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The embodiment of low-field MRI for the diagnosis of infant hydrocephalus in Uganda

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Abstract— Compared to other parts of the world, the incidence of hydrocephalus in children is very high in sub-Saharan Africa. Magnetic resonance imaging (MRI) would be the preferred diagnostic method for infant hydrocephaleus. However, in practice, MRI is seldom used in sub-Saharan Africa due to its high prize, low mobility, and high power consumption. A low-cost MRI technology is under development by reducing the strength of the magnetic field and the use of alternative technologies to create the magnetic field. This paper describes the embodiment design process to match this new MRI technology under development with the specific characteristics of the healthcare system in Uganda.

A context exploration was performed to identify factors that may affect the design and implementation of the low-field MRI in Ugandan hospitals and Ugandan healthcare environment. The key-insights from the technology- and context-exploration were translated into requirements which were the starting point for the design process. The concept development did have a focus on Cost-effective design, Design for durability & reliability, and Design for repairability. The final design was validated by stakeholders from the Ugandan Healthcare context.

Keywords— MRI, Uganda, infant hydrocephalus, health diagnostics, design for healthcare, low-resource settings, human-centred design.

I. INTRODUCTION

A. Hydrocephalus in Uganda

Hydrocephalus is a pediatric, neurological disease, where cerebrospinal fluid accumulates in the brain [1]. This accumulation causes pressure and consequently results in symptoms like immense headaches and the pupils of the eyes going downwards, also known as sunsetting. In the case of newborns, the head expands since they only have the soft fontanelles connecting the bones in their skull. The head of an infant with hydrocephalus can grow up to unusually massive proportions. If not treated with care, the disease can have lethal consequences [2].

Compared to other parts of the world, the incidence of hydrocephalus in children is very high in sub-Saharan Africa (SSA) [3]. Nutrition deficiency, low weight at birth and delay in diagnosis are all explanations of this higher incidence [4]. It is estimated that there are in between 45.000 to 200.000 new cases per year under infants in SSA, of which an estimated 1000 to 2000 in Uganda [5].

Every treatment for hydrocephalus includes infiltration of the fragile infant's skull. Therefore, choosing the right treatment relies on good information surrounding the diagnosis and the anatomy of the patient's brain. Different imaging modalities (i.e. CT, ultrasound or MRI) can be used to assess the severity and the nature of the condition and to assess treatment options [8]. One commonly used technique for a diagnosis in low-income countries is CT. The high energy radiation used for CT scans causes higher risk to cancer in later stages of life, especially when used for young children [6]. It is therefore suggested to limit the use of CT for infants. Using MRI does not have negative influences on the patient's health and provides sharper tissue contrast in the brain, potentially revealing more information on the structure of the brain. In practice, MRI is seldom used in SSA for diagnosing hydrocephalus because of its low availability.

Even with proper and accessible diagnostic tools, treatment is challenging. East-Africa counts 27 neurosurgeons for a population of 270 million. Uganda, on a population of about 41 million, has 6 [8][7].

B. MRI Scan pro's and cons

In most cases, magnetic resonance imaging (MRI), as highlighted above, would be the preferred diagnostic method for infant hydrocephaleus. With MRI, body parts can be studied in great detail utilizing electromagnetic fields [2]. The basic components in an MRI system that allow for the detection and location of MR signals are (See Fig. 1) [8]:

- 1) The magnet
- 2) The gradient coils
- 3) The radiofrequency transceiver

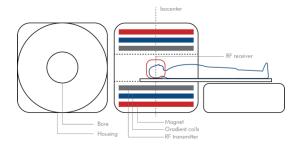


Fig. 1. A simple representation of a regular high-field MRI one can find in western hospitals [8].

A common MRI machine in an average Western hospital used for diagnosis uses magnetic fields up to 3T and images can reach spatial resolutions of several micrometers. This makes MRI a very powerful technique, but several reasons make it not suitable for low-income countries. First of all, the high price of an MRI. An MRI machine costs roughly 1 million Euro's per achieved Tesla [9, 10]. Secondly, MRI machines have a low mobility. There is a great variety of hardware that needs the help of professionals to install, and the MRI system and the surrounding hardware consumes a lot of space and weight. The third disadvantage is the high power consumption. The cooling system, gradient amplification and the RF transmitters all use a lot of power. The total power used in an operating MRI system can go up to 100 kW [9]. All together, these disadvantages would make current MRI systems hard to implement in low-income countries.

C. LUMC-TU Delft project

Drastically lowering the costs and technical complexity of MRI would increase the availability of MRI in low-income countries like Uganda [2]. To develop such a low-cost MRI, a consortium was initiated of Penn State University (USA), Mbarara University of Science and Technology (Uganda), CURE Children's Hospital (Uganda), Delft University of Technology (Netherlands) and Leiden University Medical Center (Netherlands). The primary strategy to lower costs is to reduce the strength of the magnetic field and the use of alternative technologies to create the magnetic field than the expensive superconducting coil. The proposed alternative is a novel approach in which permanent magnets in Halbach arrays are used to create the magnetic field [2, 11] (See Fig. 2). This also opens doors to make an MRI machine that is portable and easy to install on-site. A lower magnetic field would also yield lower resolution images [8]. This can be tolerated since for infant hydrocephalus, a relatively low image resolution can still be sufficient to provide a reliable diagnosis and treatment planning.

The proposed set up by the consortium can be used to work towards the creation of 3D pediatric brain images with an affordable, portable MRI system that will not exceed the costs of 50,000 US dollars.



Fig. 2. The (permanent) magnet in Halbach arrays in which the patients are inserted [11].

For a successful implementation, it is crucial that this technology is integrated in an MRI product system that adequately addresses the challenges within the context of sub-Saharan Africa and is equipped with all necessary functionalities to diagnose infants with hydrocephalus [8]. Based on our previous experiences with developing medical devices for low-resource settings [12, 13], we initiated the design trajectory of this MRI project.

II. DESIGN SETUP

The design process consisted of three phases: (1) Explore, (2) Define, and (3) Design. During the Explore phase, the future use-context and the technical specifications were analyzed and key take-ways for each were generated. The 'Define' phase aimed to gather all the insights from the 'Explore' phase, to combine them, and assess their impact on the design in the form of design requirements. In the 'Design' phase, based on these design requirements ideas were generated to conceptualize the system, and embody (parts of) it. All these stages were in close collaboration with the technical R&D teams and stakeholders in the Ugandan healthcare system.

III. EXPLORATION

A context exploration was performed to identify factors that may affect the design and implementation of the low-field MRI in Ugandan hospitals and Ugandan healthcare environment. Several public and private hospitals in Uganda were visited, and interviews with a broad mix of hospital staff were conducted. Moreover, observations were taken, and whenever necessary, documented in writing and photos [8]. Literature research was executed to support the field research. The context insights and key takeaways were divided into a) Ugandan Healthcare System, b) Ugandan Hospital Setting, and c) the Diagnostic Imaging Process. The main insights and take-aways are reported in the next sections

A. Uganda

For a lot of medical equipment, increasing accessibility to Low and Middle-Income Countries (LMICs) starts by reducing costs. However, high equipment cost is not the only challenge to overcome. The lack of health personnel and proper training, inconsistent power supplies, unavailability of spare parts and high cost of operation (maintenance and consumables) all hinder the implementation and operation of advanced medical equipment [8][14].

Lack of health personnel - Understaffing is a crucial problem in many Ugandan hospitals. Only six out of the fourteen regional referral hospitals have one or two radiologists, and in total, Uganda counts 7 radiologists and 42 radiographers [8].

Maintenance and repairs - As replacement costs are high, equipment faces high workloads and generally the equipment's lifetime is extended beyond manufacturers recommendations for as long as possible. However: the older the equipment, the harder it is to find spare parts as OEMs discontinue their production. Additionally, in some cases, OEMs do not deliver appropriate manuals and tools to perform repairs. If they do (in newer equipment), cost is still an issue [8].

Installation - Often, expert personnel is needed to install hi-tech equipment. The scarcity of highly skilled personnel to install such equipment causes high costs — often a substantial margin of the product's purchasing price. The costs can rise to 25.000 euros for the installation of a CT scanner, as special personnel needs to be found and accommodated [8].

In total 13 key take-aways were derived from the context analysis of the Ugandan healthcare system.

B. Hospital

At hospital level, the following insights were made:

Poor pathways and road infrastructure hinders installation and movement of equipment. Forklifts and cranes are not easily available. As pathways between hospital buildings are generally of poor quality – usually unpaved, muddy, and with ramps – even light equipment movement is often discouraged [8].

Lack of space - Space in hospitals is crucial. Equipment such as a CT scanner that takes up a lot of surface area, needs a separate and shielded room, a dedicated control room and another dedicated equipment room. When possible, rooms have multiple purposes, although classifications are made (e.g. imaging room) [8].

Pests - Often, pests find their way into hospital buildings through open doors and windows. Sensitive equipment can be damaged when pests interfere with electronics. One case shows the severity of this challenge: rats chewed through the wiring and defecated over the electronics of the CT scanner, rendering it inoperable [8].

Heat and humidity - A hot and humid environment is common in hospital wards, consulting rooms, and some

imaging rooms that are not equipped with air-conditioning. Heat and humidity can cause electronics to overheat and damage equipment [8].

Power supply - Hospitals have to deal with an inconsistent power supply. Challenges with power supply of imaging equipment can cause uncertainties whether it will be operable. Power surges and drops can all cause damage to equipment and make a back-up power supply with stabilizer crucial to protect equipment and continue operations during blackouts.

In total 10 key take-aways were derived from the context analysis of the Ugandan hospitals.

C. The diagnostic imaging process

The diagnostic imaging process can be split into three parts: pre-imaging, imaging, and post-imaging. Challenges which can occur and should be taken into account in the design are:

Nervous patients or parents - Patients (adults and children) or parents are sometimes afraid of medical machines or the procedures involved. Claustrophobia frequently occurs in adult patients during MRI scanning. During the scanning of their child, parents may become anxious and panicky [8].

Immobile patients - Immobile patients sometimes cause challenges when they need to be moved to the scanner. The patient's dependency on life support equipment often hinders their mobility [8].

Parents help with preparations - During preparations, parents of children that are being scanned often help out with preparatory works [8].

Lying still - Lying still is a challenge for most children. Even when anaesthesia is used, the child may need to be strapped down because they can have spasms [8].

In total, 10 key take-aways were derived from the analysis of the diagnostic imaging process.

IV. SYNTHESIS

In the synthesis phase, all insights from the Explore phase were translated into design requirements. Subsequently, a selection of focus areas was formulated to be considered during the design phase.

A. Key Context-Related Requirements

The key (context) challenges were translated into design requirements (see Table 1), and were added to the technical and functional requirements to complete the programme of requirements.

TABLE I. KEY CHALLENGES TRANSLATED INTO DESIGN REQUIREMENTS [8]

| Key challenge | Design requirement |
|--------------------------------------|------------------------------------|
| -Installation personnel is expensive | The product should enable easy |
| and scarce | and low-cost installation |
| -Pathways are unpaved and poor | The product should be |
| -Equipment is moved over uneven, | transportable and installable over |
| muddy, unpaved pathways | rough pathways and uneven |

| -Cranes or forklifts are not readily | surfaces without the need for |
|---|--|
| available | forklifts or cranes |
| -Space in the hospital is scarce | The product should occupy as little |
| | space as possible |
| | The product should not require |
| | placement in a separate, dedicated |
| | room |
| -The grid power supply is unstable, | The product should be able to deal |
| deeming a back-up power supply | with an inconsistent power supply |
| necessary | adequately |
| -Pests are present in all hospital | The product should prevent pests |
| environments | from damaging sensitive |
| | equipment as well as reasonably |
| Heat and humidity are a problem | possible The product should provide active |
| -Heat and humidity are a problem in rooms that are not air- | cooling for patients inside of the |
| conditioned | bore The product should enable |
| -Imaging and equipment rooms are | adequate cooling for electronics by |
| mostly, but not always, equipped | their built-in cooling fans |
| with air-conditioning | their bunt in cooling rans |
| -Dust can accumulate in hospital | The product should be resistive to |
| rooms | dust and mud |
| -Gravel and mud could accumulate | The product should be able to |
| in rooms | prevent dust from entering |
| | electronics compartments |
| -Parents help prepare patients in | The product should allow a relative |
| the imaging room | to remain in contact with the |
| -Parents may enter the scanner with | patient during the imaging |
| the child, or remain present in the | procedure |
| room | The product should prevent |
| | bystanders from being exposed to |
| | harmful levels of magnetic field |
| | strength as well as reasonably |
| D.C. (11, 131 | possible |
| -Patients, especially children, | The product should prevent the |
| frequently move during scanning | patient from moving during the |
| -Patients are often strapped to keep them from moving | entire imaging sequence |
| I them from moving | I |

B. Design Principles and table of requirements

Three design principles were defined based on the context research, which are crucial for all components as well as the integrated design of the MRI. These design principles are [8]:

Cost-effective design - It was found that in this context, cost-effectiveness of solutions is particularly desired. This impacts chosen production methods and subsequent optimization for cost-effective production of all parts.

Design for durability and reliability - The relatively harsh and uncontrolled environment increases the stresses that any product is exposed to. It is essential that any product in this context is designed to be durable and reliable. Products in this context should prevent the use of maintenance-sensitive components or many moving parts sensitive to wear.

Design for repairability -The scarcity of spare parts and maintenance personnel renders broken products useless more often and longer than necessary. Products in this context benefit from using standardized parts and enabling easy access to wear-sensitive components, enabling easier repair.

C. Main requirements

This resulted in the following main requirements:

TABLE II. MAIN REQUIREMENTS [8]

| ID | Requirement | |
|---|---|--|
| | Main product-side requirements – The product should: | |
| P1 | enable an ergonomic operation that reduces (physical) strain on the | |
| | operator | |
| P2 | enable a patient to be inserted and removed safely | |
| P3 | enable easy and low-cost installation | |
| P4 be transportable and installable over rough pathways and une | | |
| | surfaces without the need for forklifts or cranes | |
| P5 | occupy as little space as possible | |
| P6 | not require placement in a separate, dedicated room | |
| P7 | allow bystanders to remain close to the patient | |
| P8 | provide active cooling for patients inside of the bore | |
| P9 | prevent the patient from moving during the entire imaging sequence | |
| | Main context-side requirements – The product should: | |
| C1 | enable adequate cooling for electronics by their built-in cooling | |
| | equipment | |
| C2 | prevent pests from damaging sensitive equipment | |
| C3 | be able to deal with inconsistent power supple adequately | |
| C4 | be resistive to dust and mud | |
| | Main technological requirements | |
| T1 | no ferromagnetic materials may be used within 100 mm distance | |
| | from the magnet's bore openings | |
| T2 | no ferromagnetic materials may be used within 50 mm surrounding | |
| | the magnet's sides | |
| T3 | no metal (ferro or non-ferro) objects may be used within 40 mm | |
| | surrounding the radiofrequency transceiver coil | |
| T4 | the RF coil should be concentric with the magnet's bore | |

V. Design

A. Initial Design Exploration

As an initial design exploration, two principal design solutions have been developed during the field research. By taking identified challenges in the early stage and translating them to initial designs, these designs could then be tested within the field early on and function as a stepping stone towards the actual development phase. The designs yielded several crucial factors to consider.

The principal solutions were assessed on (1) the ease with which installation can be done, (2) the fit with the hospital environment, and (3) the ease with which it can be operated by hospital staff [8].

- (1) Installation Integrated electronics and equipment are desired, ensuring proper placement and preventing misuse, ensuring operability of the system at all times, and reducing the time and effort required to install. Freedom to place technological equipment anywhere should be avoided, as misplacement and misuse may cause malfunctioning. The same goes for laptops or desktops. A wholly integrated design may, however be difficult to transport.
- **(2) Fit with hospital environment -** Space is crucial in hospital environments. Enabling flexible placement and a small surface area will make the system better implementable in a broad range of hospitals. A fully integrated system reduces the need for separate equipment rooms.
- (3) Ease of operation A standing operation is undesired as workloads are high and personnel should not stand an entire day. However, the patients infants are often carried and brought in by parents. Unless everything is within hands' reach, the operator will stand and walk around the machine to prepare it for scanning. The design should, therefore, facilitate an

ergonomic upright position of the operator while preparing the patient, and a sitting position while performing the scanning.



Fig. 3. The two initial designs. The different interpretations enable testing on several diverse design considerations.

B. Conceptual Design

Main design challenges that were addressed in the conceptual design phase were:

- (1) Patient, bystander, and operator safety
- (2) Operator position
- (3) Magnet construction and transportation
- (4) Bed and RF coil system

Bystander and operator safety - WHO advises a continuous magnetic field exposure limit of 40 millitesla [15]. "Also, care should be taken to prevent hazards from metal objects being suddenly attracted to magnets in field exceeds 3 mT." [16]. The magnetic field strength of the current magnet decreases rapidly with distance: at 50 mm, the strength has been reduced to around 1% of its maximum, though at the system's openings, this level of reduction occurs at about 100 mm. That means having a shield with margins of 100 mm (front and rear) and 50 mm (sides) around the perimeter of the magnet should prevent bystanders as well as operators from coming too close, effectively preventing them from being exposed to magnetic field strengths higher than 0.6 mT (= 1% of 60 mT) [8].

Patient safety and operator position - Monitoring the patient during imaging is crucial to detect any occurring emergencies. The operator needs to be in a position where he or she can directly see the patient. Moreover, a standing, as well as sitting position, needs to be facilitated by the dimensions and orientation of the system's components. Exploration of ergonomic data yielded an ideal height for the system's bore where it should allow all people to comfortably stay in visual contact with the patient based on eye height while sitting (See Fig. 4). By considering obstructions and other components that the operator interacts with – such as the computer screen - an optimal position for the operator to sit was found (See Fig 5). The operator can comfortably view the patient while being in an ergonomic position to operate the computer for scanning.

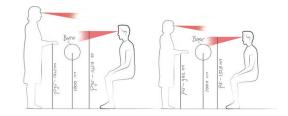


Fig. 4. Ideal ergonomic height for the system's bore



Fig. 5. Optimal position for the operator to sit

Magnet construction and transportation - To enable carrying, a substructure is needed that can handle the load. Since ferromagnetic materials are not allowed, this is built from 40x40 aluminium extrusion profiles all around, and two placed underneath the magnet. Subsequently, an aluminium handlebar is attached to facilitate lifting by at least four persons to distribute the load of the 100 kg magnet [8].

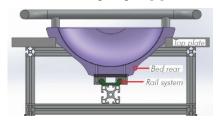


Fig. 6. Positioning of bed and rail system

Bed and RF coil system – In the bed system, space needs to be maximized to fit infants with hydrocephalus. Moreover, moving parts should be reduced to reduce maintenance dependency, and ferro and non-ferro materials are prohibited due to technological constraints in relation to the magnetic field. This poses a challenge on usable production techniques in relation to cost-effectiveness and durable design. A combination of simple 3D-printed parts was chosen, that can be printed on any standard 3D-printer. Parts are attached to a dustresistant sliding rail. Rather than just being fixated on the rail's carriages, which may cause breakage of the 3D-printed parts, the load is countered on three points by suspending the parts on the system's top plate (See Fig. 6). The bed is a semi-circular design that follows the diameter of the bore. This is the most space-saving design. Special care was taken in decreasing material thickness as a way to save space and simultaneously material cost.

VI. FINAL DESIGN

A. Main features

The system is comprised of five main components: (1) Magnet assembly, (2) Bed assembly, (3) electronics frame, (4)

electronics casings, and (5) monitor and mount. For final dimensions, see Fig 7.

These components are separable from one another, reducing the maximum liftable weight to only 100 kg and so enabling easy installation and transport over rough pathways. Moreover, thanks to its low static magnetic field and total weight, no special infrastructure such as a shielded room or fortified flooring is required for its placement. Its relatively small size for an MRI is another advantage that enables flexible placement and reduces expensive infrastructure requirements [8].



Fig. 7. Dimensions of final design.

The magnet, is enclosed in an aluminium shell (1 mm) to shield the system from outside (electromagnetic) noise. It equips active cooling for patients in case air conditioning is not present. A light-weight bed assembly functions to slide the patient in and out of the bore, and therefore it is the only component with a moving part. The only moving part in the system is a dust-resistant aluminum sliding rail system. The space below the bed is utilized to serve as storage for any necessary imaging equipment, such as RF coils, pillows, and blankets. The electronics frame weighs around 30 kg. Inside, two 19 inch rack cases (each 8U high) are installed for mounting of the amplifiers, data acquisition unit, computer, and uninterruptible power supply. The electronics come premounted in the casings for protection during transport. The frame has ventilation mesh on both sides to allow ample airflow to cool the electronics in case the system is placed in a room that is not air-conditioned – something that frequently occurs in Ugandan hospitals. The mesh prevents pests and bugs from entering. The touch screen monitor is the interface to the operator. It is placed on an adjustable mount so that anyone can work ergonomically with it.

B. Installation

The design is comprised of five separable components which include handles to facilitate lifting. For example, the magnet with an expected weight of 100 Kg can be carried by four persons by the integrated handles (See Fig 8.).

Sensitive electronics are easily and safely transported inside the separate 19-inch cases. Simply placing them in the electronics frame and connecting them appropriately enables a plug and play way of installing. Subsequently, the magnet can be placed on top of the electronics. The three cables that connect to the magnet's gradient coils can then be connected. The bed can be easily aligned with the magnet's bore and then attached rigidly to the magnet sub-assembly. Now also the monitor can be mounted in the desired location on the magnet's handlebar, and the system is ready to go [8] (see Fig. 9).



Fig. 8. The magnet, despite its weight (100 kg), can still be lifted by 4 persons.



Fig. 9. Plug and play installation of the MRI Scanner.

C. Operation

The system's operator can comfortably reach and prepare the patient while standing. The operator will often run around the room or in between rooms to gather the necessary equipment while preparing the patient. To reduce strain during the preparation of the patient, a comfortable height of the bed is chosen so that the operator can comfortably reach the patient. While scanning the operator has the possibility to ergonomically operate the system while sitting down. As the scanning process can last up to fifteen minutes and there are often multiple procedures per day, standing may tire the operator. While sitting, this design ensures that the patient is still visible, increasing safety. However, the operator is discouraged from interacting with the patient while sitting as he can hardly reach the patient comfortably [8].

The bed- and coil-system: Since the sliding mechanism cannot enter the bore (because aluminium would cause interference with the signal, and its size alone would reduce the already limited space inside the bore), the coil and bed are both suspended on sidewalls (f. Aligning the coil concentrically with the bed allows the bed to push the coil along into the bore, without losing the rigidity and stability of the sliding rail system. This system hereby allows changing the coil without having to attach it to a rail (adding parts that can wear out easily), or without losing crucial space in the bore (which occurs in the case of placing the coil simply on the bed

- something that's done in current MRI systems). By taking the coils outside of the magnet, it is more easily interchangeable, and it enables the operator to slide it gently and controlled over the patient's head, preventing it from colliding with the patient's head. The coil still needs to be pulled out together with the bed, so a single attachment must be made. This is done by a strap that connects the coil's headrest and the bed. Straps subsequently attach the coil's headrest to the coil itself. These straps cannot be removed, the coil and the headrest are inseparable components, simply because the one cannot function without the other. Headrests are also coil-specific: they do not fit other coil sizes [8].



Fig. 10. The bed height is comfortable for handling the patient while standing and allows the operator to see still and visually monitor the patient while.



Fig. 11. The suspended coil in front view. The black part is the headrest, the red part is the top plate of the bed, green is the sliding rails. The coil is only suspended on the top plate and not attached to the rails (left). Patient positioning (right) [8].

Patient movement A velcro strap around the patient's head will prevent the patient from moving during scanning. Movement can often cause issues with the MR image, and being able to fixate the head will increase chances that the image is successful without needing anesthetic. Straps are currently used for this purpose in many imaging procedures in Ugandan hospitals.

Patient positioning To help the operator position the patient, the headrest has a visual indicator as to where the center of the patient's head should be placed. Moreover, the bed's sliding rails have only one position: whenever the bed is slid all the way in, the coil is placed at the magnet's isocenter

VII. EVALUATION

The design was tested in two ways: By a physical prototype and by interviews with medical staff of the CURE Children's Hospital in Uganda and a Biomedical Engineer of Mbarara University of Science and Technology (MUST).

A. Prototype

A 1:1 prototype (See Fig. 11) of the bed assembly was made in order to test the design on the following aspects: 1) use and interaction and 2) structural. The prototype was not tested by the intended user-group nor by using live patients. Instead, due to COVID-19 restrictions, it was tested by the author by using a life-size doll (doll with anthropometric dimensions of a 3-month-old child).

Use and interaction: The placement of the coil and headrest onto the bed goes as intended. Headrest slides out easily, and placement of the patient on the headrest goes well. Placing straps around the patient's head also works as intended. So does the strap and press-button to connect the headrest to the bed. Sliding the coil over the patient's head goes easily. Sliding the bed forward and backward requires an uncomfortable amount of force. The pillow is missing in the prototype, which may cause discomfort to the patient. The velcro head strap has lots of play, and it is argued that it cannot be tightened sufficiently to keep the patient's head still. Attachment of the headrest to the bed with the red strap is crucial, as without it the bed will slide from under the patient. Users may forget this. In the worst case, the patient will remain inside of the bore with the coil, while the bed slides backwards.

B. Stakeholder validation

Interviews were conducted through videoconferencing. The CAD model of the MRI scanner, its use and features were presented to the interviewees. The interviewees then had time to discuss and comment [8].

Director Research & Medical Doctor - CURE The fact that the operator is in the same room as the patient was well received. Moreover, the fact that thereby the mother can also be there to calm the child was noted as a positive feature. The sliding mechanism was noted as being "ingenious". Further, it was noted that head, knees, and shoulders of the patients all need to be strapped. Both emphasized the need to prevent sedation, and proposed the use of music to calm the child for this cause. Safety railings on the side were noted as a nice-tohave, but if there are straps for the child may not be needed. If there, the railings were preferred to be retractable to increase access to the child. For installation as well as operation, a mobile solution was proposed, adding wheels. For postoperation patients, moving the patient is difficult while you want an immediate image. A mobile system can prevent an entire ICU team from escorting the post-op patient to the imaging room, it was argued. For installation, carrying was noted as acceptable, but it was misunderstood why wheels weren't added. Additionally, it was noted that a separate location for placing the oxygen tank is needed. It was rightly commented that when sliding the coil over the entire bed, the entire body of the infant can be scanned provided it fits through the coil. This would increase the value of the system significantly [8].

Biomedical Engineer - MUST - Structure of aluminium profiles as well as the fact that the bed can slide in only one position was well received. Additionally, the system being fixed was judged as better than a mobile system, as a mobile system would affect the positioning. Another reason that was mentioned for why a fixed system is better is that immobile patients can be wheeled to the MRI room and then moved onto the MRI bed. Carrying was noted as being "fairly difficult" due to the 100 kg weight. It was proposed that the design should facilitate lifting by forklift as well. It was noted that the flat bottom of the magnet assembly is likely sufficient to facilitate forklift carrying. Headphones were proposed as a solution to keep the noise down for the patient. Finally, a safety issue with battery packs underneath the magnet was noted. It was proposed to place back-up batteries in a separate room. [8]

VIII. RECOMMENDATIONS

Finally, we come to recommendations for improvement.

Connection and installation of electronics - When installation needs to be as easy as possible, instructions should be considered. A simple instruction manual can be added, and colour-coded cables could make things even simpler.

Bore length - A shorter bore could benefit the child patient: it could facilitate airflow, reduce anxiety, and increase patient visibility.

Pediatric full-body scanning - when the RF coil can slide all the way over the bed, an infant's full body may be scanned (as long as the body fits inside the maximum diameter coil). With several minor adaptations to the current design, this may be enabled. Adaptations should be in line with context challenges.

Cleaning - Aluminum extrusion profiles may be especially difficult to clean due to their geometry. Different structural members may need to be considered. Moreover, the bed needs to be optimized for cleaning. A watertight bed should ensure that secretion is contained in the bed and does not end up in for example, the magnet assembly which is notably harder to access for cleaning. 3D-printed parts may need to be coated to enable effective cleaning.

Bed alignment - Alignment of the bore with the bed is crucial, as a slight deviation may block the bed from sliding in. Two solutions can be explored: 1) include a proper alignment tool into the design that ensures accurate alignment during installation, even on crooked floors or 2) increase the margins between the components, so that accurate alignment is less of an issue and blockage does not occur when the bed is misaligned.

Preventing patient movement - Additional straps may need to be included in the bed design to reduce movement of the patient.

A downside of the taken design approach is the limited number of hospitals and users that were consulted. As hospital conditions elsewhere in Uganda or Africa may vary, it is uncertain as to what degree the research can be generalized. Moreover, validation of the design was done through interviews and discussions with potential users. This can cause an incomplete assessment as the conversation is guided by the designer's interpretation. It also may cause interviewees to react overly positive to the designer's presentation of the product or even lie as not to insult his or her work. Whenever possible, validation through observing real users using a physical prototype in a representative environment should allow for a better, more impartial assessment.

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