Essure: A Crisis Communication Case-Study

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Recognition and demand for family planning has become more popular within the past two decades. Women now desire to have control over their fertility and choose when they no longer wish to become pregnant. The Essure procedure was created to fill the void in permanent birth control options. Essure is a small metal device permanently placed in a woman to prevent pregnancy. This device "works with the body to create a natural barrier that keeps sperm from reaching eggs" (How Essure Really Works). Once the device is implanted, it takes roughly three months for the body to form a surrounding barrier. In order to have the procedure done, a patient must have an appointment with a doctor who is trained in the Essure procedure.

While Essure provides a seemingly appealing option to permanent sterilization that avoids surgery, some questions have been raised regarding the effectiveness of the procedure. In addition, there have been questions regarding the honesty and transparency of many studies and follow-ups recorded by Essure. Since 2013, the Federal Food and Drug Administration has recorded a 1,400% increase in complaints related to the procedure (John & Pearson, p. 51). Due to the high increase in complaints, both the policies for education and implementation of the device must be addressed.

One key issue with Essure is the side effects, both short and long term. Some of these include persistent pain, perforation of the uterus/fallopian tubes, intra-abdominal or pelvic device migration, abnormal or irregular bleeding, allergy/hypersensitivity reaction, pregnancy, as well as overall device removal (St. John & Pearson, 2017). Inadequate education prior to this procedure does not allow patients to adequately prepare for post-procedure life. Since patients are not always fully aware of risks potentially accompanied by Essure, many are surprised when they experience things such as pain, irregular bleeding or allergic reactions. This causes an

extreme sense of alarm to patients who believe they have undergone a safe procedure. This fear results from the fact that they simply weren't aware of the full list of potential side effects.

Another issue with Essure is the inability for patients to take action against Bayer. Since there are "pre-emption laws" that protect makers of medical devices from class action lawsuits, women are not able to sue Bayer after they have experienced extreme or unspoken side effects. In addition to this, there has become a decreased liability for injury and suffering for manufacturers whose devices are given premarket approval (St. John & Pearson, 2017). This creates an environment where patients are suffering and in some cases even being harmed, but are not able to take corrective action or be compensated in any way.

One major concern raised regarding research and statistics surrounding the Essure procedure is the reliability of the published studies. Bayor Essure has been very selective with what subsets of patients they include in publications. For example, a whole subset of trial participants were not given a follow up on the procedure and were excluded from effectiveness analysis (St. John & Pearson, 2017). This creates a lack of transparency in statistics shared by Essure regarding the procedure. A study published by Essure which followed up with women five years after the procedure communicated 100% effectiveness. However, after further investigation, it was discovered that only 71% of women were actually included in the follow-up analysis (Dhruva, Ross & Gariepy, 2015). Essures website advertises strengths in follow-ups, this information would prove otherwise.

There have also been concerns noted about the effectiveness of the procedure in preventing pregnancy. While Essure reports that the procedure is 99% effective, studies present the contradicting numbers of being only 81-86% effective (St. John & Pearson, 2017). Again, this proves the fact that Essure is not transparent with their communication or claims about the

procedure and device. Many patients are not followed up with for more than a year after the procedure, so Essure does not provide statistics on women who still experience pregnancy post-procedure.

Although patients are required to find a doctor who is trained in the Essure procedure, some training for doctors seems to be ineffective. Many cases have been reported of the Essure device not properly placed during the procedure. This forced some women to get a hysterectomy, the procedure that most use Essure as an alternative to begin with (St. John & Pearson, 2017). Another study performed by Jost, et. al. found that some cases of an ineffective Essure procedure was caused by the physicians deviating from protocol (2013).

The root of most problems in this case study stem from poor communication between Bayer Essure and patients who undergo the procedure. There is not enough literature or studies to educate patients on the risks and side effects of the procedure, and Bayer Essure does not maintain communication with patients long after the procedure. And when they do choose to engage in communication, they show a tendency to significantly downplay concerns or testimonies that the device has led to significant amounts of pain (St. John & Pearson, 2017). Bayer Essure has been unwilling to change the product or reevaluate policies even though there have been significant concerns raised in the past few years.

Women seeking options for birth control exist as a main stakeholder. These are people who are desire a sterilization procedure and often looking for a non-surgery option. They are interested in finding a safe method of preventing further fertility in their future. While there is an understandable amount of uncomfortable pain expected, most women are seeking a procedure that won't require them to go through significant pre or post procedure life changed.

Another important stakeholder is the doctors who perform the procedures. Each doctor has taken an oath to "do no harm" and should be acting in the patient's best interest (St. John & Pearson, 2017). These stakeholders are in charge of the procedure and should be fully aware of all the risks and side effects that could occur. They work closely with Bayer Essure, the company who spupplies the Essure procedure package for each patient. This company has worked to provide an option of sterilization for women but also strives to make money from their product. A fine line must be drawn between the push to make money as a company and ensuring that a safe and effective procedure is being provided. Since doctors have created the Essure procedure, they, too, are under the oath to do no harm. Regulatory agencies, such as the Federal Food and Drug Administration, serve as another stakeholder. They want to ensure that products with FDA approval are not causing severe risks to patients.

There are a few ethical questions that must be asked in regard to the Essure procedure. The first deals with the decreasing liability for injuring and suffering (St. John & Pearson, 2017). The decrease in liability raises questions as to whether or not the manufacturers are purposefully distributing faulty procedure kits and then refusing to take care of patients who might experience problems after the procedure. Again, this goes against the doctor's oath to do no harm.

Another ethical concern is the faulty display of statistics and testimonies (St. John & Pearson, 2017). For example, there was a patient who had reported that she was experiencing "extreme pain." In the records, though, Essure crossed out the word extreme which made the patients problem seem less significant (St. John & Pearson). Bayor also selects only certain patients to follow up with post-procedure to ensure that their success rate remains as high as possible in the data that they report. However, just because the numbers of post-Essure

pregnancies are not reported does not mean that they did not occur. This raises questions about the level of transparency that Bayor Essure is willing to have with their patients.

Altering testimonies and skewing statistics communicates that Bayor Essure is more concerned with pushing their product and making money than they are with the safety and satisfaction of their customers. Through their actions, they have proven that they are more concerned with making money and are choosing to ignore the interests of their primary stakeholders.

While there have been significant concerns about the effectiveness and safety of the Essure procedure, there is still an opportunity for Bayor to provide a procedure that is beneficial to patients. One major step that is essential for Bayor Essure is to evaluate company goals and objectives. Currently, Essure is torn between the desire to make money as a company and a desire to provide a quality product to patients. Before any other steps are taken, Essure must be clear on what their main goal as a company is. Then every step taken to resolve the crisis must be in line with that company goal and mission. Since Essure is operated by doctors, they must first and foremost act under the oath to do no harm.

Another option for Essure is to improve communication with stakeholders. Several Essure-Problems Facebook forms are full of active users and patients who have had trouble with the Essure procedure. Bayor Essure has significant opportunity to engage in, not just monitor, comments that are being made. If patients are having obvious problems with the procedure, Essure has the opportunity to turn a negative experience into a positive one. In order to accomplish this, though, they must be actively engaging with patients and staying in touch with them more than just a year after their procedure. Another way to improve communication between the company and patient is to utilize forms and feedback lines where patients can voice

any concerns or problems that they have encountered with Essure. This gives Essure the opportunity to listen to concerns and improve the procedure for future patients.

Education for both the patient and the doctor is another area that has significant room for improvement. Pamphlets, fliers and videos could be utilized to ensure that the patient is fully aware of the steps of the procedure as well as the potential risks and side effects. This literature can also take advantage of promoting the benefits of Essure as long as it is honestly communicating the negative side effects that could occur. Bayor Essure also has opportunity to improve the education of doctors performing the procedure. A study from J.E. Rios-Castillo et. al. (2013) reported that one of the most common factors in procedure failure is inexperience of surgeons. Not only should each doctor have to go through extensive training, but the training should be constantly updated and reassigned every few years to ensure that up-to-date processes are being used.

Moving forward in this crisis Bayor Essure needs to follow three steps. First, they need to issue an immediate recall of the product. This recall needs to last long enough for extensive research and testing to ensure a higher success rate and reduce rate of injury or side effects. Recalling the product and taking the time to adequately research it shows the patients that the company is truly concerned with providing a safe and effective method of sterilization. This also proves to the patients that Essure first and foremost cares about the wellbeing of those undergoing their procedure. Once the product is well-researched and ready to go back on the market, small groups of women should be tested and followed throughout the process to ensure that the proper corrections have been made.

The second step that Essure needs to take is to revamp education of the procedure to ensure that patients know exactly what the procedure entails. Extensive videos and literature with

information regarding what to expect before, during and after the procedure should be provided to each client. This will lead to a more educated patient who is aware of full benefits as well as side effects of the procedure. Bayor Essure also needs to create an extensive training program for doctors performing the procedure. This program should be constantly updated and required for doctors every three years. Having extensive training lowers the risk of having a doctor who is not properly educated resulting in improper implementation of the device. This will lead to a smoother procedure for both the patient and the doctor.

The third step that must be taken by Bayor Essure is to actively engage and monitor past, present and future clients on social media and other feedback forms. This will allow the company to maintain a relationship with the patients and continually be checking in. This also communicates to the patient that the company cares about their experience with Essure beyond just the procedure. Active communication also shows the patient that Essure is constantly looking for ways to improve the product or procedure to ensure the highest amount of customer satisfaction. If Bayer Essure is willing to take these three steps they have significant opportunity to improve the reputation of the entire company.

References

Bahk, C., Goshgarian, M., Donahue, K., Freifeld, C., Menone, C., Pierce, C., & ... Dasgupta, N. (2015). Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US. Pharmaceutical Medicine - New Zealand, 29(6), 331-340. doi:10.1007/s40290-015-0106-6

Dhruva, S. S., Ross, J. S., & Gariepy, A. M. (2015, October 8). Revisiting Essure - Toward Safe and Effective Sterilization | NEJM. Retrieved March 26, 2018, from http://www.nejm.org/doi/full/10.1056/NEJMp1510514

How Does the Essure® Procedure Work? (n.d.). Retrieved March 26, 2018, from http://www.essure.com/what-is-essure/how-essure-works

Jost, S., Huchon, C., Legendre, G., Letohic, A., Fernandez, H., & Panel, P. (2013). Essure® permanent birth control effectiveness: a seven-year survey. European Journal Of Obstetrics & Gynecology & Reproductive Biology, 168(2), 134-137. doi:10.1016/j.ejogrb.2012.12.042

Ríos-Castillo, J. E., Velasco, E., Arjona-Berral, J. E., Monserrat Jordán, J. A., Povedano-Cañizares, B., & Castelo-Branco, C. (2013). Efficacy of Essure hysteroscopic sterilization - 5 years follow up of 1200 women. Gynecological Endocrinology, 29(6), 580-582. doi:10.3109/09513590.2013.777419

St. John, B., & Pearson, Y. E. (2017). Crisis communication and crisis management: An ethical approach. Los Angeles: Sage.