Protocol

Implementation Evaluation of a Digital Learning Health System Tool (Neotree) Across Networks of Newborn Care Facilities in Malawi: Protocol for a Mixed Methods Study

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Abstract

Background: In the last 2 decades, neonatal mortality has significantly reduced globally. However, it still contributes to almost half of the deaths of children under 5 years of age. Improving access to quality health care during pregnancy, childbirth, and the postpartum period is urgently needed in low- and middle-income countries (LMICs) to ensure that the sustainable development goal targets for neonatal and infant mortality are met. Health care delivery in low-resource settings is characterized as fragmented, with poorly staffed health facilities working in silos, with limited opportunities for cross-learning and collaboration. Neotree, a digital health intervention, has been developed and implemented in Zimbabwe and Malawi to improve neonatal survival by optimizing and standardizing the quality of newborn care in health facilities linked within a network of care. Understanding the key factors that affect the success of Neotree implementation and its effectiveness in a network of health facilities will inform the development of a context-specific and robust scale-up plan.

Objective: We aim to understand how Neotree is implemented and used in a network of health facilities in Kasungu District for newborn care, the intervention mechanisms, and the contextual factors that affect both implementation and intervention effectiveness.

Methods: We designed a mixed methods process evaluation as part of a wider effectiveness and economic evaluation of Neotree across a network of 11 health facilities in Kasungu District, Malawi. The evaluation is guided by the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework, the realist approach, and other implementation science frameworks. Methods include periodic analysis of routine newborn data (collected via Neotree), qualitative interviews and focus group discussions with stakeholders, direct observations of newborn care, health facility and health care provider surveys, and review of documents related to the implementation plans, processes, and reports. Data will be collected over multiple rounds between December 2024 and September 2027.

Results: This research project was initiated in December 2024. As of April 2026, all 11 health facilities have been enrolled in the intervention. Routine clinical data are being captured using Neotree, and data collection for the mixed methods process evaluation is underway. The study is excpected to be completed in April 2027, and results are expected to comeout towards the end of the year(2027).

Conclusions: This study will identify the barriers and facilitators of successful implementation of a digital learning health system tool, Neotree, in a low-resource setting. It will enable us to explain the mechanism through which Neotree could contribute to the quality of health care and better health outcomes for the newborns. Furthermore, the results of the study will guide future scale-up of Neotree in Malawi and other similar settings.

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Introduction

Background and Rationale

In the last 2 decades, neonatal mortality has reduced by 45% globally. Nevertheless, everyday, 6500 babies die within the first 28 days of birth, contributing to almost half of all deaths in children under 5 years of age [1]. A significant number of these deaths occur in sub-Saharan Africa (46%) [2,3]. Progress has been uneven; some countries in sub-Saharan Africa have reported little or no progress for decades despite achieving an overall reduction in under-5 child mortality [2,4-6]. For instance, Malawi is one of the few countries in the region that achieved the Millennium Development Goal for under-5 child mortality [7]. But the progress in reducing neonatal mortality has not been as rapid as it was for infants and children aged 1 to 5 years. For decades, neonatal mortality stalled at 27 per 1000 live births, with recent reports showing a slight reduction to 24 per 1000 live births [8].

Even in countries where neonatal survival rates have improved, much effort is needed to accelerate these gains to meet the Sustainable Development Goals (SDGs) [1,2,9]. With the current pace of progress, as many as 65 countries in Africa and Asia will fail to achieve the SDG neonatal mortality target of 12 deaths per 1000 live births by 2030 [2,9].

Quality of care (QoC) across many health conditions is often suboptimal in low- and middle-income countries (LMICs), contributing significantly to the preventable mortality burden [10]. Improving access to high-quality health care is therefore essential for reducing neonatal mortality [10,11]. Among other factors, the quality of newborn care is influenced by multiple health system functions, conceptualized by the World Health Organization (WHO) as 6 health system building blocks, which are as follows: service delivery, health information systems, health human resources, health financing, access to essential medicines, and leadership and governance [10,12-14]. There is a growing body of literature that outlines the potential role of digital health interventions in improving performance of the health system building blocks, such as service delivery, human resources, and health information systems [15-17]. Recognizing the demand for digital health and the opportunity presented by an ever-growing global digital ecosystem, the WHO has developed frameworks and strategies to lead the digital health initiative globally [18,19].

Health care delivery in low-resource settings is often fragmented, and health facilities are poorly staffed with limited access to specialty services and opportunities for cross-learning and collaboration [10,20]. In such settings, WHO recommends a network-of-care approach to health service delivery to improve access to quality health care. A network of care is defined as "a collection of public and/or private health facilities and health workers deliberately interconnected to promote multidisciplinary teamwork and collaborative learning in order to provide comprehensive, equitable, respectful, person-centered care from home/community to primary through to tertiary levels" [21]. The network approach can ensure continuity of care, harness collaborations among health care providers across levels of health care, and facilitate resource mobilization between health facilities [21,22]. The existing evidence in the maternal and newborn health space suggests that it has the potential to improve efficiency, QoC, and health outcomes [20].

A low-cost digital health intervention, Neotree, has been developed and implemented in Zimbabwe and Malawi to improve neonatal survival by optimizing and standardizing the quality of newborn care [23-25]. Neotree is an open-source digital learning health system tool uniquely combining bedside CDS, embedded low-dose-high-frequency education, and real-time data capture linked with data visualization dashboards that support data use for decision-making [26,27]. Neotree has undergone multiple usability, feasibility, and acceptability assessments in both contexts. Evidence confirms that Neotree is highly usable, adaptable to the local context, and provides up-to-date management guidelines [23,24]. It is also perceived as feasible and acceptable among health care professionals (HCPs), parents, and carers, with the potential to improve newborn care in low-resource settings [25].

From September 2022 to August 2024, supported by the Foreign, Commonwealth & Development Office (FCDO) Regional Evidence Fund, we successfully adapted Neotree for implementation from tertiary to primary facilities in Malawi [28]. Following the ADAPT framework [29], we collaborated closely with health care managers, Ministry of Health officials, frontline nurses, and clinicians to tailor assessment scripts, clinical decision support (CDS) algorithms, and training materials to fit the context of primary care settings. A 4-month pilot in 1 primary and 1 community health center demonstrated feasibility and acceptability and provided valuable insights into implementation strategies. Preliminary findings underscored the importance of standardized clinical

training, consensus on newborn care standards at the primary care level, and metrics for assessing care quality.

Therefore, this process evaluation is designed to evaluate the implementation of Neotree across a network of facilities in Kasungu District, Malawi. This is part of a wider clinical and cost-effectiveness evaluation of the Neotree system, which will enable us to establish a plausible explanation for any observed changes in QoC and newborn survival and to develop implementation requirements. In this protocol, we outline the process evaluation questions and described the theoretical frameworks and methods to be used.

Aims for Process Evaluation

We aim to understand how Neotree is implemented and used in a network of health facilities in Kasungu District for the care of newborns, the intervention mechanisms, and the contextual factors that affect both implementation and the effectiveness of intervention.

Specifically, we will answer the following questions: (1) to what extent was the Neotree intervention implemented as planned (fidelity)? (2) To what extent was Neotree adopted by health care workers to provide care for newborns? (3) To what extent was Neotree used by health care workers during the care of newborns (reach)? (4) To what extent was Neotree integrated into the routine health care system for the provision of newborn care (maintenance)? (5) How and why does Neotree work, or not work, to improve clinical outcomes and QoC, where, for whom, and in what circumstances? (6) What contextual factors trigger mechanisms that lead to the clinical effectiveness or ineffectiveness of Neotree?

Methods

Neotree Intervention

The intervention package includes the introduction of the Neotree system within routine clinical care. The Neotree system has 4 core functionalities. First, it is a CDS system with embedded evidence-based algorithms that support HCPs in the assessment, diagnosis, and management of newborns [30]. Second, it allows real-time data capture on the newborn care process (including assessment, referral or admission, and discharge). Third, it provides low-dose high-frequency training to help improve the competency of HCPs in delivering newborn care. Fourth, a data pipeline and data dashboard enable aggregate data to be fed back to clinical staff, administrators, and policymakers supporting quality improvement initiatives.

We have codeveloped a preliminary theory of change outlining the key inputs, activities, and anticipated implementation and clinical outcomes. This builds on the learning health system theory of change [24], and it will be further refined and iterated over the course of this evaluation (Multimedia Appendix 1).

Intervention Delivery Plan

Neotree implementation follows a staggered approach in which the health facilities are enrolled in the intervention step by step (Figure 1). This approach is informed by years of implementation experience in similar low-resource settings across a smaller number of facilities. The Neotree implementation itself is divided into three periods: (1) preimplementation orientation and setup; (2) implementation and operational phase; and (3) maintenance.

Figure 1. Neotree implementation timeline. Blue represents the initial phase or the period right before the rollout of Neotree (preparatory phase), orange represents the period right after Neotree is introduced to the health facilities, and green represents the period of maintenance. PHC: primary health care center.

Implementation period		Implementation sites				
		Kasungu District Hospital and Bua	PHC 2 & 3	PHC 4 & 5	PHC 6 & 7	PHC 8, 9, & 10
2024	November					
	December					
2025	January	Orientation + Setup				
	February					
	March	Operational				
	April					
	May		Orientation + Setup			
	June					
	July	Maintenance	Operational			
	August					
	September			Orientation + Setup		
	October					
	November		Maintenance	Operational		
	December					
2026	January				Orientation + Setup	
	February					
	March			Maintenance	Operational	
	April					
	May					Orientation + Setup
	June					
	July				Maintenance	Operational
	August					
	September					
	October					
	November					Maintenance
	December					
2027	January-December					

Preimplementation, Orientation, and Setup

Several activities will be conducted. Preparation for implementation includes facility needs assessment, training, usability testing and adaptation, stakeholder engagement, and procurement and setup of hardware and software.

A needs assessment and situational analyses (facility infrastructure, staffing, and guidelines) will be conducted at each facility to assess the baseline status of health facilities' capacity to provide newborn care as well as their suitability for a digital intervention. Think-aloud usability sessions with clinical staff will be conducted to adapt Neotree scripts to fit the clinical context and to codevelop data dashboards [27]. Participatory workshops will be carried out to map the integration of Neotree within the clinical workflow at each site. Following this, technical training on the use of the system and clinical training in essential newborn care will be provided.

To ensure meaningful stakeholder engagement, meetings with health officials will be conducted at different levels of the health system to secure regulatory approvals and formalize referral networks and information flows within the network of health facilities (eg, a memorandum of understanding) and between sites and the implementation team. Similarly, meetings with senior clinicians, health officials, the technology team, and the research and implementation teams will be held to agree on key performance indicators (eg, for referrals and data quality). All health facilities will be provided with Android tablets with the Neotree app installed, a printer, an extension, a router, and a dashboard screen for hospitals only. If facilities lack essential equipment, such as thermometers and saturation probes, they will be provided.

Implementation and Operational Phase

This is characterized by intensive supervision of the health facilities and troubleshooting support by the implementation team. A dedicated team of clinical implementation experts, IT personnel, and the project lead will be stationed in Kasungu District for the entire implementation period. This period will continue for 2 months after the initial setup of the Neotree system and the onsite training at each site.

Maintenance Phase

During this period, the supervision and troubleshooting will continue but to a lesser frequency. A maintenance agreement will be negotiated with each site, outlining the key roles and responsibilities of both the site personnel and the Neotree implementation team during this phase. This phase will continue until the end of the project.

As this is a real-world implementation of the intervention, the implementation process will be adapted iteratively as required. However, the key components of the intervention, namely the provision of the Neotree system with its CDS, data-capture, and education-hub capabilities, and the mandatory training on how to use Neotree, will remain fixed. All changes to the initial intervention plan will be documented as part of the process evaluation.

Study Setting and Selection of Study Facilities

The study will be conducted in 1 district hospital and 10 linked primary health care centers (PHCs) in Kasungu District, Malawi. Kasungu District is one of the 28 districts found in the central region of Malawi, and it has a population

of 842,953 according to the 2018 national census [31], and with a 2.9% annual growth rate, the population is estimated to be currently closer to 991,000. The recent Malawi Demographic and Health Survey (MDHS) reported that 98% of births took place in a health facility, and 46% of mothers and their newborns received postnatal care within 2 days of birth [8]. The district has 1 hospital and 40 PHCs, including 7 Christian Health Association of Malawi (CHAM) facilities. Not all PHCs provide maternal and child health (MCH) services; only 28 provide MCH services. Kasungu District Hospital, included in the study, is the only government hospital that provides a secondary level of care for the whole of the district. The 10 PHCs will be selected purposively from the 28 that provide MCH services, based on the following criteria: availability of basic emergency obstetric and neonatal care services; patient load (ie, number of live births per month); distance from the main road and from Kasungu District Hospital (to ensure representation of both remote and more accessible facilities). In addition, we will also consider other relevant variables, such as case fatality rates (CFRs), where possible.

Study Design and Evaluation Framework

We will use a mixed methods design, guided by the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework [32], the realist evaluation approach [33], the ecological framework [34], and the 6 sustainability actions [35,36].

Frameworks for Process Evaluation

RE-AIM Framework

The effectiveness of an innovation depends on the quality and outcomes of the implementation process, and RE-AIM provides the effectiveness measure as well as the reasons why an intervention is found to be effective or not [32]. Our process evaluation will measure the proportion and characteristics of the target population that engages with Neotree (reach), the impact of Neotree on key outcomes such as CFRs and QoC (effectiveness), the uptake of Neotree by HCPs and facilities (adoption), the fidelity and adaptations of Neotree implementation (implementation), and the existing attributes that promote the sustainability of Neotree use over time (maintenance). We will assess both the quality and quantity of what is being delivered under implementation fidelity.

Realist Approach to Understand the Mechanisms

We will adopt a realist approach to codevelop and test program theories based on context-mechanism-outcome (CMO) configurations to understand how Neotree (ie, the intervention) works to improve newborn outcomes, where, for whom, and in what circumstances. Mechanisms are defined as "new human responses, actions, and interactions" that are triggered by the use of intervention resources [33]. These mechanisms then interact with contextual factors to generate outcomes [37].

We will develop our preliminary program theory based on potential CMO configurations, informed by formative research, literature reviews, as well as stakeholder consultations. Textbox 1 illustrates example CMO configurations for the Neotree-guided clinical assessment. We will then test and refine these CMO configurations iteratively using qualitative methods, such as focus group discussions (FGDs) and semistructured interviews (SSIs), as detailed in the *Methods* section.

Textbox 1. Examples of an initial context-mechanism-outcome theory for Neotree.

1. Where the HCP trusts digital tools and is motivated to use them, for example, via the network of care in Kasungu (context), digitized admission forms with embedded educational prompts and cues support clinical assessment, as they enhance HCPs' capacity to assess babies on admission (mechanism); as a result, babies assessed on admission or prior to referral receive a completed digital record and an accurate clinical assessment (outcome).
2. Where HCPs' background clinical skills and training are suboptimal (context), digitized admission forms with embedded educational prompts and cues to support clinical assessment enhanced HCPs' capacity to assess and manage babies on admission (mechanism); as a result, babies assessed on admission or prior to referral receive a completed digital record and an accurate clinical assessment (outcome).
3. Where resources are constrained, such as staffing (context), digitized admission forms with embedded educational prompts and cues to support clinical assessment may not be used optimally to enhance HCPs' capacity to assess and manage babies on admission (mechanism); as a result, babies assessed on admission or prior to referral may not receive a completed digital record and an accurate clinical assessment (outcome).

Defining Context: Ecological Framework

Contextual factors external elements to Neotree's codevelopment, including other interventions and policies that may impact its implementation and intended outcomes. We will use the ecological framework to outline the individual, relational, organizational, and policy or societal-level factors that influence implementation outcomes, such as adoption, reach, fidelity, and sustainability of the Neotree intervention [34]. Individual factors are related to HCPs' knowledge and skills regarding Neotree and their perceptions. Organizational factors encompass an enabling environment within the health facility, including the existing digital health landscape, which facilitates or hinders the use of Neotree. The policy or societal-level factors are related to existing national-level agendas or interests that foster the use of digital health interventions and existing policy frameworks. This framework will be used as an input in defining context within the realist approach.

Framework for Sustainability

Sustainability is defined as the continuity of an intervention beyond the project phase [38]. In this assessment, we will be using the 6 critical actions for sustainability by Spicer et al [35]. The 6 sustainability actions capitalize on the need for planning and adoption opportunities, ownership of the innovation by the government, institutionalization of the innovation within the existing health system, motivation of microlevel actors who use the innovation, community engagement, and an existing financial plan by the government to ensure continuity of the innovation when the funding period ends.

Data Collection

The evaluation work will run from December 2024 to December 2027 (Table 1). The implementation of the research activities is in line with the implementation of the Neotree intervention. A summary of the implementation outcomes, research questions, research methodologies, and data sources is presented in Table 2.

Table 1. Field data collection plan.

Data collection and sites	Round 1	Round 2	Round 3
Health facility assessment and HCP[a] survey			
KDH[b] and Bua	January 2025	March 2026	April 2027
PHCs[c] 2 and 3	April 2025	May 2026	June 2027
PHCs 4 and 5	September 2025	August 2026	August 2027
PHCs 6 and 7	November 2025	November 2026	September 2027
PHCs 8, 9, and 10	April 2026	December 2026	September 2027
Neotree data analysis			
All sites at the time of analysis	Quarterly analysis of data captured using Neotree	Quarterly analysis of data captured using Neotree	Quarterly analysis of data captured using Neotree
Qualitative interviews			
Kasungu and Lilongwe	June-August 2025	March-May 2026	October-December 2026
FGDs[d]			
Kasungu	No FGDs	March-May 2026	October-December 2026
Facility observation			
KDH, and 3 PHCs	June-August 2025	No observation	October-December 2026
Document collection for a review			
Kasungu network	October 2025	November 2026	July 2027

[a]HCP: health care professional.
[b]KDH: Kasungu District Hospital.
[c]PHC: primary health care center.
[d]FGD: focus group discussion.

Table 2. Implementation outcomes, research questions, measurements, and sources of data.

Implementation outcomes and research question	Measurement/indicators	Data source
Reach		
What is the extent of Neotree use for the care of a newborn?	• The proportion of babies cared for in each implementation site using Neotree • The proportion of babies discharged using Neotree	• Neotree data and facility record • Neotree data
Do the beneficiaries represent the target population?	• Characteristics of newborns who received service using Neotree	• Neotree data
What is the size of the overall population of newborns (size of the target population) during the evaluation period?	• The total number of newborns during the implementation period	• Admin report
Adoption		
What is the level of adoption of Neotree for (1) digital data capture, (2) CDS[a], and (3) use and reuse of data?	• Number of facilities established as part of the Neotree newborn care network and using Neotree • Number of additional clinicians trained on Neotree-led newborn care and management • Proportion of eligible HCPs who use Neotree according to agreed protocol/clinical flow to: ◦ Assess, diagnose, and manage a baby	• Desk review of reports and documents • HCP[b] survey and desk review • HCP survey • Observation checklist

Implementation outcomes and research question	Measurement/indicators	Data source
	◦ Admit a baby at point of admission ◦ Discharge a baby at point of discharge ◦ Refer a baby at point of referral • Number of facilities in the network that use Neotree data in QI[c] initiatives	
How do Neotree adopters differ from nonadopters? (facility level and HCP level) What prompts adoption?	• Reason for adoption/nonadoption	• Qualitative interviews and FGDs[d]
Fidelity		
Has Neotree been implemented according to the implementation plan?	• Number of training, mentoring, and supervision sessions delivered at each HF[e]	• Review of reports and documents
	• Number/proportion of newborn care staff trained on Neotree intervention	• Review of reports and documents
What is the quality of implementation?	• Number of supervision visits during the operational and maintenance phases	• Review of reports and documents
	• Perceived adequacy and quality of training, support and supervision given on Neotree	• Qualitative interviews and FGDs, HCPs survey
	• Average length of training supervision period per facility (duration or exposure time)	• Review of reports and documents and HCPs survey
Maintenance/sustainability		
To what extent is Neotree embedded within the health system to deliver newborn care? How integrated is Neotree into the routine system?	• Number (%) of health facilities continuing to use Neotree after maintenance period	• Review of reports and documents and HCPs survey
	• The status of the 6 sustainability actions: planning opportunities for reflection and adoption, strong government ownership, motivating microlevel actors, institutionalizing the innovation, managing financial uncertainties, and fostering community ownership.	• Qualitative interviews and FGDs
Contextual factors		
What are the individual, organizational and policy factors that affect implementation as well as outcomes?	• Barriers and facilitators of implementation (individual, social, and political factors)	• Qualitative interviews and FGDs
Mechanism		
What are the new human responses, actions and interactions triggered by the intervention?	• Triggers of change or outcome in the target population as new human responses, actions, and interactions	• Qualitative interviews and FGDs
Outcome		
What happens as a result of interaction between various contextual factors and responses to intervention (resources)	• Both intended and unintended consequences or outcomes of the intervention in relation to context and mechanism	• Qualitative interviews and FGDs

[a]CDS: clinical decision support.
[b]HCP: health care professional.
[c]QI: quality improvement.
[d]FGD: focus group discussion.
[e]HF: health facility.

Quantitative Data (Facility Records/Data)

HCPs capture routine clinical data when they use Neotree during the care of a newborn. These data will be analyzed quarterly to capture the intervention's reach and the adoption of Neotree by HCPs over time, compared with existing health facility records. Reach assesses the proportion of the target population (babies) for whom Neotree has been used, and adoption captures the number of facilities and HCPs using Neotree.

HCPs' Survey

The primary purpose of this survey is to establish HCPs' clinical knowledge in providing newborn care. This survey will also inform the process evaluation by establishing the fidelity of Neotree implementation by inquiring about health care providers' exposure to Neotree implementation activities, such as training, orientation, and support. Data will be collected using a self-administered questionnaire. Data will be collected at baseline, then a follow-up assessment will be carried out at midterm and at the end of the intervention period. The tool assesses HCPs' experience with digital

health tools, their knowledge of the assessment and management of newborns, and their confidence to perform newborn care activities, as well as the type and quality of training received. It was adapted from the maternal and newborn QoC survey tool developed by the Maternal and Child Integrated Program [39] and the WHO standard–based questionnaire [40]. The tool will be pretested in a similar context and will be checked for clarity, understandability, and consistency.

Document Review

We will examine the implementation fidelity and adaptation of Neotree in the network of health facilities, as carried out by implementers. We will review implementation documents, monitoring plans, and reports produced by the implementation team. This process will capture the content of what was implemented, the implementation process, and the dose and quality of the implementation according to the set plan. A checklist will be prepared and used to guide the document review, following the READ approach [41]. READ stands for Ready your materials, Extract data, Analyze data, and Distil your findings. This will be done at the midterm and the end of the intervention period.

Nonparticipatory Observation

Some of the questions around adoption of the intervention will be answered through nonparticipatory observation of the clinical care given to newborns. The observation will capture the day-to-day provision of newborn care and the practices related to the use of Neotree for the same purpose in selected health facilities. The observation has two parts: (1) the first part captures the organization and state of health care provision in the health facility, recorded as field notes in the form of an unstructured checklist; and (2) the second part uses a checklist to capture the provision of key newborn care interventions in action for each observed baby. In addition, field notes will be captured in the form of a diary.

The observation will be conducted at the 2 facilities with the lowest CFR and another 2 health facilities with the highest reported CFR. The selection of these facilities will be decided based on a preliminary analysis of the data available in health facility records. These facilities will be selected from the 11 health facilities where Neotree will be implemented. Observations will be conducted when the implementation of Neotree begins and will be repeated 1 year after implementation (Figure 1, Gantt chart). An observation tool will be adapted from the every newborn–birth assessment tool [42].

Qualitative Interviews and Focus Group Discussion

The qualitative interviews and FGDs will explore the implementation process in depth. Some of the questions that will be answered through qualitative interviews include the following: the reasons for the adoption or nonadoption of Neotree, perceptions surrounding Neotree and its potential impact, barriers and enablers to Neotree implementation, and the perceived mechanisms. In addition, to address the realist aspect of our approach, the qualitative questions will explore the CMOs in relation to the implementation of the Neotree intervention. The questions are open-ended with a set of probes (Multimedia Appendix 2). The qualitative interview and FGD guides are developed based on the above frameworks and will undergo pretesting. The tools will be finalized by incorporating comments and feedback from the pretest.

Sample Size and Sampling Strategy

Data collected during the implementation period will be analyzed to report on coverage/reach of the intervention over time. For the facility observation, all babies (0-28 days of age) who received care during the 1-week period will be observed. The number of babies observed may vary depending on the patient load of the facility.

Qualitative Interviews and FGDs

We will conduct SSIs with three groups of key informants, who will be selected purposively: (1) HCPs at health facilities (health centers and hospitals); (2) health care managers and policymakers at the district health office, regional health office, and the Ministry of Health; and (3) implementers. Characteristics of the health facilities, such as location and level of health facility, will be considered when selecting key informants from these facilities. These key informants will also respond to questions related to CMO in our realist approach. An average of 20 interviews will be conducted across the 3 periods throughout the intervention, roughly 6 months apart. The total number of interviews will be decided based on the saturation level of the data generated. Whenever possible, the interviews will be conducted with the same respondent to allow longitudinal reporting of changes from the same source. One FGD will be conducted in the hospital and one in the PHCs to establish and identify collective norms around newborn care, the use of Neotree, and the perceived sustainability of Neotree beyond the project period (Table 3).

Table 3. Number of key informants for the qualitative interviews.

Key informants	First round	Second round	Third round (end line)
Health care provider	3-4	3-4	3-4
Health facility in-charge	6-7 (health center: 5-6, hospital: 1)	7-8 (health center: 6-7 and hospital: 1)	10-11 (health center: 9-10; hospital: 1)
District health office	3 (DHO[a] in-charge, MNCH[b] focal person, and health information focal person: 1 each)	3 (DHO in-charge, MNCH focal person, and health information focal person: 1 each)	3 (DHO in-charge; MNCH focal person; health information focal person: 1 each)
Regional health office	2 (MNCH department and health information specialist)	2 (MNCH department and health information specialist)	2 (MNCH department and health information specialist)

Key informants	First round	Second round	Third round (end line)
Ministry of health	2-3 (maternal newborn department, health information department, etc)	2-3 (maternal newborn department, health information department, etc)	2 (maternal newborn department, health information department, etc)
Implementers	2-3 (clinical implementation specialist, operational manager, and Neotree charity)	2-3 (clinical implementation specialist, operational manager, and Neotree charity)	2-3 (clinical implementation specialist, operational manager, and Neotree charity)
Total	20-22	21-23	22-23

[a]DHO: district health office.
[b]MNCH: maternal neonatal and child health.

Data Processing and Analysis

Data Analysis Procedures

For both reach and adoption, routine clinical data from Neotree will be monitored over time and analyzed quarterly. We will capture the proportion of newborns cared for using Neotree in each implementation site compared with the health facility register, the proportion of babies discharged using Neotree, and their characteristics (Reach). We will also assess whether use of Neotree is maintained over time after the intervention has concluded by analyzing the same Neotree data (sustainability). Stata (version 18; StataCorp LLC) software will be used to clean and analyze the data [43].

For the nonparticipatory observation, data from the observation checklist will be transferred to Excel, then imported into Stata (version 18). Descriptive analysis will be carried out to capture the uptake and the timing of Neotree use and to identify characteristics of the babies that could influence its use.

NVivo 14 (Lumivero) will be used to manage qualitative transcripts, as well as field notes from facility observations [44]. All interviews and FGDs will be transcribed verbatim and translated into English. The transcripts will be imported into NVivo software. We will read and reread the transcripts to understand the data well. A predefined list of codes guided by the theoretical frameworks will be developed, and all qualitative data will be coded using both deductive and inductive approaches. Following a thematic analysis approach, the coded data will be reviewed to identify patterns among the codes and will be grouped into subthemes that will fall under the components of the theoretical frameworks, and the results will be narrated [45]. We will conduct preliminary analyses after each phase of data collection, which will inform the content and approach of subsequent rounds of data collection. The preliminary findings will also help shape the initial theory of change, in consultation with the implementation team in workshops. Furthermore, to ensure the credibility of the qualitative work, we will share the preliminary findings with the study participants, as well as stakeholders, to validate our interpretation of the results and triangulate data from FGDs and in-depth interviews conducted with various groups of informants to produce a more comprehensive set of results. We will also provide a detailed description of the phenomena under study during the write-up [46,47].

For the realist approach, the initial theory will be shared with key stakeholders in a workshop, and we will discuss potential CMOs and configure their interactions. These suggestions from the workshop will be included in the qualitative interview tools for further exploration during field data collection. The responses in the qualitative interviews will be coded using both inductive and deductive approaches, and multiple CMO configurations will be generated. The CMOs will be shared again with stakeholders and respondents at a workshop, where they will check whether our results match the reality of the setting, as well as what they shared with us in the interviews. Feedback will be gathered to further refine the CMOs, which will then be tested in subsequent data collection. This iterative process will continue during the 3 rounds of field data collection. The iterative process will also allow the identification of semipredictable patterns and further exploration of the true mechanism. Finally, the initial generative mechanism will be refined further and explained by underlying behavioral theories [48].

Data Management and Quality Assurance

The field research team will receive a 1-day orientation on the research methodology, the data collection process, tools to be used, and ethical issues (such as consent procedures for study participants and securing the privacy and confidentiality of participants during fieldwork). Our field research staff will have ample experience in field data collection and qualitative research methodology. The field team will be closely supervised and supported by the research fellow from University College London (UCL) during fieldwork. Any challenges that arise during fieldwork will be dealt with by the team of researchers at UCL, and solutions will be sought in accordance with good research practice.

Ethical Considerations

This protocol received ethical approval from the University College London Research Ethics Committee (6279/001) and COMREC (College of Medicine Research and Ethics Committee; P.06/23-0113) in Malawi. Permission letters were secured from the Ministry of Health, the Kasungu District Health Office, and each health facility. Written consent will be obtained from each respondent who will take part in the quantitative survey, qualitative interviews, as well as FGDs, prior to the interview. Participants will receive an information sheet that details the research purpose, benefits, and potential risks to the participants, if any, and they will be given the autonomy to decide whether to take part in the study or not.

No personal identifiers will be collected from the participants. The names of the health facilities will also be anonymized during the analysis and reporting of the findings.

As part of the research process, data from ongoing research activities will be analyzed, and preliminary results and learnings will be shared periodically with the implementation team to support the successful implementation of Neotree, as well as with the in-country stakeholders through workshops to get their input and validate the study results. Furthermore, the results will be published in peer-reviewed journals and shared at international and local scientific conferences to reach the scientific community.

Results

This research project was initiated in December 2024. As of April 2026, all 11 health facilities have been enrolled in the intervention. Data are being captured using the Neotree system. Two rounds of data for the process evaluation have been collected, and a preliminary analysis was generated from the first round of data and was used to inform the second round of fieldwork. As a result of the unprecedented changes in the funding landscape in 2025, we had to revise the implementation plan, and we went ahead of the original timeline to roll out Neotree in all sites. Similarly, the plan for the research activities was revised in accordance with the change in the implementation pace. The field work is expected to be completed in April 2027, and result will comeout towards the end of 2027.

Discussion

Study Implications, and

This paper describes the design, methods, and theoretical frameworks that will be used in the process evaluation of a digital health intervention in Malawi. Neotree has passed through a series of development and assessment stages, including feasibility and acceptability assessments—prerequisites for an effectiveness evaluation.

Informed by theories and implementation science frameworks, this evaluation will provide evidence on implementation processes, strategies, and attributes of a digital health intervention in a low-resource setting. It will generate a detailed understanding of whether Neotree effectively improves newborn health outcomes in a network of health facilities (from primary health care up to tertiary-level care). Our realist approach will also help identify the different contextual settings in which Neotree could or could not be effective. Furthermore, the results will inform future scale-up of Neotree and strategies for the successful implementation of other digital health interventions that are similar in scope in low-resource settings.

Strengths & Limitations

The major strength of this study is that it builds on a prior acceptability and feasibility assessment of the Neotree intervention in the same setting, and it is informed by theories and implementation science frameworks. The longitudinal nature of the study will help capture the implementation process and outcomes at different implementation phases (early, intensive, and light-touch phases). In addition, data will be triangulated from multiple sources using a mix of methods, which will provide a holistic understanding of the implementation process and outcomes and further improve the accuracy of the study results. However, we acknowledge that the study is limited to 1 district in Malawi, which might limit the transferability of the study findings to other districts with significant contextual differences.

Dissemination

The findings from this study will be disseminated through scientific publications, oral/poster presentations at international and local research conferences, the development of policy briefs, and sharing the findings with in-country stakeholders.

Conclusions

In conclusion, this study will identify barriers and facilitators of successful implementation of a learning digital health system tool, Neotree, in a low-resource setting. It will enable us to explain the mechanism by which Neotree could contribute to the quality of health care and better health outcomes for newborns. Furthermore, the results of the study will guide future scale-up of Neotree in Malawi and other similar settings.

Generative AI Use

Generative AI was not used for this manuscript.

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Authors' Contributions

SL, EW, MH, and TC conceptualized the study and developed the protocol methodologies. SL led the development of the protocol and the writing of the manuscript. MH, AR, and SSG worked on the funding applications, and MH and SSG secured the funding. All authors reviewed the manuscript at different stages and provided valuable input. All authors read and approved the final version of this manuscript.

Conflicts of Interest

MH is a trustee of the Neotree charity [49], but she receives no financial payment for this role. The other authors declare no conflicts of interest.

Multimedia Appendix 1

Logic model/theory of change.
[PDF File (Adobe File), 155 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Qualitative data collection tools.
[PDF File (Adobe File), 473 KB-Multimedia Appendix 2]

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Abbreviations

CDS: clinical decision support
CFR: case fatality rate
CHAM: Christian Health Association of Malawi
CMO: context-mechanism-outcome
COMREC: College of Medicine Research and Ethics Committee
FCDO: Foreign, Commonwealth & Development Office
FGD: focus group discussion
HCP: health care professional
LMIC: low- and middle-income country
MCH: maternal and child health
MDHS: Malawi Demographic and Health Survey
PHC: primary health care center
QoC: quality of care
RE-AIM: reach, effectiveness, adoption, implementation, and maintenance
SDG: sustainable development goal
SSI: semistructured interview
UCL: University College London
WHO: World Health Organization

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