Crowdsourcing Unmet Clinical Needs in Minimally Invasive Surgery

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1 Background

Successfully developing new medical devices, including minimally invasive technologies, is heavily dependent on addressing an appropriate clinical need, "Get [the clinical need] right and you have a chance, get it wrong and all further effort is likely to be wasted" [1, p. 3]. While formalized methods, such as ethnographic research, can be effective when applied to medical technology development, less formal and potentially less effective methods are reported as commonly used [2,3] due to constraints on user accessibility and other factors [2,4]. These informal methods include processes such as "informal expert review" where input on clinical needs is primarily generated through the involvement of a small number of experts [3].

However, studies of unmet needs in non-medical applications have demonstrated that users with varying levels of expertise are equally likely to submit a need statement that is rated as high-quality and that increasing group size consistently leads to a larger number of high-quality need statements [5]. Similarly, a need statement submitted first may be equally likely to be rated high quality as one submitted after a prolonged period of time [6]. Combined, these results suggest that high quality unmet needs can be generated quickly when relying on large crowds. Using an inclusive crowds with diverse expertise levels can be beneficial by increasing the size of the user population.

Previous methods for generating need statements from non-medical user groups were adapted and streamlined for use at a conference for minimally invasive surgery (MIS). These new methods were used in a preliminary feasibility study to determine if crowds of clinician conference attendees can be a source for unmet clinical needs in MIS technology.

2 Methods

A crowdsourcing exercise for unmet clinical needs was held during the Society of Laparoendoscopic Surgeons (SLS) in New York, NY in September, 2015. The meeting includes educational content for a multispecialty audience primarily comprised of clinicians using MIS tools. This crowdsourcing data collection protocol was reviewed and designated IRB exempt by the University of Minnesota (Study No. 1508E77344).

During the conference, one 20 minute presentation discussed the topic of future technology and was co-presented by faculty in urology and mechanical engineering. The co-presenters introduced the concept of a clinical need as a critical input to any new technology development process.

The co-presenters further described the value of clinician and engineering collaboration in order to communicate unmet needs effectively from the clinical setting to the engineering labs and research centers with necessary expertise to develop solutions. At the conclusion of the talk, attendees were given instructions on submitting their own description of an unmet clinical need and were encouraged to do so during the final minutes of the presentation time. The desired need statements were described as only relating to a need, not a potential solution or invention for a need (to limit confusion or concerns about IP ownership). The instructions included a comment to avoid constraining the scope of statements to what is currently feasible. The scope of needs could relate to potential new surgical tools, improved communication while using tools, or could be directed towards more effective training and use of existing tools.

Attendees were shown information on a projected slide and were provided with a printed postcard version with details for submitting a need statement. Figure 1 represents a grayscale version of the information provided on the printed card. The reverse side (not shown) included several example need statements as guides. Attendees were instructed to take cellular phones out and use them during the final minutes of the presentation to submit need statements.

Figure 1: Instructions for Need Statement Submissions

Attendees saw a phone number on the slide and printed card. The phone number was a dedicated number created specifically to collect text messages during the conference. The phone number was provided as a bundled service from OneReach (www.onereach.com, Boulder, CO). OneReach provides a number of software platforms commonly used for customer or conference attendee feedback. These software platforms include a system to create a unique phone number and an interface to program custom outgoing text messages and custom auto-replies to incoming messages.

Attendees could type a need statement into a text message phone app and simply send the message to the provided phone number. In addition, attendees could send predefined keywords to generate auto-replies with additional information. For example, if an attendee sent a message of "info", this person's phone would receive a text message reply with additional details about the study.

The directions provided to attendees did not stipulate any particular sentence form or length for a need statement;

however, suitable examples were provided. Attendees sending need statements received a brief thank you as a reply. Each incoming message was stored remotely by OneReach and final data was downloaded at the conclusion of the study.

Any statements received through alternate communications (e.g. email) were copied and sent to the OneReach number. Several post-processing steps were performed prior to analyzing data. Some original messages exceeded the allowable length of a text message (160 characters). These were divided into multiple messages in raw data and were reconstructed after exporting. Messages with several independent statements (e.g. different topics) were manually separated after exporting. Abbreviations were replaced with complete words.

3 Results

The number of attendees in the presentation varied during the talk; however, an approximate count is 30 people. Table 1 provides an overview of need statement submissions. Approximately half of the talk attendees submitted need statements.

Table 1: Overview of Need Statement Submission

Description	Qty
Raw messages from attendees	17
Messages copied from other sources (e.g. email)	2
Unique individuals submitting need statements	14
Total need statements after processing	20

A small number of need statements would be difficult to consider further due to unclear or insufficient information. Two statements were brief and overly general. One statement included confusing language due to spelling errors or inadvertent spelling auto-correct.

Table 2 includes a randomly selected sample of 5 need statements, omitting unclear examples as described above. After a manual review, no statements were identified as duplicates.

Table 2: Examples of Submitted Need Statements

Use robot to focus energy for non -invasive surgery.

I want the ability to see through blood.

See through scar tissue so can avoid injury to bowel or bladder.

The vaginal route is considered a minimally invasive/gold standard approach to hysterectomy yet residents are not adequately trained in vaginal hysterectomy compared to total laparoscopic.

I wish my assistant could read my mind.

4 Interpretation

The crowdsourcing study successfully communicated the idea of clinical needs and generated a diverse list from the small attending group. The results suggest that the use of this method for larger groups could potentially capture a more comprehensive list of unmet needs. The list from this study included a diverse range of topics that may appeal to a wide range of technology developers. In addition, many of the need statements in candid verbatim language can be useful as topics for future in-depth user research.

Previous non-medical crowd studies included a follow-up process to rate the importance of need statements in order to identify top priorities [5,6]. This follow-up was not performed for the present study. Future work is warranted to evaluate prioritization methods for crowdsourced surgical tool need statements.

While printed materials were available throughout the multi-day conference, the targeted session with explicit discussion on the value of identifying unmet needs and instructions to submit text messages during the session generated nearly all messages for the conference. The results suggest value in future work to increase collaborative educational efforts about clinical needs in these settings. Additional improvements could be made through highlighting the need submission process during multiple subsequent sessions as this might help capture needs that arise while attending subsequent presentations. In addition, placing the phone number on a more permanent location, such as a name badge, might increase prolonged engagement.

Further development of this method can include open source dissemination to allow a range of stakeholders to review submitted needs as well as opportunities to state an interest in contributing to certain items and potentially initiating collaborations with others.

References

[1] Zenios, S. A., Makower, J., Yock, P. G., Brinton, T. J., Kumar, U. N., Denend, L., and Krummel, T. M., 2010, *Biodesign: The Process of Innovating Medical Technologies*, Cambridge University Press, Cambridge, UK.

[2] Money, A., Barnett, J., Kuljis, J., Craven, M., Martin, J., and Young. T., 2011, "The Role of the User within the Medical Device Design and Development Process: Medical Device Manufacturers' Perspectives," BMC Medical Informatics and Decision Making, **11**(15), pp. 1-12.

[3] Vredenburg, K., Mao, J.Y., Smith, P.W., and Carey, T., 2002, "A Survey of User-centered Design Practice," Proceedings of the SIGCHI Conference on Human Factors in Computing Systems: Changing Our World, Changing Ourselves, pp. 471-478.

[4] Martin, J., and Barnett, J., 2012, "Integrating the Results of User Research into Medical Device Development: Insights from a Case Study," BMC Medical Informatics and Decision Making, **12**(74), pp. 1-10.

[5] Schaffhausen, C. R., & Kowalewski, T. M., 2015, "Assessing Quality of User-Submitted Need Statements From Large-Scale Needfinding: Effects of Expertise and Group Size," Journal of Mechanical Design, 137(12), 121102.

[6] Schaffhausen, C. R., & Kowalewski, T. M., 2015, "Assessing Quality of Unmet User Needs: Effects of Need Statement Characteristics", Unpublished, Under Revision.