ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

ALMA MATER STUDIORUM - UNIVERSITY OF BOLOGNA
CESENA CAMPUS

Department of Electrical, Electronic, and Information Engineering
"Guglielmo Marconi" – DEI"

MASTER'S DEGREE IN BIOMEDICAL ENGINEERING
Curriculum of Human Movement

HEALTH TECHNOLOGY MANAGEMENT AND MONITORING OF PREGNANCY IN A LOW-RESOURCE SETTING: A CASE STUDY.

Graduation thesis in
Context Sensitive Design of Medical Devices

Supervisor:
Professor Stefano Severi

Candidate:
Camilla Rondini

Correlators:
Caterina Giuliani
Francesco Amelia
Massimo Migani

Academic Year: 2024/2025
Session: 12/03/2026

Abstract

Health Technology Management (HTM) represents a critical challenge in low-resource settings, where patient safety and clinical efficacy depend on the sustainability of medical device lifecycles. This thesis analyzes both the implementation of an HTM system and the first phase of the development of appropriate technological solutions for obstetric monitoring at Luisa Guidotti Hospital in Zimbabwe.

The work is structured around two main pillars. Firstly, a management system based on WHO guidelines was studied appropriately for the context of Luisa Guidotti Hospital. Then it was implemented, starting with the creation of a digital inventory and the establishment of preventive and corrective maintenance protocols. This experience, compared with an internship at the Policlinico Sant'Orsola-Malpighi in Bologna, highlighted how, despite the positive reception from local staff, the long-term sustainability of such systems is heavily constrained by resource limitations and the need for administrative simplification.

Secondly, the thesis addresses neonatal and maternal care through the Fetal Heart Rate (FHR) monitoring, with a particularl attention to the Moyo Fetal Heart Rate Monitor, a compact digital fetal monitor designed for intermittent auscultation. Based on the limitations identified in the FHR monitoring field, and the characteristics of the Moyo device, we started the biodesign process for a new medical device to optimize Intermittent Auscultation. This new proposal integrates the fetal heart rate monitoring of the original Moyo with uterine contraction tracking, aiming to reduce operator dependency and improve diagnostic accuracy without leading to excessive medicalization.

In conclusion, the study demonstrates that the effectiveness of technology in constrained settings depends on a participatory approach and context-sensitive design. While digitalization can support staff in overcrowded wards, technological integration must always be accompanied by continuous training and a lean management structure to not increase the workload on clinical staff, and to ensure a real improvement in clinical outcomes.

Commentato [CG1]: ??

Index of Contents

Introduction

This thesis explores the intersection between the efficient management of healthcare technologies and the design of "context-sensitive" medical devices in low-resource settings. The entire project is structured around two main pillars: the implementation of a Health Technology Management (HTM) system and the technological evolution of fetal monitoring through the study of the Moyo device.

The work originated within the Context Sensitive Design of Medical Devices course held by Professor Stefano Severi, where concepts of Biodesign, appropriate technology, and contextual device development were explored. While the initial approach was theoretical, focusing on the Identify and Invent phases of the biodesign approach from needs finding to high-level architecture, the project found its practical dimension through direct engagement with the reality of Luisa Guidotti Hospital in All Souls (Mutoko, Zimbabwe). Through discussions with Dr. Massimo Migani, the hospital's medical director, a clear clinical need emerged to enhance intermittent auscultation during labor monitoring by integrating uterine contraction measurement into the Moyo device, which is currently in use at the facility.

Parallel to this project, an HTM system was developed by exporting a model originally designed for another low-resource setting in Wolisso, Ethiopia. To better understand the practical aspects of HTM in a high-resource setting, an internship was conducted within the Clinical Engineering and administrative departments of the Policlinico Sant'Orsola-Malpighi in Bologna. After this preparatory phase, a month was spent on-site at Luisa Guidotti Hospital, working alongside clinical staff and biomedical technicians to understand their operational methods, hospital organization, and approach to maternity care.

The scientific and narrative path of this thesis reflects this dual soul of management and design. The first chapter provides the definition of HTM according to World Health Organization (WHO) guidelines and describes the application of these principles at Policlinico Sant'Orsola, used as a case study to understand complex administrative workflows. The second chapter analyzes the Zimbabwean healthcare system and the specific context of the All Souls mission hospital, detailing the implementation of the HTM system on-site and the results achieved after five months. The third chapter shifts the focus to maternal and neonatal care, offering an overview of the stages of labor and the auscultation methods currently in use. The fourth chapter is dedicated to the Moyo device, analyzing its structure and current use cases, while the fifth describes the design process for our now device proposal, which integrates uterine contraction monitoring, its clinical aims and technical specifics and their proposed validation. In the six chapter the opinions on our device are evinced through the analysis of the answer given a survey conducted among clinical staff, regarding its acceptability.

Finally, the seventh chapter offers a comprehensive reflection on the project, examining the critical relation between technological innovation and operational sustainability. In fragile settings, the act of safeguarding existing technology is as innovative as the act of invention itself. Moreover, the discussion looks at frugal innovation as a design necessity, measuring the success of a system like HTM or a device like the one we propose by its ability to empower technicians and clinicians without eroding their fundamental diagnostic skills. Ultimately, the thesis concludes by proposing a holistic approach where clinical engineering and context-sensitive design act as drivers, ensuring that the quality of care is no longer a privilege dictated by geography but a right supported by appropriate technology.

1. Health Technology Management

1.1 Definition and structure

As defined by the World Health Organization, Health Technology Management (HTM) is a process designed to ensure that the technology available within a healthcare system is safe, effective, and properly managed to support the best clinical outcomes [1]. This is achieved through different phases embracing the entire lifecycle of a medical device, involving rigorous planning and procurement alongside the technical maintenance of equipment and training of medical staff.

According to the WHO framework [2], the medical device lifecycle is an integrated, multi-stage process that ensures technology remains safe and effective from its initial concept and development to its final disposal.

This cycle begins with the identification of health needs and design, followed by rigorous regulation and pre-market evaluation of safety and performance. It then proceeds through Health Technology Assessment (HTA) to determine clinical and economic value, moving into the operational management phase which includes procurement, logistics, and inventory control. The process continues with ensuring safe use and maintenance through staff training and technical support, alongside constant post-market surveillance to monitor devices in use and ultimately concludes with decommissioning and safe disposal.

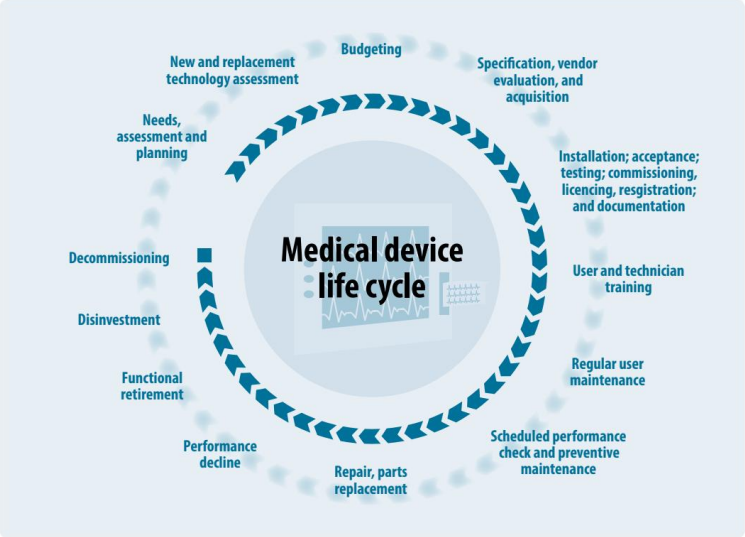


Fig 1: the lifecycle of a medical device

Within this holistic framework, Health Technology Management (HTM) acts as the operational bridge between these stages, particularly through management, maintenance, and disposal, ensuring that every device is coherently integrated into the healthcare environment.

The first phase is planning, a fundamental step that occurs both during the design and the operational stages of the management system. Initially, it involves a careful review of critical factors that significantly influence the appropriateness and cost-effectiveness of the entire programme.

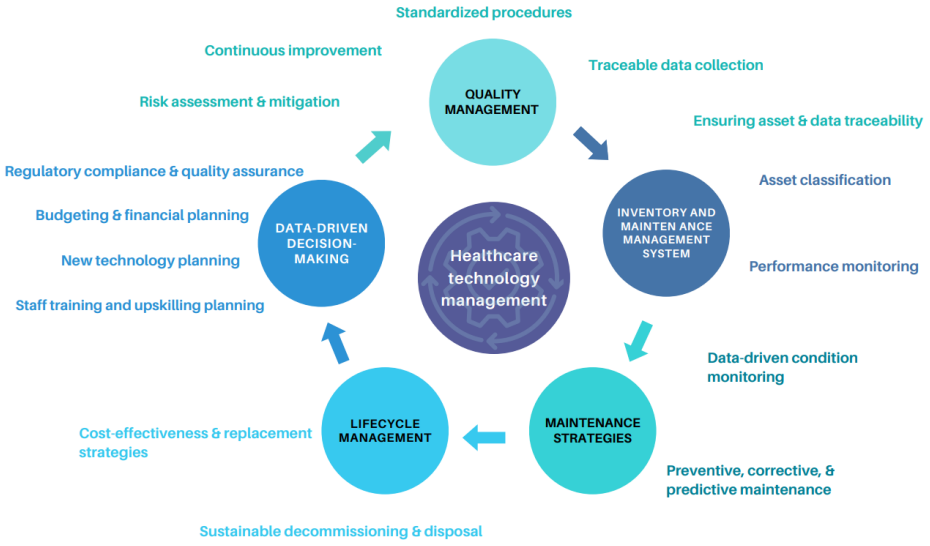


Fig 2: the Healthcare Technology Management structure

One primary consideration involves the rationale for the types of equipment to be included in the inventory: this selection can range from simple to complex medical devices, and may even include non-medical equipment, such as maintenance tools or electronic means. Another essential factor is the evaluation of available resources, specifically financial, technical, and human assets necessary for the system's implementation. Ultimately, planning requires the identification of the maintenance methodology, defining whether the service will be provided through internal resources, external service providers, or a combination of both.

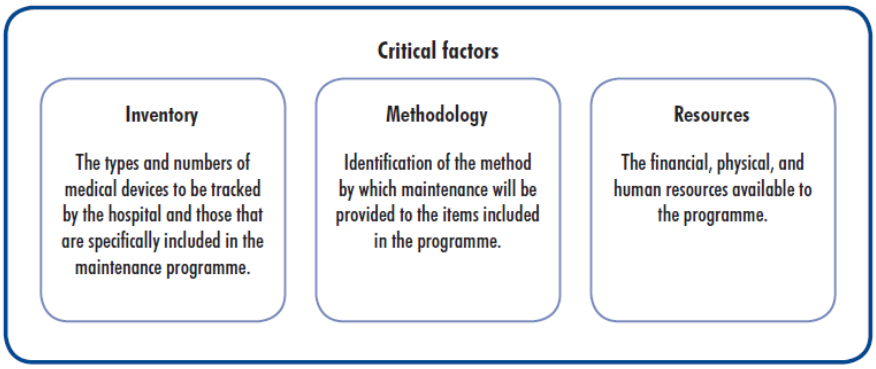


Fig 3: Scheme of the critical factors to consider in the planning of an HTM system

1.1.1 Inventory

The inventory serves as the foundation for all other HTM activities. According to the World Health Organization guidelines, an effective inventory isn't limited to a simple list, but it serves as a dynamic database to support technical, clinical, and financial decision-making. Its establishment requires a rigorous and multi-step methodology, that starts with the planning.

Initially this looks like defining the scope of the database: clinical engineers in collaboration with economical administration, and in small contexts even with the managers, must decide which equipment to include based on its clinical impact and maintenance requirements, focusing on the utilization rates together with "high-risk" or "mission-critical" assets. It's fundamental that the equipe responsible for the inventory reassesses inventory equipment inclusion often, particularly when mission criticality or utilization rates change.

1.1.2 Nomenclature

The second crucial element is the adoption of a standardized nomenclature. Without a consistent naming convention such as Global Medical Device Nomenclature or Universal Medical Device Nomenclature System, the system risks data duplication and communication failures between different departments. It doesn't necessarily need to be a standard nomenclature; each health-care facility has various needs regarding the information about the items included in the inventory, and those can be satisfied by different kinds of Identification systems: an identification trough sequential numbers, coded numbers or a more advance system like one with barcodes. Once the method is defined, every device included in the inventory has to be labeled with the univocal identification code.

The efficacy of any inventory is rooted in its comprehensive data collection. As emphasized by the WHO guidelines, to ensure full traceability requires the systematic capture of the core data for each asset. Those extend beyond the basic identifiers like the unique ID number, together with the manufacturer name, model, and serial number, to include some technical and administrative information. For instance, the database should record the current operational condition (working, out of service, or in need of maintenance), as well as the purchase price and date, which are vital for calculating the remaining life cycle and planning replacements, and the warranty status. To be significant, the inventory must be continually verified and updated to reflect the current status of each device.

Item	Brief description/purpose	Type of inventory
Equipment identification number	Unique identifier for each piece of equipment	Medical equipment
Type of equipment/item	Identifies what the item is, using standard and uniform nomenclature, such as the Universal Medical Device Nomenclature System (UMDNS) or Global Medical Device Nomenclature (GMDN)	All
Brief description of equipment/item	Describes the item, including its function/purpose	All
Manufacturer	Identifies the company that makes the item, including the name, address and contact details of the manufacturer	All
Model/part	Unique identifier of the product line (assigned by the manufacturer)	All
Serial number	Unique identifier of the item (assigned by the manufacturer)	All
Physical location within health-care facility	Includes room number or department; allows medical equipment to be located when preventive maintenance is due; may include storeroom information for consumables and spare parts	All
Condition/operating status	Identifies equipment as "in service" or "out of service"; includes reason for being out of service, such as calibration due, preventive maintenance due, under repair, awaiting spare parts or damaged beyond repair	Medical equipment, testing equipment

Power requirements	Clarifies the required power to run the equipment, such as 110V, 220V, 380V or three-phase; may be useful for identifying equipment that requires transformers or other special attention	Medical equipment, testing equipment
Operation and service requirements	Identifies any special requirements needed in operation or service of equipment	Medical equipment
Date inventory performed/updated	Date the equipment was entered into the inventory and the last date the information was updated	All
Maintenance service provider	Lists details of provider including name, contact details and contract details when medical equipment is maintained by an outside service organization (including when under warranty by manufacturer) or peripheral workshop; information on maintenance performed	Medical equipment, testing equipment
Purchase supplier	Used as a point of contact regarding purchase, reorders, warranty replacements, etc.	All

Fig 4: Some of the information to insert in the inventory

Furthermore, the inventory management process described in these pages facilitates maintenance tasks and safety inspections. This informational baseline is what allows the transition from theoretical planning to practical operation, defining the most appropriate maintenance strategy for each device.

1.1.3 Maintenance

This strategy is typically structured around two complementary pillars: Inspection and Preventive Maintenance (IPM) and Corrective Maintenance (CM). Preventive activities consist of scheduled interventions designed to guarantee safety and extend the equipment's lifecycle through periodic performance verifications, while Corrective maintenance comes into effect to restore functionality after a detected malfunction or failure. The management challenge lies in finding the optimal balance between these two approaches, aiming to minimize equipment downtime and at the same time contain overall operating costs.

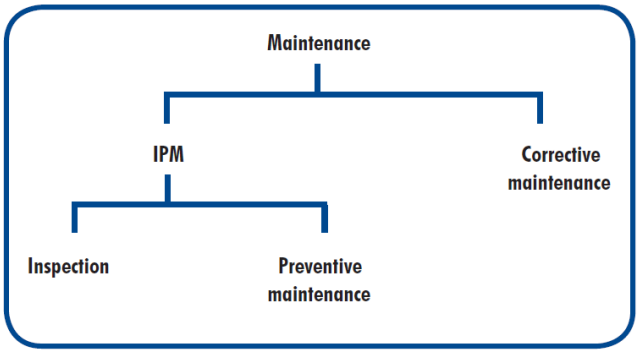


Fig 5: The maintenance scheme

The primary goal of IPM is to ensure device safety and reduce the probability of failure through scheduled interventions. These include performance verification to confirm that a device operates as intended by the manufacturer, and safety inspections, which focus on protecting both patients and operators from potential hazards, such as electrical leakage or mechanical instability.

Corrective Maintenance, on the other hand, involves the restoration of a device to its operational state following a failure. An advanced HTM system prioritizes these interventions based on the risk level of the equipment, a classification derived directly from the inventory data. In this context, it's fundamental to track the 'down-time' of the devices to better understand the operational timeline, especially since an excessive repair period can compromise clinical services. The time a device spends out of order serves as a good indicator of both the clinical engineering section's efficiency and the quality of its resources, as well as the level of communication between technicians and healthcare professionals and the general attention given by staff to the equipment.

This operational phase also includes acceptance testing, the final step of the procurement process, where new equipment is inspected upon arrival to ensure it meets all safety and performance specifications before entering the clinical use.

1.1.4 Resources

The success of a maintenance system relies heavily on rigorous resource planning, which the HTM framework divides into three vital areas: financial, physical, and human assets. Experience from the WHO indicates that the operational phase requires a continuous supply of spare parts and access to up-to-date service manuals, and that the lack of these resources is one of the leading causes of programme failure. Furthermore, the human element must be addressed through ongoing training for both technical and clinical staff. Technical personnel require regular updates on standard and emerging technologies, while clinicians must be trained on the correct use of

devices to prevent user errors, which often account for a significant portion of corrective maintenance requests. Planning for these resources must be proactive, ensuring that the clinical engineering department doesn't function merely as a reactive unit but collaborates with the administration to ensure the best outcome of the system.

Financial resources represent the primary constraint and must be managed through a dual-budgeting approach, consisting of a Capital budget and an Operating budget. The Capital Budget is used for high-cost, long-term investments, such as major medical devices, specialized test instrumentation, and the initial workshop setup. In contrast, the 'Operating Budget' must be planned to cover recurring expenses, including staff salaries, continuous technical training, and the procurement of spare parts and consumables. A critical aspect of financial planning is the 'Total Cost of Ownership' (TCO). The concept defines the fact that the purchase price of a medical device typically represents only a fraction of the total expenses incurred over its entire lifecycle, considering the ongoing maintenance and repair needs.

	Initial costs	Operating costs
Physical resources	Space, tools, test equipment, computer resources, vehicles.	Operation, utilities, maintenance, calibration.
Human resources	Recruiting, initial training.	Salaries, benefits, turnover, continuing education.
Direct maintenance	(not applicable)	Service contracts, parts and materials, travel, shipping.

Fig 6: The financial resources to consider

Physical resources are defined as the infrastructure necessary to perform technical tasks safely and efficiently, including not only adequate workshop space partitioned for different types of equipment, but also the availability of certified test equipment and tools. Without calibrated analysis tools it is in fact impossible to perform the performance verification required for IPM. Furthermore, access to library resources, specifically service manuals, wiring diagrams, and even software codes is highlighted as a mandatory requirement; this technical documentation provides the foundation that allows the performance of effective corrective maintenance.

Finally, human resources are the most crucial yet complex asset. Effective HTM requires a cohesion of skills, ranging from managerial and high-level technical tasks to routine maintenance. A formal training programme is essential for all the personnel involved, as

medical technology evolves rapidly and continuously. This training must particularly target two groups: the clinical users, to ensure they can handle new diagnostic and therapeutic modalities, and the technical staff, who must remain updated on equipment maintenance. Addressing user competence is strategic, given that a significant percentage of equipment failures are actually 'no fault found' incidents caused by improper operation, which can be mitigated through robust user training and support.

1.1.5 Computerized Maintenance Management System, CMMS

A preferred option in modern HTM architecture to manage this vast amount of data and activities is to rely on a dedicated information system: the Computerized Maintenance Management System (CMMS). This serves as the backbone of the system, where inventory data, maintenance schedules and service histories converge to provide a real-time overview of the system's status. The CMMS enables the monitoring of key performance indicators, such as the ratio of preventive to corrective maintenance, the average time to repair, and the overall reliability of devices. This data-driven approach guides the procurement and replacement policies, facilitating improved access, quality and use of medical products and technologies.

1.2 Application in a high resource context

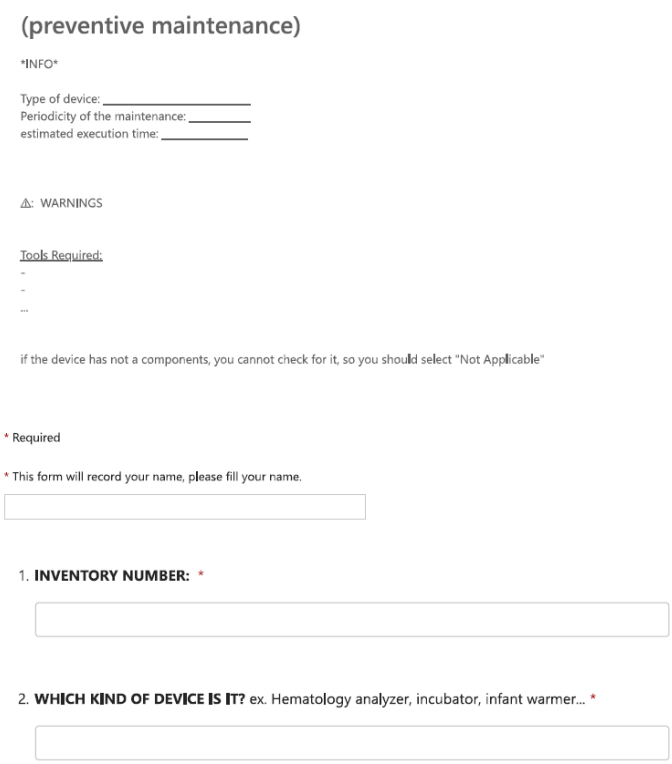
During my internship, I had the opportunity to observe the application of a CMMS in a high-resource setting such as the Sant'Orsola-Malpighi University Hospital in Bologna, focusing on both administrative and technical operations. I had the possibility to work alongside the technicians of the clinical engineering department during preventive and corrective maintenance interventions, and to understand the backbones of an HTM system by engaging with the administrative personnel. The management model adopted by the Sant'Orsola Hospital is a practical implementation of the theoretical framework provided by the World Health Organization, characterized by high technological complexity and a rigorous organizational structure. The hospital's approach reflects the complex interactions between basic technical assistance and comprehensive clinical engineering model, where the safety and efficiency of the technological assets are central to achieving positive clinical outcomes.

Inventory management at Sant'Orsola serves as a primary example of the data-driven approach advocated by the WHO. The hospital hosts thousands of medical devices, from basic diagnostic tools to advanced robotic surgery systems and high-end imaging equipment, all organized through a categorization system that enables precise tracking of each asset's lifecycle. By maintaining a detailed and up-to-date database, the clinical engineering department can effectively plan for technical interventions and manage the risks associated with such a diverse and high-density technological park. This Hospital is an example of a mixed maintenance strategy: a balanced integration of internal and external resources is used to check on different devices. While routine safety checks and first-line interventions are managed by technicians of the Clinical Engineering

Department through coordinated protocols, more complex technologies are covered by specialized Original Equipment Manufacturer (OEM) service contracts. This methodology ensures minimal downtime of critical equipment while optimizing costs through competitive outsourcing for less specialized devices.

In the practical phase of the internship, I could observe how theoretical HTM maintenance guidelines are translated into standardized operations using digital preventive maintenance (IPM) checklists. These forms ensure that every technician follows the same rigorous inspection protocol regardless of the device they are evaluating. The checklist defines a systematic assessment of physical integrity, checking the external case for eventual or structural damage, as well as a thorough verification of safety of components such as power supply cables, battery integrity, and alarm systems. Furthermore, the protocol demands a detailed inspection of functional components: sensors, drag mechanics, and cooling systems like fans and radiators. Even environmental and support factors are assessed, with evaluations on the resting structure of the device, on the functionality of wheels and of braking systems.

There was even the opportunity to work alongside some technicians on corrective maintenance procedures; when malfunction notifications arrived from the wards to the clinical engineering department, the supervisor assigned the tasks to technicians not already involved in preventive maintenance. Once in the designated ward, technicians consulted usually with nurses or with the laboratory staff to identify the devices to be repaired and assessed the situation. Minor or known issues were resolved on the spot; otherwise, the technicians returned to the department searching for necessary spare parts in the warehouse and requesting them if not available, or asking for the intervention of the external service company responsible for that specific device. In the latter situations, equipment downtime inevitably increased due to the waiting time of the approval of the economic and administrative department, the purchase of the spare parts or the booking of an external intervention and the subsequent lead time for their arrival at the hospital.



(preventive maintenance)

INFO

Type of device: _____
Periodicity of the maintenance: _____
estimated execution time: _____

⚠: WARNINGS

Tools Required:
-
-
...

if the device has not a components, you cannot check for it, so you should select "Not Applicable"

* Required

* This form will record your name, please fill your name.

1. **INVENTORY NUMBER:** *

2. **WHICH KIND OF DEVICE IS IT?** ex. Hematology analyzer, incubator, infant warmer... *

Fig 7: An example of a part of preventive maintenance checklist used at Sant'Orsola Hospital

4. **BUTTON INTEGRITY**
Look at the symbols on the device, are they still visible? Are they broken? Can they miss leading the operator?
How do the buttons are? *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not Applicable

5. **POWER SUPPLY**
Check for cables, plugs and socket integrity.
If the cable is separable, you can try to replace it with a new one.
Check also for batteries integrity if they are present and for the charger too.

How is it? *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not Applicable

Fig 8: An example of a part of preventive maintenance checklist used at Sant'Orsola Hospital

This was a formative experience, where I could verify firsthand the reality of the application of a CMMS on a health facility with high volume of patients. While for the most part the processes were coherent to the WHO management guidelines, their rendition in real life revealed some critical points. Firstly, the dependence of the maintenance order on the prioritization of the right tasks, and then a quite clear gap between technical efficiency and administrative fluidity. Even when a technician identified a fault during a preventive check the transition to corrective maintenance wasn't always immediate, because the authorization process for acquiring spare parts or specialized consumables led to illogical delays. In a high-resource context, these delays are often absorbed by the stocks in the technological park; however, in a limited-resource setting like Zimbabwe, such bureaucratic obstacles would result in prolonged equipment downtime, directly impacting patient care. This experience highlighted that an effective HTM system must not only be digitally advanced but firstly optimized, and administratively lean, as an overly complex system risks being a barrier to patient care, the primary goal of any health institution.

2.Situation of Zimbabwe and appropriate HTM development

2.1 General background

2.1.1 Zimbabwe health structure

The Republic of Zimbabwe is a lower-middle-income country in Southern Africa, bordered by Zambia, Mozambique, Botswana and South Africa. Independent since 1980, it's subdivided into eight provinces, and two cities with provincial status, including the capital, Harare, a reflection of a high diversity of ethnicity, with sixteen official languages and a copious amount of religious expression.

Demographic data from 2022 shows a remarkably young population, with more than one-third under age 15 and about one-third between the ages of 15 and 29. 61.2% of Zimbabweans reside in rural areas, primarily the elderly, women and children, while the remaining 38.8% living in urban centers is composed of a disproportionately large number of working age males [6]. The life expectancy at birth is estimated at approximately 61 years, in particular 64.4 years for females and 57.5 years for males [5].

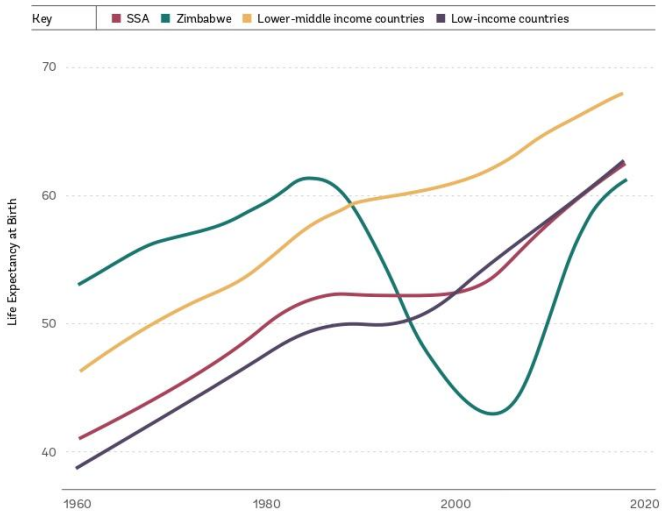


Fig 9: Trends in life expectancy at birth, Zimbabwe in green [7]

The healthcare system currently operates through a mix of public facilities, mission hospitals (especially in rural areas), and a private sector concentrated in urban centers. Despite the goal of Universal Health Coverage (UHC), the sector faces significant financing challenges regarding financial sustainability. In 2021, Zimbabwe's current health expenditure (CHE) represented only 2.79% of the country's gross domestic product (GDP), with public health spending per capita remaining below international

benchmarks.

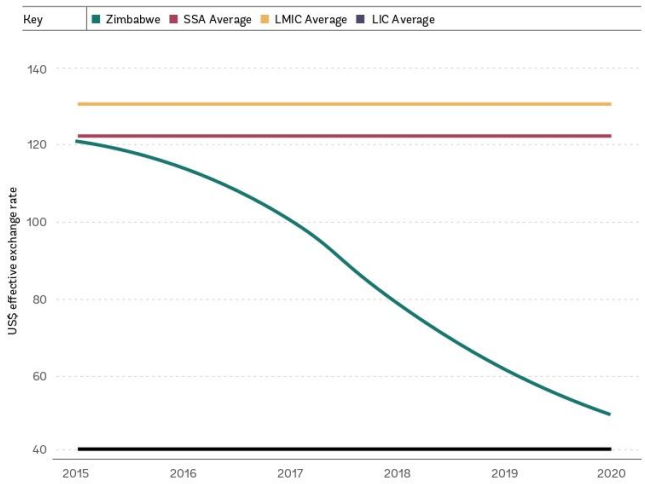


Fig 10: Total Health Expenditure (THE) per capita, Zimbabwe in green

The system is characterized by a various funding landscape: the government primarily funds health care through taxes, which account for 32.74% of CHE, while the sector remains heavily reliant on external sources that contribute for a substantial 45.03%. Despite the presence of insurances, the burden on citizens remains significant as out-of-pocket spending represents 10.26% of CHE. [7]

The Zimbabwean healthcare infrastructure is organized into a four-tier hierarchy designed to provide stratified levels of care from local clinics to central referral hospitals. At the foundational level, primary healthcare is delivered through a vast network of over 1,500 facilities, including rural health centers, clinics, and health posts which serve as the first point of contact for the population living in rural areas [5,7]. These are often managed by nurses and provide essential services like maternity care and disease prevention, and here village and community health workers play a vital role in reaching both rural and urban populations.

The secondary district level includes around 63 district hospitals, providing general medical care to both inpatients and outpatients and receiving referrals from smaller clinics. For many in rural areas, these are the first "real" hospitals they visit, though they often have a limited number of doctors available.

Then there are eight provincial hospitals serving as regional referral centers, that provide both general and specialist care and are staffed by doctors and nurses to bridge the gap between rural needs and specialized medicine.

The last part of the system is the quaternary level, represented by six major central referral hospitals equipped for the most complex medical cases and specialized surgeries and serving as teaching/training institutions. However, there is a marked geographical imbalance: these high-level facilities are almost exclusively concentrated in the metropolitan provinces of Harare and Bulawayo [7].

This centralization creates a significant barrier for the rural majority, who often don't have the resources to pay for travelling and stay in the vicinity of one of the more competitive structures. Consequently, while quaternary hospitals offer the most advanced care, they frequently suffer from overcrowding, due to patients seeking basic care that could and should be managed at the district level, if those facilities were better funded. [8]

2.1.2 Luisa Guidotti Hospital, Mutoko

The healthcare landscape in Zimbabwe the majority of health facilities, approximately 86%, are located in rural areas, but despite this distribution, these regions often face severe resource limitations. In this context, mission-run institutions, mostly church-affiliated hospitals and clinics, play a vital role, delivering roughly 68% of all rural health services.

The Luisa Guidotti Hospital, situated within the All Souls Mission in Mutoko (Mashonaland East), is a key pillar of this healthcare network. Historically, the facility's identity is defined by the legacy of Luisa Guidotti, who managed the mission until her death. The leadership was then taken over by Dr. Maria Elena Pesaresi, and in 2010 the management structure evolved with the arrival of Dr. Massimo Migani, that over time has assumed the full management of the hospital.

The Luisa Guidotti Hospital is a rural mission hospital and the first referral center for the communities around the Mutoko district. While its direct catchment area includes an estimated 8,955 residents of nearby wards and villages, its effective service area is much larger. By receiving referrals from numerous smaller clinics in Mutoko East, Mutoko North, and parts of the adjacent Mudzi District, the hospital serves a population of roughly 60,000 to 62,000 people. [9]

In practice, village health posts and rural health centers manage basic needs, and when patients require more accurate care such as childbirth, hospitalization, or surgery they are referred to Luisa Guidotti. For cases requiring advanced specialist care, the hospital refers patients further up to provincial or central facilities, such as Harare Central Hospital. The hospital’s reputation for quality care attracts patients from as far as Harare or other provinces, particularly for services that are elsewhere expensive or

inaccessible. It's often subject to mission where specialist from around the world comes to perform high level surgery, enhancing the abilities of the personnel already present.

The facility is a registered hospital with a 120-bed capacity, organized into several departments that support a wide range of clinical services:

- **Outpatient and diagnostics:** An Outpatient Department (OPD) with an attached pharmacy, an onsite laboratory for biochemistry tests, and a radiology department which is a primary provider for three districts
- **Inpatient wards:** General wards for adult patients and a dedicated pediatric ward
- **Maternal and child health:** A separate maternity ward with a labor room and an "expecting mothers' home"
- **Specialized units:** A Dental Department (the only oral health center for the region), an Eye Clinic, and a Rehabilitation department for physiotherapy
- **Chronic care:** An Opportunistic Infections (OI) Clinic focusing on HIV-related conditions and a TB/Isolation ward
- **Education:** As an accredited training center, operating as a School of Nursing on campus, training Primary Care Nurses and midwives

Fig 11: The rendering of the Luisa Guidotti Hospital

2.2 HTM specifics in Luisa Guidotti Hospital

The experience of developing a Healthcare Technology Management (HTM) system at the Luisa Guidotti Hospital required, first and foremost, a profound paradigm shift. It's a fundamental pillar in the implementation of any device to recognize that a management model designed for a High-Income Country cannot simply be transposed to a Low-Resource Setting, but the needs of the population and the receptive area should dictate the technical characteristics and the implementation specifics of the device, which both have to consider the particular social, environmental, cultural, political, and economic concerns of the target context.

The base of this project was in fact the concept of Appropriate Technology, essential for fostering a context-sensitive innovation. With this approach cultural appropriateness, financial sustainability, technical viability, and real clinical impact take precedence over the mere importation of unsuitable and unsustainable Western solutions.

Methodologically, the work was inspired by the principles of the Biodesign Process: Identify, Invent, Implement. It was however evident in the practical application at Mutoko that the boundaries between these stages proved to be less distinct than in theory, and identifying needs and implementing solutions often merged into an iterative process dictated by daily necessities.

The hospital's organizational structure included an Administrative Director and a Medical Director, supported at the time by two clinical engineering technicians, who we worked with for the development of the new HTM system. It was not imposed from above; instead, it was created together with them from scratch, and it was the result of a several-week assessment period, working side-by-side with the local technical staff.

The identification process, so first the needs finding and the following needs screening, was assessed in part with the hospital staff. Firstly, the pre-existing maintenance reality was assessed and at the start of the project, and maintenance management reflected the typical challenges of rural areas. The existing inventory was outdated, and the workshop was somewhat disorganized, often serving as a "parking lot" for devices that were out of use or awaiting inspection, about which very little prior information was known. The main activities in the field of device management performed by the technicians were corrective maintenance actions, and they were recorded exclusively in paper registers, making traceability and historical examinations difficult, and an analysis of large data volume complex. Preventive maintenance on the other hand was systematically performed only on oxygen concentrators, leaving the rest of the equipment vulnerable to unexpected failures and reliant on only the understanding of health professionals and corrective action.

We had to face these working habits to understand which steps to take, and together with the hospital staff we defined as the goal to have an optimized, computer based management system.

So, in the second Inventory step, evaluating the presence of a computer, the possibility to connect to internet and the capability of technicians, we decided to use a SharePoint structure, drawing inspiration from a similar successful experience in Wolisso, Ethiopia. We then discussed and defined the criteria for the medical devices inventory; together, we determined which devices to report through a mix of mission based and maintenance based prioritization of the devices [1], so giving precedence on the most impactful devices on the majority of patient care and secondly to devices that have a significant potential to harm a patient if they do not function properly, and have a significant potential to function improperly if they are not provided with an adequate level of IPM. We didn't take a risk based maintenance approach, because the hospital didn't possess a large number of devices whose failing would directly imply a damage on the patient; being a rural facility there aren't intensive care wards, were the patient is fully attached to the machines.

After this decision, we defined how to create the unique code to assign to each asset, and how to proceed with physical labelling to ensure every device was always traceable to its digital record. Even after those moment of discussion and idea gathering, many procedural details were discussed and refined during the implementation phase, adapting the system to the needs that emerged as the HTM system was being developed.

2.3 HTM implementation in Luisa Guidotti context

2.3.1 Inventory

Once the foundations were established, we moved to the Implement phase, the most operational one. As suggested by the WHO guidelines, we firstly updated the already existing inventory. We defined acronyms for the devices and departments, assigning each a coded identification number: department acronym, type of equipment acronym and number of that kind of device in the department. We then proceeded ward by ward labelling the device using paper tags, a black marker and adhesive tape, while at the same time inserting each device in the inventory.

	DEPARTMENT	ACRONYM
1	Adult	ADL
2	Pediatric	PED
3	Out patient department	OPD
4	Opportunistic Infection	OIC
5	Maternity	MAT
6	Laboratory	LAB
7	X Ray	XRY
8	Dental	DEN
9	Eye clinic	EYE
10	Rehab	RHB
11	Isolation	ISL
12	Pharmacy	PHR
13	Theatre	THE
14	CSSD	STR
15	Workshop	WRK
16	FCH	FCH
17	Kitchen	KTC
18	Laundry room	LND
19	School of nursing	SON
20	Surgical ward	SRG
21	Staff ward	STW

	DEVICE	ACRONYM
1	Anaesthetic Machine	ANM
2	Auto refractometer	ARF
3	Baby Heart Rate Monitor	BHR
4	Barometer	BMT
5	Bed	BED
6	Blood and Infusion Warmer	WRM
7	Blood pressure machine	BPM
8	Bubble CPAP	BCP
9	Cardiotocograph	CTG
10	Cart	CRT
11	Compressor	CMP
12	Cradle	CRD
13	Defibrillator	DEF
14	De-ionising water plant	DIW
15	Dental Chair	DNC
16	Diathermy	DTM
17	Echograph	ECO
18	Electrical Surgical Knife	ESK
19	Electrocardiograph	ECG
20	Facoemulsificator	FEC
21	Fetal Heart Rate Monitor	FHR

Fig 12: The departments acronyms and some of the devices acronyms

Fig 13: A label example on a scialytic lamp

With the device code we populate different fields with core data information: the Inventory Code Number of the device, the department where is located, a brief description of its type of equipment and of its working status, a comment field, the manufacturer, the name of the model, its serial number and a flag for the presence of its manual.

Inventory Code Number	Departement	Type of equipment	Status	Comments & different location
FCHHBD001	FCH	Height Board	OK	
FCHHBD002	FCH	Height Board	OK	
FCHSCA001	FCH	Scale	OK	
FCHSCA002	FCH	Scale	OK	
FCHHBD003	FCH	Height Board	OK	
FCHSAT001	FCH	Saturimeter	OK	
FCHUSS001	FCH	Ultrasound Scan	OK	
FCHGLC001	FCH	Glucometer	OK	
FCHBED001	FCH	Bed	OK	
FCHIVP001	FCH	IV Pole	NP	Wheels are not working
FCHBED002	FCH	Bed	OK	
FCHCRD001	FCH	Cradle	OK	
FCHSUC001	FCH	Suction Machine	OK	
FCHMON001	FCH	Patient Monitor	OK	
FCHTHR001	FCH	Thermometer	OK	
MATRTE001	MAT	Resuscitre	OK	
MATRTE002	MAT	Resuscitre	NO	Not working at all
MATMON001	MAT	Patient Monitor	NP	SpO2 and temperature not working
MATSAT001	MAT	Saturimeter	OK	Batteries have to be changed
MATSAT002	MAT	Saturimeter	OK	Charging system to check

Fig 14: One part of the effective inventory

Name of Manufacturer	Model Name	Serial Number	Operation Manual
ADE	MZ10042		
FAZZINI			
SECA	7001021008	5700055148140	
SALTER	2356S		
ADE	MZ10040	165240005556	
Hunan			
Fukuda Denshi	UF-750XT	37061665	
CareSens	GM01WAA	F066210L0971	
Surgimed			
SNELL			
Ca-mi	NEW ASKIR 30	2399	
MASmed	MAS-V900	21090712040238	
UEBE Medical GmbH	0816		
Drager	Babytherm8004		
OHMEDA	IWS3300		
MASmed	MAS-V900	21090712040233	
ROHS			
ACARE	AH-M1		

Fig 15: One part of the effective inventory

A specific inventory for the warehouse was created, and the present assets were labelled using the same logic as the one used for medical devices, except for the ones we defined as out of use, that we disposed or opened to use as spare parts supply. While we were uploading the inventory, we reorganized and in part cleaned the workshop, using a distinct logic to position each labelled asset in a coherent place, to have an accurate awareness of the available resources such as work tools or spare parts.

Inventory Code Number	Departement	Type of equipme	Status	Comments & different location
WRKTSR001	WRK	SpO2 Simulator	OK	
WRKTSR002	WRK	SpO2 Simulator	OK	
WRKTSR003	WRK	SpO2 Simulator	OK	
WRKMON001	WRK	Patient monitor	NP	It turns on but doesn't work
WRKTSR004	WRK	ECG Simulator	OK	
WRKMON002	WRK	Patient monitor	OK	Transfarred to OPD
WRKWRN001	WRK	Wrench	OK	Dimension 24
WRKWRN002	WRK	Wrench	OK	Dimension 23
WRKWRN003	WRK	Wrench	OK	Dimension 22
WRKWRN004	WRK	Wrench	NP	Dimension 17, a part is broken
WRKWRN005	WRK	Wrench	OK	Dimension 8
WRKWRN006	WRK	Wrench	OK	Dimension 7
WRKWRN007	WRK	Wrench	OK	
WRKSAT001	WRK	Saturimeter	OK	
WRKDRL001	WRK	Drill	OK	Bench drill press
WRKDRL002	WRK	Drill	OK	
WRKDRL003	WRK	Drill	OK	
WRKDRL004	WRK	Drill	OK	
WRKGRD001	WRK	Grinder	OK	
WRKGRD002	WRK	Grinder	OK	

Fig 16: One part of the effective inventory

Name of Manufacturer	Model Name	Serial Number	Operation Manual
CONTEC	MS100	24070100020	YES
NELLCOR	OXIMAXN 560	10006664A0206	
NELLCOR	N-550	647641201	
BLT	V6	V026E002456	
Ming Sheng	SKX2000C	20C24050701	YES
COMEN	NC3	N5211026106	
CEDORE	R09100240		
MEGPRO			
LABOR	DIN3113		
LABOR	DIN3113		
LABOR	DIN3113		
ROHS	Finger tip pulse oxymeter		
FOX	F12-921A	09F12921A201606910050	
Makita	BDT146		
Ameen	AMD 1100		
BOSH	GSH3E	611320703	
BOSH	GWS 7 115	3601C88108	
Makita	BL 1830	862596A7	

Fig 17: One part of the workshop inventory

Inside the reorganization of the warehouse, we create even an inventory for the most common spare parts, to better understand which were the most used and when to

restock them. It was simpler than the other two, with only the spare part name and its quantity.

SPARE PARTS	#
probes adaptor	4
cable for ECG tester	1
ECG probe	1
power cables	32
SpO2 probe	3
pressure cuff	9
aspirator filters	11
baloon for anesthesia machine	4
helmet	1
welder visor	3
visor	1
protection glasses	1
air brush painting	4
blades for hacksaw	4
blades for circular saw	9
blades for grinding	9
for sterilizer	

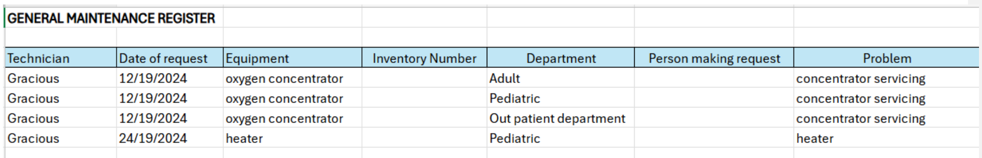
Fig 18: Spare parts inventory

Fig 19: The reorganization of the warehouse

2.3.2 Corrective Maintenance

We then addressed the corrective maintenance procedures flow, using a hybrid approach, working both with the technicians and with the wards. We implemented a digital general maintenance register to complement the notebooks already in use, where the corrective requests have to be inserted with all the inherent specifics: the technicians responsible for the manutention, the insertion date in the system, the specifics of the device, who made the request and the details of the problem, its urgency defined in less than a week weeks or months, its status and the eventual completion date. The workflow of the technicians consists in:

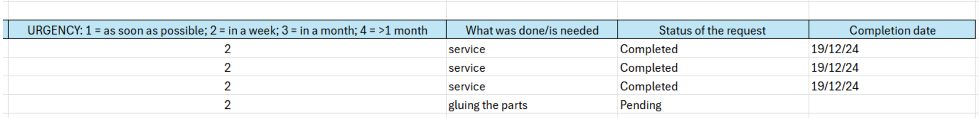
- Being directly called by the ward, assess the reported issue and writing the intervention to be done in the notebook.
- Report the pending request in the weekly meeting with the supervisor, discuss the priority to assign at each issue and plan the workflow
- Transcribe the discussed request in the corrective excel sheet on the SharePoint
- Once completed the intervention, change the status of the request on the excel sheet in completed and fill out the completion data field



GENERAL MAINTENANCE REGISTER

Technician	Date of request	Equipment	Inventory Number	Department	Person making request	Problem
Gracious	12/19/2024	oxygen concentrator		Adult		concentrator servicing
Gracious	12/19/2024	oxygen concentrator		Pediatric		concentrator servicing
Gracious	12/19/2024	oxygen concentrator		Out patient department		concentrator servicing
Gracious	24/19/2024	heater		Pediatric		heater

Fig 20: General corrective maintenance register



URGENCY: 1 = as soon as possible; 2 = in a week; 3 = in a month; 4 = >1 month	What was done/is needed	Status of the request	Completion date
2	service	Completed	19/12/24
2	service	Completed	19/12/24
2	service	Completed	19/12/24
2	gluing the parts	Pending	

Fig 21: General corrective maintenance register

A good prospective was to assess the intervention from the beginning, acting on the health workers who are the first to notice the malfunctions. We needed to find a way to create a higher attention around the condition of the device in the wards without it being too demanding, and given that some were already using a paper register, we remained consistent with this method. We created a paper form resembling the structure of the corrective sheet used by the technician, to have similar information and so to assure the uniformity of the technical request. The workflow of the clinical staff consists of:

- Fill the paper register with the relevant information of the requested intervention

- Inform the technicians when they check on the department or call them if the issue is urgent; write the technician called in the register
- Record the completion date when the work is completed

DEPARTMENT:

Date of request	Equipment	Inventory Number	Requester	Problem	Technician	Completion date

Fig 22: The model of the corrective form in use in the wards

This assures to have a visible, trackable timeline of both open and completed maintenance requests, encouraging clinical staff to provide accurate problem descriptions and fostering a culture of technical accountability, both for them and for the technicians. Moreover, by keeping a detailed history of interventions for each device, both in the SharePoint page and in the wards, technicians are better equipped to make informed decisions and to manage the entire lifecycle of the equipment more effectively.

2.3.3 Preventive Maintenance

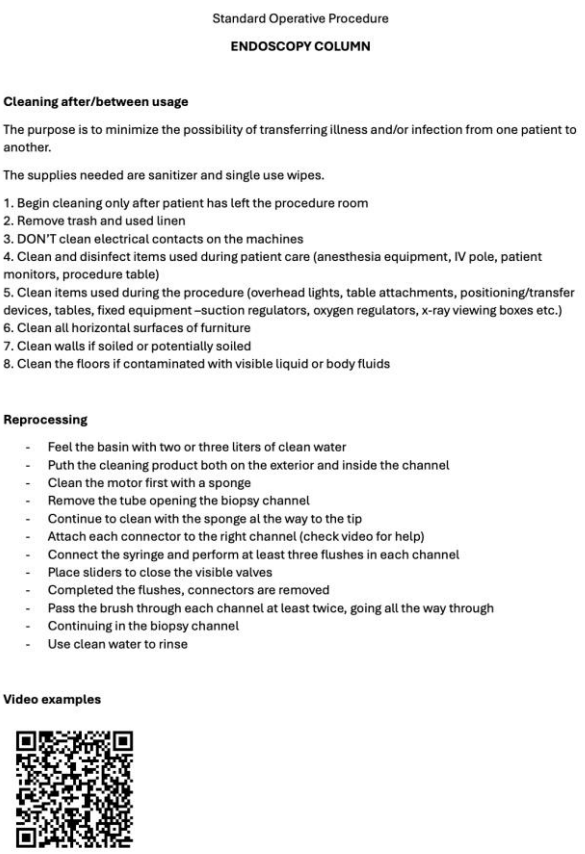
We structured the management of preventive maintenance (PM) at Luisa Guidotti Hospital around several interconnected digital modules. Within the SharePoint ecosystem, the workflow is organized into three primary sections accessible via the main navigation: PM Checklists, Response Tracking, and the Planner (also reachable through a shortcut on the dashboard).

Introducing scheduled maintenance represented a significant cultural shift for the local reality, where it was before introduced only on oxygenators, changing the air filters. To bridge this gap, we organized collaborative workshops with technical and administrative staff to illustrate the strategic value of a proactive approach. The discussions focused on how systematic interventions could minimize equipment downtime, identifying potential faults before they escalate into failures, and extend the operational lifespan of the hospital's assets. Furthermore, we emphasized that PM is a driver for patient safety, ensuring diagnostic and life-support tools remain reliable, while simultaneously allowing the administration to optimize resource allocation and procurement by identifying aging equipment well in advance.

The technical foundation of the program was defined on three main components: the Recurrent Preventive Procedures, which define the type and the frequency of interventions for each class of device; the Custom Checklists, standardized digital forms designed to guide technicians through each type of inspections, and Standard

Operating Procedures (SOPs), instructional guides for the correct clinical use and basic care of the devices.

The need for the implementation of SOPs emerged because a significant challenge identified was the improper or inconsistent handling of medical equipment by staff, frequently generated by insufficient training or a lack of explicit guidance. While basic paper Standard Operating Procedures (SOPs) were already present in the wards, they lacked necessary detail and were rarely utilized. To address this, a revised format was developed, designed to be highly visible and affixed to walls for immediate access by staff without digital devices. By combining localized written instructions with visual aids, the new format aims to standardize device usage and enhance patient safety across all departments.



Standard Operative Procedure

ENDOSCOPY COLUMN

Cleaning after/between usage

The purpose is to minimize the possibility of transferring illness and/or infection from one patient to another.

The supplies needed are sanitizer and single use wipes.

1. Begin cleaning only after patient has left the procedure room
2. Remove trash and used linen
3. DON'T clean electrical contacts on the machines
4. Clean and disinfect items used during patient care (anesthesia equipment, IV pole, patient monitors, procedure table)
5. Clean items used during the procedure (overhead lights, table attachments, positioning/transfer devices, tables, fixed equipment –suction regulators, oxygen regulators, x-ray viewing boxes etc.)
6. Clean all horizontal surfaces of furniture
7. Clean walls if soiled or potentially soiled
8. Clean the floors if contaminated with visible liquid or body fluids

Reprocessing

- Feel the basin with two or three liters of clean water
- Puth the cleaning product both on the exterior and inside the channel
- Clean the motor first with a sponge
- Remove the tube opening the biopsy channel
- Continue to clean with the sponge al the way to the tip
- Attach each connector to the right channel (check video for help)
- Connect the syringe and perform at least three flushes in each channel
- Place sliders to close the visible valves
- Completed the flushes, connectors are removed
- Pass the brush through each channel at least twice, going all the way through
- Continuing in the biopsy channel
- Use clean water to rinse

Video examples

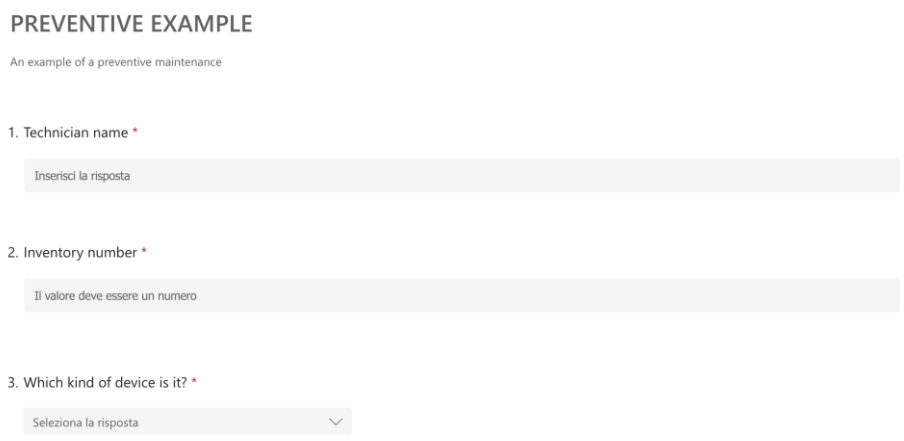
Fig 23: An example of SOP, created for an endoscopy column

Once the general inventory was finalized, we identified with clinical staff which device categories needed the implementation of PM Checklists, based on clinical criticality. The initial roll-out focused on essential equipment, including oxygen concentrators, neonatal incubators, CPAP machines, ventilators, and surgical systems (endoscopy and laparoscopy), cardiotocographs (CTG), baby and adult resuscitators, as well as diagnostic tools like ECGs, blood pressure machines and patient monitors.

To ensure the adaptability of the system, we adopted a type-based standardization inspired by the protocols used at the Policlinico Sant'Orsola-Malpighi in Bologna. For instance, a single unified checklist is applied to all oxygen concentrators regardless of the manufacturer. These digital checklists were built via Microsoft Forms, and followed a rigorous sequence:

1. **Identification:** Technician ID, date, and asset inventory code.
2. **Visual and functional Inspection:** Verification of physical integrity, alarms, and sensor accuracy.
3. **Safety and hygiene:** Electrical safety checks and disinfection status.
4. **Integrated workflow:** A final query regarding malfunctions. If a fault is detected, the system automatically redirects the user to a Corrective Maintenance form, ensuring seamless continuity between inspection and repair.

All the checklist were inspired by the following model of a preventive checklist:



4. Integrity of the case *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

5. Button integrity *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

6. Power supply *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

7. Switches, led and alarms *

- ◯ Perfect
- ◯ Something doesn't work properly, but it's OK
- ◯ Something is totally broken (write it at the end)
- ◯ Not applicable

8. Display *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

9. Are settings correct? *

- ◯ Perfect
- ◯ Wrong, but I set them correctly
- ◯ Totally wrong, and I don't know the correct settings (call someone who can help)
- ◯ Not applicable

10. Connectors and cables *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

11. Sensors *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

12. Drag mechanics *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

13. Wheels and braking systems *

- ◯ Perfect
- ◯ Wheels slightly damaged
- ◯ Brakes sligthly damaged
- ◯ Both wheels and brakes are slightly damaged
- ◯ Broken (write it the end)
- ◯ Not applicable

14. Structure on which the device rests *

- ◯ Perfect
- ◯ Wheels slightly damaged
- ◯ Broken (write it the end)
- ◯ Not applicable

15. Filters *

- ◯ Perfect
- ◯ Wheels slightly damaged
- ◯ Broken (write it the end)
- ◯ Not applicable

16. Ventilation and cooling *

- ◯ Perfect
- ◯ Wheels slightly damaged
- ◯ Broken (write it the end)
- ◯ Not applicable

17. Fluids *

- ◯ Perfect
- ◯ Slightly lower with respect to the needed amount
- ◯ Not enough fluids (write it at the end)
- ◯ Not applicable

18. Heating system *

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

19. Final check *

Does it work properly?

- ◯ Perfect
- ◯ Slightly damaged
- ◯ Broken (write it at the end)
- ◯ Not applicable

20. Comments *

Inserisci la risposta

21. If you need to report something wrong in the device, click the link below to be redirected to the corrective maintenance report document. Otherwise you can send the checklist.

https://luisaguidottihospital-my.sharepoint.com/:x:/r/personal/sharepoint_lgmissionhospital_org/_layouts/15/Doc.aspx?sourcedoc=%7Bf23006ce-15ba-4ddf-b1ad-74c92c537dec%7D&action=edit&wdinitialsession=a88e28b4-b068-4db4-6483-d960cc3419e0&wdrldsc=2&wdrldc=1&wdrldr=ReloadInEditMode%2CTransitionNonMetro%2COnSaveAsWebMet

Inserisci la risposta

Fig 24: The model of the general PM checklist

A critical requirement from the hospital administration was the ability to perform long-term data analysis. While each Microsoft Forms generates a separate excel files, managing multiple isolated spreadsheets would be inefficient. To solve this, we implemented a system of unified PM response collection through an automation layer using Microsoft Power Automate.

This tool serves as a bridge, automatically consolidating entries from each Microsoft Form into a single Excel file in real-time. This unified archive allows the management to monitor maintenance compliance, track recurring technical issues, and make data-driven decisions regarding equipment replacement and workload distribution. Whenever possible, frugal solutions were studied to overcome the lack of dedicated equipment for functionality and safety checks, ensuring they could still be carried out reliably and systematically, and to guarantee the project's long-term autonomy, the local technicians were trained to update and create new checklists independently. Those actions were taken to ensure that the HTM system can evolve alongside the hospital's needs without further external intervention.

The scheduling and delegation of technical tasks are managed through the Preventive Maintenance Planner, a system designed collaboratively with the hospital’s directorship and technical staff. By evaluating clinical priority and technical complexity, we established appropriate preventive maintenance intervals for each equipment category. These schedules were then integrated into Microsoft Planner to automate the notification workflow; technicians receive automated email alerts as deadlines approach, and their individual dashboards display only the tasks assigned to them. The interface is logically segmented into "buckets" representing various hospital departments, such as the NICU, Maternity, or OPD.

Each task in the system corresponds to a unique inventory code and includes the due date, the assigned technician, and a direct link to the relevant digital checklist. A significant advantage of this architecture is its long-term sustainability: once the recurring frequency is established, the plan remains active indefinitely unless manually adjusted, drastically reducing administrative overhead. This centralized approach not only minimizes the risk of oversight through automated reminders, but also provides the administration with a tool to track pending and completed interventions. To maintain the system's accuracy, the HTM team is responsible for updating the Planner whenever a device is decommissioned or a new asset is added to the inventory.

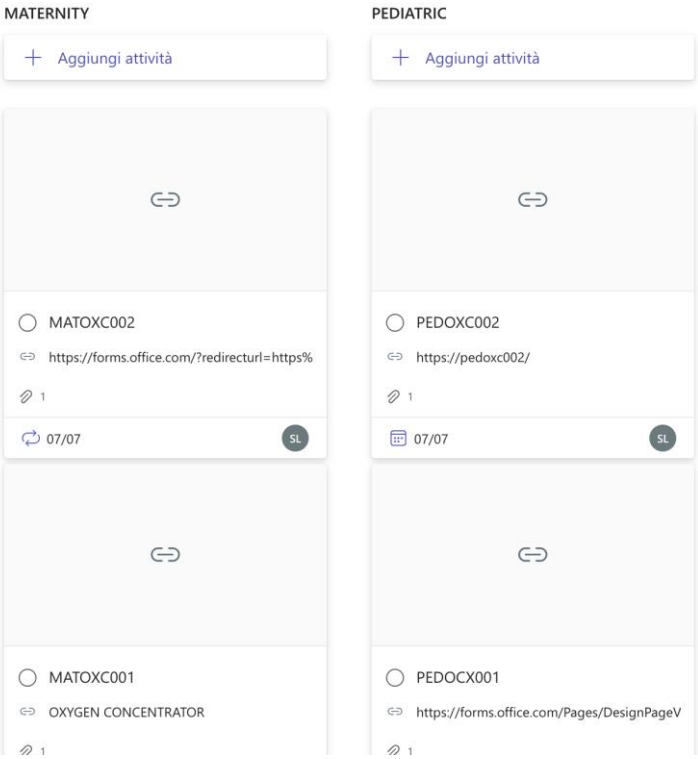


Fig 25: An example of the structure of the planner

All these modules were framed in SharePoint page, to make them easily accessible, and two more sections were added. A structured library of technical manuals and the WHO guidelines on clinical engineering in developing regions were inserted in the Useful Documentation section, with the downloadable corrective maintenance template, to ensure that physical record keeping remains synchronized across all hospital wards and to reduce reliance on paper storage. Meanwhile, the Tutorials section addresses the need for scalable training, allowing the staff to access video demonstrations of usage and care for the hospital's most sophisticated devices, instead of relying only on lists of rules or intermittent external workshops. This transition to multimedia learning fosters professional independence, allowing technicians to revisit intricate maintenance steps whenever necessary and ensuring that every team member adheres to the same high standards of care.

<

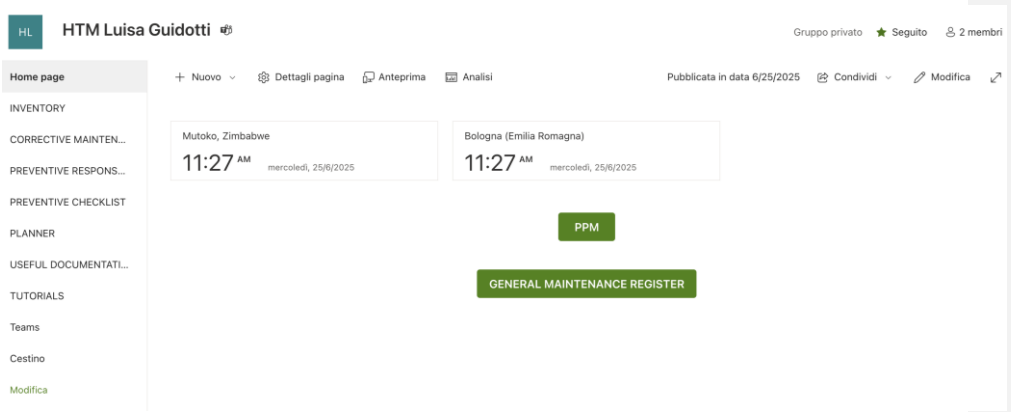


Fig 26: The homepage of the SharePoint

3.Results of the HTM implementation

The integration of a robust Health Technology Management (HTM) framework at Luisa Guidotti Hospital was characterized by a gradual, side-by-side progression rather than a top-down imposition. The priority was to immerse in the local context, creating genuine engagement with both technical and medical staff before suggesting any structural changes. This ensured the resulting strategy was not just a theoretical model, but a tool specifically calibrated to the hospital's unique operational capacity.

Five months after the first implementation, a comprehensive evaluation involving two technicians and various clinical staff members provided a clear picture of the system's performance. The feedback was overwhelmingly positive in terms of organizational clarity, with the HTM system earning a perfect 10/10 for improving technical work coordination.

Crucially, the technicians did not find the new protocols heavy on their work schedule, rating the added workload at a 1.5/10. Communication between departments saw a similar transformation, scoring 10/10 thanks to the adoption of formalized request channels. When weighed against the previous paper-only methods, the digital-integrated structure was rated 10/10 for its better management capabilities.

The inventory emerged as the most key feature, while the digital system (utilizing SharePoint, Microsoft Forms, and Planner) received a usability score of 6.5/10, it succeeded in creating a "common language" for equipment across the facility.

The interface between the HTM system and daily clinical duties—specifically regarding fault reporting—yielded the following insights:

- **Professional synergy:** The technician-clinician relationship saw a significant improving (8/10).
- **Responsiveness:** The introduction of ward-based paper registers for maintenance had a moderate impact on the frequency of technician visits (6/10).
- **Procedural comfort:** Clinical staff reported a 7/10 confidence level in filing formal requests.
- **SOP integration:** The use of Standard Operating Procedures remains a bigger hurdle, scoring 5/10, indicating that these guides are not yet a reflexive part of the daily workflow of the hospital staff.

While the Inventory was the cornerstone of the project, a post-implementation vulnerability was identified: once the direct supervision phase ended, the frequency of updates dropped significantly at a 0/10 in terms of consistency. This suggests that while the foundation is solid, the habit of uploaded documentation hasn't yet been fully internalized by the technical team.

Regarding Preventive Maintenance (PM), we established a sophisticated backend using Microsoft Power Automate to centralize data into a master Excel file.

- **Organization & planning:** Both metrics received a 10/10 score from technicians.
- **Tool usability:** The checklists and planning interface scored 8.5/10, while the centralized Excel tracking earned a 9/10.
- **Challenges:** Despite the tool's effectiveness (9/10), the actual interface of Microsoft Planner was rated 6/10. More notably, the tutorial videos were almost entirely ignored, with a usage rate of only 1/10. PM remains the most "culturally" difficult component to sustain, as proactive maintenance is a relatively new concept in this environment.

The transition from informal verbal requests to a structured paper-to-digital workflow was a major milestone. Since the registers were placed in wards, technicians reported a 10/10 increase in reported faults, proving that the system encouraged more systematic communication of issues, especially those previously overlooked or underreported. This allowed for a 10/10 improvement in task prioritization.

However, the frequency of transferring data from these paper logs into the main digital HTM system was rated 0/10, and while the staff is diligent in filling out the forms, the final step of digital centralization remains neglected.

After five months, it is evident that while the benefits of the HTM system are recognized, some elements have begun to lapse. The implementation was ambitious, requiring a significant shift in long-standing professional habits, and lead us to some key conclusions:

- **Sustainability:** The inventory and corrective maintenance workflows are the most "sticky" and likely to survive long-term in this kind of rural context.
- **Support limits:** One month of on-site presence followed by remote help was insufficient to cement such a complex cultural change.
- **Preparation:** Future deployments would benefit from extensive preliminary digital tailoring before arriving on-site. This would allow the field duration to be dedicated exclusively to intensive training and cultural integration.

Ultimately, this project demonstrated that while a single month cannot rewrite years of established practice, it can lay a functional foundation. Success in low-resource settings depends on a participatory approach that prioritizes long-term presence and constant, adaptable dialogue.

4. Maternity care context in Zimbabwe

4.1 History of maternity care

4.1.1 The golden era of primary health care (1980–1990)

Following independence in 1980, Zimbabwe was globally recognized as a model for public health in Sub-Saharan Africa. The government established a robust Primary Health Care (PHC) framework aligned with WHO standards, focusing on decentralizing maternal services to rural areas.

During this decade, the country achieved a remarkable 25% reduction in Under-5 Mortality (U5MR), dropping from 104 deaths per 1,000 live births in 1980 to approximately 75 in 1990. Maternal Mortality (MMR) was also exceptionally low for the region, estimated between 150 and 250 per 100,000 live births, with over 90% of pregnant women accessing antenatal care and 70% of deliveries assisted by skilled personnel. This era proved that structured clinical protocols, when backed by political will, could achieve a good standard of care in a developing context.

4.1.2 The decades of reversal: HIV/AIDS and socio-economic collapse (1990–2005)

The trajectory of clinical success was interrupted in the 1990s by a dual crisis that was heavy on the healthcare infrastructure. The rapid spread of the HIV/AIDS epidemic, which saw adult prevalence rates peaking at approximately 27-29% in 1997, overwhelmed obstetric and neonatal wards. The virus became the leading cause of indirect maternal attrition, while the lack of early prevention of mother-to-child transmission protocols led to a growth in neonatal infections that overwhelmed the capacity of neonatal wards. Simultaneously, the implementation of Economic Structural Adjustment Programmes (ESAP) led to drastic cuts in public health spending and the introduction of user fees for maternal services, which severely restricted resources for medical staff and healthcare access for the most vulnerable populations. During this period, the health indicators achieved in the 1980s underwent a severe reversal: Neonatal mortality stagnated or rose back toward 30-35 per 1,000 live births, while the Maternal Mortality Ratio (MMR) more than doubled, reaching a peak of approximately 555-650 per 100,000 live births by the early 2000s. This era of systemic shock created the baseline against which subsequent clinical protocols were eventually measured, as they were designed for urgent damage control in a fragile system.

4.1.3 Specialized protocol integration (2002–2015)

As the healthcare landscape evolved, the integration of clinical protocols became more specialized to address specific neonatal and obstetric risks:

The Integrated Management of Neonatal and Childhood Illness IMNCI (2002–2012) was implemented nationally by 2012, and clinical evaluations documented a 30% reduction in neonatal mortality in areas where the protocol was fully implemented. Crucially, this 30% improvement was measured against the post-crisis baseline of the early 2000s, representing an important effort to recover the survival rates that had significantly deteriorated during the 1990s.
In 2013 The Modified Obstetric Early Warning System was integrated into government hospitals to identify intra-partum emergencies. It improved pre-operative stabilization for caesarean sections and increased timely clinical responses from 4% to 62.
In the period between 2011 and 2015 the Results-Based Financing protocol aimed to reduce financial barriers to healthcare access, successfully narrowing the gap in reachability of emergency obstetric services.

4.1.4 Systemic erosion and the post-pandemic reality

While the COVID-19 pandemic introduced resource stock-outs that led to crisis of antenatal clinics, its had the ability to expose failures which were developing in the system for over two decades, a decline rooted in the structural crises of the late 1990s. The most alarming metric of this crisis is the recent trend in neonatal mortality. While global modeled estimates from World Bank suggest a neonatal mortality rate of approximately 22-24, primary data from the 2023-2024 ZDHS Key Indicators Report reveals a more critical reality of 37 deaths per 1000 live births, a 28% increase since 2015. This represents the highest neonatal mortality level recorded in the country in over two decades, effectively erasing the clinical gains made since the early 2000s. Crucially, this surge in newborn deaths occurs alongside a significant reduction in the Maternal Mortality Ratio (MMR), which fell to 212 per 100,000 live births in the same period. This stark divergence suggests that the increasing risk for newborns is not due to a lack of evidence based clinical protocols, which have been successfully integrated and updated for over 40 years, but due to a lack in resources necessary for their execution. While these protocols remain theoretically robust and effective in preventing maternal deaths during labor, the failure to convert fiscal policy into tangible clinical resources such as functional neonatal intensive care units and essential medicines has made them insufficient to guarantee newborn survival.

4.1.5 The governance crisis and the "implementation gap"

The contemporary governance of maternal health in Zimbabwe presents a profound dichotomy between high-level strategic planning and fiscal execution. The Zimbabwe Society of Obstetricians and Gynecologists (ZSOG), through its 2022–2025 Strategic Plan, has developed a program for clinical excellence aiming for a zero preventable maternal mortality benchmark.

However, this vision is pressured by an economic environment with a severe gap between budget allocation and actual expenditure. According to UNICEF, in 2024 only 27% of the health budget was actually spent in the latest fiscal cycle. This economic failure translates directly into critical shortages of any type of medical supply, particularly of life saving assets, and a deteriorating workforce due to the "brain drain" of trained personnel to higher resource settings.

4.2 Antenatal Care (ANC) and the challenge of risk stratification

4.2.1 Actual antenatal care services

The standard protocol for maternal care is theoretically aligned with the WHO model of integrated services, focusing on early identification of obstetric risks. Ideally, a pregnant woman enters the system through primary healthcare clinics, where screenings for risk conditions such as anaemia, HIV, and hypertension should be mandatory. Data from the ZDHS (2015; 2024) confirm a remarkably high level of health-seeking behavior: over 93% of pregnant women seek professional ANC and approximately 80-84% opt for institutional deliveries. This behavior highlights that the neonatal mortality crisis is not due to a lack of community engagement or health facilities rejection, however, the practical execution of this surveillance is inconsistent. While skilled personnel presence appears high on paper (85%), the clinical utility of visits is compromised by the absence of basic diagnostic tools (UNICEF, 2024). Healthcare providers are in fact unable to perform effective clinical investigations, preventing the risk stratification required by WHO protocols and making the ANC visits largely performative rather than preventive.

This systemic failure is most evident in urban centers like Harare. Here the prevalence of Pregnancy-Induced Hypertension (PIH) reaches 19.4%, and despite the proximity to major referral hospitals, the system frequently fails to provide consistent blood pressure monitoring and urinalysis required to manage it. The stakes of this surveillance are high: failure to intervene during the antepartum period leads to a threefold increase in low birth weight and a fourfold increase in stillbirths. Consequently, high neonatal mortality in urban areas is not a result of distance from care, but of the clinical emptiness of that care. This crisis is even more pervasive for women in rural provinces like Manicaland, where facility closures and the absence of point-of-care testing leave high-risk conditions entirely unattended. Ultimately, the lack of resources at both the primary and referral levels nullifies the proactive efforts of Zimbabwean women, transforming what should be vital preventive visits into missed opportunities for life-saving intervention.

4.2.2 Intrapartum management: rural fragility and the second stage crisis

As a patient transitions to the intrapartum phase, the rural-urban divide is further exacerbated by a technological and infrastructural gap. While geographic distance remains a primary barrier, the lack of appropriate infrastructures in remote areas makes even the timeliest arrival ineffective. UNICEF (2024) emphasizes that having reliable sources of energy is now more critical than the distribution of clinical guidelines; without reliable assets, even basic life-saving monitoring remains an insurmountable challenge in remote areas. Furthermore, financial mechanisms like Results-Based Financing (RBF), intended to bridge these gaps, have been severely undermined by hyperinflation and limited digital capacity. Consequently, a phenomenon of facility bypassing has emerged: women with fewer resources often ignore dysfunctional rural clinics to seek care in urban centers, further pressuring a system already overstretched.
During the second stage of labor, the system faces its most acute technical obstacle, the erosion of manual obstetric skills. International standards from Federation of Gynaecology and Obstetrics FIGO (2025) advocate for Assisted Vaginal Birth (AVB), mainly with vacuum extraction, to avoid the complications associated with late-stage Cesarean Sections. However, a notable disappearance of AVB skills has occurred in low-resource settings, with rates in Zimbabwe often falling below 3%; this lack of expertise results in an over-reliance on CS as a default rescue measure rather than a precise intervention. This trend is particularly dangerous in facilities lacking sterile supplies and consistent water, where performing an emergency CS significantly increases the risk of post-cesarean sepsis. Consequently, without the ability to perform AVB, the system is forced into high-risk surgical interventions that require specialized means for effective postoperative care, resources that are rarely available.
A central theme of the ZSOG 2022-2025 program is the training of the medical workforce through clinical mentorship and multidisciplinary collaboration. A key pillar is the application of the WHO ICD-10 framework, shifting the focus from counting deaths to identifying contributory conditions. By analyzing specific factors like prolonged labor or previous CS, the system can address iatrogenic errors that lead to mortality. Furthermore, training modules now aim to re-establish CS as a last choice surgery, highlighting the need for surgical sterility and postoperative vigilance to avoid sepsis.

4.2.3 Postpartum care and technical divergence from international guidelines

The puerperium is where the system's greatest vulnerability is revealed. The dramatic neonatal mortality rate indicates an interruption in the warm chain, a protocol of 10 passages by WHO that aims to avoid neonatal hypothermia, and postnatal monitoring. While the International Federation of Gynecology and Obstetrics (FIGO) suggests success rates for Vaginal Birth After Cesarean (VBAC) can reach 80% [17] most Zimbabwean districts lack the capacity to reach this success rate due to the absence of

24-hour emergency surgical backup and continuous fetal monitoring, the necessary conditions to authorize the execution of a vaginal birth after a cesarian section.
The divergence from the FIGO gold standards is most evident in neonatal care. While international standards focus on advanced resuscitation, the Zimbabwean priority remains anchored in basic infrastructure characteristics: safe water, vaccines availability, and stable electricity (UNICEF, 2024). Ultimately, stabilizing the system requires a dual approach: a massive reinvestment in primary infrastructure alongside the practical training of healthcare workers, particularly in rural areas, to change the mortality and distress rates that affect fragile patients such as mothers and newborns. To address these systemic gaps, it is essential to analyze the critical phases of labor where clinical decisions rely on accurate diagnostic data.

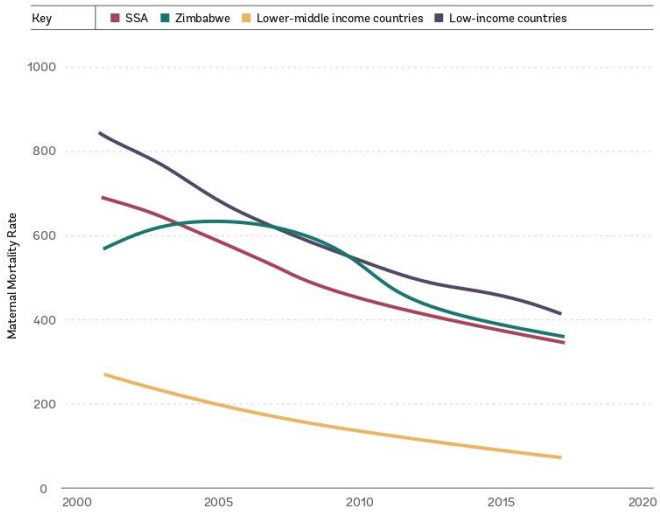


Fig 27: Trend in the maternal mortality rate, 2000-2017

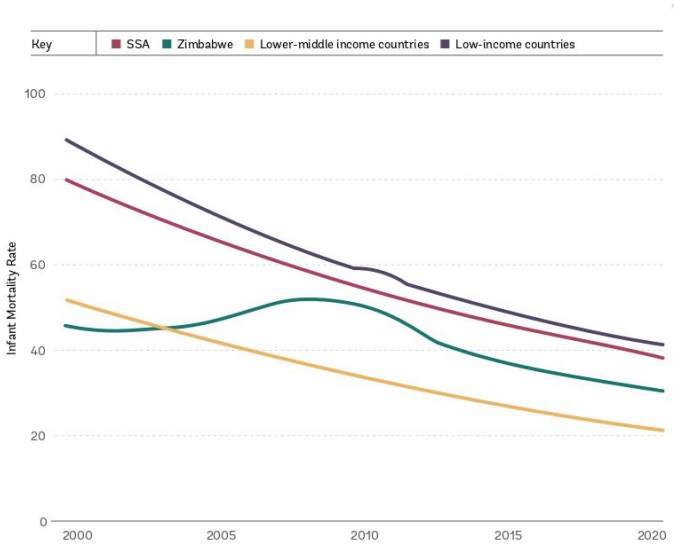


Fig 28: Trend in the infant mortality rate, 2000-2019

4.3 The physiological stages of labor and the necessity of monitoring

Labor represents the final physiological sequence of pregnancy, characterized by a series of coordinated events that facilitate the delivery of the fetus and the placenta. From a clinical perspective, labor is categorized into three distinct stages. The First Stage, dilatation, begins with the onset of regular uterine contractions and continues until full cervical dilation of 10 cm. It's subdivided into a latent phase, marked by irregular contractions and slow cervical changes up to 5 cm, and an active phase, where cervical dilation progresses rapidly from approximately 5 cm to completion as the cervix flattens and dilates. The Second Stage, expulsion, spans from full dilation to the actual birth, driven by maternal expulsive efforts and uterine contractions. Finally, the Third Stage, placental, involves the expulsion of the placenta and fetal membranes, typically within a 30-minute window from birth.

Throughout these stages, constant monitoring by a midwife or clinician is essential to detect early signs of fetal distress. This condition reflects a compromise in fetal circulation, often resulting in inadequate oxygenation through the placenta. The etiology of such distress is multifactorial, ranging from maternal conditions like hypertension and diabetes to mechanical issues such as umbilical cord prolapse or compression, or placental insufficiency, where the restriction of blood flow hinders the delivery of nutrients and oxygen, potentially leading to acute hypoxia and acidosis. Since these internal physiological shifts are often asymptomatic, the monitoring of the Fetal Heart Rate (FHR) remains the most critical diagnostic proxy for real time fetal well-being, regardless of the setting.

4.3.1 Monitoring modalities: Intermittent Auscultation (IA)

Intermittent Auscultation (IA) involves the periodic surveillance of the Fetal Heart Rate (FHR) at regular intervals during labor. We have different solutions traditionally employed for Intermittent Auscultation (IA). Each of these instruments presents specific advantages and limitations within the context of low-resource settings:

- **Pinard Horn:** The oldest and most widespread tool, typically made of wood or metal. It is a zero-cost, durable device that allows for the precise localization of the fetal heart; however, its clinical efficacy is highly user-dependent, requiring significant experience and a quiet environment for accurate interpretation.

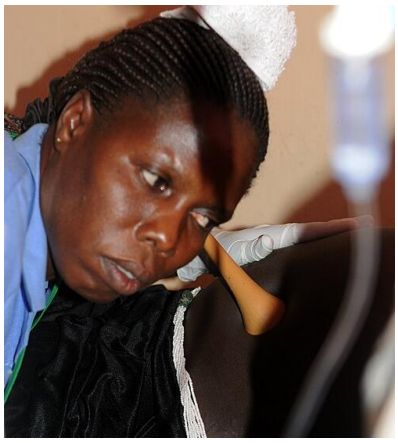


Fig 29 : Pinard horn in use

- **Fetoscope**: A specialized stethoscope used to perceive the fetal heartbeat, generally from the 20th week of gestation, and in low-income countries it remains a primary tool for intermittent monitoring during labor.

Fig 30: Fetoscope

- **Portable fetal doppler**: These are ultrasound-based transducers that facilitate FHR identification by providing superior sound quality compared to the Pinard horn. While easier to use, they face sustainability challenges in low-resource environments due to the constant need for batteries, stable electricity, and specialized maintenance.

Fig 31 :Portable fetal doppler

- **Partograph**: Although not a monitoring device per se, the partograph is the "gold standard" graphical tool recommended by the WHO for recording IA data. It tracks cervical dilation, fetal heart rate, and contraction patterns, allowing clinicians to promptly identify the need for obstetric intervention.

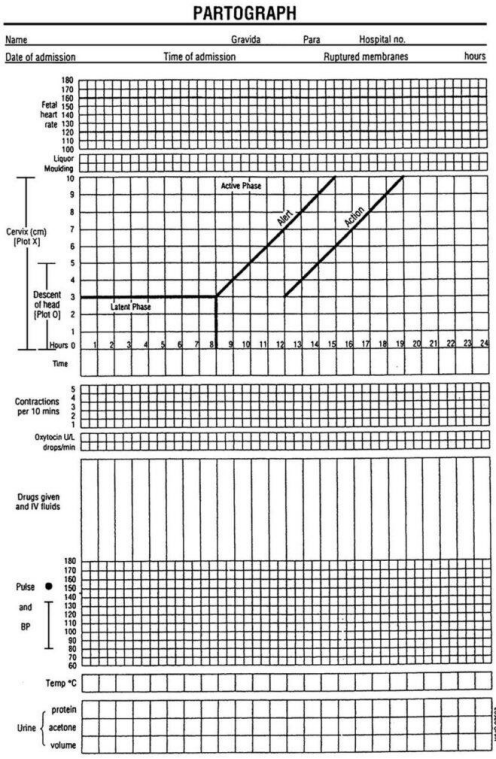


Fig 32:Partograph

This method remains the gold standard for low-risk pregnancies, as advocated by FIGO and WHO, particularly in settings where access to electronic monitoring is limited. These IA systems are extremely adaptable, and can be used in various operating settings, independently from an electric energy access and even outside of a classical hospital location. Their main defect is the high operator dependency involved; a poorly trained healthcare professional would perform an ineffective IA regardless of work conditions.

The primary objective of IA is twofold: to identify early signs of fetal hypoxia or acidosis to allow for prompt intervention, and to confirm fetal well-being in reassuring cases, thereby avoiding the 'false alarms' that often lead to unnecessary obstetric interventions [13].

In clinical practice, IA requires a rigorous protocol: checking the FHR at regular intervals, every 15 minutes during active labor and every 5 minutes during the expulsive phase, for one minute immediately after a contraction to document the baseline and any variations. It offers significant practical advantages: it ensures direct, 'one-to-one' contact between the healthcare provider and the woman, allowing for a global clinical assessment that includes maternal skin tone, respiratory rate, and uterine activity

through manual palpation [13]. Furthermore, IA promotes maternal mobility, allowing women to assume upright or free positions that can facilitate labor progression and reduce pain. From an organizational standpoint, the minimal instrumentation required makes IA the only viable and sustainable strategy in low-resource settings, where sophisticated electronic monitors are often unavailable or impractical.

4.3.2 Monitoring modalities: Continuous Auscultation (CA)

While intermittent auscultation remains the standard of care for low-risk pregnancies, the CA is required in case of high risk ones or if a low risk one switches at any time to a high risk. Recent technological advancements have introduced innovative systems designed to provide more consistent surveillance without the rigidity of traditional CTG.

- **Cardiotocography (CTG):** A sophisticated electronic system engineered to simultaneously acquire, process, and display fetal heart rate (FHR) and uterine activity. In standard clinical practice, both parameters are monitored externally through non-invasive transducers on the mother's abdomen: the FHR is detected via an ultrasound transducer based on the Doppler effect, while uterine contractions are measured using a tocodynamometer. The signals are recorded and then plotted on a time-dependent graph (the CTG trace) on a monitor or printed on paper. In high-risk scenarios, or when the external signal is inadequate, internal monitoring with fetal scalp electrodes and intrauterine pressure catheters may be utilized, though this requires ruptured membranes.

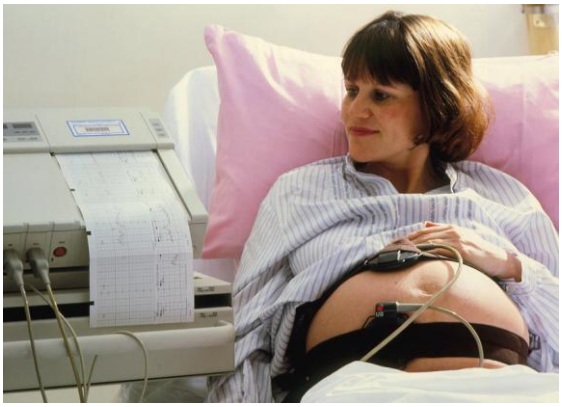


Fig 33: An example of CTG.
We can see well the two transducers and the trace being printed.

- **Wearable and wireless systems**: A significant shift in the state of the art where wearable sensors monitor fetal and uterine parameters non-invasively. A prominent example is the Monica AN24 (or Novii Wireless Patch), which utilizes

adhesive electrodes on the maternal abdomen to simultaneously record FHR and MHR, extracting them from fetal and maternal ECG signals, and uterine activity. The latter is measured via Electrohysterogram (EHG), which detects the electrical potentials of the myometrium through abdominal electrodes, demonstrating higher sensitivity in detecting contractions and being less influenced by maternal movement or body mass index than the tocodynamometer.

This approach offers crucial clinical advantages: it eliminates the need for restrictive abdominal belts, supports maternal mobility, and reduces signal interference providing a more reliable record of labor progression.
The preference for Intermittent Auscultation over continuous monitoring in low-resource settings is not merely a matter of costs, but is rooted in clinical outcomes. While continuous Cardiotocography (CTG) is the standard in high-risk pregnancies, it has been associated with a significant increase in cesarean sections and operative vaginal deliveries (forceps or vacuum extraction) with reduction in acute events such as neonatal seizures (0.15% vs 0.3% in trials), but without showing a corresponding reduction in perinatal mortality or long-term neurological complications like cerebral palsy.
In general a lower medicalized approach is to prefer, and furthermore in contexts where access to safe emergency surgery may be limited and the risks associated with cesarean sections are higher, IA is clinically safer for low-risk women as it avoids unnecessary surgical interventions while maintaining effective surveillance. Consequently, both FIGO and WHO guidelines recommend IA as the standard of care for low-risk intrapartum monitoring.

Cardiotocography (CTG) provides a continuous electronic record of both the fetal heart rate and uterine contractions. Despite its technological sophistication, the FIGO Consensus Guidelines (2015) advise against the routine use of continuous CTG for low-risk pregnancies. Evidence shows that in physiological labors, electronic monitoring does not improve neonatal outcomes but significantly increases the rate of unnecessary obstetric interventions. This includes the practice of 'admission tracing', a 20-30 minute CTG recording upon hospital arrival, which has been shown to increase Cesarean section rates without improving perinatal safety. Consequently, an alternative approach like intermittent CTG (alternating electronic monitoring with IA) is sometimes adopted, though FIGO and WHO maintain that Intermittent Auscultation remains the standard of care, reserving continuous CTG strictly for cases where a clinical problem emerges.
Therefore, continuous CTG should be reserved for specific clinical indications where the risk of fetal hypoxia is elevated, including:

- **Maternal factors**: Severe hypertension, fever (suggesting chorioamnionitis), vaginal hemorrhage, or epidural analgesia.

- **Fetal/obstetric factors**: Fetal growth restriction, meconium-stained amniotic fluid, induced or augmented labor using oxytocin/prostaglandins (which increases the risk of uterine hyperstimulation), and previous Cesarean sections.
- **Auscultatory findings**: Any abnormalities detected during IA that require a more detailed diagnostic picture.

4.3.3 Interpretation of FHR Patterns and Contraction Synergy

During labor, the fetal heart rate is intrinsically linked to uterine contractile activity. Each contraction acts as a temporary stressor, tightening uterine muscles and compressing placental blood vessels, which temporarily reduces the oxygen supply to the fetus. In a healthy, well-oxygenated fetus, this is managed through compensatory autonomic reflexes, with the heart rate promptly returning to baseline as the contraction ends. However, in compromised states or during uterine hyperstimulation, often an iatrogenic result of excessive oxytocin, this re-oxygenation window is lost, leading to profound fetal distress.

When interpreting FHR through CTG or IA, the relationship between the timing of decelerations and the peak of contractions provides the primary diagnostic map of fetal well-being. In worst case scenarios, it can lead to identification of dangerous baseline anomalies: persistent bradycardia (<110 bpm) or tachycardia (>160 bpm), absent or minimal variability (a strong indicator of potential hypoxia) and decelerations. Decelerations are temporary drops in FHR classified by their relationship to contractions:

- **Early decelerations, physiological**: These occur simultaneously with the contraction and are typically caused by fetal head compression during the descent through the birth canal in the second stage of labour. They are physiological, show preserved internal variability, and do not indicate hypoxia.

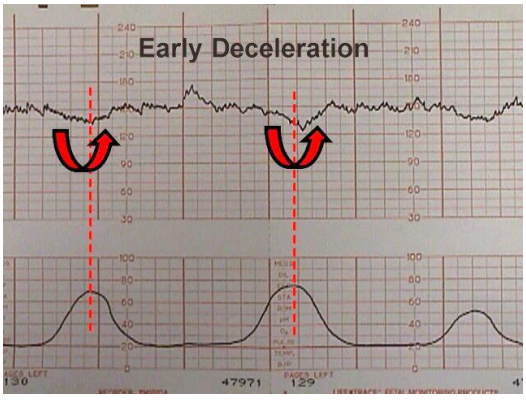


Fig 34: Trace demonstrating early decelerations.

- **Variable decelerations, compensatory to pathological:** Characterized by an abrupt V-shape, these are the most common and usually indicate umbilical cord compression. While often well-compensated if they are isolated preserve the variability and show rapid recovery, they become clinically concerning if they occur in >50% of contractions or exhibit a 'slow recovery' and loss of variability, signaling increasing fetal stress [13].

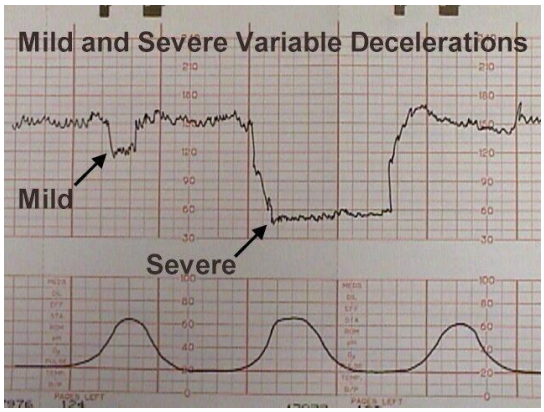


Fig 35: Trace demonstrating variable decelerations

- **Late decelerations, pathological:** Unlike early decelerations, these begin after the contraction peak, showing a wider U-shape and reduced variability. This timing reflects a response to transient hypoxia and are never physiological; they indicate uteroplacental insufficiency and a critical depletion of fetal oxygen reserves. Repetitive late decelerations are a definitive warning sign of fetal distress requiring immediate clinical intervention, such as maternal repositioning or expedited delivery.

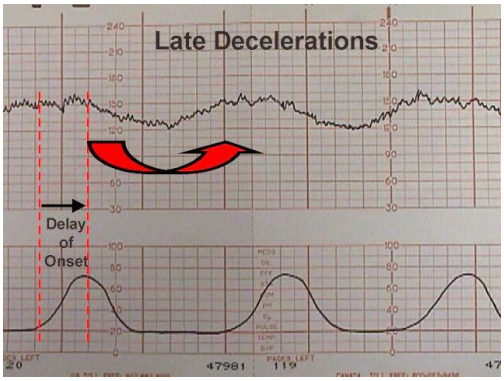


Fig 36: Trace demonstrating late decelerations

- **Prolonged decelerations:** Lasting longer than 2 minutes, these represent a significant drop in FHR that mandates urgent evaluation.

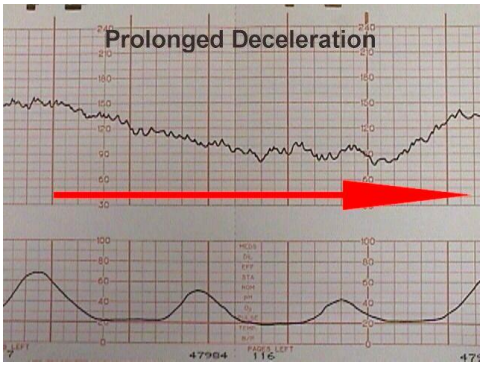


Fig 37: Trace demonstrating late decelerations

Ultimately, the integration of advanced fetal monitoring technologies must be balanced with the clinical reality of the setting. In environments like Zimbabwe, the challenge remains to provide the technical and clinical foundation necessary for reliable intermittent auscultation in low risk pregnancy, before passing to the monitoring recommended by FIGO for high-risk patients.

4.3.4 Moyo Fetal Heart Rate Monitor device in labor monitoring

One response to the logistical and technical barriers in low-resource maternal health programs is the Moyo Fetal Heart Rate Monitor, by Laerdal Global Health. This device can be classified as an advanced Portable Fetal Doppler device: while it shares the core technology of handheld Doppler ultrasound transducers, utilizing the Doppler shift to detect fetal heart rate, it's specifically engineered for low-resource settings.

Designed specifically for high-pressure environments, the Moyo utilizes a Doppler ultrasound sensor to provide real-time Intermittent Auscultation , displaying the FHR on a monitor and synchronously playing its audible output. Unlike traditional IA devices or basic handheld Dopplers that often require the mother to stay still while clinicians hold the probe in a fixed position, the Moyo is a portable, battery-operated system designed to be worn by the patient. This supports maternal mobility, a key recommendation of both FIGO and WHO to facilitate labor progression, and ensures operational continuity during power outages.

Fig 38: Moyo device

Furthermore, it includes a 'prolonged abnormal FHR alarm system, vital in overcrowded wards where continuous one-on-one midwifery care is not always feasible, and features the integration of maternal heart rate (MHR) pads, which can measure MHR when needed. These allow clinicians to distinguish between maternal and fetal pulses, helping to verify the origin of the heart rate being measured and drastically reducing the risk of diagnostic error, such as fetal-maternal heart rate confusion.

From an economic and sustainability perspective, the Moyo is designed as a low-cost solution tailored for large-scale implementation. Unlike high-fidelity hospital monitors that require significant capital investment and expensive consumables, the Moyo minimizes the Total Cost of Ownership (TCO). Its affordability is not only reflected in the initial purchase price, a fraction of a standard CTG unit, but also in its long-term maintenance: there is no need for consumables, it's designed for harsh conditions to reduce the frequency of replacements, and the battery-operated system eliminates the need for costly Uninterruptible Power Supply (UPS) systems, often required to protect sensitive equipment from Zimbabwe's power surges.

By providing a standardized alternative to traditional methods, the Moyo is significantly less operator-dependent than the Pinard stethoscope or basic fetoscopes, and enhances maternal comfort. The clinical efficacy and user acceptance of this technology are evident: a study showed that 72% of respondents preferred Moyo over traditional devices like fetoscopes and standard handheld Dopplers. Additionally, 66.4% of users found the device comfortable to use, and 82.3% expressed interest in its future use [19]. Both midwives and women viewed the Moyo as a comfortable and effective option for intrapartum FHR monitoring, effectively accommodating

preferences for intermittent surveillance. To understand its specific application, it is necessary to examine how the Moyo's design aligns with the clinical progression of labor, particularly in high-volume obstetric settings.

4.3.5 Clinical application across the stages of labor

The Moyo device is primarily engineered for use during the first stage (dilatation) and the second stage (expulsion) of labor. Its primary medical indication, as specified in the Moyo User Guide, is to screen for and monitor fetal distress specifically in the intrapartum setting, and being an IA only in low risk pregnancy.

- **First stage (active phase):** During the transition to the active phase (from 5–6 cm to full dilation), the frequency and intensity of contractions increase. The Moyo device is used here to provide intermittent but high-frequency surveillance. It's portable and features a neck strap and abdominal belts, and this configuration is specifically designed to promote maternal mobility, allowing the woman to walk or change positions to favor cervical dilatation and physiological labor progression.
- **Second stage (expulsive phase):** This is the most critical window for the Moyo monitor. As maternal expulsive efforts begin, the risk of umbilical cord compression and reduced placental perfusion reaches its peak. The device's ultrasound Doppler sensor allows for rapid reassessment of the FHR between and during contractions, theoretically permitting a switch to CTG if fhr patterns suggest to.

Fig 39: Moyo doesn't impair mathernal mobility

4.3.6 Technical specificity and alarm parameters

The User Guide highlights several technical features that define its use-case compared to traditional intermittent auscultation:

1. **The "prolonged abnormal FHR" alarm:** A distinctive feature of the Moyo is its built-in alarm system. It triggers a notification if it detects a heart rate that remains outside the physiological baseline for a sustained period. This is crucial for identifying persistent bradycardia (<110 bpm) or tachycardia (>160 bpm), even in overcrowded maternity wards. Those are key indicators of fetal distress and prompt clinical interventions.
2. **Maternal and fetal differentiation:** One of the most common errors in late-stage labor monitoring is the accidental recording of the maternal pulse instead of the fetal heart rate. The Moyo addresses this with integrated maternal heart rate pads (electrodes) on the back of the device. By placing the mother's thumbs on these pads, the clinician can simultaneously view both heart rates on the display, ensuring the FHR data is accurate and not a reflection of maternal tachycardia.
3. **Color coded visual alerts:** The FHR value is displayed using a traffic-light color system for immediate risk stratification.
   - Green: Indicates a heart rate within the normal physiological range (110-160 bpm).
   - Yellow/Red: Triggers visual warnings when the FHR falls below or exceeds safety thresholds, signaling a prolonged abnormal FHR.
4. **30 minute FHR histogram:** One of the most significant technical assets is the display of a 30-minute FHR history (histogram). Unlike basic Dopplers that only show a snapshot of the current heart rate, this feature allows clinicians to identify trends over time, such as decelerations or a loss of variability, providing a longitudinal perspective.
5. **Sensor displacement alarm:** To ensure data integrity, the device includes a specific alarm that triggers if the sensor is wrongfully displaced from the mother's abdomen. This is crucial for a "strapped-on" device, as it prevents the clinician from relying on a flatline or missing signal caused by maternal movement rather than fetal pathology.

The combination of visual and auditory alerts together with the histogram, can help significantly reducing the time-to-action, even in overcrowded context.

4.3.7 Clinical criticality: the risk of technological disengagement

While the Moyo's capacity for short-term continuous monitoring is a powerful asset in high-risk scenarios or overcrowded wards, its clinical application must be carefully

balanced to avoid a shift toward unnecessary medicalization. Furthermore, a primary risk of utilizing a device that can be strapped to the mother is the potential for operator disengagement. As FIGO (2015) emphasizes, fetal monitoring is not merely the observation of a heart rate, but a holistic assessment of the woman in labor. When an operator relies on a continuous audible output or an automated alarm, there is a danger of reducing the frequency of direct interaction. True Intermittent Auscultation requires the midwife to interface with the patient, performing a global assessment that includes different factors. A manual palpation of the abdomen is necessary to assess the frequency, duration, and intensity of contractions in real-time; assessment of maternal well-being, including skin color, respiratory rate, and emotional state. Lastly, giving a supportive presence has been shown to improve obstetric outcomes and reduce the need for interventions.

A "strapped-on" approach might inadvertently suggest that the device can replace the clinician's vigilance. However, clinical evidence confirms that technology cannot substitute the critical diagnostic value of feeling a contraction while simultaneously listening to the FHR. Therefore, the Moyo should be viewed as a tool to enhance the accuracy of the assessment, particularly in resource-constrained environments, rather than a means to bypass the essential one-to-one human interaction required for safe, physiological childbirth.

4.3.8 Integration into the Zimbabwe health strategy

In the context of the ZSOG Strategic Plan for 2022-2025 and UNICEF's 2024 response, the Moyo serves a specific "triage" function. In overcrowded wards where the ratio of midwives to patients is low, the device acts as an automated sentinel. It allows a single healthcare worker to monitor multiple women effectively; if a Moyo alarm sounds, it signals an immediate need for clinical escalation, such as a intervention on the mother, preparation for an assisted vaginal birth (AVB) or shift to continuous CTG to resolve a second-stage crisis.

This technical capability is vital in regions like Manicaland or Mashonaland West, where the lack of sophisticated electronic infrastructure often leaves higher risk labors unattended. The Moyo provides a rugged, battery-operated solution that maintains the FIGO Gold Standard of safety even when the broader system is in a state of structural demise.

Even though existing technologies like the Moyo Fetal Heart Rate Monitor have successfully help the implementation of intermittent auscultation, the clinical reality at facilities such as Luisa Guidotti Hospital revealed a persistent diagnostic gap. Even with improved fetal heart rate (FHR) visibility, clinicians often lack the ability necessary to distinguish between benign physiological responses and pathological distress, often because of shortage of contextual data, specifically the timing and intensity of uterine contractions.

The maternity ward at Luisa Guidotti Hospital provides a unique perspective on the implementation of fetal monitoring in a rural missionary setting. Unlike high-volume urban hospitals, the challenge here is not strictly overcrowding, but rather the optimization of clinical surveillance and the enhancement of maternal experience.
The ward's operational context is defined by:

- **Human resources & training:** The unit is managed by midwives and a general practitioner. A significant factor in this setting is the varied level of specialized obstetric training among the staff. In this scenario, the Moyo acts as a critical support tool, providing objective data that assists midwives in their decision-making process, compensating for gaps in specialized fetal heart rate interpretation.
- **Physical infrastructure:** With a two-bed labor room, the environment allows for more focused care. The hospital is equipped with three Moyo devices, one traditional CTG monitor, and utilizes the Partograph for labor tracking.
- **Maternal compliance and mobility**: A central pillar of the care model at Luisa Guidotti is encouraging active labor. Mothers are invited to move, walk, and change positions frequently to facilitate labor progression. The Moyo's portable and wearable design is essential here: it ensures continuous or frequent monitoring without confining the woman to a bed, significantly improving maternal compliance and comfort compared to traditional stationary monitors.

5. A new IA proposal

While Moyo has successfully standardized fetal heart rate monitoring at Luisa Guidotti, a diagnostic missing link remains. The effectiveness of the device is currently limited by the lack of synchronized uterine contraction data. For a midwife to correctly interpret a deceleration shown on the Moyo, she must manually palpate the mother's abdomen to determine if the drop in heart rate is synchronous with a contraction (benign) or delayed (pathological). This requires high clinical precision and constant physical presence.
The realization that FHR data alone can lead to diagnostic uncertainty, led to the collaboration with the University of Bologna to create a device that adds the missing dimension of uterine activity, providing a complete clinical picture in a single, easy-to-read portable interface. The point was doing so without arriving to a portable CTG, already existing and insidious given the higher CS associated with its usage.

To fully understand the clinical and technical value of the proposed device, it is essential to distinguish its role from both traditional Intermittent Auscultation (IA) and continuous Cardiotocography (CTG).
The Moyo device has successfully bridged the gap between manual IA and continuous surveillance. Observational studies in Africa have shown that using Moyo in low-risk pregnancies increases the detection of fetal heart rate (FHR) abnormalities (8% vs. 1.6% with the Pinard horn) and improves readiness for intervention [14].
However, this increased sensitivity comes with a known trade-off: an increase in obstetric interventions, such as cesarean sections (rising from 2.6% to 5.4%), without necessarily improving neonatal outcomes in low-risk populations [14]. This reflects the "intensive monitoring paradox": more data often leads to more medicalization. Despite this, the user experience has been overwhelmingly positive, with 66% of women finding it comfortable and over 80% expressing a desire to use it again [19]. Staff also appreciated its dual-mode flexibility (intermittent or continuous), which lightens the workload in crowded settings [13].
When discussing the simultaneous monitoring of FHR and contractions, the industry standard is Cardiotocography. Traditional CTG systems are fixed, wired machines, but the state of the art has evolved toward wireless and wearable solutions.
While these technologies offer superior performance in obese patients and reduce signal interference, they remain cardiotocographs at their core. They measure the same parameters to produce the same continuous tracing and therefore carry the same clinical implications regarding birth medicalization and its outcomes.
The core challenge identified was to optimize Intermittent Auscultation by creating a tool that offers the objectivity of electronic monitoring without the logistical and clinical burdens of traditional CTG. This led to the formalization of the Need Statement:

Commentato [CG2]: prima di passare alla soluzione metti il need statement come riepilogo della tua need analysis

“A way to optimize intermittent auscultation during labor in settings where the midwife-to-patient ratio is not always adequate, in order to reduce operator related errors and improve the effectiveness and consistency of fetal monitoring”

5.1 New medical device design

Commentato [CG3]: Medical device design

5.1.1 Stage I - Identify: need finding and strategic focus

Following the Biodesign methodology, the development began with the Identify phase, reassessing the clinical workflow through direct field research. A one-month immersion at Luisa Guidotti Hospital provided the strategic focus: while CTG remains the gold standard for high-risk cases, its routine use in low-risk pregnancies often leads to unnecessary medicalization and increased surgical interventions. After other refinements we defined specifically the need we needed to meet, an optimization of intermittent auscultation during labor in low-risk pregnancy. This involves addressing the operator-dependency problem of the Pinard horn and the maintenance problems of standard Dopplers, ensuring that the interpretation of FHR, especially decelerations, is taken within the context of other physiological data and is no longer solely dependent on the years of experience of the individual operator.

5.1.2 Stage II - Invent: concept generation and "must-have" criteria

During the invent phase, to better optimize intermittent auscultation we focus to solving the diagnostic missing link of the simultaneous acquisition of FHR and uterine activity within a portable, wearable format. Based on the "must have" criteria identified during stakeholder analysis (including pregnant women, midwives, NGOs), the device incorporates several critical features:

- **Dual sensor acquisition:** Unlike Moyo, our device includes both an ultrasound Doppler probe for FHR and a tocodynamometer to record contractions. This allows the device to automatically calculate the frequency of contractions and correlate them with the heart rate.
- **Dynamic trend interface:** The device features a two-screen interface. Screen 1 provides immediate numerical values, while Screen 2 visualizes a one-minute trend starting from the onset of a contraction. This trend tracking is crucial for identifying late decelerations, the primary sign of uteroplacental insufficiency.
- **Maternal signal differentiation:** To avoid the dangerous confusion of maternal and fetal pulses, the device maintains integrated maternal heart rate (MHR) pads, allowing for real-time differentiation.

Specifics: clinical benefit and their validation

The clinical value of our device aims to improve the standard of intrapartum care through a series of measurable benefits. The device's implementation is guided by the following clinical and operational goals:

- **Monitoring accuracy and objectivity:** By enabling continuous FHR measurement and automated documentation of contraction frequency (last 10 minutes), the device reduces reliance on manual counting or memory-based estimations. This improves the objectivity of clinical assessments and could be validated by comparing device-recorded data with manually collected charts to highlight improvements in data reliability.
- **Reduction of unnecessary interventions:** The device supports the correct interpretation of physiological decelerations, particularly those following contractions. This minimizes the misinterpretation of benign patterns as pathological, limiting unjustified referrals to CTG and the subsequent hyper medicalization such as unnecessary cesarean sections. Validation would involve a comparative study of cesarean rates before and after implementation, while monitoring neonatal outcomes to ensure safety.
- **Support in understaffed conditions:** In environments with low midwife-to-patient ratios, the continuous FHR display and integrated alarm systems allow for the early detection of complications without requiring constant bedside presence. This impact will be assessed through qualitative data collection, such as interviews and surveys, to explore midwives' perceptions of workload management and safety.
- **Documentation and traceability:** The storage of FHR trends, contraction frequency, and patient identifiers ensures more complete clinical records and facilitates retrospective evaluations. This benefit is validated by auditing medical records before and after the device's introduction to measure improvements in documentation accuracy and completeness.
- **Maternal comfort and mobility:** The wearable format allow women to remain mobile, facilitating physiological labor progression. Validation relies on maternal satisfaction surveys focusing on comfort and freedom of movement compared to conventional, more restrictive monitoring methods.
- **Remote clinical consultation (telemedicine):** The device improves the completeness of medical records and enables the transmission of recorded data to referral centers, providing expert input for complex cases within decentralized health systems and avoiding unnecessary patient transfers. This functionality will be validated through feasibility studies on data transmission success rates and surveys for clinicians at referral centers regarding data quality.

Specifics: technical requirements and their validation

To ensure viability and successful adoption in low resource contexts, our device should adhere to environmental, economic, and operational constraints:

- **Cost and affordability:** The device targets a manufacturing price point below €300 per unit. This directly addresses the costs of conventional equipment, usually higher; a standard CTG machines cost several thousand euros, while our device would remain accessible to lower budget structures. This could be validated with comparison against existing solutions, like the original Moyo.
- **Monitoring accuracy:** To provide clinical data quality comparable to hospital-grade standards, the device ensures FHR capture with an accuracy of ±5 BPM and a response delay of less than 5 seconds. Validation will involve comparative clinical studies matching the device's readings against standard CTG monitors and the reference Moyo device.
- **Portability and ergonomics:** Maintaining maternal mobility is a priority. The device is compact and lightweight, with target dimensions of 96×96×24 mm and a weight of approximately 300 grams. This requirement would be validated through user feedback to ensure it allows upright and lateral positioning during labor.
- **Ease of use and usability:** Designed for high-pressure environments, the interface is intuitive and requires minimal training. Key features include an easy-to-read display and a low-maintenance design. Usability testing with midwives and doctors will validate that staff can operate the device and interpret alarms correctly in normal working conditions.
- **Environmental resistance:** The monitor is engineered to operate in extreme conditions, supporting temperatures up to 60°C and relative humidity up to 90%. Its durability will be confirmed through environmental stress tests to simulate prolonged exposure to heat and moisture without signal degradation.
- **Battery life:** To guarantee continuity during frequent power outages, a minimum battery autonomy of 12 hours is required. This exceeds the average labor duration and is validated through endurance testing under realistic operating conditions.

To complete the technical and clinical profile of our device, we must examine its operational architecture and how it positions itself against the current "gold standard" of fetal surveillance. The following section explores the high-level operational architecture that supports these clinical and technical goals.

Main operating principles and workflow

Considering the must have criteria identified and the clinical and technical requirements defined, we arrived a high-level architecture of the device designed

around a user-centered, low-intervention workflow adapted for the structural challenges of hospitals like Luisa Guidotti.

Regarding the **intended use**, the device is specifically engineered to support midwives executing intermittent auscultation during labor in low-risk pregnancy, where cardiotocography is not clinically mandated by guidelines.
The idea is to maintain similar hardware to the original Moyo, where a tocodynamometer transducer would be added to record the number of contractions registered in a ten-minute window, and have the primary screen would show both of those numbers and, if needed to distinguish between maternal and fetal signals, the maternal heart rate. There would be added the option to switch to a secondary visualization, where it would be possible to check a one-minute trend of the FHR recorded at fixed intervals, with the start of the contraction highlighted.
Structurally, the device is designed for maternal comfort and mobility: the central display unit is worn around the neck, while the Doppler and tocodynamometer sensors are secured to the abdomen with adjustable bands, with the midwife retaining responsibility for periodic probe verification.

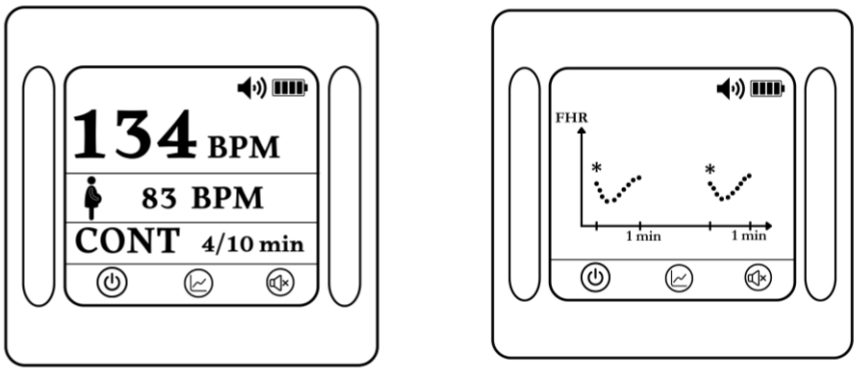


Fig 40: Screen 1 and screen 2

The **intended users** are professional midwives, formally trained in labor management, and the application of intermittent auscultation protocols for low-risk pregnancies.
In terms of the **intended environment**, the device is primarily destined for use in labor and delivery rooms within low-resource hospitals or primary health centers. These settings are often characterized by staffing constraints that prevent the continuous bedside presence of a healthcare provider. The device's portability also makes it suitable for decentralized health centers and it strategically supports remote consultation: data recorded by the device can be transmitted via mobile networks to designated referral facilities, enabling real-time support from more experienced clinicians even from a distance.

The **patient population** consists of pregnant women in active labor whose pregnancies are classified as low-risk according to current clinical standards. The device is not intended for use in high-risk pregnancies or in obstetric cases where complications necessitate the use of traditional, continuous cardiotocography.

The ideal workflow would be the folllowing:

1. **Setup and patient preparation:** Upon initiating the monitoring session, the midwife assists the laboring woman in wearing the device. The central unit is turned on, and worn around the neck via an ergonomic strap, ensuring the monitor is always visible to both the clinician and the mother. The dual-sensor system, the ultrasound Doppler transducer and the tocodynamometer, is positioned on the abdomen and secured with adjustable soft belts.
2. **Signal verification:** The device measures the fetal heart rate, displays its numerical value according to a colour code, where green indicates a normal physiological range (110–160 bpm), yellow signals a baseline below 110 bpm and red indicates tachycardia above 160 bpm. Altogether, it emits the audio records of the fht and it starts showing the upgrading number of contractions, measured each 10 minutes.
3. **FHR vs. MHR discrimination:** If doubts are present on the identity of the heart rate registered, the interface also allows the mother to place her thumbs on integrated sensors to measure her maternal heart rate (MHR), providing differentiation from the fetal signal when needed.
4. **Automated contraction monitoring:** Each detected contraction triggers a soft audio alert, and the system automatically updates the contraction count. If the frequency suggests uterine hyperstimulation, a high risk during induced labors, a high-priority alarm is triggered.
5. **Adaptive monitoring phases:** The device adapts its monitoring frequency based on the stage of labor selected by the operator:
    - Active Phase: Records FHR for 1 minute post-contraction every 10 minutes.
    - Second (Expulsive) Stage: Records FHR for 1 minute post-contraction every 5 minutes.

    If the midwife is managing multiple tasks and cannot observe the screen continuously, she can switch to Screen 2, that shows a one minute trend of the FHR recorded at fixed intervals (every 5 or 10 minutes depending on the labor phase). This trend begins from the onset of a contraction, which is marked by an asterisk, allowing for better clinical interpretation. If the situation observed is showing some characteristics transforming it in a higher risk pregnancy, the monitoring method and device has to be switched to a CA one.

6. **Alarm response and signal integrity:** In the event of a significant clinical deviation or a loss of signal (e.g., sensor displacement due to movement), the device emits a distinct, high-priority alarm. This mechanism ensures that no clinical decision is made based on poor-quality data or phantom signals, reducing operator-related errors.
7. **Post delivery maintenance:** Following the birth, the device and sensors are detached for disinfection according to hospital hygiene protocols. The unit is then connected to a power source to ensure the 12-hour battery life is fully restored for the next patient, maintaining operational readiness.

5.2 Technical differentiation: why our device is not a CTG

It is crucial to clarify that our proposed device does not fit into the CTG category. It is designed to optimize the quality of intermittent auscultation, not to replace it with a continuous trace.

- **Trace vs. numerical analysis:** While CTG offers a detailed real-time trace to evaluate heart rate variability, our device prioritizes clarity and objective counting. It correlates the end of a contraction and the FHR for exactly one minute, a critical window for identifying late decelerations without requiring the midwife to manually track time with a stopwatch.
- **Evidence based outcomes:** Continuous CTG has historically led to a significant increase in C-sections in low-risk cases, with the only major benefit being a slight reduction in neonatal seizures. Our device aims to occupy a strategic middle ground: providing a higher level of surveillance than the Pinard horn while avoiding the risks associated with complex CTG traces.

By alerting staff only when specific physiological limits are exceeded or when the FHR-contraction correlation suggests distress, it reduces the surveillance load. This allows the midwife to move away from the monitor and return to the bedside, establishing the essential one-to-one human interaction that is the gold standard for safe, physiological childbirth.

Feature	Conventional CTG (Cardiotocography)	Proposed Device
Primary goal	To identify potentially danger FHR – contractions trace	To optimize the quality of intermittent auscultation of FHR
Intended patients	Only to be used on high-risk pregnancies	Only to be used on low-risk pregnancies

Workflow	Provides a continuous, real-time trace of FHR together with the contraction frequency	Provides the value of the FHR and the number of contractions in the last 10 minutes
Analysis type	Detailed trace analysis and heart rate variability.	Numerical analysis: prioritizes clarity and objective counting.
Timing of monitoring	Continuous monitoring, often disconnected from specific event windows.	Correlates FHR with the end of a contraction for exactly one minute.
Movent	If classic model without wireless transducer, the mother has to lay in bed	The mother can move freely
Midwife Role	Often tied to monitoring the screen/trace.	Reduces surveillance load, promoting one-to-one human interaction at bedside.

Fig 41: Summarization of the main differences between classic CTG and our new device proposal

5.2.3 Stage III - Implement:

While the project has reached a solid conceptual and technical definition, the transition to the implementation phase is not immediate. Moving from documented specifications to a functional medical device requires a multi layered strategy that addresses industrial and regulatory compliance. Specifically, the design must undergo a design for manufacturing process to ensure that components, such as the doppler and tocodynamometer sensors, can be produced reliably and cost-effectively.

The possible implementation depends on securing the interest of diverse stakeholders, including manufacturing partners capable of adhering to medical-grade quality standards and healthcare institutions willing to facilitate clinical validation, such as Luisa Guidotti Hospital itself. This stage also involves a transition from laboratory prototypes to minimum viable products suitable for field testing in low-resource environments. Such real-world testing is essential to ensure that the device actually reduces the surveillance load for midwives without introducing new complexities into the labor room workflow.

6.Results

To refine the our device proposal and validate its clinical relevance, a structured questionnaire was developed and administered to a cohort of 18 healthcare professionals, including 17 Italian midwives and one Zimbabwean obstetrician. This survey sought to bridge the gap between technical design and the practical realities of labor wards, focusing on usability, workload management, and the preservation of the patient-provider relationship.

6.1 The human element and workload mitigation

The survey results unequivocally highlight that technology must not replace the physical presence of the midwife. When asked about the importance of performing intermittent auscultation (IA) in close physical proximity, participants assigned a score of 9.3/10. This confirms that labor monitoring is a deeply relational and supportive act; therefore, the device is designed to complement, not hinder, this presence.

However, a score of 8.5/10 regarding the helpfulness of a support device during "clinical overload" reveals a widespread demand for tools that mitigate the pressures of understaffed environments. Our device is perceived as a viable solution to provide reassurance (7.3/10) and reduce cognitive load (7.4/10) when continuous one-on-one presence is impossible. It functions as a "digital sentinel" that enhances safety without severing the human connection essential to physiological birth.

6.2 User interface and feature validation

The design of the dual-screen interface received high marks for its alignment with clinical logic:

Numerical Feedback (Screen 1): Rated 7.9/10, the real-time display of FHR and 10-minute contraction frequency is seen as an effective optimization of standard IA protocols.

Post-Contraction Trends (Screen 2): This feature, which visualizes a one-minute trend synchronized with a contraction (marked with an asterisk), received a score of 7.1/10. This slightly lower score suggests that graphical trend visualization is a novel workflow for midwives. While it requires dedicated training, clinicians recognize its potential for more objective decision-making.

Adaptive Monitoring: The inclusion of a "labor phase" button—automatically adjusting monitoring frequency between the active phase (every 10 min) and the second stage (every 5 min)—was highly valued (8.4/10), confirming that midwives appreciate devices that respect the dynamic nature of labor.

Interestingly, regarding sampling intervals, the majority of respondents preferred discrete data points (>10 seconds) over continuous lines.

This confirms a design success: Our device provides enough data to be safe, but avoids the granular "tracing" characteristic of continuous monitoring (CTG), thus preserving the spirit of intermittent auscultation.

6.3 Comparative value and stakeholder insights

Compared to the original Moyo, the addition of uterine contraction monitoring was viewed as a major advancement (8.1/10). This confirms that adding uterine activity to a portable, wearable format is perceived as a meaningful improvement.

Regarding Alarms, the feedback reinforced our planned strategy. Clinicians prioritized alerts for FHR abnormalities (14 votes), incorrect probe positioning (8 votes) and FHR/MHR overlap (1 vote). Notably, 0 votes were given to "start of contraction" alarms, reinforcing the goal of avoiding "alarm fatigue" and unnecessary distractions. Midwives also suggested future iterations could include fetal movements (9 votes) and contraction intensity (7 votes).

6.4 Risks, limitations, and ethical considerations

While the strongest perceived benefit is operational efficiency (9 votes), clinicians raised valid concerns regarding over-reliance (9 votes) and the potential for data misinterpretation (6 votes).

A score of 6.6/10 on whether the device helps monitor patients "more effectively" reflects healthy professional skepticism. There is a fear that technology might inadvertently encourage clinicians to distance themselves from the bedside. This risk must be addressed through protocol integration and clear training that emphasizes the device as a support tool, not a substitute for clinical judgment.

6.5 Conclusion: a context-specific solution

The personal interest in using the device scored 6.5/10. While not overwhelmingly high for high-resource settings where CTG is the standard, this figure accurately reflects the intended niche of our device: the specific "structural demise" identified in regions like Zimbabwe.

By integrating the feedback from both Italian and Zimbabwean professionals, we have confirmed that our device addresses a tangible, unmet need. It provides a pathway to standardize intrapartum care and improve early identification of fetal distress while maintaining the autonomy of the midwife. The next phase of development will focus on integrating these insights into a functional prototype, moving one step closer to a safer reality for maternal health in low-resource settings.

7.Conclusions

The work presented in this thesis was built upon two complementary pillars: the practical implementation of a Health Technology Management system and the launch of a context-sensitive design process for our device. While these initiatives are in their early stages, they provide a robust foundation for a technologically appropriate healthcare model at Luisa Guidotti Hospital.

The first objective achieved was the creation of a comprehensive inventory, together with the initial transition to a structured maintenance plan. However, a deeper reflection emerges in low-resource settings, as the act of maintaining is more innovative than the act of inventing. While the focus is often on donating new equipment, sustainability is found in the maintenance routine. Without the HTM backbone, even the most advanced device can become technological waste within months. The inconsistency in participation observed after the initial implementation phase confirms that an HTM system is not just a technical tool, but a cultural shift. Real success lies in the recognition by local stakeholders that having functional technology resources is a proactive, daily responsibility, and to strengthen the healthcare structure they have to move from a culture of disposable technology to one of ownership.

Commentato [CG4]: ??

The second pillar was the design specification of our device. By immersing ourselves in the labor ward, we moved with the goal to provide the most fitting solution, one that empowers the midwife's decision-making rather than replacing it. A critical clinical reflection emerged: if our device were used as a substitute for clinical vigilance, it could replicate the criticality of the CTG, such as unjustified increases in cesarean sections. This highlights that appropriate technology must be context-sensitive not only in its hardware but in its clinical philosophy. The device must remain a tool that supports intermittent auscultation, preserving the physiological nature of birth while providing the objective data necessary to act in high-pressure environments.

This project has demonstrated that biomedical engineer acts as a bridge between clinical practice, technological logic, and systemic organization. However, the month spent at Luisa Guidotti revealed that technical validation is insufficient without cultural validation. Academic knowledge from high-resource settings, like the one we gained through the internship at Sant'Orsola, must be re-calibrated in the local reality. The success of a device or a management flowchart is determined by how it fits into the existing social and clinical situation, and the engineer's role is therefore to be a helper in this transition. Furthermore, this work highlights the potential for reverse innovation: a device like our, born within the characteristics of Zimbabwe, could provide high-resource hospitals with a pathway to return to a less invasive, less medicalized approach to obstetrics.

The essence of this work lies in the realization that biomedical engineering, in fragile contexts, is not a luxury but a fundamental necessity for global health equity. The impact

of an HTM system and appropriate design has effects across multiple levels, impacting both the structure and the personnel. From a clinical and organizational perspective, the transition from reactive maintenance to strategic planning allows the hospital to move beyond a state of perpetual emergency, transforming data into decision making occasions for local management. However, a device is only truly appropriate when the staff does not feel replaced by the machine, but rather empowered by it, complementing its work with the implemented tool and not perceiving it as a rigid imposition or an alienating protocol.

In conclusion, this experience demonstrates that the success of any technological innovation is ultimately determined by the people who use it and the technicians who safeguard it, and that technology is a powerful enabler, but it depends entirely on its ability to integrate into the specific social and clinical fabric. Through context-driven innovation and a participatory approach, it is possible to contribute to closing the gap in global health. The start of the biodesign process for our new device and the implementation of the HTM system at Luisa Guidotti Hospital are concrete steps toward a quality of care no longer defined by zip codes.

Bibliography

1. Medical equipment maintenance programme overview. World Health Organization; 2025 (WHO medical device technical series).
2. Development of medical device policies, second edition. Geneva: World Health Organization; 2025 (WHO medical device technical series). Licence: CC BY-NC-SA 3.0 IGO.
3. Introduction to medical equipment inventory management. World Health Organization; 2025 (WHO medical device technical series).
4. Data Computerized maintenance management system. World Health Organization; 2025 (WHO medical device technical series).
5. Procedura aziendale gestione del ciclo di vita delle attrezzature e degli altri beni mobili, PA11 Rev 7, https://www.aosp.bo.it/it/content/documentazione-e-modulistica
6. Zimbabwe National Statistic Agency Home - ZIMSTAT
7. Encyclopædia Britannica Zimbabwe | History, Map, Flag, Population, Capital, Pronunciation & Facts | Britannica
8. World Bank. 2022. Zimbabwe Health Sector Public Expenditure Review 2022. © World BankWHO Zimbabwe Annual Report 2022, WHO Zimbabwe Annual Report 2022 .pdf
9. Fondazione Marilena Pesaresi, https://fondazionemarilenapesaresi.org/
10. WHO: Health Budget Brief Zimbabwe (2024).
11. World Bank Data: Trends in Under-5 Mortality.
12. The WHO application of ICD-10 to deaths during pregnancy, childbirth and puerperium: ICD MM.
13. S. D. D. Lewis. Figo consensus guidelines on intrapartum fetal monitoring: Intermittent auscultation. International Journal of Gynecology and Obstetrics, 131:9–12, 2015.
14. Laerdal, Moyo - Fetal Heart Rate Monitor | Laerdal Global Health
15. Kamala B, Kidanto H, Dalen I, Ngarina M, Abeid M, Perlman J, Ersdal H. Effectiveness of a Novel Continuous Doppler (Moyo) Versus Intermittent Doppler in Intrapartum Detection of Abnormal Foetal Heart Rate: A Randomised Controlled Study in Tanzania. Int J Environ Res Public Health. 2019 Jan 24;16(3):315. doi: 10.3390/ijerph16030315. PMID: 30678354; PMCID: PMC6388236.
16. Ubom AE, Barnea ER, DiSimone N, et al. FIGO good practice recommendations: Assisted vaginal birth and the second stage of labor. Int J Gynecol Obstet. 2025;171:970-982. doi:10.1002/ijgo.70528

17. Barnea ER, Ramasauskaite D, Ubom AE, et al. FIGO good practice recommendations for vaginal birth after cesarean section. Int J Gynecol Obstet. 2025;171:17-31. doi:10.1002/ijgo.70406
18. Mhazo and Maponga International Journal for Equity in Health (2022) 21:42 https://doi.org/10.1186/s12939-022-01646-z
19. James N, Acharya Y (2021) Integrated management of neonatal and childhood illness strategy in Zimbabwe: An evaluation. PLOS Global Public Health 1(11): e0000046. https://doi.org/10.1371/journal.pgph.0000046
20. Mdoe P, Yeconia A, Buu F, Kusulla S, Blacy L, Guga G, Mduma E, Kidanto H. Midwives' and Women's Perception on Moyo Fetal Heart Rate Monitor for Intrapartum Fetal Heart Rate Monitoring; A Cross-Sectional Study. Med Devices (Auckl). 2020 Mar 18;13:87-92. doi: 10.2147/MDER.S241741. PMID: 32256129; PMCID: PMC7092687.
21. Kamala BA, Kidanto HL, Wangwe PJ, Dalen I, Mduma ER, Perlman JM, Ersdal HL. Intrapartum fetal heart rate monitoring using a handheld Doppler versus Pinard stethoscope: a randomized controlled study in Dar es Salaam. Int J Womens Health. 2018 Jul 9;10:341-348. doi: 10.2147/IJWH.S160675. PMID: 30022861; PMCID: PMC6042559.
22. Merriel, A.;Bobb T. Murove, B. T.;Samuel W.D. Merriel, S. W. D.;Thabani Sibanda, T.;Sikangezile Moyo, S.;and Joanna Crofts, J.. 2016. Implementation of a Modified Obstetric Early Warning System to Improve the Quality of Obstetric Care in Zimbabwe. International Journal of Gynecology & Obstetrics 2016, 136 (2), 175–179. https://doi.org/10.1002/ijgo.12028.ZDHS (2023/2024): Preliminary reports on Neonatal and Maternal Mortality. 136, 2 (November 2016), 175–179.
23. Scientific Research Publishing (Kadenge et al.): Evolution of PHC in post-independence Zimbabwe. Muti et al. BMC Cardiovascular Disorders (2015) 15:111DOI 10.1186/s12872-015-0110-5
24. Zimbabwe Society of Obstetrician and Gynaecologists (ZSOG) (2022).Zimbabwe Society of Obstetrician and Gynaecologists Strategic Plan (2022-2025).
25. Alfirevic, Z., Devane, D., & Gyte, G. M. (2017). Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database of Systematic Reviews.
26. B. F. K. S. B. L. G. G. e. a. Mdoe P, Yeconia A. Midwives' and women's perception on moyo fetal heart rate monitor for intrapartum fetal heart rate monitoring; a cross-sectional study. Volume 13:87–92, 2020.
27. D. I. N. M. A. M. P. J. E. H. Kamala B, Kidanto H. Effectiveness of a novel continuous doppler (moyo) versus intermittent doppler in intrapartum detection of abnormal foetal heart rate: A randomised controlled study in tanzania. Int J Environ Res Public Health., 2019.

Acknowledgments

Un proverbio che mi è stato citato spesso recita “Chi semina datteri non mangia datteri”. Questi anni di magistrale sono stati davvero una grossa semina, a tratti fatta al buio. Ho passato periodi molto duri in cui mi chiedevo il senso della fatica che stavo facendo e degli scarsi risultati che mi sembrava di ottenere, e se non avessi fatto una scelta ben al di sopra delle mie capacità.
Non mi ero resa conto, forse, di tutta la ricchezza umana e accademica che stavo assorbendo in una strada per me così tanto in salita, e di tutto il bene che le persone intorno a me mi hanno voluto. Qualcuno mi ha sempre accompagnata, o tirata, incoraggiata, spinta per un tratto di strada, che non ho mai dovuto fare da sola.
Vorrei ringraziare innanzitutto i miei genitori, che sono un esempio di vita e di tenacia straordinario, e per cui non sarò mai abbastanza riconoscente. Grazie per avermi sostenuta in questi anni di studio, grazie perché se ho finito questo percorso è anche merito vostro. Ringrazio il professor Severi per il suo esempio nel trasformare una realtà tecnica come l’ingegneria in un mondo di relazioni e di scopi che servono la persona e non la superano. Insieme a Caterina, Francesco e Massimo vorrei ringraziarlo per aver creato questo progetto e per come lo stanno portando avanti nelle sue molte incognite.
Vorrei ringraziare Elena per avermi tirata in mezzo a quest’avventura, per aver fatto nascere un’amicizia scompaginata e che sa di bene e per non avermi buttata in mezzo ai ragni africani quando non riusciva più a sopportarmi. Ringrazio tutte le persone con cui ho vissuto a Mutoko per avermi fatto fare esperienza della bellezza che c’è nel poco; Massimo per aver riacceso la speranza di un bene che c’è anche dove non lo aspetti.
Vorrei ringraziare tutti i miei compagni di corso con cui ho condiviso difficoltà, momenti di studio folli e scambi di appunti, perché è bello andare avanti insieme.
Ringrazio Alicja perché è la coinquilina migliore che uno possa trovare, perché le voglio molto bene e a volte mi manca molto mentre preparo la cena. Grazie a Veronica, che c’è dal primo giorno e che mi conosce meglio delle mie tasche, e quando mi lamento troppo mi fa tornare alla realtà. Grazie al gruppo dei Bea Fioi per avermi adottata e custodita, e a tutti gli amici di Correggio per avermi accompagnata sempre, anche quando ero distante.
Filippo, vorrei ringraziarti. Sei il laureato ad honorem oggi, perché molti dei miei esami li ho sudati con te. Grazie per avermi fatto credere nelle mie capacità, per la tua testardaggine e il tuo volermi bene. Sono davvero contenta di costruire una casa insieme a te.
Grazie davvero a tutti voi, e grazie al Signore, perché spesso mi ricorda che forse sono concentrata sui semi sbagliati, e mi indica quali portano ai frutti davvero importanti.