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Innovators' views on involving users and patients in surgical device development: a qualitative interview study

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Abstract

Objectives: Involving end-users and patients in the development of surgical devices, even when patients are not end-users, is deemed important in policy and in academia since it could improve strategic choices in research and development (R&D). Nonetheless, research into innovators' views on end-user and patient involvement is rare. This study explores what end-users and patients are being involved by innovators during development, what methods for involvement are being used, and what topics are being discussed with these end-users and patients.

Design: A qualitative study featuring semi-structured interviews with innovators of surgical devices. Interviews were recorded and a thematic analysis was performed on verbatim transcripts.

Participants: 15 interviews were conducted with 19 innovators of 14 surgical devices.

Setting: Innovation practices of surgical devices in the Netherlands and Belgium.

Results: End-users were engaged in R&D with formal methods and in unsystematic ways. These users all work in the clinical domain, e.g., as surgeons or nurses. The innovators engaged users to analyse problems for which a device could be a solution, define functionalities, make design choices, analyse usability, ensure safety, and improve aesthetics. Patients were rarely involved. Innovators stated that patients are not considered to be end-users, that physicians can represent patient interests, and that involving patients is unethical as false expectations could be raised.

Conclusion: Innovators involve end-users with methods and unsystematic ways in the development of surgical devices. Despite governmental calls for patient involvement in the development of medical devices and surgical devices, innovators do not generally involve patients.

ARTICLE SUMMARY

Strengths and limitations of this study

- Despite ample research on user and patient involvement in the development of medical devices, this is the first study to explore innovators' views on how end-users and patients are being involved in the development of surgical devices.
- This is also the first study to explore innovators' views on the role of patients in the development of surgical devices, when patients are not end-users, but do experience potentially far-reaching impacts on their lives because of these innovations.
- The qualitative research design with open-ended interviews allowed for a detailed exploration of innovators' views without a theoretical predisposition.
- Purposive sampling led to a selection of surgical devices that was varied in terms of complexity, impact on workflow, impact on clinical outcomes, safety issues, and impact on patients' lives, thus increasing the transferability of the results.
- Some interviewees were familiar with the research project, which might have led to a social-desirability bias in interviews. By probing into experiences rather than opinions and asking for concrete examples this bias was minimised.

1. INTRODUCTION

Involving end-users and patients in the development of medical devices is regarded as one of the cornerstones of a sound innovation practice.[1–5] It should increase the probability that devices meet proper clinical goals[6,7], comply with technically standards[8], are cost-effective[7], and meet ethical norms.[8,9] However, the theoretical foundation of

end-user and patient involvement is fragmented and sometimes incongruent[10], leaving important choices open for debate.

First, it is debated *who* should be involved. Many argue that only end-users should participate in development.[2,5] The ISO norm on user-centred design leaves it up to designers to choose whether only end-users or a broader range of stakeholders that experience the effects of a device should be involved in development.[2] Others argue that patients should always be involved in device development, even when clinicians are the end-users and patients are not.[1,4,9,11,12] This is primarily so, they maintain, because patients may have different preferences compared to clinicians: studies have found that patients prefer less invasive treatments, shorter recovery periods, a longer lifespan of devices, and more safety precautions.[11,13] These findings suggest that if patients are not being included in consultations, their functional requirements might not be taken into account in R&D. Second, it is also unclear which participatory *methods* are most suitable. Within user-centred design, multiple methods like interviewing, observation, and questionnaires are employed.[14] There are, nevertheless, no guidelines that explain which methods should be used in different developmental stages.[10] Third, opinions differ as to what *topics* are to be discussed with end-user and patients during development. Some argue that they should be involved to identify needs, others would maintain that they are to unravel problems, make design choices, or make contributions to research.[9,10]

This study is focussed on surgical devices, i.e. devices that are used to perform or support surgical procedures an operation room (OR). This helps to explore how innovators prefer to involve patients when they are not end-users.

Manufacturers, engineers and other actors designing novel or improved surgical devices (henceforth: innovators) primarily decide how stakeholders are involved. They also have direct experience with the innovation practice, and so their motivations for involving end-users and patients are invaluable for further general work on stakeholder involvement. Hence, it is important to explore their vision on end-user and patient involvement, something which, to our knowledge, has been done in only one, rather old study so far.[15]

The following questions are answered: are end-users and patients involved in the development of surgical devices, and if so, which end-users are patients are involved? What methods for involvement are used? And what topics are discussed with end-users and patients?

2. METHODS

Patient and public involvement

This study precedes a larger research project addressing the methodology of stakeholder involvement in the development and evaluation of surgical innovations. Patient involvement forms the topic of the present study, and actual patient engagements are part of future research outputs within this project.

Design

This qualitative study is rooted in a grounded theory methodology.[16] This is characterised by its open nature: data generation started with open questions, so that codes, theme's and theory could be identified inductively.[16,17] Another guiding principle is constant comparison: newly assigned codes and themes are constantly related to former findings, so that similarities, differences, and patterns in the data could be identified.[16] This report is written in

line with the Standards for Reporting Qualitative Research.[18]

Participant selection

Participants were recruited between November 2018 and October 2019. We aimed to include a maximum diversity of surgical innovators, which we had defined as persons working to create new or improved surgical devices with the aim to disseminate these devices.[19] Surgical devices were defined according to the WHO definition of medical devices as 'any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article' to be used in the diagnosis, investigation or treatment of human beings.[20] We have limited our scope to devices that are used to perform or support surgical procedures. This delimitation makes the innovation trajectories of these devices more comparable. The selection of surgical devices is interesting, because patients are not the end-users of surgical devices, yet undergo the procedures. This helps to explore how innovators prefer to involve patients when they are not end-users. In order to increase the transferability of our findings, we attempted to select a diverse set of surgical devices, and a diverse set of participants that worked on different devices.[21] These could range from robotic systems such as the Da Vinci System[22] to simpler devices like novel surgical sutures.[23] These innovations can vary in technical complexity, their impact on the surgical workflow[24], clinical outcomes[25,26], safety issues[26,27], and impact on patients' lives.[26] We also aimed to select devices in various developmental stages, from the first functional prototypes to fully functioning devices that had already received CE marking, because otherwise findings could be biased to devices that had reached certain development stages, or were already met with commercial

success. We selected participants working at small and medium sized enterprises with 1-250 employees[28], as market scans suggests these enterprises make up for about 95 percent of the companies in medical technology in the Netherlands, and 90 percent in Europe.[29,30] Using purposive sampling, respondents were identified by searching websites of conferences of health technologies, via reports on health technologies, and via the network of the researchers.[21] We invited representatives of companies that matched our selection criteria to join our study by e-mail. After data saturation was reached – the point when no new codes are generated in interviews - no new participants were invited to participate.[21]

Data collection

Data were collected via semi-structured interviews. This method is appropriate for open-ended, rich data generation, because open-ended questions can be asked, and more detailed answers can be prompted in a setting where participants feel comfortable.[31] A week before the interview, all interviewees received an information letter and an informed consent form. They were asked to sign the consent form at the beginning of the interview. A topic guide with open questions was created by KW, MT and RR with open-ended questions inquiring what, if any, stakeholders were involved during the development process; and how they were involved. This guide was refined in between interviews to achieve more information on important topics that had emerged.[32] (See the supplemental material). Conversations started with general questions about the innovation trajectory, important development or design decisions, and patients and end-users that where involved. Subsequently, they focussed on how these patients and end-users were involved, and what was discussed. The interviews took place in the offices or workplaces of the interviewees

and lasted 60 to 90 minutes. Interviews were audio-recorded and transcribed verbatim. All interviews were conducted by a trained and experienced qualitative researcher (KW). During three interviews, one other experienced researcher participated (in two instances, this was MT, a female researcher specialised in qualitative research, and in one instance a female PhD-student from the same research group).

Data analysis

The verbatim transcripts were analysed using Atlas.ti software for qualitative data analysis (version 8). Transcripts were read before coding commenced to familiarise with the data.[17] The analysis was performed during and after data collection, so that emerging codes and themes could be incorporated in the interview protocols for more data generation on important themes.[32] The data analysis was performed by the first author (KW), and the codes and themes were discussed with two other researchers (MT and RR) to check whether codes were properly assigned to quotes in the transcripts. During the analysis, codes were grouped into themes. When no new codes were generated a sufficient degree of data saturation was assumed to have been reached.[21] All participants received the first draft of the paper, to allow them to check whether their quotes and the descriptions of their innovation practices had been described properly.[33]

Reflexivity

This research was conducted as part of a larger project that is aimed at developing methods for early health technology assessment, with a strong focus on integration of early modelling approaches and methods of stakeholder participation. The authors of this paper are from the evidence-based surgery group (EBS) based at the Radboudumc in Nijmegen, the Netherlands. This group was known by some interviewees as

proponents of stakeholder involvement in the development and evaluation of surgical devices. In the case of some interviews, this may have led to a social-desirability bias, perhaps yielding an optimistic view on user participation. By prompting and asking for concrete examples during the interviews[34], sampling of diverse cases, and selection of participants unaware of the EBS group, we aimed to account for this possible bias.

3. RESULTS

Respondents

Of the 18 companies that were approached, 14 participated. We held 15 interviews with representatives of these companies: representatives of one company were interviewed twice. During the interviews we focussed on the development trajectory of one device per company. During five interviews two representatives were present, so a total of 19 people were interviewed. Four of these 19 interviewees were female, and all (except one) participant had a Dutch or Belgian nationality. A wide range of devices was included, including mechanical bedside aids, robotics, implantable devices, catheters, and endoscopes. The development stages ranged from proof-of-concept phase to devices already commercially available. As regards the size of the companies, 13 out of 14 enterprises were 'micro' (less than five employees) or 'small' (less than 25 employees).

Table 1 offers a case-by-case overview of the respondents, their functions, as well as information regarding the stakeholders they involved, methods they used to this aim, and the purpose of involving these stakeholders.

Table 1: case-by-case overview of the devices, development stages, profession of interviewees, end-users, method and topics

Case	**Device**	**Development stage**	**Profession interviewees**		**Who is consulted**	**Methods used**[1]	**Topics**
1	Diagnostic device	Proof of concept	1	CEO	Urologists	*Interviews*	Design Usability
			2	Production manager			
2	Mechanical aid (two interviews)	First functional model	3	CEO (joint CEO)	ENT Surgeons	Conversations Feedback congress	Problem structuring Functionality Design
			4	CEO (joint CEO)			
3	Diagnostic device	Used in hospitals	5	Founder and Chief Compliance Officer	Sterilisation department	Conversations Observations	Problem structuring Design Usability Aesthetics
4	Mechanical aid	First functional model	6	CEO	Surgeons with differing specialties	*Interviews*	Design Usability
			7	Founder			
5	Bedside aid	Proof of concept	8	CEO	Neurosurgeons Anaesthesiologists Nurses Students	*Cocreation session* Conversations	Problem structuring Design Usability
			9	CMO			
6	Mechanical aid	Product tested in first hospitals	10	Clinical Field Engineer	Surgeons with differing specialties	*Interviews* Conversations Observations Feedback congress	Problem structuring Design Usability Safety
			11	CTO			
7	Mechanical aid	Product tested in first hospitals	12	CEO	Eye surgeons	*Interviews* *Surveys* Feedback congress Feedback studies Feedback in use Feedback education Observations	Problem structuring Design Usability Functionalities
8	Diagnostic device	First functional models	13	PhD Student	Radiologists	Conversations Observations Feedback congress	Problem structuring Design Functionalities Safety
9	Catheter	Used in hospitals	14	Manager clinical research	Cardiologists Technicians hospital	Conversations Observations Feedback in use	Design Functionalities Safety Usability
10	Diagnostic device	Used in hospitals	15	Founder, CSO	Radiologists	Conversation Observations Feedback in use	Problem structuring Design Functionality Usability Aesthetics
11	Implantable	Concept formulation	16	Intern	ENT Surgeons Students	*Interviews*	Problem structuring Design
12	Implantable	First functional model	17	Market Development Manager	Orthopaedic surgeons	Observations Feedback in use Feedback studies	Design
13	Mechanical aid	Concept formulated	18	Founder, Medical director	Gynaecologists Surgeons with differing specialties Sterilisation department Technicians hospital	*Interviews* Conversations Observations Feedback in use Feedback research Feedback congress	Problem structuring Design
14	Catheter	Concept formulated	19	CEO	Cardiac surgeons	*Interviews* Observations	Problem structuring

					Nurses Students	Conversations	Design

[1]**Formal methods to involve stakeholders are in italics**
Abbreviations: CEO = chief executive officer, CMO = Chief medical officer, CTO = Chief technical officer, CSO = Chief scientific officer, ENT = Ear, nose, and throat

3.1 What end-users and patients are involved?

[Insert figure 1]

Figure 1 presents an overview of all the types of end-users that were involved by innovators in order to inform R&D decisions.

In all cases, clinical end-users were engaged during development. In 13 out of 14 cases the end-users were medical specialists. In nine cases surgeons with varying specialties were engaged. In the development trajectory of six devices other specialists like urologists were involved. In three cases, medical students were consulted alongside medical specialists, because they were seen as potential future end-users. In two cases, employees at the sterilization departments of hospitals were consulted, because these persons clean or test surgical devices.

Consulting patients appeared to be uncommon: there is one example in our study, where consultation was done to familiarise with the severity of the disease, not to inform any R&D choice made by the innovators. Innovators gave three reasons for not involving patients in making R&D choices. First, patients are not seen as end-users, because they do not use the surgical devices in the sense of handling these. One interviewee stated that patients are often seen as 'biomechanical objects':

> 'I think the opinion of the patient is a little bit underappreciated. The patient is seen as a biomechanical object, sometimes. And at times you have to look at it like this, otherwise you cannot do operations. (…) The opinion of the patients is not per definition seen as important in the development trajectory. It is more of an

> endpoint than an input: patient reported outcome measures are seen as important.' [Case 12, Market Development Manager].

A second argument for not involving patients is that physicians are representatives of patients, and therefore innovators do not deem involving patients necessary.

> 'I think that we hope that via physicians, who primarily have patient-contact, can gather information about patients. So, we do not directly consult patients' [Case 11, Intern].

The third reason for not consulting patients is that engaging patients in R&D is perceived as unethical, because it might raise expectations about future health benefits that innovators cannot yet realise.

> 'No. I would not do that. I don't think that is very ethical. Maybe [the device] will not work out at all' [Case 1, Chief Executive Officer (CEO)].

3.2 How are these stakeholders consulted?

[Insert figure 2]

Figure 2 represents an overview of all methods used by innovators for involving end-users and patients.

Unsystematic ways

Informal conversations and observations are the most commonly used ways of gathering information from stakeholders (9/14 cases). Many innovators are health professionals and discuss their ideas with a group of experts in their network. These conversations often took place in the operating room (OR).

> 'On a certain moment you start drawing, and you ask people: what is your opinion? And when people are enthusiastic you think: maybe I have to start requesting a patent' [Case 4, Founder].

Observations are performed by innovators that are trained as engineers (9/14 cases). These are unsystematic ways of observing, without a protocol.

> 'That has always been my policy with my PhD students, that I say: I don't want you to think, I want you to look. Just go to that operation theatre. Watch for ten or twenty operations and don't start thinking.' [Case 2, CEO].

A third unsystematic way of obtaining information was via feedback in use (n=5/14).

> 'Then they call and say: it does not work. Then I say well, what is wrong? And then a piece is skewed. That is only possible if you pulled out the motor. (…) So, now we have ensured that you cannot pull the motor out of the device: there is a screw in it' [Founder, Medical director; Case 13].

Methods

Formal methods were used in eight cases. In seven of these cases systematic interviews were employed.

> From the moment you start developing, is my personal opinion, you have to ask the end-user whether you are on the right track. You have interviews with potential end-users. Multiple, if you want to do it correctly. [Case 4, Founder].'

Besides interviewing, one innovator used surveys to quantify the opinion of surgeons on functionalities and usability of the innovation. Another innovator used cocreation sessions as a means to gather information from nurses and students.

3.3 What topics are addressed?

[Insert figure 3]

Figure 3 presents the six topics that are discussed with end-users consultations: the problem a device should help to solve, functionalities, design choices, usability safety, and aesthetics.

Defining the problem

In 10 out of 14 discussed devices, the healthcare problem for which the surgical device could be a solution was analysed with end-users. When it comes to the relation between the problem and the device development a 'technology push' and a 'problem pull' can be distinguished. Four cases feature a form of technology push: here problems were explored with end-users, a form of the technology was already available, and its application in a new setting was being considered. The six remaining devices where problems were analysed with end-users are examples of problem pull: the problem was analysed with end-users before any form of technology was conceived of. In these cases, healthcare professionals experienced a problem during their work. One interviewee told that moving patients on OR beds was so arduous that employees often walked away, or developed back pain. When problems like these are discussed, innovators map multiple perspectives on a problem.

> 'It is a multifactorial problem. Ranging from ergonomics, hygiene, your operation: so everyone has its own concerns regarding the problem. The fun thing is to bring all these

problems together and face them.' [Case 5, Chief Medical Officer and founder].

In contrast, one example of technology push involved an engineer with an idea for a mechanical aid in the OR that was based on mechanics known in car manufacturing. He had not identified the surgical procedure with the biggest need for such a device. Hence, he interviewed multiple surgeons to identify the procedures where the aid could solve a problem.

Functionalities

Innovators state that they involve stakeholders to specify functionalities, i.e. the essential functions a device should have. Functionalities are often formulated early in the design trajectory and remain stable over this trajectory. In the case of wildly varying quality of endoscopes in the operation theatre, the essential functionality was clear from the start: guaranteeing the quality of endoscopes in terms of light intensity and vision angle. In two cases innovators stated that it is hard to make devices with functionalities that substitute acts of a physician. Where the devices replace physicians, physicians tend not to be enthusiastic.

'What I get confirmed from anyone I speak to, and which I don't like at all, is that new devices are only welcome if the device is an accessory. (…) You have gained prestige by learning this trick, you are good at it, and then I am there with a device that is better than you are, at once. Well, then the surgeon gets depressed' [Case 10, Founder, Chief Scientific Officer].

Designing the device

Under 'design' we group any decision about the shape or physical property of devices. Designing is a broad category,

since the interviewed innovators start thinking about the shape of devices from the onset of development trajectories, and do not stop thinking about design changes. According to the interviewees, the discussed topics change with each design iteration. In an early development stage, innovators ask design feedback in a broad fashion, probing into what general design users would prefer, or whether they think initial sketches are good solutions. As the devices' design becomes more concrete in prototypes or functional models, the questions on design become more specific, too.

Usability

Usability entails making the device functional for the relevant end-users. Innovators described a case of engaging stakeholders for usability where only strong people with big hands were involved. Smaller people, like women or Asian people on average, were not empowered to use the devices during this test phase.

> 'The surgeon used the device for several hours, and after using it he got a tremor in his hands. You need to be quite strong. We have to find a balance between it being usable, and without losing functionality. (…) Such huge guys with huge hands – that differs from a little woman working as a surgeon' [Case 4, CEO].

The quote also illustrates that the innovators thought they had to choose between functionality and usability. At the time of the interview, the innovators faced the dilemma what to prioritise: working on functionality, or on usability so that everyone could use the device. A subset of usability is fitting a device into the workflow of the OR. Interviewees observe the acts in the OR and think about ways in which the

novel device does not distort the practice of all the people involved in the OR.

Safety

Innovators state that they need to ensure that their devices cause no harm. In two examples, innovators had to think about how devices should be designed so that they could be sterilized fast and thoroughly. In another example a device was redesigned because some problems occurred in use in specific cultural contexts.

> 'If you firmly pull [the clip], you panic, it breaks. In Europe it didn't cause problems. But someone in the USA said – yes, I can break it! Sharp pieces… (…). Well, then we make a breakage prevention piece. (…) We build something for safety, for a completely futile problem' [Case 10, Founder, Chief Scientific Officer].

Aesthetics

Discussions with end-users are also focussed at aesthetics. Things need to look good in order to be used. Many mechanical aids are made so that underlying constructions are not seen, with caps hiding the underlying construction.

> 'Well, physicians, more than other people, also want a product that looks nice. That's why we have made that cap' [Case 10, Founder, Chief Scientific Officer].

4. DISCUSSION

This research explored whether and what end-users and patients are involved by innovators during development, what methods for involvement are used, and what topics are discussed with these end-users and patients. The findings suggest that

innovators involve clinical end-users like medical specialists both by formal methods and in unsystematic ways in the development of their devices to examine problems, functionalities, design choices, safety issues, and aesthetics. Contrary to the call for patient involvement in the development of medical devices, innovators do not generally involve patients. Innovators in this study stated that patients are not the direct end-users and therefore less relevant, that clinicians are able to represent patients, or that involving patients is unethical because false expectations could be raised.

A strength of this study is that we have studied a diverse sample of surgical that was varied in terms of complexity, impact on workflow, impact on clinical outcomes, safety issues, and impact on patients' lives, thus increasing the transferability of the results.[33] Furthermore, Dutch and Belgian companies fall under European legislation, and many of the companies aimed to implement their devices in the USA and India, which implies that their development practices as well as our findings are not specific for the Dutch-Belgian context.

This study also comes with potential limitations. First, one researcher (KW) predominantly preformed the interviews, analysed the data, and subsequently discussed findings with the other authors. As a result, an observer bias might have occurred – although we have found no indication for such a bias in our data. Second, we have included two cases that were used outside the OR, yet do support surgical interventions. These are a testing device for surgical devices and a diagnostic device used by radiologists to prepare surgical operations. As these devices met our inclusion criteria, we decided to include them in our research. Third, we have

limited our analysis to *devices*, i.e. did not focus on surgical *procedures*. Therefore, our findings are not transferable to innovation of procedures, the development of which follows different paths. We believe that the restriction to surgical devices helps to illuminate how innovators seek to involve patients who may perceive the impact of using devices, without strictly 'using' these devices.

Our results are in agreement with previous studies that showed no patient participation in the development in surgical[35–37] or medical devices.[15,38] To the best of our knowledge, only one recent study does present patient involvement in surgical device development.[11] Thus, our findings are in line with the overall absence in the literature of patient involvement in surgical device development. On the other hand, representatives of clinical end-users are commonly involved in device development.[15,36,38] Formal methods employed were focus groups[11,15,35], surveys[11,35,36], workshops[36], observations[11,35,36] and interviews[38] whereas in our study interviewing was the most frequently employed formal method. In our study, a fairly large proportion of innovators used formal qualitative methods: eight out of 14 cases, as opposed to one out of 11 cases in a comparable study by Money et al.[15] An explanation is that involvement methods have become more accepted and valued in recent years. The topics discussed with stakeholders in the present study are comparable with those present in the literature.[11,35,36]

As previous research has shown that patients do have distinct preferences that are not articulated by healthcare professionals[9,12,13], our finding that patient participation is as yet uncommon implies that devices might be developed that are not in line with patient preferences. In accordance with this suggestion, not using formal methods might result in

devices that are not aligned with end-user preferences, because information gathered in unsystematic ways is less trustworthy.

However, our findings also suggest that not involving patients in device development is not a matter of forgetfulness or negligence: innovators have clear arguments for not involving patients, which are rooted in their experience with device development. Current guidelines or advises for patient involvement do not take these arguments in account[1,2,4], which probably renders them less effective. Closing the gap by aligning innovators' considerations and guidelines on patient participation might be an important step forward.

In conclusion, this study suggests that despite the common call for patient involvement[1,4,9], innovators of surgical devices do not seem to see an active role for patients in R&D. They do, however, involve clinical stakeholders, both by formal methods and in unsystematic ways, in various steps of the development trajectory. These findings suggest that innovators' views on patient involvement and the methodology of stakeholder participation in R&D of surgical devices deviates from the perspectives currently found in the literature and policy advices. More work is needed to align these perspectives.

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Figure legends

Figure 1. Overview of end-users that were engaged by innovators in making R&D choices, ordered per case. Every case is given equal weight. See table 1 for a detailed overview of all stakeholders involved by innovators.

Figure 2. Overview of methods what were used by innovators to engage end-users in R&D ordered per case. Every case is given equal weight. See table 1 for a detailed overview of all methods used by innovators.

Figure 3. Overview of R&D topics what were examined with end-users, ordered per case. Every case is given equal weight. See also table 1 for an overview of topics that were the focus of end-user involvements of each case.

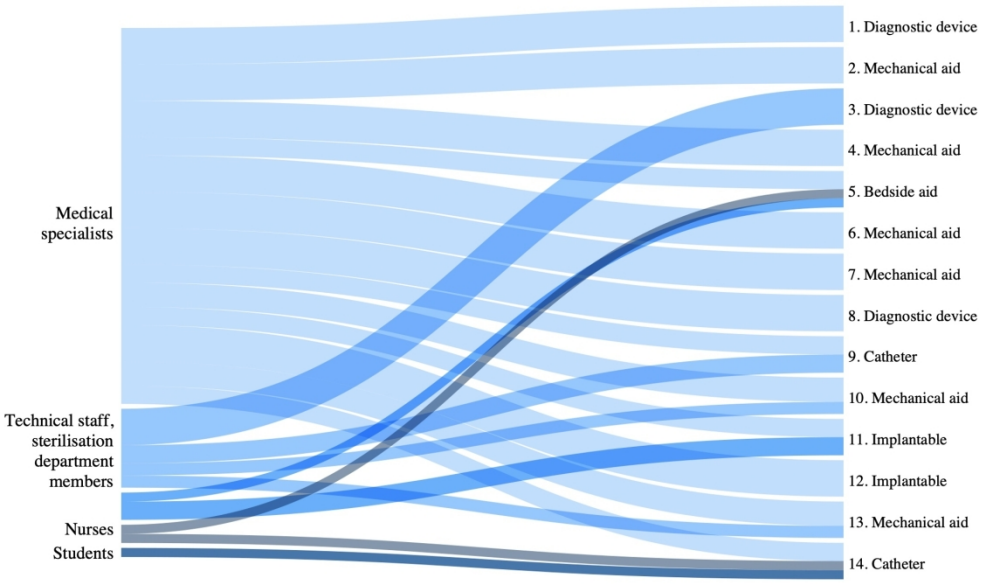

Figure 1: Overview of end-users engaged in R&D

382x224mm (144 x 144 DPI)

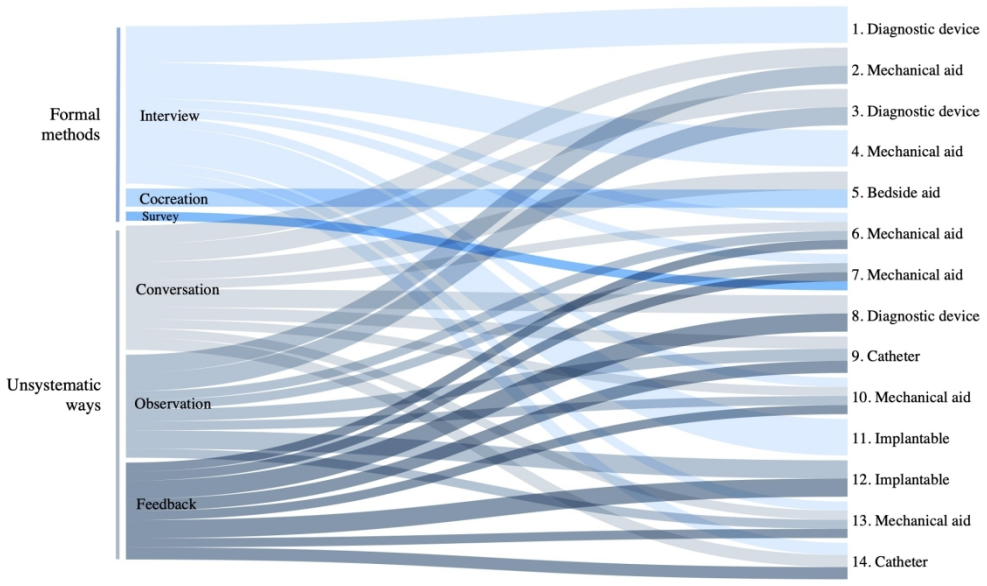

Figure 2: Overview of methods used to engage end-users in R&D

385x225mm (144 x 144 DPI)

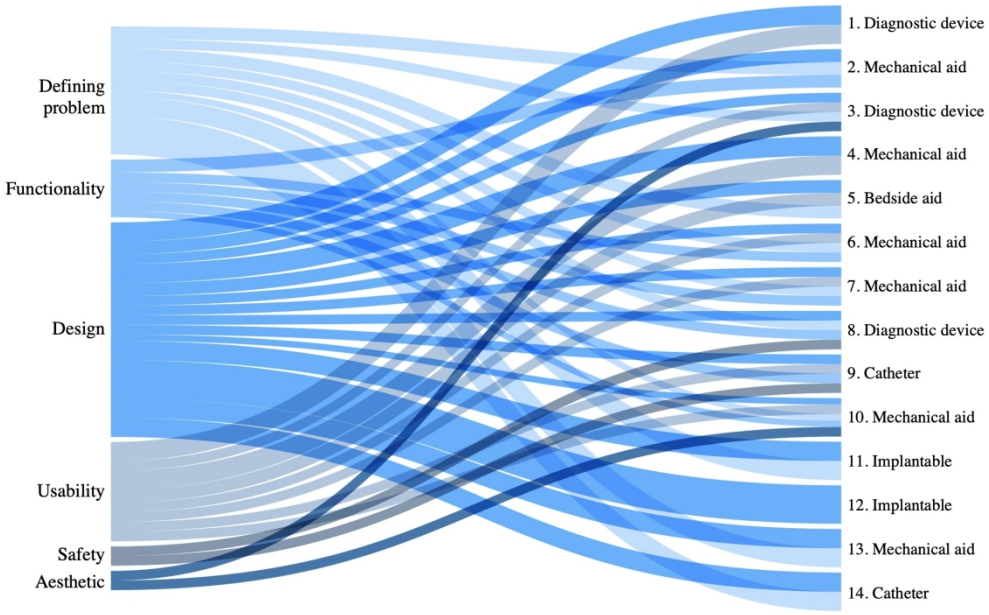

Figure 3: Overview of topics that were been discussed with end-users during R&D

360x222mm (144 x 144 DPI)

Supplemental material: Interview protocol

Introduction

- Recording
- Introduction interviewer, research project
- Introduction specific research
- Informed consent and questions

Phases product development		**Main question**	**Prompts**
		Which phases in product development do you distinguish?	
WHO			
People outside company	People per phase	Not taking your employees into account: which people are involved in product development in the just mentioned phases?	Why these people? Who decided to include these people?
HOW			
		How are these people involved in these phases?	
	Methodical	Method Number participants Setting Repetition Analysis Findings	Why this method?
	Non-methodical	Method Number participants Setting Repetition Analysis Findings	Why this method?
WHY			
	Purpose	For what reason where these people involved?	Why are these reasons important?
	Practice	How did involving these people lead to that purpose? What was the added value of the consultations?	
ADDITIONAL			
	First idea	When did the first idea or concept of the device occur?	
	Important changes	What was an important change in the design? What led to that change? Which people were involved in that alteration?	
CLOSE			

	Do you have additional questions? Word of thanks.	

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the SRQRreporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

		Reporting Item	Page Number
Title			
	#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
Abstract			
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Introduction			
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3-4

Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Methods			
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	5
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	7
Context	#7	Setting / site and salient contextual factors; rationale	6
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5-6
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	7

Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	8-9
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	6-7
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	6-7
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	5-7
Results/findings			
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-15

Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	8-15
Discussion			
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	15-16
Limitations	#19	Trustworthiness and limitations of findings	15-16
Other			
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	17
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	17

None The SRQR checklist is distributed with permission of Wolters Kluwer © 2014 by the Association of American Medical Colleges. This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Innovators' views on involving users and patients in surgical device development: a qualitative interview study

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Abstract

Objectives: Involving end-users and patients in the development of surgical devices, even when patients are not end-users, is deemed important in policy and in academia since it could improve strategic choices in research and development (R&D). Nonetheless, research into innovators' views on end-user and patient involvement is rare. This study explores what end-users and patients are being involved by innovators during development, what methods for involvement are being used, and what topics are being discussed with these end-users and patients.

Design: A qualitative study featuring semi-structured interviews with innovators of surgical devices. Interviews were recorded and a thematic analysis was performed on verbatim transcripts.

Participants: 15 interviews were conducted with 19 innovators of 14 surgical devices.

Setting: Innovation practices of surgical devices in the Netherlands and Belgium.

Results: End-users were engaged in R&D with formal methods and in unsystematic ways. These users all work in the clinical domain, e.g., as surgeons or nurses. The innovators engaged users to analyse problems for which a device could be a solution, define functionalities, make design choices, analyse usability, ensure safety, and improve aesthetics. Patients were rarely involved. Innovators stated that patients are not considered to be end-users, that physicians can represent patient interests, and that involving patients is unethical as false expectations could be raised.

Conclusion: Innovators involve end-users with methods and unsystematic ways in the development of surgical devices. Despite governmental calls for patient involvement in the development of medical devices and surgical devices, innovators do not generally involve patients.

ARTICLE SUMMARY

Strengths and limitations of this study

- The qualitative research design with open-ended interviews allowed for a detailed exploration of innovators' views without a theoretical predisposition.
- Purposive sampling led to a varied selection of surgical innovators working on the development a diversity of surgical devices, which increases the transferability of the results.
- The included Dutch and Belgian companies fall under European legislation, and many of the companies aimed to implement their devices in the USA and India, which implies that the findings are not specific for the Dutch-Belgian context.
- Some interviewees were familiar with the research project, which might have led to a social-desirability bias in interviews; by probing into detailed experiences and concrete examples this bias was minimised.

1. INTRODUCTION

Involving end-users (such as surgeons, nurses, etc.) and patients in the development of surgical devices is regarded as one of the cornerstones of a sound innovation practice.[1–5] It should increase the probability that devices meet proper clinical goals[6,7], comply with technical standards[8], are cost-effective[7], and meet ethical norms.[8,9] However, the theoretical foundation of end-user and patient involvement is fragmented and sometimes incongruent[10], leaving important choices open for debate.

First, it is debated *who* should be involved. Many argue that only end-users should participate in development.[2,5] The International Organization for Standardization (ISO) norm on

user-centred design leaves it up to designers to choose whether only end-users or a broader range of stakeholders that experience the effects of a device should be involved in development.[2] Others argue that patients should always be involved in device development, even when clinicians are the end-users and patients are not.[1,4,9,11,12] A reason for patient involvement is that patients and clinicians have different preferences, and that clinicians are not always able to represent patient preferences. Studies have found that patients prefer less invasive treatments, shorter recovery periods, a longer lifespan of devices, and more safety precautions: points clinicians did not mention.[11,13] These findings suggest that if patients are not being included in consultations, their functional requirements might not be taken into account in research and development (R&D). Second, it is also unclear which participatory *methods* are most suitable. Within user-centred design, multiple methods like interviewing, observation, and questionnaires are employed.[14] There are, nevertheless, no guidelines that explain which methods should be used in different developmental stages.[10] Third, opinions differ as to what *topics* are to be discussed with end-user and patients during development. Some argue that they should be involved to identify needs, others would maintain that they are to unravel problems, make design choices, or make contributions to research.[9,10]

This study is focussed on surgical devices, i.e. devices that are used to perform or support surgical procedures an operation room. This helps to explore how innovators prefer to involve patients when they are not end-users. Manufacturers, engineers and other actors designing novel or improved surgical devices (henceforth: innovators) primarily decide how end-users and patients are involved. They also have valuable

direct experience with the innovation practice. Hence, it is important to explore their vision on end-user and patient involvement, something which, to our knowledge, has been done in only one, rather old study so far.[15]

The aim of this study is to explore whether and what end-users and patients are being involved by innovators during development, what methods for involvement are being used, and what topics are being discussed with these end-users and patients.

2. METHODS

Patient and public involvement

Patients or public representatives were not involved in the design or future dissemination of this study. This study precedes a larger research project addressing the methodology of stakeholder involvement in the development and evaluation of surgical innovations. Patient involvement forms the topic of the present study, and patient engagements are part of future research outputs within this project.

Design

This qualitative study is rooted in a grounded theory methodology.[16] This is characterised by its open nature: data generation started with open questions, so that codes, theme's and theory could be identified inductively.[16,17] Another guiding principle is constant comparison: newly assigned codes and themes are constantly related to former findings, so that similarities, differences, and patterns in the data could be identified.[16] This report is written in line with the Standards for Reporting Qualitative Research.[18]

Participant selection

Participants were recruited between November 2018 and October 2019. We aimed to include a maximum diversity of surgical innovators, which we had defined as persons working to create new or improved surgical devices with the aim to disseminate these devices.[19] Surgical devices were defined according to the WHO definition of medical devices as 'any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article' to be used in the diagnosis, investigation or treatment of human beings.[20] We have limited our scope to devices that are used to perform or support surgical procedures. This delimitation makes the innovation trajectories of these devices more comparable. The selection of surgical devices is interesting, because patients are not the end-users of surgical devices, yet undergo the procedures. This helps to explore how innovators prefer to involve patients when they are not end-users. In order to increase the transferability of our findings, we attempted to select a diverse set of surgical devices, and a diverse set of participants that worked on different devices.[21] These could range from robotic systems such as the Da Vinci System[22] to simpler devices like novel surgical sutures.[23] These innovations can vary in technical complexity, their impact on the surgical workflow[24], clinical outcomes[25,26], safety issues[26,27], and impact on patients' lives.[26] We also aimed to select devices in various developmental stages, from the first functional prototypes to fully functioning devices that had already received CE marking, because otherwise findings could be biased to devices that had reached certain development stages, or were already met with commercial success. We selected participants working at small and medium sized enterprises with 1-250 employees[28], as market scans suggests these enterprises make up for about 95-97 percent of

the companies in medical technology in the Netherlands, and 90 percent in Europe.[29,30] These market scans indicate that there are 500-700 SME medical technology companies in the Netherlands, and that surgical devices have a market share of roughly 5-10%.[29,30] The market share in Belgium is considered comparable.[31] Using purposive sampling, respondents were identified by searching websites of conferences of health technologies, via reports on health technologies, and via the network of the researchers.[21] We invited representatives of companies that matched our selection criteria to join our study by e-mail. After data saturation was reached – the point when no new end-users, patients, methods or involvement aims were distinguished in the analysis of the last two interviews - no new participants were invited to participate.[21]

Data collection

Data were collected via semi-structured interviews. This method is appropriate for open-ended, rich data generation, because open-ended questions can be asked, and more detailed answers can be prompted in a setting where participants feel comfortable.[32] A week before the interview, all interviewees received an information letter and an informed consent form. They were asked to sign the consent form at the beginning of the interview. A topic guide with open questions was created by KW, MT and RR with open-ended questions inquiring what, if any, end-users and patients were involved during the development process; and how they were involved. This guide was refined in between interviews to achieve more information on important topics that had emerged.[33] (See the supplemental material). Conversations started with general questions about the innovation trajectory, important development or design decisions, and patients and end-users that were involved. Subsequently, they focussed on how these

patients and end-users were involved, and what was discussed. The interviews took place in the offices or workplaces of the interviewees and lasted 60 to 90 minutes. Interviews were audio-recorded and transcribed verbatim. All interviews were conducted by a trained and experienced qualitative researcher (KW). During three interviews, one other experienced researcher participated (in two instances, this was MT, a female researcher specialised in qualitative research, and in one instance a female PhD-student from the same research group).

Data analysis

Atlas.ti software for qualitative data analysis supported the analysis (version 8). Verbatim transcripts were read before coding commenced to familiarise with the data.[17] The analysis was performed during and after data collection, so that the constructed codes and themes could be incorporated in the interview protocols for more data generation on important themes.[33] The data analysis was performed by the first author (KW), and the codes and themes were discussed with two other researchers (MT and RR) to check whether codes were properly assigned to quotes in the transcripts. During the analysis, codes were grouped into themes. When no new codes were generated a sufficient degree of data saturation was assumed to have been reached.[21] All participants received the first draft of the paper, to allow them to check whether their quotes and the descriptions of their innovation practices had been described properly.[34]

Ethical approval

The ethics committee of the region Arnhem-Nijmegen (*Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen*), a certified medical research ethics committee in The Netherlands, has approved the research design and output (CMO file number: 2021-8101). The aim, conditions, advantages and disadvantages

of participation was communicated via an information letter, and all participants were given several days to consider participation. All participants gave written consent through a standardised consent form.

Reflexivity

This research was conducted as part of a larger project that is aimed at developing methods for early health technology assessment, with a strong focus on integration of early modelling approaches and methods of stakeholder participation. The authors of this paper are from the evidence-based surgery group (EBS) based at the Radboudumc in Nijmegen, the Netherlands. This group was known by some interviewees as proponents of stakeholder involvement in the development and evaluation of surgical devices. In the case of some interviews, this may have led to a social-desirability bias, perhaps yielding an optimistic view on user participation. By prompting and asking for concrete examples during the interviews[35], sampling of diverse cases, and selection of participants unaware of the EBS group, we aimed to account for this possible bias.

3. RESULTS

Respondents

Of the 18 companies that were approached, 14 participated. We held 15 interviews with representatives of these companies: representatives of one company were interviewed twice. During the interviews we focussed on the development trajectory of one device per company. During five interviews two representatives were present, so a total of 19 people were interviewed. Four of these 19 interviewees were female, and all (except one) participant had a Dutch or Belgian nationality. A wide range of devices was included, including mechanical bedside aids, robotics, implantable devices, catheters, and endoscopes. The development stages ranged from proof-of-concept phase to devices already commercially available. As regards the size of the companies, 13 out of 14 enterprises were 'micro' (less than five employees) or 'small' (less than 25 employees).

Overview

Table 1 offers a case-by-case overview of the interview participants, their functions, and the themes that have been constructed. Four end-user themes were constructed: medical specialists, nurses, medical students, and hospital technicians/sterilisation department members. Six methods themes were created. Three of these are grouped under unsystematic ways of data collection: conversations, observations, and feedback; the three other themes entail formal methods of data collection: interviews, cocreation, and surveys. Six topics themes were created: defining the problem, functionality, design, usability, safety and aesthetics. All these themes are described below. We have analysed the data for clustering of themes but did not find significant patterns that are valuable to report.

Table 1: case-by-case overview of the devices, development stages, profession of interviewees, end-users involved in R&D, methods and topics

Case	**Device**	**Development stage**	**Profession interviewees**		**Who is consulted**	**Methods used**[1]	**Topics**
1	Diagnostic device	Proof of concept	1	CEO	Urologists	*Interviews*	Design Usability
			2	Production manager			
2	Mechanical aid (two interviews)	First functional model	3	CEO (joint CEO)	ENT Surgeons	Conversations Feedback congress	Problem structuring Functionality Design
			4	CEO (joint CEO)			
3	Diagnostic device	Used in hospitals	5	Founder and Chief Compliance Officer	Sterilisation department	Conversations Observations	Problem structuring Design Usability Aesthetics
4	Mechanical aid	First functional model	6	CEO	Surgeons with differing specialties	*Interviews*	Design Usability
			7	Founder			
5	Bedside aid	Proof of concept	8	CEO	Neurosurgeons Anaesthesiologists Nurses Students	*Cocreation session* Conversations	Problem structuring Design Usability
			9	CMO			
6	Mechanical aid	Product tested in first hospitals	10	Clinical Field Engineer	Surgeons with differing specialties	*Interviews* Conversations Observations Feedback congress	Problem structuring Design Usability Safety
			11	CTO			
7	Mechanical aid	Product tested in first hospitals	12	CEO	Eye surgeons	*Interviews* *Surveys* Feedback congress Feedback studies Feedback in use Feedback education Observations	Problem structuring Design Usability Functionalities
8	Diagnostic device	First functional models	13	PhD Student	Radiologists	Conversations Observations Feedback congress	Problem structuring Design Functionalities Safety
9	Catheter	Used in hospitals	14	Manager clinical research	Cardiologists Technicians hospital	Conversations Observations Feedback in use	Design Functionalities Safety Usability
10	Diagnostic device	Used in hospitals	15	Founder, CSO	Radiologists	Conversation Observations Feedback in use	Problem structuring Design Functionality Usability Aesthetics
11	Implantable	Concept formulation	16	Intern	ENT Surgeons Students	*Interviews*	Problem structuring Design
12	Implantable	First functional model	17	Market Development Manager	Orthopaedic surgeons	Observations Feedback in use Feedback studies	Design
13	Mechanical aid	Concept formulated	18	Founder, Medical director	Gynaecologists Surgeons with differing specialties Sterilisation department Technicians hospital	*Interviews* Conversations Observations Feedback in use Feedback research Feedback congress	Problem structuring Design
14	Catheter	Concept formulated	19	CEO	Cardiac surgeons	*Interviews* Observations	Problem structuring

					Nurses Students	Conversations	Design

[1]**Formal methods to involve end-users are in italics**
Abbreviations: CEO = chief executive officer, CMO = Chief medical officer, CTO = Chief technology officer, CSO = Chief scientific officer, ENT = Ear, nose, and throat

3.1 What end-users and patients are involved?

In all cases, clinical end-users were engaged during development. In 13 out of 14 cases the end-users were medical specialists. In nine cases surgeons with varying specialties were engaged. In six cases other specialists like urologists were involved. In three cases, medical students were consulted alongside medical specialists, because they were seen as potential future end-users. In three cases, employees at the sterilization departments or technicians of hospitals were consulted, because these persons clean or test surgical devices. Consulting patients appeared to be uncommon: there is one example in our study, where the innovators stated that they talked with patients to familiarise with the severity of the disease without informing any step in the R&D process. This is why patients are not included in table 1. Innovators gave three reasons for not involving patients in making R&D choices. First, innovators see physicians as representatives of patients, and therefore innovators do not deem involving patients necessary. Second, innovators perceive engaging patients in R&D as unethical, because it might raise expectations about future health benefits that innovators cannot yet realise. Third, patients are not seen as end-users, because they do not use the surgical devices in the sense of handling these in the operation room. Instead, one interviewee stated that patients are often seen as 'biomechanical objects': 'And at times you have to look at it like this, otherwise you cannot do operations. (…) The opinion of the patients is not per definition seen as important in the development trajectory. It is more of an endpoint than an

input: patient reported outcome measures are seen as important.' [Case 12, Market Development Manager].

3.2 How are these end-users consulted?

Unsystematic ways of data collection

Conversations are the first way of gathering information from end-users (9/14 cases). Many innovators are health professionals and discuss their ideas with a group of experts in their network. The second unsystematic way is observing without a protocol (9/14 cases). This was often performed by innovators that are trained as engineers. A third unsystematic way of obtaining information was via unsystematic feedback in use (5/14 cases).

Formal methods

Formal methods were used in eight cases. In seven cases systematic interviews were performed. Besides interviewing, one innovator used surveys to quantify the opinion of surgeons on functionalities and usability of the innovation. Another innovator used cocreation sessions to gather information from nurses and students.

3.3 What topics are addressed?

The problem

In 10 out of 14 discussed devices, the healthcare problem for which the surgical device could be a solution was analysed with end-users. A 'technology push' and a 'problem pull' can be distinguished. Four cases feature a form of technology push: here problems were explored with end-users from the perspective of a technology that was already available, and its application in a new setting was being considered. An example of technology push involved an engineer with an idea for a mechanical aid in the operation room that was based on

mechanics known in car manufacturing. He interviewed multiple surgeons to identify the procedures where the aid could solve the most pressing problem. The six remaining represent examples of a problem pull: the problem was analysed with end-users before any form of technology was conceived of. In all these cases, healthcare professionals experienced a problem during their work. One interviewee told that moving patients on OR beds was so arduous that employees often walked away, or developed back pain. When problems like these are discussed, innovators map multiple perspectives on a problem and seek to bring them together in the functionalities and design of a device.

Functionalities

Innovators state that they involve end-users to specify functionalities, i.e. the essential functions a device should have. Functionalities are often formulated early in the design trajectory and remain stable over this trajectory. In the case of wildly varying quality of endoscopes in the operation theatre, the essential functionality of a device was clear from the start: guaranteeing the quality of endoscopes in terms of light intensity and vision angle. In two cases innovators stated that it is hard to make devices with functionalities that substitute acts of a physician. Where the devices replace physicians, physicians tend not to be enthusiastic.

Designing the device

Under 'design' we group any decision about the shape or physical property of devices. Designing is a broad category, since the interviewed innovators start thinking about the shape of devices from the onset of development trajectories, and do not stop thinking about design changes. According to the interviewees, the discussed topics change with each design

iteration. In an early development stage, innovators ask design feedback in a broad fashion, probing into what general design users would prefer, or whether they think initial sketches are good solutions. As the devices' design becomes more concrete in prototypes or functional models, the questions on design become more specific, too.

Usability

Usability entails making the device functional for the relevant end-users. Innovators described a case of engaging end-users for usability where only strong people with big hands were involved. Smaller people, like women or Asian people on average, were not empowered to use the devices during this test phase: 'The surgeon used the device for several hours, and after using it he got a tremor in his hands. You need to be quite strong. We have to find a balance between it being usable, and without losing functionality. (…) Such huge guys with huge hands – that differs from a little woman working as a surgeon' [Case 4, CEO].

This illustrates that the innovators were balancing functionality and usability. At the time of the interview, the innovators faced the dilemma what to prioritise: working on functionality, or on usability so that everyone could use the device. A subset of usability is fitting a device into the workflow of the operation room. Interviewees observe the acts in the operation room and think about ways in which a novel device does not distort the acts people perform.

Safety

Innovators state that they need to ensure that their devices cause no harm. In two examples, innovators had to think about how devices should be designed so that they could be sterilized fast and thoroughly. In another example a device

was redesigned because users could break off a piece from a device.

Aesthetics

Discussions with end-users are also focussed at aesthetics. Things need to look good in order to be used. Many mechanical aids are made so that underlying constructions are not visible, with caps hiding the underlying construction.

4. DISCUSSION

This research explored whether and what end-users and patients are involved by innovators during development of surgical innovators, what methods for involvement are used, and what topics are discussed with these end-users and patients. The findings suggest that innovators involve clinical end-users like medical specialists both by formal methods and in unsystematic ways in the development of their devices to examine problems, functionalities, design choices, safety issues, and aesthetics. Contrary to the call for patient involvement in the development of medical devices, innovators do not generally involve patients. Innovators in this study stated that patients are not the direct end-users and therefore less relevant, that clinicians are able to represent patients, or that involving patients is unethical because false expectations could be raised.

A strength of this study is that we have studied a diverse sample of surgical devices varying in complexity, impact on workflow, impact on clinical outcomes, safety issues, and impact on patients' lives, thus increasing the transferability of the results.[34] Furthermore, Dutch and Belgian companies fall under European legislation, and many of the companies aimed to implement their devices in the USA and India, which

implies that their development practices as well as our findings are not specific for the Dutch-Belgian context. Another strength is that we have likely involved a significant number of surgical device companies in the Netherlands and Belgium.

This study also comes with potential limitations. First, one researcher (KW) predominantly preformed the interviews, analysed the data, and subsequently discussed findings with the other authors. As a result, an observer bias might have occurred – although we have found no indication for such a bias in our data. Second, data saturation is a recently contested concept to establish trustworthiness.[36] *Information power* is another means to establish trustworthiness, via sample size.[37] Since the design of our research was narrow and specific, we deem the sample size of 19 innovators divided over 14 cases appropriate. Third, we have included two cases of devices that were used outside the operation room, yet do support surgical interventions. These are a testing device for surgical devices and a diagnostic device used by radiologists to prepare surgical operations. As these devices met our inclusion criteria, we decided to include them in our research. Fourth, we have limited our analysis to *devices*, i.e. did not focus on surgical *procedures*. Therefore, our findings are not transferable to innovation of procedures, the development of which follows different paths. We believe that the restriction to surgical devices helps to illuminate how innovators seek to involve patients who may perceive the impact of using devices, without strictly 'using' these devices.

Our results are in agreement with previous studies that indicate that innovators do not involve patients in the development in surgical devices.[38–40] A study on innovators'

perspectives on user involvement in a broader range of various medical devices also found that innovators rarely see patients as valuable participants in R&D.[15,41]. On the contrary, the academic literature presents many examples of patient involvement in the domain of electronic health resources, likely because patients are clear and important end-users of these technologies.[42] To the best of our knowledge, only one recent study presents patient involvement in surgical device development.[11] This study shows that patients voice specific needs that healthcare professionals do not. Hence, an advantage of patient involvement is that innovators can take specific patient needs into account in R&D. On the other hand, clinical end-users are commonly involved in device development.[15,39,41] Formal methods employed were focus groups[11,15,38], surveys[11,38,39], workshops[39], observations[11,38,39] and interviews[41] whereas in our study interviewing was the most frequently employed formal method. In our study, a fairly large proportion of innovators used formal qualitative methods: eight out of 14 cases, as opposed to one out of 11 cases in a comparable study by Money et al.[15] An explanation is that involvement methods have become more accepted and valued in recent years. The topics discussed with end-users in the present study are comparable with those present in the literature.[11,38,39]

As previous research has shown that patients do have distinct preferences that are not articulated by healthcare professionals[9,12,13], our finding that patient participation is as yet uncommon implies that devices might be developed that are not in line with patient preferences. In accordance with this suggestion, not using formal methods might result in devices that are not aligned with end-user preferences, because information gathered in unsystematic ways is less trustworthy. However, our findings also suggest that not involving patients in device development is not a matter of forgetfulness or negligence: innovators have clear arguments

for not involving patients, which are rooted in their experience with device development. Current guidelines or advises for patient involvement do not take these arguments in account[1,2,4], which probably renders them less effective. Hence, it is important to work out how patients can be involved in the development of surgical devices in ways that are productive, effective and meaningful for innovators. Most likely there is not one blueprint for all surgical devices – probably every case requires a tailored approach for meaningful patient involvement.

In conclusion, this study suggests that despite the common call for patient involvement[1,4,9], innovators of surgical devices do not seem to see an active role for patients in R&D. They do, however, involve clinical end-users, both by formal methods and in unsystematic ways, in various steps of the development trajectory. These findings suggest that innovators' views on end-user and patient involvement, and the methodology of end-user and patient participation in R&D of surgical devices deviates from the perspectives currently found in the literature and policy advices. More work is needed to align these perspectives.

Author contributions: KW, MT, MR and RR generated the idea to study innovators views on user and patient involvement. All authors developed the research design. KW, with help of MR, identified and recruited potential participants. KW conducted all interviews, MT joined in two interviews. KW analyzed the interviews and interpreted the data, with various discussions with MT and RR. KW wrote the original manuscript draft, and MT, MR and RR edited the draft. KW responded to reviewers' feedback and MT, MR and RR reviewed this response. KW created the planning, and MT, MR and RR gave feedback.

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Data statement: No data are available. All relevant data are presented in this study.

Ethics: The ethics committee of the region Arnhem-Nijmegen (*Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen*), a certified medical research ethics committee in The Netherlands, has approved the research design and output (CMO file number: 2021-8101). The aim, conditions, advantages and disadvantages of participation was communicated via an information letter, and all participants were given several days to consider participation. All participants gave written consent through a standardised consent form.

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Supplemental material: Interview protocol

Introduction

- Recording
- Introduction interviewer, research project
- Introduction specific research
- Informed consent and questions

Phases product development		**Main question**	**Prompts**
		Which phases in product development do you distinguish?	
WHO			
People outside company	People per phase	Not taking your employees into account: which people are involved in product development in the just mentioned phases?	Why these people? Who decided to include these people?
HOW			
		How are these people involved in these phases?	
	Methodical	Method Number participants Setting Repetition Analysis Findings	Why this method?
	Non-methodical	Method Number participants Setting Repetition Analysis Findings	Why this method?
WHY			
	Purpose	For what reason where these people involved?	Why are these reasons important?
	Practice	How did involving these people lead to that purpose? What was the added value of the consultations?	
ADDITIONAL			
	First idea	When did the first idea or concept of the device occur?	
	Important changes	What was an important change in the design? What led to that change? Which people were involved in that alteration?	
CLOSE			

	Do you have additional questions? Word of thanks.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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		Reporting Item	Page Number
Title			
	#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
Abstract			
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Introduction			
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3-4

Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Methods			
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	5
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	7
Context	#7	Setting / site and salient contextual factors; rationale	6
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5-6
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	7

Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	8-9
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	6-7
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	6-7
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	5-7
Results/findings			
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-15

Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	8-15
Discussion			
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	15-16
Limitations	#19	Trustworthiness and limitations of findings	15-16
Other			
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	17
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	17

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BMJ Open

Innovators' views on involving users and patients in surgical device development: a qualitative interview study

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Abstract

Objectives: Involving end-users and patients in the development of surgical devices, even when patients are not end-users, is deemed important in policy and in academia since it could improve strategic choices in research and development (R&D). Nonetheless, research into innovators' views on end-user and patient involvement is rare. This study explores what end-users and patients are being involved by innovators during development, what methods for involvement are being used, and what topics are being discussed with these end-users and patients.

Design: A qualitative study featuring semi-structured interviews with innovators of surgical devices. Interviews were recorded and a thematic analysis was performed on verbatim transcripts.

Participants: 15 interviews were conducted with 19 innovators of 14 surgical devices.

Setting: Innovation practices of surgical devices in the Netherlands and Belgium.

Results: End-users were engaged in R&D with formal methods and in unsystematic ways. These users all work in the clinical domain, e.g., as surgeons or nurses. The innovators engaged users to analyse problems for which a device could be a solution, define functionalities, make design choices, analyse usability, ensure safety, and improve aesthetics. Patients were rarely involved. Innovators stated that patients are not considered to be end-

users, that physicians can represent patient interests, and that involving patients is unethical as false expectations could be raised.

Conclusion: Innovators involve end-users with methods and unsystematic ways in the development of surgical devices. Despite governmental calls for patient involvement in the development of medical devices and surgical devices, innovators do not generally involve patients.

ARTICLE SUMMARY

Strengths and limitations of this study

- The qualitative research design with open-ended interviews allowed for a detailed exploration of innovators' views without a theoretical predisposition.
- Purposive sampling led to a varied selection of surgical innovators working on the development a diversity of surgical devices, which increases the transferability of the results.
- The included Dutch and Belgian companies fall under European legislation, and many of the companies aimed to implement their devices in the USA and India, which implies that the findings are not specific for the Dutch-Belgian context.
- Some interviewees were familiar with the research project, which might have led to a social-desirability bias in interviews; by probing into detailed experiences and concrete examples this bias was minimised.

1. INTRODUCTION

Involving end-users (such as surgeons, nurses, etc.) and patients in the development of surgical devices is regarded as one of the cornerstones of a sound innovation practice.[1–5] It should increase the probability that devices meet proper clinical goals[6,7], comply with technical standards[8], are cost-effective[7], and meet ethical norms.[8,9] However, the theoretical foundation of end-user and patient involvement is fragmented and sometimes incongruent[10], leaving important choices open for debate.

First, it is debated *who* should be involved. Many argue that only end-users should participate in development.[2,5] The International Organization for Standardization (ISO) norm on user-centred design leaves it up to designers to choose whether only end-users or a broader range of stakeholders that experience the effects of a device should be involved in development.[2] Others argue that patients should always be involved in device development, even when clinicians are the end-users and patients are not.[1,4,9,11,12] A reason for patient involvement is that patients and clinicians have different preferences, and that clinicians are not always able to represent patient preferences. Studies have found that patients prefer less invasive treatments, shorter recovery periods, a longer lifespan of devices, and more safety precautions: points clinicians did not mention.[11,13] These findings suggest that if patients are not being included in consultations, their functional requirements might not be taken into account in research and development (R&D). Second, it is also unclear which participatory *methods* are most suitable. Within user-centred design, multiple methods like interviewing, observation, and questionnaires are employed.[14] There are, nevertheless, no guidelines that explain which methods should be used in different developmental stages.[10] Third, opinions differ as to what *topics* are to be discussed with end-user and patients during development. Some argue that they should be involved to identify needs, others would maintain that they are to unravel problems, make design choices, or make contributions to research.[9,10]

This study is focussed on surgical devices, i.e. devices that are used to perform or support surgical procedures an operation room. This helps to explore how innovators prefer to involve patients when they are not end-users. Manufacturers, engineers and other actors designing novel or improved surgical devices (henceforth: innovators) primarily decide how

end-users and patients are involved. They also have valuable direct experience with the innovation practice. Hence, it is important to explore their vision on end-user and patient involvement, something which, to our knowledge, has been done in only one, rather old study so far.[15]

The aim of this study is to explore whether and what end-users and patients are being involved by innovators during development, what methods for involvement are being used, and what topics are being discussed with these end-users and patients.

2. METHODS

Patient and public involvement

Patients or public representatives were not involved in the design or future dissemination of this study. This study precedes a larger research project addressing the methodology of stakeholder involvement in the development and evaluation of surgical innovations. Patient involvement forms the topic of the present study, and patient engagements are part of future research outputs within this project.

Design

This qualitative study is rooted in a grounded theory methodology.[16] This is characterised by its open nature: data generation started with open questions, so that codes, theme's and theory could be identified inductively.[16,17] Another guiding principle is constant comparison: newly assigned codes and themes are constantly related to former findings, so

that similarities, differences, and patterns in the data could be identified.[16] This report is written in line with the Standards for Reporting Qualitative Research.[18]

Participant selection

Participants were recruited between November 2018 and October 2019. We aimed to include a maximum diversity of surgical innovators, which we had defined as persons working to create new or improved surgical devices with the aim to disseminate these devices.[19] Surgical devices were defined according to the WHO definition of medical devices as 'any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article' to be used in the diagnosis, investigation or treatment of human beings.[20] We have limited our scope to devices that are used to perform or support surgical procedures. This delimitation makes the innovation trajectories of these devices more comparable. The selection of surgical devices is interesting, because patients are not the end-users of surgical devices, yet undergo the procedures. This helps to explore how innovators prefer to involve patients when they are not end-users. In order to increase the transferability of our findings, we attempted to select a diverse set of surgical devices, and a diverse set of participants that worked on different devices.[21] These could range from robotic systems such as the Da Vinci System[22] to simpler devices like novel surgical sutures.[23] These innovations can vary in technical complexity, their impact on the surgical workflow[24], clinical outcomes[25,26], safety issues[26,27], and impact on patients' lives.[26] We also aimed to select devices in various developmental stages, from the first functional prototypes to fully functioning devices that had already received CE marking, because otherwise findings could be biased to devices that had reached certain development

stages, or were already met with commercial success. We selected participants working at small and medium sized enterprises with 1-250 employees[28], as market scans suggests these enterprises make up for about 95-97 percent of the companies in medical technology in the Netherlands, and 90 percent in Europe.[29,30] These market scans indicate that there are 500-700 SME medical technology companies in the Netherlands, and that surgical devices have a market share of roughly 5-10%.[29,30] The market share in Belgium is considered comparable.[31] Using purposive sampling, respondents were identified by searching websites of conferences of health technologies, via reports on health technologies, and via the network of the researchers.[21] We invited representatives of companies that matched our selection criteria to join our study by e-mail. After data saturation was reached – the point when no new end-users, patients, methods or involvement aims were distinguished in the analysis of the last two interviews - no new participants were invited to participate.[21]

Data collection

Data were collected via semi-structured interviews. This method is appropriate for open-ended, rich data generation, because open-ended questions can be asked, and more detailed answers can be prompted in a setting where participants feel comfortable.[32] A week before the interview, all interviewees received an information letter and an informed consent form. They were asked to sign the consent form at the beginning of the interview. A topic guide with open questions was created by KW, MT and RR with open-ended questions inquiring what, if any, end-users and patients were involved during the development process; and how they were involved. This guide was refined in between interviews to achieve more information on important topics that had emerged.[33] (See the supplemental material).

Conversations started with general questions about the innovation trajectory, important development or design decisions, and patients and end-users that were involved. Subsequently, they focussed on how these patients and end-users were involved, and what was discussed. The interviews took place in the offices or workplaces of the interviewees and lasted 60 to 90 minutes. Interviews were audio-recorded and transcribed verbatim. All interviews were conducted by a trained and experienced qualitative researcher (KW). During three interviews, one other experienced researcher participated (in two instances, this was MT, a female researcher specialised in qualitative research, and in one instance a female PhD-student from the same research group).

Data analysis

Atlas.ti software for qualitative data analysis supported the analysis (version 8). Verbatim transcripts were read before coding commenced to familiarise with the data.[17] The analysis was performed during and after data collection, so that the constructed codes and themes could be incorporated in the interview protocols for more data generation on important themes.[33] The data analysis was performed by the first author (KW), and the codes and themes were discussed with two other researchers (MT and RR) to check whether codes were properly assigned to quotes in the transcripts. During the analysis, codes were grouped into themes. When no new codes were generated a sufficient degree of data saturation was assumed to have been reached.[21] All participants received the first draft of the paper, to allow them to check whether their quotes and the descriptions of their innovation practices had been described properly.[34]

Ethical approval

The ethics committee of the region Arnhem-Nijmegen (*Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen*), a certified medical research ethics committee in The Netherlands, has approved the research design and output (CMO file number: 2021-8101). The aim, conditions, advantages and disadvantages of participation was communicated via an information letter, and all participants were given several days to consider participation. All participants gave written consent through a standardised consent form.

Reflexivity

This research was conducted as part of a larger project that is aimed at developing methods for early health technology assessment, with a strong focus on integration of early modelling approaches and methods of stakeholder participation. The authors of this paper are from the evidence-based surgery group (EBS) based at the Radboudumc in Nijmegen, the Netherlands. This group was known by some interviewees as proponents of stakeholder involvement in the development and evaluation of surgical devices. In the case of some interviews, this may have led to a social-desirability bias, perhaps yielding an optimistic view on user participation. By prompting and asking for concrete examples during the interviews[35], sampling of diverse cases, and selection of participants unaware of the EBS group, we aimed to account for this possible bias.

3. RESULTS

Respondents

Of the 18 companies that were approached, 14 participated. We held 15 interviews with representatives of these companies: representatives of one company were interviewed twice. During the interviews we focussed on the development trajectory of one device per company. During five interviews two representatives were present, so a total of 19 people were interviewed. Four of these 19 interviewees were female, and all (except one) participant had a Dutch or Belgian nationality. A wide range of devices was included, including mechanical bedside aids, robotics, implantable devices, catheters, and endoscopes. The development stages ranged from proof-of-concept phase to devices already commercially available. As regards the size of the companies, 13 out of 14 enterprises were 'micro' (less than five employees) or 'small' (less than 25 employees).

Overview

Table 1 offers a case-by-case overview of the interview participants, their functions, and the themes that have been constructed. Four end-user themes were constructed: medical specialists, nurses, medical students, and hospital technicians/sterilisation department members. Six methods themes were created. Three of these are grouped under unsystematic ways of data collection: conversations, observations, and feedback; the three other themes entail formal methods of data collection: interviews, cocreation, and surveys. Six topics themes were created: defining the problem, functionality, design, usability, safety and

aesthetics. All these themes are described below. We have analysed the data for clustering of themes but did not find significant patterns that are valuable to report.

Table 1: case-by-case overview of the devices, development stages, profession of interviewees, end-users involved in R&D, methods and topics

Case	Device	Development stage	Profession interviewees		Who is consulted	Methods used[1]	Topics
1	Diagnostic device	Proof of concept	1	CEO	Urologists	*Interviews*	Design Usability
			2	Production manager			
2	Mechanical aid (two interviews)	First functional model	3	CEO (joint CEO)	ENT Surgeons	Conversations Feedback congress	Problem structuring Functionality Design
			4	CEO (joint CEO)			
3	Diagnostic device	Used in hospitals	5	Founder and Chief Compliance Officer	Sterilisation department	Conversations Observations	Problem structuring Design Usability Aesthetics
4	Mechanical aid	First functional model	6	CEO	Surgeons with differing specialties	*Interviews*	Design Usability
			7	Founder			
5	Bedside aid	Proof of concept	8	CEO	Neurosurgeons Anaesthesiologists Nurses Students	*Cocreation session* Conversations	Problem structuring Design Usability
			9	CMO			
6	Mechanical aid	Product tested in first hospitals	10	Clinical Field Engineer	Surgeons with differing specialties	*Interviews* Conversations Observations Feedback congress	Problem structuring Design Usability Safety
			11	CTO			
7	Mechanical aid	Product tested in first hospitals	12	CEO	Eye surgeons	*Interviews* *Surveys* Feedback congress Feedback studies Feedback in use Feedback education Observations	Problem structuring Design Usability Functionalities
8	Diagnostic device	First functional models	13	PhD Student	Radiologists	Conversations Observations Feedback congress	Problem structuring Design Functionalities Safety
9	Catheter	Used in hospitals	14	Manager clinical research	Cardiologists Technicians hospital	Conversations Observations Feedback in use	Design Functionalities Safety Usability
10	Diagnostic device	Used in hospitals	15	Founder, CSO	Radiologists	Conversation Observations Feedback in use	Problem structuring Design Functionality Usability Aesthetics
11	Implantable	Concept	16	Intern	ENT Surgeons	*Interviews*	Problem structuring

		formulation			Students		Design
12	Implantable	First functional model	17	Market Development Manager	Orthopaedic surgeons	Observations Feedback in use Feedback studies	Design
13	Mechanical aid	Concept formulated	18	Founder, Medical director	Gynaecologists Surgeons with differing specialties Sterilisation department Technicians hospital	*Interviews* Conversations Observations Feedback in use Feedback research Feedback congress	Problem structuring Design
14	Catheter	Concept formulated	19	CEO	Cardiac surgeons Nurses Students	*Interviews* Observations Conversations	Problem structuring Design

[1]Formal methods to involve end-users are in italics

Abbreviations: CEO = chief executive officer, CMO = Chief medical officer, CTO = Chief technology officer, CSO = Chief scientific officer, ENT = Ear, nose, and throat

3.1 What end-users and patients are involved?

In all cases, clinical end-users were engaged during development. In 13 out of 14 cases the end-users were medical specialists. In nine cases surgeons with varying specialties were engaged. In six cases other specialists like urologists were involved. In three cases, medical students were consulted alongside medical specialists, because they were seen as potential future end-users. In three cases, employees at the sterilization departments or technicians of hospitals were consulted, because these persons clean or test surgical devices. Consulting patients appeared to be uncommon: there is one example in our study, where the innovators stated that they talked with patients to familiarise with the severity of the disease without informing any step in the R&D process. This is why patients are not included in table 1. Innovators gave three reasons for not involving patients in making R&D choices. First, innovators see physicians as representatives of patients, and therefore innovators do not deem

involving patients necessary. Second, innovators perceive engaging patients in R&D as unethical, because it might raise expectations about future health benefits that innovators cannot yet realise. Third, patients are not seen as end-users, because they do not use the surgical devices in the sense of handling these in the operation room. Instead, one interviewee stated that patients are often seen as 'biomechanical objects': 'And at times you have to look at it like this, otherwise you cannot do operations. (…) The opinion of the patients is not per definition seen as important in the development trajectory. It is more of an endpoint than an input: patient reported outcome measures are seen as important.' [Case 12, Market Development Manager].

3.2 How are these end-users consulted?

Unsystematic ways of data collection

Conversations are the first way of gathering information from end-users (9/14 cases). Many innovators are health professionals and discuss their ideas with a group of experts in their network. The second unsystematic way is observing without a protocol (9/14 cases). This was often performed by innovators that are trained as engineers. A third unsystematic way of obtaining information was via unsystematic feedback in use (5/14 cases).

Formal methods

Formal methods were used in eight cases. In seven cases systematic interviews were performed. Besides interviewing, one innovator used surveys to quantify the opinion of surgeons on functionalities and usability of the innovation. Another innovator used cocreation sessions to gather information from nurses and students.

3.3 What topics are addressed?

The problem

In 10 out of 14 discussed devices, the healthcare problem for which the surgical device could be a solution was analysed with end-users. A 'technology push' and a 'problem pull' can be distinguished. Four cases feature a form of technology push: here problems were explored with end-users from the perspective of a technology that was already available, and its application in a new setting was being considered. An example of technology push involved an engineer with an idea for a mechanical aid in the operation room that was based on mechanics known in car manufacturing. He interviewed multiple surgeons to identify the procedures where the aid could solve the most pressing problem. The six remaining represent examples of a problem pull: the problem was analysed with end-users before any form of technology was conceived of. In all these cases, healthcare professionals experienced a problem during their work. One interviewee told that moving patients on OR beds was so arduous that employees often walked away, or developed back pain. When problems like these are discussed, innovators map multiple perspectives on a problem and seek to bring them together in the functionalities and design of a device.

Functionalities

Innovators state that they involve end-users to specify functionalities, i.e. the essential functions a device should have. Functionalities are often formulated early in the design trajectory and remain stable over this trajectory. In the case of wildly varying quality of

endoscopes in the operation theatre, the essential functionality of a device was clear from the start: guaranteeing the quality of endoscopes in terms of light intensity and vision angle. In two cases innovators stated that it is hard to make devices with functionalities that substitute acts of a physician. Where the devices replace physicians, physicians tend not to be enthusiastic.

Designing the device

Under 'design' we group any decision about the shape or physical property of devices. Designing is a broad category, since the interviewed innovators start thinking about the shape of devices from the onset of development trajectories, and do not stop thinking about design changes. According to the interviewees, the discussed topics change with each design iteration. In an early development stage, innovators ask design feedback in a broad fashion, probing into what general design users would prefer, or whether they think initial sketches are good solutions. As the devices' design becomes more concrete in prototypes or functional models, the questions on design become more specific, too.

Usability

Usability entails making the device functional for the relevant end-users. Innovators described a case of engaging end-users for usability where only strong people with big hands were involved. Smaller people, like women or Asian people on average, were not empowered to use the devices during this test phase: 'The surgeon used the device for several hours, and after using it he got a tremor in his hands. You need to be quite strong. We have to find a balance between it being usable, and without losing functionality. (…) Such huge guys with

huge hands – that differs from a little woman working as a surgeon' [Case 4, CEO].

This illustrates that the innovators were balancing functionality and usability. At the time of the interview, the innovators faced the dilemma what to prioritise: working on functionality, or on usability so that everyone could use the device. A subset of usability is fitting a device into the workflow of the operation room. Interviewees observe the acts in the operation room and think about ways in which a novel device does not distort the acts people perform.

Safety

Innovators state that they need to ensure that their devices cause no harm. In two examples, innovators had to think about how devices should be designed so that they could be sterilized fast and thoroughly. In another example a device was redesigned because users could break off a piece from a device.

Aesthetics

Discussions with end-users are also focussed at aesthetics. Things need to look good in order to be used. Many mechanical aids are made so that underlying constructions are not visible, with caps hiding the underlying construction.

4. DISCUSSION

This research explored whether and what end-users and patients are involved by innovators during development of surgical innovators, what methods for involvement are used, and what

topics are discussed with these end-users and patients. The findings suggest that innovators involve clinical end-users like medical specialists both by formal methods and in unsystematic ways in the development of their devices to examine problems, functionalities, design choices, safety issues, and aesthetics. Contrary to the call for patient involvement in the development of medical devices, innovators do not generally involve patients. Innovators in this study stated that patients are not the direct end-users and therefore less relevant, that clinicians are able to represent patients, or that involving patients is unethical because false expectations could be raised.

A strength of this study is that we have studied a diverse sample of surgical devices varying in complexity, impact on workflow, impact on clinical outcomes, safety issues, and impact on patients' lives, thus increasing the transferability of the results.(34) Furthermore, Dutch and Belgian companies fall under European legislation, and many of the companies aimed to implement their devices in the USA and India, which implies that their development practices as well as our findings are not specific for the Dutch-Belgian context. Another strength is that we have likely involved a significant number of surgical device companies in the Netherlands and Belgium.

This study also comes with potential limitations. First, one researcher (KW) predominantly preformed the interviews, analysed the data, and subsequently discussed findings with the other authors. As a result, an observer bias might have occurred – although we have found no indication for such a bias in our data. Second, data saturation is a recently contested concept to establish trustworthiness.[36] *Information power* is another means to establish

trustworthiness, via sample size.[37] Since the design of our research was narrow and specific, we deem the sample size of 19 innovators divided over 14 cases appropriate. Third, we have included two cases of devices that were used outside the operation room, yet do support surgical interventions. These are a testing device for surgical devices and a diagnostic device used by radiologists to prepare surgical operations. As these devices met our inclusion criteria, we decided to include them in our research. Fourth, we have limited our analysis to *devices*, i.e. did not focus on surgical *procedures*. Therefore, our findings are not transferable to innovation of procedures, the development of which follows different paths. We believe that the restriction to surgical devices helps to illuminate how innovators seek to involve patients who may perceive the impact of using devices, without strictly 'using' these devices.

Our results are in agreement with previous studies that indicate that innovators do not involve patients in the development in surgical devices.[38–40] A study on innovators' perspectives on user involvement in a broader range of various medical devices also found that innovators rarely see patients as valuable participants in R&D.[15,41]. On the contrary, the academic literature presents many examples of patient involvement in the domain of electronic health resources, likely because patients are clear and important end-users of these technologies.[42] To the best of our knowledge, only one recent study presents patient involvement in surgical device development.[11] This study shows that patients voice specific needs that healthcare professionals do not. Hence, an advantage of patient involvement is that innovators can take specific patient needs into account in R&D. On the other hand, clinical end-users are commonly involved in device development.[15,39,41] Formal methods employed were focus groups[11,15,38], surveys[11,38,39], workshops[39], observations[11,38,39] and

interviews[41] whereas in our study interviewing was the most frequently employed formal method. In our study, a fairly large proportion of innovators used formal qualitative methods: eight out of 14 cases, as opposed to one out of 11 cases in a comparable study by Money et al.[15] An explanation is that involvement methods have become more accepted and valued in recent years. The topics discussed with end-users in the present study are comparable with those present in the literature.[11,38,39]

It is being suggested that innovators should consider involving patients in the development of surgical devices.[1,4] This begs the question whether they should always involve patients, or only in specific cases. On the basis of our results, we cannot readily explain in what cases involving patients improves innovation, and we encourage future work that addresses this question. However, we would suggest that it is a valuable effort to ask patient representatives in case of doubt. Moreover, prior research has shown that innovators should not be too quick to decide that patient involvement is not relevant, as patients may desire distinct requirements for surgical devices that are not articulated by healthcare professionals.[9,12,13] A compelling case is the user-centred development of a remotely operated echocardiography robot by Giuliani et al.[11] Having conducted focus groups with patients and doctors to determine requirements for the robot, the authors found that patients expressed requirements that doctors did not formulate: open and continuous communication during the intervention, an assistant to be present in case of technical failure, and more security features and privacy warrants.[13] These results demonstrate that healthcare professionals and patients demand different requirements. Therefore, it can be valuable to involve patients in innovation even when they are not end-users. The results also show that patient involvement can be feasible.

Our findings suggest that not involving patients in device development is not a matter of forgetfulness or negligence: innovators have arguments for not involving patients, that are rooted in their experience with device development. Current guidelines or advises for patient involvement do not take these arguments in account, which probably renders them less effective.[1,2,4] Hence it is important to work out how patients can be involved in the development of surgical devices in ways that are productive, effective, and meaningful for innovators. Another suggestion is that formal methods could be used more often. Not using formal methods might result in devices that are not aligned with end-user preferences, because information gathered in unsystematic ways is less trustworthy.

In conclusion, this study suggests that despite the common call for patient involvement[1,4,9], innovators of surgical devices do not seem to see an active role for patients in R&D. They do, however, involve clinical end-users, both by formal methods and in unsystematic ways, in various steps of the development trajectory. These findings suggest that innovators' views on end-user and patient involvement, and the methodology of end-user and patient participation in R&D of surgical devices deviates from the perspectives currently found in the literature and policy advices. More work is needed to align these perspectives.

Author contributions: KW, MT, MR and RR generated the idea to study innovators views on user and patient involvement. All authors developed the research design. KW, with help of MR, identified and recruited potential participants. KW conducted all interviews, MT joined in two interviews. KW analyzed the interviews and interpreted the data, with various discussions with MT and RR. KW wrote the original manuscript draft, and MT, MR and RR edited the draft. KW responded to reviewers' feedback and MT, MR and RR reviewed this response. KW created the planning, and MT, MR and RR gave feedback.

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Ethics: The ethics committee of the region Arnhem-Nijmegen (*Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen*), a certified medical research ethics committee in The Netherlands, has approved the research design and output (CMO file number: 2021-8101). The aim, conditions, advantages and disadvantages of participation was communicated via an information letter, and all participants were given several days to consider participation. All participants gave written consent through a standardised consent form.

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Supplemental material: Interview protocol

Introduction

- Recording
- Introduction interviewer, research project
- Introduction specific research
- Informed consent and questions

Phases product development		**Main question**	**Prompts**
		Which phases in product development do you distinguish?	
WHO			
People outside company	People per phase	Not taking your employees into account: which people are involved in product development in the just mentioned phases?	Why these people? Who decided to include these people?
HOW			
		How are these people involved in these phases?	
	Methodical	Method Number participants Setting Repetition Analysis Findings	Why this method?
	Non-methodical	Method Number participants Setting Repetition Analysis Findings	Why this method?
WHY			
	Purpose	For what reason where these people involved?	Why are these reasons important?
	Practice	How did involving these people lead to that purpose? What was the added value of the consultations?	
ADDITIONAL			
	First idea	When did the first idea or concept of the device occur?	
	Important changes	What was an important change in the design? What led to that change? Which people were involved in that alteration?	
CLOSE			
		Do you have additional questions? Word of thanks.	

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQRreporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

		Reporting Item	Page Number
Title			
	#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
Abstract			
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2

Introduction			
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3-4
Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Methods			
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	4-5
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research	7

		questions, approach, methods, results and / or transferability	
Context	#7	Setting / site and salient contextual factors; rationale	5-6
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5-6
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	7
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	8-9
Data processing	#13	Methods for processing data prior to and during analysis, including transcription,	6-7

		data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	6-7
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	5-7
Results/findings			
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-15
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	8-15
Discussion			
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	13-15
Limitations	#19	Trustworthiness and limitations of findings	13-14

Other

Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	16
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	16

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