Design Science

Characterizing the use of contextual factors in engineering design: an exploration of global health designer practice

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Abstract

Incorporating contextual factors into engineering design processes is recommended to develop solutions that function appropriately in their intended use contexts. In global health settings, failing to tailor solutions to their broader context has led to many product failures. Since prior work has thus far not investigated the use of contextual factors in global health design practice, we conducted semi-structured interviews with 15 experienced global health design practitioners. Our analysis identified 351 instances of participants incorporating contextual factors in their previous design experiences, which we categorized into a taxonomy of contextual factors, including 9 primary and 32 secondary classifications. We summarized and synthesized key patterns within all the identified contextual factor categories. Next, this study presents a descriptive model for incorporating contextual factors developed from our findings, which identifies that participants actively sought contextual information and made conscious decisions to adjust their solutions, target markets and implementation plans to accommodate contextual factors iteratively throughout their design processes. Our findings highlight how participants sometimes conducted formal evaluations while other times they relied on their own experience, the experience of a team member or other stakeholder engagement strategies. The research findings can ultimately inform design practice and engineering pedagogy for global health applications.

Keywords: Global health, Contextual factors, Design practitioners, Design process, Contextual engineering

Received 18 May 2023
Revised 17 July 2024
Accepted 19 July 2024

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Des. Sci., vol. 10, e36
journals.cambridge.org/dsj
DOI: 10.1017/dsj.2024.28

the Design Society a worldwide community

Cambridge University Press

1. Introduction

A critical objective of engineering design is to ensure consideration of all factors necessary for successful implementation (Otto & Wood 2001), including tailoring to the wider context in which the solution must live and operate (C. Atman *et al.* 2009). Professional design practitioners are encouraged to consider the influence of relevant *contextual factors*, that is, characteristics of the potential solution's broad use context, throughout their design processes (Green, Palani Rajan & Wood 2004;

Kilgore *et al.* 2007; Aranda-Jan, Jagtap & Moultrie 2016). Even further, scholars suggest that design practitioners should *incorporate* contextual factors into their design processes, that is, consider the implications of specific contextual factors when arriving at design decisions throughout their design process (Mosyjowski *et al.* 2020; Burleson *et al.* 2023). Scholars highlight the importance of developing a holistic understanding of the use context (Jagtap 2019*b*; Dugan *et al.* 2021) and have determined that "failing to have adequate contextual knowledge" can be a top reason for project failures (Wood & Mattson 2016).

Exploring and understanding the use context is a central part of front-end design of health products (Martin *et al.* 2006; Coulentianos, Daly & Sienko 2020*a*). In low- and middle-income countries (LMICs), special attention to the broader socioeconomic and historical context is recommended so that products can be tailored to the situations in which they must function (Rismani & Van der Loos 2017; Piaggio *et al.* 2021). Neglecting to incorporate relevant contextual factors has led to health product failures, including medical devices (Aranda-Jan *et al.* 2016; Fisher & Johansen 2020) and information communication technology products (Toyama 2015). An estimated 40% of medical equipment in LMICs is out of service (Perry & Malkin 2011; Ssekitoleko *et al.* 2021); these devices are often initially designed for use in other contexts and then donated (Emmerling, Dahinten & Malkin 2018). Moreover, the number of commercialized medical devices designed specifically for use in LMICs has been shown to fall short of the projected demand within these countries (Sabet Sarvestani & Sienko 2018). As such, there have been more calls for healthcare innovations to be designed specifically for LMIC markets (Clyde *et al.* 2019), particularly through contextually attentive and community-centered design approaches (Okeke *et al.* 2019; Rodriguez *et al.* 2023).

While some studies have suggested that experienced design practitioners are skilled at tailoring their solutions to their use context (Eteläpelto 2000; Mazzurco & Daniel 2020), limited research has investigated exactly *how* design practitioners learn and incorporate contextual factors into their design processes. Some prior work suggests that experienced design practitioners investigate broader contextual factors primarily during early stages of their design process (C. J. Atman *et al.* 2007), often through stakeholder engagements (Coulentianos *et al.* 2020*a*; Jagtap & Larsson 2020). Moreover, although prior work has shown that global health designers in LMICs prioritize investigating contextual information (Burleson, Sienko & Toyama 2020; Coulentianos *et al.* 2020*a*), to the best of our knowledge, studies have not investigated *how* they go about incorporating them into their design processes. As such, this study explores the behaviors of experienced design practitioners as they incorporate contextual information throughout design processes in global health settings.

2. Background

2.1. Incorporating contextual factors into global health design processes

All products operate and function within specific situations and environments that are composed of many *contextual factors*, that is, characteristics of the solution's broad use context including social, political, environmental and institutional situations (Aranda-Jan *et al.* 2016; Burleson *et al.* 2023). In global health

https://doi.org/10.1017/dsj.2024.28 Published online by Cambridge University Press

applications, particularly those aimed for implementation in LMICs, design practitioners are especially encouraged to consider a wide range of contextual factors (Nieusma & Riley 2010; Janzer & Weinstein 2014; Johansson *et al.* 2020). Moreover, when the objective of engineering design includes more than just device performance, such as improving health outcomes, it is even more imperative that design practitioners consider the wider context, including cultural, political and environmental considerations (Riley 2012; Clyde *et al.* 2019; Penty 2019). Thus, when designing for improved social and health outcomes within LMICs, engineers frequently investigate the use context with the goal to incorporate contextual factors (Lissenden, Maley & Mehta 2015; Jagtap 2019*a*, 2021), particularly during front-end needs assessments and back-end field testing (Burleson *et al.* 2020).

To some extent, scholars have investigated how engineering designers consider broader aspects of the design context, for example, Schön determined that experienced designers followed implicit patterns of reasoning that were *contextually dependent* (Schön 1988) and reflectively interpret context as they proceed through their design processes (Schön 1983). C. Atman *et al.* (2009) uncovered that contextual issues drove engineering design processes as teams regularly toggled between discussing "close" and "broad" factors during team discussions. However, prior work has yet to investigate granular details regarding *how* engineering designers go about identifying, collecting, synthesizing and then applying contextual information into their design processes, particularly in a global health setting.

2.2. Characterizing "context" and its use in design

Across engineering design literature, the term "context" is used to describe broad conditions (e.g., environmental and social) within a particular environment or setting. Scholars have defined context as attributes that "extend beyond technological feasibility and local implementation concerns into the broader societal, cultural, environmental, and ethical realms" (C. Atman *et al.* 2009). Others defined context as "the circumstances that form the setting" of the product, including the problem, social and institutional context (Subrahmanian, Reich & Krishnan 2020). Simon (1969) claimed that the engineer must design the *inner* environment of an artifact to be "at the service of the goals in the context of the *outer* environment" (Simon 1969). More commonly, engineering design references the "target market," which places emphasis on specific customers and their needs within their local environment (Dieter & Schmidt 2009). Overall, it is evident that design practitioners must develop some level of contextual understanding and adequately apply it during their design processes so that the products function within the intended use environments (Jagtap 2019*b*).

Some scholars have developed frameworks and classifications of "context." For example, Atman (2019) characterized "broad" contextual factors, that is, those that are more indirect to the product such as the environment, and "close" contextual factors, such as those related to the technology (C. J. Atman 2019). Green *et al.* (2004) defined context in three groups: customer context (beliefs, values, practices and demographics), market context (aspects of competing products) and usage context (situation in which the product will be used) (Green *et al.* 2004). Hales & Gooch (2004) defined a *context model* that defined context in five levels: external environment, market, company, project and personal (Hales & Gooch 2004). In a review of design research in LMICs, authors suggested five "contextual aspects" to

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consider in design processes, including income, rural or urban, design sectors (e.g., water and health), country differences and gender (Jagtap 2021). More specifically, a review by Aranda-Jan *et al.* (2016) characterized nine categories of *contextual factors*, which were defined as characteristics of the use environment: technological, industrial, infrastructure, environmental, institutional, public health, economic, political and socio-cultural (Aranda-Jan *et al.* 2016). To understand "perceptions of context," the authors conducted a literature review and interviews with medical device practitioners to identify classifications of factors that researchers and practitioners perceive as "context." Their analysis uncovered high prevalence of contextual factors mentioned in institutional, technological and infrastructural categories, and minimal political factors. Burleson *et al.* (2023) built on this research to further investigate which contextual factors can be *used* in design, not only *perceived*, by investigating novice engineering designers. This study uncovered specific examples of contextual factors across the nine classifications, as shown in Table 1.

Engineering designers in global health settings are regularly encouraged to use contextual information during design, that is, incorporate contextual factors into their design processes. Contextual factors can influence the ways designers explore and define problems (Burleson *et al.* 2020; Coulentianos *et al.* 2020*b*), develop solutions (Hu & Reid 2018) and test and verify solutions (Ventrella, MacCarty & Zhang 2018; Burleson *et al.* 2019). Many people-focused design approaches and methods provide some recommendations for incorporating contextual information into their design processes. *Systems engineering* draws a designer's attention to context-specific socio-technical systems surrounding a problem that a solution must be integrated (da Costa Junior, Diehl & Snelders 2019; Haberfellner *et al.* 2019). *Design ethnography* requires in situ observations and interviews to identify contextual information and learn more about the problem and task at hand (Wood & Mattson 2019; Pink *et al.* 2022). *Contextual inquiry* provides designers with methods into investigate the use context and environment surrounding a new technology, particularly when being integrated into a specific organizational setting (Holtzblatt & Jones 2017; Augstein *et al.* 2018). Other methods, such as *participatory design*, *empathic design* and *human centered design*, focus on working closely with stakeholders to uncover contextual factors and identify deeper needs (Heylighen & Dong 2019; Holeman & Kane 2020; Drain, Shekar & Grigg 2021). These methods encourage engineering designers to collect a breadth of contextual information to inform decisions throughout their design processes. However, existing recommendations lack explicit guidance concerning specific ways designers can incorporate unique contextual factors at specific stages in their design process.

2.3. Practices of experienced design practitioners

In design research, investigating experienced design practitioners is frequently used to uncover behaviors and strategies associated with successful design practices (Cross 2004). Experienced designers have been shown to reflectively frame the context in which they are working in (Schön 1983; Goel & Pirolli 1992) and identify critical contextual considerations (Mazzurco & Daniel 2020). Prior work has also shown that experienced design practitioners focus on contextual factors during early stages of design (C. J. Atman *et al.* 2007; Borgford-Parnell, Deibel & Atman 2013), often through stakeholder engagements (Coulentianos *et al.* 2020*a*; Jagtap & Larsson

https://doi.org/10.1017/dsj.2024.28 Published online by Cambridge University Press

Table 1. Definitions of contextual factors developed by Aranda-Jan *et al.* (2016) and expanded by Burleson *et al.* (2023)

Contextual factor classifications	Definition and frequencies of contextual factors identified by Aranda-Jan *et al.* (2016)	Examples and frequencies of contextual factors uncovered in study of novice practice by Burleson *et al.* (2023)
Institutional	Factors referring to the social organizations and bureaucratic structures created for the functioning or delivery of specific services to the population (n = 68).	Existing practices and procedures; capacity and capability of institutional staff; institutional resources; institutional financial capacity (n = 85).
Technological	Factors specific to the design of the product (n = 53).	Compatibility with the technical context; context-specific standards; availability of consumables; available technologies in the context (n = 48).
Infrastructural	Factors of the built environment (human-made such as buildings, roads and electrification) (n = 47).	Utilities; transportation; road quality; distances; materials; housing design (n = 22).
Geographical and environmental	Factors of the natural environment such as temperature, humidity and rain (n = 31).	Weather; temperature; humidity (n = 12).
Public health	Factors related to the health of the population and clinical practice, such as mortality, morbidity, sanitation and hygiene (n = 30).	Local healthcare; health demographics (n = 26).
Socio-cultural	Factors defined by the individual's frame of beliefs, thoughts, lifestyle and cultural characteristics (n = 25).	Esthetics; education and literacy rates; language; stigmas and taboos; symbols; religion and cultural tradition (n = 16).
Manufacturing and industrial	Factors external to the product but are required to produce/supply the product (n = 23).	Availability of manufacturing; materials; maintenance (n = 36).
Economic	Factors referring to the economic aspects (n = 12).	Income level, country-level classification; cost of labor (n = 21).
Political	Factors referring to the political organization of the context (n = 1).	None identified.

2020). Importantly, when compared to novices, experienced design practitioners show a more comprehensive awareness of stakeholders' contextual constraints, leading to more holistic and integrative solutions (Eteläpelto 2000; Björklund 2013). In a study on the mental activities of novices and experienced designers, authors found that experienced designers spend more time analyzing the broader context and developed more interpretations of their design with respect to the overall context (Ruckpaul, Nelius & Matthiesen 2015). While prior work highlights critical behaviors and skills that experienced designers use to consider context during their design processes, there is limited research examining *how* design practitioners incorporate contextual factors during design processes within global health design settings.

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3. Methods

We set out to investigate how design practitioners incorporate contextual factors during their design processes in global health applications. Here, “contextual factors” were defined as characteristics of a potential solution’s broad use setting (Aranda-Jan *et al.* 2016) and “incorporate” was defined as an instance when a participant’s decision during a design process was influenced, completely or in part, by a contextual factor (Burleson *et al.* 2023). The following research questions guided this study:

1. *What contextual factors do experienced global health designers incorporate into their design processes?*
2. *How do experienced global health designers identify and incorporate contextual factors during their design processes?*

3.1. Participant recruitment and summary

We recruited 15 experienced global health design practitioners. Recruitment was conducted through a purposeful and convenience sampling strategy (Etikan, Musa & Alkassim 2016; Patton 2018) through the study team’s network of design professionals (e.g., pre-existing connections and relevant listservs) across global health design domains (e.g., medical device engineering and information technology). This sampling strategy was justified for the sake of recruiting participants known to be of high quality and to take advantage of existing professional rapport to strengthen the quality of the interviews. We reached out via email and social media (e.g., LinkedIn) with informational flyers about the study. In the flyers, we included our team’s contact information for participants to submit their request to participate. We screened all interested participants; admitted participants were required to:

(1) Have participated actively in the design of at least one health product intended for use in a LMIC within the last 5 years.
(2) Have a minimum of 3 years of professional engineering design experience in a global health design field.

For each admitted participant, we scheduled a 90-minute video interview, distributed a brief survey to collect relevant demographics, and collected participant consent via email. Ultimately, we included 15 participants in our study; ten identifying as male and five as female. Most participants (eight) were based in North America with four based in sub-Saharan Africa, two in Europe and one in South Asia. On average, our participants had 11 years of design experience (low: 3 years; high: 28 years). Our participants worked and implemented products across a wide range of global regions, mainly sub-Saharan Africa, South Asia and Southeastern Asia. A variety of global health products were discussed during interviews, such as neonatal monitoring, therapeutic devices, prosthetics and information systems for public health awareness and monitoring. Most of our participants (11) were part of micro-enterprises (fewer than 10 employees) or small-enterprises (10–49 employees). One participant was part of a medium enterprise (50–249 employees), and three were part of large enterprises (larger than 250 employees). Table 2 provides a complete list of participants, using regional classifications to protect their identity.

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Table 2. Description of participants in this study

Identifier	Gender	Organization size[a]	Region based in	Race	Design domain	Regions worked in/products implemented in	Years of design experience
A	Male	Micro	North America	White	Medical devices	Sub-Saharan Africa, Southern and Southeast Asia	20
B	Female	Small	North America	White	Medical devices	All regions	12
C	Male	Medium	North America	White	Information technology	South Asia	11
D	Female	Micro	North America	South Asian	Medical devices	South Asia	10
E	Male	Large	North America	South Asian	Information technology	Sub-Saharan Africa, Southern and Southeast Asia, South America	10
F	Female	Large	Europe	N.p.[b]	Medical devices	Sub-Saharan Africa, South Asia	5
G	Male	Small	North America	White	Medical devices	All regions	27
H	Male	Micro	South Asia	South Asian	Medical devices & information technology	South Asia	5
I	Female	Small	North America	White	Medical devices	Sub-Saharan Africa, South America, Southern and Southeast Asia	9
J	Female	Small	North America	South Asian	Medical devices	Sub-Saharan Africa	3
K	Male	Micro	Sub-Saharan Africa	African	Medical devices	Sub-Saharan Africa	3
L	Male	Micro	Sub-Saharan Africa	African	Medical devices	Sub-Saharan Africa	5
M	Male	Large	Europe	White	Medical devices	Sub-Saharan Africa, South Asia	28
N	Male	Micro	Sub-Saharan Africa	South Asian	Medical devices	Sub-Saharan Africa	5
O	Male	Small	Sub-Saharan Africa	African	Information technology	Sub-Saharan Africa	8

[a]Classification by the Organisation for Economic Co-operation and Development (OECD): micro enterprises (fewer than 10 employees), small enterprises (10–49 employees), medium enterprises (50–249 employees) and large enterprises (250 or more employees).
[b]N.p. = Not provided by the participant.

3.2. Data collection

The interview protocol was developed using a phenomenological approach (Bevan 2014) with semi-structured questions to elicit conceptions of what contextual information they paid attention to and how they went about informing their design processes based on this contextual information. We designed the protocol to be conducted for 90 minutes over videoconferencing software and included the following stages shown in Table 3. Due to the in-depth nature of the questions and time constraints associated with the interviews, we chose to ask participants to focus on only one project that they recently worked on so that they could easily recall details more thoroughly.

To answer our research question regarding *what* contextual factors participants incorporated during their design processes, we chose to use the taxonomy presented by Aranda-Jan *et al.* (2016), which identified nine high-level categories for contextual factors based on an investigation of medical device design literature and practice. We created a corresponding slide deck, each with one to two contextual

Table 3. Semi-structured interview protocol used in this study

Interview stage	Duration	Primary questions
Introductions, overview of study goals and warm-up	10 mins	Tell me a bit of your design background. My goal here is to understand how you and your team incorporated relevant contextual information into your design process. Can you think of a specific project that might be a good example of this?
Design experience overview	10 mins	Considering your recent work on [blank] project, can you describe the background and objectives of this project? What were the outcomes of this project? What stage is it at now?
Understanding project context and stakeholders	15 mins	Tell me more about your project's intended end user(s)? Who were other key stakeholder groups?
Understanding the design context	15 mins	Walk me through how you went about learning about your end users, stakeholders and their context. Tell me more about the context of use in which you aimed to implement the project? What information about the context did you need to collect to incorporate into your design decisions?
Deep dive into incorporating contextual factors	40 mins	Walk through specific contextual categories (technological, industrial, environmental, infrastructural, institutional, economic, socio-cultural, public health and political): Can you describe if you incorporated these contextual factors into your design decisions? If yes, how did you do so? What other contextual factors did you consider that I have not shown you yet?
Wrap-up	10 mins	Is there anything about the product's context that you wish you had learned or incorporated sooner? Is there anything you would like to add that you feel I did not touch on?

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Table 4. Set of cards shown to study participants of contextual factor categories; categories derived from Aranda-Jan *et al.* (2016) and definitions were derived from our team's previous work (Burleson *et al.* 2023)

Socio-cultural Factors defined by the end user's frame of beliefs, thoughts, lifestyle and cultural characteristics	*Infrastructure* Factors of the built environment (human-made) such as buildings, roads and electrification	*Geographical/Environmental* Factors of the natural environment, climate and landscape, such as temperature, humidity and rain
Institutional Factors referring to organizations and bureaucratic structures for the function or delivery of services	*Economic* Factors referring to the economic situation, such as income levels and capacity	*Political* Factors referring to the political organization of the context
Public health Factors related to the health of the population, such as mortality, morbidity and local health concerns	*Technology* Factors specific to the technical performance of the product locally, such as availability of consumables	*Industrial* Factors external to the product but are required to produce/supply the product

factor "cards" including revised definitions from our team's prior work (Burleson *et al.* 2023), as shown in Table 4. These slides were screen-shared one at a time during the interview's "deep dive" section. Our team used a previous version of this interview protocol in a study that investigated novice practices incorporating design processes (Burleson *et al.* 2023). The final protocol was formally piloted independently with two engineering designers (not included in this study), each with at least five years of professional design experience. Interviews were recorded and transcribed by a third-party transcription service. The University's Institutional Review Board determined exempt status for this study (HUM00199822).

3.3. Data analysis

Due to the exploratory, in-depth nature of the dataset, we followed a team-based consensus strategy (Cascio *et al.* 2019) and negotiated agreement approach (Garrison *et al.* 2006) using a "unit of meaning," which designates the unit of analysis not as a specific length of text (e.g., paragraphs or pages) but rather a specific instance that can have varying length in the text (Campbell *et al.* 2013). In our case, our unit of meaning was designated as an instance in which a participant provided evidence of a specific decision being influenced by a contextual factor, that is, a contextual factor incorporated into their design process.

Following the three-stage coding process recommended for in-depth semi-structured interview data analysis (Campbell *et al.* 2013), we first developed an initial codebook of contextual factor categories consisting of a taxonomy of primary codes ("contextual factor classifications"), inspired by Aranda-Jan et al.: (1) economic, (2) environmental, (3) industrial, (4) infrastructure, (5) institutional, (6) political, (7) public health, (8) socio-cultural and (9) technological (Aranda-Jan *et al.* 2016). Additionally, within each classification, we developed a secondary

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Table 5. First draft of secondary codebook ("contextual factors") from Burleson *et al.* (2023)

Classifications (primary codebook)	Contextual factor (secondary codebook)
(1) Economic	(1a) Income level, (1b), Country-level classification, (1c) Cost of labor
(2) Environmental	(2a) Weather, (2b) Temperature, (2c) Humidity
(3) Industrial	(3a) Availability of manufacturing, (3b) Materials, (3c) Maintenance
(4) Infrastructure	(4a) Utilities, (4b) Transportation, (4c) Road quality, (4d) Distance, (4e) Materials, (4f) Housing design
(5) Institutional	(5a) Existing practices and procedures, (5b) Capacity and capability of institutional staff, (5c) Intuitional resources, (5d) Institutional financial capacity
(6) Political	None identified
(7) Public health	(7a) Local healthcare, (7b) Health demographics
(8) Socio-cultural	(8a) Esthetics, (8b) Education and literacy rates, (8c) Language, (8d) Stigmas and taboos, (8e) Symbols, (8f) Religion and cultural tradition
(9) Technological	(9a) Compatibility with the technological context, (9b) Context-specific standards, (9c) Availability of consumables, (9d) Available technologies in the context

codebook ("contextual factors"); the first draft of this codebook was derived from our team's prior work investigating novice design practice, presented in Table 5 (Burleson *et al.* 2023).

Additionally, we used a description of design activities (Gericke & Blessing 2012) to create three codes to categorize the design decisions participants made to incorporate contextual factors, as shown in Table 6. Each identified incorporation of a contextual factor was coded with a classification, contextual factor and design activity.

Two study team members first started by independently coding transcripts and calculating intercoder reliability (ICR) using the following equation: the number of agreements divided by the sum of agreements and disagreements (O'Connor & Joffe 2020). A unit was defined as an agreement when both coders categorized it into the same classification, contextual factor code and design activity code.

In the second data analysis stage, the coders resolved all disagreements by either reconciling the discrepancies or iterating the codebook to increase reliability. The process of independently coding, calculating ICR and resolving disagreements by reconciliation or codebook iteration continued until the average ICR for one-third of our full dataset (five transcripts) reached 0.88 (high: 0.95; low: 0.79), which is considered very strong (Wilson-Lopez, Minichiello & Green 2019). Then, the finalized codebook was applied to all transcripts by a single coder. This process led to the authors extensively editing and clarifying the secondary codebook of contextual factors. By the end of the data analysis process, the secondary codebook included 32 contextual factors, each with its own definition as well as inclusion and exclusion criteria for each code (see the Supplementary Material for the full codebook and coding results). Inclusion and exclusion criteria aided our coding

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Table 6. Codebook for design activities where contextual factors were incorporated

Design activity code	Description (Gericke & Blessing 2012)
Establishing a need and analyzing the task	Initiation of the design process by a product idea, the identification of a need or a problem, detailed analysis of the initial description of the task/need/product idea, additional information gathering
Conceptual, embodiment and detailed design	Development of abstract/principle solutions (concepts) which solve the problem, detailing the conceptual solution, integration of sub-solutions, refinement and finalization of the solution
Implementation, use, and closeout	Integration, manufacturing, installation, test, approval, launch of the product, operation, monitoring, maintenance of the product, recycling, disposal, update/evolution of the product

process, per recommendations from the literature (MacQueen *et al.* 1998; DeCuir-Gunby, Marshall & McCulloch 2011).

Excerpts within each design activity code were reviewed, and themes were identified. First, to answer our first research question regarding *which* contextual factors participants incorporated into their design processes, we summarized and synthesized key patterns across the contextual factors and their classifications. Next, to answer our second research question regarding *how* participants incorporated contextual factors into their design process, we conducted an iterative thematic analysis (Terry & Hayfield 2020) to identify patterns of incorporation across the coded design activities, including participant rational and approach for incorporating contextual factors.

4. Results

Participants displayed definitive patterns and procedures for incorporating contextual factors into their work. In total, we identified 351 instances of participants incorporating contextual factors in their previous design experiences. Overall, participants made it clear that investigating and incorporating contextual factors was necessary and integral throughout their design processes. Participants perceived all contextual categories as important and as potentially impactful to their designs. Even though some aspects were prioritized more than others, there was no indication that any of the categories we presented could be ignored throughout design processes, as they may become potentially relevant and crucial to their solution's success. Overwhelmingly, participants highlighted that having a broad view of context throughout their design process was critical for their project's success.

4.1. Classifications of contextual factors participants incorporated during design

We classified the 351 instances into nine contextual classifications identified by Aranda-Jan *et al.* (2016) as well as 32 subcategories that we developed through our iterative coding process, which are presented in the Supplementary Material. We identified definitive patterns across the classifications and contextual factors, as

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Table 7. Taxonomy of contextual factors incorporated by 15 participants, including total count identified and number of participants for each classification

Classifications and contextual factors	Total count	Total participants
Socio-cultural	*66*	*15*
Symbols	16	10
Cultural tradition and practices	12	8
Language	11	10
Education and literacy rates	11	9
Esthetics	8	5
Stigmas and taboos	8	6
Political	*61*	*15*
Regulations and Regulatory Processes	23	13
Stakeholder power dynamics	23	11
Political systems & culture	10	7
Global Priorities	5	5
Institutional	*51*	*11*
Existing practices and procedures	18	9
Capacity and capability of institutional staff	11	7
Institutional financial capacity	9	6
Institutional resources	8	5
Indoor environment	5	4
Industrial	*43*	*13*
Supply & Manufacturing	26	12
Maintenance	10	8
Distribution	7	6
Technological	*41*	*14*
Available technologies in the context	17	11
Compatibility with the technical context	15	10
Availability of consumables	9	8
Infrastructure	*27*	*15*
Utilities	15	12
Transportation & Road quality	6	5
Distance	5	5
Attributes of the built environment	1	1
Public health	*24*	*13*
Healthcare system and practices	16	9
Health demographics	8	7

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Table 7. Continued

Classifications and contextual factors	Total count	Total participants
Environmental	*21*	*14*
Weather	16	13
Natural environment	5	5
Economic	*17*	*13*
Individual and household characteristics	8	8
Regional and national characteristics	6	6
Labor market characteristics	3	3

shown in Table 7; this section provides an overview of the ways that participants incorporated contextual factors, ordered in the frequency of categories identified. Detailed description of categories and subcategories, including inclusion and exclusion criteria as well as examples, is provided in the Supplementary Material.

4.1.1. Socio-cultural contextual factors

Socio-cultural contextual factors referred to the social and cultural characteristics of individuals and groups, such as social behavior, norms, knowledge, beliefs, arts and customs. Most participants incorporated local *symbolism* by carefully selecting colors, shapes and figures that had meaning in their specific context (Participants B, C, F, G, I, J, K, L, M, N, O). For example, one participant described how her product only functioned in contexts that attached meanings to colors in a similar manner:

> "We do hear that the color means different things in different cultures…so the color, of course, matters quite a bit [and] our conclusion is that it doesn't work well everywhere for that reason." – Participant B.

Participants also incorporated *cultural tradition and practices* in a variety of ways, for example, during implementation, they developed training programs and materials based on cultural norms and expectations (Participants B, D, M, O). In another example, Participant D prioritized "integrating [the product] with the traditional attire" in her intended context. Similarly, participants incorporated local *esthetics*, for example by designing their product and packaging in ways that were visually pleasing within the target context (Participants C, D, H, M). One participant described advocating for incorporating context-specific esthetics in his design group:

> "For these products that go typically to Africa, for instance, our [European] designers like simple black and white boxes with black print that are really minimalistic. But, it turned out that was not so popular in Africa. They wanted photos, they wanted colors…which the [European] designers really hated, but I said, 'No, we need to go with that because that's what they find attractive.' So then we did that instead of this boring black and white thing. That's more a Western thing to make it minimalistic." – Participant M.

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Additionally, participants incorporated local *language* and *education and literacy rates* by using context-specific languages (Participants A, B, C, F, N, O) and graphics (Participants B, C, D, F, G, I, J) on their products and manuals. For example, one participant described:

> "There's a range of languages we have to cater to, so having pictures makes it easier for it to be universal and means less work in translating stuff." – Participant F.

4.1.2. Political contextual factors

Political contextual factors referred to the systems, institutions and culture of decision-making and forms of power. Unlike other categories used in this study, prior work did not provide initial sub-categories (Aranda-Jan *et al.* 2016; Burleson *et al.* 2023). As such, through our iterative and inductive analysis we identified four distinctive subcategories: (1) regulations and regulatory processes, (2) stakeholder power dynamics, (3) political systems and culture and (4) global priorities.

Regulations and regulatory processes included policies, regulations and/or initiatives that were enacted in the intended context (e.g., nationally and regionally). Participants primarily fell into one of two categories: prioritizing (1) local regulations or (2) global regulations. For participants who focused on meeting local regulations (Participants B, E, H, J, M, O), they incorporated "certain local regulations that we had to meet" (Participant E), such as data privacy laws. For participants who designed their products to meet stricter standards than what was required in the use country context, they aimed to ensure their product would be transferable to other contexts (Participants D, A, F, N, O). For example, one participant described his rationale for incorporating broader regulations into his design process:

> "And for us, in our context, when we talk about standards, for example, both at the hardware level, software level, you realize if you want to do a multinational business and you're only targeting a country-level standard, it's hard to scale through. What that means you will be filing for a standard check in every country. So for us, strategy-wise what we have been able to do is look go back and look at what global standards are acceptable in the countries that we want to deploy in and then try to see what does it mean to go after that standard, that certification so that it is easy recognizing the countries that are want to go in and then adopt such standards." – Participant O.

Many participants aligned their solutions with existing regulations as a way to ensure an enabling environment and incentives for their product (Participants C, D, K), for example, one participant described his strategy for aligning their product with a changing national policy:

> "I think there was a very enabling political environment in the early days, which was key to the uptake basically…I think one common misconception is that there's a meritocracy on design ideas, that the best design wins, in a sense, and I'd love if that were true. I feel there was also a key element of timing…And [in this] context the government was already changing their [policies]…Basically [our product] got its foothold not because it was necessarily such an amazing idea, but during that transition [between policies] it was just the best story in town." – Participant C.

Stakeholder power dynamics referred to the ways different individuals or groups interacted with each other, particularly when one or more individuals or groups

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held more power than the other. To incorporate these dynamics, participants engaged influential stakeholders throughout their design processes. During early stages, participants identified budget priorities and goals to incorporate into their designs such that their solutions would align with powerful stakeholders' interests (Participants C, E, G, N). During conceptual and detailed design, participants selected features that these influential stakeholders would find valuable (Participants F, O), for example, one participant described:

> "[The] Ministry of Health picking over products is quite a high barrier for us…we try to make sure that we bring value, [which] is where the features come in, which features should be removed and which ones are [included is] very important." – Participant F.

During later implementation stages, participants emphasized the importance of building rapport among influential stakeholders within the context (Participants A, G, H, I, K, O). Participants aligned and framed their products so that these stakeholders would approve or assist them through various implementation stages (e.g., customs and national health approvals). For example, one participant shared:

> "'Having friends in high places,' as the saying goes, is super helpful at that point, because they're going to direct money towards your procurement program." – Participant G.

Political culture and systems referred to formal and informal mechanisms by which civic decisions were made, including sets of attitudes and beliefs that give meaning to political processes (e.g., underlying assumptions and rules that govern behavior in a political system and political affiliations). Many participants described learning and participating in the local political culture during their design processes, emphasizing the importance of working within the unspoken "rules" of a local system. For example, one participant described:

> "Sure you could go around, and you could disrupt the system… but you then realize who's supporting you? And who's supporting the adoption of this system? You have to work through the government. These are very political conversations." – Participant E.

Some participants highlighted the importance of remaining neutral with respect to local political movements (e.g., local political parties and individual politicians). For example, one participant worked on developing a product name that would be perceived as neutral within the context and specifically not affiliated with a political movement. Another participant stressed the importance of understanding the local political movements:

> "So you have to look out for those things and you have to be neutral…because if your product is depicted as a product that is pro-some-politician and that politician leaves, then other people will not use that product ever again. So you have to be very, very careful. Because to the politicians, a good product they would want to come up as their initiative and many [designers] fall for that. So, because he is in that position as the minister this year or five years and he or she wants to come out as, 'Oh, this is the product I've been pushing so…' There's a lot of political press time that they want to get from that to work out for them getting into office the next time. So you have to be

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> careful on how you engage with them so that you're not perceived in a wrong way." – Participant O.

Global priorities referred to multinational initiatives that developed priorities and provided incentives for organizations to work toward solving problems in specific contexts. Participants described various global entities that influenced their design process, for example, United Nations, Gates Foundation, and the World Health Organization. These organizations had identified priorities within LMICs, which led many organizations to allocate resources and funding, including local governments. As such, some participants described aligning their solutions with these global priorities, either early-on as they were establishing their need (Participants A, F, G, H) or later during implementation, framing their solution to these global goals (Participant B). For example, one participant described some of the motivation for establishing their design process:

> "The UN had the development goals and infant mortality is [part of] one of them. So we would try to connect our concepts and our products to those development goals because, frankly, that's what the Gates Foundation was funding. So a lot of what we did followed the money and the money followed the public health priorities" – Participant A.

4.1.3. Institutional contextual factors

Institutional contextual factors referred to constraints or norms within the organization or institution of which the solution must be operational. For participants developing solutions intended for use within hospitals, institutional factors were particularly important. Participants incorporated the *capacity and capability of institutional staff* into their design processes, for example, by embedding training materials based on staff members' baseline knowledge and skills (Participants C, M, O). Additionally, some participants incorporated *institutional financial capacity* and *institutional resources* by setting cost requirements (Participants B, F, H, O) and functional requirements (Participant G). Participants also incorporated considerations of the *indoor environment* by including features to improve usability (Participants A, B, F), for example, designing a screen readable in the dark since the lights were often off within a specific room in the hospital. Notably, most participants incorporated factors related to *existing practices and procedures*, for example, designing their product to function within an institution's available storage and cleaning procedures (Participants F, I, K, M).

4.1.4. Industrial contextual factors

Industrial contextual factors referred to the broader technical enterprises that are required for the artifact's performance and operability within its intended context of use, such as those relating to supply chain and manufacturing. Many participants incorporated *maintenance* considerations either by reducing the need for maintenance, for example, making it more durable or using fewer components (Participants A, D, F, H, M, N) or developing a local maintenance program or line of communication for eventual service (Participants F, N). Nearly all participants incorporated *supply and manufacturing* considerations, for example, as it related to eventual implementation within a particular context. For example, participants made detailed design changes based on available manufacturing capabilities and

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materials (Participants C, D, L, N). Participants also changed their product size, weight, and packaging based on accessible *distribution* methods (Participants A, B, C). While some participants described that industrial contextual factors could be incorporated during later implementation stages, many participants provided examples of industrial factors influencing their detailed design decisions, for example:

> "I mean, obviously we had to completely iterate… Find aspects of the physical design to make it more manufacturable: what dimensions we have, what tolerances we have… turns out that we had dependence on a specific industrial process [that wasn't available to us]." – Participant C.

4.1.5. Technological contextual factors

Technological contextual factors referred to aspects that directly affected a product's performance, including its adequate operability and functionality within its intended context. Most participants emphasized the importance of being *compatible with the technical context* by designing product features to integrate existing and available technology in the intended context, such as mechanical compatibility and digital and physical interoperability. For example, Participant J described, "there's no way we're going to use iPhones – it had to be Android, because that was the standard here" and Participant M claimed, "[it's] important that you do have the right cables and the plugs, so it will fit right."

Nearly all participants incorporated *available technologies in the context* into their design processes, for example, setting performance requirements (Participants A, D, E, G, H, N) and making design choices such that users in the target context would be familiar with primary features and interfaces (Participants A, F, M, O). Additionally, participants stressed the *availability of consumables* during their design processes and many included spare parts in their final product or reduced components to minimize the need for consumables in target contexts where these were limited (Participants A, B, F, G, H, I, K, M).

4.1.6. Infrastructure contextual factors

Infrastructure contextual factors referred to the external factors for functionality and operability within the location-specific built environment, such as availability of water and electricity and quality of roads and transportation services. Participants in this study incorporated a variety of information on local *utilities* into their design processes, such as including features so that fluctuating power input did not damage their products' components (Participants A, G, I). Additionally, participants incorporated *distances* (i.e., time or length) between places and resources, for example, by scoping their target users based on location accessibility (Participants C, O) and specifying specific battery life to accommodate local travel (Participant G). One participant incorporated *attributes of the built environment*, making a detailed design choice based on the most common type of door handle within the intended context (Participant H). Participants also incorporated *transportation and road quality* into their design processes by making detailed design choices so that users could carry their product on common transportation modalities (Participants G, K, M). For example, one participant described:

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> "And of course, transport on these roads involves a lot of shaking and bumping, so everything needs to be tested for that, which we do. We have these bumper machines there to really shake products to make sure that they can endure it." – Participant M.

4.1.7. Public health contextual factors

Public health contextual factors referred to local health status and health outcomes of specific groups of people, as well as organized local efforts to prolong life, promote health, and prevent disease. Many participants incorporated local *health demographics* by making detailed design decisions to accommodate average sizes, for example (Participants B, J, N). Additionally, most participants incorporated factors related to the local *healthcare system and practices* primarily when determining their target users and market. Participants stressed how different health systems, for example, rural versus urban and private versus public, greatly influenced critical decisions throughout their design process. As such, participants often carefully selected their intended use case based on health system factors, for example, Participant F described:

> "I think it matters more which hospitals we're catering to within those contexts… when we tried to cater to both [rural and urban health systems] we were in a bit of a deadlock." – Participant F.

4.1.8. Environmental contextual factors

Environmental contextual factors referred to the external conditions that affected the functionality and operability of the product within the location-specific natural environment, such as local humidity and temperature of the artifact's context of use. Most participants incorporated local *weather* into their design process, primarily by selecting materials that withstood local temperature, humidity, and rainfall (Participants A, B, C, D, F, G, H, I, K, L, M, N, O). Some participants also incorporated *natural environment* factors, for example, including protection from high levels of dust (Participants I, J, N) and installing additional filters to accommodate high mineral levels (Participant M). As an example, Participant I described their process for incorporating the environmental context:

> "[To incorporate] environmental constraints…we really focus on temperature, humidity, power limitations, and then dust getting inside devices and breaking them down, which I think is often overlooked for reasons that I guess medical device design, you're kind of thinking that it's going to be in a clean sterilized place. Whereas if there's no screens on windows or a lot of hospital rooms will be open air or even clinical rooms where doctors are seeing patients will be open to the air. So I think designing for that extra element that weather is going to get in there. But we really work to keep dust out [of our product]." – Participant I.

4.1.9. Economic contextual factors

Economic contextual factors referred to aspects of context-specific economic capacity, structures and individual and household attributes. Most participants specified cost requirements based on either the income level of *individuals and households* (Participants C, D, H, J, L, N, O) or *national and regional characteristics* (Participants B, F, K, M). To incorporate these factors, participants sometimes

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chose to make their medical device reusable (Participant B) and developed pricing strategies for implementation in different countries, that is, different prices in different contexts (Participants F, M). Additionally, a few participants incorporated local *labor market characteristics* into their decisions for manufacturing (Participants A, D, M). Overall, participants stressed the importance of identifying the appropriate costs for their particular contexts, since costs eventually informed other key design decisions; one participant described this concept:

> "[Economic factors are] a huge driver behind the design and every aspect of the design, why we originally didn't go with [higher-end feature] because those cost more. So it's balancing those competing requirements again and finding a price point that appeals to the end user." – Participant D.

4.2. How participants incorporated contextual factors during design

We identified that participants conducted a series of steps that involved building and maintaining relationships with stakeholders to collect and identify relevant contextual information to incorporate in their design process. We found that participants were heavily focused on identifying a match between their design outcomes and target context, and they were willing to keep adjusting the target context until they identified a good match. During early project scoping, participants identified contextual goals and context-specific requirements. Once a project was underway, participants incorporated contextual factors into their physical and digital product features as much as they felt was possible; almost half of the identified contextual factors were coded under "conceptual, embodiment and detailed design." When a participant felt that they could not modify the design to accommodate a contextual factor, they either rescoped the problem (e.g., narrowing the target market) or developed supplemental solutions to support implementation or sustained use (e.g., training materials or workshops). All 351 identified contextual factors were discretely categorized into these three primary design activities, as shown in Table 8.

We found that experienced designers incorporated relevant contextual factors in one of four ways: (A) considering the contextual factor as not applicable, (B) narrowing and refining their target context(s), (C) incorporating contextual factors into product features or (D) incorporating contextual factors into decisions outside of their product, for example, implementation, maintenance and training. The incorporation did not happen in a linear fashion (i.e., B then C then D); rather, as our participants stepped through their design processes, they incorporated relevant contextual factors as they became evident; we have characterized this process in the following descriptive model (Figure 1). This section breaks down the various stages our research uncovered (1–4) and incorporation strategies (A–D), as shown in the figure.

4.2.1. Participants identified target context(s)

At the earliest stages, participants determined what context(s) they planned to implement their products in based on company priorities, existing partnerships, global health priorities, and many other project-specific factors. Designers in smaller organizations had more influence with respect to deciding the target contexts, while in larger

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Table 8. Results of contextual factors coded into key design activities

Design activities	Counts	% of total
Establishing a need and analysis of task	77	22%
Conceptual, embodiment and detailed design	161	46%
Implementation, use and closeout	113	32%

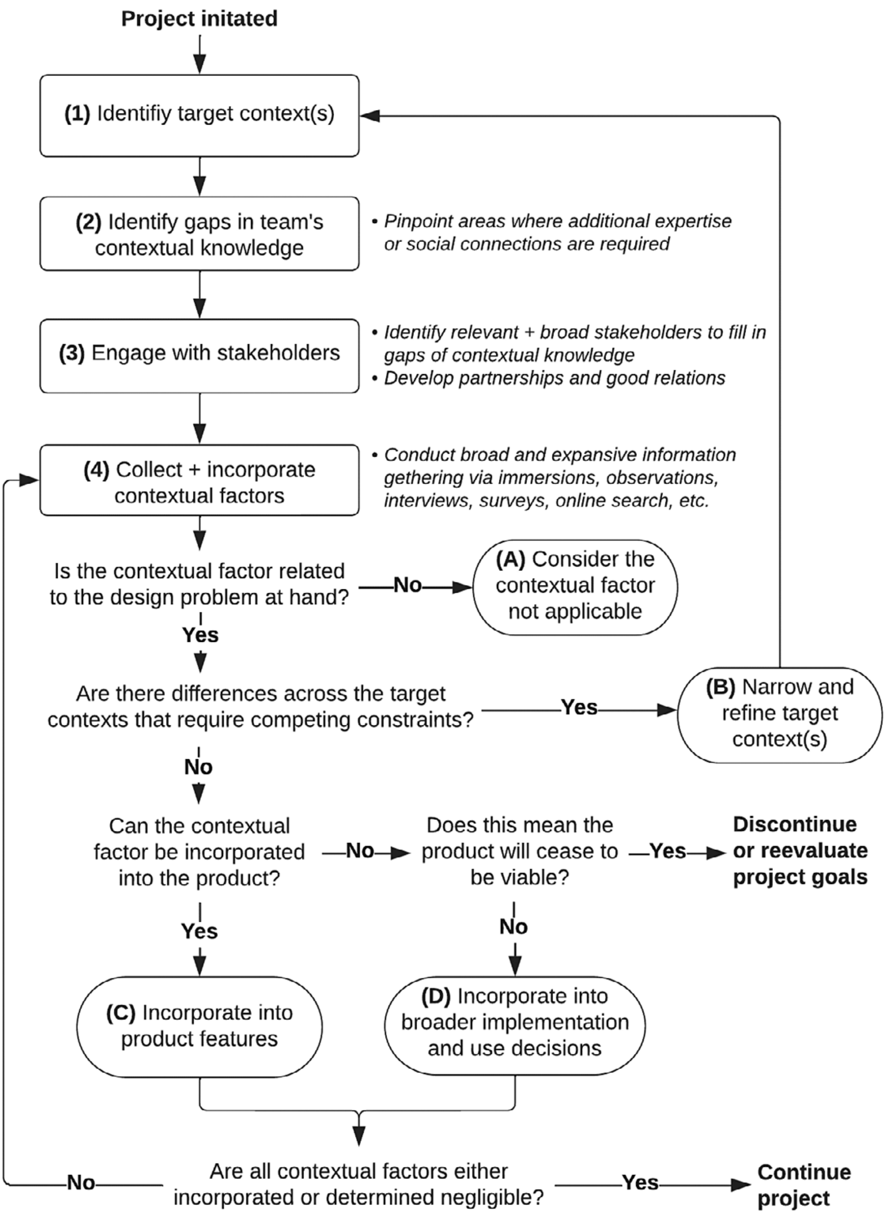

Figure 1. A descriptive model representing participants' approaches for incorporating contextual factors into their engineering design processes.

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companies, the target contexts were often determined by other groups within the company. A key consideration participants made was whether to aim for a single context (e.g., a specific market in sub-Saharan Africa) or consider a broader application (e.g., multiple markets in sub-Saharan Africa and South Asia).

Designing for multiple contexts. Six participants (Participants A, B, F, G, I, M) initially sought to design a solution that could address a global health issue across multiple contexts. As they began their research, they relied on data from multiple contexts, comparing information from different counties. For example, Participant A described their team collecting contextual data from at least eight countries across Latin America, sub-Saharan Africa and Southeast Asia. These participants relied on multiple partnerships in different countries, showcasing a strong awareness of the differences across the contexts. Participant F described:

> "It's always important when you're developing to take into account multiple different contexts and making sure that what you're building works for all of them. Or, understanding which ones you're building for specifically. [You can't] look at one low resource context and expect the same in other contexts." – Participant F.

Designing for a single context. Most participants (Participants C, D, E, H, J, K, L, N, O) originally aimed to develop a solution for a specific context (e.g., one country or region). These participants focused their attention on one context and only a few mentioned that transferability to other contexts was something they would consider investigating later if they chose to expand to additional markets. However, many participants still investigated similar problems and solutions in other regions to learn from their solutions and identify design considerations that may translate to their own context. For example, during problem scoping, Participant C investigated solutions used in other parts of the world, but due to the localized stigmatized nature of the public health concern they were working with, they chose to frame to focus on privacy of the patient:

> "There's a trend in some other locations [that we] dismissed…I mean, good luck convincing a traditional household, especially a [religion] household, to take videos of women swallowing medication for a stigmatized disease and then sending it in. Some of those ideas are non-starters in [this] context, even though they're fiercely championed by physicians in other places. We've been privy to some of those conversations on alternatives." – Participant C.

In another example, Participant J investigated if a device that was originally designed for use in Southern Asia could be implemented in sub-Saharan Africa. She described her process comparing differences across the contexts:

> "There were lots of difference in context between [Asian country] and [African country] that did not directly transfer over. There were lots of design changes that we were trying to make, and it was difficult." – Participant J.

4.2.2. Participants identified gaps in teams' contextual knowledge

As participants stepped through their design processes, they acknowledged and identified gaps in their individual and team knowledge of the target context(s) (Figure 1: "(2) Identify gaps in teams' contextual knowledge"). Participants stressed that all the identified contextual factor categories had the potential to influence their design processes. For example, participants claimed:

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> "It's hard to prioritize any [contextual factors] over the others…[some designers] end up designing themselves into problems because they don't know the other contexts." – Participant A.

> "I think it is important to have the wider picture…Gosh, all of these things are important to consider for the overall success of implementing a device." – Participant I.

As such, throughout all design activities, participants displayed a perpetual consciousness of contextual factors, and importantly, sought additional resources, primarily through stakeholder feedback, when they identified gaps in their knowledge or understanding of specific factors. For example, one participant described:

> "I don't think one person can sort of know all this. So you have to find your experts." – Participant G.

4.2.3. Participants engaged with stakeholders

To identify and incorporate contextual factors, participants relied on partnerships with individuals and institutions within the intended context of use (Figure 1: "(3) Engage with stakeholders"). Participants B, D and E highlighted the importance of partnerships:

> "I think the fact that it was co-developed with a [African country] team for their own use, adds to our confidence [in the product]." – Participant B.

> "Operating internationally means that unless you move and relocate there, you're going to have to rely on some partners or have boots on the ground and are familiar with the area." – Participant D.

> "So thinking about the bigger picture on the problem that you're trying to solve again, it kind of goes back to this kind of things like the institutional, the economic, the political reasons that you just can't solve. Not with just one solution. That takes partnership." – Participant E.

In addition to formal partnerships, participants conferred with a broad set of stakeholders throughout all stages of their design processes, to collect their contextual knowledge and experiences:

> "Early on you just need to have stakeholders, right? You need to have individuals who are going to be there with you through the whole process, who are willing to be patient, who will give you feedback along the way. And that will bring along a lot of the social, cultural, institutional, public health stuff." – Participant G.

> "We did our best to engage with each of those [stakeholders] as we could…doing our best to leverage all those connections and experts to apply the ideas across context. That's been a very active outreach that we've had." – Participant C.

Engagement with stakeholders occurred throughout participants' design processes. Participants brought prototypes to their stakeholders as a way to test their assumptions specifically related to their design's suitability in the context of use. Many participants highlighted the role that prototypes played in getting more detailed contextual information from their stakeholders:

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> "When we actually had [prototypes] that folks could react to, that's really when the conversations got real… [We'd been] hearing and seeing how things are done today, but then here, we have this assumption around what a solution could be [in this context]. How do we now learn whether an assumption is true or not? Well, you got to have them react to something." – Participant E.

> "We brought super early prototypes, like markup models there first, and so they could evaluate them. And then they came here and looked at some that we had developed further based on what we had learned from them." – Participant L.

Many participants described the role their position and power played in investigating and incorporating contextual information, providing them access to individuals and institutions. Participants described their process observing and collecting relevant data while also taking steps to be considerate:

> "There's still a resistance to somebody coming in and telling them that, 'Hey, you could be doing this differently. You could be doing it better.' So I really wanted to be sensitive of that. And being [the same race as the people I'm working with], nevertheless doesn't grant me any leniency in that regard. I'm still viewed as an outsider. As soon as I opened my mouth and my accent, it's evident. They're like, 'Oh, you're not from here, so you don't understand.'" – Participant D.

4.2.4. Participants identified and incorporated contextual factors

Relying on their partnerships and stakeholders, participants primarily identified relevant contextual information through observations, interviews and conversations, pilot studies and surveys (Figure 1: "(4) Collect and incorporate contextual factors"). Often, participants stressed the importance of spending time in the context of use to observe:

> "These are the things that we wouldn't notice if we didn't [observe]…It's really hard to learn any of these lessons without going there and being with the people." – Participant A.

To a lesser extent, designers cited secondary research, such as benchmarking existing solutions. For example, Participant E conducted a historical analysis of similar technologies in other contexts to determine factors for their success. Participant K described his process for benchmarking technologies in their specific context:

> "We were trying to find out, like a literature review, for what others have done in terms of how they came up with the function of the device. So basically we are just trying to maybe look for similarities and the methods which they used in terms of designing a device…So we were trying to make something which is simple as well as cheap, but without compromising the functionality." – Participant K.

None of our participants described using a formal methodology to collect and categorize contextual information; rather, participants described how they used observations and conversations to develop their "design intuition," that is, their ability to make intuitive decisions about what would work or not work in the context. Participant C described this phenomenon in detail:

> "The benefit of those immersions…it's less a report that you could synthesize in terms of things you observe and more an intuition that you gain and an ability to reject other

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hypotheses and ideas that people bring…an ability to see an idea and then say, "Oh, that'll never work because of X, Y, Z thing," even if they've never written it down. I feel that the design intuition is the strongest outcome of a lot of those immersions and [pilot] studies." – Participant C.

While other participants expressed similar sentiments as Participant C, some described feeling a tension when identifying and incorporating contextual factors due to their more subjective and non-quantifiable nature. For example, Participant J described:

"I feel a lot of things I brought up were not necessarily concrete changes I was able to implement, but it was so much about assessing the context and then figuring out, "Okay, these are the potential paths I could take, or these are the potential paths that I absolutely should not be taking." So it was a lot of pitting factors against each other and it's really difficult to quantify it and to make that judgment call, which I think, which to me as an engineer, I wish I had a quantified method of doing this, but I don't." – *Participant J.*

As participants identified relevant contextual factors, sometimes they made very quick and intuitive decisions for how to incorporate them into design features; other times they were more systematic with their reasoning, stepping through the analytical questions presented below in Figure 1 in a methodological manner. By coding each incorporation as either: "identifying a need and analyzing the task," "conceptual, detailed, and embodiment design," or "implementation and use," we were able to identify the primary ways that participants incorporated contextual factors, and added an incorporation when the participant provided rational that a contextual factor was not applicable. These types of incorporation (Figure 1: Incorporations A–D) are described below. If all relevant contextual factors were accounted for in these ways, then the designers moved forward with the project. On the other hand, if participants were unable to fully account for relevant contextual factors and incorporate them in these ways, designers did not hesitate to discontinue or reevaluate the overall goals of the project:

Incorporation A – Identified the contextual factor was not applicable: Participants evaluated contextual factors based on their applicability to their design problem at hand, and would ignore contextual information if they determined it was negligible. For example, Participant B acknowledged that availability of maintenance would typically be a significant factor in their intended context of use, however, for her specific project it was not necessary to consider since the product was intended to be thrown out once it was used.
Incorporation B – Refined and narrowed the target context: If the contextual factors across multiple contexts led to competing constraints, i.e., the realization that a universal design decision would not accommodate both contexts, then participants narrowed their target context(s). For example, Participants A and F described their rationale for refining their target context and choosing between implementation in urban or rural contexts, due to critical differences between socio-cultural, infrastructure, and public health contexts.
Incorporation C – Incorporated into product features: Participants aimed to incorporate most contextual factors into product features; such that the product would be as contextually-suitable as possible. Along with many other examples, participants selected parts based on locally-available materials, created features

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that were compatible with local technology, and designed their solutions to physically fit in available storage and be compatible with local transportation.

Incorporation D – Incorporated into broader implementation and use decisions: If contextual factors could not be easily incorporated into product features, participants integrated relevant information into decisions surrounding the product's use and implementation, e.g., they developed communication plans, maintenance procedures, and training programs. Participants from the U.S. and Europe especially emphasized their development of "lines of communication" with their partners and end users so that they could collect and navigate issues that arose from working across contexts. For example, Participant G described using an instant messaging platform to answer questions and receive updates and Participant N described working closely with those with higher levels of education to help reduce stigma related to the overarching health concern.

Discontinued or reevaluated overall project goals: Participants were conscious when their solutions did not meet the problem in their target context, and were not afraid to stop their projects when this was realized. In many cases, participants were attentive to situations in which their solutions would not be appropriate in a given context, such as Participant C describing, "there are lots of cases where it either can't or shouldn't be used." Moreover, some participants described fully terminating the project altogether. For example, Participant E described his detailed contextual analysis of market characteristics, including a variety of economic, political, and socio-cultural factors, which ultimately led to his decision to discontinue the project due to a lack of market viability. Another participant, described a problem framing they ultimately did not pursue because they did not feel an engineering solution would be suitable:

> "People would push us to work on [the broader public health problem], the root causes…and the challenge with that is it's a drug accessibility problem, and it's an education problem, [etc.] and it didn't really fit our skillset very well. So we were aware of that." – Participant A.

Continued project: When participants determined that they had sufficiently incorporated relevant contextual factors into their target scope, product features, and implementation decisions, they were comfortable with moving forward to product launching.

5. Discussion

This work asked the questions: (1) *What contextual factors do experienced global health designers incorporate into their design processes?* and (2) *How do experienced global health designers identify and incorporate contextual factors during their design processes?* To address our first question, we categorized the contextual factors that participants reported incorporating into their design processes and identified 32 categories presented in Table 7 and the Supplemental Material. To address our second question, we developed a descriptive model representing how participants approached incorporating contextual factors into their design processes (Figure 1). Our analysis uncovered a variety of themes regarding *what* contextual factors participants incorporated and *how* they went about doing so.

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5.1. Context is thoroughly considered throughout design processes

Although none described using a formal or named methodology for incorporating contextual factors, participants stressed the importance of incorporating contextual factors into their design processes, and they displayed an inherent and holistic perception of context, aiming to develop a "contextual intuition," with the ultimate goal of producing a product that was tailored to their intended use context. Our findings build on literature that suggests intuition is a key characteristic of experienced product designers (Otto & Wood 2001; Cross 2021); however, designer intuition related to incorporating contextual factors has been minimally studied (Björklund 2013). In an effort to characterize this intuition, we presented a descriptive model (Figure 1) that describes how participants became aware of contextual factors, evaluated their relevance and incorporated them into their design processes.

Participants conveyed that potentially any contextual factor could impact their design processes and eventual product outcomes. With this mindset, participants investigated context nearly continuously as they completed various design tasks from start to finish, seeking information and perspectives from partners and stakeholders throughout. Participants examined each piece of information and considered each contextual factor as relevant until proven otherwise. Overall, participants were deeply invested in understanding all aspects of context, were very attuned to contextual factors that they determined to be relevant to their design, and rarely (if ever) assumed that a contextual factor that affected the design could be ignored. Sometimes participants made conscious tradeoffs, but they rarely ignored an impinging contextual factor.

Participants stressed the importance of regularly engaging within the use context throughout their design process through observational research, interviews, and conversations. Although secondary research is highly recommended in design textbooks to identify important design considerations (Otto & Wood 2001; Dieter & Schmidt 2009), participants emphasized secondary research much less than collection of primary data, and, it appears that contextual information primarily emerged from partnerships, stakeholders, and observations versus from their secondary research. Notably, our study revealed a common strategy in which participants brought prototypes into the target context(s) to elicit additional contextual factors while also testing out their assumptions regarding what would work in the context or not. This finding aligned with prior research suggesting that engaging stakeholders with prototypes in the use context can elicit critical design information (Coulentianos *et al.* 2020*a*,*b*; Rodriguez-Calero *et al.* 2020; Coulentianos *et al.* 2022; Rodríguez-Calero *et al.* 2023), and adds that it specifically enabled design practitioners to become aware of more specific and nuanced contextual factors related to their solutions that they did not identify during earlier design stages.

While it is clear that participants preferred to incorporate contextual factors directly into their design features (because this practice ultimately made the product more contextually suitable), they were willing to consider other options for incorporation, for example, refining problem scope or considering factors during implementation, and they considered these types of incorporations as part of their role as a product designer.

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5.2. Going beyond traditional methods and focuses

Participants went beyond the traditional focuses of engineering design to understand and incorporate contextual factors; not only did participants iterate the design of their product, but they also reframed their target use context. Participants were also willing to terminate a project when they felt like it was too much of a mismatch in their intended context. Additionally, experienced designers spent considerable time learning and navigating aspects of the political context, applying what they learned to their engagements with stakeholders. Notably, experienced designers incorporated contextual factors not only into their product design, but also into broader implementation and use decisions.

5.2.1. Iteration and termination

Participants rescoped their problems very often, whenever new contextual information or constraints required it. If they were unable to incorporate diverging contexts into their design features (e.g., realizing that a universal device would not succeed across the different contexts), they chose which context to target (e.g., scoping for urban vs. rural hospitals, access to electricity vs. no access). Not only were participants willing to narrow their scope, but they were also willing to give up a project altogether. In engineering design literature, iteration, including problem reframing, is routinely cited as a critical attribute of experienced engineers' design processes (Adams *et al.* 2011; Paton & Dorst 2011; C. J. Atman 2019) and participants in this study displayed both a willingness and aptitude to consciously reframe their design problem with a goal to find a match between their design problem and the solution use context. Some engineering textbooks mention a designer's judgment for termination as an important skill (Pahl *et al.* 2007), but fail to provide guidance for developing this judgment or evaluating when a project should be terminated. Our findings suggest that a misalignment between the problem scope and contextual factors is one reason to terminate a design project. When participants were unable to incorporate relevant contextual factors effectively in one of the three ways identified in this study (Incorporation B, C or D in Figure 1), they were confronted by too many obstacles, leading them to abandon their project within that use context or reevaluate the project's overall goals.

Some of our participants displayed attributes of what scholars call an "activist engineer," which is defined as someone who steps back from their work and reflects on the questions: "What is the real problem and does this problem *require* an engineering intervention?" (Karwat *et al.* 2015). In our study, participants regularly rescoped and reframed their target use context, taking the time to consider the effects broader contextual factors had on their design processes. As previously mentioned, when there was a misalignment between contextual factors and the design problem, participants acknowledged that an engineering solution would be inappropriate to continue to pursue. Our work builds on existing literature, suggesting that solving complex problems, like those in the field of global health, require responsible problem framing (Riley 2012), deep individual reflection (Karwat 2020), systems thinking (Lönngren & Svanström 2016) and attention to broader sociotechnical considerations (Mazzurco & Daniel 2020).

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5.2.2. *Goals, duration and politics of stakeholder engagement*

Experienced design practitioners determined which individuals or organizations were knowledgeable about a specific context, could provide necessary political support and information, and could provide them with access to potential end users or additional hard-to-reach stakeholders. Historically, design engineering texts primarily suggest involving two types of stakeholders: (1) customers making the purchase and (2) end users (Otto & Wood 2001; Dieter & Schmidt 2009; Zeiler 2017). In the medical device design literature, recommendations expand to stakeholders throughout the "cycle of care," for example, patients, physicians, nurses and other representatives in the healthcare system (Denend *et al.* 2010). However, these recommendations present a narrow view of "stakeholder" compared to what recent scholarship suggests (Coulentianos *et al.* 2022) and what participants exhibited in this study, which was an aim for a holistic view of the individuals, organizations and technical experts surrounding their design issue and solution space in their intended use context.

Effective engagement with stakeholders requires good relations and rapport. Our study revealed the importance of managing multiple stakeholder relationships throughout a design process to allow for relevant contextual information to surface. Most participants considered their individual identity and power when engaging in partnerships, building relationships with stakeholders, and entering physical spaces, aiming to respectfully assimilate and collect applicable information. These findings echo what many science and technology studies scholars point out – that engineering design processes and outcomes are *social* and depend on distribution of power and resources within a society (Nieusma & Riley 2010; Wajcman 2010; Costanza-Chock 2020).

To engage with stakeholders, experienced designers cultivated a variety of partnerships; and did so across a spectrum of formality. On one end, participants developed formal partnerships with individuals or institutions to co-design and co-develop their products. On the other hand, participants invested in rapport building with knowledgeable stakeholders (e.g., potential end users, political stakeholders, contextual experts), engaging with stakeholders in ways that were expected and appropriate for the scenario. Partnerships are commonly referenced in engineering design literature, especially for gaining access to end users for data collection and manufacturers for implementation decisions (Dieter & Schmidt 2009). However, our study revealed that participants did not solely rely on partnerships for "logistics" but also to learn tacit contextual "rules" within the existing cultural and institutional systems, while developing social and political rapport. The ways our participants described their relationships and partnerships appeared to be a more nuanced combination of what scholars refer to as "strategic partnerships, network ties and alliances" (Fernandes *et al.* 2022).

5.2.3. *Integrating implementation into design processes*

Experienced designers think beyond the designed product and incorporate contextual factors into implementation, maintenance processes and training. Traditional engineering approaches, such as design for manufacturing, focus on minimizing part count and selecting manufacturing processes, for example, wall thickness and angles of molds (Otto & Wood 2001). However, participants expanded their analyses to include broader considerations regarding implementation and use.

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Importantly, participants perceived implementation and use considerations as a key part of their decision-making throughout their design processes, rather than something that can be ignored until the end. While traditional engineering design education tends to focus narrowly on the product, our findings suggest that in practice, design practitioners have many opportunities to incorporate critical contextual factors by considering their implementation, maintenance and training strategies throughout their design processes.

5.3. Areas of future work

This exploratory work identified several avenues for deeper investigation. First, this work included a diverse pool of participants from a variety of geographic locations, educational backgrounds, organizational structures and sizes, years of experience and other personal attributes, such as race, gender and age. Expanding the scope of study to include a larger sample could provide a richer understanding of how the variations in approaches to incorporating contextual factors differ across industries, organizational contexts and designer positionality. Since knowledge and insights accumulate with time, participant age and experience level likely influence their practices and behavior related to incorporating contextual factors. Future work could evaluate how different experiences and knowledge across one or more contexts influence a designer's ability to incorporate contextual factors during design processes. Prior work has shown that individuals on teams draw attention to contexts differently (Borgford-Parnell *et al.* 2013) and these dynamics should be studied further. Specifically, different organizations will have decision-making structures that likely influence the types of decisions designers can make (e.g., whether a team can decide to pursue a new idea or terminate an ongoing project).

Future work should also investigate the effectiveness of the identified strategies and approaches for facilitating the integration of contextual factors into design processes across different design domains and engineering sectors. Overall, these future research directions have the potential to deepen our understanding of how contextual factors shape engineering design processes and to inform the development of strategies for supporting more contextually informed design practices.

5.4. Limitations

Design practitioners in our study likely did not recall every instance of information incorporated into their design processes, and we also did not analyze contextual factors that participants evaluated but did not make a conscious decision to incorporate. Additionally, our purposeful sampling method presumably attracted highly engaged designers and contextually attentive design practices; our sample likely omitted less engaged designers and examples of poor context inclusion. Also, we did not attempt to assess the quality of the participants' selected projects, so our analysis does not explicitly link contextual factors with any markers of design quality. Importantly, our study assumes that years of experience represents an ability to do "good design," since experience accrued over time likely develops the skills, insights and judgment necessary for producing high-quality design outcomes.

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6. Implications

Our findings highlight how global health design practitioners incorporated contextual factors throughout their design processes in four ways: reframing the problem, adjusting the product, integrating into implementation decisions or determining not applicable. Throughout their design processes, participants actively sought contextual information and made conscious decisions to adjust their solutions to accommodate contextual factors. Their processes did not appear linearly; rather, the processes were determined based on what information emerged throughout their design tasks – design practitioners incorporated contextual factors as they became aware of them, regardless of the which stage they were in during their design process. Our resulting descriptive model (Figure 1) and taxonomy of contextual factors (Table 7 and Supplementary Material) can be used by practicing and novice designers to incorporate more contextual considerations into their design processes.

Participants learned about relevant contextual factors largely through primary research, including in-person immersions, stakeholder engagements and partnerships with individuals and institutions in the use context. While some recommendations from engineering design literature suggest involving stakeholders to determine a broader understanding of the context of use, these mainly focus on early-stage problem definition activities (Gause & Weinberg 1989; Borgford-Parnell *et al.* 2013; Jagtap 2021). However, our findings showed that experienced designers engaged with their stakeholders regularly throughout their design processes, and were always willing to collect and integrate new relevant information concerning their intended context into their design processes. Our findings revealed that many contextual factors were identified during the middle phases of design processes, for example, when initial concepts were introduced to stakeholders or when detailed design decisions were being made. As such, we recommend regular engagement with broad stakeholders and readiness to collect and incorporate additional relevant contextual factors throughout the full duration of design processes.

7. Conclusion

Although tailoring products to specific use contexts is a well-known attribute of engineering design, studies have thus far not investigated experienced engineering design practice with respect to the types of contextual factors incorporated or the processes used by experienced designers. Our results build on existing contextual factor categorization (Aranda-Jan *et al.* 2016; Burleson *et al.* 2023) to present a more detailed list of 32 secondary subcategories within nine primary categories. Moreover, we present a descriptive model that captures participants' approaches for incorporating contextual factors throughout their design processes, which can be used by both novices and professionals to expand their contextual considerations. We recommend that engineering designers fully consider all categories to determine if contextual factors are applicable to their design project. We suggest that to improve incorporation of contextual factors during engineering design processes, particularly within global health settings, engineering designers should develop strong relationships with a broad set of stakeholders in the use context, not just end-users, and regularly conduct engagements. Designers should remain open

https://doi.org/10.1017/dsj.2024.28 Published online by Cambridge University Press

to new contextual information as it arises, and address each consideration with intention to incorporate appropriately into their design process. Ultimately, these findings expand our conceptualization of context in design and can be applied by practicing and novice engineers.

Supplementary material

The supplementary material for this article can be found at http://doi.org/10.1017/dsj.2024.28.

Acknowledgements

We thank the engineering designers who participated in this study. We also thank Laura Murphy and Nick Moses for their participation during interview protocol pilot sessions. We acknowledge the University of Michigan Design Science Program, Department of Mechanical Engineering, School of Information, and Rackham Graduate School for their support of this study.

Financial support

This material is based upon work supported by the National Science Foundation under Grant No. 2201981; Funder ID: 10.13039/501100001809 (https://doi.org/10.13039/501100001809). Additional financial support was provided by the University of Michigan Center for Global Health Equity.

Competing interest

The authors declare none.

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