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Evaluation of open-ended, clustering, and discrete choice methods for user requirements development in a low-income country context

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ABSTRACT

High quality user requirements are positively correlated with successful design outcomes, but engaging stakeholders within low-income contexts can present financial and time-related challenges to product developers from non-local industrial and academic institutions with limited knowledge of the context. Existing literature provides guidance for engaging stakeholders during the early stages of product design in high-income country contexts, but few studies have examined the effectiveness of these methods in low-income country contexts. This study evaluated three user requirements elicitation and prioritization methods including open-ended, clustering, and discrete choice. Ghanaian healthcare delivery stakeholders with varying types of expertise, years of experience, and from various types of healthcare facilities were recruited to allow for diversity of responses. Participants included physicians ($n = 10$), nurses/midwives ($n = 16$), biomedical technicians ($n = 14$), and public health officers ($n = 7$). A hypothetical mechanical device for managing and treating postpartum hemorrhage was chosen to characterize each method's ability to elicit and prioritize user requirements. The open-ended method captured general requirements of a design concept, yet resulted in predominantly generic requirements. The results from the open-ended method were used to inform the clustering and discrete choice methods. The clustering and discrete choice methods were useful for inferring in-depth user requirements and eliciting stakeholder priorities. The clustering method revealed that usability and affordability were high-priority requirements among all four stakeholder groups. An individual difference scaling analysis was performed using the clustering method outcomes, which indirectly identified ease-of-use, availability, and effectiveness as the priority user requirements categories. Stakeholders ranked ease-of-use as the highest-priority user requirement, followed by performance, cost, and place-of-origin requirements, using the discrete choice method. Given the significance of the ease-of-use requirement, an analytical framework based on sub-requirements was developed for quantifying stakeholder needs. Lastly, the relative merits of the three elicitation approaches and their implications for use with different stakeholder groups were examined.

1. Introduction

Engaging stakeholders with little or no engineering or product design background can be challenging in settings with limited methodical engineering design tradition and experience (ISO, 2019). There have been many attempts to reinvent and refine engineering design culture and education in order to identify essential needs based on the voice of the customer and realize high impact solutions in practice (Malkin and Von Oldenburg Beer, 2013; Martin et al., 2006; Oden et al., 2010). Once the need for a new product is established, efficient and easy-to-administer methods that directly and systematically engage stakeholders to elicit user requirements, which define the need/problem, are required. User

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Abbreviations: URs, user requirements; CA, conjoint analysis; QFD, quality function deployment; LMICs, lower middle income countries; HICs, high income countries; LICs, low income countries; PPH, postpartum hemorrhage; INDSCAL, individual differences scaling analysis; IRB, institutional review board.

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requirements (URs) are any function, constraint, or other property required for a designed product to meet the needs of stakeholders; the requirements are translated into quantifiable and measurable engineering specifications to guide the design process (Dieter, 2012; Pahl et al., 2006). The process of eliciting and refining URs is challenging due to the ambiguous and iterative nature of the task (Ashok et al., 1990; Jiao et al., 2006).

When performed appropriately, UR elicitation processes and their subsequent mapping to engineering specifications should ensure customer satisfaction and willingness to choose, adopt, purchase, or use the final product. UR elicitation is a critical phase when developing a successful product as studies have shown that in many instances product failure can be traced to key decisions made during front-end design phases, particularly during the elicitation of URs (Cooper, 1988; Davis, 1993; McGuinness and Conway, 1989; Ulrich et al., 2020). Studies have indicated that investing time and resources during the front end of design results in products having shortened and more cost effective development time (Cooper, 2019; Cooper and Kleinschmidt, 1994; Gupta and Wilemon, 1990). Reduction in time to market, as a result of increased investment in front-end design has been observed within successful company case studies (Markham, 2013; Rosenau, 1988). Rigorous UR elicitation approaches should: 1) identify the “right” types of needs, 2) elicit “real” URs, which may involve qualitative information, and 3) translate the requirements into “effective” quantitative engineering specifications (Shah and Robinson, 2007). In order to achieve completeness and consistent URs, engineering designers leverage qualitative and quantitative methods to clarify ambiguous information elicited from users (Chua et al., 2010).

To develop quality requirements, design experts have advocated for the collection of information from diverse sources including end users, other stakeholders, and product-use environments through the use of a variety of methods including interviews, focus groups, surveys, customer complaints, sales data, and codes and standards (Dieter, 2012; Dym and Little, 2008; Nuseibeh and Easterbrook, 2000). Additional qualitative methods used for eliciting implicit and explicit requirements that have been highlighted in the published literature include design ethnography, free association, open-ended responses, and clustering techniques. Design ethnography, a collection of methods derived from anthropology, facilitates the investigation of tacit knowledge about potential end users’ behaviors, their environments, and interactions between potential end users and their environments (Leonard-Bardon, 1995). The use of design ethnography is particularly suitable for identifying end users’ needs, especially for designers who are unfamiliar with a given environment. Free association involves the presentation of elicitation stimulus probes or cues about requirements to end users, who are asked to verbalize the concepts that immediately come to mind (Collins and Loftus, 1975). Free association is most appropriate for exploratory purposes and to capture open-ended inquiries. Open-ended responses ask direct questions to elicit feedback about users’ preferences as informed by their background and professional role (Schilling, 2006). An open-ended approach is suitable when the design team is new to an environment or has limited background for a design task and is interested in capturing general information. Clustering methods identify how stakeholders perceive and represent URs, such as which ones are viewed as similar and which are dissimilar. Clustering methods are suitable for making comparisons across different stakeholder groups as well as individual users (Ersal et al., 2011a; Toms et al., 2001). While these methods have their merits and are relatively simple to administer, analysis is not always straightforward and their outcomes are often subjective, colloquial, context and linguistic dependent, and can be difficult to map to quantitative engineering specifications (Chua et al., 2010; Jiao et al., 2006; Kroll et al., 2014; Nuseibeh and Easterbrook, 2000).

Quantitative methods have been developed to elicit, prioritize and translate URs more systematically. Conjoint analysis (CA), discrete choice, and quality function deployment (QFD) are among the most common quantitative methods used to elicit and quantify URs, and each method has specific data analysis protocols. CA, which follows standard principles from experimental design, is used by marketing specialists and engineers (Green et al., 2004). When using CA, potential stakeholders and end users are presented choice-sets containing several product options that are defined in terms of their requirements. The levels (numerical values) of the requirements will vary across and within choice-sets following experimental design principles. Users are asked to choose, rank or rate the products or options, and their responses are evaluated in a computational model that assesses the “part worth” of each level of each requirement. While CA results in numerical outputs, it requires extensive resources to administer.

The discrete choice method, also based on preference structure modeling, involves presenting two design options with distinct numerical specifications to stakeholders to elicit their preferences, whichcan assist in prioritizing and quantifying URs (Louviere et al., 2000). Through an iterative process, UR rankings can be established, and engineering specifications can be refined, which allows estimation of the trade-offs between design features. This procedure can be conducted with relatively few queries from the user, especially if the goal is to elicit rank order information rather than point estimates of quantitative parameters from a statistical model.

The five A’s – availability, accessibility, appropriateness, affordability and accountability – are critical high-level requirements for ensuring “that medical devices produce maximum public health benefits at affordable costs in all intended settings” (WHO, 2012). Intended settings include lower middle income countries (LMICs), which account for more than two-thirds of the world’s population. Historically, donated medical devices have accounted for upward of 80% of medical devices used in low income countries (LICs) (Dyro, 2004). Medical devices procured through other means, including imported devices typically designed for use in high income countries (HICs), stripped down versions of HIC models, and older models no longer supported in HICs have proven difficult to maintain due to challenges associated with sourcing spare parts, lack of public infrastructure, as well as the availability of trained technicians, have largely proven to be ineffective in non-intended use environments (Dyro, 2004; Howitt et al., 2012; Malkin and Von Oldenburg Beer, 2013; McDonald et al., 2019).

Many medical devices intended for use within low-resource settings fail to reach scale because they are not contextually appropriate and do not effectively address stakeholders’ needs, among other factors. The design of appropriate and affordable devices requires engineers to have a thorough understanding of the targeted use setting. Furthermore, in addition to needing to be safe and effective, medical devices need to be easy to use and maintain (Howitt et al., 2012; Sarvestani et al., 2021). Moreover, the challenges presented by LMIC settings need to be addressed at the beginning of the design process (Sarvestani and Sienko, 2014). Design approaches that consider local and regional constraints, cultural contexts, and stakeholder needs, and enhance the capacity of the local healthcare workforce are particularly effective (Aranda-Jan et al., 2016; Malkin and Von Oldenburg Beer, 2013; Perry and Malkin, 2011; Burleson et al., 2020; Rodriguez et al., 2023). Involving end users and other stakeholders from the outset allows designers and engineers to elicit needs and identify preferences as expressed by the end users and stakeholders themselves (Howitt et al., 2012).

Establishing requirements for medical devices can be challenging when considering the diversity of stakeholders involved throughout the life cycle of medical devices, including doctors, nurses, patients, caregivers, regulatory specialists, public and private payers, professional and advocacy groups, government officials, legislators, insurance companies, clinical engineers, maintenance personnel, and trainers (Freeman, 2010; Grech and Borg, 2008; Sawyer et al., 1996; Yock et al., 2015) (Yock et al., 2015; Freeman, 2010; Grech and Borg, 2008; Sawyer et al., 1996). Coulentianos et al. (2022) established a list of stakeholders engaged by design practitioners during the early phases of medical device design processes, spanning users (e.g., active and passive users, secondary user), implementation stakeholders (e.g., manufacturing, government, regulatory, community partners), and expert advisors, which were all involved in front-end design activities, including requirements elicitation (Coulentianos et al., 2022). The beneficiaries, users, payers, and purchasers of medical devices can differ (Sheth and Uslay, 2007), leading to conflicting priorities and needs (Shah and Robinson, 2008), making it difficult to establish robust URs.

Given the current knowledge gap on how to effectively and efficiently capture, prioritize, and translate URs into engineering specifications, especially in settings with limited systematic practice of engineering design process, the objective of this study was to empirically compare the quality of outcomes of three UR elicitation and prioritization methods: a qualitative method based on responses to open-ended questions, an association method in which users cluster requirements according to their own criteria, and a discrete choice method. These three methods were used with multiple stakeholders and evaluated, with a real-life scenario, using a medical device case study involving the design of a device to manage postpartum hemorrhage (PPH) in low-resource settings.

2. Methods

Open-ended responses, clustering, and discrete choice methods were used to collect the preferences from four stakeholder groups in Ghana. Over 60 medical doctors, nurses/midwives, biomedical engineering technicians, and public health officers with varying levels of experience providing direct care for pregnant women or professionally supporting the care providers from diverse healthcare settings within Ghana were approached using word of mouth and snowball methodologies. Due to time and funding constraints, recruitment was terminated after 60 participants were recruited. Among the 60 professionals recruited, 47 agreed to participate in this study. Table 1 shows the stakeholder participant types, locations, numbers, and years of experience. The engagement of public health officers was explicitly of interest in an LMIC setting as government stakeholders have been reported to reveal information about the healthcare socio-cultural context and systems and structures (Coulentianos et al., 2020) and can have competing goals with regard to other stakeholders (Mattson and Wood, 2013).

Data collection used semi-structured interviews and survey techniques. The following description of PPH complications was provided at the start of each interview: “The leading cause of maternal mortality is obstetric hemorrhage, accounting for up to 44% of deaths in some areas. PPH is the most common type of obstetric hemorrhage, and the most common cause of maternal death in developing settings. Immediate PPH (heavy bleeding directly following childbirth or within the first 24 h) is the most common type of PPH and can be caused by uterine atony (when the uterus fails to contract properly after delivery); retained placenta; inverted or ruptured uterus; or cervical, vaginal, or perineal lacerations. Hence, there is a need to develop a mechanical device for management and control of PPH in low-resource settings.”

Table 1
Participants’ background and demographics.

Stakeholder Group by Type	Total Participants	Location	Years of Experience (mean)
Medical doctors	10	Komfo Anokye Teaching Hospital, Ghana Health Services (Accra)	1–20 (7)
Nurses/ Midwives	16	Komfo Anokye Teaching Hospital, Kumasi South Hospital, community health posts (rural northern Ghana)	2–30 (17)
Biomedical engineering technicians	14	Komfo Anokye Teaching Hospital, Ghana Health Services (Accra), University of Ghana (Legon), Korle Bu Teaching Hospital	1–32 (8)
Public health officers	7	Komfo Anokye Teaching Hospital, Ghana Health Services (Kumasi)	1–19 (7)

A study team member recorded the participants’ responses to the open-ended questions described in Method I. The responses elicited via Method I informed the URs for the clustering method and the questions for the discreet choice method. The time required by participants to complete each component of the protocols described in Methods I-III was recorded. Two study team members digitized (using Microsoft Excel), reviewed, and crosschecked participant responses for accuracy.

2.1. Method I: open-ended responses

For the open-ended (qualitative) method, the study team interviewed 12 out of the 47 participants (selected based on participant availability; at least one participant from each stakeholder group was interviewed): one medical doctor, eight nurses/midwives, two biomedical engineering technicians, and one public health officer. The open-ended responses method used in this study had two steps:

1. After reviewing the description of PPH with the participant, they were asked the following question, presented in a way that was understandable for those unfamiliar with engineering design terminology: *“What are the user requirements and design characteristics of a mechanical device that could help to manage and assist with early control of PPH (indicate by whom and where the device could be used)?”*
2. After responding, the participant was asked to rank their requirements, and to give additional input to indicate how they would quantify each requirement.

Following data collection, a study team member and a trained research assistant applied frequency analysis to the digitized stated requirements to identify the number of times a requirement was mentioned. Then, the study team grouped URs with similar meanings and calculated the collective frequencies of requirements, regardless of stakeholders’ affiliation, to infer the importance of each requirement. For example, easy-to-use and user-friendly were grouped and labeled as ‘easy-to-use’ given that ‘easy-to-use’ was a commonly used term in the literature.

2.2. Method II: clustering

The clustering method required that participants group requirements from a list of URs and label each cluster. All 47 participants completed this portion of the study (see Table 1 for participant breakdown). The list was developed based on standard requirements in the device design literature (Yock et al., 2015) and supplemented by the outcomes of the open-ended responses described above. The labels, created by the participants for their self-identified clusters, provided insight regarding their representations of similarities among requirements.

The requirements clustering method had two steps:

1. After being given a list of URs (Table 2), the participants were instructed, *“Considering the different requirements of a device to address PPH, group your conceptual device’s requirements into the categories that you think make the most sense. Note: Requirements can be clustered in as many categories as you see fit.”*
2. After doing so, each participant was instructed to assign a descriptive label to each cluster. For example, a “low-cost” label could be assigned to the cluster of: maintainable locally, inexpensive, and widely available. The provided labels facilitated the interpretation of the clusters.

Descriptive data were computed for the clusters. In addition, the UR clusters for all participants were analyzed using individual differences

Table 2
Generic list of user requirements, based on open-ended responses for use with the clustering method.

The appropriate PPH device should:
1. Be easy to use
2. Be inexpensive
3. Require minimal training time
4. Be safe for patient and user
5. Be effective immediately
6. Reduce the procedure time
7. Reduce the number of procedural steps
8. Be widely available
9. Be suitable for use in health posts (rural regions), district and regional hospitals
10. Be suitable for use in district and regional hospitals
11. Be single-use
12. Auto-disable
13. Have multiple uses
14. Be made from locally available materials
15. Be maintainable by local technicians
16. Reduce training time to less than a day
17. Require minimal post-operation visits
18. Cause minimal complication
19. Be designed and manufactured locally
20. Be designed and manufactured in the United States/European Union
21. Be easily cleaned
22. Minimize pain for the patient
23. Be one-size-fits-all (adjustable size)
24. Be available in different sizes
25. Be portable
26. Be fixable in the field
27. Be powered mechanically
28. Be powered mechanically and electrically
29. Be culturally acceptable

scaling analysis (INDSCAL), which is a weighted multidimensional scaling tool used to evaluate participant differences when making dis (similarity) classifications (Carroll and Chang, 1970). INDSCAL enables engineering designers to evaluate, approximate, and visualize the representation of URs from proximity matrices using Euclidean distance (Petiot and Grognet, 2006). INDSCAL reveals the optimal number of dimensions that participants considered when selecting their clusters. These dimensions represent the primary categories of URs that arenot articulated directly by stakeholders but emerge from similarities in the data — in this case, each participant's clustering. INDSCAL provides information about how much each participant relies on a given dimension when judging the similarity of URs. Here, INDSCAL was chosen over traditional multidimensional scaling (a type of principal components analysis) to learn about the heterogeneity across the four stakeholder groups and across participants.

The data analyzed by INDSCAL were the proximity matrices representing each participant's (i.e., K_i, $i = 1–47$) clustering of the URs (i.e., $n = 29$) (Table 2). Thus the clustering procedure led to 47 distinct 29×29 binary proximity matrices. The similarity matrix for each participant was created based on the expressed UR clusters. For example, if five URs (1, 3, 5, 17, and 23 from the list of URs - Table 2) for participant K_4 were placed in the same cluster, then a "1" was entered in each cell of the 29×29 matrix representing all pairwise combinations of those five URs. For URs not in the same cluster, their pairwise entries in the 29×29 proximity matrix were "0". The binary proximity matrix for each participant was entered into the INDSCAL function (SPSS® V20, IBM Corp), using the nominal option. The stress value was used to compare model fits for different numbers of dimensions; the scree plot was examined for an elbow to determine the number of dimensions (Carroll and Chang, 1970).

2.3. Method III: discrete choice

This method determined the preference rankings of UR differences among the four stakeholder groups. All 47 participants completed this portion of the study. The study team gave each participant eight sets of paired-choices of hypothetical devices (A and B) with four requirements categories selected as attributes: performance, cost, ease-of-use, and place of origin, with two levels within each category (see Table 3 for experimental design). The paired-choices were determined based on the preference outcomes from the first method (open ended) and literature recommendations, to help the study team infer orderings of utility differences among the preferences. Each paired-choice was printed on a separate card (Fig. 1) and given to each participant. After being given a card for each of the eight pairs, the participants were asked to record their answers on a questionnaire:

> "*Which one of the following devices, A or B, would you choose to assist with PPH control and management?*"

The study team assumed that higher performance, lower cost, ease-of-use, and locally made (made in Ghana) were the dominant levels of each of the requirements (indicated by asterisks in Table 3). This paradigm allowed the preference rank order of UR utility differences to be estimated separately by stakeholder group.

Based on the principles of utility theory (Fishburn, 1970), the choice of an option was represented through a utility function U_j (j being an option). For example, in the case of devices A and B presented in Fig. 1, choosing device A is modeled as the utility of device A ($U_{(A)}$) being greater than that of device B for that participant, i.e., $U_{(A)} > U_{(B)}$.

The additive utility function, $U_{(A)}$, is represented as an additive combination of attribute-based utilities, v_j;therefore, attributes with identical values in a pair of choices can be dropped. Hence, for the specific comparison between devices A and B, where they share common values on two attributes, the utility ordering on the two remaining attributes that differ across those two devices is inferred from the choice (note: levels for cost and performance used in the following equations are illustrative and only for demonstration purposes):

$U_{(A)} = v_{cost}$ (\$50) $+ v_{performance}$ (95%), and $U_{(B)} = v_{cost}$ (\$10) $+ v_{performance}$ (75%)

The levels for the other two URs are not shown because they cancel in the additive utility representation. Hence, the inference for the participant choosing device A over B is:

v_{cost} (\$50) $+ v_{performance}$ (95%) $> v_{cost}$(\$10) $+ v_{performance}$ (75%)

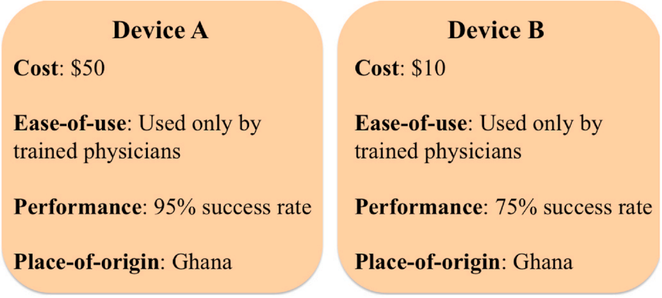
and this implies an ordering of utility differences across the two URs:

$v_{performance}$ (95%) - $v_{performance}$ (75%) $> v_{cost}$ (\$10) - v_{cost} (\$50)

In this case, the choice model shows that if A is chosen over B, the difference between 95% and 75% on the attribute performance is more important than the advantage of the lower cost of \$10 over \$50 on the UR cost. All eight choice pairs had this structure, which allowed utility differences across attributes to be ordered and utility tradeoffs across attributes to be measured. The proportion of such orderings was tested

Table 3
List of URs selected as attributes and associated attribute levels for the discrete choice method; different combinations of attribute levels formed the hypothetical devices A and B. Careful construction of choice pairs permits inferring ordering of utility differences from choice. Note: Higher performance, lower cost, ability to be used by a less-trained health worker, and locally made (i.e., made in Ghana) were the dominant levels of each of the requirements, as indicated by "*".

User requirements selected as attributes	Attribute levels
1. Performance	95% effective* 75% effective
2. Cost	\$10.00* \$50.00
3. Ease-of-use	Used only by a trained physician Used by less-trained health worker*
4. Place of origin	US Ghana*



Device A
Cost: $50
Ease-of-use: Used only by trained physicians
Performance: 95% success rate
Place-of-origin: Ghana

Device B
Cost: $10
Ease-of-use: Used only by trained physicians
Performance: 75% success rate
Place-of-origin: Ghana

Fig. 1. Hypothetical devices with specified requirements.

across stakeholder groups using Fisher's exact test because of the relatively small sample size (Upton, 1992). This analytic procedure of comparing utility differences is more robust, especially in small sample sizes, such as in this study, than more common discrete choice methods that assume a particular error distribution and estimate model parameters such as part worths (e.g., models based on logistic regressions, conjoint analysis) (Krantz et al., 2006).

The study was reviewed by an Institutional Review Board (IRB) at the University of Michigan in Ann Arbor, Michigan, USA, which determined that it met US federal criteria for exemption (HUM00066084, 7/17/2012). Although the University of Michigan IRB does not require in-country ethics committee approvals for exempt studies because investigators conducting exempt research do not have a regulatory obligation under the Common Rule to obtain such approvals, the Ghanaian Ministry of Health was informed of this study in person by a study team member. Participants were fully informed about the nature of the study prior to each interview and were asked for their verbal and written consent. No form of identifier was collected from the participants.

3. Results

3.1. Method I: open-ended outcomes

Method I elicited 18 unique URs. Nine of the 12 participants cited inexpensive, easy-to-use, and task-shifting (a device facilitates a task to be performed by less trained health workers) as their desired requirements, whereas only four cited locally maintainable, immediately effective, and safe. The most number of requirements stated by a participant was 14 (by a medical doctor), and the fewest was 3 (by a nurse). The average time to elicit the requirements was approximately 10 min per participant.

The majority of URs for the PPH device were generic and universally applicable to any other medical device. Only two URs specific to the PPH device were cited by a medical doctor ("device must be fixable on the abdomen") and a nurse/midwife ("device must automatically detect PPH").

3.2. Method II: clustering outcomes

The stakeholder groups assigned a total of 26 unique labels to their clusters of requirements. Medical doctors, nurses/midwives, biomedical technicians, and public health officers had combined totals of 14, 16, 15, and 13 labels, respectively. All groups cited affordability, usability, effectiveness, safety, and availability as cluster labels (Table 4). Usability and affordability were among the top three labels for all groups, whereas safety was the top level for only three groups. Not all participants used exactly the same titles for labeling, but the study team consolidated similar titles with similar meaning. For instance, easy-to-use and user-friendly were categorized under usability, and low-cost and inexpensive were classified under affordability.

Other than usability, affordability, and safety, the other labels varied depending on each group's professional concerns, needs, and interests. The public health officer group had the greatest variety of labels (seven different labels ranked among the top three). Also, effectiveness was only mentioned by medical doctors and public health officers. Table 4 shows the frequency of participants' responses for each requirement cluster (top three) among the four stakeholder groups. The average time spent per respondent for this method was approximately 15 min.

Table 4
Clustering method – Top three labels mentioned by stakeholder; frequency % are indicated after each requirement.

Medical Doctors ($n = 10$)	Nurses/ Midwives ($n = 16$)	Biomedical Engineering Technicians ($n = 14$)	Public Health Officers ($n = 7$)
1. Usability (87.5%)	1. Usability (71.4%)	1. Affordability (85.7%)	1. Affordability (64.3%, rank 1)
2. Affordability (62.5%, rank 2)	2. Affordability (57.1%)	2. Usability (75.4%)	2. Effectiveness (64.3%, rank 1)
3. Effectiveness (62.5%, rank 2)	3. Availability (35.7%)	3. Safety (42.9%)	3. Usability (57.1%, rank 2)

The input provided by each participant for the clustering method was then further evaluated using INDSCAL to model the UR clusters. The individual INDSCAL findings for each of the four stakeholder groups are presented first, followed by the estimated weights from a combined analysis of all 47 participants and their preference weights for each of the identified dimensions. The comparison of the stress metric revealed that two dimensions were appropriate for each of the stakeholder groups. All the stakeholder groups agreed on the first dimension, but there were differences across the groups on what constituted the second dimension.

Ease-of-use emerged as the common UR category for dimension one for all the groups. The ease-of-use category was an aggregate of URs, including 'be easy-to-use', 'require minimal training time', and 'reduce procedure time'. For medical doctors and public health officers, a second dimension emerged: the effectiveness of the device, which was based on cluster labels such as 'effective immediately', 'minimize post-operation visits', and 'minimize pain'. For the remaining two stakeholder groups, nurses/midwives and biomedical engineering technicians, availability of the device emerged as the second dimension. This term captured cluster labels such as 'suitable for health posts', 'suitable for district and regional hospitals', 'made from locally available materials', and 'inexpensive'.

The INDSCAL procedure was also conducted for all 47 participants as a whole. According to the stress metric, the two-dimensional solution was the best fit for the UR space: dimension one was ease-of-use and dimension two was availability. INDSCAL also led to the analysis of derived subject weights, a map of study participants' weighting on each of the two dimensions. This analysis presents the derived subject weights, demonstrating how much weight was given to each dimension when participants rated UR similarity.

3.3. Method III: discrete choice outcomes

In this section, participants' preferred URs (selected as attributes) are discussed. The study team assumed that medical doctors represented the frontline of healthcare delivery and led the treatment process for PPH patients. Hence, Fisher's exact test was used to compare preference proportions (Table 5) between this group and each of the other three groups. In the language of statistics, the medical doctors group was treated as the "reference group." This test showed no statistically significant comparisons between medical doctors and each of the other three stakeholder groups across all eight choice pairs ($p>0.05$), but statistical power was admittedly low due to the relatively realistic sample sizes. However, these sample sizes mimic sample sizes one encounters in low-resource UR elicitation studies. Table 5 shows the proportion of responses within each stakeholder group for preference differentiation between devices A and B.

Table 5
Choice proportions by stakeholder group.

Discrete choice question	Device choice	Preferred characteristic	Medical Doctors	Nurses/ Midwives	Biomedical Engineering Technicians	Public Health Officers	Total
a	A	Performance	0.90	0.87	0.62	0.86	0.80
	B	Cost	0.10	0.13	0.38	0.14	0.20
b	A	Performance	0.70	0.81	0.64	0.57	0.70
	B	Cost	0.30	0.19	0.36	0.43	0.30
c	A	Performance	0.20	0.50	0.54	0.71	0.48
	B	Usability	0.80	0.50	0.46	0.29	0.52
d	A	Cost	0.40	0.33	0.43	0.43	0.39
	B	Usability	0.60	0.67	0.57	0.57	0.61
e	B	Place of origin (US)	0.0	0.21	0.21	0.14	0.16
	A	Usability	1.0	0.79	0.79	0.86	0.84
f	B	Performance	0.30	0.57	0.29	0.57	0.40
	A	Usability	0.70	0.43	0.71	0.43	0.60
g	B	Place of origin	0.20	0.21	0	0.14	0.13
	A	Cost	0.80	0.79	1	0.86	0.87
h	A	Place of origin	0.10	0.07	0.07	0	0.07
	B	Performance	0.90	0.93	0.93	1	0.93

Overall, the outcomes of the utility preferences showed that stakeholders were most interested in the ease-of-use requirement, followed by performance, cost, and place-of-origin (Table 5 – last column). Table 6 shows the lists of rank-ordered requirements by stakeholder group. Although there was disagreement about the order of the first two device requirements, ease-of-use versus performance, all groups agreed about the order of the last two, cost and place-of-origin. The average time spent for this method was approximately 5 min per participant.

4. Discussion

This study investigated three requirements elicitation methods within a low-resource context and showcased how different elicitation methods can inform a user requirement development process progressively. Other studies have applied requirements elicitation methods in LMICs and reported the outputs of such methods as surveys, focus groups, interviews, brainstorming, brainwriting (Mindila et al., 2019) and choice experiments (Chou et al., 2021). While those studies explored one particular method in detail, this study compared differences in elicitation method outcomes across methods.

It is generally recognized that stakeholder involvement throughout a medical device design process is preferable to interaction during select phases of design. Increased stakeholder involvement has been shown to increase the likelihood of developing products that are safe, usable, clinically effective, and appropriate to the cultural context (Aranda-Jan et al., 2016; Chavan et al., 2009; Martin et al., 2008; Burleson et al., 2023). Historically, medical device industry interactions with stakeholders have predominantly occurred during the prototype and post-market evaluation stages of a design process, given a technology- versus need-driven approach (Caldwell et al., 2011; Martin et al., 2008). Lack of stakeholder involvement during the establishment and refinement of URs and translation to engineering specifications can lead to engineers making assumptions. Therefore, it is particularly important to capture stakeholder input when defining and prioritizing URs and engineering specifications to increase the likeliness of developing solutions that are superior in functionality, usability, and quality (Shah and Robinson, 2007). However, there are tradeoffs that exist among the various qualitative and quantitative methods for eliciting such UR input, yet there have been limited studies that compare the effectiveness and efficiency of such techniques (Shah et al., 2009). This study compared the requirements elicited and their prioritization from multiple stakeholder groups using three methods.

The primary finding of this study was that open-ended responses effectively captured general requirements, whereas the clustering and discrete choice methods were most useful for eliciting detailed requirements and stakeholder priorities. While the clustering method was effective in capturing tacit and poorly articulated URs, the discrete choice method was the easiest for the stakeholders to perform, considering the time to complete the task, but required knowledge of the key URs in advance in order to construct the choice questions.

Administering the open-ended response method was time consuming while yielding limited results, given most of the elicited requirements were generic. Also, URs elicited through this method became repetitive after engaging with fewer than 10 participants. Providing input with this method was challenging for most of the participants, demonstrating the difficulty of expressing URs for a hypothetical design in the absence of a physical model or prototype to assist with the articulation of their thoughts (Yock et al., 2015; Coulentianos et al., 2020; Rodriguez-Calero et al., 2020; Coulentianos et al., 2022). Although the open-ended response method did not take as long to perform as the clustering method, the clustering produced more PPH-specific design requirements than the open-ended responses. Therefore, the open-ended response results suggest the need for a guiding mechanism to elicit and establish more specific URs.

The clustering method revealed participants' concerns for a hypothetical PPH device directly, by clustering and labeling each cluster, and indirectly, using an INDSCAL. It also identified the requirements in the form of cluster labels defined by each participant, and primary requirement categories in the form of dimensions revealed in INDSCAL. However, its administration was the most time consuming. A comparison between the outcomes of the open-ended responses and the clustering methods identified low-cost and usability (here: easy-to-use and task-shifting) as the two most important requirements. However, the stakeholder groups showed different orderings in the frequency of labeling them (Table 4).

An INDSCAL was used to model the participants' representations of

Table 6
Discrete method – Ranked order device requirements analysis from inferred rank order of utility differences by stakeholder group.

Medical Doctors	Nurses/Midwives	Biomedical Engineering Technicians	Public Health Officers	Total
1. Ease-of-use	1. Performance	1. Ease-of-use	1. Performance	1. Ease-of-use
2. Performance	2. Ease-of-use	2. Performance	2. Ease-of-use	2. Performance
3. Cost	3. Cost	3. Cost	3. Cost	3. Cost
4. Place of origin	4. Place of origin	4. Place of origin	4. Place of origin	4. Place-of-origin

URs categories, indicated as INDSCAL dimensions. Ease-of-use was the common UR category among all stakeholder groups. Availability, for nurse/midwife and biomedical engineering technician groups, and effectiveness, for medical doctor and public health officer groups, were the second identified dimensions.

INDSCAL outcomes provide a visual representation for each participant's preference on primary URs (dimension) based on their expressed clustering of the 29 URs. These outcomes provide engineering designers with an opportunity to utilize an indirect approach in identifying participants' primary UR categories and their evaluations. Participants may not be able to articulate UR categories with open-ended responses for a specific design challenge, but as in this study they may be able to understand individual specific URs and cluster them based on similarity. When the clustering is complete, they can assign labels to their own clusters. In this way, the designer can have a better understanding of the primary UR categories because they consist of more specific, quantitative, and sometimes actionable, items. INDSCAL can also provide information about how different stakeholder groups represent URs. As revealed in this study, all groups agreed on ease-of-use as a major UR category, but groups did not agree entirely on the second dimension (availability versus effectiveness).

Multidimensional scaling techniques such as INDSCAL take symmetric proximity matrices, such as those collected in this study, and perform analyses similar to singular value decomposition. Each additional dimension is analogous to adding another eigenvector to the representation. The goal is to have a parsimonious description of the proximity matrices with as few dimensions as possible; the stress metric essentially evaluates the residual between the observed proximity matrix and the model-implied proximity matrix, similar to residuals in the context of regression analysis. A solution with the same number of dimensions as there are rows and columns in the proximity matrix will produce a perfect fit as assessed by stress. This is analogous to an eigenvector decomposition that uses all eigenvectors to reproduce the original matrix. For an example of how multidimensional scaling techniques can be adapted to quantitative engineering design see (Ersal et al., 2011b). There are additional checks on INDSCAL solutions such as examining for degenerate solutions and overfitting (Borg et al., 2005).

Administering the discrete choice method was simple and short. Given that this method was implemented to assess tradeoffs between two potential devices (described with four attribute levels) and prioritize preferences, the outcome was a set of utility orderings that can be useful in defining engineering specifications and design constraints. When studying and developing products for multiple stakeholders, a major challenge is how to incorporate and translate different, sometimes conflicting URs, into the design problem definition. The discrete choice method was used to demonstrate how differences between stakeholder preferences can be investigated.

An interesting outcome of the discrete choice method was the resulting rankings of ease-of-use as the most important requirement (above performance) for medical doctors and biomedical engineering technicians, and as the second most important requirement (below performance) for nurses/midwives and public health officers. Links between the effectiveness of medical devices and their ease-of-use have been documented (Hegde, 2013). Some studies have investigated how improving ease-of-use can improve device performance and effectiveness. For example, a study by Lang et al. (2013) uncovered five main URs to improve adherence of adolescents to a medical device after realizing that the device was not adapted for that specific user group, which affected the device's effectiveness (Lang et al., 2013). Furthermore, regulatory bodies require usability testing during a medical device design process, recognizing the high impact of user error on effectiveness of medical devices (Wiklund et al., 2015). It is therefore not surprising that the requirements of ease-of-use and performance emerged as closely ranked (i.e., first and second) for the discrete choice method.

Given the small sample sizes, the statistical power in this study could detect relatively large differences in proportions. Implementation of the discrete choice method requires careful attention to the construction of choice pairs so choice data can lead to ordering of utility differences. In this study, the eight choice pairs for the discrete choice method were selected in advance (i.e., the study team hypothesized the four URs and selected the levels). However, it is possible to use the outcomes of the clustering method to inform the selection of major URs and levels.

The carefully selected choice pairs in this study allowed for an easy-to-deliver method to elicit URs, which is less computationally intensive and complex to perform compared to CA. While the procedure used in this study did not permit computation of part worths, because the eight choice pairs were carefully selected we were able to find orderings of utility differences for each of the four stakeholder groups. Hence, the discrete choice method is suitable for a faster prioritization and analysis of URs, especially when access to software and complex tools are limited.

Effective design for LICs requires one to abandon top-down design approaches traditionally seen in product and engineering design, transitioning to the bottom-up approaches that focus on the end user and other stakeholders who will be affected by the designed artifact (Caldwell et al., 2011; WHO, 2010). Carefully eliciting user requirements and fully understanding the context in which a product will be used are key strategies for accomplishing this bottom-up approach (Salvador et al., 2010). Designing for LICs bring additional challenges such as reduced contact with stakeholders, cultural barriers that must be overcome, diverse and complex stakeholders groups, among others (Aranda-Jan et al., 2016; Coulentianos et al., 2020; Howitt et al., 2012; Sarvestani and Sienko, 2018). Given these constraints, it is therefore imperative to find the appropriate methodologies to elicit user requirements within this setting. This study found that the discrete choice method was simple and quick to implement. It allowed for the quantification of preferences and sorting of stakeholders' engineering specifications preferences (e.g., quantified user requirements). The results from this study suggest that the discrete choice method is particularly relevant for refining user requirements and engineering specifications that are ambiguous in nature (e.g., appropriate cost and efficacy-related requirements). Once a requirement has been identified as important (such as through open-ended interviews or clustering), discrete choice can be used to define it more precisely.

Additionally, trends related to the stakeholder groups were observed within this data set. For example, medical doctors and public health officers displayed opposing trends in choice proportions with respect to performance and usability. Medical doctors placed significant importance on usability when compared to performance, while public health officials placed more importance on performance versus usability. This finding points to the importance of engaging the "right" (i.e., most appropriate or relevant) stakeholders to explore certain user requirements, for example, engaging end users (such as medical doctors) when exploring usability requirements while engaging decision makers (such as public health officials) when exploring cost and purchasing requirements.

The limitations of this study included a small number of participants per stakeholder group and a limited number of stakeholder groups. Specifically, it was challenging to recruit healthcare providers due to their clinical commitments. The small sample size prevented the use of more complicated statistical models. Furthermore, stakeholders such as patients and community health workers were not recruited and therefore not represented. Their involvement could have potentially expanded the quantity and quality of the URs gathered during the open-ended responses with respect to cultural and societal considerations. Even though no significant differences among group preferences using the discrete choice method were observed, this does not imply that differences will not exist among stakeholder groups for other design scenarios. In many real-world design scenarios, the sample sizes may be even smaller than those used in this study. Therefore, while this sample size is not ideal from the perspective of statistical power, it is analogous to non-research based design tasks.

5. Conclusion

The benefits and limitations of three UR elicitation and prioritization methods were characterized based on data collected from four health-related stakeholder groups in Ghana. The qualitative methods yielded general requirements, while the quantitative method produced prioritized, detailed requirements. Each method elicited similar high-priority general requirements among all stakeholder groups. Despite the differences in URs elicited applying the three distinct methods, each individual method or their use in combination, may benefit any given design undertaking. Engineering designers, who are new to a setting or unfamiliar with the stakeholders' needs can benefit from starting their URs elicitation process with an open-ended response method study. Outcomes from an open-ended response method can be used to establish a list of URs for use in a clustering method study. The clustering can be analyzed descriptively as well as with algorithms such as INDSCAL. Clustering and INDSCAL evaluations can then provide categories of URs that can be used in a choice based method study. Of course, designers should be cognizant of the quality of output they will obtain given the method they choose to use.

Such evidence-based methods, as presented here, may benefit from emerging interdisciplinary fields such as implementation engineering, which promotes uptake of scientifically designed and tested products into routine healthcare in both clinical and policy contexts, by engaging stakeholders effectively in the design process as early as possible (Johnson, 2013).

Declaration of competing interest

There are no competing interests to report.e

Data availability

Data will be made available on request.

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