METHODS FOR MEDICAL DEVICE AND EQUIPMENT PROCUREMENT IN LOW AND MIDDLE-INCOME COUNTRIES

BY

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ABSTRACT

40-70% of medical devices and equipment in low- and middle-income countries (LMICs) are broken, unused or unfit for purpose: ad-hoc, undiscerning and inefficient procurement methods and processes contribute towards this problem. This thesis presents the findings of four original studies on medical device and equipment procurement within LMICs. Chapter I reports findings of a systematic literature review on procurement and prioritization methods; recommendations from reviewed literature are synthesised. Chapter II describes fieldwork conducted in The Gambia and Romania to explore the processes and dynamics behind medical device procurement in contrasting settings. Findings suggest procurement processes are strongly influenced by political/cultural power dynamics; health technology assessment evidence is rarely considered. Chapter III discusses the feasibility of conducting medical device specific economic evaluations for informing procurement planning. A case study on the cost-effectiveness of alternative treatment interventions for femur-shaft fracture fixation in Sub-Saharan Africa is presented. Chapter IV consists of a critical appraisal of the medical device specific elements of the One Health Tool for health system planning. The thesis concludes with a discussion contextualizing the findings and suggestions for further research.

DEDICATION

This dissertation is dedicated to my family: for you have inspired me to pursue knowledge and instilled in me a drive to excel and surpass my limits.

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To my partner, Dave: Let us never be satisfied. Thank you for putting up with late nights, early mornings and me.

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LIST OF ABBREVIATIONS

ACORD	Agency for Cooperation in Research and development
AFD	Aide au developpement
AUSAID	Australian Agency for International Development
CADTH	Canadian Agency for Drugs and Technologies in Health
CE	Conformité Européene marking
CEA Registry	Cost-effectiveness analysis registry
CENETEC	Centro Nacional de Excelencia Tecnologica en Salud
CHE York	Centre for Health Economics - York
CHEPA	Centre for Health Economics and Policy Analysis
CIDA	Canadian International Development Agency
CPCI	Conference Proceedings Citation Index
DANIDA	Danish International Development Agency
DFID	Department for International Development
EBRD	European Bank for Reconstruction and Development
EU	European Union
FDA	Food and Drug Administration
GIZ	Deutsche Gesellschaft fur Internationale Zusammenarbeit
GPPA	Gambian Public Procurement Authority
HE	Health economic
HITAP	Health Intervention and Technology Assessment Program - Thailand
HIV/AIDS	Human immunodeficiency virus infection/ Acquired immune deficiency syndrome
HMIC	Health Management Information Consortium
HNA	Health Needs Assessment
HTA	Health technology assessment
HTAi	Health Technology Assessment international
IAC	Interagency Committee on Sustainable Development

INAHTA	International Network of Agencies for Health Technology Assessment
ISO	International Standards Organisation
JICA	Japan International Cooperation Agency
LMIC	Low and middle income countries
MDE	Medical devices and equipment
MSF	Medecins Sans Frontieres
MSH	Management Sciences for Health
NHS EED	National Health Service Economic Evaluation Database
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SIDA	Swedish International Cooperation Agency
SWISSAID	Schweizerische Stiftung for Entwicklungszusammenarbeit
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Emergency Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WHO-CHOICE	WHO - Choosing Interventions that are Cost-Effective group

INTRODUCTION

MEDICAL DEVICES AND EQUIPMENT IN LOW- AND MIDDLE-INCOME COUNTRY HEALTH SYSTEMS

Over 5.8 billion persons living in low- and middle-income countries (LMICs) require access to health care services. (1) Successful health care delivery hinges on the availability of qualified health care personnel, sustainability of health care financing, and safety and availability, appropriateness, accessibility and acceptability of health care technologies. (2–4) Policy, debates and research on health technologies historically focused on the role of medicines or clinical interventions;(5,6) recently, however, health technologies more generally have come under scrutiny, including medical devices and equipment. (MDEs) (7)

MDEs are broadly defined as products used in health care provision, whether for assistive, diagnostic, treatment or monitoring purposes. Examples include implants, in-vitro diagnostics, delivery beds, malaria nets, surgical instrumentation as well as more complex clinical equipment such as linear accelerators.(7) The World Health Organization (WHO) recognizes the importance of MDEs in ensuring universal health coverage and urges its member states to carefully select, procure, manage and distribute technologies. (8–10) Reports from LMICs, however, suggest that MDEs frequently fall into disuse in resource poor settings: 40-70% of products are estimated to be broken or remain unused in health facilities. (11,12)

In its “Priority Medical Devices” report, the WHO suggests such issues arise due to mismatches in MDE demand and supply and undiscerning procurement systems.(3) LMIC demand focuses on the procurement of technically simple, low-cost and easy to use devices able to function in settings with little to no infrastructure and user training. In contrast, MDE manufacturers are primarily active in, and attuned to, the needs of high-income settings. High-income country health systems are well resourced, staffed by a technologically savvy workforce, and include hygienic and well-serviced health care facilities/infrastructure.

MDE deployment challenges in LMICs may also arise due to a lack of technical experts able to advise on the selection of setting-appropriate devices.(13) Regulatory bodies able to oversee and advise on tendering are also routinely absent.(14) These challenges result in the procurement of products unfit for use in LMICs and directly translate to lost health care resources and poor population health outcomes.

This PhD explores the procurement of MDEs within LMICs, specifically the methods and tools available to LMIC stakeholders for reaching product selection decisions within procurement planning. For the purposes of this thesis, procurement planning is defined as a specific element of MDE management, separate from subsequent activities including product tendering, distribution, and use and decommissioning. (Figure 1) While all these elements are relevant to planning in that they invariably define the decision-space in which stakeholders operate, the current work will not address any specificities relating to the efficiency or design of different tendering systems, financing arrangements or MDE decommissioning procedures. Instead, the methodological and normative aspects of procurement planning are explored, with particular focus on prioritization of MDE purchases given severe resource constraints.

Thesis aims

The studies within this thesis were designed to meet the following aims:

1. Identify reported methods and tools available to LMIC decision-makers on MDE procurement and prioritization to determine relevant issues/factors and document common challenges and best practices as described in the global literature; *(Chapter 1)*
2. Empirically explore MDE procurement processes and dynamics in designated LMIC settings to ascertain the motives, constraints and incentives of decision-

makers in the selection, purchasing and use of specific health products; *(Chapter 2)*

3. Informed by the above and using LMIC appropriate case studies, to explore and critically discuss the role of health technology assessment methods, in particular MDE specific health economic evaluations, for their relevance in procurement planning; *(Chapter 3)*
4. Informed by the above findings, to critically appraise and discuss the role of health system planning tools - in particular the One Health Tool developed at the initiative of the Interagency Working Group on Costing (World Bank, World Health Organization among others) - for their usefulness and relevance in MDE procurement planning. *(Chapter 4)*

Chapter 1: Systematic literature review of medical device and equipment procurement methods for LMICs

KD designed and conducted a systematic literature review to identify methods used or recommended for MDE procurement or prioritization within LMICs. A systematic review protocol outlines the design of the review, its aims and objectives as well as methods employed.(15) A second manuscript reports review findings and provides a synthesis of recommended procurement methods and practices as described in appraised documents; a list of prioritization criteria for MDE selection is also outlined. The review highlights that both feasibility and normative criteria are relevant to MDE procurement: i.e. issues of servicing and maintenance capacity, user training and robustness of product design need to be considered alongside health needs and value for money when selecting and purchasing MDEs. Notably, health technology assessment

methods are mentioned sparingly throughout the literature, suggesting limited uptake of such methods for informing MDE procurement.

Chapter 2: Medical device procurement in The Gambia, Romania and in the view of international experts: findings of a qualitative study

Informed by early findings of the systematic literature review, KD designed and conducted a qualitative study with health care professionals, health facility managers, biomedical engineers and regional and national policy and decision-makers in the public health systems of The Gambia and Romania. The study also includes interviews with international consultants in engineering, health economics and health policy active in major international organizations and consultancies. Interviews explore how and why stakeholders select certain MDEs for procurement over others; Bourdieu's theory of a logic of practice is used for data interpretation.(16) Findings suggest that MDE procurement processes are uncoordinated and greatly influenced by socio-political factors, including considerations of prestige and power. Neither country uses transparent health technology assessment based systems for resource allocation. The early findings of this study led to the formulation of a BMedSci student project into differences between the public and private health care sector in MDE prioritization and management experiences in a province of India – this study was undertaken by Vatsal Gupta and supervised by KD and Dr. Semira Manaseki-Holland. (Appendix 1)

Chapter 3: Long-bone fracture care for low-income settings: an economic evaluation of alternative treatment strategies

Notably, both of the above studies highlight that decision-makers in LMIC contexts rarely use health technology assessment and health economic evaluation related evidence in procurement planning. KD explores and discusses the feasibility and usefulness of MDE-specific evaluations for LMIC procurement via the use of a case study. A health economic evaluation exploring the cost-effectiveness of alternative treatment strategies for the fixation of femur shaft fractures in the Global Burden of Disease Africa D and E regions in Sub-Saharan Africa is presented. The chapter includes a critical discussion of methods and issues encountered in conducting the study, specifically on the use of the generalized cost-effectiveness analysis methods championed by the World Health Organization. (17) The chapter also presents MDE-evaluation relevant insights on the use of the Bill and Melinda Gates' Foundation guide to health economic evaluation.(18)

The case study designed by KD was informed by a qualitative BMedSci student project focused on the adoption of the SIGN intramedullary nail for long-bone fracture repair within Tanzania. This study was conducted by A. Gummaraju and supervised by KD and Dr. Semira Manaseki-Holland. (Appendix 2)

Chapter 4: Tools for medical device procurement planning: A critical appraisal of the One Health Tool

The final chapter presents a critical appraisal of the One Health Tool for health system planning. KD undertook this appraisal during an internship at the World Health Organization within the Essential Medical Products Department in March-May 2015.

KD developed a checklist informed by the findings of the three studies undertaken above, including considerations relevant to health technology assessment, MDE procurement, use or management, and used this to appraise the MDE related inputs and methodological assumptions of the One Health Tool. The relevance and usefulness of such tools for MDE related procurement planning in LMICs is further discussed.

Discussion and concluding remarks

The studies included in this thesis complement and build upon previous MDE related research undertaken by the WHO. The systematic review presented in Chapter 1 expands upon a literature review included in the WHO's "Priority Medical Devices" report and adds original insights and value in two ways.(3) First, the study included here systematically searches, identifies and appraises globally relevant literature on MDE procurement and offers a comprehensive characterization of this literature, including relevant summative insights on best procurement practices. In contrast to the "Priority Medical Devices" report, the systematic review therefore also captures insights from the WHO's own publications and research in this area. Second, the systematic review includes a clear and concise account of relevant MDE prioritization criteria, derived via the use of reproducible and validated methods previously specified in a study protocol.

The qualitative study presented in Chapter 2 additionally adopts a rigorous qualitative research design to explore the dynamics of MDE procurement in contrasting low- vs. middle-income country settings. While differences in MDE management between countries have been noted in previous WHO publications(3), no qualitative exploration of the issues contributing to such differences was previously undertaken. Research summarized here emphasises the role of social and political dynamics in MDE

procurement and suggests improved MDE resource allocation processes and practices will require investment into, and empowerment of, professionals with a working knowledge of both biomedical engineering and health technology assessment methods.

Chapters 3 and 4 include an MDE specific critical appraisal of health economic evaluation methods and health system planning tools first pioneered by the WHO. (19,20) Drawing on insights from research presented in Chapters 1-2, case studies "testing" the applicability, relevance and usability of WHO proposed methods and tools were designed. Original insights and recommendations on what methods appropriate for MDE focussed health economic evaluations and MDE related resource allocation planning are presented.

The thesis concludes with an overall summary of research findings, their place and relevance in the global literature, including a discussion on potential limitations and avenues for further research.

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Figure 1: Medical device management process

CHAPTER 1: METHODS FOR MEDICAL DEVICE AND EQUIPMENT PROCUREMENT AND PRIORITIZATION WITHIN LOW- AND MIDDLE-INCOME COUNTRIES: FINDINGS OF A SYSTEMATIC LITERATURE REVIEW

The systematic review protocol enclosed in this chapter has been published:

Diaconu K., Chen Y.-F., Manaseki-Holland S., Cummins C., & Lilford R. (2014). Medical device procurement in low- and middle-income settings: protocol for a systematic review. *Systematic Reviews*, *3*(1), 118. http://doi.org/10.1186/2046-4053-3-118

See following page.

SYSTEMATIC REVIEWS

PROTOCOL Open Access

Medical device procurement in low- and middle-income settings: protocol for a systematic review

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Abstract

Background: Medical device procurement processes for low- and middle-income countries (LMICs) are a poorly understood and researched topic. To support LMIC policy formulation in this area, international public health organizations and research institutions issue a large body of predominantly grey literature including guidelines, manuals and recommendations. We propose to undertake a systematic review to identify and explore the medical device procurement methodologies suggested within this and further literature. Procurement facilitators and barriers will be identified, and methodologies for medical device prioritization under resource constraints will be discussed.

Methods/design: Searches of both bibliographic and grey literature will be conducted to identify documents relating to the procurement of medical devices in LMICs. Data will be extracted according to protocol on a number of pre-specified issues and variables. First, data relating to the specific settings described within the literature will be noted. Second, information relating to medical device procurement methodologies will be extracted, including prioritization of procurement under resource constraints, the use of evidence (e.g. cost-effectiveness evaluations, burden of disease data) as well as stakeholders participating in procurement processes. Information relating to prioritization methodologies will be extracted in the form of quotes or keywords, and analysis will include qualitative meta-summary. Narrative synthesis will be employed to analyse data otherwise extracted. The PRISMA guidelines for reporting will be followed.

Discussion: The current review will identify recommended medical device procurement methodologies for LMICs. Prioritization methods for medical device acquisition will be explored. Relevant stakeholders, facilitators and barriers will be discussed. The review is aimed at both LMIC decision makers and the international research community and hopes to offer a first holistic conceptualization of this topic.

Keywords: Developing countries, Prioritization, Procurement, Medical devices

Background

Medical devices and equipment are crucial for quality health service delivery. Reports and research on low- and middle-income countries cite a lack of basic medical devices as well as medical equipment falling into disuse within these settings [1,2]. This severely impairs health care provision and also translates to lost resources and funds. The WHO Priority Medical Devices project suggests two potential causes for this problem [2]. First, medical device manufacturers target high-income country economies due to a higher potential profit. Thus, medical device supply and equipment design are restricted to products and specifications suitable for deployment settings with advanced infrastructure and technologically knowledgeable human resources. Second, issues around the judicious procurement of medical devices arise for low- and middle-income countries (LMICs) [see Additional file 1: Definitions: Medical device procurement]. Inappropriate selection of products impedes equipment uptake and use within deployment settings. Medical devices should be appropriate for and

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readily available in LMIC settings as well as accessible and affordable for health care facilities, their staff and national governments [2-5].

However, little is known about how medical device procurement does or should take place within LMICs, and processes may substantially differ from those employed in high-income countries (HICs). Within the latter settings, technology acquisitioning processes are guided by principles of quality care delivery and value for money to ensure containment of rising health care costs. A diverse range of stakeholders is involved in deliberation of potential purchases: clinicians, public health commissioners, researchers and patients. The review of clinical and cost-effectiveness evidence as well as value-based criteria such as equity form the basis of such deliberations [6-10]. The WHO Baseline Country Survey on medical devices illustrates that in contrast to HICs, LMICs undertake medical device procurement at national rather than regional or facility level ([11] and Table 1: Author's calculation: chi-square with 3 degrees of freedom, total sample n =162, p <0.01). The survey fails, however, to provide more granular detail on stakeholders involved in these processes as well as principles pursued—e.g. is cost-effectiveness a desired feature of potential purchases?

To guide decision makers in the procurement of medical devices for LMICs, numerous recommendations, guidelines and tools have been issued by international think tanks and public health organizations. Substantial heterogeneity can be observed in relation to these: recommendations may focus on procurement for specific interventions or service delivery packages, clinical areas or specialties, as well as entire health facilities and ancillary services offered [12-14]. The WHO itself recommends medical equipment selection for procurement take the shape of 'availability matrices' [15]. This involves targeting clinical areas and interventions associated to a country's highest burden of disease and identifying medical equipment key for investment in or provision of said services.

To date, no systematic review and appraisal of the literature around medical device procurement recommendations, guidelines and research exists. We propose to undertake such a systematic review to identify how medical device procurement and prioritization within LMICs should take place in the future, based on research which reports on procurement and prioritization processes as well as recommendations put forth in publicized guidelines and similar materials. The current paper serves as a study protocol for this exercise. We believe that a systematic review on this topic would prove beneficial to decision makers and procurement practitioners within LMICs by helping identify initial core principles for equipment purchasing. Further, we wish to explore prioritization methodologies proposed within the literature. Under resource constraints, prioritization is a crucial part of a procurement process and directly informs equipment selection. Medical device-specific prioritization criteria will be identified, and this may inform the wider debate on how prioritization processes are shaped and implemented [16-18]. Identified principles and methodologies will be discussed and interpreted in light of information relating to settings described, type of medical equipment proposed for procurement, as well as type of issuing organization and reason for document development.

The main research question is: What methods inform or are recommended for LMIC specific medical device and equipment procurement? In the course of exploring the above study question, we also expect to consider: the evidence base used to inform medical device procurement methods and processes and the factors impacting upon medical device procurement and the methods proposed for medical device prioritization.

Methods/design

Search strategy

Early scoping searches on medical device procurement methods for LMICs revealed a large body of grey literature, issued by international public health agencies, think tanks or similar institutions, but very few journal articles or research studies. It was therefore important to design search and selection strategies to be as broad and inclusive as possible, with no time or language restrictions. The range of documents to be included will, however, be restricted to freely available digitized material, partly due to resource constraints, partly because we believe this

Table 1 Procurement of medical devices at national level in relation to country income classification (World Bank 2014)

Country classification	Does procurement of medical devices occur at national level? (Responses from WHO Baseline Country Survey 2010)	
	Yes	No
Low income	25	8
Low-middle income	31	7
Upper-middle income	30	17
High income	17	27
Total	103	59

Author's calculation: chi-square with 3 degrees of freedom, total sample n =162, p <0.001.

Table 2 Type of search conducted and sources searched

Search type	Search sources	
OVID MEDLINE search algorithm and keyword searches	Bibliographic databases	OVID MEDLINE, OVID Embase, Cochrane Library, CRD databases (DARE, NHS EED, HTA), CEA Registry, LILACS, African Index Medicus, Econlit, HMIC
Keyword searches	Website searches	TRIP, National Guideline Clearinghouse, International Guideline Library, NHS Evidence and Clinical Evidence (NICE), Clinical Evidence (BMJ), INAHTA, CADTH, HTAi, Web of Science, CHE York, CHEPA, Cost Effectiveness Analysis Registry, Office of Health Economics
	Organizational databases/websites	WHO Health Technology e-documentation centre, WHO, UNDP, UNICEF, UNAIDS, WB Group (IBRD particularly), MSF, AfDB, ADB, EBRD
	National donor agencies	DFID, USAID (including MSH), AUSAID, GIZ, BMZ, JICA, and other relevant agencies that may be identified during the search
	Grey literature databases	ZETOC, CPCI
Contacting experts	Contact with experts to identify additionally relevant literature	

most closely mirrors the various materials that LMICs would be able to access. We acknowledge this as a limitation of the study; however, scoping searches indicate that the majority of documents to be retrieved are part of the grey literature and digitized and freely available through the World Health Organization and ancillary institutions. A full list of sources to be searched is provided in Table 2.

To identify relevant documents from the literature, search terms grouped around three distinct topics will be employed: medical devices and equipment, procurement and LMICs. Guided by a consensus definition of medical devices [19], the review will focus on any type of medical device ranging from consumables (e.g. bandages, needles) to routine medical equipment (e.g. stethoscopes, ECG machines) and devices (e.g. condoms) as well as medical furniture (e.g. delivery beds). Search terms will refer to medical devices and equipment, medical supplies and medical or biomedical technologies and will include relevant subject headings. Further search terms and subject headings include synonyms for procurement and terms around LMICs and income levels.

An OVID MEDLINE search string is provided in Table 3. Where possible, keyword combinations similar to the search string provided will be used in all sources in order to identify the relevant material. No restrictions around the specific type of material to be retrieved will be employed: databases, reports, notices, presentations, conference proceedings, journal articles, manuals and books will all be reviewed provided that they are freely available and digitized. Native language speakers will be identified

Table 3 Example of search strategy for MEDLINE (OVID SP) up to week 2 of January 2013

No.	Search strategy
1.	device.mp. or exp "Equipment and Supplies"/
2.	(device* or equipment* or suppl*).mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
3.	exp Technology, Radiologic/ or exp Technology Assessment, Biomedical/ or exp Fiber Optic Technology/ or exp Educational Technology/ or exp Biomedical Technology/ or technology.mp. or exp "United States Office of Technology Assessment"/ or exp Technology/ or exp Food Technology/ or exp Technology, High-Cost/ or exp Technology Transfer/ or exp "National Center for Health Care Technology (U.S.)"/ or exp Wireless Technology/ or exp Technology, Dental/ or exp Green Chemistry Technology/ or exp Technology, Pharmaceutical/ or exp Remote Sensing Technology/
4.	1 or 2 or 3
5.	(procure* or purchas* or acqui* or commission* or buy*or order*).mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
6.	(countr* adj2 (income or poor or poverty or develop* or resource or low* or mid*)).mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
7.	(third adj2 world).mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
8.	(emerging adj2 (econom* or market*)).mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
9.	developing country.mp. or exp Developing Countries/
10.	6 or 7 or 8 or 9
11.	4 and 5 and 10

Conducted last: 28 January 2013, 15:10 (GMT). Number of records identified: 2,297.

to assess, select and report on non-English studies, thus, limiting potential translation bias.

Selection and inclusion

All records identified in the search will then be screened for potential inclusion into the review (see Figure 1 for a selection algorithm). At first stage, only titles will be considered and all documents mentioning medical devices, either specific devices or equipment/supplies in general or interventions likely to make use of equipment (e.g. vaccinations, orthopaedic surgery) will be retained. This is to ensure that documents are indeed focused on the topic of interest. One researcher will undertake title review; however, a second independent researcher will check a random 10% sample of documents for each of the sources searched. Any disagreements will be resolved through discussion or consultation with a third reviewer.

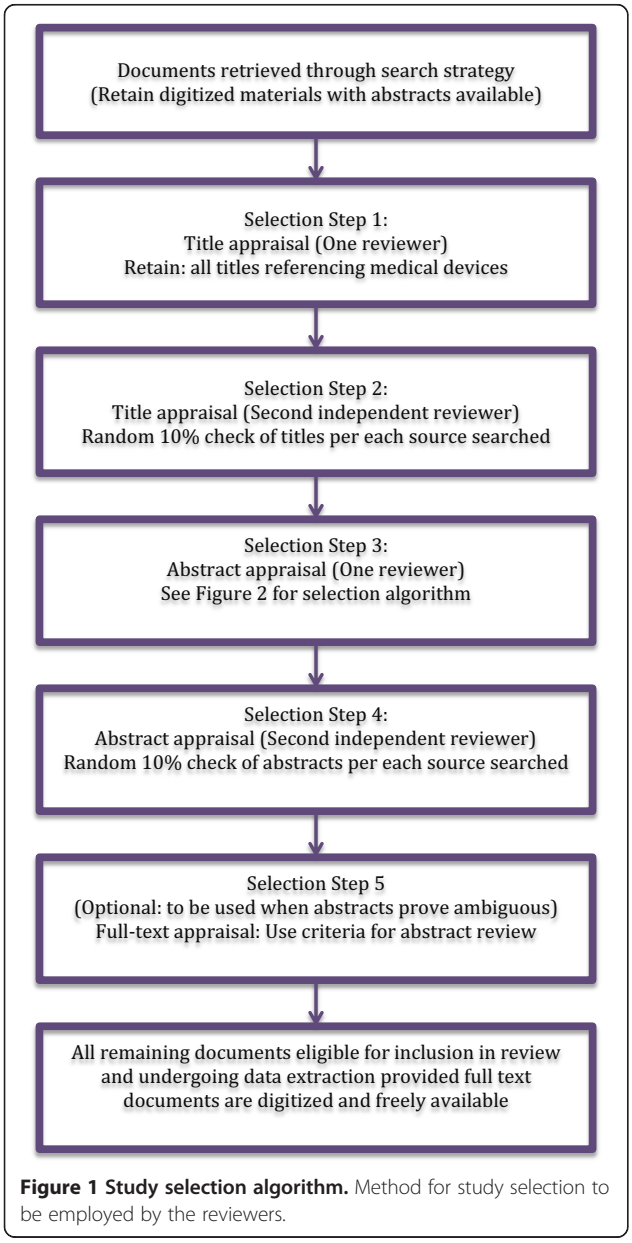

Figure 1 Study selection algorithm. Method for study selection to be employed by the reviewers.

Abstracts will then be reviewed in light of four pre-specified selection criteria or questions (Figure 2). These are directly linked to the outcome questions to be investigated and are formulated so as to retain documents including recommendations or discussions of medical device procurement and prioritization processes, or documents clearly indicating factors which may impact upon medical device procurement. In addition, we have chosen to include only documents discussing processes relating to the procurement of more than one device: this is because we consider that any prioritization process potentially employed in procurement would fundamentally rely on the comparative assessment or evaluation of more than one technology/product. Reviewers will, however, take into account that documents may restrict their focus to one device while still including a discussion on the relative merits of similar devices: e.g. a document on the procurement and pre-qualification of a particular intrauterine contraceptive device may still be included provided that it includes a more detailed discussion on similar devices and their specifications [20]. Documents discussing only regulatory issues relating to procurement or medical device supply have also been excluded as they are considered too narrow in focus to provide meaningful information on the outcome question set.

The selection questions to be used are detailed below and have been piloted by two independent reviewers on a sample of 20 documents retrieved from OVID MEDLINE and the WHO E-Health Technology Documentation Centre. The latter database has been identified in scoping searches as including a large body of relevant material and was therefore considered suitable for piloting. The questions were deemed appropriate for the purposes of this study and are outlined below along with examples of documents identified in the piloting process as appropriate/inappropriate for inclusion. These examples were made available to reviewers for consultation during the study selection phase of the review.

A. Is the record a guideline, recommendation or policy document aimed at health service providers/commissioners/managers, or does the record include a clearly stated recommendation for medical device procurement within low and middle income settings?
   Example of 'yes': World Health Organization [21]: Procuring Single-use Injection Equipment and Safety Boxes. The executive summary indicates that the objective of the document is to "accompany pharmacists, physicians, procurement staff and programme managers through the process of

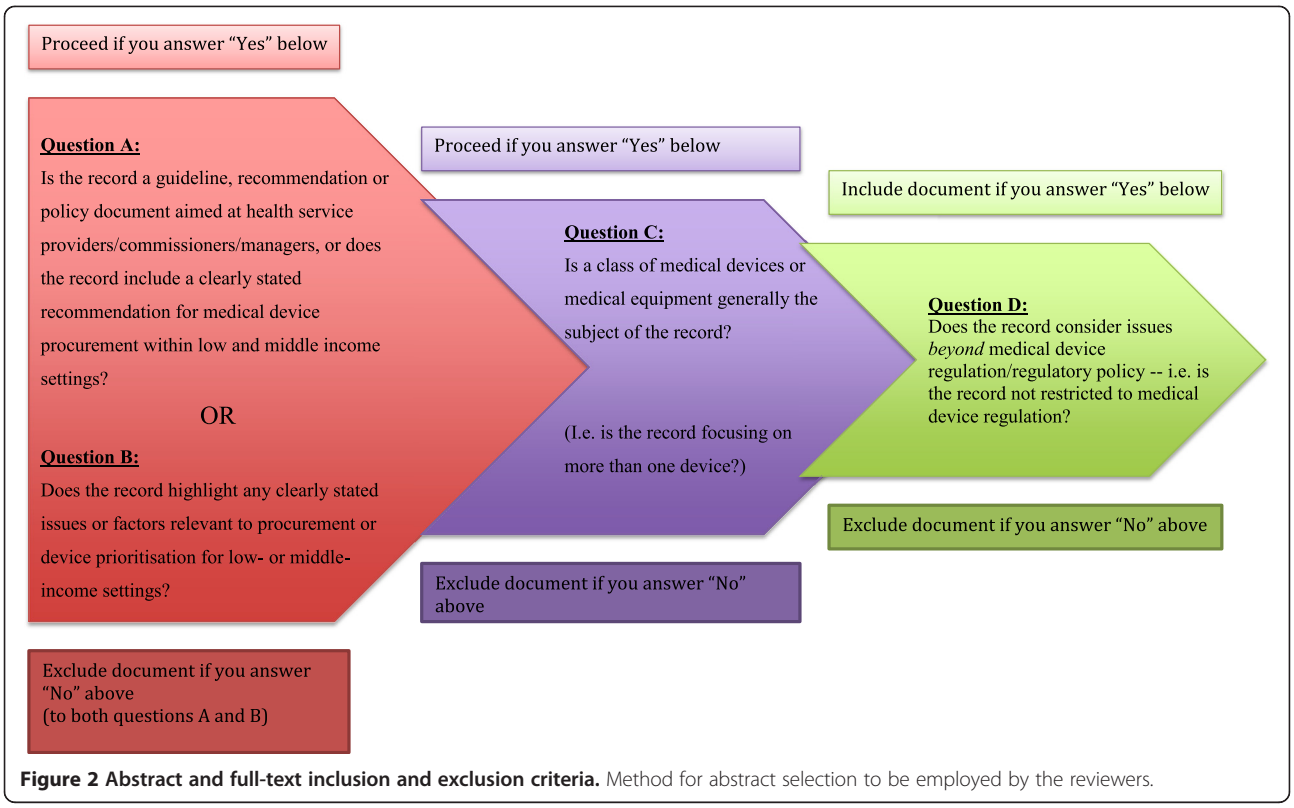

Figure 2 Abstract and full-text inclusion and exclusion criteria. Method for abstract selection to be employed by the reviewers.

procuring single-use injection equipment and safety boxes of assured quality, on a national or international market, at reasonable prices".
Example of 'no': Ross et al. [22]. Study protocol: Ethics, Economics and the Regulation and Adoption of New Medical Devices: Case Studies in Pelvic Floor Surgery [22]. Rejected because the methods section of the abstract indicates this study uses examples from a Canadian context; no link to LMICs is stated.

B. Does the record highlight any clearly stated issues or factors relevant to procurement or device prioritisation for low- or middle-income settings?
Example of 'yes': Anderson, B. O et al. [23]. Optimisation of breast cancer management in low-resource and middle-resource countries: executive summary of the Breast Health Global Initiative consensus, 2010 [23]. Abstract indicates that journal article includes a discussion on "programme infrastructure and capacity (including appropriate equipment and drug acquisitions, and professional training and accreditation)."
Example of 'no': Porto, J. P et al. [24]. Nosocomial infections in a paediatric intensive care unit of a developing country: NHSN 45(4), 475–479 [24]. Rejected because abstract does not mention procurement or device prioritization.

C. Is a class of medical devices or medical equipment generally the subject of the record? (i.e. is the record focusing on more than one device?)
Example of 'yes': Kalifa et al. [25]. Imaging in pediatrics. Strategy and economic implications for the Third World, Annales de Pediatrie 39(2): 67–70 [French] [25]. Abstract mentions medical imaging equipment and provides two distinct examples: ultrasonography and roentgenography.
Example of 'no': Malkin, R., Anand, V. [26]. A Novel Phototherapy Device ©. [26]. Rejected because abstract indicates document focuses on product development of a single device.

D. Does the record consider issues *beyond* medical device regulation/regulatory policy—i.e. is the record not restricted to medical device regulation?
Example of 'yes': Kalifa et al. [25]. Imaging in pediatrics. Strategy and economic implications for the Third World, Annales de Pediatrie 39(2): 67–70 [French] [25]. Abstract indicates that document content is not restricted to device regulation, instead focusing on two medical device classes and their use in LMICs.
Example of 'no': World Health Organization [27]. Medical Device Regulations: Global Overview and Guiding Principles [27]. Rejected because document is restricted to a discussion on global regulatory frameworks and principles.

Please note that the selection questions are used as detailed in Figure 2. This means that documents will be included in the review if answers:

- A, C, D = Yes
- B, C, D = Yes
- A, B, C, D = Yes

The selection criteria will be re-evaluated as necessary by reviewers, and any amendments to this original study protocol will be noted in the published systematic review. We acknowledge that abstracts may prove ambiguous, and that reviewers may therefore wish to refer to full-text documents at times. When this is needed, reviewers should make use of the same four questions specified above for study selection, and note that, a full-text review has been carried out. A random 10% sample of abstracts obtained from each of the sources searched will undergo screening by a second independent reviewer, and all disagreements will be resolved through discussion or consultation with a third reviewer.

Data extraction

All documents which were screened and deemed eligible will be included in the proposed study. The task of data extraction will be split across reviewers, who will read full-text documents to obtain data on a pre-specified list of variables and questions (see Table 4: Data extraction template). Similar to the selection criteria, the data extraction template has been piloted on a random sample of 17 documents which were deemed eligible for inclusion from OVID MEDLINE and the WHO E-Health Technology Documentation Centre.

To address our study aims and outcome questions, data relating to the following five domains will be extracted:

- Document identifier and characteristics: This covers information unique to the document (e.g. authors, year of publication, journal) as well as a categorization of the document according to purpose of publication (e.g. guideline, research study).
- Described setting: Information on country descriptions will be noted where available in order to provide a context to data extracted and further interpretation.
- Methodological data: This is the most substantial task and covers information relating to prioritization and procurement methodologies as well as factors affecting procurement processes. Where explicit prioritization methodologies are described, reviewers will be instructed to extract quotes or keywords describing these processes in order to allow for close textual interpretation. Further questions require reviewers to provide dichotomous 'yes/no' answers relating to the use of evidence in procurement (e.g. use of cost-effectiveness evidence, health needs assessments), availability of procurement policies/ frameworks (e.g. health technology management frameworks), influence of stakeholders (e.g. which institutions or facilities affect the process of procurement) as well as influence of processes/ health campaigns (e.g. quality assurance, targeted programmes or interventions). For any additional information, reviewers wish to capture, an additional "notes" section is provided.
- Equipment related data: Any information available related to the equipment to be procured is captured here: clinical area equipment is used in, equipment specification, cost of procurement, and maintenance, installation or decommissioning information among others.
- Capacity building: Reviewers are asked to note any proposed training strategies related to medical device procurement in LMICs.

Analysis and interpretation

Two methods of data analysis will be employed for this systematic review, each corresponding to the type of data extracted. Where reviewers are tasked with extracting quotes or keywords, relating in particular to prioritization methods described in the literature, qualitative meta-summary was deemed the most appropriate method for analysis [28]. Treating extracted quotes and keywords as a primary (i.e. uninterpreted) description of phenomena that document authors wish to report, qualitative meta-summary proposes the grouping of topically similar data and the generation of further abstractions aimed at describing underlying themes and processes. This allows for a richer contextual interpretation of data, something particularly valuable when trying to generate initial theses in relation to how medical device procurement and prioritization is viewed within the literature.

For data otherwise extracted, i.e. dichotomous data extracted on remaining pre-specified variables, narrative synthesis was deemed appropriate [29]. In the first instance, this will entail generating descriptive statistics and examining associations between variables through the use of chi-square (or Fisher's exact) tests as appropriate. Associations between the following variables may be investigated: presence of health technology management frameworks (and actors engaged in technology management) and use of commissioning strategies for procurement, health service delivery levels, evidence in procurement (e.g. health needs assessments) as well as health facility equipment priorities and assigned maintenance responsibilities for health care facility staff. Further explorations will focus on the disease areas or type of equipment cited and specifications recorded for these in addition to instructions on deployment in health facilities and human resource training

Table 4 Data extraction template

No.	Question/item	Tick if applicable	Answer (if applicable) Example answers below
1.	Study ID + bibliographic information		
2.	Type of record		
	• Is the record a guideline/recommendation/policy document or an academic article?		
	• Is the document part of a greater study/document? (if so, appraise that document as well but link information relating to evidence)		
	• Are the authors contactable?		
3.	Institution of origin and who the institution reports to		
	• Record institution (if this is an academic article, record university)		
	• Why did the institution develop the record?		
	• Under what remit does the institution operate? (e.g. if university was commissioned to develop record, record how the institution commissioning the research will use the record, if specified)		
4.	Setting/country of origin and any information regarding the below (note if specified in record)		
	• Economic and development indicators: HDI level, GDP, GDP/capita, Health expenditure as % GDP, % total government expenditure or medical device expenditure as % of health budget		
	• What does the disease burden look like? Is any epidemiological evidence presented?		
	• How is health care funded?		
	• What other factors related to country/countries in question are mentioned (e.g. income inequality, access to health care, national security, infrastructure, health service infrastructure)?		
5.	Methodological data: Answers to be recorded to the below questions from the record considered.		
	1) Is prioritization of medical device purchasing/selection explicit?		
	a) If yes, describe the method presented in the record and further evaluate below questions.		
	2) Is it clear who/what institutions hold the responsibility for medical device management?		
	a) If yes, note the institutions and their remit (e.g. national, international).		
	3) Are budget impact (national, local or by facility level) or national health care/service funding policies mentioned and if so is any relation to procurement or prioritisation made explicit?		
	4) Is health technology assessment mentioned?		
	Health technology assessment example phrases: evidence base; clinical and cost effectiveness data; HTA appraisal systems; HTA process—i.e. timing, cost, staffing, expertise, national/international remit.		
	a) If yes, is it clear how the HTA evidence is integrated into the prioritisation and procurement decisions? Describe the mechanism.		
	b) Is it clear who is responsible for HTA appraisal and for issuing recommendations? Who has access to the HTA evidence? How is this disseminated?		
	5) Are direct care providers mentioned?		
	Examples of direct care providers: nurses, medics, volunteers etc.		
	a) If so, is it clear what their influence on purchasing/prioritisation is? (e.g. do they directly commission, do they prefer certain suppliers)		
	b) Are any issues regarding staff training and ability to deliver services mentioned? (e.g. staff may not be trained to use a particular device)		
	c) Is it clear how staff is involved in the maintenance of medical devices?		
	6) Are care pathways or clinical guidelines mentioned?		
	Examples of clinical guidelines: WHO guidelines for diabetes management, etc.		
	a) Is it clear what clinical guidelines or care pathway information was used in device selection or prioritisation?		

Table 4 Data extraction template *(Continued)*

7) Is health needs assessment mentioned?

a) If yes, what are the health priorities of the population in question and how were they derived in the HNA process?

b) Is it clear how the health needs assessment informed procurement decisions?

8) Are commissioning strategies for health services and equipment mentioned?

For example: Afghanistan's MSH guide on "Equipment for BPHS for Health Posts" refers to a national procurement strategy so both documents would need to be evaluated and the national procurement strategy would form the basis for the guide assessed.

a) If yes, record what types of strategies are mentioned? (e.g. national, international)

b) If yes, what is the relation of said strategy to the current record being assessed? Does one form the basis of the other, do they operate complementarily and is adherence to one or the other or both mandatory?

c) Follow up on the national or local strategy and undertake a record assessment.

9) Are health service delivery facilities (e.g. hospitals, health centres, mobile units) mentioned?

a) If yes, which facilities are directly mentioned?

b) If yes, is it clear which medical devices are a priority for each facility or facility level?

c) If yes, are ambient conditions of the facility necessary for device performance mentioned? (e.g. running water, electricity availability)

d) If yes, and if a device list is present, is it clear if device purchasing was restricted to a particular class of devices: e.g. consumables that do not require electricity, mobile devices that need little maintenance, etc.

10) Does the record mention expert advice on the device procurement/prioritisation?

a) If yes, what kind of expert would be consulted and what documentation do said experts provide to inform device procurement/prioritisation?

11) Are particular standards regarding devices mentioned? Mentions of standardization regarding devices could include naming specific brands, product specifications, specific suppliers, specific regulatory nomenclatures)

12) Are any costs mentioned in the record?

a) If so, record which costs are mentioned.

13) Are execution strategies mentioned in regards to particular health campaigns? (either of national or international importance)

Examples include: HIV/AIDS campaigns which are commissioned through UNAIDS

a) If yes, who/what institution advises on device procurement and prioritisation?

b) Is it clear what the recommendations regarding device procurement are? Note down recommendations.

14) Are more up to date versions of lists/guidelines/methods of the same record present?

a) If yes, appraise newer record versions as well.

15) Is evidence of evaluation strategies regarding procurement lists, guides, methods present?

a) What evaluation strategies are mentioned?

b) Who undertakes said evaluations?

c) Is it clear what evidence is being used to inform evaluations?

6. Equipment related data: Answers to be recorded to the below questions.

1) What are the main categories of equipment included in record?

a) Renewable supplies

b) Surgical supplies

c) Condition specific

d) Record the equipment categories mentioned.

2) How detailed is the equipment specification? (i.e. are measurements mentioned; is a description provided;)

3) How many distinct products are mentioned?

4) Is a mix of devices mentioned and is it clear if certain devices are complementary (i.e. they need to be used in conjunction with one another)?

Table 4 Data extraction template *(Continued)*

	5) Does the list mention how many items of one product to purchase?
	6) Are any national/regional device coverage targets set? (i.e. how many devices/institution/region
	7) Is any cost data present and if so, note down what cost data is available.
	8) Is any information on installation available and if so, note what recommendations are given.
	9) Is any information on maintenance available and if so, note what recommendations are given.
	10) Is any information on necessary ambient conditions supplied and if so, note what said conditions are. (i.e. "needs constant electricity supply")
	11). Is any recommendation regarding device disposal given and if so note what said recommendation is.
7.	Capacity building: Answers to be recorded to the below questions.
	1) Does the record outline any strategies for training people in medical device purchasing or medical device management?
	a. If yes, record what said strategies are.
8.	Notes
	Recording of any additional information that seems of relevance.
	Example: WHO Priority Medical Devices frequently refers to diagnostic coding systems and disability classification systems.

Provided as Excel spreadsheet to reviewers. Data extraction template provided to reviewers.

levels, as well as installation and maintenance necessities. The influence of publication year issuing organization and reason for document development on details associated to the above variables may also be explored. Documents may also be grouped according to their type (e.g. research studies, guidelines) to highlight potential differences in reporting on procurement or prioritization processes. Capacity building strategies related to procurement will be discussed. Mind-maps showcasing associations may be created to provide visual representations.

Reporting

For reporting purposes, we will follow the PRISMA statement for systematic reviews and refer readers to this protocol for further clarifications [30]. We expect that we will not be able to report on all items in the statement, e.g. relating to risk of bias within or across studies (items 12, 15, 19, 22) or to quantitative outcomes, synthesis of results or additional subgroup analyses (items 13, 20, 21). Outcomes will be discussed as aforementioned through the use of qualitative meta-summary or narrative synthesis. Registration with PROSPERO is not appropriate in the case of this review, as it does not concern itself with a clinical intervention.

Discussion

It is unclear how medical device procurement and prioritization take place within LMICs. Internationally proposed guidelines, recommendations or reports—whether developed by public health agencies or research institutions—are routinely issued to counsel LMICs on this topic and may impact upon their national policy formulation. It is therefore germane to understand the procurement/prioritization methodologies proposed within this literature. The aims of this systematic review are to identify said methodologies, explore the factors reported as affecting procurement practices in LMICs and create an initial framework for how medical device prioritization and procurement should be designed and conceived in resource-constrained settings.

We acknowledge several limitations of the proposed endeavour. First, we note the difficulty associated with undertaking a first-line review on a topic associated with methodologically diverse literature. We expect that documents reviewed will range from procurement notices and emergency medical device lists to procurement manuals or research studies on medical device prioritization. As little prior evaluative literature on this topic exists and as heterogeneous priority setting criteria are suggested to be equally legitimate [31], we are reluctant to quality appraise studies we include in the review or limit inclusion to only one type of study which may advance a particular prioritization methodology. This may imply more laborious and complex data analysis and may furthermore undermine the validity of any findings. Reviewing the literature obtained from such diverse sources, however, is greatly beneficial for hypothesis generation as it allows for consideration of multiple viewpoints and identification of minutiae associated with medical device prioritization and procurement for LMICs. In particular, it will allow for the mapping of all the different types of literature and potential methodological differences on this topic.

Second, we make no concerted effort to identify or include national policy documents relating to medical devices in this review. This is because the focus of the review is normative and concerns itself with the identification of procurement and prioritization methodologies within

internationally disseminated recommendations and guidelines as well as research studies. We are thus interested in answering the question of how procurement and prioritization *should* take place considering current research and guideline materials. We acknowledge that national policies may in fact employ different procurement or prioritization methodologies, which we may fail to identify here and thus, encourage further inquiries into both the policy literature as well as the empirical implementation literature beyond. Should materials meet inclusion criteria, they will be selected for review. It is beyond the scope of this review to undertake an appraisal of all internationally available policy documents. Indeed, we caution that a systematic review of policies alone may fail to identify macro-level issues and themes relating primarily to international decision making paradigms (e.g. paradigms of international donor organizations or funding bodies supporting LMIC procurement). An inquiry into the normative bases of medical device procurement for LMICs is valuable in the initial exploration, and identification of issues, paradigms and processes is to be considered by decision makers. Review findings may provide a starting point to future policy analyses or research endeavours within this field.

Furthermore, the review may be limited in scope, as it is not designed to identify and include prioritization methodologies referring to entire intervention packages rather than devices or equipment. To make sure that applicable methodologies are not discounted, reviewers will consult experts in international health to identify any such relevant methodologies and discuss the findings of the current review in light of these.

An accurate understanding of medical device procurement and prioritization methods is of particular importance in resource-constrained settings with limited financial capabilities, human resource skills and health infrastructure. The findings of this systematic review will provide initial hypotheses as to what factors and stakeholders affect these processes and may aid in the formulation of a quality assurance framework able to provide LMIC decision makers with a rounded conceptualization of the topic.

Additional file

Additional file 1: Definitions: Medical device procurement. Definitions for medical device/equipment procurement and prioritization within procurement cycles are provided.

Abbreviations

HICs: high income countries; HIV: human immunodeficiency virus; LMICs: low- and middle-income countries (World Bank definitions apply); MSH: Management Sciences for Health; PRISMA: preferred reporting items for systematic reviews and meta-analyses; PROSPERO: international prospective register of systematic reviews maintained by the Centre for Reviews and Dissemination, University of York, UK; TB: tuberculosis; UNAIDS: the joint United Nations Programme in HIV/AIDS; UNFPA: the United Nations Population Fund; USAID: United States Agency for International Development; WHO: World Health Organization.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KD developed and drafted the current study protocol. YFC, SMH, CC and RL participated in the critical drafting of the protocol and offered advice on the research methodologies employed. All authors read and approved the final manuscript.

Authors' information

Karin Diaconu is a doctoral researcher exploring medical device prioritization and the use of health economic methodologies for prioritization purposes in low- and middle-income countries at the University of Birmingham. Yen-Fu Chen is a senior research fellow with considerable experience in health technology assessment and systematic reviews within the Warwick Centre for Applied Health Research and Delivery at the University of Warwick. Semira Manaseki-Holland is a senior clinical lecturer with substantial health service management experience in low- and middle-income settings at the University of Birmingham. Carole Cummins is a senior lecturer and researcher involved in the NIHR Birmingham and Black Country Collaboration for Leadership in Applied Health Research and Care (BBC-CLAHRC) at the University of Birmingham. Professor for Clinical Epidemiology, Richard Lilford is the director of the BBC-CLAHRC at the University of Birmingham and head of the Warwick Centre for Applied Health Research and Delivery at the University of Warwick.

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1. SYSTEMATIC REVIEW

1. 1. INTRODUCTION

Successful health service delivery hinges on the safety, availability, accessibility, appropriateness and affordability of medical technologies, including medical devices and equipment (MDEs). (1,2) Rising costs and the pro-technology bias encountered among patients and clinicians challenge health systems globally and prompt countries to explore cost-effective health care solutions. (3)

To ensure efficient resource allocation and optimal technology usage, high-income countries (HICs) have invested in the development of health technology assessment (HTA) methods and institutions. Organizations such as the National Institute for Health and Care Excellence in the United Kingdom, the Canadian Agency for Drugs and Technologies in Health and the Medical Services Advisory Committee in Australia have been established to guide procurement decisions on the basis of evidence-review and cost-effectiveness principles. (4–6) Such agencies are increasingly emerging across low- and middle-income countries (LMICs); notable examples include organisations in Thailand, Taiwan and Mexico. (7–11) HTA methods are however inconsistently used across settings. For example, Griffiths et al suggest substantial differences exist in the use of health economic methods across LMICS.(12) Findings of the 2015 WHO Global Survey on Health Technology Assessment similarly indicate that MDE specific HTA appraisals focus predominantly on technology safety and clinical effectiveness rather than value for money.(13)

Inefficient spending patterns relating to MDEs have been reported across LMICs resulting in technology deployment difficulties. Estimates suggest that between 40-70%

of MDEs in resource poor settings are broken, unused or unfit for purpose. (1,14) In the Priority Medical Devices report, the World Health Organization (WHO) suggests three causes for this problem: indiscriminate procurement methods, substantial infrastructural/financing challenges and absence of national regulatory authorities. (5)

Little is known about how MDE procurement takes place within resource-constrained settings. The WHO Baseline Survey on Medical Devices is a recent attempt to explore this. (16) The survey's findings suggest that LMICs predominantly conduct procurement at central ministry level within the public sector. However, the survey does not provide further granular information on how LMICs plan or select what devices to procure. Identifying best practices and common pitfalls in MDE planning may pre-empt challenges in technology deployment, adoption and use and lead to improved population health outcomes. Ascertaining pragmatic MDE prioritization criteria and methods is very timely given the recent global focus on health system strengthening.

This chapter reports on the findings of a systematic literature review meant to explore the following research questions:

- What methods inform or are recommended for MDE procurement in LMICs?
- What evidence-base is used in, or what factors impact upon, procurement methods/processes?
- What prioritization criteria are used in MDE procurement?

1. 2. METHODS

The protocol presented in Section 1. 0. offers a full account of methods used. For ease, methods are briefly presented below.

Searches and study selection

Both bibliographic databases and grey literature were searched with no language or time restrictions imposed. KD and Matthew Bentham (MB) selected documents according to pre-specified screening and eligibility criteria. See Tables 1-2 for details on sources searched and search strategy employed; Figures 1-2 illustrate the document screening and abstract selection criteria.

Searches retrieved documents referencing MDEs, LMICs and procurement. Two independent reviewers (KD and Samantha Burn - SB) screened titles for relevance, discarding documents not referencing medical technologies. KD and MB further screened abstracts according to pre-specified inclusion/exclusion criteria. (Figure 2) Documents with explicit references to MDE procurement processes or procedures within LMICs were retained; material focusing on the procurement/evaluation of a single device or on LMIC medical technology regulatory issues was excluded. Disagreements on the inclusion/exclusion of studies involved consultation of a third reviewer (SB) and were resolved by consensus.

Data collection

One reviewer (KD or MB) extracted data on a pre-specified list of questions from all included documents. (see Protocol) Questions related to: accounts of MDE procurement and technology management processes; the relevance of health HTA and health needs

assessments in procurement; the input of health care professionals or specialist staff (e.g. biomedical engineers, economists) in procurement decisions; device installation, maintenance and decommissioning procedures/recommendations; health service delivery levels and clinical guideline procurement recommendations; budget impact, technology costs and intended national/regional coverage levels. KD ascertained if documents included explicit accounts of MDE prioritization processes and extracted quotations or descriptions of processes for qualitative analysis. Please see Appendix 7 for a full list of references and data extracted.

Analysis

Two methods of analysis were employed to summarize and interpret the data extracted. (Figure 3) Narrative synthesis was used to offer a summative and descriptive overview of issues relevant to research questions posed.(17) Qualitative meta-summary was used to explore MDE prioritization for those documents outlining explicit prioritization methods/processes. KD iteratively applied descriptive codes to the extracted data and then grouped similar codes into categories and themes. Emergent patterns and relationships between themes were explored to arrive at summative findings. (18)

Reporting

PRISMA reporting guidelines were followed as applicable. (19,20)

1. 3. FINDINGS

Bibliometric analysis:

The search strategy located 11,220 unique records of which 217 were selected for inclusion, all published 1984-2013. As several records retrieved were entire books or journal issues where more than one chapter or article met the inclusion criteria, data was extracted from 250 individual documents. Figure 3 shows a PRISMA flow-chart outlining the study selection process. Section 1. 6. includes a full reference list of included records and the ancillary electronic files include a full list of data extracted.

Tables 3-4 present characteristics of included documents. The majority are peer-reviewed journal articles (n=125, 50%) and recommendations or guideline documents synthesizing lessons from international procurement experiences/practices. (n=72, 29%) The WHO and other UN associated organizations authored 141 (56%) documents. Only 50 (20%) documents refer to specific countries or regions, the remaining documents referencing resource poor settings or LMICs in general. (Table 4)

As procurement methods may differ by technology, data on cited health conditions/clinical interventions (Table 5) and MDE descriptions (Table 6) was also extracted. Predominantly, documents reference HIV/AIDS and associated comorbidities (n=29, 12%) and interventions for reproductive, maternal and child health. (n=23, 9%) MDEs referenced include laboratory devices (n=22, 9%), equipment for surgical care (n=16, 6%) and reproductive health (n=16, 6%). No consensus classification system for

equipment or devices was stated; authors instead categorized equipment according to size, cost, clinical area or health service delivery level. (Table 6)

Narrative synthesis: Procurement structures and methods

1. What methods inform, or are recommended for, MDE procurement in LMICs?

A distinction must be made between descriptions of MDE procurement structures – i.e. how stakeholders interact and reach decisions, from procurement methods – i.e. algorithms or approaches used to determine which technologies to purchase.

i) *Procurement stakeholders and their interactions*

Appraised documents identify different stakeholder groups interacting to reach procurement decisions. Stakeholders range from international donor agencies, LMIC governments and ministries of health to individual LMIC health facilities. Stakeholders operate at different health system levels and appear to perform different procurement tasks (Figure 4). Across documents, authors indicate that procurement activities frequently involve all stakeholder groups outlined; only one document described processes where donors solely undertook procurement on behalf of LMICs. (21)

At macro level, authors of reviewed documents describe international donor agencies and LMIC governments engaging in procurement partnerships. LMICs possess the human resource and health system capacity to support donor campaigns; in turn, donors share financial and technical resources. For example, Management Sciences for Health (on behalf of USAID) prompted the government in Afghanistan to use health economic

and ethical criteria in defining the basic and hospital care package. (22,23) Donors (e.g. USAID) and international agencies (e.g. UNICEF) enjoy a greater share of market power than LMICs due to their involvement in multi-country procurement. Donors thus provide an advantageous negotiation position for LMICs, helping secure flexible payment or bulk-pricing arrangements. (24,25)

Potential disadvantages of donor involvement include sudden discontinuation of assistance arrangements and financial aid restrictions. (25) For example, donors may restrict financing to countries adhering to strict procurement/tendering regulations; such restrictions may preclude LMIC governments from strengthening technology-manufacturing capacity through the award of national procurement contracts. (24) Similarly, funding opportunities may be restricted to donor-preferred causes such as HIV/AIDS diagnosis and treatment, and preclude investments into incipient health system infrastructure, including for example sanitary provisions (e.g. water and sewage), electricity supply and infection prevention and control protocols. (26)

At meso level, LMIC governments, their ministries of health and relevant subunits engage in the minutiae of acquisition planning, tendering and equipment distribution/oversight activities. Stakeholders set procurement targets - i.e. project what equipment to procure via the use of experience or needs based planning methods (see next section) - and agree national technology distribution plans. (1,27)

Not all medical device procurement decisions are made at regional, country or supra-national level: individual health facilities also engage in direct acquisition. (28,29)

Authors of reviewed documents caution that such practices are inconsistent: hospitals frequently lack dedicated funding for MDE procurement and may instead rely on donations, reuse and recycling practices, to meet technological needs. (28,30,31).

Whichever stakeholders engage in procurement processes, the literature is largely unclear on how stakeholder views are aggregated or divergent opinions handled - only three documents including descriptions of such accounts were identified. Nobre et al. point to the usefulness of multi-criteria decision analysis methods, aimed to aggregate and integrate individual stakeholder opinions to reach final technology selection decisions. (32) Consensus methods or DELPHI processes (33) and routine committee based evaluations of procurement processes (34) are further discussed.

ii) Procurement methods

Thorough review of the literature suggests two main MDE procurement methods are used, or proposed for use, across LMICs. Stakeholders either rely on experience to determine what equipment to procure or engage in needs-assessment exercises to determine what equipment is most appropriate for meeting current health service needs. When using the former method, past procurement and consumption patterns are reviewed and used as a template for reaching current and future decisions. For example, this method was used in the development of the first Core Medical Equipment lists collated by the WHO. To develop the latter lists, biomedical engineers and clinical experts reached a consensus on the type of MDEs that different health care facilities should stock based on professional expertise and experience. This method is particularly

useful in areas affected by little to no innovative practice, e.g. it may be used to keep an existing laboratory functional provided service delivery does not change. (27)

In contrast to experience-based methods, needs-based procurement relies on stakeholders explicitly defining health priorities at any given time and agreeing service delivery targets based on context specific epidemiological information. For example, the WHO Priority Medical Devices Availability Matrix identifies conditions corresponding to the highest global (or national) burden of disease and indexes interventions corresponding to these conditions. (35) Devices necessary for carrying out each intervention are listed and added to a 'wish list'. Such methods thus identify prescient health needs and evaluate procurement options in the context of defined vertical/horizontal programs, available budgets, present physical infrastructure and human resource skill mix/availability. (36–38) Needs-based methods may also rely on the development of basic or advanced health care packages- e.g. see the Basic Package for Primary Care Services by the Ministry of Health in Afghanistan. (22,23)

In practice, stakeholders are reported to use mixed-method approaches. For example, CENETEC in Mexico uses historical procurement trends to recommend what equipment to buy in clinical areas with little to no innovative or updated practice, and needs-based methods to issue procurement recommendations for national priority health care areas such as tele-medicine or cancer care. (39)

2. Factors and evidence inputs considered in procurement decisions

Table 7 summarizes factors and evidence inputs referenced as influencing procurement; the citation frequency of each item is suggested as a proxy for the relative importance of the factor in decision-making.

Equipment cost, specialist recommendations and technology regulatory approval are the primary factors that appear to influence procurement decisions. Authors of reviewed documents caution that the true cost of MDEs is underestimated in practice as stakeholders neglect to include costs associated with MDE maintenance, servicing and user training requirements. (1,39–44) Across the literature, the input of specialists is recommended to ensure improved technology procurement: e.g. biomedical engineers can advise on maintenance/servicing/user training issues, and health economists on the relative cost-effectiveness of technologies. (1,42,45–51) Appraised documents also cited international certification (e.g. approval by the FDA, a CE mark in the EU, inclusion in a WHO prequalification scheme) as a proxy for technology safety, a desired feature in MDEs to be procured. (41,52,53)

Evidence inputs identified across the literature include: health needs assessment (HNA) exercises/reports, clinical guidelines and health technology assessment exercises/reports. HNA is cited in relation to needs-based procurement methods: i.e. routine health-needs appraisals clarify national investment priorities. (35) Authors of reviewed documents widely endorse the use of clinical guidelines for technology selection; however note these do not historically include clear technology

investment/use recommendations.(35) Additional inputs considered are MDE availability checklists and tools designed around clinical guidelines. (54–56)

Few documents cite the use of HTA, though where referenced, the relevance of HTA for MDE procurement, more specifically for product selection, is strongly emphasised. (42,49) Authors of reviewed documents comment on the difficulty of undertaking HTA (health economics in particular) within resource constrained settings due to data paucity, lack of specialist capacity and funding, and a general lack of knowledge on how such evidence may feed into decision making processes. (1,50,51) MICs, however, have made substantial progress in the use of HTA for the promotion of transparent and evidence-based decision making: e.g. see HITAP in Thailand, CENETEC in Mexico and a bill for the promotion of HTA use across Latin America. (34,39,50)

Data on the factors cited as affecting medical device uptake or use in LMICs was also extracted. Frequent challenges of relevance to procurement decision-makers include careful technology specification and alignment to deployment setting and ambient conditions/skills mix encountered therein. (Table 8)

Findings of the meta-synthesis: MDE prioritization criteria

One hundred and one of the 250 reviewed documents included explicit accounts of MDE prioritization methods; these documents were included in the meta-synthesis to explore and identify MDE prioritization criteria. Please see Appendix 3 for a full account of findings generated and codes and abstracted themes/topics developed during the meta-synthesis.

Five main prioritization criteria corresponding to both normative and feasibility issues were identified across reviewed documents. Criteria are listed below in order of descending citation frequency. (Appendix 3) MDEs are prioritized for procurement when they:

- Are of LMIC-appropriate technical specification, i.e. MDEs :
    - Align with the skills and coverage levels of available human resources: e.g. technologies are easy to use and do not rely on the presence of specialist staff;
    - Align with the infrastructure impositions encountered in resource poor deployment settings: e.g. technologies include water filters and provisions for uninterrupted power supply;
- Correspond to essential or priority health interventions, i.e. MDEs :
    - Relate to health services already delivered within the current health system structure or add to the range of services to be delivered;
    - Relate to an established health priority and are clinically effective;
- Are financially sustainable for the health system;
- Are cost-effective;

- Are politically and socially acceptable in intended deployment settings.

Recurrent themes in the literature concern the identification of priority health areas and services as well as the identification of technologies suitable to deployment settings. (See Table 9 for data extracted on LMIC friendly technical specifications.) For example, the WHO, USAID and UNFPA all recommend prioritizing MDEs used in interventions addressing prominent disease burdens or supporting existing health service delivery efforts. (30,35,57) Purchases are further screened and prioritized according to their suitability to LMIC settings: i.e. MDEs for which no trained professionals are present or which lack established maintenance or decommissioning services are deprioritized for purchase/marked for disinvestment. (31,39,41,58–60)

Budget constraints, experiences gained in past procurement cycles, political/cultural support and equity considerations also influence prioritization decisions. Current and future budget impact is balanced against evaluations of past procurement performance: e.g. if supply chains are not present to source a particular technology, this is either deprioritized or alternative sources for investment identified. (61) The consideration of budget impact at product selection and technology purchasing/adoption stages in LMICs therefore contrasts with practices in high-income settings. For example, countries such as the UK view budget constraints as secondary to adoption decisions and HTA assessors are urged not to reach technology selection decisions based on a product's likely budget impact.(62) Non-invasive, culturally acceptable technologies with records of accomplishment and safe use are preferred; however, technologies endorsed by political groups may further bypass normal prioritization or decision-making channels and be procured on the basis of strong advocacy. (63)

Patterns in extracted texts suggest different types of criteria are considered at different decision making-levels. (Figure 5) This may be due to stakeholders at each health-system level undertaking/being responsible for different prioritization steps. For example, micro-level stakeholders - i.e. health care professionals in individual health facilities - are described as prioritizing equipment according to technical specifications and design: portable, durable, electric-surge resistant equipment. (64,65) Meso-level stakeholder - i.e. regional and specialist authorities engaged in procurement planning in the context of interventions/programs- in turn prioritize equipment that is affordable, sustainable financially for long-term use, and ideally cost-effective. (38,66)

1. 4. DISCUSSION

The current manuscript is the first review to systematically appraise LMIC specific medical device procurement literature. The findings of this systematic review suggest that MDE procurement within LMICs presents substantial differences to technology procurement within HICs. While individual health facilities may have the capacity to directly tender in the latter settings, review findings indicate this practice is not consistent across LMICs. HICs further use HTA and health economic principles and methods to select technologies appropriate for reimbursement and advise on the containment of health care costs. (4,5) Only a fifth of documents included here reference such methods for MDE procurement. Difficulties in using health technology assessment and/or health economics within LMICs are widely noted in the literature; political, cultural and specialist support for the use of such methods is lacking and the necessary data on local epidemiology, costs and treatment impact for LMICs is also scarce. (8) Such methods are, however, recommended for the development of transparent and rational procurement practices(67–69) and more or less intense implementation pathways can be pursued. For example, Chalkidou et al (7) propose the development of a holistic decision-making system where HTA principles are incorporated in all stakeholder deliberations and applied to all publicly funded health care services. In contrast, Lilford et al. (70) recommend the use of a pragmatic decision-algorithm to identify contentious investment options for which a full HTA report and health economic analysis is to be commissioned.

The review further identifies two over-arching methods used or proposed for MDE procurement: experience-based methods rely on the perceived success of previous procurement exercises; need-based methods instead identify current health needs and develop bespoke technology procurement plans to tackle these. It is necessary to conceptualize methods as embedded within specific decision-making systems: documents included in this review cited a wide-user buyer divide. Stakeholders at meso or macro health system levels are responsible for procuring technologies but are not direct technology users and cannot call on MDE use experience during product selection stages. In contrast, MDE users are likely to be heavily influenced by their own clinical or procurement experience and may neglect to objectively consider all potentially appropriate technologies that would meet health service needs and be financially sustainable. While no consensus emerges on how LMIC based MDE procurement should occur, opinions in the literature converge on what evidence inputs and factors should be considered in decision-making. Table 10 synthesises recommendations and best practice noted in the literature.

The findings of the meta-synthesis echo previous work on normative and feasibility criteria considered by decision makers in technology investment and prioritization. (68,71–73) In contrast to previous conclusions, however, MDE procurement is chiefly driven by feasibility concerns: i.e. as MDEs run the substantial risk of being unused due to technology misalignment to deployment settings. Decision makers should therefore prioritize products with appropriate technical specifications and established maintenance services. Further research into a unified set of criteria able to guide LMIC

medical device and equipment procurement is needed. Criteria identified here may serve as a first draft of such a document.

The findings of this review should be interpreted with due caution - this was a hypothesis generating exercise meant to explore the state of the literature; best practices in MDE procurement were synthesised to inform current professionals and researchers in this field of global trends. The search and selection algorithms were deliberately broad and only digitised materials were consulted. Materials were substantially heterogeneous, ranging from procurement bids and reports to guideline documents or procurement checklists. Normative and descriptive findings were not always clearly distinguished in the included documents and therefore are presented here alongside one another. Reviewed documents frequently included reflections on past procurement experiences (descriptive accounts) alongside notes on desired or optimal practices (normative accounts). A full picture of these accounts is offered: Tables 7-8 include key references to both descriptive and normative accounts under "areas of concern"/"best practice" respectively; Table 9 summarizes normative recommendations on MDE design as derived from descriptive accounts in the literature (references in Appendix 3); Table 10 summarizes normative positions echoed in the literature with relevant examples referenced. Despite the variability in sources, perspectives and accounts included, the systematic review offers a comprehensive account of methods and prioritization criteria relevant to MDE procurement efforts.

Despite the variability in sources and accounts included, the systematic review offers a comprehensive account of methods and prioritization criteria relevant to MDE procurement efforts.

1. 5. CHAPTER SUMMARY AND KEY FINDINGS

A systematic review of the literature on LMIC-specific MDE procurement methods is presented; 250 individual documents were appraised. Documents were identified following a thorough search of both bibliographic and grey literature and application of strict inclusion and exclusion criteria. Materials included research articles, procurement reports, recommendation documents as well as guidelines or checklists. Across documents, a diverse set of recommendations on how MDE procurement should be undertaken emerges; recommendations and notes on best practice were synthesised using both narrative synthesis and qualitative meta-summary.

> *Key Finding 1: The literature suggests two main methods are used (either solely or in combination) for product selection; stakeholders are either guided by past procurement experience or focus on identifying products to address a high priority condition.*

Experience based-methods imply the review and/or evaluation of historical procurement trends and updating procurement practices as needed on a case-by-case basis. The opinions and personal experiences of stakeholders, of both the procurement process and products selected, form the foundation of this method. (E.g. see (27,74)) Needs-based methods in contrast rely on stakeholders first identifying a health area of need and then products necessary for service provision in this area. (E.g. see (35)) Methods are likely to be combined in practice.

> *Key finding 2: MDE cost and technical specifications/alignment to ambient conditions are the primary factors influencing product selection. Evidence*

sources such as health needs assessments are also relevant, however, health technology assessment is mentioned in few documents.

The systematic review also explored what factors, issues or evidence sources were noted as relevant to procurement planning. Authors noted that cost is the most significant factor affecting MDE selection: high product costs are prohibitive for resource constrained settings and decision-makers therefore procure cost-minimizing technologies. Authors of reviewed documents emphasise, however, that decision-makers may neglect to consider the full life-cycle cost products are likely to incur; costs for user training, maintenance and servicing are frequently not considered. Where such costs have not been accounted for during product selection, devices are likely to remain unused during deployment.

Use of relevant evidence may improve procurement planning; the systematic review therefore documented the types of evidence sources decision-makers may turn to when selecting MDEs. Notably, the review suggests health needs assessments play a major part in procurement planning. In contrast, health technology assessment (HTA) reports/health economic (HE) evaluations are referenced in a minority of cases, suggesting the relevance and potential of such methods is not widely realized across stakeholders.

Key Finding 3: The literature suggests MDE procurement is a complex process where stakeholders acting at different health system levels undertake different actions.

Authors of reviewed documents emphasize that a multitude of stakeholders are engaged in MDE procurement. Macro-level stakeholders for example may set the overall

direction or scope for MDE related resource allocation; meso-level agents (e.g. regional planners) may instead be responsible for the tendering and distribution of products. End-users – that is clinicians and patients – are mainly consulted on issues of clinical need and product experience. The involvement of multiple stakeholders and tendering at meso-level by planning decision-makers, rather than clinicians, creates a user-buyer divide. This divide leaves room for discoordination when stakeholders do not realize effective and efficient communication channels between decision-making levels.

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1. 8. TABLES

TABLE 1: SOURCES SEARCHED*

Search type	Search sources	
OVID Medline searched as per search algorithm detailed in protocol	Bibliographic databases	OVID Medline, OVID Embase, Cochrane Library, CEA Registry, HMIC, Econlit, VHL Portal (includes LILACS) African Index Medicus, NHS EED, Web of Science (including CPCI)**
Key word searches	Website searches	TRIP, National Guideline Clearinghouse, Office of health economics International Guideline Library, CHEPA, CHE York HTAi, CADTH, INAHTA
	Organizational databases/websites	WHO e-health documentation centre and WHO website, UNICEF, UNAIDS, UNFPA, African development bank, Asian Development Bank, EBRD, World Bank, MSF, UNDP
	National/regional donor or research agencies	DFID, MSH, AUSAID, GIZ, BMZ, JICA, SWISSAID, CIDA (Canada), DANIDA, AFD, ACORD, SIDA, IAC
	Grey literature	ZETOC

*Pascal was mentioned in the protocol but was not accessible; 'Solutions for public health', BMJ Clinical Evidence and EBRD were searched but found not relevant – searches were discontinued.

**Latter bibliographic databases searched via key-word searches as per below table rows.

TABLE 2: SEARCH STRATEGY

1. device.mp. or exp "Equipment and Supplies"/

2. (device* or equipment* or suppl*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

3. exp Technology, Radiologic/ or exp Technology Assessment, Biomedical/ or exp Fiber Optic Technology/ or exp Educational Technology/ or exp Biomedical Technology/ or technology.mp. or exp "United States Office of Technology Assessment"/ or exp Technology/ or exp Food Technology/ or exp Technology, High-Cost/ or exp Technology Transfer/ or exp "National Center for Health Care Technology (U.S.)"/ or exp Wireless Technology/ or exp Technology, Dental/ or exp Green Chemistry Technology/ or exp Technology, Pharmaceutical/ or exp Remote Sensing Technology/

4. 1 or 2 or 3

5. (procure* or purchas* or acqui* or commission* or buy*or order*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

6. (countr* adj2 (income or poor or poverty or develop* or resource or low* or mid*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

7. (third adj2 world).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

8. (emerging adj2 (econom* or market*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

9. developing country.mp. or exp Developing Countries/

10. 6 or 7 or 8 or 9

11. 4 and 5 and 10

Conducted last: 28 January 2013, 15:10 (GMT)

Number of records identified: 2297

TABLE 3: TYPES OF DOCUMENTS INCLUDED IN THE SYSTEMATIC REVIEW AND TYPE OF ISSUING ORGANIZATION

	Research institutions or academic groups	LMIC national health authorities	International consultants, NGOs or public health monitoring organizations	Hospitals or health care delivery facilities	Medical device manufactu -rers	Government sponsored donor organizations and the World Bank	WHO and UN associate	Not identi-fied	Total number of documents (% of total)
Article	47	8	25	16	2		25	2	125 (50.00%)
Bulletin			3			1			4 (1.60%)
Checklist							3		3 (1.20%)
Presentation				1		1	3		5 (2.00%)
Consultative document							1		1 (0.04%)
Evaluation		1							1 (0.04%)
Guideline	1	2	6				25		34 (13.60%)
Information booklet									1 (0.04%)
Manual							14		14 (5.60%)
Policy		2							2 (0.08%)
Procurement notice		10	1						11 (4.40%)

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	Research institutions or academic groups	LMIC national health authorities	International consultants, NGOs or public health monitoring organizations	Hospitals or health care delivery facilities	Medical device manufactu -rers	Government sponsored donor organizations and the World Bank	WHO and UN associate	Not identi-fied	Total number of documents (% of total)
Recommendation	4	1	5	3		5	19	1	38 (15.20%)
Report						1	6		7 (2.70%)
Resolution							1		1 (0.04%)
Spread sheet / database							2		2 (0.08%)
Website							1		1 (0.04%)
Total number of documents (% of total)	50 (20.00%)	24 (9.60%)	40 (16.00%)	20 (8.00%)	2 (0.08%)	8 (3.20%)	101 (40.40%)	3 (1.20%)	250

*Definitions: Research institutions or academic groups = Universities, specialist research bodies or collaborations; LMIC national health authorities = national governments, government units or departments; International consultants, NGOs or public health monitoring organizations = Organizations such as Management Sciences for Health, the Centre for Disease Control among others; Hospitals or health care delivery facilities = organizations with clinical health service delivery remit; Medical device manufacturers = commercial entities and device suppliers; Government sponsored donor organizations and the World Bank = USAID, DFiD, GIZ, CIDA and the WB; WHO and UN Associate = WHO, PAHO and UNDP, UNFPA, UNAIDS; Not identified = document authors solely, no identified issuing organization.

Article = peer-reviewed material published in academic journal or magazine; Bulletin = notification; Presentation = conference presentation or talk/speech; Consultative document = draft document circulated for comment; Evaluation = audit document; Guideline = document identifying guiding principles and procedures; Information booklet = document providing basic information on interventions/devices; Policy = LMIC issued document relating to device management; Procurement notice = tendering or bidding documents, initial advertisements of tender; Recommendations = Research or review documents providing clearly stated summary recommendations; Report = document with pre-specified topic, may include research evidence, discussion of current and best practice; Resolution = document with statement of intent; Spread sheet/ database = collection of medical device specifications and prices; Website = online published article/database

TABLE 4: PARTICULAR COUNTRIES AND REGIONS REFERENCED IN DOCUMENTS INCLUDED* (FREQUENCIES OF CITATION) GROUPED ACCORDING TO 2014 WORLD BANK COUNTRY CLASSIFICATION

Low-income countries	**Low-middle income country**	**Upper-middle income countries**	**High income country**	**Referenced regions**
Benin (1)	Bolivia (1)	South Africa (1)	Chile (1) **	Balkan countries (1)
Guinea-Bissau (1)	Cameroon (1)	Peru (1)	USA (1) ***	Eastern Europe (2)
Congo (1)	Guyana (1)	Brazil (3)		Africa (1)
Mali (1)	Mongolia (1)	China (2)		
Chad (1)	Pakistan (1)	Thailand (1)		
Eritrea (1)	Philippines (1)	Mexico (1)		
Ethiopia (2)	Vietnam, (1)			
Gambia (1)	Zambia (1)			
Afghanistan (2)	Lesotho (1)			
Bangladesh (2)				
Kenya (1)				
Malawi (1)				
Morocco (1)				
Nepal (3)				
Tanzania (3)				
Uganda (1)				
Zimbabwe (1)				

*Citations are made in 50 documents (one document may refer to more than one country). Remaining documents reference LMICs generally.
** Chile was classified as an upper middle income country up to 2014.
*** The USA is used as a comparator in one study.

TABLE 5: SPECIFIC HEALTH CONDITIONS, DISEASE AREAS AND SERVICES/INTERVENTIONS CITED ACROSS THE INCLUDED LITERATURE (FREQUENCIES OF CITATION)*

Health conditions and disease areas cited and frequency of citations		**Service areas/interventions cited and frequency of citations**	
AIDS/HIV and associated comorbidities	29	Interventions for reproductive, maternal and child health	23
Cancer	16	Surgery and trauma care	13
High burden diseases: diarrhoea, malaria, HIV, respiratory issues	7	Emergency medicine and disaster response	4
Malaria	5	Injection practices	2
Cardiological conditions	3	Imaging	2
Respiratory conditions, asthma and COPD	3	Blood safety	1
Tropical diseases	2	Forensic science	1
Gastroenterological conditions	2	Primary care	1
Tuberculosis	2		
Bacteriological diseases and interventions	1		
Measles	1		
H1N1, H5N1	1		
Narcotic use	1		
Renal disease	1		
Non-communicable diseases	1		
Fractures and orthopaedic conditions	1		
Cardiovascular disease	1		

*Total n= 124, remaining documents do not include references to specific health conditions. (One document may reference more than one condition/clinical area.)

TABLE 6: EQUIPMENT CATEGORIES FOR PROCUREMENT AS NOTED IN THE REVIEWED LITERATURE (N=131)

Classification of equipment (frequency of citation)		Equipment or device cited (frequency of citation)	Selected key references*
Cost and size	High cost (>$25,000) (1) Large medical equipment (1)		SR20: Nah, 2007 SR78: Miao, 2007
Risk associated with use	High risk: implants (1)		SR 35: Keller, 2010
Area of use	Surgical care and trauma (16) and emergency care (7)	Anaesthetic (5) Instrumentation and other devices (7) Oxygen supply and monitoring: concentrators and pulse oximeter (3) Intensive care (1) Instrumentation and resuscitation equipment (7)	SR40: Arevalo, 2007 SR57: McCunn, 2010 SR6.: Bewes, 1984 SR167: WHO, 2007
	Reproductive, maternal and child health (16)	Condoms and contraceptives (6) Birth kits and instrumentation (8) Obstetric instrumentation and devices (2)	SR42: Chandani, 2001 SR82: Nessa, 1992 SR138: WHO, 1991
	Cancer treatment (5)	Radiotherapy: megavoltage, linear accelerator (5)	SR162: Borras, 1993
	Diagnosis (27)	Laboratory and RDT (16) Imaging and laboratory (6), CT and ultrasound (4), X-ray (1)	SR149: WHO, 2003 SR158: Palmer, 2011
	Gastroenterology (1)	Gastroenterological equipment (1)	SR84: Nicholls, 1984
	Respiratory (4)	Ventilators, nebulizer, equipment for diagnosis of COPD (1), or asthma diagnosis/monitoring (4)	SR197: IUaTBLD, 2008
	Cardiology (4)		SR15: Ribeiro, 2010
	Ophthalmic (1)		SR161: PAHO, 1999

Classification of equipment (frequency of citation)		Equipment or device cited (frequency of citation)	Selected key references*
	Orthopaedic (1)		SR71: Ruyter, 1984
	Cold chain, blood supply and transfusion services (9)	Biotechnologies (1) Refrigeration, injections, transfusion devices and storage (3) Cold chain (2) Vaccines (1) Infection control (2)	SR19: Thorsteinsdottir, 2007 SR148: Lloyd, 1999 SR58: Ansa, 2002 SR256: Woodle, 2000
	Infectious diseases (11)	HIV diagnosis and treatment (6) Malaria diagnosis and treatment (2) Tuberculosis (3)	SR28: Walkowiak, 2008 SR90: Onwuwejke 2000 SR92: Parsons, 2011
Health service delivery level	Primary (1)	Primary level health care equipment(1)	SR141: Kaur, 2001
	Secondary or tertiary (9)	Hospital: diagnostic and imaging, instrumentation (9)	SR4: Unknown, 2005
General descriptors	Miscellaneous (11)	Consumables/disposables, instruments, minor diagnostics and treatment/monitoring (8) Waste management (1) Injections (4)	SR18: Hussein, 2004 SR154: Pruss, 1999 SR117: Ekwueme, 2002

*References marked SR refer to documents included in the systematic review.

TABLE 7: EVIDENCE INPUTS AND FACTORS CONSIDERED IN MEDICAL DEVICE PROCUREMENT PLANNING

Factors/evidence input	Definition	Area of concern	Selected key references*	Best practice	Selected key references*
Costs (n=161)	Costs considered in the procurement planning process	Costs associated with medical device installation, maintenance and disposal, user training are not routinely included during product selection.	SR143: WHO, 2011 SR122, 124-131: WHO, 2010	Include all afferent expenses associated with medical device deployment to health facilities.	SR241: Martin, 2005 SR247: Free, 1993 SR122, 124-131: WHO, 2010
Specialist expertise (n=78)	Biomedical engineer, health economist, clinical or procurement specialist input into decision making	Lack of availability within LMICs and potential lack of technology specific expertise in aid/donor organizations.	R79: Mullally, 2008 SR26: Mundy, 2012 SR34: Mundy, 2012	Create national training programs/specialized procurement units to advise on biomedical engineering issues/health economics.	SR63-69: Bloom, 1989 SR80: Mytton, 2010
Regulations and standards (n=72)	Equipment conformity to international regulations/approvals: FDA, EU- CE mark	International registration may result in product price increases and prove difficult to review via national structures.	SR163: WHO, 2012 SR133: WHO, 2011	High-risk equipment should be internationally certified to ensure it is safe for use.	SR35: Keller, 2010
Health needs assessment (n=86)	Identified population health priorities and/or technological needs	May not provide full/trustworthy information and be disregarded in national decision making under financial constraints.	SR38: Aid-Khalet, 2001 SR56: Mavalankar, 2004	Participatory structures where health facilities may participate in commissioning/procurement planning/tender.	SR122, 124-131: WHO, 2010 SR176: WHO, 2000

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Factors/evidence input	Definition	Area of concern	Selected key references*	Best practice	Selected key references*
Clinical guidelines (n=71)	Patient management guidelines for interventions/clinical areas	Lack information on medical device necessities for low-resource settings.	SR184: Anderson, 2008	Incorporate medical device procurement necessities and advise on LMIC friendly specifications.	SR41: Briggs, 2008 SR44: Dyer, 2010
Health technology assessment (n=54)	Methods of economic, health impact, policy, regulatory and organizational evaluation	Data paucity on health impacts, medical device coverage, equipment life span, true costs of equipment.	SR24: PAHO, 2012 SR249: Withanachchi, 2007	Within resource constraint, adopt transparent and evidence-based processes to evaluate different invest options.	SR106: Panerai, 1989 SR198: Teerawattananon, 2005

*Numbers in bracket refer to citation frequency. References marked SR refer to documents included in the systematic review.

TABLE 8: CHALLENGES AFFECTING SUCCESSFUL MEDICAL DEVICE UPTAKE AND USE

Factor (frequency of citation)	Definition	Area of concern	Best practice
Alignment to deployment setting (n=175)	Device alignment to healthcare delivery level and conditions encountered in deployment setting	No clear indication which devices correspond to which service delivery level/what conditions/staff skills	Consult clinical guidelines/experts
Ambient conditions in deployment setting (n=95)	Ambient conditions in deployment settings affecting successful medical device uptake/use	Reflective of lacking infrastructure, medical devices do not reach full life-expectancy	Develop technological needs assessment: note present conditions; consult LMIC friendly specification list
Skill mix in deployment setting (n=134)	Skill mix in deployment settings affecting successful medical device uptake/use	Lack of safe medical device use and preventive maintenance training; medical devices do not reach full life-expectancy	Provision of training manuals and supplier training for any purchase
Device specifications (n=135)	Device specifications to accord to the conditions in which it is to be used: e.g. durability, humidity/temperature resistance	No clear indication of LMIC friendly device specifications	Device specifications should conform to LMIC environment and settings (see Table 9)
Installation and maintenance provision (n=66)	Service availability/affordability for installation and preventive/corrective equipment maintenance; including financial resources	Lacking financial and human resources to carry out maintenance/servicing of available devices	Installation and maintenance services should be included as part of medical device procurement and all ancillary costs considered in procurement
Decommissioning and disposal (n=16)	Provision for safe medical device decommissioning and disposal; including financial resources	Lacking financial and human resources to carry out	Identify decommissioning or disposal mechanisms and consider any cost implications

TABLE 9: MEDICAL DEVICE SPECIFICATIONS AND DESIGN DESIRABLE FOR LMIC SETTINGS

Design domain	Specification
User friendliness	Easy to use; rapid; low training needs
Portability	Compact and portable (choose desktop variety if theft is an issue) Avoidance of bulky and heavy design
Reliance on external factors	Elimination of external power sources Include water purification system Minimal need for sample preparation Minimal need for spare parts
Design	Long shelf-life at ambient temperature Rapid High sensitivity and specificity for diagnostic technology High throughput
Material	Robust Choice of durable material

TABLE 10: A SYNTHESIS OF RECOMMENDATIONS EXPRESSED IN THE LITERATURE FOR CONSIDERATION BY INTERNATIONAL DONORS, LMIC STAKEHOLDERS AND THE INTERNATIONAL RESEARCH COMMUNITY

Recommendation	Explanation
Close the feedback loop	The WHO deplores the mismatch created by low-resource settings procuring high-end technologies. (1) Authors in the literature recommend LMICs and donor institutions evaluate past procurement efforts and create participatory structures for health facility representatives to engage in planning/procurement consultations. This increases transparency and pre-empts technology adoption/use issues by informing all stakeholders of health facility needs/infrastructure/skill mix.
Fully cost out potential purchases	Authors in the literature note discrepancies in costing practices, we therefore recommend national costing templates are created and disseminated to facilities and procurement agents for MDE purchases. Costing templates should be context specific and include: a) Expenses related to equipment installation, servicing (inspection, installation, preventive and corrective maintenance, decommissioning and disposal); b) Investments into infrastructural refurbishments of deployment health facilities and user training that would aid in keeping MDEs operational. The WHO Cost-It templates present a good starting point for this at hospital or program level. We remind users to include inspection, installation and decommissioning/disposal costs in templates under the 'other' headings. (75)
Make MDE servicing a legal requirement	Authors in the literature recommend LMIC regulatory agents develop minimum, legally binding, standards for national/regional MDE servicing. Procured equipment should be subject to specialist inspection and installation once in deployment settings; service provisions/funding allowances for preventive and corrective maintenance, decommissioning and disposal should be identified before tendering.

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Recommendation	Explanation
Include explicit MDE availability recommendations in clinical guidelines.	We note that historically clinical guidelines do not include specific recommendations on what medical devices should be available for specific interventions - authors note this as an issue for biomedical engineers or procurement agents engaged in product selection.
Develop a list of generic specifications for LMIC friendly equipment.	Authors in the literature recommend the elaboration and listing of generic medical device and equipment technical specifications to aid LMIC procurers. The list of broad product features we have identified in this review is a start in this endeavour, but international engineering expertise is needed to create technical specifications or target product profiles specific to LMICs. (Table 9)

MDE= Medical devices and equipment; LMICs= Low- and Middle-income Countries

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1. 9. FIGURES

FIGURE 1: SEARCH AND SELECTION ALGORITHM

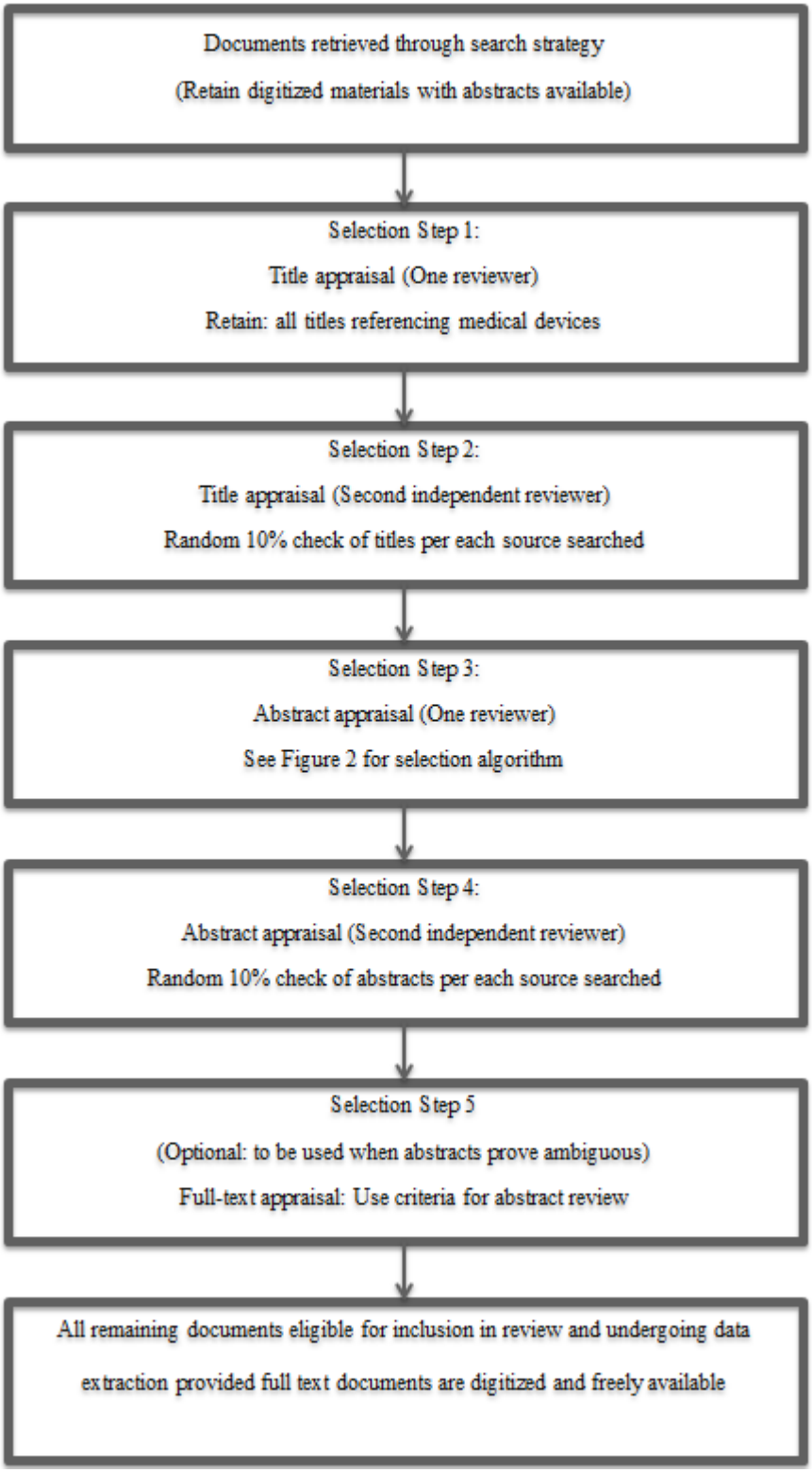

FIGURE 2: ABSTRACT SELECTION ALGORITHM AND CRITERIA

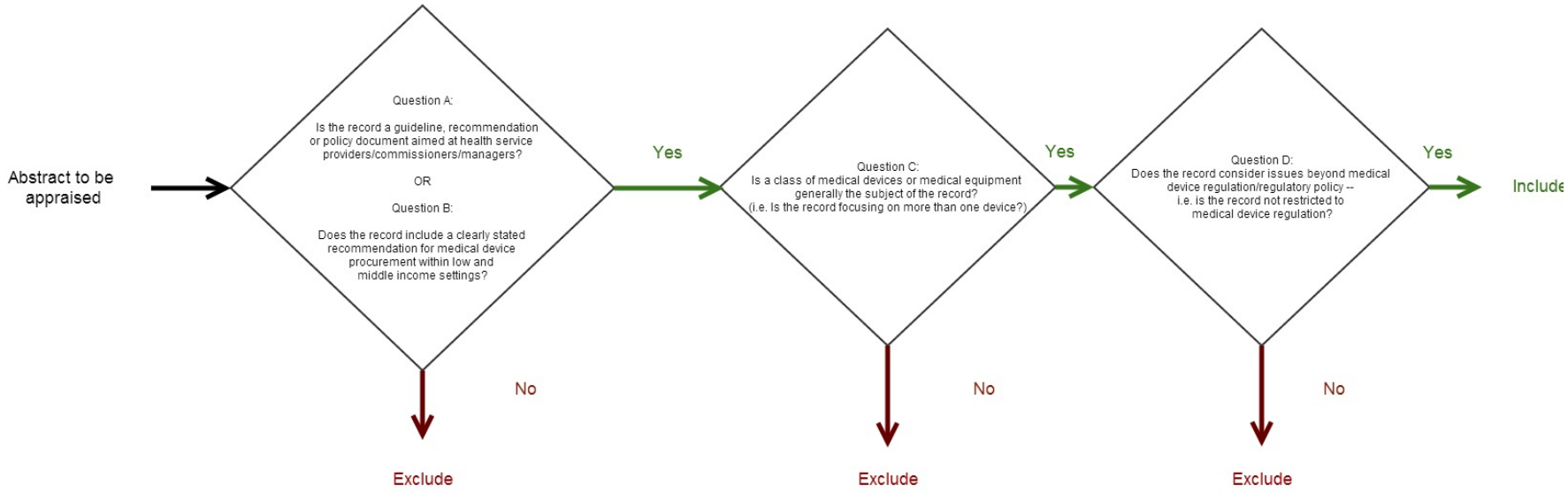

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FIGURE 3: PRISMA FLOWCHART

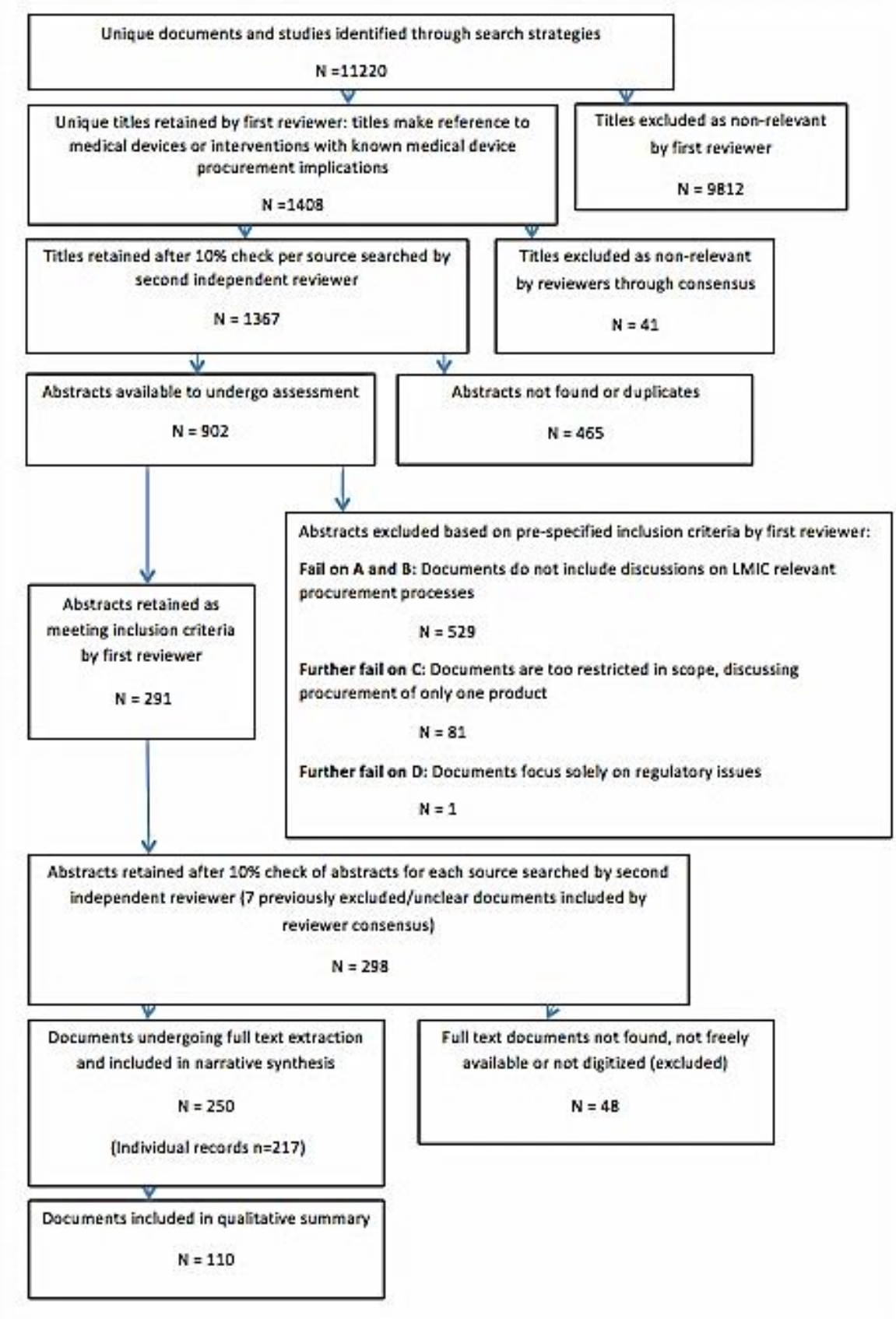

FIGURE 4: STAKEHOLDERS, METHODS AND MEDICAL DEVICE PROCUREMENT STEPS BY HEALTH SYSTEM LEVEL

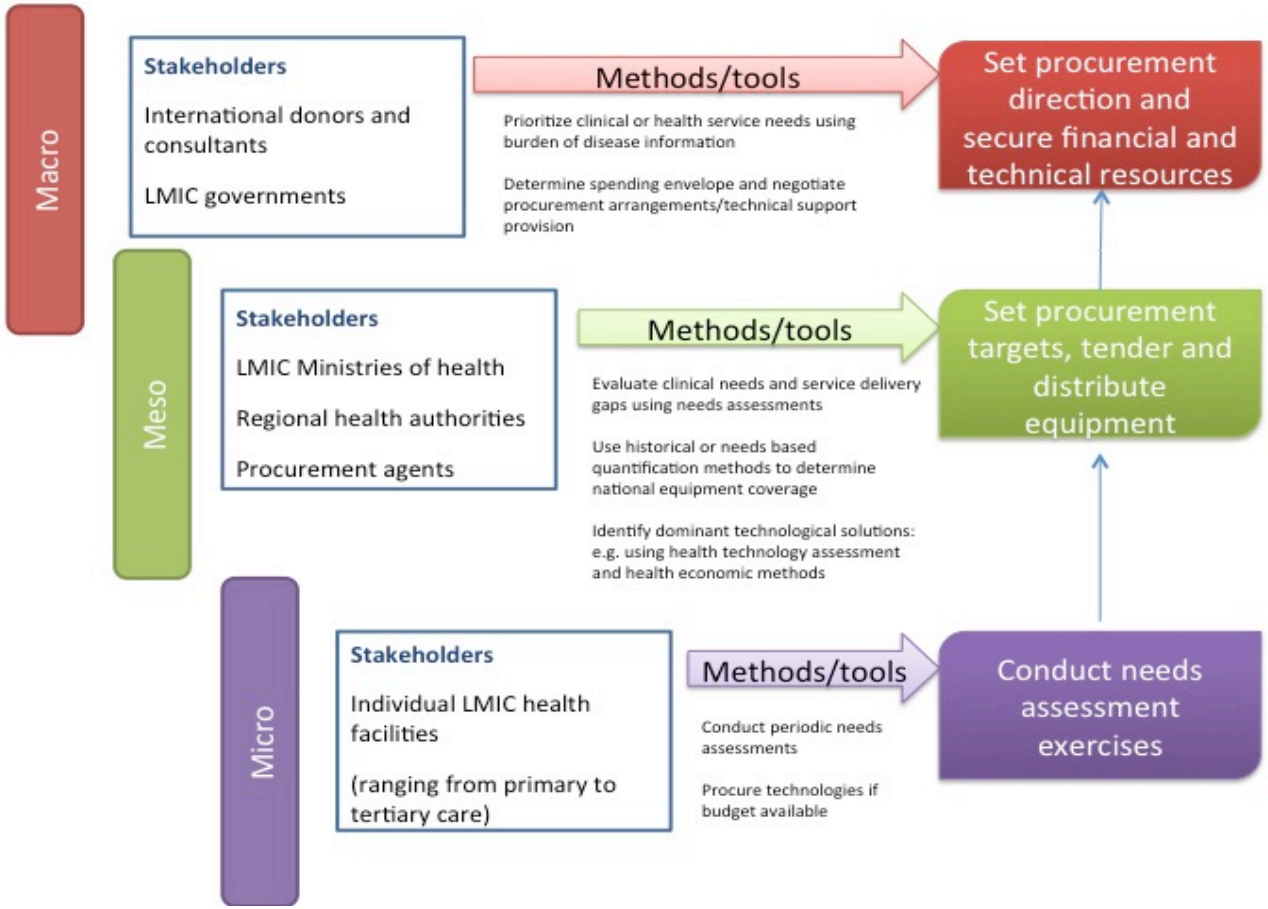

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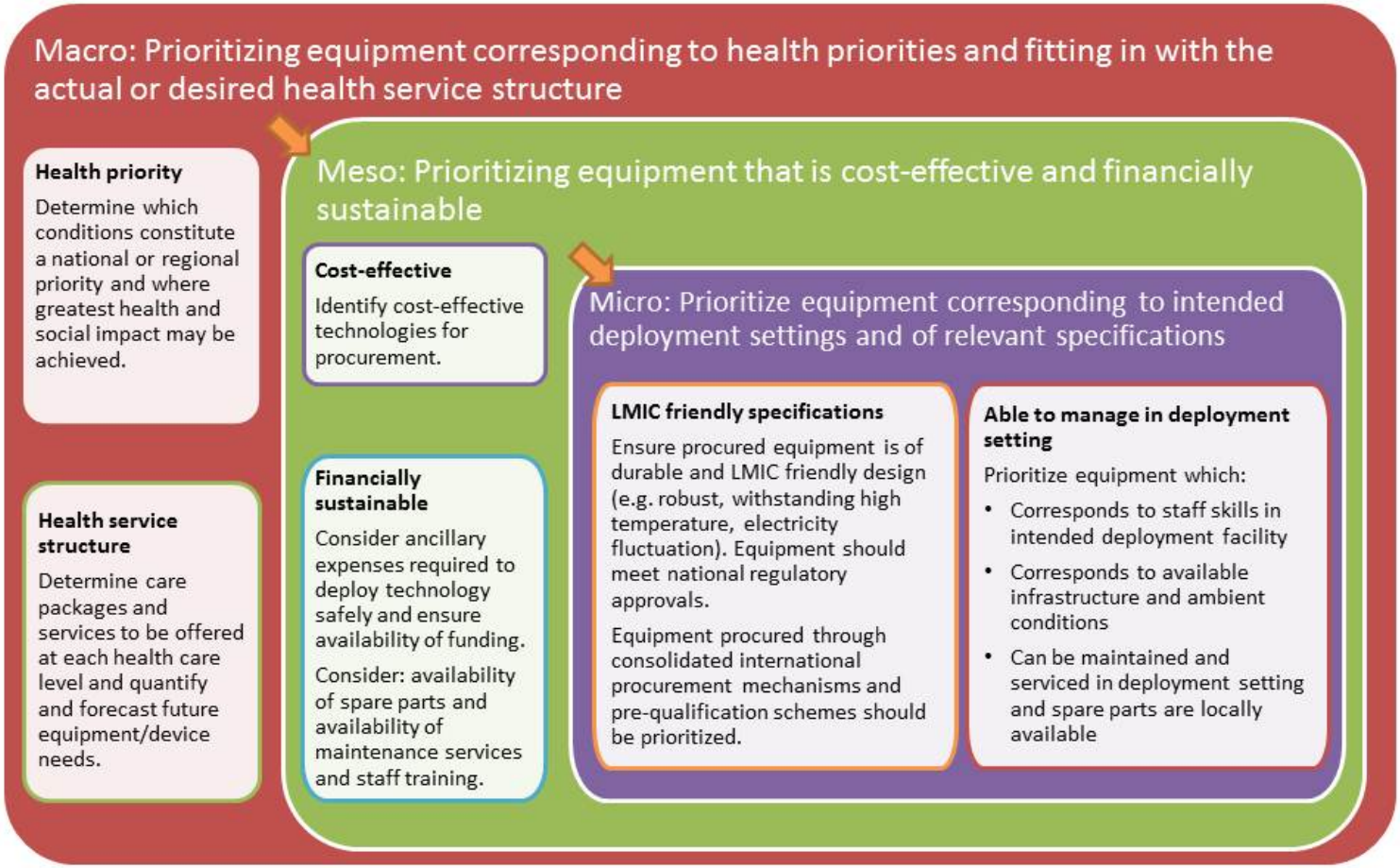
FIGURE 5: MEDICAL DEVICE PRIORITIZATION: DECISION-MAKING INPUTS CONSIDERED AT DIFFERENT HEALTH SYSTEM LEVEL



CHAPTER 2: MEDICAL DEVICE PROCUREMENT IN THE GAMBIA, ROMANIA AND IN THE VIEW OF INTERNATIONAL EXPERTS: FINDINGS OF A QUALITATIVE STUDY IN TWO CONTRASTING LMICS

This manuscript will be refined for submission to a peer-reviewed journal as follows:

K. Diaconu, A. Lindenmeyer, C. Cummins, I. Filip, A. Morar, M. Ndow, B. Cham, R. Lilford, S. Manaseki-Holland: ***The dynamics of medical device procurement under resource constraints: Findings of a qualitative study in The Gambia and Romania***

Contributions:

KD has designed and conducted this study, conducting all primary fieldwork and data collection, as well as analysis and manuscript drafting. AL acted as a reflective and critical partner during data analysis and interpretation of findings and provided critical feedback during manuscript drafting. CC, RL, SMH supervised this work and similarly provided critical support and feedback during all study stages, ranging from design, data collection to analysis and drafting. IF, AM, MN, BC assisted in fieldwork and data collection in Romania and The Gambia, and acted as reflective partners during analysis and interpretation of findings.

2. 1. INTRODUCTION

Low- and middle-income countries (LMICs) face substantial challenges in the delivery of health services. Difficulties arise due to financial constraints, lack of technical capacity and/or trained workforce to manage or deliver services, and the restricted availability and accessibility of medicines and medical devices and equipment (MDEs). (1,2) MDEs are key health system components used across the spectrum of service delivery from disease prevention and diagnosis to treatment and monitoring. (3) Examples include in-vitro diagnostics, biotechnologies, implants, consumables, medical furniture and complex equipment such as Magnetic Resonance Imaging systems. (4,5)

Current reports suggest that MDEs are not functional or poorly maintained in LMICs, resulting in impaired care provision and adverse health outcomes. (1,6,7) The World Health Organization (WHO) ascribes such issues to: undiscerning product selection and procurement, the absence of regulatory authorities able to oversee procurement and inspect devices, and the lack of funds necessary to procure high-quality products or keep devices operational during their life span. (5,8,9)

Recognizing the relevance of MDEs in achieving universal health coverage, the WHO and international organizations such as Management Sciences for Health issued guidance on procurement and product selection. (10,11) Chapter 1 presents the findings of a systematic literature review of the international bibliographic and grey literature on MDE procurement: recommendations for best practice are summarized and discussed. Reviewed documents recommend careful consideration of life-cycle costs and technical specifications during product selection. Procurement decision-makers should consider the overall cost of devices, including user training, maintenance and decommissioning,

and select products that can withstand the local conditions of resource poor deployment settings, e.g. lack of clean water or interrupted electricity supply. Additional recommendations within the reviewed literature (12,13) and elsewhere (14–16) concern the use of health economic or health technology assessment evidence to promote transparent decision-making and maximize health utility given scarce resources. The principal argument within this literature is that MDE procurement within LMICs could be greatly improved if health technology assessment methods were taken up.

To explore the dynamics and specificities of procurement processes and methods in both low and middle-income countries, KD designed and conducted a qualitative study involving semi-structured interviews and fieldwork components in The Gambia and Romania. To gain insights into processes and decision-making dynamics in LMICs more generally, high-level experts in international agencies consulted on MDE procurement were also interviewed. The primary aim of the study was to explore the context in which procurement decisions were made and the roles played by various actors: doctors, nurses, local and national managers, policy makers and international agencies. The study explored the barriers and facilitators that decision-makers at various health system levels – ranging from individual health care facilities to regional or national authorities – encountered during product selection. Additionally, the study sought to identify what guidelines, tools or information sources stakeholders used to reach product selection decisions: were stakeholders using the developed guidelines on MDE procurement or relying on different decision-rules to support their choices?

KD designed this study as an open-ended inquiry into MDE procurement in both settings. Bourdieu's theory of the logic of practice offered a theoretical lens for

interpretation, (17) suggesting that difficulties in the implementation of rational and systematic MDE procurement processes in LMICs may emanate from stakeholders attributing significant symbolic relevance to MDEs. The dynamics, constraints, motivations and incentives stakeholders face when engaged in such 'games' were explored and documented. (See next section)

2. 2. DATA AND METHODS

Settings: The study sought to encompass one low- and middle-income country each to explore potential differences due to health system development. KD visited the Gambia and Romania, each for a two-week period, during September-October 2013. Specific country choice was dictated by practical considerations: KD had contacts in the ministries of health in both countries. The time frame was sufficient to visit all regions of the Gambia and two regions within Romania. Plans were put in place in collaboration with MN and IF in advance of fieldwork to visit a suitable range of health facilities and to recruit relevant participants. (Table 1) KD and MN/IF visited 11 health facilities across The Gambia and 7 facilities across the Sibiu and Alba regions in Romania (Table 2).

Interviews and focus groups: A topic guide for semi-structured interviews and focus groups was developed. (Appendix 4) KD and MN/IF conducted pilot interviews with an eligible participant in each country: the topic guide was appropriate for both settings. Interviews and focus groups were conducted in private offices/meeting rooms and lasted 40 minutes on average; two Gambian participants and one Romanian participant were interviewed in an informal setting. Interviews with international consultants were conducted by phone and lasted approximately one hour. Participants were provided with a study information and consent sheet (Appendix 5), the latter being returned to KD prior to each interview.

Participants and sampling: KD targeted participants from each stakeholder group identified as relevant to MDE procurement in the systematic literature presented in Chapter 1. (Table 1) Purposive and convenience sampling strategies were employed to

target professional groups with relevant experience (Table 3). A snowball approach was used to allow participants to recommend further individuals likely to be eligible for inclusion in the study; 75 health care professionals, managers and administrators, consultants and policy makers were recruited on the spot (Table 4). One Romanian hospital refused participation due to the manager's negative experiences with UK research institutions. Additionally KD approached and interviewed four international experts frequently consulted on issues of MDE procurement in high-level international organizations or consultancies. KD had no contact with participants before study commencement; participants had no prior knowledge of the interviewer.

Ethics: The study was approved by the University of Birmingham Ethics Committee, the Gambian Special Cases Committee for Ethical Review and was cleared by the Regional Inspectorates for Public Health in Alba and Sibiu, Romania. (Appendix 6)

Data collection: Interviews and focus groups were conducted until data saturation for each participant group was reached; saturation was discussed after each facility visit and phone interview with experts. Three repeat interviews were conducted with stakeholders at regional- and country-health system levels: two in the Gambia and one in Romania. All interviews/focus groups were audio-recorded and transcribed verbatim. Reflective field notes were written up after each interview/focus group. Transcripts were not returned to participants for checking. Interviews in Romania were conducted in Romanian (KD's native language) and one interview in Gambia was conducted in Spanish; a native Romanian speaker (Razvan Sandru - Gesellschaft fuer Internationale Zusammenarbeit) and Spanish-fluent researcher (Alice Kilpatrick - University of Edinburgh) verified transcript translations.

Potential barriers to obtaining a full, undistorted picture were noted in a field diary by KD and MN/IF and are acknowledged as study limitations. Where participants were interviewed at work, interviews were occasionally rushed. In the case of focus groups conducted in the presence of superiors, some participants did not take part due to discomfort. The effect of an English language barrier was minimal in The Gambia; IF decoded colloquialisms used by Romanian health care professionals. Analysis and interpretation of the decision-making dynamics in Romania may be colored by KD's prior experiences in the country.

Notably, only one focus group was conducted in Romania. Participants in Romanian health facilities were less likely to agree to focus group discussions due to an inherent resistance to information sharing. One-to-one interviews were welcomed, as participants did felt they could voice negative or critical opinions when senior staff members were not present.

Analysis: A general inductive approach was used for coding and the framework method initially chosen for analysis.(18) NVivo was used for analysis; collections of Romanian, Gambian and international expert transcripts acted as cases for generating framework matrices. KD first familiarized herself with the data by listening to recordings and reading transcripts and field notes. KD, CC and SMH coded three transcripts from different participant groups, discussed and agreed a coding structure, which KD applied to all further transcripts. (Appendix 8) Relations between codes - including similarities and differences - were noted for further exploration and codes were grouped into categories and reduced iteratively. The constant comparison method was used to check code content and structure; coding, analysis and interpretation of data were conducted

simultaneously. (19) KD and AL critically discussed relations between codes and emerging themes; in discussions, Bourdieu's theory of the logic of practice was deemed a suitable lens for interpretation. (17) This theory was not consistently used from design to interpretation of findings: this was a novel study purposefully designed to be exploratory. (20)

Bourdieu's theory was chosen for its unique combination of subjectivist and objectivist elements: it posits the existence of agents in a structured reality that agents co-structure via their participation. (17) Bourdieu's reality is made up of different 'fields': e.g. the field of scholarly inquiry. Fields are temporally and spatially bound, arbitrary in the goals set and principles followed (the *nomos*) and the rules and procedures enacted (the *habitus*). The dispositions and motivations of agents engaging with the field (the *illusio*) revolve around relations of power and ownership of *capital*. For Bourdieu, capital can be economic, cultural or symbolic - it is the bargaining chip used to substantiate the interactions and dynamics within each action field. (See Box 1 for an example)

Research team and reflexivity: KD is a female PhD student at the University of Birmingham, where she trained in the use of qualitative research methods. KD designed the study, organized and conducted fieldwork in The Gambia and Romania. Prior to study commencement, KD had substantial knowledge of high-income country health technology assessment methods and systems: KD is familiar with NICE health technology assessment guidelines and resource allocation processes in the UK in particular. During field visits, she adopted a critical external "observer" point of view and wished to uncover the motivations and dynamics behind stakeholders' MDE product selection decisions: it was important to discern what "value commitments" participants

held.(21) KD did not adhere or advocate for any particular theory while conducting the study or first analysing the data: exploring the transparency and reproducibility of the decision-making processes and motivations of stakeholders was a first analytical priority. KD later employed Bourdieu's theory of the logic of practice to contrast behaviours and motivations of country participants (i.e. short-termist behaviours arising from specific cultural and political dynamics) to those of experts (i.e. views echoing long-term utility maximization and rational action theory).

KD's interpretation of findings, as well as study participants' attitudes and responses towards KD, may additionally be coloured by KD's status as a Romanian national. In The Gambia, KD identified as Romanian and was therefore perceived as a citizen of a fellow-developing nation: this meant participants approached KD openly, in many cases affirming KD was not biased towards a "Western" attitude. In contrast, in Romania KD was frequently acknowledged as "not fully Romanian" due to belonging to a German minority and having chosen to study abroad in the UK; Romanian participants therefore viewed KD as a "Westerner".

SMH, CC, RL and AL all assisted in study design, data analysis/interpretation and manuscript preparation; SMH additionally oversaw the first interviews and provided critical feedback on KD's performance. MN and IF, both public health professionals with experience in qualitative methods, acted as research assistants in the Gambia and Romania respectively; BC and AM facilitated the progress of the study by assisting in the ethical approval procedure. MN and IF were monetarily rewarded for their time assisting in data collection.

Reporting: COREQ reporting standards are followed. (22)

MDE Procurement: How does it happen?

Figures 1 and 2 outline procurement processes in The Gambia and Romania. In both countries, procurement is initiated by the requests of health care workers or medical personnel in health facilities. Requests for new products are based on clinical practice needs (clinicians decide on what to procure based on their experience) or demands of the local population. Health facilities usually do not possess the discretionary funds necessary to procure new products, thus relaying requests to regional or national level authorities.

At regional levels, requests are centralized, verified and further relayed to national authorities. Differences in request handling at ministerial level were apparent: Gambian officials prioritize requests until funds are exhausted. In contrast, the Romanian Ministry of Health first allocates funds for outfitting eight national referral hospitals, considering requests from smaller municipal and city hospitals only after these investments.

Legal restrictions apply in both countries; facilities and regional authorities are prohibited from procuring MDEs that cost more than 100,000 Dalasi in The Gambia and 30,000 Euro in Romania. Most minor MDE purchases - e.g. syringes, dressings, stethoscopes and minor diagnostic or monitoring equipment - fall below this threshold. Due to restricted funds, facilities in The Gambia usually enter donation arrangements with hospitals or universities abroad. In Romania, hospitals seek co-financing for investments from local councils or charities. Procurement based on public means must

be conducted publicly and transparently: in The Gambia, bids for government procurement contracts are placed in national newspapers; in Romania, an online bidding platform is used. The Gambian Public Procurement Authority and Romanian Office for Medical Devices and Equipment oversee and audit bids and processes.

MDE Procurement Decisions: What Do They Mean?

In conversation with participants, KD explored processes and methods behind product selection. During the analysis of this data, KD and AL became aware of the relevance of Bourdieu's theory on the logic of practice for interpretation. (Table 5)

1. MDE procurement as a *field* of service delivery

Discussions on procurement and product selection revolved around service delivery and the relevance of MDEs. Individual products are prized for their function in patient treatment and their role in the provision of safe and high-quality health services. Gambian participants noted that the absence of equipment might result in negative health outcomes and loss of patient confidence in facilities and their ability to provide care:

> *"Maybe sometimes you know you do have a review meeting on the outcome of a case that we are not very happy with, for example, the case of a maternal death. (...) We sit and debate on that day, just to find out, what went wrong. Sometimes also you might find out that certain equipment is lacking, so that is why."*
>
> ***(Nursing Officer, Major Health Centre, Gambia)***

"Not having drugs or adequate equipment means the people lose confidence in the facility. They notice we do not have, so they do not come. Why would they?" ***(Officer in charge, hospital, Gambia)***

MDEs are an instrument by which the public and health system can place pressure and expectations on health care providers. Should facilities not have the equipment to diagnose or treat specific ailments, the facility's relevance in the overall system decreases, patients are referred elsewhere and public displeasure may follow:

"This hospital, it's a regional hospital, but here all patients come in from smaller hospitals. Then, what happens, since we can't do the studies [tests], well – (...) we refer to Banjul." ***(Doctor, Cuban medical delegation, Major Health Centre, Gambia)***

"Each year we keep praying that nothing happens to this one [sterilizer], because if it does, it is another scandal." ***(Principal Nursing Officer, Hospital, Gambia)***

Romanian respondents viewed the possession of MDEs as a mark of quality: e.g. the availability of high-end complex equipment in facilities indicates that the country can/cannot rise to European/Western standards of care.

"So, at the level of, the priority of the ministry is to ensure the efficient functioning of a regional emergency hospital within each region. (...) With at least second-class equipment fit, to ensure coverage for multiple traumas, at European efficiency standards." ***(National policy maker, Romania)***

"There are things, which exist in the West, but do not exist here, and we live very well even without those things. (…) It's a joke: we live." ***(Medical director, Municipal Hospital, Romania)***

2. The *nomos* of MDE procurement: Why select this product?

When asked for the reasons behind product selection, participants were apprehensive initially but a common understanding and articulation of motivations emerged in time (the *nomos*).

Gambian health care workers indicated that the MDE requests submitted to health facility management or the Central Medical Store were in response to observed needs. Clinicians observed patient demands or need for a specific service and selected a suitable MDE for procurement based on their own clinical experience as opposed to external guidelines or international recommendations.

*"If someone has high blood sugar, so checking the blood sugar of that person is necessary, despite the machine not being available. It's our responsibility to request it so that the authorities know that there's a need for it."****(Interview, Ophthalmic nurse, Major Health Facility, Gambia)***

A similar discourse pattern was observed in Romania. Managers iterated that patient demand was the driving factor behind clinicians' procurement requests.

"We realized that within the diagnoses put within the hospital, among the radius of this town, there were a lot of urological problems (…) We have patients. Now,

tell me what you [the doctor] need. (...) A scope like this. OK, we get that."

(Manager, Hospital, Romania)

Managers had less altruistic motivations and requests were often prioritized based on a product's potential return on investment in order to ensure the facility's survival in a precarious and underfunded health system. Romania had undergone repeated health system reforms in recent years and most minor to medium sized hospitals had closed. Managers of remaining facilities were anxious over their facility's performance and relevance; continued development and expansion of clinical services (including the purchase or leasing of MDEs) became a vehicle for attracting funding, patients and staff, and remaining operational. Availability of high-end equipment in facilities ensures patients are not referred elsewhere and draws funding from the national health insurance provider (reimbursement for services can only be claimed by hospitals offering end-treatments).

"I tried in the past years, since I am here - so three years - to improve the material base, it's very important for a hospital. (...) After the reform 3 years ago, when 2 years ago they[the ministry] reduced the number of hospitals, they[the ministry] have positioned themselves regionally, to cover an area of about 30-40km, if you look at the map of the country, what it looks like. (...) So then we said, as a strategy for the future, we tried to raise our "addressability" [ability to address population demands/service needs]. Because in the end this is it - health is a business too - it sounds ugly you know, business, but this is the truth. If you have money you live, if you don't you don't." ***(Manager, Hospital, Romania)***

At ministerial level, decision-makers had less difficulty in articulating motivations. Acknowledging patient needs and requests by individual facilities, decision-makers at this level were nonetheless bound to follow national policies on service delivery and to ensure financial sustainability for the health system:

> *"As I said, we have to prioritize based on needs. And most of our priorities now, I think all countries, African countries are trying to target the Millennium Development Goals: improving maternal and child health. So, the priority is based on that, (...) so we do get equipment for providing services at the various level, yes."* ***(National Medical Stores, Gambia)***

> *"First of all, we are talking about following health policies, and after the policies, about investments, requests from the territories, investments in health. So, at the level of, the priority of the ministry is to ensure the efficient functioning of a regional emergency hospital within each region. So at least 8 (...)As a second priority, we talk about ensuring outpatient clinics and main county hospitals - so, equipping all the county hospitals in all county capitals. Ensuring a minimal equipment fit, or standard (...)This fit was agreed by a committee of specialists in the field and discussed with the World Bank, it is within the available budget - or a potentially available budget - but which can ensure a pathway for the patient - an appropriate clinical pathway."*
>
> ***(Government official, Romanian Ministry of Health)***

Given resource constraints, procurement requests underwent further prioritization at different health system levels. Criteria listed as relevant to prioritization by participant groups in both countries are summarized in Table 6. Criteria mentioned are similar to

those identified in the systematic literature review presented in Chapter 1, with two notable exceptions. Participants did not discuss normative criteria such as cost-effectiveness or value for money, but additionally considered implementation issues: e.g. urgency of providing health care services and securing product purchases.

3. The *habitus* of procuring: What dynamics frame stakeholder interactions?

Bourdieu describes *habitus* as a socially constituted principle governing social interactions within the field; the *habitus* limits agents to a specific range of critical thought and action. (23) Breaking away from the habitus means adopting an external view of the field, one that KD and the study team was privileged to hold in The Gambia and Romania.

Decision-making within the Gambia appears to be strongly influenced by duty of care towards patients. The dynamics observed and described by participants were team-oriented, based on open dialogue and negotiation: e.g. KD noted that Gambian health care professionals frequently conduct team meetings to reflect on practice issues (including MDEs) in the *bantaba* - a round, central meeting place within each facility. Requests for MDE procurement still followed a specific chain of command and were reported to the Officer in Charge/CEO of each facility, but could additionally be discussed in an informal environment aimed at promoting dialogue.

> *"When the heads of department request, we go through that requisition (...)At that point I don't know, but most of the time, what we think is ideal, is for example, if the head of departments make their requisition, then they sit as a team, and they see and prioritize the requisitions they need."* ***(Principal Nursing Officer, Major Health Centre, Gambia)***

Participants appeared to face severe resource constraints with a strong sense of camaraderie. This is reflected not only in their actions - e.g. by émigré Gambians

sending in support for the country - but by the terms used by participants - e.g. 'brothers and sisters':

> *"The provision of the equipment, normally by the government, philanthropists and as well as some donor groups, for instances some of our brothers and sisters could be somewhere in the western world and form an association to help back home their families and their communities and their country, as a result they mobilize some funds to buy this equipment or going to some institutions like hospitals and gather some second hand materials." (**Regional health authority representative, Gambia)***

However, severe resource constraints impede planning and result in un-coordinated and short-term practices. The Gambia does not have a MDE procurement policy and a working inventory of MDEs was only collated recently; there is no distribution plan for MDEs and products are given out on a per-request basis. The system is reactive and vulnerable to manipulation:

> *"There's no overall plan. For instance, if we - I remember we need blood pressure machines. I went to the main stores in Kotu, I couldn't find. But somebody gave me a drop that you know, the ministry has been donated some BP machines, you know. So, I went there, and he said no no no, this is for the provinces and I need to go there. So, I said, but you know, could you give me 5 minutes? Then I was able to convince him and I got a few. But if I had not got that relationship, somebody else could not have had. These things are lined up."*
>
> ***(CEO, Hospital, Gambia)***

This lack of central planning and monitoring results in an attitude of carelessness by individual MDE users and hopelessness in the minds of government decision-makers:

> "*I will still advocate for transparency - more transparency, more accountability for resources. Because, what I actually realize is that - because it's government, many people don't tend to care much, so, yeah, that's what I also feel. Sometimes, they'll even tell you - ah it's not coming from your pocket - but it's actually coming from your pocket. Yeah, somehow, because you're being taxed, you're doing this, you're doing that. It's still your money - it's just the same money. Actually there is more transparency and accountability. And then, if the laws that are made by GPPA - that is the regulating body - are actually or strictly followed, I believe the mechanisms will be improving.* ***(Government official, Gambia)***

Within Romania, decision-making is a hierarchy-driven process, framed by the laws governing the health system. Professionals in facilities noted that it was the hospital manager and the government that ultimately decided what was to be bought. Meetings between the medical director, accountant and manager at the hospital were described more as a formality rather than a decision-making mechanism.

> *"Interviewer: I understand. So, is there discrimination between departments and wards? Who decides who is a priority: the gynecological ward or...?*
>
> *Participant: The manager decides, certainly."****(Medical director, Hospital, Romania)***

Managers expounded on their role in decision-making, and the powers held within facilities, while clinicians and accountants shied away from describing themselves as participants of the process:

> *"The personnel being smaller and easier to control, as it's a small hospital, any problem that comes up I find out about the second day, in a little summary of priorities for me. I need to know what happens in the hospital, telemedicine isn't working, the oxygen station is broken, we miss something in the emergency care kit."* ***(Manager, Hospital, Romania)***

Managers' role as final decision-makers also endangers them: managers lose their position should the hospital enter into debt for more than three consecutive months. This regulation constrains decision-making and inhibits managers from showing initiative:

> *"Let's say it like that, we do not have enough autonomy. But now I read they are modifying the laws, with penalties and so on. We live under constant threat of penalties and restrictions."* ***(Manager, Hospital, Romania)***

> *"When they are told, when it's put in the law. It's in the law, if from March, you have so many debts you are dead. You cannot think of something else, what creativity can you have."* ***(Regional public health authority representative, Romania)***

Hospitals with little funds rely on the ministry for updating their stock. Participants viewed the ministry as both an adversary and benevolent patron able to fulfill facility requests, although few requests are honored:

"Yes, I can tell you a fortunate case from 2012, (...) We received a sum of money for the procurement of medical equipment - of course with the agreement that the local authority would co-finance these with a percentage between 5-10%. This was then. And then we finally felt like the Ministry acknowledged us. (...)We did the same last year, but in 2013 we unfortunately heard no echo. (...)I think they do acknowledge, and I am sure they listen, but there are no funds."
(Financial Director, Hospital, Romania)

4. MDEs: More than economic *capital*?

The final concept relevant to this analysis is that of *capital*: Bourdieu distinguishes economic, cultural and symbolic forms of capital.(23,24) Capital determines and defines one agent's position or domination over another. Participants across both countries ascribed symbolic relevance to MDEs due to their role in service provision and their ability to confer status and garner recognition for health facilities:

"Every hospital should have their own sterilizing department and system if they want things [services] to really work and make the target of qualitative delivery of care. Service care." ***(Principal Nursing Officer, Hospital, Gambia)***

The procurement and possession of devices substantiates the power of procurement stakeholders. Participants' accounts reflect that facility managers make the final decisions of what to request or procure at micro health system level, while ministry officials wield power over procurement at macro level.

"You know, here, everything is administration. They decide on everything, every unit head, your only problem is if you need something you write it and request it

from them. If they have it, they will provide, if they don't then well that's what happens." ***(Dental worker, Major health centre, Gambia)***

"And then there is cardiology, similar, at this point still I say, why should my patients leave (this county), because I am a county with pretty powerful economic development and I have the possibility to keep them here in Sibiu, or to have the services here, why won't you [the Ministry] let me provide them? I have the ability, why not let me? Because you're [Sibiu county] cheating the other, and they [the Ministry] don't allow it. They [the Ministry] won't approve anything. ***(Representative regional public health authority, Romania)***

The second form of both economic and symbolic capital relevant to MDE procurement is funding. Across Romania and The Gambia, participants face severe constraints. MDEs cannot be purchased or maintained due to lack of financial resources: the availability of financial resources impacts facility 'survival'.

*"It's a problem until you don't have money. (...)If we had money we would procure, if we had money we'd get equipment, if we had money we'd buy drugs. So for example this year I cut the meal tickets [for staff]. (...)Probably we will have some sort of legal battle with the union but we will see what happens when they ask us to court. I don't know what to say - the situation in our system is horrible. "****(Financial Director, Hospital, Romania)***

'Technical capacity' is a third form of economic capital relevant to selecting and maintaining MDEs: technical experts are needed to assist in technology inspection, procurement, maintenance or resource allocation planning. Within both the Gambia and

Romania biomedical engineers and health economists were largely absent. The Gambia had access to one technician and one qualified biomedical engineer within the UK Medical Research Council Centre and one health economist within the WHO country office. The scarcity of biomedical engineers and technicians results in impaired service provision:

> *"The fact that there is no immediate engineers to fix them when they are down, so when they are down, they need to contact us. You can imagine the turnaround time, how long it takes for it to be fixed. (...)So we realize, we purchase them, fine. But we need to have somebody there to make sure that they are in good order."* ***(Biomedical engineering technician, Gambia)***

In Romania, KD found no health economists or biomedical engineers to interview and regional authorities noted that few members within the ministry were trained in public health. In contrast to The Gambia, participants rarely discussed MDE maintenance issues as hospitals purchasing MDEs are legally required to ensure services are available for preventive and corrective maintenance of equipment. Hospitals therefore require manufacturers to provide such services; maintenance costs are routinely included in MDE tenders.

Technical expertise could also be disseminated/accessed via guidelines or recommendations. Few participants professed any knowledge of international MDE procurement guidance or health technology assessment methods. One Gambian clinician mentioned he was aware of guidance relating to MDEs for maternal, reproductive and child health. One Gambian technician and WHO country office representative additionally knew of procurement process and health technology

assessment guidance. In Romania, financial directors and managers said that they conducted an informal cost-benefit analysis before engaging in procurement; when prompted it became clear that these analyses did not explicitly consider clinical evidence or patient outcomes.

5. Improving MDE procurement: international expert comments on *field* and *habitus*

Chapter 1 highlighted that stakeholders at supra-national levels also influence procurement; such stakeholders include consultants in health policy, biomedical engineering and health economics in international organizations such as USAID, the World Bank or WHO. To explore experts' transnational experiences and reflections, KD conducted in-depth interviews with four such high-level consultants active across international organizations, consultancies and academia.

In contrast to respondents in The Gambia and Romania, respondents in this group focused on the *field* of 'resource allocation'. Experts do not differentiate between investment decisions in MDEs, medicines, health services or programs: the *nomos* or end-goal is to maximize health utility given scarce resources.

Consultants view MDE procurement in LMICs as an ad-hoc and uncoordinated resource allocation exercise susceptible to corrupt and collusive decision-making practices:

> *"I think it's really very variable what you see in the field. In general I would say that the default is a totally ad-hoc process that's based on the influence of industry."* ***(Health policy and health economics consultant)***

Opinions voiced by participants in this group suggest that corruption and collusion are part of the *habitus* of LMIC stakeholder interactions.

> *"Another obvious indication of the problem [corruption/collusion] is when you look and see what they're buying and you see: oh, ok, according to NICE guidelines - which have a certain spending envelope – a certain thing [device] is not cost-effective and then you see that Columbia and Romania are buying it. There's a problem there."* ***(Health policy and health economics consultant)***

> *"Something that's in the back of my mind is always the whole issue of corruption and collusion and so on. Because we know that that has happened many times in the devices business and it is not something we have very good defences against it. It's part of our procurement challenge that when you look at the specifications you need to be able to see in the specifications whether they are wide enough to ensure competition but on the other hand specific enough so that the buyer gets something they can use."* ***(Consultant on health systems and financing)***

Such issues may be perpetuated by hierarchical decision-making structures, a lack of open communication and the wish of central level stakeholders to retain power and/or prestige:

> *"Telling someone the state of your facilities – if it's too bad it will look bad on you, if it's too good you might not get what you want. (...) So your status is important and it affects how you relate to people and therefore what you give away to them. And that information I think is always the key block, because*

giving away information, giving away power, control and it's hard to do when that's your responsibility." ***(Biomedical engineer)***

Participants consider that these issues, coupled with the lack of knowledge of international guidelines or recommendations on MDE procurement, result in suboptimal procurement and resource allocation practices.

When asked about solutions to this problem, experts indicate that development of a transparent and systematic decision-making system would be ideal.

"I think that you have to handle this [corrupt and collusive practices] in the context of the design of benefits plans. (...) There should be an effort depending on what the problem is, but starting with maybe the most expensive things or perhaps starting with what's the big health problem (...) to look at what the most cost-effective alternative is." ***(Health policy and health economic consultant)***

Participants acknowledge, however, that the success of such systems hinges on the availability of both decision-makers with the political capital to influence behaviors and analysts with the required technical expertise to advise on potential health system investments. In the case of MDEs, ministry stakeholders could thus empower biomedical engineers and health economists to advise on product selection given a country's unique care context. Examples of such efforts include the National Center for Health Technology Excellence in Mexico (CENETEC) (10) or the Health Intervention and Technology Assessment Program in Thailand (HITAP). (25)

Participant responses indicate that strengthening of technical expertise and capacity in biomedical engineering and health technology assessment is a first priority for LMICs, given that MDE procurement recommendations and tools already exist:

> *"I think that there's more of a political, technical, case to be made right now more than tools or capacity, which I believe exists. Of course they could be better, of course they could be tailored, but I think one is just making a case to decision makers that this is an essential function of the health system.[to appraise investments]"* ***(Health policy and health economic consultant)***

Technical experts or analysts are therefore prized as a form of symbolic *capital* due to their role in staffing and creating rational resource allocation systems:

> *"So I think it is almost, you almost need like, like a neutral broker. Someone who's paid for the service and not in commission on the actual deal to find out what is the best way to buy a particular device or maybe even that might be the wrong question."****(Consultant on health systems and financing)***

Experts deplore the lack of human and financial resources to develop HTA systems across LMICs, resulting in minimal take-up of such methods:

> "*High-income countries tend to use health technology assessment more and more compared to the others. Which is a shame because it should happen the opposite way. (...) But it's not happening partly because of limited resources for health technology assessment"* ***(Consultant health economist)***

2. 4. DISCUSSION

Findings within this study suggest that technology procurement is a complex game wherein health care professionals endeavor to address patient needs and health facility managers act to strengthen and expand their institutions' role within the health system. A user-buyer divide exists in both settings: while clinicians note patient needs and log procurement requests, it is health facility managers and/or policy-makers at central government levels that ultimately decide what products to purchase. The process and criteria for product selection and/or prioritization are not consistent or well defined. In The Gambia, product selection is discussed at ad-hoc governmental meetings. Stakeholders at this level have little to no knowledge of local needs or expertise relating to international MDE procurement recommendations or technical requirements (e.g. biomedical engineering and product technical specifications), methods (e.g. health technology assessment) or tools (e.g. checklists). Similarly, in Romania, the government relies on a group of clinical experts for decisions on outfitting the main eight referral hospitals but the criteria and decision-making process behind final MDE procurement for small and medium-sized facilities are unclear.

In both countries, procurement is far from a rational and systematic resource allocation exercise. Instead, processes are driven by contextual and cultural factors such as hierarchical structures and the struggle of facility managers to ensure institutions' 'relevance' and 'survival'. International experts acknowledge and deplore the effect of such issues on decision-making and draw attention to corrupt and collusive decision-making practices in LMICs more generally. Experts note the difficulties LMICs face in contextualizing international recommendations and guidance in the absence of technical

expertise, local data and the political capital necessary to support transparent decision-making. Biomedical engineers are needed to advise on or undertake product selection and maintenance, and economists should advise health ministries on medium to long-term resource allocation and service planning.

Barriers and facilitators to rational and transparent policy making

It is pertinent to acknowledge barriers and facilitators to rational and transparent policy making and resource allocation. In both settings, the health system's lack of stable and predictable funding acts as the primary barrier to rational decision-making. The acute lack of funds to support health service delivery means that stakeholders cannot adequately plan future service delivery or resource allocation, or indeed have to overturn plans already made in order to cover basic services for which funds have become scarce. Participants in Romania, for example, reflected that funds for intervention delivery ran out in the third quarter of the year, making any plans for MDE acquisition moot.

The opaqueness of decision-making structures and stakeholders' unwillingness to share information are further barriers to rational resource allocation. In Romania, health facility managers and staff were unclear on how and why the Ministry of Health would allocate MDEs to individual areas/facilities. No appeal mechanisms for rejected MDE requests exist and government officials were reticent to discuss the exact criteria for resource allocation, only indicating that expert committees made decisions to support national health policies. Interviewed regional representatives instead suggested that health policy played a minimal role and that political pressures or incentives predominantly influenced decisions. Expert consultants also identified the systemic lack

of transparency and stakeholders' unwillingness to share information - and thus to give up power and open oneself up for criticism - as barriers. Corrupt and collusive practices were also noted though no direct examples were offered in interviews.

Wider literature on priority setting suggests participatory structures promoting open communication among stakeholders facilitate rational resource allocation. (21,26) However it is important to note that such structures need to cover all health system levels so that stakeholders are empowered to participate in all relevant deliberations. For example, Gambian stakeholders created participatory structures for health facility representatives to engage in resource allocation decisions at *meso* health system level, however local and regional representatives were still effectively excluded from ministry level meetings. The Gambian Permanent Secretary for Health, the representative of the National Medical Stores and Finance Ministry were instead responsible for resource allocation at ministry level. However, Gambian participants were more knowledgeable than Romanian counterparts when asked about the motivations behind MDE procurement, echoing The Gambia's emphasis on achieving the MDGs.

Stakeholders acknowledged the presence of technical analysts - versed in health technology assessment and/or possessing relevant technical knowledge of biomedical engineering - as a further facilitating factor to rational policy making. When empowered to take part in resource allocation planning, such professionals can assist stakeholders in undertaking needs assessments or systematic evidence evaluations to inform product selection and use. Analysts of this type are additionally likely to possess the relevant knowledge of international methods and tools that may be helpful in product selection. For example, The Gambia has access to biomedical engineers and in those cases where

engineers have been consulted, MDEs with suitable specifications to The Gambian infrastructure were procured, and successfully adopted, used and maintained in health facilities.

While the lack of knowledge of international resources on MDE procurement should certainly be acknowledged as a barrier to rational policy-making, it is worth noting that this is not the primary factor behind poor decision-making. The above sections emphasize that even should analysts and/or professionals with relevant knowledge be available, the lack of funding for the health system, opaqueness of decision-making and lack of suitably empowering participation structures will counteract any potential benefits professionals may bring unless these systems also change.

Limitations

Findings presented here should be interpreted with due caution. The study is restricted to two case studies of MDE procurement in LMICs, purposefully including a low-income (The Gambia) and upper middle-income country (Romania) to capture maximum divergence. Conclusions reached apply to the public health sector: processes and/or stakeholder motivations within non-governmental, international organizations or the private sector were not explored. While contexts will differ across settings, the current study illustrates the potential use and relevance of Bourdieu's theory on the logic of practice for the contextualization of procurement decision-making processes and dynamics in LMICs.

Study findings highlight the need for further capacity building within LMICs and for careful contextualization of international procurement guidance. Interventions targeted

at obtaining MDE procurement and management improvements need to focus on putting in place people able to understand, navigate and ultimately change the *fields*, *nomos* and *habitus* encountered among LMIC stakeholders. Methods, tools and guidance to empower these professionals are available. (10,15,16,27) To aid The Gambia in more systematic product selection, investments in local biomedical engineering capacity and the development of a national policy on medical devices could be a first step. Engineers would have recourse to internationally developed tools and guidance and could adapt this to the Gambian setting if empowered by the ministry and health system. In contrast, Romania may benefit more from capacity creation in health economics. The creation of a health technology assessment body to incorporate views from stakeholders and advise national decision-makers on procurement would foster dialogue, enhance transparency and promote rational resource allocation. The impetus for capacity building in biomedical engineering and health economics is rarely realized or acknowledged by country respondents: it is the responsibility of experts, high-level LMIC stakeholders and the international community to insist on, and pursue, capacity creation.

2. 5. CHAPTER SUMMARY AND KEY FINDINGS

Informed by the preliminary findings of the systematic review, a qualitative study into the procurement processes of two contrasting LMICs – The Gambia and Romania – was planned and carried out. The aim of this study was to explore the empirical aspects of MDE procurement planning and decision-making.

> *Key Finding 4: Fieldwork findings largely corroborate conclusions drawn from the literature review: procurement is a complex, multi-level, multi-stakeholder process driven by stakeholder experiences. Limited evidence is considered during product selection.*

The study found that across both the Gambia and Romania, MDE procurement is driven largely by the clinical and management experience of physicians and health facility managers or policy-makers. In line with systematic review findings, different stakeholders are involved with managing MDE procurement. Health facility managers and clinicians were able to influence the procurement of devices that fall below a specific cost-threshold (e.g. 30,000 EURO in Romania) at institutional level. National level stakeholders were instead responsible for the selection, purchase and distribution of high-cost technologies across national health facilities.

> *Key Finding 5: Decision-making dynamics are strongly influenced by culture and considerations of power and prestige. These dynamics are substantiated by stakeholders equating MDEs to objects of symbolic relevance.*

Study participants across both settings recognized MDEs as indispensable elements of service delivery and prized technologies as symbolic forms of capital. The relevance of

MDEs results from participants conceptualizing the possession of technologies as proxies for institutional prestige or quality of care. Facilities with more up to date and varied MDEs are able to attract further funding both via reimbursement mechanisms, as well as directly via patient fees. Given this symbolic relevance attributed to MDEs, procurement decision-making does not take the form of rational resource allocation, but ad-hoc and prestige driven processes. Cultural and socio-political elements, such as health facility's managers need to rigidly control asset purchases and the struggle for health facility survival in an underfunded health system, additionally influence stakeholder interactions and dynamics.

> *Key Finding 6: The uncoordinated and socially constructed procurement environment is susceptible to manipulation; experts note the presence of corrupt and collusive practices across LMICs generally.*

Given the multitude of incentives and factors influencing MDE procurement – as well as lack of an evidence-based and transparent MDE selection and resource allocation framework - corrupt and collusive practices take hold. International experts with cross-national experience iterate the presence of such issues across LMICs more generally. Experts therefore suggest that attempts to improve MDE procurement must include careful stakeholder management, including technical capacity creation, and perception negotiation to be successful.

> *Key Finding 7: Changes in procurement systems can only be brought about by careful country-specific and sensitive implementation: this requires suitable professionals foremost. Frameworks, methods and tools to improve processes exist, the human resources to implement them in LMICs do not.*

The fieldwork in both countries uncovered similarities across low- and middle-income settings. The main point of comparison is the dearth of biomedical engineering and/or health technology assessment professionals able to advise on MDE procurement issues. Knowledge of international procurement guidance was additionally poor across both settings. Notably, however, study findings suggest MDE procurement challenges are substantially different across low- versus middle-income settings: The Gambia is struggling with procurement and management of minor low-cost technologies (e.g. glucometers), whereas Romanian stakeholders mainly focus on the procurement of medium- and high-cost technologies (e.g. ultrasound and CT scanning machines). International expert opinions complement the in-country fieldwork and suggest MDE procurement differences between low- and middle-income countries exist. Experts advise that contextually relevant interventions must be designed to improve resource allocation processes. Investments into the human resource capacity of countries are at the forefront of improving MDE procurement. In this case, both countries would benefit from the availability of technical experts in biomedical engineering and health technology assessment to advise on technical design and value-for-money of alternative devices.

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2. 7. BOXES

BOX 1: BOURDIEU'S THEORY OF THE LOGIC OF PRACTICE: THE EXAMPLE OF A FOOTBALL GAME

Two teams of eleven players are engaged in a football game.

Field: The overarching structure or process that frames agents' actions: the competition or the football game itself.

Nomos: The "fundamental law of a field" (28), the implicit or explicit tautology that prompts players to engage in the game: each team's and player's desire to win and proceed to the national championship.

Habitus: The rules of the game and the space to manoeuvre within and around the rules. Players are cognisant of the off-side rule, optimal goal scoring strategies, create new strategies and dynamics in the course of play. For example, players adapt to individual passing skills, enacting new tactics.

Capital: The instrument around the possession of which the field is structured; capital can be economic, cultural or symbolic. The football is economic capital; the knowledge and skill in handling the ball, planning or enacting a strategy is cultural capital. Player status conferred by experience, skill or possession of the ball is symbolic capital.

2. 8. TABLES

TABLE 1: PARTICIPANTS TARGETED FOR INCLUSION

Participant type	Justification
Health care professionals in small or medium sized health facilities (up to 250 beds).	Clinicians are primary MDE users.
Institutional, regional or national health facility, service and program managers	Previous literature review notes stakeholders as relevant to the procurement process.
Regional or national policy makers, including regulatory, public health and finance officials	Stakeholders influence policy, financing and/or regulatory structures relating to devices.
International consultants active in medical device procurement	International organizations such as the WHO, World Bank and other think tanks and academic institutions offer medical device procurement consultancy for LMICs.

TABLE 2: NUMBER OF INTERVIEWS AND FOCUS GROUPS CONDUCTED

	The Gambia	Romania	International consultants	Total
Interviews	17	18	4	39
Focus groups	10	1	-	11

TABLE 3: NUMBERS AND TYPES OF STUDY PARTICIPANTS

Participant category	The Gambia	Romania	International consultants	Total
Health care professionals (including laboratory technicians)	42	5	0	47
Health facility managers	6	6	0	12
Health facility financial administrators	0	5	0	5
Regional health authorities	1	1	0	2
Procurement agents	3 (2 national, 1 regional)	1 (Hospital level)	0	4
Expert assistance:			0	
Biomedical engineers	2	0		2
Other (e.g. think tank/NGO)	1			1
Ministry representatives	1	1	0	2
International experts	0	0	4	4
Total	56	19	4	79

TABLE 4: NUMBERS AND TYPES OF VISITED HEALTH FACILITIES

	The Gambia	**Romania**
Minor health centres	5 (all regions)	NA: general practitioner practices
Major health centres	2 (all regions)	NA: Referral is GP to municipal hospitals.
Hospitals	4 (all regions)	7 (2 counties only)

TABLE 5: CONCEPTS IN BOURDIEU'S THEORY OF THE LOGIC OF PRACTICE ILLUSTRATED BY CASE

Concepts in Bourdieu's theory of the logic of practice	**Cases (transcript collections)**		
	The Gambia	**Romania**	**Expert group**
Field	Health service delivery		Resource allocation
Nomos	Avoiding negative patient outcomes and meeting service needs	Meeting patient demand and ensuring the survival of health facilities	Ensuring transparent resource allocation and maximizing utility given resource constraints
Habitus	Empathy and understanding between care providers Severe resource constraints leading to ad-hoc procurement and careless behaviors as providers lose hope in improving service delivery and achieving impact	Adversarial power game between individual health facilities as well as with the ministry Power game sustained via legislation which includes threats to facility survival and the employment of managers therein	Critical appraisal of national procurement systems
Capital	Medical devices and equipment Funding to procure medical technologies Technical capacity to select and maintain products Information and its communication/sharing		

TABLE 6: PRIORITIZATION CRITERIA EMPLOYED BY DIFFERENT PARTICIPANT GROUPS

Stakeholder group mentioning criteria	The Gambia	Romania
Health care professionals	Patient need Patient impact Urgency Avoidance of negative outcomes (e.g. death) Quality, maintenance and durability	Ensuring service provision Meeting patient and physician needs
Health facility managers/CEOs	Service provision Managing patient demand Developing the health facility	Addressing patient and physician demand Equipment durability, design, throughput, maintenance Increasing financing allocation through investment in new equipment Developing health facility
Regional authorities	Service provision in region: timely, coverage	Service provision in region: timely, coverage
National level stakeholders	Coverage Service provision Equipment durability, design, throughput Meeting targets: MDGs	Coverage Service provision Rising to European care standards, meeting IMF/WB standards

2. 9. FIGURES

FIGURE 1: MDE PROCUREMENT IN THE GAMBIA

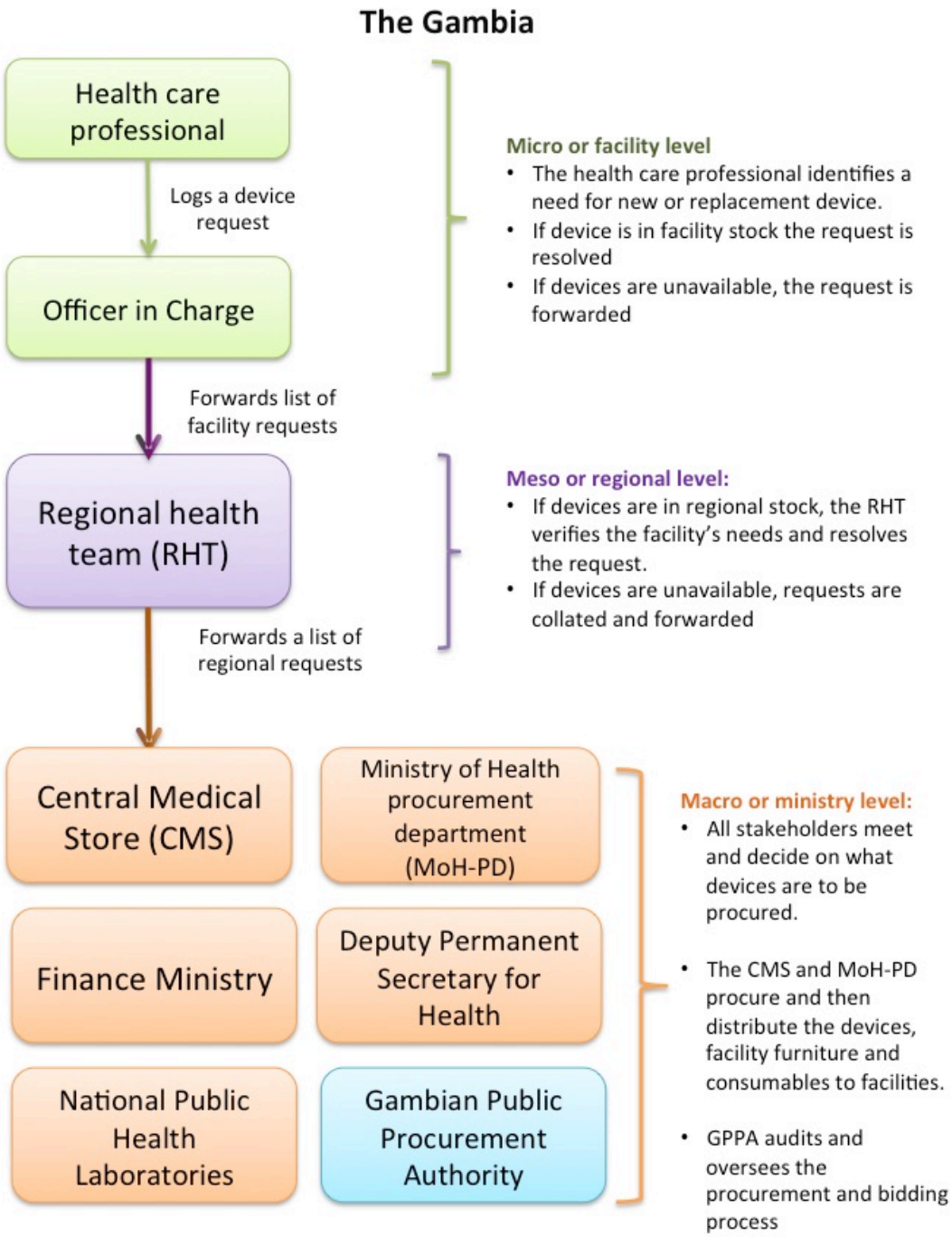
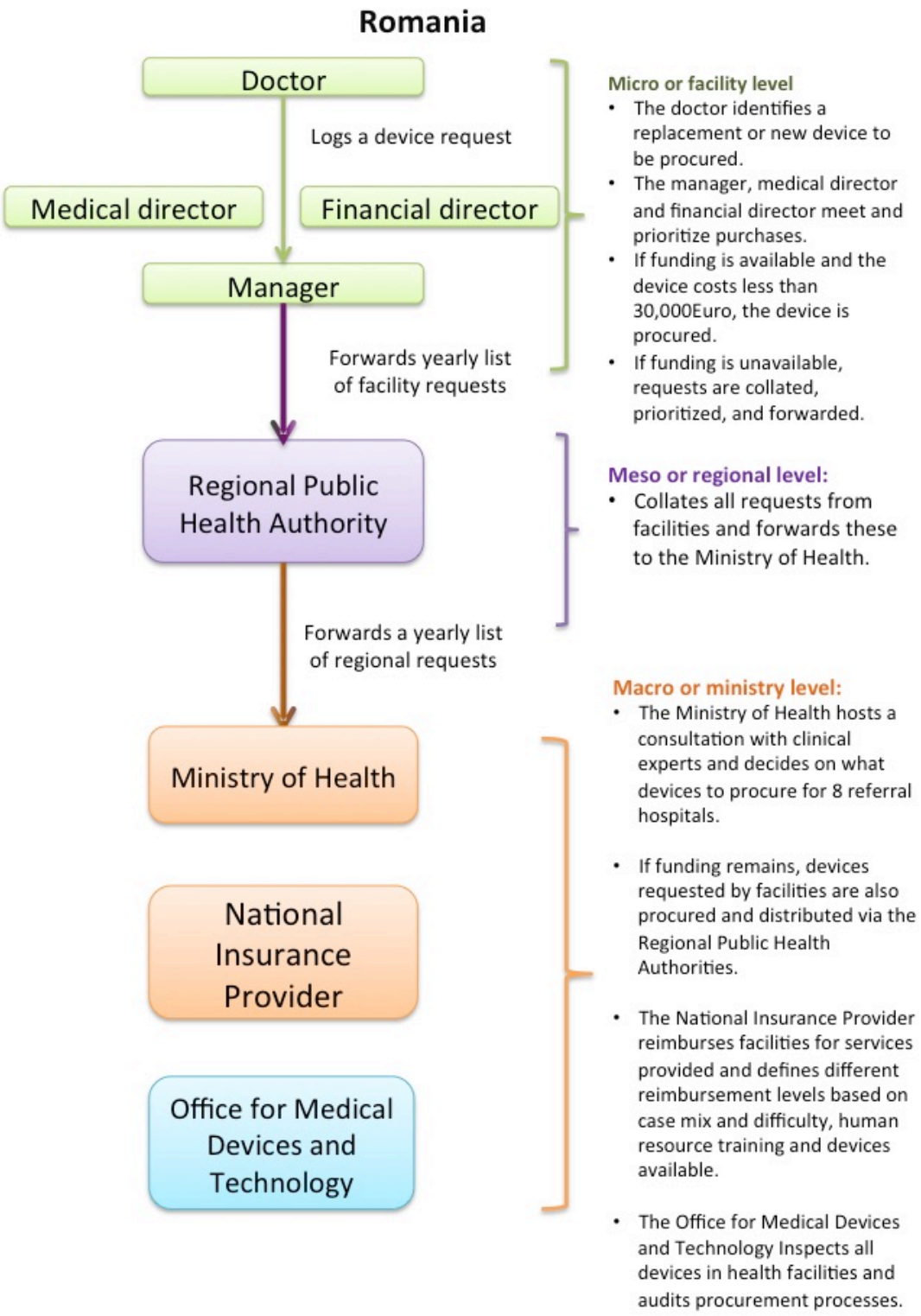


FIGURE 2: MDE PROCUREMENT IN ROMANIA



CHAPTER 3: THE FEASIBILITY OF CONDUCTING HEALTH ECONOMIC EVALUATIONS FOR MDE PROCUREMENT: REFLECTIONS ON A GENERALIZED COST-EFFECTIVENESS ANALYSIS CASE STUDY OF INTERVENTIONS FOR FEMUR SHAFT FRACTURE FIXATION IN SUB SAHARAN AFRICA

Please see Appendix 9 (Electronic only) for ancillary files to this chapter.

3. 1. INTRODUCTION

The usefulness of health technology assessment (HTA) for informing resource allocation decisions is widely acknowledged across higher-income countries (1–5) and receiving increasing attention within low- and middle-income countries (LMICs).(6–9) Evidence on the efficacy, value for money and affordability of different health technologies – including medicines and medical devices and equipment (MDEs) – is critical to policy-makers and health system planners trying to achieve universal health coverage in resource poor settings.(6) While HTA has the potential to improve the allocative efficiency of health systems and increase the transparency of decision-making processes (10,11), its use is severely hampered by the absence of reliable data, technical capacity and political support. (12)

The WHO emphasizes that HTA systems, alongside regulatory and management frameworks, are key components of health systems, and should play an important role in MDE administration and policy-making. (13) Reports and research from resource poor settings, however, suggest 40-70% of MDEs fall into disuse due to undiscerning procurement efforts, lack of regulatory systems and absent maintenance and servicing capacity (14–17) – all issues that HTA frameworks should ascertain and address. Inconsistencies in the way HTA is implemented and used across LMICs may perpetuate such issues. (18) The 2015 Global Survey on HTA suggests that where present, HTA appears to focus on the evaluation of safety and clinical effectiveness of MDEs; factors such as cost-effectiveness, budget impact and/or implementation issues are considered infrequently. (18) LMIC specific health economic (HE) evaluations of MDEs, rather than medicines or intervention packages, are therefore also rare. (18–20)

This could be attributed to several issues. First, unlike medicines, MDEs are used across patients and clinical departments/units and routinely procured in sets: e.g. surgery kits, including instrumentation and minor devices such as oximeters. HE evaluations should therefore account for the shared resource use of MDEs.

Second, decision-makers and analysts may not find it worthwhile to commission/conduct evaluations of single MDEs. Current practice assumes that cost-effectiveness models implicitly consider the cost-effectiveness of MDEs and can therefore help inform procurement choices. For example, Ginsberg et al include surgical and diagnostic equipment for lumpectomies, colonoscopies and radiotherapy among the service packages evaluated for treatment of breast, cervical and colorectal cancers.(21) Screening interventions in combination with surgical treatment are shown to be highly cost-effective, potentially leading decision-makers to assume investments into the equipment considered to reach these estimates are cost-effective as well. This is particularly problematic due to the implementation challenges MDEs face in the eventual deployment setting. (See Chapters 1-2 and (20,22)) In the case of Ginsberg et al, it is furthermore unclear which specific devices were chosen for the hypothetical implementation of each intervention. Indeed, the authors issue a warning to policy-makers to consider the available infrastructure and human resource mix carefully before embarking upon service implementation.

There may be minimal value in evaluating basic, clinically efficacious and low-cost technologies such as stethoscopes and glucometers. (19) Such products are already included on the WHO's Core Medical Equipment Lists and are deemed safe, appropriate and highly cost-effective for LMICs by expert consensus.(23) It is potentially more useful to conduct evaluations of MDEs which present contentious

investment decisions(19): e.g. see Burn et al. on pulse-oximetry (24) or Teerawattananon on laparoscopic surgery (10). However, there is a dearth of health economic analysts available to assist with such tasks in LMICs(18), with notable exceptions in countries that have made substantial efforts of integrating HTA into national policy-making and built human resource capacity in this area, for example, Thailand (25), Poland and Brazil. (7)

Third, should health economists be available it may be considered that their time is better-spent contextualizing models and findings from studies conducted elsewhere. Contextualization and translation of study findings from one setting to another may however not be advisable; in addition to issues of heterogeneity in underlying population, setting characteristics or intervention implementation, the relevance, methodology or "application" of health economics to the overall health system may differ. (26) For example, the qualitative study presented in this thesis (see Chapter 2) suggests that The Gambia and Romania face substantially different challenges. Within the Gambia, infrastructure is currently so minimal that it may be most relevant to evaluate entire service or infrastructure packages. In Romania, it may instead only be worthwhile to evaluate the introduction of additional services.

However, despite the above points, it remains pertinent to explore methods available to analysts or decision-makers for determining the relative value-for-money of different MDEs. This chapter explicitly focuses on exploring the applicability and feasibility of one such HE evaluation method for informing MDE procurement planning.

3. 2. METHODS

Chapter aims and structure

The chapter proceeds in two parts. First, a case study exploring the cost-effectiveness of alternative treatment strategies for femur fracture fixation following generalized cost-effectiveness analysis principles is presented. (See section below) The purpose of the case study is to 'road-test' the feasibility of generalized cost-effectiveness analysis methods and principles for the appraisal of interventions with substantial MDE procurement implications. Success in this endeavour is defined as the analyst's ability to construct an appropriate economic model and obtain a cost-effectiveness estimate.

In a second part, the challenges encountered in developing the case study will be discussed. In particular, comments on the feasibility of conducting such a study from the point of view of an economist not previously exposed to generalised cost-effectiveness tools or methods will be presented. Critical reflection will focus on the following items:

- Tools: are the software programs made available to LMIC and other analysts easy to use and suitable for modelling purposes?
- Methods: what challenges arise during implementation of GCEA and development of the case study economic model?
- Data and inputs: How easy is it to obtain relevant data to populate an economic model for a GCEA type analysis? What other type of inputs may be needed?
- Expertise, effort and time-scale: When and how should GCEA be used?

The NICE Guide to Methods of Technology Appraisal 2013 will be followed to gage the relative success of the case study method and economic model for informing decision-makers. (5) Specifically, the usefulness of the case study will be considered in light of:

- Strength of clinical evidence underpinning the model;
- Appropriateness of the model, including consideration of the decision-problem modelled, plausibility of inputs and assumptions made, implications for current health service delivery/budget impact.

To summarize, the purpose of this chapter is to explore if a MDE specific HE model using GCEA can be constructed and to document challenges arising during this process and propose further points of methodological research/development.

Generalized Cost Effectiveness Analysis

The WHO CHOosing Interventions that are Cost Effective (WHO-CHOICE) group endorses an economic evaluation method known as *generalized cost-effectiveness analysis* (GCEA). The hallmark of this method is the comparison of all potential treatments against a hypothetical null scenario where no treatment is available. (27) This type of sectoral cost-effectiveness analysis seeks to identify the most cost-effective treatment pathway under the assumption that LMIC policy-makers could reallocate all funds and resources towards the most cost-effective program.

To aid in this type of evaluation, WHO-CHOICE developed a comprehensive guideline document and tool-set.(28) Tools are Excel based and consist of: a dynamic life-table population model known as PopMod (Part Two: 2 in (28)), a costing template able to

capture both health facility, regional and program costs – CostIt (29) and a tool for carrying out stochastic league table simulations for uncertainty analysis known as MCLeague. (30)

The WHO-CHOICE guidelines state devices are to be considered integral parts of interventions: their full economic cost needs to be captured and the choice of products to be appraised within interventions be made explicit. GCEA additionally draws attention to program budgeting and marginal analysis which is better suited to deal with MDEs and infrastructure investment appraisals when these need to be considered separately to specific interventions or vertical programs.(31,32) GCEA adopts a societal perspective, endorses the use of the disability-adjusted life-year (DALY) for valuation of intervention effectiveness and proposes the use of an annual 3% discount rate of both costs and health effects. (28)

In contrast, the Bill and Melinda Gates Reference Case (BMG-RC) for Economic Evaluation endorses the traditional *incremental cost-effectiveness analysis* already in use within the United Kingdom National Institute for Health and Care Excellence.(33) The BMG-RC proposes that decision-makers and analysts within LMICs focus on comparing the effectiveness and value for money of the main interventions that are feasible/of interest to the health system. Recommendations are to adopt a health system perspective (valuing all potential expenses that may befall the health system in future, including out of pocket expenses), use the DALY for valuation of intervention effectiveness and discount costs and effects at 3% annually. The GCEA-suggested comparison of interventions against a null scenario is to be carried out in additional analyses; exploring the effect of 3% discounting for health effects and a discount rate reflecting regional rates of government borrowing for costs is also recommended. (34)

While BMG-RC is not as comprehensive a document as the guideline issued to support GCEA, the reference case recommends a specific reporting standard that analysts should follow. Comprehensive guidance on how to carry out ICEA is already available elsewhere.(e.g. see (5,34) for a comprehensive list of materials)

In practice, decision-makers may wish to consider more than just the cost-effectiveness or relative value for money of alternative interventions/programs when reaching investment decisions. *Multi-criteria decision-analysis (MCDA) methods* draw upon quantitative and qualitative research techniques and allow for the consideration of further relevant factors, including: equity (3), feasibility, cultural acceptability and affordability of offering a service (9,35) and severity of disease (36). Using MCDA, decision-makers and analysts may transparently specify and consider all criteria pertinent to a decision-problem; individual expert value judgments are then aggregated to identify the best possible investment option. (37,38) Similar to HTA generally, the purpose of MCDA is to consider all relevant evidence including that provided by the Global Burden of Disease (39), cost-effectiveness analysis (27,34) and evidence based-medicine. As illustrated in Chapter 1 (Tables 8 and 9), this is particularly relevant to MDEs: it is not only the cost and cost-effectiveness of MDEs that affects their uptake and use in health facilities, but also criteria relating to product design, and maintenance and decommissioning services available to manage technologies. The systematic review outlined in this thesis (Chapter 1) identified only one MCDA study relating to MDEs: Nobre et al (40) illustrate the use of the technique for a procurement problem in a public hospital in Brazil.

Program budgeting marginal analysis (PBMA) may be of further relevance to decision-makers contemplating MDE investment decisions. PBMA implies detailed review of a

current program budget (i.e. identifying how resources are spent) to inform further marginal analysis (i.e. how marginal gains in relevant outputs can be achieved subject to changes in resource allocation either within or across programs).(31) PBMA is supported by a seven step process where decision-makers are invited to establish the aim and scope of the exercise – i.e. allocation within or across programs, decide on a program budget, convene a marginal analysis advisory panel, elicit locally relevant decision-making criteria and assess options for service growth and resource gains from scaling back services or disinvestments. (ibid) The exercise concludes by evaluating all investment and disinvestment options, validating results and re-allocating resources. (32) PBMA can be seen as holistic process rather than unique method, and can incorporate methods such as MCDA as well as other decision-making aides such as participatory action research and the accountability for reasonableness framework. (ibid) For MDE investment decisions, PBMA can be particularly useful if it incorporates cost-effectiveness analysis: considering the relative cost-effectiveness of MDEs and separately the opportunity costs associated with the procurement of different products can help decision-makers clarify which devices are best suited for investment. For example, when considering facility specific investments into surgery it may be beneficial to invest in comprehensive open-surgery kits rather than devices for laparoscopic surgery, considering the latter are more expensive and less likely to be indicated for use across all patient categories.

Notably, the above methods necessitate the availability of both suitable data and sufficient financial resources and technical capacity (i.e. analysts with the relevant health economic modelling / social science methods knowledge). The aforementioned resources are particularly scarce across LMICs; in their absence, decision-makers may

turn to the use of heuristics to reach MDE investment decisions. One such method is described in detail by Lilford et al (including KD as a co-author) in: "An approach to prioritization of medical devices in low-income countries: an example based on the Republic of South Sudan." The approach involves specifying all potential MDE investment options; MDEs are first appraised at face value:

- costly devices, which exceed available budgets, are ruled out;
- basic technologies, which prove safe and effective, are purchased;
- and remaining products undergo further appraisal. The latter involves consideration of available human resources to adequately use products (including training or hiring requirements) and maintenance services (including financial resources needed) for ensuring products reach full life expectancy. Should trained personnel and servicing capacity not be available (or obtainable), products are ruled out; remaining products then undergo a best evidence review exercise to determine they are the safest and most effective technology available for offering the desired service. Where the evidence review is inconclusive, a full health economic model is commissioned.

The approach described is pragmatic and tailored specifically to decision-making under severe resource constraints. Such heuristic methods can prove particularly helpful when used in conjunction with resources listed in the systematic literature review on procurement methods and tools (See Chapter 1).

Limitations

This study was carried out by one analyst (KD) and a series of pragmatic limitations therefore apply. First, the case study focused on identifying an area of clinical practice involving interventions with substantial MDE procurement implications. Orthopaedic interventions for femur fracture fixation were chosen, informed by fieldwork conducted in Tanzania by A. Gummaraju (Appendix 2). As all interventions fall within the same program category (i.e. treatment of femur fracture – orthopaedic services) this endeavour does not fully correspond to the intended use of GCEA – that is, comparison of service packages/vertical programs. The case study presented here applies GCEA principles to an intra-sectoral set of interventions, rather than inter-sectoral programs. This restriction in scope, as well as other simplifying modelling choices set out in the next section (e.g. adopting a health service rather than societal perspective), was necessary to reduce appraisal complexity and ensure a manageable workload. This restriction however limits the potential usefulness and validity of reflective comments made here. It is, however, pertinent to note that decision-makers proceeding to set up an entire service (e.g. orthopaedic services) may well be interested in applying this type of intra-sectoral GCEA.

Second, as the purpose of this case study was to explore how GCEA applies to MDE appraisals, the analyst chose not to proceed beyond initial model construction and calculation of a cost-effectiveness estimates. While the relevance of such analyses for decision-making in practice is not disputed, (20,41) data availability and quality was low in this case and analyses would have held little meaning in appraising the appropriateness of GCEA for the purpose selected here. A narrative overview of key

sources of uncertainty is provided to enable future analyses of this type if/when data becomes available. It should be noted that difficulties in undertaking sensitivity analyses are routinely experienced by analysts involved with LMIC specific evaluations (20).

3. 3. CASE STUDY: APPLYING GENERALIZED COST-EFFECTIVENESS TO TREATMENTS FOR THE FIXATION OF FEMUR SHAFT FRACTURES IN ADULT NON-ELDERLY PATIENTS IN SUB-SAHARAN AFRICA

3. 3. 1. DEFINITION OF THE DECISION PROBLEM

The availability and accessibility of safe anaesthetic and surgical care has received increasing global attention. At its 68th Global Assembly, the WHO passed a resolution on Strengthening Emergency and Essential Surgical Care and Anaesthesia as a Component of Universal Health Coverage. (42) Deliberations at the assembly were informed by findings of the Lancet Commission on Global Surgery.(43) The Commission notes that anaesthetic and surgical services were previously neglected in favour of disease or program specific issues and argues that such services should be recognized as essential components of resilient, responsive and functional health systems. (44) The effects in mortality and disability reduction of surgical services are likely to be particularly high in LMIC health systems. (45) Estimates from Sub-Saharan Africa and South Asia suggest only 13-31% of surgical need is currently met. (46) The associated loss in output is assessed at 2.5% of GDP for LMIC economies.(47)

Similar to further research in this area (48,49), the commission's findings stress that LMICs need urgent and expansive investments into the surgical and anaesthesia workforce and appropriate hospital infrastructure and equipment. (43,50,51) Verguet and colleagues estimate investments into operating rooms for carrying out 5000 major operations per 100 000 population per year for 2012-30 at 300-420billion US$. (50)

While this represents 1-8% of total annual health expenditure across LMICs (50) surgery is still highly cost-effective, particularly when focused on the treatment of injuries, obstetric complications, timely management of abdominal and life-threatening conditions and elective care for hernias. (52–55)

ORTHOPAEDIC SURGERY IN LMICS

This case study focuses on orthopaedic surgery, more specifically surgery for the fixation of femur shaft fractures due to trauma or injury in adult non-elderly patients located in LMICs in Sub-Saharan Africa. Violence and injuries are among the top ten causes of death across Sub-Saharan Africa (56) and the tenth cause of disability worldwide. (57) The burden of disability due to trauma/injury in productive aged society members is particularly high in low-income countries due to road traffic accidents and self-inflicted, violent or occupational injuries.(53,57,58) Fractures alone account for 22 million years lived with disability in 2013, with musculoskeletal, fracture and soft tissue injuries estimated to contribute 20.8% of global years lived with disability, assessments ranging from 10.8% in Mali to 30.0% in South Korea. (39)

Across Sub-Saharan Africa the availability of orthopaedic services able to cater to the volume of trauma and injury is low: across a sample of 267 hospitals, Chokotho et al estimate a mean of 1.4 orthopaedic surgeons available in district hospitals (n=185) and 2.4 surgeons in tertiary or referral facilities (n=82). (59) Closed fracture care was available in 75% of district hospitals, 82% of tertiary and referral hospitals respectively; however, only 37% of district and 40% of referral hospitals had instrumentation necessary for surgical treatment of orthopaedic fractures; implants were available in 7% and 8% of district and referral facilities respectively. (ibid)

Information on the cost-effectiveness of orthopaedic services in LMICs – particularly the cost-effectiveness of femur-fracture care – is scarce. Chao et al place the cost-effectiveness of orthopaedic services, including treatments such as club-foot surgery and tibia fixation, at 381.15$US (2012) per DALY averted. (53,54) This indicates orthopaedic surgery is comparable in cost-effectiveness to ophthalmic surgery and caesarean deliveries; certain interventions may potentially be more cost-effective than antiretroviral therapy for HIV. (54) However, studies included in obtaining this estimate are likely to under-estimate the true cost of services as they focus on provision of surgery under the auspices of volunteer missions or emergency response in Haiti, Nicaragua and The Dominican Republic(60,61); follow-up treatment and salary costs may thus not be accurately captured and cost-effectiveness over-estimated. (53) The cost-effectiveness of alternative treatments for femur fracture fixation is still undetermined: Chen et al (60) do not include femur specific interventions within their study and Gosselin et al (61) include only a small number of patients afflicted by such injuries.

SURGERY FOR THE FIXATION OF FEMUR SHAFT FRACTURES

Fractures of the femur shaft result in loss of mobility and, depending upon treatment modality and extent of injury, may lead to mortality inducing complications such as adult respiratory distress syndrome, pulmonary embolism, pneumonia, systemic infection and organ failure.(62) Femur shaft fractures are particularly important when occurring in productive aged society members in LMICs as they are likely to result in work absenteeism, leaving entire households and families bereft of income.(62–64) Quick (less than 24 hour) and effective long-bone fracture stabilization (resulting in fracture union and full weight-bearing) is likely to result in increased patient mobility,

decreased morbidity due to lower rates of adverse treatment effects and lower hospital costs for patients and the health system.(62,64)

In a recent qualitative study with femur and tibia fracture patients in Uganda, O'Hara et al note, however, that injured patients and family members may present late for treatment due to financial constraints. (63) While treatment and hospital stay may be subsidized by public funds, patients still bear the high costs of femur implants – whether plates or intramedullary nails; this is the main barrier to accessing high-quality treatment and patients are therefore routinely treated with traction. (63)

Skeletal traction is the traditional treatment offered in low-income settings – the length of stay in hospital may extend to several months and complications are frequent; high-income countries have long ago moved towards the use of plating and intramedullary nailing as a treatment standard. (65) With the advent of low-cost implants such as the SIGN nail (an orthopaedic implant designed for insertion into the femur with no power reaming or image intensification) these latter interventions for fracture fixation are declining in cost and an evaluation of the most cost-effective (or cost-minimizing) fracture treatment for LICs becomes relevant. (ibid) In particular, authors in the literature call for further research comparing skeletal traction, intramedullary nailing or plating and external fixation for fixation of femur shaft fractures. (62,64)

The economic model presented in this chapter builds upon a previous study of which KD is one author (Appendix 2) which explored the barriers and facilitators to the adoption of an innovative orthopaedic implant device – the SIGN nail –in Tanzania. The main facilitators behind SIGN adoption by individual surgeons and health facility managers were technology cost (the nail is currently donated) and usability (the product

is routinely revised due to clinician feedback), endorsement/recommendation of fellow clinicians and the existence of a feedback loop between product users and developers/manufacturers. As in the case studies in The Gambia and Romania (See Chapter 2), health facility or national level stakeholders in Tanzania did not appear to consider HTA related evidence within their decisions-making process. Stakeholders reflected upon cost-savings ensured by the use of the SIGN nail, however did not consider the relative clinical effectiveness of the product or alternative interventions beyond standard care (traction). Considering Tanzania's limited orthopaedic service delivery capacity (4 referral hospitals offer orthopaedic services for a population over 44 million) and the potential for adoption of the SIGN nail or other similar orthopaedic products as 'usual' care, it would be relevant to evaluate alternative treatment strategies from the perspective of the health system. As other countries are likely to be in a similar position, further LMICs in Sub-Saharan Africa were also included. (59)

3. 3. 2. DATA AND METHODS

AIM

The aim of this evaluation is to determine cost-effective treatment strategies for the fixation of femur shaft fractures in adult non-elderly patients in LMICs in Sub-Saharan Africa. Boxes 1-2 briefly summarize population, interventions/comparators, outcomes and setting information.

METHOD AND MODEL

Generalized cost-effectiveness analysis amended where necessary due to data paucity or contextualization of the decision-problem.(28)

A decision-tree was chosen as model structure as femur shaft fractures are acute conditions, likely to resolve in union or mal- or non-union in a relatively short period. Figure 1 illustrates a theoretical decision-tree developed with the assistance of clinicians; all potential fracture fixation interventions provided in LMIC settings have been included. Effectiveness estimates for several interventions included in Figure 1 were not available - i.e. for open reduction definitive external fixation, closed reduction and internal fixation with plating, closed reduction with definitive external fixation. Figure 2 displays the reduced decision-tree used as a basis for modelling.

TARGET POPULATION

This study is restricted to adults aged 16-65 affected by fractures of the femur shaft and under-going first line treatment after injury; patients with substantial comorbidities, including cranial injury, were excluded from analysis. Patients under 16 were excluded as they are unlikely to be skeletally mature; elderly patients were similarly excluded as they are likelier to present with fractures of the femur head rather than femur shaft.(66,67)

SETTING

Consistent with previous health economic evaluations undertaken by the WHO under the auspices of the WHO-CHOICE group(21,68), this analysis is restricted to specific Global Burden of Disease sub-regions, namely Africa – D (AfrD) and Africa – E (AfrE). AfrD includes countries in Sub-Saharan Africa affected by high child and high adult mortality, e.g. The Gambia, Guinea, Niger, Mauritania and Sierra Leone. AfrE includes countries affected by high child and very high adult mortality, e.g. Cote D'Ivoire, Ethiopia, Rwanda, Malawi and Zimbabwe among others.

It is estimated that 7% of the population within these regions has access to surgical services (Lancet commission, Meara et al 2015). The availability of orthopaedic services is additionally likely to be low: in a sample of 267 hospitals from east-central and southern Africa, a mean of 0.3 orthopaedic surgeons were available in 185 district hospitals, and a mean of 0.6 per referral or tertiary care facilities (n=82).(59)

PERSPECTIVE

The study is conducted from the perspective of the health service as per recommendations from the BMG-RC. While adopting a societal perspective is recommended as ideal practice by WHO-CHOICE, it was deemed impractical in this case because it would require additional data collection for estimation of indirect costs. (69) The systematic literature search undertaken (See Data and Evidence Sources below) identified only two articles including costs of treatment sought, however no indirect costs appear to be captured by either study. (70,71)

Production and time losses incurred by patients seeking orthopaedic care specifically would need to be quantified via other means (41). To enable meaningful inclusion of such costs in the model, a range of costs should be collected (potentially via survey) across the AfrD and AfrE settings, including estimates on the costs to care access, out of pocket expenses while seeking treatment, wages/profits foregone due to hospital stay. Debts incurred by the absence of family members (e.g. mothers) performing a caring role in the household would also need to be estimated.

As orthopaedic specific literature is sparse in this area, it may be appropriate to capture at least some of these costs in the model from literature on other surgical interventions (e.g. see O'Neill et al on breast cancer care in Haiti(72), Nguyen et al on hospitalised injury in Vietnam(73)) and perform sensitivity analyses. As this was a feasibility study, and full access to papers and data collected by the aforementioned authors was not available, it was instead deemed more pragmatic to adopt a health service perspective at this stage. Informed by AG's study in Tanzania and in line with BMG-RC, however, the

base case analysis includes implant costs, which are likely the highest out of pocket expenses sustained by patients.(34)

TIME HORIZON AND DISCOUNT RATE

In line with BMC-RC and WHO-CHOICE guidelines, base case analysis adopted a life-time horizon for DALY calculations and assumed a 10-year implementation period for estimation of costs.(27,34) A 3% annual rate was used to discount both health effects and costs; additional analyses include no discounting of health effects.

INTERVENTIONS AND COMPARATOR

In line with WHO-CHOICE guidelines, this evaluation considers all plausible interventions for femur shaft fracture fixation.(27) The null scenario – i.e. patients not receiving any treatment – is the main comparator; additional analyses conducted according to BMG-RC guidelines compare the effectiveness of surgical interventions to the 'traditional' treatment on offer - i.e. traction. (34) To construct the null comparator, mortality rates associated with femur fracture were identified; surviving patients were all assumed to proceed to long-term disability in line with a no-treatment scenario.

Operative and non-operative interventions modelled are described in more detail in Box 2. Briefly, operative interventions consist of open and closed fracture reduction, further categorized into surgical procedures relying on internal, external or external-internal fixation with intramedullary nails, femur plates or external fixation devices. Skeletal traction with cast or brace application is the only non-operative intervention considered. The latter is currently the most frequently offered treatment in LMICs. (70)

The choice of interventions was informed by repeated consultations with orthopaedic surgeons with experience in low-income country health care delivery. Deepa Bose is a consultant at Queen Elizabeth Hospital in Birmingham and Secretary of the World Orthopaedic Concern. She contributed to the formulation and design of this evaluation. Informal discussions on the choice of interventions offered across Sub-Saharan Africa were held with Prof. Chris Lavy (University of Oxford). Choice of interventions was further informed by the BMedSci student project carried out by A. Gummaraju. (Appendix 2)

OUTCOMES

Health benefits of alternative interventions are quantified in DALYs averted. Calculations for Years of Life Lost (YLLs) and Years of Life Lived with Disability (YLDs) were conducted similarly to studies in the Global Burden of Disease series(74). Results are reported for four types of DALY to ensure sensitivity relating to methodological DALY calculation assumptions (75) are captured:

i. Age weighted and discounted DALYs using standard Japanese life-expectancy (80 years of life for men, 82.5 years for women);

$$YLL = \frac{KCe^{ra}}{(r+\beta)^2}\Big[e^{-(r+\beta)(L+a)}[-(r+\beta)(L+a)-1] - e^{-(r+\beta)a}[-(r+\beta)a-1]\Big]$$

$$YLD = DW\left\{\frac{KCe^{ra}}{(r+\beta)^2}\Big[e^{-(r+\beta)(L+a)}[-(r+\beta)(L+a)-1] - e^{-(r+\beta)a}[-(r+\beta)a-1]\Big]\right\}$$

ii. Not-age-weighted and discounted DALYs, using standard Japanese life-expectancy;

$$YLL = \frac{N}{r}\,(1 - e^{-rL})$$

$$YLD = \frac{I \times DW \times L(1 - e^{-rL})}{r}$$

iii. Simple DALYs: not-age weighted, no discounting, using standard Japanese life-expectancy;

$$YLL = N \times L$$

$$YLD = I \times DW \times L$$

iv. Age weighted and discounted DALYs using AfrD and AfrE standard life-expectancy (formulas identical to i) using standard life expectancy of 57 years for men, 60 for women for Afr D).

YLL = Years of life lost due to premature mortality.

YLD = Years of life lived with disability

K = Age weight modulation constant 1 or 0

C = Adjustment constant 0.1658

R = Discount rate 0.03

a = Age of death

β = Age weighting constant 0.04

L = Standard life expectancy (for YLL) or duration of disability (for YLD) at time of death or injury

N = Number of deaths

I = Number of incident cases

DW = Disability weights

Disability weights for fractures of the femur (other than femur neck) from the Global Burden of Disease Study 2010 were used: 0.192 (uncertainty interval 0.121-0.280) for short term injury with or without treatment and 0.053 (uncertainty interval 0.035-0.079) for long term injury with or without treatment. (76)

Clinical outcomes extracted from the literature to derive DALYs were mortality and the status of fracture union; DALYs were calculated in relation to the number of patients experiencing a mal- or non-union of the femur shaft fracture. Due to data paucity and irregular reporting, it was not possible to stratify outcomes into successful union, mal- and non-union; the latter two outcomes were instead aggregated. Incidence rates were converted to one-year probabilities as per Fleurence and Hollenbeak. (77)

DATA AND EVIDENCE SOURCES

Demographic data for the AfrD and AfrE Global Burden of Disease regions were obtained from the WHO. (78)

EFFECTIVENESS ESTIMATES

Parameter estimates for intervention effectiveness for use in base case analysis were sourced from best evidence available across the AO Foundation Surgery Reference database for clinical care and documents identified in a systematic evidence search. Table 1 includes all parameter estimates retrieved from documents and Table 2 provides a summary of study characteristics.

The AO Foundation conducted systematic searches of Medline (last updated 2007) to identify comparative studies evaluating the effectiveness of fixation interventions. Studies were transparently classified into four classes of evidence; for the purposes of this case study, only studies within classes I-III were to be used, i.e. randomized control trials, cohort or case control studies.

To identify further relevant evidence, KD also conducted a systematic literature search to identify studies on long-bone (femur, tibia, humerus) fracture fixation effectiveness and costs in the target population. (Box 3) A. Gummaraju and KD independently reviewed titles and abstracts for relevance according to a pre-established algorithm. Studies were included only if they:

1. Mention any intervention/comparator pair of interest: plating, traction, casting, intra-medullary nailing, and progression of fracture when no treatment is administered.

2. Document any or all:

    a. Clinical outcomes of interest, clinical or radiographic: union (mal- or non-union), functional outcomes (mobility, range of motion, weight bearing, leg length discrepancy) etc.

    b. Utility outcomes: DALY or QALY.

    c. Intervention costs.

Studies were excluded if they: did not refer to the interventions of interest, the population was not over 16 and no outcomes of interest were reported.

The search strategy identified 361 studies of potential relevance, 207 abstracts were appraised and 118 found relevant for use in potential evaluations of the tibia, humerus or femur. (Figure 3) 30 articles related specifically to the femur; KD extracted data from the 19 articles for which full text versions were available to the University of Birmingham. (Appendix 9) KD categorized studies into three classes of evidence and only used estimates from references classed A-B: A – for randomized control trials or trials, B – for cohort or case control studies, C – for case series and studies with no comparator group.

Mortality estimates for the null treatment scenario or following intramedullary nailing, for the populations age group of interest, were not available across results from the above searches. Mortality estimates following intramedullary nailing were sourced from a multi-centre cohort study in India; and mortality estimates for the null treatment scenario were extracted from a prospective cohort study by Enninghorst et al.(79)

Incidence estimates for femur shaft fracture were also obtained from the latter study. (ibid)

COST ESTIMATES

Costs were obtained from diverse sources. Due to data paucity, an ingredients approach could not be used. Instead KD extracted cost data from the articles identified via the above literature search and references from the Lancet Commission on Global Surgery to estimate costs for operative and non-operative treatments. All documents appraised ignored or excluded the costs of implants: KD obtained estimates for such costs by first searching the UNICEF online product catalogue (no estimates were available) and then searching Alibaba (a global trading website) for femur compression plates and intramedullary nails from manufacturers that have obtained both CE and ISO 13485:2003 certifications specifically. Domestic taxes applicable to the import of such items were excluded from the analysis. All costs were converted to international dollars as per guidance issued by WHO-CHOICE and using published purchasing power parity conversion factors. (80)Table 3 details costs sourced from the literature and assumptions used for cost calculation. Opportunity costs were excluded from the analysis. (See also Appendix 9)

ASSUMPTIONS

Due to data paucity and the complexity of the theoretical decision-model considered (See Figure 2 for the final decision tree), a number of simplifying modelling decisions and assumptions were made:

- Only patients undergoing first-line treatment after injury were considered; patients undergoing surgery or stabilization following an initial negative fracture fixation outcome (i.e. non-union or mal-union) were not included.
- To ensure integration of all available data, the decision tree was constructed to consider the following outcomes for each intervention node: potential death (mortality estimate obtained from literature) and potential non-union or mal-union (estimate obtained from literature).
- Where mortality estimates were not available, i.e. following open reduction with intramedullary nailing or plating and open reduction with intramedullary nailing after temporary external fixation, a baseline all-cause mortality following musculoskeletal trauma and surgery was used. (Lancet Commission on Global Surgery: Foote et al 2015)

To construct the available model further simplifying assumptions relating to the modality of fixation were made. For example, our model does not distinguish between reamed vs. unreamed fixation, or fixation undertaken with or without image intensification during surgery.(81) Considering such factors would have doubled the size of decisions to be modelled for the intramedullary nailing interventions.

HETEROGENEITY

Differences in the clinical effectiveness and costs of treatments due to diversity in fracture and patient characteristics could not be explored due to data paucity. Classification of patients into subgroups according to the type of fracture sustained (simple, wedge, complex) was not possible, as the literature did not consistently report relevant outcomes at this level of detail. Heterogeneity due to differences in patient groups – as appraised by the injury severity score of patients – could also not be investigated. Patients with a high injury severity score (ISS above 25 points) present with life-threatening injuries and are frequently managed consistent with the principle of 'damage control orthopaedics'. (DCO) The latter involves prioritizing the treatment of urgent conditions and temporarily managing the femur fracture via external fixation; surgeons only proceeding to final fracture fixation upon patient stabilization. (82) In contrast to patients characterized by a high ISS, patients with limited injuries are routinely treated using 'early treatment care' – i.e. fixation of femur shaft injury up to 24 hours after admission. (82) Mortality is likely to be high in the former patient group (ISS over 25) and health outcomes likely better in the latter group (ISS under 25). A further source of heterogeneity is setting specific: it is likely that the incidence rate of femur fracture varies in settings exposed to high levels of armed violence (e.g. civil wars or conflicts)(67) or settings with minimal traffic regulations. (58) Variations in femur fracture incidence due to these issues are therefore likely in the AfrD and AfrE regions.

UNCERTAINTY

Deterministic and probabilistic sensitivity analyses relating to second order parameter uncertainty (69) were conducted as follows:

- Deterministic analyses:
    - capacity utilization rates of operating rooms were varied at 50 and 95% as per WHO-CHOICE recommendations reflecting likely surgical service utilization in the femur fracture population;
    - costs were discounted at 6 and15% as per WHO-CHOICE recommendations reflecting different discounting scenarios - in the first case, double to base case, in the second the rate reflects the regional bank bond lending rate in Kenya;
- Probabilistic analyses:
    - Monte Carlo simulations (1000 iterations) were conducted to generate cost-effectiveness estimates and calculate the net monetary benefit of each intervention (and ancillary likelihood of the intervention being cost effective):
        - effectiveness was estimated by calculating DALY values corresponding to mortality and non-union estimates repeatedly randomly sampled from beta distributions corresponding to the mortality and non-union data extracted from the literature;
        - population level intervention costs were similarly estimated using cost estimates repeatedly randomly sampled from gamma distributions corresponding to all costs extracted from the literature.

Distributions for all parameters were estimated using the method of moments as per Briggs et al. (83)

Using the above estimates, cost-effectiveness was estimated by calculating costs per DALY averted in comparison to both the null scenario and traction. To reflect the regional Africa D-E decision-problem most accurately DALYs were calculated using African life expectancy; similar to base case analyses, DALYs were age-weighted and used 3% cost discounting. The net monetary benefit method was used to estimate the probability that interventions are cost-effective at different cost-thresholds ranging from I$1- 10,000.

Limitations

Results of sensitivity analyses should be interpreted with due caution: substantial issues around data availability and quality apply. Parameter point estimates for non-union probabilities were derived from studies in the AO registry and documents identified via systematic literature searching. For studies from the AO registry, full text articles could not be accessed – i.e. references (84–86). The point estimates obtained from the AO database were converted to one-year probabilities (where follow-up time was not specified this was assumed to be one year). Notably, effectiveness estimates obtained thusly correspond to average incidence from underpowered studies not studying the exact interventions of interest – for example, the Canadian Orthopaedic Society point estimate extracted reflects the overall incidence of union across patients treated with both reamed and unreamed intramedullary nailing. It is likely that Mclaren's meta-analysis up to 1987 would be the only high-powered study relevant for data extraction, however no full text for this was available and no information on included populations

is provided in the AO database. Non-union estimates for the traction comparator were sourced from Gosselin et al, a study identified via systematic literature search.(87) The study is a retrospective study conducted within one hospital. The risk of bias is high: authors are evaluating the use of the SIGN nail (likely introduced by them into the health facility) versus skeletal traction using Perkins method.(87) Estimates from Opondo et al could have alternatively been used, however the risk of bias is similarly high here; in this "quasi-experimental" study patients were given a choice of treatment.(70)

The potential quality of estimates sourced from studies where no full text was available is under question; the risk of bias in other studies (e.g. (70)) is also high. The initial point estimates obtained from either these studies therefore do not appear robust enough to yield the sensitivity analyses conducted here meaningful. Variation in union-rates due to types of technology used (e.g. with or without reaming) may of course be a used as a proxy to explore the uncertainty around the union estimates included, however, it is unlikely that this would be relevant to decision-makers.

Higher quality data from sufficiently powered head-to-head trials comparing one or more of the interventions modelled could allow for extraction of meaningful high-quality point estimates and calculation of relevant confidence intervals around which to undertake sensitivity analyses.

To construct the null scenario it would also be relevant to estimate the probability of non-union after surviving a femur fracture. Information on union outcomes in patients not presenting for treatment was not deducible from available literature - all patients were therefore assumed to progress without treatment. In further studies it may be

appropriate to consult expert opinion and gage the range of union/non-union estimates likely to be observed in this population.

The costing approach adopted here combines bottom-up and top-down costing(88). The set-up costs of operating rooms were obtained from a modelling study (50). The model proceeded on the assumption that operating rooms would need to be set up to offer orthopaedic services (50); in practice, even should such rooms be built and equipped, they are likely to be used across clinical areas. The final per patient costs included in the base case here may therefore be over-estimated; deterministic analyses where operating room capacity use was varied to 50% may therefore offer a proxy for the likely cost-effectiveness of services in practice.

Implant costs included are averages obtained from a cursory search of digitally available online catalogues. While only ISO and CE approved implants were chosen, it would still be recommended to conduct further searches and include potential domestic taxes in future models before exploring any cost uncertainty. Demand and supply constraints could additionally be built into a model (20) given the limited availability of orthopaedic services in Sub-Saharan Africa more generally. (59)

REPORTING

The CHEERS checklist is followed for reporting (89). All items in the checklist are addressed except items 20a, 20b and 21 as these explicitly relate to results of uncertainty analyses. This study had no dedicated funding and no conflict of interest is applicable.

3. 3. 3. RESULTS

EFFECTIVENESS

DALYs resulting from each of the interventions included in the decision tree (Figure 2) are outlined in Table 4a; calculated estimates for Africa D, Africa E and Sub-Saharan (regions Africa D and E) are provided. Table 4b outlines DALYs averted as compared to the null no-treatment scenario and to the traditional treatment on offer (traction). The null scenario reflects all surviving patients hypothetically progressing to non-union, valued using a long-term disability weight of 0.053. DALYs for all other interventions involve the use of 0.192 as a disability weight.

Across all scenarios, traction is dominated; assuming African life expectancy, traction exceeds the no-treatment scenario by 30,786 DALYs. Calculation of DALYs for traction assumes the same mortality as for the null scenario – this is due to lack of mortality data for this intervention and assuming that traction is not able to avert mortality by itself. DALYs for this intervention may further be inflated due to the initial parameter value used for non-union probability. The parameter was sourced from a case-series study conducted by the SIGN-IM nail manufacturers to compare the use of intramedullary nailing to traction in Cambodia. The study is relatively small (n=87), and the traction comparator group consisted of the last 50 patients treated with traction within the specific hospital setting. The study may therefore suffer both from observer and selection bias.

In comparison, DALY estimates for operative treatments rely on parameter estimates sourced from higher-quality evidence. Across operative treatments, closed-reduction with intramedullary internal fixation (CRIF) appears most clinically effective.

Assuming African life expectancy, CRIF averts 251,166 DALYs in comparison the no-treatment scenario and 281,952 DALYs in comparison to traction across Sub-Saharan Africa. The dominance of CRIF is clinically plausible: similar to IM-nailing interventions, union-rates are high and mortality estimates are additionally lower than for open-surgery. (0.0126 vs. 0.017 probability of death) However, total DALY averted estimates for all operative interventions are similar, ranging from 235,730-251,166 in comparison to the no treatment scenario and 265,939-281,952 in comparison to traction. The similarity in DALY estimates obtained is due to similarity of input parameters: mortality estimates for ORIF-IM, ORIF-P and ORIF-IM following EF are identical. The AO reference database and systematic search failed to identify suitable high quality mortality estimates for these interventions and estimates from an Indian prospective cohort study were therefore used.

INTERVENTION COSTS

The total patient costs for each of the interventions considered in the decision tree (Figure 2) are outlined in Table 5. Costs were calculated using references identified via the systematic literature search or from the Lancet Commission on Global Surgery. Equivalent annual costs for the operating room make up more than 80% of the final per patient cost. Operating room costs were calculated based on Verguet et al's estimate of likely construction and MDE investments for surgery rooms. (50)The current model assumes operating rooms are used solely for orthopaedic surgery – this is an implausible assumption and implies costs are overestimated. Costs for low-, low-middle and upper-middle income countries were presented by Verguet and colleagues; the model assumes that 2 operating rooms would need to be constructed for each 100,000 population and calculates necessary investments for low-income countries only.

Estimates incorporate costs for procedures and hospital stay sourced from a study in Kenya (70) and implant costs sourced from MDE manufacturers. The latter may be underestimated as no taxes were included. The highest costing intervention is ORIF-IM after EF due to the high external fixator cost (200$I). Of all compared treatments, traction costs the least, incurring health systems only 714$I per patient. The null-scenario assumes the health service incurs no costs on behalf of patients: this is likely a gross-underestimation of costs as patients may need to access pain-management and physiotherapy services. While physiotherapy services may be rare across LMICs (given relatively low access to orthopaedic services in general), it is likely that pain-management at least is available via minor or major health centres. Traction costs already include such services and can therefore also act as a proxy for the null scenario costs.

COST-EFFECTIVENESS

Table 6 notes the cost/DALY averted for each intervention considered in comparison to the no-treatment scenario and traction respectively. CRIF-IM is the most cost-effective service against both comparators, costed at 1087$I/DALY averted. The second most cost-effective intervention is ORIF-P, costed at 1143$I/DALY averted. ORIF-IM-EF and ORIF-IM are similarly valued, suggesting neither strategy clearly dominates. The cost-effectiveness of all interventions as compared to the 1* GDP/capita threshold advised by the WHO-CHOICE group are presented in Table 7 (assuming age-weighted and discounted DALYs calculated using African life expectancy).

SENSITIVITY ANALYSES

Results of the deterministic analyses varying cost discount and capacity utilization rates are presented in Table 8. The cost-effectiveness of traction as compared to the null treatment scenario does not vary: no fixed costs relating to fracture treatment were included in the model. The cost data available from Opondo et al. (70) included costs relevant to hospital capacity utilization (e.g. bed usage and investigation fees), however no infrastructure or MDE costs were otherwise included. In contrast, surgical interventions are sensitive to variation in discount rates and capacity utilization; this variation is expected as total per patient costs are driven largely by operating room/infrastructure/MDE costs: i.e. the latter make up 85-88% of the total per patient cost per surgical intervention.

Table 9 presents statistics describing the estimates generated via Monte Carlo simulation. Notably, confidence intervals for surgical interventions are relatively narrow, suggesting the interventions are likely to be cost-effective against both the no treatment comparator on traction. This should be interpreted with due caution however as costs for both the null and traction are likely to be underestimated in this model. See notes above on traction costs included and additionally: no costs for the null comparator could be sourced - e.g. costs for pain management after musculoskeletal injury in Sub-Saharan Africa should be included in future model versions. Sensitivity analyses suggest traction has the most variable cost-effectiveness: however, this may simply be driven by the high uncertainty underpinning both the traction and null treatment estimates included in the model. Results could be refined should higher quality estimates for the latter scenarios become available.

To graphically illustrate simulation results, cost-effectiveness planes were generated. Figures 4 and 5 illustrate that surgical interventions achieve relatively similar effects (DALYs averted) for the same costs: the clustering of these estimates reflects the similarity in parameters used to calculate DALYs - interventions achieve similar rates of non-union and mortality. In contrast, the cost-effectiveness of traction is more variable: parameter estimates for this intervention are more uncertain and given the high uncertainty in the comparison of this treatment against the null the spread of estimates on the CE plane is to be expected.

Figure 6 additionally presents the cost-effectiveness acceptability curves of all interventions against the null comparator at different cost thresholds. (Note that probabilities of mutually exclusive interventions sum to 1 as per Briggs et al. (83)recommendations on presenting such CEACs) The likelihood of interventions being cost-effective increases abruptly up to a threshold of I$1000 for surgical treatment options with only marginal increases and consistent decreases being recorded thereafter. I.e. while the probability of CRIF-IM being cost-effective continues to increase, the probability of ORIF-IM, ORIF-P and ORIF-IM after EF being cost-effective decreases beyond I$2150 and tends towards a probability of 0.2. The graphic supports base case findings, which suggest CRIF-IM is the most cost-effective surgical treatment option on average, followed by ORIF-IM after EF. Notably however, the CEACs suggest that traction appears as the most cost-effective option for the lowest cost thresholds (i.e. thresholds under I$550). Traction may of course be beneficial in specific patient groups: while in the base case model traction incurred more DALYs than the null (therefore did not avert any DALYs), MC simulations suggest traction may avert DALYs in 49% of

cases. For cost thresholds beyond I$550 traction is clearly less cost-effective than surgical interventions.

3. 3. 4. DISCUSSION

The study presented here employed GCEA methods for exploring the cost-effectiveness of femur fracture fixation in the adult populations of AfrD and AfrE Global Burden of disease regions. Study findings suggest CRIF-IM and ORIF-IM after EF are the most cost-effective services for this decision-problem in the LMICs of considered regions; however, the services cannot be considered cost-effective for all countries within the region at the 1* GDP/capita threshold.(28) (Table 7) Results are reassuring given that closed-fracture is currently frequently on-offer across Sub-Saharan Africa,(59) although implants for the procedure may need to be sourced and budgeted for by health systems, rather than patients, to ensure better service-take up.

Previous studies have placed the cost-effectiveness of orthopaedic interventions at 361$I/DALY averted in Haiti, 381$I/DALY averted in the Dominican Republic and 502$I/DALY averted in Nicaragua. However, all these studies are based on cost estimates of high-income country volunteer missions abroad and are critiqued by the Disease Control Priorities (Version 3) project for not including relevant staff-time, surgical equipment and infrastructure, implant and patient follow-up costs. Estimates obtained here include such costs and are therefore more realistic given the decision-problem in AfrD and AfrE; this would imply orthopaedic surgical fixation with IM nailing would be of similar cost-effectiveness to glaucoma surgery (54).

The usefulness of findings is limited, however, given the likely cost-inflation due to inclusion of operating room-costs. The model presented here assumes operating rooms would be set-up solely for orthopaedic use – this is likely to be inaccurate, although

further operating rooms would need to be constructed given current levels of availability and need for orthopaedic surgery. (59)

It is likely that both operating room construction and procurement of implants would not be affordable for LMICs. NICE Guidelines suggest budget impact should not play a determining role in the adoption of interventions(5), however LMIC policy-makers dispose of incredibly limited budgets for service delivery in general. Surgical interventions in particular – when involving scale-up of surgical infrastructure – are likely to take-up a significant proportion of health care budgets.

While it was possible to construct a GCEA model for the above set of interventions, it was incredibly difficult to obtain high-quality comparative data for populating the model. Further comments on the feasibility of model construction follow.

3. 4. DISCUSSION: REFLECTIONS ON THE FEASIBILITY OF CONSTRUCTING A HEALTH ECONOMIC MODEL FOR MDE PROCUREMENT USING GENERALIZED COST-EFFECTIVENESS ANALYSIS

The purpose of this chapter was to explore the feasibility of using GCEA for the evaluation of interventions relying on the substantial presence/procurement of MDEs. Key problems encountered in this process relate to the availability and appropriateness of HE modelling tools, insufficient methodological guidance on model construction, including difficulties with implementing the societal perspective, and difficulties in sourcing suitable parameter data.

Availability and appropriateness of HE modelling tools

Although GCEA software - that is the software suite including PopMod and MC League - is publicly available and free, the WHO-CHOICE group requires analysts to request access to the software. In the case of this analysis, the software was provided after more than nine months from the initial request, during this time model development continued and it was no longer deemed pragmatic to switch to the use of PopMod. While GCEA methods are extensively described in the WHO Guide to Generalized Cost-Effectiveness Analysis, the software manual is rather brief and pre-supposes a relatively high level of health economics knowledge. The WHO-CHOICE group cautions this is the case and supplies training in the use of the method or software via a tutorial (analysts that have timely access to the software will find this helpful). Queries can additionally be sent to the WHO-CHOICE group.

PopMod is constructed as a dynamic life-table model - while this may be recommended for evaluation of complex interventions or vertical programs it may prove too complex for the evaluation attempted here. WHO-CHOICE guidelines specify that GCEA is suited to exploring regionally efficient mixes of interventions and that more complex decision-problems should be approached using a mix of ICEA and GCEA. In that sense, reflections collected via the use of this case study must be interpreted with due caution: the case-study does not reflect the intended GCEA-use scenario envisioned by WHO-CHOICE.

Insufficient guidance on model construction

Several shortcomings of GCEA became apparent during the construction of the health economic model. First, if PoPMod is used, GCEA is restricted to one specific type of economic model. The model resembles a Markov model for evaluation of complex interventions for long-term conditions with recurring events. The PoPMod model accounts for births, deaths and disease interactions. This requires analysts to be discriminant in the disease areas and interventions chosen for modelling. The case study presented here is not suitable for such an approach as it focuses on the evaluation of interventions for an acute condition. Simplifying the GCEA-designed-model - as was done here via the use of a decision tree - is only theoretically mentioned in the GCEA methods guide (see above on mixing ICEA and GCEA) and no further guidance on using GCEA given different or more specific decision-problems than set out in the original document is available. Following GCEA methods was therefore quite difficult in this case.

GCEA guidelines endorse the use of age-weighted and discounted DALYs, however, fail to advise analysts on how to explore differences in DALY estimates given different assumptions, e.g. no age weighting or use of the simplified DALY. In line with recommendations by Fox-Rushby et al (75), the case-study calculated DALYs averted using all relevant formulae. The guideline document similarly proposes the use of regional cost-effectiveness thresholds, set in relation to GDP per capita. Shortcomings of such methods have been summarized elsewhere.(90)

Analysts may encounter additional difficulties while conducting sensitivity analyses for GCEA models. For example, in the case study presented here it was particularly challenging to calculate relevant confidence intervals for the Monte Carlo simulation estimates. In particular, surgical intervention cost-effectiveness estimates did not follow a normal distribution - this may certainly arise as an issue in any type of modelling (83)but may apply to multiple intervention comparators in a GCEA scenario. Guidance on how to deal with this skewness or any other similar statistical challenges (e.g. estimation of parameter distribution via method of moments) is not provided in the WHO-CHOICE handbook.

Most importantly, using GCEA relies on the construction of a null-treatment comparator scenario. Articles using WHO-CHOICE methods fail to provide substantial insight into how this is done and the methods guide provides only a theoretical outlook on how to proceed. Supposing the use of PoPMod, the null may potentially be easily constructed, however in the absence of this, the method is particularly challenging to implement. Guidance should be issued not only on ‘how to’ construct this sort of comparator but also on what issues to expect, or pitfalls to avoid, while doing so. For example, due to limited data, analysts may be tempted to use null probabilities in their

analysis – this is unlikely to reflect the reality of the decision-problem and is an over-simplification applied to the concept of 'no treatment'. Guidance should specify how analysts can determine what interventions are to be considered lifesaving and also include recommendations on disability weights to use in the construction of the null.

The implementation of a societal perspective was additionally difficult. Particularly in the case of traction – an intervention likely to result in substantial production time loss for individuals affected – production costs should be captured. A discussion on how to include such costs is presented in the WHO-CHOICE manual. (28) Details on how to estimate such costs, however, or what proxies one may use if these costs are not available and data collection improbable, should also be included. GCEA further advises analysts to use an ingredients approach for costing and to include programme costs in analyses. While this may be useful for vertical programme appraisal, it is unlikely to be of particular use in situations where resources are shared not only across interventions but also further across health system areas more generally. This is the case for MDEs, and for the case-study presented: construction costs for operating rooms were included in the analysis although this assumed operating rooms being constructed and used solely for the treatment of fractured femurs.

Difficulties in sourcing suitable parameter data

GCEA is particularly data-intensive: inputs for all potentially relevant interventions must be sourced to enable a GCEA-type comparison. In this case, the analysis had to be simplified and outcomes negative outcomes (e.g. non-union and mal-union) aggregated to account for gaps in available data.

The high data collection/data use burden is particularly challenging for LMIC stakeholders or analysts due to data paucity, but HIC stakeholders will also find this particularly onerous. Little guidance is given on pragmatic methods for data sourcing given resource constraints in LMICs and generally limited research literature; e.g. the use of surveys or expert opinion elicitation methods may be useful in such cases. Guidance on how and when to use such methods would be helpful for further development of GCEA. Little guidance is further devoted to data appraisal. Implementation of GCEA assumes analysts have a background in epidemiological or health service research more generally and are able to make sensitive and relevant judgments on the appropriateness of clinical data used.

3. 5. CONCLUSION

Developing a GCEA specific HE model focused on the appraisal of MDE-intensive interventions is indeed possible, however, not necessarily feasible. The study presented here suggests that GCEA studies are time-consuming and data-intensive and therefore may be best targeted to evaluations where sufficient quality data is available. While the WHO-CHOICE issued methodological guidance is a robust and comprehensive guide on how to design a GCEA evaluation, further guidance on how to conduct and then use GCEA findings is needed. It is necessary for GCEA conducted analyses to meet international methodological standards (e.g. (89)) and to include all relevant details on model construction, in particular the null scenario constructed to represent natural disease progression and management.

The key features that set apart the NICE methodological guidance(5), and indeed the BMG reference case(34), are the focus (and guidance) on integration of findings into decision-making paradigms. This includes recommendations on contextualizing findings where possible, considering budget impact and also identifying sources for resource release or alternative management strategies given different service scale-up options.

3. 6. CHAPTER SUMMARY AND KEY FINDINGS

Chapter 3 explored the feasibility and relevance of HE/HTA for MDE procurement using a case study economic evaluation on orthopaedic interventions for femur fracture fixation. The methods and challenges for undertaking HE/HTA have been recently discussed in more detail elsewhere(18,91,22)however, to the author's (KD) knowledge, this is the first study to reflect on MDE related HE/HTA for procurement decision-making in particular.

The chapter critically reflects on the use of generalized cost-effectiveness analysis – GCEA (27,28), while also making reference to the traditionally popular incremental cost-effectiveness analysis - ICEA used in the UK, Canada and Australia (1,92,2) and endorsed by the Bill and Melinda Gates Foundation. (34)

> *Key Finding 8: Undertaking MDE specific evaluations using GCEA is a very labour intensive and complex process challenged by lack of appropriate data and insufficient guidance. Alternative methods, including heuristics or multi-criteria decision analysis may be more suitable for evaluating MDEs and/or narrowing down where HE evaluations (using GCEA/ICEA) are needed.*

The case study compared the use of several MDE intensive interventions for femur fracture fixation in Sub-Saharan Africa: surgical interventions (including internal and external surgical fixation with plates, intramedullary nails and external fixators) were compared to standard care (traction) and a no-treatment scenario. The lack of suitable and high-quality comparative effectiveness data and contextually relevant cost-data was extremely challenging. While such issues equally impinge on the use of GCEA and

ICEA, GCEA is particularly vulnerable to such issues due to two reasons. First, GCEA implies a higher workload: compared to a traditional comparison of two interventions and associated evidence appraisal/retrieval and HE modelling, GCEA involved the comparison of six alternative scenarios for the case study presented here. Second, GCEA requires the construction of a no-treatment comparator scenario – i.e. a null scenario. Limited guidance is available on how such a scenario should be constructed in the absence of data: information on natural disease progression without any intervention is rarely available. While GCEA appears promising for the comparison of vertical programs and multiple macro-interventions therein (e.g. see (68)), it appears un-manageable and largely un-suitable for MDE evaluation when used for intra-sectoral purposes. Heuristics(19), multi-criteria decision analysis or program budgeting marginal analysis (37,38,20), may instead prove more favourable for implementation as they consider multiple issues (e.g. demand and supply constraints (22)) and can narrow down which technologies should undergo HE evaluations.

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3. 8. BOXES

BOX 1: POPULATION, INTERVENTIONS/COMPARATORS, OUTCOMES AND SETTING

Population: Patients affected by fractures of the femur shaft (not femur head), aged 16-65, not presenting with contra-indication to surgery or life-threatening comorbidity (e.g. significant head-injury).

Interventions/Comparators: Relevant surgical and non-surgical interventions for which effectiveness data is available compared to a no-treatment baseline. Figure 1 illustrates all relevant interventions and Box 2 defines the content of each intervention. Figure 2 illustrates all interventions for which effectiveness data was available and which were included in the model.

Outcomes: Mortality and fracture union versus mal- and non-union.

Setting: Africa D and Africa E regions of the Global Burden of Disease study.

BOX 2: INTERVENTIONS FOR THE FIXATION OF FEMUR SHAFT FRACTURES

Operative treatments:

Open reduction involves dissecting soft tissue surrounding the fractured bone in order to insert fixation devices. Open reduction is recommended for complex fractures where multiple bone fragments need to be re-aligned or for severe trauma, when wound debridement needs to occur. Open reduction is routinely faster than closed reduction, but may lead to infections and delayed union/non-union due to reduced blood supply to the fracture site.

ORIF-IM *Definitive internal fixation with intramedullary nails:* Muscle is opened to achieve insertion of a load-bearing nail into the bone canal. The canal may (reamed IM nailing) or may not (unreamed IM nailing) be widened before nail insertion; the latter can occur in antegrade or retrograde fashion. Titanium nails are currently preferred. Usually requires specialized surgical equipment (e.g. for reaming) and fluoroscopy; the SIGN-IM nail is an interlocking nail not requiring the latter additions. Weight-bearing may be attempted before union.

ORIF-P *Definitive internal fixation with plates:* Muscle is opened to enable insertion of a titanium plate close to fractured bone. Plates are secured with multiple screws. Contra-indicated for patients with multiple injury, coagulopathy and cranial injury (Buchholz and Brumback 1996). Weight-bearing is only attempted after fracture union.

ORIF-IM or ORIF-P following EF *Temporary external fixation and definitive internal fixation with intramedullary nails or plates:* Used when patients are not clinically stable enough to be treated with internal fixation directly and/or when fracture is unstable. An external fixator device is used (e.g. Wagner device) and pins are applied to stabilize the fracture externally. Upon patient stabilizations, surgeons proceed to definitive internal fixation via IM nailing or plating (see above). Pin infection may set in depending upon time spent with temporary fixation, risks as for internal fixation apply.

ORIF-EF *Definitive external fixation:* External fixator device is used to secure stabilization of fracture. World War II developments initially saw the insertion of pins proximal and distal to fracture; further devices were then designed – most commonly used in the Wagner device version. Murphy 1988 reports vastly superior outcomes following IM-nailing compared to external fixation, thus definitive external fixation is not routinely recommended.

Closed reduction implies the manipulation of fractures without opening adjoining soft tissue – see above and brief notes below.

CRIF-IM *Definitive internal fixation with intramedullary nails*: IM-nail is inserted through end of bone. Risk of infection is low, haematoma is not disturbed therefore aiding healing.

CRIF-P *Definitive internal fixation with plates:* Plates are inserted through a minimally invasive technique via proximal and distal incisions into the extraperiosteal tunnel. Current system in use is the Less Invasive Stabilization System.

CRIF-EF *Definitive external fixation:* Fracture is stabilized via minimally invasive insertion of pins and fixated externally.

Non-operative treatments:

Traction with cast or brace support: Performed as skin traction in children mainly, however may be used as both skin or skeletal traction on adults when other treatments are not available. Involves the insertion of a percutaneous pin in the affected bone – this is then secured to a weight which ensures lengthening and stabilization. Patients need to remain supine for a minimum of 6 weeks. A Spica cast or brace may be applied as aftercare for several months to ensure weight-bearing. Union outcomes are unsatisfactory compared to surgical interventions. Note that casts may also be used after surgical treatments to promote earlier weightbearing.

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BOX 3: SEARCH STRING FOR SYSTEMATIC EVIDENCE SEARCH FOR PARAMETER ESTIMATES

Description: Strategy for Ovid MEDLINE(R) <1946 to January Week 4 2015>

1 economics/ (26542)
2 exp "costs and cost analysis"/ (183857)
3 exp "economics, hospital"/ (19797)
4 economics, medical/ (8583)
5 economics, nursing/ (3911)
6 economics, pharmaceutical/ (2538)
7 (economic$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab. (431744)
8 (expenditure$ not energy).ti,ab. (17597)
9 (value adj1 money).ti,ab. (23)
10 budget$.ti,ab. (17480)
11 or/1-10 (555515)
12 randomized controlled trial.pt. (381609)
13 controlled clinical trial.pt. (88411)
14 random allocation.sh. (81683)
15 double blind method.sh. (126945)
16 single blind method.sh. (19689)
17 or/12-16 (546657)
18 animal/ not human/ (3881514)
19 17 not 18 (497354)
20 ((femor$ or femur) adj2 fracture$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (22699)
21 ((humer$ or humerus) adj2 fracture$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (7340)
22 ((tibi$ or tibia) adj2 fracture$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (13235)
23 (long bone adj2 fracture$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (1268)
24 or/20-23 (40817)
25 ((femor$ or femur) adj2 neck$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (18782)
26 24 not 25 (32322)
27 exp Fracture Fixation/ (47033)
28 (manage$ adj2 fracture$).mp. (1680)
29 or/27-28 (47910)
30 26 and 29 (15338)
31 (child$ or pediatr$ or paediatr$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (1907302)
32 (elder$ or older or geriat$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (436517)
33 exp Child/ (1556226)
34 exp Aged/ (2373638)
35 or/31-34 (4165456)
36 30 not 35 (8051)
37 19 or 11 (1033663)
38 36 and 37 (259)
39 remove duplicates from 38 (257)

3. 9. TABLES

TABLE 1: CLINICAL EFFECTIVENESS AND MORTALITY ESTIMATES OBTAINED FROM LITERATURE*

Intervention or Comparator	Parameter type	Point estimate	Uncertainty interval or range	Source
ORIF-IM	Probability of non-union	0.0446	NR	AO: Canadian Orthopaedic Trauma Society (2003) Nonunion following intramedullary nailing of the femur with and without reaming. Results of a multicenter randomized clinical trial. J Bone Joint Surg Am; 85-A:2093-6.
ORIF-IM	Mortality	0.017	(1.4,2.25)	Lancet Commission: Foote et al (2015): Musculoskeletal trauma and all-cause mortality in India: a multicentre prospective cohort study
ORIF-P	Probability of non-union	0.047	NR	AO: Varjonen L, Majola A, Vainionpaa S, et al (1990) Problems associated with longitudinal fractures of the femoral shaft in adults. A comparison between intramedullary nailing, interlocking intramedullary nailing and plating. Ann Chir Gynaecol; 79:46-9
ORIF-P	Mortality	0.017	(1.4,2.25)	Lancet Commission: Foote et al (2015): Musculoskeletal trauma and all-cause mortality in India: a multicentre prospective cohort study
ORIF-IM after EF	Probability of non-union	0.0434	NR	AO: Stephen DJ, Kreder HJ, Schemitsch EH, et al (2002) Femoral intramedullary nailing: comparison of fracture-table and manual traction. a prospective, randomized study. J Bone Joint Surg Am; 84-A:1514-21.
ORIF-IM after EF	Mortality	0.017	(1.4,2.25)	Lancet Commission: Foote et al (2015): Musculoskeletal trauma and all-cause mortality in India: a multicentre prospective cohort study

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Intervention or Comparator	Parameter type	Point estimate	Uncertainty interval or range	Source
CRIF-IM	Mortality	0.0126	NR	AO: Canadian Orthopaedic Trauma Society (2006) Reamed versus unreamed intramedullary nailing of the femur: comparison of the rate of ARDS in multiple injured patients. J Orthop Trauma; 20:384-7.
CRIF-IM	Probability of non-union	0.0039	NR	AO: McLaren AC, Roth JH, Wright C (1990) Intramedullary rod fixation of femoral shaft fractures: comparison of open and closed insertion techniques. Can J Surg; 33:286-90. Davlin L, Johnson E, Thomas T, et al (1991) Open versus closed nailing of femoral fractures in the polytrauma patient. Contemp Orthop; 22:557-63.
Traction	Probability of non-union	0.4276	NR	Systematic search: Gosselin RA, Heitto M, Zirkle L Cost-effectiveness of replacing skeletal traction by interlocked intramedullary nailing for femoral shaft fractures in a provincial trauma hospital in Cambodia (Provisional abstract)
Traction	Mortality	0.1666667	NR	*Author's assumption: minimum estimate for mortality in traction group is identical to null scenario as the intervention cannot be life-saving
Null	Mortality	0.1666667	NR	J Trauma Acute Care Surg. 2013 Jun;74(6):1516-20. Population-based epidemiology of femur shaft fractures. Enninghorst N1, McDougall D, Evans JA, Sisak K, Balogh ZJ.
Null	Probability survival without treatment	0.8333333	NR	*Author's assumption: all surviving patients with fracture continue without treatment to create the null

*If estimates were mentioned as rates in reference documents, one year transition probabilities were calculated as per Fleurence and Hollenbeak.

TABLE 2: STUDY CHARACTERISTICS

Reference	Study type	Objective	Setting	Population	Follow-up	Outcomes	Notes on quality assessment
AO: Canadian Orthopaedic Trauma Society (2003) Nonunion following intramedullary nailing of the femur with and without reaming. Results of a multicenter randomized clinical trial. J Bone Joint Surg Am; 85-A:2093-6.	RCT	Compare non-union outcomes following IM nailing with and without reaming	Canada – multiple centres	224 skeletally mature patients, excluded if: time to surgery less than 24 hours, femoral canal less than 9mm, medical contraindication to surgery, previous joint dislocation, grade IIIb or all IIIC open fractures, MI history, a pathological fracture, femoral neck or inter trochanteric fracture, not able to return to follow up, unwilling or intra artical fracture 6cm close to physeal scar.	2, 6, 12, 26, 52 weeks post-surgery	Fracture non-union assessed clinically and radiologically by blinded	Treatment assignment by computer generated list and closed envelopes. Patient reported outcomes collected additionally by an independent blinded research assistant but non-union diagnosed by treating surgeon. Take into account ISS as potential confounder (<, > 18 points).
Lancet Commission: Foote et al (2015): Musculoskeletal trauma and all-cause mortality in India: a multicentre prospective cohort	Multicentre, prospective cohort study	Document mortality following musculoskeletal trauma and interventions for fracture fixation	India – 14 hospitals	4612 patients (96% of sample) presenting with musculoskeletal trauma and with complete follow-up.	30 days or hospital discharge	All-cause mortality, secondary outcome of reoperation or infection	Only abstract available

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Reference	Study type	Objective	Setting	Population	Follow-up	Outcomes	Notes on quality assessment
study							
AO: Varjonen L, Majola A, Vainionpaa S, et al (1990) Problems associated with longitudinal fractures of the femoral shaft in adults. A comparison between intramedullary nailing, interlocking intramedullary nailing and plating. Ann Chir Gynaecol; 79:46-9	Prospective cohort study	Compare union outcomes following IM nailing, interlocked IM nailing and plating	NR	64 patients with 55 closed fractures and 9 open.	23 months	Union status	Only abstract available; estimate from AO used
AO/Systematic search: Stephen DJ, Kreder HJ, Schemitsch EH, et al (2002) Femoral intramedullary nailing: comparison of fracture-table and manual traction. a prospective, randomized study. J Bone Joint Surg Am; 84-A:1514-21.	RCT	Comparing outcomes of IM-nailing post manual traction and table traction	Canada – Toronto	87 patients with AO type 32 fracture, exclusion of poly trauma or multiple extremity injuries	6 months and 1 year (only 79 patients)	Radiological union and rotational alignment	Sequentially numbered sealed envelopes for randomization, under-powered. Intervention with manual traction table + IM used as a proxy for likely nailing following use of a Wagner device.

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Reference	Study type	Objective	Setting	Population	Follow-up	Outcomes	Notes on quality assessment
AO: Canadian Orthopaedic Trauma Society (2006) Reamed versus unreamed intramedullary nailing of the femur: comparison of the rate of ARDS in multiple injured patients. J Orthop Trauma; 20:384-7.	RCT	Comparing incidence of adult respiratory distress syndrome in patients with reamed vs. unreamed nailing of the femur	Canada	322 fractures in 315 patients, 100% follow-up	NR	NR	Meets class I AO evidence standard criteria: Concealment Blind or independent assessment for important outcomes F/U rate of 85%+ Adequate sample size Intention to Treat Analysis Used
AO: McLaren AC, Roth JH, Wright C (1990) Intramedullary rod fixation of femoral shaft fractures: comparison of open and closed insertion techniques. Can J Surg; 33:286-90.	Meta-analysis of studies up to 1987	Compared closed vs. open intramedullary nailing	NR	3243 fractures: CRIF for n=2529 vs. ORIF-IM n=714	NR	Union, infection, mal-rotation, shortening and range of motion	Meets class II AO evidence standard criteria: Violation of any of the criteria for good quality RCT Blind or independent assessment in a prospective study or

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Reference	Study type	Objective	Setting	Population	Follow-up	Outcomes	Notes on quality assessment
							use of reliable data* in a retrospective study F/U rate of 85%+ Adequate sample size Controlling for possible confounding**
Systematic search: Gosselin RA, Heitto M, Zirkle L Cost-effectiveness of replacing skeletal traction by interlocked intramedullary nailing for femoral shaft fractures in a provincial trauma hospital in Cambodia (Provisional abstract)	Retrospective case series	Establish the cost-effectiveness of the SIGN intramedullary nail compared to traction	Cambodia – Italian Trauma Centre	87 patients: 50 patients (52 fractures) treated by Perkins traction, 37 by IM nailing. Patients undergoing second line treatment excluded.	Min 4 months, mean 6.5	Non-union and weight-bearing assessed radiologically and by treating surgeon	Comparator group not adequately described; potential selection bias as last 50 patients make up the comparator group. Outcome assessment may be biased – conducted by SIGN developers. Not all patients were followed up.
J Trauma Acute Care Surg. 2013 Jun;74(6):1516-20. Population-based	Prospective cohort study	Explore epidemiology of femur shaft fractures	NR	Patients presenting with femur shaft fracture in catchment area of 850,000	12 months	Patient demographics, injury mechanism, ISS	Classified as level III study by authors.

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Reference	Study type	Objective	Setting	Population	Follow-up	Outcomes	Notes on quality assessment
epidemiology of femur shaft fractures. Enninghorst N, McDougall D, Evans JA, Sisak K, Balogh ZJ.				population including all ages and prehospital deaths.		and clinical outcomes, mortality, adverse events	

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TABLE 3: REFERENCES FOR INTERVENTION COSTS

Source: cost type	Point estimate	Range or CI	Base Year, Currency	Country	Notes on estimation	Reference	Cost (I$)
Systematic search: Conservative treatment with traction: cost per patient	13594	400-40000	2011, Kenyan Shilling	Kenya	Costs of ward bed, drugs, radiographs, laboratory investigations, physiotherapy and theatre fees are included; fixed costs such as infrastructure and depreciation value of the initial equipment costs were not considered, same with implants (SIGN nail was used). Base year assumed was end of study 2011.	Opondo et al: Cost effectiveness of using surgery versus skeletal traction in management of femoral shaft fractures at Thika level 5 hospital, Kenya (2012)	714
Systematic search: Operative treatment with intramedullary nailing (SIGN nail)	9761	4750-27000					513
Systematic search: Charges per case of early mobilization	59561	(38,618 - 106,780)	2010, USD	USD	Retrospective study collecting data over 9 years, unclear what costs were included and how changes in cost make-up were accounted for.	Harvin et al: Early femur fracture fixation is associated with a reduction in pulmonary complications and hospital charges: a decade of experience with 1,376 diaphyseal femur fractures. (2012)	59561
Systematic search: Charges per case of late mobilization	97018	(48,249 - 205,570)					97018
Lancet Commission: Operation room and surgical	LICs: 319002, LM: 412488,		2012, USD	*Cross-country and regional	Costs estimated via mathematical modelling given initial expert and survey responses. Costs do not include	Verguet et al: Timing and cost of scaling up surgical services in low-income and middle-income countries from 2012 to 2030: a	LICs: 319002, LM: 412488,

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Source: cost type	Point estimate	Range or CI	Base Year, Currency	Country	Notes on estimation	Reference	Cost (I$)
equipment costs (including construction)	UM:1906 064				implants but include equipment costs estimated in relation to construction costs	modelling study	UM:190 6064
Lancet Commission: Costs of surgical procedures	LICs: 179, LMs: 219, UMs: 332						LICs: 179, LMs: 219, UMs: 332
IM nail costs*	150	50-250	2015, USD	NA	All costs refer to devices certified under ISO 13485:2003 and CE certified, made of titanium	Alibaba: http://www.alibaba.com/product-detail/Femur-Reconstruction-Intramedullary-Nail-I_60159330271.html?spm=a2700.7724838.30.16.pRplwt&s=p	150
Femoral plate costs*	80	1-160				Alibaba: http://www.alibaba.com/product-detail/Proximal-Femur-Lateral-Locking-Compression-plate_60359405688.html?spm=a2700.7724838.30.26.0Mkc4P and http://www.alibaba.com/product-detail/Femoral-Proximal-Locking-Plate-femur-implant_60147792131.html?spm=a2700.7724838.30.18.0Mkc4P	80

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Source: cost type	Point estimate	Range or CI	Base Year, Currency	Country	Notes on estimation	Reference	Cost (I$)
External fixator costs*	50	1-100				Alibaba: http://www.alibaba.com/product-detail/2-3-Ring-external-fixator-used_60291976172.html?spm=a2700.7724838.30.26.mbVaZ4&s=p and http://www.alibaba.com/product-detail/GX201102-Large-hoffmann-external-fixation-femur_60289384866.html?spm=a2700.7724838.30.58.mbVaZ4	50

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TABLE 4A: AFRICA D, AFRICA E AND TOTAL DALYS INCURRED IN THE NULL SCENARIO AND UNDER INTERVENTIONS MODELLED

Population and Interventions		**DALYs associated with each intervention**			
		Age weighting, discounting (Japanese life-expect.)	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expect.)**
Africa D	Null	159,431	1629549	279,711	125,223
	Traction	177,747	2461490	311,845	139,611
	ORIF-IM	19,211	300331	33,706	15,088
	ORIF-P	19,556	315989	34,311	15,359
	CRIF-IM	10,010	33723	17,558	7,886
	ORIF-IM after EF	17,705	231939	31,064	13,905
Africa E	Null	181,196	1,854,741	317,885	142,836
	Traction	201,989	2,801,320	354,361	159,234
	ORIF-IM	21,873	341,834	38,374	17,241
	ORIF-P	22,265	359,613	39,062	17,548
	CRIF-IM	11,423	38,263	20,041	9,007
	ORIF-IM after EF	20,171	264,417	35,388	15,902
Africa D and E	Null	340,628	3,484,290	597,596	268,059
	Traction	379,736	5,262,811	666,206	298,845
	ORIF-IM	41,084	642,165	72,080	32,329
	ORIF-P	41,821	675,602	73,373	32,906
	CRIF-IM	21,434	71,985	37,598	16,893
	ORIF-IM - EFafter EF	37,876	496,356	66,452	29,807

TABLE 4B: AFRICA D, AFRICA E AND TOTAL DALYS AVERTED BY EACH INTERVENTION COMPARED TO THE NULL SCENARIO

Regions and Interventions		DALYs averted in comparison to null scenario and traction							
		Age weighting, discounting (Japanese life-expectancy)	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expectancy)**	**Age weighting, discounting (Japanese life-expectancy)**	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expectancy)**
Africa D	Comparator	Null: no treatment				Comparator: Standard care			
	Traction	-18,316	-831,941	-32,134	-14,388				
	ORIF-IM	140,220	1,329,218	246,005	110,135	158,536	2,161,159	278,139	124,523
	ORIF-P	139,875	1,313,560	245,400	109,864	158,191	2,145,501	277,534	124,252
	CRIF-IM	149,421	1,595,826	262,153	117,337	167,736	2,427,768	294,287	131,725
	ORIF-IM after EF	141,726	1,397,609	248,647	111,318	160,042	2,229,551	280,781	125,706
Africa E	Comparator	Null: no treatment				Comparator: Standard care			
	Traction	-20,793	-946,580	-36,476	-16,398				
	ORIF-IM	159,323	1,512,907	279,510	125,595	180116	2459486	315986	141993
	ORIF-P	158932	1495128	278822.96	125288	179724.36	2441707.08	315299	141687
	CRIF-IM	169773	1816478	297844	133828	190566	2763058	334320	150227

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Regions and Interventions		DALYs averted in comparison to null scenario and traction							
		Age weighting, discounting (Japanese life-expectancy)	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expectancy)**	**Age weighting, discounting (Japanese life-expectancy)**	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expectancy)**
	ORIF-IM after EF	161026	1590324	282497	126934	181818	2536904	318973	143333
Africa D and E	Comparator	Null: no treatment				Comparator: Standard care			
	Traction	-39,108	-1,778,521	-68,610	-30,786				
	ORIF-IM	299,544	2,842,124	525,515	235,730	338,652	4,620,645	594,125	266,516
	ORIF-P	298,807	2,808,687	524,223	235,152	337,915	4,587,208	592,833	265,939
	CRIF-IM	319,194	3,412,304	559,997	251,166	358,302	5,190,825	628,607	281,952
	ORIF-IM after EF	302,752	2,987,934	531,144	238,252	341,860	4,766,455	599,754	269,038

TABLE 5: INTERVENTION COSTS USED IN MODELLING

Costs derived from literature		**Operative**				**Non-operative**	**Null**
		Open reduction			Closed reduction	Traction	
Region	**Cost components**	ORIF-IM	ORIF-P	ORIF-IM after EF	CRIF-IM	Traction (cast or brace)	
Africa D	Surgery room/per patient	4037	4037	4037	4037	0	0
	Surgical implant	150	80	200	150	0	0
	Procedure and hospital stay	513	513	513	513	714	0
	Total cost per patient	4700	4630	4750	4700	714	0
	Total costs - treatment	128154900	126246210	129518250	128154900	19468638	0
Africa E	Surgery room/per patient	4036	4036	4036	4036	0	0
	Surgical implant	150	80	200	150	0	0
	Procedure and hospital stay	513	513	513	513	714	0
	Total cost per patient	4699	4629	4749	4699	714	0
	Total costs - treatment	144771491	142614861	146311941	144771491	21997626	0
Africa D and E	Surgery room/per patient	4037	4037	4037	4037	0	0
	Surgical implant	150	80	200	150	0	0
	Procedure and hospital stay	513	513	513	513	714	0
	Total cost per patient	4700	4630	4750	4700	714	0
	Total costs - treatment	272957200	268891880	275861000	272957200	41466264	0

TABLE 6: COST-EFFECTIVENESS OF ALTERNATIVE INTERVENTIONS IN COMPARISON TO NULL SCENARIO AND STANDARD CARE (I$/DALY AVERTED)

Regions and Interventions		**Cost (I$) per DALY averted**							
		Age weighting, discounting (Japanese life-expectancy)	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expectancy)**	**Age weighting, discounting (Japanese life-expectancy)**	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expectancy)**
Africa D	Comparator	Null: no treatment				Comparator: Standard care			
	Traction	-6997	-154	-3988	-8907				
	ORIF-IM	914	96	521	1164	686	50	391	873
	ORIF-P	903	96	514	1149	675	50	385	859
	CRIF-IM	858	80	489	1092	648	45	369	825
	ORIF-IM after EF	914	93	521	1163	688	49	392	875
Africa E	Comparator	Null: no treatment				Comparator: Standard care			
	Traction	-1058	-23	-603	-1341				
	ORIF-IM	909	96	518	1153	682	50	389	865
	ORIF-P	897	95	511	1138	671	49	383	851

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Regions and Interventions		Cost (I$) per DALY averted							
		Age weighting, discounting (Japanese life-expectancy)	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expectancy)**	**Age weighting, discounting (Japanese life-expectancy)**	**No age weighting, discounting**	**No age weighting, no discounting**	**Age weighting, discounting (African life-expectancy)**
	CRIF-IM	853	80	486	1082	644	44	367	817
	ORIF-IM after EF	909	92	518	1153	684	49	390	867
Africa D and E	Comparator	Null: no treatment				Comparator: Standard care			
	Traction	-1060	-23	-604	-1347				
	ORIF-IM	911	96	519	1158	684	50	390	869
	ORIF-P	900	96	513	1143	673	50	384	855
	CRIF-IM	855	80	487	1087	646	45	368	821
	ORIF-IM after EF	911	92	519	1158	686	49	391	871

TABLE 7: COST-EFFECTIVENESS OF TREATMENTS MODELLED COMPARED TO THE 1* GDP/CAPITA ($I) THRESHOLD

Regions and Interventions		1 * GDP/capita level			1 * GDP/capita level		
		Lower quartile	**Average**	**Upper quartile**	**Lower quartile**	**Average**	**Upper quartile**
Estimates Africa D		626.17	3601.73	3623.22	626.17	3601.73	3623.22
Africa D	Comparator	Null: no treatment			Comparator: Traction		
	Traction	×	×	×			
	ORIF-IM	×	✓	✓	×	✓	✓
	ORIF-P	×	✓	✓	×	✓	✓
	CRIF-IM	×	✓	✓	×	✓	✓
	ORIF-IM after EF	×	✓	✓	×	✓	✓
Estimates Africa E		554.56	1953.01	3205.45	554.56	1953.01	3205.45
Africa E	Comparator	Null: no treatment			Comparator: Traction		
	Traction	×	×	×			
	ORIF-IM	×	✓	✓	×	✓	✓
	ORIF-P	×	✓	✓	×	✓	✓
	CRIF-IM	×	✓	✓	×	✓	✓
	ORIF-IM after EF	×	✓	✓	×	✓	✓

TABLE 8: RESULTS OF DETERMINISTIC SENSITIVITY ANALYSES VARYING DISCOUNT RATE AND CAPACITY UTILIZATION

Intervention	Discount rate		Capacity utilization		Discount rate		Capacity utilization	
	6%	15%	50%	95%	6%	15%	50%	95%
	Comparator: Null				Comparator: Traction			
Traction	-860.96	-860.96	-860.96	-860.96				
ORIF-IM	1316.09	1853.66	784.92	1344.42	946.75	1393.12	505.70	970.28
ORIF-P	1302.03	1840.93	769.56	1330.44	934.33	1381.61	492.38	957.91
CRIF-IM	1235.21	1739.74	736.69	1261.80	897.93	1321.28	479.62	920.24
ORIF-IM after EF	1327.77	1865.08	796.86	1356.08	956.60	1402.79	515.72	980.11

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TABLE 9: DESCRIPTIVE STATISTICS OF PROBABILISTIC SENSITIVITY ANALYSES

Comparator	Intervention	Statistics describing Monte Carlo simulation results								
		Minimum	25th Percentile	Median	75th Percentile	Maximum	Mean	Lower confidence limit	Upper confidence limit	Base case estimate
Null	ORIF-IM	0.08	473.54	1079.39	2225.26	14071.90	1622.29	990.08	1191.19	1158.14
	ORIF-P	1.43	463.47	1117.87	2210.87	20967.51	1644.02	1034.40	1211.14	1143.65
	ORIF-IM after EF	0.33	479.23	1174.95	2405.27	14790.40	1702.42	1062.78	1277.90	1157.96
	CRIF-IM	0.33	456.79	1094.64	2206.47	14003.24	1605.08	1012.13	1209.30	1087.29
	Traction	-426899.70	-846.84	-16.92	718.70	916271.40	261.13	-2052.84	2575.11	-1347.39
Traction	ORIF-IM	-1438.13	234.09	870.00	2099.51	11017.53	1388.86	789.17	968.00	868.63
	ORIF-P	-2762.30	232.32	905.37	1994.78	11387.43	1396.21	783.09	1013.23	855.20
	ORIF-IM	-1723.18	268.75	958.96	2071.39	15254.49	1457.24	862.54	1112.04	871.21

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Comparator	Intervention	Statistics describing Monte Carlo simulation results								
		Minimum	25th Percentile	Median	75th Percentile	Maximum	Mean	Lower confidence limit	Upper confidence limit	Base case estimate
	after EF									
	CRIF-IM	-1992.62	226.83	899.71	1957.24	11819.45	1367.14	803.78	977.77	821.30

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3. 10. FIGURES

FIGURE 1 THEORETICAL DECISION TREE

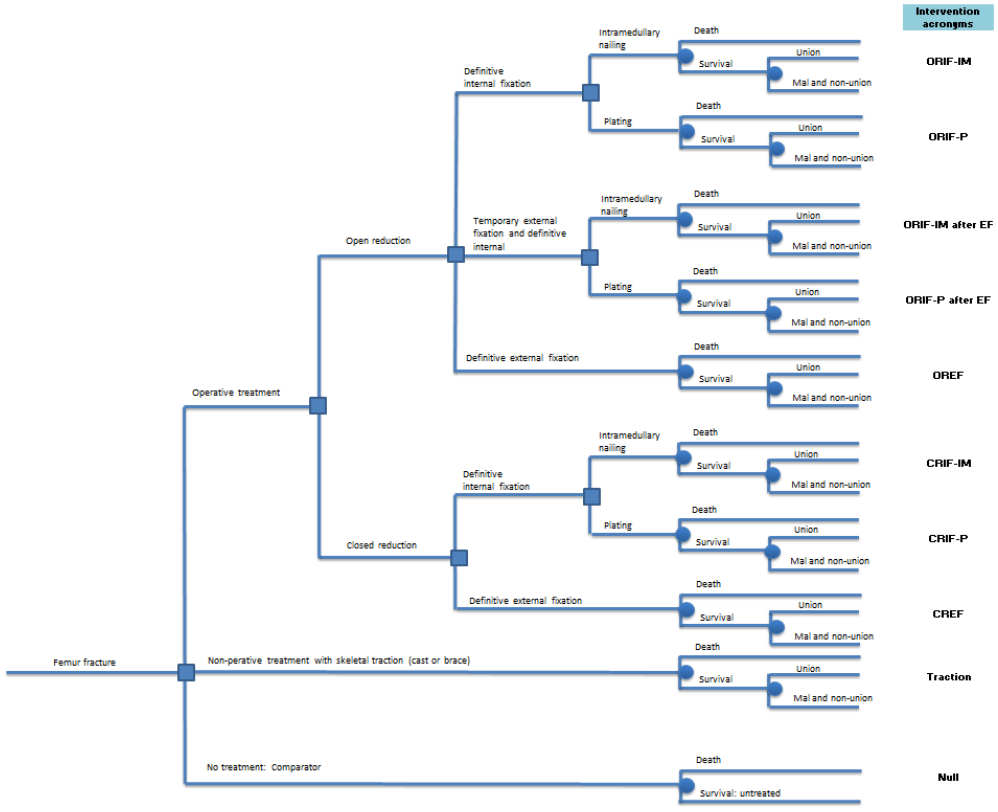


FIGURE 2 DECISION TREE USED FOR MODELLING

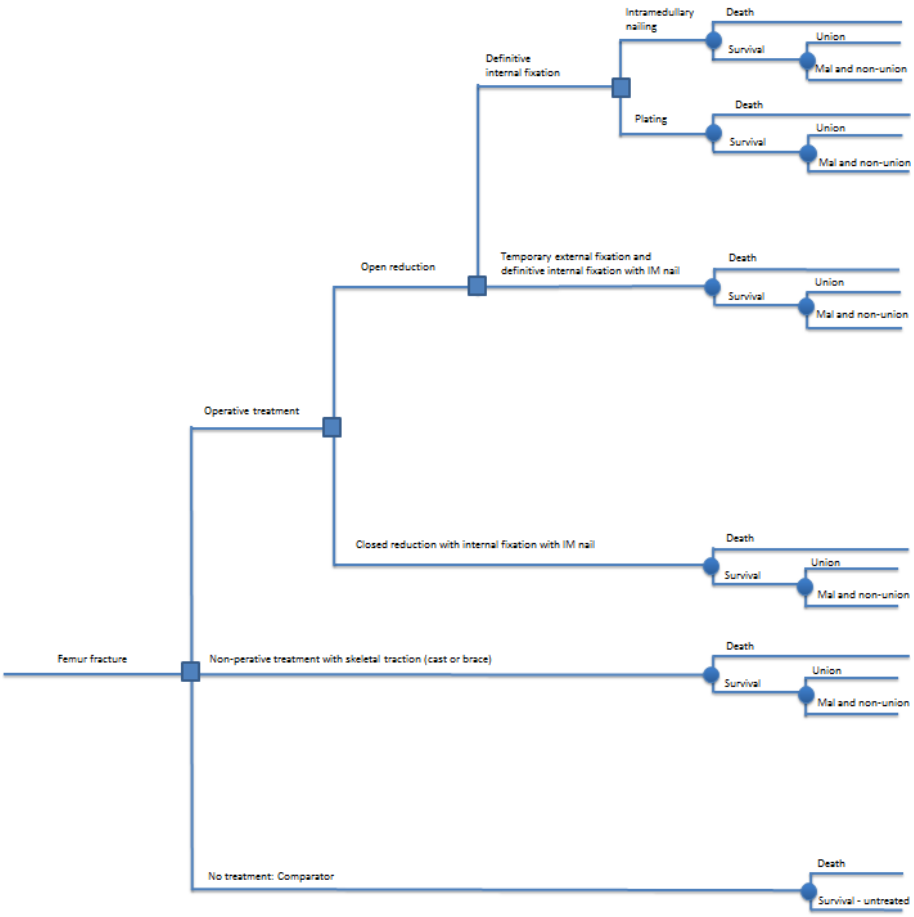


FIGURE 3 PRISMA FLOW DIAGRAM OF SYSTEMATIC SEARCH

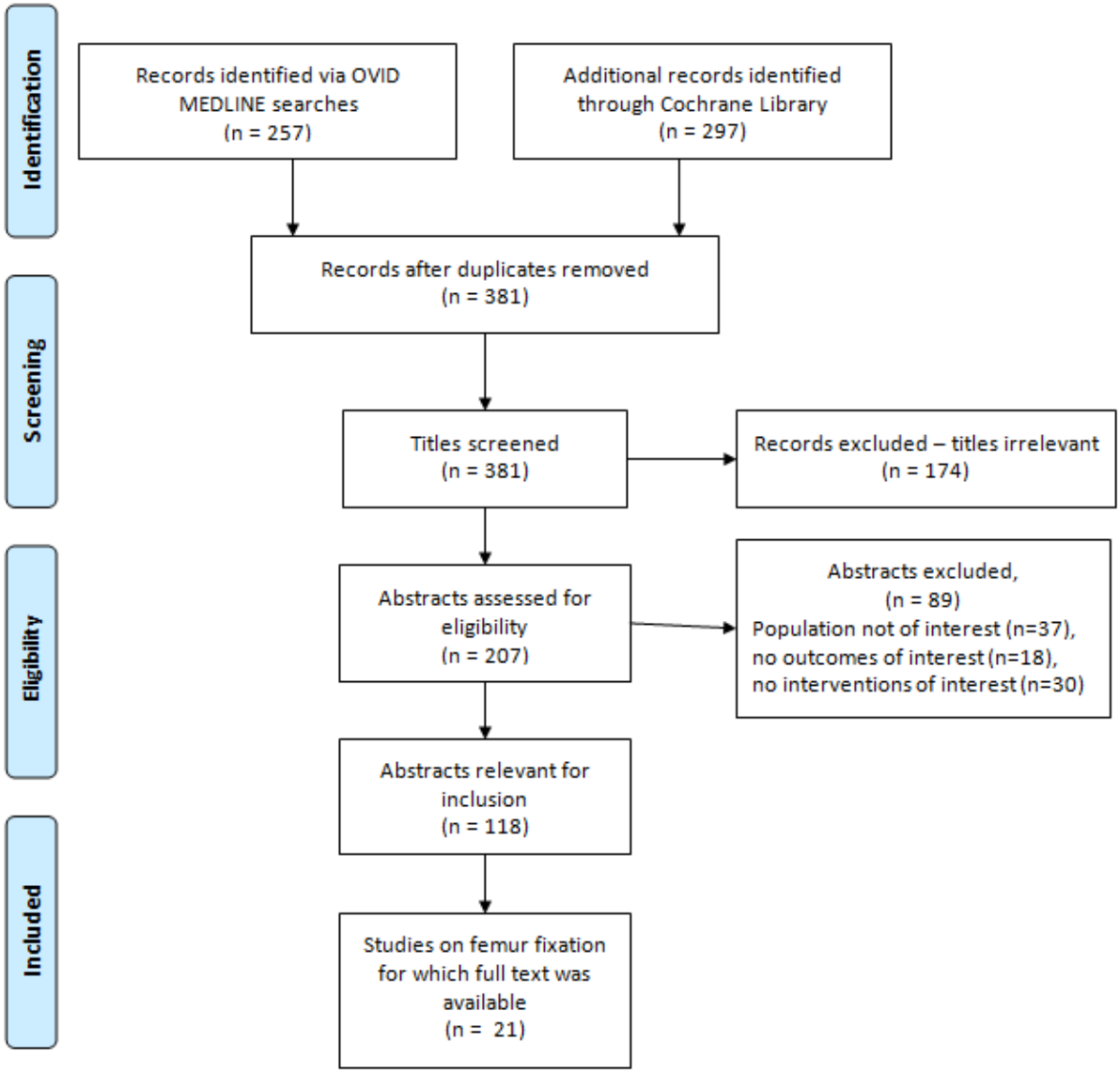


FIGURE 4: COST EFFECTIVENESS PLANE: ALL INTERVENTIONS AGAINST NULL COMPARATOR

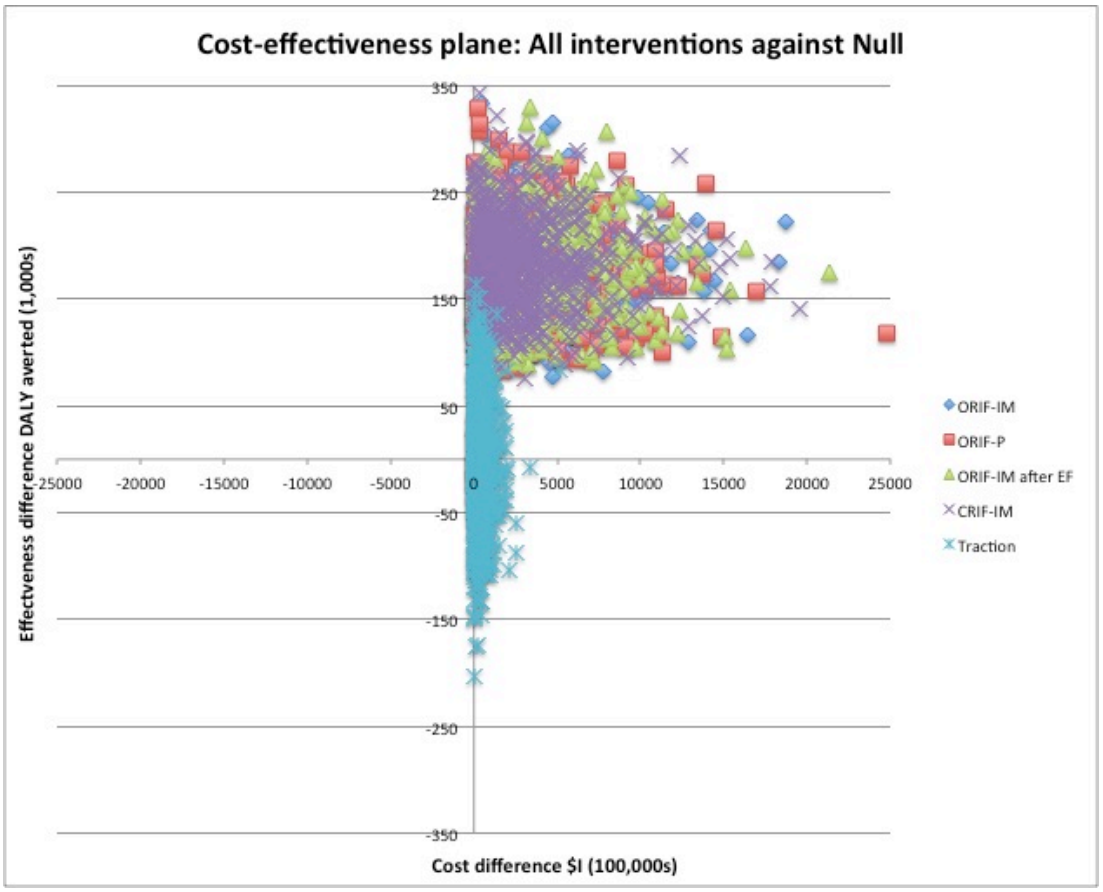


FIGURE 5: COST EFFECTIVENESS PLANE: SURGICAL INTERVENTIONS AGAINST TRACTION COMPARATOR

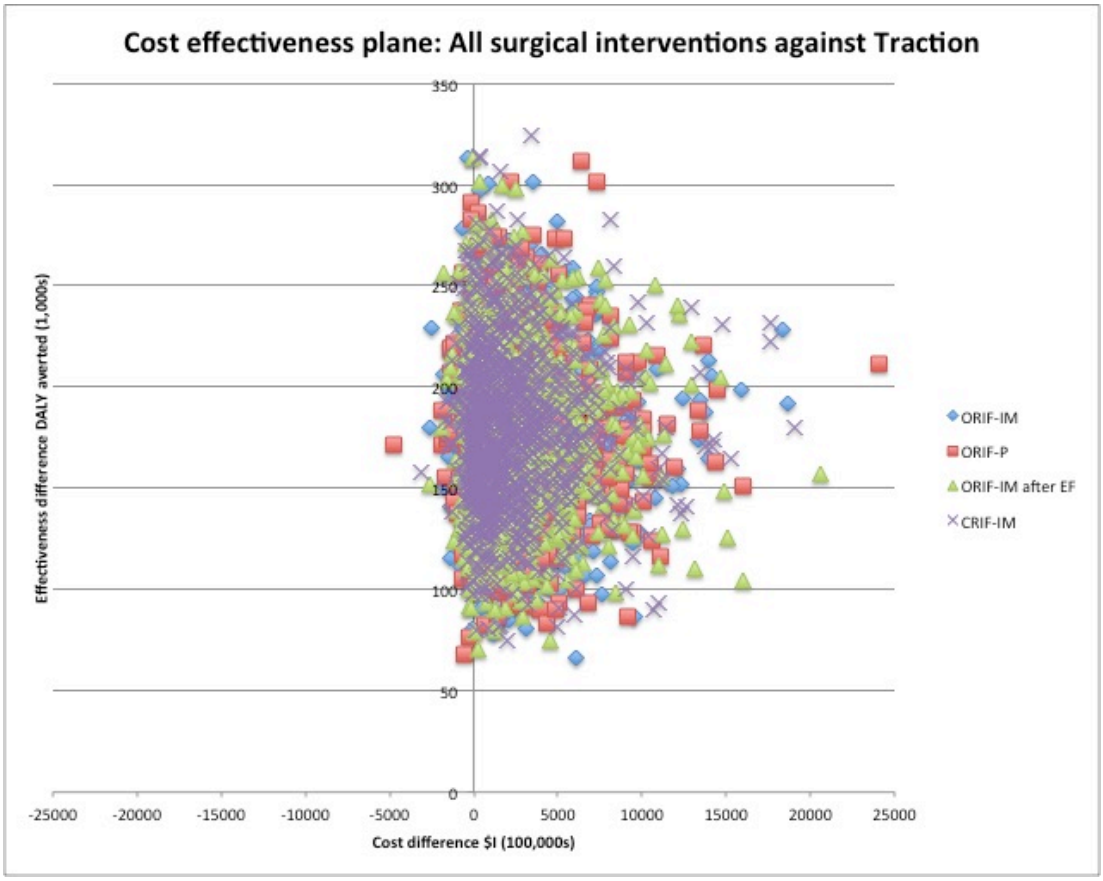
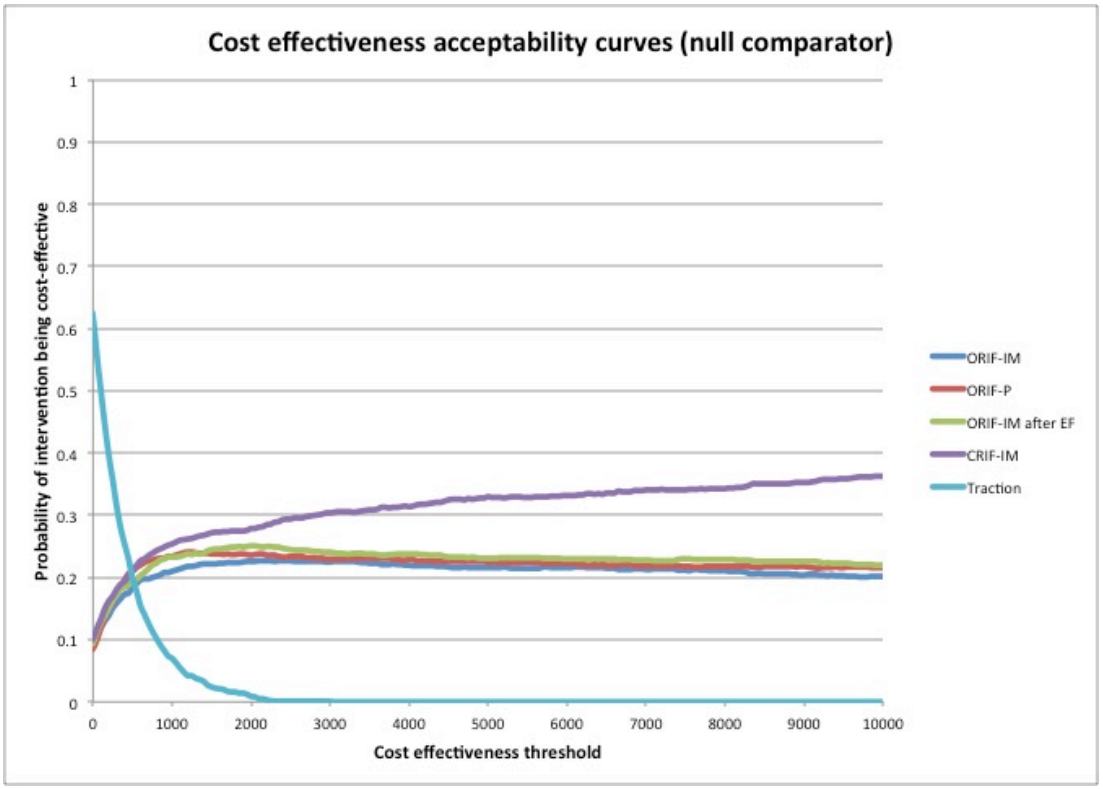


FIGURE 6: COST EFFECTIVENESS ACCEPTABILITY CURVE: ALL INTERVENTIONS AGAINST NULL COMPARATOR



CHAPTER 4: MEDICAL DEVICE AND EQUIPMENT PROCUREMENT PLANNING: AN APPRAISAL AND RECOMMENDATIONS FOR THE REVISION OF THE ONE HEALTH TOOL

KD designed and conducted the research presented here during an internship at the World Health Organization (WHO) in March-May 2015. Mrs. Adriana Velazquez Berumen (Senior Advisor for Medical Devices) supervised the project and provided critical feedback and support alongside staff within the WHO Medical Devices Unit; Ms. Karin Stenberg (Advisor on the One Health Tool) additionally reviewed research findings upon project completion. Contents of this chapter are included in an internal WHO report.

4. 1. INTRODUCTION

Sustainable and effective health service delivery relies on judicious, transparent and realistic health care planning.(1) While MDEs are critical components of health systems and services, findings presented in Chapters 1-2 suggest that MDE procurement planning in LMICs is fraught with challenges.

First, product selection is frequently undiscerning. LMICs lack the necessary technical experts in biomedical engineering and health technology assessment (health economics in particular) to advise what products are appropriate and cost-effective for use in settings with limited infrastructure and human resource skills. (Chapter 2) Additionally, no generally agreed and unified set of criteria exists to assist/guide stakeholders in product selection. (Chapter 1) Stakeholders could use existing tools or checklists, developed for specific clinical or service delivery areas (e.g. 2,3), however knowledge of such resources among LMIC decision-makers is limited. (Chapter 2)

Second, MDE costing for planning purposes frequently neglects expenses associated with user training and product servicing. (Chapter 1) Such costs should ideally be captured at the product selection and procurement stage to ensure products are used safely and to full capacity. Products for which no maintenance or training budget is available may be inappropriately handled and prematurely fall into disuse. (4,5) Value-for-money should also be considered at product selection stages: considering the cost-effectiveness of alternative purchases and interventions before embarking on investment decisions may lead to improved patient outcomes and more efficient resource allocation. (Chapters 2-3)

Third, MDE procurement processes may be un-coordinated and opaque. Findings of the qualitative study presented in Chapter 2 suggest that procurement decisions are driven by socio-political considerations of health facility prestige and competitiveness. In the absence of transparent and rational resource allocation processes, informed by evidence-based criteria and/or technical expertise, health systems are left susceptible to corruption and collusion. (Chapter 2)

Careful and informed MDE investment planning may mitigate such issues via the use of well-designed planning tools. For example, procurement checklists can prompt decision-makers to consider all potential factors impacting upon product selection, distribution, use and decommissioning of individual devices.(6) Tools may additionally provide guidance on how to undertake specific planning steps, e.g. to assist planners in product life cycle costing or consideration of value-for-money.(7)

The aim of this chapter is to appraise one such planning tool - the One Health tool (OHT), specifically its MDE components and functions. OHT is a UN developed costing tool intended for use in LMIC health system planning efforts. (See Box 1) The appraisal presented here aims to determine whether OHT and its functions accurately capture relevant planning considerations related to MDE costing domains (e.g. product maintenance and user training) and MDE procurement/use recommendations set out in Chapters 1-3 within this thesis (e.g. availability of biomedical engineers for product selection and maintenance service provision).

While OHT was designed for costing of horizontal or vertical health service plans, the tool is currently also used for costing of MDE procurement options. (8) Given its popularity among international organizations and analysts, and potential to influence

LMIC decision-making behaviour, it is relevant to consider whether the tool is designed to address the various procurement challenges outlined in this thesis. The chapter proceeds by introducing the methods and findings of ann appraisal of OHT and concludes with a discussion on the feasibility of using the program for procurement planning.

4. 2. APPRAISAL AIMS AND METHODS

The current study was undertaken within an internship at the World Health Organization (WHO) Medical Devices and Equipment Unit between March-May 2015. KD proposed the project during the internship application process, and later refined this with assistance from Adriana Velazquez Berumen – WHO Focal Point and Senior Advisor on Medical Devices.

AIMS AND RESEARCH QUESTIONS

The aim of this study was to appraise OHT's planning functionality and inputs, specifically as they relate to MDEs. Documenting the tool's MDE related features, strengths and shortcomings will enable improved MDE costing to the benefit of stakeholders engaged in MDE resource allocation planning - or health system planning more widely.

Informed by Chapters 1-3 in this thesis, in particular the findings of the systematic review and qualitative study, KD devised two main research questions applicable to OHT's appraisal:

1) What is the medical device and equipment related content of OHT?

2) How can OHT be used for medical device and equipment oriented planning?

The above questions relate to two key appraisal concepts: 1) appraising OHT inputs and 2) appraising OHT functions. This appraisal does not consider the general ease of use of the tool - rather it considers whether OHT is 'fit for purpose' when used for MDE

resource allocation planning. Feedback on OHT user experiences is routinely collected by the product developers/WHO following training sessions. (9)

CHECKLIST DEVELOPMENT PROCESS

The two main research questions posed above served as a starting point for the development of an appraisal checklist. (See Box 2) KD first specified a draft list of question items and iteratively refined these in collaboration with the biomedical engineers within the Medical Device and Equipment Team, including Yael Rodriguez Guadarrama, Gabriela Jimenez Moyao, Didier Mukama, Ying-Ling Lin. All engineers had experience in MDE management within public health care systems, including within LMICs across Asia, Sub-Saharan Africa and Latin America.

CHECKLIST CONTENT: RATIONALE FOR INCLUSION OF QUESTION ITEMS

The rationale for inclusion of individual question items and corresponding questions are listed in Table 1.

Question items relating to OHTs MDE inputs: KD devised appraisal questions relating to OHT's MDE inputs by referring to the systematic review data extraction template presented in Chapter 1 (Question items 2) and the findings of the systematic review (Question items 1). (ibid)

Questions relating to OHTs MDE planning functionality: Reflecting on the findings noted in Chapter 1-2, KD further developed question items relating to OHTs planning functionality.

APPRAISAL PROCESS

Before applying the appraisal checklist, KD familiarized herself with the structure and content of OHT. Technical manuals and the software itself were studied and test projections created to visualize how OHT operates. Specifically, KD attempted projections relating to health system recovery planning for Sierra Leone and Liberia given the recent Ebola Virus Disease outbreak. (Box 3) Using the developed question list (Box 2), KD then proceeded to appraise OHT and document its features.

Best practices synthesized from the international literature (Chapter 1) are used as benchmarks for gaging OHT performance. (Table 1) Devices should only be selected for procurement when their technical specifications allow for storage and functioning in unfavourable ambient conditions (e.g. settings with high temperature, interrupted or minimal electricity supply, unclean water, no sewage) and use by potentially low-skilled health care workers. (10) Investments in user training or infrastructure upgrades are also relevant to MDE selection and should be carefully considered during planning. (ibid and Chapter 3)

The appraisal was conducted independently of OHT developers and appraisal findings were presented in an internal seminar at the WHO and refined iteratively in light of expert comments by the Senior Advisor for Medical Devices (Adriana Velazquez Berumen) and the Technical Officer on Costing and Priority Setting within the Health Systems Governance and Financing Unit (Karin Stenberg). In discussion with the two units, KD proceeded to formulate recommendations for the revision of OHT.

4. 3. 1. OHT: An overview

OHT is a freely available software program meant to support resource-poor countries in costing and planning efforts. Given user input, OHT estimates the investment requirements of different health programs, interventions and policies and links these to health outcome and budget impact projections. The tool aims to inform decision makers of the cost, clinical effectiveness and value for money of alternative policy or program options(11).

OHT consists of separate easily editable modules (Figure 1) – e.g. for infrastructure, health financing – that facilitate the interaction of multiple stakeholders including clinical experts, financing professionals, logisticians and health care managers. The modules allow planners to provide baseline and target assessments describing the current and future (desired) health system structure, outputs and services, as well as financial resources available. The tool adopts a short to medium-term health system perspective and by default uses a 5-year planning period; this can be shortened or lengthened by users as needed. OHT relies on both impact and costing modules (See Box 1) to complete individual planning projections. 'Bottlenecks' - e.g. financing or other resource gaps, which impede the delivery of a service (e.g. low availability of health care workers) - can be flagged by the tool and thus inform decision-makers of key health system development constraints.

4.3.3. MDEs within OHT

Descriptive findings: Several OHT modules contain MDE related inputs (MDE template lists) and utilities (functions to estimate the number of MDEs to purchase and their overall costs).

The *configuration screen* and *logistics module* allow users access to one general 'Drugs and Supplies' list that includes MDEs. (Figure 6) Users can edit this list by adding or deleting items or can alternatively upload their own list. This list additionally includes editable fields for product unit costs, safety stock and wastage estimates.

Within the *infrastructure module* users have access to health facility specific MDE lists; five separate lists exist for health post, health centre, district hospital, provincial hospital and central hospital. (see Figure 7 for an example of a health post list) These OHT lists build upon past lists developed by the WHO (Figure 8 and Box 3) and include additions corresponding to the disease programs specific to OHT, i.e.: Child health; Reproductive and maternal health; Immunization; Nutrition; Water and Sanitation (WASH); HIV; TB; Malaria; NCDs and Mental Health Services. For example, a review of the health post and health center lists reveals that rapid diagnostic tests for TB and malaria diagnosis were added to the WHO's original MDE lists for health post and health center (Box 4) to form the OHT health facility specific input lists. (12)

Separate lists exist for Medical Equipment and Facility Furniture. All items on these lists are included in the general ‘Drugs and Supplies’ list that can be accessed via the tool configuration screen. (Figure 6) OHT lists include columns for the generic medical device name, quantity of items needed per health care facility, device cost (in national currency) and device working life (in years). For target setting purposes, an additional

column (tick-box only) allows the user to specify whether devices are to be purchased in USD rather than national currency. All MDE lists available in OHT are editable: users can add or remove items from the lists. OHT further allows users to upload their own MDE input list in Excel or CSV format, provided a specific template is followed.
The *infrastructure and logistics modules* additionally have predefined variables able to capture:

- Health facility rehabilitation costs, including costs for the maintenance and replacement of medical devices and equipment; (Figures 9-10)
- Estimates for safety stock (as percentage of need at the end of each year) and wastage (percentage of drug or supply that will be lost, ruined or expired within a year). (Figure 6)

The former costs are specified as overall general estimates per health facility, while the latter are to be specified for each item included on the 'Drugs and Supplies' list. (In the case of consumables, a single item may refer to a set, e.g. a set of disposable gloves.)

The *human resource module* includes editable tables where users can input the number of health care workers (e.g. nurses, doctors, program managers) needed to carry out a specific intervention/program or policy. OHT includes a field for technicians here. (Figure 11) Users have the option of adding different types of staff.

Critical appraisal: A full account of critical appraisal findings is presented in Table 1. There are two main issues that limit OHTs functionality and planning accuracy:

i) MDEs included within OHT are linked to individual health care facilities rather than interventions. This restricts the tools functionality for vertical program planning. This issue can be traced back to previous WHO-MDE lists that were designed to be facility

specific. (Box 4) Experts developed these original lists by identifying the common procedures, and clinical departments included in different types of health care facility and then defining what MDEs would be needed to undertake said procedures. Without an accurate account of what interventions experts considered when producing the lists, it is difficult to link individual products to interventions.

More recently, the WHO has proposed an alternative approach to MDE selection: the 'availability matrix' method relies on listing devices needed for carrying out specific interventions, further grouped into clinical areas. For example, for the area of reproductive, maternal, newborn and child health and within this, the intervention named ‘diagnosis of complications', products such as pulse-oximeters and examination gloves are listed among others.(13) This approach has been used in the development of the Interagency List of Medical Devices for Reproductive, Maternal, Newborn and Child Health (13) and is currently used to develop device lists specific to cancer management interventions. (ibid and (12))

The 'availability matrix' approach, however, has three shortcomings that make its use impractical for planning within OHT. First, many MDEs are generic to several clinical areas and interventions, e.g. medical furniture, gloves and injection equipment as well X-ray machines. Using the availability matrix alone for MDE selection may thus result in double counting: ideally, an MDE planning tool should distinguish between products intended for shared or dedicated use by different clinical departments.

Second, depending upon the spending envelope, several variants of the same MDE could be purchased to undertake the same intervention: e.g. a surgical monitoring and anesthesia unit may be suitable to surgery in high-resource settings, but a pulse-

oximeter and robust but low-tech anesthesia machine may be more suitable for use in low-resourced settings. The availability matrix fails to specify how MDEs are selected in such cases; biomedical engineering expertise is needed to conceptualize such decisions.

Third, when selecting MDEs it is prescient to consider the human resource skills, infrastructure and maintenance capacity of eventual deployment settings (Chapters 1-3 and(10)): it is unclear if/how the availability matrix approach accounts for these issues.

ii) MDE related information is captured in separate OHT modules

In its current format, OHT captures information related to devices in several different modules; this makes MDE related planning a lengthy process, as several inputs need to be crosschecked. For example, OHT requires users to specify wastage and safety stock estimates for each product in the logistics module. Maintenance and rehabilitation costs are meanwhile specified in the infrastructure module as general costs per health facility, rather than per device. This is problematic as wastage estimates depend upon the type of maintenance procedures put in place: e.g. preventive maintenance and careful calibration of minor devices such as oximeters may result in longer product life spans. OHT currently assigns all products on MDE lists a generic 5-year life span - this is obviously inadequate for consumables, however may be a realistic reflection of the life span of electronic equipment given unfavourable deployment settings. Additionally, problems may arise due to conflicting user input: e.g. logisticians may input different data from biomedical engineers/MDE managers. Where possible, information such as this should therefore be collected in one central module.

4. 3. 4 Recommendations for OHT revision

The following recommendations may assist in OHT revision:

1) Development of the following product lists:
    - *A generic list of medical furniture for different types of health care facility*, including furniture, stationery items and cleaning materials. Products detailed in this group would correspond to the shared resources necessary for various facilities to function and quantification criteria based on facility size, number of beds and/or population numbers should be provided.
    - Two types of MDE lists:
        i. *Core equipment lists for each type of health care facility*, including: consumables such as syringes, gloves, needles and basic devices shared across clinical areas – e.g. stethoscopes, weighing scales, simple laboratory equipment. This should also include, where necessary, the information systems relevant for managing patient records or samples. Currently, OHT does not include laboratory information systems or electronic records management systems (Table 1), however, such digital resources are now recommended as standard and cost-saving practice. (14)
        ii. *Condition/clinical area specific medical device and equipment lists*. These could be developed using the availability matrix approach as detailed and exemplified above. (15) Interventions corresponding to one specific clinical area and subsequently

devices associated to these should be identified using a transparent decision algorithm. It will be necessary to link interventions to the specific devices needed for carrying out services and to program filters into OHT to allow users to choose MDEs suited to specific programs and interventions. As best practice, safe, cost-effective products suited to the infrastructure and human resource skills encountered in deployment settings should be included in these lists. (See (10) for a MDE selection algorithm)

2) When using the above lists for planning purposes within OHT, tool developers should:

- Make available a master MDE list (including all products specified in lists in point 1) as a default option. Users should be encouraged to use up to date functional inventories of equipment and devices present within a country's health care facilities for baseline assessment. This is to ensure current, contextual, country-specific information is entered into the tool. For target setting purposes, users should be encouraged to plan and select products for procurement as per the principle employed in point 1). Users should first be encouraged to select vertical programs, subgroups or interventions to be provided. OHT should automatically identify medical devices and equipment corresponding to the latter programs/interventions and compare this to information provided at the baseline assessment stages to inform users of further investments

required. The tool should flag the purchase of any financially unsustainable purchases as bottlenecks. While a universal cost-threshold may be inappropriate, it is important to consider a relative threshold - for example, the purchase of MDEs which exceed half a country's health care budget.

In summary, the development of three list groups is recommended:

a) Generic lists of medical furniture
    a. For Health Post
    b. For Health Centre
    c. For District Hospital
    d. For Provincial
    e. Central Hospitals
b) Core lists of medical devices and equipment:
    a. For Health Post
    b. For Health Centre
    c. For District Hospital
    d. For Provincial
    e. Central Hospitals
c) Clinical area specific lists of equipment and devices.

To ensure MDE specific information is collated and easily accessible, all lists should include the following headings (including the general 'Drugs and Supplies' list):

I. Generic device name (Optional separate columns for GMDN(16) or UMDNS(17) codes to allow for quick cross-checking)

II. Units per health care facility (for furniture and core lists) or quantification criteria for intervention/clinical area specific lists

III. Unit costs (ideally local currency, local prices if data is available)

IV. Year that costs were specified, last updated and the original currency of costs indicated

V. Life-span of devices (in months)

VI. Replacement time-frame (in months or fractions thereof)

VII. Purchase in USD necessary (tick-box)

VIII. Type of maintenance necessary (choose among health facility specific or specialist, each to be costed out separately and link to the infrastructure upgrade requirement screen for costing out infrastructure investments)

IX. User training (tick-box - if yes, a reminder to include such costs in the Human Resources module as appropriate under training)

X. Safety stock necessary per health care facility

XI. Wastage estimate per health care facility

Items IV-VI and VIII-IX are optional and present additions/alterations to OHTs current functionality. Item IV (year costs were specified, last updated and currency specified in) is useful in understanding where/how cost-data for individual products was last obtained and updated - an older date provided in this column may encourage users to seek up-to-date pricing information. Item V (life span of devices in months) is a modification of the current life-span field (life-span in years) already included in OHT: as smaller items such as consumables or reagents may be usable for periods shorter than a year, a monthly life span is more appropriate for planning. Item VI (replacement time-frame in months - or fractions thereof) refers to the period after which MDEs are required to be

replaced by national/international policy: i.e. an X-ray unit may need to be replaced every 10 years due to national regulation to ensure the health and safety of health care staff and patients. Product replacement time may therefore differ from life span. Items VIII-IX are self-explanatory and prompt users to consider which products may require additional investments for user training or maintenance.

Lists should be developed in shareable and editable format, ideally in a template file that can be uploaded to OHT (the tool currently provides guidance on how such lists should be structured). (9)

The methodology supporting product selection for inclusion on the MDE lists mentioned above needs to be distinguished from methods used to select medicines within the Essential Medicines List. (18,19) To be accepted onto the Essential Medicines List, medicines undergo a rigorous and transparent selection process: items selected as part of the 'core list' correspond to priority health conditions and are reviewed for safety, efficacy and relative cost-effectiveness and affordability. Such a rigorous review would be impractical for the static medical furniture or core health facility equipment lists proposed here – most items on these lists are likely to be safe and uncontentious investment options; lists developed by expert consensus informed by the MDE selection/prioritization criteria outlined in Chapter 1 may be used instead. However, safety, relative cost-effectiveness and affordability should guide discussions for the development of intervention/clinical area specific lists of equipment. For example, resource-stratified clinical guidelines for breast cancer (2,20) may be used to create resource-level stratified MDE lists.

4. 4. DISCUSSION

This chapter includes the first MDE specific appraisal of OHT - the main health system planning tool available free of charge to LMICs. The descriptive and analytical findings presented here illustrate that OHT is a comprehensive planning platform, able to capture health service planning inputs relating to infrastructure, human resources and financing among others. OHT is a helpful starting point for costing out MDE purchases; however, its structure is currently too rigid to deal with the peculiarities of MDE procurement and relevant planning given specific health programs or services.

OHT possesses a basic set of functions and inputs necessary for assisting LMIC decision-makers in health system planning and resource allocation. The tool currently allows users to edit generic health facility specific MDE lists to indicate what products are present in the health system and which are yet to be purchased. The tool further prompts users to specify other MDE-related investments: e.g. relating to safety stock and wastage and health facility maintenance - including a nominal sum for MDE specific maintenance. OHT can thus be used as a starting point for MDE related costing exercises and planning purposes, however, two main issues limit its planning functionality.

First, although OHT allows users to engage in program specific planning and tailor what interventions are/are not to be offered in the health system, the tool cannot link selected interventions to specific MDEs. This means that in addition to intervention or program selection, users must engage in a fairly labour intensive process of reviewing OHTs generic MDE lists during both baseline assessment and target setting stages. Challenges arise as decision-makers involved in planning and/or logisticians do not possess the

necessary clinical or biomedical engineering related knowledge to complete this process. (21) Second, OHT captures information related to MDEs in several different modules, making the tool difficult to navigate and increasing the reporting burden on users. Further points where OHT may require revision are outlined in Table 1.

To mitigate these issues, further development of OHT input lists is proposed. A first step is the creation of static lists for medical furniture and basic MDEs for each type of health care facility. The current OHT and WHO lists could serve as a basis for this. (Box 1) Additionally, clinical area and/or intervention specific lists should be created and linked to specific programs or intervention sub-groups. Users should thus be able to select a specific program or intervention sub-group and be presented with a correspondingly tailored list of products. This approach is similar to that within the Integrated Healthcare Technology Package (IHTP) (22) and within the availability matrix used for product selection by the WHO(15). Additionally, MDE related information should all be captured in individual lists on a per product basis: this will prompt users to consider product features, including maintenance and training necessary for safe deployment, and logistical challenges at early procurement stages.

Only one other (complete) tool for MDE related planning currently exists. (8) IHTP was developed under the auspices of the WHO and focuses solely on health technologies and projecting procurement and management scale-up given local epidemiology and service scale-up. IHTP is not freely available for use.(22) The tool adopts a bottom-up approach to the selection of health technologies; this is similar to what is proposed here: i.e. users first select what services are to be offered and based on this IHTP offers suggestions for the types of products to be considered for procurement. IHTP is not suitable for impact analysis, however, thus limiting its use for resource allocation.

The findings of this appraisal must be interpreted with due caution. Although KD formulated appraisal questions transparently, the appraisal of OHTs current functionality and potential for further use included substantial subjectivity. The appraisal process has been iterative and the team involved in this exercise cautions that they have not been extensively involved with OHTs (or know of data evaluating OHTs) use in LMIC settings. Furthermore, the appraisal checklist specified here was not previously piloted on any other planning tool or MDE resource allocation planning method. While KD attempted to obtain access to IHTP to first pilot the checklist, access was not granted by the WHO in this case. To further develop and refine the checklist, planning experts, biomedical engineers and health technology managers should be consulted. DELPHI or other consensus methods may prove particularly useful in such endeavours and may help identify any further concepts of relevance to the MDE specific appraisal of OHT. To validate the checklist, surveys engaging MDE resource allocation planning stakeholders with experience of using OHT should be conducted and responses compared to findings and recommendations outlined here.

Notably however, the appraisal checklist presented here draws upon recent relevant evidence on MDE procurement planning as outlined in Chapters 1-3. Concepts relating to MDE affordability and costing, maintenance and servicing in deployment settings, quantification of stock (including estimation of wastage and safety stock) were probed via multiple questions. Findings of the research presented in Chapters 1-3 have not only been integrated into the checklist but have also served to guide OHT's appraisal; leading experts on MDE management for LMICs were additionally consulted during the appraisal checklist development and appraisal process.

4. 5. CHAPTER SUMMARY AND KEY FINDINGS

Despite difficulties in using health technology assessment and economic evaluation methods in LMICs, MDE investment decisions must be reached in practice. To prevent MDEs falling into disuse, it is therefore crucial to ensure all product purchases are appropriate costed.

Chapter 4 summarizes a critical appraisal of the One Health Tool (OHT) for MDE related investment planning, management and costing. Use of OHT is promising as it is able to capture both health and budget impact information and evaluate investments associated to different health service expansion plans. The tool is relatively easy to use, however proves too rigid to assist in sensitive and context-specific MDE procurement planning. For example, OHT is currently unable to link individual interventions to MDEs required to carry out services and additionally includes simplistic technology management assumptions (e.g. a uniform 5-year life span of all MDEs).

> *Key Finding 9: Regardless of planning tools used to inform/reach MDE investment decisions, information relating to shared/dedicated resource use, user training, maintenance and servicing capacity, safety stock and wastage must be captured. For information to be meaningful and easily accessible, MDEs should be linked to interventions where necessary and presented in a centralized database/list.*

Issues with the tool can be traced back to inappropriate input materials. Device lists input into OHT do not link individual products to interventions but to health service level or health facility type. The tool therefore assumes users have considerable and

detailed knowledge of linkages between individual devices, interventions and health facilities. Planning is additionally complicated by lack of information of which devices fall into different product categories: e.g. facility furniture and common necessities (e.g. delivery beds and stethoscopes), clinical area specific technologies (e.g. dental equipment), or intervention critical products (e.g. colonoscopes for colonoscopies). Such information would for example allow users to determine what MDEs constitute a dedicated or shared resource across clinical areas: e.g. an ultrasound machine can be shared by the internal medicine and paediatric department. Recommendations for restructuring available medical device lists to take into account such considerations are set out.

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BOX 1: ONE HEALTH TOOL: PLANNING PRINCIPLES AND FUNCTIONS

Background To enable a standardized health systems approach to costing, Avenir Health developed OHT under the direction of the United Nations Interagency Working Group on Costing. (11,23) OHT has been used in over 25 countries. (23)

Configuration: Users choose a region or country to initiate new planning projections; projections include several planning modules (Figure 1). Country databases, including demographic and disease incidence/prevalence estimates, are available for download from Avenir Health. OHT can project costs for two planning scenarios: horizontal delivery (Figure 2) or vertical program planning (Figure 3). Users select programmes and health services/interventions to model - these may already be provided within the health system, be subject to re-development or newly introduced. By default, OHT includes a list of programmes and services focused on achieving the Millennium Development Goals: e.g. Water and Sanitation (WASH) and Human Immunodeficiency Virus. Interventions included in OHT reflect WHO guidelines or evaluations by the WHO-CHOICE (Choosing interventions that are cost-effective) group - e.g. see Ginsberg et al. (24)

Users can add or delete interventions from this list as well as upload their own context specific intervention lists. Interventions are assigned to a relevant vertical program and further classified according to the health care level at which they are carried out – i.e. outreach, community, clinic and hospital level. This classification scheme links program and delivery channel oriented planning. (Figures 4-5)

Baseline assessment: In individual planning modules (Figure 1), users first perform a baseline assessment of the health system and its capacity to offer health services by specifying the type of interventions already offered, availability of health care professionals/associated staff and of physical resources, i.e. facilities, medicines and medical devices and equipment.

Target setting and planning: Users set policy objectives and/or formulate health system, sector or disease specific development plans. For each plan users must specify the interventions for which costs and outcomes need to be modelled - i.e. interventions to be phased out, introduced or augmented. Each alternative plan is saved by OHT as a projection. The projections include the costs and likely health outcomes incurred by the interventions selected by users. (See Box 2 for examples)

Costing: OHT supports programme specific and sector wide costing, budgeting and financing analysis and uses an ingredients approach for cost-estimation. (25) Variable costs are estimated using population numbers and a database of disease incidence. Costs are editable and standard cost lists for infrastructure, medicines, MDEs and human resource are included. Program management/ monitoring activities are estimated by specifying the type of health care professionals to be employed, a standard salary per professional and the relative time needed for activities.

Data and impact projections: DemProj is the software used to link the health outcome and costing modules of OHT. (26) The health impact modules used by OHT are condition or program specific tools previously developed to model intervention health impact (e.g. the AIDS Impact Model, TB Impact and the Lives Saved Tool (LiST) among others).

BOX 1: OHT APPRAISAL QUESTIONS

Part 1: Inputs

What is the medical device and equipment related content of OHT?

1. Identify and discuss any and all medical device input lists within the tool.
    a. What devices and equipment are considered by OHT?
    b. What methods were used for list development?
    c. Are additions or deletions necessary?
2. What information on devices is captured by OHT, e.g. are the following included:
    a. Device characteristics:
        i. Unique device identifier or device name.
        ii. Technical specifications or functional group (i.e. are devices grouped by clinical area, location within health facility or departments, function, size, cost or other characteristics?)
    b. Maintenance requirements (including routine and corrective maintenance, need for user training).
    c. Specifications for user training.
    d. Specifications for safety stock and wastage.
    e. Device life-cycle costs: product cost, distribution, maintenance, spare parts, training, decommissioning.

Part 2: Planning functionality

How can OHT be used for medical device and equipment oriented planning?

1. Can OHT accommodate medical device and equipment procurement planning for:
    a. Single interventions (or packages)
    b. Vertical programs
    c. Horizontal programs or per health care delivery level
    d. Specific health facility types
2. Does OHT include estimates to aid in specifying safety stock and wastage of devices?
3. Can OHT calculate device coverage levels per regions or facilities?
4. What does OHT consider a "bottleneck in service delivery" in relation to devices? I.e. will OHT alert planners to the need to: specify safety stock, wastage; attain specific coverage levels based on population or facility estimates; specify training components for staff; specify maintenance and decommissioning components?
5. Does OHT include variables related to:
    a. Biomedical engineering capacity within a country or region/per clinical area
    b. Technical capacity for medical device and equipment repair
    c. Health system infrastructure and necessary building-works or upgrades to infrastructure to enable device functioning (e.g. water, electricity, sewage systems)
    d. Electronic health system infrastructure to aid in device management and/or patient management (e.g. electronic patient records, laboratory information systems)

BOX 3: USING OHT FOR SIERRA LEONE RECOVERY PLANNING AFTER EBOLA VIRUS DISEASE OUTBREAK 2014

OHT was proposed as a recovery-planning tool for countries affected by the 2015 Ebola Virus Disease outbreak. Two specific projections relating to recovery planning in Liberia and Sierra Leone were attempted to appraise OHTs applicability to MDE procurement planning. These exercises are 'test scenarios' – as such KD attempted to use the tool given only generically available information and guidance to gage the tools functionality and data input requirements.

1) Projecting equipment costs for one tertiary hospital including CT scanning ability in Liberia.

This was a costing exercise, hampered only by data paucity in OHT. Default population and cost data for Liberia was uploaded to OHT and the default input list of MDEs for a central level hospital used to project costs. Initial estimates suggested 26,051,666 Liberian Dollars (LRD) would be needed, excluding CT which is costed at 0 in OHT. Excluding further equipment (a linear accelerator and equipment necessary for radiotherapy were excluded upon communication with Liberian partners) and adding a CT scanner with 10 year operating life(Google search: $USD165,000), estimates for the medical equipment within the hospital reached 39,266,568 LRD. This excludes servicing costs.

2) Projecting MDE related costs for 20% expansion of TB diagnostic services in Sierra Leone: This task could not be completed as OHTs functions do not extend to this level of planning and further expert input and data were needed.

Current data from Sierra Leone suggested TB diagnosis via microscopy, tissue culture and X-ray were not available. Initially, the following were chosen for projection: i) Microscopy: diagnostic test for active TB case finding and ii) Microscopy: test to monitor treatment for pulmonary TB cases; both services were expanded from 0% coverage to 20%. Issues arose after services were chosen for projection: OHT does not link the intervention to specific medical devices; biomedical engineers and clinical experts would be needed to advise on the laboratory equipment relevant to TB microscopy. When consulting MDE lists for district and central hospitals it additionally became apparent microscopy equipment had no reference cost attached: TB laboratory equipment for microscopy was costed out at 0 in OHT.

Considering recent WHO recommendations, microscopy was replaced by genotypic molecular testing, carried out via the use of Xpert MTB/RIF assay. Only Xpert cartridge costs were available: 49,445.242438 Sierra Leonean Leone (SLL). OHT did not include Xpert cartridges in the facility MDE lists. Further expertise would be needed to specify the number of cartridges per facility rather than population (population per facility can be specified elsewhere) – additional data relating to health facility coverage/population and likely throughput of tests per cartridge is needed to complete this task.

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WHO Core Equipment Lists

Development and content: The WHO Technical Advisory Group on Health Technologies developed Core equipment lists in 2010. (27,28)Biomedical engineers, clinical specialists, health technology managers and infrastructure/logistics professionals from across LMICs mapped out the different rooms and service areas routinely included in specific health facilities and identified what furniture and equipment is necessary for each type of health care facility and the services generally provided therein. (8) No written account of methods used for the development of these lists exists and it is additionally unclear what criteria or factors experts considered during product selection.

The WHO further states(29):
"WHO has not reviewed the safety, efficacy, quality, applicability, or cost acceptability of any of the technologies referred to hereafter. Therefore, inclusion of the aforesaid lists herein does not constitute a warranty of the fitness of any technology or of any resulting product and any future development thereof, for a particular purpose. Besides, the responsibility for the quality, safety and efficacy of each technology or each resulting product remains with its developer, owner and/or manufacturer."

Organization: Lists are organized by health care facility type. Five separate lists exist for health post, health centre, district hospital, provincial hospital and central hospital. All baseline lists can be found on the WHO's website and are freely downloadable. (29)

Presentation: Medical device lists include columns for device location (area, unit and subunit), device type (medical equipment, furniture, instrument or accessory), a generic device name, and term names and unique numeric identifiers corresponding to GMDN (30)and UMDNS nomenclatures(17). Lists were provided in a PDF format for consultation until 2015; they are currently available for download as editable Excel files.

Availability: All lists can be downloaded from http://www.who.int/medical_devices/innovation/health_care_facility/en/index1.html

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TABLE 1: OHT APPRAISAL CHECKLIST: QUESTION ITEMS AND RATIONALE FOR QUESTION INCLUSION

Appraisal Question	Rationale and supporting evidence
Section 1: What is the medical device and equipment related content of OHT?	
1. Identify and discuss any and all medical device input lists within the tool.	The systematic review highlighted that different types of MDE lists are used for planning purposes: it is relevant for planners to understand what product categories are included/excluded from lists and how lists were developed (i.e. do included items correspond to 'gold standards').
1a. What devices and equipment are considered by OHT?	
1b. What methods were used for list development?	
1c. Are additions or deletions necessary?	
2. What information on devices is captured by OHT, e.g. are the following included:	The systematic review noted the importance of uniquely identifying, and clearly categorizing, MDEs. In the absence of unique product

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Appraisal Question	Rationale and supporting evidence
2a. Device characteristics: i. Unique device identifier or device name. ii. Technical specifications or functional group (i.e. are devices grouped by clinical area, location within health facility or departments, function, size, cost or other characteristics?)	identifiers or a clear categorization system, MDE procurement planning is increasingly difficult: e.g. products with similar/inappropriate specifications may be acquired and stock tracking/verification is challenging.
2b. Maintenance requirements (including routine and corrective maintenance, need for user training).	Absence of maintenance services, whether preventive or corrective, and training on safe MDE use lead to products breaking or falling into disuse prematurely; this directly results in lost resources and impairs health service provision.
2c. Specifications for user training.	
2d. Specifications for safety stock and wastage.	Health care professionals in The Gambia and Romania frequently mentioned stock outs of MDEs (referring to consumable items) as well as wastage of products due to MDE transport in unfavorable conditions (i.e. hot humid countries - referring to products such as blood pressure machines and laboratory reagents which react

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Appraisal Question	Rationale and supporting evidence
	adversely to protracted heat exposure). 'Stock out' or 'wastage' estimates may not be relevant for all items, however OHT should minimally require the specification of such estimates for consumables/single-use products.
2e. Device costs or prices, including an indication for which devices should be procured.	To judge whether MDEs are affordable, details on all MDE life-cycle cost components must be specified; if only one total cost is specified, details on whether this accounts for shipping, distribution, installation and calibration, maintenance and spare parts, training and decommissioning are needed. The health economic analyses presented in Chapter 3 highlight the difficulty of sourcing adequate cost-data relating to MDEs; data on

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Appraisal Question	Rationale and supporting evidence
	MDE servicing and ancillary infrastructure are particularly difficult to obtain. (See Chapter 3 - estimation of costs for alternative interventions modelled, specifically operating room costs)
Section 2: How can OHT be used for medical device and equipment oriented planning?	
1. Can OHT accommodate medical device and equipment procurement planning for:	Interviews with health facility managers and regional/national health service planners/MDE management personnel in The Gambia and Romania emphasized the importance of adopting a unified perspective when selecting, procuring and managing MDEs. Planning should account for shared resource use and additionally consider which health facilities are best positioned and equipped to use and maintain specific MDEs; this ensures both improved service delivery and enables timely patient referral to better equipped facilities as relevant.
1a. Single interventions (or packages)	
1b. Vertical programs	
1c. Horizontal programs or per health care delivery level	
1d. Specific health facility types	

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Appraisal Question	Rationale and supporting evidence
	It is worth noting however that professionals engaged in MDE procurement and resource allocation frequently work at either health facility or regional/national horizontal or vertical program level (Chapter 1): OHT should therefore enable the capture of multiple planning perspectives.
2. Does OHT include estimates to aid in specifying safety stock and wastage of devices?	Interview and focus group participants across The Gambia and Romania noted MDEs frequently broke or were used up without replacement stock being available (e.g. in case of consumables). In the absence of an electronic MDE management system (See also question 5d) it was difficult to adequately monitor and quantify how many products would be needed to enable minimal service delivery.

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Appraisal Question	Rationale and supporting evidence
3. Can OHT calculate device coverage levels per regions or facilities?	Policy makers and national procurement representatives in both The Gambia and Romania mentioned the use of 'informal' coverage targets for different MDEs: e.g. 1 Magnetic Resonance Imaging machine per 150,000 people. Should policy makers indeed set such MDE coverage targets, it is relevant to explore how this is accounted for in OHT
4. What does OHT consider a “bottleneck in service delivery” in relation to devices? I.e. will OHT alert planners to the need to: specify safety stock, wastage; attain specific coverage levels based on population or facility estimates; specify training components for staff; specify maintenance and decommissioning components?	This question item was included after a first cursory review of OHTs functions. OHT is able to flag 'bottlenecks' in service delivery/funding/capacity: i.e. identify points where insufficient resources are provided to ensure service delivery. Findings in Chapter 1 and 2 suggest several such 'bottlenecks' could apply to devices, including: specifying insufficient

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Appraisal Question	Rationale and supporting evidence
	safety stock and wastage for consumable/single use devices; inability to attain specific coverage levels based on population or facility estimates as per national policies (see Item 3 above); not specifying costs for MDE relevant user training or product maintenance and decommissioning.
5. Does OHT include variables related to:	Interviews in The Gambia emphasized how, in the absence of MDE manufacturers within LICs, as well as obligatory MDE maintenance contracts, MDEs frequently fall into disuse. The publicly funded health system therefore needs to compensate for shortcomings in the availability of maintenance services and trained servicing personnel. Depending on the complexity of MDEs, only specifically trained engineers may be able to ensure product maintenance - e.g. medical physicists for brachytherapy.
5a. Biomedical engineering capacity within a country or region/per clinical area	
5b. Technical capacity for medical device and equipment repair	

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Appraisal Question	Rationale and supporting evidence
5c. Health system infrastructure and necessary building-works or upgrades to infrastructure to enable device functioning (e.g. water, electricity, sewage systems)	The systematic review in Chapter 1 emphasized that when selecting MDEs for procurement, stakeholders assign foremost relevance to the ambient conditions encountered in the eventual deployment setting. Availability of electricity, clean water, and temperature controlled storage/treatment rooms are relevant both for MDE selection and continued use.
5d. Electronic health system infrastructure to aid in device management and/or patient management (e.g. electronic patient records, laboratory information systems)	To accurately account for MDE stock and appropriately manage this at regional and national scales, functional inventories or information systems are needed. Interview participants in both The Gambia and Romania emphasized the need for such systems: they could serve to set alerts for low 'stock' as well enable improved, long-term, planning practices.

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TABLE 2: ONE HEALTH TOOL APPRAISAL

	Appraisal Question	Notes on best practice	OHT Inputs and functions	Notes
Medical Device and Equipment Inputs used by OHT	1. Identify and discuss any and all medical device input lists within the tool. a. What devices and equipment are considered by OHT? b. What methods were used for list development? c. Are additions or deletions necessary?	MDE lists developed using a transparent product selection algorithm and including sufficient information for linking MDEs to specific interventions or health facilities	OHT uses the following MDE lists: • One general 'Drugs and Supplies' list accessible via the configuration screen and logistics module • Separate health facility specific lists for Medical Equipment and Facility Furniture for health post, health centre, district hospital, provincial hospital and central hospital.	MDE lists within OHT are static: i.e. products listed are not linked to the health interventions they perform. If lists were dynamic, MDEs on lists would be added or deleted depending upon the interventions or programs users select within a projection.
	2. What information on devices is captured by OHT, e.g. are the following included:	MDEs grouped according to transparent decision-algorithm	OHT - MDE input lists include: a. Device characteristics	i) Information on MDEs is disparately presented in OHT:

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	Appraisal Question	Notes on best practice	OHT Inputs and functions	Notes
	a. Device characteristics: i. Unique device identifier or device name. ii. Technical specifications or functional group (i.e. are devices grouped by clinical area, location within health facility or departments, function, size, cost or other characteristics?) b. Maintenance requirements (including routine and corrective maintenance, need for user training). c. Specifications for user training. d. Specifications for safety stock and wastage. e. Device costs or prices, including an indication for which devices should be procured.	MDE maintenance requirements specified, including preventive and corrective maintenance and spare parts (for entire life-cycle) and decommissioning MDE user training requirements specified Indications on quantification provided, including consideration of safety stock and wastage where necessary Indications of product cost and components reflected in cost (e.g. maintenance, warranty); information on how up to	i. Device name - this is a unique text identifier. ii. Devices are classified into either equipment or furniture and are grouped according to the health care facility they are to be used in. b. Maintenance of devices is captured via the infrastructure module - users can specify rehabilitation costs of individual facilities, including device maintenance. c. User training is not considered. d. Users can specify the necessary safety stock	e.g. users specify maintenance, safety stock, wastage in different modules of the tool. A potential improvement, for example, would see safety stock and wastage for individual devices placed alongside the MDE health facility specific lists. ii) It is unclear how the devices on the preloaded MDE lists were chosen for inclusion in OHT.

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	Appraisal Question	Notes on best practice	OHT Inputs and functions	Notes
		date costs are	and projected wastage of devices within the logistics module, using the 'Drugs and Supplies' list. e. Device costs for each MDE are included in each of the lists presented. During baseline assessment users can indicate what devices are already present within the national health system; during target setting users can choose what MDEs are still to be procured and also indicate whether products are to be purchased in USD.	
MDE procurement planning functionality in OHT	1. Can OHT accommodate medical device and equipment procurement planning for: a. Single interventions (or packages) b. Vertical programs c. Horizontal programs or per	Transparent planning methods	Users can use the OHT MDE lists to select what MDEs are to be procured. The lists indicate what products are generally required for	MDE lists are static rather than dynamic: i.e. user selections of the types of programs or health interventions to offer do not

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	Appraisal Question	Notes on best practice	OHT Inputs and functions	Notes
	health care delivery level d. Specific health facility types		each type of health care facility. Users can also select what MDEs are to be procured from a general Drugs and Supplies list when attempting program specific planning.	automatically affect the MDE lists. For example, even should users select to offer only TB services, OHT will not restrict the MDE list to items only needed for the management of TB.
	2. Does OHT include estimates to aid in specifying safety stock and wastage of devices?	Realistic estimates of safety stock and/or wastage to be included to ensure service can be provided sustainably even in periods of high demand or financial difficulty	OHT allows users to specify their own estimates for safety stock needs and wastage.	Background research into frequently used estimates for safety stock and wastage may be warranted. This would allow OHT developers to include a recommendation estimate.
	3. Can OHT calculate device coverage levels per regions or facilities?	MDE coverage per region and nation can be calculated	This function is not automatic in OHT, however, this could be deduced: MDEs are assigned to different health care facilities and OHT calculates health	The Global Health Observatory now includes indicators and for the availability of certain MDEs (e.g. CT scanners). The WHO

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	Appraisal Question	Notes on best practice	OHT Inputs and functions	Notes
			facility/population ratios for coverage purposes.	and other UN organizations also propose benchmarks for MDE availability; benchmarks could be presented as informational sources for users wishing to procure specific types of MDEs.
	4. What does OHT consider a “bottleneck in service delivery” in relation to devices? I.e. will OHT alert planners to the need to: specify safety stock, wastage; attain specific coverage levels based on population or facility estimates; specify training components for staff; specify maintenance and decommissioning components?		MDE procurement costs are included in the overall investment estimate of a specific health program/policy. Should a financing gap exist - i.e. should OHT calculate insufficient resources to meet the investment requirement - the tool will alert users to a 'bottleneck'.	Additional bottlenecks could be specified, in particular relating to: i. low coverage levels of basic technologies (indicators for basic technology availability in countries are included in the Global Health Observatory) ii. No provision for user training in equipment use: this is

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	Appraisal Question	Notes on best practice	OHT Inputs and functions	Notes
				relevant for emergency preparedness and infection, prevention and control in particular.
	5. Does OHT include variables related to: a. Biomedical engineering capacity within a country or region/per clinical area b. Technical capacity for medical device and equipment repair c. Health system infrastructure and necessary building-works or upgrades to infrastructure to enable device functioning (e.g. water, electricity, sewage systems) d. Electronic health system infrastructure to aid in device management and/or patient management (e.g.	Health systems to employ biomedical engineers and technicians to advise on MDE management and conduct MDE maintenance respectively. Where resources permit, information systems for MDE management and patient/record/sample management should be present.	a-b. In the human resource module, users can specify the number of technicians needed within the health system. c. In the infrastructure module, users can specify what infrastructure works are to be carried out within the planning cycle. This includes building and equipping new health care facilities. Users can specify building costs	a-b. The Global Health Observatory will include estimates of the international availability of biomedical engineers. It may be useful for OHT to provide users with average estimates for informational purposes during planning. d. The WHO strongly recommends investments in health information systems for laboratories and

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	Appraisal Question	Notes on best practice	OHT Inputs and functions	Notes
	electronic patient records, laboratory information systems)		and use MDE lists as explained above. Users can also enter estimates for water, sewage and electricity works and utilities - this can be either as a % of building costs or overall estimates. d. In the health information systems module, users can specify the type of IT infrastructure to be procured for the health system.	patient record management.

FIGURE 1: OPENING SCREEN OF THE ONE HEALTH TOOL

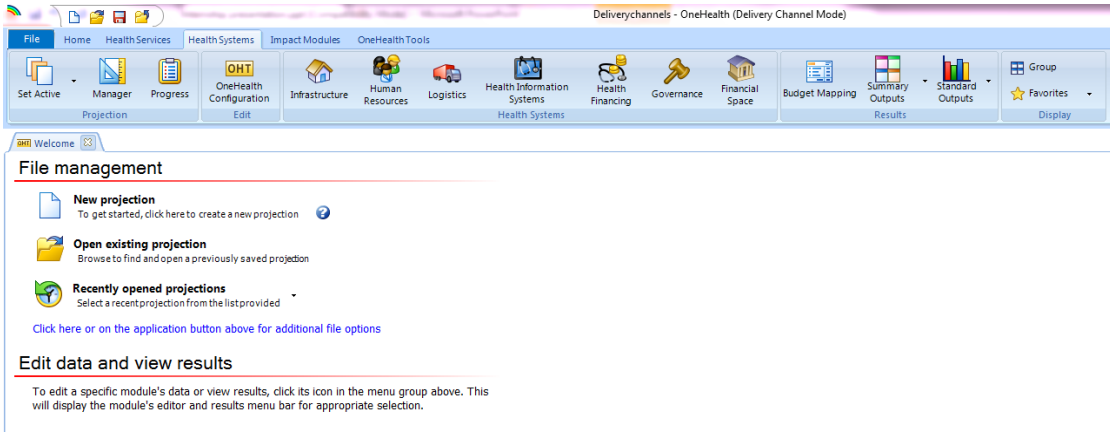


FIGURE 2: ONE HEALTH CONFIGURATION – DELIVERY CHANNELS

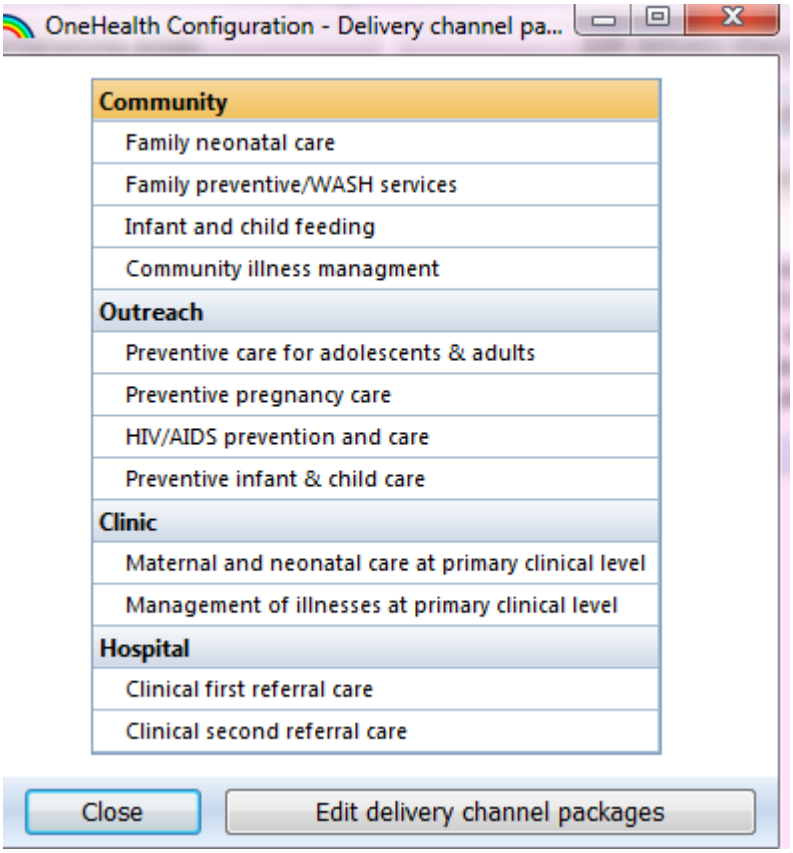


FIGURE 3: VERTICAL PROGRAMMES IN OHT

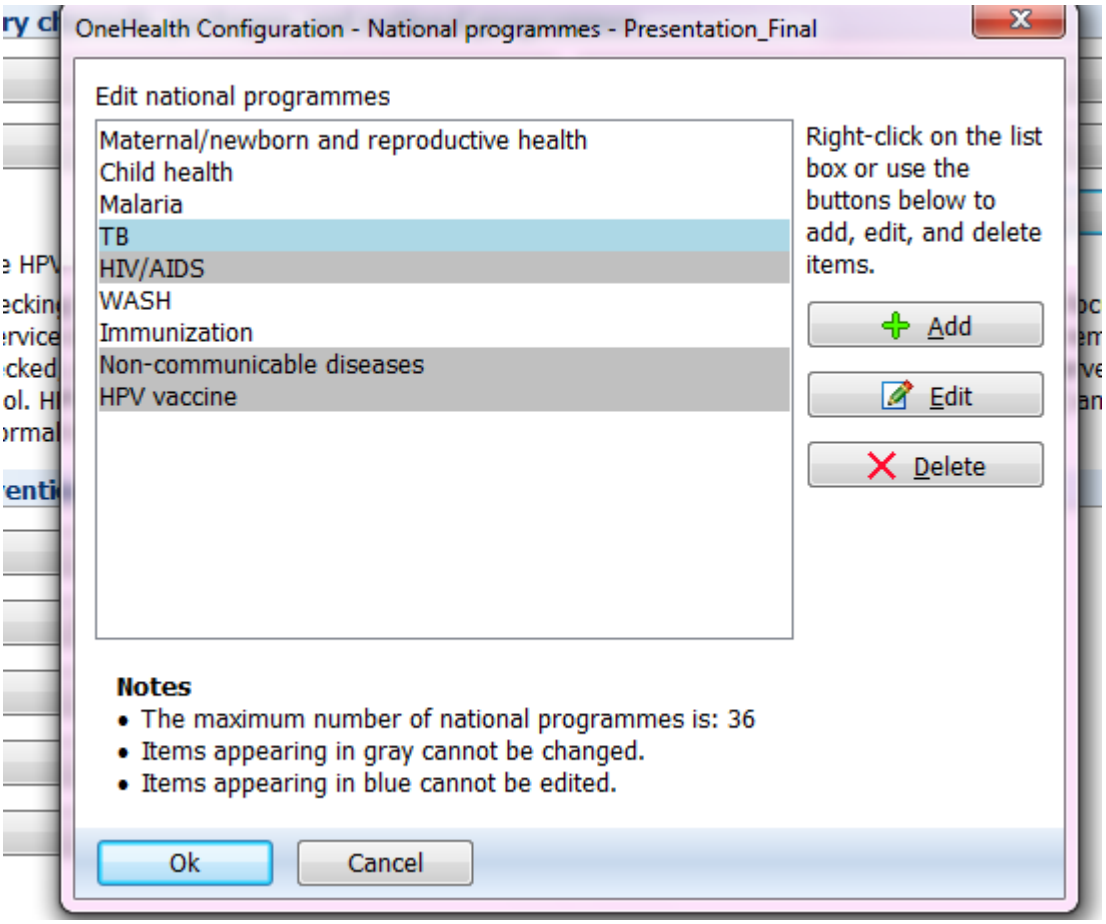


FIGURE 4: SUBGROUP CONFIGURATION SCREEN

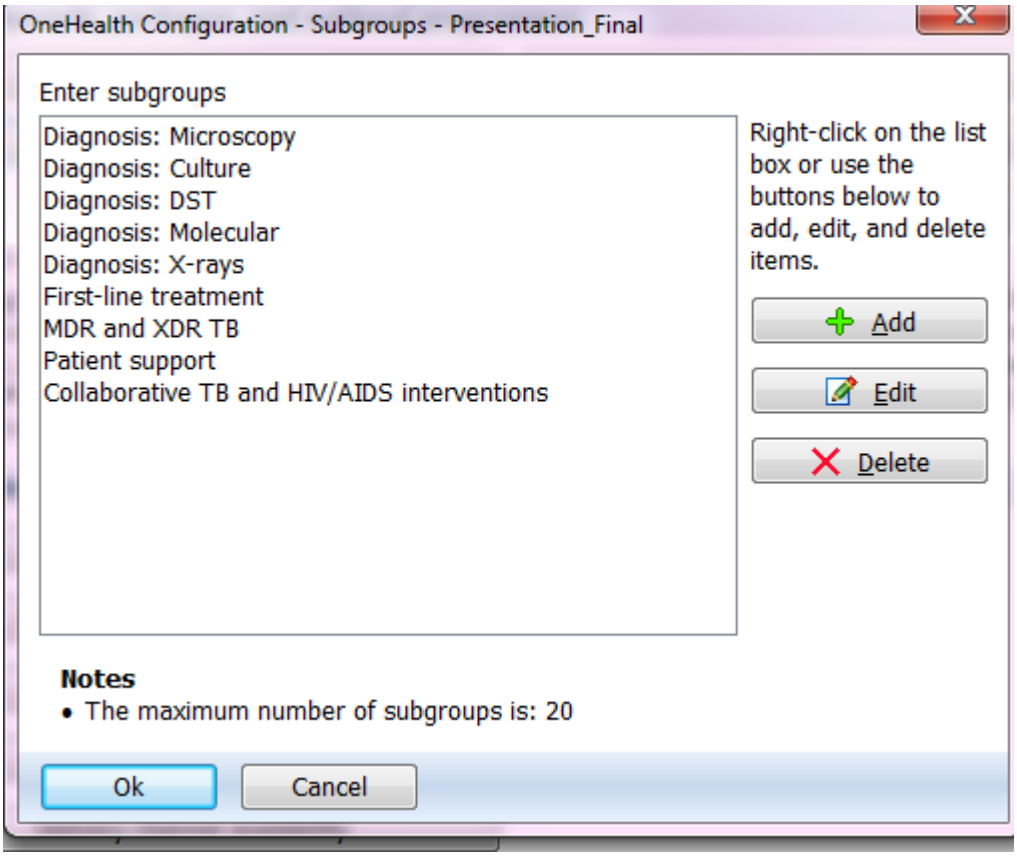


FIGURE 5: INTERVENTIONS AND DELIVERY CHANNEL SPECIFIC PACKAGES

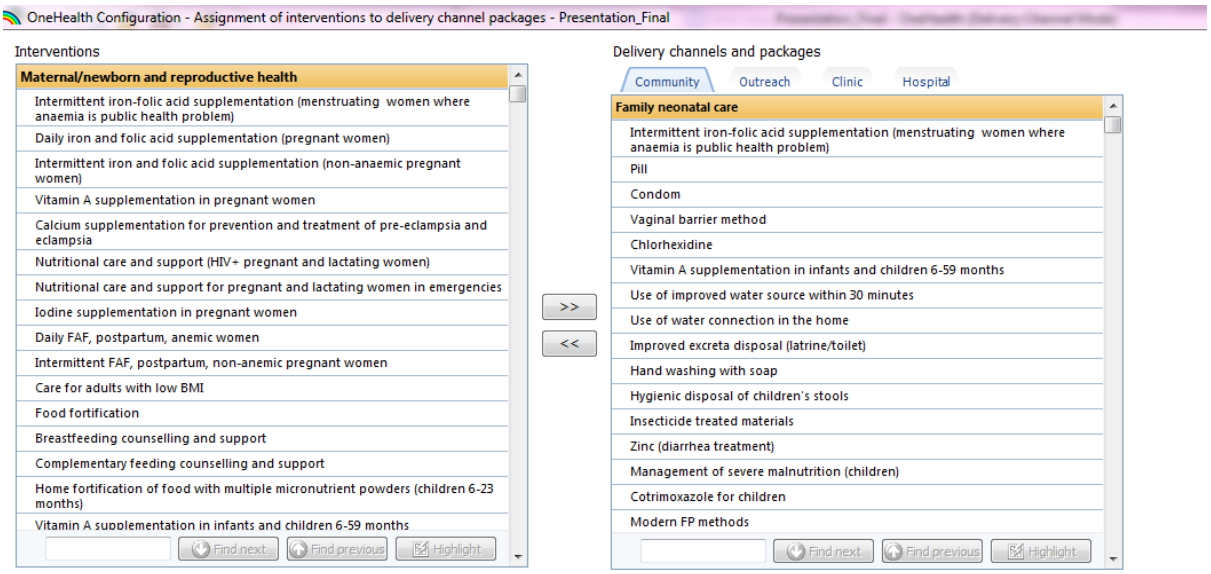


FIGURE 6: OHT DRUG AND SUPPLY LIST

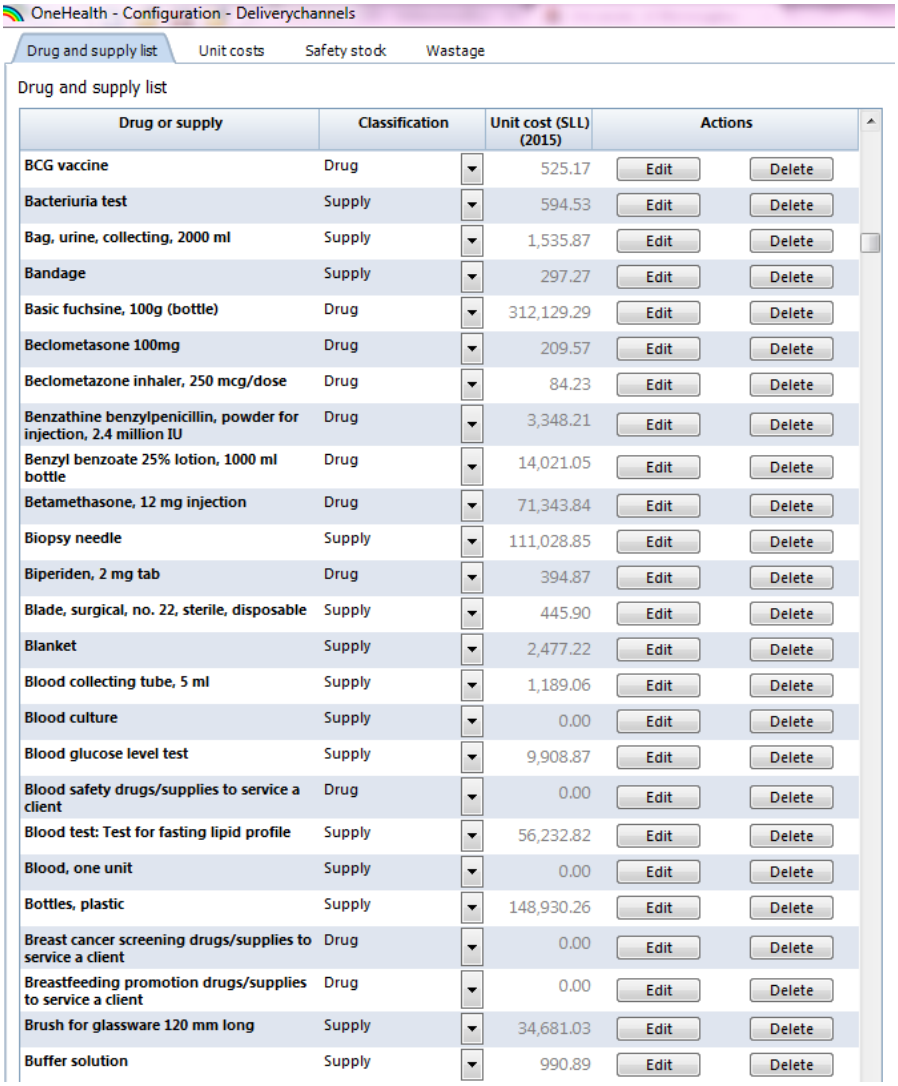
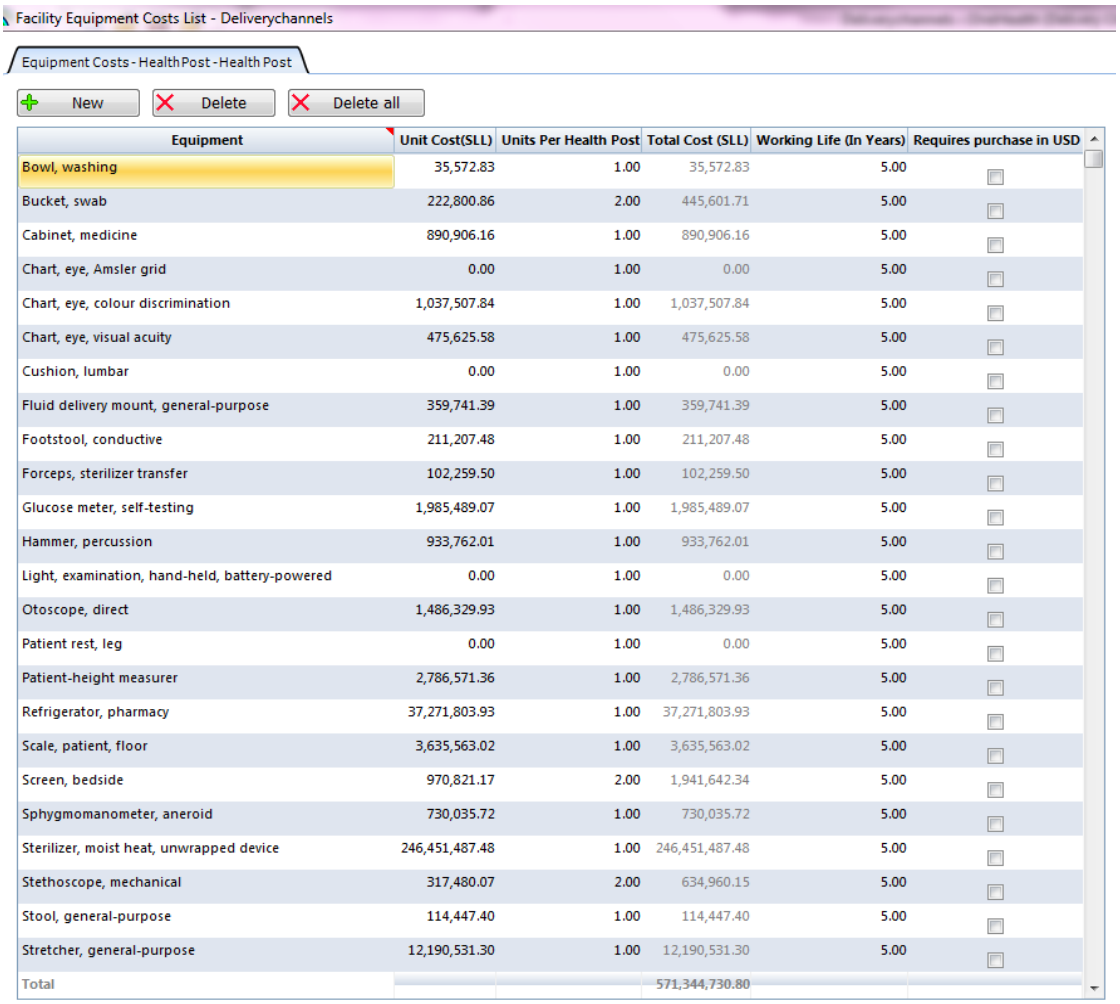
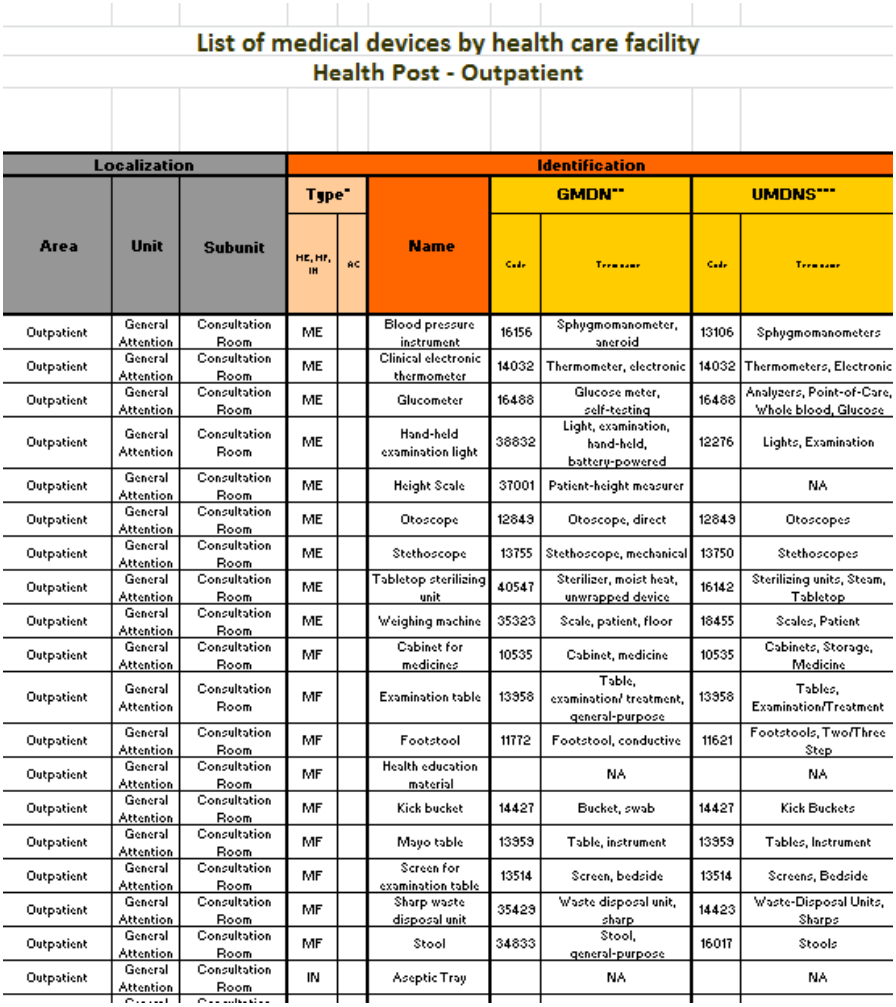


FIGURE 7: OHT HEALTH CARE FACILITY SPECIFIC LIST



Equipment	Unit Cost(SLL)	Units Per Health Post	Total Cost (SLL)	Working Life (In Years)	Requires purchase in USD
Bowl, washing	35,572.83	1.00	35,572.83	5.00	
Bucket, swab	222,800.86	2.00	445,601.71	5.00	
Cabinet, medicine	890,906.16	1.00	890,906.16	5.00	
Chart, eye, Amsler grid	0.00	1.00	0.00	5.00	
Chart, eye, colour discrimination	1,037,507.84	1.00	1,037,507.84	5.00	
Chart, eye, visual acuity	475,625.58	1.00	475,625.58	5.00	
Cushion, lumbar	0.00	1.00	0.00	5.00	
Fluid delivery mount, general-purpose	359,741.39	1.00	359,741.39	5.00	
Footstool, conductive	211,207.48	1.00	211,207.48	5.00	
Forceps, sterilizer transfer	102,259.50	1.00	102,259.50	5.00	
Glucose meter, self-testing	1,985,489.07	1.00	1,985,489.07	5.00	
Hammer, percussion	933,762.01	1.00	933,762.01	5.00	
Light, examination, hand-held, battery-powered	0.00	1.00	0.00	5.00	
Otoscope, direct	1,486,329.93	1.00	1,486,329.93	5.00	
Patient rest, leg	0.00	1.00	0.00	5.00	
Patient-height measurer	2,786,571.36	1.00	2,786,571.36	5.00	
Refrigerator, pharmacy	37,271,803.93	1.00	37,271,803.93	5.00	
Scale, patient, floor	3,635,563.02	1.00	3,635,563.02	5.00	
Screen, bedside	970,821.17	2.00	1,941,642.34	5.00	
Sphygmomanometer, aneroid	730,035.72	1.00	730,035.72	5.00	
Sterilizer, moist heat, unwrapped device	246,451,487.48	1.00	246,451,487.48	5.00	
Stethoscope, mechanical	317,480.07	2.00	634,960.15	5.00	
Stool, general-purpose	114,447.40	1.00	114,447.40	5.00	
Stretcher, general-purpose	12,190,531.30	1.00	12,190,531.30	5.00	
Total			571,344,730.80		

FIGURE 8: WHO MEDICAL DEVICES LISTS BY HEALTH CARE FACILITY



List of medical devices by health care facility

Health Post - Outpatient

Localization			Identification						
			Type*			GMDN**		UMDNS***	
Area	Unit	Subunit	HE, HF, IH	AC	Name	Code	Term name	Code	Term name
Outpatient	General Attention	Consultation Room	ME		Blood pressure instrument	16156	Sphygmomanometer, aneroid	13106	Sphygmomanometers
Outpatient	General Attention	Consultation Room	ME		Clinical electronic thermometer	14032	Thermometer, electronic	14032	Thermometers, Electronic
Outpatient	General Attention	Consultation Room	ME		Glucometer	16488	Glucose meter, self-testing	16488	Analyzers, Point-of-Care, Whole blood, Glucose
Outpatient	General Attention	Consultation Room	ME		Hand-held examination light	38832	Light, examination, hand-held, battery-powered	12276	Lights, Examination
Outpatient	General Attention	Consultation Room	ME		Height Scale	37001	Patient-height measurer		NA
Outpatient	General Attention	Consultation Room	ME		Otoscope	12849	Otoscope, direct	12849	Otoscopes
Outpatient	General Attention	Consultation Room	ME		Stethoscope	13755	Stethoscope, mechanical	13750	Stethoscopes
Outpatient	General Attention	Consultation Room	ME		Tabletop sterilizing unit	40547	Sterilizer, moist heat, unwrapped device	16142	Sterilizing units, Steam, Tabletop
Outpatient	General Attention	Consultation Room	ME		Weighing machine	35323	Scale, patient, floor	18455	Scales, Patient
Outpatient	General Attention	Consultation Room	MF		Cabinet for medicines	10535	Cabinet, medicine	10535	Cabinets, Storage, Medicine
Outpatient	General Attention	Consultation Room	MF		Examination table	13958	Table, examination/ treatment, general-purpose	13958	Tables, Examination/Treatment
Outpatient	General Attention	Consultation Room	MF		Footstool	11772	Footstool, conductive	11621	Footstools, Two/Three Step
Outpatient	General Attention	Consultation Room	MF		Health education material		NA		NA
Outpatient	General Attention	Consultation Room	MF		Kick bucket	14427	Bucket, swab	14427	Kick Buckets
Outpatient	General Attention	Consultation Room	MF		Mayo table	13959	Table, instrument	13959	Tables, Instrument
Outpatient	General Attention	Consultation Room	MF		Screen for examination table	13514	Screen, bedside	13514	Screens, Bedside
Outpatient	General Attention	Consultation Room	MF		Sharp waste disposal unit	35429	Waste disposal unit, sharp	14423	Waste-Disposal Units, Sharps
Outpatient	General Attention	Consultation Room	MF		Stool	34833	Stool, general-purpose	16017	Stools
Outpatient	General Attention	Consultation Room	IN		Aseptic Tray		NA		NA

FIGURE 9: DELIVERY CHANNELS AND HEALTH SYSTEM INFORMATION, INCLUDING FACILITY CONSTRUCTION, REHABILITATION AND OPERATING COSTS

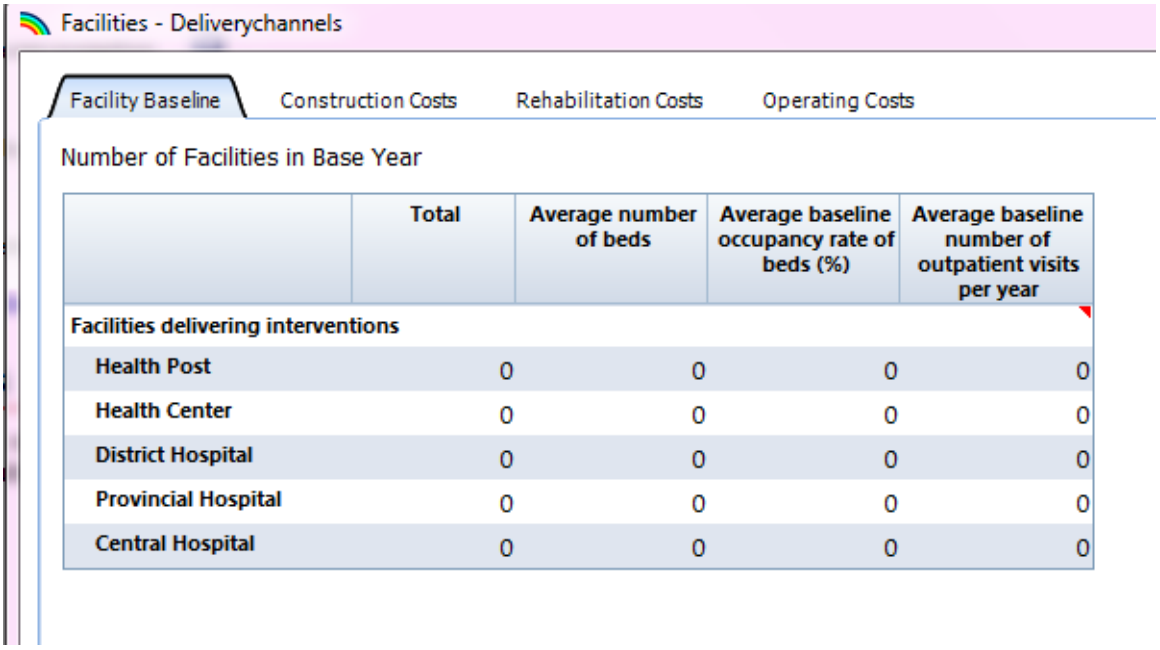


FIGURE 10: REHABILITATION AND MAINTENANCE

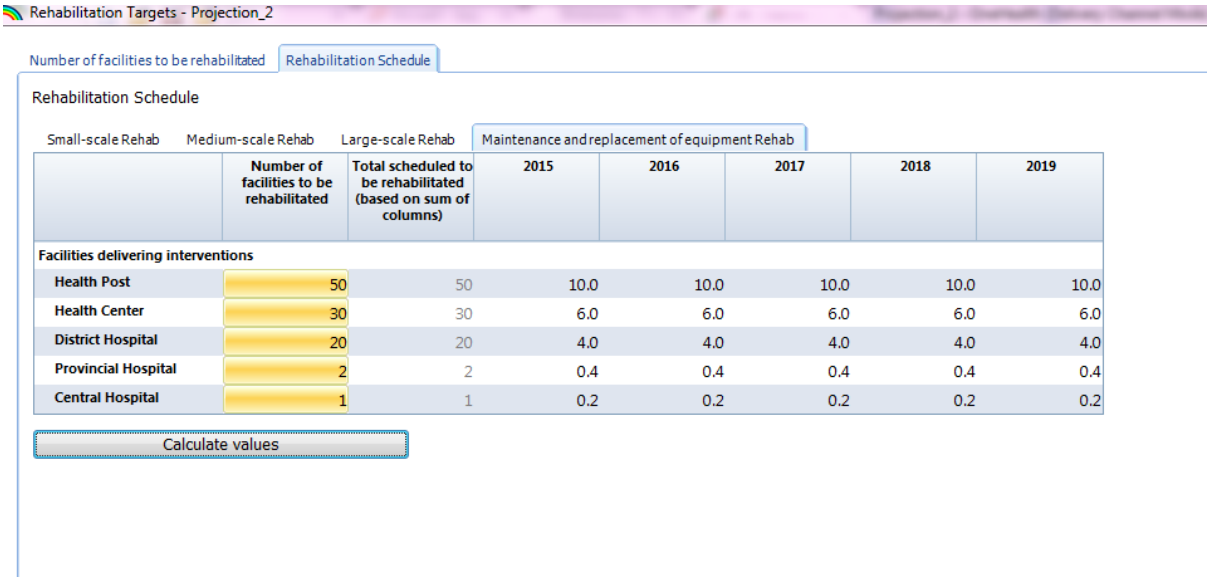
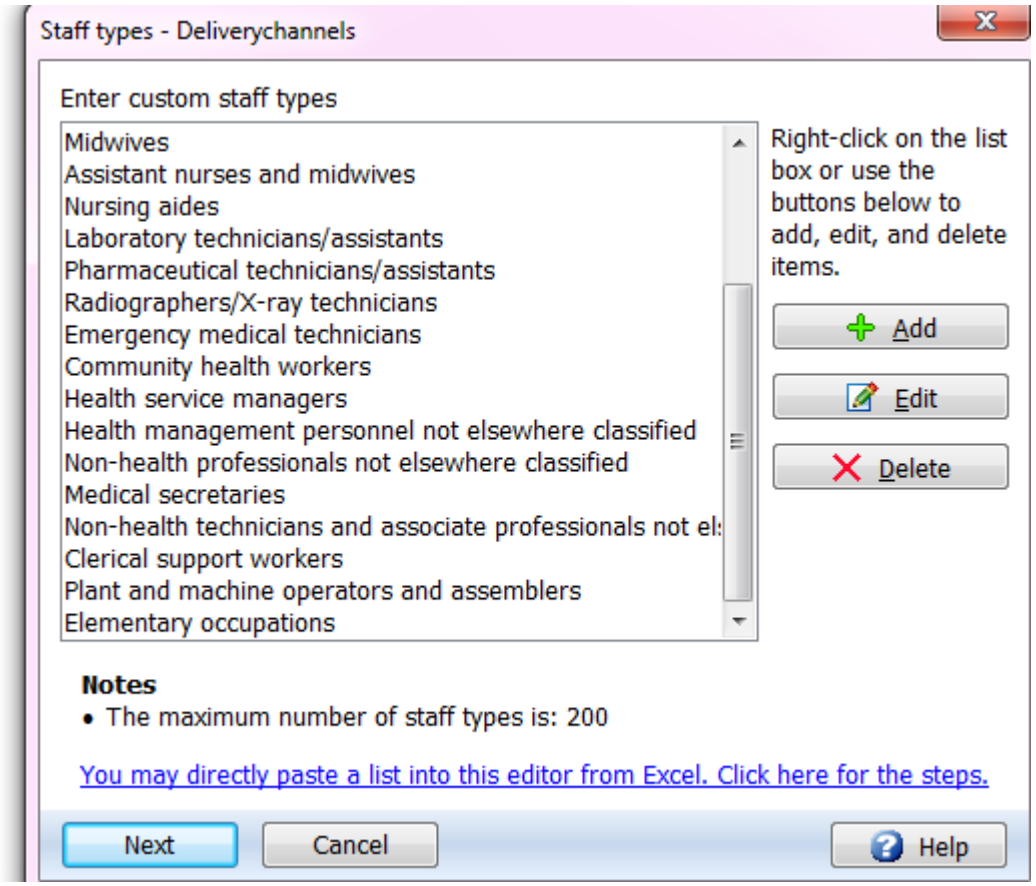


FIGURE 11: HUMAN RESOURCES INCLUDED



DISCUSSION AND CONCLUDING REMARKS

This thesis explored medical device and equipment (MDE) procurement in low and middle-income countries (LMICs), specifically procurement planning methods and processes. The thesis assumes that given improved methods and processes, difficulties in the uptake and use of MDEs in LMICs may be pre-empted. Four original research studies were undertaken and key findings are outlined further below.

Research presented here should be interpreted with due caution. Study limitations are summarized in detail in individual chapters; however, two crosscutting limitations are noteworthy. First, this thesis has focused exclusively on MDE procurement in the public health care sector of LMICs. A considerable volume of health service delivery in LMICs falls on the private sector and MDE procurement may occur substantially differently therein.(1) Second, research presented here did not explore the role of regulatory, financing or tendering system differences on MDE procurement. (E.g. see (2,3)) Studies presented here were not designed to explore such issues, although the relevance of these factors in procurement and procurement planning is noted across chapters.

The MDE procurement landscape: From the normative to empirical

Chapter 1: Systematic literature review on MDE procurement methods

A systematic review of the literature on LMIC-specific MDE procurement methods is presented; 250 individual documents were appraised. Documents were identified following a thorough search of both bibliographic and grey literature and application of strict inclusion and exclusion criteria. Materials included research articles, procurement reports, recommendation documents as well as guidelines or checklists. Across documents, a

diverse set of recommendations on how MDE procurement should be undertaken emerges; recommendations and notes on best practice were synthesised using both narrative synthesis and qualitative meta-summary.

> *Key Finding 1: The literature suggests two main methods are used (either solely or in combination) for product selection; stakeholders are either guided by past procurement experience or focus on identifying products to address a high priority condition.*

Experience based-methods imply the review and/or evaluation of historical procurement trends and updating procurement practices as needed on a case-by-case basis. The opinions and personal experiences of stakeholders, of both the procurement process and products selected, form the foundation of this method. (E.g. see (4,5)) Needs-based methods in contrast rely on stakeholders first identifying a health area of need and then products necessary for service provision in this area. (E.g. see (6)) Methods are likely to be combined in practice.

> *Key finding 2: MDE cost and technical specifications/alignment to ambient conditions are the primary factors influencing product selection. Evidence sources such as health needs assessments are also relevant, however, health technology assessment is mentioned in few documents.*

The systematic review also explored what factors, issues or evidence sources were noted as relevant to procurement planning. Authors noted that cost is the most significant factor affecting MDE selection: high product costs are prohibitive for resource constrained settings and decision-makers therefore procure cost-minimizing technologies. Authors of reviewed documents emphasise, however, that decision-makers may neglect to consider

the full life-cycle cost products are likely to incur; costs for user training, maintenance and servicing are frequently not considered. Where such costs have not been accounted for during product selection, devices are likely to remain unused during deployment.

Use of relevant evidence may improve procurement planning; the systematic review therefore documented the types of evidence sources decision-makers may turn to when selecting MDEs. Notably, the review suggests health needs assessments play a major part in procurement planning. In contrast, health technology assessment (HTA) reports/health economic (HE) evaluations are referenced in a minority of cases, suggesting the relevance and potential of such methods is not widely realized across stakeholders.

> *Key Finding 3: The literature suggests MDE procurement is a complex process where stakeholders acting at different health system levels undertake different actions.*

Authors of reviewed documents emphasize that a multitude of stakeholders are engaged in MDE procurement. Macro-level stakeholders for example may set the overall direction or scope for MDE related resource allocation; meso-level agents (e.g. regional planners) may instead be responsible for the tendering and distribution of products. End-users – that is clinicians and patients – are mainly consulted on issues of clinical need and product experience. The involvement of multiple stakeholders and tendering at meso-level by planning decision-makers, rather than clinicians, creates a user-buyer divide. This divide leaves room for discoordination when stakeholders do not realize effective and efficient communication channels between decision-making levels.

Chapter 2: A qualitative study exploring MDE procurement in contrasting settings

Informed by the preliminary findings of the systematic review, a qualitative study into the procurement processes of two contrasting LMICs – The Gambia and Romania – was planned and carried out. The aim of this study was to explore the empirical aspects of MDE procurement planning and decision-making.

> *Key Finding 4: Fieldwork findings largely corroborate conclusions drawn from the literature review: procurement is a complex, multi-level, multi-stakeholder process driven by stakeholder experiences. Limited evidence is considered during product selection.*

The study found that across both the Gambia and Romania, MDE procurement is driven largely by the clinical and management experience of physicians and health facility managers or policy-makers. In line with systematic review findings, different stakeholders are involved with managing MDE procurement. Health facility managers and clinicians were able to influence the procurement of devices that fall below a specific cost-threshold (e.g. 30,000 EURO in Romania) at institutional level. National level stakeholders were instead responsible for the selection, purchase and distribution of high-cost technologies across national health facilities.

> *Key Finding 5: Decision-making dynamics are strongly influenced by culture and considerations of power and prestige. These dynamics are substantiated by stakeholders equating MDEs to objects of symbolic relevance.*

Study participants across both settings recognized MDEs as indispensable elements of service delivery and prized technologies as symbolic forms of capital. The relevance of MDEs results from participants conceptualizing the possession of technologies as proxies

for institutional prestige or quality of care. Facilities with more up to date and varied MDEs are able to attract further funding both via reimbursement mechanisms, as well as directly via patient fees. Given this symbolic relevance attributed to MDEs, procurement decision-making does not take the form of rational resource allocation, but ad-hoc and prestige driven processes. Cultural and socio-political elements, such as health facility's managers need to rigidly control asset purchases and the struggle for health facility survival in an underfunded health system, additionally influence stakeholder interactions and dynamics.

> *Key Finding 6: The uncoordinated and socially constructed procurement environment is susceptible to manipulation; experts note the presence of corrupt and collusive practices across LMICs generally.*

Given the multitude of incentives and factors influencing MDE procurement – as well as lack of an evidence-based and transparent MDE selection and resource allocation framework - corrupt and collusive practices take hold. International experts with cross-national experience iterate the presence of such issues across LMICs more generally. Experts therefore suggest that attempts to improve MDE procurement must include careful stakeholder management, including technical capacity creation, and perception negotiation to be successful.

> *Key Finding 7: Changes in procurement systems can only be brought about by careful country-specific and sensitive implementation: this requires suitable professionals foremost. Frameworks, methods and tools to improve processes exist, the human resources to implement them in LMICs do not.*

The fieldwork in both countries uncovered similarities across low- and middle-income settings. The main point of comparison is the dearth of biomedical engineering and/or health technology assessment professionals able to advise on MDE procurement issues. Knowledge of international procurement guidance was additionally poor across both settings. Notably, however, study findings suggest MDE procurement challenges are substantially different across low- versus middle-income settings: The Gambia is struggling with procurement and management of minor low-cost technologies (e.g. glucometers), whereas Romanian stakeholders mainly focus on the procurement of medium- and high-cost technologies (e.g. ultrasound and CT scanning machines). International expert opinions complement the in-country fieldwork and suggest MDE procurement differences between low- and middle-income countries exist. Experts advise that contextually relevant interventions must be designed to improve resource allocation processes. Investments into the human resource capacity of countries are at the forefront of improving MDE procurement. In this case, both countries would benefit from the availability of technical experts in biomedical engineering and health technology assessment to advise on technical design and value-for-money of alternative devices.

Improving MDE procurement: the role of health technology assessment, health economics and planning tools

Both of the above studies tangentially touched on the role of HTA methods and HE for MDE procurement selection. The studies highlight that HTA and HE are not frequently considered in product selection. In contrast, feasibility criteria, i.e. as relating to product technical specifications or design characteristics that would ensure favourable deployment in LMICs, are cited as the main issues considered in product selection.

The qualitative study suggests that social dynamics, cultural and political factors also play a substantial part in procurement by shaping the decision-making landscape. Stakeholders across both the Gambia and Romania, and across LMICs generally in the opinion of experts, have limited to no knowledge of HTA/HE methods for product selection. The 2015 WHO Global Survey on HTA similarly suggests cost-effectiveness of alternative products is rarely considered in HTA exercises and MDE investment decisions more generally. (7) This may be due to the low availability of analysts to help implement such methods. (ibid)

Chapter 3: Exploring the feasibility of using HTA and generalized cost-effectiveness analysis for informing MDE procurement

Chapter 3 explored the feasibility and relevance of HE/HTA for MDE procurement using a case study economic evaluation on orthopaedic interventions for femur fracture fixation. The methods and challenges for undertaking HE/HTA have been recently discussed in more detail elsewhere(7–9)however, to the author's (KD) knowledge, this is the first study to reflect on MDE related HE/HTA for procurement decision-making in particular.

The chapter critically reflects on the use of generalized cost-effectiveness analysis – GCEA (10,11), while also making reference to the traditionally popular incremental cost-effectiveness analysis - ICEA used in the UK, Canada and Australia (12–14) and endorsed by the Bill and Melinda Gates Foundation. (15)

> *Key Finding 8: Undertaking MDE specific evaluations using GCEA is a very labour intensive and complex process challenged by lack of appropriate data and insufficient guidance. Alternative methods, including heuristics or multi-criteria decision analysis may be more suitable for evaluating MDEs and/or narrowing down where HE evaluations (using GCEA/ICEA) are needed.*

The case study compared the use of several MDE intensive interventions for femur fracture fixation in Sub-Saharan Africa: surgical interventions (including internal and external surgical fixation with plates, intramedullary nails and external fixators) were compared to standard care (traction) and a no-treatment scenario. The lack of suitable and high-quality comparative effectiveness data and contextually relevant cost-data was extremely challenging. While such issues equally impinge on the use of GCEA and ICEA, GCEA is particularly vulnerable to such issues due to two reasons. First, GCEA implies a higher workload: compared to a traditional comparison of two interventions and associated evidence appraisal/retrieval and HE modelling, GCEA involved the comparison of six alternative scenarios for the case study presented here. Second, GCEA requires the construction of a no-treatment comparator scenario – i.e. a null scenario. Limited guidance is available on how such a scenario should be constructed in the absence of data: information on natural disease progression without any intervention is rarely available. While GCEA appears promising for the comparison of vertical programs and multiple macro-interventions therein (e.g. see (16)), it appears un-manageable and largely un-

suitable for MDE evaluation when used for intra-sectoral purposes. Heuristics(17), multi-criteria decision analysis or program budgeting marginal analysis (18–20), may instead prove more favourable for implementation as they consider multiple issues (e.g. demand and supply constraints (9)) and can narrow down which technologies should undergo HE evaluations.

Chapter 4: MDE procurement planning using the One Health Tool

Despite the difficulties documented above, MDE investment decisions must be reached in practice. To prevent MDEs falling into disuse, it is therefore crucial to ensure all product purchases are appropriate costed.

Chapter 4 summarizes a critical appraisal of the One Health Tool (OHT) for MDE related investment planning, management and costing. Use of OHT is promising as it is able to capture both health and budget impact information and evaluate investments associated to different health service expansion plans. The tool is relatively easy to use, however proves too rigid to assist in sensitive and context-specific MDE procurement planning. For example, OHT is currently unable to link individual interventions to MDEs required to carry out services and additionally includes simplistic technology management assumptions (e.g. a uniform 5-year life span of all MDEs).

> *Key Finding 9: Regardless of planning tools used to inform/reach MDE investment decisions, information relating to shared/dedicated resource use, user training, maintenance and servicing capacity, safety stock and wastage must be captured. For information to be meaningful and easily accessible, MDEs should be linked to interventions where necessary and presented in a centralized database/list.*

Issues with the tool can be traced back to inappropriate input materials. Device lists input into OHT do not link individual products to interventions but to health service level or health facility type. The tool therefore assumes users have considerable and detailed knowledge of linkages between individual devices, interventions and health facilities. Planning is additionally complicated by lack of information of which devices fall into different product categories: e.g. facility furniture and common necessities (e.g. delivery beds and stethoscopes), clinical area specific technologies (e.g. dental equipment), or intervention critical products (e.g. colonoscopes for colonoscopies). Such information would for example allow users to determine what MDEs constitute a dedicated or shared resource across clinical areas: e.g. an ultrasound machine can be shared by the internal medicine and paediatric department. Recommendations for restructuring available medical device lists to take into account such considerations are set out.

Overarching conclusions

Two issues not directly addressed by this thesis are of additional relevance to LMIC decision- and policy-makers.

Human resources for MDE management

Studies presented here suggest MDE procurement in LMICs is conducted in the absence of trained technical experts with relevant knowledge of biomedical engineering and HTA.

The systematic review presented in Chapter 1, highlighted that MDE costs and technical specifications are the primary factors considered during product selection. Similarly, findings in Chapter 3 emphasize that it is necessary to apply health economic methods pragmatically in LMICs, e.g. by restricting evaluation of MDEs to products which can be feasibly introduced, adopted, used and maintained in LMICs. Findings in Chapter 4 corroborate the above findings and suggest that both biomedical engineers and HTA professionals have important roles to play in health system planning. While HTA professionals and biomedical engineers could separately advise on issues of value for money and maintenance/product selection and procurement technical specification, coordination of advisory efforts is still needed to ensure optimal MDE selection. In practice, professionals should therefore combine skills from these two domains; analysts/engineers/professional units trained in multi-disciplinary methods could thus help bridge the user-buyer divide experienced by clinicians and resource allocation planners. Sound training in biomedical engineering, including contact with clinicians would ensure clinical and patient care perspectives are considered. Similarly, training in HTA and HE methods will ensure biomedical engineering professionals are not solely influenced by

'impressive, high-tech' specifications and instead seek to ensure products present value for money and are used towards achieving overall health maximization.

The above conclusions are also substantiated by findings of the qualitative study conducted in The Gambia and Romania. Findings here highlighted the low availability of engineers and also their restricted role in decision-making. In The Gambia, only one biomedical engineer was present in the public health care system; however, their role was confined to training technicians for product maintenance and offering ad-hoc advice on high cost MDE procurement. Similarly, a biomedical engineer in a non-governmental Gambian organization and expert biomedical engineer emphasize that the role of engineers is not acknowledged as relevant within health systems; the biomedical engineer appears to be equated to a technician rather than a trained professional of engineering and management.

Similarly, health technology assessment professionals were largely absent across both settings and few participants recognized the role/importance of such professionals for procurement. Committees made up of ministry of health officials, public health professionals, economists and service coordinators met in both settings to evaluate service packages or programmes to offer to populations. Participants did not mention the use of MDE-related HTA evidence - including review of technical specifications and cost-effectiveness – for decision-making.

Both biomedical engineers and HTA analysts are therefore largely absent across The Gambia and Romania. Interviewed participants emphasized however that such professionals would play a great role in resource allocation planning and MDE management, should they be available.

Two recent surveys into biomedical engineering and HTA capacity in LMICs also suggest such professionals come in low supply and are not used to full potential.(7,21) The 2015 WHO Biomedical Engineering survey highlights the relatively low availability of engineers per 10,000 people in low-income settings compared to middle and high-income countries. (Table 1) In contrast to biomedical engineering expertise, health technology assessment professionals and units are better represented across LMICs, although the recent WHO survey into global HTA capacity notes that the lack of qualified human resources is the main barrier to the use of such methods. (7) Survey findings suggest two out of three countries use some form of HTA for decision-making. (ibid) The survey findings emphasize however, that HTA processes are largely focused on issues of safety and clinical effectiveness rather than value for money or budgetary impact. Following HTA recommendations is not mandatory for decision-makers and survey findings emphasize that little consideration is given to issues of ethics, equity and (health service delivery) feasibility. (ibid)

Recommendations distilled from the global literature on MDE procurement and best practices therein additionally emphasize the key role of biomedical engineers and health economists in MDE procurement. (3,22–24)Engineers are crucial to MDE procurement and management as they identify products with LMIC appropriate technical specifications and assist in their overall management, including user training, maintenance and decommissioning. (ibid) In turn, health economists are needed to ensure the full budget impact of MDEs is recognized before procurement is initiated; value for money should be considered at this stage of the procurement cycle. In contrast to the focus of country level HTA initiatives, international efforts such as WHO-CHOICE (11)and Disease Control Priorities (25) focus on the value for money of different services and interventions;

difficulties in service implementation due to feasibility issues and necessary product procurement/infrastructure upgrades are frequently acknowledged as limitations in such studies.

Leveraging the knowledge base around MDE procurement resources

To improve the current procurement and use of MDEs in LMICs, and ultimately health service delivery, it is necessary to promote the uptake and development of available tools, methods and guidelines. Relevant instruments to assist MDE procurement decision-makers in LMICs exist but stakeholders are not sufficiently aware of them. The lack of awareness may be due to tool specificity (e.g. different tools focus on different clinical areas – e.g. (26,27)), lack of transparency (e.g. detail on how 'core' or 'essential' lists were developed(4)) or due to tool complexity (e.g. One Health tool).

This thesis identified several instruments that LMIC stakeholders may use when facing issues of MDE selection and procurement. Core equipment lists(4,28), guides on the set-up of specific service areas including MDE selection recommendations(26) as well as checklists for guiding MDE procurement stakeholders(29) exist. However, materials are specific to diverse health care areas and rarely acknowledge that procurement officials in LMICs are non-experts that procure across specialties.

In the absence of technical experts, MDE procurement is frequently relegated to pharmacists or clinicians with little experience in MDE management and associated challenges. Pharmacists and clinicians are often not experienced enough (or too focused on their own clinical area) to select products with LMIC appropriate technical specifications, and estimate the necessary user training or servicing requirements of products. The primary reason for MDEs falling into disuse is that their technical specifications are not

appropriate for LMICs. (Chapter 1) Products selected are often not robust enough to withstand high temperatures, arid environments, or require a stable electricity supply or clean water for functioning. Replacement of spare parts and maintenance is quasi impossible due to underdeveloped supply chains and low availability of technicians. Absent or lacking user training and high product utilization rates further complicate this issue.

This inexperience, coupled with the strong influence of industry in LMICs and lack of formal mandatory HTA systems, encourages corrupt and collusive procurement decision-making practices.(30) International experts interviewed for the study in Chapter 2 suggest that collusive/corrupt practices occur primarily when decision-makers restrict procurement to one specific company/manufacturer.

To discourage this, and provide all procurement stakeholders with a baseline level of expertise needed to develop a product profile for contextually specific procurement, this thesis provides pragmatic recommendations and syntheses of decision-relevant information. These recommendations are a reflection of recent rigorous research, relevant specifically to stakeholders and decision-makers in LMICs; however, implementation of any recommendations/use of suggestions made here should be conceptualized and implemented in a fair, publicly defensible and legitimate manner. (31) In particular, decision-makers should be aware of the "Accountability for Reasonableness" framework developed by Daniels and Sabin when designing/developing an MDE procurement/resource allocation system. (ibid)

Daniels and Sabin insist that resource allocation of public funds should be a legitimate, transparent and public process, open to participation of all relevant stakeholders.

Professionals at all health system levels should therefore be made aware of national/regional MDE management processes and feel empowered to feed into these. Processes should be transparent, draw upon publicly defensible resource allocation criteria and be conducted in the interest of the public good (32); criteria for MDE selection and resource allocation should be grounded in up to date, contextually appropriate, evidence.

The MDE resource allocation system should be responsive to change and accountable to all: a fair and publicly accessible system for enabling and resolving appeals must therefore also exist. The system should further encourage the voicing of diverging opinions and create pathways for logging appeals; the process for considering and resolving appeals must also be clearly set out. All of the above steps must be cemented in regulation: national health policies and health laws can firmly define the MDE procurement decision space and ensure only relevant 'rules' feed into this particular resource allocation 'game'. (See Chapter 2) Failing to abide by legally binding processes, or failure to transparently disclose decision-making practices/amend decisions as relevant upon receipt of new evidence could therefore be challenged.

The next sections briefly detail resources decision-makers in LMICs may find useful in MDE resource allocation.

Chapter 1 lists design characteristics specific to MDEs intended for deployment in LMICs. The WHO and other international agencies have initiated similar efforts to support MDE procurement, albeit this has been trialled for emergency response situations – e.g. see personal protective equipment specifications for use during the recent Ebola Virus outbreak(33). UNICEF, USAID Grand Challenges and MSF similarly support the use and

development of generic product profiles to advise non-expert procurement stakeholders. (34)

Guidance for non-expert procurement stakeholders has also been developed – Chapter 1 acts as a resource repository for this. The WHO Global Forums on Medical Devices(1,35) additionally provide the opportunity for LMIC stakeholders to exchange ideas on best practices and common pitfalls encountered in MDE management.

Chapters 3 and 4 additionally provide comments on two further resources available to LMIC stakeholders for assisting in MDE product selection, more specifically GCEA and the One Health Tool (OHT) for health system planning. While GCEA sets out guidance for conducting cost-effectiveness analyses,(11) it is a complex and data-intensive method requiring substantial expert input for model design. Methodological guidance fails to advise analysts on consideration of MDE associated deployment challenges documented here. Best selection practices identified in Chapter 1 may assist analysts in narrowing down which MDEs are suitable for deployment and therefore health economic appraisal. It is impractical to conduct cost-effectiveness analyses of all MDEs that can be potentially procured(8,17); it may instead be advisable to use pragmatic decision-making frameworks. (17)

VALUE AND LIMITATIONS

Findings documented contribute original insights towards research carried out in several domains.

- *Health technology assessment:* Several international initiatives exist to improve resource allocation in LMICs. (e.g. see (25,36) and the International Decision Support Initiative initiated by NICE International) Notably this includes not only the development and promotion of GCEA and ICEA methods in resource constrained settings but also guidance on the implementation of HTA via national agencies and comments on the successful integration of such efforts into overall decision and policy-making. (30,37)Findings noted here emphasize that MDE specific HTA should consider both feasibility criteria (e.g. LMIC appropriate product design and technical specifications) and value for money. Contextually appropriate HTA exercises are needed for informing MDE procurement to capture all relevant stakeholders and influence underlying stakeholder interactions/dynamics.

- *Decision-making in LMIC health systems:* Recent research into decision-making in LMICs emphasized the relevance of equity and feasibility criteria alongside normative (cost-effectiveness) criteria.(38–40) Conclusions of both the systematic review and qualitative study support such findings and offer further insight into the various factors of relevance in MDE procurement. In particular, the qualitative study in The Gambia and Romania suggests that MDEs are viewed not as simple 'instruments' by which to achieve improved population health, but as forms of

symbolic capital. Additionally, findings of the systematic review and qualitative study highlight that LMIC stakeholders assign limited relevance to, or are only limitedly aware of, normative criteria for decision-making.

- *Biomedical engineering*: Traditionally, biomedical engineering research activity has focused on product testing and design/technical specification or issues of regulation. Translation of such research/expertise into practice – in particular in the area of MDE procurement – has led to the development of Core Medical Device Lists(4), the Compendium for Innovative Technologies (41)and the creation of MDE procurement advisory agencies. The latter include for example CENETEC in Mexico, charities such as HUMATEM and private enterprises such as Fisthail Consulting (UK). Knowledge exchange mechanisms such as the WHO Global Forum on Medical Devices have also recently shot to the fore.(1) Research presented here highlights, however, the low availability and perceived relevance of biomedical engineers in MDE procurement across LMICs. The availability of engineers is likely to impact not only on procurement and resource allocation, but also on day-to-day functioning of health systems: in the absence of publicly employed engineers to assist in preventive and corrective MDE maintenance, health systems must rely on scarce commercially available maintenance services. Research presented here further suggests LMICs have limited knowledge of the various resources and tools available to them for procurement decision-making. To improve MDE procurement, biomedical engineers should engage more closely with clinicians and health technology assessment experts/health economic analysts. The success of MDE procurement in LMICs – that is the rational and pragmatic use of

scarce health resources – hinges on selecting the most appropriate, acceptable, affordable, available and cost-effective product available.

This thesis acted as a hypothesis generating exercise meant to identify issues, stakeholders, dynamics and methods of relevance in MDE procurement. Nine key findings, spanning the four presented studies, are available and will be communicated to researchers and decision-makers with an interest in MDE procurement via peer-reviewed publications and conference participation.

Research presented here also serves to identify areas where further inquiries are needed. Two areas are particularly noteworthy:

1. Research into MDE management frameworks and the role of specialised human resources therein. Differences between private and public MDE management frameworks should be investigated, and where necessary used to revise current practices in either sector. For example, the study presented in Appendix 1 highlights the efficiency of MDE maintenance in the private sector of India; decision-makers across Indian provinces are currently considering outsourcing MDE maintenance to private rather than publicly funded contractors. (42) Similarly, the role of health economists or biomedical engineers in MDE management could be investigated via global surveys.
2. Research into the links between MDE management and population health outcomes. Links between the various MDE management frameworks and population health outcomes should also be probed: findings here suggest that countries where biomedical engineers and health economists are empowered to inform resource allocation, will have better population health outcomes. It is critical that research into MDE management is conducted to determine what

constitutes successful vs. wasteful management – the link of this to population health outcomes may be explored further via systems dynamics modelling.

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TABLE 1: RESULTS OF THE WHO GLOBAL BIOMEDICAL ENGINEERING SURVEY 2010-2015

Country Income grouping	Summary of Number of biomedical engineers per ten thousand		
	Mean	Standard Deviation	Frequency
High-income	0.66782712	1.0871152	40
Low-income	0.00943365	0.02199022	17
Lower-middle income	0.12689962	0.26591026	34
Upper-middle income	0.18624437	0.3249349	33
Total	0.30108152	0.69903259	124

*Table as presented by WHO.

APPENDICES

APPENDIX 1: MAINTENANCE OF MEDICAL DEVICES IN THE HEALTH SECTOR OF INDIA: AN EXPLORATORY QUALITATIVE STUDY

By Vatsal Gupta – Intercalating BMedSci Student

University of Birmingham

This paper is submitted in the style of the World Health Organization Bulletin Research Journal. Guidelines for writers are attached as an appendix. The word limit for this piece of work was 3,000. The journal requires two short paragraphs to be included at the start of the paper to identify what was already known about the research topic and what this study adds to it. Please note that the exact location of our study has not been mentioned, as it could facilitate identification of participants and thus breach confidentiality.

Maintenance of Medical Devices in the Health Sector of India: An Exploratory Qualitative study

Keywords: Maintenance, Medical Device/s, Qualitative, Exploratory, Health-Sector, India

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Disclaimer: The contents of this article are the author's sole responsibility. All views expressed in the article are the author's and not an official position of the institution. Any inquiries related to the article's content should be directed to the author.

Conflicts of Interest: The author declares that they have no competing interests

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Word Count: *Abstract:* 250 *Study:* 2,993

Number of tables and figures: 9 figures, 3 tables, 2 case-studies (included at the end of the study)

Outlook:

Existing literature has identified over 50% of medical devices to be in a broken-down state in lower and middle-income countries (L/MICs). Some of these studies have cited poor maintenance provision to be one of the causes for this break-down. Moreover, a forthcoming systematic review carried out by our research team, identified maintenance of devices to be greatly neglected in LMICs. However, thus far no study has been conducted to specifically investigate issues of device maintenance in these countries. It is important to study this as many of these countries; particularly MICs such as India, are set for exponential growth of their device market due to forthcoming planned investments.

We then conducted the first study to specifically explore issues affecting medical device maintenance in a MIC setting. The setting of our research was the Northwest province of India, chosen for its diversity in urbanized and semi-urbanized cities. We also as a secondary aim, compared maintenance between the public and private healthcare sectors in this province.

Abstract

Objectives:

Maintenance of medical-devices is of importance in optimizing-utility, encouraging cost-efficiency and enhancing quality-of-care. Existing literature reported device maintenance to be neglected and understudied in low/middle-income countries (L/MIC). This warrants exploration as these countries have recently experienced a rise in demand for devices. India is a MIC with a device market set to undergo substantive growth within a range of private and public hospitals. We explored issues regarding maintenance of medical-devices in the North-West province of India, and the secondary-aim was to compare maintenance between the public and private healthcare sectors.

Methods:

This qualitative study used semi-structured interviews with 31 health-care practitioners, administrators and directors from different institution sizes, in both private/public sectors. Purposive sampling using a snowball approach was used to select the participants. Interviews were audio-recorded and conducted using a validated topic-guide. Thematic framework analysis employing an inductive and grounded approach was used for data analysis.

Findings:

We identified three themes that have a compounding-effect in causing delayed maintenance, (i) absence of Biomedical engineers (BE), (ii) Poor user-responsibility/accountability for devices, procedural-delay in fault-reporting, (iii) Discrepancy in after-sales maintenance by companies. Quality of maintenance was found to be poorer in the public-sector, due to greater prevalence of these issues. We also found that, despite awareness of these problems being existent amongst decision-makers, there was a lack-of-willingness to act, demonstrating neglect of device maintenance, particularly in the public-sector.

Conclusions:

Increased delegation of responsibility within the maintenance-process and regulation of company service is recommended. Employment of Biomedical-Engineers is imperative.

Introduction

Medical devices are equipment that facilitate diagnosis/prevention/treatment of disease and other conditions[1]. Historically, medical devices have been under-recognized and only recently been acknowledged by the World Health Organization, to be integral parts of health service provision, carrying substantial national-level budgetary expenditure implications [2-4].

Maintenance of medical devices is of paramount importance in optimizing utility, encouraging cost-efficiency and enhancing quality of patient care[5]. Moreover, it has implications for patient/user safety and satisfaction[5, 6].

An effective maintenance programme comprises of inspection and preventive maintenance (IPM) to reduce failure-rates, and corrective maintenance (CM) to return broken-down devices to functioning states[5, 6].

In a higher-income country setting, maintenance of devices is carried out as part of set policies/guidelines, with due regulation[5, 7]. This ensures standardized and effective service provision for all patients alike. However, an extensive systematic literature review by our team (unpublished) has highlighted that, device maintenance is largely neglected and a gap in knowledge exists regarding device maintenance in low/middle-income countries (L/MIC) [8]. Previous studies have also reported, that on-average 50% of devices remain out-of-use in LICs, referencing poor maintenance as part of the reasoning[9-13]. However, no studies have yet been conducted on medical device maintenance in MICs. It is important to study this as many of these countries have recently experienced a significant rise in demand for medical devices, due to rising populations and increased awareness of benefits of healthcare delivery[14, 15].

Therefore, the primary aim of our study was to then to explore issues regarding maintenance of medical devices in the healthcare sector of a MIC, India. A secondary aim was to compare maintenance between the public and private healthcare sectors.

India is a MIC, with the second largest population in the world[16]. It has a rapidly expanding health care sector comprised of a public and affluent private-sector[17]. Indian medical devices market was worth US$3.6 billion in 2010, and is set for substantial

growth to reach US$6.4 billion (compound annual growth rate 15.5%) by 2014, due to forthcoming planned investment[14, 15].

As of yet, no research has been conducted on the effectiveness/perceptions/efficacy of device maintenance in India and warrants exploration due to its implications on cost, maximizing-utility and quality of care. Lessons may be important to other MICs.

Method:

[Written in accordance with the criteria for reporting qualitative research (COREQ)] [18]

A qualitative study was undertaken in the Northwest province of India[19, 21]. This province was chosen for its large-size and diversity of urbanized and semi-urbanized cities.

Study Design

Due to limited previous literature, and in order to investigate the range of issues, a qualitative study-design was chosen. Semi-structured interviews were undertaken with health care practitioners/administrators/directors, across a range of hospitals that differed in size in both public/private-sectors. Interviews were used as the primary method of data collection as we explored experiences/perceptions of medical device maintenance. Focus groups, although initially planned, were not undertaken, due to identification of sensitive issues concerning budgeting and management of hospitals during preliminary discussions with potential interviewees. A 'grounded-theory' framework was used to orientate the study.

Participant and Institution Selection

Eligibility for the institute and participants is illustrated in table 1.

Purposive sampling using a snowball approach was used, to study variety of opinion amongst specific participants and opportunistic sampling to achieve diversity. Recruitment and approach of participants followed a two-pronged strategy, firstly through collaborators and secondly through a field approach, see figure 1. Choice of institutions was based on maximizing representation of a range of levels of care, size and funding of institution. Table 2 illustrates characteristics and provides justification for chosen limits of institutions.

Setting

Interviews were predominantly conducted at hospitals and a few in the participant's homes. To ensure confidentiality, all interviews were conducted in the absence of non-participants.

Data Collection

All interviews (average duration of 45 minutes) were audio-recorded, and were conducted using a topic guide to maximize consistency. This topic guide was previously validated in Gambian and Romanian studies (personal communication with Karin Diaconu) and pilot-tested upon arrival in India. Interviews were conducted until data saturation was reached.

Analysis

VG conducted all interviews and subsequent transcription. A thematic framework, using Nvivo software was used to analyze data, taking an inductive approach (illustrated by figure 2)[21-23]. Firstly, data-immersion was undertaken. Subsequently, a thematic-framework was identified in which texts describing similar views of participants were highlighted (open coding) [24,25,26]. Codes were then categorized to create meaningful clusters[27]. Subsequently, data were indexed, to find links amongst categories/sub-categories of codes (axial coding). Deviant cases were identified and analyzed for correlations and contradictions. Subcategories were then linked to core-categories to identify themes (selective coding). Data were finally charted and mapped, during which themes were analyzed to generate theory[28]. One researcher completed coding. Coding was initially completed sector-wise i.e. public/private-sector and was triangulated with the research-team.

Ethics

The BMedSc Population Sciences and Humanities Internal Ethics Review Committee granted ethical-approval. For India, an independent ethical committee provided a declaration stating institutional consents to be sufficient. Consequentially, participants were only selected from consenting institutions (1 institution refused). Free and informed consent was obtained from all study participants. Confidentiality was ensured through assignment of unique participant numbers.

Results

Altogether, 31 participants were interviewed. Participant demographics are detailed in table 3. One individual refused to participate, due to fear of confidentiality-breach. All participants were working in the public or private-sector or sometimes both.

In India, we found maintenance to be contracted to the manufacturing company, negotiated at time of device purchase. This can be either a Comprehensive maintenance contract (CMC), which includes servicing and replacement of spares/consumable parts

or Annual Maintenance Contract (AMC) that only includes servicing. The path for device maintenance is illustrated, as found to be described, in figure 3.

We identified that participants across both sectors repeatedly referenced delay in medical-device maintenance. They attached importance to this topic, as delayed maintenance provision would result in equipment down-time, thus impairing service provision. Upon further exploration, several themes relating to this topic emerged and are presented below. Figures 4-6 illustrate the broad categories involved in development of these themes.

Lack of Specialists – Biomedical-Engineers

Majority of participants mentioned a lack of biomedical engineers (BE) to be a fundamental cause for maintenance delay, particularly at the point of initial device breakdown. Participants identified that in BE absence, there was no system of in-house repair. Therefore, any fault with a device, minor or major, had to be reported to manufacturing companies, which are based in other states within the country. Consequentially, even for minor repairs, there was significant delay in sending company engineers and thus device maintenance.

"... it's a big problem because sometimes there are very small problems with equipment and we have to wait for company person to come ... which could be easily solved by a biomedical engineer"

(Principal, Government Hospital)

With regards to public-vs-private-sector comparison, deficiency of BE was reported to be equally prevalent in both sectors. There was however, some reporting of occasional technician employment in both sectors. These technicians though were stated to be under-qualified, lacking in training and were incorrectly identified to be similar to BE, by some participants. We, interpreted this to be evidence for a lack of awareness of the exact role of BE and their possible undervalued nature. Further validating this interpretation was the finding that, few participants referenced wider BE role in cost-saving/device selection/user-training with majority only seemingly aware of their role in maintenance delay.

"You don't have people with professional-degrees rather more of handymen" (Director, Corporate Hospital)

"We call biomedical-engineers, local-repairers. Sometimes, they are available, but they are not experts." (Clinician, Government Hospital)

We identified that it was particularly decision-makers (superintendents/principals/directors) across both sectors that repeatedly referenced BE absence and its impact, demonstrating awareness at the highest administrative level. The fact that BE are still not employed, highlights a possible lack-of-availability of BE in India.

Lack of responsibility/ Procedural-Delay

Another identified source of delay was at the stage of fault-identification. Majority of participants mentioned a lack-of-circumscribed responsibility/accountability for devices to cause delay in reporting of faults and therefore delay in initiation of the maintenance-process, thus prolonging device-downtime. Participants also stated that poor delegation of accountability resulted in improper use of devices and so contributed to increased failure rates.

" Users have to be made accountable for equipment in the Government-sector" (Director, Corporate Hospital)

The procedure of fault-reporting was another frequently referenced root of delay. Participants reported this procedure to be unnecessarily lengthy due to inclusion of a needless amount of personnel in fault-report validation. Consequently, this led to delay in notifying companies of faults and thus prolonged device downtime. We interpreted this to be a recurrence of the aforementioned sub-theme of 'lack-of-responsibility', where failure to delegate direct power/accountability for maintenance of a device, resulted in undue delay.

With regards to public/private-sector comparison, majority of participants referenced these issues of lack-of-responsibility and procedural delay to be exclusive to the public-sector. Participants explicated that due to direct fear of incurring losses, individuals in

the private-sector were made/felt directly responsible for devices, which cultivated into increased urgency for fault-identification and reporting as well as pressurising of companies to provide prompt service.

"In government, fault-reporting is so lengthy, a small screw will take 1 / 2 months to be fixed... Which is not the case in private-sector. Reason is whatever time device is not working; It is direct loss to him. ... ...Nobody is in a hurry in government" (Clinician, Small Private)

We identified referencing of 'procedural delay' to be predominantly by decision-makers (superintendents/directors/principals), leading us to deduce that awareness of this problem exists at the highest-level. We interpreted, that the fact that they continue to persist with this process demonstrates poor prioritization of maintenance. Further validating our argument is that clinicians working for both private and government sectors still persevere with delay issues in public institutions whilst being aware of better practice in their private practice.

"In private, action is taken immediately"

"In the Government, person taking care of the instrument, should have power to contact companies directly. Process should be shortcut"

(Clinician, Working in both Government & Private Hospitals)

Poor company response

Majority of participants also referenced discrepancy in company response to be a source of delay.

With regards to comparison between private and public-sector, majority of participants reported company response to be poor for the public-sector and excellent for the private. Reasons stated for this discrepancy were that of delayed payments in the public-sector and brand loyalty in the private. Participants reported, that as a consequence of procedural delay, payments to companies by the public-sector were often delayed and at times unpaid, whilst in the private, payments were always prompt.

Majority of participants also highlighted the importance of brand loyalty in the private-sector. They explained how private hospitals preferred to house devices from the same brand in return for lucrative discounts from companies and prompt maintenance. Brand loyalty was stated to be impossible in the public-sector due to adherence to a set procedure of procurement, the tender-system.

We then interpreted delayed payments and lack of brand loyalty to be negative motivators for companies, in providing prompt service to public hospitals. This, then cascades into delayed maintenance and increased device downtime in the public-sector.

"An important thing in Government sector is that, most of times older dues are not paid to companies… so the company refuses repair" (Director, Corporate Hospital)

"Even multinational-companies are not responding to our calls whilst to private-sector they are quicker as they think they could get more market from them." (Superintendent, Government Hospital)

Consequences of Delay

Some participants highlighted key impacts of delayed maintenance specific to the public-sector. They revealed that due to delayed maintenance, a growing trend in public hospitals was to simply procure new devices and condemn (dispose) repairable ones, thus causing significant wastage of good resources.

A minority of participants also talked about how delay in maintenance was creating a rich-poor divide as lower-socioeconomic groups, who are predominantly dependent on public hospitals and cannot afford private treatment, receive delayed healthcare due to increased device downtime in public hospitals.

"sometimes in the Government, rather than going for maintenance, we go for purchase of a new machine …"

(Clinician, Government Hospital)

"lower socioeconomic groups, can only come to the government sector so if devices are not working, the patient suffers "

(Clinician, Government Hospital)

Discussion

This was the first study undertaken to evaluate issues affecting medical device maintenance in MICs. Our study is novel in two aspects. Firstly, we identified sub-optimal maintenance issues, specific to a MIC setting. This is important, as the majority of existing literature have focused on reasons for prolonged device breakdown in LICs. (e.g. Mullally, S., & Frize, M. (2008). Survey of clinical engineering effectiveness in developing world hospitals: equipment resources, procurement and donations. Conference Proceedings : ... Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Conference, 2008, 4499–502. http://doi.org/10.1109/IEMBS.2008.4650212;) Secondly, we identified reasons for a clear divide in quality of maintenance between sectors, with maintenance being substantially poorer in the public than private-sector.

India's Northwest province was chosen due to its diverse health care sector and participants from different institution sizes, in both private/public-sectors were interviewed. From the results, we identified three main themes that elucidate why medical device maintenance procedures in India are sub-optimal (figure 7). Absence of Biomedical engineers (BE) resulted in outsourcing of maintenance to companies situated in distant locations and limited avenues for in-house repair. Poor delegation of responsibility/accountability and procedural-delay were identified to hinder fault-identification and fault-reporting. Prompt after-sales maintenance service by companies was found to be dependent on brand-loyalty and timely payments, which cannot be assured at all times. These themes were found to have a compounding effect in causing delay and thus prolonged device-downtime. Figure 8 and case studies 1,2 illustrate how these themes impact different stages of the maintenance-process.

Regarding the secondary aim, themes of lack of responsibility/accountability and procedural delay were found to be exclusive to the public-sector; furthermore, this sector received poor company service due to aforementioned reasons. In contrast, the private sector enjoys prompt service in return for brand-loyalty with clinicians showing urgency for maintenance, due to delegated accountability and direct motivation by profits (figure 9).

Unavailability of BE and its impact was a theme observed to be consistent with previous studies conducted in LICs [13,30]. These studies also reported findings on limited employment of under-qualified technicians, which was also a finding in our study[11, 30].

BE, in addition to fault-repair, have a wider role in hospital device-management encompassing user-training, preventative-maintenance and device-selection[5, 31,32]. However, we found awareness of these additional roles to be significantly lacking, with BE often being identified only for their role in fault-repair and sometimes being misclassified as local repairmen, demonstrating their undervalued nature. World Health Organization. (2010). Medical devices: Managing the Mismatch (An outcome of the Priority Medical Devices project).

We found, that despite awareness of the impact of lack of responsibility/ accountability at the highest administrative level, there was a lack of willingness/ability to change the process. This demonstrates poor prioritization of device maintenance, a theme consistent with a forthcoming systematic review, which reported neglect of maintenance by decision-makers in LICs [8]. Moreover, as procurement of devices in LMICs is centralized, funding is assured only for the actual purchase and not for follow-up service of devices, further evidencing neglect[8].

It was difficult to identify what avenues for preventive maintenance (PM) exist in the public-sector as company service is poor and BE are absent. This could then contribute to greater frequency of failure rates and create divide between sectors regarding functioning devices. This is consistent with previous LIC studies that reported poor adherence to PM schedules[11, 13,30,33]. This area warrants further research.

Delayed maintenance procedures within public-sector have wide-ranging consequences. First, purchase of new equipment is preferred to the corrective maintenance of already available devices. This translates to lost resources.

Second, service provision is impaired. This impacts principally upon low-socioeconomic groups who make up 46.7% of the population[34].

Principally, we recommend employment of BE for both sectors. In addition to reducing delay in device repairs, their role in user-training, preventative-maintenance and device-selection are fundamental aspects of device management. However, there are few BE available for employment in India due to lack of training institutions, as only few B-tech biomedical programs in private/semi-private exist, which calls for development of quality courses[35]. Moreover, 65% of devices, in India are imported[36] and thus local BE face a substantial knowledge-gap, a barrier consistent with a previous LIC study[37]. (I

know this detail is true .e the 65% of devices are imported and biomedical program are good but cannot find a good reference for this)

Secondly, we recommend user-training (clinician/nurses/orderlies) as part of device deployment. For example, Medicines and Healthcare products Regulatory agency (MHRA) advises users to take an active role in fault-checking, cleaning and fault-reporting of devices[5, 6]. Adoption of such processes would boost user responsibility/accountability for devices, particularly in the public-sector.

Thirdly, we propose that India could develop its own regulatory boards/systems with regards to devices. These may operate similarly to the MHRA in the UK, and function to limit discrepancy of service provision and ensure observance of AMC/CMC by companies[5, 6]. This recommendation is however difficult to achieve as Department of Health is reported to have nominal jurisdiction over medical devices, due to their neglected nature[35]. Furthermore, the vast and diverse nature of India's healthcare system presents a substantial challenge on influence of such an agency at a national level. (same here)

The study had a large sample-size allowing saturation of findings and rich high-quality data to be collected. Purposive sampling with a snowball approach helped us to include a range of participants. Approach to analysis was inductive and through a thematic framework, allowing flexibility in consideration of themes.

Limitations were that there was no researcher triangulation in data-collection, which could enhance researcher bias. This was limited by maintaining a reflexivity-journal and frequent debriefing after interviews. Regarding lack of method triangulation, although focus-groups were planned, they were not appropriate for sensitivity reasons and could have affected validity. Although collaborators were initially sourced through researcher links (possible selection-bias), final recruitment was after extensive linking.

Conclusion

From the results, we identified problems to be embedded at each stage of the maintenance process of devices, primarily in the public sector, causing major delay. We found that, despite awareness of these problems being existent amongst decision-makers, there was a lack-of-willingness to act, demonstrating neglect of device maintenance, particularly in the public-sector. We then recommend, delegation of responsibility within the maintenance process and increased regulation of company service provision. However, imperatively we recommend that BE be employed in both sectors. Future research should focus on quantifying this delay in maintenance and investigating other MIC for similar findings.

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Tables

TABLE 1: ELIGIBILITY CRITERIA

Inclusion criteria:	**Exclusion criteria:**
Participant should have a relevant profession in the health care setting related to device management, maintenance or purchase or prioritization of purchase. This includes health care practitioners, policy makers, administrators, managers or other occupations dealing with maintenance of medical devices (e.g. consultants)	Individual does not provide informed consent or is unwilling to take part

TABLE 2: CHOICE OF INSTITUTIONS AND CHOSEN LIMITS (WITH JUSTIFICATIONS)

Institution characteristic	**Limits**	**Justification**
Level of care	Primary/Secondary/Tertiary Predominantly Secondary	• Secondary-care hospitals have more devices than primary facilities • Secondary-care hospitals are not final referral centers, which may benefit from special resource-allocations conditions in the public sector
Size	Maximum: 600 beds Minimum: 10 beds	• Limits chosen to ensure comparability to similar research being conducted in Gambia and Romania (ongoing) • Hospitals >1000 beds will have specialist equipment needs due to diverse population treated
Funding	Government Hospitals Private Corporate Hospitals Small Private Hospitals	• [redacted] fulfill secondary aim of comparing maintenance between private and government sector

TABLE 3: PARTICIPANT DEMOGRAPHICS

Participant characteristic	Number
Number of interviews	31
Gender	Males: 28 Females: 3
Type of Institution management	Government: 6 Corporate Private: 5 Small-Private: 7
Type of participants	Government Clinicians: 13 Government Superintendents: 3 Government Principals: 2 Corporate Clinicians: 8 Small Private Clinicians: 7 Corporate Directors: 7 Small-private hospital owners: 6 Chief Medical health officer: 1 Biomedical engineer: 1 Medical Device company owner: 1 Private & government experience combined: 5

Note: Some participants had dual roles: Example: some participants were clinicians as well as being directors of hospitals public/private sector

Figures available upon request.

Case study 1: Maintenance in the government sector

Scenario: Broken down Computed Tomography (CT) machine

Lack of Biomedical Engineers

- CT machine was out of order. As there were no Biomedical Engineers (BE) employed by the hospital, there was no one to identify the fault. It was also not clear whether the fault was minor or major, which could have been identified by the biomedical engineer with possible repair of minor fault. Hence the faults were reported to the manufacturing company. The company was based in another state and took time in sending its engineers, thus prolonging device downtime.

"No no biomedical engineers in our department definitely not in our institute" (Clinician, Government Hospital)

Lack of responsibility

- When Clinician no.1 identified that CT machine is not working, he/she did not take any action, as he/she was not accountable for that device. As a consequence the clinician thought that his/her colleague would report the fault. When their colleague comes across the fault, they too thought another colleague would report the fault. The action of fault reporting is delayed as there is no direct responsibility allocated by the hospital for devices This leads to delay in notifying companies and resolution of the fault.

" Definitely in government sector there is nobody directly responsible for particular instrument … we try take some personal responsibility … but responsibility is not properly allocated" (Clinician, Government Hospital)

"person isn't given power to call (the company) to ask them to come and check equipment … so again there is a long process … needs to be cut short." (Clinician, Government Hospital)

Procedural Delay

- Finally the fault was reported, however the fault report was passed between a number of individuals before sending to the company adding to the delay in reporting the fault. At times this report needs authorisation from upto 5-7 individuals before completing the whole cycle and coming back to the 1st person (superintendent) who finally notified the company. This whole process took 3 weeks. Meanwhile, the CT machine remained out of order and patients suffer diagnostic service.

… for everything for maintenance HOD has to write to superintendent then file will go to clerk. Clerk will find whether equipment is under CMC or not if it is they will pass it to accountant. Again, superintendent will OK it and give consent. Again it will come back to clerk, clerk will make the order it will then go to HOD and superintendent to sign and only then it will be issued. Such a long process

(Prinicipal, Government Hospital)

"In Government sector, once the breakdown occurs, then the head of the department writes to principal, then a complete report is made. Then that report is sent to the company, then company expects the advance of the payment to be made… Then the engineer comes, then he makes a report. Then that report goes to a committee. Then the committee decides that okay this has to be rectified and this much money has to be paid and again tenders are floated and the whole process takes many weeks to months"
(Director, Corporate Hospital)

Poor company response

- Finally the report reached the manufacturing company. The head of the company reviewed the report and pulled out the hospital file. He/she found that the hospital still had not paid for maintenance from the previous year. There was also no guarantee of future purchase as this is a government hospital and all purchase is followed through a procedure. The company refused to repair the device. The CT machine remained out of order.

"company people do not bother about government calls. They think that these are the hospitals where nobody is responsible … for private sector their response is quick"
(Superintendent, Government Hospital)

Wastage of Resources

- After 2 months the CT machine was still out of order. The hospital had no choice but to procure a new device even though the old machine was repairable. The old machine was moved into the stores for imminent disposal.

"And if they are not coming then we have to throw out the machine…" (Superintendent, Government Hospital)

Case study 2: Maintenance in the private sector

Scenario: Broken down X-ray machine

Lack of Biomedical Engineers

- X-ray machine was out of order. As there were no Biomedical Engineers (BE) employed by the hospital, there was no one to identify the fault. It was also not clear whether the fault was minor or major, which could have been identified by the biomedical engineer with possible repair of minor fault. Hence the faults were reported to the manufacturing company.

"See, there is a shortage. If you ask me, there is definitely a shortage." (Director, Corporate Hospital)

Individuals given direct responsibility

- The clinician responsible for the X-ray machine identified the fault. Afraid of losses due to device downtime, immediately, he/she reported the fault to the concerned personnel. The hospital had made the individual responsible/accountable for the device. There was no delay in fault identification and reporting at this level.

"…in the private sector, since it is my money or the boss' money, bosses are keen that it gets repaired" (Clinician, Government Hospital)

Excellent company response due to prompt payments and brand loyalty

- The company head received the report and drew the hospital file. He/she found payments to be prompt from the hospital and saw that the hospital houses most of its devices from his/her company. Motivated by the possibility of future purchases the head sent out an engineer immediately.

"I need to run my hospital… So I am ready to pay maintenance charges …

"we feel that it's better to keep all the monitors of the same brand, same ventilators of the same brand etc. so that we get good maintenance service and it helps in future negotiations" (Director, Corporate Hospital)

"But, the private one they approach quickly to the company. … In the private it takes very short course. Quick response" (Clinician, Government Hospital)

- The device was promptly repaired.

APPENDIX 2: ADOPTION OF SURGICAL INNOVATIONS IN LOW-INCOME COUNTRIES: A QUALITATIVE STUDY OF THE INTRAMEDULLARY NAIL AND INTERLOCKING SCREW SYSTEM IN TANZANIA

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Keywords: Innovation, Medical Devices, Deployment, Adoption, Low and middle income countries, Fracture care

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Abstract

Background: The need for innovative health technologies for low resource settings is well understood by policy makers and researchers. There are currently no guidelines to facilitate introduction of new technologies to low resource settings. A case study of the intramedullary nail and interlocking screw system (SIGN-nail), a device which allows internal fixation of fractures at a low cost without the need for image intensification, in Tanzania was used to explore barriers and facilitators for introduction of innovative technologies to low resource settings.

Methods: Sixteen qualitative semi-structured interviews were conducted in three of four national referral hospitals with orthopedic facilities in Tanzania. Orthopedic surgeons, theatre nurses, administrators and technology manufacturers were interviewed. Two institutions used the SIGN-nail and one did not. Interview transcripts were analyzed using conventional content analysis.

Findings: Collaboration between technology users and manufacturers are driving factors behind technology adoption. Existing demand for affordable and efficacious fracture care, the training program and reporting-feedback system used by SIGN manufacturers, ensured successful adoption and continued use of the device. Challenges in technology adoption resulted from lacking infrastructure and deficient skill mix among users, manufacturers not advertising products publicly, resistance to change by senior clinicians and issues in technology import due to customs delays.

Interpretation: Our findings suggest continued collaboration, communication and knowledge exchange/training between technology developers, users and policy makers are primary facilitators to technology adoption and continued use.

Funding: The University of Birmingham, Population Sciences and Humanities Bachelor of Medical Sciences program. This study received no funding form SIGN and is independent.

Introduction

In May 2015, delegates of the 68th World Health Assembly supported a resolution on the strengthening of basic and emergency surgical and anaesthetic services, including the promotion of increased access to safe, quality and cost-effective surgical care. Critical to this effort is the availability and accessibility of affordable, appropriate, high-quality medical technologies, including surgical devices and equipment.(1-3) However, many available technologies are geared towards use in high-income countries and prove expensive or unsuitable for low resource settings.(2-4) Uninterrupted electricity and clean water supply may be lacking, spare parts or consumables needed to keep devices operational may be unavailable or unaffordable, health care staff trained in the use of advanced technologies may be absent and the finances needed for device servicing unobtainable.(6-11) There is a need for innovative technologies that are affordable, address the above issues, and solve or compensate for problems with existing technologies.(5,8,9)

Before manufactures can meaningfully engage with the production of such innovative technologies, however, it is necessary to explore the processes and reasons behind technology adoption. In a qualitative study on the adoption of CT scanners in Brazil, Silva and Viana suggest that technology adoption decisions are driven by clinician demand or industry influence. Guidelines on “whether, when and how” health facilities should invest in new technologies are lacking; adoption decisions are thus guided by considerations of institutional prestige and the choice of a technologically advanced product. A study on the adoption of MRI scanners in the USA has noted similar findings.(10,11) In the case of surgical technologies, Wilson identified several drivers for technology adoption: patient demand for innovative interventions, low costs to surgeons applying the technology, aggressive product promotion by manufacturers and perceived benefits such as better post-operative outcomes. Importantly, Wilson notes that the evidence base for efficacy of the technology may be a secondary factor in adoption decisions.(6)

A systematic literature review of medical device and equipment procurement methods for LMICs by our team likewise indicates that technology acquisition decisions are often reached on an ad-hoc basis in the absence of agreed guidelines or health policies. (Unpublished - work in progress: Diaconu et al: "Methods for medical device and equipment procurement within low- and middle-income countries: Findings of a systematic literature review") Technical and economic criteria primarily influence

technology adoption choices. Decision makers prefer cost-saving technologies with specifications consistent with conditions encountered in deployment settings.

While the papers cited provide insights into technology adoption choices, they pertain largely to middle- or high-income economies or to procurement methods of any and all medical devices rather than innovations. That is, studies focus on the introduction of technologies, which have been used and potentially evaluated in higher income settings rather than de novo products/designs. Questions of innovative technology adoption - particularly of surgical innovations - in LICs thus remain unanswered.

To begin to address this gap in the literature, we have conducted a case study of the intramedullary nail and interlocking screw system (SIGN-nail),(12) and its introduction to public sector hospitals in Tanzania. The aim of this case study is explore the adoption of surgical innovations in LICs and formulate recommendations for the effective introduction of technologies to resource-poor settings. Our case study illustrates the institutional and governmental processes behind technology adoption choices; we also identify barriers/facilitators to the adoption and sustained use of the SIGN-nail in Tanzanian national referral hospitals.

Methods

Ethical approvals were granted by the University of Birmingham and Tanzanian National Institute of Medical Research. (Appendices 1-2)

This is a qualitative case study employing semi-structured interviews for data collection and a grounded theory approach for analysis.(13)

AG conducted the interviews under the supervision and guidance of all co-authors. KD, CC and SMH conducted routine remote supervision meetings via Skype to discuss project progress, potential issues in participant recruitment and data collection, including transcription, emerging themes and data saturation. IN and BH facilitated AG's contact with surgical staff in individual health care facilities and clarified any queries relating to data collection or the Tanzanian health care system.

Setting: Tanzania was selected due to widespread use of the SIGN–nail (Box 1) in the public health sector. Government run national referral hospitals were targeted and selected as they provide the majority of orthopaedic care in Tanzania. Referral hospitals are additionally responsible for treating the bulk of orthopaedic patients, thus proving generally comparable to the majority of public health care providers in LICs.(14) Of the four national referral hospitals in Tanzania, three make use of the SIGN-nail and one does not. Interviews were conducted in two hospitals that use the SIGN-nail and one hospital that does not; the latter served as a comparator for identifying factors that prevent the uptake of the technology. The SIGN manufacturers provided details of contacts in the hospitals that were able to facilitate data collection; all approached institutions were assured that the study is independent from the manufacturers.

Participants: AG interviewed sixteen health care professionals in three Tanzanian referral hospitals; no approached person declined participation. Participants were selected through purposive sampling for their involvement in the treatment/management of long bone fractures or the selection and introduction of new technologies in their institution. Orthopedic surgeons, general surgeons, theatre nurses and members of hospital management were targeted and identified through chain referral.

Data collection: All interviews in Tanzania were conducted in private, face-to-face, one-on-one, in the participant's workplace in English, using topic guides piloted in the UK and Tanzania. Participants had no prior knowledge or relationship with the interviewer. The interviewer clarified he had no relationship with the technology manufacturer. Two SIGN developers and manufacturers provided answers to interview questions via email.

The research team discussed data saturation during data collection and interviews continued until this was achieved. No repeat interviews were conducted. Interviews ranged between 15-45 minutes and were audio-recorded. AG, a third year medical student at the University of Birmingham, conducted, transcribed and analyzed all interviews. Participants were not shown transcripts for correction.

Prior to study commencement AG undertook a course in qualitative research methods; he received further training in qualitative research methods from SMH and KD, both supervisors having conducted previous qualitative studies in low- and middle-income countries.

Informed consent was obtained from all participants prior to interview. Participants were encouraged to share their views and experiences freely. Participants were asked open questions regarding the treatment of long bone fractures and the process for introducing new technologies in their institution, along with their attitude towards the intramedullary nail and interlocking screw system, the associated training program and reporting database for patient outcomes.

Data Analysis: Data were analyzed using conventional content analysis.(13) Transcripts were coded inductively using NVIVO 10 beta software and charted by code.(15) The coding rationale was discussed within the research team and with external researchers. Content analysis was used to index the text and identify emergent themes.(16) Conclusions drawn from the data were then discussed within the research team and with external researchers to minimize personal bias and reduce the risk of misinterpretation.

Findings

Table 1 describes Tanzanian participant characteristics. We also received written responses to interview questions from the technology manufacturers and present comments and findings of this in Box 2.

Following coding, we identify the following themes:

- Barriers and facilitators encountered in technology adoption;
- Motivating factors for technology adoption;
- Factors influencing continued technology use and/or supply.

Emergent themes and subthemes along with supporting quotes are presented in Table 2.1.

Barriers and facilitators encountered in technology adoption

While all health technologies must be approved by the Tanzania Food and Drug Authority (TFDA) prior to use,(17) participants reported that no formal system or process for technology adoption existed within individual health facilities. Hospital management and individual clinical departments were described as responsible for adoption decisions.

Participants within the hospitals using the SIGN technology noted that the primary facilitating factor for adoption was the recommendation of a 'trusted contact'. Surgeons with prior experience of the technology would visit Tanzanian health facilities and recommend the use of the SIGN-nail given infrastructural conditions encountered. Visiting surgeons from the US would also operate using the SIGN technology, thus demonstrating and promoting its use.

In hospitals not making use of the nail, the absence of such a recommendation was noted as the main barrier to adoption. Due to its particular business model, the SIGN nail is currently available only through direct contact with the manufacturers - lack of a trusted contact impedes this. Participants at this institution mentioned that their hospital would be willing to pay for the device if it were available on the market.

Participants in the hospitals using the SIGN-nail revealed a further barrier to technology adoption. Junior surgeons reflected that senior practitioners opposed the initial use of the technology; this resistance to new clinical practice was gradually overcome as the benefits of using the technology became apparent.

All participants mentioned the absence of suitable theatres for orthopedic surgery and lack of surgical equipment and trained clinical staff as a further barrier to adoption. However, participants in the institution that does not use the SIGN nail reported that suitable theatres, trained staff and necessary equipment are available; therefore, these do not pose a barrier here. The developers too noted lack of capacity in recipient hospitals as a barrier to rollout of the SIGN nail.

Motivating factors for technology adoption

Within the hospitals using the SIGN technology, participants mentioned three reasons for adoption. First, surgeons and managers reflected that using the SIGN-nail ensured cost-savings for the health facility. Participants mentioned that the shorter hospital stay, the reduced postoperative complications and availability of the device as a charitable donation greatly decreased the cost of fracture care to the hospital. This was noted as the main motivation for the adoption of the device in institutions.

Second, alongside technology adoption, facilities would benefit from a free but mandatory training program: this improved human resource skills and reduced hospital costs by increasing staff efficiency, reducing complication rates and hospital length of stay. Surgeons reflected that the practical training program, using live patients in particular, improved technique and enabled them to use the device independently (Table 2.1). Some surgeons accessed additional training at yearly conferences run by the technology developers in the USA. Attending surgeons later share learned techniques at home institutions. The technology manufacturers also regularly visit the institutions to monitor outcomes and provide further training when changes have been made to the device. However, theatre nurses recommended that the developers provide formal training for nurses to ensure proper technique in the preparation of the device. (Table 2.1).

Third, the SIGN reporting system enables surgeons to receive feedback on any conducted operations. Surgeons are required to upload individual case notes with patient X-rays, before and after each operation, onto an online database. The developers can

then offer feedback with a view to improve future patient outcomes. Once a threshold of 20 operations has been reported the developers automatically replenish the institutions stock of intramedullary nails.

Factors influencing continued technology use and/or supply

Participants mentioned three reasons for continuing to use the SIGN-nail after adoption. First, surgeons reported improved patient outcomes when using the SIGN-nail as compared to other treatments. Patients treated with the SIGN-nail stayed in hospital for shorter periods of time, recovered quicker and encountered a lower incidence of complications such as postoperative infection.

Second, surgeons and managers felt the communication with the manufacturer was productive and reciprocal as the developers repeatedly made changes to the device based on user feedback. Participants mentioned that this allowed them to take ownership of the product as well as making the device easier to use and better suited to the target setting and population. Third, users appreciated the manufacturer being a reliable supplier of the device; the predictable supply ensures that institutions are able to sustainably integrate the technology into the hospital model. However, hospital based participants and developers both reported shipment delays due Tanzanian customs procedures.

Participants also reflected on barriers to the continued use of the SIGN-nail. Surgeons cited two particular concerns related to surgery reporting mechanisms. Some surgeons were unable to report surgeries due to breakage of X-ray machines, rendering it impossible to upload pre and post-operative X-rays to the database. Other surgeons experienced difficulty in meeting the developer's minimum follow-up requirement of 20%. Many patients were lost to follow-up, as patients could not afford to return to the hospital for a follow-up appointment. Both of these posed a problem in replenishing stock of SIGN-nails: manufacturers send out new nail shipments only when follow-up requirements are met.

Senior surgeons and managers echoed these views and noted that at times it was difficult for their colleagues to report operations due to time and resource constraints. Each of the two hospitals using the SIGN-nail had a senior orthopedic surgeon who was responsible for uploading operation reports to the online database. These surgeons ensured that all SIGN-nail insertions were recorded. Developers similarly noted that reporting mechanisms impose a cost on hospitals, either in the form of X-rays or clinical time.

Discussion

This is one of the first studies to explore the adoption of an innovative surgical medical-device in a low-income country.

The SIGN intramedullary-nail is a technology targeted towards use in low-income countries, disseminated through an atypical business-model, which entails minimal health facility/patient costs, offers surgeons access to specialized training and imposes a patient monitoring/user-feedback mechanism. Participants in Tanzanian health-facilities consider the device a cheaper and more effective treatment alternative for long-bone fractures and initially adopted the technology based on favorable recommendations from trusted colleagues. Device dissemination thus hinges on "word of mouth" and the recommendation of current to potential users, and facilitation of contact between the latter and manufacturers. We identify the lack of trusted contacts to mediate between developers/potential users as the principal barrier in adoption.

Further barriers noted are lacking health facility infrastructure and/or inability of health facility staff to report patient outcomes to manufacturer standards. Similar to issues encountered in device donations, institutions should only select technologies for use if these can be supported by the necessary infrastructure and human resource skill mix available.(2,6,9,18) Albeit a complex device, the SIGN nail was successfully adopted in hospitals with available surgical theatres and trained staff. The ancillary training program offered by the manufacturers helped adoption and ensured an upgrade in human resource skill mix. The additional reporting mechanism guaranteed continuous communication between users and technology developers, thus closing any potential feedback loop relating to product design, efficacy or user concerns. This is in line with international recommendations for developers to conduct post marketing surveillance to ensure that the device is safe and efficacious for the length of its life cycle.(19)

The SIGN case and business-model illustrates how initial technology adoption choices are driven by peer-networks and demands for cheaper and more effective health interventions. This finding supports wider trends within the literature, which suggest users in low-resource settings prefer technologies and innovations that respond to clear demands for cheaper and more effective healthcare. (Unpublished - work in progress: Diaconu et al: "Methods for medical device and equipment procurement within low- and middle-income countries: Findings of a systematic literature review")

Continued technology use is driven by constant collaboration and communication between technology recipients/users and donors/manufacturers/developers. In order to increase access to such technologies and innovations in particular, developers/manufacturers should be accessible to potential clients and advertise their products widely. The WHO Compendium of Innovative Technologies is one potential avenue to achieve this.(2,6,19) Developers should also ensure that their business model is suited to the capabilities and needs of the recipient. In this case, the fact that the device was donated made it accessible to institutions and patients that would not be able to afford it otherwise. However, should such a device become more widely available, it may not be possible to offer all support structures included in the current business model against no cost. Support systems may then need to be costed out to continue their application, thus imposing a restraint on the device's on-going efficient use.

Our findings are limited in that the study was conducted in publicly funded health care facilities and using a medical device supplied through an atypical business-model; conclusions may therefore not reflect the views and experiences of charitable and private sector hospitals. The latter also provide a significant proportion of Tanzania's healthcare(14) and of that of LICs worldwide. Additionally, a great number of participants enjoy a close relationship with the manufacturers: it is possible participants may therefore feel less inclined to voice negative attitudes. The particular business model supporting SIGN nail provision may additionally unduly influence participants' views: devices are provided free of charge and participants may therefore hesitate to provide any negative views of the product. Additionally, the interviewer's views may also be colored by participants' reports of the product's benefits. The use of only one interviewer minimized the effects of interviewer bias. Many participants were not native English speakers, however, all participants were proficient in English and language did not become a barrier in conducting the interviews. Where issues in comprehension occurred, the interviewer asked the participant to clarify their response. It was ensured that the question was well understood before proceeding.

Conclusion

Collaboration between developers, recipient institutions and policy makers is essential in the successful introduction of innovative surgical technologies. Provision of training and continued technical support by developers is likely to promote the sustained and correct use of the new technology. Such provisions may however restrict or slow down dissemination due to incurred program costs. Further case studies on different devices and settings - particularly the private health care sector - are needed to inform potential recommendations in this area.

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Boxes

Box 1. The Intramedullary nail and interlocking screw system (SIGN nail)

The SIGN nail system is an orthopedic surgical implant developed by SIGN fracture care international. It is widely used in resource-limited settings and disaster zones in 53 countries. The device is used for the internal fixation of long bone fractures and does not require image intensification for its insertion. Currently, most institutions acquire it on a non-commercial charitable basis from the US based developer, SIGN fracture care international. Institutions and patients thus do not pay for the device itself, but may on occasion pay for customs charges incurred through technology import. The developer may cover these on a per-need basis. The device is associated with both an online database onto which users upload case reports and a user training program provided free of charge by SIGN surgeons. The prolonged relationship between donor and recipient, as well as the complexity of device use, make the SIGN nail a unique case study in the introduction of innovative health technologies.

Box 2. Developers' comments

Senior management at SIGN fracture care international mentioned that their business followed a charitable model, the motive of the organization being to widen access to fracture care in developing countries. The developers stated that they plan to continue charitable donations of SIGN nails and wish to roll out the product further.

Inefficiencies and lack of capacity in local institutions were noted as a barrier to the adoption of the device. In addition, developers noted that the rising cost of approval by regulatory bodies (e.g. the FDA) has been a severe limiting factor in the development and deployment of innovative devices.

Tables

Table 1. Tanzanian Participant Information (n=16)

Characteristic	Number of participants (n=16)
Gender	Male: 13
Position	Nurse: 4 Orthopedic surgeon: 5 Hospital director: 3 General surgeon: 2 Resident, trauma and orthopedics: 1 Hospital administrator (non-clinical): 1
Hospital use of SIGN nail	Yes: 12 No: 4

Table 2: Themes identified across interviews

Domain	Themes and definitions	Illustrative quotes
Barriers and facilitators encountered in technology adoption	Lacking adoption system = Lack of a formal system for the adoption of new technologies in institutions	"There is no formal system, just an in built culture" Orthopaedic surgeon "I think the decision makers in the hospital should depend on evidence on whatever technique they want to introduce." Hospital director
	Trusting and acting on peers opinions on technology = Presence of trusted contacts to broker interaction with the developers	"The SIGN system was brought in by visitors from the USA, these were orthopaedic surgeons. They would come in with supplies. One of the supplies they brought us was the SIGN system." Orthopaedic surgeon "Surgeons at local hospital s seek us out after hearing about our programme at one of the local orthopaedic meetings or surgeons already using it want to spread SIGN further in their county" Developer
	Absence of trusted contacts	"The problem is to access the developers. Because we are ready to get some funds… there is not even the option to contribute a small amount of money and get the nail. Because if we had that option we would have said ok we can go and beg from here and there to get that money but we never got that offer." Chief of surgery
	Resisting change in current practice	"There is no real physical barrier; the barrier is the people themselves. There are people who would like to change and there are people who resist. There are people with their own attitudes. But we don't have any physical barriers" Hospital director "Usually each change has got its resistance, even if it is a change for the better… I think the issue was that the first case took us a long time and we thought, this is very difficult to do and we have some senior surgeons who said that it's difficult to teach an old dog new tricks." - Orthopaedic surgeon
	Lacking capacity in recipient hospitals	"We have only 2 universities that train orthopaedic surgeons…. in a population of 40,000,000 we are less than 50…. we need more orthopaedic surgeons, we need more implants."

		Resident in orthopaedics "Many hospitals in Tanzania still don't have theatres where you can perform orthopaedic surgery safely." Orthopaedic surgeon "local hospital inefficiencies create barriers to patient care" Developer
Motivating factors for technology adoption	Releasing resources for further treatments through use of the SIGN nail = Reduced running costs to institutions and patients as a result of adopting the SIGN nail - e.g. reduced length of stay	"I saw it being used [at another hospital] There was an orthopaedic registrar who came here to practice… we find it very good because most of the wards were getting cleared so patients needing other procedures could be taken care of. So we can treat many more patients without having to wait for the orthopaedic surgeons… even a well trained registrar can do it perfectly, and it would reduce hospital stay." -Hospital director
	Provision of a training programme	"There was training for Orthopaedic surgeons and for nurses to teach them how to handle the instruments…I think it's good training instead of sitting in a class where somebody shows you on a model, you are trained how to do it on a real patient so it's easy for an orthopaedic surgeon." - Orthopaedic surgeon "It was useful because I was able to work alone after that." Orthopaedic surgeon "Further training is provided via the surgical database which is reviewed by orthopaedic surgeons on our board"Developer "This process has evolved more as SIGN surgeons learn more how to teach and learn" – Developer
	Reporting and feedback = renewed communication between developer and recipient; collection and provision of feedback by developers	"Through the database there is a discussion. You report, they review it and they comment…it's a form of learning." - Resident in orthopaedics "It is like we are closer and they can work on things quicker. [The database] is for raising concerns and requests like this instrument has broken, we need this, and this one is not working. It's like we are in the same setting. "

		- Theatre nurse
	Better patient outcomes	"The SIGN nail needs less hospital stay, if a patient comes in today and you do the SIGN nail, after 2 days you can discharge the patient. And if the wound is healing well, no sepsis, no infection, in 12-18 months you can remove the nail and the patient can continue with his old life." -Registrar in orthopaedics
Factors influencing continued technology use/supply	Changes made to device based on user feedback	"The improvements are mostly made after suggestions from surgeons depending on their experiences with it and that is good practice because it lets the orthopaedic surgeon have ownership of the implant." - Orthopaedic surgeon
	Reliable supply of the device	"For every nail you insert, you have to record, do pre op X-rays and post op X-rays and send the information to the SIGN headquarters. That nail will be replaced immediately." - Orthopaedic surgeon
	Delays in shipment	"When we run out of SIGN nails we just report, we tell the team responsible for reporting and ordering, then they order through SIGN. Sometimes we have a problem with the clearing and forwarding processes" -Theatre manager "Sometimes we have problems with the transportation of the nail, when they come from the US maybe they get stuck in Dar es Salaam with the customs people." Orthopaedic surgeon "Customs tie up the shipment, it is the local hospital's responsibility to clear the package from customs and pay any duties. Sometimes customs officers decide to increase the rate beyond their capacity so the shipment must be returned" - Developer

APPENDIX 3: FINDINGS OF THE QUALITATIVE META-SYNTHESIS AND SUPPORTING CODING STRUCTURE (CHAPTER 1)

Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
1. Identification and understanding of health needs is a first step in identifying where greatest population impact can be achieved: relevant health care areas, including technology purchases, are prioritized. 2. Verification of health needs may play a role in restricting the procurement of medical devices: i.e. should devices and equipment not correspond to a priority health condition they should not be procured.	Identifying the priority health problems of a defined population in order to achieve health impact and benefits. (ES: 21.39%)	General health condition	References to disease areas, issues or clinical guidelines without reference to these being a priority	27.72	"disease problem" (SR20) "burden of disease" (SR26) "from health problem to clinical guideline" (SR124)
		Health needs assessment	Analyses of the health needs of a population, including epidemiological evidence	32.67	"certificate of need" (SR23) "needs assessment (SR26) "situational analysis" (SR57) "local needs identified through prevalence and checked with providers" (SR140)
		Achieving population benefits	References to how tackling a health problem (whether specified or not) yields benefits to populations	14.85	"benefit to the population, social impact, community and professional demand, importance for improving patient condition, expected benefits in

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
					health outcomes" (SR 85) "treating and diagnosing TB is beneficial both for HIV and non-HIV patients" "maximize use on different patient types" (SR 55) "targeting health needs and adverse outcomes (risks)" (SR 130)
		Health priorities	Discussion of health priorities or identified clinical areas/fields of priority	9.9	"clinical area to focus on: trauma care" (SR 218) "prevalent emergency condition in reproductive health (SR 208) "forensic science" (SR 232)
		Achieving impact	Addressing health issues with the aim of achieving impact	21.78	"potential impact upon mortality reduction" (SR102)

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
3. Cost-effective medical devices are prioritized for procurement. 4. Financing arrangements and constraints impact upon the choice of technologies for procurement: i.e. if funding streams for particular conditions are available, devices for those conditions are prioritized within the funding round. 5. Devices and equipment imposing minimal costs upon the health system are prioritized for procurement.	Methods of intervention or technology evaluation (ES: 14.85%)	Economic approaches to evaluation, including health economics	References to economic methods of evaluation to inform decision making	27.72	"establish cost-effective way of dealing with disease problem" (SR 18) "cost-efficiency and effectiveness"(SR 157)
		Health technology assessments for evaluation	Methods beyond economic evaluation, including consideration of needs, political support and other value considerations	7.92	"health technology assessment" (24) "based on technology assessment and a six element approach: (…) boundaries and constraints, performance measures and measurement of actual performance" (SR 95)
	Defining financial boundaries and seeking cost-minimizing solutions (ES: 18.32%)	Financial constraints or thresholds	Budget constraints or thresholds set for equipment	15.84	"depending upon a cost-threshold a certificate of need process is adhered to" (SR 23)
		Cost-reduction	Mentions of approach to minimize costs	20.79	"reduce cost" (SR 40)

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
			associated with technology purchases		"average and reasonable cost" (SR 43) "ongoing costs" (SR 55) "bulk purchases lead to cost reductions" (SR 153)
	Exploring feasibility of purchases by defining financing arrangements and potential impact (ES: 8.42%)	Linking impact with financial feasibility	Compound mention of impact and technological effectiveness	9.9	"impact, effectiveness, scalability" (SR 29) "usefulness" (SR 56)
		Financing arrangements	Financing sources for device procurement / management	6.93	"procurement linked to aid contracts and programs chosen by donors… diversion of money into different programs is unfavourable" (SR 53) "financing ability" (SR 80)
5. Consensus decision making methods and evaluations of past procurement processes	Methods for evidence evaluation and reaching medical device/technology	Procedural evaluations	Evaluations of processes related to procurement, including planning and further	3.96	"Evaluation of technologies may not be sufficient, review the entire process: what do

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
and outcomes are preferred for reaching medical device and equipment prioritization decisions.	selection decisions (ES: 3.33%)		management		we want to achieve and how can it best be done?" (SR 161)
		Consensus methods	Methods of reaching agreement regarding medical device procurement	4.95	"consensus method (involving experts) but focused on the review of systematic evidence" (SR 191)
		Multi criteria decision making	Mathematical method of aggregating judgments on predetermined criteria	0.99	
6. Health care services and packages to be provided at each health care level directly influence which devices and equipment are prioritized and procured. 8. For newly introduced	Defining the health service structure (ES: 33.66%)	Care packages and services to be provided at different health system levels	Determination of interventions and services to be provided at primary, secondary or tertiary care levels	43.56	"defining basic packages of care at each service delivery level" (SR 29) "Collaborate with provincial and national authorities to find the suitable package for the setting" (SR 54) "distance from clinical

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
health services, policies for medical device management should be put in place.					sites and structuring of services" (SR 87)
		Defining services and procurement plans by defining targets and ensuring forecasting is done	Setting procurement targets and planning according to population/service use forecasts	23.76	"ensuring adjustment to patient volume" (SR 40) "create purchasing plans with projections of use" (SR 61) "ability to deliver pre-specifies treatment targets" (SR 73)
	Creating policies for medical device procurement and management (ES: 9.9%)	Creating policies and frameworks to address prioritization and device management	Mention of policies or management frameworks relating to medical devices and their procurement	9.9	"plan for a national policy on injection equipment and safety boxes" (SR 153) "waste management policies should include details on where disposal happens in facilities, and whether disposal is regional or national" (SR 154) "Prioritization is included

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
					as part of a health management policy but not with specific detail as to how to undertake this" (SR 226)
9. Prioritize equipment which can be safely used and managed in deployment settings. i) Prioritize equipment with LMIC friendly specifications. ii) Prioritize equipment that can be easily used and maintained within health facilities.	Desired features of medical devices for LMICs (ES: 28.71%)	Risk and safety	Associated risk of device use or misuse and issues of safety	19.8	"high risk devices" (SR 35) "safety" (SR 29) and "safety profiles" (SR 80) "variability and risk" (SR 176)
		Device specifications	Desired or undesired characteristics of devices to be procured	47.52	"long-life" (SR 40) "resistant to ambient conditions" (SR 54) "electricity, device design (e.g. whether hand-held or desktop operated – theft may be an issue), weight, operating temperature and humidity, hard and robust casings, battery life, display type" (SR 55)

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
					"high sensitivity and specificity" (SR 43) "function and simplicity" (SR 107) "devices are to compensate for lacking human resource skills and have reduced operational features" (SR 115)
		Quality and standards	Reference to pre-qualification of products, and quality assurance and control procedures	18.81	"quality equipment" (SR 54) and "quality assured products" (SR 181) "pre-qualification for the IUD showed one product suitable for most patients and manufacturing capacity was suitable to low-income settings as well" (SR 207)
	Managing equipment in the field in LMICs: what is needed	Matching facilities and their staff to medical device	Convergence of facility design and conditions, staff abilities/training	49.5	"facility type and conditions as well as experience of surgeon

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
	(ES: 32.34%)	specifications	needs and medical device specifications in deployment setting		should dictate prioritization" (SR 60) "skills and knowledge of staff" (SR 80) "available local technical skills" (SR 87)
		Maintenance and spare parts	Discussion of how maintenance should be conducted, why it is needed, how spare parts fit into the problem	27.72	"maintenance and service need priority and should be adapted to local needs" (SR 61) "minimal parts and consumables, simple, minimal maintenance and expert input" (SR 163)
		Supply of maintenance and spare parts	Who provides services and spare parts?	19.8	"local supplier availability for instrument maintenance and reagent supply" (SR 87)
	Regulatory issues, approvals and surveillance processes (ES: 5.94%)	Regulation	Specification of devices and how they accord with international or national regulatory	5.94	"ICF and ISO are used to delineate core sets of assistive products" (SR 125)

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
			frameworks		"prioritize health technology assessments at stages of pre-market clearance or post-market surveillance" (SR 126)
10. Political, social and value considerations influence prioritization decisions. 11. Past procurement experiences influence current prioritization processes.	Procurement processes in LMICs: reports of relative successes (ES: 10.89%)	Procurement processes in LMICs	Descriptions of how procurement processes work/do not work in LMICs	10.89	"Centralized procurement discouraged although may be advantageous, different timings of arrival observed" (SR 56) "developing a rational and efficient tendering procedure involves not only price but also maintenance and service considerations, all should be adapted to local needs" (SR 61)
	Political and social economy of procurement (ES: 10.89%)	Political aspects of procurement	Mention of how politics shapes procurement	7.92	"Prioritization occurs around six factors: … (technology) to be politically responsible" (SR 86)

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Findings of the meta-synthesis	Topic/ theme (Effect size*)	Code	Definition	Effect size %	Example quotes or fragments
					"Prioritization entails … the need for organizational sponsorship and development" (SR 102)
		Value considerations in procurement	Account of which value judgments are incorporated in procurement	13.86	"Prioritization occurs around six factors: … (technology) to be culturally acceptable" (86) "7 questions guide the definition of what is essential or not, including consideration of access (…) equity" (SR 29)

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APPENDIX 4: INTERVIEW TOPIC GUIDE (CHAPTER 2)

Semi-structured interview and focus group topic guide:

Prioritization of medical devices in The Gambia

This guide comprises a list of topics and instructions that the researcher can use to generate discussion in interviews and focus groups and to keep the discussion on track. The researcher will not necessarily use all of them in each interview/focus group – this will depend on the extent to which the research questions are answered without being prompted.

Guidance for interviewer:

Begin by introducing yourself and try to ensure that the participant/participants are relaxed. First go over the consent forms and explain all data handling procedures: audio recordings, transcribing, where data is stored, for how long, and that the data will be anonymised. Emphasize that participants do not need to answer questions should they not wish to do so and that they can withdraw up to two months after the time of interview/focus group.

Explain that the interview or focus group will go on for about an hour – an hour and a half maximum. Loosely describe that the interview or focus group consists of discussion around 3 segments, emphasizing that you want to understand a) the processes behind medical device selection and prioritization in the Gambia as well as the barriers and facilitators affecting this and b) the way donated medical equipment is used and managed within The Gambia.

1. Participant introduction

Ask participants to introduce themselves briefly and include relevant information on participant names, age, gender as well as professional experience. Probe about how long participants have been in their role, what organizations they have previously been employed in in order to ascertain their range of professional experience and where/when their educational training took place.

Sample question: Q1. *Could you please introduce yourself and tell me about your past educational and professional experience?*

2. Research topic: questions around primary objectives

This section will focus on medical device experience and selection/prioritization practices as well as the management and utilization of donated medical equipment. It is important to understand the organizational/ institutional/ regional/national landscape as well as the range of issues affecting medical device selection/prioritization.

Sample questions/instructions:

Q2. Tell me about your experience with medical devices.

Q3. What kind of medical devices do you regularly use or manage?

*Q4. Were these devices acquired in The Gambia or donated? (*Probe can revolve around: medical equipment donation, functioning of said equipment, meeting needs, maintenance)

Q5. Tell me about medical device selection: how do people in your facility choose which devices to buy? (Probe can revolve around: staff involved in procurement

decisions, methods for reaching decisions, factors affecting decisions, dynamics around procurement (e.g. national-regional instructions/restrictions?)

Q6. Who makes device selection choices? Why do you think that is?

Q7. What factors affect which medical devices are bought or selected for buying?

Q8. What needs do you associate with medical devices? (Probe about whether these needs are addressed?)

Q9. What is a priority medical device? How do you know that?

Q10. What guidance or tools – if any – do you need in order to undertake device procurement/ selection?

Q11. What is the most pressing issue for medical device procurement?

Q12. What are your suggestions for medical device selection and prioritization?

Q13. What are your suggestions for medical device/equipment donations?

3. Research topic: questions around secondary objectives

This section focuses on the current use of medical device procurement guidelines/systems/recommendations and aims to identify what types of guidelines are used and how effective/used they are.

Sample question: *Q14. Do you or your facility currently use any guidance or guidelines on what medical devices to buy?*

(Probe around satisfaction, issues, benefits)

Guidance for interviewer:

Close the interview/focus group by thanking the participants for taking part and explain how the findings of the current research will be used.

Added question:

- *If you have a device you have not used before, how do you acquire training/learn about its management?*
- *What's your experience of receiving donated medical equipment you did not have exposure to beforehand?*

APPENDIX 5: STUDY INFORMATION AND CONSENT SHEET (CHAPTER 2)

Interview consent form:

Prioritization of medical devices in The Gambia

This is a study investigating how health care professionals, managers, consultants and policy-makers within The Gambia undertake prioritization, selection or procurement of medical devices and medical equipment. The study will also investigate how donated medical equipment is managed and utilised within The Gambia.

You are asked to participate in an interview undertaken by one of the researchers in the study – the interview will last approximately 1-1.5 hours and will be arranged at a time convenient for you. During the interview, you will be asked questions around how choices are made regarding which devices are procured in your institution or within The Gambia and regarding how medical equipment/device donations are managed. You can choose not to answer a question if you do not want to.

All of the information you provide will be anonymised and kept confidential. For ease, we would like to audio record the interview with you – this data will be kept safe and confidential at the University of Birmingham in the UK. We would also like to use relevant quotations in future research reports, publications and presentations – these will not identify you in any way and no identifying information will be attached to these quotes. Quotations may use a fake name for labelling, and general information on the facility type/country you are from may be included: e.g. 'hospital, low-income country'.

The benefit of this study is that it will inform the development of a wider international medical device procurement method which could aid staff such as yourself in future medical device selection and prioritization decisions if implemented. You could thus be able to save money for your institution and increase efficiency. The findings of this research will be made freely available to The Gambia Ministry of Health and all participants and institutions that took part.

Please initial the below statements in the right hand column if you agree to take part in the study.

I have been given enough information about this research study	
I understand how the information I provide will be used	
I agree to speak to the researchers about my experience relating to medical devices	
I understand that I can leave the study up to two months after my focus group and do not have to answer questions if I do not want to	
I am happy for the researchers to audio record what I say and use and store the recorded data	
I give permission for my words to be used in publications and presentation but understand that my name will never be mentioned and that I will not be identified through this	

Participant name/Unique ID: ……
Signature: ……..
Researcher witnessing consent: ……..
Date: ……

APPENDIX 6: ETHICAL APPROVALS

The ethical approval letters were redacted from the e-thesis due to confidentiality.