Improving the Pelvic Exam Experience: A Human-Centered Design Study

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Abstract: Many women are traumatized by pelvic examinations, causing them to experience increased anxiety or avoid these exams completely. Use of a vaginal speculum is necessary during the majority of pelvic examinations. The traditional speculum design is uncomfortable for most patients and lacks considerations for the health care provider. Incorporating Human-Centered Design methodology into the resolution of this problem allows for the consideration of the patient and doctor experiences when making design decisions. Interviews and observation can provide valuable insight for improvements to the design and user experience. Through empathic design, it is possible to develop an instrument that is functional and ergonomic for the health care provider while also promoting the physical and emotional comfort of the patient being examined. This paper challenges current medical standards and provides a novel approach to pelvic examination using a new vaginal speculum.

Keywords: Empathy, Gynecology, Medical Device, Human-Centered Product Design, Healthcare

1. Introduction

Pelvic examinations utilizing a vaginal speculum are one of the most common medical procedures women experience. According to the Centers for Disease Control and Prevention (CDC), there were 71.6 million visits to an Obstetrician and Gynecologist in the United States in 2012 (CDC, 2012). Approximately 160 million cervical cancer screenings are performed globally each year as part of gynecologic pelvic exams, 55 million of which occur in the United States (Kumar et al., 1994). Despite its prevalence and recognized necessity, the majority of women find gynecological examinations embarrassing and stressful (Szymoniak et al., 2009).
A vaginal speculum is necessary to perform cervical cancer screening, also known as a pap smear, and is used when evaluating pain, bleeding, and/or symptoms of infection. The vaginal speculum is a medical tool used by health care professionals to access and visualize the vaginal canal, cervix, and uterus. The current design of a typical speculum was updated in 1870 by Thomas Graves and has since only been slightly modified. In general, each speculum is comprised of two blades with a hinged joint that can be opened and locked into position to allow hands-free visualization of and access to the vagina.

2. Background

2.1 Pelvic Examination

The female pelvic examination can be a frightful process for a patient. Nevertheless, pelvic exams are crucial when screening for cervical and vaginal cancer, testing for infections and sexually transmitted diseases, evaluation of pelvic pain, and many other important health-related factors (Huber, Pukall, Boyer, Reissing, & Chamberlain, 2009).

Physicians are typically trained to ensure patient comfortable by talking them through each step of the examination, covering the patient’s legs with a drape, and heating the speculum prior to use (Kawada & Hochner-Celnikier, 2013). According to current medical textbooks, the following steps constitute the pelvic examination:

- External inspection;
- Insertion of the speculum;
- Collection of specimens for cytology;
- Inspection of the vaginal walls and cervix;
- Removal of the speculum;
- Performance of manual examination with lubricated and gloved fingers; and
- Performance of rectovaginal examination with new gloves (LeBlond, Brown, Senuja, & Szot, 2015; Kawada & Hochner-Celnikier, 2013).

2.2 The Speculum

The vaginal speculum has played an essential, yet problematic role in the history of women’s health care. The speculum is one of the leading causes of the fear and anxiety experienced by women prior to a pelvic examination. Despite this, the speculum is needed for “all situations in which visualization of the inner canal or cervix is necessary for evaluation, including situations involving trauma” (M. Zinnante, personal interview, October 5, 2016).

Before the vaginal speculum became an integral part of the pelvic examination, physicians often avoided examining their patients vaginally or rectally (Sandelowski, 2000). Even in the medical field, the female body was the subject of much controversy. To maintain a woman’s virtue, the physician would blindly examine the vagina without removing any of the patient’s clothing (Sandelowski, 2000). He (traditionally the medical profession was numerically male dominated) would either avoid eye contact with the woman or would intentionally hold her gaze “to assure her he was not looking at her genitals” (Sandelowski, 2000, p. 75), and thus ensure her virtue remained in tact with his honorable intentions (see Figure 1).
The speculum has been seen throughout history, with some designs dating back to ancient Pompeii. During the 1800s, more than 200 specula variations were created (Eveleth, 2014). In the 1840s Dr. J. Marion Sims developed the first prototype of the modern vaginal speculum (Rossmann, 2008). This version required the patient to lie on her side with the speculum placed from behind and required the support of a medical assistant (see Figure 2).
The Graves and Pederson specula are the most universally used specula in gynecological practice today, despite the design remaining almost completely unchanged (see Figure 4) for the past 140 years (Rossmann, 2008).

![Figure 3. Specula throughout history. Clockwise from Top Right: Nelson’s speculum, Sims’ speculum; PELIspec® vaginal speculum with smoke extractor; Plastic specula; UltraSpec® plastic speculum; Pink speculum, small; Stainless steel four-way vaginal expander; Fergusson speculum; Vaginal speculum, France, c. 1801-1900; Vaginal speculum, Roman, c. 100BCE-400CE; Meadows speculum; Vaginal speculum, France, c. 1801-1830; PELIspec® single-use plastic vaginal speculum.](image)

![Figure 4. Left: Traditional Graves speculum; Right: Plastic Bridea Orchid Speculum](image)

There are no set industry standards for specula size, and manufacturers vary in their categorization (see Figure 5). Physicians are simply trained to “select a bivalve speculum of suitable size” (Kawada & Hochner-Celnikier, 2013, Chapter 11). However, many factors affect the appropriate size of speculum needed. As such, physicians incorrectly choose speculum size an estimated three to five percent of the time (M. Zinnante, personal interview, October 5, 2016).
Vaginal length, vaginal width, and introital size can vary considerably, depending on “race/ethnicity, age, parity, and height” (Bates Carroll, & Potter, 2011, p. 652). Vaginal size can vary from 40 to 125 mm in length and from 18 to 65 mm in width (see Table 1). Other factors that may influence the physician’s choice of speculum size are the pelvic wall integrity, organ prolapse, and history of sexual trauma.

Table 1. Vaginal length and width ranges (Bamhart et al., 2006; Bates et al., 2011; Lloyd, Crouch, Minto, Liao, & Creighton, 2005; Pendergrass et al., 2001; Weber, Walters, Schover, & Mitchell, 1995)

| Source      | Vaginal Length range (cm) | Vaginal width range (cm) |
|-------------|---------------------------|--------------------------|
| Bamhart     | 4.0 – 9.5                 | 1.87 – 3.7               |
| Bates       | 4.1 – 9.5                 | -                        |
| Lloyd       | 6.5 – 12.5                | -                        |
| Pendergrass | 5.5 – 11.9 (anterior)     | 2.1 – 6.5                |
| Weber       | 7.2 – 12.1                | -                        |
3. Research

3.1 Physician Perspectives

The comfort of the female patient during a pelvic exam is central to compliance in women’s health care. Physicians who perform female pelvic exams are tasked with issues and concerns that are unique to female healthcare. Pelvic exams can also be difficult for the physician for various reasons.

Huber et al. (2009) conducted a study with respect to physician experiences with female patients who are difficult or impossible to examine gynecologically. When asked, “What do you think are the main reasons that women are difficult or impossible to examine?” the most common response (87%) was a previous negative experience with a pelvic exam, followed by anxiety or fear regarding the exam (79%), a previous history of emotional trauma (69%), a previous history of genital trauma (58%), and pain (52%) (Huber et al., 2009, p. 795).

Vaginismus, a “sexual pain disorder characterized by extreme fear and avoidance of vaginal penetration,” is one of the most prevalent issues with performing pelvic exams (M. Zinnante, personal interview, October 5, 2016; Huber et al., 2002. p.796). Dr. Marian Zinnante, an obstetrician/gynecologist at Women’s Care Associates in Texas (USA) states that in these situations she may need to spend 7 to 8 minutes guiding the patient through breathing exercises before she can even begin insertion of the speculum (see Figure 6).

![Figure 6. Image depicting attempt to insert speculum into patient experiencing vaginismus. From Introduction to the Basic Pelvic Examination http://www.accessmedicine.com in partnership with The McGraw-Hill Companies](image)

Physicians also cite ethnicity, body habitus (size), and age as additional factors that can contribute to a difficult pelvic exam. Ethnicity can greatly influence the size and shape of the vaginal canal. The Pendergrass et al., study (2000) took vaginal casts for measurement and analysis from women in three ethnic groups: Caucasian, Afro-American, and Hispanic. The results showed significant differences in vaginal length, width, introital diameter, and internal vaginal shape between the three groups (Pendergrass et al., 2000).

Furthermore, women who are shorter with a higher Body Mass Index (BMI) tend to have shorter vaginal canals with more of abdominal pressure exerted on the pelvic walls. This can create issues when selecting an appropriate speculum size and keeping the speculum in place during the exam. Older women tend to experience vaginal atrophy due to a lack of estrogen in the tissue. The tissue is drier, thinner, and more fragile, like “crepe paper,” according to Dr. Zinnante, and can make the exam “difficult and uncomfortable for the patient” (M. Zinnante, personal interview, October 5, 2016).
3.2 Lubrication and the Pelvic Exam

Use of an externally lubricated speculum and performing the manual exam prior to speculum exam can facilitate the pelvic examination in many ways. However, the current medical standard of care discourages the use of speculum lubrication and performing the manual exam first for fear or contaminating specimens collected during the exam. According to Harer, Valenzuela, & Lebo, (2002), the “traditional unfounded belief that lubricant cannot be used [during a speculum exam] should be abandoned” (p. 888).

The majority of recent studies support the assessment that lubrication of the speculum does not alter the cytology of cervical specimens (Amies, Miller, & Koutsy, 2002; Casselman, Crutcher, & Jadusingh, 1997; Gilson, Desai, Cardoza-Favarato, Vroman, & Thornton, 2006; Gungorduk, Ozdemir, Gökçü, & Sanci, 2015; Harer et al., 2002; Pawlik & Martin, 2009; Simavli, Kaygusuz, Kinay, & Cukur, 2014; Uygur et al., 2012).

Still, current medical textbooks continue to teach that the speculum should be placed in the vagina after being lubricated with water only (Kawada & Hochner-Celnikier, 2013) and that “use of an unlubricated speculum should precede the digital examination of the vagina “ (Leblond et al., 2015, Chapter 35). The American College of Gynecology (ACOG) perpetuates the outdated teaching that lubrication will interfere with cervical cytology, stating, “Care should be taken to avoid contaminating the slide with lubricant” (Cervical Cytology: Evaluation and Management of Abnormalities, ACOG Technical Bulletin no. 183, 1993).

One study, conducted by Holton et al. (2008), provided evidence-based data to determine that lubricants may contaminate cervical cytology. However, in this study the lubricant was applied directly onto the cervical cytology slides, not to the speculum or during a manual exam prior to speculum exam. This indicates that a similar interference or contamination may occur only if lubricant were applied directly onto the cervix, which is not common practice (Simavli et al., 2014).

It has been proven that women experience less pain and discomfort during speculum examination when lubricating gel is applied to the speculum or introduced prior to speculum examination. Additionally, if the medical provider performs the manual exam prior to speculum exam, he or she is more likely to choose an appropriate speculum size and visualize the cervix more efficiently. As such, it is only logical to perform the manual exam prior to speculum examination and incorporate the use of lubrication when performing speculum examinations (VandenBerg & Prasad, 2012).

4. Case Study – The patient perspective

Anxiety, pain, and discomfort have often been cited as the three main reasons for patient avoidance of the pelvic examination. Some women describe their pelvic exam experience as traumatic and extremely painful. When the exam is performed without care or concern for the patient’s fears or sensitivities, it can produce traumatic experiences.

One such exam is described in detail in Kapsalis’ book Public Privates (1997). The patient explained the fear and anxiety she felt during her first pelvic exam upon hearing “clanking metal instruments”, being chastised by the male physician, and being told to “relax” and that “it doesn’t hurt” (Kapsalis, 1997, p. 163). The physical exam that followed is described as being quick, “without any warning” resulting in the patient screaming in pain and crying (Kapsalis, 1997, p. 163). She did not return for a pelvic exam until 11 years later as a result of this traumatic experience.

The pelvic exam often produces feelings of discomfort, embarrassment, vulnerability, and shame, which can lead to avoidance despite knowledge of the necessity of the exam. Additional reasons for
avoidance of pelvic exams are the fear of discovering infection or illness, fear of pain, and modesty (Huber et al., 2009, p. 792).

To verify these findings, we formed the Female Pelvic Exam Experience Questionnaire with Institutional Review Board approval and offered it to women over 18 years of age who had experienced at least one pelvic exam in her lifetime. Thirty-two participants were recruited through an online social media venue (e.g. Facebook). The participants’ identities were anonymous to us to ensure authentic responses with this sensitive topic. Data was collected on the their current ages, ages at first pelvic exam, and total number of pelvic exams they have experienced (see Table 2).

Table 2. Demographic Makeup of Survey Respondents

|                          |            |
|--------------------------|------------|
| Gender: Female           | 100%       |
| Age at time of survey:   | 29.5 (5.6) |
| mean (SD)                |            |
| Age at first exam:       | 18.7 (3.8) |
| mean (SD)                |            |
| Number of Pelvic Exams:  | 13.7 (10.8)|
| mean (SD)                |            |

SD = standard deviation

The survey included fifteen open-ended questions regarding emotional and physical responses to the pelvic exam experience. We asked respondents to detail if they experience anxiety prior to an exam and what causes this anxiety, what emotions they feel prior to and during an exam, if they have ever avoided having a pelvic exam and why, if their fears or concerns have changed over time, and their emotional and physical responses to the vaginal speculum.

In general, the responses of the survey were consistent with our suspicion that the pelvic exam induced anxiety in the majority of women and that even the thought of the vaginal speculum summoned fear and anxiety in women. When asked what emotions were invoked when imagining a pelvic examination, survey respondents listed anxiety (33%), nervousness or fear (29%), and indifference or apathy (16%) as their top three reactions. Other reactions included discomfort (9%), embarrassment or self-consciousness (7%), awkwardness (2%), vulnerability (2%), and anger (2%).

The majority of respondents (69%) acknowledged experiencing anxiety prior to a pelvic exam, citing discomfort and pain, modesty and feelings of excessive exposure, and fear of test results as the top three causes of their anxiety. 55% of respondents experience anxiety, in general, unrelated to the pelvic exam. When asked if she has ever avoided having a pelvic exam even when a physician recommended one, 42% of respondents said yes. The most common reason provided for avoiding a pelvic exam was lack of access to a physician they trusted (25%) followed by financial reasons (19%), fear of test results (19%), inconvenience (13%), discomfort and pain (12%), and “not wanting to go” (12%).

More than half (59%) of respondents acknowledged that their fears or concerns prior to a pelvic exam have changed over time. The most prominent (37%) emotion felt prior to the respondents’ first pelvic exams was one of modesty, embarrassment, or self-consciousness, followed by fear of discomfort or pain (27%), not knowing what to expect (21%), fear of judgment from the practitioner (9%), and fear of test results (6%). The most prominent (50%) fear or concern experienced before the respondents’ most recent exams was anxiety regarding negative test results, followed by fear of discomfort or pain (42%), modesty or embarrassment (4%), and fear of judgment from the practitioner (4%).

With regard to the vaginal speculum, all respondents indicated they have experienced the use of a vaginal speculum during at least one pelvic exam. Among those who had experienced both metal and
plastic specula, the majority either had no preference (41%) or preferred plastic (41%), while 18% preferred metal. 6 out of the 7 respondents who preferred plastic cited the coldness of metal specula as the reason for her preference.

Many of the respondents (67%) experienced a negative emotional reaction when imagining or visualizing a speculum. Of these, the most common feeling elicited was anxiety (39%), followed by a mild non-descript emotional response (28%), fear (22%), intimidation (6%), and annoyance (5%). Physically, the respondents stated that the most common feeling caused by the speculum was pressure (33%), followed by discomfort (36%), coldness (22%), pain (8%), hard or roughness (7%) and an odd or indescribable sensation (4%).

5. Discussion and Problem Identification

Our proposed method of creating a better pelvic exam experience is a holistic approach consisting of training physicians to perform pelvic examinations in a way that has been informed by human-centered and empathic design and incrementally implementing the adoption of a new speculum design. Alternative clinics have proven that these methods not only make patients more comfortable, but may also lead to better health outcomes through consistency of care and improving patient compliance (Kapsalis, 1997).

5.1 New approach to training of physicians

Altering textbooks and teaching methods to incorporate more of a patient-centric exam may have a significant impact. The proposed new training will consist of instructing practitioners to:

- Increase patient involvement in the examination;
- Position the patient in a flat, supine position;
- Perform the bimanual examination prior to speculum examination and select the appropriate speculum size based on findings;
- Individualize the pelvic exam experience for the patient; and
- Encourage conversation throughout the examination.

The pelvic exam is a situation in which the physician and the patient traditionally have a very disparate distribution of power, causing the female patient to feel subordinate and without control of the manipulation of the most intimate parts of her body. If the practitioner can create an environment that encourages the female patient to take control in minor ways, it could have unexpected positive effects (Acta, 2004). As found in the study conducted by Larsen, Oldeide, & Malterud (1997) and confirmed in our own study, being undressed in front of the practitioner can evoke feelings of modesty, self-consciousness, shyness, and vulnerability in the female patient. The Larsen et al. study (1997) concluded that the pelvic examination must be individualized, with the practitioner acknowledging the power imbalance and being alert to “signals from the patient [that] might indicate more respectful or careful approaches” (p. 152).

The medical practitioner’s attitude can greatly impact the entire examination, influencing both the patient’s level of comfort and the practitioner’s performance. When the patient feels like she is being communicated with effectively and is more in control of what is happening to her body, it can decrease anxiety and discomfort for both the patient and the practitioner (Domar, 1986; Kapsalis, 1997). Involving the patient in the bimanual exam by requesting that she tighten and relax her Kegel (vaginal) muscles can not only assist the practitioner in assessing the integrity of the pelvic floor, but
also give the patient a sense of control, thereby reducing her stress and anxiety (Carter, Rad, Schwarz, Van Sell, & Marshall, 2013; Linden, 2005).

Selection of the speculum without assessment of vaginal length and orientation of the cervix within the vaginal vault can lead to unnecessary patient discomfort. A study performed by Carter et al., (2013) suggests that the “Rad technique,” performing a bimanual examination prior to insertion of the speculum, can lead to selection of the most appropriate size of speculum and easier visualization of the cervix. This can provide for a quicker exam and less discomfort for the patient (Carter et al., 2013).

The Rad technique corrects for three misconceptions of conventional practice in performing pelvic examination that lead to patient discomfort. These include performing of the speculum exam prior to the bimanual exam, using of a large speculum for multiparous women, and positioning the table and patient at a 30 degree incline (Carter et al., 2013).

As outlined by Carter et al. (2013), the following constitute the Rad technique:

- Place the patient in a flat supine position to afford maximum relaxation of the abdominal rectus muscles;
- After gloving, inspect and palpate the external genitalia;
- Apply vaginal lubricant to the tip of the index finger and perform bimanual examination with increased patient involvement. Reglove;
- Select the size and shape of the speculum based on the assessment made during the bimanual examination;
- Without additional lubrication, gradually insert the speculum in the direction of the cervix, using care to avoid pinching the tissue with the speculum or pushing labia minora into the vagina;
- Obtain samples for cytology as indicated;
- If indicated, perform a rectovaginal examination after regloving (pp. 613-614).

5.2 Revision to design of speculum

Our proposed revision to the speculum is one that is less intimidating visually and physically, consisting of folded spring steel blades coated in a soft, heat-resistant silicone. To ensure proper visualization of the cervix, the lower blade of the speculum must be slightly longer than the top blade (see Figure 7).

The use of spring steel as the mechanism for opening the blades decreases the strain on the medical provider’s hands and eliminates the alarming sounds of clanking metal. The provider will simply need to pinch the speculum closed, insert it into the vagina, and then allow the self-promoted spring
action of the bent steel to open the vagina (see Figure 8). The force exerted by the bend of the spring steel will be strong enough to withstand the pressure exerted by the vaginal walls without stretching the vaginal opening to an uncomfortable extent.

Figure 8. Appearance models made from 3D printed plastic, Maple, spring steel, and PlastiDip.

Incorporating materials used in sexual aids, such as silicone, will promote comfort and create a visual aesthetic closer to that of objects employed by women for enjoyment (see Figure 9). Additionally, the softness of the silicone will increase patient comfort as it can conform to the contours and individual shape of the vagina more easily.

Figure 9. Design inspiration: sexual aids made of silicone; generic kitchen tongs made of spring steel coated in silicone.
Initial iterations were created using foam, wire, and paper to ideate on blade shape and size and the ways in which the bend could be made. Several low fidelity prototypes were produced using insulation foam, maple, and strips of spring steel. The prototypes allowed us to explore tension of the spring steel, the ergonomics of the grip, and the positioning of the spring steel. Appearance models were then made using Computer-Aided Design (CAD), rapid prototyping, and cast silicone (see Figure 8).

Future iterations will allow for optimization of the resistance and distribution of force throughout the blades of the speculum. Additional prototyping using steel coated medical grade, heat-resistant silicone is indicated for user testing. Further research and testing is suggested for the development of standard sizes and optimized hand position and grip. High fidelity models will permit us to begin user testing and validation with Federal Drug Administration approval.

5.3 Incremental Implementation

The medical profession is notoriously reluctant to embrace new techniques and devices. Contrary to recent studies and common belief, many physicians proclaim that the traditional speculum is “comfortable for most people” and “good enough for a clientele not inclined to protest” (Rossmann, 2008, p. 49).

Regardless of a new device’s potential for improving the patient experience, practitioners who perform pelvic exams must be convinced of “the need for an improved device and...its efficacy, ease of use, and economic value” (Rossmann, 2008, p.48). To combat this resistance to change, we suggest an incremental approach to redesigning the speculum. The Initial changes will be made to the locking mechanisms, replacing it with the spring action of the spring steel, and materials, coating the blades in silicone. If the changes are subtle enough to not cause hesitation on the part of the medical provider, it is more likely to have universal adoption.

6. Conclusion

Anxiety, pain, and discomfort have been cited as the three main reasons for patient avoidance of the pelvic examination. Comfort of the female patient during a pelvic exam is vital to compliance in women’s health care, yet is oftentimes not achievable by the medical provider using current standards of care. Within the field of health and wellness, designers can improve the experience of the user beyond the functional needs.

We have proposed a holistic approach to improving the pelvic exam experience. This involves incremental adoption of a new speculum design and training physicians to increase patient involvement, perform the bimanual examination prior to speculum examination, and select the appropriate speculum size based on findings. Designers offer a valuable service in transforming a medical product into a consumer product that a user can relate to, actually want to use, and previously generated stigmas can be reduced.

Many medical devices are purely functional and have been designed without the consideration of the emotional and physical comfort of the patient. Designers have a unique opportunity to disrupt the healthcare industry by innovating with an empathic, human-centric approach. By allowing the patient’s emotional response to inform the design, designers can create medical devices that are less intimidating to the patient. This may reduce avoidance of care and improve health outcomes. This methodology can have a significant effect on healthcare from both patient and provider perspectives.
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