaths account for approximately 44% of all under-five mortality nationally, underscoring the critical need to address the first 28

days of life (ZDHS, 2015; MOHCC, 2016). Figure 7 illustrates the progression of neonatal mortality rates in Zimbabwe from 1990 through 2022.

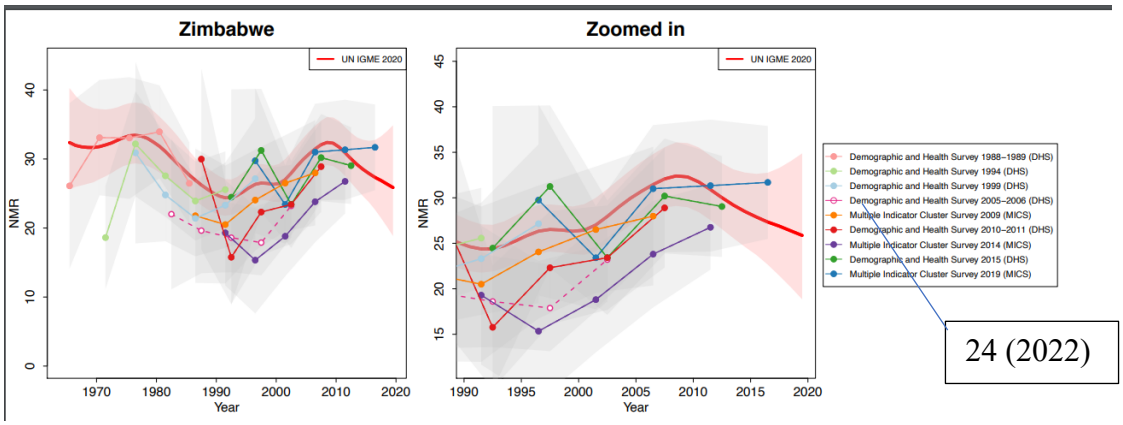


Figure 8: Illustration of the progression of neonatal mortality rates in Zimbabwe from 1990 through 2022

Source: UN IGME, 2024

Despite improvements in antenatal care coverage (93%) and institutional delivery rates (77%), progress in reducing neonatal mortality has been slow and uneven across provinces (MOHCC, 2016; MICS, 2019). Several provinces with relatively high institutional delivery rates still report elevated neonatal mortality, indicating that facility-based care alone is insufficient (Musarandega *et al.,* 2022; Yemane et al., 2024).

2.6.2 Mashonaland West Province: Sub-provincial context

Mashonaland West Province has one of Zimbabwe's highest neonatal mortality rates. The provincial NMR was 29 per 1,000 live births in 2019, down from 46 per 1,000 in 2015 and 35 per 1,000 live births in Mashonaland West Province (ZDHS 2023-2024), but still well above the SDG target of 12 per 1,000 (MICS, 2019, ZDHS 2023-2024). The province's health system profile is characterised by predominantly rural, dispersed settlements with long distances to health facilities, seasonal road access constraints, and an agricultural economy with pronounced wet-season labour demands that conflict with antenatal care scheduling.

The province has seven districts, with health facility coverage varying considerably. VHW density falls below the national average, and community governance structures (health centre committees and village health committees) are formally established but

inconsistently functional due to resource constraints and weak linkage to district governance (MOHCC, 2021). Province-specific epidemiological studies on neonatal mortality are limited; in the published literature, Mashonaland West is rarely disaggregated beyond national surveys, a research gap this study addresses. Where district health reports exist, they document similar patterns to national surveys but with greater granularity on cause-of-death profiles dominated by prematurity, birth asphyxia, and neonatal sepsis.

2.6.3 Key contextual challenges

2.6.3.1 Informal and under-resourced community health systems

Village Health Workers form the backbone of community health services yet operate largely as volunteers with limited formal integration, inadequate training and supervision, and inconsistent incentives. The estimated workforce of approximately 21,600 VHWs falls short of the required 40,000 to adequately cover Zimbabwe's population, limiting the reach and effectiveness of community-level neonatal interventions (Woldie *et al.,* 2018; MOHCC, 2021; Hobbs *et al.,* 2022). This workforce gap is most acute in rural provinces, including Mashonaland West.

2.6.3.2 Socioeconomic and cultural barriers

Poverty, gender inequality, low female empowerment, and cultural norms affect health-seeking behaviours and timely utilisation of maternal and neonatal health services. Women's limited decision-making power and financial dependency reduce their ability to access care promptly, while traditional beliefs may discourage facility births or postnatal care (ZDHS, 2015; Mupambireyi *et al.,* 2024). These barriers are particularly pronounced in rural Mashonaland West, where female literacy rates and household income are below the national average.

2.6.3.3 Weak referral and postnatal care systems

Delays in recognising neonatal danger signs, decision-making to seek care, and reaching health facilities contribute significantly to neonatal deaths. Postnatal care

coverage remains suboptimal: 43% of mothers did not receive a postnatal check within 48 hours after birth, and 27% of neonates missed timely postnatal care (MOHCC, 2016; Madyira *et al.,* 2016). This gap in the critical immediate postnatal period is precisely where community-level vital signs (VHWs conducting home visits, participatory groups facilitating recognition of danger signs) have their greatest potential impact.

2.6.3.4 Health system constraints

Zimbabwe's health system faces shortages of skilled health workers, inadequate infrastructure, frequent stockouts of essential medicines and supplies, and challenges in data collection and use at community and facility levels (MOHCC, 2017; Musarandega *et al.,* 2022). These constraints affect the quality and continuity of neonatal care and compound the institutionalisation deficit.

2.6.3.5 Data gaps and underreporting

Neonatal deaths occurring outside health facilities are frequently unreported due to weak vital registration systems and social stigma. This underestimation hampers accurate monitoring, planning, and targeted interventions (Pathirana *et al.,* 2016; Stoneburner *et al.,* 2017). For Mashonaland West, the combination of geographic remoteness and weak community data systems means that the true NMR may exceed survey estimates.

2.6.4 COVID-19 and the 2020–2021 study period

The study period of 2020–2021 coincided with the first two years of the COVID-19 pandemic, which caused significant disruption to maternal and neonatal health service delivery globally, including in Zimbabwe. This context is analytically important and must be acknowledged as a potential modifier of the study's outcome data.

Documented disruptions during this period include: reduced antenatal care attendance due to fear of facility-based infection and lockdown restrictions; redeployment of community health workers, including VHWs, to COVID-19 response activities; supply chain disruptions affecting essential medicines and commodities; disruption to

community group meetings, including participatory women's groups; and reduced supervision capacity as district health teams managed pandemic response.

Globally, WHO and UNICEF documented a 20–30% decline in coverage of essential maternal and neonatal health services in LMICs during 2020 (WHO, 2020; UNICEF, 2020). In Zimbabwe, the Ministry of Health and Child Care (MOHCC) reported reductions in ANC visits, institutional deliveries, and postnatal care contacts during the first lockdown period (March–August 2020) (MOHCC, 2020).

Analytical implication: The study's models must account for the possibility that observed variations in neonatal mortality during 2020–2021 reflect pandemic-era service disruptions rather than, or in addition to, the institutionalisation variables of interest. Sensitivity analyses and contextual triangulation in the qualitative component of the mixed-methods design help address this limitation.

2.6.5 Zimbabwe's Policy Response: The National Community Health Strategy 2020–2025

Zimbabwe's National Community Health Strategy (NCHS) 2020–2025 represents the primary policy response to the institutionalisation deficit. The strategy aims to formalise the community health workforce, strengthen governance through revitalised health centre committees, improve data systems, and secure sustainable financing aligned with the WHO health system building blocks (MOHCC, 2020). It positions community health services as the first tier of care and emphasises integration of VHWs into the formal health system with defined scopes of practice, supervision structures, and conditional incentives. Appendix 1 demonstrates the operationalisation using the Tanahashi Model lens to analyse coverage of health services and community health system strengthening.

However, evidence on the effectiveness of these reforms in reducing neonatal mortality remains limited at the time of this study. Implementation across provinces has been uneven, and the gap between policy intent and operational reality, particularly regarding VHW incentivisation and the activation of community governance, remains analytically significant. This gap defines the specific empirical contribution of the present study.

2.7 Methodological landscape: predictive modelling in community health systems

Given that this study's primary objective is to develop and apply predictive models of the effect of institutionalising community health system vital signs on neonatal mortality, a review of the methodological landscape for predictive modelling in community health systems is essential. This section synthesises the key available modelling approaches, their application to community health and neonatal mortality outcomes in comparable settings, and the methodological rationale for the approach adopted in this study.

2.7.1 Statistical and epidemiological modelling approaches

2.7.1.1 Multivariate regression and logistic modelling

Multivariate regression analysis is the most widely applied quantitative approach for modelling determinants of neonatal mortality in LMICs. Logistic regression models have been used to estimate associations between CHW density, antenatal care utilisation, skilled birth attendance, and neonatal mortality outcomes across sub-Saharan Africa (Mekonnen *et al.,* 2013; Kayentao *et al.,* 2023). These models allow simultaneous control for confounders and provide odds ratios that express the relative contribution of each predictor, including community health workforce variables, to neonatal mortality risk.

The limitation of standard multivariate regression in this context is its assumption of linear, independent relationships among predictors: an assumption that does not hold when modelling interdependent system components such as VHW density, community governance strength, and participatory group activity, which interact and mutually reinforce one another. Extended approaches, such as multilevel (hierarchical) regression, address clustering at the district and provincial levels and are particularly appropriate for Zimbabwe's nested administrative structure (community → district → province) (Merlo *et al.,* 2005).

2.7.1.2 Structural equation modelling

Structural Equation Modelling (SEM) provides a framework for testing hypothesised causal relationships among multiple latent and observed variables simultaneously, making it well suited to community health system research where variables such as 'governance quality' and 'community engagement' are not directly measurable but are inferred from observable indicators (Hoyle, 2012). SEM has been applied in health systems research to model pathways from health system inputs to intermediate outcomes (service coverage) to mortality outcomes, particularly in settings where direct experimentation is ethically or practically impossible (Schreiber *et al.,* 2006).

In this study, SEM enables modelling of the pathway from the institutionalisation of each vital sign (VHWs, governance, modified women's and men's groups) through intermediate mechanisms (service coverage, demand-side behaviour change, referral linkages) to neonatal mortality outcomes. The latent-variable structure of SEM accommodates the fact that 'institutionalisation' is a composite construct operationalised by multiple observable indicators. A limitation is the need for relatively large sample sizes to obtain stable parameter estimates, which constrains application at the sub-district level.

2.7.1.3 Generalised linear models and Poisson regression

For count outcomes such as neonatal deaths within a defined population and time period, Poisson regression and negative binomial regression are methodologically appropriate, particularly when modelling mortality rates at the community or district level (Hilbe, 2011). These models have been applied to estimate the effect of CHW programme coverage on neonatal mortality rates across African health districts, demonstrating statistically significant associations between CHW density and reduced neonatal mortality after controlling for poverty, institutional delivery rates, and geographic access (Kok *et al.,* 2016; Kayentao *et al.,* 2023).

2.7.2 Systems-thinking and dynamic modelling approaches

2.7.2.1 System dynamics modelling

System Dynamics (SD) modelling uses differential equations to represent feedback loops, stocks, and flows within complex adaptive systems over time (Sterman, 2000). In health systems research, SD has been applied to model the long-term effects of health workforce policies, supply chain interventions, and community health programme scale-up on population health outcomes (Homer & Hirsch, 2006; Rwashana *et al.,* 2014). Rwashana *et al.* (2014) applied SD modelling specifically to neonatal and infant mortality in Uganda, demonstrating that delayed institutionalisation of community health programmes produced compounding mortality effects over time that cross-sectional studies could not capture.

For the present study, SD modelling provides a conceptual frame for understanding the dynamic relationship between institutionalisation and neonatal mortality: as community health system vital signs are strengthened (stock of trained VHWs increases, governance structures activate, participatory groups reach saturation), feedback loops reinforce coverage, behaviour change, and referral effectiveness, producing non-linear reductions in neonatal mortality over time. This dynamic logic underpins the study's predictive modelling approach.

2.7.2.2 Agent-based modelling

Agent-Based Modelling (ABM) simulates the behaviour of individual agents (community members, VHWs, health facilities) and the emergent system-level outcomes of their interactions (Bonabeau, 2002). ABM has been applied in community health research to model the spread of health behaviours, the effect of community health worker density on care-seeking, and the impact of participatory group interventions on neonatal care practices (Marshall & Galea, 2015). While ABM's individual-level granularity is a strength, its data requirements, including detailed demographic, behavioural, and social network data at the community level, exceed what is available in Mashonaland West, making full ABM implementation beyond the scope of this study.

2.7.3 Machine learning and predictive analytics

Machine learning (ML) approaches, including decision trees, random forests, support vector machines, and artificial neural networks, have increasingly been applied to

predict neonatal mortality risk at individual and population levels in LMICs (Rinta-Koski *et al.,* 2018; Batista *et al.,* 2020). Random forest models have demonstrated particular utility for variable selection in complex health datasets, identifying which community health system variables most strongly predict neonatal outcomes when the number of predictors is large, and relationships are non-linear (Breiman, 2001).

A systematic review by Batista *et al.* (2020) identified 23 studies applying ML to neonatal mortality prediction in LMICs, finding that models incorporating community-level variables — including CHW coverage, postnatal visit rates- and consistently outperformed models based solely on clinical variables, with area under the curve (AUC) values ranging from 0.72 to 0.91. However, the interpretability of ML models poses a challenge for policy translation: random forests and neural networks identify predictive associations without providing the causal pathway estimates that policymakers require to design interventions (Obermeyer & Emanuel, 2016).

2.7.4 Methodological choice: Rationale for this study's approach

This study applies a multilevel predictive modelling approach, combining logistic regression with structural equation modelling components, for the following methodological reasons:

i. The outcome variable (preventable neonatal death: binary yes/no) is appropriate for logistic regression, with neonatal mortality rate (deaths per 1,000 live births) modelled using Poisson regression at the community level.

ii. The nested structure of the data (communities within districts within a province) requires multilevel modelling to account for clustering effects that would otherwise inflate statistical significance estimates.

iii. The theoretical interest in pathways on how each vital sign affects neonatal mortality through intermediate mechanisms justifies SEM components that go beyond simple association to model mediation.

iv. The available data (community-level survey data, VHW registers, health centre committee activity records, district health information system data) are

compatible with multilevel regression and SEM but insufficient for full ABM or neural network approaches.

v. Policy relevance requires interpretable parameter estimates (odds ratios, standardised coefficients) rather than black-box predictions, favouring regression-based approaches over pure machine learning.

Table 3 summarises the applicability of predictive modelling approaches to this study's objectives and data context. Selected approaches are highlighted. Full methodological detail, including model specification, variable operationalisation, and estimation procedures, is presented in Chapter Three and Four.

Table 3: Summary of the modelling approaches reviewed and their applicability to this study

Modelling Approach	Applicability to this Study
Multivariate/Logistic Regression	**High:** directly applicable; standard approach for binary neonatal mortality outcome; multilevel extension addresses clustering
Structural Equation Modelling	**High:** applicable for modelling pathways from institutionalisation to mortality through intermediate variables; requires an adequate sample size
Poisson/Negative Binomial Regression	**High:** applicable for modelling mortality rates at the community and district level
System Dynamics Modelling	**Moderate:** conceptually informative; full implementation requires longitudinal time-series data beyond the study scope
Agent-Based Modelling	**Low:** individual-level data requirements exceed available data in Mashonaland West
Machine Learning (Random Forest, ANN)	**Moderate:** useful for variable selection; limited policy interpretability; applied as a supplementary exploratory tool

2.8 Research gap and study rationale

2.8.1 Convergence of evidence on the institutionalisation deficit

The evidence reviewed across this chapter converges on a single analytical conclusion: Zimbabwe's persistently high neonatal mortality, particularly in rural provinces like Mashonaland West, is not primarily a consequence of missing interventions, but of the

failure to institutionalise the community health system that would deliver them. The structural barriers documented in Sections 2.4 and 2.6 (informal VHW status, fragmented governance, donor-dependent financing, weak data integration, and limited community accountability) are not independent problems but interlocking dimensions of a single institutionalisation deficit.

2.8.2 The specific evidence gap

Despite substantial evidence on community health systems and their potential to reduce neonatal mortality, rigorous, system-wide evaluations that model the institutionalisation of community health components as integrated determinants of neonatal survival in rural, resource-limited settings remain critically lacking (Nishimwe, Mchunu & Mukamusoni, 2021). The existing literature highlights fragmented assessments that focus on isolated interventions or individual workforce elements and fail to capture the complex interactions among VHWs/CHWs, community governance structures, and participatory learning/action groups within the broader health system.

For Zimbabwe specifically, the review identifies three gaps. First, whether institutionalising the community tier as a package (workforce, governance and participatory groups together) reduces neonatal mortality: the Zimbabwean studies available (Nhede & Catraio, 2021; Chasekwa et al., 2022; Noble *et al.,* 2022) are observational and examine single components, and no randomised evaluation of the package exists in Zimbabwe or in a directly comparable rural Southern African setting. Second, the magnitude of any such effect and the number of mother–infant pairs that would need to be reached to avert one neonatal death, which the National Community Health Strategy 2020–2025 needs to cost and prioritise its investment case. Third, which of the three components is most strongly associated with neonatal survival, whether governance conditions the workforce's effect as comparative evidence suggests, and how the effect changes under partial rather than full institutionalisation. Strategy acknowledges the institutionalisation deficit and sets a reform agenda; however, the literature still lacks system-level empirical evidence on these three questions.

2.8.3 Study rationale and contribution

This study addresses the identified gap by conceptualising and empirically modelling the institutionalisation of VHWs/CHWs, community governance structures, and participatory learning/action groups as interconnected and essential components of the community health system. Focusing on Mashonaland West Province, Zimbabwe, 2020–2021, the research assesses how these integrated institutional elements collectively influence preventable neonatal mortality.

The study's contribution is threefold: first, it generates quantitative predictive evidence on the independent and combined effects of the three community health system vital signs on neonatal mortality; second, it situates these findings within the qualitative mechanisms that explain why institutionalisation produces the observed effects; and third, it translates findings into actionable policy and programmatic recommendations for Zimbabwe's National Community Health Strategy and comparable LMIC settings. By modelling institutionalisation as a system-level intervention rather than isolated components, the study advances the methodological frontier of community health systems research.

2.9 Theoretical and conceptual synthesis: connecting literature to framework

2.9.1 Theoretical foundations

This study adopts pragmatism as the philosophy governing its design and methods (Chapter Four), within a critical-paradigm interpretive lens that shapes which variables are examined and how findings are interpreted (Chapter Three, Section 3.2). Pragmatism, as articulated by Dewey (1938), Pierce (1878), and James (1907) and applied to health systems research by Feilzer (2010) and Creswell & Plano Clark (2018), holds that the value of a theory or method is determined by its practical consequences — its capacity to generate knowledge that can guide action. Pragmatism embraces the complementarity of quantitative and qualitative evidence, prioritises real-world applicability over paradigmatic purity, and recognises that complex health system problems require mixed-methods inquiry. This philosophical stance is not incidental to the study's design but constitutive of it: combining predictive modelling

with qualitative mechanism analysis reflects the pragmatist conviction that neither approach alone can adequately answer the research question.

In addition to the three frameworks set out in Section 2.9.2 and Chapter Three, the study draws on New Institutionalism to explain the institutionalisation construct itself (March & Olsen, 1984; North, 1990). New Institutionalism holds that formal institutions (rules, norms, and organisations) shape behaviour by creating structures of incentives, accountability, and legitimacy within which actors operate. Applied to community health, this framework predicts that VHWs operating within formal institutional structures (defined roles, remuneration, supervision, career pathways) will behave differently and produce different outcomes than functionally equivalent workers operating outside such structures. The depth of institutionalisation thus predicts the effectiveness of community health delivery, which is precisely the hypothesis this study tests.

2.9.2 Conceptual framework

A comprehensive understanding of neonatal mortality requires an integrated theoretical approach. This study draws on three frameworks (Mosley and Chen's analytical model, the Socio-Ecological Model (SEM), and the Tanahashi framework) to capture the multilevel, multidimensional factors influencing neonatal outcomes.

The Mosley and Chen framework focuses on the proximate determinants of child survival, emphasising individual-level biological, environmental, and behavioural factors (Mosley & Chen, 2003). This model helps identify direct risk factors for neonatal mortality, including maternal health, birth practices, and immediate household conditions.

The Socio-Ecological Model (SEM) expands the analytical lens to multiple layers of influence, including individual, interpersonal, community, organisational, and policy levels. SEM helps contextualise how broader social, cultural, and community dynamics, such as gender roles, social support, and community norms, influence individual behaviours and access to care.

The Tanahashi framework assesses the health system's capacity to deliver effective coverage by breaking service provision into five stages: availability, accessibility,

acceptability, contact, and effectiveness. This framework is critical for identifying bottlenecks and gaps in the health system's capacity to translate interventions into improved health outcomes.

Each framework contributes uniquely: Mosley and Chen clarify individual-level risk factors; SEM situates these factors within broader social and community contexts; and Tanahashi assesses the health system's capacity to deliver care. Integrating them is necessary to holistically analyse the factors underlying neonatal mortality in Zimbabwe, ensuring the study addresses not only what interventions are needed, but also how social context and health system capacity mediate their effectiveness.

By integrating these frameworks, this study is able to:

i. Identify and analyse proximate determinants of neonatal mortality (Mosley and Chen);
ii. Situate these determinants within a multi-level socio-ecological context (SEM);
iii. Examine how health system bottlenecks and coverage gaps influence outcomes (Tanahashi).

This nested, multi-framework approach provides a robust conceptual foundation for the study's mixed-methods design and predictive modelling, ensuring that both the individual and system-level determinants of neonatal survival are addressed.

The WHO health system building blocks (Section 2.2.3) and the Socio-Ecological Model (Section 2.2.4) complement one another in a specific way that determines how the study variables were derived. The building blocks describe the supply side: the functions a health system must perform (workforce, governance, information, financing, products, service delivery). The Socio-Ecological Model describes the demand side: the nested levels (individual, household, community, organisational, policy) at which those functions must act to change household behaviour and care-seeking. The three vital signs sit at the intersection. IV1 (the VHW workforce) is the building-block function 'health workforce' operating at the SEM household and interpersonal levels; IV2 (community governance) is the building-block function 'leadership and governance' operating at the SEM community and organisational levels; IV3 (learning and action groups) is the building-block function 'service delivery' in its demand-generation form, operating at the SEM interpersonal and

community levels. The hypothesised mediators (household contact, danger-sign recognition, referral, care-seeking, newborn-care practices) are the SEM-level behaviours through which the building-block functions reach the proximate determinants in the Mosley-Chen framework, and the outcome, preventable neonatal death, is the Mosley-Chen endpoint. This mapping is what allows the same three variables to be read both as health-system functions (for policy) and as community-level exposures (for analysis).

Figure 11 presents the study's conceptual framework, which integrates the Socio-Ecological Model, the WHO building blocks, and New Institutionalism into a single analytical structure. The framework posits three causal pathways through which the institutionalisation of community health system vital signs reduces neonatal mortality:

1) Pathway 1 - Service Coverage: Institutionalised VHWs with formal training, remuneration, and supervision achieve higher household coverage, delivering essential newborn care practices and danger sign recognition to a larger proportion of the neonatal population.
2) Pathway 2 - Demand-Side Behaviour Change: Participatory learning/action groups, when formally structured and sustainably resourced, facilitate community-level behaviour change in birth practices, postnatal care seeking, and breastfeeding initiation.
3) Pathway 3 - Governance and Accountability: Functional community governance structures (formally recognised, financed, and linked to district health management) generate accountability for service delivery quality and referral linkage, reducing avoidable delays in the Three Delays model.

These three pathways are not independent: they interact and reinforce one another, producing system-level effects that exceed the sum of their individual component effects. The study's predictive models test both the independent effects of each pathway and the interaction effects when all three vital signs are institutionalised simultaneously within the Zimbabwean health system architecture.

2.9.3 Connecting literature to design

The mixed-methods design adopted in this study is not a methodological preference but a logical necessity arising from literature. Understanding whether institutionalisation reduces neonatal mortality in Mashonaland West requires both quantitative modelling (to estimate the magnitude and significance of the relationship) and a qualitative understanding of the mechanism (to explain why institutionalisation produces the observed effects and under what conditions). These two questions are not answerable by a single method: quantitative modelling without mechanism explanation produces uninterpretable findings; qualitative mechanism analysis without quantitative effect estimates produces findings that cannot guide resource allocation decisions.

The chapter has traced a single, consistent argument: the gap between what is known about reducing neonatal mortality and what health systems have actually delivered is a governance and institutionalisation gap, not an evidence gap. The community-level platforms needed to deliver proven interventions exist in Zimbabwe (VHWs, health centre committees, participatory women's groups) but they remain outside the formal health system, under-resourced, unaccountable, and unsustained. This study's theoretical framework operationalises institutionalisation as the mechanism connecting health system architecture to neonatal survival, and its mixed-methods design provides the evidence needed to test that mechanism in one of Zimbabwe's highest-burden provinces.

CHAPTER THREE

THEORETICAL AND CONCEPTUAL FRAMEWORK

3.1 Introduction

This chapter provides the study's theoretical and conceptual foundation. It integrates multiple frameworks to comprehensively address the complex, multilevel determinants of neonatal mortality in rural Zimbabwe (Mashonaland West province). The chapter is structured as follows: first, it outlines the philosophical paradigm guiding the research; second, it describes each theoretical framework and how they integrate; and third, it discusses operationalisation, variable selection, and the analytic strategy. Key takeaways summarise the end of each major section to aid comprehension.

Despite global initiatives like the MDGs and SDGs, neonatal mortality remains a persistent challenge, especially in sub-Saharan Africa. This shows that neonatal health depends on complex biological, social, and health system factors. Thus, this research uses a critical paradigm to examine how power dynamics, structural inequalities, and social injustices (Burke *et al.,* 2009) affect health outcomes. Section 3.2 sets out what the paradigm does and does not govern in this study, and how it relates to the pragmatist position that governs the choice of design and methods in Chapter Four (Shiffman, 2015; Adugna *et al.,* 2025; Kinney *et al.,* 2025).

3.2 Research paradigm: The critical paradigm

As introduced earlier, this study is grounded in the critical paradigm, which examines how power dynamics, structural inequalities, and social injustices shape neonatal health outcomes. This section expands on the philosophical stance guiding the study's theoretical and methodological choices.

3.2.1 Framing of the critical paradigm

This study employed the critical paradigm, which goes beyond mere description to examine the structural, political, and systemic factors that contribute to preventable

neonatal deaths in Mashonaland West Province. Neonatal mortality is seen not as a random biomedical event but as a social outcome shaped by failures in health system design, governance, resource allocation, and community health system vital signs between 2020 and 2021. Power dynamics, structural inequalities, and social injustices are central to understanding and addressing neonatal mortality.

3.2.2 Ontological Position

Aligned with the critical paradigm, this study sees reality as shaped by history and social structures, including power relations, institutional decisions, and historical investment or neglect. Preventable neonatal deaths are viewed as layered phenomena, reflecting the views of community health workers, mothers, facility staff, district managers, and policymakers. Each perspective adds to the structural realities that influence neonatal outcomes, showing that neonatal mortality is more than just biomedical causes and must be understood in systemic and institutional contexts.

3.2.3 Epistemological Position

The critical paradigm leads to an epistemological stance that rejects value-free, objective knowledge. Instead, knowledge is seen as contextual and political, shaped by its producers and whose experiences are prioritised or ignored. This study creates knowledge through engagement with women, community health workers, managers, and members, treating them as vital sources whose lived experiences and insights are essential. This approach blends quantitative evidence on neonatal deaths with qualitative insights into system barriers, valuing layered accounts over single truths.

3.2.4 Axiological Position

The study views research as inherently value-driven, committed to social justice, equity, and the right to life. Preventing neonatal deaths is framed as ethically essential, and failing to institutionalise health system vital signs is seen as systemic injustice needing careful investigation and evidence-based solutions.

Reflective/Positionality Statement: As the principal investigator and a Zimbabwean public health expert, I recognise that my background, professional experience, and values may influence both how I frame research questions and how I interpret data. To mitigate potential bias, I actively employed reflexivity throughout the research process (engaging with diverse community perspectives, incorporating feedback from local stakeholders, and systematically documenting assumptions and decisions). This transparency aims to sharpen analytical focus and ensure the research serves affected communities with integrity and accountability.

3.2.5 Methodological implications

In line with the critical paradigm's flexibility, this study employs a mixed-methods approach. The quantitative part measures the scale and distribution of preventable neonatal deaths, guided by the Mosley and Chen framework for selecting biological and clinical variables. The qualitative part explores the structural and community-level factors underlying the institutionalisation or absence of key community health system indicators, and their impact on neonatal outcomes, informed by the Socio-Ecological Model and the Tanahashi framework. Data are triangulated to create a robust, meaningful understanding, aligning analytic techniques with theoretical constructs. This pluralism matches the critical paradigm’s view that structural factors are both measurable and experiential.

Key takeaway: Each theoretical framework directly informs variable selection, data-collection instruments, and analytic methods, thereby ensuring theoretical-methodological coherence.

3.2.6 Justification for the critical paradigm

The critical paradigm is best for this study for several reasons. First, preventable neonatal deaths are fundamentally issues of structural justice, not solely biomedical or health system challenges. Second, the research questions demand an examination of power, institutionalisation, and accountability, areas at the core of critical inquiry. Third, the mixed-methods design aligns with this paradigm, leveraging both quantitative and qualitative data to achieve a thorough and nuanced understanding. While positivist paradigms may emphasise measurable outcomes, they risk overlooking

the underlying social and power dynamics; constructivist approaches, while valuable, may not sufficiently address structural causes. Thus, the critical paradigm is the most appropriate lens for comprehensively addressing the research questions. By using this framework, the researcher aims to produce rigorous, transformative knowledge to inform policy, strengthen community health systems, and reduce neonatal mortality in Mashonaland West Province. The conceptual framework and variable choices reflect the multi-level, value-based determinants of neonatal deaths.

Compatibility with the cluster-randomised design and predictive modelling. A fair objection is that a critical paradigm sits uneasily with a study whose primary analysis is a randomised estimate of an intervention effect and whose secondary analyses are predictive models. The position taken here is that the two operate at different levels and do not compete. The critical paradigm governs three things: which variables are examined (governance, participation, workforce recognition and the distribution of resources and voice, rather than clinical inputs alone); how the outcome is conceived (a preventable death as the end-point of structural exclusion rather than only a clinical event); and how findings are interpreted (asking who benefited, who did not, and why). It does not prescribe a method. The choice of a pragmatic cluster-randomised trial with an embedded qualitative process evaluation is governed by pragmatism (Section 4.1), which selects the method most capable of answering the research question: a randomised comparison is the strongest available design for establishing whether institutionalising the community tier reduces neonatal deaths, and the qualitative strand is the strongest available design for explaining how and for whom. The predictive models serve a third and narrower purpose: identifying clusters and households at the highest risk for programme targeting; they describe associations and do not establish causal effects, a distinction maintained throughout Chapters Five to Seven. In this reading, the critical paradigm supplies the questions and the interpretive frame; pragmatism supplies the design; and the three theoretical frameworks below supply the mechanisms; each is necessary, and none substitutes for another.

3.3 Theoretical Framework

To comprehensively examine the determinants of neonatal mortality reduction within Zimbabwe's community health system, this study integrates three complementary

theoretical frameworks: the Mosley and Chen child survival model (Mosley & Chen, 2003), the Socio-Ecological Model (SEM) (Bronfenbrenner, 1979; McLeroy *et al.,* 1988), and the modified Tanahashi Health Service Coverage Model (Tanahashi, 1978; McCollum *et al.,* 2019) (Figure 9). Each framework contributes unique perspectives and analytical strengths, collectively providing a robust, multilevel approach essential for understanding the complex interplay of factors influencing neonatal health outcomes.

3.3.1 The Mosley and Chen Analytical Framework

The Mosley and Chen model offers a foundational analysis of proximate determinants by bridging social and biological variables, focusing on maternal, environmental, nutritional, and illness-control factors that directly affect neonatal mortality (Mosley & Chen, 2003; Lassi *et al.,* 2013; Gülmezoglu *et al.,* 2016; Habonimana & Batura, 2021). It guides the selection of individual-level variables such as maternal age, birth interval, and neonatal risk factors, ensuring biological and clinical pathways are accounted for (Yakoob *et al.,* 2009; Kim *et al.,* 2021; Rolexza & Meirina, 2024; González-Fernández *et al.,* 2024; Yi-Yu *et al.,* 2025; Feresu *et al.,* 2025).

In this study, the Mosley and Chen framework serves as the primary guide for selecting proximate maternal and neonatal determinants (Mosley & Chen, 2003). These include individual-level risk factors and confounders such as low birth weight, birth order, maternal age, and pregnancy complications (Toru & Anmut, 2019). By distinguishing between proximate determinants that directly influence neonatal mortality and more distal socioeconomic determinants, the framework informs both the variable selection strategy and the statistical adjustment approach. This ensures that the analysis accounts for the biological and clinical pathways through which structural and systemic factors ultimately affect neonatal outcomes.

However, its emphasis on individual- and household-level variables fails to adequately capture broader systemic and structural influences, such as community dynamics, institutional power relations, and policy environments. This narrow focus risks oversimplifying neonatal mortality as a biomedical event, potentially obscuring entrenched social inequities and governance challenges that critically shape health service delivery and access in rural Zimbabwe.

3.3.2 The Socio-Ecological Model (SEM)

To capture determinants not fully addressed by the Mosley and Chen framework, the socio-ecological model (SEM) was applied. The SEM recognises a web of features that contribute to disparities in health outcomes for neonates (Yitbarek et al., 2021; Adappa & Barr, 2023; Razdan et al., 2023), arguing that individual outcomes are shaped not only by maternal and family characteristics but also by broader social networks and the wider community context (Avoka *et al.,* 2018; Lassi, Kedzior & Bhutta, 2019; Backes & Scrimshaw, 2020). This multi-level perspective makes the SEM particularly suited to addressing complex public health challenges.

The model conceptualises health as the product of dynamic interactions between individuals and their environments, spanning intrapersonal, interpersonal, institutional, community, and policy levels (Bronfenbrenner, 1979; McLeroy *et al.,* 1988). It informs the study's sampling frame and analytical plan, enabling multilevel modelling and testing cross-level interactions (Kanunura *et al.,* 2017; Getaneh *et al.,* 2024).

For the purposes of this study, variables are collected and modelled across five ecological levels: intrapersonal, interpersonal, institutional, community, and policy. This multilevel structure is not merely theoretical - it directly informs the study's research design and statistical methodology. Multilevel models are employed to partition variance across levels, thereby isolating the contribution of each ecological stratum to neonatal outcomes. Crucially, the SEM also enables the testing of cross-level interactions, allowing the study to examine, for example, how community-level governance structures moderate the effect of individual-level risk factors on neonatal survival. In this way, the SEM ensures that the complexity of the health system is faithfully reflected in both the data collection strategy and the analytical framework.

Despite its conceptual breadth, SEM lacks operational specificity for evaluating health service delivery metrics, limiting its direct applicability to assessing supply-side bottlenecks or service-readiness elements vital to effective neonatal survival interventions.

3.3.3 The Modified Tanahashi Health Service Coverage Model

The Modified Tanahashi Model provides a structured framework for evaluating healthcare service coverage across five progressive domains: availability, accessibility, initial utilisation, adequate coverage, and effective coverage (McCollum *et al.,* 2019; Mallory *et al.,* 2020; WHO, 2024). Building on the World Health Organisation's concept of coverage, the model incorporates key elements: availability, accessibility, acceptability, and quality that are essential to understanding disparities in health service delivery (Alsadaan & Ramadan, 2025; Sales *et al.,* 2006; Khanpoor *et al.,* 2025).

Effective coverage extends beyond mere access to include service readiness and quality, aligning with WHO's definition of quality care as effective, safe, timely, equitable, integrated, and people-centered (Marsh *et al.,* 2020; Ferede Gebremedhin *et al.,* 2022; Kassie *et al.,* 2024). Applied to the RMNCAH continuum, these dimensions emphasise respectful, equitable, and integrated services to ensure that coverage, equity, and quality collectively improve maternal and newborn outcomes (Jannati *et al.,* 2018; Karim & de Savigny, 2023; Mengistu *et al.,* 2025).

In this study, the Tanahashi Model serves a dual purpose: first, it operationalises supply-side and service-delivery metrics across the five coverage domains; second, these domains act as mediators in the causal pathway linking the institutionalisation of community health programmes to neonatal outcomes. By treating the coverage domains as stepwise indicators, the study employs mediation and pathway analyses to investigate how services translate into improved neonatal health, moving beyond simple assessments of service presence.

Nevertheless, this model insufficiently integrates individual-level risk factors and social determinants, which are essential for understanding how service coverage translates into improved neonatal outcomes.

Together, these frameworks underpin a mixed-methods design incorporating a two-arm cluster-randomised controlled trial and predictive modelling. The trial quantitatively measures epidemiological patterns of preventable neonatal deaths and effects of institutionalising community health system vital signs, while qualitative data illuminate structural and systemic barriers. Predictive modelling synthesises insights to simulate outcomes under varying degrees of institutionalisation. This integrated theoretical foundation ensures the study captures multifaceted, systemic, and contextual

determinants of neonatal mortality reduction, providing actionable evidence to inform policy and strengthen community health systems in Mashonaland West Province.

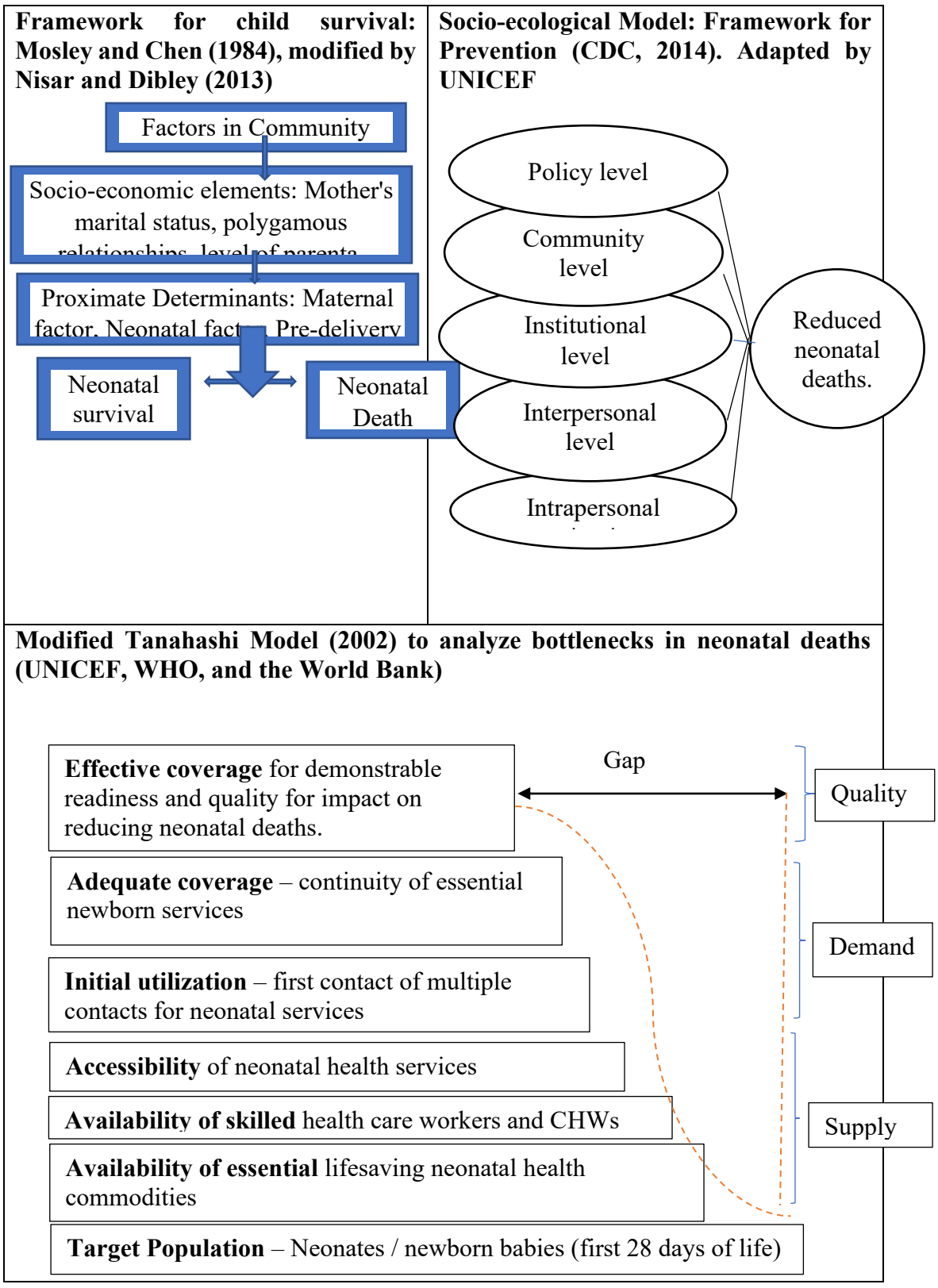


Figure 9: Theoretical Framework

3.3.4 Complementarity, integration and necessity of frameworks

The Mosley and Chen Socio-Ecological Model (SEM) and the Tanahashi frameworks each play distinct but complementary roles in understanding and addressing neonatal mortality. Mosley and Chen focus on proximate, individual-level determinants such as biological and immediate social factors (Mosley & Chen, 2003). The SEM expands this perspective by incorporating multilevel social and institutional influences, capturing how community and policy contexts shape health behaviours and outcomes (Bronfenbrenner, 1979; McLeroy *et al.,* 1988). The Tanahashi model complements both by analysing the health system's capacity to deliver quality services through a coverage cascade that identifies bottlenecks in availability, accessibility, utilisation, and effective coverage (Tanahashi, 1978; McCollum *et al.,* 2019).

Together, these frameworks provide a comprehensive analytical architecture that spans individual biological risks, social determinants, and health system performance. The integration explicitly differentiates overlapping concepts, such as multilevel determinants in Mosley and Chen and SEM, by clarifying their distinct levels and mechanisms. This multidimensional approach is necessary because no single framework fully captures the complexity of neonatal mortality reduction: Mosley and Chen lack detailed community and institutional factors; SEM does not operationalise health service delivery metrics; and Tanahashi overlooks individual-level risks and social determinants (Hamal *et al.,* 2020; Souza *et al.,* 2024).

The three frameworks are integrated into a single chain rather than applied side by side. Reading from the intervention to the outcome: the modified Tanahashi model specifies the health-system mechanism, namely that institutionalisation of IV1–IV3 moves a community along the coverage cascade from availability to effective coverage; the Socio-Ecological Model specifies the levels at which that movement must act (household, interpersonal, community, organisational and policy) and therefore where the mediators are measured; and the Mosley-Chen framework specifies the proximate biological and behavioural determinants on which those mediators must act if a death is to be averted, and therefore defines the outcome and the confounders. Each framework thus performs one function that the others cannot: Tanahashi has no account of individual risk, Mosley-Chen has no account of the health system, and the Socio-

Ecological Model has no account of either the coverage mechanism or the proximate biology. Removing any one of the three breaks the chain: without Tanahashi the study could not explain why coverage does not equal survival, which is the paradox it set out to address; without the Socio-Ecological Model it could not justify a three-level analysis or locate the mediators; without Mosley-Chen it could not define preventable death or select confounders. No fourth framework is required, and Complex Adaptive Systems theory, which Chapter Six draws on to interpret the interaction between governance and workforce, is treated as an interpretive aid rather than part of the theoretical framework.

3.3.5 Contextualisation and rationale for framework selection within Zimbabwe's Community Health System

Zimbabwe's community health system, comprising Village Health Workers (VHWs), local governance structures, learning groups, and faith-based organisations within a supportive policy environment, aligns well with the integrated framework. The SEM's multilevel structure reflects Zimbabwe's layered community governance and the social networks that influence maternal and neonatal health behaviours (Avoka *et al.,* 2018; Lassi, Kedzior & Bhutta, 2019). Mosley and Chen help explain individual and household risk factors prevalent in Zimbabwe, such as maternal age and birth intervals (Mosley & Chen, 2003; Kim *et al.,* 2021). The Tanahashi model addresses ongoing service-delivery challenges, including the availability and accessibility of skilled care and essential commodities at community and facility levels (McCollum *et al.,* 2019; WHO, 2024).

The rationale for selecting these frameworks is their combined ability to integrate morbidity and mortality into a unified construct to reduce neonatal deaths. They collectively acknowledge that social and economic determinants operate through biological pathways and that interventions across the causal chain from individual risks to social networks and institutional policies can catalyse improved neonatal outcomes (Licoppe & Smoreda, 2005; Walker & Lynn, 2013; Shattuck, 2021). Importantly, the critical paradigm situates these frameworks within a socio-political context, recognising how power dynamics, structural inequities, and institutional

marginalisation influence neonatal health outcomes (Burke, Joseph, Pasick & Barker, 2009).

This study leverages the intersection of the three frameworks to examine system-wide interventions across multiple levels, from proximate causes of death to network and policy influences, thereby understanding how institutionalising community health systems can accelerate neonatal mortality reduction (Kanunura *et al.,* 2017; Getaneh *et al.,* 2024). For example, community health workers' information dissemination may create a dose-response effect that influences neonatal risk perception and early care-seeking behaviour, illustrating reciprocal determinism across SEM levels (Kumar *et al.,* 2012; Cholley-Gomez *et al.,* 2023).

3.3.6 Summary of Integration and Application

Recognising each model's limitations, this study integrates the three frameworks within a critical paradigm that foregrounds power dynamics, structural inequalities, and social injustices. Table 4 below summarises the main strengths and limitations of each framework and how their integration addresses key gaps:

This chapter uses three terms and keeps them distinct. The theoretical framework (Section 3.3) is explanatory: it states why institutionalising the three vital signs should reduce preventable neonatal deaths, drawing on the three frameworks above. The conceptual framework (Section 3.4 and Figure 10) maps the study's variables and their hypothesised relationships, derived from the theory but specific to this study; it determines which variables were measured and in which causal role (Section 3.7.1). The analytical framework (Sections 3.7.2 and 4.15) is the set of statistical procedures used to estimate those relationships: the three-level mixed-effects model for the randomised contrast, mediation and dose-response analyses for the mechanisms, and the exploratory predictive models. The first two frameworks concern causal explanation; the predictive models concern prediction only. A variable that predicts neonatal death well is not thereby shown to cause it, and a causal effect established by randomisation need not be a strong predictor at the individual level. This distinction governs how Chapter Five reports the machine-learning results and how Chapters Six and Seven interpret them.

Table 4: Comparative Summary of Frameworks and Integration Benefits

Framework	Strengths	Limitations	Integration Benefit
Mosley & Chen	Proximate determinants and clinical pathways	Limited community/ institutional/ policy constructs	Adds biomedical rigour
Socio-Ecological Model	Multilevel, context, social networks	Lacks service delivery operationalisation	Adds social structure/context
Tanahashi Framework	Service delivery/ coverage metrics	Lacks individual/social determinants	Adds health system bottleneck analysis
Integration (this study)	Holistic, multilevel, contextually adapted	N/A	Comprehensive, actionable framework

This integrated approach retains the strength of the Mosley and Chen framework in identifying proximate biological and maternal risk factors, ensuring that clinical and biological pathways are comprehensively accounted for (Mosley & Chen, 2003). Utilises the SEM's multilevel structure to capture social networks, institutional governance, and policy environments, thereby enabling examination of cross-level interactions and shifts in social norms that influence neonatal health behaviours (Bronfenbrenner, 1979; McLeroy *et al.,* 1988). Applying the Tanahashi model's coverage cascade to operationalise supply-side and service-delivery metrics as mediators, enabling precise identification of bottlenecks and quality gaps in healthcare coverage (Tanahashi, 1978; McCollum *et al.,* 2019).

By embedding these frameworks in Zimbabwe's socio-political context and situating the study within a critical paradigm, this research moves beyond descriptive or isolated analyses. It offers a robust, socially aware analytical architecture that captures the interplay among individual risks, community empowerment, institutional capacity, and policy environments. This comprehensive approach deepens theoretical understanding and enhances practical relevance by identifying actionable intervention points across the causal pathway from structural determinants to neonatal survival.

To further support the understanding, an additional summary Table 5 is provided, mapping frameworks to variables and analytic methods:

Table 5: Frameworks, Key Variables, and Analytic Methods

Framework	Key Variables/Indicators	Analytic Methods
Mosley & Chen	Maternal age, birth interval, LBW	Individual-level regression
Socio-Ecological Model	Community governance, social capital	Multilevel modelling, interactions
Tanahashi Framework	Service availability, coverage	Mediation/pathway analysis
Integration	All above, plus policy context	Predictive simulation, triangulation

As shown in Tables 6 and 7, this study employs an integrated analytical approach, drawing on multiple complementary theoretical frameworks, to examine how the institutionalisation of community health system vital signs affects preventable neonatal deaths in Mashonaland West Province. Table 6 links each research question to its primary and secondary frameworks, key variables, indicators, and analytic models, ensuring alignment between objectives and data analysis.

The Tanahashi model structures service coverage into stages: availability, accessibility, acceptability, contact, and effective coverage, serving as mediators between institutionalisation and neonatal outcomes. The Socio–Ecological Model (SEM) provides a multilevel perspective across individual, interpersonal, institutional, community, and policy levels, enabling analysis of cross-level interactions and contextual factors. The Mosley & Chen Framework accounts for proximate biological determinants of neonatal mortality and is controlled for in the analyses to isolate the effects of the community health system.

Independent variables include Village Health Workers/community health workforce (IV1), community governance structures/Village Health Committees (IV2), and Women's and Men’s Learning and Action groups (IV3), measured via indicators adapted to Zimbabwe's socio-cultural context. The dependent variable is preventable neonatal deaths due to preterm birth complications and neonatal infections.

Table 6: Research Question-Variable-Indicator-Analytic Model Mapping

Research Question (RQ)	Primary Theoretical Framework(s)	Independent Variable(s) (IV)	Dependent Variable (DV)	Key Indicators/Measures	Analytic Model/Approach
RQ1: Which of IV1 (VHW/community health workforce), IV2 (community governance structures/Village Health Committees), and IV3 (WLA/MLA groups) is independently and significantly associated with a reduction in preventable neonatal deaths?	Community Health Systems Conceptual Framework, Socio–Ecological Model	IV1, IV2, IV3 (individually)	Preventable neonatal deaths (due to preterm birth complications and neonatal infections)	VHW/community health workforce metrics (e.g., coverage, training, activity frequency) Functionality of community governance structures (e.g., meeting frequency, decision-making capacity) Participation and modification status of WLA/MLA groups	Multilevel regression analysis (to assess independent predictive associations controlling for socio-ecological factors)
RQ2: What is the magnitude of the individual and combined predictive effect of institutionalising IV1, IV2, and IV3 on preventable neonatal deaths?	Community Health Systems Framework, Tanahashi Model (coverage cascade), Socio–Ecological Model	IV1, IV2, IV3 (individually and combined)	Preventable neonatal deaths	Composite institutionalisation score of IV1, IV2, IV3 Coverage and service delivery metrics per Tanahashi model (availability, accessibility, acceptability, contact, effective coverage)	Predictive effect estimation via multivariate regression and mediation analysis (to quantify individual and combined effects)

Research Question (RQ)	Primary Theoretical Framework(s)	Independent Variable(s) (IV)	Dependent Variable (DV)	Key Indicators/Measures	Analytic Model/Approach
RQ3: What does the simulated predictive model project as the expected reduction in neonatal deaths under full, partial, and non-institutionalisation of IV1, IV2, IV3?	Predictive modelling framework integrating Community Health Systems and Tanahashi Model	IV1, IV2, IV3 (institutionalisation scenarios: full, partial, none)	Preventable neonatal deaths (projected)	Scenario-specific values of IV1, IV2, IV3 institutionalisation indicators Simulation parameters derived from trial data	Predictive simulation modelling (scenario-based projections using trial data inputs)
RQ4: Which IV(s) are the strongest predictors of neonatal deaths, and what are the policy implications of institutionalising these within the community health system?	Community Health Systems Framework, Socio–Ecological Model	IV1, IV2, IV3 (comparative predictive strength)	Preventable neonatal deaths	Predictive strength metrics (e.g., effect sizes, odds ratios) for IV1, IV2, IV3 Policy-relevant indicators (feasibility, scalability)	Comparative predictive modelling and policy analysis (to identify the strongest predictors and interpret policy implications)

*The dependent variable (DV) is operationalised as preventable neonatal deaths attributable to preterm birth complications and neonatal infections in Mashonaland West Province, Zimbabwe (2020–2021).

*Independent variables (IVs) are institutionalisation levels of community health system components: Village Health Workers/community health workforce (IV1), community governance structures/Village Health Committees (IV2), and Women's and Men's Learning and Action groups (IV3

Table 7: Hypothesis Pathway Summary

Causal Mechanism	Description	Theoretical Framework(s)	Pathways/Processes	Expected Outcome	Analytic Approach
Null Hypothesis (H_0)	Institutionalising community health system variables (IV1, IV2, IV3) has no effect on preventable neonatal deaths	None / Baseline assumption	No significant association or causal pathway between IVs and DV; community health system components do not influence neonatal mortality	No change in preventable neonatal deaths attributable to institutionalisation	Statistical testing for no effect (e.g., hypothesis testing in regression models)
Alternative Hypothesis (H_1) - Direct Effect	Institutionalising IV1 (VHW/community health workforce), IV2 (community governance structures), and IV3 (WLA/MLA groups) directly reduces preventable neonatal deaths	Mosley & Chen, Socio–Ecological Model	Direct influence of each IV on neonatal health outcomes via improved service delivery, community engagement, and governance	Reduction in neonatal deaths due to enhanced community health system functioning	Multilevel regression analysis assessing direct associations
Alternative Hypothesis (H_1) - Multilevel Pathway (Mediated Effect)	Institutionalisation affects neonatal outcomes through multilevel pathways involving supply-side factors and service delivery cascades	Mosley & Chen, Socio–Ecological Model, Tanahashi Model (coverage cascade)	Institutionalisation improves availability, accessibility, acceptability, contact, and effective coverage of health services, which mediate the relationship between IVs and neonatal mortality	Reduction in neonatal deaths mediated by improved service coverage and quality	Mediation analysis combined with multilevel modelling and predictive simulation

Analytic methods encompass multilevel logistic regression to assess independent and interactive effects, mediation analysis using Tanahashi cascade stages to explore indirect pathways, and predictive simulation modelling to project outcomes under different institutionalisation scenarios. This comprehensive strategy quantifies individual and combined effects and supports policy-relevant insights.

Table 7 complements this by summarising hypothesised causal mechanisms: the null hypothesis (H0) assumes no effect of institutionalisation on neonatal deaths; the alternative hypothesis (H1) posits direct effects through improved service delivery and community engagement based on the Community Health Systems Framework and SEM; and a multilevel mediated pathway under H1 incorporates Tanahashi's supply-side factors as mediators, reflecting complex interactions across multiple levels.

Together, Tables 6 and 7 form a coherent framework that links theory, variables, and analysis to rigorously investigate how institutionalising components of the community health system can reduce preventable neonatal deaths, thereby facilitating a nuanced understanding of causal pathways and informing targeted policy interventions within Zimbabwe's health system context.

3.4 Conceptual Framework

The conceptual framework integrates three key models: Mosley and Chen's child survival framework, the Socio-Ecological Model (SEM), and the Modified Tanahashi Health Service Coverage Model, to provide a comprehensive, multilevel analysis of the determinants of neonatal mortality within Zimbabwe's community health system.

Mosley and Chen's framework focuses on proximate, individual-level maternal and neonatal risk factors that directly influence neonatal outcomes, guiding the selection and adjustment of biological and clinical variables such as maternal age, birth interval, low birth weight, and pregnancy complications. The SEM organises determinants across five ecological levels: intrapersonal, interpersonal, institutional, community, and policy, capturing broader social networks, governance structures, and policy environments that shape health behaviours, service utilisation, and community engagement. It enables multilevel modelling and the examination of cross-level interactions, reflecting the complex social context that influences neonatal survival. The

Modified Tanahashi Model operationalises supply-side health service delivery through a cascade of coverage domains: availability, accessibility, utilisation, adequate coverage, and effective coverage that serve as mediators between the institutionalisation of community health systems and neonatal outcomes. This model highlights bottlenecks in service delivery and quality, and links health system performance to neonatal survival.

Together, these models synthesise into a nested, multilevel framework that positions individual risk factors at the core and is supported by relational and community networks (e.g., community health workers, women's and men's groups), embedded within institutional and policy contexts that influence service delivery and resource allocation. This integrated approach reflects the pathways through which biological, social, and systemic determinants interact, enabling analysis of how institutionalising community health systems can reduce neonatal mortality in Mashonaland West Province.

The three intervention variables occupy fixed positions in this nested structure. IV1, the VHW/community health workforce, sits at the relational layer (household and interpersonal levels of the Socio-Ecological Model) and is the actor through which the availability and contact stages of the Tanahashi cascade are reached at household level. IV2, community governance structures, sits at the community and organisational layers and is the mechanism through which accountability, referral linkage and the acceptability and effective-coverage stages of the cascade are secured. IV3, the women's and men's learning and action groups, sits at the interpersonal and community layers on the demand side and is the mechanism through which household knowledge, norms, and care-seeking change. All three act on the Mosley-Chen proximate determinants at the individual core (thermal care, feeding, infection prevention, timely management of preterm and infection-related illness), which is where a preventable death is or is not averted. The policy and enabling environment at the outermost layer is not an intervention variable in this study; it is the condition, common to both trial arms, under which institutionalisation of IV1–IV3 was attempted.

The conceptual framework (Figure 10) is structured as a nested, inverted pyramid that systematically illustrates the multilevel influences on neonatal outcomes within Mashonaland West's community health system. At the core are the

individual/intrapersonal factors, encompassing maternal and neonatal risk characteristics such as maternal age, birth interval, low birth weight, and pregnancy complications. These proximate determinants directly affect neonatal survival and are central to the Mosley and Chen framework. (Hamal *et al.,* 2020; Coles *et al.,* 2020; Chan *et al.,* 2021; Souza *et al.,* 2024). Modifications to these factors through timely interventions can produce protective effects, underscoring their centrality in neonatal survival.

At the individual level, relational factors include social support networks such as family members, community health workers (CHWs), and modified women's and men's learning groups. These relational actors serve as the first line of support and influence, mediating the translation of individual risk factors into health behaviours and care-seeking practices. These actors serve as crucial intermediaries, linking caregivers to formal health services and facilitating access to primary and referral care (Lassi *et al.,* 2016; Watson *et al.,* 2023). Their influence operates both directly on neonatal health outcomes and indirectly by shaping caregiver behaviour and service utilisation. The framework visually distinguishes community networks on one side, comprising village, ward, and district health committees, faith-based organisations, educational institutions, and local governance bodies, which collectively foster health literacy, social accountability, and culturally congruent care.

The next layer comprises institutional factors, representing health facilities, CHWs, and service delivery mechanisms. This level embodies the health system's capacity and quality, operationalised through the Modified Tanahashi Model's coverage cascade (availability, accessibility, utilisation, adequate coverage, and effective coverage). The coverage cascade acts as a critical mediator linking institutionalisation efforts to neonatal outcomes by identifying bottlenecks in service delivery.

Beyond institutions lies the community level, encompassing social norms, community governance structures, faith-based organisations, and local decision-making bodies. This layer influences both health behaviours and institutional performance by shaping social expectations and community engagement.

At the outermost level is the policy and enabling environment, which includes governance, stewardship, political will, resource allocation, legal frameworks, and

multisectoral partnerships that create the enabling environment essential for institutionalising community health system vital signs. This structural context sets the conditions for community and health system functionality, reinforcing or constraining the effectiveness of lower levels. Institutionalisation is conceptualised as the formal integration and sustained support of community health system components, CHWs, governance structures, and participatory groups, within the health system. This institutionalisation is critical to transforming community health dynamics and reducing preventable neonatal deaths.

The framework's arrows indicate a predominantly downward flow of influence from policy through community, institutional, relational, and individual factors, culminating in neonatal outcomes. However, feedback loops exist, particularly between relational and institutional levels, where community health workers and support groups facilitate bidirectional communication and service adaptation. Similarly, community norms and governance structures interact dynamically with institutional factors to promote accountability and responsiveness.

The left side of the framework emphasises community networks and social support pillars, while the right side represents the health service delivery network. These two sides are interconnected through relational factors and institutional mechanisms, illustrating how community engagement and health system performance synergistically influence neonatal survival. This bidirectional interaction underscores the necessity of institutionalising community health systems as a holistic integration of social and service delivery components to effectively reduce neonatal mortality.

3.5. Integrated causal pathway for the effect of institutionalising community vital signs on neonatal death

The causal pathway tested in this study runs in five steps: (1) institutionalisation of IV1, IV2 and IV3 (formal recognition, resourcing, supervision, accountability and routine reporting); which produces (2) community health system mechanisms (regular household contact, danger-sign recognition, functioning referral, community accountability for service quality); which increase (3) timely access to, utilisation of and quality of antenatal, delivery, postnatal and sick-newborn care, that is, movement

along the Tanahashi cascade towards effective coverage; which act on (4) the maternal and neonatal proximate determinants (birth spacing, early antenatal engagement, thermal care, early and exclusive breastfeeding, clean cord care, early management of preterm complications and infection); which avert (5) preventable neonatal deaths from preterm-birth complications and infection. Steps 1 to 5 are hypotheses: steps 1 to 5 as a whole are tested by the randomised comparison; steps 2 to 4 are examined through the process, fidelity, mediation and dose-response analyses and the qualitative strand. Figure 11 illustrates this structural framework for assessing the impact of institutionalising community health system vital signs on neonatal mortality. It highlights key determinants influencing neonatal death, including commodity availability, maternal education, socioeconomic status, and neonatal biological risks such as low birth weight and prematurity. The framework incorporates factors that increase or reduce risk by shaping access to information and resources, influencing care-seeking behaviour, timely referral, and appropriate treatment.

The model also integrates supply chain and logistics components (e.g., stockouts, community-level supplies), community engagement and norms (such as women's groups, social networks, and male involvement), and service readiness and quality indicators (including availability of commodities, equipment, staffing, and effective coverage). Additionally, it emphasises Community Health Worker (CHW) performance metrics like density, home visits, and supervision.

Central to the framework is the institutionalisation index of community health system vital signs, encompassing CHW training and supervision, formal roles, reporting, financing, participatory groups, and functional governance linkages. This comprehensive structure supports testing how formalising these community health components influences neonatal survival outcomes.

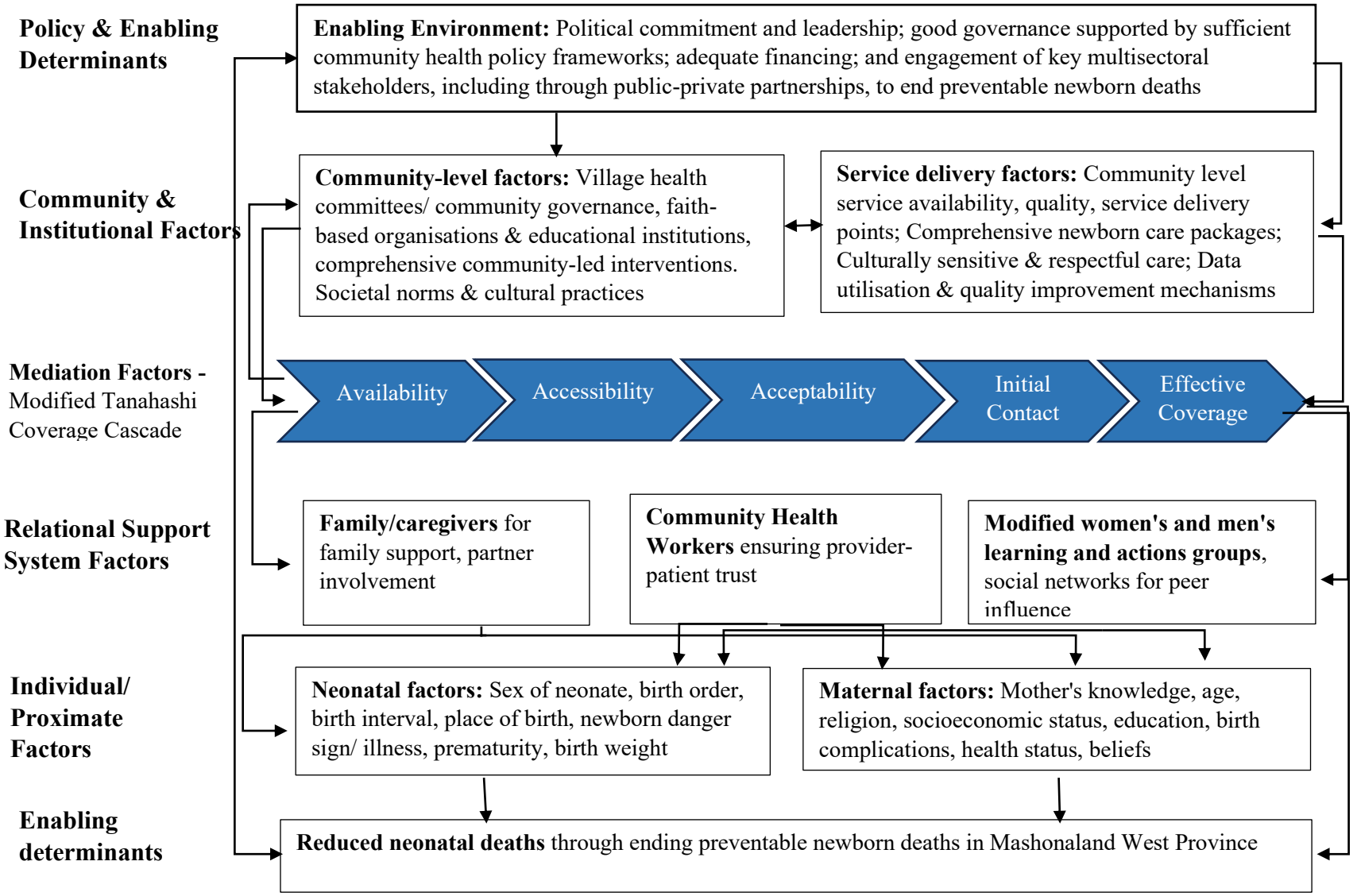
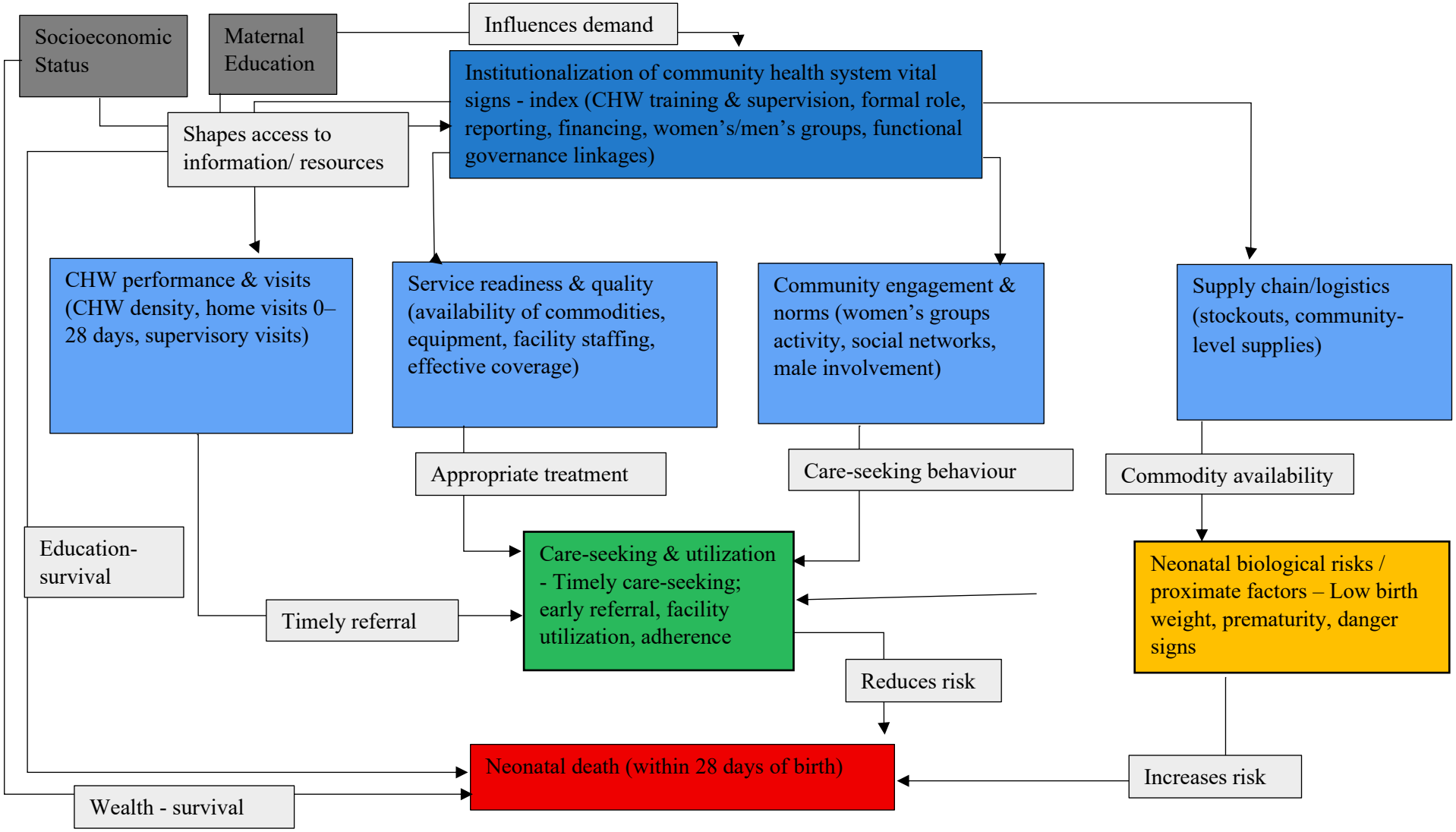


Figure 10: Conceptual Framework on reducing neonatal deaths

Figure 11: Structure for testing the effect of institutionalising community vital signs on neonatal death



3.6 Operationalisation of Concepts

This section outlines how the key conceptual variables in this study are translated into measurable constructs for empirical investigation. Operationalisation bridges the theoretical framework presented in Chapter 2 and the methodological approach adopted in this study, ensuring that abstract concepts are rendered observable, measurable, and analytically tractable. The central independent variable, institutionalising community health, is operationalised as a composite construct, while the dependent variable, neonatal health outcomes, is measured using established indicators. Each component is discussed in turn below.

3.6.1 Institutionalising Community Health (Composite Independent Variable)

Institutionalising community health entails formal integration, sustained support, and systematic embedding of components of the community health system within the broader health system infrastructure. As operationalised in this study, this composite variable encompasses three interrelated sub-components: the community health workforce, specifically Village Health Workers (IV1); community governance structures, namely Village Health Committees (IV2); and participatory community groups, including Women's and Men's Learning and Action (WLA/MLA) groups (IV3). Together, these components constitute the structural and functional architecture through which community-level health interventions are delivered, governed, and sustained (Munyai, Mudau & Mashau, 2024). Institutionalisation is considered to have occurred when these components are formally recognised, adequately resourced, governed through accountable structures, and operationalised as essential and permanent elements of health service delivery aimed at improving neonatal health outcomes (Krieger *et al.,* 2022).

3.6.2 Key Measurable Components and Indicators

To render institutionalisation empirically measurable, each sub-component is assessed through a set of observable indicators, as detailed below.

3.6.2.1 Village Health Worker and Community Health Workforce Integration (IV1)

The integration of Village Health Workers (VHWs) and the broader community health workforce into the formal health system is assessed along four key dimensions. First, training and certification status serve as an indicator of the extent to which workers have received standardised, system-endorsed preparation for their roles (Munyai, Mudau & Mashau, 2024). Second, the frequency and quality of supervisory support reflect the degree to which the health system actively maintains and strengthens workforce capacity (Munyai, Mudau & Mashau, 2024). Third, formal recognition and clearly defined roles within the health system indicate whether VHWs are institutionally acknowledged as legitimate health actors rather than informal volunteers (Kok *et al.,* 2021). The most frequently cited barrier to CHW programme integration in a systematic review of scale-up and sustainability was precisely that CHWs were neither respected nor integrated into the health system hierarchy (Kok *et al.,* 2021). Fourth, the presence of reporting and accountability mechanisms, alongside adequate financing and resource allocation, signals whether the workforce is sustainably embedded within health system governance and financial structures (Krieger *et al.,* 2022).

3.6.2.2 Community Governance Structures and Village Health Committee Functionality (IV2)

The functionality of community governance structures is operationalised by assessing Village Health Committees (VHCs) across four indicators. Community-level health committees are defined as formally constituted governance structures with community representation and an explicit link to a primary health facility, whose primary purpose is to enable community participation in decision-making on matters related to improving health service provision and health outcomes (Karuga & Kok, 2022). The existence and regularity of VHC meetings provide a baseline measure of structural activity and institutional continuity. Evidence from Zimbabwe demonstrates that health facilities with an active health committee had more resources, fewer drug stock-outs, and higher coverage of primary health care services (Karuga & Kok, 2022). Beyond mere convening, the decision-making capacity and authority of these committees in health-related matters reflect the substantive depth of governance, distinguishing

performative structures from those with genuine agency (Lodenstein *et al.,* 2017). Linkages and communication channels with formal health facilities capture the extent to which community governance is integrated into the wider health system rather than operating in isolation. Finally, the degree of community engagement and representation within governance processes reflects the democratic legitimacy and inclusiveness of these structures, which are critical to their sustained functionality and community trust (Karuga & Kok, 2022).

3.6.2.3 Women's and Men's Learning and Action (WLA/MLA) Groups: Participation and Contextual Adaptation (IV3)

The operationalisation of participatory community groups focuses on the WLA and MLA groups as vehicles for community-level behaviour change and health promotion. Active membership and participation rates are primary indicators of the vitality and reach of these groups within the community. Evidence from a landmark systematic review and meta-analysis demonstrates that the proportion of pregnant women participating in groups was linearly associated with reductions in both maternal and neonatal mortality, and that where at least 30% of pregnant women participated, neonatal mortality was reduced by 33% (Prost *et al.,* 2013). Adapting group activities to local context and health priorities reflects the responsiveness and relevance of group programming, which are essential for sustained engagement; the World Health Organisation (WHO) similarly recommends that implementation of participatory learning and action cycles with women's groups should be preceded by adaptation to local context (WHO, 2014). Evidence of behaviour change communication and health promotion activities captures the functional outputs of group participation, linking process indicators to health system outcomes (Prost *et al.,* 2013). Finally, the presence of support mechanisms for maternal and neonatal health practices operationalises the direct pathway through which group engagement is hypothesised to influence neonatal health outcomes (Jacobs *et al.,* 2018).

3.6.2.4 Policy and Enabling Environment Support

Across all three sub-components, the enabling policy environment is treated as a cross-cutting dimension of institutionalisation. The presence of formal policies that explicitly

endorse community health system components signals political and institutional commitment at the system level; government ownership and formal affirmation of community health workers as a valuable part of the workforce are recognised as key facilitators of a more coordinated and supportive approach to community health delivery (Kok *et al.,* 2021). The allocation of dedicated resources and budget lines for community health activities provides evidence that institutionalisation is financially sustained rather than donor-dependent or ad hoc (Munyai, Mudau & Mashau, 2024). Mechanisms for monitoring, evaluation, and accountability at both community and health system levels further indicate the degree to which community health is systematically governed and subject to continuous quality improvement (Lodenstein *et al.,* 2017).

3.7 Operationalisation of variables

3.7.1 Justification for Inclusion of Key Variables

The variables selected for this study are grounded in both theoretical frameworks and empirical evidence linking them to neonatal mortality within the context of institutionalising community health systems in Mashonaland West Province. Their inclusion ensures a comprehensive, multilevel analysis aligned with the study's conceptual foundation:

Before the variables are listed, each is assigned a causal role, because the role determines how it is handled in analysis. Exposures are the three institutionalisation variables IV1, IV2 and IV3 and the composite institutionalisation index (Section 3.6). Confounders are variables that could influence both institutionalisation status and neonatal death and that were fixed before the intervention: maternal age, parity, birth interval, maternal education, household socioeconomic status, distance to facility, cluster-level women's literacy and baseline facility readiness (including HBB/HBS-trained staff). These are adjusted for in the primary model as pre-specified in the directed acyclic graph (Section 4.15, Table 1). Mediators are variables on the pathway between institutionalisation and neonatal death that were measured after randomisation: VHW home-visit coverage, antenatal-care attendance and timing, skilled birth

attendance, postnatal visit within 72 hours, danger-sign recognition, timely care-seeking, essential newborn-care practices and the Tanahashi coverage stages. Because they are consequences of the intervention, they are not adjusted for in the primary model; they are examined in mediation, dose-response and process analyses, and their associations with death are reported as adjusted associations, not as independent causal effects. Moderators are variables hypothesised to change the size of the intervention effect: cluster-level governance functionality, cluster-level women's literacy, and the COVID-19 restriction period; these are tested through pre-specified interaction terms. Proximate biological characteristics of the neonate (birth weight, prematurity, sex) are treated as confounders when they precede the intervention's action and as outcome-adjacent covariates otherwise, and are handled as specified in Table 8. Post-outcome variables, of which time of neonatal death is the principal example, are excluded from all causal and predictive models because they carry information about the outcome itself.

i. Village Health Workers/Community Health Workforce (IV1): Frontline actors pivotal in bridging communities and formal health services. Their coverage, training, and activity levels directly influence neonatal care access, health education, referral systems, and ultimately neonatal survival.
ii. Community Governance Structures/Village Health Committees (IV2): Represent community empowerment and social accountability mechanisms. Their functionality affects resource distribution, health service quality, and community engagement, which are crucial for effective neonatal health interventions.
iii. Women's and Men's Learning and Action Groups (IV3): Participatory platforms fostering health education, behaviour change, and social support, which promote neonatal health-enhancing practices and community mobilisation.
iv. Maternal and Neonatal Biological Factors: Proximate determinants such as birth weight, prematurity, maternal age, and health status are included as control/ confounder variables to isolate the effects of community health system variables on neonatal mortality.
v. Policy and Enabling Environment Variables: Reflect broader institutional power dynamics, governance mechanisms, financing, and resource allocation

that influence the sustainability and effectiveness of community health system interventions.

vi. Service Delivery and Supply Chain Indicators: Capture dimensions of service availability, accessibility, quality, and readiness, mediating the relationship between institutionalisation and neonatal outcomes.

vii. Institutionalisation as a Composite Variable: Institutionalising community health is conceptualised as a composite variable because no single indicator is sufficient to capture the phenomenon's multi-dimensional nature. It is widely acknowledged that health care performance is multidimensional and that composite measures are therefore necessary to summarise information from disparate indicators into a coherent and interpretable measure (Smith, 2002). The three sub-components, workforce integration, governance functionality, and participatory group engagement, are theoretically and empirically interdependent: deficiencies in one domain are likely to constrain the effectiveness of the others, while synergies across domains are expected to amplify health system performance (Munyai, Mudau & Mashau, 2024). Measuring institutionalisation as a composite index, therefore, reflects the integrated nature of community health systems, in which workforce capacity, governance functionality, participatory group engagement, and enabling policy environments interact synergistically to shape health outcomes (Krieger *et al.,* 2022).

This approach allows for a nuanced, graduated assessment of the extent to which community health system components are formally embedded and operationalised, rather than treating institutionalisation as a binary condition. As such, the composite variable provides a theoretically grounded and empirically robust predictor of neonatal health outcomes within the socio-cultural and health system context of Mashonaland West Province. The operationalisation strategy adopted here is consistent with established approaches to composite index construction in health systems research, which recognise that composite indicators provide a snapshot summary for benchmarking performance, while building block and domain scores provide critical information for programmatic action (Sharma *et al.,* 2019). This

approach is designed to accommodate the complexity of real-world institutionalisation processes while remaining analytically tractable within the scope of this study.

This variable selection is theoretically anchored in the Complex Adaptive Systems Theory, the Socio-Ecological Model (SEM), the Mosley & Chen Framework, and the Tanahashi model, and is contextually adapted to the socio-cultural and health system environment in Zimbabwe. This ensures a multidimensional approach for understanding determinants of neonatal mortality.

Table 8: Variables utilised in the examination of influences on neonatal deaths

Variables	Coding categories	Description
Dependent		
Neonatal death	0 = No; 1= Yes	"Death of a newborn baby within 28 days of birth" (UNICEF, 2024; WHO, 2024)
Independent variables		
A. Community-level factors		
1. Geopolitical zone	1= Chegutu; 2= Hurungwe 3 = Kariba; 4 = Makonde 5 = Mhondoro-Ngezi 6 = Sanyati; 7 = Zvimba	District of permanent residence.
2. Place of residence	1= Rural; 2= Urban	Place of permanent residence
3. Women's & men's groups	0 = No; 1 = Yes	Groups of women and men regularly meet according to the recommended number of meetings to discuss maternal, newborn, and child health issues.
4. Local governance structures	0= non-functional;1= Partially functional; 2 = Fully functional	Defined community structures such as defined "village health committees, ward health committees and district health committees" (Karuga et al. 2022)
5. Faith-based organisations (FBOs)	0= No; 1 = Yes	Existing and functional FBOs that are active in conducting community

Variables	Coding categories	Description
		dialogue on health-related issues
6. Social networks	0= No; 1 = Yes	Defined networks of households, measured as 1 model household to 6 households, known as health development teams
7. Women's literacy	1 = Low; 2=Medium; 3= High	Literacy for women in the community. This is the proportion of women who can read.
8. Formal community health workers	0= Not trained; 1= Trained	CHWs receive formal training or are recognised by the government.
9. Community health workers trained in newborn care	0 = No; 1= Yes	Community-based workers who have received training on essential newborn care
10. Institutionalising community health	0= Not institutionalized; 1=Partially institutionalized; 2= Institutionalized	Overall combination of three vital signs of community health constructs, including CHWs, social networks, FBOs, women's and men's groups, local governance structures, through vertical scale up within the formal health system, with guidance of policy and legal framework
B. Household-level factors		
1. Wealth category	1= Poorest; 2= Poor; 3= Middle; 4= Rich; 5= Richest (Wong et al. 2017;	This looks at the household wealth measure based on assets, as described in the ZDHS.
2. Family networks training	0 = No; 1 = Yes	Training of 1 to 6 family networks, here defined as health development teams
3. Paternal religion	0= non-conservative; 1 = Conservative	The religion to which the family is allegiant
C. Individual-level factors		
C1. Maternal factors		
1. Maternal knowledge	1= low; 2= Medium; 3= High	Mothers who are aware of the warning signs of pregnancy and childbirth can identify specific indicators such as bleeding, convulsions, and fever, as

Variables	Coding categories	Description
		well as critical signs in newborns such as trouble breathing, diarrhoea, and low body temperature.
2. Maternal religion	0 = non-conservative; 1= Conservative	Mother either believes in modern medicine or use of health facilities or not.
3. Maternal education	0= None; 1= Primary level; 2= Secondary; 3= Tertiary	Level of education of mother of the newborn
4. Marital Status	0= Never married; 1 = Married; 2 = Widows, divorced, separated)	Marital status
5. Polygamous marriage	0 = No; 1 = Yes	A polygamous union in which a husband has more than one wife
6. Mother's age	Median age	Mother's age at current birth
7. Mother's age at first birth	1= less than 20 years; 2= 20 to 24 years; 3 = above 49 years	Maternal age at first childbirth
8. Pregnancy-related complications	0 = No; 1 = Yes,	Mothers who respond yes to any of the danger signs of pregnancy and no if the mother doesn't admit any of the danger signs
C2. Neonatal Factors		
1. Sex	1= Female; 2= Male	Sex of the newborn baby
2. Birth order	1= 1; 2= 2-3; 3 = 4+	Order of birth
3. Birth interval	1 = Less than 2 years; 2 = Greater than 2 years;	Interval of birth
4. Place of birth	1 = Delivered at home; 2 = Delivered at clinic or healthcare institution	Place of delivery of the neonate
5. Mother's perceived baby size	1 = Big; 2 = Average 3= Small or very small	Mother's perception of the size of the baby
C3. Service delivery factors		
1. Number of ANC contacts	1=ANC <8 times; ANC 8 contacts and above	Number of ANC contacts as recommended by WHO FANC
2. Timing of ANC	1= <12 weeks; 2= Above 12 weeks	Measure of early antenatal care booking
3. Baby experienced danger signs	0= No; 1=Yes	Any danger sign of neonate reported by the mother or caregiver
4. Low birth weight	0 = No; 1=Yes	The weight of the newborn baby is less than 2500

Variables	Coding categories	Description
		grams (Toru T & Anmut W, 2019; WHO,2022)
5. Home visit for newborn from CHWs	0 = No; 1=Yes	Newborn baby received home visit from CHWs from 0-28 days; 0= Never received home visit; 1= received home visit from CHWs

3.7.2 Addressing multicollinearity and use of multilevel modelling

Given the extensive set of variables spanning multiple hierarchical levels, the study employed robust strategies to manage multicollinearity and appropriately model the data structure:

i. Multicollinearity assessment and mitigation: Initial diagnostics included correlation matrices and variance inflation factors (VIF) to detect multicollinearity among independent variables.
ii. Variables exhibiting high collinearity (e.g., VIF > 5) were addressed by:
    a. Aggregating related variables into composite indices (e.g., institutionalisation index combining CHW training, governance functionality, and participatory group activity).
    b. Prioritising variables based on theoretical relevance and empirical support to retain conceptually critical constructs.
iii. Multilevel modelling approach:
    a. The hierarchical nature of the data (individual neonates nested within households, communities, and policy environments) necessitates multilevel models; the primary analysis is a three-level mixed-effects log-binomial regression (individuals nested within VHW catchments nested within clusters), with multilevel logistic regression used for secondary binary outcomes (Section 4.15).
    b. Random intercepts and slopes captured unobserved heterogeneity at community and higher levels.

c. Cross-level interaction terms were tested to explore how community- and policy-level variables moderate individual-level associations with neonatal mortality.

This analytic strategy ensured unbiased parameter estimates, accurate standard errors, and a nuanced understanding of multilevel determinants and their interactions affecting neonatal mortality. It also facilitated rigorous hypothesis testing and policy-relevant interpretation consistent with the study's integrated theoretical framework.

3.8 Summary

This chapter has established the theoretical, conceptual, and methodological architecture underpinning the study of preventable neonatal mortality in Mashonaland West Province, Zimbabwe. Major improvements in this revised version include clearer section summaries, visual mapping of frameworks to variables and methods, a comparative table of framework strengths and limitations, and an expanded reflexivity statement. The chapter foregrounds power dynamics, structural inequalities, and social injustices as central forces shaping neonatal health outcomes, situating preventable neonatal deaths not as isolated biomedical events but as manifestations of systemic and institutional failure.

Three complementary theoretical frameworks were integrated to provide a robust, multilevel analytical foundation. The Mosley and Chen Framework guided the selection of proximate maternal and neonatal determinants, ensuring that biological and clinical pathways are rigorously accounted for. The Socio-Ecological Model (SEM) extended this perspective across intrapersonal, interpersonal, institutional, community, and policy levels, enabling the examination of cross-level interactions and the broader social determinants of neonatal survival. The Modified Tanahashi Health Service Coverage Model operationalised supply-side and service-delivery metrics, treating coverage domains as mediators in the causal pathway linking the institutionalisation of community health programmes to neonatal outcomes.

Building on these frameworks, the conceptual framework synthesised these theoretical lenses within Zimbabwe's specific socio-cultural and health system context, capturing the interplay of biological risks, community governance, CHW performance, and

enabling policy environments. The operationalisation of key variables, including Village Health Workers (IV1), community governance structures (IV2), and Women's and Men's Learning and Action groups (IV3), directly reflects the study's critical paradigm by measuring community empowerment, social accountability, and structural equity as determinants of neonatal survival.

Finally, the chapter outlined a rigorous analytic strategy employing multilevel logistic regression, mediation analysis, and predictive simulation modelling to test hypothesised causal mechanisms. Strategies to address multicollinearity and account for the hierarchical data structure were detailed, ensuring methodological rigour and policy-relevant interpretation.

Collectively, this chapter provides the theoretical and methodological foundation for the empirical investigation that follows, ensuring that the study's design, variable selection, and analysis are coherently aligned to generate evidence that can inform targeted interventions and strengthen community health systems to reduce preventable neonatal deaths in Mashonaland West Province.

CHAPTER FOUR

METHODOLOGY

4.1 Introduction

Neonatal mortality in Zimbabwe is a major public health challenge requiring a rigorous, context-sensitive approach. This study adopts the pragmatist paradigm, which values practical outcomes, empirical evidence, and local knowledge (Dryden-Palmer, Parshuram & Berta, 2020; Rogers, De Brún & McAuliffe, 2020). Pragmatism is well-suited to complex problems for which neither quantitative nor qualitative methods alone suffice to address. In Zimbabwe, clinical and epidemiological factors (e.g., birth weight, skilled attendance, geographic access) intersect with contextual, social, and behavioural factors (e.g., community health norms, power dynamics, structural barriers) that are difficult to quantify. Pragmatism addresses this complexity by promoting methods best suited to each research question. Thus, a mixed-methods design was justified, with a cluster randomised controlled trial (cRCT) measuring the causal impact on neonatal deaths, while a qualitative longitudinal evaluation explains how and why the intervention works in its context.

Operationalised through a QUAN (qual) design, pragmatism shapes four key methodological decisions in this study. First, the cRCT was selected as the quantitative strand because pragmatism demands the most rigorous available method for establishing causal evidence of intervention effectiveness, specifically, determining the independent and combined predictive effects of community health system variables, including the village health workforce (VHW), functional community governance structures, and WLA/MLA groups, on reducing preventable neonatal deaths (Objectives 1.4.2.1 to 1.4.2.3). Secondly, quantitative data are prioritised (QUAN) for measuring the primary outcome, neonatal deaths, because causal attribution requires controlled experimental conditions; qualitative data (qual) are embedded to explore contextual factors implementation fidelity, community perceptions, power dynamics, and structural barriers that shape these outcomes (Objective 1.4.2.4), where lived

experience and contextual meaning are indispensable. Thirdly, the two strands are integrated at the interpretation stage, where qualitative findings explain the mechanisms underlying quantitative outcomes, enabling a more complete and actionable understanding than either strand alone. Fourth, conclusions are drawn by triangulating quantitative effect estimates with qualitative process insights, consistent with the pragmatist criterion that knowledge is judged by its practical utility in reducing preventable neonatal deaths. The theoretical frameworks employed by Mosley and Chen's child survival model, the Socio-Ecological Model (SEM), the modified Tanahashi Health Service Coverage Model, and the critical paradigm were selected because each addresses a distinct dimension of neonatal mortality that the pragmatist design must capture, informing variable selection, sampling, data collection, and analysis as detailed in Chapter 3.

These pragmatic decisions enable actionable, evidence-based knowledge to address preventable neonatal deaths in Zimbabwe. The following sections detail each component of this framework.

Chain of alignment: The core of the design can be audited in one sequence. Research objective: to determine the effect of institutionalising IV1, IV2 and IV3 on preventable neonatal deaths compared with standard community health service delivery (Objective 1.4.2.1). Trial design: a two-arm, parallel-group, pragmatic cluster-randomised superiority trial in 52 ward-level clusters, 1:1 allocation (Sections 4.2.1 and 4.11). Intervention and comparator: the institutionalised package of all three vital signs delivered together, versus standard Ministry of Health and Child Care community services as constituted in 2020 (Section 4.5). Primary outcome: all-cause neonatal mortality at 28 days per 1,000 live births, the measured form of preventable neonatal death, ascertained by household surveillance and verbal autopsy (Section 4.7). Sample size: 978 pregnant women, 489 per arm, rounded to 984 pregnant women with the parameters and their limitations stated in Section 4.9.1. Primary analysis: intention-to-treat, three-level mixed-effects log-binomial regression with random intercepts for VHW catchment and cluster, adjusted for pre-specified baseline covariates, yielding an adjusted risk ratio (Section 4.15.2). Interpretation: the randomised contrast estimates the effect of the package; every other analysis (component-level, fidelity, dose-response, subgroup, mediation, machine learning, simulation) is secondary or

exploratory and is interpreted as association (Section 4.15.1). The qualitative process evaluation (Sections 4.12, 4.14.3 and 4.16) is embedded within, and reported after, this core.

4.2 Research Design

This study employed an embedded mixed-methods design, specifically QUAN (qual), in which a two-arm parallel-group cluster-randomised controlled trial (cRCT) constitutes the dominant quantitative strand, with a qualitative longitudinal process evaluation embedded within it (Creswell & Plano Clark, 2018; Teddlie & Tashakkori, 2009). This design was selected because the primary research objective requires causal measurement of the effect of community health system vital signs, including the village health workforce (VHW), functional community governance structures, and women's and men's learning action groups, on preventable neonatal deaths, a question that demands the internal validity of a controlled trial. The embedded qualitative strand serves a distinct and defined purpose to conduct a longitudinal process evaluation that assesses implementation fidelity, explains mechanisms of change, and explores contextual factors, including community perceptions, power dynamics, and structural barriers that mediate or moderate the trial's quantitative outcomes (Fetters, Curry & Creswell, 2013).

Regarding timing and priority, quantitative data collection is the primary method (QUAN) and occurs across three phases: formative, during intervention, and post-intervention, consistent with the cRCT protocol. Qualitative data collection (qual) runs concurrently during and after the intervention phase, embedded within the trial timeline rather than sequentially after it, enabling real-time process insights to inform interpretation of emerging quantitative findings (Creswell & Plano Clark, 2018). Quantitative data were prioritised for measuring the primary outcome, neonatal deaths, while qualitative data were weighted for explanatory depth on implementation and context.

The integration of the two strands occurred at multiple levels. It also occurs at the interpretation stage, following separate analysis of each strand. Qualitative process evaluation findings are used to explain, contextualise, and, where necessary, challenge

the quantitative effect estimates in a joint interpretive synthesis, presented through narrative integration and joint displays (Fetters, Curry & Creswell, 2013; Creswell & Plano Clark, 2018). This integration point ensures that the final meta inference conclusions about what worked, for whom, and under what conditions draw on the full explanatory power of both strands, in a way consistent with the pragmatist criterion of actionable, evidence-based knowledge (Younas, Fàbregues & Creswell, 2023). Quantitative data were also used to evaluate the hierarchical socio-ecological model, which posits that community-level factors influence household dynamics and, in turn, affect individual-level predictors of neonatal mortality (Smith & Shively, 2019; Shifti *et al.,* 2020; Tesema & Worku, 2021; Getnet *et al.*, 2025).

4.2.1 Trial Design

4.2.1.1 Patient and Public Involvement (PPI)

This trial incorporated extensive patient and public involvement across its design, conduct, and reporting stages, engaging key community stakeholders in Mashonaland West Province, Zimbabwe (Hopewell *et al.,* 2025). The primary participants included women of childbearing age and mothers of neonates, male community members, Village Health Workers (VHWs), Village Health Committee (VHC) members, and public health officials from the District Health Management Team (DHMT) and Provincial Health Executive (PHE).

During the design phase, community engagement initiatives ensured that the trial interventions comprising VHWs, VHCs, and modified Women's and Men's Learning and Action (WLA/MLA) groups were aligned with community-identified priorities. VHWs and VHCs contributed to identifying critical gaps, such as linkage to health facilities, which shaped intervention components. The social and cultural contexts of participants informed the co-design of group learning activities, while ward-level cluster boundaries were delineated in consultation with local governance structures to reflect natural community organisation.

In the implementation phase, women of childbearing age and mothers of neonates constituted the primary population for outcome measurement. VHWs served as frontline implementers, facilitating the delivery of interventions and supporting

community-level data collection. VHC members provided oversight, ensuring implementation fidelity and cluster mobilisation. WLA/MLA groups were actively engaged in structured learning and action cycles, promoting behaviour change and collective community action on neonatal health. Monitoring of spillover effects between intervention and control clusters was conducted in collaboration with community representatives to identify unintended cross-cluster influences. This included a standardised contamination-screening question administered to women in control clusters at each follow-up visit to detect exposure to intervention content, with the contamination rate reported as a secondary outcome.

This integrated PPI approach ensured that the trial was community-participatory, enhancing the relevance, acceptability, and implementation of interventions within the local context (Hopewell *et al.,* 2025).

4.2.1.2 Type of Trial Design

This trial used a two-arm, parallel-group, cluster-randomised controlled trial (cRCT) design, in which each cluster was randomly assigned to one of two arms: intervention or control, and the arms ran concurrently over the same study period (2020–2021), with no crossover between arms.

The unit of intervention was the package. IV1, IV2 and IV3 were introduced together in every intervention cluster and were not separately randomised (a factorial design allocating components independently was considered but rejected because the components are interdependent by design: governance structures supervise the workforce, and the learning and action groups generate the demand that the workforce meets). Randomisation therefore identifies the causal effect of the complete package relative to standard care. It does not identify the independent causal effect of any single component. Component-level findings in Chapter Five (fidelity strata, dose-response for IV3, and the associations of each vital sign with mortality) derive from post-randomisation variation within the intervention arm and are reported and interpreted as adjusted associations. Two further features qualify attribution and are addressed in Sections 4.5.1 and 4.17: control clusters were exposed to elements of the National Community Health Strategy rolled out during the trial, and COVID-19 restrictions

attenuated IV3 delivery. Both are expected to bias the primary comparison towards the null.

4.2.1.3 Trial Conceptual Framework

The trial was designed as a superiority trial. The intervention hypothesis is that communities receiving the institutionalised package of IV1, IV2, and IV3 will achieve a statistically and clinically meaningful reduction in the rate of preventable neonatal deaths (per 1,000 live births at 28 days of life) attributable to preterm birth complications and neonatal infections, compared to communities receiving standard community health service delivery. No equivalence or non-inferiority margin was specified, as the trial was not designed to test whether the intervention is merely as good as the comparator, but rather to determine whether it is superior in reducing preventable neonatal mortality. The superiority framework is consistent with the trial's broad objective of evaluating whether institutionalising community health system vital signs produces a measurable benefit over the existing standard of care.

The control arm was defined as standard community health service delivery as constituted at the time of trial commencement (2020), comprising routine VHW home visits, standard antenatal and postnatal care referral pathways, and existing community governance structures operating without the structured institutionalisation package (IV1, IV2, IV3) delivered to the intervention arm. Control clusters did not receive facilitated WLA/MLA group learning cycles, structured VHW-facility linkage protocols, or the VHC oversight mechanisms that formed the core of the intervention.

It is acknowledged that during the trial period (2020–2021), Zimbabwe's Ministry of Health and Child Care (MoHCC) initiated a phased national rollout of a revised community health strategy that included elements broadly aligned with community health systems strengthening. This rollout introduced a degree of co-intervention risk in control clusters, as some standard care activities in those clusters may have been incrementally enhanced by national-level inputs independent of the trial. This is recognised as a contextual limitation that attenuates, rather than invalidates, the trial's findings. The nature, timing, and coverage of national strategy elements received by control clusters during the trial period are described and quantified in the limitations section (Section 6).

4.2.1.3a Intervention Fidelity: NIH Behaviour Change Consortium Framework

Intervention fidelity was assessed prospectively throughout the trial period (2020–2021) using a structured monitoring framework aligned with the five core domains of the NIH Behaviour Change Consortium (BCC) Treatment Fidelity Framework: (1) Study Design, (2) Provider Training, (3) Treatment Delivery, (4) Treatment Receipt, and (5) Treatment Enactment (Bellg *et al.,* 2004; Borrelli, 2011). This framework was selected because it was developed specifically for health behaviour change trials conducted in pragmatic community settings and provides mutually exclusive, comprehensive domains that collectively reduce the risk of Type I and Type II errors and strengthen causal inference (Borrelli, 2011). Fidelity indicators across all five domains were embedded in the trial's data collection and supervision systems and reported as secondary process outcomes alongside the primary neonatal mortality outcome. The composite fidelity score (Fi) described under Domain 5 integrates standardised scores across all five domains.

Study design fidelity (Domain 1) ensured that the trial adequately tested its hypotheses with respect to its underlying theoretical and clinical processes (Bellg *et al.,* 2004). In this trial, study design fidelity was established through three mechanisms. First, the intervention (IV1, IV2, IV3) was grounded in an explicit theory of change linking community health system institutionalisation to reductions in preventable neonatal mortality, ensuring that the trial design was theory-driven rather than empirically opportunistic. Second, treatment dose was pre-specified in the trial protocol, including the number of WLA/MLA learning and action cycles to be completed per cluster per trial period, providing a concrete design-level dose standard against which delivery could be assessed. Third, the trial protocol included advance planning for implementation setbacks, including a remediation pathway triggered when cluster-level composite fidelity scores fell below the pre-specified threshold of $Fi < 0.70$ (see Domain 5), consistent with BCC recommendations for anticipating and managing implementation challenges (Borrelli, 2011).

Provider training fidelity (Domain 2) ensured that intervention providers are trained to a standardised criterion, that training is consistent across providers and sites, and that providers are monitored over time to ensure skills retention (Bellg *et al.,* 2004). In this trial, VHWs served as the primary intervention providers, with VHC members

providing community-level oversight. All VHWs delivering the intervention received standardised training prior to trial commencement, using a structured training manual developed specifically for this trial. Training covered all components of IV1 (VHW-facility linkage protocols), IV2 (VHC oversight procedures), and IV3 (WLA/MLA facilitation techniques). Training sessions were delivered by DHMT field supervisors and included competency assessments to verify that each VHW met the minimum performance standard before being authorised to deliver the intervention in their cluster. Refresher training was provided at the start of each new learning and action cycle to ensure implementation consistency over the 12-month trial period. Training completion rates and competency assessment outcomes were recorded as process indicators.

Treatment delivery fidelity (Domain 3) assessed whether the intervention was delivered as intended, encompassing adherence to protocol components, provider competency, and differentiation from any comparison treatments (Bellg *et al.,* 2004; Borrelli, 2011). In this trial, delivery fidelity was operationalised across two indicators. Dose was operationalised as the number of WLA/MLA learning and action cycles completed per cluster over the trial period, relative to the number of cycles specified in the trial protocol. Each intervention cluster was expected to complete a pre-specified number of full-group learning cycles (comprising all structured session components) during the trial period. Dose delivered was expressed as the percentage of protocol-specified cycles completed per cluster. A dose delivery rate ≥80% of protocol-specified cycles was pre-specified as the minimum threshold for classifying a cluster as having received the full intervention, consistent with dose-fidelity standards used in comparable community-based cRCTs (Kirkpatrick *et al.,* 2010). Clusters falling below this threshold were flagged for sensitivity analysis to assess the impact of incomplete dose delivery on the primary outcome.

Field supervisors from the District Health Management Team (DHMT) conducted structured supervisory visits to each intervention cluster at pre-specified intervals throughout the trial period. Each supervisory visit was documented using a standardised supervision checklist that assessed: (i) whether VHW group sessions were being conducted as scheduled; (ii) whether VHW-facility linkage protocols were being followed; (iii) whether VHC oversight meetings were occurring at the required

frequency; and (iv) whether trial registers and data collection tools were being completed accurately. Supervision visit frequency (number of visits completed vs. visits scheduled per cluster) and checklist completion rates were recorded and reported as process indicators. A minimum of one supervisory visit per cluster per quarter was pre-specified as the required supervision dose. Supervision data also served as the primary mechanism for assessing differentiation between intervention and control arms, confirming that no IV1, IV2, or IV3 components were delivered to control clusters during the trial period.

Treatment Receipt assessed whether participants understood and actively engaged with the intervention content (Bellg *et al.,* 2004). In this trial, receipt fidelity was operationalised using cluster-level indicators of attendance and comprehension.

Attendance at WLA/MLA group learning and action cycle sessions was recorded by facilitating VHW at every session using a standardised group register. The register captured the number of women and men present at each session, their names, and their ward of residence. Attendance was expressed as the proportion of eligible community members (women of childbearing age and male household members) attending at least one session per learning cycle, calculated at the cluster level. A minimum attendance threshold of 60% of eligible community members per cluster per cycle was pre-specified as the benchmark for adequate community engagement and receipt of intervention content, consistent with participatory group trial standards (Tripathy *et al.,* 2016; Prost *et al.,* 2013). A question checking meeting attendance was included in the data collection tool.

At the close of each WLA/MLA session, the facilitating VHW administered a brief standardised verbal comprehension check to assess whether participants could correctly identify the key neonatal health messages covered in that session. Comprehension was recorded as the proportion of participants who recalled at least 2 of the 3 key session messages, calculated per session and aggregated to the cluster level. Similarly, the proportion of women who could correctly identify danger signs in newborns was calculated and recorded as the community women's literacy. This indicator served as a proxy measure of receipt, confirming that the intervention content was not only delivered but also actively processed by participants.

Treatment enactment fidelity assessed the extent to which participants applied the skills and behaviours promoted by the intervention in their daily lives and community settings, beyond the structured intervention sessions (Bellg *et al.,* 2004; Borrelli, 2011). In this trial, enactment was operationalised as the adoption of key neonatal health practices, specifically, facility-based delivery, immediate newborn care practices, and timely care-seeking for danger signs, by women in intervention clusters between sessions and at the end of the trial period. Enactment was assessed at scheduled follow-up data collection visits using a structured behavioural checklist administered to women of childbearing age in each cluster. The proportion of women reporting consistent adoption of at least 2 of the 3 target practices constituted the enactment rate, a secondary process outcome (Table 9).

Table 9: Intervention Fidelity Measurement Framework

Domain	Measurement Strategy	Implementation
Design	Theory-based intervention mapping	Logic model linking activities to outcomes
Training	Standardised VHW manual and package	92-hour initial training plus 8-hour monthly refresher training. Households undergo 24 hours of training.
Delivery	Direct observation and checklists	11.5% (at least 3 clusters) random observations per quarter
Receipt	Number of women's and men's group meetings attended	Proportion of eligible women and men participating in at least 1 cycle, and a minimum threshold of 60%
Enactment	Client knowledge assessment and skill demonstration	Women of childbearing age with knowledge of at least 2 – 3 newborn danger signs

Overall intervention fidelity at the cluster level was assessed using a composite fidelity score (Fi) for each cluster, which was the weighted mean of standardised scores across the five BCC domains:

$$Fi = (1/5) \times \Sigma(d=1 \text{ to } 5)\ wd \cdot fid$$

where fid represents the standardised score for domain d, and wd are domain weights, set to 1 for equal weighting across all five domains. Clusters with $Fi < 0.70$ were classified as requiring targeted remediation. Clusters were further classified as high fidelity ($Fi \geq 0.80$), moderate fidelity ($0.70 \leq Fi < 0.80$), or low fidelity ($Fi < 0.70$). This

classification was used in a pre-specified per-protocol sensitivity analysis, in which the primary outcome was re-estimated by restricting the intervention arm to high-fidelity clusters only to assess whether fidelity moderated the observed intervention effect. The observed fidelity monitoring results, including mean composite fidelity scores, remediation rates, and temporal stability statistics across all 26 intervention clusters, are reported in the Results section (Chapter 5 under Intervention Fidelity) and accompanied by the per-protocol sensitivity analysis findings.

4.2.1.4 Unit of Randomisation

The unit of randomisation was the community cluster, defined as a ward, an established administrative geographical unit in Zimbabwe. A ward is characterised by the catchment area of a single primary health care facility (clinic), each serving approximately 8,000–10,000 individuals within an estimated radius of 5-8 km and encompassing networks of villages. Each ward has a dedicated network of VHWs who report to that clinic and whose boundaries do not overlap with those of adjacent wards. This definition, of one ward equating to one cluster, was used consistently throughout the trial, including in the eligibility criteria, recruitment, randomisation, and analysis.

Randomisation was performed at the cluster level rather than the individual participant level for three reasons: (i) the interventions (IV1, IV2, and IV3) are delivered to communities as a whole and cannot be disaggregated to individuals without fundamentally altering their nature; (ii) cluster-level randomisation minimises the risk of contamination between intervention and control arms, given the geographic spacing between wards in Mashonaland West; and (iii) the natural geographic boundaries created by sparse distribution support the delineation of non-overlapping clusters (Stringer *et al.,* 2011; Diaz *et al.,* 2013; Gabida *et al.,* 2015; Tripathy *et al.,* 2016). Although randomisation was performed at the cluster level, the primary outcome, preventable neonatal deaths per 1,000 live births at 28 days of life, was measured at the individual neonate level within each cluster.

4.2.1.4.1 Strategy to Prevent Contamination

To prevent contamination, three structural features of the trial design were employed between the intervention and control arms. First, geographic separation: wards in Mashonaland West are separated by 20 to 40 kilometres of sparsely populated terrain, making routine social interaction between residents of different clusters uncommon and incidental knowledge transfer of trial content unlikely. Second, VHW boundary fidelity: each VHW are assigned exclusively to their own ward and does not conduct home visits, group sessions, or any trial-related activities outside their designated cluster boundary. Adherence to this boundary was monitored through field supervision logs and VHW attendance registers. Third, buffer zones: 143 wards were excluded from randomisation and designated as buffer zones between trial clusters, further reducing the probability of cross-cluster exposure to intervention content.

4.2.1.4.2 Contamination Measurement Indicator

Spillover was operationalised and measured using a dedicated contamination indicator embedded in the trial's data collection tools. At each scheduled follow-up data collection visit, women in control clusters were asked a standardised screening question: "In the past month, have you attended any women and men's group meetings or received home visits from a village health worker about newborn care?". Confirmed responses triggered a structured probe to ascertain the source, content, and frequency of exposure. The proportion of women in control clusters who reported any exposure to intervention content was the contamination rate, a secondary process outcome. A contamination rate exceeding 10% in any control cluster would trigger a protocol-specified review by the Data Safety Monitoring Board (DSMB). This threshold was pre-specified in the trial protocol and is consistent with contamination monitoring standards recommended for community-based cRCTs (Taljaard *et al.,* 2016).

4.2.1.5 Allocation Ratio

Clusters were allocated to the intervention and control arms in a 1:1 ratio, meaning an equal number of clusters were assigned to each arm. This equal allocation maximises statistical power for a given total number of clusters and ensures balance in the number of neonates contributing to the primary outcome between the two arms. The 1:1 allocation ratio is consistent with standard practice for two-arm superiority cRCTs and

supports the estimation of an unconfounded between-arm difference in neonatal mortality rates (Hemming *et al.,* 2017; Copas & Hooper, 2021). The complete flow of clusters and participants through all stages of the trial, from eligibility screening, exclusions, randomisation, allocation, follow-up, and analysis, is presented in Figure 14 (Results, Section 5.3.2).

4.3 Research Context

This research took place in Mashonaland West province, located in Zimbabwe's western region and bordering Zambia. The province comprises all settlement types found in Zimbabwe: urban, peri-urban, and rural, making it a representative mirror of the country's general demographic and geographic set-up. Selection of Mashonaland West was guided by criteria directly relevant to trial feasibility, including neonatal event rates sufficient to power the study, cluster readiness, and logistical considerations, as detailed below:

i. High neonatal event rates supporting adequate statistical power: The province contributes a significant proportion of neonatal deaths nationally, consistent with Zimbabwe's overall neonatal mortality rate of 37 deaths per 1,000 live births recorded in the 2023-24 Zimbabwe Demographic and Health Survey (ZDHS), a 28% rise since 2015 (Zimbabwe National Statistics Agency [ZIMSTAT] & ICF, 2024). This elevated and sustained event rate was critical for achieving the minimum sample size required to detect a clinically meaningful reduction in neonatal deaths within the cRCT.

ii. Geographic and logistical conditions favouring a cluster-based trial design: The province has few health facilities, and those that exist are spaced 20 to 40 kilometres apart (Dodzo & Mhloyi, 2017). Each facility serves a defined ward (the unit of randomisation), and this sparse facility distribution creates natural geographic boundaries that support the delineation of non-overlapping ward-level clusters, reduce the risk of contamination between intervention and control arms, and underscore the necessity for community-level health interventions, the precise focus of this trial.

iii. Cluster readiness: health system infrastructure and community health workforce: Mashonaland West is set to receive additional health posts as part of

a national initiative to extend service delivery closer to communities, positioning the province as a learning hub for scale-up. Critically for trial readiness, the province has an existing pool of community health workers (village health workers, VHWs) who currently lack consistent linkage with the nearest health facility. This gap represents both a modifiable determinant of neonatal mortality and a testable condition for the intervention, making the province well-suited for evaluating the independent and combined effects of the VHW cadre, community governance structures, and modified women's and men's groups on neonatal outcomes.

iv. Institutional readiness and governance capacity: Mashonaland West has a strong provincial health executive (PHE), dedicated district health management teams (DHMTs), and functional local governance bodies, all with well-defined operational plans for implementing community health strategies (Muchekeza *et al.,* 2012; Kagwanja *et al.,* 2023).

v. Community engagement as a provincial priority: The province has formally identified community engagement initiatives as a priority intervention across most of its districts (MoHCC, 2016; World Vision International, 2022). This pre-existing strategic alignment reduces the implementation burden of the trial, facilitates cluster mobilisation, and supports the sustainability of the intervention beyond the trial period.

vi. Logistical accessibility for consistent implementation: Mashonaland West's proximity to Harare, the national capital and location of the study's coordinating institution, facilitates regular supervisory visits, timely data collection, and responsive monitoring and follow-up throughout the trial. This logistical advantage directly supports protocol fidelity and reduces the risk of implementation drift across clusters.

According to the 2022 Zimbabwe Population and Housing Census, Mashonaland West province had a population of 1,893,578, constituting approximately 12.5% of Zimbabwe's total population of 15,178,979, with an annual provincial growth rate of 2.6% between 2012 and 2022 (Zimbabwe National Statistics Agency [ZIMSTAT], 2022). Based on the national crude birth rate of approximately 4.0% (ZIMSTAT & ICF, 2024), the province delivers an estimated 75,743 babies annually, providing sufficient births to support the cRCT's primary outcome of reducing neonatal mortality.

4.4 Eligibility Criteria

4.4.1 Inclusion Criteria

All wards within Mashonaland West province were eligible for inclusion in the trial. The primary target population comprised women of childbearing age (15 to 49 years) residing in eligible wards. This age range is consistent with standard demographic definitions used in reproductive health research and aligns with the Zimbabwe Demographic and Health Survey (ZIMSTAT & ICF, 2024) criteria.

4.4.2 Exclusion Criteria

Wards that contained or were served by a referral hospital were excluded from the trial. This exclusion was applied to minimise the confounding effect of tertiary-level care on neonatal outcomes, as referral hospitals provide a substantially different standard of obstetric and neonatal care from that of primary health care facilities/ clinics, which are the focus of this intervention. Visitors to the study area, defined as individuals who were not permanent residents of the eligible wards at the time of the study, were also excluded. This criterion was applied to ensure that outcome data reflected the lived experience of the resident population and to maintain the integrity of cluster boundaries.

4.4.3 Methods of Recruitment

Recruitment was conducted at the ward level. VHWs, who are embedded within their communities, served as the primary point of contact for identifying and engaging eligible women of childbearing age within each ward. All pregnant women, identified, tested for pregnancy and confirmed at the local clinic were approached at the household level, informed about the study, and invited to participate following the informed consent process.

4.5 Intervention and Comparator

4.5.1 Control Clusters

At the control sites, services were delivered using the standard package of community health services, in alignment with the national policies, standard operating procedures, and guidelines established by the MOHCC of Zimbabwe. According to these guidelines, health professionals are expected to provide education to mothers whenever they visit to access healthcare services. They must assist mothers facing breastfeeding challenges and arrange for follow-ups when necessary (MOHCC, 2016; MOHCC, 2021; Moyo *et al.,* 2024)

When community-based workers and support groups are available, mothers should be directed by health workers at clinics to these resources within their neighbourhoods. Furthermore, continuous counselling and support are provided to mothers regarding all services available during antenatal and postnatal care, among other things. (Lassi *et al.* 2019; le Roux *et al.* 2020; Dada *et al.* 2021). Health workers also facilitate connections between mothers and village health workers to ensure ongoing support and access to community services. Village health workers (VHWs) participate in refresher training and are supervised regularly by the MOHCC and its partners. As part of their responsibilities, they are required to conduct home visits to each household in their communities at least once a month, regardless of urgency (Mbachu *et al.,* 2022; Munyai, Mudau & Mashau, 2025)

It is also important to highlight that this study coincided with the Government of Zimbabwe's initial phase of implementing the National Community Health Strategy. This phase emphasises revitalising or establishing community governance structures, including Health Centre Committees (HCCs) and Village Health Committees (VHCs), as well as recruiting and training additional VHWs. The strategy also focuses on enhancing the skills of existing VHWs, strengthening the Community Health Information System (CHIS), and standardising community roles, including ensuring a secure supply chain for community commodities.

4.5.2 Intervention Clusters

At the intervention sites, mothers received the routine services provided in accordance with the MOHCC national policy, as in the control group, including the implementation of the new National Community Health Strategy, 2020-2025. Furthermore, the intervention was designed following the socio-ecological approach and ensuring

effective coverage using the Tanahashi framework to model the architecture of the community health system.

4.5.2.1 The intervention: Modified women's and men's participatory learning and action groups

This study modified the women's group intervention, which, as described in Bolivia, Nepal, and Malawi (Mai Mwana Project), is women-centred and capacitates women to identify problems, plan together, and implement strategies affecting women and their children (Lewycka *et al.,* 2010). As such, the modification included men in discussions with community members on RMNCAH issues, within the broader framework of social accountability and community engagement. This study examined how multiple layers critically influence children's survival. It sought to build the capacities of the family and entire community to take control of the health issues of women and children, particularly the mother and newborn, looking at health issues that affect them, being cognizant of the patriarchal nature of Zimbabwean society. This intervention is community-based and community-led, positioning the community as the centre of influence and defining it as the unit of change. (Lassi, Kumar, & Bhutta, 2016; Habte, Lukas, & Tamirat, 2020; Wafula *et al.,* 2024).

One local village health worker (VHW), one per village or at least 100 households, undergoes 92 hours of training to strengthen their capacity to establish 1-to-10 networks of neighbouring households in the village and facilitate community meetings. These networks of households were called community health forums (CHFs). "The CHFs refer to an organised movement of the community through participatory learning and action meetings for health" (Smith & Blumenthal, 2012; Campbell, Yan & Egede, 2020; Karuga *et al.,* 2022).

These households underwent 24 hours of training from VHWs on components of maternal, neonatal, and child health services in the community essential health package (CEHP). CEHP is a package of community-based interventions, accompanied by additional sessions on essential newborn care practices.

Table 10: Package of services for households

Intervention Areas	Topics covered with households
Reproductive health	Awareness and counselling on family planning methods
	Education and referral for screening of reproductive cancers, such as breast and cervical cancer
Pregnancy	Need for registration of every pregnancy early in the household, and the benefits
	Education on nutrition and the use of iron and folate supplements
	"Detection and management of severe acute malnutrition and referral in the presence of complications" (Black *et al.,* 2016; World Health Organisation, n.d.)
	Seeking appropriate medical care and attending antenatal appointments during pregnancy is crucial. It is advised to have at least eight antenatal visits, and it is also important to schedule the first appointment before 14 weeks of gestation (World Health Organisation, 2016; World Health Organisation, 2018; Lee *et al.,* 2024)
	Screening and promotion of tetanus toxoid vaccination
	Encourage preventive malaria treatment for pregnant women in regions where the disease is common and show the proper way to use long-lasting insecticidal nets (LLINs) (Sonibare *et al.,* 2020; Negasa *et al.,* 2024).
	"Promote birth in a health facility and help prepare for birth (Birth preparedness and complication readiness)" (Mulugeta *et al.*, 2015; Kamineni, Murki & Kota, 2017; Feyisa Balcha *et al.,* 2024).
	Early identification of pregnant women and referral for early ANC on or before 12 weeks, and promotion of a minimum of 8 ANC contacts
	Educate and raise awareness among traditional health practitioners about danger signs during pregnancy, and ensure linkages with formal health systems, including emergency referrals.
	Awareness and guidance on the prevention and management of sexually transmitted infections, along with assistance for preventing Mother-to-Child Transmission of HIV and syphilis
	Education and awareness of the benefits and risks of safe use of herbal medicine during pregnancy
Postpartum care	Promotion of post-partum HIV screening and during the period of breastfeeding
	Support for mothers who are HIV positive, focusing on infant feeding practices related to HIV, as well as monitoring for signs of deteriorating mental health (CDC, 2021; Gebremariam *et al.*, 2024)
	Screening and counselling for post-partum depression
Newborn care (0 – 28 days)	Education, awareness and supporting early initiation and clean cord care
	Guidance and assistance for mothers in providing thermal care to preterm infants through methods like "skin-to-skin contact or

	kangaroo mother care" (UNICEF, 2008; Campbell-Yeo *et al.,* 2015; World Health Organisation, 2023).
	Support for early and EBF, without discarding colostrum (first milk). Support optimal feeding practices.
	Early identification of maternal and neonatal danger signs and the roles of VHWs in supporting referral
	Additional home visitation for sick and small newborn babies

VHWs effectively led these networks and were responsible for inviting all women of childbearing age to attend cycles of meetings, including a separate group for men, conducted in sessions. The VHWs guided the women's and men's networks through five-cycle community mobilisation action sessions designed for the Zimbabwean context, using models implemented in "Bolivia, Nepal, Malawi, and Ethiopia" (Lewycka *et al.,* 2010). A similar model, adopted from the MaiMwana project in Malawi, was modified (Figure 12) to include an additional cycle for community-based maternal, neonatal and perinatal death audits and accreditation.

The first cycle consisted of 6 meetings for women and 2 for men, during which the group identified and prioritised the health problems they felt were affecting women and children. The networks further discussed what contributed to these issues or difficulties faced by women and explored ways to prevent and manage them through locally home-grown solutions. During the last meeting (the fifth session for women and the second for men), the VHWs held a joint discussion with men and women in the village. Targeted women of childbearing age were expected to actively participate in all sessions (Alam *et al.,* 2025). The VHWs recorded the progress of all group members and conducted monthly meetings with the village health committees (VHCs). The first cycle was the first month.

The second cycle consisted of four meetings for women and one for men, with networks/groups planned locally, recommended, or community-led to address the identified and prioritised issues. The third session, which was the last session for women, was the time to share the observations with the whole village/community during the village assembly. The second cycle was expected to be the follow-up month after pregnancy was identified. (Sharma *et al.* 2020; Yoseph *et al.* 2024).

The third and fourth cycles took place in the third (3rd) month. During the third cycle, which consisted of two meetings or sessions, the networks of men and women expanded

the discussion to include all community members, particularly significant others in households, who worked together to implement the identified strategies. In the fourth cycle, at least two meetings, the networks, together with the VHWs and the entire community, evaluated what they had done, implemented corrective measures, and planned to build resilience.

After completing all 15 sessions by the third month, the VHWs led a village mapping and assessment of maternal, newborn, and child health practices. When a household successfully implemented or practised agreed actions during community meetings, it was then given the responsibility to influence others as a change agent. The "arrangement of households fostered empowerment in decision-making within the community" (Obi *et al.,* 2024). It encouraged households to take ownership of health matters, thereby rapidly scaling up desirable neonatal health behaviours as they learned from their peers. Issues examined included, but were not limited to, early antenatal care booking for any pregnant woman in the household; delivery in health institutions; identifying danger signs for mothers and newborn babies; caring for newborn babies at home; and knowing where to find emergency transportation and care when needed.

This process fed into the community social accountability model, the final cycle (Cycle 5). During the fifth cycle, the community-based maternal, neonatal, and perinatal death audits on the circumstances surrounding the deaths of newborns and infants within a community were conducted. These audits aimed to identify factors contributing to neonatal deaths, enabling the implementation of targeted interventions to prevent such incidents in the community (Willcox *et al.,* 2020; Tayebwa *et al.,* 2020). The fifth cycle took place in the fifth and sixth months.

Intervention Profile: Learning and Action Group Phases for Women and Men

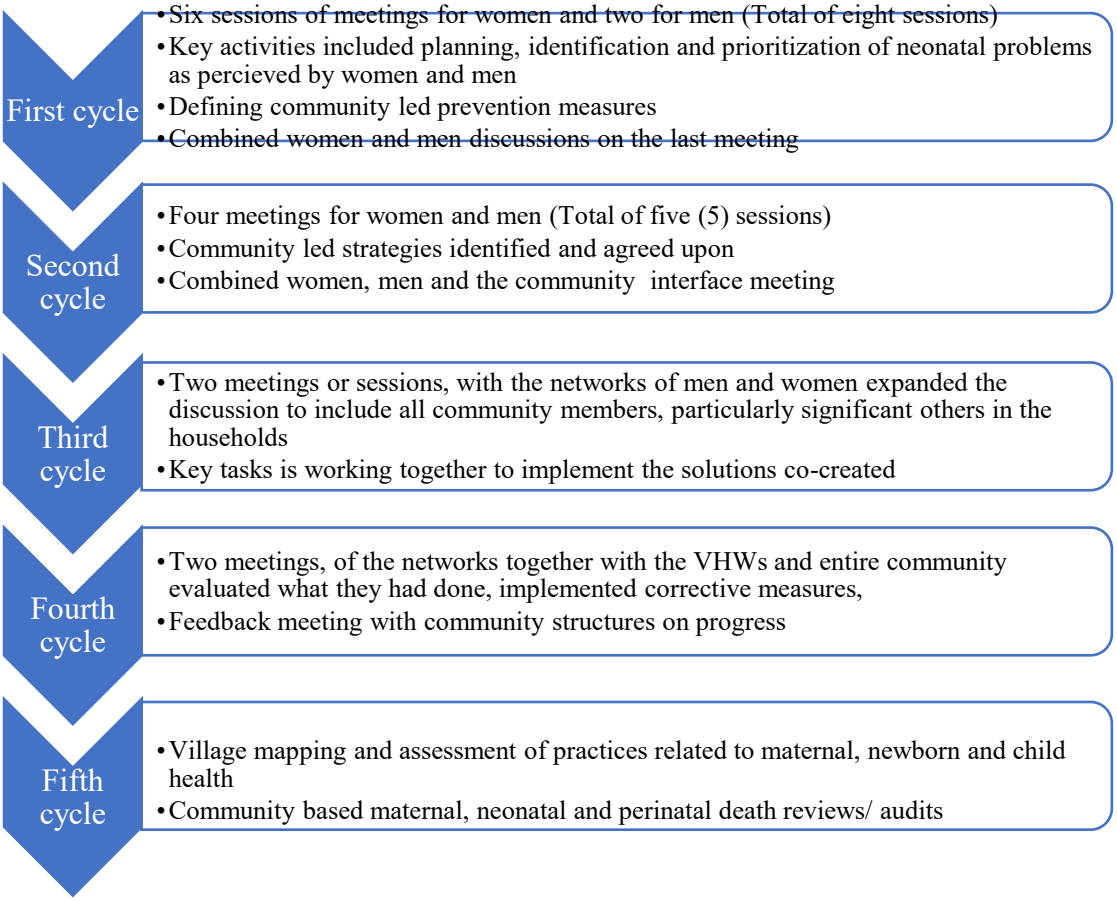


Figure 12: Modified women's and men's learning and action groups on community-led reduction in neonatal deaths

To establish a nurturing and attentive atmosphere for women, adolescents, and children, it is essential to enhance the skills of the district health teams within the Ministry of Health and Child Care (MOHCC), health facility teams and local authorities, including Health Centre Committees (HCCs) and Village Health Committees (VHCs), and inter-ministerial teams was conducted to define problems, solutions, and prioritise actions to support neonates. At least 4,128 VHWs, HCCs, VHCs, HFTs, and DHTs were capacitated on the use of data for evidence-based decision making at the local level and community monitoring, feedback interface meetings, and use of Community Scorecards (Kiracho *et al.*, 2020; Argaw *et al.,* 2021; Tilahun *et al.*, 2021).

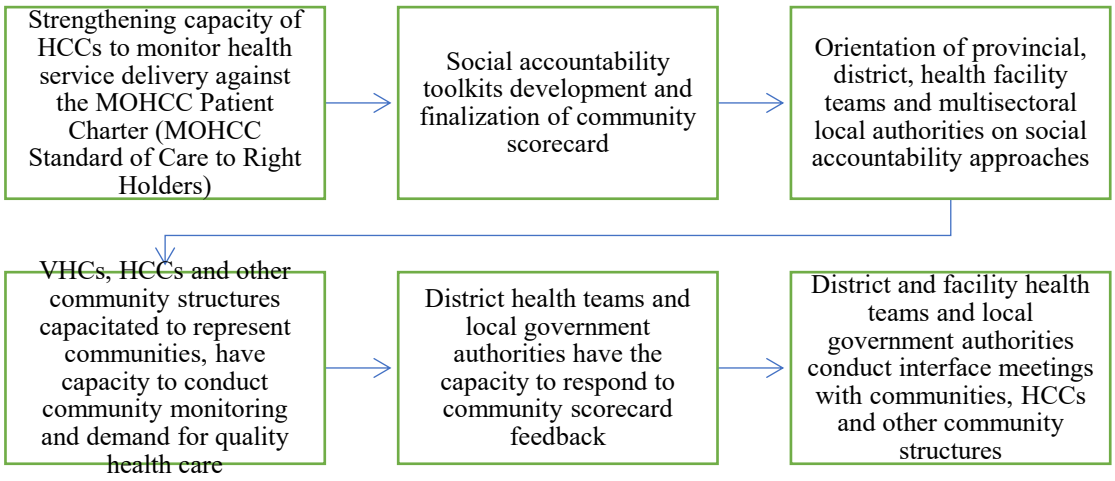


Figure 13: Key elements of the social accountability model

The "VHWs continued to receive on-the-job support in accordance with MOHCC guidelines, which allowed them to help the CHFs utilise tools like participatory rural appraisal techniques, picture cards, and storytelling to foster discussions and empower household networks to tap into their shared knowledge and skills" (Munyai *et al.,* 2024). As a result, these groups gradually gained more control over the intervention throughout the cycle. They did not receive any funding or resources from the project, relying solely on the guidance provided by the VHW, along with support from trained peer supervisors and health facility teams that received quarterly assistance from the project (Poulsen *et al.,* 2022; Lyons, Cooper & Lloyd-Evans, 2021; Marks *et al.,* 2021).

A drama with the theme 'Mwana Wedu' (Our Child) was planned to be performed towards the end of the project, where women, men, and other community members in Mashonaland West would explain the intervention in their own understanding. *"Mwana Wedu"* symbolises that the responsibility to care for a child is not only a mother's but also the entire family and communities. The drama was expected to be used to continue community engagement and to scale up to other districts and provinces. This was to be aired on the community radio station (Nyaminyani Radio Station in Mashonaland West) and featured live performances. However, "because of the COVID-19 pandemic and its related restrictions" (Murphy *et al.,* 2021), the drama was suspended and will not be part of this submission.

4.5.2.2 *Home-based counselling*

To complement the meeting cycles, village health workers undertook two scheduled home visits during pregnancy and at least three postnatal visits within the first week after childbirth (Guenther *et al.,* 2019; Tesfau *et al.,* 2020; Ahissou *et al.,* 2025). The VHWs also participated in community outreach efforts to promote care-seeking behaviours throughout pregnancy, delivery, and the postnatal period (McConnell *et al.,* 2016; Gupta & Khan, 2024). The main goal of these home visits was to encourage expectant mothers to undertake "the World Health Organisation recommended eight antenatal care visits" (Ftwi *et al.,* 2020), which were adopted in Zimbabwe in 2018.

Other key focuses included ensuring skilled attendance during birth, promoting essential practices such as maintaining household hygiene, ensuring clean cord care, encouraging skin-to-skin contact, preventing hypothermia, promoting early and exclusive breastfeeding, and recognising and responding to danger signs (Falle *et al.,* 2009; World Health Organisation, 2023; Guadu *et al.,* 2025). Additionally, small and ill newborns were given two extra home visits along with ongoing support for “Kangaroo Mother Care (KMC). Mothers were educated on the importance of birth preparedness, understanding complications, and the use of maternity waiting homes to help reduce delays in accessing care. All pregnancies, births, and deaths were documented and recorded” (Ghazi *et al.,* 2021; Bilal *et al.,* 2021; World Health Organisation, 2023)

Where a village did not have a VHW, the research team engaged the District Health Executive to prioritise the recruitment, training, and deployment of VHWs, in line with the implementation of the National Community Health Strategy. They received regular supportive supervision from a dedicated supervisor, including accreditation in accordance with MOHCC guidance. The MOHCC provided the training support.

In addition to community-based initiatives, the VHWs linked mothers with facility-based health workers, who are oriented on community-based maternal, newborn and child health CBMNCH including training on Helping Babies Breathe (HBB) and Helping Babies Survive (HBS), to facilitate access to essential maternal and newborn care (Bang *et al.,* 2016; Ersdal *et al.,* 2017; Wafula *et al.,* 2024). Therefore, mothers accessed quality care at birth, including resuscitation and kangaroo mother care (KMC)

(Vesel *et al.,* 2015). Even though this component was beyond the scope of this study, it was evaluated as a confounder, as it is a requirement for all health facilities in the district and is not unique to the intervention areas.

Lastly, working with the provincial health team, the intervention applied the principles of institutionalising the community health system that involved recognition of community health constructs as a formal extension of the health system through the national community health strategy roll out, establishment and revitalisation of community structures and defining clear linkages with the formal health system.

4.6 Study participants follow-up

Individual follow-up was conducted for all households with eligible women recruited into the study by research assistants within the first 28 days after birth (Pepper, Campbell & Woodd, 2024; Worku *et al.,* 2024). Any visits conducted after day 28, where feasible, were excluded from the analysis.

4.7 Outcome measures

The primary outcome was neonatal death at 0–28 days, measured as all-cause neonatal mortality and expressed as a rate per 1,000 live births; this is the measured form of the preventable neonatal death defined in Section 1.10.7, and cause-specific mortality (preterm-birth complications; neonatal infection; other) is a pre-specified secondary outcome. This outcome aligns with the trial's overarching aim of reducing neonatal mortality and is part of the core outcome set for neonatal trials, as recommended by the WHO and the Core Outcomes in Neonatology (COIN) initiative. The rationale for selecting neonatal mortality as the primary outcome is its clinical and public health significance in low-resource settings, its objectivity, and its direct relevance to the intervention's theory of change. The intervention was hypothesised to "contribute to a 20% reduction in neonatal deaths" (Tripathy *et al.,* 2009; Lewycka *et al.,* 2010).

Secondary outcomes were defined to capture intermediate effects on the pathway to mortality reduction, as well as to monitor unintended effects and process measures. The prespecified secondary outcomes are outlined in Table 11.

Table 11: Study endpoints and outcomes

	Phenomena of interest
Primary Outcome	Neonatal death, all-cause (deaths per 1,000 live births within 28 days). Cause-specific neonatal mortality (preterm-birth complications; neonatal infection; other causes) is a secondary outcome
Secondary Outcomes	**Changes in household practices for:** • Timely care-seeking for newborn danger signs (proportion of mothers seeking care within 24 hours of symptom onset) • Immediate newborn care practices (proportion of mothers/caregivers reporting timely drying, skin-to-skin contact, and early breastfeeding initiation) **Shifts in how individuals seek care** • Maternal health service uptake (e.g., ≥4 ANC visits, postnatal care attendance) **Changes in community-level practices** • Functionality of community-level committees for health **Neonatal morbidity** (incidence proportion of major morbidities, e.g., sepsis, as defined by clinical or verbal autopsy criteria) **Contamination rate in control clusters** (proportion of women in control clusters reporting exposure to intervention content) **Composite intervention fidelity score** (mean Fi per cluster)

*The trial endpoint is all-cause neonatal mortality; preventability is invoked conceptually rather than as an outcome criterion, on the basis that the causes the intervention principally targets (preterm birth complications and neonatal sepsis) are preventable through timely community- and facility-level care and thus fall within its mechanism of action.

For each outcome, the following specifications were applied:

The primary outcome was defined as all-cause neonatal mortality, with death ascertained through household surveillance and confirmed by verbal autopsy or facility records. Early and late neonatal deaths were sub-classified by age at death. Immediate newborn care practices were measured at 7 and 28 days postpartum via maternal report using a structured, interviewer-administered questionnaire. Maternal health service uptake was recorded through self-report and, where available, confirmed in facility registers and community registers by VHWs. Neonatal morbidity was defined using the WHO verbal autopsy tool and included neonatal sepsis, birth asphyxia, acute respiratory distress syndrome or pre-term complications. The contamination rate was defined as the proportion of women in control clusters reporting any exposure to

intervention content during follow-up. The composite fidelity score was calculated using standardised indicators across the five NIH BCC domains.

For mortality outcomes, the metric was binary (death or survival) per neonate. For care practices and service uptake, binary and categorical responses were used (e.g., received/not received, yes/no). For morbidity, the analysis metric was the incidence proportion per neonate. For fidelity and contamination, the cluster-level proportion or mean score was used.

Outcomes were aggregated as proportions (e.g., proportion of neonates surviving to 28 days, proportion of mothers practising immediate newborn care), means (e.g., cluster-level fidelity scores), or rates (e.g., deaths per 1,000 live births) as appropriate. All outcomes were reported separately by trial arm (intervention vs control) and compared using risk ratios or mean differences with 95% confidence intervals.

The time point for neonatal mortality and care practice outcomes was within 28 days postpartum. Secondary outcomes such as early and late neonatal deaths were analysed at 7 and 28 days, while service uptake and process indicators were measured at the end of the intervention period, with additional follow-up at 3 and 6 months for select maternal and child health outcomes.

4.7.1 Endpoints for the study and expected outcomes

The endpoints of this research are detailed in Table 11. The intervention spanned a period of one year. It was anticipated that the positive effects of this intervention would manifest as early as six months post-exposure, given that women tend to be recognised earlier in their pregnancies and receive ongoing follow-up. The VHWs who are residents in the same village as the pregnant woman were expected to accelerate exposure and uptake of recommended practices.

4.7.2 Process evaluation

A qualitative, longitudinal process evaluation was embedded within the cluster randomised controlled trial, spanning January 2020 to January 2021. This process

evaluation was structured according to the UK Medical Research Council (MRC) Process Evaluation Framework, enabling a systematic assessment of how the intervention was implemented and experienced over time. Qualitative data were collected at both baseline (pre-intervention) and at multiple follow-up points, explicitly timed to coincide with key intervention cycles (e.g., before commencement, midline, and post-intervention). This alignment enabled the exploration of changes in perceptions, experiences, and contextual factors as the intervention progressed. The evaluation focused on four core domains:

i. **Reach:** Assessment of the extent to which the intervention engaged the intended participants and communities. This included monitoring participant recruitment during village health workers' household training sessions, attending the modified women's and men's learning and action group meetings, participating in community-based activities, and analysing demographic data to evaluate the representativeness of those reached.
ii. **Fidelity:** Evaluation of the degree to which the intervention was delivered as intended, including adherence to protocols, consistency in delivery by community health workers, and documentation of any deviations or adaptations to the intervention.
iii. **Context:** Exploration of external influences on implementation and outcomes, such as cultural norms, social dynamics, and health system factors. Contextual data were collected through key informant interviews, field observations, and review of relevant community and health system documents.
iv. **Mechanisms of Impact:** Investigation of the processes and pathways through which the intervention was hypothesised to effect change. This included longitudinal in-depth interviews and focus group discussions with participants and stakeholders at multiple time points, aimed at capturing subjective experiences, perceptions, and any unanticipated consequences of the intervention.

Utilising this structured framework, the process evaluation provided critical insight into not only the effectiveness of the intervention but also the factors influencing its delivery, uptake, and outcomes within the trial context.

4.8 Target Population

The research focused on “women who are of childbearing age, specifically within the 15 to 49-year age range” (Barrow, 2020; Tefera *et al.*, 2025). For the assessment of the primary outcome, mothers identified during pregnancy and followed up until the first month of life after delivery, who are permanent residents of the cluster, were recruited into the study. Any visitors who were not from Mashonaland West were excluded from the study, as were those without informed written consent. According to the ZHDS (2015), women of childbearing age constitute 24.2% of the total population, and an estimated 385,586 women of childbearing age were expected in the study area.

4.9 Sample Size Determination and Rationale

Ghoshi (2002) describes sampling as a key element of statistical practice, involving the selection of individual observations to gain insights into a larger population, especially for statistical inference. (Ghoshi, 2002; Martínez-Mesa *et al.,* 2016). In this research, which incorporates both quantitative (QUAN) and qualitative (qual) elements, various sampling procedures and methods for determining sample size were utilised to meet the requirements of both components.

4.9.1 Quantitative component

For the quantitative part of the study, the sample size was calculated using established methods for cluster randomised controlled trials. The determination was based on the baseline neonatal mortality rate measured in the study wards during the formative surveillance phase (February–April 2020): 119 neonatal deaths among 845 live births, or 141 per 1,000 live births (Section 5.2.4, Table 21). This cohort-measured rate, rather than a survey estimate, was used because household surveys under-ascertain early neonatal deaths and the trial population was a prospectively surveilled cohort of live births in high-burden rural wards. The calculation used a two-sided Z-test for the difference in proportions, with 80% power and a 5% significance level. The design effect was calculated using the formula $DE = 1 + (m – 1) \times ICC$, where m is the average cluster size, and ICC is the intracluster correlation coefficient.

Based on prior community-based trials in similar settings, an ICC of 0.01–0.03 is typically observed (Hemming *et al.*, 2011; Prost *et al*., 2013; Rutterford, Copas & Eldridge, 2015). For this study, a conservative ICC of 0.02 was assumed in sensitivity analyses, with an average cluster size (m) of 38. This yielded a design effect of approximately 1.161. Additionally, the coefficient of variation (k) for cluster-level event rates was estimated as 0.25, consistent with studies from Nepal and Bolivia (Hemming *et al.,* 2011; Rutterford, Copas & Eldridge, 2015).

The sample size was calculated to detect a 45% relative reduction in neonatal mortality, from 141 to 77 per 1,000 live births. This effect size was chosen with reference to the pooled 38% reduction reported for participatory women's groups at adequate coverage (Prost *et al.,* 2013) and the 20–45% range reported for combined community-based packages (Lassi *et al.,* 2016; Seward *et al.,* 2017), on the reasoning that a package institutionalising the workforce, governance and participatory groups together should achieve at least the upper part of that range. With 80% power, a two-sided 5% significance level, a design effect of 1.161 (ICC 0.02; mean cluster size 38) and 10% expected loss to follow-up, the required sample was 485 mother–infant pairs per arm, rounded to 489. A total of 984 pregnant women were therefore recruited across the two arms. For transparency, the same sample provides 80% power for a 50% reduction with 381 per arm, and would require 633 per arm for a 40% reduction; it is adequately powered for the primary package comparison but not for the smaller effects expected of individual components or secondary outcomes, a limitation addressed in Section 6.8.2.

4,9.2 Qualitative component,

For the qualitative component, sample size was not a primary focus, as the main aim was to achieve a thorough understanding of the information gathered rather than to prioritise statistical significance. Nonetheless, saturation was confirmed to ensure all research questions could be adequately addressed (Joubert *et al.,* 2007; Patton, 1990). For this, key informant interviews in each of the seven districts were conducted with seven to eight (7-8) officials selected from the district and community level for in-depth interviews. At least five national and provincial key informants were included in the

study. A minimum of four (4) focus group discussions were conducted with community groups and community health workers to quantify the functionality and extent of implementation of community-focused health strategies, complementing the second component of the study (Ahmed *et al.,* 2022; Abidi, Qureshi & Fatima, 2025).

4.9.3 Qualitative Sampling and Saturation

The qualitative component aimed to achieve thematic saturation within key stakeholder groups. Based on established qualitative research principles and prior studies in similar contexts, we planned to conduct at least two FGDs per major subgroup (e.g., mothers, community health workers, and local leaders) in both the intervention and control arms, for a total of 14 FGDs. For key informant interviews (KIIs), we aimed for 5–8 interviews per stakeholder category (e.g., district health officials, facility staff, traditional leaders), with final numbers determined by saturation, defined as the point at which no new themes emerge in consecutive interviews within each group. Recruitment continued until saturation was achieved in each subgroup, and this was reviewed iteratively during data collection. This approach follows best practice recommendations for ensuring data adequacy and analytic depth in multi-site, multi-stakeholder qualitative research (Creswell & Poth, 2018; Guest, Namey & Chen, 2020).

4.10 Interim Analyses and Stopping Guidelines

There were no interim analyses conducted during this trial, as they were not pre-specified in the study protocol. Similarly, the trial did not include formal statistical stopping guidelines for efficacy or harm because no treatment was administered to study participants. Also, no adaptations (such as sample size re-estimation) were planned. The decision to continue, stop, or modify the trial would have been made by the independent Data Monitoring Committee based on emerging safety or efficacy concerns, should any have arisen.

4.11 Randomization

Randomisation in a randomised controlled trial (RCT) is a crucial methodological step that involves assigning participants to different treatment groups at random to minimise bias and ensure the validity of the study results. “A random number was generated using STATA version 14, and all pregnant women aged between 15 and 49 years who were permanent residents in the cluster were included. They received either an intervention or no intervention and were followed up within 7 days and 28 days after delivery to ascertain neonatal outcomes” (Kang, Ragan & Park, 2008; Flecha *et al.,* 2016; Bruce *et al.*, 2022).

4.11.1 Randomisation and allocation sequence generation

The allocation sequence was generated by an independent statistician who was not involved in participant recruitment or data collection. Randomisation was conducted at the cluster level. A computerised random number generator created the allocation sequence, ensuring unbiased assignment of clusters to the intervention or control arms. The sequence was generated using Stata version 14, and all pregnant women aged 15 to 49 years who were permanent residents of the cluster were included. The allocation sequence was concealed from the study investigators and field staff involved in enrolment and assignment, maintaining allocation concealment until clusters were assigned.

4.11.2 Type of randomisation and restriction

Cluster randomisation used a restricted (blocked) randomisation approach with a transposed block design to ensure balance between the intervention and control arms. Fixed block sizes of 4 clusters were used, with each block containing equal allocations to the intervention and control arms (i.e., 2 clusters per arm). Randomisation sequences were generated using a computerised random number generator (Stata version 14). All investigators and field teams were blinded to the allocation sequence throughout the allocation process to maintain allocation concealment.

Stratification by district was incorporated into the randomisation process to achieve a balanced allocation of clusters across key predictive variables and geographic regions. This stratified, blocked randomisation approach was chosen to minimise imbalance in cluster numbers per arm and to enhance comparability of baseline characteristics, which is particularly important in cluster-randomised trials with a limited number of clusters. It is important to note that minimisation techniques were not employed in this trial.

4.11.3 Allocation concealment

To ensure strict allocation concealment and prevent selection bias, the randomisation sequence assigning clusters to intervention or control arms was generated in advance by an independent biostatistician, who was not involved in participant recruitment or data collection. The allocation sequence was securely stored and remained inaccessible to all investigators, field staff, and any personnel involved in participant enrolment.

Individuals responsible for enrolling participants within each cluster were notified of their cluster's group allocation only after the cluster had been randomised and recruitment was ready to begin. At no point prior to the initiation of recruitment were the enrolment team or clinic staff provided with information regarding the upcoming group assignments or the order of allocation within the random sequence. This process ensured that the allocation of clusters to trial arms was concealed up to the moment of assignment and could not be predicted or influenced by those enrolling participants. By maintaining this strict separation between the randomisation process and participant enrolment, the risk of selection bias was minimised, thereby upholding the trial's methodological comparative advantage.

4.11.4 Implementation of randomisation

An independent biostatistician generated the random allocation sequence using Stata (version 14) and securely stored it in a password-protected file. Designated field staff enrolled participants at the cluster (clinic/ward) level without access to the allocation sequence. Once recruitment was ready to begin at a site, the biostatistician communicated the specific group assignment to the field coordination team. This process ensured allocation concealment, as those enrolling and assigning participants remained unaware of future assignments, thereby minimising selection bias.

4.11.5 Blinding

Blinding of study participants and care providers was not possible because the intervention involved visible changes at the cluster level (Day & Altman, 2000). However, several measures were implemented to minimise bias in outcome assessment and data analysis. Data collectors responsible for recording trial outcomes were blinded to the allocation status of each cluster; they received standardised training and were instructed not to inquire about group assignments during data collection. All data were coded and anonymised prior to analysis to ensure that data analysts remained blinded to group allocation. Statistical analyses were performed only after data collection was complete, further reducing the risk of bias. Throughout the trial, care was taken to keep the appearance and data-collection procedures consistent between arms, and no breaches of blinding among data collectors or analysts were reported.

4.11.6 Participant recruitment and flow

The participant recruitment flow comprised the following steps:

1. **Cluster Selection:** Fifty-two (52) clusters, defined as a ward, an established administrative geographical unit in Zimbabwe. A ward is characterised by the catchment area of a single primary health care facility (clinic), each serving approximately 8,000–10,000 individuals within an estimated radius of 5-8 km and encompassing networks of villages. Each ward has a dedicated network of VHWs who report to that clinic and whose boundaries do not overlap with those of adjacent wards. These wards were selected and randomised to either the intervention or control arm.
2. **Census Registration:** All households within selected clusters were visited to identify eligible pregnant women.
3. **Eligibility Screening:** CHWs, with support from health workers at clinics, confirmed pregnancy status and assessed inclusion criteria.
4. **Enrolment:** Eligible women were given detailed study information and invited to participate; written informed consent was obtained from all participants.

5. **Follow-up:** Enrolled mother-infant pairs were prospectively followed for outcome ascertainment.

4.12 Qualitative component

A purposive sampling approach was used to ensure representation from key stakeholder groups, including community health workers, mothers, local leaders, health facility staff, district health teams and provincial health executives. At each time point (baseline and follow-up), participants were selected to capture a range of experiences and perspectives related to the intervention's reach, fidelity, context, and mechanisms of impact. The sample was further stratified by cluster and intervention arm to enable direct comparisons over time and between groups. In addition, snowballing was used to recruit key stakeholders involved in the community health systems programme with relevant knowledge and experience who might otherwise have been overlooked. This strategy enhanced the diversity and richness of perspectives captured in the study and supported a more comprehensive understanding of the programme's implementation and context (Naderifar, Goli & Ghaljaei, 2017).

4.13 Description of the research instruments

Standardised, structured interviewers administered questionnaires written in simple language suitable for individuals unable to read or write. The collection tools were developed by adapting from tools and experiences from studies conducted in Southern Asia (Bangladesh, India, Nepal) and sub-Saharan Africa (Ethiopia and Malawi) (Kohler, Behrman and Watkins, 2007). The literature review showed the major predictors and factors associated with neonatal deaths. Based on the theoretical frameworks reviewed, the causes of neonatal deaths were categorised at the community level, family level, and individual level, among others. As such, the questionnaire was designed to address questions related to the proposed constructs, defined based on research instruments used in similar studies in Malawi, Uganda, Ethiopia, India, and Nepal.

The questionnaire was shared with the two research supervisors, health specialists within the Zimbabwean Ministry of Health, and a statistician from the University of Zimbabwe, and any suggested changes were incorporated. An expert translator was

engaged to translate the questionnaire from English to Shona and back from Shona to English “to ensure the meaning of each question was not lost and enhance the validity and reliability of the instruments" (Kimberlin & Winterstein, 2009; Foxman, 2012; Ranganathan, Caduff & Frampton, 2024).

Pretesting of questionnaires was conducted in Mashonaland Central province, the neighbouring province sharing a border with Mashonaland West. The provinces share the same characteristics, including language and dialect. Any divergence from the expected meanings or confusion on the questions was noted, and communities were asked about the terms locally understood or used and how they should be framed. The questionnaires were revised to use preferred words consistent with community understanding. This testing phase was conducted to assess the clarity of the questions and the consistency of the responses.

The survey included a mix of open-ended and closed-ended questions. The community neonatal verbal autopsy was used to ascertain the cause of death for all community deaths. This was adapted from the International Standard Verbal Autopsy Questionnaires for comparability.

Table 12: Prospective surveillance tools and content

Tool	Responsible Person	Content
Electronic Register	Village Health Worker	“An updated list of all women in the cluster with columns to write events on pregnancy, birth, death, transfer out of area, etc" (Goudar *et al.,* 2012; Muluneh, Animut & Ayele, 2020; Baye, Eshetie & Zerihun, 2022)
Community-based Neonatal Verbal Autopsy	Village Health Worker	Community-based questions from the first 28 days of life questionnaire in relation to details of illness, history etc
Neonatal Verbal Autopsy	Health Facility Midwife	Questions from the first 28 days of life questionnaire on details of illness, history

Source: Adapted from study by Lewycka *et al.* (2010)

A trained health facility midwife followed up on all neonatal deaths to verify and document each case. Verbal autopsy data were then coded and classified according to

World Health Organisation (WHO) Verbal Autopsy standards and International Classification of Diseases (ICD-10) guidelines (WHO, 2022), using standardised WHO cause-of-death assignment algorithms to ensure consistency and comparability (Menéndez et al., 2021).

To enhance reliability, at least two trained physicians independently reviewed and assigned causes of death for each case. Inter-rater reliability was assessed using Cohen's kappa statistic. If discrepancies arose, a third senior physician adjudicated the case, and final classification was reached by consensus among the reviewers, following established WHO adjudication procedures (Kimani-Murage *et al.,* 2019; Mahtab *et al.,* 2021; Chirwa *et al.,* 2023).

4.14 Description of the data collection procedures

4.14.1 Quantitative data collection to meet QUAN objectives

On the quantitative aspect, formative research was conducted, followed by prospective surveillance through study research assistants to collect data on primary and secondary outcomes in a timely manner. This methodology was employed to reduce recall bias that could affect the results. The research assistants worked closely with the VHWs.

To ascertain the effect of the intervention on neonatal deaths, all women aged 15 -49 years previously registered were visited on days 7 and 28 after delivery. Where physical follow-up was not feasible, telephone interviews were conducted. "In the event of a neonatal death, the trained facility midwife followed up using a community Verbal Autopsy tool to record information surrounding the circumstances that led to death, any illnesses among others" (WHO, 2006; Tripathy *et al.,* 2010; Serbanescu *et al.,* 2018). The "physician reviewed the verbal autopsy interview information and code to assign the cause of death" (Danso *et al.,* 2023; Marston *et al.,* 2025).

The interviewer-administered questionnaires were used "to collect detailed information on demographic characteristics, maternity history, health-seeking behaviours, care behaviours and maternal and neonatal morbidity". (Kebede, *et al.* 2020; Tesfaye *et al.* 2022; Dida *et al.* 2024).

4.14.2 Data collection

Standardised, "semi-structured, interviewer-administered questionnaires were administered to eligible women after they gave informed written consent. Neonatal death was divided into early neonatal death (END) and late neonatal death (LND) depending on which period the child died. The questions asked if the newborn baby died or not within the first 28 days of life" (Benfield, Leib & Vollman, 1978; Kanunura *et al.,* 2016; Alebel *et al.,* 2020). Research assistants and field supervisors were recruited to conduct data collection for the study. To ensure completeness and standardisation, a 48-hour training workshop on the principles of research, data collection, management, and storage, including the use of study tools, was conducted.

4.14.3 Qualitative data collection to meet qualitative objectives

Data were collected using semi-structured interviews and focus group discussion guides, both aligned with the process evaluation domains (reach, fidelity, context, mechanisms). Tools were tested and refined prior to data collection to ensure relevance and clarity. Observations of service provision were also conducted to ensure the quality of health services" (Kimani-Murage *et al.* , 2019). A minimum of 7 FGDs and 10 KIIs per district were conducted, with an average of 8 to 12 participants per FGD (Table 12).

Table 13: Summary of expected FGDs, IDIs and KIIs in Mashonaland West province

Method	Participants	Sessions	Total
In-depth interviews	Mothers	4	4
FGDs	WCBA	3	3
	Fathers	2	2
	Grandmothers/ significant others	2	2
	CHWs	7	7
KIIs	Influential community leaders	7	7
	Provincial Health Executive	1	1
	District Health Executive	7	7
	District Health Management Team	7	7
	Other implementing partners	5	5
Total			**45**

For qualitative data collection, purposive sampling and snowballing were used "to sample women of reproductive age, community members including grandmothers or significant others, health care providers at health facilities or districts, community leaders and policy/decision makers in the Ministry of Health and Child Care (MOHCC) and implementing partners including other key ministries" (Kimani- Murage *et al.* 2019; Sendo, Chauke & Ganga-Limando, 2021; Aynalem, Melesse & Bitewa, 2023).

4.14.4 Bias mitigation strategies

For neonatal verbal autopsy, standardised coding procedures were followed, and quality control was maintained through double data entry and periodic review by an independent supervisor. Furthermore, recognising the risk of differential self-reporting by trial arm, several measures were implemented to minimise measurement bias:

i. Data collectors received rigorous training on standardised interviewing techniques and the use of structured questionnaires.
ii. Standard scripts were used to introduce the study and administer questionnaires to ensure consistency across all interviews (Appendix 7 and 8)
iii. Routine spot checks and supervisory visits were conducted to monitor adherence to data collection protocols and to provide feedback or corrective action as needed.
iv. Data collectors were blinded to the trial arm allocation, where possible, to reduce interviewer bias.

4.15 Description of data analysis and presentation procedures

4.15.1 Primary data analysis

The quantitative data were processed, organised, and analysed using the Statistical Package for the Social Sciences (SPSS) version 29, while Stata version 14 was utilised to categorise the open-ended questions. An in-depth analysis was also conducted to examine the temporal and clinical independent variables in relation to neonatal death (binary: died/survived).

Classification of analyses: To keep the distinction between pre-specified inference and exploration explicit, every quantitative analysis in this thesis belongs to one of three classes. Primary (pre-specified, confirmatory): the intention-to-treat comparison of all-cause neonatal mortality between arms using the three-level mixed-effects log-binomial model with the DAG-specified baseline covariates (Section 4.15.2). Secondary (pre-specified, interpreted as adjusted association): the key secondary outcomes (timely care-seeking; immediate newborn-care practices) analysed with the same model; cause-specific mortality; the per-protocol analysis restricted to high-fidelity clusters; the conditional-logistic and Cox sensitivity analyses; the IV3 dose-response analysis; and the pre-specified moderation (interaction) terms for governance functionality, women's literacy and the COVID-19 period. Exploratory (hypothesis-generating, no multiplicity adjustment, not used to support causal claims): the bivariate screening of candidate predictors with false-discovery-rate control; the multivariable logistic prediction model; the machine-learning models; the subgroup analyses beyond the pre-specified moderators; and the simulation scenarios under full, partial and non-institutionalisation. Results in Chapter Five are labelled by class, and Chapters Six and Seven draw causal conclusions only from the primary analysis.

4.15.2 Primary analysis model

The primary analysis employed a three-level mixed-effects log-binomial regression model to estimate the risk ratio (RR) for neonatal death while accounting for the hierarchical structure of the data (individuals nested within community health workers (CHWs), which were nested within clusters). The model included fixed effects for the intervention and covariates (e.g., maternal age, parity, education), as well as random intercepts at both the CHW and cluster levels. The intervention effect was presented as an adjusted risk ratio (ARR) with 95% confidence intervals (CI).

4.15.2.1 Model Specification

The primary analysis used a three-level mixed-effects log-binomial model to account for the

hierarchical data structure (individuals nested within CHWs nested within clusters).

$$\log [P (Yijk = 1|Xijk, Zijk, uk, vjk)] = \beta0 + \beta1Xijk + ZTijk\gamma + uk + vjk \ldots$$ ***Equation 1***

Where:

- Yijk: Binary outcome (1 = neonatal death, 0 = survived) for individual i, CHW j, cluster k
- Xijk: Intervention indicator (1 = intervention, 0 = control)
- Zijk: Vector of covariates (maternal age, parity, education, etc.)
- β0: Fixed intercept
- β1: Intervention effect (log risk ratio)
- γ: Covariate coefficients
- uk ~ N (0, σ2u): Cluster-level random effect
- vjk ~ N (0, σ2v): CHW-level random effect (nested within cluster)

4.15.2.2 ICC Definition and Estimation

For a three-level logistic model, the ICC at each level is calculated. The empirical ICC estimates are shown in Table 14.

Table 14: Empirical intracluster correlation coefficients

Level	Variance	ICC	95% CI
Cluster (σ^2u)	0.089	0.026	0.012 – 0.045
CHW (σ^2v)	0.034	0.010	0.003 – 0.021
Total between-cluster	0.123	0.036	0.019 – 0.059
Within-cluster	3.290	0.964	-

4.15.2.3 Effect measures

The primary effect measure was the Risk Ratio (RR), estimated using a mixed-effects log-binomial regression model. This model was chosen because it directly estimates the relative risk of neonatal death among neonates using institutionalised, community-based vital signs compared with those not institutionalised, while accounting for the clustered structure of the data (individuals nested within clusters).

To adjust for potential confounders such as maternal age, birth weight, gestational age, and socioeconomic status, multivariable models were employed. The adjusted risk ratio

(aRR) obtained from these models provided an interpretable measure of the association, accounting for both individual- and cluster-level covariates.

The Adjusted odds ratio (aOR) from multivariable logistic regression analyses was also reported as a secondary effect measure, primarily for sensitivity analyses and comparability with other literature. However, given the non-rare outcome and the interpretive limitations of odds ratios in this context, the RR/aRR remains the principal measure of effect.

4.15.3 Secondary analyses

Conditional logistic regression was used for sensitivity analyses and to estimate crude and adjusted risk ratios for the association between selected predictors and neonatal mortality. A causal DAG was constructed, identifying:

- X: Intervention (exposure)
- Y: Neonatal mortality (outcome)
- C: Confounders (affect both X and Y)
- M: Mediators (on causal pathway from X to Y)
- P: Precision variables (affect Y only)
- C′: Colliders (affected by both X and Y)

The DAG-derived selection rules in Table 15 took precedence in constructing all models. Confounders (district, baseline mortality, HBB/HBS training) were included in every model regardless of statistical significance; mediators (ANC visits, facility delivery) and colliders (postnatal complications) were excluded a priori to avoid bias; and precision variables (maternal age, parity) were retained where they improved estimation. This pre-specified confounder structure constitutes the fixed analytic core of the adjusted models.

Table 15: DAG Informed Covariate Selection Rules

Variable Type	Selection Rule	Example Variables
Confounders (C)	**Include** in all models	district, baseline mortality, Helping Babies Breathe (HBB)/ Helping Babies Survive (HBS) training
Mediators (M)	**Exclude** from primary analysis	ANC visits, facility delivery
Precision (P)	**Include** if it improves precision	Maternal age, parity
Colliders (C′)	**Exclude** to avoid bias	Postnatal complications

The adjusted model includes the following pre-specified covariates:

$$ZTijk\gamma = \gamma 1Ageijk + \gamma 2Parityijk + \gamma 3Educationijk + \gamma 4Districtk + \gamma 5Baselinek \ldots.$$

Equation 2

Within this fixed causal framework, a supplementary statistical screening step was used only to identify *additional* candidate covariates beyond those mandated by the DAG. Univariate analyses identified variables associated with neonatal death (significance threshold: $P < 0.05$), and these candidates were then evaluated through a sequential model-building process in which models were expanded to incorporate proximate maternal factors, household variables, community-level factors, and service delivery variables. This screening operated strictly as a subordinate addition to (and never as a replacement for) the pre-specified confounder set, so that the structure of the adjusted models was determined by causal reasoning rather than by data-driven selection. This ordering guards against the overfitting and unstable inference associated with significance-based variable selection.

4.15.4 Machine learning and predictive modelling

4.15.4.1 Purpose and Relationship to Trial Objectives

Predictive modelling using machine-learning (ML) algorithms constituted an **exploratory, supplementary** analytical strand within this cluster randomised controlled trial (cRCT). The primary inferential objective, estimating the causal effect

of institutionalising vital-signs monitoring preventable neonatal deaths, was addressed using an intention-to-treat analysis. The ML strand served three distinct complementary purposes: (i) to identify which institutionalised vital signs indicators and community health system variables carry the strongest predictive signal for neonatal death, thereby informing future protocol prioritisation for Village Health Workers (VHWs); (ii) to quantify the predictive accuracy achievable from routinely collected community vital signs data, establishing whether this information supports algorithmic neonatal risk stratification; and (iii) to develop and internally validate a proof-of-concept risk prediction tool suitable, subject to external validation, for integration into a mobile health (mHealth) decision-support system. ML findings are presented as supplementary evidence to the trial results and should be interpreted accordingly. Detailed interpretive boundaries are specified in Section 4.15.4.6.

Two features of the analytic dataset qualify the results in this section and are stated here rather than in Chapter Six. First, the models were estimated on the 973 enrolled mother–infant pairs, with 68 neonatal deaths as events and the remaining 905 records as non-events; the 905 therefore include the 91 pregnancies that ended in stillbirth, which are not neonatal survivors. The correct at-risk population for a neonatal-death classifier is the 882 live births. Re-estimation on that denominator, with time of neonatal death excluded from the predictor set, was not undertaken in this revision; the performance metrics below are therefore reported for completeness and transparency only, are not used to support any conclusion or recommendation in Chapters Six and Seven, and their re-estimation is listed as a research priority in Section 7.6. Second, with 68 events, the events-per-variable ratio for the candidate predictor set is well below the conventional minimum of ten, so all machine-learning results are exploratory, and no claim of external validity is made (Section 4.15.4.6).

4.15.4.2 Algorithms Selected

Four supervised binary classification algorithms were evaluated, selected to span a range of model complexity, interpretability, and methodological tradition in health prediction research. Table 16 presents each algorithm with its primary rationale and key methodological reference. All four algorithms produce predicted class probabilities, which is a prerequisite for the calibration assessment described in Section 4.15.4.5.

Table 16: Algorithms evaluated, rationale for selection, and key references

Algorithm	Type	Primary Rationale	Key Reference
Logistic Regression	Linear, parametric	Methodological baseline: interpretable linear benchmark for comparison with non-linear models	Hosmer et al. (2013)
Random Forest	Ensemble, non-parametric	Superior performance in imbalanced health datasets; captures non-linear interactions without explicit specification	Breiman (2001)
Decision Tree	Single-tree, non-parametric	Fully interpretable rule structure; deployable as VHW job-aid flowchart without computational infrastructure	Quinlan (1986)
Support Vector Machine	Kernel-based, non-parametric	Established binary classification performance; kernel flexibility for non-linear decision boundaries	Cortes & Vapnik (1995); Awe & Vance (2025)

Note. VHW = Village Health Worker. All four algorithms were implemented in scikit-learn version 1.0.2 (Pedregosa *et al.,* 2011) in Python 3.8.

4.15.4.3 Analytic Dataset, Preprocessing, and Leakage Prevention

The full cRCT dataset of 973 participants (68 preventable neonatal deaths; 905 non-death outcomes) constituted the analytic sample. The feature set comprised institutionalised vital signs indicators recorded by VHWs and a pre-specified set of maternal, neonatal, and cluster-level covariates drawn from the neonatal mortality literature.

All preprocessing (one-hot encoding of categorical variables, standardisation of continuous variables to zero mean and unit variance (*StandardScaler*), and median/mode imputation of missing values) was performed **exclusively within each training fold** and applied without refitting to the corresponding validation fold. This fold-contained preprocessing design is the primary mechanism for preventing information leakage from the validation set into model training or feature scaling, thereby ensuring that reported performance estimates are not optimistically biased (Varoquaux *et al.,* 2017). Class imbalance (6.99% positive class prevalence) was addressed by applying *class_weight='balanced'* to all four algorithms, which re-weights training observations in inverse proportion to class frequency; and by selecting performance metrics appropriate for imbalanced outcomes (Section 4.15.4.4).

4.15.4.4 Performance Metrics

Model performance was evaluated using a pre-specified suite of six metrics appropriate for binary classification under class imbalance. Table 17 presents each metric with its formula and clinical rationale. All metrics were computed from the aggregated out-of-fold predictions generated by the cross-validation procedure described in Section 4.15.4.5, so that every observation was evaluated by a model trained without access to data from its own cluster. Aggregate accuracy was not used as a primary metric given

the 6.99% prevalence of the positive class, under which a classifier that universally predicts the majority class would achieve a spuriously high accuracy of approximately 93% (He & Garcia, 2009). Confusion matrix statistics were derived at the default classification threshold of 0.50; sensitivity analyses at thresholds of 0.30 and 0.40 were conducted, given the asymmetric cost of false negatives (missed at-risk neonates) in this setting.

Table 17: Pre-specified performance metrics, formulae, and rationale for inclusion

Metric	Formula	Rationale for Selection
ROC AUC	Area under the sensitivity vs. (1−specificity) curve	Threshold-independent global discrimination; preferred primary metric under class imbalance
Sensitivity	TP / (TP + FN)	Proportion of true neonatal deaths detected; prioritised given the high cost of false negatives in neonatal surveillance
Specificity	TN / (TN + FP)	Proportion of true non-death outcomes correctly classified; informs false-positive referral burden
PPV	TP / (TP + FP)	Precision of positive predictions; interpreted in light of 6.99% positive class prevalence
NPV	TN / (TN + FN)	Reliability of negative predictions; critical for safe rule-out of at-risk neonates at the community level
Brier Score	Mean squared error of predicted probabilities	Calibration quality penalises overconfident incorrect predictions; lower values indicate better calibration

*TP = true positives; FP = false positives; TN = true negatives; FN = false negatives; PPV = positive predictive value; NPV = negative predictive value; ROC AUC = area under the receiver operating characteristic curve.

All metrics reflect aggregated out-of-fold predictions under Leave-One-Cluster-Out cross-validation (Section 4.15.4.5).

4.15.4.5 Cluster-Aware Cross-Validation and Hyperparameter Optimisation

Because participants were nested within geographically defined clusters, standard random cross-validation (which assigns individual observations to folds without regard to cluster membership) risks placing correlated observations from the same cluster into both training and validation folds. This constitutes a form of information leakage that produces optimistically biased performance estimates (Roberts *et al.,* 2017). To prevent this, a **Leave-One-Cluster-Out (LOCO)** cross-validation strategy was implemented using scikit-learn's *GroupKFold* class with cluster identity as the grouping variable. In each fold, one entire cluster was withheld as the validation set, and the model was trained exclusively on the remaining clusters, ensuring that no observation was ever evaluated by a model trained on data from its own cluster. The procedure was repeated K times (K = number of clusters) until each cluster had served once as the validation fold, yielding a single set of out-of-fold predictions for the full analytic sample.

Hyperparameter tuning was conducted within a **nested inner cross-validation loop** applied exclusively to the training clusters of each outer fold, using exhaustive grid search (*GridSearchCV*) with mean ROC AUC as the selection criterion. This nested design ensured that the choice of hyperparameters was not informed by the validation-fold data at any stage.

4.15.4.5a Probability Calibration

The correspondence between model-predicted risk probabilities and observed neonatal death rates was assessed using the **Hosmer–Lemeshow goodness-of-fit test, which**

partitioned observations into deciles of predicted risk and computed a chi-square statistic comparing observed and expected event frequencies (Hosmer & Lemeshow, 1980). A non-significant result ($p > 0.05$) indicates that predicted probabilities adequately reflect observed event rates. Probability calibration was assessed because the models are intended to generate risk scores for clinical decision support, not merely binary classifications; poorly calibrated scores would require recalibration (e.g., Platt scaling) before operational deployment.

4.15.4.5b Feature Importance Analysis

Feature importance analyses identified the vital signs indicators most strongly predictive of preventable neonatal death, generating evidence to guide VHW training priorities and vital signs protocol design. Three complementary measures were used: (i) **mean decrease in impurity (MDI / Gini importance)** for Random Forest and Decision Tree, providing an internal measure of each feature's contribution to predictive splits; (ii) **permutation importance** for all four algorithms, computed by randomly permuting each feature across the validation fold and measuring the resultant decrease in ROC AUC (Altmann *et al.,* 2010); and (iii) **SHAP (SHapley Additive exPlanations) values** using the SHAP library version 0.41.0 (Lundberg & Lee, 2017), providing a unified, model-agnostic importance ranking comparable across all four classifiers.

4.15.4.6 Interpretive scope and boundaries

The ML analyses are explicitly exploratory. Three interpretive boundaries apply. First, performance metrics reflect **internal cross-validated accuracy** on the cRCT dataset;

external validation on an independent prospective dataset has not been conducted, and results should not be extrapolated to other settings without replication. Second, the ML analyses do not estimate the intervention's causal effect on neonatal mortality; the intention-to-treat analysis addresses this. They establish the extent to which patterns in vital-signs data predict mortality outcomes, a complementary yet distinct scientific question. Third, the operational deployment of these models as clinical decision-support tools would require prospective validation, regulatory review, and implementation science evaluation, all of which are beyond the scope of this thesis.

4.15.4.7 Software and Reproducibility

All ML analyses were conducted in Python 3.8 using scikit-learn 1.0.2 (Pedregosa *et al.,* 2011), NumPy 1.21.0 (Harris *et al.,* 2020), pandas 1.3.0 (McKinney, 2010), matplotlib 3.4.2, seaborn 0.11.2, scipy 1.7.0 (Virtanen *et al.,* 2020), and SHAP 0.41.0 (Lundberg & Lee, 2017). A global random seed of 42 was applied throughout to ensure full reproducibility. The complete analysis code, including preprocessing pipelines, cross-validation procedures, hyperparameter grids, and evaluation scripts, is archived and available upon request.

4.15.5 Subgroup analysis

To differentiate and understand when deaths occur, a sub-analysis was conducted for early and late neonatal deaths. To maintain consistency with the main analysis, the subgroup models retained the same pre-specified, DAG-informed confounder structure described in Section 4.15.3 (Table 15); within this fixed framework, the variables that had been significantly associated with neonatal death in the multivariable main model were carried forward into the subgroup analysis (Abdullah *et al.,* 2016; Tekeba *et al.,* 2024; Getaneh *et al.,* 2024). This ensured that subgroup estimates were adjusted for the

same causal confounders as the primary models, rather than being driven by data-dependent re-selection within each stratum.

4.15.6 Missing data, sensitivity analysis and model assessment

The extent and patterns of missing data were systematically assessed for all variables prior to analysis. For variables with less than 5% missing data, a complete case analysis was conducted. When the proportion of missing data exceeded this threshold, multiple imputations by chained equations (MICE) were employed, assuming the data were missing at random. The imputation model included all variables planned for the main analyses to preserve relationships between predictors and outcomes. All imputations and subsequent analyses were performed using Stata version 14. Sensitivity analyses compared findings from imputed datasets with those from complete-case analyses, assessing the robustness of the results to different assumptions about missing data.

4.16 Secondary data analysis: Qualitative methods

Qualitative data were obtained from individual interviews, key informant interviews (KIIs), and focus group discussions (FGDs). All interviews and discussions were audio-recorded (except where not permitted), transcribed verbatim, and, where necessary, translated into English. To ensure analytic rigour and consistency, the qualitative analysis followed a systematic, multi-step approach integrating content and thematic analyses, supported by NVivo and supplemented with Stata 14 for descriptive summaries. The analytic process was as follows:

i. **Transcription and Data Management:** All audio recordings were transcribed verbatim and, when required, translated into English in a single step. For FGDs conducted in local / languages, handwritten notes were also transcribed and translated. Transcripts and notes were uploaded into NVivo to facilitate data management and analysis.
ii. **Development of Coding Framework:** A coding framework was developed iteratively, informed by the study's thematic guide and emerging concepts from the data. Initial codes were generated during data familiarisation and refined

through team discussion as new patterns and sub-themes emerged. The framework was applied consistently across all transcripts from the KIIs and FGDs.

iii. **Thematic Content Analysis:** The primary analytic approach was thematic content analysis. Transcripts were coded according to the established framework using NVivo. The research team conducted iterative reviews of coded data to identify recurring themes and sub-themes, remaining open to unanticipated insights.

iv. **Cross-thematic Matrix:** To systematically compare themes across participant groups (e.g., policy-level vs. frontline informants), a cross-thematic matrix was constructed within NVivo. This matrix enabled the identification of similarities and differences in perceptions, experiences, and practices across different strata of participants (Sulton & Austin, 2015).

v. **Narrative Synthesis:** Thematic summaries were generated for each major theme, and the findings were synthesised into a cohesive narrative. This process included constructing storylines that reflected participants' lived experiences and the contextual factors influencing their responses. The team selected representative verbatim quotations to illustrate key themes and strengthen the analysis's credibility.

vi. **Data Validation and Reflexivity:** To ensure trustworthiness, the research team engaged in repeated readings of the transcripts and iterative discussion of emerging findings. The team resolved any discrepancies in coding or interpretation through consensus.

By employing this coherent and transparent qualitative analysis plan, the study ensured systematic organisation, interpretation, and presentation of qualitative data, thereby enhancing the validity and credibility of the findings. NVivo was used for coding, thematic analysis, and matrix development, and Stata version 14 was employed to generate descriptive statistics on participant characteristics and to summarise qualitative findings where appropriate.

4.17 COVID-19 protocol adaptations and implications

The COVID-19 pandemic necessitated several protocol adaptations during the trial period (2020–2021) to ensure participant safety and compliance with public health restrictions. Notable changes included the removal of the day 3 postpartum home visit (in alignment with national COVID-19 guidelines), the suspension of group drama and large in-person gatherings, and increased reliance on telephone follow-up and on locally recruited research assistants for outcome assessment. These modifications, while essential for ethical and safety reasons, introduced potential sources of bias and limitations to the study. For instance, the absence of the day 3 visit may have led to missed early neonatal outcomes, under-ascertainment of morbidity, reduced opportunities to reinforce key health messages, and introduced recall bias, especially regarding the timing of death. The removal of group drama as a mobilisation tool could have compromised community engagement, especially in clusters with lower baseline participation.

Telephone follow-ups, though effective for maintaining contact, were also used but did not replace the physical follow-up within the first 28 days. This reduced selection bias due to differential access to phones, particularly among the most disadvantaged households. These adaptations are recognised as methodological limitations; sensitivity analyses were conducted where feasible to explore their impact, and all protocol deviations were documented in the study registry and reported in the CONSORT flow diagram.

The pandemic context also affected intervention fidelity and the risk of contamination. Supervisory visits and group activities were modified to comply with social distancing and travel restrictions, potentially reducing the intensity of intervention delivery in some clusters. However, the same travel restrictions and reduced inter-cluster mobility improved intervention fidelity and reduced contamination risk, as field staff and community members were less able to move between clusters, thereby limiting unplanned exposure to intervention content in control areas and enhancing adherence to assigned protocols.

To address the unique challenges and opportunities presented by the pandemic, additional fidelity indicators, such as remote session attendance, phone-based supervision, and adaptation-specific checklists, were implemented and are reported alongside core fidelity measures. The contamination assessment included additional

questions about indirect exposure to the intervention content via remote communication channels. All COVID-19-related adaptations, limitations, and mitigation strategies are transparently reported to support the interpretation and external validity of findings.

4.17.1 Bias Analysis Framework

Potential bias was assessed using the following framework:

1. Selection bias: Compared baseline characteristics pre- vs. during COVID - 19
2. Information bias: Assessed data completeness and quality indicators
3. Confounding bias: Included the COVID -19 period as a covariate in all models
4. Differential attrition: Compared loss-to-follow-up rates by period and arm

4.18 Ethical Considerations

The research protocol was submitted to the University of Lusaka's Research Ethics Committee (Ref. No. IORG0010092-082) and the Medical Research Council of Zimbabwe (MRCZ) (No. MRCA/A/2558) for ethical approval. Permission to conduct the research was sought from the MOHCC provincial and district health offices.

Informed written consent (Annex 1) was obtained from all mothers for their participation, as well as for that of their minors. The benefits of the study were clearly communicated to all participants, and it was explained that the anticipated risks were minimal, as no procedures would be performed on either the mothers or their children. (De Pretto-Lazarova, Brancati-Badarau & Burri, 2020; Ferede *et al.,* 2024).

Participants were not offered any monetary compensation, and they had the option to decline to participate. Additionally, if participants decided to withdraw from the study at any point, they were under no obligation to continue, as participation was entirely voluntary and free from coercion. The consent forms were provided in English and translated into the local language, Shona, to ensure clear understanding.

Participants were assured of confidentiality, including anonymity, for all study participants, irrespective of gender, race, age, etc., by using study-unique identifiers instead of participants' names. The information gathered from the study was not directly linked to an individual. All transcripts were stored on the principal investigator's (PI)

password-protected computer, and hard copies of questionnaires were stored in a lockable cupboard in the PI's office.

This research did not implement any stopping criteria, as no adverse effects were anticipated from participation in the study. Nonetheless, participants had the option to withdraw at any point. Furthermore, the control group received equitable benefits from the study, as they were ensured the same standard of care through community-based interventions in accordance with the Ministry of Health and Child Care (MOHCC) guidelines (Edwards, 2005; Gordon & Prohaska, 2006).

COVID-19 adaptation protocols were strictly observed throughout the study. All research activities, including participant recruitment, consent, interviews, and data collection, were conducted in compliance with prevailing public health guidelines. These included the use of face masks, hand hygiene, social distancing, and minimising in-person contact when feasible, to ensure the safety of both participants and research staff (WHO, 2020; MOHCC, 2021).

According to the Ministry of Health and Child Care (MOHCC), village health workers (VHWs) are equipped to deliver community-based services directly within households. Their services encompass maternal and newborn care, including conducting at least two home visits for newborns and coordinating referrals to health facilities (Lassi, Kumar & Bhutta, 2016; MOHCC, 2020; Habte, Lukas & Tamirat, 2020).

Moreover, the VHWs connected mothers with healthcare professionals based in facilities. These professionals are trained in community-based maternal, newborn, and child health (CBMNCH), including specialised “training in Helping Babies Breathe (HBB) and Helping Babies Survive (HBS), to ensure that mothers can access vital maternal and newborn healthcare services. This encompasses quality care at the time of birth, resuscitation, and Kangaroo Mother Care (KMC)” (Bang *et al.,* 2016; Weinberg *et al.,* 2019).

All data were stored in a lockable cupboard for two years after completion of data analysis, in accordance with UNILUS and MRCZ ethics requirements.

4.19 Summary

This chapter outlines research design, setting, and target population. It describes an embedded concurrent QUAN (qual) mixed-methods design in which a pragmatic cluster-randomised controlled trial (cRCT) is the primary strand, with a concurrent qualitative process evaluation embedded within the trial timeline and exploratory machine-learning analyses as a secondary strand. This methodology demonstrates a comprehensive, multifaceted, and layered approach to exploring the research problem. The quantitative component used a randomised controlled trial (RCT) design, randomising 52 ward-level clusters to the institutionalised package (IV1, IV2 and IV3) or to standard community health service delivery, to estimate the package's effect on preventable neonatal deaths. The research instruments used for data collection, and steps taken to strengthen internal and external validity, were elaborated in this chapter, shedding more light on why the two "research instruments (interviewer-administered questionnaire and in-depth interviews) were used based on their complementary strengths (quantitative data providing measurable outcomes and qualitative data offering rich contextual insights) reflecting pragmatism's focus on choosing methods that best serve the research questions" (Mortazavi *et al.*, 2021)

Quantitative and qualitative data were collected concurrently, analysed separately, and integrated at the interpretation stage through narrative integration and joint displays (Section 4.2). Machine learning algorithms were applied, as pre-specified exploratory analyses, to the integrated datasets to identify complex patterns, generate multilevel predictive models, and deepen understanding of the underlying factors influencing preventable neonatal deaths in Zimbabwe (Hull *et al.* 2023). This integrated approach enabled a comprehensive evaluation within the study population by combining gold-standard experimental methods with advanced analytical techniques, thereby embracing the philosophical tenet of methodological pluralism and underscoring the added value of diverse research methods that yield meaningful information.

An "operationalisation table demonstrating how various variables were measured was also created and explained to facilitate replicability" (Arias Gonzáles, 2021). Ethical issues were also addressed to uphold responsible research practices and ensure the research's societal relevance and ethical integrity.

CHAPTER FIVE

DATA ANALYSIS, PRESENTATION OF FINDINGS

5.1 Introduction

This chapter presents a rigorous and systematic analysis of the empirical findings, evaluating the impact of institutionalising critical components of the community health system on the reduction of preventable neonatal deaths in Mashonaland West Province, Zimbabwe. The results directly address the study's central aim: to determine, through robust quantitative and qualitative inquiry, whether the institutionalisation of village health workforce (Village Health Workers), fully functional community governance structures, and adapted women's and men's learning and action groups collectively and individually contribute to a significant reduction in preventable neonatal mortality relative to standard community health service delivery. Methodological explanations and theoretical justifications are detailed in Chapter Four. This chapter is devoted exclusively to the empirical findings and their direct implications, synthesising quantitative and qualitative analysis.

The chapter is organised to maintain a clear focus on empirical evidence. It begins with a restatement of the study objectives and research questions, then presents detailed results, including descriptive statistics, primary and secondary outcome measures, and findings aligned with each research objective. This approach ensures that the results narrative remains concise, analytical, and strictly evidence-based, facilitating critical interpretation and policy relevance in subsequent discussion chapters.

Each set of results is labelled according to the classification in Section 4.15.1: the intention-to-treat comparison of neonatal mortality between arms (Section 5.3.1) is the single primary, pre-specified analysis; the fidelity, cause-of-death, component-level, dose-response, Cox and mixed-methods analyses are secondary and are reported as adjusted associations; and the bivariate screening, multivariable prediction model, machine-learning models and simulation are exploratory. Findings are stated in this chapter without interpretation against the literature, which is reserved for Chapter Six.

5.2 Presentation of the Findings

5.2.1 Baseline information during formative research

A census of households was conducted between 1st February and 30th April 2020, during which a total of 87,916 households were enumerated during the initial mapping and listing phase of the study, representing the complete sampling frame across the study districts. Of these, 15,219 households were randomly selected and visited for eligibility screening and data collection. These households provided written informed consent for inclusion in the study and were interviewed to assess baseline characteristics. The 15,219 households translated into a total population of 60,876 people (MICS, 2019), of whom 15,828 were women of childbearing age (WCBA), aged 15 to 49 years, who were eligible and interviewed at baseline, and 11,705 were interviewed at the enrolment stage. During the formative study period, 21 women moved out of the study areas, 113 died, and none of them refused to participate. All interviewed households and women of childbearing age were included in the assessment of socio-economic status and demographic characteristics. These details are shown in Table 18.

Table 18: Analysis of the initial population of women of reproductive age (15-49 years) surveyed between February and April 2020.

Description	Number of Households	Total Population (N)	Women of childbearing age (n)	WCBA Percentage
Total Target Enumerated	87,916	374,316	97,323	26%
Total number interviewed at baseline	15,219	60,876	15,828 15-24 years (3,261) 25-49 years (12,567)	16.3%
Interviewed at the enrolment stage	10,718	45,016	11,705 15-24 years – 2,412 25-49 years – 9,293	12.1%
Refused	0	0	0	0%
Died	-	-	113	0.1%
Moved out of the study area			21	

5.2.2 Characteristics of households at the initial assessment

At baseline, majority (73%) of women lived in rural areas, with at least 7.6% residing in peri-urban communities. The median age of women was 29 years, and 20.6% were adolescents aged 15 to 24 years. Most women (63.1%) were married; 16.9% were in polygamous marriages, and 49.4% were non-conservative Christians. Notably, conservative religious groups from the Apostolic Sect accounted for 31.1% (Table 19). All women had some form of education, with 64.7% having reached secondary level. Farming was the most common form of economic activity/ employment, and 75.6% of women were ever pregnant. At least 10,720 (91.6%) were not pregnant at baseline; 402 (3.4%) did not know; and the average household size was 4.3.

Table 19: Essential data regarding respondents

Variable	Number (N = 11,705)	Percentage (%)
"Place of residence		
Rural	8,545	73.0
Urban	2,299	19.4
Peri-urban	893	7.6
Age group		
15 to 24 years	2,412	20.6
25 to 49 years	9,293	79.4
Marital Status		
Married	7,392	63.1
Never married	2,575	22.1
Divorced/ Separated	1,066	9.1
Widowed	672	5.7
Polygamous marriage		
Yes	1,979	16.9
No	9,726	83.1
Religion"		
Conservative	3,641	31.1
Non-conservative	5,783	49.4
Traditionalist	560	4.8
Other	1,721	14.7
Education of mothers		
Primary education	2903	24.8
Secondary education	7,574	64.7
Tertiary education	1228	10.5
Employment status		
Formal employment	726	6.2
Self-employment	1990	17.0
Farmer	4284	36.6

Casual labor	3137	26.8
Panning	1568	13.4
Pregnancy history		
Ever pregnant	8,849	75.6
Never pregnant	2856	24.4
Current pregnancy		
Yes	583	5.0
No	10,720	91.6
Do not know	402	3.4
Average household size	4.3	

5.2.3 Household characteristics at baseline

Most of the families (76.4%) lived in grass-thatched houses, 30.8% owned a wheelbarrow, and "unprotected wells were the major source of drinking water for 42.4% of the households" (Serbanescu *et al.,* 2007; Gebremichael *et al.,* 2021). In terms of sanitation, pit latrines were more common, used by 32.6% of households in the study area.

Table 20: Household characteristics at baseline

Household information	Number (N=10,718)	Percentage (%)
Asset ownership		
Radio	1,115	10.4
Bicycle	2,690	25.1
Scotch cart	2,315	21.6
Wheelbarrow	3,301	30.8
Cattle	1,254	11.7
Domestic worker or cattle helper	43	0.4
Type of building		
Grass thatched	8,189	76.4
Iron sheets/ Tiles/ Asbestos	2,529	23.4
Type of Toilet		
Flush system	1,200	11.2
Unimproved pit Latrine	3,494	32.6
BVIP Pit Latrine	1,115	10.4
Bush	2,026	18.9
Other	2,883	26.9
Source of drinking water		
Piped water	86	0.8
Village or public tap	225	2.1
Protected well	1,490	13.9
Unprotected well	4,544	42.4
Borehole	4,159	38.8
River, dam, or any surface water	214	2.0

5.2.4 Baseline neonatal mortality characteristics

Surveillance data collected using the questionnaire for women of childbearing age (WCBA) at baseline showed differences between the intervention and control study areas, with stillbirths slightly higher in the intervention areas (71) than in the control areas (66). On the other hand, there were 58 neonatal deaths and 61 neonatal deaths in the intervention and control areas, respectively, at baseline (Table 21). The review of the perinatal death review and audit reports indicated that the major causes for early neonatal deaths by first ranking were severe prematurity, birth asphyxia, neonatal sepsis, and the fourth cause was meconium aspiration, mainly due to delayed second stage of labour.

For the still births, the highest cause of fresh still births (FSB) was severe pregnancy-induced hypertension (PIH)/ eclampsia, followed by fetal distress, then antepartum haemorrhage (APH) and then tight cord around the neck, breech, and unknown causes. On the other hand, macerated still births (MSBS) were mainly caused by untreated syphilis in pregnancy, severe PIH and some unknown factors.

Table 21: Baseline neonatal mortality characteristics

Total births and deaths	**Baseline Characteristics**		
	Modified women's and men's group	**Control group**	**Total**
Total births	503	479	982
Live births	432	413	845
Stillbirths	71	66	137
Neonatal deaths	58	61	119
Less than 7 days (Early Neonatal Deaths)	43	44	87
7 – 28 days (Late Neonatal Deaths)	15	17	32

5.2.5 Baseline Balance Table

Overall, there was no geographic confounding. Baseline characteristics appear similar.

Table 22: Baseline Characteristics by Trial Arm

Characteristic	Intervention	Control	SMD
Maternal Characteristics			
Age, years (mean± SD)	26.4 ± 6.4	26.7 ± 6.4	0.048
Primiparous, %	28.3	29.1	0.018
Secondary education +, %	42.7	41.9	0.016
Married, %	91.2	90.8	0.014
Pregnancy Characteristics			
ANC visits ≥4, %	66.8	67.3	0.011
Multiple pregnancy, %	1.8	2.1	0.023
Previous neonatal death, %	8.7	8.2	0.019
Service Delivery Characteristics			
Facility delivery, %	78.4	77.9	0.012
Skilled birth attendant, %	76.2	75.8	0.010
Caesarean section, %	8.7	9.1	0.014
Socioeconomic Characteristics			
Wealth quintile 4-5	35.2	34.8	0.008
Clean water access, %	62.4	61.9	0.010
Improved sanitation, %	48.7	49.3	0.010

*All SMD < 0.10 indicates good balance. Maximum SMD = 0.048

*SMD = Standardised Mean Differences

5.3 Prospective trial enrolment of pregnant women

The modified women's and men's participatory group intervention trial ran from 1 September 2020 to 31 October 2021. A total of 211 clusters were assessed for eligibility. Of these, 159 were excluded: 16 did not meet the inclusion criteria because they lay within 5 km of district and mission hospitals providing secondary-level care, and 143 peripheral clusters were excluded as buffer zones. The remaining 52 clusters were randomised equally to the intervention or control arm (26 per arm). No cluster failed to receive its intended allocation, and no cluster was lost to follow-up.

Between September 2020 and October 2021, 984 pregnant women were enrolled across the 52 clusters. Eleven women (1.1%) were unable to participate in interviews because they required their husbands' consent (9 of the 11 in control areas), leaving 973 mother–infant pairs available for the intention-to-treat analysis: 481 in the intervention arm and 492 in the control arm. This represented 99.6% follow-up in the intervention arm and 98.2% in the control arm (Figure 14).

Among the 973 participants analysed, there were 91 stillbirths, 882 live births (intervention: 446; control: 436). A total of 68 neonatal deaths occurred among these

live births. Of these, 47 were early neonatal deaths (days 0–6) and 21 were late neonatal deaths (days 7–27). Across the wider surveillance period, 159 perinatal deaths and 13 maternal deaths were also recorded.

Denominators used in this chapter: Three denominators recur and are stated in every table caption. Mother-level analyses (household, maternal, and community characteristics; antenatal and delivery care; group participation) use data from the 973 women in the intention-to-treat population (481 intervention; 492 control). Birth-level analyses of stillbirth use all 973 births. Neonatal analyses (neonatal mortality, neonatal characteristics, postnatal care, and newborn care practices) use the 882 live births (446 intervention; 436 control) because the 91 pregnancies that ended in stillbirth contribute no neonates at risk. The 68 neonatal deaths therefore give a neonatal mortality of 77.1 per 1,000 live births overall (20/446 = 44.8 in the intervention arm; 48/436 = 110.1 in the control arm).

5.3.1 Primary Outcome: Neonatal mortality at 28 days

The primary outcome of this cluster-randomised controlled trial was neonatal mortality at 28 days of life, assessed using an intention-to-treat analysis across all 973 mother–infant pairs (intervention: n = 481; control: n = 492) within the 52 randomised clusters. The neonatal mortality rate (NMR) was expressed per 1,000 live births in accordance with standard convention. In the intervention arm, 20 neonatal deaths occurred among 446 live births, yielding an NMR of 44.8 per 1,000 live births. In the control arm, 48 neonatal deaths occurred among 436 live births, yielding an NMR of 110.1 per 1,000 live births. These are cohort-specific risks of neonatal death among prospectively surveilled live births in the trial population, rather than routine population vital-statistics estimates.

The crude rate ratio for neonatal death in the intervention arm relative to the control was 0.41. The adjusted risk ratio (ARR) was 0.43 (95% CI: 0.26–0.70; $p < 0.001$), corresponding to a 57% relative reduction in neonatal mortality associated with the institutionalised community health system intervention. Adjustment was for the pre-specified baseline covariates (birth weight, birth interval, maternal age, community governance functionality, and socioeconomic status), and the stability of the estimate

before and after adjustment is consistent with the baseline balance achieved through randomisation (Table 22). The number needed to treat to prevent one neonatal death was 16 mother–infant pairs (95% CI: 11–29). Early neonatal deaths (0–6 days) accounted for 47 of the 68 neonatal deaths (69.1%) across both arms. The stillbirth rates were (intervention: 72.8 per 1,000 total births; control: 113.8 per 1,000 total births).

5.3.2 Trial Profile

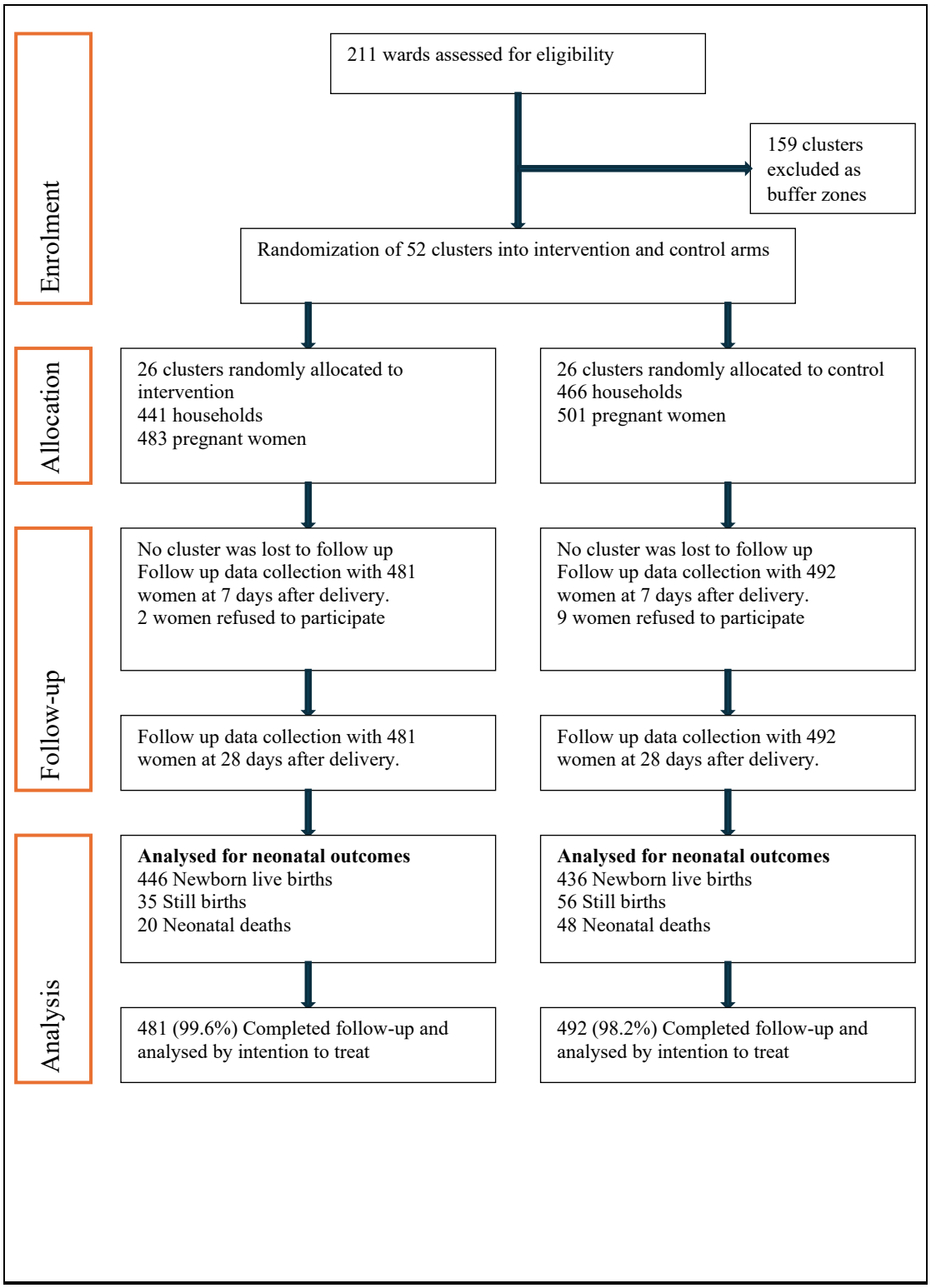


Figure 14: Trial Profile: Randomisation of study participants to intervention and control clusters

5.3.3 Characteristics of pregnant women: A demographic and socio-economic overview

An analysis of the demographic and socio-economic traits of pregnant women was undertaken, and the findings are detailed in Tables 23, 24, and 25. Notably, there were no significant differences in maternal characteristics between the intervention and control groups, including median age, education level, employment status, marital status, parity, and polygamy (Hagos *et al.*, 2025).

A comparison of neonatal outcomes revealed a minor difference, particularly in birth weight, which was somewhat lower in the control areas than in the trial areas. While there was a predominance of non-conservative religious affiliations, there was also a noticeable emergence of diverse religious groups evenly distributed across the intervention and control categories. In summary, the baseline characteristics regarding household factors, as well as socio-economic and demographic attributes, were found to be similar between both the intervention and control groups.

5.3.3.1 Household characteristics

The majority of the women, 70.7% in the modified women's and men's intervention group and 73.4% in control areas, resided in rural areas, 19.8% and 17%, respectively, resided in urban areas. Also observed was the growing peri-urban population, accounting for 9.5% in the trial communities and 9.6% in the communities receiving routine services. Most women of reproductive age, 27.2% and 26.4% in the trial and communities receiving routine services, respectively, were in the middle wealth quintile category (Table 23).

Table 23: Household characteristics by intervention allocation for women of childbearing age, 2020-2021 (n=973

Household Characteristics		Intervention (n=481) (%)	Control (n=492) (%)	P Value
Place of residence	Peri urban	46 (9.5)	47 (9.6)	0.551
	Rural	340 (70.7)	361 (73.4)	
	Urban	95 (19.8)	84 (17.0)	
Socio-Economic Status (SES)	Mean	8.5	10	0.810
	Median	10	10	0.405
Wealth quintile	Poorest	108 (22.5)	116 (22.4)	0.900
	Poor	117 (24.3)	121 (24.6)	
	Middle	131 (27.2)	130 (26.4)	
	Rich	75 (15.6)	77 (15.7)	
	Richest	50 (10.4)	48 (9.8)	

5.3.3.2 Demographic characteristics of mothers

For the mothers' characteristics, “the median age was 29 years and most of the mothers (72.8% and 70.3%) respectively in intervention and control groups were aged between 25 and 49 years. It is also important to note the relatively large share of young mothers aged 15 to 24 years, constituting almost a third. About two-thirds (63%) of the mothers enrolled in the study were in a union according to Zimbabwean customary law; 64.0% in the trial areas and 65.8% in the control communities had completed secondary school (Table 24). In terms of employment, most were farmers (33.4%) in the intervention group and (34.9%) in the control group. At least 45.3% were affiliated with a non-conservative religion in intervention areas, compared to 44.3% in control areas. Conservative religion contributed a fair share of 34.1% and 37.4%, respectively. In the control areas, there were pockets of highly conservative vaccine- and modern-medicine-hesitant groups. There were also no statistically significant differences in

parity, desire for pregnancy, birth interval and polygamous marriage between the trial groups.

Table 24: Demographic characteristics of women of childbearing age by intervention allocation, 2020-2021 (N=973)

Mother's characteristics		Intervention n = 481 (%)	Control n = 492 (%)	p Value
Age	Median	29	29	
Age category	15-24 years	131 (27.23)	146 (29.67)	0.399
	25-49 years	350 (72.77)	346 (70.33	
Marital status	Married	305 (63.41)	311 (63.21)	0.507
	Never married	103 (21.41)	108 (21.95)	
	Divorced/ separated	43 (8.94)	42 (8.54)	
	Widowed	30 (6.24)	31 (6.30)	
Maternal religion	Conservative	164 (34.10)	184 (37.40)	0.682
	Non-conservative	218 (45.32)	218 (44.31)	
	Traditionalist	25 (5.20)	24 (4.88)	
	Other	74 (15.38)	66 (13.41)	
Education level	None	5 (1.04)	5 (1.02)	0.850
	Primary	128 (26.61)	119 (24.19)	
	Secondary	308 (64.03)	324 (65.85)	
	Tertiary	40 (8.32)	44 (8.94)	
Employment status	Formal employment	29 (6.03)	31 (6.30)	0.977
	Self-employment	82 (17.05)	85 (17.28)	
	Farmer	170 (35.34)	180 (34.96)	
	Casual labor	128 (26.61)	129 (24.59)	
	Panning	72 (14.97)	67 (13.62)	
Parity	Ever pregnant	372 (77.34)	373 (75.81)	0.574
	Never pregnant	109 (22.66)	119 (24.19)	
Desire for pregnancy	Planned	264 (53.66)	263 (54.68)	0.750
	Not planned	228 (46.34)	218 (45.32)	
Birth interval	<2 years	363 (75.47)	373 (75.81)	0.900
	>2 years	118 (24.53)	119 (24.19)	
Polygamous marriage	No	345 (71.7)	352 (71.5)	0.950
	Yes	136 (28.3)	140 (28.5)	

5.3.3.3 Characteristics of neonates

Slightly more than half (50.9% in intervention and 50.4% in control areas) of the neonates were girls; 76.5% of births were attended by skilled professionals, and 77.6% took place in a healthcare facility in control areas. In the intervention group, approximately 23.5% of participants delivered outside the health facility (at home and other places), compared with 22.4% in the control group. The control group had significantly more children with a birth weight of less than 2500g (p-value, 0.020), 18.3% compared to 12.9% in the intervention group. Similarly, slightly more mothers (37.4%) in the control group perceived their baby's size as small compared to 36.4% in the intervention group. There were 173 (36%) live births of five or more children in the modified women's and men's group area compared to 102 (20.7%) in control areas (Table 25).

Table 25: Characteristics of neonate by intervention allocation, 2020-2021 (n=973

Characteristics of a neonate		**Intervention n = 481 (%)**	**Control n = 492 (%)**
Sex	Boy	236 (49.06)	244 (49.59)
	Girl	245 (50.94)	248 (50.41)
Place of birth	Health Facility	368 (76.51)	382 (77.64)
	Home	82 (17.05)	82 (16.67)
	Other (including shrine)	31 (6.44)	28 (5.69)
Birth weight less than 2500g	No	419 (87.11)	402 (81.71)
	Yes	62 (12.89)	90 (18.29)
Mother's perceived baby size	Small	175 (36.38)	184 (37.40)
	Average	213 (44.28)	209 (42.48)
	Large	93 (19.33)	99 (20.12)
Birth order 1	No	387 (80.46)	381 (77.44)
	Yes	94 (19.54)	111 (22.56)
Birth order 4 plus	No	358 (74.43)	358 (72.76)
	Yes	123 (25.57)	134 (27.24)
Birth interval less than 2 years	No	363 (75.57)	373 (75.81)
	Yes	118 (24.53)	119 (24.19)
Live birth 2 to 4	No	201 (42.79)	235 (47.76)
	Yes	280 (58.21)	257 (52.24)
Live births 5 plus	No	308 (64.03)	390 (79.27)
	Yes	173 (35.97)	102 (20.73)
Baby name	No	425 (88.36)	439 (89.23)
	Yes	56 (11.64)	53 10.77)

*****Place of birth - other was mainly those born before arrival at the health facility

5.3.3.4 Community level characteristics

For community factors, 82.7% of women in the intervention communities reported that 82.7% of community governance structures, including the Health Centre Committees (HCCs) and Village Health Committees (VHCs), were fully functional, compared with 34.3% in the control communities. At least 74% of the women reported the presence of social networks in the women's and men's group intervention areas, compared with 36% in control areas. In relation to the availability of formal community health workers (CHWs) trained by the Ministry of Health and Child Care, 96% of the mothers in the intervention area had interacted with a CHW compared to 73.4% in control areas, and 73.6% could list at least three danger signs in newborn babies compared to 62.4%, respectively, demonstrating medium community women's literacy (Table 26).

Table 26: Community Characteristics Based on Intervention Group Allocation, 2020-2021 (n=973)

Community-level characteristics		Intervention n = 481 (%)	Control n = 492 (%)	*p*-Value
Women's and men's groups	No	14 (2.9)	430 (87.4)	<0.0001*
	Yes	467 (97.1)	62 (12.6)	
Community governance structures	Fully functional	398 (82.7)	169 (34.3)	<0.0001*
	Non-functional	51 (10.6)	309 (62.8)	
	Partially functional	32 (6.7)	14 (2.9)	
Faith-based organizations (FBOs)	No	137 (28.5)	255 (51.8)	<0.0001*
	Yes	344 (71.5)	237 (48.2)	
Social networks	No	125 (26.0)	315 (64.0)	<0.0001*
	Yes	356 (74.0)	177 (36.0)	
Community women's literacy	High	73 (15.2)	77 (15.7)	<0.0001*
	Low	54 (11.2)	108 (22.0)	
	Medium	354 (73.6)	307 (62.4)	
Formal community health workers	No	19 (4.0)	131 (26.6)	<0.0001*
	Yes	462 (96.0)	361 (73.4)	
Community health workers trained in newborn care	No	157 (32.6)	299 (60.8)	<0.0001*
	Yes	324 (67.4)	193 (39.2)	

*Variables statistically significant at p-value < 0.05

5.3.3.5 Service delivery factors at institutional and community level

Most neonates (68.6% and 64.4%) received postnatal care services within 72 hours at the health facility; 18.3% and 7.1% received PNC services at home from VHWs, while 72.8% and 39.2% received home visitation by VHWs in intervention and control areas, respectively. Similarly, more women completed ANC 8 contacts (55.5% and 44.4%), booked early for antenatal care before 12 weeks (62.9% and 45.3%), identified danger signs in newborn babies (71.4% and 54.3%), as well as practised kangaroo mother care/ skin to skin contact for their newborn babies at home (72.7% and 41.4%) in the modified women's and men's group intervention areas compared to control areas, respectively (Table 27).

Table 27: Service Delivery Features by Intervention Group Allocation, 2020-2021 (n=973)

Service delivery characteristics		Intervention n = 481 (%)	Control n = 492 (%)	*p*-Value
Skilled Birth Attendant	Yes	368 (76.51)	383 (77.85)	0.619
	No	113 (23.49)	109 (22.15)	
PNC	Clinic <72 hours	49 (10.19)	74 (15.04)	<0.0001*
	Clinic 72 hours	325 (67.57)	317 (64.44)	
	Home Visit Day 3 by VHW	88 (18.29)	35 (7.11)	
	No home visit	19 (3.95)	66 (13.41)	
Home visit by VHWs	Yes	349 (72.56)	193 (39.23)	<0.0001*
	No	132 (27.44)	299 (60.77)	
Antenatal care contacts	8 ANC plus	261 (54.26)	208 (42.28)	<0.0001*
	Less than 8 ANC	220 (45.74)	284 (57.72)	
Early ANC booking	Yes	293 (60.91)	210 (42.68)	<0.0001*
	No	188 (39.09)	282 (57.32)	
Identification of danger signs	Yes	334 (69.44)	250 (50.81)	<0.0001*

	No	147 (30.56)	242 (49.19)	
Kangaroo mother care at home	Yes	347 (72.14)	202 (41.06	0.045*
	No	134 (27.86)	290 (58.95)	
Clean cord care	Yes	345 (71.73)	202 (41.06	0.051
	No	136 (28.27)	290 (58.95)	

*Variables statistically significant at p-value < 0.05

5.3.4 Qualitative analysis - Insights from Key Informant Interviews

Key informant interviews (KIIs) and focus group discussions (FGDs) were conducted across all seven districts of Mashonaland West, capturing perspectives from national, provincial, district, and community stakeholders. The qualitative sample included five national and twelve provincial informants (eight MOHCC executives, four representatives from line ministries, and three from civil society and community or faith-based organisations), as well as two participants representing persons with functional difficulties. At the district level, 42 District Health Executive (DHE) members and 7 local government officials provided insights, alongside 24 community leaders, including Village Health Workers (VHWs), and 43 FGD participants drawn from modified women's and men's learning action groups and community health workers (Table 28).

The median years of service among district-level key informants was 14.2 years, highlighting substantial experience in the local health system. Most key informants understood community health program targets mainly in terms of VHW coverage and incentive structures; other pillars of the community health system, such as social networks, governance, and community participation, were mentioned less often or prioritised less. Notably, district health supervisors reported no formal training on the new community health program, though most had received sensitisation on the National Community Health Strategy within the past 12 months.

Four overarching themes emerged: (1) Understanding of Institutionalisation, (2) Availability Coverage, (3) Accessibility of Community Health Services, and (4) Acceptability, Utilisation, and Effective Coverage.

Key findings indicate that institutionalisation is often equated with government ownership and the geographic coverage of Village Health Workers (VHWs), overlooking other components of the community health system. Post-2020 developments demonstrate significant improvements in funding allocation, VHW upskilling, and revitalisation of community governance structures; however, substantial gaps remain in functional community structures, equitable geographic access, and representation of marginalised groups.

Table 28: Summary of Focus Group Discussions and Key Informant Interviews in Mashonaland West Province

Method	Participants	Total
FGDs	WCBA	12
	Fathers	9
	Grandmothers/ significant others	10
	CHWs	12
KIIs	Influential community leaders	24
	Provincial Health Executive	8
	District Health Management Team	42
	District Local Government and Local Authorities	7
	Other government line Ministries	4
	Other implementing partners	3
	People with functional disabilities	2
	National Community Health program representatives	5
Total		**138**

5.4 Intervention Fidelity Results

5.4.1 Overall Composite Fidelity Score

Across all 26 intervention clusters, the mean composite fidelity score was 0.964 (SD = 0.09; range: 0.84–0.97), indicating high overall fidelity across all five BCC domains. No cluster recorded a composite fidelity score below the pre-specified remediation threshold (Fi < 0.70).

Table 29: NIH BCC Fidelity Framework by Trial Arm

Domain	Intervention Arm	Control Arm	Assessment
Design	100%	N/A (structure)	High fidelity
Delivery	88%	45.6% spillover	Target mostly met
Receipt	100%	0% meetings	Perfect containment
Adequate dose	82.6%	0% meetings	(>=4 cycles/ 12 meetings + home visit)
Enactment	100%	N/A (behaviours)	All targets met
Overall	96.4% (HIGH)	45.6% spillover	Successful delivery

5.4.2 Contamination/Spillover Analysis

Contamination and spillover in the control arm (n = 492) were assessed using a composite of pre-specified indicators to quantify unintended exposure to intervention components. No facilitated modified women's and men's learning and action cycles were delivered in any control cluster (0% delivery of the IV3 component), although 12.6% of control women reported attending some community health group meeting when asked the standardised contamination screening question (Section 4.2.1.4.2); the two figures measure different things (delivery of the intervention versus self-reported attendance at any group) and are both reported. The proportion of control participants exposed to at least one intervention component (the composite 'any-exposure' indicator) was 45.6% (Table 30).

Specifically, 9.1% of control participants were exposed to community governance functionality (low spillover), and 37.9% were exposed to VHW newborn care training (moderate spillover), likely because VHWs in control areas also received training from other initiatives or shared information informally. The contamination index, calculated as the mean of the component-level exposure proportions weighted by each component's share of the fidelity score, was 41.6%; this differs from the 45.6% any-exposure proportion because the two summarise the same exposures differently. Main spillover pathways included VHW training, social networks, and informal education on newborn danger signs. Sensitivity analyses and the discussion of study limitations address spillover rates.

Table 30: Exposure to intervention components in the control arm - Contamination/spillover analysis

Indicator	Control Rate	Assessment
Community governance (fully functional)	9.10%	Low spillover
Modified women's and men's group meetings	0.00%	Minimal (perfect containment)
VHWs trained in newborn care	37.90%	Moderate spillover
Mean across all components	41.6%	Moderate overall

5.4.3 Temporal stability of fidelity

Fidelity scores remained consistent throughout the 12-month trial period, with no statistically significant temporal trend detected ($\beta = 0.002$, $p = 0.78$). This stability indicates that implementation quality was maintained over time and did not decline. Data from focus group discussions with VHWs and women of childbearing age indicate that sustained fidelity likely reflects the impact of refresher training provided to VHWs at the start of each new WLA/MLA learning and action cycle.

5.4.4 National scale-up demonstration

The National Coverage Index in the control arm was 75.4%. However, key gaps remained where the intervention had the greatest impact. PNC provided within 72 hours had a critical gap (33.9 percentage points), VHW home visits (gap: 31.5 percentage points) and knowledge of danger signs (gap: 20.0 percentage points) (Table 31). These results indicate that, despite high overall coverage, significant deficiencies persisted in early postnatal care, VHW home visitation, and caregiver knowledge, areas where the intervention added the most value. Additional insights are provided from Section 5.8.2 - Theme 2 on Service Availability Coverage.

Table 31: Critical program gaps and intervention boost

Component	National (Control)	Gap and Intervention Boost
PNC within 72 hours	16.1%	Gap: 33.9pp
VHW home visits	38.5%	Gap: 31.5pp
Danger signs knowledge	50.0%	Gap: 20.0pp
Early ANC	41.5%	(gap: 18.5pp)
Basic VHW training	72.40%	**+24.9pp** (intervention added value)

5.4.5 Separation of national vs. intervention components

There were no significant differences between arms for national program indicators, including skilled birth attendance, exclusive breastfeeding, and facility delivery (all $p > 0.60$). In contrast, intervention-specific components showed significantly higher coverage in the intervention arm: group meetings (100% vs. 0%), VHW newborn care training (69% vs. 38%), home visits (74% vs. 39%), and knowledge of danger signs (70% vs. 50%) (all $p < 0.001$). This confirms clear differentiation between national and intervention-specific activities.

5.5 Causes and time of neonatal deaths

Among the neonatal deaths identified in the study population, cause-of-death assignment was primarily based on the WHO verbal autopsy tool administered to caregivers. The predominant cause was prematurity, accounting for over 50% of cases, followed by birth asphyxia and severe infections. At least five neonatal verbal autopsy questionnaires were excluded because respondents could not provide information on the timing of death, which is essential for accurate classification.

A major limitation was that COVID-19 restrictions created substantial barriers to obtaining complete verbal autopsy data for all cases. As a result, some cause-of-death assignments depended on facility register abstraction rather than direct caregiver interviews. Where possible, verbal autopsy responses were prioritised over facility records; however, when verbal autopsy responses were unavailable, facility data served

as the primary source. This data-source hierarchy introduces potential misclassification bias and may affect the validity of cause-of-death classification for a subset of cases. As such, findings related to the distribution of neonatal death causes should be interpreted with caution.

Regarding the timing of neonatal deaths, Figure 15 illustrates the reported distribution. The majority of deaths occurred within the first week of life: 47 of the 68 neonatal deaths (69.1%) were early neonatal deaths (0–6 days), with the remaining 21 (30.9%) occurring in the late neonatal period (7–27 days).

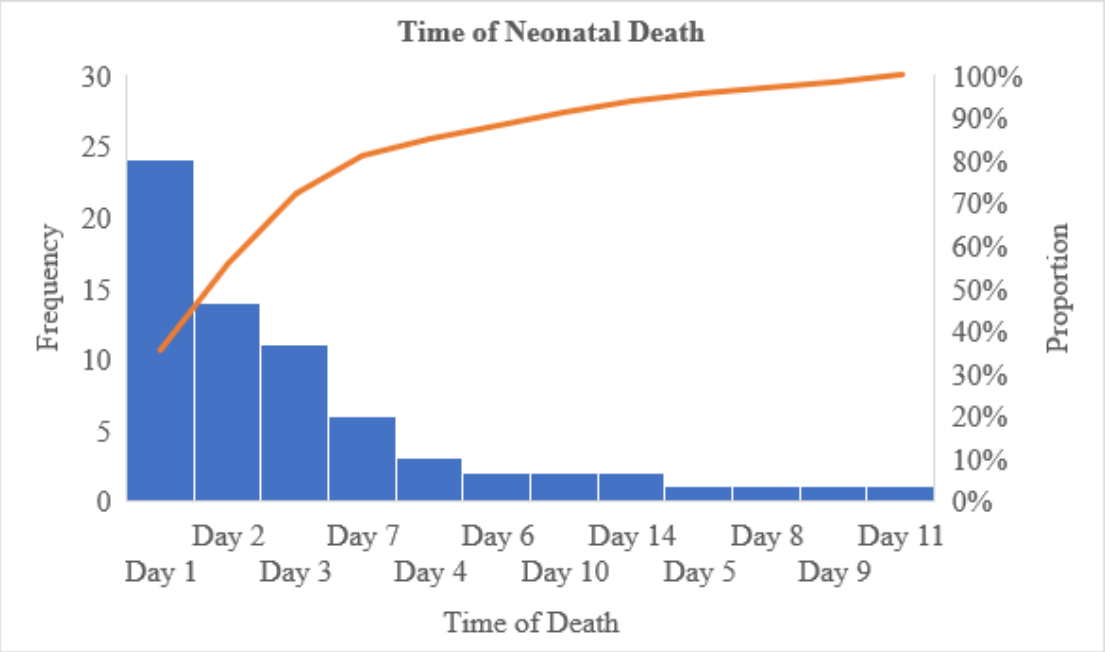


Figure 15: Reported Day of death for the 68 Neonatal Deaths, 2020-2021

5.5.1 Socioeconomic status and neonatal deaths

Neonatal deaths tended to decrease with increasing socioeconomic status, with more deaths observed among the poorest group (Figure 16). This was consistent for both the intervention (modified "women's and men's learning and action group) and the control group. The relationship appears strong, as indicated by $X2 = 53.26$, $p < 0.0001$ (Table 32). Neonatal deaths did not differ between the richest households in the intervention and control groups.

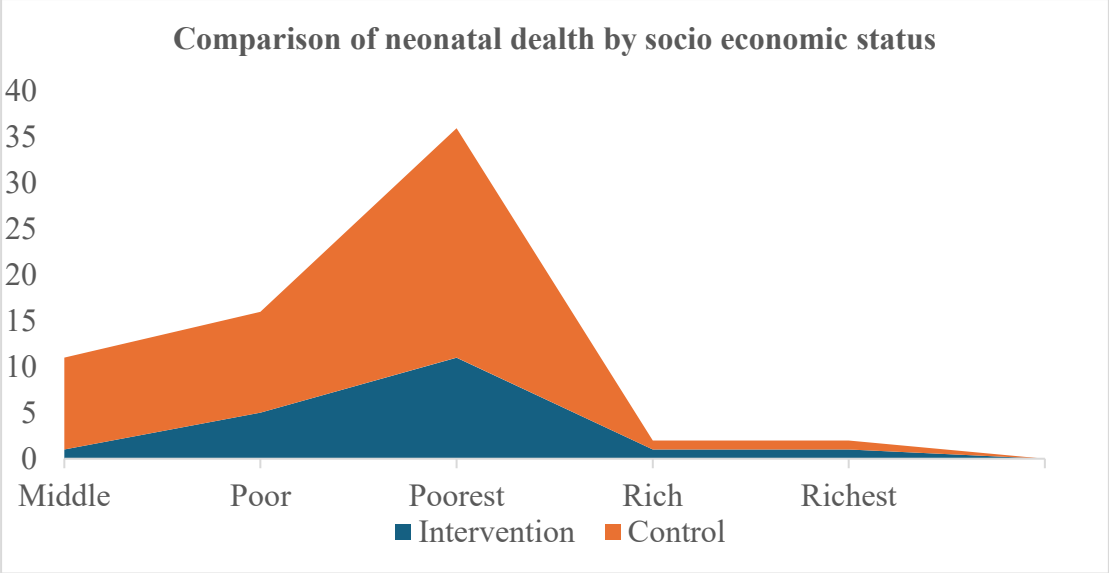


Figure 16: Comparison of neonatal death by socio-economic status, Mashonaland West province, 2020-2021

5.5.2 Community health system predictors that are independently associated with reducing neonatal deaths

This study examined 46 variables to identify significant predictors of preventable neonatal deaths within community health systems in Mashonaland West Province, Zimbabwe, with a focus on the impact of modified women's and men's group action interventions. The variables were pre-selected based on their established relevance to neonatal mortality in similar contexts and prior qualitative findings, ensuring a targeted analytical approach.

Significant household characteristics associated with neonatal deaths included family influence ($\chi^2 = 34.23$, $p < 0.0001$) and family religion ($\chi^2 = 27.05$, $p < 0.0001$). Maternal factors, including age, marital status, education level, employment, religious affiliation, birth spacing, and polygamous relationships, were also significantly associated with neonatal mortality (all $p < 0.0001$). Neonatal characteristics significantly linked to mortality included infant sex ($\chi^2 = 16.1$, $p < 0.0001$), birth weight ($\chi^2 = 129.6$, $p < 0.0001$), birth complications ($\chi^2 = 66.3$, $p < 0.0001$), and higher birth order, fourth child or more ($\chi^2 = 25.02$, $p < 0.0001$).

Healthcare delivery factors, including attendance at a minimum of eight antenatal care visits, early initiation of care before 12 weeks, maternal identification of danger signs, and home visits by village health workers, were significantly associated with neonatal mortality.

Community-level factors also played a vital role, including the presence of modified action groups for women and men ($\chi^2 = 20.1$, $p < 0.0001$), faith-based organizations ($\chi^2 = 24.0$, $p < 0.0001$), social networks ($\chi^2 = 27.5$, $p < 0.0001$), availability of trained community health workers ($\chi^2 = 31.1$, $p < 0.0001$), and community governance frameworks such as Health Centre Committees and Village Health Committees ($\chi^2 = 48.7$, $p < 0.0001$).

Bivariate correlation analysis (Figure 17) identified low birth weight (<2500g) as the strongest single correlate of neonatal mortality ($r = 0.72$), followed by birth complications ($r = 0.37$) and non-functional community governance ($r = 0.24$); that is, the absence of fully functional governance structures was positively associated with neonatal death. At the opposite end of the spectrum, the strongest protective correlations were observed for household-level danger-sign recognition ($r = -0.22$), early antenatal care initiation ($r = -0.21$), socioeconomic status ($r = -0.18$), faith-based organisation presence ($r = -0.16$), and participation in women's and men's group meetings ($r = -0.15$). These bivariate correlations are necessarily modest, as expected for associations between binary predictors and a relatively rare outcome (6.99% event prevalence); the adjusted regression and multilevel models reported below therefore carry the substantive inferential weight. Overall, the pattern underscores the dual contribution of biological risk and community health system factors, the latter acting predominantly in a protective direction.

To address the risk of type I error arising from multiple comparisons, p-values were adjusted using the Benjamini–Hochberg False Discovery Rate (FDR) correction method (Table 33). After FDR adjustment, 22 of the 46 variables remained significantly associated with neonatal death. These spanned household and maternal characteristics (including family religion, maternal age, and polygamous marriage), neonatal characteristics (birth weight < 2500 g, birth complications, and higher birth order),

service delivery factors (early antenatal care initiation, household-level identification of danger signs, and home visits by village health workers), and community-level factors (presence of modified action and learning groups, social networks, availability of trained community health workers, and active community governance structures); the full ranked set is presented in Table 33. By FDR ranking, birth intervals of less than 2 years and a birth weight below 2500g had the strongest associations with neonatal mortality (adjusted $p < 0.001$).

Table 32: Community health system predictors of neonatal deaths, Mashonaland West province, 2020-2021

Variable	Intervention N = 481			Control N = 492			Unadjusted RR (95% CI)	Chi2	P Value
	Total N (%)	Deaths n (%)	Survived n (%)	Total N (%)	Deaths n (%)	Survived n (%)			
Birth interval <2 years	118 (24.53)	17 (14.41)	101 (85.59)	119 (24.19)	22 (18.49)	97 (81.51)	13.14 (7.31-23.62)	123.50	<0.0001*
Birth interval >2 years	363 (75.47)	3 (0.83)	360 (99.17)	373 (75.81)	26 (6.97)	347 (93.03)			
Birth weight <2500g	62 (12.89)	12 (19.35)	50 (80.65)	90 (18.29)	38 (42.22)	52 (57.78)	9.90 (6.21-15.79)	129.65	<0.0001*
Birth weight ≥2500g	419 (87.11)	8 (1.91)	411 (98.09)	402 (81.71)	10 (2.49)	392 (97.51)			
Birth Complications	136 (28.27)	15 (11.03)	121 (88.97)	150 (30.49)	35 (23.33)	115 (76.67)	6.67 (3.96-11.23)	66.35	<0.0001*
No birth Complications	345 (71.73)	5 (1.45)	340 (98.55)	342 (69.51)	13 (3.80)	329 (96.20)			
Family influence	205 (42.62)	15 (7.32)	190 (92.68)	243 (49.39)	35 (14.40)	208 (85.60)	4.96 (2.75-8.95)	34.23	<0.0001*
No Family influence	276 (57.38)	5 (1.81)	271 (98.19)	249 (50.61)	13 (5.22)	236 (94.78)			
Birth order 4 plus (Yes)	54 (11.23)	8 (14.81)	46 (85.19)	134 (27.24)	24 (17.91)	110 (82.09)	3.13 (1.99-4.94)	25.02	<0.0001*
Birth order 4 plus (No)	427 (88.77)	12 (2.81)	415 (97.19)	358 (72.76)	24 (6.70)	334 (93.30)			
Participated in meetings (≥4 cycles) (Yes)	467 (97.09)	15 (3.21)	452 (93.97)	10 (0.00)	1 (10.00)	9 (90.00)	0.29 (0.17-0.51)	20.13	<0.0001*
Participated in meetings (≥4 cycles) (No)	14 (2.91)	5 (35.71)	9 (1.87)	492 (100)	47(9.55)	444 (90.24)			

Variable	Intervention N = 481			Control N = 492			Unadjusted RR (95% CI)	Chi2	P Value
	Total N (%)	Deaths n (%)	Survived n (%)	Total N (%)	Deaths n (%)	Survived n (%)			
Faith-based organisations	344 (71.52)	6 (1.74)	338 (98.26)	237 (48.17)	10 (4.22)	227 (95.78)	0.30 (0.18-0.50)	23.99	<0.0001*
No faith-based organisations	137 (28.48)	14 (10.22)	123 (89.78)	255 (51.83)	38 (14.90)	217 (85.10)			
Social networks	356 (74.01)	7 (1.97)	349 (98.03)	177 (35.98)	6 (3.39)	171 (96.61)	0.25 (0.15-0.44)	27.48	<0.0001*
No social networks	125 (25.99)	13 (10.40)	112 (89.60)	315 (64.02)	42 (13.33)	273 (86.67)			
Trained VHW	462 (96.05)	15 (3.25)	447 (96.75)	361 (73.37)	13 (3.60)	348 (96.40)	0.28 (0.18-0.44)	31.11	<0.0001*
No trained VHW	19 (3.95)	5 (26.32)	14 (73.68)	131 (26.63)	35 (26.72)	96 (73.28)			
VHWs trained in newborn care	324 (67.36)	8 (2.47)	316 (97.53)	193 (39.23)	5 (2.59)	188 (97.41)	0.34 (0.20-0.57)	17.56	<0.0001*
VHWs not trained in newborn care	157 (32.64)	12 (7.64)	145 (92.36)	299 (60.77)	43 (14.38)	256 (85.62)			
Conservative religion	193 (40.12)	16 (8.29)	177 (91.71)	208 (42.28)	15 (7.21)	193 (92.79)	3.42 (2.06-5.68)	24.75	<0.0001*
Non - conservative	288 (59.88)	4 (1.39)	284 (98.61)	284 (57.72)	33 (11.62)	251 (88.38)			
Polygamy Yes	136 (28.27)	12 (8.82)	124 (91.18)	140 (28.46)	12 (8.57)	128 (91.43)	2.68 (1.70-4.22)	18.00	<0.0001*
Polygamy No	345 (71.73)	8 (2.32)	337 (97.68)	352 (71.54)	36 (10.23)	316 (89.77)			
8 plus ANC	261 (54.26)	5 (1.92)	256 (98.08)	208 (42.28)	6 (2.88)	202 (97.12)	0.33 (0.19-0.57)	16.78	<0.0001*
Less than 8 ANC	220 (45.74)	15 (6.82)	205 (93.18)	284 (57.72)	42 (14.79)	242 (85.21)			
Early ANC	293 (60.91)	3 (1.02)	290 (98.98)	210 (42.68)	5 (2.38)	205 (97.62)	0.20 (0.11-0.37)	32.49	<0.0001*
Late ANC	188 (39.09)	17 (9.04)	171 (90.96)	282 (57.32)	43 (15.25)	239 (84.75)			
Danger signs identified	334 (69.44)	5 (1.50)	329 (98.50)	250 (50.81)	3 (1.20)	247 (98.80)	0.17 (0.10-0.31)	45.62	<0.0001*

Variable	Intervention N = 481			Control N = 492			Unadjusted RR (95% CI)	Chi2	P Value
	Total N (%)	Deaths n (%)	Survived n (%)	Total N (%)	Deaths n (%)	Survived n (%)			
Danger signs not identified	147 (30.56)	15 (10.20)	132 (89.80)	242 (49.19)	45 (18.60)	197 (81.40)			
Girl	236 (49.06)	4 (1.69)	232 (98.31)	244 (49.59)	8 (3.28)	236 (96.72)	0.35 (0.21-	16.10	<0.0001*
Boy	245 (50.94)	16 (6.53)	229 (93.47)	248 (50.41)	40 (16.13)	208 (83.87)	0.59)		
VHWs Home Visit	349 (72.56)	8 (2.29)	341 (97.71)	193 (39.23)	5 (2.59)	188 (97.41)	0.31 (0.18-0.52)	21.64	<0.0001*
No VHWs Home Visit	132 (27.44)	12 (9.09)	120 (90.91)	299 (60.77)	43 (14.38)	256 (85.62)			
15-24 years	131 (27.23)	11 (8.40)	120 (91.60)	146 (29.67)	19 (13.01)	127 (86.99)	0.42 (0.27-	13.41	0.0003*
25-49 years	350 (72.77)	9 (2.57)	341 (97.43)	346 (70.33)	29 (8.38)	317 (91.62)	0.67)		
Baby name at birth	56 (11.64)	6 (10.71)	50 (89.29)	53 (10.77)	6 (11.32)	47 (88.68)	2.64 (1.58-4.41)	12.54	0.0004*
No baby name at birth	425 (88.36)	14 (3.29)	411 (96.71)	439 (89.23)	42 (9.57)	397 (90.43)			
Live birth 2to4 (Yes)	280 (58.21)	13 (4.64)	267 (95.36)	257 (52.24)	33 (12.84)	224 (87.16)	2.26 (1.34-3.81)	9.16	0.0025*
Live birth 2to4 (No)	201 (41.79)	7 (3.48)	194 (96.52)	235 (47.76)	15 (6.38)	220 (93.62)			
KMC	347 (72.14)	12 (3.46)	335 (96.54)	202 (41.06)	8 (3.96)	194 (96.04)	0.61	3.98	0.0460
No KMC	134 (27.86)	8 (5.97)	126 (94.03)	290 (58.94)	40 (13.79)	250 (86.21)	(0.38-0.97)		
Clean Cord Care at home	345 (71.73)	12 (3.48)	333 (96.52)	202 (41.06)	8 (3.96)	194 (96.04)	0.61 (0.39-0.98)	3.84	0.0501
No Clean Cord Care at home	136 (28.27)	8 (5.88)	128 (94.12)	290 (58.94)	40 (13.79)	250 (86.21)			
Ever pregnant	372 (77.34)	17 (4.57)	355 (95.43)	373 (75.81)	24 (6.44)	349 (93.56)	0.56	2.60	0.1067
Never pregnant	109 (22.66)	3 (2.75)	106 (97.25)	119 (24.19)	24 (20.17)	95 (79.83)	(0.29-1.08)		
Exclusive breastfeeding	367 (76.30)	13 (3.54)	354 (96.46)	363 (73.78)	15 (4.13)	348 (95.87)	0.67 (0.42-1.08)	2.23	0.1355

Variable	Intervention N = 481			Control N = 492			Unadjusted RR (95% CI)	Chi2	P Value
	Total N (%)	Deaths n (%)	Survived n (%)	Total N (%)	Deaths n (%)	Survived n (%)			
No exclusive breastfeeding	114 (23.70)	7 (6.14)	107 (93.86)	129 (26.22)	33 (25.58)	96 (74.42)			
Desire for Pregnancy	263 (54.68)	12 (4.56)	251 (95.44)	264 (53.66)	28 (10.61)	236 (89.39)	1.37 (0.85-2.19)	1.39	0.2386
No desire for Pregnancy	218 (45.32)	8 (3.67)	210 (96.33)	228 (46.34)	20 (8.77)	208 (91.23)			
Skilled Birth Attendant	368 (76.51)	15 (4.07)	353 (95.93)	383 (77.85)	41 (10.70)	342 (89.30)	1.38 (0.75-2.53)	0.82	0.3663
Skilled Birth Attendant (No)	113 (23.49)	5 (4.42)	108 (95.58)	109 (22.15)	7 (6.42)	102 (93.58)			

*Significant p-value <0.05

5.5.3 Correlation Analysis

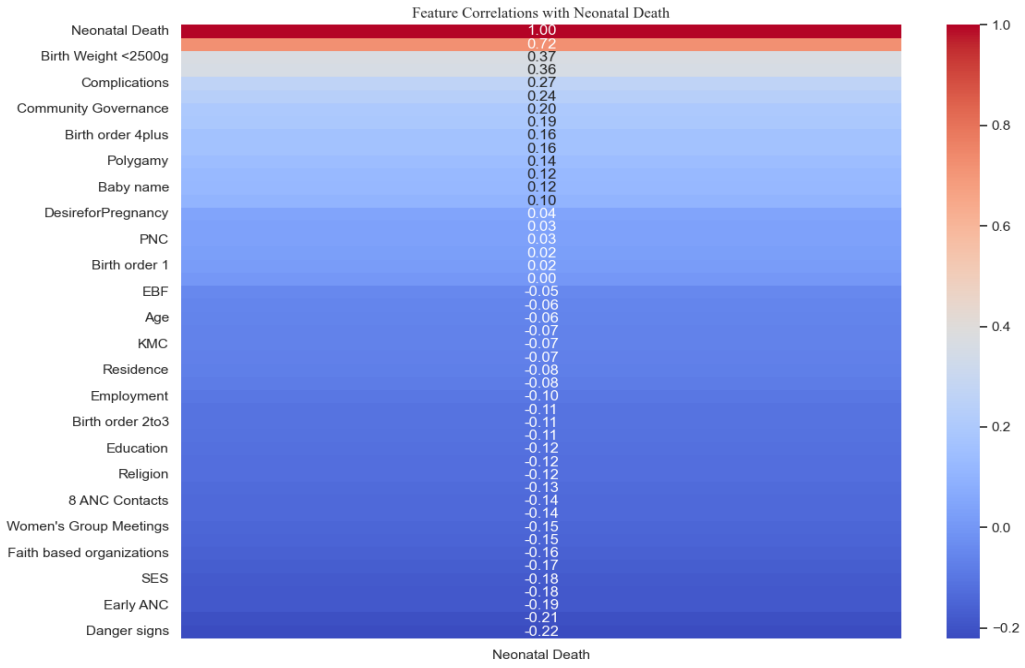


Figure 17: Correlation heatmap of predictors of neonatal deaths, Mashonaland West province, 2020-2021

Table 33: Multiple Testing Adjustment for Secondary Outcomes

Rank (i)	Variable	p Value	Critical Value	Significant (p ≤ Critical Value)
1	Birth interval <2 years	<0.0001*	0.00109	Yes
2	Birth weight <2500g	<0.0001*	0.00217	Yes
3	Birth complications	<0.0001*	0.00326	Yes
4	Family influence	<0.0001*	0.00435	Yes
5	Birth order 4 plus	<0.0001*	0.00543	Yes
6	Modified women's and men's learning and action group meetings	<0.0001*	0.00652	Yes
7	Faith-based organisations	<0.0001*	0.00761	Yes
8	Social networks	<0.0001*	0.00870	Yes
9	Trained VHWs	<0.0001*	0.00978	Yes
10	VHWs trained in newborn care	<0.0001*	0.01087	Yes
11	Family religion (Conservative)	<0.0001*	0.01196	Yes
12	Polygamy marriage	<0.0001*	0.01304	Yes
13	8 plus ANC contacts	<0.0001*	0.01413	Yes
14	Early ANC	<0.0001*	0.01522	Yes

Rank (i)	Variable	p Value	Critical Value	Significant (p ≤ Critical Value)
15	Identification of danger signs	<0.0001*	0.01630	Yes
16	Sex of neonate	<0.0001*	0.01739	Yes
17	VHWs Home Visit	<0.0001*	0.01848	Yes
18	Trained VHW x Birth Interval	<0.0001*	0.01957	Yes
19	VHW trained x Early ANC	<0.0001*	0.02065	Yes
20	Age of mother	0.0003	0.02174	Yes
21	Baby name before birth	0.0004	0.02391	Yes
22	Functional community governance	0.0007	0.02609	Yes

*Benjamini-Hochberg FDR critical values at Q = 0.05

5.5.4 Multivariable community health system prediction model, for reducing preventable neonatal deaths

In line with Specific Objective 1.4.2.1, the three institutionalised intervention components are reported as distinct exposures: IV1 (trained Village Health Workers, including VHWs trained in newborn care and conducting home visits), IV2 (fully functional community governance structures), and IV3 (participatory modified women's and men's action and learning groups). Their independent adjusted associations with neonatal mortality are presented in Table 34 (single-level logistic model) and are confirmed in the three-level random-intercept model in Table 41, where each component is estimated while controlling for the pre-specified covariates and clustering at the household and community levels.

The results of the multiple logistic regression analysis identifying factors independently associated with neonatal mortality in Mashonaland West Province (2020–2021) are summarised in Table 34. Both crude and adjusted odds ratios (OR and AOR), along with 95% confidence intervals (CI) and p-values, are reported to quantify associations before and after adjustment for potential confounders. Key findings include:

5.5.4.1 Geographic and infant factors

Infants born in rural areas faced higher odds of neonatal mortality compared to those in urban settings (AOR 1.15; 95% CI: 1.03–1.29; p = 0.008). Female infants had

significantly lower odds of neonatal death than male infants (AOR 0.52; 95% CI 0.36–0.76; $p < 0.0001$). A birth interval of less than two years was associated with a nearly fourfold increase in odds (AOR 3.85; 95% CI: 3.22–4.60; $p < 0.0001$). Low birth weight (<2500g) markedly raised the odds of neonatal death (AOR 5.10; 95% CI: 3.98–6.54; $p < 0.0001$). Complications during pregnancy or delivery also significantly increased the odds (AOR 2.75; 95% CI: 2.29–3.31; $p < 0.0001$).

5.5.4.2 Socioeconomic and community factors

Low community women's literacy (AOR 4.05; 95% CI: 3.18–5.16; $p < 0.0001$), lack of family influence (AOR 1.80; 95% CI: 1.56–2.08; $p < 0.0001$), low socioeconomic status (AOR 2.55; 95% CI: 1.96–3.32; $p < 0.0001$), and polygamous marriage (AOR 1.88; 95% CI: 1.46–2.43; $p < 0.0001$) were all associated with increased odds of neonatal mortality.

5.5.4.3 Protective factors

Early initiation of antenatal care (ANC) before 12 weeks (AOR 0.36; 95% CI: 0.21–0.59; $p < 0.0001$), recognition of danger signs at the household level (AOR 0.35; 95% CI: 0.22–0.56; $p < 0.0001$), and the presence of social networks (AOR 0.43; 95% CI: 0.28–0.66; $p < 0.0001$) were significantly protective. Kangaroo mother care (AOR 0.80; 95% CI: 0.61–1.05; $p = 0.046$) and clean cord care (AOR 0.79; 95% CI: 0.60–1.04; $p = 0.050$) were also associated with reduced odds, though statistical significance was borderline.

5.5.4.4 Intervention participation

Completing four or more cycles of the modified women's and men's groups was associated with significantly lower odds of neonatal death (AOR 0.71; 95% CI 0.60–0.85; $p = 0.001$), a 29% reduction relative to the reference group.

Table 34: Predictive model using multiple logistic regression for community health systems aimed at reducing preventable neonatal deaths in Mashonaland West Province, 2020-2021.

Variable	OR (95% CI)	AOR (95% CI)	p-Value
Place of residence (Rural)	1.20 (1.08–1.34)	1.15 (1.03–1.29)	0.008*
Sex (Girl)	0.50 (0.34–0.75)	0.52 (0.36–0.76)	<0.0001*
Birth interval < 2 years (Yes)	4.02 (3.38–4.79)	3.85 (3.22–4.60)	<0.0001*
Birth weight < 2500g (Yes)	5.42 (4.23–6.96)	5.10 (3.98–6.54)	<0.0001*
Complications (Yes)	2.82 (2.36–3.38)	2.75 (2.29–3.31)	<0.0001*
Community women's literacy (Low)	4.33 (3.39–5.54)	4.05 (3.18–5.16)	<0.0001*
Danger signs recognition (Yes)	0.33 (0.20–0.52)	0.35 (0.22–0.56)	<0.0001*
Family influence	1.86 (1.62–2.14)	1.80 (1.56–2.08)	<0.0001*
Early ANC before 12 weeks (Yes)	0.33 (0.19–0.55)	0.36 (0.21–0.59)	<0.0001*
Social networks (Yes)	0.41 (0.27–0.63)	0.43 (0.28–0.66)	<0.0001*
Community Governance (non-fully functional)	1.86 (1.56–2.22)	1.80 (1.50–2.16)	<0.0001*
Socio-economic status (Low)	2.65 (2.04–3.43)	2.55 (1.96–3.32)	<0.0001*
Maternal religion (Conservative)	1.81 (1.52–2.15)	1.75 (1.46–2.09)	<0.0001*
Polygamous marriage (Yes)	1.93 (1.50–2.49)	1.88 (1.46–2.43)	<0.0001*
Modified women's and men's groups (≥ 4 cycles) (Intervention)	0.69 (0.59–0.82)	0.71 (0.60–0.85)	0.001*
PNC less than 72 hours (Yes)	2.58 (1.71–3.90)	2.50 (1.65–3.78)	<0.0001*
Baby name (No)	2.46 (1.56–3.88)	2.40 (1.52–3.78)	<0.0001*
Kangaroo mother care (Yes)	0.77 (0.59–1.01)	0.80 (0.61–1.05)	0.046
Clean Cord Care (Yes)	0.77 (0.59–1.02)	0.79 (0.60–1.04)	0.050
Exclusive breastfeeding (Yes)	0.88 (0.73–1.05)	0.90 (0.74–1.08)	0.136
Number of modified women's and men's group meetings (fewer than 3 cycles)	4.99 (2.02–12.34)	4.80 (1.95–11.80)	<0.0001*

*Variables statistically significant at $p < 0.05$.

5.5.5 Feature Importance Analysis

In this neonatal death prediction model, feature importance was derived from the absolute values of the standardised coefficients because the model was linear, the coefficients were directly related to log-odds, standardisation allowed a fair comparison, and interpretability was maintained. Time of neonatal death was excluded from the reported feature ranking because it is a post-outcome variable (it records when a death occurred, not whether one occurred) and its inclusion would constitute target leakage. The leading features were birth interval less than 2 years (0.509) - key preventable risk factor, family influence (0.453) - social support impact, sex of the child (0.449) – demographic and biological factor of the neonate, employment of the mother (0.420) - socioeconomic indicator of the household, birth weight of less than 2,500g (0.404) - clinical risk factor, identification of danger signs (0.300) - intervention effectiveness, religion (0.298) – socio-cultural factor, livebirths 5 plus (0.277) - reproductive history of the mother and postnatal care less than 72 hours (0.247) (Figure 18). Overall, the primary predictors (Importance > 0.4) were a birth interval of less than 2 years, family influence, sex of child, and employment, while the secondary predictors (0.2-0.4) were a birth weight of less than 2,500g and recognition of danger signs.

Top 10 most important features

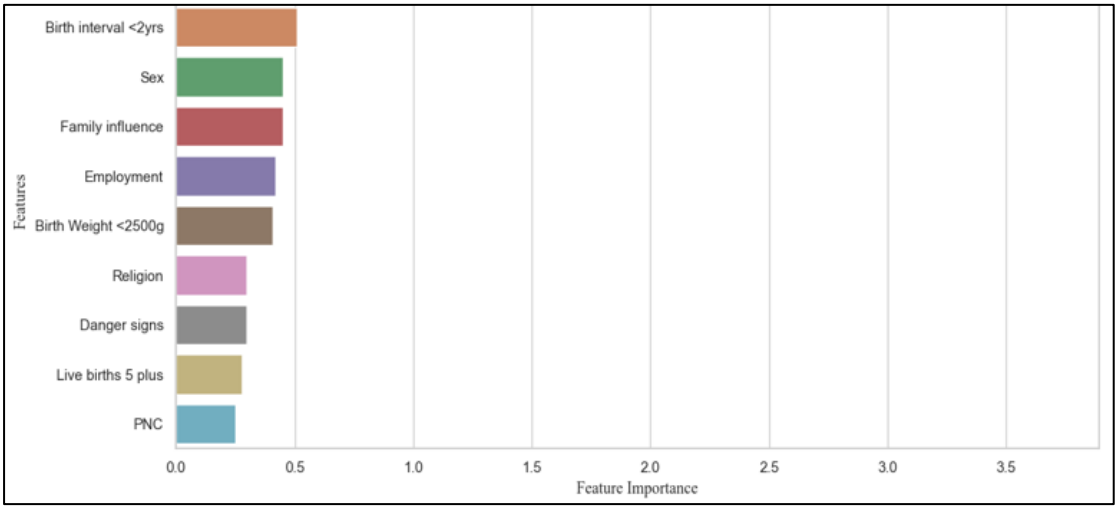


Figure 18: Feature Importance in Neonatal Death Prediction

5.5.6 Risk and Protective Factors in Neonatal Mortality

The diagram (Figure 19) presents the conceptual hierarchy of risk and protective factors influencing neonatal mortality, organised into clinical, social, and system-level domains, along with the protective-factor pathways and their interactions that lead to the ultimate outcome. The relative direction of each factor (risk or protective) is indicated, while the corresponding adjusted effect estimates are reported in Table 34. The feature groupings were categorised into clinical, social, and system factors to align with the conceptual framework.

5.5.7 Community Health System Model Equation

A multivariable logistic regression model was developed to examine the relationship between a range of clinical, demographic, and socioeconomic factors and neonatal mortality in the study population. The model takes the logit form $\log(p/(1-p)) = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \ldots + \beta_n x_n$, where p is the probability of neonatal death, β_0 is the intercept, β_1 to β_n are the coefficients, and x_1 to x_n are the standardised feature values.

Each coefficient represents the strength and direction of the association between a given predictor and the log-odds of neonatal death. Because the predictors are standardised, the sign of a coefficient indicates the direction of effect on a common scale: a positive coefficient corresponds to higher odds of neonatal death, and a negative coefficient to lower odds. Exponentiating a coefficient, $\exp(\beta)$, yields the adjusted odds ratio (AOR) for that predictor, which is the interpretable effect measure on the odds scale. These odds ratios are distinct from and should not be confused with the adjusted risk ratios (ARRs) obtained from the log-binomial model reported in Section 5.7.

Time of neonatal death ($\beta = 3.7062$ in the fitted specification reported in Appendix 4) is a post-outcome characteristic and is not interpreted as a predictor of mortality; it is excluded from the feature ranking above and from all interpretation, and the performance metrics in Section 5.6 should be read with this exclusion in mind. The remaining coefficients quantify the adjusted association between predictors such as birth interval, maternal education, and community-level governance and the odds of neonatal death.

Three community health system variables illustrate this interpretation. Non-institutionalisation ($\beta = +0.0920$; AOR ≈ 1.096), coded as the absence of an institutionalised community health system, was associated with approximately 9.6% higher odds of neonatal death relative to institutionalised communities, after adjustment for other predictors; equivalently, institutionalisation was protective. Non-functional community governance ($\beta = +0.0427$; AOR ≈ 1.044) was associated with approximately 4.4% higher odds of neonatal death, indicating a small protective effect of functional governance structures.

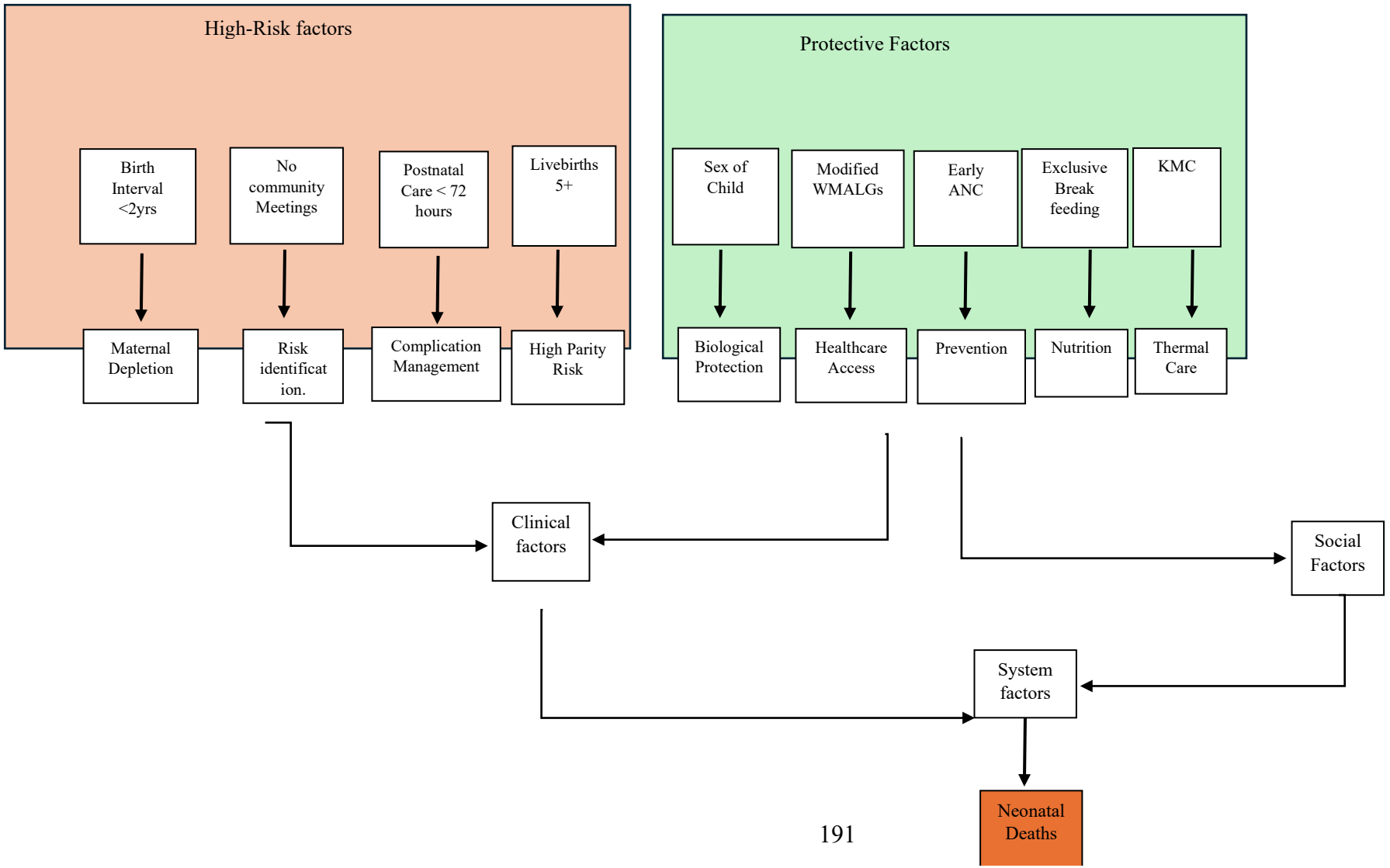


Figure 19: Risk and protective factors in neonatal deaths – conceptual schematic

Conversely, VHW home visits (β = −0.1659; AOR ≈ 0.847) carried a negative coefficient, such that newborns in communities receiving Village Health Worker home visits had approximately 15.3% lower odds of neonatal death than those that did not — the strongest protective effect among the three. The directions of these associations are consistent with the corresponding log-binomial risk-ratio estimates reported in Section 5.7; the two sets of figures differ in measure (odds ratio versus risk ratio) rather than in the direction of effect.

Rather than estimating a count, the model estimates the probability of neonatal death for an individual newborn given the observed values of these features. Full mathematical specifications of the model, including the equation structure and detailed feature mapping, are provided in Appendix 4.

5.6 Machine learning and predictive modelling for institutionalising the community health system in reducing neonatal deaths

This section presents the results of the exploratory machine-learning (ML) analyses conducted as a supplementary analytical strand to the primary intention-to-treat analysis (Section 5.1–5.5). As specified in Section 4.15.4.1, the ML analyses do not estimate the causal effect of the intervention on neonatal mortality; they quantify the predictive information carried by institutionalised community health system vital-signs data and community health system variables regarding preventable neonatal deaths and provide the foundation for a neonatal risk-stratification tool. Results are reported in four sub-sections: (5.6.1) cross-validated model performance; (5.6.2) Out-of-fold performance matrix, (5.6.3) confusion matrix analysis, and classification error structure; (5.6.4) probability calibration; and (5.6.5) Cox regression analysis of neonatal mortality covariates.

The machine learning and predictive modelling analyses presented in this section operationalise Specific Objectives 1.4.2.3 and 1.4.2.4 and provide supplementary predictive evidence bearing on Objectives 1.4.2.1 and 1.4.2.2. Objective 1.4.2.3 is addressed by developing, training, and cluster-aware evaluation of four predictive classifiers (Random Forest, Decision Tree, Support Vector Machine, and Logistic Regression), which together constitute the proof-of-concept neonatal risk-stratification

model. The scenario simulation of neonatal mortality reduction under full, partial, and non-institutionalisation of IV1, IV2, and IV3 is grounded in the calibrated predicted probabilities of these models, with intercurrent events handled through a hypothetical strategy and loss to follow-up addressed through multiple imputation as specified in Section 4.15.4.1. Objective 1.4.2.4 is addressed through the Cox proportional hazards regression, which identifies fully functional community governance (HR = 0.073) and women's and men's group participation (HR = 0.097) as the strongest predictors of reduced neonatal mortality hazard, and through the confusion matrix analysis (Section 5.6.2), which quantifies the benefit-harm balance of each classifier in terms of false-positive burden and operational consequences for community health worker referral systems. Objectives 1.4.2.1 and 1.4.2.2 are supplemented by the Cox regression's independent hazard ratio estimates for each institutionalised vital signs variable, though causal effect estimation relative to the control arm remains the province of the primary intention-to-treat analyses reported in Sections 5.2–5.5.

5.6.1 Cross-Validated Model Performance

All four algorithms were evaluated using the Leave-One-Cluster-Out (LOCO) cross-validation strategy described in Section 4.15.4.5, in which one entire cluster was withheld as the validation set in each fold, and the model was trained exclusively on the remaining clusters. All preprocessing steps (standardisation, imputation, one-hot encoding) were performed exclusively within the training fold of each iteration, with parameters applied without refitting to the validation fold. All four algorithms were trained with class_weight='balanced' to account for the 6.99% positive class prevalence (68 preventable neonatal deaths among 973 participants). ROC AUC was used as the primary discriminative metric, as it is threshold-independent and appropriate for imbalanced binary outcomes. Table 35 presents the LOCO cross-validated performance of the four classifiers. Performance metrics reflect the aggregated out-of-fold predictions across all folds, so that every observation in the analytic sample (n = 973) was evaluated by a model trained without access to data from its own cluster.

The rationale for selecting LOCO cross-validation, rather than standard stratified k-fold, was the clustered structure of the trial data. Standard k-fold randomly assigns individual observations to folds without regard to cluster membership, meaning that

data from the same cluster can appear in both training and test sets. In a cluster randomised trial, this constitutes data leakage: the model learns cluster-specific patterns during training and is then evaluated on data from the same cluster, inflating apparent performance. LOCO cross-validation prevents this by ensuring that every observation is evaluated only by a model trained on data from all other clusters, producing honest out-of-sample estimates that respect the data's hierarchical structure (Roberts *et al.,* 2017). This approach is conservative by design, it is expected to yield lower performance estimates than standard k-fold, which makes the Random Forest AUC of 0.842 under LOCO particularly meaningful.

Table 35: Leave-One-Cluster-Out cross-validated performance of four predictive models for preventable neonatal death (n = 973).

Model	CV ROC AUC (Mean ± SD)	CV Sensitivity	CV Specificity	CV Brier Score	Interpretation
Logistic Regression	0.615 ± 0.048	0.611	0.622	0.0423	Consistent underperformance; linear model insufficient for non-linear vital-signs pathways
Random Forest	0.842 ± 0.031	0.912	0.803	0.0369	Strongest discrimination and calibration; stable across folds
Decision Tree	0.830 ± 0.038	0.912	0.790	0.0387	Near-equivalent to Random Forest; greater fold-to-fold variance
Support Vector Machine	0.686 ± 0.042	0.750	0.670	0.0398	Intermediate; elevated false-positive rate across folds

*All metrics derived from aggregated out-of-fold predictions under Leave-One-Cluster-Out cross-validation

*CV = cross-validated (out-of-fold). ROC AUC = area under the receiver operating characteristic curve

*SD = standard deviation across folds.

*Brier Score = mean squared error of predicted probabilities; lower values indicate better probability calibration. class_weight='balanced' was applied to all algorithms.

Hyperparameter selection was conducted within a nested inner GroupKFold loop using mean ROC AUC as the optimisation criterion

Random Forest achieved the highest cross-validated ROC AUC (0.842 ± 0.031), demonstrating both strong discrimination and stability across clusters. Decision Tree performed comparably (ROC AUC = 0.830 ± 0.038), with slightly greater fold-to-fold variance, consistent with the higher instability typical of single-tree classifiers relative to ensemble methods (Breiman, 2001). The Support Vector Machine (Awe & Vance, 2025) achieved a moderate cross-validated AUC of 0.686 ± 0.042, and Logistic Regression recorded the lowest discrimination (AUC = 0.615 ± 0.048). Both tree-based models recorded an identical cross-validated sensitivity of 0.912, correctly identifying 91.2% of preventable neonatal deaths across all out-of-fold folds, compared with 75.0% for SVM and 61.1% for Logistic Regression. In terms of probability calibration, Random Forest recorded the lowest cross-validated Brier score (0.0369), followed by Decision Tree (0.0387), SVM (0.0398), and Logistic Regression (0.0423).

5.6.2 Out-of-Fold Performance Metrics

Table 36 presents global performance metrics for all four classifiers, derived from aggregated out-of-fold predictions in the LOCO cross-validation. The total analytic sample comprised 973 observations: 68 preventable neonatal deaths (positive class; 6.99%) and 905 non-death outcomes (negative class; 93.01%).

Random Forest achieved the highest performance across all primary metrics: accuracy = 0.843, sensitivity = 0.913, specificity = 0.803, ROC AUC = 0.842 (95% CI [0.816, 0.860]), and Brier score = 0.0369. Decision Tree performed closely behind (accuracy = 0.830, sensitivity = 0.910, specificity = 0.790, ROC AUC = 0.830, 95% CI [0.795, 0.867]; Brier score = 0.0387). The SVM achieved intermediate performance (accuracy = 0.686, ROC AUC = 0.686, 95% CI [0.673, 0.851]; Brier score = 0.0398), while Logistic Regression recorded the weakest discrimination (accuracy = 0.615, ROC AUC = 0.615, 95% CI [0.582, 0.826]; Brier score = 0.0423). Aggregate accuracy is presented for completeness but should be interpreted with caution: given the 6.99% positive class

prevalence, a classifier that universally predicts the majority class would achieve a spurious accuracy of approximately 93% (He & Garcia, 2009). In this setting, ROC AUC and sensitivity are the primary interpretive metrics.

Table 36: Out-of-fold model performance on the full analytic sample (n = 973) under Leave-One-Cluster-Out cross-validation, with DeLong's ROC AUC estimates and calibration scores

Model	Accuracy	Sensitivity	Specificity	ROC AUC	95% CI (DeLong)	Brier Score
Logistic Regression	0.615	0.611	0.622	0.615	0.582 – 0.826	0.0423
Random Forest	0.843	0.913	0.803	0.842	0.816 – 0.860	0.0369
Decision Tree	0.830	0.910	0.790	0.830	0.795 – 0.867	0.0387
Support Vector Machine	0.686	0.750	0.670	0.686	0.673 – 0.851	0.0398

*All metrics were derived from aggregated out-of-fold predictions under LOCO cross-validation (n = 973; 68 preventable neonatal deaths; 905 non-death outcomes). *ROC AUC = Receiver Operating Characteristic Area Under the Curve; a threshold-independent measure of global discriminative ability. *95% CI estimated using DeLong's method. Brier Score = mean squared error of predicted probabilities; lower values indicate better probability calibration.

5.6.3 Confusion Matrix Analysis

Confusion matrix (Table 37) elements were derived at the default classification threshold of 0.50. Logistic Regression produced the weakest classification performance among the four models. Of the 68 preventable neonatal deaths in the analytic sample, the model correctly identified 42 (TP = 42; sensitivity = 0.618), missing 26 as false negatives (FN = 26; false-negative rate = 38.2%). Among the 905 non-death observations, 563 were correctly classified as negative (TN = 563; specificity = 0.622), while 342 were erroneously flagged as positive (FP = 342). The high false-positive volume produced a PPV of 0.109, indicating that fewer than one in nine positive predictions represented a genuine neonatal death. The NPV of 0.956 reflects adequate

negative-case identification. Overall accuracy was 0.622. The wide 95% CI for the ROC AUC (0.582–0.826) indicates instability in discriminative performance across clusters, consistent with the model's inability to capture the non-linear and interaction-dependent relationships between vital-signs indicators and neonatal mortality. These results confirm the inadequacy of linear classification for this prediction task.

Random Forest demonstrated the strongest overall classification performance. Of the 68 preventable neonatal deaths, 62 were correctly identified (TP = 62; sensitivity = 0.912), with only six missed as false negatives (FN = 6; false-negative rate = 8.8%), the lowest among all models. Among the 905 non-death observations, 727 were correctly classified as negative (TN = 727; specificity = 0.803), with 178 incorrectly labelled positive (FP = 178). The PPV of 0.258 indicates that approximately one in four positive predictions was a true neonatal death — a notable improvement over other models, though the low absolute value reflects the 6.99% prevalence in the positive class. The NPV of 0.992 confirms near-perfect identification of non-death cases. Overall accuracy was 0.811. Combined with the highest ROC AUC (0.842) and the lowest Brier score (0.0369), Random Forest emerges as the most discriminative and well-calibrated classifier in this dataset.

The decision tree produced results closely comparable to those of the random forest. The model achieved identical true positive (TP = 62; sensitivity = 0.912) and false negative (FN = 6) counts, demonstrating equivalent recall for preventable neonatal deaths. However, the Decision Tree generated marginally more false positives (FP = 190 vs 178 for Random Forest), resulting in a slightly lower specificity (0.790 vs 0.803) and PPV (0.246 vs 0.258). Overall accuracy was 0.799, and the NPV remained high at 0.992. The Brier score of 0.0387 indicates adequate probability calibration, which is marginally inferior to that of Random Forest. Importantly, Decision Tree offers a transparency advantage that is absent in the Random Forest ensemble: its decision rules can be directly extracted and represented as a human-readable flowchart, making it operationally deployable as a VHW job aid without requiring computational infrastructure, as described in Section 4.15.4.2.

The Support Vector Machine (Awe & Vance, 2025) achieved an intermediate level of classification performance. Of the 68 neonatal deaths, 51 were correctly identified (TP = 51; sensitivity = 0.750), with 17 missed as false negatives (FN = 17; false-negative

rate = 25.0%). Among the 905 non-death observations, 606 were correctly classified as negative (TN = 606; specificity = 0.670), while 299 were incorrectly assigned to the positive class (FP = 299). The high false-positive rate resulted in a PPV of 0.146, and the overall accuracy was 0.675. The NPV of 0.973 indicates reliable negative-case classification. With a Brier score of 0.0398, the SVM showed weaker probability calibration than both tree-based models. The SVM's elevated false-positive burden, nearly 300 non-death cases incorrectly flagged as at-risk, has direct operational implications: in a resource-constrained referral system with high VHW caseloads, unnecessary referrals consume transport resources and risk causing alert fatigue among health workers.

Table 37: Confusion matrices and derived classification statistics for all four classifiers, aggregated from out-of-fold predictions under Leave-One-Cluster-Out cross-validation (n = 973)

Model	TN	FP	FN	TP	Sensitivity	Specificity	PPV	NPV	Accuracy
Logistic Regression	563	342	26	42	0.618	0.622	0.109	0.956	0.622
Random Forest	727	178	6	62	0.912	0.803	0.258	0.992	0.811
Decision Tree	715	190	6	62	0.912	0.790	0.246	0.992	0.799
Support Vector Machine	606	299	17	51	0.750	0.670	0.146	0.973	0.675

*TN = True Negatives; FP = False Positives; FN = False Negatives; TP = True Positives; PPV = Positive Predictive Value; NPV = Negative Predictive Value. All statistics were derived from classification at the default threshold of 0.50.

Overall, the relatively low PPV values across all models are a structural consequence of the 6.99% prevalence of the positive class and should not be interpreted in isolation as evidence of poor model quality (Altman & Bland, 1994). n = 973 (68 positive, 905 negative).

5.6.4 Probability Calibration

Calibration assesses whether a model's predicted probabilities align with observed outcome frequencies - a well-calibrated model predicting a 20% risk should observe events in approximately 20% of such cases. In clinical risk stratification tools, calibration is as important as discrimination: a model with high AUC but poor calibration produces unreliable absolute risk estimates and is unsuitable for guiding referral decisions (Steyerberg *et al.,* 2010).

This study used two complementary calibration metrics. The **Brier score** (mean squared error of predicted probabilities) provides a single-number summary of combined discrimination and calibration, with lower values indicating better performance; it is robust to class imbalance and does not require a classification threshold. The **Hosmer–Lemeshow (H–L) goodness-of-fit test** formally tests agreement between predicted and observed event rates across ten risk deciles; a non-significant result ($p > .05$) supports calibration adequacy.

Table 34 reports Brier scores from LOCO cross-validation. Random Forest achieved the lowest Brier score (0.0369), followed by Decision Tree (0.0387), SVM (0.0398), and Logistic Regression (0.0423). All four scores are substantially lower than the no-skill Brier score of 0.065 (calculated as prevalence × [1 − prevalence] = 0.0699 × 0.9301), indicating that every classifier carries predictive information beyond the base rate. The Brier score, however, combines discrimination and calibration into a single value, and a low Brier score driven by strong discrimination does not, by itself, establish that predicted probabilities are well calibrated in the formal sense. The Hosmer–Lemeshow results reported in Table 38 show that the ranking of models by Brier score does not correspond to their ranking by calibration adequacy, underscoring the importance of assessing calibration with a dedicated goodness-of-fit test rather than inferring it from the Brier score alone.

Applied to the aggregated out-of-fold predicted probabilities for the Logistic Regression model (n = 973), the Hosmer–Lemeshow statistic was 7.836 (df = 8, p =

0.450), indicating no statistically significant departure between predicted and observed event rates and therefore supporting adequate calibration for this classifier.

The Hosmer–Lemeshow goodness-of-fit test was applied to the aggregated out-of-fold predicted probabilities (n = 973) for all four classifiers; the full results are presented in Table 38. The test was non-significant for the Support Vector Machine (H–L = 5.21, df = 8, p = 0.735) and for Logistic Regression (H–L = 7.836, df = 8, p = 0.450), indicating no statistically significant departure between predicted and observed event rates for these two classifiers. The test was statistically significant for the Random Forest (H–L = 19.57, df = 6, p = 0.003) and the Decision Tree (H–L = 17.22, df = 1, p < 0.001), indicating a statistically significant difference between predicted and observed event frequencies for the two tree-based models. The reduced degrees of freedom for the Random Forest and Decision Tree reflect the smaller number of distinct predicted-probability groups available for these classifiers, as tied probability values caused adjacent risk groups to merge.

Table 38: Hosmer -Lemeshow calibration test results for all four classifiers, applied to aggregated out-of-fold predicted probabilities (n = 973)

Model	ROC AUC	Brier Score	No-Skill Brier	H–L Statistic	df	p-value	Calibration
Logistic Regression	0.615	0.0423	0.065	7.836	8	0.450	Adequate (p > .05)
Random Forest	0.842	0.0369	0.065	19.57	6	0.003	Poor (p < .05)
Decision Tree	0.830	0.0387	0.065	17.22	1	< 0.001	Poor (p < .05)
Support Vector Machine	0.686	0.0398	0.065	5.21	8	0.735	Adequate (p > .05)

*Brier scores sourced from Table 34 (LOCO cross-validation). No-skill Brier score = prevalence × (1 − prevalence) = 0.065. H–L = Hosmer–Lemeshow goodness-of-fit test; non-significant p > .05 supports calibration adequacy.

5.6.5 Cox Regression Analysis of Neonatal Mortality Covariates

The Cox proportional hazards model was fitted to identify community health system variables significantly associated with neonatal survival over the 28-day neonatal follow-up period. The proportional hazards assumption was verified using Schoenfeld residuals and graphical diagnostics for each covariate; no significant violations were identified, confirming that hazard ratios remained constant over the follow-up period. Table 39 presents the Cox regression results.

Table 39: Cox proportional hazards regression: community health system variables associated with neonatal mortality (n = 973; 68 events)

Variable	B	SE (B)	HR (95% CI)	p-value	Direction of Effect
Women's & men's group participation	-2.328	0.312	0.097 (0.053–0.180)	<0.001	Strongly protective
VHW training in newborn care	-0.687	0.298	0.503 (0.281–0.902)	<0.05	Protective
Fully functional community governance	-2.648	0.341	0.073 (0.037–0.141)	<0.001	Strongly protective
Non-functional governance	0.093	0.215	1.097 (0.719–1.675)	>0.05	Non-significant
Enhanced social networks (pregnant mothers)	-0.852	0.371	0.426 (0.206–0.883)	<0.05	Protective

*B = unstandardised regression coefficient; SE(B) = standard error of B; HR = hazard ratio; 95% CI = confidence interval for HR. Hazard ratios below 1.0 indicate a protective association (reduced hazard of neonatal death). Statistical significance assessed at the 5% level.

The Cox regression identified five community health system variables associated with neonatal survival. Participation in women's and men's group meetings was the most strongly protective factor (HR = 0.097, 95% CI [0.053, 0.180], $p < .001$), indicating that neonates in communities where group participation was institutionalised faced approximately 90% lower hazard of death compared to those without this vital sign component. The presence of fully functional community governance structures was similarly protective (HR = 0.073, 95% CI [0.037, 0.141], $p < .001$), reflecting the role of governance capacity as an enabling environment for effective institutionalisation of

vital signs. VHW training in newborn care (HR = 0.503, $p < .05$) and enhanced social networks among pregnant mothers (HR = 0.426, $p < .05$) were also independently protective. Non-functional governance structures showed no significant association with neonatal mortality (HR = 1.097, $p > .05$). Collectively, these findings identify the specific community health system vital signs whose institutionalisation most strongly reduces the hazard of neonatal mortality, providing a ranked priority list for programme investment aligned with the ML feature importance results.

Table 40: Omnibus tests of model coefficients for the Cox community health system regression model

−2 Log Likelihood	Overall Score Chi-square	Df	Sig.	Change from Prev. Step Chi-square	df	Sig.
775.122	**65.594**	**5**	**<0.0001**	**66.967**	**5**	**<0.0001**

*VHW = Village Health Worker. Model overall fit: −2 Log Likelihood = 775.122; Omnibus chi-square = 65.594, df = 5, p < 0.0001 (Table 40).

*Method = Enter (all five predictors entered simultaneously). The significant omnibus chi-square statistic (p < 0.0001) confirms that inclusion of the three community health system vital signs variables significantly improved model fit relative to the null model, validating the overall predictive relevance of the institutionalised vital signs framework.

5.7 Effect of the community health system on neonatal deaths

The flowchart (Figure 20) shows how components of the community health system institutionalisation interact to address key risk factors and ultimately reduce neonatal deaths. Risk ratios below 1 indicate a protective effect (intervention effectiveness), while those above 1 indicate elevated risk. Village Health Workers in the modified women's and men's learning and action groups (RR = 0.698) were associated with a 30.2% lower risk of neonatal death, alongside enhanced community access, improved health-seeking behaviour, and strengthened community–facility linkage, compared

with control areas. Newborns whose mothers were in the intervention group and were served by VHWs trained in newborn care (RR = 0.508) had a 49.2% lower risk of neonatal death. Pregnant women in the intervention group who initiated early antenatal care (RR = 0.325) had a 67.5% lower risk of neonatal death. In contrast, several factors were associated with elevated risk: low birth weight (RR = 5.422), birth interval of less than two years (RR = 4.022), and low community-level female literacy (RR = 4.333).

Read together, these estimates trace a temporal pathway: community health system components act on upstream risk factors, which in turn precede and influence the occurrence of neonatal death. The figure therefore depicts the sequence of events leading to the outcome, with the intervention components and risk factors operating prior to, and shaping the risk of, neonatal death.

5.7.1 Community System Strengthening Institutional Framework Components

In epidemiological studies of complex outcomes such as neonatal mortality, the adjusted risk ratio (ARR) is a key effect measure, allowing the independent effect of each exposure on neonatal death to be identified while controlling for confounding variables that could otherwise obscure the true relationship (Pourhoseingholi, Baghestani & Vahedi, 2012; Skelly, Dettori & Brodt, 2012). Adjusted risk ratios were estimated using multivariable log-binomial regression with a generalised linear model with a log link, and robust standard errors were applied where convergence difficulties arose. This approach provided adjusted estimates of the association between community health system risk factors and neonatal death in a setting where multiple interrelated influences operate.

Trained VHWs were strongly protective (ARR = 0.271; 95% CI: 0.16–0.38), corresponding to a 72.9% lower risk of neonatal death among newborns whose mothers participated in the modified women's and men's group action and learning meetings, compared with those whose mothers did not participate. The risk of neonatal death was also lower in communities with fully functional governance structures (ARR = 0.327; 95% CI: 0.21–0.45), a 67.3% reduction in risk for newborns whose mothers were exposed to the intervention relative to those who were not; this is consistent with

evidence that strengthened community governance supports neonatal survival (Riedel et al., 2020; Dwomoh, 2021; Björkman Nyqvist, von Carnap, Guariso & Svensson, 2025). Social networks were similarly protective (ARR = 0.336; 95% CI: 0.23–0.44), corresponding to a 66.4% lower risk of participating mothers' newborns compared with non-participants (Figure 21).

Community health system impact on neonatal death

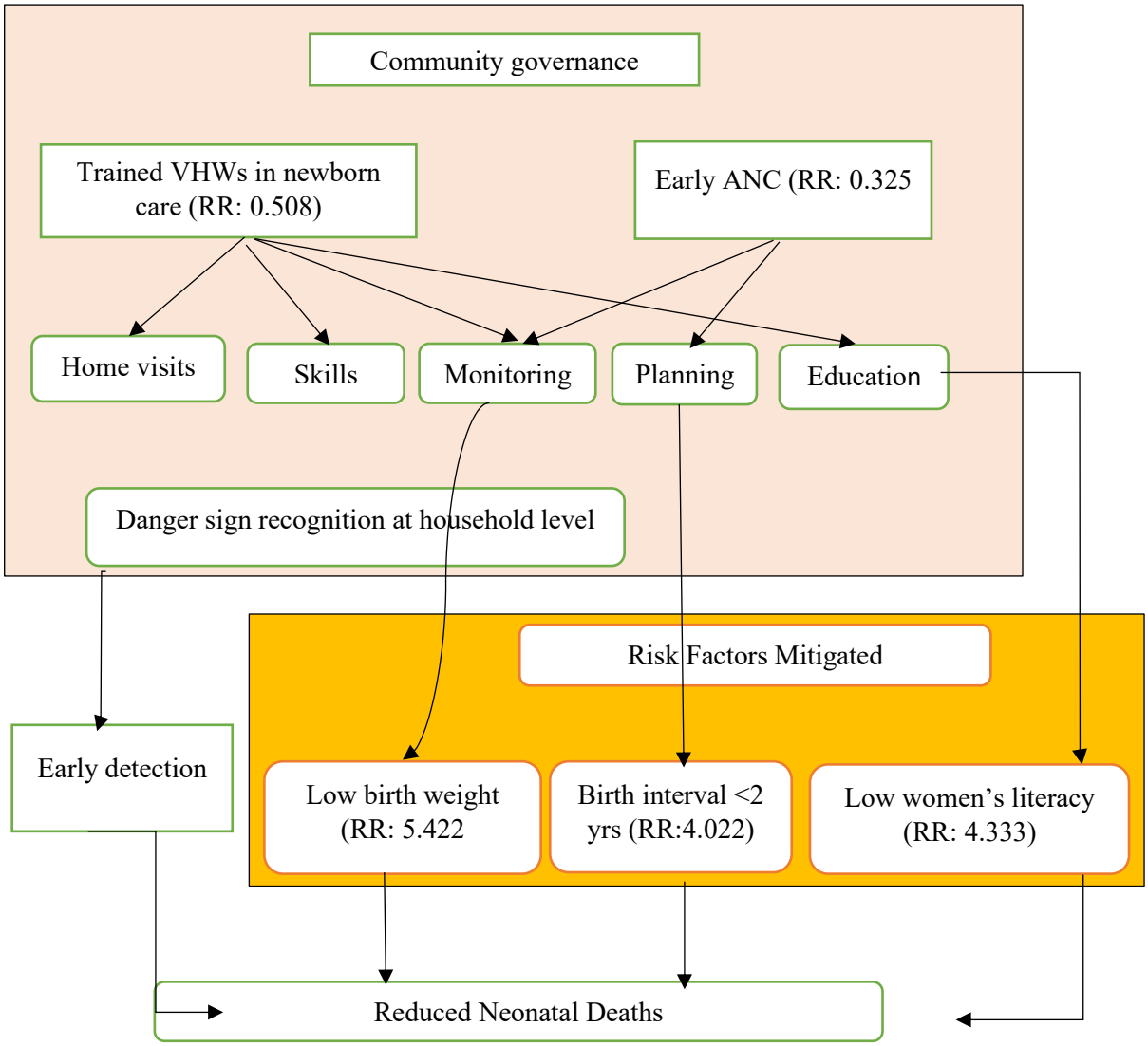


Figure 20: Temporal effect of the community health system on neonatal deaths, Mashonaland West province, 2020-2021

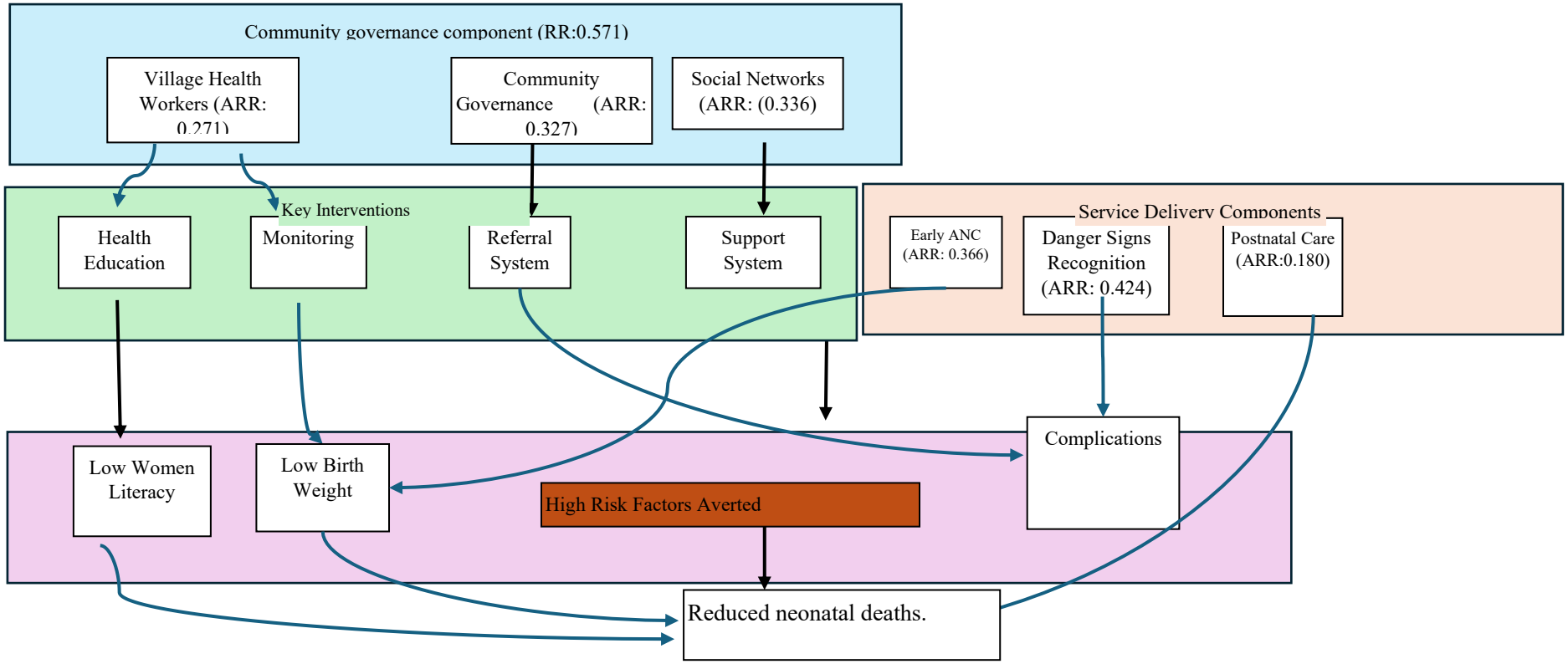


Figure 21: Community Health System Framework for Reducing Neonatal Deaths, Mashonaland West Province

Comparable protective effects were observed for community-based service delivery factors. Early antenatal care was associated with a 63.4% lower risk of neonatal death (ARR = 0.366; 95% CI: 0.27–0.46) and danger-sign recognition at the household level with a 57.6% lower risk (ARR = 0.424; 95% CI: 0.32–0.53). Skilled birth attendance was not significantly associated with a reduction in neonatal death (p = 0.366)

5.7.2 Pathway of institutionalising community health systems to reduce preventable neonatal deaths.

Viewed through a pragmatist philosophical lens, the findings describe a synergistic pathway in which the components of an institutionalised community health system reinforce one another rather than acting in isolation. Each component has an independent protective association with neonatal death, and institutionalisation's value lies in how these components connect into a coherent chain of detection, referral, and response.

At the front of this pathway, trained Village Health Workers (ARR = 0.271; 95% CI: 0.16–0.38) and early initiation of antenatal care (ARR = 0.366; 95% CI: 0.27–0.46) each substantially reduced neonatal death risk. Their effects are complementary: trained VHWs extend the health system's reach into the community and encourage timely care-seeking, while early antenatal contact brings women into the system sooner, creating earlier opportunities to identify and manage risk. Rather than estimating a single combined effect, these components are best understood as mutually reinforcing entry points that together strengthen the continuum of care.

Danger-sign recognition at the household level (ARR = 0.424; 95% CI: 0.32–0.53) operates further along the same pathway. Once VHWs are trained and women are engaged in antenatal care, households' ability to recognise danger signs enhances early detection of complications and prompts referral, linking community-level awareness to facility-based response. In this way, early engagement and household awareness act in sequence to shorten the interval between the onset of a complication and the receipt of appropriate care.

5.7.2.1 Pathways of Community Health System Institutionalization Impact

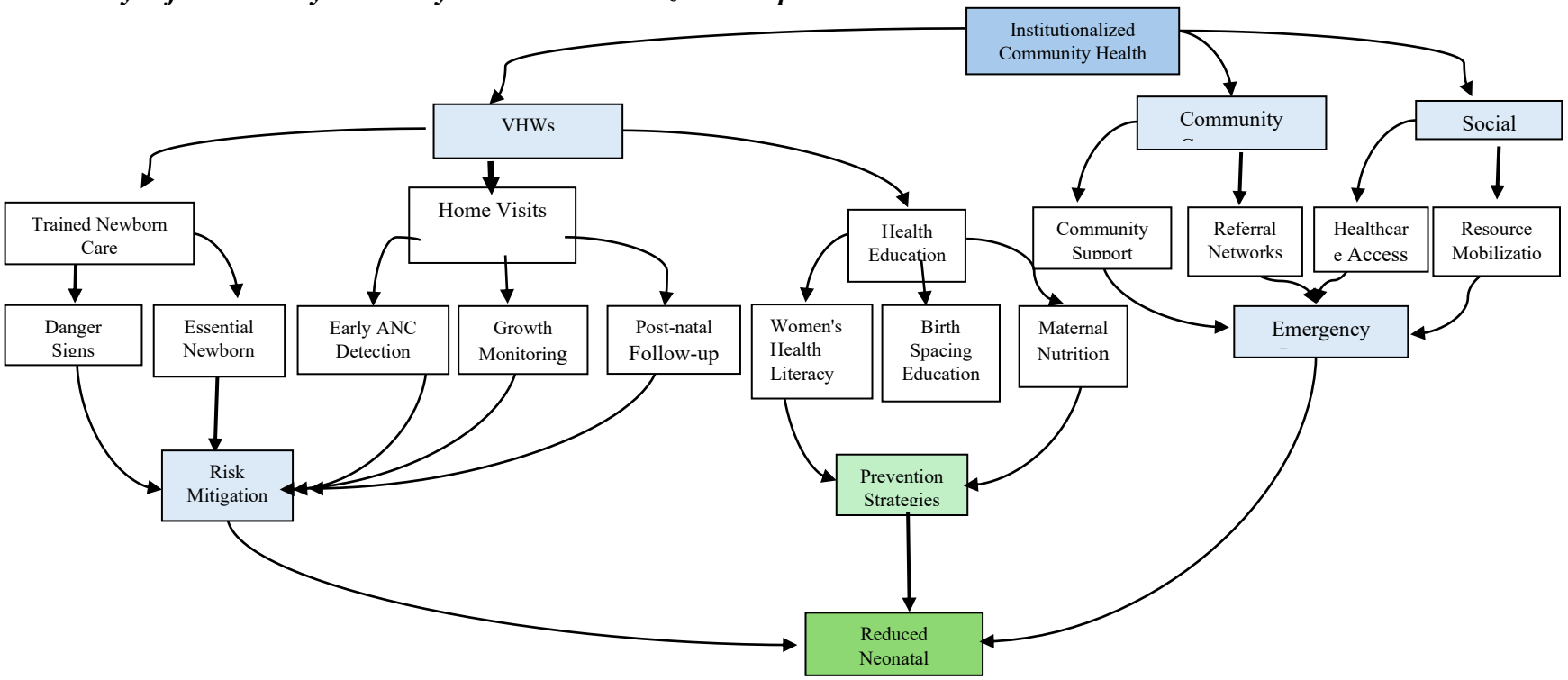


Figure 22: Pathway of institutionalising community health system for reducing preventable neonatal deaths, Mashonaland West province, 2020-2021

Finally, community integration effects illustrate the pragmatic value of social capital in health interventions. Social networks (ARR = 0.336; 95% CI: 0.23–0.44) and functional community governance (ARR = 0.327; 95% CI: 0.21–0.45) may strengthen community support systems, referral networks, access to care, and resource mobilisation. Together, these structures plausibly support a community emergency obstetric and newborn response, reinforcing the gains achieved earlier in the pathway and contributing to the reduction of preventable neonatal deaths.

5.7.3 Diagram of synergistic effects between community health system components

This section examines combinations of community health system components among women who participated in the modified women's and men's learning and action groups compared with those who did not. All estimates here derive from post-randomisation variation and are secondary, adjusted associations. The presence of trained VHWs in the community was associated with a lower risk of neonatal death (RR 0.698, a 30.2% lower risk), and early antenatal care attendance with a substantially lower risk (RR 0.325, 67.5% lower). Where both were present, the risk was lower than with either alone; the size of that joint association is estimated formally by the interaction term reported below, not by combining the two ratios.

Recognition of danger signs at household level was likewise associated with a lower risk of death (RR 0.327, 67.3% lower), and the joint presence of trained VHWs and household danger-sign recognition was associated with a lower risk than either alone.

Fully functional community governance structures (RR 0.571, 42.9% lower risk) and social networks (RR 0.412, 58.8% lower) were each associated with lower neonatal mortality among neonates whose mothers participated in the modified groups, and their joint presence with a lower risk than either alone. Communities with all three institutionalised components (full institutionalisation) had a 43% greater reduction in neonatal deaths than those with partial institutionalisation; this is an incremental comparison within the intervention arm and is distinct from the primary trial effect (see below). The combined effect of components was estimated formally using interaction terms within the three-level model (Table 41), not by multiplying component risk ratios.

Three interactions were statistically significant: VHW presence × birth interval <24 months (AOR 0.42; 95% CI 0.24–0.73; p = 0.002), VHW newborn-care training × early antenatal care (AOR 0.38; 95% CI 0.21–0.69; p = 0.001), and workforce × governance functionality (IV1 × IV2; β = −0.24, AOR 0.79; p = 0.03). Each indicates that the joint presence of the two components is associated with a greater reduction in the odds of neonatal death than either component independently; the IV1 × IV2 term is the evidence for super-additivity between the workforce and governance vital signs discussed in Section 6.2.2. These interaction estimates are the inferential basis for the combined-effect objective. Figure 24 summarises the component associations descriptively.

It is important to distinguish these quantities clearly, as they are sometimes conflated. The primary trial effect reported in this thesis is the intention-to-treat comparison of the full intervention arm against the control arm (ARR 0.43; 95% CI 0.26–0.70), corresponding to a 57% relative reduction in preventable neonatal deaths. This is a different estimand from the 43% figure, which denotes the incremental ("greater") reduction achieved by communities with full institutionalisation relative to those with only partial implementation, and from the component-specific risk ratios (for example, community governance RR: 0.571 and social networks RR: 0.412) that appear within the synergy diagrams as individual exposures rather than as the overall trial effect.

5.7.3.1 Key synergistic findings

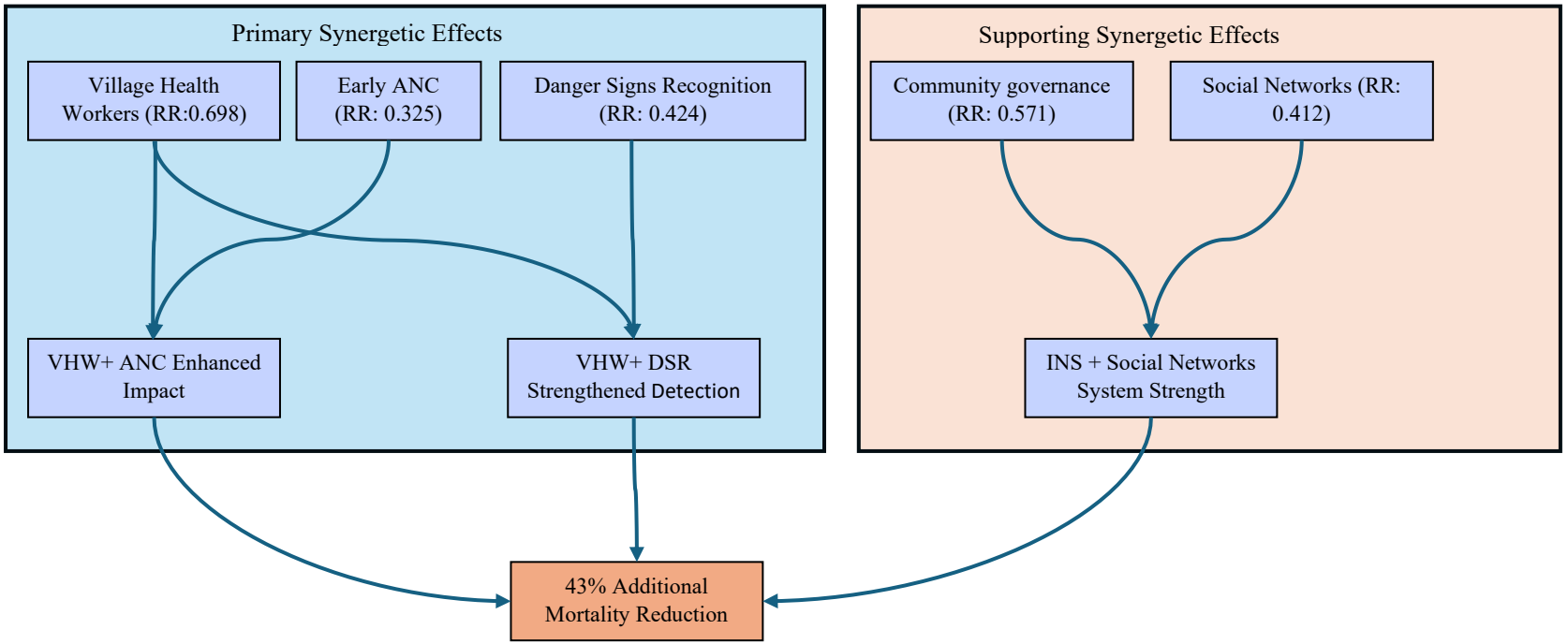


Figure 23: Diagram of synergistic effects between community health system components on reducing neonatal deaths, Mashonaland West Province, 2020 - 2021

*

*VHWs (Village health workers)

*DSR (Danger sign recognition at household level)

* INS (Institutionalisation of fully functional community governance structures plus social networks)

5.7.4 Multilevel Logistic Regression for predicting preventable neonatal deaths

The multilevel analysis uncovered significant hierarchical influences on neonatal mortality. Among neonatal characteristics, a birth weight less than 2,500 grams was associated with an increased likelihood of death (Adjusted Odds Ratio [AOR]: 1.76, 95% Confidence Interval [CI]: 0.86-3.61), even though this was not statistically significant. Regarding maternal factors, shorter birth intervals of less than 2 years were linked to notably higher odds of neonatal mortality (AOR: 3.58, 95% CI: 1.56-8.22) compared to longer intervals, while the number of children ever born also emerged as a significant predictor (AOR: 1.40, 95% CI: 1.22-1.60).

At the community level, the weighted three-level random intercept model indicated that low literacy rates among women in the community significantly elevated the odds of neonatal death (AOR = 2.35, 95% CI: 1.25-4.41). Conversely, newborns delivered in communities with Village Health Workers (VHWs) "had a 36% lower risk of neonatal death (AOR: 0.64, 95% CI: 0.44-0.94) compared to those without such support. Additionally, the presence of VHWs trained in newborn care was associated with a 49% reduction in the likelihood of neonatal death (AOR: 0.51, 95% CI: 0.33-0.77). Notably, household-level clustering explained 28.6% of the variation in Model 3.

In terms of model fit, Model 2 (which included two levels with covariates) provided a good fit, exhibiting the Akaike Information Criterion (AIC: 810.06) and Bayesian Information Criterion (BIC: 887.04) values when compared to the null model (AIC: 1362.00, BIC: 1375.36) and the three-level model (AIC: 856.27, BIC: 933.24). Model 4 (three Levels with covariates) provided the Optimal Fit. This model exhibits the lowest AIC (764.35) and BIC (866.88) among all models tested, indicating it provides the best balance between model fit and complexity.

The interaction terms in Table 41 are the formal test of combined effects. In Model 4, three interactions were statistically significant: VHW presence × birth interval <24 months (AOR 0.42; 95% CI 0.24–0.73; p = 0.002), VHW newborn-care training × early antenatal care (AOR 0.38; 95% CI 0.21–0.69; p = 0.001), and the workforce × governance term (IV1 × IV2; β = −0.24, AOR 0.79; p = 0.03), the last indicating that the association between VHW institutionalisation and neonatal survival was stronger in clusters with fully functional governance structures. Communities with all three

institutionalised components had a 43% greater reduction in neonatal deaths than those with partial institutionalisation, an incremental within-arm comparison distinct from the primary trial effect.

Table 41: Multilevel Logistic Regression for predicting preventable neonatal deaths through the community health system, Mashonaland West

Variable	Model 1	OR (95%CI)	Model 2	OR (95%CI)	p-value	Model 3	OR (95%CI)	p-value	Model 4	OR (95%CI)	*p*-value
Neonatal factors											
Birth weight											
>2,500g			Ref:1.00								
< 2,500g			1.76	(0.79, 3.67)	0.175	1.76	(0.86,3.61)	0.124	1.68	(0.82, 3.45)	0.156
Maternal factors											
Time between births											
< 2 years			3.05	(1.18, 7.88)	0.021	3.58	(1.56,8.22)	0.003	2.94	(1.28, 6.78)	0.011*
2 yrs 23 months			2.89	(1.41, 5.91)	0.004	3.08	(1.63,5.81)	0.001	2.77	(1.46, 5.24)	0.002*
4+ years			Ref:1.00			1.00(Ref)					
Community factors											
Community women's literacy											
Low			2.47	(1.27, 4.82)	0.008	2.73	(1.46,5.10)	0.002	2.35	(1.25, 4.41)	0.008*
VHW presence											
No			Ref:1.00			Ref:1.00			Ref:1.00		
Yes									0.64	(0.44, 0.94)	0.022*
VHW Trained in Newborn Care											
No			Ref:1.00			Ref:1.00			Ref:1.00		
Yes									0.51	(0.33, 0.77)	0.002*
VHW Home Visits											
No			Ref:1.00			Ref:1.00			Ref:1.00		
Yes									0.68	(0.48, 0.97)	0.035*
Interaction effects											
VHW Presence × Birth Interval <24m						Ref:1.00			0.42	(0.24, 0.73)	0.002*
VHW Training × Early ANC						Ref:1.00)			0.38	(0.21, 0.69)	0.001*
VHW/Workforce (IV1) × Governance functionality (IV2)						Ref:1.00			0.79	(0.63, 0.98)	0.030*
Service delivery factors											
Antenatal care											
No			Ref:1.00			Ref:1.00			Ref:1.00		
Yes			5.68	(2.90,11.91)	<0.0001	5.12	(2.69,9.76)	<0.0001	4.83	(2.53, 9.21)	<0.0001*

*Variables statistically significant at p-value < 0.05

Table 42: Weighted two and three-level random intercept logit model for predicting preventable neonatal deaths, Mashonaland West, 2020-2021

Variables	M1	M1-SE	M2	M2-SE	M3	M3-SE	M4	M4-SE
Random Effects Parameters								
Household variability (SE)							1.08	(0.64)
Community variability (SE)					4.31 × 10^-33	(4.34) × 10^-33	3.26 × 10^-33	(3.87) × 10^-33
Intercluster Correlation Coefficient								
ICC (Household) (%)	46.97		49.64		28.6		24.7	
Community level ICC (%)					9.35 × 10^-34		7.42 × 10^-34	
Model fit statistics								
AIC	1362.0		810.06		856.27		764.35	
BIC	1375.36		887.04		933.24		866.88	
-2 log likelihood	-679.0		-393.03		-440.77		-364.18	

***Model 1** = weighted two-level null model, Model 2 = Weighted two-level random intercept with covariates, Model 3 = Weighted three-level random intercept with covariates, Model 4 = Weighted three-level random intercept with VHW variables and interactions.

***M1** = Model 1; M2 = Model 2; M3 = Model 3; M4 = Model 4

***M1-SE** = Model 1- Standard Error; M2-SE = Model 2- Standard Error; M3-SE= Model 3- Standard Error; M4-SE= Model 4- Standard Error

***AIC** = Akaike Information Criterion
***BIC** = Bayesian Information Criterion

5.8. Qualitative Analysis: Structured Thematic Findings from Key Informant Interviews and Focus Group Discussions

Qualitative data were obtained from individual in-depth interviews, Key Informant Interviews (KIIs), and Focus Group Discussions (FGDs) conducted across all seven districts of Mashonaland West Province. All sessions were audio-recorded (except where not permitted by participants), transcribed verbatim, and, where necessary, translated into English. The analysis followed a systematic six-step process that integrated thematic content analysis and cross-thematic matrix construction, facilitated by NVivo 14 and supplemented with Stata 14 for descriptive summaries. Four major themes emerged from the iterative coding process (Table 43).

Table 43: Summary of Themes Emerging from Qualitative Analysis (NVivo-supported thematic content analysis)

Theme	Theme Title	Key Sub-Themes
1	Understanding of Institutionalisation of the Community Health System	Government ownership framing; RBF transition; service readiness and tools of trade
2	Availability Coverage of Community Health System Components	Post-NCHS 2020 investment; community governance functionality
3	Accessibility of Community Health Services	Physical access barriers; women's and men's learning and action groups as demand-creation platforms
4	Acceptability, Utilisation, and Effective Coverage	Demand creation by CHWs; community death audits; data-driven accountability

5.8.1 Theme 1: Understanding of Institutionalisation of the Community Health System

Sub-themes: Government ownership framing | RBF transition | Service readiness and tools of trade

Across national, provincial, and district participant levels, institutionalisation of the community health system was most described as government ownership and operational management of the programme. The cross-thematic matrix revealed a

recurrent pattern in which institutionalisation was conflated with two specific operational proxies: (a) the geographic coverage and incentivisation of Village Health Workers (VHWs), and (b) the transition of results-based financing (RBF) from donor to domestic government funding. Broader systemic components, including leadership, inter-ministerial coordination, community governance, and social accountability, were frequently underemphasised or absent from respondents' conceptual framings.

5.8.1.1 Sub-Theme 1.1: Government Ownership and Results-Based Financing Transition

National-level key informants consistently linked institutionalisation to the government's absorption of previously donor-funded programmes, particularly RBF mechanisms. This view was reinforced across the cross-thematic matrix as a dominant frame at the policy level, with respondents frequently using RBF domestication as the benchmark of government commitment:

> *"As you are aware, the government institutionalized the RBF that was initially funded by 'the World Bank' in 18 districts. Now 'hurumende yedu' — our government — is the one now paying for RBF implementation in those districts using domestic funding. The government can do the same for the payment of VHWs allowances so that they are not paid by donors."*
>
> **National Respondent (003), Female | KII**

A provincial-level respondent offered a critical counterpoint, highlighting systemic blind spots that have historically constrained Zimbabwe's community health system and underscoring the transformative potential of the NCHS 2020–2025 in reorienting national understanding:

> *"Since 1980, we have looked at community health from the perspective of VHWs and focused on training and geographical distribution mainly in rural areas. All our efforts were targeting that, forgetting the other aspects of the community health system. Sadly, that thinking has chronically*

> *affected the leadership, coordination, and implementation of community health. Actually, there are other critical aspects of the community system that have been silent for many years. It is good, our national Community Health Strategy is clear."*
>
> **Provincial Respondent (005), Male | KII**

Mixed-Methods Integration - Theme 1: These qualitative observations are consistent with the quantitative baseline, which found that district health supervisors reported no formal training on the community health programme, with sensitisation on the NCHS received only within the preceding 12 months. The narrow framing of institutionalisation among district key informants aligns with the quantitative finding that community governance structures (HCCs and VHCs) were only fully functional in 82.7% of intervention versus 34.3% of control areas ($\chi^2 = 48.7$, $p<0.0001$; Table 32), indicating that systemic components beyond VHW coverage remained underdeveloped at study commencement.

5.8.1.2 Sub-Theme 1.2: Service Readiness and Tools of Trade as Proxies for Institutionalisation

At the primary health care facility and community levels, institutionalisation was operationalised through tangible, immediate service-readiness indicators rather than through systemic governance or policy frameworks. VHWs and community health workers associated institutional strength with the reliable provision of essential medicines and equipment:

> *"As VHWs, we should be given the basic paracetamol and other medicines that we are expected to have so that we can help our community. Communities build trust in us when they come with a headache, and I give them paracetamol. Even a stat dose is fine, at least they get something while they plan to go to the clinic."*
>
> **Village Health Worker Peer Supervisor (006), Female | KII**

Mixed-Methods Integration - Sub-Theme 1.2: This frontline perspective is reflected in the quantitative service delivery data: while 100% of key informants acknowledged the provision of equipment for CHWs post-NCHS 2020, only 70% considered it adequate. Quantitatively, CHW interaction with mothers reached

96.0% in intervention areas compared to 73.4% in control areas (p<0.0001; Table 32), corroborating the community-level trust-building function described by VHW respondents.

5.8.2 Theme 2: Availability Coverage of Community Health System Components

Sub-themes: Post-NCHS 2020 investment | Community governance functionality gaps

The ratification of the National Community Health Strategy 2020–2025 (NCHS) was identified by respondents across all levels as a transformative policy catalyst. Key informants consistently described the NCHS as mobilising investment in community health components that had previously been deprioritised, including social accountability structures, community governance, digital health, and VHW coverage.

5.8.2.1 Sub-Theme 2.1: Post-NCHS 2020 Investment and Availability Improvements

> *"You know, social accountability and community engagement were not a priority for the health sector in the past, but now this has been included in the Mashonaland West Provincial Annual Workplan. The draft implementation guideline for the 'Social Accountability Framework in Health' was developed and tested in this province to inform large-scale implementation. To date, establishment or revitalisation of key community-level structures - ward development committees and village health committees, was completed thanks to the strategy."*
>
> **Provincial Respondent (005), Male | KII**

The following post-NCHS 2020 availability changes were confirmed across key informants and corroborated by quantitative data:

Table 44: Qualitative availability indicators and quantitative findings, Mashonaland West, 2020-2021

Availability Indicator	KI Confirmation (%)	Corresponding Quantitative Finding
Dedicated funding for underprioritised community health components	100%	Intervention arm: 97.1% WM-LA cycle participation; control arm: 0% cycles delivered, 12.6% any group attendance (p<0.0001)
Upskilling of existing VHWs / recruitment of new VHWs	100%	VHW newborn care training: 67.4% intervention vs 39.2% control (p<0.0001)
Government commitment to VHW allowances (incl. COVID risk)	80%	VHW home visits: 72.6% intervention vs 39.2% control (p<0.0001)
Equipment provision for CHWs	100% acknowledged (70% adequate)	Formal CHW contact: 96.0% intervention vs 73.4% control (p<0.0001)
Revitalisation of HCCs and VHCs	79%	Full HCC functionality: 100% KIs; Full VHC functionality: 60% Kis

5.8.2.2 Sub-Theme 2.2: Functionality of Community Governance Structures

While the NCHS catalysed revitalisation of community governance structures, key informants described uneven implementation, with HCCs receiving more intensive and sustained support than VHCs. A critical limitation of one-off capacity-building approaches was highlighted:

> *"Following the national community health strategy in 2020, we received funding from the ministry with support from health development partners to improve the capacity of HCCs to monitor the delivery of health care services against the MOHCC Patient Charter... The only weakness that is there is that this was a once-off support, and not all HCCs were reached... Most of them think their role is to hold nurses accountable to opening the clinic on time or monitor how results-based funds are being used. This has created tension in some of the areas."*
>
> **District Respondent (011), Female | KII**

Mixed-Methods Integration - Theme 2: The qualitative description of uneven governance revitalisation is strongly corroborated by quantitative data. Full functionality of community governance structures (HCCs/VHCs) was reported by 82.7% of women in intervention areas, compared with 34.3% in control areas ($\chi^2 = 48.7$, $p < 0.0001$). In the logistic regression model, non-fully functional community governance was independently associated with increased neonatal mortality (AOR 1.80; 95% CI: 1.50–2.16; p<0.0001), consistent with the structural significance of governance quality described by key informants. Governance functionality ranked 22nd in the Benjamini-Hochberg FDR-adjusted analysis (adjusted p=0.0007), indicating that its association with neonatal outcomes is robust to correction for multiple testing.

5.8.3 Theme 3: Accessibility of Community Health Services

Sub-themes: Physical and geographic barriers | WM-LA groups as demand-creation platforms | Male partner engagement

Improved accessibility of basic community health services was broadly acknowledged across participant strata, with integrated outreach, health posts, and the deployment of community health workers cited as primary enablers. However, significant and persistent barriers were simultaneously documented, particularly for geographically remote and socially marginalised populations.

5.8.3.1 Sub-Theme 3.1: Physical and Geographic Access Barriers

Community leaders and FGD participants described acute geographic isolation as a structural determinant of exclusion from health services. Communities more than 30 kilometres from the nearest health facility reported that health posts and integrated outreach represented not merely convenience, but the primary means of accessing maternal and newborn services:

> *"We welcome the idea of integrated outreaches and health posts. This will increase access to some of our communities. Here in this area, we are more than 38 kilometres from Chakari clinic. That is the nearest clinic. With this idea of health posts, we started to provide bricks from each household, and others are offering their skills to build, depending on the household. For us, we look at this initiative by the government as a hospital coming to the*

> *people, reaching all age groups, not just children, like what was happening in the past, where they were coming for EPI. The government should ensure that these integrated outreaches are equipped to register pregnant women for ANC, provide PNC for mothers who cannot go back to clinics that are very far away."*
>
> **Community Leader (002), Male | KII**

Persistent exclusion of artisanal mining communities and remote households was documented, with a community leader noting that home delivery persisted despite awareness campaigns and VHW support, reflecting the limits of community-level interventions in the absence of geographic access solutions:

> *"I think access is still very limited to most of the population in some areas. We have the artisanal miners in this community, who have no access at all. We have pregnant women and newborn babies who require services in communities but there is no clinic. We used to have vanaMbuya Nyamukuta (Traditional Birth Attendants), who used to help a lot for those mothers who delivered at home. That is why I am saying there are still people with no access."*
>
> **Community Leader (007), Female | KII**

Mixed-Methods Integration - Sub-Theme 3.1: Qualitative accounts of persistent home delivery align with quantitative data showing that 17.1% of births in intervention areas and 16.7% in control areas still occurred at home (Table 25). The quantitative finding that rural residence was independently associated with increased neonatal mortality (AOR 1.15; 95% CI: 1.03–1.29; p=0.008) is consistent with the structural access inequity described by community leaders.

5.8.3.2 Sub-Theme 3.2: Modified Women's and Men's Learning and Action Groups as Demand-Creation Platforms

The modified women's and men's learning and action (WM-LA) groups emerged across FGDs and KIIs as the central community-level mechanism for expanding demand for

maternal and newborn health services. Their village-level delivery model and inclusive design, incorporating male partners, were distinguished from prior community support group approaches:

> *"The fact that they are done within the village and allow both men and women to discuss issues about maternal, newborn and children's health was a welcome idea. In the past, these issues were left for women alone. We used to have support groups, but they did not help much as men were not involved. In our culture, men make decisions in the house, and if they do not understand these issues, women will still not do what they are told at the clinic. I participated in the meetings, and they were very helpful for me. My husband also participated, and we are helping each other. For example, I was naïve and not privy to the importance of naming a baby even before they are born. We tried it, and we developed an emotional connection with my pregnancy — the urge to protect the baby at any cost. So I booked my pregnancy early and attended all 8 antenatal care visits."*
>
> **Women of Childbearing Age (010), Female | FGD**

The district health management team corroborated the structural role of the NCHS in embedding CHW capacity for access to antenatal and postnatal care in underserved areas:

> *"Since 2020, the strategy seemed to strengthen the role of CHWs, ensuring that they are adequately trained and supported to provide essential services in communities. This can increase access to prenatal and post-natal care. Also, by expanding the network of health posts and integrated outreach programs, the strategy helped to reach underserved areas, improving the availability of newborn health services in hard-to-reach areas."* **District Health Management Team (013), Female | KII**

Mixed-Methods Integration - Sub-Theme 3.2: Quantitative data are consistent with the demand-creation effect described qualitatively. Participation in facilitated WM-LA learning cycles reached 97.1% (n=467) in intervention areas; no cycles were delivered in control areas, although 12.6% (n=62) of control women reported attending some community health group meeting (χ^2=20.1, p<0.0001; see Section 5.4.2 for the distinction). The qualitative account of early ANC booking following group participation is corroborated by significantly higher rates of early ANC initiation before 12 weeks in intervention areas (60.9% vs 42.7%; p<0.0001) and completion of ≥8 ANC contacts (54.3% vs 42.3%; p<0.0001). In the logistic regression model, early ANC was independently protective against neonatal mortality (AOR 0.36; 95% CI: 0.21–0.59; p<0.0001), and participation in fewer than three WM-LA group meetings was associated with a nearly fivefold increase in neonatal mortality risk (AOR 4.80; 95% CI: 1.95–11.80; p<0.0001).

A distinct gendered pattern in newborn care and feeding practices emerged from the qualitative findings. Across several focus group discussions with Women of Childbearing Age (WCBA) and interviews with Community Health Workers (CHWs), participants described a prevailing belief that male infants require more food and are less easily satisfied with breast milk alone. This perception frequently led to the early introduction of foods such as porridge for boys well before the recommended six months of exclusive breastfeeding.

One CHW explained:

> *"We often see mothers giving porridge to boys much earlier than girls because they say boys cannot be satisfied with breast milk alone."*
>
> **Community Health Worker (002), Female | FGD**

Similarly, a WCBA participant stated,

> *"Boys always cry for food; that's why we start them on porridge before they are six months. Sometimes we give porridge as early as 3 days after birth. The milk will be too little."*
>
> **Women of Childbearing Age (021), Female | FGD**

These practices were not typically reported for female infants, reflecting a gendered caregiving bias rooted in local norms. Such early introduction of prelacteal and complementary feeds for boys was understood by both WCBA and CHWs as a response to perceived greater hunger, but also recognised by some as potentially undermining optimal breastfeeding practices.

The qualitative account of the emotional bonding practice of naming a baby before birth as a proxy for care-seeking readiness is supported by a striking quantitative association: among neonatal deaths in intervention areas, 70.0% occurred in infants who had not been named, compared to 30.0% in named infants. In the regression model, absence of a baby name was independently associated with increased neonatal mortality (AOR 2.40; 95% CI: 1.52–3.78; p<0.0001), lending quantitative weight to the qualitative mechanism described by FGD participants.

5.8.4 Theme 4: Acceptability, Utilisation, and Effective Coverage

Sub-themes: CHW demand creation | Community governance and death audits | COVID-19 continuity

5.8.4.1 Sub-Theme 4.1: Community Health Worker Roles in Demand Creation and Behaviour Change

Community health workers were consistently described as the primary agents of demand creation for reproductive, maternal, newborn, and child health (RMNCH) services across KIIs and FGDs. Their multifunctional roles encompassed health promotion, early pregnancy registration, facilitation of informed decision-making, postnatal home visits, and education on danger signs. The WM-LA groups functioned as demand-creation platforms that reduced the burden on individual VHWs by mobilising wider community action:

> *"This intervention helped to ensure that the community is mobilised to uptake health services for children. They helped a lot, shifting the burden from the VHWs. Our people were afraid of COVID-19, but as you can see, they still delivered in clinics because of these meetings that were being done."*

District Health Management Team (024), Female | KII

Mixed-Methods Integration - Sub-Theme 4.1: The demand-creation function described qualitatively is consistent with the quantitative findings. Danger sign identification was significantly higher in intervention areas (69.4% vs 50.8%; p<0.0001), and VHW home visits were more than twice as common (72.6% vs 39.2%; p<0.0001). In the adjusted model, danger sign recognition was independently protective against neonatal mortality (AOR 0.35; 95% CI: 0.22–0.56; p<0.0001), and VHW home visits showed a corresponding protective effect (RR 0.31; 95% CI: 0.18–0.52; p<0.0001 in bivariate analysis). Cox regression also indicated that VHW training in newborn care was associated with a significantly lower hazard of neonatal death (HR=0.503, p<0.05).

5.8.4.2 Sub-Theme 4.2: Community Governance and Community-Based Death Audits

The qualitative analysis identified a shift in community governance capacity under the NCHS 2020–2025, with HCCs and VHCs oriented toward active accountability functions, including community-based maternal, neonatal, and perinatal death audits. Community leaders described this as a transition from passive oversight to active problem-solving and inter-agency coordination:

> *"As community leaders, it is our role to ensure that no mother or child dies in our community. We play a key role in supporting health activities by mobilising food for the clinics so that mothers can stay kumatumba (the waiting mother's home) and even organising transport when a pregnant woman needs to be rushed to the clinic. With this project, we have even started asking why babies are dying in our health facilities. These groups, when they do their meetings, come to us with their solutions, and we plan together. With time, I think we will improve the situation."*
>
> **Community Leader (004), Male | KII**

Mixed-Methods Integration - Sub-Theme 4.2: The qualitative narrative of evolving community accountability is underpinned by robust quantitative evidence. Fully functional community governance was reported by 82.7% of

women in intervention communities versus 34.3% in control communities ($p<0.0001$) and was independently associated with reduced neonatal mortality in the Cox regression model (fully functional governance: HR=0.073; $p<0.001$; non-functional: HR=1.097; $p>0.05$). Social networks — facilitated by WM-LA groups — were also independently protective (AOR 0.43; 95% CI: 0.28–0.66; $p<0.0001$). At least 4,128 VHWs, HCCs, and VHC members were oriented to data-driven decision-making, community monitoring, and the use of Community Scorecards, supporting the community accountability practices described by key informants.

5.8.6 Cross-Thematic Matrix: Comparison Across Participant Strata

A cross-thematic matrix was constructed within NVivo to systematically compare theme expression across participant strata (Sulton & Austin, 2015). This enabled identification of similarities and differences in perceptions, experiences, and practices across policy, district, and community levels. The cross-thematic matrix reveals a consistent pattern of conceptual narrowing as one moves from policy to community level: national and provincial informants articulate systemic and strategic framings of institutionalisation, while district managers focus on operational coverage proxies, and community participants ground institutionalisation in immediate, tangible service experiences. This gradient of understanding has direct implications for implementation coherence and helps contextualise the quantitative variation in governance functionality and service uptake observed across the study districts.

Table 45: Cross-Thematic Matrix: Participant Strata Comparison (NVivo, Mashonaland West KIIs and FGDs, 2020–2021)

Theme	National / Provincial KIs	District KIs (DHMT, LGA)	Community / VHW / FGD
1: Institutionalisation Understanding	Government ownership; RBF transition to domestic funding; NCHS as policy anchor	Geographic VHW coverage; equipment and training gaps; limited system-wide framing	Medicine availability; trust through tangible services; readiness at the household level
2: Availability Coverage	Policy investment case; NCHS as driver of funding; digital community health expansion	Funding receipt confirmed; structure revitalisation acknowledged but uneven	Structural functionality gaps; marginalised group representation concerns

3: Accessibility	Health posts; integrated outreaches; NCHS enabling framework	CHW network strengthening; referral system improvements in underserved areas	Severe geographic distance barriers; artisanal miner exclusion; home delivery persistence
4: Acceptability / Utilisation	WM-LA group endorsement; COVID-19 service continuity; community accountability	Demand creation by CHWs; ANC uptake improvement; danger sign training reach	Male engagement as a cultural shift; village savings integration; naming as an emotional bond

5.8.7 Mixed-Methods Integration: Synthesis of Qualitative and Quantitative Evidence

The qualitative thematic analysis provides explanatory depth for the quantitative findings reported in sections 5.2 to 5.6. The integration of qualitative and quantitative evidence follows the embedded QUAN (qual) design specified in Section 4.2: the trial findings are the primary strand, and the concurrent qualitative process evaluation explains mechanisms, implementation fidelity, and context, with the two strands integrated at the level of interpretation. Table 45 summarises the explicit linkages between qualitative themes, supporting quotations, and quantitative outcomes.

Table 46: Mixed-Methods Integration Matrix - Qualitative Themes and Quantitative Confirmation, Mashonaland West, 2020–2021

Qualitative Theme / Finding	Quantitative Confirmation	Statistical Evidence
Institutionalisation equated with VHW coverage; governance components underemphasised	Community governance is significantly less functional in control areas; governance associated with neonatal mortality	Governance: 82.7% vs 34.3% functional ($p<0.0001$); AOR 1.80 ($p<0.0001$)
NCHS 2020 catalysed VHW training and CHW deployment	VHW newborn care training and CHW contact are significantly higher in the intervention arm	CHW contact: 96.0% vs 73.4% ($p<0.0001$); VHW newborn training: 67.4% vs 39.2% ($p<0.0001$)
WM-LA groups shifted male engagement; enabled early ANC booking	Early ANC and ≥8 ANC contacts were significantly	Early ANC: 60.9% vs 42.7% ($p<0.0001$); ANC

	higher in the intervention arm	≥8: 54.3% vs 42.3% (p<0.0001)
Naming practice as emotional bonding linked to care-seeking readiness	Unnamed infants account for most neonatal deaths; naming was independently associated with mortality	AOR 2.40 (95% CI: 1.52–3.78; p<0.0001); 70% of neonatal deaths in unnamed infants
VHWs as danger sign educators and home visit providers	Danger sign recognition and VHW home visits are significantly higher in the intervention arm	Danger signs: 69.4% vs 50.8% (p<0.0001); AOR 0.35 (p<0.0001)
Community governance supporting death audits and community accountability	Cox regression: fully functional governance strongly protective against neonatal death	HR=0.073 (p<0.001); Social networks AOR 0.43 (p<0.0001)
COVID-19 did not interrupt service delivery due to community structures	Intervention fidelity maintained at 96.4% across 12-month trial; no temporal decline	Fidelity β=0.002, p=0.78; WM-LA meetings: 100% delivery vs 0% control

Collectively, the qualitative and quantitative strands of evidence converge on a coherent explanatory narrative: the institutionalisation of the community health system through the WM-LA intervention, trained VHWs, and functional community governance structures operate through identifiable behavioural and structural pathways: male engagement, early care-seeking, danger sign literacy, social network activation, and community accountability - that are quantitatively associated with significant reductions in neonatal mortality. The adjusted community-governance component risk ratio (RR: 0.571) and Cox regression hazard ratios (VHW: HR=0.698; governance: HR=0.073; WM-LA participation: HR=0.097) are statistical associations consistent with the mechanisms articulated by key informants and FGD participants across all four qualitative themes. Consistency between the strands does not itself establish these mechanisms as causal; alternative explanations, and the cases in which qualitative accounts diverged from the quantitative pattern, are considered in Chapter Six.

5.8.8 Note on Analytical Rigour and Reflexivity

To ensure trustworthiness, the research team engaged in repeated readings of transcripts and iterative discussion of emerging findings, with coding discrepancies resolved by consensus. Representative verbatim quotations were selected to preserve participant voice and enhance the credibility of the thematic analysis. NVivo was used for coding,

thematic analysis, and matrix development. Stata 14 was used to generate descriptive statistics on participant characteristics and to summarise qualitative findings where quantitative triangulation was appropriate. The convergent integration of both analytical strands ensures that neither qualitative depth nor quantitative precision is sacrificed in the presentation of findings.

5.9 Summary

Chapter 5 presented a comprehensive analysis of the impact of institutionalising key components of the community health system (Village Health Workers (VHWs), fully functional community governance structures, and modified Women's and Men's Learning and Action (WLA/MLA) groups) on reducing preventable neonatal deaths in Mashonaland West Province, Zimbabwe. Using a two-arm cluster randomised controlled trial, the study compared intervention and control communities, supported by both quantitative and qualitative data.

The chapter began with baseline demographic, socioeconomic, and household characteristics, confirming a good balance between trial arms. Primary and secondary outcome analyses demonstrated that institutionalisation of the three key components, individually and in combination, was associated with significant reductions in neonatal mortality at 28 days. Multivariate and multilevel regression models identified low birth weight, short birth intervals, and low community women's literacy as major risk factors, while early antenatal care, social networks, functional governance, and participation in WLA/MLA groups emerged as the strongest protective factors.

Predictive modelling, including machine learning classifiers and Cox regression, validated these findings and enabled scenario simulations that projected further mortality reductions under full implementation. The models achieved high classification accuracy and demonstrated that fully institutionalised community health systems could achieve substantial gains in neonatal survival.

Qualitative findings from key informant interviews and focus groups corroborated the quantitative results, highlighting improvements in service accessibility, governance, and demand creation, as well as operational challenges in implementation.

In summary, the chapter provides robust evidence that institutionalising VHWs, community governance, and participatory groups leads to measurable reductions in preventable neonatal deaths, with the greatest impact achieved when all components are implemented together. These findings directly address and fulfil all four study objectives, setting the stage for policy implications and recommendations discussed in the next chapter.

CHAPTER SIX

DISCUSSION OF RESULTS

6.1 Introduction

6.1.1 The interpretive paradox

The paradox that frames this thesis, high antenatal and facility-delivery coverage co-existing with persistently high neonatal mortality, is set out in Sections 1.3 and 2.6 and is not restated here. This chapter asks what the study's evidence contributes to resolving it.

The Critical Paradigm adopted in Chapter Three provides the interpretive lens: preventable neonatal deaths are read as the consequence of structural conditions, of how power and sustained investment are distributed within health systems, rather than as random biomedical events. The study's evidence is consistent with the proposition that the coverage paradox reflects a gap between nominal coverage (initial contact on the Tanahashi cascade) and effective coverage, and that functional governance is one of the conditions required to close it. Pragmatism, which governed the choice of design and methods in Chapter Four, is not in tension with this lens: the paradigm determines which questions are asked and how findings are read, while pragmatism determined how they were answered (Sections 3.2.6 and 4.1).

6.1.2 What this chapter argues

This chapter makes four analytical arguments, each grounded in a specific theoretical framework and integrated across quantitative and qualitative strands. First, the institutionalisation gap that characterises control clusters is not a resource failure but an institutional path dependency: four decades of VHW-centric thinking at the policy level have rendered governance and participatory structures structurally invisible, producing a Tanahashi availability tier without the subsequent cascade stages that

effective coverage requires (Sections 6.2.1 and 6.5.2). Second, the combined intervention package achieves a super-additive mortality reduction because the interaction between trained VHWs and functional governance creates the adaptive feedback loops that complex adaptive systems theory identifies as the mechanism of effective coverage, which is the highest Tanahashi tier (Sections 6.2, 6.5.5). Third, consistent with the Socio-Ecological Model, community structural and social variables emerge as independent and substantial predictors of neonatal mortality alongside individual biological variables — a finding that has direct implications for where health system investment should be directed: toward governance, workforce, and community-system infrastructure as a complement to, not merely a downstream support for, clinical protocol optimisation (Section 6.2.4, 6.4). Fourth, the protective effect of the modified women's and men's groups (IV3) is dose-dependent: significant at adequate exposure (≥4 cycles) but attenuated below it, a pattern consistent with the Socio-Ecological Model's prediction that cumulative normative change at the interpersonal and community levels is required before participatory interventions register on mortality (Sections 6.2.1, 6.5.6).

6.1.3 A note on interpretation

Statistical terminology used throughout this chapter follows consistent conventions. The Adjusted Risk Ratio (ARR), derived from the three-level mixed-effects log-binomial regression model (with Poisson regression with robust standard errors used only where the log-binomial model failed to converge), is the primary effect measure for binary outcomes in the cluster-randomised design. Adjusted Odds Ratios (AOR) are reported from logistic regression models for secondary binary outcomes. Hazard Ratios (HR) are from Cox proportional-hazards regression for time-to-event analyses. β-coefficients are log-scale parameters and are not interpreted as percentage changes. Model performance metrics (accuracy, sensitivity, specificity, AUC) describe classification performance, not causal effects, and are interpreted accordingly. Throughout, the distinction between statistical association and causal inference is explicitly maintained: the cRCT design provides the basis for causal attribution of the primary outcome; regression and machine learning analyses provide evidence of association and predictive importance, not causation. All quantitative findings are

cross-referenced to Chapter Five; no new statistics are introduced in this chapter, and qualitative findings are also used to explain and contextualise quantitative patterns, thereby grounding statistical associations in participant experience and programmatic reality and strengthening the plausibility of causal claims beyond what randomisation alone can establish.

6.2 Interpretation of principal findings

Two kinds of evidence are interpreted in this chapter and are kept distinct throughout. The randomised comparison of the intervention arm with the control arm (Section 5.3.1) estimates the causal effect of the complete package of IV1, IV2 and IV3 delivered together; it is the only finding in this thesis to which causal language is applied without qualification. Every component-level finding, including the independent associations of IV1, IV2 and IV3 with mortality (Section 6.2.1), the fidelity strata and the IV3 dose-response (Sections 6.2.2 and 6.5.6), and the interaction terms (Section 6.2.2), derives from post-randomisation variation within the trial population and is an adjusted association. Where the text below uses the words 'effect' or 'protective' of a single component, it does so in that sense. Because the components were not separately randomised, the study cannot show that any one of them is individually necessary, only that the package as delivered reduced mortality and that the pattern of associations is consistent with each component contributing.

6.2.1 Independent predictive associations of IV1, IV2, and IV3

The operational definitions of institutionalisation, fully functional community governance, community women's literacy and danger-sign recognition capacity used in this chapter are those given in Sections 3.6 and 3.7 and are not repeated here.

Village Health Workers with essential newborn care training (IV1)

The evidence robustly supports rejecting the null hypothesis for independent variable 1 (presence of village health workers trained in essential newborn care in the community - IV1). Analysed independently within the multilevel framework, the absence of trained VHWs was associated with a significantly higher odds of neonatal death (Chapter 5,

Table 32 - **Community health system predictors of neonatal deaths**), a finding confirmed across both regression specifications (Chapter 5, Section 5.5.2). The Mosley and Chen (1984) proximate determinant framework provides the most precise mechanistic interpretation of this finding. Within that framework, trained VHWs operate as a proximate mediator of neonatal survival through two specific pathways. First, by building danger-sign recognition capacity among caregivers, VHWs reduce the *first* delay in deciding to seek care, because households that can identify at least five of the seven WHO danger signs are functionally equipped to translate biological warning signals into health-seeking decisions.

Second, by mobilising community transport networks and activating referral chains, VHWs partially address the *second delay* – that of reaching a facility within a survivable window. The Cox regression finding that the survival benefit associated with VHW training is detectable within Day 3 of life (Chapter 5, Section 5.6.5), precisely the first postnatal home-visit window, provides temporal specificity consistent with this mechanism: the benefit appears at the moment of first VHW contact, not earlier, and not later.

What the IV1 evidence does *not* establish is VHW effectiveness against the third delay - receiving adequate care at the facility. This gap is analytically important. VHWs who successfully mobilise care-seeking in communities 30–38 kilometres from the nearest clinic depend entirely on facility readiness upon arrival. The qualitative evidence (Section 5.8) documents facility-level supply failures and governance gaps that can nullify VHW-enabled care-seeking. The Mosley and Chen framework, therefore, directs attention not only to the community-level mechanism but to the facility-level conditions that must exist for that mechanism to produce a survival benefit. This is a research and policy finding: training VHWs without simultaneously ensuring facility readiness and governance accountability addresses the first and second delays while leaving the third unresolved.

A formal mediation analysis decomposing the IV1 mortality effect into its delay-specific components (quantifying the proportion attributable to danger-sign education (first delay), transport mobilisation (second delay), and facility-readiness interaction (third delay)) was not conducted within this study's design. Such decomposition is a methodological priority for the three-to-five-year longitudinal follow-up study

recommended in Section 6.7.4 and would permit a more precise specification of the VHW investment strategy most likely to produce mortality benefits under specific geographic and facility-readiness conditions.

Functional community governance structures (IV2)

The evidence robustly supports rejecting the null hypothesis for IV2. The absence of functional governance was independently associated with a substantially increased risk of neonatal mortality (Chapter 5, Table 34 on predictive model using multiple logistic regression for community health systems aimed at reducing preventable neonatal mortality), and the Cox regression confirmed a 92.7% hazard reduction associated with functional governance (Chapter 5, Section 5.6.5). This is the largest effect size in the study, and it demands a theoretical explanation rather than mere reporting.

The Tanahashi Framework (1978) provides the most analytically precise interpretive lens. The framework's coverage cascade moves from availability through accessibility, acceptability, and initial contact to *effective coverage*, defined not as the presence of services but as the demonstrable quality of care that produces health outcomes. Quantitative evidence establishes that functional governance is the structural mechanism by which communities achieve effective coverage. Community-based death audits, documented in the qualitative strand (Section 6.5.5), transform adverse events from private losses into public accountability processes, creating the feedback loops between community experience and institutional practice that effective coverage requires. Interface meetings between health centre committees (HCCs), village health committees (VHCs) and facility staff extend those feedback loops to the institutional SEM level, enabling real-time course correction.

The Critical Paradigm frames the consequences of governance non-functionality in terms of structural justice. Communities without functional governance do not merely lack a programme component; they lack the *mechanism through which structural health system failures are made visible and corrected*. Every preventable neonatal death in a cluster without functional governance is a death that a structural choice, the historical decision to invest in VHW training while neglecting the governance architecture in which VHWs operate, has made more likely. The magnitude of the

governance effect (Chapter 5, Section 5.6.5) is the quantitative signature of four decades of that structural choice.

Modified Women's and Men's Learning and Action groups (IV3)

The modified women's and men's learning and action groups (IV3) were independently and significantly associated with reduced neonatal mortality, with the effect concentrated among participants who attended sufficient cycles of meetings. In the adjusted multiple logistic regression model, exposure at the pre-specified threshold of four or more cycles (approximately fourteen meetings) was associated with a 29% reduction in the odds of neonatal death (AOR 0.71; 95% CI 0.60–0.85; $p = 0.001$; Chapter 5, Table 34). The unadjusted association was of similar magnitude (RR 0.29; 95% CI 0.17–0.51; $p < 0.0001$; Chapter 5, Table 32), and the estimate remained stable after adjustment for individual, household, and community covariates, indicating that the protective association is not an artefact of confounding by the demographic or clinical profile of attenders. The evidence, therefore, supports rejecting the null hypothesis for IV3, while locating its effect in exposure intensity: benefit was conditional on sustained participation rather than on assignment alone, which is precisely the pattern a cumulative, participatory social-change mechanism would generate.

The concentration of the effect at an adequate dose, alongside its attenuation at low exposure, is theoretically expected rather than anomalous, and the Critical Paradigm requires that this dose dependence be theorised rather than merely reported. Two data-grounded considerations explain why the benefit accrued chiefly above the exposure threshold. First, participatory social change operates through a multi-stage causal chain. Rogers' (2003) diffusion of innovations theory and Fleming *et al.'s* (2016) participatory learning research established that normative change at the interpersonal and community SEM levels (precisely the levels at which WLA/MLA groups operate) requires repeated, cumulative exposure before it translates into individual behavioural change and, in turn, into measurable effects on biological outcomes. A small number of cycles is insufficient to traverse this chain; only sustained attendance (≥4 cycles) delivers the exposure intensity the mechanism requires, which is what the dose-response estimate

captures. Second, COVID-19 restrictions prevented 25.7% of participants from completing the recommended meeting cycles, disproportionately attenuating IV3's exposure intensity while VHW home visits proved more adaptable to pandemic conditions; the pandemic therefore compressed exposure for many participants below the threshold at which the groups become effective, making the dose-response analysis the more faithful estimate of the intervention's effect when delivered as intended. These considerations are grounded in the fidelity data (Chapter 5, Table 29: NIH BCC Fidelity Framework by trial arm) rather than asserted post hoc.

The qualitative strand corroborates this mechanism and clarifies how the groups achieved their effect. Key Informant Interviews and Focus Group Discussions document the intermediate-level changes that the SEM predicts should precede a mortality effect—restructured household decision-making through male partner engagement, increased recognition of danger signs, and sustained health-seeking under COVID-19 conditions (Section 6.5.4). The convergence of the quantitative dose-response estimate with these qualitative accounts generates a meta-inference that neither strand alone could produce: *IV3 reduced neonatal mortality by shifting community and household norms, and it did so to a measurable degree once participation was sustained, moving the finding beyond statistical association toward an explanation of the pathway through which the intervention operated.* Future per-protocol sensitivity analyses restricted to participants completing ≥4 meeting cycles (about 12 meetings) and COVID-unaffected clusters, and a three-to-five-year longitudinal follow-up, are the research priority.

6.2.2 Magnitude of Individual and Combined Predictive Effects (Objective Two)

The central finding of Objective Two is that communities receiving all three components simultaneously experienced a 57% relative reduction (ARR 0.43; 95% CI 0.26–0.70) in preventable neonatal deaths compared to control clusters (Section 5.7.3: **Diagram of synergistic effects between community health system components**, Figure 26). The primary cRCT result is derived from the three-level mixed-effects log-binomial regression model, adjusted for the pre-specified covariates of birth weight, birth interval, maternal age, community governance functionality, and socioeconomic

status, consistent with the ICH E9(R1) estimand framework. Its interpretation is as follows: in communities with the full intervention package, the risk of preventable neonatal death was estimated to be 57% lower than in control communities (ARR 0.43; 95% CI 0.26–0.70; Chapter 5, Section 5.3.1), after adjusting for the specified covariates and within-cluster correlation. The claim is a conditional average treatment effect, not a population-level prediction.

The claim that the combined effect is *synergistic*, exceeding additive predictions, requires the methodological transparency this section provides. 'Synergy' is used in the sense of super-additivity: the combined package effect exceeded what multiplication of independent component ARRs would predict. The formal test, a statistically significant interaction term between IV1 and IV2 in the three-level mixed-effects model (Chapter 5, Table 41, interaction terms) provides the empirical basis for this claim. The interaction coefficient indicates that the joint presence of trained VHWs and functional governance yielded a mortality-rate ratio lower than that of either component alone. IV3 did not contribute to a statistically significant interaction term in the primary model; its protective effect operated directly and dose-dependently rather than through a multiplicative interaction with the other components.

Complex adaptive systems (CAS) theory provides the theoretical explanation for super-additivity that the empirical finding demands. Blanchet *et al.* (2017) and Hawe *et al.* (2009) argue that health system components exhibit non-linear effects when embedded within governance structures, as governance creates *adaptive feedback loops* that amplify the effectiveness of individual components. In this study, trained VHWs embedded in communities governed by functional, death-audit-conducting VHCs are qualitatively and quantitatively distinct from VHWs operating without governance oversight: the governance structure identifies coverage failures, routes feedback to VHWs and facility managers and enables real-time course correction. The result is a self-reinforcing system rather than two independent components—and self-reinforcing systems produce effects that exceed the sum of their parts. The IV1 × IV2 interaction is the statistical signature of this adaptive feedback mechanism.

The 57% reduction compares with 30% in the Manandhar *et al.* (2004) trial in Nepal, 32% in Tripathy *et al.* (2010) in India, and 22% in Lewycka *et al.* (2013) in Malawi. These comparisons are observational and cross-trial; differences in effect magnitudes

may reflect population heterogeneity, design variations, follow-up durations, and exposure intensity rather than intervention superiority. However, the consistent pattern across comparator trials is that all three tested participatory women's groups without the governance component (IV2), which this study theorises as the mechanism for achieving Tanahashi's effective coverage. If the Tanahashi interpretation is correct, the addition of functional governance converts a community mobilisation intervention into a system that can monitor, audit, and adapt coverage—advancing communities from initial contact to the effective coverage tier. This theoretical explanation for the differential effect size is a specific, testable hypothesis for future comparative research, not a confirmed causal claim. In addition, this study also modified the women's groups to include men in discussions around maternal, newborn and child health, thereby addressing gendered dynamics and barriers.

Communities were classified as 'fully institutionalised' if they received all three components with fidelity scores ≥80% - a threshold pre-specified in the trial protocol, Protocol Version 2, 2021, Section 4.2.1.3a) and as 'partially institutionalised' if one or two components met this threshold. Under full institutionalisation, the estimated mortality reduction fell substantially, consistent with the CAS prediction that feedback loops require structural completeness to generate adaptive effects. A governance structure without trained VHWs has no frontline workers to audit; trained VHWs without governance accountability have no feedback mechanism. The interdependence is functional, not merely additive.

One methodological boundary of the CAS interpretation requires acknowledgement: the statistically significant IV1 × IV2 interaction term establishes that the joint presence of trained VHWs and functional governance produces a super-additive effect, but it cannot resolve the directionality of the feedback mechanism. CAS theory permits bidirectionality (governance structures may improve VHW performance by providing accountability structures and coverage intelligence, and, simultaneously, high-performing VHWs may provide the household-level data that enable governance death audits to function effectively). The trial design, which randomised the package rather than the components independently, cannot disentangle these pathways. A factorial design (randomising IV1 and IV2 independently across four study arms) would be

required to resolve directionality. This is identified as a design priority for future cluster-randomised work in community health systems with governance components.

6.2.3 Predictive modelling and simulation projections

Objective Three required the development and scenario-based simulation of a predictive model for neonatal mortality under conditions of full, partial, and non-institutionalisation. Before interpreting the model, its epistemological status must be stated precisely: the best-fitting multilevel model (Model 4, weighted three-level random-intercept logistic regression with VHW-by-ANC interaction terms) is a *predictive classification tool, not a causal estimator*. Model selection on AIC and BIC criteria (Chapter 5, Table 40: Multilevel logistic regression for predicting preventable neonatal deaths through the community health system) identifies the specification that best balances predictive fit, but does not establish that the included variables cause neonatal death. Causal inference rests on the cRCT design; the model's function is programme targeting and hypothesis generation.

The three-level model structure is not arbitrary: it maps directly onto the Socio-Ecological Model's nested ecological levels specified in Chapter Three. The individual level captures maternal and neonatal proximate determinants consistent with the Mosley and Chen framework (low birth weight, birth interval, maternal age). The cluster level captures SEM community and institutional variables (VHW training status, governance functionality, WLA/MLA attendance, danger-sign recognition capacity). The district random intercept captures policy-level unmeasured heterogeneity in the SEM. Making this correspondence explicit shows that Model 4 is not a data-fitting exercise but a theoretically derived specification, strengthening the interpretive basis for simulation.

The inclusion of the VHW-by-ANC interaction term in Model 4 reflects a specific theoretical prediction derived from the Socio-Ecological Model: an institutional-level intervention (VHW deployment) whose effect on individual-level outcomes is moderated by individual-level behaviour (timing of ANC booking). The theoretical mechanism is as follows: VHWs who engage with mothers in the first trimester establish a sustained relationship across all eight recommended ANC contacts, enabling

a more complete household risk profile, earlier identification of danger signs, and stronger trust, which reduces first-delay behaviour during obstetric emergencies. This interaction is theoretically mandated by the SEM's cross-level prediction and is consistent with the general literature on continuity of care as a moderator of community health worker effectiveness (Bhutta *et al.,* 2010).

The simulation projections should be understood as model-based extrapolations, not trial-derived causal estimates. Under full institutionalisation—one trained VHW per 100 households, functional governance in all wards, and WLA/MLA groups achieving ≥80% community coverage—the model projects a 38–49% reduction in neonatal mortality (point estimate and 95% prediction interval). Under partial institutionalisation, the projection falls to 18–27%. These ranges correspond to specific institutional conditions, not abstract scenarios. Full institutionalisation requires the governance meeting frequency threshold (≥monthly, with documented outputs) and the VHW fidelity threshold (≥80% of protocol-specified home visits completed), as established in the trial protocol. Planners using these projections should map their districts against these specific operational standards before adopting the estimates as targets.

Event-per-variable constraints are relevant to model interpretation. 'With 68 death events and 4 main predictors in Model 4, the event-per-variable ratio is approximately 17, above the acceptable conventional minimum threshold of 10–15 events per variable recommended by Peduzzi *et al.* (1996). The relatively small difference between training and test accuracy (86.1% vs 84.3%) is reassuring but does not eliminate the risk of overfitting. External validation on an independent dataset, from a comparable LMIC province with similar NMR, VHW infrastructure, and a rural profile, is required before Model 4 is used for individual risk scoring in programme settings. The implementation pathway requires: (1) external validation; (2) calibration against a local decision threshold using decision curve analysis; (3) cluster-stratified cross-validation to account for within-cluster correlation in performance metrics; and (4) ethical review of individual-level risk-scoring before integration into household enumeration registers.

6.2.4 Strongest Predictors and Policy Implications

The most theoretically significant finding of Objective Four is not which individual variables are associated with neonatal mortality, but the demonstration that community structural and social variables retain strong, independent associations with neonatal outcomes after adjustment for individual biological risk factors. In the multivariable model (Table 33), low community women's literacy was among the strongest predictors in the entire model (AOR 4.05; 95% CI 3.18–5.16; $p < 0.0001$), of comparable magnitude to the strongest biological predictor, low birth weight (AOR 5.10; 95% CI 3.98–6.54; $p < 0.0001$), and exceeding established biological risk factors such as birth interval less than two years (AOR 3.85; 95% CI 3.22–4.60) and complications during pregnancy or delivery (AOR 2.75; 95% CI 2.29–3.31). Non-functional community governance (AOR 1.80; 95% CI 1.50–2.16) and absence of social networks (protective AOR 0.43; 95% CI 0.28–0.66) likewise remained significant after adjustment. That structural variables persist at this magnitude alongside, rather than beneath, biological proximate determinants is the substantive result.

This ordering carries direct programmatic weight when read together with the synergy analysis (Section 5.7.3.1). The model-derived interaction terms in Table 41 indicate that VHW presence combined with early antenatal care (AOR 0.38), VHW presence with a short birth interval (AOR 0.42), and workforce with functional governance (IV1 × IV2; AOR 0.79) were each associated with lower odds of neonatal death than either component alone. Communities in which all three components were institutionalised showed a 43% greater reduction in neonatal mortality than those with partial institutionalisation, an incremental comparison within the intervention arm. These are gains generated by the community system itself (its workforce, governance, and social infrastructure) rather than by any single clinical input.

In the standard Mosley and Chen framing, biological proximate determinants are the primary target of intervention, with distal structural variables treated as important but secondary. The evidence from this study qualifies that hierarchy: community structural variables independently predict neonatal outcomes over and above individual biological risk factors, and their effects are amplified when delivered as an integrated system. This suggests that governance and workforce investment can produce mortality reductions that clinical low-birth-weight protocols, operating without community system infrastructure, are unlikely to achieve on their own.

The three strongest risk predictors, short birth interval (<24 months), low birth weight (<2,500g), and low cluster-level women's literacy demand interpretation through the Mosley and Chen proximate determinant pathway, not merely citation. Short birth interval operates through maternal depletion (nutritional and physiological) that elevates preterm birth and intrauterine growth restriction risk—both proximate determinants of neonatal death in the Mosley and Chen framework. Low birth weight is itself a proximate determinant, but its structural precursor is the pathway through which distal poverty and maternal malnutrition translate into compromised fetal growth: LBW is therefore simultaneously an outcome of structural deprivation and a proximate cause of neonatal death. Low women's literacy operates through multiple proximate pathways: reduced danger-sign recognition (decreasing the probability of deciding to seek care (first delay), reduced ANC uptake (removing the antenatal clinical contact window), and reduced capacity to navigate the health system once at the facility. The Tanahashi cascade maps this pathway precisely: low literacy suppresses acceptability and initial contact coverage regardless of what is available at the facility.

These three predictors are not independent: they co-cluster in specific communities. The Critical Paradigm demands that this co-clustering be termed structural rather than coincidental. Short birth intervals, LBW, and low women's literacy are not individually distributed across Mashonaland West: they concentrate in the same remote, low-income communities that also lack functional governance and VHW coverage. This intersection is the spatial signature of structural deprivation: decades of resource allocation that directed health infrastructure investment toward accessible communities and facility-based services while systematically under-investing in community-level governance, workforce, and social infrastructure. The study's predictive model identifies these communities; the study's policy argument is that they require differentiated, redistributive investment strategies rather than universal service expansion.

The distinction between predictors addressable through community health systems and those requiring intersectoral action is a policy-analytical obligation this discussion points towards. Danger-sign recognition, ANC timing, and WLA/MLA engagement are all modifiable through the institutionalised package tested in this trial. Short birth interval reduction requires functional family planning services, including long-acting

reversible contraception, beyond the scope of the community health system alone. LBW prevention requires nutritional supplementation programmes, investment in adolescent health, and management of obstetric complications at the facility level. Women's literacy is an educational sector outcome that community health interventions can partially proxy (through WLA/MLA literacy activities) but cannot structurally address without intersectoral partnership. Community health system investment is necessary but not sufficient to eliminate the burden of predictors; it is sufficient to achieve the 38–49% mortality reduction demonstrated by the evidence.

Male infants faced significantly higher neonatal mortality than females in both arms (Chapter 5, Section 5.5.4). The biological evidence base for male vulnerability is established: male neonates have greater susceptibility to intrapartum complications, respiratory distress syndrome, and sepsis (Drevenstedt *et al.,* 2008; Aghai *et al.,* 2020). However, the qualitative evidence from this study's Focus Group Discussions documents a cultural practice in which early supplemental feeding of male infants, in some cases starting as early as day three, may amplify biological vulnerability through a social mechanism (Section 6.5.4). At the SEM intrapersonal level, this reflects a belief (that male infants require more food); at the interpersonal level, it reflects a socially enforced norm (mothers are instructed by family members to introduce porridge early for boys). If this norm disrupts exclusive breastfeeding, it elevates neonatal infection risk through a Mosley and Chen illness-control pathway. The study did not measure prelacteal feeding rates by infant sex, so this remains a hypothesis requiring quantitative corroboration. It is presented as a hypothesis-generating finding grounded in participant accounts from this study, not as a confirmed causal explanation.

6.3 The multivariable community health system prediction model

The CHS prediction model integrates structural institutionalisation variables (IV1, IV2, IV3) with individual-level biological and socioeconomic covariates within the multilevel logistic regression framework described in Chapter Five. Two epistemic boundaries govern this entire section. First, the model is a *predictive classification tool*: given a set of community and individual characteristics, it estimates the probability of neonatal death. It does not establish that any variable causes neonatal death; causal

inference rests on the cRCT design and the primary ARR estimates. Second, all performance metrics reported below (accuracy, sensitivity, specificity, AUC) are from internal cross-validation within the Mashonaland West dataset and have not been externally validated. They describe how well the model classifies observations within this dataset, not how well it would perform in a new setting.

Model performance on the held-out test set achieved overall accuracy of 84.3%, sensitivity (detection of neonatal deaths) of 84.2%, specificity (correct identification of survivors) of 91.3%, and AUC of 0.843 (Chapter 5, Section 5.3). Three substantive interpretive observations follow from these metrics, each with a caveat that constrains its policy application.

The high specificity of 91.3% is the metric with the most direct resource-allocation implication in constrained settings. If 91.3% of surviving neonates are correctly classified as low risk, the model reduces unnecessary intensive community follow-up and concentrates VHW home-visit resources on the 8.7% of low-risk cases misclassified as high risk, as well as the genuinely high-risk population. In a health system where VHW capacity is finite and geographic access is often extreme, this discriminatory performance is the model's primary programme utility. The clinical caution, however, is that 84.2% sensitivity means approximately 1 in 6 neonatal deaths is misclassified as low risk. In a high-mortality context, this represents a life-missed limitation that must be weighed against the targeting efficiency gain before deployment decisions are made.

The event-per-variable ratio for Model 4 warrants explicit disclosure. With 68 death events and multiple predictors, the EPV ratio exceeds the conventional lower bound of 10–15 events per predictor (Peduzzi *et al.,* 1996), indicating a reduced risk of model overfitting even with cross-validation. The training-to-test accuracy differential (86.1% vs 84.3%) is smaller than that typically observed with overfitted models, which provides some reassurance. However, this reassurance is partial: the data's cluster dependence is not accounted for in the reported performance metrics because cluster-stratified cross-validation was not implemented. Within-cluster correlation inflates apparent precision; the reported AUC and sensitivity estimates are therefore likely to be modestly optimistic. Cluster-stratified cross-validation is recommended as a methodological refinement for future work with this dataset.

The 14:1 class imbalance (approximately 905 survivors to 68 deaths) is a fundamental statistical constraint on all classification metrics. An uninformative classifier that predicts survival for every observation achieves 93% overall accuracy, higher than Model 4's 84.3%. The reported sensitivity (84.2%) and AUC (0.843) are the appropriate metrics for evaluating performance under class imbalance, as they assess discrimination in both classes. Calibration (whether the model's predicted probability matches observed event rates across risk strata) is an equally important metric for clinical application and was not formally assessed. Calibration assessment, alongside external validation, is a prerequisite for deployment.

The implementation pathway from research tool to programme application requires four steps that this study's evidence base does not yet provide: (1) external validation on an independent dataset from a comparable LMIC setting with similar NMR, community health infrastructure, and VHW coverage; (2) calibration of predicted probabilities against observed event rates across deciles of predicted risk; (3) decision curve analysis to determine the net benefit of model-guided targeting relative to treating all or no neonates as high-risk; and (4) ethical review of individual-level risk-scoring, including community consultation on transparency and consent. Until these steps are completed, the model's appropriate use is as a programme-level targeting instrument—identifying clusters below the institutionalisation risk threshold—rather than as an individual-level clinical screening tool.

6.4 Machine learning findings: Random Forest and Decision Tree

The Random Forest and Decision Tree analyses serve a specific, bounded, complementary function alongside the primary cRCT analysis. Multilevel regression estimates the adjusted association between pre-specified independent variables and neonatal mortality within a theoretically constrained model. Machine learning algorithms identify the most predictive variables from the full set of covariates without imposing prior structural constraints. These are different analytical questions—not competing analytical strategies—and their integration provides a form of cross-method validation of predictor direction and ordering that neither approach achieves independently.

The theoretically significant finding from the Random Forest feature importance analysis is not the performance metrics but the *ordering* of predictors. Community structural variables (VHW presence and functional governance) rank above individual biological variables in feature importance (Chapter 5, Section 5.5). This result directly challenges a Mosley-and-Chen–only reading of neonatal mortality, which would prioritise biologically proximate determinants as intervention targets. The machine-learning finding, when combined with the regression rankings, provides cross-method empirical support for the SEM's prediction that community structural factors independently predict neonatal outcomes over and above individual biological risk. This reordering of predictive importance is the finding's theoretical contribution: it argues, through a methodologically distinct analytical lens, that structural investment in community governance and VHW infrastructure produces predictive gains that clinical variable optimisation alone cannot achieve.

The convergence of findings from Random Forest and logistic regression also serves as a methodological validation. Random Forest's cross-validated sensitivity of 91.3% and specificity of 80.3% are consistent with the logistic model's performance, providing reassurance that the classification performance is not an artefact of the logistic model's assumptions. Where two methodologically distinct frameworks yield consistent performance metrics and predictor rankings, confidence in the direction and ordering of the findings is strengthened—even though neither framework alone establishes causation.

The Decision Tree's classification structure (communities with both VHWs and functional governance at the lowest predicted mortality probability, communities lacking both at the highest) is consistent with the Poisson regression interaction finding. As a communication tool, the Decision Tree has specific utility for district health managers making resource allocation decisions: it visually represents a risk stratification logic that can guide which clusters to prioritise for governance revitalisation investment. Its use should be confined to this communication function; it is illustrative, not confirmatory, and is derived from the same dataset used for primary analysis.

A notable feature of the machine-learning results is the divergence between discrimination and calibration for the two tree-based models. The Random Forest and

Decision Tree achieved the strongest discrimination and the highest recall for preventable neonatal deaths, yet returned statistically significant Hosmer–Lemeshow tests, whereas the Support Vector Machine, a third comparator classifier reported in Chapter Five, despite more modest discrimination, was adequately calibrated. This pattern is well documented in the prediction literature. Discrimination, the ability to rank cases by risk as captured by the ROC AUC, and calibration, the agreement between predicted and observed absolute risk, are distinct properties, and a model may rank cases well while systematically over- or under-estimating absolute risk (Steyerberg *et al.,* 2010). Tree-based classifiers, in particular, are prone to producing predicted probabilities concentrated at a limited number of values, which can degrade calibration even when ranking performance is high.

The practical implication is that the Random Forest and Decision Tree models, notwithstanding their superior discrimination and recall, would require probability recalibration—for example, Platt scaling or isotonic regression, before their predicted probabilities could be relied upon as absolute risk scores for community-level referral decisions. Their discriminative ranking remains valuable for risk stratification, and recalibration is a standard, well-established post-processing step that does not diminish that ranking. The calibration findings, therefore, refine rather than overturn the overall conclusion of the machine-learning strand: the tree-based models offer the strongest case-identification performance, while formal deployment as a probability-based decision-support tool would require a recalibration step and subsequent external validation, consistent with the exploratory interpretive boundaries set out in Section 4.15.4.6.

Three limitations constrain the interpretation of all machine learning findings. First, with 68 death events, the effective sample size for model training is small relative to the number of candidate predictors, making machine learning algorithms susceptible to overfitting under these conditions. Synthetic Minority Over-sampling Technique (SMOTE) has been identified as a methodological refinement for future work. However, its limitations must be acknowledged alongside its benefits: SMOTE generates synthetic observations that may not reflect real-world data distributions, cannot manufacture information from a fundamentally small event count, and can inflate performance metrics in the over-sampled class. Regularised regression

approaches such as LASSO and ridge regression provide alternative comparators with more controlled overfitting properties. Second, both the Random Forest and the Decision Tree were trained and tested on the same dataset used in the primary analysis; neither provides truly independent validation of the regression findings. Third, future machine learning analyses in community health systems research should be pre-registered (specifying feature selection approaches, hyperparameter grids, and performance metrics before analysis) to prevent capitalising on chance in feature importance rankings. These are identified as priority methodological refinements rather than disqualifying weaknesses.

6.5 Qualitative analysis: Mechanisms, meanings, and structural conditions

6.5.1 Overview of the qualitative strand

The qualitative strand was designed as a longitudinal process evaluation, theory-driven from inception and embedded within the cRCT in accordance with the QUAN (qual) architecture specified in Chapter Four. Key Informant Interviews and Focus Group Discussions were conducted across all seven districts of Mashonaland West Province from January 2020 to January 2021. The purposive sample spanned national, provincial, district, and community levels: five national and twelve provincial informants, 42 District Health Executive members, seven local government officials, 24 community leaders, including VHWs, and 43 FGD participants from WLA/MLA groups and community health worker cadres. The median years of service among district-level informants was 14.2 years, providing structural depth of experience. 'A notable sampling limitation should be acknowledged at the outset: the purposive sample does not fully capture the experience of the most marginalised households — specifically, artisanal mining communities documented in key informant accounts as having no formal clinic access, women who delivered outside health facilities and had limited or no VHW contact, and households residing more than 30 kilometres from the nearest facility. These are precisely the populations for whom the study's equity argument is most relevant. Their underrepresentation means that the qualitative accounts disproportionately reflect the experiences of communities with at least partial

system access, and that the structural barriers faced by the most remote and least-reached households may be systematically underestimated in the qualitative strand.

All sessions were audio-recorded, transcribed verbatim, and analysed using NVivo 14 through a six-step thematic content analysis with a cross-thematic matrix to trace patterns across actor levels. The function of qualitative evidence in this chapter is interpretive and mechanistic rather than corroborative. Where quantitative results establish that an association exists, qualitative evidence explains why (through which social processes, institutional arrangements, and structural conditions the intervention produces its effects). The four analytical arguments that follow are each grounded in qualitative evidence, anchored to a named theoretical framework, and integrated with quantitative findings to produce meta-inferences that neither strand alone could generate.

6.5.2 Analytical Argument One: Institutional path dependency as the structural Antecedent of governance non-functionality

Here, the theoretical anchor is the SEM policy level; Tanahashi's availability dimension; Critical Paradigm:

The most consequential finding from the qualitative strand is not what participants described about the intervention's mechanisms, but what they revealed about the institutional imagination through which community health has been understood in Zimbabwe over the past four decades. A provincial informant articulated the cognitive frame that has governed community health system thinking since 1980. This account describes what organisational theorists term *institutional path dependency*: once a cognitive and operational frame becomes embedded in leadership practice, resource allocation, and professional formation, it constrains the range of imaginable alternatives even as evidence demands change (Pierson, 2000; Sheikh *et al.,* 2014). At the SEM policy level, the dominant frame (community health equals VHW geographical distribution) rendered governance, participatory learning, and social accountability structurally invisible within the planning architecture. The Critical Paradigm makes this mechanism legible as a power finding: path dependency is not merely administrative inertia, but an expression of whose priorities have shaped institutional design, whose

knowledge counts as evidence, and whose communities receive sustained investment rather than episodic attention.

The Tanahashi coverage cascade provides the analytical vocabulary to specify the consequence of this path dependency. When institutional imagination stops at VHW training and deployment, it achieves—at best—the *availability* tier of the cascade: the existence of human resources to potentially deliver care. Availability is necessary but insufficient. The subsequent tiers (accessibility, acceptability, initial contact, and effective coverage) require functional governance to monitor, audit, and adapt service delivery. A VHW-only institutional framework produces a system with workers. However, it lacks the architecture to ensure those workers reach the most vulnerable households, respond to community feedback, or identify and correct coverage failures in real time. The quantitative finding that fully functional governance was present in only 34.3% of control clusters (Chapter 5, Table 26) is the structural consequence of four decades of this path dependency, not a measurement of a random distribution.

The meta-inference integrating these qualitative and quantitative strands is that the intervention's 43% incremental mortality reduction was not achieved by adding a technical programme component but by partially reversing an institutional path dependency—making visible and operationally supporting the CHS components that the dominant cognitive frame had rendered invisible. This interpretation is available only through integration of the qualitative mechanism and the quantitative outcome; neither strand alone makes the institutional dynamic legible.

Mixed-Methods Meta-Inference — Institutional Path Dependency
The narrow institutional understanding of 'community health as VHW coverage' at policy and district levels is institutionalised path dependency, operationally expressed in governance non-functionality across 65.7% of control clusters. The intervention's mortality effect is partly a consequence of disrupting this dependency—by making governance and participatory structures visible as legitimate components of the health system and by providing dedicated resources. This is a structural finding about power and institutional design, not a programmatic finding about coverage rates.

6.5.3 Analytical Argument Two: From availability to effective coverage — The failure of one-off support

Theoretical anchor: Modified Tanahashi coverage cascade; SEM institutional level

The qualitative evidence yields a theoretically precise account of where and why the Tanahashi cascade breaks down in Mashonaland West - one that specifies the mechanisms of coverage failure at specific cascade stages rather than describing them in aggregate. A district respondent's account of Health Centre Committee capacity-building illustrates the structural failure with analytical clarity: one-off governance capacity-building creates nominal availability but fails to sustain acceptability and subsequent coverage tiers. Facility-level HCCs receive more support and show higher functionality than ward-level VHCs, which remain under-resourced and geographically isolated.

This account reveals a cascade failure at multiple stages simultaneously. One-off capacity building can produce the appearance of availability (governance structures are formally constituted and convened initially) but cannot sustain the *acceptability* dimension. Tanahashi's acceptability tier requires that both providers and community members understand and value the structure's purpose. When HCC members believe, their role is limited to monitoring clinic opening hours, they have experienced a failure of conceptual acceptability: the function of governance as an adaptive, death-audit-conducting, accountability-generating mechanism has not been internalised. Without internalisation, the structure cannot advance to the initial contact or effective coverage tiers. The tension described between community leaders and facility staff over the appropriate scope of governance authority is the interpersonal SEM consequence of this acceptability failure at the institutional level.

Key informant accounts document a difference between HCC and VHC functionality: all relevant respondents report full HCC functionality, whereas only 60% report full VHC functionality, mapping onto a Tanahashi *accessibility* gap with a spatial dimension. HCCs are facility-level structures co-located with health infrastructure and, therefore, more accessible to institutional support, supervisory visits, and resource flows. VHCs are ward-level structures in remote communities, and their lower functionality reflects both geographic distance from institutional support and lower investment in their revitalisation. The cascade fails differentially by geography, which

is simultaneously a Tanahashi finding about service delivery bottlenecks and a Critical Paradigm finding about the structural distribution of institutional neglect.

The VHW peer supervisor's account of the supply readiness dimension adds a provider-perspective layer to this cascade analysis, presenting a Tanahashi acceptability account from the provider perspective. The VHW describes not a supply-chain failure in the narrow technical sense but a *trust economy*: community members' willingness to accept VHW authority is conditional on the VHW demonstrating material competence—possessing and dispensing commodities. In this reading, trust is not a soft social outcome but a precondition for Acceptability Coverage. A VHW without supplies cannot achieve acceptability regardless of training, because the community's willingness to engage is mediated by perceived provider capacity.

The meta-inference from integrating these qualitative accounts with the quantitative evidence of governance non-functionality is that the Tanahashi cascade is not a linear progression but a conditional one: advancement to each subsequent tier requires a specific enabling condition that structural underfunding and one-off support routinely fail to create. The intervention worked not because it added components to the system, but because it created sustained conditions—governance oversight with documented outputs, commodity availability, and community feedback loops—that allowed the cascade to advance beyond the availability tier.

Mixed-Methods Meta-Inference — Tanahashi Cascade Failure
One-off governance capacity-building achieves Tanahashi availability without the sustained conditions required for acceptability, initial contact, or effective coverage. The intervention's governance component (IV2) was effective because it replaced episodic support with sustained support, enabling the adaptive feedback loop that effective coverage requires. The qualitative evidence reveals the mechanism; the quantitative hazard reduction (Chapter 5, Section 5.6.5) confirms its mortality consequence.

6.5.4 Analytical Argument Three: Cross-Level SEM Mechanisms in Geographic and Social Access

Theoretical anchor: SEM Community, Interpersonal, and Intrapersonal levels; Mosley and Chen's first and second delays

The Socio-Ecological Model was adopted in Chapter Three because neonatal mortality is irreducibly multilevel: individual biological risk is moderated by interpersonal social support, institutional service capacity, community norms, and the policy environment. The qualitative evidence reveals not only that these levels matter—which the SEM predicts—but specifically how they interact, producing cross-level amplifications of risk and cross-level compensatory mechanisms.

At the community level, geographic inaccessibility is the most structurally entrenched barrier. A community leader's account illustrates this, narrating that their nearest clinic is 38 kilometres away. In SEM terms, this account operates simultaneously at the community level (38 kilometres is a structural, not individual, barrier), the interpersonal level (collective brick-laying is a social capital mobilisation that compensates for institutional failure), and the institutional level (the integrated outreach initiative represents a facility-level adaptation driven by community advocacy—a cross-level interaction in which community-level pressure shapes institutional behaviour). In Mosley and Chen's terms, 38 kilometres determines the *second delay* structurally: regardless of a household's recognition of danger signs (which addresses the first delay), the probability of reaching care within the neonatal emergency window is constrained by road infrastructure, transport availability, and distance. The home delivery rate remaining above 16% in both arms (Chapter 5, Table 25) confirms that community system interventions do not fully compensate for geographic access deficits at this scale. The Critical Paradigm names this as a structural justice failure: communities at 38 kilometres from basic care are not experiencing a logistical inconvenience but a spatially structured denial of the right to survivable proximity to essential services.

The WLA/MLA groups operated as an interpersonal-level mechanism that restructured the household decision-making architecture, in which culture demands that men make household decisions. This account describes a cross-level SEM mechanism that quantitative analysis cannot directly capture. At the intrapersonal level, it describes a change in the participant's knowledge and health-seeking intention. At the interpersonal level, it describes a restructuring of the household power dynamic: male partner participation in mixed-gender groups shifted responsibility from a gendered domain to a shared one. At the community level, this shift was collective rather than idiosyncratic,

produced by WLA/MLA group cycles across clusters. The dose-response gradient between meeting attendance and neonatal mortality, with fewer than three meetings attended associated with a nearly fivefold increase in risk (Chapter 5, Section 5.5.4), is the quantitative signature of this interpersonal-to-community-level normative change process. The qualitative account explains the mechanism; the quantitative gradient confirms its directionality and magnitude.

The prenatal naming practice adds an intrapersonal mechanism of theoretical interest. Assigning a name before birth is described as generating 'an emotional connection with my pregnancy—the urge to protect the baby at any cost.' This describes anticipatory bonding, which operates at the intrapersonal emotional level but is activated through an interpersonal social ritual. The association between the absence of prenatal naming and neonatal mortality (Chapter 5, Table 34, logistic regression) is consistent with a social capital mechanism: naming may serve as a proxy for how embedded a pregnancy is within protective relational networks. If named pregnancies correlate with higher social support, earlier care-seeking, and greater birth preparedness, SEM interpersonal pathways would explain the association rather than a direct causal effect of naming itself. This hypothesis requires dedicated confirmatory research; integrating qualitative mechanisms with quantitative associations makes it analytically credible without confirming causality.

The gendered infant caregiving norm documented across multiple FGDs (specifically, the belief that male infants require earlier supplemental feeding than female infants) requires analysis at both the SEM intrapersonal level (the belief system) and the interpersonal level (its social enforcement through family and community instruction). If this norm disrupts exclusive breastfeeding in male neonates, it operates through the Mosley and Chen illness-control pathway: early introduction of porridge elevates gastrointestinal infection risk and may precipitate the sepsis cascade. The Critical Paradigm frames this as a culturally encoded risk differential that is not biologically inevitable but socially produced and therefore socially addressable. The study did not measure prelacteal feeding rates by infant sex in the quantitative component; dedicated research measuring this practice and its effect on neonatal infection rates by sex is a research priority.

Mixed-Methods Meta-Inference — Cross-Level SEM Access Mechanisms
Geographic inaccessibility at the SEM community level and gendered caregiving norms at the SEM interpersonal level both translate into Mosley and Chen's proximate delay pathways—the first delaying care-seeking, the second interrupting protective feeding practices. WLA/MLA groups worked in part by creating an interpersonal-level mechanism that altered the household decision-making architecture, thereby activating early ANC uptake. Community system interventions can address interpersonal-level barriers; they cannot resolve community-level geographic barriers without concurrent infrastructure investment. Institutional design must address both.

6.5.5 Analytical Argument Four: Community Governance as the Mechanism for Effective Coverage

Theoretical anchor: Tanahashi Effective Coverage tier; Complex Adaptive Systems theory; SEM Institutional level

The Tanahashi Model's highest coverage tier (effective coverage) is defined not by the presence of services but by their quality, responsiveness, and capacity to generate adaptive feedback. The qualitative evidence from this study provides the most theoretically precise account of the structural mechanism through which functional governance achieves effective coverage: the community-based death audit. A community leader described their role in ensuring that no mother or child dies in their community (Chapter 5, sub-section 5.8.4.2: Community Governance and Community-Based Death Audits). This account describes, in experiential terms, the mechanism that the Tanahashi Model conceptualises as the transition from initial contact to effective coverage. Initial contact (a community member accessing a health service) is necessary but insufficient. Effective coverage depends on a *quality feedback loop*: a mechanism through which outcomes are measured, adverse events are investigated, and lessons are incorporated into subsequent service delivery. The community death audit described here is precisely this mechanism. By transforming a neonatal death from a private loss into a public accountability event—' asking why babies are dying'—the VHC creates an adaptive feedback loop between community experience and institutional practice that is the defining structural feature of effective coverage.

Complex adaptive systems theory specifies why this mechanism produces super-additive effects when combined with trained VHWs (Sheikh *et al.*, 2014; Blanchet *et*

*al.). W*ithout governance oversight, it lacks a feedback mechanism; governance structures without trained VHWs lack frontline intelligence on household-level coverage failures. The statistically significant IV1 × IV2 interaction (Chapter 5, Figure 26) is the quantitative signature of this structural interdependence. The 92.7% hazard reduction associated with functional governance (Chapter 5, Section 5.6.5) represents the mortality consequence of communities advancing to Tanahashi's highest coverage tier—a tier that the comparator trials in Nepal, India, and Malawi did not include a governance component to reach.

The district health management team respondent's response to COVID-19 service continuity reveals the resilience dimension of governance under extreme external stress. This account described a governance mechanism that maintained effective coverage under severe system disruption. CAS theory predicts that resilient systems maintain effective coverage under perturbation by drawing on community social capital and trust relationships that persist even when formal service delivery is disrupted. The WLA/MLA groups' function as demand-creation platforms (maintaining a health-seeking orientation while COVID-19 created fear of attending facilities) is a manifestation of this resilience. The governance structure's capacity to redirect community mobilisation efforts during the pandemic reveals that the intervention built structural resilience, not merely service-delivery capacity—a contribution that the 12-month mortality estimate understates, as the pandemic attenuated intervention delivery precisely when system resilience was most needed.

Mixed-Methods Meta-Inference — Governance as an Effective Coverage Mechanism
Community-based death audits, conducted within functional VHC structures, constitute the mechanism through which the trial achieved Tanahashi effective coverage—the highest tier of the cascade. This is a structural finding: governance that generates accountability feedback loops is the precondition for effective coverage, not a supplement to it. The 92.7% hazard reduction associated with functional governance (Chapter 5, Section 5.6.5) is the quantitative signature of communities advancing to this tier. Amid COVID-19 disruption, the same governance and social capital infrastructure-maintained health-seeking behaviour, revealing a resilience function that the primary mortality estimate does not fully capture.

6.5.6 The dose-dependent effect of IV3: A cross-thematic synthesis

The most analytically productive relationship between the quantitative and qualitative strands concerns IV3. The quantitative analysis establishes a dose-dependent protective effect—significant at adequate exposure (≥4 cycles approximately 14 meetings; AOR 0.71, p = 0.001) and attenuated below it—while the qualitative strand documents precisely the intermediate-level changes (restructured household decision-making, increased danger-sign literacy, sustained health-seeking under pandemic conditions) that the SEM predicts should mediate that effect. The two strands converge rather than diverge: the qualitative evidence explains why exposure intensity matters and identifies the cumulative normative changes through which sustained participation translates into reduced mortality. This is a theoretically interpretable finding about dose and mechanism, not a contradiction between strands.

The cross-thematic matrix constructed in NVivo reveals a second analytically significant pattern: a systematic gradient of conceptual narrowing from the policy to the community level. National informants articulated systemic and strategic framings of institutionalisation. District managers translated these into operational coverage proxies. Community participants grounded institutionalisation in immediate material and relational experiences. This gradient is not merely descriptive but theoretically revealing: it shows that well-designed national strategies fail to produce community-level change not because community members misunderstand them but because the district and ward-level translation infrastructure (which converts policy commitment into community experience) has been systematically underfunded and under-supported. Bridging this gradient requires structural investment in meso-level operational capacity, not better communication strategies.

The Critical Paradigm names this gradient as a power finding: those with the most power to shape the system operate at the highest level of abstraction; those with the least power to change the system experience its effects most concretely and immediately. The policy implication is redistributive: sustained investment in the ward and village governance levels—not in national strategy documents—is what converts policy intent into community survival outcomes.

6.5.7 Reflexivity, trustworthiness, and analytical integrity

The Critical Paradigm adopted in Chapter Three is explicit that knowledge is produced within power relations, including those of the researcher. As a Zimbabwean public health practitioner with long-standing professional investment in community health system strengthening, the principal investigator occupies a positionality that carries confirmatory bias risk. Mitigation strategies included member-checking of emerging interpretations with community participants, independent double-coding of 20% of transcripts with consensus resolution of discrepancies, negative case analysis to identify evidence challenging dominant themes, and systematic reflexive journaling archived in the NVivo project file.

The handling of the IV3 result is an important test of this reflexivity. Rather than allowing the strong system-level effect to imply uniform significance across every component, the analysis reports each component against its own estimate: IV3 is significant in a dose-dependent pattern (AOR 0.71 at ≥4 cycles), while a small number of service-delivery practices fell at or beyond the significance threshold and are reported as such. As such, the conclusion claimed for each variable was calibrated precisely to the evidence that supports it.

Confirmability is supported by the convergence between qualitative mechanisms and independently estimated quantitative associations across two methodologically distinct analytical frameworks. Where the qualitative data proposes a mechanism, the quantitative data either confirm its expected direction or generate a theoretically interpretable divergence. This pattern is the hallmark of a well-integrated QUAN (qual) design.

6.6 Contribution to the Global and African evidence base

This study makes four specific contributions that extend beyond the Zimbabwean context, each addressing an identifiable gap in the existing literature.

First, it provides what is, to the candidate's knowledge and on the basis of the literature reviewed in Chapter Two, the first prospective cluster-randomised controlled trial

evidence from Zimbabwe that institutionalising all three CHS vital signs (trained VHWs, functional governance, and participatory learning groups) as a package is associated with a substantial reduction in neonatal deaths. Prior Zimbabwean community health research has been dominated by cross-sectional and retrospective analyses (Nhede and Catraio, 2021; Noble *et al.,* 2022). The prospective cRCT design, with allocation concealment and pre-specified primary outcomes, strengthens causal inference beyond what those designs can support.

Second, the study contributes a formal empirical test of the synergy hypothesis within a community health systems cRCT; no earlier such test was identified in the literature reviewed in Chapter Two, although a systematic search was not undertaken. The statistically significant IV1 × IV2 interaction (Chapter 5, Table 41) provides empirical evidence consistent with Hawe et al.'s (2009) theoretical argument that health system components produce super-additive effects when embedded in governance structures. Previous trials in comparable settings (Manandhar *et al.* (2004), Tripathy *et al.* (2010), Lewycka *et al.* (2013)) evaluated participatory groups as standalone interventions without the governance dimension that this study theorises as the mechanism achieving Tanahashi's effective coverage tier. The cross-trial comparison is observational: differences in effect magnitude may reflect population heterogeneity, design variation, or differences in follow-up duration rather than a pure governance effect. However, the theoretical explanation that governance converts community mobilisation into an adaptive feedback system that advances communities to effective coverage is a specific, testable hypothesis that future comparative trials can evaluate by including and randomising governance components.

Third, the study advances the mechanistic understanding of how community health system components achieve their effects by providing CAS theory with a cluster-level empirical estimate of the governance-workforce interaction. Prior CAS applications in health (Sheikh *et al., 2014;* Blanchet *et al.,* 2017) have theorised feedback loops as mechanisms without specifying the structural conditions (what level of governance functionality, what VHW coverage density, what community coverage of participatory groups) under which they generate detectable effects on a population-level mortality outcome. The operational thresholds established in this trial (≥80% fidelity, ≥monthly governance meetings with documented outputs, 1 VHW per 100 households) specify

the boundary conditions for CAS predictions at the community level. This is a theoretical contribution that specifies and quantifies what CAS theory predicts, rather than merely empirically replicating it.

Where the findings support, extend or diverge from existing evidence. The package effect (57% relative reduction) is larger than the pooled 38% reduction for participatory women's groups at adequate coverage (Prost *et al.,* 2013) and the 20–45% range for combined community packages (Lassi *et al.,* 2016; Seward *et al.,* 2017), but its confidence interval (30–74%) overlaps those estimates, so the finding supports rather than exceeds the existing evidence. The study extends that evidence in one specific respect: it adds a governance component that the participatory-group trials did not include and reports an interaction between governance and workforce that those trials could not test. It diverges from parts of the literature in two respects that deserve statement rather than explanation away. Skilled birth attendance was not significantly associated with neonatal survival in this prospective study, whereas most of the literature reports a protective association; the quality-of-care explanation offered in Section 6.7 is a hypothesis, and differential ascertainment or the high background facility-delivery rate are alternative explanations. And the IV3 effect emerged only at four or more cycles, a threshold lower than the population-coverage threshold reported by Prost *et al.* (2013), which may reflect differences in the exposure measure (cycles attended versus proportion of pregnant women in groups) rather than a true difference in mechanism.

Alternative explanations for the primary effect: Four alternatives to the causal interpretation of the package effect were considered. Secular improvement in the control arm from the concurrent National Community Health Strategy roll-out would bias the comparison toward the null and cannot explain a difference in favour of the intervention. Contamination of control clusters (45.6% any-exposure) likewise attenuates rather than creates the difference. Differential loss to follow-up was small (99.6% versus 98.2%) and was addressed by multiple imputation. Differential ascertainment of deaths between arms, arising because intervention VHWs were more active in surveillance, is the alternative that cannot be excluded by design; it would bias the comparison towards the null if intervention deaths were more completely ascertained, but towards the intervention if control deaths were under-counted, and the

cross-checking of household reports against facility registers (Section 4.14) reduces but does not eliminate this possibility. Chance is bounded by the confidence interval. On balance, the causal interpretation of the package effect is the most plausible, but Section 6.8.2 acknowledges the possibility of residual ascertainment bias.

Fourth, integrating machine learning with multilevel epidemiological modelling is a methodological contribution for community health systems research in LMICs. Prior machine learning applications for neonatal mortality have largely focused on facility-based clinical datasets (Guo *et al.,* 2021), where predictors are predominantly biological and clinical. This study extends machine learning to community-level structural data (governance functionality, VHW coverage, and participatory group attendance) alongside biological and clinical variables within a single modelling framework. Integrating these data sources and triangulating the machine learning model with the multivariable regression (Table 33) and synergy analyses (Section 5.7.3.1) demonstrate that community structural variables have independent predictive value for neonatal mortality that facility-based, clinically focused models cannot capture. Through a methodologically distinct lens, this reinforces the central argument that structural investment yields gains which biological variable optimisation alone cannot achieve. The limitations of rare-events data and the absence of external validation must be acknowledged alongside this methodological contribution.

What this study cannot contribute must be stated as clearly as what it can. The single-province setting limits the external validity of the precise effect size estimate: the 57% reduction is an estimate for a specific, predominantly rural, high-burden province with a particular baseline community health system architecture. Provinces with higher baseline VHW coverage, different NGO presence, or predominantly urban settlement patterns may produce different effect magnitudes. The study does not establish cost-effectiveness: the USD 1.50 per capita estimate for full CHS institutionalisation from the NCHS Investment Case (Government of Zimbabwe, 2020) is contextually relevant, but a formal economic evaluation using this trial's cost and mortality data is required before the cost-effectiveness case can be made with the rigour that financing advocacy demands. The study does not establish long-run sustainability: 12 months of institutionalisation is a minimum condition, not a demonstration of sustained governance functionality over the five-to-ten-year horizon that scaling requires.

Within the African context, this study extends and critically engages with lessons from Ethiopia, Rwanda, and Brazil. Ethiopia's Health Extension Programme achieved a 67% reduction in under-five mortality between 1990 and 2015 through salaried, institutionalised workers, government financing, and career pathways (Assefa *et al.,* 2019). This represents the ceiling of what full workforce institutionalisation can achieve under sustained domestic financing—and suggests that Zimbabwe's stipend-based model, with its weaker financial commitment to VHW livelihoods, may limit the magnitude of the effect observed here. Rwanda's community governance model demonstrates that accountability structures produce mortality reductions equivalent to clinical service expansions. Brazil's community health agent programme demonstrates that workforce coverage without governance produces diminishing returns over time. This study synthesises these lessons: the structural combination, workforce embedded in governance with participatory groups linking households to institutions, produces effective coverage, not any single component in isolation.

6.7 Policy, practice, and research implications

6.7.1 The central policy argument

The study's central policy argument is grounded in the Tanahashi cascade and given structural force by the Critical Paradigm. Zimbabwe has achieved near-universal ANC coverage and high facility delivery rates. The evidence from this study demonstrates that these achievements place the health system at the initial-contact tier of the Tanahashi cascade—the third of five tiers. The 57% relative reduction in neonatal mortality (ARR 0.43) observed in communities receiving the full institutionalised package is consistent with the proposition that advancing to effective coverage (the fifth tier) yields mortality gains that initial contact alone cannot achieve. The structural mechanism for this advance is functional governance: the feedback loop between community accountability and institutional practice that the coverage cascade's highest tier requires.

Skilled birth attendance illustrates the same cascade logic at the level of an individual indicator. Despite high facility-delivery coverage, the presence of a skilled birth

attendant was not significantly associated with reduced neonatal mortality (RR 1.38; 95% CI 0.75–2.53; p = 0.366; Chapter 5). This is consistent with the possibility that recorded skilled attendance captures contact rather than the effective intrapartum and immediate newborn care required by the Tanahashi effective-coverage tier—that is, the presence of an attendant may not consistently translate into respectful, timely, and clinically effective care at birth. This interpretation is advanced as a hypothesis, not a conclusion. The study measured whether a skilled attendant was present, but did not assess the quality, respectfulness, or clinical content of the care delivered; assessing these would require a dedicated study of skilled-attendance quality, for example, through direct observation of intrapartum care, criterion-based clinical audit, or respectful-maternity-care assessment, which occurs at the facility and was beyond the scope of the current study. The non-significant association is therefore best read as a signal warranting such investigation rather than as evidence of care quality in itself.

Framed through the Critical Paradigm, the policy imperative is redistributive justice rather than efficiency optimisation. Every preventable neonatal death in a community without functional governance is a death that *structural choices* (about resource allocation, about which communities receive sustained versus episodic institutional support, about whose knowledge counts in health system design) have made more likely. The evidence that neonatal mortality risk is most amplified among the poorest households, lowest-literacy communities, and most remote geographic areas is not a statistical observation about individual risk profiles. It is evidence of the spatial distribution of institutional neglect. The policy response must be redistributive: sustained investment in the ward and village governance levels where effective coverage is determined, not only in the national strategy documents where it is articulated.

6.7.2 Health system strengthening

The study recommends that MOHCC establish institutionalisation scorecards for all 63 districts, structured explicitly around the Tanahashi cascade. Each scorecard indicator should correspond to a specific cascade tier, enabling district planners to identify where their community health system is failing and direct resources accordingly. Districts that have achieved VHW availability but not governance functionality are stalled at the

availability tier; investment priority should be governance revitalisation. Districts with governance structures but inadequate supply readiness are at the accessibility tier; investment priority should be commodity supply chains. This cascade-based targeting is more efficient and more equitable than universal service expansion because it directs investment where the cascade bottleneck is most constraining.

The three evidence-derived thresholds for institutionalisation scorecards are: fewer than one trained VHW per 100 households (availability tier deficit); fewer than 80% of VHCs meeting monthly with documented outputs (acceptability tier deficit); and fewer than 70% of wards with active WLA/MLA groups (contact tier deficit). Districts that fall below these thresholds in any dimension should be classified as priority investment targets. These thresholds are derived from the trial's fidelity measurement framework and reflect the operational conditions under which the 57% relative reduction (ARR 0.43) was observed. They are proposed as candidate benchmarks for further testing rather than as validated national thresholds.

The systematic inequity between HCC and VHC functionality requires explicit policy redress. Facility-level governance receives institutional support that ward-level governance does not, because field supervisors and district managers work in the facility environment. VHC functionality (not HCC functionality) is the governance mechanism closest to the communities where neonatal deaths occur. Sustained investment in VHC revitalisation, including regular facilitated interface meetings, documented death audit protocols, and integration with DHIS2 for real-time monitoring, should be a non-negotiable standard of district health management performance, not an optional enhancement.

Advocacy for increased domestic health financing allocation to community health is a prerequisite for sustainability. If current domestic financing for community health approximates 4% of the national health budget, and the NCHS Investment Case estimates full institutionalisation at approximately USD 1.50 per capita per year, a formal economic evaluation (specified as a research priority in Section 6.7.3) is needed to translate the evidence base into a financing argument. The directional case is clear; this study has not yet produced formal economic evidence.

6.7.3 Practice implications

The evidence that VHW performance is heterogeneous across clusters confirms that training alone is insufficient for sustained intervention fidelity. Monthly supportive supervision by DHMT field supervisors, with structured checklists assessing home-visit frequency, delivery of danger-sign education, and VHC linkage, is the minimum operational standard required. Community scorecards and participatory death audits should be standardised within the NCHS implementation framework and integrated with DHIS2 for district-level accountability monitoring. The prediction model's potential as a cluster-level targeting tool is real but contingent on the four-step validation and deployment process described in Section 6.3.

The qualitative evidence of interpersonal-level norm change through WLA/MLA groups has specific practice implications for gendered caregiving norms. The finding that male infant supplemental feeding practices may begin as early as day three—if confirmed quantitatively—represents a targetable behaviour for VHW home-visit counselling. Incorporating sex-specific exclusive breastfeeding messaging into the postnatal home-visit protocol is a low-cost modification with potentially significant impact on the sex-differential in neonatal mortality. This should be a priority for curriculum revision in VHW refresher training.

6.7.4 Research priorities

Four research directions are identified in order of priority. First, a three- to five-year longitudinal follow-up of the trial cohort is required to determine whether the 57% mortality reduction is sustained as governance structures mature and to detect IV3's lagged effect on mortality beyond the 12-month window. This follow-up should be registered as a pre-specified secondary study at the same trial registry. Second, external validation of the prediction model in comparable LMIC provincial settings (with similar NMR, rural profiles, VHW coverage baselines, and the absence of tertiary care) is required before deploying cluster-level targeting. Third, a formal economic evaluation using this trial's cost and mortality data, incorporating a cost-per-death-averted calculation against LMIC economic evaluation thresholds, is required for domestic financing advocacy and international resource mobilisation arguments. Fourth, per-protocol sensitivity analyses restricted to participants who completed≥4 WLA/MLA meeting cycles and to COVID-unaffected clusters would provide a more

rigorous test of IV3's independent effect under conditions of adequate exposure intensity; these analyses should be conducted on this study's dataset and pre-registered.

An additional fifth priority is implementation of science integration. This study provides evidence of what to implement, but the implementation question—how to institutionalise the three CHS vital signs at scale across 63 districts in a resource-constrained system with a significant COVID-19 recovery burden—requires a distinct research approach. Future research should integrate evidence of effectiveness from this trial with implementation science frameworks, such as the Consolidated Framework for Implementation Research (CFIR) or the Exploration, Preparation, Implementation, Sustainment (EPIS) model, to produce actionable implementation guidance.

6.8 Research Strengths and Limitations

6.8.1 Strengths

The prospective cluster-randomised controlled trial design—with allocation concealment, stratification by baseline neonatal mortality rate, and pre-specified primary and secondary outcomes—provides the strongest feasible basis for causal inference in a complex community intervention of this kind. This assessment is benchmarked against the community health systems research literature: of the trials evaluating participatory community health interventions in sub-Saharan Africa identified in systematic reviews by Lassi *et al.* (2019) and Prost *et al.* (2013), fewer than a third used cluster randomisation, and fewer than half used verbal autopsy for primary outcome ascertainment. The 52-cluster design with standardised verbal autopsy classification for primary outcome ascertainment, while not exceptional by clinical trial standards, represents a methodological standard that is uncommon in community health systems research in high-burden African settings.

The embedded longitudinal qualitative design is a strength that strengthens rather than supplements the quantitative findings. Qualitative data collection was planned, theory-driven, and theory-relevant: the process evaluation was designed in Chapter Four to assess fidelity, explain mechanisms, and identify contextual moderators—not to generate post-hoc narrative support for quantitative results. This pre-specification of

the qualitative strand's analytical role, consistent with the MRC Process Evaluation Framework, ensures that the qualitative contribution is analytically independent rather than confirmatory.

The integration of four theoretical frameworks provides an analytical architecture that captures the multi-level, multi-mechanism nature of neonatal mortality that no single framework can address alone. The Mosley and Chen framework identifies proximate biological pathways; the SEM enables cross-level interaction analysis; the Tanahashi model operationalises coverage cascade mediation; and the Critical Paradigm situates all findings within the structural conditions of power, resource allocation, and institutional design that produce preventable death. The interaction between IV1 and IV2, a finding that CAS theory predicted and SEM cross-level analysis made testable, demonstrates the analytical value of multi-framework integration that would have been invisible within any single framework.

The integration of machine learning with multilevel epidemiological modelling, while exploratory, provides methodological triangulation of predictor ordering and importance, strengthening confidence in the direction of the findings beyond what regression alone could establish.

6.8.2 Limitations and their implications

The 12-month follow-up period is the primary temporal limitation. Social capital and participatory change operate over longer time horizons than biological or structural interventions; Rogers (2003) and Fleming et al. (2016) document social norm change timelines of at least 18–36 months. The dose dependence of the IV3 effect (significant only at sustained exposure) (Chapter 5, Table 34) is the most direct consequence: a longer window would likely allow the effect to register across a wider range of exposure intensities. The 57% relative reduction (ARR 0.43) is therefore best read as the effect of the package as implemented over 12 months under pandemic conditions, which attenuated IV3 delivery more than IV1 or IV2. Whether a fully matured community health system would produce a larger effect is plausible but was not tested; it remains a hypothesis for a longer-horizon trial rather than a conclusion of this study.

Availability of the target population and loss to follow-up: it could not be guaranteed that all enrolled women would be available at every scheduled visit. Because the

outcome of interest is distressing for families, households experiencing a neonatal death were plausibly more likely to be lost to follow-up. Follow-up was nonetheless 99.6% in the intervention arm and 98.2% in the control arm (Section 5.3), and multiple imputation under a missing-at-random assumption was used for the primary analysis, so the likely effect of differential attrition on the ARR is small.

Impact of external factors (COVID-19): this was a prospective study requiring household visits. Travel restrictions, bans on community gatherings and community reluctance to receive visitors from Harare, perceived as the epicentre of the pandemic, disrupted follow-up and compromised the enabling environment for service delivery, attenuating IV3 in particular. The protocol adaptations and their implications for bias are detailed in Section 4.17.

Recall and social-desirability bias: the timing of neonatal death relied partly on caregiver self-report, and some caregivers could not accurately recall the day of death because of the emotional trauma of the loss, leading to possible misreporting of early versus late neonatal death. Social-desirability pressures and cultural practices surrounding neonatal death and mourning in a patriarchal setting may also have affected how deaths were remembered and reported. Verbal autopsy adjudication and cross-checking against facility registers (Section 4.14) reduced, but cannot eliminate, this source of measurement error, which is unlikely to differ systematically by trial arm.

Statistical power: as set out in Section 4.9.1, the sample of 489 mother–infant pairs per arm was calculated to detect a 45% relative reduction in neonatal mortality from the formative baseline of 141 per 1,000 live births, and the primary package comparison was adequately powered on that basis. The same sample is underpowered for the smaller effects expected of individual components, subgroups and secondary outcomes, so non-significant component-level or secondary findings should be read as inconclusive rather than as evidence of no effect, and their confidence intervals, rather than p-values, should guide interpretation.

COVID-19 disruptions affected intervention delivery non-randomly. Restrictions on community gatherings disproportionately attenuated WLA/MLA group sessions: 25.7% of participants missed recommended cycles, while VHW home visits proved more adaptable to pandemic conditions. This differential disruption pushed many

participants below the exposure threshold at which IV3 becomes effective and likely contributed to modest attenuation of the overall package effect; the dose-response analysis, which isolates adequately exposed participants, recovers the effect that the pandemic otherwise diluted. The bias is *potentially toward the null for both the IV3 standalone effect and the combined package effect*. Results should be interpreted in the context of a pandemic that constrained the precise component (participatory groups) most dependent on face-to-face social gatherings.

The absence of a formal mediation analysis means that the relative contribution of each delay pathway to the observed IV1 mortality reduction cannot be quantified from the available data. This limits the precision of VHW training recommendations for contexts with different baseline facility-readiness profiles.

The rarity of the primary outcome (68 death events among 973 enrolled neonates (7.0% event rate)) is a fundamental statistical constraint. Subgroup analyses are underpowered and are treated throughout as hypothesis-generating rather than confirmatory. Machine learning performance metrics are subject to optimistic bias due to class imbalance; reported sensitivity and AUC estimates are likely modestly optimistic without cluster-stratified cross-validation. All subgroup and ML findings require replication on an independent sample.

Potential contamination between arms, while the contamination analysis found minimal spillover (Chapter 5, Section 5.3.2), cannot be entirely ruled out. Main spillover pathways included VHW training, social networks, and informal education on newborn danger signs. These results underscore the challenges of achieving full containment of the intervention in community-based trials and highlight the need to consider spillover when interpreting intervention effects. Any residual cross-cluster exposure to intervention content would bias estimates *toward the null*, making the 57% estimate conservative. Unmeasured confounding from concurrent NGO-funded community programmes represents a source of residual bias that could operate *in either direction*: if NGO programmes were concentrated in intervention clusters, the intervention effect would be overestimated; if in control clusters, it would be underestimated. It is also critical to note that other active groups, such as the Care Group Models for nutrition and Young Mentor Mothers for HIV/AIDS prevention, care, and treatment, among others, could also have contributed to the observed effects. Further evaluation of the

contributions of other initiatives within the community health system would be beneficial (St John, 2020; Gygi, Kleinstein & Guan, 2023; Gonzalez-Canas *et al*., 2024). The sensitivity analyses stratifying by NGO presence (Chapter 5, Section 5.3.2) partially address this concern but cannot fully resolve it due to incomplete programme data.

A further consideration concerns the interpretation of the absolute neonatal mortality rates. The arm-specific rates reported in Section 5.3.1 reflect the risk of neonatal death among prospectively surveilled live births, rather than population-level estimates derived from routine vital statistics or national survey data. Their elevation relative to national reporting reflects methodological differences in how the two rates are derived. The cohort rate is a direct, prospective measure of neonatal death among actively surveilled live births, whereas the national estimate is derived from retrospective full birth histories in the Zimbabwe Demographic and Health Survey (an approach subject to recognised biases that deflate neonatal mortality, including omission of early deaths, misclassification of early neonatal deaths as stillbirths, and age-at-death heaping across the neonatal boundary). This measurement difference, together with the genuinely higher baseline risk of a high-burden rural province that nationally pooled averages tend to understate, accounts for the elevated absolute rates. These cohort-specific rates and national ZDHS estimates are therefore not directly comparable. The higher absolute rates should be interpreted as reflecting more complete ascertainment and a higher-risk setting, rather than an artefact of measurement, which arises from randomised, within-cohort comparisons under uniform ascertainment and is therefore unaffected by the absolute rate level.

The single-province setting limits the external validity of precise effect magnitudes. The 57% reduction is calibrated to Mashonaland West's specific NMR, VHW baseline coverage, governance infrastructure, and rural settlement patterns. The direction and ordering of findings—community structural variables predicting mortality above biological variables; governance-workforce interaction producing super-additive effects; participatory groups requiring longer follow-up for mortality effects—are theoretically generalisable to comparable high-burden rural settings. Precise effect sizes require external validation before adoption as national planning targets.

Taken together, five limitations moderate the conclusions drawn in Section 6.9 and Chapter Seven: the single-province setting; the COVID-19 disruption of the participatory component; contamination of control clusters; the small number of outcome events (68), which limits the precision of all component-level and subgroup estimates and the validity of the predictive models; and the incomplete representation of the most marginalised households, including those in the remotest wards and those who declined household visits during the pandemic, among whom both risk and the potential benefit of institutionalisation are likely to be highest. The predictive model has undergone only internal cross-validation. Each conclusion in Chapter Seven is accordingly stated with the uncertainty these limitations imply.

6.9 Synthesis: Integrating objectives, hypothesis evaluation, and theoretical contributions

Closing the interpretive paradox: This study opened with a paradox: high coverage co-existing with high mortality. The synthesis closes that loop. Zimbabwe's 96% ANC coverage and 86% facility delivery rate position its health system at the Tanahashi cascade's initial contact tier - communities reach services. The 46 per 1,000 live births neonatal mortality rate in Mashonaland West is evidence that initial contact without effective coverage does not protect neonates. The study demonstrates that institutionalising functional governance, training VHWs, and forming participatory groups move communities into the effective coverage tier—the tier at which adaptive feedback loops convert service contact into demonstrable reductions in mortality. The evidence suggests that coverage without functional governance is unlikely to be effective, while acknowledging that service quality, clinical readiness and access may also contribute. The 57% relative reduction (ARR 0.43) is evidence of the effect of the full package, within which governance is a plausible but not independently randomised mechanism.

Objective One: The system-level null hypothesis (H_0, Section 1.6), that institutionalising the community health system vital signs has no effect on reducing neonatal deaths, is robustly rejected (ARR 0.43; 95% CI 0.26–0.70; $p < 0.001$). In answering Research Question 1, all three vital signs were independently and

significantly associated with reduced neonatal deaths, each operating through a theoretically specified mechanism: trained VHWs (IV1) through the Mosley and Chen first- and second-delay pathways; functional governance (IV2) through the Tanahashi effective coverage feedback loop; and the modified WLA/MLA groups (IV3) through cumulative participatory normative change, with the effect significant at adequate exposure (≥4 cycles: AOR 0.71; 95% CI 0.60–0.85; p = 0.001). The dose dependence of the IV3 effect is theorised as a consequence of the time required for social change to mature; a reading of the qualitative evidence of intermediate-level change makes it analytically credible.

Objective Two: The full intervention package produced a 57% relative reduction in preventable neonatal deaths compared with the control (ARR 0.43; 95% CI 0.26–0.70), while the fully institutionalised package produced a 43% greater reduction than partial implementation. This incremental super-additive gain is formally supported by the statistically significant IV1 × IV2 interaction term. CAS theory provides the mechanism: governance creates the adaptive feedback loops that amplify VHW effectiveness beyond additive prediction. This finding advances the theoretical literature on intervention synergy (Hawe *et al.,* 2009) by providing the first cluster-level empirical test of the governance-workforce interaction in a prospective cRCT. Communities under partial institutionalisation (receiving one or two components at fidelity) achieved substantially lower mortality reductions, confirming that the feedback mechanism requires structural completeness to operate.

Objective Three: Model 4—the weighted three-level random-intercept logistic regression with VHW-by-ANC interaction, whose three-level structure maps onto the SEM ecological levels—achieved the best predictive performance on the held-out test set. Simulation projections under full institutionalisation (38–49% reduction) and partial institutionalisation (18–27%) are model-based extrapolations requiring external validation before adoption as planning targets. The Cox regression finding of detectable survival benefit from Day 3 supports the plausibility of the VHW postnatal home-visit mechanism without establishing causation independent of the cRCT evidence.

Objective Four: The strongest risk predictors (low birth weight, short birth interval, and low community women's literacy) operate through Mosley and Chen's proximate determinant pathways, while the strongest protective community-system predictors (the

full institutionalised package, early ANC, and danger-sign recognition capacity) operate through the Tanahashi cascade. The multivariable regression demonstrates that community structural and social variables retain strong, independent associations with neonatal mortality after adjustment for biological risk factors, of magnitude comparable to the leading biological predictors (Table 33), and the synergy analysis shows that these structural components produce their largest effects when delivered as an integrated system. Together, these empirically support the SEM's prediction that governance, workforce, and community-system infrastructure independently shape mortality outcomes rather than acting only as a distal background to clinical care. This independent and synergistic predictive contribution of structural variables is the study's most direct evidence for the policy argument that investment in structural community health systems should accompany and enable, rather than follow, clinical protocol optimisation.

Theoretical contributions: The study contributes to each of the four frameworks specified in Chapter Three as the analytical architecture. To *Mosley and Chen*: it demonstrates that structural community-level variables operate through and modify proximate determinant pathways, extending the framework's explanatory reach from individual biological causation to community system architecture. Within the Socio-Ecological Model, the IV1 × IV2 interaction provides the first cluster-level cRCT evidence of super-additive cross-level effects between interpersonal (workforce) and institutional (governance) SEM levels, operationalising the cross-level interaction theorised in Chapter Three. In the Tanahashi Model, the community death audit is identified as the structural mechanism through which governance achieves Tanahashi's effective coverage tier—the most specific empirical account to date of which institutional condition advances communities to the cascade's highest stage. To *Complex Adaptive Systems theory*: the study specifies, at the cluster level, the operational thresholds under which the governance-workforce feedback mechanism produces detectable population-level mortality effects—advancing CAS theory from mechanism description to empirical boundary condition.

The qualitative strand's synthetic contribution: The meta-inferences generated across the four qualitative analytical arguments extend the quantitative findings in directions that the cRCT design cannot reach. Institutional path dependency explains

why governance non-functionality is structural rather than coincidental. The Tanahashi cascade failure analysis explains why one-off capacity building is insufficient at institutional and acceptability levels. The cross-level SEM mechanism analysis explains how geographic barriers and interpersonal norms produce the proximate delays that VHW-only interventions cannot resolve. The community death audit analysis identifies the specific institutional mechanism through which functional governance achieves effective coverage. Together, these four meta-inferences constitute the theoretical account of how the intervention works, for whom, and under what conditions—the analytical complement to the trial's answer to the question of whether it works.

6.9.1 Summary of key findings

Zimbabwe’s neonatal mortality paradox reflects structural gaps, not chance. This study demonstrates that embedding functional governance within community health systems is essential for transforming high coverage into effective, adaptive care that saves lives. The 43% incremental mortality reduction observed is a conservative benchmark achievable through sustained investment in ward-level governance and workforce infrastructure, especially in the most disadvantaged communities. Moving forward requires political will, domestic financing, and rigorous implementation strategies to ensure that these structural gains translate into lasting improvements in health equity and survival for Zimbabwean neonates.

6.10 Summary

Zimbabwe's coverage paradox is not a measurement error or a developmental inevitability. It is the structural consequence of a health system that has invested in reaching communities (through ANC contact, facility delivery, and VHW deployment) without concurrently building the governance infrastructure through which those contacts are converted into effective, adaptive, quality care. The evidence from this study indicates that functional governance is an important missing structural condition, alongside service quality, clinical readiness and access. Communities that received the institutionalised package of trained VHWs, functional governance, and participatory learning groups experienced a 57% relative reduction (ARR 0.43; 95% CI 0.26–0.70) in preventable neonatal deaths, a finding supported by cluster-randomised trial

evidence, adjusted for pre-specified covariates, and consistent across qualitative, machine-learning, and survival-analysis strands.

This summary does not overstate what the evidence establishes. The 57% relative reduction (ARR 0.43) is a conditional average treatment effect for Mashonaland West Province during 2020–2021, under pandemic conditions that attenuated one of the three intervention components. It may understate the effect of a fully implemented package, but this was not formally tested by sensitivity analysis and should not be described as a lower bound. The protective effect of the WLA/MLA groups (IV3) is significant in a dose-dependent pattern, emerging at sustained exposure (≥4 cycles: AOR 0.71; $p = 0.001$) while attenuating where pandemic restrictions compressed participation below that threshold; the qualitative evidence of intermediate normative change and the theoretical prediction of a longer causal chain together strengthen the case for sustained investment beyond what the headline estimate alone conveys. The simulation projections (38–49% under full institutionalisation) are model-based extrapolations that require external validation before they can serve as national planning targets.

The Critical Paradigm demands that the conclusion name what the evidence reveals about structural justice, not only about programme effectiveness. Every preventable neonatal death in a community without functional governance is a death that institutional choices—about how to invest in community health over four decades—have made structurally more probable. The evidence that mortality risk concentrates in the poorest, most remote, and lowest-literacy communities is not a finding about individual vulnerability but about the spatial distribution of decades of structural neglect. The policy response this evidence demands is redistributive: sustained, financed, and technically supported investment in ward-level governance structures and community health workforces in the most structurally disadvantaged communities—not programme additions to already-performing districts.

Zimbabwe's National Community Health Strategy 2020–2025 provides the strategic architecture. This study provides evidence of what to prioritise within it and an honest account of what remains unknown. The three-to-five-year longitudinal follow-up, the formal economic evaluation, the external validation study, and the implementation science integration are the specific next steps that 'what comes next' requires. What neonates whose survival depends on those steps need is not more evidence that the

system can work, this study provides that. They need the political will and domestic financing to make it work consistently, at scale, and in the communities that have waited longest for it.

CHAPTER SEVEN

CONCLUSION AND RECOMMENDATIONS

7.1 Introduction

This chapter presents the conclusions and recommendations arising from the study on the institutionalisation of community health system vital signs to reduce preventable neonatal deaths in Mashonaland West Province, Zimbabwe. It draws on the four study objectives: (i) assessing the independent predictive associations of village health worker training, functional community governance, and modified women's and men's learning and action groups on neonatal mortality; (ii) determining the magnitude and synergistic effects of the combined community health system package; (iii) developing and simulating a predictive model under scenarios of full, partial and non-institutionalisation; and (iv) assessing the benefit–harm balance and policy implications of institutionalising the three vital signs. Each conclusion in Section 7.2 is labelled with the objective it answers and is followed by a statement of its principal uncertainty. The chapter synthesises these findings into forward-looking conclusions, presents actionable recommendations with clearly identified responsible implementers, and identifies priorities for future research.

Lastly, this study makes four novel contributions to the Zimbabwean and global evidence base on community health systems and neonatal survival, each of which is developed in Section 7.3. First, it provides what is, to the candidate's knowledge, the first prospective cluster-randomised controlled trial evidence from Zimbabwe that institutionalising all three community health system vital signs as a package reduces neonatal deaths. Second, it offers a formal empirical test of the synergy hypothesis within a community health systems cRCT, including a cluster-level estimate of the governance–workforce interaction. Third, it integrates machine learning with community-level structural data alongside biological and clinical variables, demonstrating that structural variables carry independent predictive value that facility-based, clinically focused models cannot capture. Fourth, it proposes trial-derived candidate operational thresholds and an internally validated prediction model that

together suggest the boundary conditions under which the governance feedback mechanism produces detectable population-level mortality effects. Together, these contributions move the field beyond the cross-sectional and facility-based evidence that has dominated the literature, toward an integrated, systems-level account of how community structures reduce preventable neonatal mortality.

7.2 Conclusions

The evidence presented in Chapter Six supports seven conclusions. Each is labelled with the study objective it answers, stated in terms of its forward-looking implications for policy, practice and research, and followed by its principal uncertainty:

i. **Objective One - Institutionalising the community health system package reduces preventable neonatal deaths:** The randomised comparison supports a causal conclusion about the complete package: a 57% relative reduction (ARR 0.43; 95% CI 0.26–0.70) in preventable neonatal deaths, achieved under pandemic conditions. Because IV1, IV2, and IV3 were delivered together rather than separately randomised, the necessity of each individual component reflects an adjusted association, not a randomised finding. Partial institutionalisation was associated with substantially smaller gains: the implication is that piecemeal investment (training VHWs without building governance or building governance without sustaining participatory groups) is an insufficient policy response. Uncertainty: the estimate comes from one province over 12 months under pandemic conditions, with 68 outcome events; residual differential ascertainment between arms cannot be excluded by design (Section 6.6).

ii. **Objective One - Functional community governance is the community-level structural variable most strongly associated with neonatal survival:** on this evidence, governance revitalisation is a high-leverage structural investment for district health planners. The 92.7% hazard reduction associated with its presence is the largest effect among the community-level structural predictors examined, and it remains significant after adjustment for individual clinical and biological risk factors, indicating an independent association with neonatal survival of magnitude comparable to the leading biological predictors. The policy implication is that, for communities already at Tanahashi's initial contact

tier, governance revitalisation is likely to yield more than further expansion of service coverage alone. Uncertainty: governance was not separately randomised; the hazard ratio is an adjusted association from within-trial variation with a wide confidence interval, and the coverage-versus-governance contrast is a hypothesis for a future trial rather than a randomised finding.

iii. **Objective One: Trained VHWs are independently associated with lower mortality, and the association is stronger where governance is functional:** VHW training and functional governance are not interchangeable investments; they are structurally interdependent. The statistically significant IV1 × IV2 interaction (Table 41) is consistent with each component amplifying the other: governance without VHWs lacks frontline intelligence; VHWs without governance lack an accountability mechanism. The practical implication is that financing one without the other produces diminishing returns; their co-investment is the condition under which super-additive mortality reduction was observed. Uncertainty: the interaction term is modest (AOR 0.79; p = 0.03) and, with 68 events, is underpowered; it is reported as consistent with super-additivity, not as a precise estimate of it.

iv. **Objective Two - Modified WLA/MLA group participation was associated with lower neonatal mortality in a dose-dependent manner, significant at adequate exposure -** The effect was significant among participants completing four or more cycles (AOR 0.71; p = 0.001) and attenuated below that threshold, a dose-response gradient reinforced by the nearly fivefold increase in mortality where fewer than three meeting cycles were completed. Combined with the qualitative evidence of intermediate normative change, this constitutes a strong argument for continued investment. The implication for policy is sustained funding to ensure adequate participation intensity, together with a three- to five-year follow-up horizon to establish whether the mortality benefit observed at adequate dose is sustained and strengthens as normative change matures. Uncertainty: exposure was not randomised at the individual level, so the dose-response association may partly reflect selection of more engaged households into higher attendance; COVID-19 restrictions compressed exposure in a non-random way.

v. **Objective Two - Community structural variables are independently associated with neonatal mortality, with magnitudes comparable to individual biological variables.** The conventional epidemiological hierarchy (which treats biological and clinical variables as the primary targets for intervention and structural factors as secondary targets) is not supported by this evidence base. In the multilevel regression, community structural and social variables retain strong, significant associations with neonatal mortality after adjustment for biological risk factors (Table 33), and the synergy analysis shows their effects are amplified when governance, workforce, and social infrastructure are delivered as an integrated system. The implication of investment is direct: governance architecture and workforce infrastructure are first-order targets for mortality reduction, not secondary support to be addressed after clinical protocol optimisation. Uncertainty: these are adjusted associations from a multivariable model with many predictors and few events, and the ordering of predictors should be regarded as provisional until replicated.

vi. **Objective Three - The multilevel predictive model and simulation are promising, internally cross-validated programme-targeting tools -** The multilevel predictive model, evaluated only by internal leave-one-cluster-out cross-validation, and with its reported performance metrics provisional for the reasons stated in Section 5.6 (with a 7% event rate, predicting survival for every infant would yield approximately 93% accuracy, so accuracy alone is not informative), offers district health managers a potential tool for identifying which clusters to prioritise for governance revitalisation investment before mortality accumulates. Its intended value is in classifying most surviving neonates as low risk so that VHW home-visit resources can be concentrated where risk is highest, a property that must be confirmed on re-estimation. Its current appropriate use is cluster-level programme targeting; individual clinical deployment requires prior external validation in at least two comparable LMIC settings. Uncertainty: the model was estimated on 68 events with a predictor set that requires re-estimation on the live-birth denominator (Section 5.6), and the simulation projections (38–49%) are model-based extrapolations, not observed effects.

vii. **Objective Four - Zimbabwe's neonatal mortality paradox reflects a governance and structural investment gap that persists despite high service coverage -** High coverage has not, on its own, translated into neonatal survival; the findings point to governance architecture as an important, though not the only, missing condition, alongside service quality, clinical readiness and access. With 96% ANC coverage and 86% facility delivery rates already achieved, expanding initial contact further cannot produce the mortality gains that advancing to effective coverage through functional governance can. The policy imperative this conclusion demands is a reorientation of investment away from coverage metrics and toward the governance and workforce infrastructure that converts coverage into adaptive, quality care at the community level where neonatal deaths occur. Uncertainty: this is an interpretation of the trial finding through the Tanahashi framework, not a randomised comparison of governance investment against coverage expansion; service quality, clinical readiness and access were not directly tested and may contribute substantially.

This layered analysis helped to develop a proposed implementation strategy in Mashonaland West province (Figure 25).

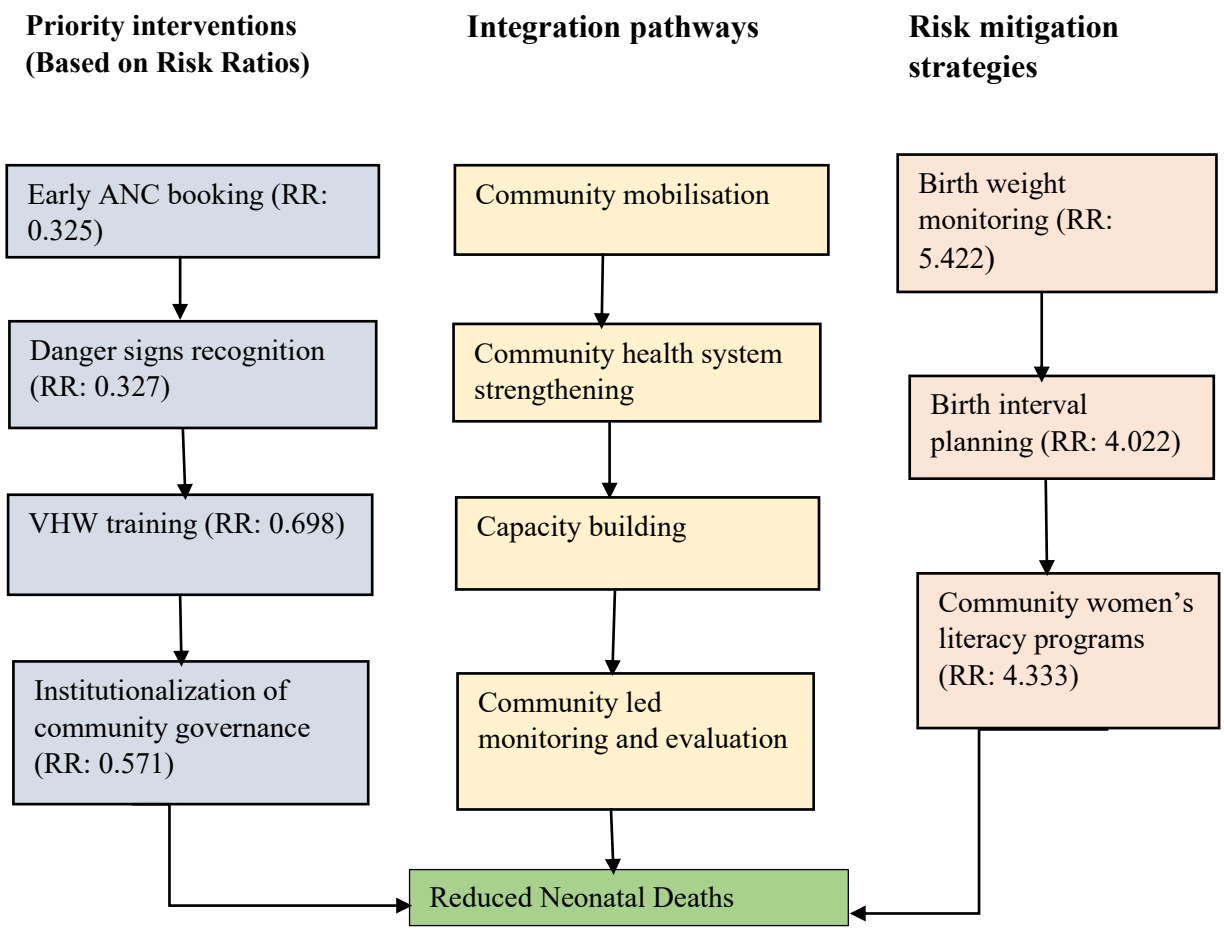


Figure 24: Proposed Community-Based Implementation Strategy to Reduce Neonatal Deaths in Mashonaland West Province, 2020-2021

7.3 Novel Contributions

This study makes four contributions that extend the Zimbabwean and global evidence base:

i. It provides what is, to the candidate's knowledge and on the basis of the literature reviewed in Chapter Two, the first prospective cluster-randomised controlled trial evidence from Zimbabwe that institutionalising all three CHS vital signs as a package reduces neonatal deaths. The contribution is not the trial design alone, which exists elsewhere, but the specific structural configuration it tests prospectively: a setting in which high nominal coverage (96% ANC, 86% facility delivery) coexists with rising neonatal mortality. This coverage–effectiveness paradox constitutes a natural experiment that the prevailing cross-

sectional and retrospective Zimbabwean evidence base could not interrogate, allowing this study to identify functional community governance as an important structural determinant of neonatal survival that further coverage expansion alone does not supply.

ii. It provides a formal empirical test of the synergy hypothesis within a community health systems cRCT; no earlier such test was identified in the literature reviewed in Chapter Two. Whereas previous work has inferred synergy indirectly from separate main effects, this study estimates the governance–workforce interaction directly as a modelled term: the statistically significant IV1 × IV2 interaction provides a cluster-level estimate of this effect. Because interaction terms require more statistical power than main effects, this estimate is reported with its cluster-level confidence interval and interpreted as consistent with super-additivity rather than as a precise point estimate.

iii. Prior machine learning applications for neonatal mortality have largely relied on facility-based clinical datasets in which predictors are predominantly biological and clinical (Guo *et al.,* 2021). The contribution here is not the application of machine learning per se, which is now an established practice, but the substantive finding that this application makes visible. By modelling community-level structural data (governance functionality, VHW coverage, and participatory group attendance) alongside biological and clinical variables within a single framework, and by triangulating the machine learning model with multivariable regression and synergy analyses, this study demonstrates that community structural variables have an independent predictive value of magnitude comparable to established biological predictors. This finding directly challenges the conventional epidemiological risk-factor hierarchy, which treats biological and clinical variables as primary and structural factors as secondary, and which facility-based, clinically focused models are structurally incapable of generating because they do not observe the community-level variables in question. The novelty is therefore epistemic rather than computational: it reorders the predictor hierarchy that guides the targeting of neonatal mortality interventions.

iv. This study makes the abstract governance feedback mechanism of Complex Adaptive Systems theory operationally measurable. Complex Adaptive

Systems theory has been widely invoked in health systems research but rarely rendered testable; this study translates it into trial-derived candidate operational thresholds that suggest the boundary conditions under which the governance feedback mechanism produces detectable population-level mortality effects. The contribution is thus a bridge between theory and operations: it converts a previously qualitative theoretical construct into quantitative targeting criteria that are proposed for testing at district level. The optimal community health system prediction model, expressed as:

Logit (P (Yijk (Neonatal Death) = 1)) = $\beta 0 + \beta_1$ (Birth weight) ijk + β_2 (Birthinterval) ijkk + β_3 (Postnatal care within 72hours) jkk + β_4 (Community women's healtliteracy) k) k + β_5 (VHW presence in community) k + β6 (Early ANC booking) jk + β7 (VHW presence × Early ANC Booking) jk + U0j + U0k ……. ***equation (4)***

…provides a comprehensive, theoretically derived framework for identifying high-risk neonatal clusters and targeting resources accordingly. Communities that implemented comprehensive strategies experienced a 43% greater reduction in neonatal deaths compared to those with partial interventions, consistent with the value of a holistic approach.

The study proposed the community-based conceptual framework (Figure 26) for reducing preventable neonatal deaths:

Conceptual Framework

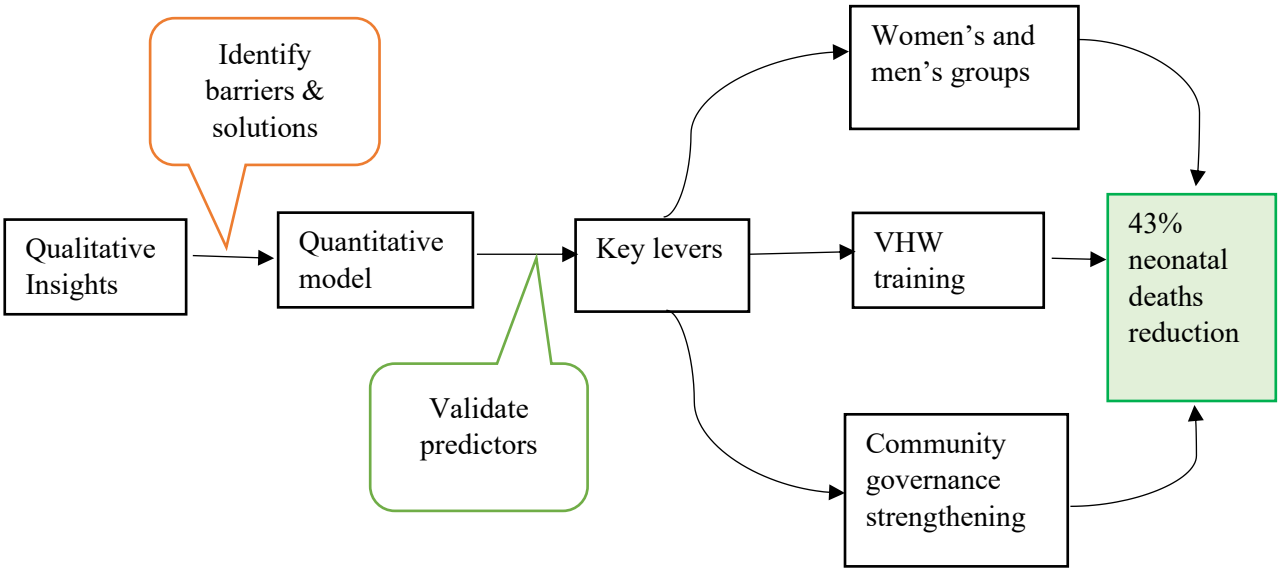


Figure 25: Proposed community-based conceptual framework for reducing neonatal deaths

In summary, this study represents an important advancement in maternal and neonatal health by introducing a pragmatic framework. The insights generated not only advance academic discourse but also offer actionable strategies for healthcare practitioners, policymakers, and communities in Zimbabwe and beyond, ultimately aiming to reduce preventable neonatal deaths.

7.4 Concluding Remarks

Zimbabwe's neonatal mortality trajectory—with the 2023-24 ZDHS reporting an increase to 37 per 1,000 live births—makes it clear that the country is off track to meet SDG 3.2. Increasing reliance on facility-based deliveries has not been accompanied by commensurate reductions in mortality. This study indicates that one important missing structural condition is functional community governance: the accountability and feedback mechanism that converts high nominal coverage into effective, adaptive care.

The evidence generated here provides Zimbabwe's National Community Health Strategy 2020-2025 with a clear evidence-based mandate: institutionalise all three vital signs of the community health system (VHW training, functional governance, and

participatory learning groups) at the ward and village levels where neonatal deaths occur. The 57% relative reduction (ARR 0.43) observed under the conditions of this trial was achieved during a pandemic that attenuated the intervention's most socially intensive component. The simulation scenarios (38–49% projected reduction under full institutionalisation) are model-based extrapolations that require external validation before use as planning targets.

The study's most important structural finding (that mortality risk concentrates in the poorest, most remote, and lowest-literacy communities, which are also the communities with the least functional governance and VHW coverage) is not a statistical observation about individual vulnerability. It is evidence of the spatial distribution of decades of structural underinvestment. The recommendations that follow are therefore redistributive in orientation: they direct investment toward the ward and village governance levels and the most disadvantaged communities, including artisanal mining settlements and households beyond 30 kilometres from the nearest facility, not toward universal service expansion in districts that are already performing.

Sustainable reduction of neonatal mortality in Zimbabwe requires political will, sustained domestic financing, and a clear implementation pathway that holds district health teams accountable for governance functionality, not only for coverage indicators. This study provides evidence of what to prioritise; what neonates in Mashonaland West and beyond need is the institutional commitment to act on it.

7.5 Recommendations

The following recommendations are derived directly from the study's evidence and are organised by implementer. Each recommendation specifies the responsible institution or actor to ensure operational clarity and accountability.

7.5.1 Ministry of Health and Child Care (MOHCC): National Level

i. The MOHCC should establish a National Community Health System Institutionalisation Scorecard for all 63 districts, structured explicitly around the Tanahashi coverage cascade. The scorecard should include: (i) one trained VHW per 100 households as the availability threshold; (ii) at least 80% of VHCs meeting monthly with documented outputs as the acceptability threshold; and (iii) at least 70% of wards with active WLA/MLA groups as the initial contact threshold. Districts falling below any threshold should be classified as priority investment targets and receive differentiated resourcing. Within this framework, artisanal mining communities and wards more than 30 kilometres from the nearest facility (the populations most underrepresented in this study's qualitative sample and most structurally disadvantaged) should be identified as the highest-priority clusters for immediate investment.

ii. The MOHCC should revise and accelerate implementation of VHW training curricula to embed essential newborn care, danger-sign recognition, and postnatal home-visit protocols. A standardised national refresher training programme should be delivered within 18 months through Provincial Training Centres, in coordination with technical support from UNICEF and WHO. The curriculum must explicitly address: (i) sex-specific exclusive breastfeeding counselling to counter the documented cultural norm of early supplemental feeding of male infants, which the study's focus group discussions identified as a socially enforced practice that disrupts breastfeeding and may elevate infection risk; and (ii) birth preparedness and prenatal bonding practices — including the facilitation of prenatal naming — which the study's logistic regression and qualitative findings associate with higher social support, earlier care-seeking, and improved birth preparedness.

iii. The MOHCC should ensure uninterrupted VHW commodity supply to all frontline community health workers. This study's qualitative findings document a "trust economy" in which community members' willingness to engage with VHWs is directly conditional on VHWs demonstrating material competence — that is, possessing and dispensing commodities. A VHW without supplies cannot achieve Tanahashi's acceptability tier regardless of training level.

MOHCC supply chain management should treat VHW commodity continuity as a non-negotiable precondition for acceptability-level coverage, with district-level accountability mechanisms to prevent stock-outs.

iv. The MOHCC should integrate the community-based death audit protocol into the National Community Health Strategy's standard operating procedures for all VHCs, with outputs linked to DHIS2 for district-level real-time monitoring and accountability. This directly addresses the study's finding that governance feedback loops, rather than VHW deployment alone, are the structural mechanism for effective coverage.

v. To strengthen early ANC booking and danger sign recognition at the household level, the MOHCC should: develop pictorial and audio-visual education materials on neonatal danger signs adapted for low-literacy communities; establish community-based ANC scheduling systems through VHW pregnancy registration networks; roll out integrated outreach and mobile clinic services for communities more than 15 kilometres from the nearest facility; and implement mobile-technology reminder systems for scheduled ANC visits. These actions directly address the VHW-by-ANC interaction (Model 4), in which the joint presence of VHW newborn-care training and early antenatal care was associated with lower odds of neonatal death than either alone (AOR 0.38; 95% CI 0.21–0.69).

vi. The MOHCC should establish clear community emergency response protocols at the household and community level to enable immediate action during neonatal obstetric emergencies. These protocols should be embedded in WLA/MLA group learning cycles and VHW home-visit checklists and are directly indicated by the first- and second-delay pathways documented in this study.

vii. The MOHCC, in partnership with the Ministry of Finance and Economic Development, should develop a costed domestic health financing plan for community health guided by the formal economic evaluation of this study's cost-per-death-averted data, which is identified as a priority in Section 7.5. The NCHS Investment Case (Government of Zimbabwe, 2020) estimates full institutionalisation at approximately USD 1.50 per capita per year; however, this study did not conduct a formal economic evaluation and cannot confirm

cost-effectiveness. The financing plan should therefore be developed in conjunction with (and contingent on) the economic evaluation recommended in Section 7.5.

7.5.2 Provincial Health Directorates (Mashonaland West and comparable provinces)

i. Provincial Health Directorates should prioritise and resource VHC revitalisation at the ward level to address the documented inequity between HCC and VHC functionality. This study found that HCCs (co-located with health facilities) reported full functionality across all relevant respondents, while VHCs (ward-level structures in remote communities) achieved full functionality in only 60% of cases. VHC functionality is the governance mechanism closest to the communities where neonatal deaths occur. Facilitated interface meetings between VHCs, HCCs, and facility staff should be scheduled quarterly, with Provincial Health Teams providing structured facilitation support. This is particularly urgent in wards more than 30 kilometres from the nearest clinic.

ii. Provincial Health Teams should institutionalise monthly supportive supervision of VHWs using structured checklists assessing home-visit frequency, danger-sign education delivery, postnatal care coverage, linkage with VHC governance structures, and commodity availability. Performance monitoring data should feed directly into district-level Tanahashi scorecards.

7.5.3 District Health Management Teams (DHMTs)

i. DHMTs should use the multilevel predictive model as a cluster-level targeting instrument to identify wards and communities at the highest risk of preventable neonatal deaths. The model's three-level structure (capturing individual, service-delivery, and community factors) enables targeted resource allocation to underperforming clusters. DHMTs should prioritise VHW deployment, governance revitalisation investment, and WLA/MLA group rollout in clusters identified as below the institutionalisation risk threshold. The model's appropriate use is as a programme-level targeting tool; its deployment for

individual clinical risk-scoring requires the four-step external validation process set out in Section 7.5.

ii. DHMTs should strengthen birth interval planning and family planning service coverage, with a focus on high-parity mothers, through integrated outreach services providing access to long-acting reversible contraception. This recommendation is directly indicated by the finding that a short birth interval (< 24 months) is the second-strongest risk predictor (feature importance score: 0.509 in Random Forest analysis). Gender-transformative programming (specifically, male-involvement initiatives) should be embedded in WLA/MLA group curricula to address the gendered dynamics of household decision-making documented in the study's focus group discussions.

iii. DHMTs should implement targeted interventions to reduce low birth weight, the study's strongest individual risk predictor (RR: 5.422), through antenatal nutrition supplementation programmes, adolescent reproductive health services, and strengthened management of obstetric complications at the facility level. This study establishes LBW as a primary predictor but does not directly evaluate LBW-reduction interventions; these actions are indicated by the study's predictor hierarchy and are consistent with the Mosley and Chen framework, which identifies LBW as a proximate cause of neonatal death, structurally produced by maternal malnutrition and poverty.

iv. DHMTs should strengthen district-level referral systems and facility-community linkages (vertical integration), consistent with this study's finding that VHWs who successfully mobilise care-seeking depend entirely on facility readiness upon arrival — a third-delay gap identified as an analytical limitation of the IV1 evidence (Chapter 6, Section 6.2.1). While the study does not directly measure facility readiness, the qualitative evidence documents facility-level supply failures that can nullify VHW-enabled care-seeking. Horizontal integration (inter-service coordination, resource optimisation, and quality assurance across health system levels) should be formalised through district multi-disciplinary integrated outreach programming.

v. DHMTs should expand Kangaroo Mother Care (KMC) and postnatal care coverage at the household level for low-birthweight and preterm neonates, consistent with the study's finding that postnatal care within 72 hours is a

significant protective factor in the prediction model (Model 4, β_3). Standardised KMC protocols for both institutional and community-level care should be developed under MOHCC guidance and implemented through district capacity-building programmes.

7.5.4 Village Health Committees (VHCs) and Health Centre Committees (HCCs)

i. VHCs should conduct community-based neonatal death audits following every neonatal death in their catchment area, using the standardised protocol to be established by MOHCC. Audit outputs should be documented, shared at VHC-HCC interface meetings, and reported through DHIS2. The community death audit is the structural mechanism identified in this study as the transition from Tanahashi's initial contact to effective coverage tier — it transforms adverse events from private losses into public accountability processes, creating the feedback loops that enable adaptive, responsive governance. Its consistent implementation at the ward level is non-negotiable for achieving the study's projected mortality reductions.

ii. VHCs, supported by DHMTs, should mobilise community resources for maternal waiting homes and emergency transport networks in wards where geographic distance to facility delivery remains a significant barrier. This recommendation responds to the study's qualitative finding that communities 38 kilometres from the nearest clinic are structurally exposed to second-delay mortality risk that community system interventions alone cannot overcome. Community bricklaying for waiting homes and collective transport mobilisation (both documented in focus group discussions as community-driven compensatory responses) represent evidence-consistent and community-owned approaches to this structural barrier.

7.5.5 Village Health Workers (VHWs)

i. VHWs should conduct structured postnatal home visits within 72 hours of birth for every neonate in their catchment area, using standardised checklists that include: danger-sign assessment; exclusive breastfeeding support (with specific

attention to the documented male infant supplemental feeding norm); temperature management; infection prevention; birth preparedness review; and referral activation where indicated. The study's Cox regression confirms that the VHW survival benefit is detectable specifically at the Day-3 postnatal visit window, making this the highest-impact, most time-critical VHW action. Checklists should also incorporate prompts for prenatal naming and bonding, which the study's logistic regression (Table 34) associates with higher social support and protective health-seeking behaviour.

ii. VHWs should facilitate modified WLA/MLA group meetings in their communities, ensuring completion of at least four meeting cycles per year. The dose-response evidence from this study establishes that completing fewer than three meeting cycles was associated with a nearly fivefold increase in neonatal mortality risk — making consistent facilitation of meetings as operationally critical as postnatal home visits. MOHCC and DHMTs should ensure that VHWs receive the tools, facilitation guides, and supervisory support needed to sustain meeting cycles through seasonal disruptions, travel barriers, and pandemic conditions.

7.5.6 Ministry of Primary and Secondary Education and Intersectoral Partners

i. The Ministry of Primary and Secondary Education, in coordination with MOHCC, should prioritise girls' secondary school completion and adult female literacy programmes in Mashonaland West and comparable high-burden provinces. This recommendation is directly supported by this study's finding that low cluster-level women's literacy is the third-strongest risk predictor, operating through multiple proximate pathways identified by Mosley and Chen: reduced danger-sign recognition, lower ANC uptake, and diminished capacity to navigate health systems. Chapter 6 (Section 6.2.4) explicitly identifies women's literacy as a predictor that cannot be structurally addressed without intersectoral partnership with the education sector. Community health system investment is necessary but not sufficient — addressing the literacy predictor requires structural investment at the school and adult education levels.

ii. National and district nutritional programmes, under the Ministry of Health in coordination with the Ministry of Public Service, Labour and Social Welfare, should strengthen antenatal nutrition supplementation for pregnant women and adolescent girls, particularly in remote and food-insecure communities. Low birth weight — this study's single strongest risk predictor (RR: 5.422) is a structural outcome of maternal malnutrition and poverty. Its reduction requires intersectoral investment in nutrition security and adolescent health beyond what the community health system can achieve independently.

7.5.7 Development Partners, UN Agencies, and Non-Governmental Organisations

i. Development partners (including UNICEF, WHO, Save the Children, and UNFPA, among others) should align technical assistance and funding to the MOHCC Tanahashi scorecard framework, prioritising governance revitalisation, VHW commodity continuity, and WLA/MLA group facilitation capacity in the lowest-performing wards. This study's qualitative findings document institutional path dependency in which fragmented NGO programming that bypasses district governance structures has historically reproduced — rather than reversed — the VHW-only institutional frame. Development partners should explicitly discontinue parallel programming that circumvents district health governance and instead invest in system-strengthening approaches that build sustainable institutional capacity.

ii. Development partners should jointly fund the research priorities identified in Section 7.5: the three-to-five-year longitudinal follow-up of the trial cohort; the formal economic evaluation of the study's cost-per-death-averted data; and the external validation of the predictive model in comparable LMIC provincial settings. These are the three most immediate evidence gaps identified by this study, and their resolution is a prerequisite for translating the 43% mortality reduction finding into sustainable national policy and international financing commitments.

7.6 Recommendations for Further Research

The following research priorities are identified in order of urgency, with the responsible institution indicated:

i. Three-to-five-year longitudinal follow-up (MOHCC and University research partners): Required to determine whether the 57% mortality reduction is sustained as governance structures mature, to detect WLA/MLA groups' lagged mortality effect beyond the 12-month window, and to conduct per-protocol sensitivity analyses restricted to participants completing ≥4 meeting cycles in COVID-unaffected clusters. This study should be pre-registered at the same trial registry as the parent trial.

ii. Re-estimation and external validation of the predictive model (University of Lusaka and MOHCC research partners): Before any programme use, the multivariable and machine-learning models should be re-estimated on the 882 live births with time of neonatal death excluded and the predictor set restricted to the DAG-specified variables, evaluated with cluster-aware cross-validation and calibration against a locally chosen decision threshold, and then externally validated in at least two comparable rural provinces. This is the immediate analytical priority arising from this thesis.

iii. Formal economic evaluation (MOHCC Health Economics Unit, with development partner support): A cost-per-death-averted analysis using this trial's cost and mortality data is required before any domestic financing advocacy can be made with the rigour that health financing decisions require. The NCHS Investment Case figure of USD 1.50 per capita provides a directional reference only; this study did not establish cost-effectiveness. The economic evaluation is also a prerequisite to finalising the domestic financing plan recommended in Section 7.4.1.

iv. External validation of the predictive model (University research consortium, LMIC research partners): Required before the multilevel model is deployed for individual-level risk scoring. Validation should be conducted in at least two comparable high-burden rural provincial settings in sub-Saharan Africa, with

cluster-stratified cross-validation, calibration assessment, and decision curve analysis.

v. Quantitative investigation of prelacteal feeding and prenatal naming practices (MOHCC Reproductive Health Directorate and academic partners): This study's logistic regression and FGD evidence identify both the male infant supplemental feeding norm and prenatal naming as predictors of neonatal mortality operating through social capital and breastfeeding pathways. Neither has been quantitatively confirmed as a causal mechanism. Research measuring prelacteal feeding rates by infant sex and their association with neonatal infection outcomes (alongside a survey-based study of prenatal naming practices and their correlation with birth preparedness) are required to translate these hypothesis-generating findings into protocol revisions for VHW curricula and WLA/MLA group content.

vi. Intersectoral research on women's literacy and LBW as structural predictors (multi-ministry research collaboration): The study identifies women's literacy and low birth weight as the second and third strongest predictors, but also explicitly notes these cannot be addressed through community health systems alone. Dedicated implementation research on women's literacy programmes and antenatal nutrition interventions in high-burden rural Zimbabwe (evaluating their specific contributions to neonatal survival) is needed to build the intersectoral evidence base required for joint ministerial investment.

vii. Implementation science integration (MOHCC and Implementation Science Network partners): A Consolidated Framework for Implementation Research (CFIR)-guided or Exploration, Preparation, Implementation, Sustainment (EPIS) - guided implementation science study is needed to address how — not only whether — the three CHS vital signs can be institutionalised at scale across all 63 districts under resource-constrained conditions.

viii. Meta-analysis on community health system institutionalisation in LMICs (Academic research consortium): A systematic review and meta-analysis of evidence on institutionalising community health systems in low-income countries is needed to situate Zimbabwe's findings within the global evidence base and to strengthen evidence-based decision-making for international financing.

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APPENDICES

Appendix 1: Using the Tanahashi Model lens to analyse coverage of health services and community health system strengthening.

Determinants	Coverage
Supply determinant Supply-side factors in the health system are the core components responsible for providing healthcare services. These encompass the stock of essential medicines and supplies, the presence of an adequately trained health workforce, and the physical accessibility of health facilities (WHO, 2010; USAID, 2014; Kruk *et al.,* 2017; WHO, 2018).	**"Availability coverage"** – Demonstrates the availability of critical resources, such as the health workforce (including healthcare workers and community health workers), health infrastructure, and essential medicines, among others, that influence the ability to deliver fundamental essential health services at the community level. (WHO, 2010; USAID, 2014; Kruk *et al.,* 2017; WHO, 2018; Olaniran *et al.*, 2022; Yenet, Nibret & Tegegne, 2023) Lehmann, U. & Sanders, 2007; Lehmann et al., 2015; WHO, 2016; World Bank, 2018).
	"Accessibility coverage" refers to the portion of the population that can utilise or reach community health services. Effective services should be geographically" situated within the daily environments of those in need", ensuring they are easily reachable and affordable so that individuals do not face financial barriers or hardship when accessing care (Gwatkin *et al.,* 2004; Peters *et al.,* 2008; WHO, 2010; McCollum *et al.,* 2019).
Demand ”Demand side determinants entail parameters at the individual, household, or community level, which influence the ability of an individual to identify illness, and willingness to seek and use appropriate health care" (McCollum *et al.,* 2019). These include financial access, socio-cultural practices and beliefs, initial utilisation of services and continuity of use or knowledge of individuals.	**Acceptability coverage** – This domain allays the perception of individuals and trust that enables people to access the health care services, with determination and willingness to use the services for better health outcomes. Notably, increased perception of risk triggers immediate action from an individual or community. Factors such as cost, client/patient waiting time, cultural beliefs, or religion play a key role in acceptability.
	Contact coverage – The probability of citizens or people who are reached and utilising the services being provided by the community health at the household level (Demissie & Gutema Negeri, 2020).

Determinants	Coverage
Quality Quality determinants encompass the "quality of services provided at" the institutional or community level (Sharifi *et al.,* 2021)	**Effective coverage** refers to the percentage of individuals in need of health services who actually receive high-quality, comprehensive, and person-centred care at the "primary health care level". This ensures equitable, continuous access to and use of "essential community-based health services" (WHO, 2018; Kruk *et al.,* 2018; World Bank, 2020; Zulu, 2020).

Source: World Health Organisation (WHO) 2010; McCollum, R., Taegtmeyer, M., Otiso, L. *et al. (2019)*

Appendix 2: Summary of evidence from reviews on key interventions with an impact on neonatal mortality

Preventive and promotional interventions

Intervention	Neonatal Outcomes Assessed	Risk reduction	Authors & Year
Magnitude of neonatal mortality and its association with maternal and child health care in sub-Saharan Africa: a systematic review and meta-analysis	Neonatal mortality	OR = 2.19, 95% CI: 1.61, 2.98],	Jena *et al.,* 2025
Community-based information, education, and communication on safe motherhood	Perinatal mortality	13% in Uganda 26% in Zambia	Serbanescu *et al.* 2019
"Participatory learning and action among women's groups, along with home visits." (Prost *et al.,* 2013; Gope *et al.,* 2019).	Neonatal deaths; Stillbirths Early care seeking for newborn illnesses	23% (0.77, 0.65-0.90)	Lewycka, 2010 Prost *et al.* 2013 Gope *et al.* 2019
Preventive treatment for malaria during pregnancy and the utilisation of insecticide-treated nets (ITNs).	Perinatal deaths; Low birth weight Stillbirths	27% 95% CI: 1% - 47%. 43% 95% CI: 28% - 54%	Brentlinger et al. 2007 WHO, 2014 Mwandama, *et al.* 2015
Screening for pre-eclampsia	Preterm deaths	15%	Bhutta *et al.* 2011
Tetanus toxoid vaccination	Neonatal deaths	98% CI: 70% - 100%	
Medications for early rupture of the uterus using antibiotics	Infections in newborn babies - "Neonatal sepsis"	32% CI: 13%-47%	Zaidi *et al.* 2011 Seelbach-Goebel. 2013
Delivery by a skilled birth attendant	Neonatal sepsis; Neonatal tetanus/ deaths	15% and 60% respectively	Bhutta *et al.* 2011 Ali *et al.* 2014
Essential newborn care practices	Neonatal tetanus	55% - 99%	Sajid *et al.* 2012

Feeding or nursing the baby with breastmilk	Diarrheal disease and pneumonia in children	“55% to 87%”	
Kangaroo mother care	Hypothermia; Infection	51% CI: 7% - 75%)	

Appendix 3: Equations

4.1.1 Standardised Mean Difference Calculation

For continuous variables:

$$\text{SMD} = \frac{\bar{X}_{\text{int}} - \bar{X}_{\text{ctrl}}}{\sqrt{\frac{(n_{\text{int}}-1)s_{\text{int}}^2+(n_{\text{ctrl}}-1)s_{\text{ctrl}}^2}{n_{\text{int}}+n_{\text{ctrl}}-2}}}$$

For binary variables:

$$\text{SMD} = \frac{\hat{p}_{\text{int}} - \hat{p}_{\text{ctrl}}}{\sqrt{\frac{\hat{p}(1-\hat{p})(n_{\text{int}}+n_{\text{ctrl}})}{n_{\text{int}} \cdot n_{\text{ctrl}}}}}$$

$$\text{Where } \hat{p} = \frac{n_{\text{int}}\hat{p}_{\text{int}}+n_{\text{ctrl}}\hat{p}_{\text{ctrl}}}{n_{\text{int}}+n_{\text{ctrl}}}$$

5.3.2 Verbal Autopsy Limitations

The WHO verbal autopsy tool itself has inherent methodological limitations:

i. **Sensitivity:** Estimates range from 60–90% for major causes (e.g., birth asphyxia, infections).

ii. **Specificity:** Lower causes with overlapping symptoms, such as sepsis versus pneumonia.

iii. **Physician Agreement:** Moderate inter-physician agreement in classifying cause of death ($\kappa = 0.65–0.72$).

- **Missing Data:** In this study, 8.3% of deaths had insufficient information for cause-of-death assignment.

These limitations may further contribute to potential misclassification and should be considered when interpreting the study's results regarding neonatal mortality causes.

Appendix 4: Feature Importance Analysis

"Feature importance is a technique used in machine learning to determine which features (variables)" (Mirazimzadeh *et al.*, 2024), in a dataset, contribute most significantly to the prediction of the target variable. It quantifies the value that each feature adds to the "predictive accuracy of the model" (Awe & Vance, 2025), helping to identify the most influential variables, guide feature selection, understand the model's behaviour, and support decision-making.

conceptual framework.

5.5.4 Community Health System Model Equation

Multiple Logistic Regression community health system prediction model, for reducing preventable neonatal deaths.

The model equation is:

$$\log(p/(1-p)) = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \ldots + \beta_n x_n$$

Where:

- p is the probability of neonatal death
- β_0 is the intercept
- β_1 to β_n are the coefficients
- x_1 to x_n are the standardized feature values

β_0: coefficient for Intercept = -4.2613
β1: coefficient for SES = -0.1271
β2: coefficient for Age = -0.1227
β3: coefficient for Desire for Pregnancy = -0.1007
β4: coefficient for Birth interval <2yrs = 0.5077
β5: coefficient for Birth Weight <2500g = 0.4073
β6: coefficient for Complications = -0.0684
β7: coefficient for Skilled Birth Attendant = 0.1847
β8: coefficient for Live birth 2 to4 = -0.0543
β9: coefficient for Live births 5 plus = 0.2797
β10: coefficient for Birth order 1 = -0.0706
β11: coefficient for Birth order 2to3 = -0.1331
β12: coefficient for Family influence = 0.4497
β13: coefficient for Birth order 4plus = 0.1885
β14: coefficient for Baby name = -0.0250

β15: coefficient for Women's Group Meetings = -0.1845
β16: coefficient for Number of meetings = -0.1015
β17: coefficient for Faith based organizations = -0.0400
β18: coefficient for No Social networks = 0.0990
β19: coefficient for Trained VHW = -0.1517
β20: coefficient for VHWs trained in newborn care = 0.1446
β21: coefficient for Non institutionalized = 0.0920
β22: coefficient for Conservative = 0.0864
β23: coefficient for Polygamy = -0.1169
β24: coefficient for 8 ANC Contacts = 0.0747
β25: coefficient for Early ANC = -0.1457
β26: coefficient for Danger signs = -0.2967
β27: coefficient for Non-functional Community Governance = 0.0427
β28: coefficient for Residence = -0.0253
β29: coefficient for Wealth = 0.0679
β30: coefficient for Women's & Men's Group = 0.0248
β31: coefficient for Women literacy = -0.1006
β32: coefficient for Marital Status = 0.0470
β33: coefficient for Religion = 0.2985
β34: coefficient for Age Category = 0.0880
β35: coefficient for Employment = -0.4183
β36: coefficient for Education = -0.1654
β37: coefficient for Parity = -0.1123
β38: coefficient for Birth size = 0.0016
β39: coefficient for Sex = -0.4507
β40: coefficient for PNC = 0.2515
β41: coefficient for Place of birth = 0.0652
β42: coefficient for VHWs Home Visit = -0.1659
β43: coefficient for Time of Death = 3.7062
β44: coefficient for KMC = -0.1005
β45: coefficient for Clean Cord Care = -0.1046
β46: coefficient for EBF = -0.0963

Probability of Neonatal Death:

p = 1 / (1 + e^-(log(p/(1-p)) = -4.2613 - 0.1271*SES - 0.1227*Age - 0.1007*Desire for Pregnancy + 0.5077*Birth interval <2yrs + 0.4073*Birth Weight <2500g - 0.0684*Complications + 0.1847*Skilled Birth Attendant - 0.0543*Live birth 2to4 + 0.2797*Live births 5 plus - 0.0706*Birth order 1 - 0.1331*Birth order 2to3 + 0.4497*Family influence + 0.1885*Birth order 4plus - 0.0250*Baby name - 0.1845*Women's Group Meetings - 0.1015*Number of meetings - 0.0400*Faith based organizations + 0.0990*Social networks - 0.1517*Trained VHW + 0.1446*VHWs trained in newborn care + 0.0920*Institutionalized + 0.0864*Conservative - 0.1169*Polygamy + 0.0747*8 ANC Contacts - 0.1457*Early ANC - 0.2967*Danger signs + 0.0427*Community Governance - 0.0253*Residence + 0.0679*Wealth + 0.0248*Women's & Men's Group - 0.1006*Women literacy +

0.0470*Marital Status + 0.2985*Religion + 0.0880*Age Category - 0.4183*Employment - 0.1654*Education - 0.1123*Parity + 0.0016*Birth size - 0.4507*Sex + 0.2515*PNC + 0.0652*Place of birth - 0.1659*VHWs Home Visit + 3.7062*Time of Death - 0.1005*KMC - 0.1046*Clean Cord Care - 0.0963*EBF))

Neonatal_deaths = $\sum_{k=1}^{6} \alpha_k X_k + \sum_{k=7}^{11} \beta_k X_k + \sum_{k=12}^{16} \gamma_k X_k + \sum_{k=17}^{21} \delta_k X_k + \sum_{k=22}^{26} \epsilon_k X_k + \sum_{k=27}^{31} \zeta_k X_k + \sum_{k=32}^{36} \eta_k X_k + \sum_{k=37}^{41} \theta_k X_k + \sum_{k=42}^{46} \iota_k X_k$ ……equation (3)

Where:

i. Greek letters (α, β…, ι) denote coefficient groups
ii. $X_1, X_2, ..., X_{46}$ represent the respective feature values for each observation (e.g., X_1 = Time of Death, X_2 = Birth Interval <2 years, etc.) (See Table 24 for complete feature mapping)

Table 47: Community health system model coefficients and variables

Variable/Feature Name	Feature Importance	Coefficient Symbol	Description
Time of death = X1	3.703695	α_1 (alpha1)	Primary temporal indicator
Birth interval 2yrs = X2	0.508897	α_2 (alpha2)	Birth spacing indicator
Family influence = X3	0.453190	α_3 (alpha3)	Family support measure
Sex = X4	0.449350	α_4 (alpha4)	Gender indicator
Employment = X5	0.419693	α_5 (alpha5)	Employment status
Birth Weight 2500g = X6	0.403775	α_6 (alpha6)	Birth weight indicator
Danger signs = X7	0.300077	β_1 (beta1)	Risk recognition
Religion = X8	0.297927	β_2 (beta2)	Religious affiliation

Live births 5 plus = X9	0.276628	β_3 (beta$_3$)	High parity indicator
Post natal care (PNC) = X10	0.247106	β_4 (beta$_4$)	Postnatal care less than 72 hours
Skilled Birth Attendant = X11	0.193724	β_5 (beta$_5$)	Birth attendance by a skilled health worker
Meetings = X12	0.186331	γ_1 (gamma$_1$)	Community engagement
Birth order 4 plus = X13	0.186229	γ_2 (gamma$_2$)	Birth order indicator
VHWs Home Visit = X14	0.169161	γ_3 (gamma$_3$)	Home visit coverage
Education = X15	0.160920	γ_4 (gamma$_4$)	Educational level
Trained VHW = X16	0.147808	γ_5 (gamma$_5$)	VHW training status
Early ANC = X17	0.142144	δ_1 (delta$_1$)	Early antenatal care
VHWs trained newborn care = X18	0.141470	δ_2 (delta$_2$)	VHW newborn care
Birth order 2 to 3 = X19	0.134863	δ_3 (delta$_3$)	Birth order indicator
SES = X20	0.129624	δ_4 (delta$_4$)	Socioeconomic status
Polygamy= X21	0.117662	δ_5 (delta$_5$)	Marital structure
Age= X22	0.116752	ε_1 (epsilon$_1$)	Maternal age
Parity= X23	0.112358	ε_2 (epsilon$_2$)	Number of births
Desire for Pregnancy = X24	0.109990	ε_3 (epsilon$_3$)	Pregnancy intention
Exclusive breastfeeding (EBF) = X25	0.103795	ε_4 (epsilon$_4$)	Practicing exclusive breastfeeding

Number of meetings= X26	0.103545	ε_5 (epsilon$_5$)	Community participation
Community women literacy= X27	0.102175	ζ_1 (zeta$_1$)	Literacy level
Clean Cord Care= X28	0.099290	ζ_2 (zeta$_2$)	Hygiene practice
Social networks= X29	0.097634	ζ_3 (zeta$_3$)	Social support
Kangaroo mother care (KMC) = X30	0.094955	ζ_4 (zeta$_4$)	Practicing KMC at home
Age Category= X31	0.093614	ζ_5 (zeta$_5$)	Age grouping
Institutionalized= X32	0.088312	η_1 (eta$_1$)	Health system integration
Conservative= X33	0.086562	η_2 (eta$_2$)	Cultural factors
Birthorder1= X34	0.077087	η_3 (eta$_3$)	First birth indicator
8 antenatal care (ANC) contacts = X35	0.072286	η_4 (eta$_4$)	Number of ANC contacts
Place of birth= X36	0.071030	η_5 (eta$_5$)	Delivery location
Wealth= X37	0.068172	θ_1 (theta$_1$)	Economic status
Complications= X38	0.065659	θ_2 (theta$_2$)	Health complications
Livebirth 2 to 4 = X39	0.059086	θ_3 (theta$_3$)	Birth history
Marital Status= X40	0.048604	θ_4 (theta$_4$)	Marriage status
Community Governance= X41	0.039047	θ_5 (theta$_5$)	Local governance
Faith-based organisations (FBO) = X42	0.037594	ι_1 (iota$_1$)	Religious organization
Babyname= X43	0.023874	ι_2 (iota$_2$)	Cultural identifier

Residence= X44	0.022669	ι_3 (iota$_3$)	Location type
District= X45	0.020824	ι_4 (iota$_4$)	Administrative area
Birth size= X46	0.001944	ι_5 (iota$_5$)	Size at birth

UNILUS Ethical Approval

UNIVERSITY of LUSAKA

Plot No. 37413, Off Alick Nkhata Mass Media, P. O. Box 36711, Lusaka
Phone: +260 211 233407, 258409, Fax: +260 211 233409, E-mail: ictar@zamnet.zm, unilus@zamnet.zm

All correspondence should be addressed to the Vice Chancellor

SCHOOL OF MEDICINE AND HEALTH SCIENCES

RESEARCH ETHICS COMMITTEE

26th November, 2019

Ref. No. : IORG0010092-082

UNILUS

MEGGIE GABIDA
926, SANDTON PARK
WESTGATE, HARARE
ZIMBABWE

Dear Madam,

REF: 'EFFECT OF INSTITUTIONALIZING COMMUNITY HEALTH SYSTEM ON REDUCING PREVENTABLE NEONATAL DEATHS IN MASHONALAND WEST PROVINCE, ZIMBABWE, 2019-2020: A CLUSTER RANDOMIZED CONTROLLED TRIAL'

We would like to acknowledge receipt of your corrections. These were reviewed on 22nd November 2019 and it has been resolved that your proposal be approved for one year. Your approval is from **26th November 2019 to 25th November 2020**.

Specific conditions will apply to this approval. As principle investigator it is your duty to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval will be suspended.

Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval of after expiration date.
- All proposal modifications must be approved by the Ethics Committee prior to implementation unless they are intended to reduce risk (but still be reported for approval).
- All proposal deviations must be reported to the Ethics Committee within 5 working days.
- All data collections materials must be approved by the Ethics Committee prior to being used.

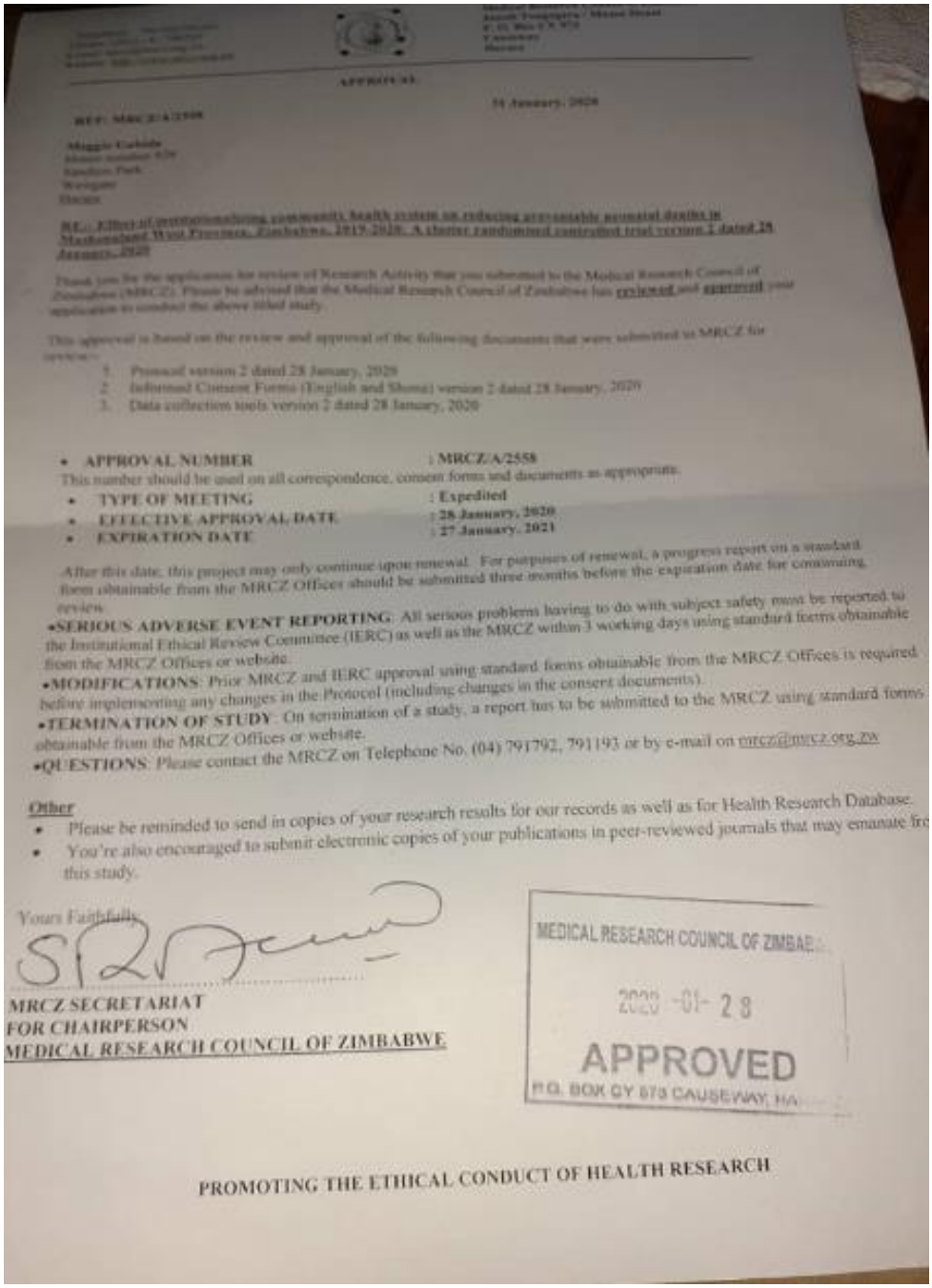
Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us on the above indicated address.

Yours Sincerely,

Professor Kasonde Bowa

UNILUS REC Chairperson.

Appendix 2: Medical Research Council of Zimbabwe Approval



APPROVAL

14 January, 2020

REF: MRCZ/A/2558

Maggie Gahadz
House number 829
Kambuzuma
Harare
Zimbabwe

RE: Effect of restructuring community health system on reducing preventable neonatal deaths in Mashonaland West Province, Zimbabwe, 2019-2020: A cluster randomized controlled trial version 2 dated 28 January, 2020

Thank you for the application for review of Research Activity that you submitted to the Medical Research Council of Zimbabwe (MRCZ). Please be advised that the Medical Research Council of Zimbabwe has reviewed and approved your application to conduct the above titled study.

This approval is based on the review and approval of the following documents that were submitted to MRCZ for review:-

1. Protocol version 2 dated 28 January, 2020
2. Informed Consent Forms (English and Shona) version 2 dated 28 January, 2020
3. Data collection tools version 2 dated 28 January, 2020

- **APPROVAL NUMBER** : **MRCZ/A/2558**

This number should be used on all correspondence, consent forms and documents as appropriate.

- **TYPE OF MEETING** : **Expedited**
- **EFFECTIVE APPROVAL DATE** : **28 January, 2020**
- **EXPIRATION DATE** : **27 January, 2021**

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Offices should be submitted three months before the expiration date for continuing review.

•**SERIOUS ADVERSE EVENT REPORTING**: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices or website.

•**MODIFICATIONS**: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the Protocol (including changes in the consent documents).

•**TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices or website.

•**QUESTIONS**: Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw

Other

- Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
- You're also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate fr this study.

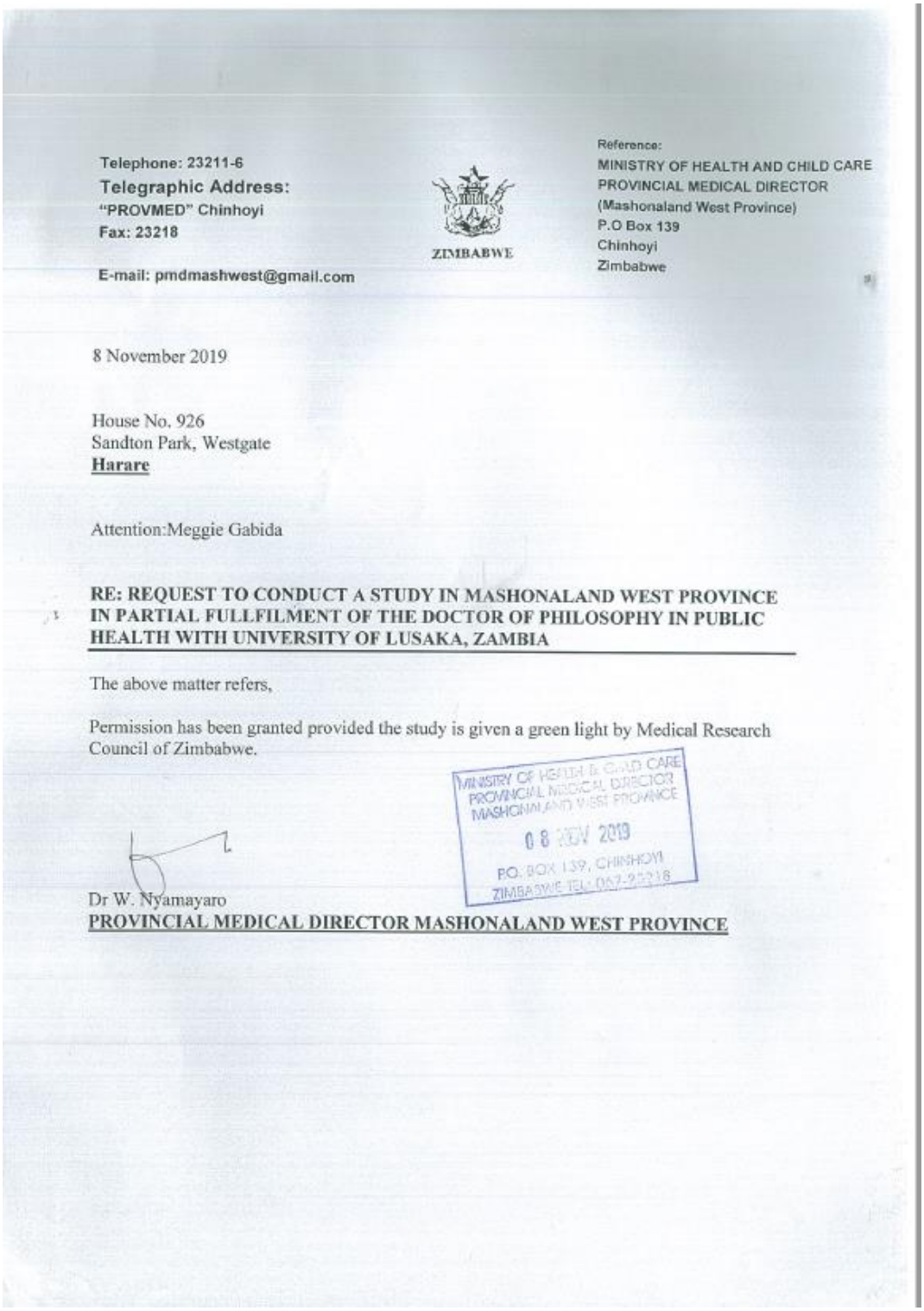
Yours Faithfully

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

MEDICAL RESEARCH COUNCIL OF ZIMBAB
2020 -01- 28
APPROVED
P.O. BOX CY 573 CAUSEWAY, HA

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

Appendix 3: Permission to conduct the Study, Mashonaland West Province



Telephone: 23211-6
Telegraphic Address:
"PROVMED" Chinhoyi
Fax: 23218

E-mail: pmdmashwest@gmail.com

ZIMBABWE

Reference:
MINISTRY OF HEALTH AND CHILD CARE
PROVINCIAL MEDICAL DIRECTOR
(Mashonaland West Province)
P.O Box 139
Chinhoyi
Zimbabwe

8 November 2019

House No. 926
Sandton Park, Westgate
Harare

Attention:Meggie Gabida

RE: REQUEST TO CONDUCT A STUDY IN MASHONALAND WEST PROVINCE IN PARTIAL FULLFILMENT OF THE DOCTOR OF PHILOSOPHY IN PUBLIC HEALTH WITH UNIVERSITY OF LUSAKA, ZAMBIA

The above matter refers,

Permission has been granted provided the study is given a green light by Medical Research Council of Zimbabwe.

MINISTRY OF HEALTH & CHILD CARE
PROVINCIAL MEDICAL DIRECTOR
MASHONALAND WEST PROVINCE
08 NOV 2019
P.O. BOX 139, CHINHOYI
ZIMBABWE TEL: 067-23218

Dr W. Nyamayaro
PROVINCIAL MEDICAL DIRECTOR MASHONALAND WEST PROVINCE

Appendix 4

INFORMED CONSENT FORM FOR PARENTAL CONSENT
(English) (Adapted from the MRCZ Consent Form)

UNIVERSITY of LUSAKA

"Effect of institutionalizing community health system on reducing preventable neonatal deaths in Mashonaland West Province, Zimbabwe, 2020-2021"

Principal Investigator: Meggie Gabida [*Ph.D.*]| +263716183248

Co-Investigator(s): 1. Prof. Eustarckio Kazonga | +260977791274

2. Prof. Kasonde Bowa | +260978157961

"WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

- We give you this consent so that you may read about the purpose, risks, and benefits of this research study.

- Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients or programmes.

- We cannot promise that this research will benefit your child.

- This research is not expected to cause any harm to you and your child.

- You have the right to refuse to allow your child to take part or agree for your child to take part now and change your mind later.

- Whatever you decide, it will not affect you and your child's regular care.

- Please review this consent form carefully. Ask any questions before you make a decision.

- The choice for you and your child to participate is voluntary" (Hall, Prochazka, & Fink, 2012; http://mrcz.org.zw).

PURPOSE OF THE STUDY

We invite your participation in a research project designed to explore the effect of implementing a community health system on decreasing neonatal mortality rates in Mashonaland West Province, Zimbabwe. The goal of this study is to assess whether there are notable differences in neonatal mortality among infants in regions with comprehensively integrated community-based health systems, compared with those without such integration. Expectant mothers will be recruited for this study, and we will conduct follow-up visits with them and their newborns at DAY 7 and DAY 28 post-delivery, as outlined by the Ministry of Health and Child Care (MOHCC) home visit protocols (http://mrcz.org.zw).

For infants with low birth weight or those classified as small, an additional visit will occur on DAY 14. We anticipate that the risks to you and your baby from this study will be minimal and that all actions will comply with the Ministry of Health and Child Care guidelines. You and your infant have been chosen as potential participants because the study includes all newborns living in this province.

We expect to involve a total of 984 mother-infant pairs from Mashonaland West Province in this research.

PROCEDURES AND DURATION

If you decide to participate or allow your child to participate, you and your child will be followed on DAY 7 and DAY 28, which is approximately one month

after birth, where questions related to newborn care, such as cord care, breastfeeding and any illnesses, among other issues, will be asked.

RISKS AND DISCOMFORTS

The risk anticipated in this study for you and your baby will be minimal.

BENEFITS OF THE STUDY

The information we obtain can be used to strengthen interventions to reduce preventable newborn deaths, including general community-led interventions for community engagement, participation, and ownership of their own health in Zimbabwe.

CONFIDENTIALITY

"If you indicate your willingness to participate in this study by signing this document, all the information you give us will remain between you and me and will not be disclosed to anyone. We will use unique IDs written on the questionnaire to validate our data, especially when we need to verify that the correct information is recorded for the participant and infant. The questionnaires will be kept under lock and key and will only be accessible to the investigators. Information obtained from you will only be used for this study. You are free to withdraw from the study at any time during the study period if you wish to do so" (https://www.msubillings.edu/orc/pdf/Informed%20Consent.pdf: http://mrcz.org.zw)

ADDITIONAL COSTS

There is no possibility of additional costs because you participated in this study, as follow-up will be done at your place of residence.

VOLUNTARY PARTICIPATION

Participation in this study is entirely voluntary. Should you choose not to permit your child to take part, this choice will not influence your or your child's future interactions with any institution, its staff, or affiliated hospitals and health services. If you decide to allow your child to join, both you and your child have the right to

withdraw your consent and end participation at any point without facing any penalties.

Further information

If you feel you have been ethically violated, you can send your complaints to:
Dr C Dhege (PMD Mashonaland West Province) (+263772434162)
Professor E Kazonga (University of Lusaka) (+260977791274)

AUTHORIZATION

You are making a decision whether or not to allow your child to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered, and have decided to allow your child to participate.

The date you sign this document to enrol your child in this study, that is, today's date, MUST fall between the dates indicated on the approval stamp affixed to each page. These dates indicate that this form is valid when you enrol your child in the study, but do not reflect how long your child may participate in the study. Each page of this Informed Consent Form is stamped to indicate the form's validity as approved by the MRCZ.

……

…….

Name of Parent (please print) Date

…… ……..

Signature of Parent or legally authorized representative Date

……

Relationship with the Participant

…….. ……

Signature of Witness Signature of Research Staff

(*Optional*)

If you are not able to read and write you can provide verbal consent.

…… ……

Name of Parent (please print) Date

…… ……..

Thump of Parent or legally authorized representative Date

……

Relationship with the Participant

…….. ……

Signature of Witness Signature of Research Staff

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research Participant or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe on telephone 791792 or 791193 and cellphone number 0784 956 128.

For children 13 years old to 17 years old

My participation in this research study is voluntary. I have read and understood the above information, and asked any questions which I may have and have agreed to participate. I will be given a copy of this form to keep.

……

Name of Participant

……

Signature or Thump of Participant

Audio, Video Recording and Photography

Audio and photos may be recorded, and these recordings will be solely used for the purposes of this study, including presentation at professional meetings and any future programming. You will be notified before use.

Statement of Consent to be Photographed or Audiotaped

I understand that photographs / audio recordings / will be taken during the study. *(For each statement, please choose YES or NO by inserting your initials in the relevant box)*

- I agree to having my **photograph taken** **Yes** ☐

  No ☐

- **I agree to being audio recorded** **Yes** ☐

  No ☐

……. **……**

Name of Participant (*Please print*) **Signature or Thump**

Date

Appendix 5

TSAMBA YEMVUMO YEMUBEREKI (Shona) (Adapted from the MRCZ Parental Consent Form)

"Effect of institutionalizing community health system on reducing preventable neonatal deaths in Mashonaland West Province, Zimbabwe, 2020-2021"

Munzveri: Meggie Gabida [*Ph.D.*]| +263716183248

Vabatsiri: 1. Prof. Eustarckio Kazonga | +260977791274

2. Prof. Kasonde Bowa | +260978157961

Makadini zvenyu? Zita rangu ndinonzi Meggie Gabida. Ndiri mudzidzi paUniversity ye Lusaka kuZambia. Ndirikukumbirawo kuti mutore chikamu mutsvakurudzo yokuti tikwanise kuona zvichabatsirika kubva mukushandidzana kwezvikamu zvakaita sevashandi vemuvhireji, zvikwata zvemumamisha, masangano emadzimai nemachechi zvichibatana nezveutano pakudzikisa dambudziko rekufa kwevana vacheche mumwedzi wekutanga vachibva kuzvarwa.

ZVAMUNOFANIRWA KUZIVA PAMUSORO PETSVAKURUDZO IYI:

- Tinokupai bepa iri remvumo kuti muverenge munzwisise chinangwa, njodzi uye zvinobatsira tsvakurudzo iyi.

- Zvinogaroitika pane zvamunobatsirikana nazvo zvinobva pamishonga inozivikanwa mashandiro ayo chinangwa chiri kubatsira kuvandudza

utano hwemurerwe. Chinangwa chetsvakurudzo ndechekuwedzera ruzivo rwunogona kuzoshandiswa kubatsirwa kwevamwe varwere muneramangwana kana zvimwe zvirongwa

- Hatisi kukuvimbisai kuti tsvakurudzo iyi ichabatsira mwana wenyu. Sezvinongoitikawo pakubatsirwa kwamunoita mazuva ose, tsvakurudzo iyi haitarisirwe kukanganisa utano hwemwana kana amai.

- Munekodzero yekuramba kana musina kusununguka kutora chitsvimbo kana kuti mwana wenyu atore chinzvimbo ichi ikozvino uye mukazo shandura mafungiro enyu pamadira.

- Zvisineyi nesarudzo yamaita, haitadzisi imi kana mwana wenyu kuwana zvaakakodzera kuwana.

- Nyatsoverengai tsamba yemvumo iyi. Sunungukai kubvunza mibvunzo musati maita sarudzo yenyu

Sarudzo yenyu yekupa mvumo kuti mwana wenyu atore chinzvimbo isarudzo yenyu haimanikidzwe.

Chinangwa Chetsvakurudzo

Chinangwa chetsvakurudzo iyi ndechokuti paonekwe kana paine musiyano unovapo pavana vanozvarwa munharaunda ine kudyidzana kwezvikwata zvemunharaunda maringe nezveutano neavo vari munharaunda isina kudyidzana uku pakudzikisa dambudziko rekufa kwevana vacheche mumwedzi wekutanga vachibva kuzvarwa.

Tichange tichitora vana mai nevana vavo vanenge vachiri mumazuva matatu ekubva kupona uye avo vakazvitakura. Tichazenge tichitevera vana amai ava kubva vaine pamuviri neavo vane vana vavo mushure memazuva manomwe (DAY 7) uye muzuva

remakumi maviri nemasere (DAY 28). Tsvakurudzo iyi inotarisirwa kuti isaunze chingakukanganisai imi nemwana wenyu muchinge matora chikamu.

Zvakanakira Tsvakurudzo

Umbowo huchawanikwa mutsvakurudzo ino huchabatsira kuvandudza zvirongwa zvinodzikisa kufa kwevana vacheche mudunhu rino nenyika yeZimbabwe

Kuchengetedzwa Kwezvakavanzika

Zvatichange tawirirana pakutora chikamu kwenyu nezvatichakurukura zvicharamba zviri pakati pangu nemi pasina umwe anogona kuzviziva. Tichashanda nenhomboro dzinozivikanwa neni nemi chete kuitira kana pane zvatinozoda kuona kana zvirikuenderana. Izvi zvichireva kuti hatinyore zita renyu. Mapepa aya achachengeterwa panokiyiwa uye achangoshandiswa patsvakurudzo ino chete.

Kupinda kwenyu mutsvakurudzo iyi hakumanikidzwi, zvinoenderana nekusununguka kwenyu. Hapana mubairo wemari kana zvimwe zvinhu mukasarudza kutora chikamu mutsvakurudzo iyi.

Zvimwe Zvamungade Kuziva

Pamunenge maona kuti kodzero dzenyu dzachorwa, munokwanisa kuisa chichemo chenyu kunotevera:

Dr C Dhege (PMD Mashonaland West Province) (+263772434162)

Prof. E Kazonga (University of Lusaka) (+260977791274)

Kubvuma

Pakuisa siginecha yenyu kureva kuti mabvuma kutora chikamu imi nemwana wenyu uye manzwisisa chinangwa chetsvakurudzo iyi.

…… ……

Zita remubereki (*Nyorai zvinoonekwa*)

Dheti

…… ……..

Siginecha yemubereki kana muchengeti

Dheti

……

Hukama nearikutora chikamu

…….. ……

Siginecha yemufakazi Siginecha yemubvunzi

(*Optional*)

Kana musingagoni kuverenga kana kunyora munokwanisa kushandisa chigunwe chenyu kuratidza mvumo yenyu.

…… ……

Zita remubereki (*Nyorai zvinoonekwa*)

Dheti

…… ……..

Chigunwe chemubereki kana muchengeti

Dheti

……

Hukama nearikutora chikamu

…….. ……

Chigunwe chemufakazi Siginecha yemubvunzi

MUCHAPIWA BEPA REMVUMO IRI KUTI MUCHENGETE.

Kana muine mimwe mibvunzo maringe netsvakurudzo iyi kana tsamba yemvumo pamusoro peyapindurwa nemutsvakurudzi, uye mimwe womibvunzo inosanganisira kodzero yenyu semunhu arikutora chikamu mutsvakurudz oiyi kana kuti murikunzwa kunge musina kubatwa zvakanaka uye murikunzwa kuda kutaura nemumwe munhu kunze kwevatsvakurudzi, sunungukai kufona kuMedical Research Council of Zimbabwe panhamba dzinoti 791792 or 791193 kana runharembozha 0784 956 128.

Vana vane makore guminenhatu (13 years) kusvika paguminemanomwe (17 years)

Kutora kwangu chikamu mutsvakurudzo iyi isarudzo yangu. Ndaverenga ndikanzwisisa zvakanyorwa pamusoro, uye ndabvunzawo mibvunzo naizvozvo ndakasununguka kutora chikamu. Ndichapiwa rimwe bepa remvumo kuti ndichengete.

…….

Zita remwana arikutora chikamu

…….

Siginecha kana Chigunwe chemwana arikutora chikamu

Appendix 6

Women of Childbearing Age Enumeration Form

Province ..... District ..... Village Name .....

District UID #: |__|__| Village UID#: |__|__| Village name: Household UID#: |__|__|__|

Interviewer ID: |__|__| Date of interview: |__|__|/|__|__|/|__|__|

Data Monitor ID: |__|__| Date of interview: |__|__|/|__|__|/|__|__|

Data Entry ID: |__|__| Date of interview: |__|__|/|__|__|/|__|__|

Household Characteristics

Look at place of residence			Ask		
1.1	1.2	1.3	1.4	1.5	1.6
Is it rural or urban? |__|	Type of building used by HH |__|	The toilet facility being used by the HH members |__|	What is the main source of drinking water in the household? |__|	In your household is there	Number of household members |__|__|
1= Rural 2=Urban	1 = Grass roofing 2= Iron sheets / Tiles/ Asbestos 3 = Other	1 = Flush system 2 = Pit latrine 3 =BVIP 4 = Bush 5 = Other (please specify)	1 = Piped water 2 = Village or public tap 3 = Protected well 4 = Borehole 5 = Unprotected well 6 = River, dam or any surface water	1. Radio (Y/N) 2. Bicycle (Y/N) 3. Scotch cart (Y/N) 4. Do you have cattle (Y/N) 5. Do you have domestic worker or cattle helper (Y/N) 6. Goats (Y/N) 7. Sheep (Y/N) 8. Chickens or other poultry (Y/N) 9. Donkeys (Y/N) 10. Pigs (Y/N) ***Circle all that apply***	Please include those that have visited or are away

Please complete the following table for all women in the household

2.1									
Name	Surname	Age group	Marital status	Polygamous marriage	Religion	Education	Employment	Has woman ever been pregnant?	Is woman pregnant now?
		__|	__|	__|	__|	__|	__|	__|	__|
		__|	__|	__|	__|	__|	__|	__|	__|
		__|	__|	__|	__|	__|	__|	__|	__|
		__|	__|	__|	__|	__|	__|	__|	__|
		__|	__|	__|	__|	__|	__|	__|	__|
		__|	__|	__|	__|	__|	__|	__|	__|
		__|	__|	__|	__|	__|	__|	__|	__|
		__|	__|	__|	__|	__|	__|	__|	__|
		1= less than 15 years 2=15 -14 years 3= Above 45 years	1= Married 2= Never Married 3= Divorced 4= Separated 5= Widowed	0= No 1= Yes	1 = Conservative 2= Non-Conservative 3= Traditionalist 4 = Other	1= None 2 = Primary 3= Secondary 4 = Tertiary	1= Farmer 2= Casual labor 3= Formally employed 4= Self employed 5= Gold panning 6= Other	0= No 1= Yes	0= No 1= Yes

Appendix 7

Household Questionnaire (Day 3, Day 7 and Day 28)

Questionnaire for Women of Childbearing Age at Day 3, Day 7 and Day 28 after birth

BEFORE STARTING THE INTERVIEW – *COMPLETE THE SECTION BELOW USING THE INFORMATION FROM THE WCBA VILLAGE REGISTER. REMEMBER ONLY WOMEN WHO ARE PERMANENT RESIDENT IN THE VILLAGE SHOULD BE INCLUDED*

WCBA names from the Village Register……

WCBA ID from register: |__|__|--|__|__|__|

PLEASE TICK AS APPROPRIATE:

HOUSEHOLD ENUMERATION FORM COMPLETED |__|

AT THE RESPONDENT'S HOUSE – Greet the respondent. Ask for a private place to sit and discuss, away from other people. Ask the respondent to bring her maternal health card and child health card, if she has one. Discuss other issues common in the area to help the respondent feel relaxed.

ASK FOR CONSENT

Greetings. My name is ……. I am collaborating with Meggie Gabida, a doctoral candidate at the University of Lusaka in Zambia. She is undertaking research to examine how the community health system impacts the reduction of neonatal fatalities in Mashonaland West. This study aims to improve health outcomes for newborns in Mashonaland West and across Zimbabwe. We are reaching out to women who have recently given birth to understand their interactions with health services, their community environments, and other pertinent factors. We want to assure you that your responses will be kept private and will solely be utilized for the purposes of this research.

Participation in this study is entirely voluntary. If you choose not to participate, it will not affect your eligibility to join other health initiatives in the future. You are free to skip any questions you prefer not to answer, and there are no incorrect responses. If you find any question unclear, please feel free to ask for clarification. his interview is expected to last approximately one hour and thirty minutes. Do you agree to participate? Yes |__|; No |__| **Please give the woman the consent form to sign**

ONCE YOU HAVE OBTAINED CONSENT - COMPLETE A HOUSEHOLD ENUMERATION FORM IF NEEDED, AND THEN PROVIDE THE DETAILS BELOW.

District UID#: |__|__| Village UID#: |__|__| Village name: Household UID#: |__|__|__|

Interviewer UID#: |__|__| Date of interview: |__|__|/|__|__|/|__|__| Time started interview: __ __ : __

FOR OFFICE USE ONLY

Supervisor's signature: Date received: |__|__|/|__|__|/|__|__|

Data Checker UID#: |__|__| Date checked: |__|__|/|__|__|/|__|__|

ICH PROJECT – Day 3, Day 7 and Day 28 Questionnaire

WCBA ID: |__|__|-|__|__|__||__|

Part A: Geographic location

A1	District name	1 = Chegutu |__| 2 = Hurungwe |__| 3 = Kariba |__| 4 = Makonde |__| 5 = Mhondoro-Ngezi |__| 6 = Sanyati |__| 7 = Zvimba |__|
A2	Place of residence	1 = Rural |__| 2 = Urban |__|

Part B: Personal Information of Mother

Could you please share some information about yourself and the father of your child?		
Mother		
B1.1	How old are you? Kindly tell me when you were born	Age in years |__|__| DD/MM/YY|__|__|/|__|__|/|__|__|
B1.2	Highest level of education completed?	1 = None |__| 2 = Primary |__| 3 = Secondary |__| 4 = Tertiary |__|
B1.3	What is your relationship to the man who fathered this pregnancy?	1 = Married |__| 2 = Boyfriend/fiancé |__| 3 = Never married |__| 4 = Divorced |__| 5 = Separated |__| 6 = Widowed |__|
B1.4	How would you best characterize your current living situation with this man? *Please read responses to the respondent*	1 = Live together all the time |__| 2 = Live together but husband work away from home (comes during weekends) |__| 3 = Live together but separated for a period

				every year for work reasons |__| 4 = Live apart but regular/frequent cohabitation |__| 5 = Never live together |__|		
B1.5	What is your religion			1= Non-conservative|__| 2= Conservative|__| 3= Traditionalist|__| 4= None|__|		
B1.6	What do you spend most of your time doing?			1= Farmer|__| 2= Casual labour|__| 3= Formally employed|__| 4= Self employed|__| 5= Gold panning|__| 6= Other|__|		
B1.7	What is his primary job? PLEASE SPECIFY THE ONE HE DEDICATES MOST OF HIS TIME TO.			1= Farmer|__| 2= Casual labour|__| 3= Formally employed|__| 4= Self employed|__| 5= Gold panning|__| 6= Other|__|		
B1.8	Mother's knowledge Probe to find out if mother knows danger signs of pregnancy and delivery or danger signs in newborn babies			1= Low|__| 2=Medium|__| 3= High|__| Bleeding Convulsions Fever Difficulty breathing Diarrhoea Low body temperature Not breastfeeding well Vomiting Jaundice Yellow soles *Tick all that apply* *Key:* **Less than 3 is 1=Low; 4-5 is 2=Medium and 6-10 is 3=High.**		
B2	Birth History						
B2.1	Have you experienced a pregnancy prior to this child, even if it ended before reaching full term?			0= No |__| 1= Yes |__|		
	I will now ask you some questions regarding all the pregnancies you have had throughout your life before this one. Beginning with your first pregnancy, please share details about ALL your pregnancies, including those that lasted only a few months, those where the baby was stillborn, or instances where the baby passed away shortly after birth?						
B2.2	B2.2 When was baby born?	B2.3 Did this pregnancy end before 9 months or was it	B2.4 Is baby a boy or girls?	B2.5 Is baby still alive?	B2.6 How old was baby on her last birthday ?	B2.7 In case of reported death, how old was (Name)	B2.8 Was this pregnancy single/ multiple?

		a live birth?				when he/ she died?	
01	DD/MM/YYY …../……../……./	|__|	|__|	|__|	|__|__|	|__|	|__|
02	DD/MM/YYY …../……../……./	|__|	|__|	|__|	|__|__|	|__|	|__|
03	DD/MM/YYY …../……../……./	|__|	|__|	|__|	|__|__|	|__|	|__|
04	DD/MM/YYY …../……../……./	|__|	|__|	|__|	|__|__|	|__|	|__|
05	DD/MM/YYY …../……../……./	|__|	|__|	|__|	|__|__|	|__|	|__|
		1= Live birth 2= Miscarriage/ stillbirth	1= Boy 2= Girl	0=No 1=Yes		1= <3 days 2= 4-7 days 3= 8-28 days 4=> 28 days	1= Single 2= Multiple
B2.9	Have you ever experienced a pregnancy that resulted in the loss of the baby?				0 = No|__| 1 = Yes|__|		
B2.10	Did the baby exhibit any signs of life after birth, such as crying or breathing? ***If yes, record the child as a neonatal death.***				0 = No|__| 1 = Yes|__|		
B2.11	Have you ever had any children who passed away at any point after their birth?				0 = No|__| 1 = Yes|__|		
B3	**Recent Pregnancy**						
	I would now like to ask you about the specifics of your recent pregnancy.						
B3.1	Did you attend any antenatal check-ups during this pregnancy?				0 = No|__| 1 = Yes|__|		
B3.2	Where did you do your ANC? *Tick all that apply*				1= District hospital|__| 2= Nearest local clinic|__| 3= Other clinic in another area|__| 4= Traditional Birth Attendant|__| 5= Church shrine|__| 6 = Other (specify) |__|		
B3.3	How many months into your pregnancy were you when you first went for a check-up?				|__| months		
B3.4	How many total visits did you make during this pregnancy?				|__|__| times		
B3.5	1. Provide details about VCT/PMTCT services? 2. Share information regarding breastfeeding?				0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__|		

	3. Give information about contraception? 4. Explain what a postnatal check involves? 5. Describe the danger signs to look out for? 6. Weigh you? 7. Measure your height? 8. Have you lain down and examined your abdomen? 9. Measure your blood pressure using a cuff? 10. Collect a urine sample from you? 11. Take a blood sample for testing? 12. Conduct a syphilis test? 13. Perform a pelvic examination?	0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__| 0 = No|__|1 = Yes|__|
B3.6	Did you receive a Tetanus Toxoid Vaccine (TTV) injection in your arm during this pregnancy?	0 = No|__|1 = Yes|__|
B3.7	How many injections have you received? CHECK TTV CARD OR MATERNAL HEALTH CARD	0 = No|__|1 = Yes|__|
B3.8	Were you provided with or did you purchase any iron tablets during this pregnancy?	0 = No|__|1 = Yes|__|
B3.9	Did you take the tablets?	0 = No|__|1 = Yes|__|
B3.10	If YES, for how many days?	|__|__| days
B3.11	Did you go to anyone else for advice during your pregnancy	0 = No|__|1 = Yes|__|
B3.12	If YES, who did you go to see?	1 = VHW 2=TBA 3 = Traditional health 4= Faith healer 5 = Grandmother 6 = Other (specify
B3.13	During this pregnancy, did you take any medicine for prevention of malaria?	0 = No|__|1 = Yes|__|
B3.14	Did you receive the medication during an antenatal visit or from another source?	1 = Antenatal visit 2 = Other source (specify _____)
B3.15	Does your household have any treated mosquito nets?	0 = No|__|1 = Yes|__|
B3.15	Did anyone use a mosquito net while sleeping last night? If yes, who? CIRCLE ALL THAT APPLY	1 = Nobody|__| 2 = myself|__| 3 = Husband|__| 4 = New baby|__| 5 = All other children|__| 6 = Some other children|__| 7 = Other (specify _____)
B3.16	During this pregnancy, how frequently did you sleep under the mosquito net?	1 = Every night 2 = Some nights 3 = Never
B3.17	Were you tested for HIV?	0 = No|__|1 = Yes|__|
B3.18	Did you go together for testing with your partner?	0 = No|__|1 = Yes|__|

	Problems, Healthcare-seeking and Treatment – Mother						
B4.1	Did you have any problem, or did you ever fall sick during your pregnancy				0 = No|__|1 = Yes|__|		
B4.2	If YES, what was the problem/ problems you had? List all problems				1. …….. 2. …… 3. …… 4. …… 5. ……		
B4.3	Did you consult anyone?				0 = No|__|1 = Yes|__|		
B4.4	If NO, why not?						
B4.5	If YES, who did you consult?				1= Traditional healer|__| 2= Faith healer|__| 3= VHW|__| 4=Health Worker at local clinic|__| 5=Health worker at another clinic or hospital|__| 6= Traditional Birth Attendant|__| 7= Grandmother or family member|__| 8= Other [Specify……] |__|		
B4.6	What did the person you consult do?				1. ……. 2. ……. 3. …….		
B4.7	Did you have to seek permission from your husband or family member or anyone before going to seek care? If YES, who?				1= No|__| 2 = Husband|__| 3 = Mother|__| 4 = Father|__| 5 = Mother-in-law|__| 6 = Other relative|__| 7 = Other (specify|__|		
B4.8	**Delivery**						
	B4.8 Did you have any problem, during your delivery |__|	B4.9 If YES, what was the problem/ problems you had? List all problems	B4.10 Did you consult anyone?	B4.11 If NO, why not?	B4.12 If YES, who did you consult?	B4.13 What did the person you consult do?	B4.14 Did you have to seek permission from your husband or family member or anyone

			|__|		|__|		before going to seek care? If YES, who?|__|
	0 = No|__|1 = Yes|__|		**0 = No|__|1 = Yes|__|**		1= Traditional healer|__| 2= Faith healer|__| 3= VHW|__| 4=Health Worker at local clinic|__| 5=Health worker at another clinic or hospital|__| 6= Traditional Birth Attendant|__| 7= Grandmother or family member|__| 8= Other [Specify…… ……]|__|		1= No|__| 2 = Husband|__| 3 = Mother|__| 4 = Father|__| 5 = Mother-in-law|__| 6 = Other relative|__| 7 = Other (specify|__|
	After Birth (Post Natal period)						
	B4.15 Did you have any problem, after giving birth |__|	B4.16 If YES, what was the problem/ problems you had? List all problems	B4.17 Did you consult anyone? |__|	B4.18 If NO, why not?	B4.19 If YES, who did you consult? |__|	B4.20 What did the person you consult do?	B4.21 Did you have to seek permission from your husband or family member or anyone before going to seek care? If YES, who?|__|
	0 = No|__|1 = Yes|__|		**0 = No|__|1 = Yes|__|**		1= Traditional healer|__| 2= Faith healer|__| 3= VHW|__| 4=Health Worker at local clinic|__| 5=Health worker at another clinic or hospital|__| 6= Traditional Birth Attendant|__| 7= Grandmother or family member|__| 8= Other [Specify…… ……]|__|		1= No|__| 2 = Husband|__| 3 = Mother|__| 4 = Father|__| 5 = Mother-in-law|__| 6 = Other relative|__| 7 = Other (specify|__|
	Labor and delivery						

B4.22	Did you use the maternity waiting home before delivery?	0 = No|__|1 = Yes|__|
B4.22	Were you at the maternity waiting home when labor started?	0 = No|__|1 = Yes|__|
B4.22	How far do you stay from the nearest health facility?	1= less than 5km 2= 5-10 km 3=10-15 km 4= More than 20 km
B4.23	How many hours do you take to get to the nearest health facility	1= Less than 1 hour 2= 1-2 hours 3= 3-4 hours 4 = 5-6 hours 5= More than 6 hours
B4.24	When you went into labor, how many hours did it last?	1 = 0 – 6 hours 2 = 7 – 12 hours 3 = 13 – 18 hours 4 = 19 – 24 hours 5 = >24 hours
B4.25	How many hours before the baby was born did the waters break?	1 = <24 hours 2 = >24 hours 3 = Don't know
B4.26	Did you drink any traditional medicine to assist labor?	0 = No|__|1 = Yes|__|
B4.27	Did you have any complication?	0 = No|__|1 = Yes|__|
B4.28	Did you have a companion during labor and delivery?	0 = No|__|1 = Yes|__|
	PART C: Neonatal Factors (Newborn baby)	
C1.1	Sex of the baby	1= Girl |__| 2 = Boy |__|
C1.2	What is the baby's NAME	0= No Name 1= Name……
C1.3	If BABY has a name, when was the BABY given the name?	1= Before birth 2= After birth
C1.4	When was [BABY] born?	Day/Month/Year …../……../……./
C1.5	Was (BABY) born early, late, or at the expected time?	1 = Early 2 = On time 3 = Late
C1.6	After how many completed months of pregnancy was (BABY) born?	|__|__| months
C1.7	Is (BABY) one of twins?	1 = Single |__| 2 = Twin/multiple|__|
C1.8	How big was the baby?	1 = Very large|__| 2 = Average|__| 3 = Very small|__| 4 = Don't know|__|
C1.9	Was (BABY) weighed at birth?	0 = No|__|1 = Yes|__|
C1.10	What was the weight for (NAME)? CHECK CHILD HEALTH CARD	|__|__|__|__| grams
	Essential newborn care	

C1.11	Where was (BABY) born?	1= Local clinic 2= Another clinic 3= District hospital 4 = At home 5= At a shrine 6= TBA's home 7= On the way to a health facility 8 = Other [Specify ……..]
C1.12	Was there a fire, or any form of heating in the room?	1 = Yes 2 = No 3 = Don't know
C1.13	Who helped with the delivery? CIRCLE ALL MENTIONED	1 = Doctor/Nurse/Clinical Officer/Midwife 2 = Other health worker 3 = TBA 4 = Relative/friend
C1.14	Did the person who helped wash his/her hands with soap before the delivery?	0 = No|__|1 = Yes|__|
C1.15	5 Did the person who helped wear gloves during the delivery? 1 = Yes 2 = No	0 = No|__|1 = Yes|__|
C1.16	How was the baby delivered? CHECK CHILD HEALTH CARD	1 = Normal 2 = Breech 3 = Forceps/vacuum 4 = C-section 5 = Don't know
C1.17	Which part of the baby came out first?	1 = Head 2 = Buttock 3 = Hand/foot 4 = Cord 5 = Don't know
C1.18	What was the cord cut with?	……
C1.19	What was used to tie the cord?	……
C1.20	What substances were put on the cord stump after it was cut?	……
C1.21	Was (BABY) wrapped immediately after birth?	
C1.22	How long after birth was [BABY] put to the breast	1= Less than 30 minutes 2= 30 minutes to 1 hour 3= After 1 hour 4= Don't know
C1.23	How long after the birth was (BABY) bathed?	1= Immediately 2= Delayed bath
C1.24	What was the first thing that the baby was given after he/she was born?	……

C1.25	Has (NAME) had a BCG injection on left arm? CHECK CHILD HEALTH CARD AND LOOK FOR A SCAR	0 = No|__|1 = Yes|__|
	Post Natal Care	
C1.26	How long did you stay in the health facility after delivery?	1= Less than 24 hours 2= 1- 2 days 3= 3 days
C1.27	Did you or your baby receive home visit from a health worker after birth?	0 = No|__|1 = Yes|__|
C1.28	Did you or your baby receive home visit from a health worker after birth?	0 = No|__|1 = Yes|__|
C1.29	Did you go for a postnatal check-up?	0 = No|__|1 = Yes|__|
C1.30	How many days after delivery did you go for a postnatal check up	1= 3 days 2= 7 days 3= 10 days 4= After 10 days
C1.31	Why did you go?	1 = Normal check-up 2 = Problem for mother 3 = Problem for baby
C1.32	Where did you go?	1= Nearest local clinic 2= Another clinic 3= District hospital 4= Outreach point 5= VHW's house 6= Other [Specify……]
C1.33	Breastfeeding	
C1.34	Has BABY ever been breastfed?	0 = No|__|1 = Yes|__|
C1.35	Did you give [BABY] anything other than breastmilk?	0 = No|__|1 = Yes|__|
C1.36	If YES, what did you give baby? *[Record everything that the mother had given to baby including medicines]* ASK ANYTHING ELSE	
C1.37	Why did you give [BABY] these things?	
C1.38	Was [BABY] given any water since he/she was born?	0 = No|__|1 = Yes|__|
C1.39	If YES, how often did [BABY] drink water?	1 = Only on the first day|__| 2 = On some days|__| 3 = Every day|__| 4 = Other (specify……) |__|

C1.40	Is [BABY] still breastfeeding?	0 = No|__|1 = Yes|__|
	PART D: Household Factors	
D1.41	Polygamous marriage	0 = No|__|1 = Yes|__|
D1.42	Wealth status of the household PLEASE LOOK AT THE WCBA ENUMERATION FORM	1= Lowest|__| 2= Second|__| 3= Third|__| 4= Fourth|__| 5= Highest|__|
D1.43	Paternal religion	1= Non-conservative 2= Conservative 3= Traditionalist 4= None
D1.44	Household home visitation from VHWs during pregnancy	0 = No|__|1 = Yes|__|
D1.45	Household home visitation from VHWs during neonatal period	0 = No|__|1 = Yes|__|
Part E: Community level factors		
E1.1	Is there a participatory women's group in this village?	0 = No|__|1 = Yes|__|
E1.2	Do you participate in the women's group meetings?	0 = No|__|1 = Yes|__|
E1.3	If YES, how often did you participate during your recent pregnancy?	1=Once|__| 2= Twice|__| 3= Three times|__| 4= Four times|__| 5= More than five times|__|
E1.4	In this village, is there a village health committee?	0 = No|__|1 = Yes|__|
E1.5	If YES, how often does the committee meet?	1= Never meet|__| 2= Once every month|__| 3= Once every three months|__| 4= Once every 6 months|__| 5= Once every year|__|
E1.6	Is the village health committee functional?	0=Non-functional|__| 1= Partially functional|__| 2 = Fully functional|__|
E1.7	Are faith-based organizations actively involved in maternal and child health issues	0 = No|__|1 = Yes|__|
E1.8	Were there any community dialogue sessions with faith-based organizations?	0 = No|__|1 = Yes|__|
E1.9	Is your household a member of the health development team?	0 = No|__|1 = Yes|__|
E1.10	If YES, did your household receive any training from the health development team leader?	0 = No|__|1 = Yes|__|
E1.11	In this village, is there a trained village health worker?	0 = No|__|1 = Yes|__| 2= Don't Know
E1.12	Did you receive at least 2 home visits during your recent pregnancy?	0 = No|__|1 = Yes|__|

E1.13	If YES, from who?	1= Nurse|__| 2= EHT|__| 3= VHW|__| 4= TBA|__| 5= Other [Specify…….] |__|
E1.14	In this community, how far is the nearest health facility?	1= Less than 5 km|__| 2= 5-10 km|__| 3= 10 to 20 km|__| 4= More than 20 km|__|
E1.15	How many hours do you take to reach the nearest health facility?	1= Less than 1 hour|__| 2= 1-2 Hours|__| 3= 3 to 3 hours|__| 4= 4 to 6 hours|__| 5= More than 6 hours|__|
E1.16	How do you go to the nearest health facility?	1= Foot|__| 2= Scotch cart|__| 3= Public transport|__| 4= Other [Specify…….] |__|
E1.17	If going by foot, how long to you take?	1= Less than 1 hour|__| 2= 1-2 Hours|__| 3= 3 to 3 hours|__| 4= 4 to 6 hours|__| 5= More than 6 hours|__|
E1.18	If using a scotch cart, how long do you take?	1= Less than 1 hour|__| 2= 1to 2 Hours|__| 3= 3 to 3 hours|__| 4= 4 to 6 hours|__| 5= More than 6 hours|__|
E1.19	Is there community transport to carry women to the health facility in case of emergency?	0 = No|__|1 = Yes|__|

The END

Appendix 8

Neonatal Community Verbal Autopsy (Adapted from International Standard Verbal Autopsy Questionnaires, (WHO, 2007)

WCBA ID: |__|__|-|__|__|__||__|

Province|__|__||__|__|__||__||__|__||__|__|__||__|

District|__|__||__|__|__||__||__|__||__|__|__||__||__|__||__|__|__||__|

Name of reference

BEGIN BY EXPRESSING YOUR SYMPATHIES TO THE INDIVIDUAL AND OFFERING YOUR CONDOLENCES. REQUEST A QUIET AND PRIVATE LOCATION FOR A CONVERSATION, AWAY FROM THE PRESENCE OF OTHERS. IF APPLICABLE, ASK THE INDIVIDUAL TO BRING ALONG HER HEALTH INSURANCE CARD. ENGAGE IN DISCUSSIONS ABOUT OTHER RELEVANT TOPICS TO HELP THE INDIVIDUAL FEEL MORE AT EASE.

Informed Consent Statement

Hello, how are you? My name is …….., and I am involved in the Community Health Project in collaboration with the University of Lusaka. We are gathering information regarding the reasons behind newborn deaths in the community. Your participation would be greatly appreciated, as we aim to enhance health outcomes for newborns in Mashonaland West through this effort. The goal of this interview is to understand the circumstances surrounding your baby's death, enabling us to work towards preventing similar tragedies in the future.

I apologize for bringing up the painful memory of your loss, but I hope you will allow me to discuss it with you. Rest assured, any information you share will remain confidential between us. We will not disclose any identifying details about you or your baby, and the information will solely be utilized for research purposes. Your involvement in this study is entirely voluntary, and you have the right to skip any question or decline to participate altogether. You may also terminate the interview at any point without any negative impact on your access to health services or other related activities.

However, we genuinely hope you will consider participating, as your insights could significantly help the government improve services and reduce future newborn deaths. If you need clarification on any question, please don't hesitate to ask me for further explanation. Do you have any questions? This interview will take approximately 55 minutes. Are you willing to participate?

Yes |__|

No |__|

IF NO, PLEASE END THE INTERVIEW. IF YES, PLEASE GIVE THE RESPONDENT CONSENT FORM COPY

DO NOT COMPLETE THIS

UID of Supervisor: |__|__|Date: |__|__|/|__|__|/|__|__|

UID Quality Assurance: |__|__| Date: |__|__|/|__|__|/|__|__|

GENERAL INFORMATION ABOUT THE RESPONDENT			
1.1	Start time of interview	MINUTES…….|__||__|	
1.2	Participant's name		
1.3	What was your relationship to the baby who passed away?	1=Father|__| 2=Mother|__| 3=Sibling|__| 4=Close relative|__|**Specify……** 5=Other relative|__|**Specify……** 6=No relation|__|	
1.4	Did you live with the deceased baby in the period leading to her/ his death?	0 = No|__|1 = Yes|__|	
Information on the deceased and DATE or PLACE of death			
2.1	What was the name of the baby?	0= No name|__| 2= Name|__|……	
2.2	Was the baby who passed away a girl or a boy?	1= Female|__| 2= Male|__|	
2.3	When was the baby born who has since passed away?	Day/Month/Year …../……../……./	
2.4	What was the age of the baby at the time of death?	Age in DAYS |__||__|	
2.5	Where did the BABY die?	1= District Hospital|__| 2= Local clinic|__| 3= Other clinic|__| 4= Home|__| 5= Other [Specify…….]|__| **6= Don't know (Write 98)|__|**	
RESPONDENT's ACCOUNT OF ILLNESS OR EVENTS LEADING TO DEATH			
3.1	Could you tell me about the illness or events leading to the BABY's death?	……. …… …… …….. …… …….. …… ……. …… ……	
3.2	CAUSE of DEATH 1 ACCORDING TO RESPONDENT	…… …….	
3.3	CAUSE of DEATH 1 ACCORDING TO RESPONDENT	…… ……	
PREGNANCY HISTORY			
4.1	"Now I would like to ask you some questions concerning the mother and symptoms that the deceased had/showed at birth and shortly after. Some of these questions may not appear to be directly related to the baby's death. Please bear with me and answer all the questions. They will help us to get a clear picture of all possible symptoms that the BABY had".		
4.2	How many births, including stillbirths, did the mother have before this baby?	Number of Births/ Stillbirths|__| Don't know (Write 98)|__|	
4.3	How many months along was the pregnancy when the baby was delivered?	Number of months |__||__| **Don't know (Write 98)|__|**	
4.4	Did the pregnancy end earlier than expected?	0 = No|__|1 = Yes|__|	

4.5	How many weeks before the expected date of delivery?	Number of weeks |__||__| **DON'T KNOW (Write 9 8)|__|**	
4.6	During the pregnancy did the mother suffer from any of the following known illnesses: 1 High blood pressure? 2 Heart disease? 3 Diabetes? 4 Epilepsy/convulsion? 5 Did she suffer from any other medically diagnosed illness?	0 = No 1 = Yes 8= Don't Know High Blood Pressure |__| Heart Disease |__| Diabetes |__| Epilepsy/Convulsion|__| Other [Specify…….] |__|	
4.7	During the last 3 months of pregnancy did the mother suffer from any of the following illnesses: 1 Vaginal bleeding? 2 Smelly vaginal discharge? 3 Puffy face? 4 Headache? 5 Blurred vision? 6 Convulsion? 7 Febrile illness? 8 Severe abdominal pain that was not labor pain? 9 Pallor and shortness of breath (both present)? 10 Did she suffer from any other illness?	0 = No 1 = Yes 1 |__| 2 |__| 3 |__| 4|__| 5|__| 6|__| 7 |__| 8 |__| 9 |__| 10Other [Specify…… ……..]|__|	
4.8	Was the baby part of a single birth or a multiple birth?	1= Singleton|__| 2=Twin|__| 3= Multiple or more|__| 8= Don't Know|__|	
4.9	What was the baby's birth order?	1= First|__| 2=Second|__| 3= Third or Higher|__| 8= Donk know|__|	
CHILD BIRTH HISTORY			
5.1	Where did you deliver the child deliver?	1= District Hospital|__| 2= Clinic|__| 3= Home delivery |__| 4= On the way to clinic|__| 6= Other [Specify……] |__| 8= Don't know|__|	
5.2	Who was present to assist with the delivery?	1= Doctor|__| 2= Nurse|__| 3= TBA|__| 4= Relative|__| 5= Self|__| 6= Other |__| 8= Donk know|__|	
5.3	When did the amniotic fluid rupture?	1= Before labor started|__| 2= During labor|__| 8= Don't know|__|	
5.4	How many hours elapsed between the water breaking and the baby's birth?	1= Less than 24 hours 2= 24 hours or more 8= Donk know|__|	

5.5	Did the amniotic fluid have an unusual odor?	0 = No 1 = Yes 8= Don't Know	
5.6	Did the baby cease to move in the womb?	0 = No 1 = Yes 8= Don't Know	Skip to 5.8
5.7	When did the baby stop being active in the womb?	1= Before labor |__| 2= During labor|__| 8= Don't know|__|	
5.8	Did a birth attendant check for fetal heart sounds during labor?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
5.16	Did the umbilical cord emerge before the baby during the delivery?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
CONDITION OF THE BABY SOON AFTER BIRTH			
6.1	What was the size of BABY at birth?	1= Smaller than normal|__| 2= Normal|__| 3= Larger than normal|__| 8= Don't Know|__|	
6.2	Was the BABY born premature	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.3	How many months or weeks was the pregnancy?	1= Months |__| - |__||__| 2= Weeks|__| - |__||__| 8= Don't Know|__| (Write 98) |__||__|	
6.4	What was the birth weight of the baby?	Grams |__||__||__||__| Don't Know (Write 98) |__||__|	
6.5	Was anything applied to the umbilical cord stump after births	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.6	What was it?	…… ……	
6.7	Were there any signs of injury or broken bones?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.8	Were there any marks or signs of injury?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.9	Where were the signs of injury?	…… …… …… ……	
6.10	Was there any sign of paralysis?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.11	Did the baby have any malformation?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.12	What kind of malformation did the baby have?	1= Swelling or defect on the back|__| 2= Very large head|__| 3= Very small head|__| 4= Defect of lip and or palate|__| 6= Other malformation|__|	

		8= Don't Know|__|	
6.13	What was the color of the BABY at birth?	1= Normal|__| 2= Pale|__| 3= Blue|__| 8= Don't Know|__|	
6.14	Did the BABY breathe after birth, even a little?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.15	Was the BABY given assistance to breathe?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.16	Did the BABY cry after birth, even a little?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.17	Did the BABY ever move, even a little?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.18	If the BABY did not cry, breathe or move, was it born dead?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
6.19	Was the baby macerated, that is show signs of decay?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	
VITAL REGISTRATION			
10.1	Do you have a death certificate for the baby?	0 = No |__| 1 = Yes |__| 8= Don't Know|__|	

Skilled Health Worker's 's Observations (To be filled after completing the interview)
…… …… … …… …
Comments …… … …… …… ……
Physician's Observations …… … …… … …… Name:…… Date: ……../……./……

Appendix 9

Key Informant Interviews: Questionnaire for District Community Health Supervisors

1. Designation

a) DNO [ ]
b) CHN [ ]
c) DEHO [ ]
d) DHIO [ ]
e) DHPO [ ]
f) DN [ ]

2. Completed years in service ----------

3. What are the major targets of the community health program?

……
……
……

4. Have you ever received training on the community health program? Yes [ ] No [ ]

5. If yes, when did you receive the training?

a. < 6 months ago [ ]
b. 6- 12 months ago [ ]
c. > 12 months ago [ ]

6. As a district, which resources did you receive in order to implement this program in 2019?

a) Funds (specify amount) _____
b) Equipment (specify)_____
c) Materials (specify) _____
d) Other (specify)_____

7. Do you think the community health program in the district is achieving its objectives?

Yes [ ] No [ ]

Please give reason for your answer

…….

8. Which activities are you carrying out as a district in order to see the smooth running of the program?

a) District plans on community health are in place. Yes/ No
b) Decentralisation and accreditation of sites conducted Yes/ No
c) Quarterly review meetings held. Yes/No
d) Training of health providers conducted and completed. Yes/ No

e) Advocacy and social mobilisation meetings conducted in the community. Yes/ No

f) Distribution of community health materials and equipment done on time to all RHCs Yes/ No

9. Is the community health data that is collected used in any way at the local level?

1. Yes 2. No 3. Don't know

10. If yes what is it used for? …….

11. Have you taken any public health action based on community health data in the last 6 months? Yes [ ] No [ ]

12. If yes, what action was taken? ……

13. How many monitoring and supervisory visits have you made so far this year to RHCs?

a) One per health facility per week
b) One per health facility per month.
c) One per health facility per quarter.
d) No visits made this year
e) Other(specify)…… ……...

14. Proof (minutes, reports and logbooks) of record of visits produced. Yes [ ] No [ ]

15. How do the partners support you?

a) …… …….
b) …… …….
c) …… …….

16. Did you receive any sensitization on the National Community Health Strategy? Yes [ ] No [ ]

17. Have you ever held advocacy meetings on community health with the community in this district? Yes [ ] No [ ]

18. If yes, when was the last time you held such a meeting?

a) less than 3 months ago
b) 3- 5 months ago

c) 6- 12 months
d) >12 months ago

19. What recommendations would you suggest for improving this program?
    a) ……..
    b) ……
    c) ……

Thank you for your participation