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November 15, 2010  
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A Mixed-Method Evaluation of Public Perceptions Regarding  
Patient Communication following a Patient Safety Breach

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A Mixed-Method Evaluation of Public Perceptions Regarding  
Patient Notification following an Infection Control Breach

By

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B.A., Luther College, 2009

A abstract of a thesis submitted to the  
Department of Behavioral Sciences and Health Education  
Rollins School of Public Health  
in partial fulfillment of the requirements of the degree of  
Master of Public Health

Behavioral Sciences and Health Education  
2010

## **Abstract**

**Background:** Unsafe injection practices in healthcare settings most often result in the notification of potentially affected patients. Few studies have highlighted public perceptions of the problem of unsafe injections, their perceived commonality and risk, as well as the information to be included within a patient notification letter. Through secondary data analysis, the Health Belief Model was used as a framework for evaluating public perceptions regarding patient notification following identification of unsafe injection practices.

**Methods:** Six focus groups were conducted during Fall 2009, with residents of Atlanta and New York City. Two groups within each city were given a sample patient notification letter for a portion of the questions while the third groups in both cities were asked to answer the questions without a notification letter.

**Results:** A total of 53 individuals participated in the six focus groups; only two had ever heard of the term “safe injection practices.” After being provided with a brief definition, most participants felt that unsafe injections were slightly more common in a hospital setting (Likert-scale of 1[not at all] to 5 [very]; Mean=3.30) than in a doctor’s office (Mean=2.13) citing themes such as greater workload. Participants somewhat agreed that they felt at risk of receiving unsafe injections (Likert-scale of 1 [strongly disagree] to 5 [strongly agree]; Mean=2.75) mainly because they felt there is always a chance. After the identification of unsafe injection practices, participants preferred to be notified via phone, letter, email, or face-to-face from the facility where the incident occurred. Over 25 different types of information were cited as necessary elements within a patient notification letter including: corrective actions by the facility, course of action for patients, and assurance of medical coverage.

**Conclusion:** The results of this study provide evidence for the implementation of patient safety programs highlighting safe injection practices to increase knowledge and awareness of patients on this growing issue. Additional programming should also focus on increasing perceived susceptibility and severity of unsafe injections. Further discussion by public health professionals should focus on determining what information should be included in a patient notification letter to decrease barriers and increase benefits of testing.

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## Acknowledgements

First and foremost, I would like to express my heartfelt thanks to my thesis committee – Dr. Colleen DiIorio and Ronda Cochran – for guiding me on the journey of composing this thesis. Without their advice and continued support, this endeavor would have not been possible. Thanks to Colleen I was able to clarify and polish my thoughts, writing, and interpretation. I would also like to extend an enormous thank you to Ronda for not only teaching me the weaving ways of a behavioral scientist, but also pushing me to never settle for less than my absolute best. The countless hours spent reading over outlines and drafts providing checkmarks and smiley faces will never be forgotten. I feel truly blessed to have her as my supervisor and mentor over the course of my time here at Rollins. I would also like to thank Krissy Brinsley-Rainisch for providing her knowledge, guidance, and continued input throughout this process. Finally, I would like to thank my family and friends for their encouragement and continued belief in me and my abilities. Without all of you I would not be where I am today.

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## **Introduction**

### *Injection safety*

Each year hundreds of thousands of Americans visit healthcare facilities for medical care. During the majority of visits, healthcare personnel provide patients with adequate care in a safe environment. However, patients also can be subjected to unsafe medical practices by healthcare personnel due to human error, incorrect execution of procedures, inadequate training, criminal intent, or simply an effort to save time and money.<sup>1,2</sup> One specific example of an unsafe medical practice is giving unsafe injections. As defined by the World Health Organization (WHO), injections are the infusion of a substance into the skin, subcutaneous tissue, muscle tissue or veins.<sup>3</sup> Injections are one of the most common healthcare procedures with roughly 16 billion injections taking place worldwide each year.<sup>4</sup> However, the proportion of injections that are not safe is unknown at this time.<sup>4,5</sup>

The WHO defines safe injections as those that do not harm the recipient, do not expose the provider to any avoidable risks, and do not result in dangerous waste for the community.<sup>4</sup> Using the same syringe to administer medication to multiple patients even after the needle was changed; using a single dose medication vial for more than one patient, and using a common bag of saline for more than one patient are all examples of unsafe injection practices.<sup>1</sup> Any medical procedure using injections, such as blood glucose monitoring, sedation for endoscopy, oncology treatment, pain management, and vaccination can potentially put patients at risk.

During any of these medical procedures, bacteria and viruses can be transmitted from an infected patient to non-infected patient through unsafe injections.<sup>1</sup> For example, during an injection, blood from an infected patient can travel up the needle and into the syringe causing the syringe to be contaminated.<sup>6</sup> When the syringe is inserted back into a medicine vial, it contaminates the medicine with the infected patient's blood. If a sterilized needle and syringe



are then used to draw out and inject the medicine into a new patient, that patient may then become infected because of the previous patient. Unsafe injections place patients, as well as healthcare personnel, at risk of acquiring infections. This risk includes contracting bacterial, fungal, and viral infections along with blood-borne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) among others.<sup>1, 4, 5, 7-14</sup>

Unsafe injections are entirely preventable, but continue to be a public health problem.

In 2002, a study conducted on behalf of the American Association of Nurse Anesthetists (AANA) found that 3% of anesthesiologists and roughly 1% of Certified Registered Nurse Anesthetists (CRNAs) reused needles and/or syringes on multiple patients.<sup>15</sup> These percentages equate to roughly 750 anesthesiologists and 250 CRNAs for a total of 1,000 providers that did not follow correct infection control procedures. A newly published study from the Centers for Disease Control and Prevention (CDC) in collaboration with the Centers for Medicare and Medicaid Services (CMS), inspected compliance with all Medicare ambulatory surgical center (ASC) health and safety standards at 68 ASCs in three states within the United States.<sup>16</sup> Overall results showed that 46 (67.5%) of the 68 facilities inspected had at least one lapse in infection control while surveyors were present. Of 67 facilities, 19 (28.4%) were cited for violations regarding injection practices or misuse of medication. Furthermore, 25 (46.3%) of 54 ASCs were found to be using improper procedures for blood glucose monitoring equipment leading to possible disease transmission.<sup>16</sup>

In recent years, epidemiological surveillance has documented numerous outbreaks of blood-borne infections due to unsafe injections.<sup>17-20</sup> A systematic review conducted by CDC researchers, highlighted 33 outbreaks of HBV and HCV in nonhospital healthcare settings occurring in the United States over the last ten years, resulting in the exposure of more than

60,000 individuals to HBV and HCV.<sup>17</sup> These outbreaks were all epidemiologically linked to lapses in infection control such as syringe reuse and improper use of single use medicine vials.<sup>18</sup> Additionally, unpublished data highlighted at the 2010 Fifth Decennial International Conference on Healthcare-Associated Infections confirm eleven more outbreaks of HBV or HCV from 2008-2009.<sup>19</sup> Nine of the eleven occurred in nonhospital settings, involved patient-to-patient transmission, and were linked to breaches in infection control.

In addition, HBV and HCV outbreaks also have been associated with fingerstick devices and inappropriate use of multi-dose medications/solutions. In 1996, two healthcare facilities experienced outbreaks of HBV that were related to the unsuitable use of fingerstick devices used to monitor blood glucose levels.<sup>21</sup> Similarly, less than a decade later, three long term care facilities experienced outbreaks of HBV that were traced back to breaches in infection control through the improper use of blood glucose monitoring devices.<sup>22</sup> Yet another outbreak of HCV prompted an evaluation of the infection control procedures at a Nebraska oncology clinic. Investigators linked the HCV to unacceptable infection control procedures performed by a nurse on staff, such as reusing disposable syringes to withdraw saline solution after withdrawing blood from central venous catheters.<sup>23</sup>

Along with HBV, HCV, and HIV, lack of proper infection control procedures also can lead to other diseases. Reusing of single dose medication vials along with using a common needle and syringe to access multiple medications led to an outbreak of *Serratia marcescens* in seven patients of an outpatient pain clinic.<sup>24</sup> A similar procedure taking place at a hemodialysis center caused ten patients to be infected with *Serratia liquefaciens* bloodstream infections.<sup>25</sup> Another investigation was launched at seven different hospitals after unusual outbreaks of bloodstream infections, surgical-site infections, and acute febrile episodes occurred after surgical

procedures.<sup>26</sup> Again the infections were traced back to improper following of infection control guidelines resulting in the use of the anesthetic propofol in unsafe injections.

Internationally, a recent report by Miller and Pisani estimates that unsafe injections cause roughly 1.3 million early deaths for a loss of 26 million years of life worldwide.<sup>5</sup> Of the worldwide incidence of HBV, HCV, and HIV, unsafe injections cause 33%, 42%, and 2% of all new cases, respectively.<sup>4</sup> Throughout the world, unsafe injections cost an estimated \$535 million (USD) a year in direct medical costs alone.<sup>5</sup> In addition to the financial costs, there are costs to psychological and emotional well-being of affected individuals and their family members.<sup>27</sup>

Unsafe injections have recently gained more public attention due to media coverage of infection outbreaks as well as resulting legal procedures.<sup>28-31</sup> In May 2010, a Nevada jury found two pharmaceutical companies liable and awarded over \$505 million in damages to a victim who contracted HCV as a result of the reuse of single dose vials of the anesthetic propofol on multiple patients that took place at an endoscopy center in 2006.<sup>28, 29</sup> Clinic staff told investigators that they were instructed by facility administrators to reuse supplies and medications in order to save money.<sup>2</sup> That same month, a Colorado woman, who also was infected with HCV from a used needle left behind by a surgical tech who was diverting fentanyl syringes, filed a lawsuit against the healthcare center as well as the healthcare provider for failing to supervise the incident.<sup>30</sup> These lawsuits were filed following large-scale patient notifications that took place after unsafe injection practices had been identified at the healthcare centers.<sup>28-30</sup>

### *Patient Notifications*

When certain infection control breaches occur, whether or not transmission of disease has been identified, patients must be notified of their potential exposure.<sup>27</sup> Because the frequency and duration of the unsafe practice is often unknown, patient notification letters are often sent to

a large number of people that could have been exposed to an infection during their stay at the healthcare facility. However, before sending the notification letters, health officials must identify the risk of patient exposure and evaluate the effect, not only on the patients receiving the letter, but also on the healthcare facility as the process of notifying patients is often highly resource and labor intensive.<sup>27</sup> Healthcare administrators also must assess whether to offer testing within a notification if/when no disease transmission has been identified.

The Association of Practitioners in Infection Control and Epidemiology, Inc. (APIC), recommends that patient notification efforts be restricted to use only where data suggest that there was potential disease transmission from infected patient/healthcare provider to one or more patients.<sup>32</sup> The APIC Committee on Blood-borne Pathogens also states that notification programs should take place with the help of local/state public health departments in order to develop a plan for investigation which will: “1) ensure confidentiality, 2) provide for appropriate notification and counseling of patients before testing, 3) provide arrangements, criteria, and funding for any necessary testing, 4) provide follow-up counseling with notification of test-results, 5) develop a mechanism to refer patients found to be HIV seropositive or HBV seropositive for appropriate care and follow-up, including definition of economic responsibility for this care, and 6) determine the need for further investigation.”<sup>32</sup>

#### *Evaluation of Patient Notifications*

In all instances, supplying medical information to the patient allows him/her to have an accurate understanding of his/her health and well-being. Along with providing the opportunity to make informed health decisions, having this information allows patients to reduce their anxiety, potentially enhancing their ability to cope.<sup>33</sup> According to an article written by Karnieli-Miller et al., patient notifications should be correct, understandable, prompt, and

compassionate.<sup>33</sup> Despite the fact that these patient notifications are very important to a person's health and well-being, they have not been adequately evaluated from a patient perspective. The few studies that have been conducted on this topic found notifications left patients confused by the unclear messaging and use of medical terminology. A recent article by Patel, Srinivasan, and Perz examining the management of infection control breaches states that communication to the patient should be written in nontechnical language, use qualitative interpretations of risk, and include recommendations of next steps.<sup>27</sup> They also state that guidance on testing procedures should be included with special focus on the reasons for testing.

While patient notifications following injection safety breaches have not been as commonly assessed, patient notifications for receiving lab results and screenings have been more thoroughly evaluated.<sup>33-38</sup> A study of 49 participants receiving lab results regarding cholesterol found that 63% preferred to be notified of results via letter, with 17% and 13% of respondents preferring phone call or face-to-face delivery, respectively.<sup>35</sup> Because the mail method demands the least amount of resources, it may be the most feasible for low-resource healthcare facilities. It also is most preferred by healthcare facilities and physicians because it allows for swift dissemination of comprehensive information to be sent directly to the patient.<sup>33</sup> This method also allows the patient to proceed at his/her own pace in regards to comprehending and processing the information, along with the ability to consult the statements as many times as necessary.<sup>39</sup> However, despite being preferred, this method is seen as the most impersonal because there is no interaction between the patient and provider leaving little opportunity for discussion and/or questions.<sup>35</sup> While verbal communication offers the ability to discuss results, ask questions, and gain encouragement, it is often time consuming and may not be conducive to dialogue as the patients may not know what questions to ask.<sup>39</sup>

A study by Baldwin et al. conducted in-depth interviews with twenty participants regarding their preferences for patient notification of lab results.<sup>34</sup> Results showed that respondents wanted detailed information provided in a timely manner. Participants also requested to be adequately informed of next steps as well as the opportunity to discuss results and/or ask questions. Respondents were adamant about ensuring privacy and confidentiality of their results. A publication regarding informing patients of medical errors states that patients want to know what happened, the error's implications on their health, why it happened, how the error will be resolved, and how future errors will be avoided.<sup>40</sup> Patients also preferred to be provided with all of the necessary information instead of being expected to ask the correct questions. Along with these concerns, patients expressed interest in being reassured that they would not be financially liable for the consequences of the error, the practitioner as well as the institution expressed regret for the error, and plans have been set in place to prevent the error from occurring in the future.

In an article on providing patient health information, Tang and Newcomb suggest guidelines for patient-care educational materials.<sup>41</sup> Their P.A.T.I.E.N.T. guidelines outline qualities of the information that should be implemented in order to ensure patient satisfaction and retention. Materials must be Personal, information should include personal identifiers; Articulate, materials should be clear and concise to promote understanding; Timely, information should be conveyed to the patient as soon as it becomes known; Informative, educational information should take into account literacy level and language barriers; Endorsed, patients prefer to receive information directly from their physicians or from sources their personal physicians recommend; Next-step, patients desire detailed information about the next-steps that need to be taken regarding personal care; and finally Therapeutic, in order to increase patient

compliance, materials should be focused on improving understanding and retention of relevant information.<sup>41</sup>

### *Health Belief Model*

Ultimately, the purpose of patient notifications in regard to a breach of patient safety is to encourage affected patients to be tested for infection thus preventing the spread and/or further progression of disease. Numerous studies have been conducted using behavioral theory to explain testing and screening behaviors with patients as well as the general public.<sup>42-48</sup> Due to its ability to explain individual behavior, one very important theory in these discussions has been the Health Belief Model (HBM). Since its beginnings in the 1950s, the HBM has been used to explain and predict a variety of health behaviors for many different populations.<sup>42</sup> This model relies on two variables: 1) the importance placed by the individual on a certain goal, and 2) the individual's estimate of the chance of accomplishing the goal by performing the given action.<sup>49</sup> Within these two variables, six constructs outline the essential features of the model in predicting health behavior (i.e., testing for HIV, HBV, and HCV following notification).

The HBM takes into account modifying personal factors and individual beliefs when predicting/explaining action. Modifying personal factors include qualities such as age, gender, ethnicity, socioeconomics, awareness, and knowledge.<sup>42</sup> These personal factors then influence individual beliefs such as perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and perceived self-efficacy. Perceived susceptibility of the outcome and perceived severity of the outcome can be grouped together to form the overall perceived threat of the outcome. The next three constructs—perceived benefits, perceived barriers and perceived self-efficacy—can be grouped together to form an overall construct of perceived expectations for performing the behavior/action. The final construct, cues to action, includes anything that

motivates the individual to carry out the behavior/action. The combination of these six constructs leads to the explanation of whether an individual will perform a behavior/action in order to prevent the given outcome (Figure 1). The model posits that if one believes he/she is susceptible to a condition, believes that condition could potentially have serious consequences, believes that there are steps that can be taken to reduce either the susceptibility or severity of the condition, and believes that the benefits of taking action will outweigh the barriers, he/she is likely to take action to reduce his/her risk.<sup>42</sup> Therefore, using this theory as a framework for behavioral interventions can lead to more successful preventative targeting in an effort to ultimately influence individual behavior.

While the HBM has not been used as a framework to evaluate effectiveness of patient notifications regarding injection safety, it has been used in a variety of other areas.<sup>50-54</sup> An area that the HBM has been particularly useful in is predicting vaccine uptake for preventable diseases. Studies by De Wit et al. and Rhodes and Arceo involving the prediction of hepatitis A and B vaccination have found that perceived susceptibility and perceived severity were able to predict vaccine uptake behavior.<sup>51, 55</sup> Participants who were already vaccinated against hepatitis A were more likely to score higher on perceived severity and susceptibility than those that had not been vaccinated.<sup>51</sup> Also addressed within these studies as affecting vaccine uptake were perceived barriers and perceived benefits to vaccination. Some of the most common barriers to vaccination cited by respondents were lack of time, cost, pain associated with injection, misconceptions about vaccines in general, and exposure of one's private lifestyle.<sup>52, 55</sup>

Preventative screening is another area that commonly employs the use of HBM in predicting and explaining health behaviors. A study examining the use of mammography showed that the odds of using mammography increased for individuals who thought of



themselves as being susceptible to breast cancer as compared to other diseases.<sup>48</sup> Perceived severity of breast cancer also was higher in respondents who have had a mammogram than those that had not.<sup>43</sup> Perceived barriers and perceived benefits were the most powerful predictors in many studies involving preventative screening.<sup>44, 46-48</sup> Participants who had already received mammograms perceived fewer barriers and more benefits to getting screened.<sup>47</sup> For those who had not already had a mammogram, common barriers cited were fear of finding cancer, inconvenience, worry, and embarrassment.<sup>47</sup> A study involving patients receiving Papanicolaou (Pap) smears found perceived benefits of early detection of cancer by the Pap smear and perceived barriers of Pap tests to be the most important behavioral predictors.<sup>44</sup> Additionally, another study found that cues to action, such as a physician referral, was the most important factor related to mammography screening.<sup>48</sup>

These studies have all used the HBM as a guide to predict and/or explain behavior. Similarly, this research uses the HBM as a framework to explain a patient's preference for testing after receiving a patient notification. As shown by the vaccine uptake research, increasing perceived susceptibility and perceived severity increases the likelihood of vaccination. The current project will use the HBM constructs of perceived susceptibility and perceived severity as guides to determine what type of information the public needs to raise their level of perceived threat. Additionally, the barriers and benefits to vaccination as well as getting screened for both breast and cervical cancers such as lack of time, unnecessary cost, fear, and early detection may be similar to those found in this study. Much like those studies, this research will highlight the barriers and benefits to getting tested after receiving a patient notification letter.

### *Limitations of Previous Research*

Based on the above information, there is a dearth in the research regarding evaluation of patient notification letters by the general public. Because the ultimate goal of these patient notification letters is to promote testing for potential infections, it is vital that these letters be evaluated by the public in order to determine whether the letters are in fact serving their purpose. Previous literature has not addressed the aspects of notification letters that are most important to patient safety. Additionally, the HBM has not been employed as a framework in evaluations of patient notifications of any kind. Therefore, this study will fill the gaps within the research by evaluating patient notification letters using the HBM as a framework in order to begin establishing a knowledge base for informing the development of patient notification letters in the future.

### *Purpose/Research Question*

The purpose of this research is to examine current patient notification letters and determine how they could be better adapted to best fit patient needs. In order to examine the perceptions regarding patient communication following a breach of patient safety with an unsafe injection practice, focus groups were conducted. Focus groups were performed in order to provide formative information to be further examined and applied within patient notification letters. A secondary data analysis of six focus groups conducted by the Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion will focus on the following research questions:

- 1) What are the general perceptions regarding patient communication following a breach of patient safety?

- 2) What are the public's perceptions of the problem of unsafe injections (knowledge of safe injection practices)?
- 3) What is the public's perceived risk of infection due to an unsafe injection practice?
- 4) What information should be included within a patient notification letter?

## **Methods**

### *Research Design*

Three focus groups were conducted in each of two major metropolitan cities: New York City, New York and Atlanta, Georgia during October and November of 2009. These cities were purposefully chosen to represent an “exposed” population (i.e., several patient notifications regarding injection safety issues have taken place within the last two-three years in New York City) and an “unexposed” population (i.e., no known patient notifications in recent years in Atlanta).

### *Participants and Recruitment*

Participants were recruited by a professional market research facility. In order to participate in these focus groups, participants must have met the following inclusion criteria 1) aged 45 years or older, 2) have medical insurance/coverage, and 3) not have worked directly in a health-related field. A maximum of nine people could participate in each focus group. All participants were non-institutionalized adults who verbally consented to participating in the study at the beginning of the focus group discussion. Participants were explained the risks and benefits that could accompany the discussion along with the opportunity to leave the room at any time.

### *Procedure*

Focus groups were led by a trained and experienced moderator who followed a structured script of both open-ended and Likert-scale questions. Participants were informed prior to the start of the focus group that they would be viewed through a one-way mirror and their voices audio recorded. Participants were asked to provide their first name for identification purposes during the discussion. They were assured that the recordings were for analytical purposes only

and their names would not be associated with their comments. Each focus group lasted roughly one hour and was held at the market research facility in each respective city. Light refreshments and honoraria were provided to the participants at the conclusion of the discussion.

### *Measures*

Two focus group scripts were developed by researchers from the Division of Healthcare Quality Promotion (DHQP) at the Centers for Disease Control and Prevention (CDC). One script was used for groups that received a sample patient notification letter during the discussion (two groups in each city) and the other was used for the remaining two groups (one in each city) who were not provided a sample letter. Both scripts included three sections—preferences for receiving health information, knowledge of safe injection practices, and responses to and preferences for a patient notification letter.

Part one was the same on both scripts and contained three open-ended questions regarding how participants prefer to receive health information and who/what organization would they trust if he/she was potentially exposed to infectious disease. Part two also was the same on both scripts and contained six open-ended questions and two Likert-scales concerning whether participants had heard of “safe injection practices,” examples of diseases that could be transmitted from unsafe injection practices, perceived commonality of unsafe injections, and perceived personal risk of unsafe injection. Using a round-robin format, each participant was asked to provide a response to the Likert-scale questions. Participants’ numeric answers to the Likert-scale questions were then matched with their qualitative reason/explanation for their numeric response.

Participants in two of the three groups in each city were then asked to read a sample of an actual de-identified patient notification letter (see Appendix). One group in each city received a

letter that was written by a healthcare facility where an unsafe practice had been identified yet there was no known disease transmission at that time. This letter outlined what may have caused the notification event, provided information on testing for potential pathogens, and included a 24-hour hotline number along with a website in order to provide patients with needed information. The second group in each city received a letter that was written by a health department notifying patients that unsafe practices had been identified along with disease transmission. This letter also outlined what may have caused the notification event along with highlighting the importance of testing as well as providing an additional phone number and website for Spanish speaking patients. Group three in both Atlanta and New York City received no letter. The third section of the focus group contained 12-14 questions for the letter and non-letter groups, respectively. Questions regarding attitudes and preferences towards his/her notification letter, such as key concerns, information about the incident, information about the diseases at risk for acquiring, actions taken following receipt, and likelihood of being tested following receipt were asked.

### *Analyses*

A mixed-method secondary data analysis was conducted on the focus group transcripts after the audiotapes were transcribed verbatim and de-identified. The Institutional Review Board at Emory University determined on May 27, 2010, that the study did not meet the threshold definition of “human subjects” as set forth for IRB purposes in Emory policies and Federal rules at 45 CFR Section 46.102(f)(2) and that no IRB review or approval was required (IRB00044552). Descriptive statistics, frequencies, chi-squared, t-tests, ANOVAs were generated for Likert-scale questions. Themes from the open-ended questions were aggregated

and characterized during group coding sessions. Individual themes were then collapsed into standardized themes and qualitatively analyzed for each question.

## **Results**

### *Participant Demographics*

Six focus groups, three in both Atlanta and New York City, were conducted during October and November 2009. Groups were composed of eight to nine participants each for a total sample size of 53 participants (Table 1). Males and females were equally represented (female=49.1%, male=50.9%) within the focus groups and participants had an average age of 54.9 (Median=53, Range=45-69) years. The majority of participants were employed in full-time positions (52.8%), Caucasian (35.9%), and had health insurance through a preferred provider organization (PPO) (45.3%). There were no statistically significant differences between the participants based on their city of residence.

### *Methods of Preferred Health Communication*

When participants were asked how they generally prefer to receive information about their health, letter/mail and email were the top two responses followed closely by face-to-face with a doctor. Other methods included: phone call, Internet, articles, magazines, newspaper, television, friends/word of mouth, and other (i.e., “do research about it” and “research on my own”). Additionally, when asked how they would prefer to receive information if potentially exposed to an infectious disease or an infection, participants responded over a phone call (42%), face-to-face from a doctor (21.7%), or through email (18.8%). These responses were followed by letter/mail, text message, and other (i.e., from the Health Department). Forty-nine percent of participants responded they would trust their personal doctors most for information if they were potentially exposed to an infectious disease or an infection, followed by the CDC (30.8%). Respondents also cited the Health Department, Internet, news/CNN/television, organizations that



“focus on that specific infection”, World Health Organization, and Journal of the American Medical Association.

Participants were then asked from whom patients should be notified when an unsafe injection practice was identified. Of the total number of responses, over half stated they wanted to be notified from a member of the healthcare staff at the facility where the incident occurred stating: “whoever administered the injection” and “whoever provided the care”. The next most common response was receiving notification specifically from the leadership of the facility where the incident occurred, citing “somebody extremely high up in the hospital.” Other responses ranged from participants’ personal doctor, a HMO, the government, and the “source that has actually diagnosed what the disease was.”

As far as what channels should be used to contact patients when an unsafe injection practice has been identified, 40% of responses were in favor of a phone call while 28% were in favor of a letter/ mailing. Other responses for methods of notification included email, followed by a face-to-face visit. Participants also were asked how many times an attempt to contact a patient should be made. All but one of the respondents stated that the notification process should continue “as long as necessary” to contact the patient.

#### *General Knowledge and Perceptions of Commonality and Risk*

When asked if they were familiar with “safe injection practices” only two participants of 53 total responded that they had heard the term used before. After being provided with a short definition of safe injection practices, respondents were asked to provide what they believed to be examples of unsafe injection practices. Responses included improper disposal of injection equipment, reuse of injection equipment, using unsterilized equipment, improper glove use, lack of hand hygiene, improper handling of injection equipment, lack of patient skin preparation, lack

of use of masks, and others (i.e., temperature of the room, doctor's wearing ties, and failing to get the air bubble out of the syringe before injecting the patient). Along with this, participants most often cited HIV/AIDS and hepatitis as diseases that could be transmitted from unsafe injection practices followed by methicillin-resistant *Staphylococcus aureus*/staph infection, influenza, and others (i.e., bacteria, flesh eating bacteria, viruses, germs, venereal disease, Ebola, "something with blood," "hemorrhagic fever diseases," and "anything airborne").

All six focus groups were asked how common it is for unsafe injection practices to occur in both the hospital and doctor's office. On a scale of 1 to 5, with 1 being not at all common and 5 being very common, participants felt that unsafe injection practices were somewhat common in a hospital setting (Mean=3.30, Median=3, Range=2-5) (Table 2). One participant stated, "I just think there's more activity in a hospital to create some kind of mistake." Participants perceived unsafe injections to be less common in a doctor's office (Mean=2.13, Median=2, Range=1-5). Another participant remarked, "I have a relationship with my doctor and they really take time." The difference between the perceived commonalties of an unsafe injection practice in a hospital versus a doctor's office was not statistically significant. Furthermore, there were no statistically significant differences found between respondents' perceived commonality of unsafe injections at neither the hospital nor the doctor's office when analyzed by city.

Several themes emerged while examining why unsafe injections would be more common in one healthcare setting versus another (i.e., hospital versus doctor's office). The most common theme was that the hospital staff faced a greater workload than the doctor's office on a daily basis. This theme of greater workload encompassed hospital patients having multiple providers rather than just one personal healthcare provider, the amount of work done by often understaffed hospital providers, and the amount of people within a hospital as one participant stated, "simply

because of the masses of people they deal with on a daily basis.” Other themes consisted of being less careful than a doctor’s office/careless in general, chance/unsafe practices just happen, personal experience/observation, and more rushed/hurried than a doctor’s office.

When asked about the commonality of unsafe injections in a doctor’s office, the most prevalent theme was that there is always a chance of unsafe injections. One respondent commented with: “we are all human and there are chances we are going to make mistakes...” The belief that healthcare staff in a doctor’s office setting are more careful than those in a hospital was the second most common theme: “they are probably a little more attentive, a little more careful.” Participants also listed additional themes of having a smaller workload than the hospital and personal experience and observation within a doctor’s office.

After analyzing the participants’ quantitative response to how common unsafe injection practices are within a hospital versus doctor’s office, their qualitative response, or reason provided with their quantitative score, was then compared across the two healthcare settings. As seen in Figure 2, there were a total of five qualitative themes given by participants when asked to provide an explanation for their quantitative response. Participants who cited the theme of workload (greater in a hospital and lesser in a doctor’s office) gave a much broader range of quantitative responses for a hospital (Range=2-5) than for a doctor’s office (Range=2). In contrast, participants who attributed unsafe injections to chance gave a broader range of responses (Range=2-5) for a doctor’s office than for a hospital (Range=4). When comparing those who referenced personal experience/observation as their explanation, unsafe injections were perceived to be much more common in a hospital setting (Range=4-5) as opposed to a doctor’s office (Range=1). Similarly, those citing the carefulness (greater in a doctor’s office

and lesser in a hospital) felt that unsafe injections were much more common in a hospital (Range=3-4) than in a doctor's office (Range=1-2).

Participants also were asked to rate their feelings toward the statement: "I am at risk (increased likelihood) of getting an infection from unsafe injection practices" on a scale of 1 to 5, with 1 being strongly disagree and 5 being strongly agree (Table 2). Most respondents had mixed feelings about their susceptibility (Mean=2.75, Median=3, Range=1-5). Atlanta respondents had a slightly higher perceived risk (Mean=2.90) than their New York City counterparts (Mean=2.59), however this difference was not statistically significant.

The most common theme that emerged from this discussion was the feeling that there was always the chance for unsafe injection practices to happen. One participant stated: "It could happen." While another emphasized the lack of feeling in control: "Because I have no control. So the practice, I just have no control over the practice, if it's unsafe, I may be aware, but I have no control. If I'm not aware, obviously the risk is greater." A feeling of self-efficacy was the second most common theme, with one participant commenting "Because I am very vigilant when I go to a doctor, and if I see something I don't agree with, I will question it." Another issue that came up when discussing perceptions of risk was the feeling that people were at a lesser risk because they did not frequently use healthcare services. "The more you have done, the risk is just there." Other important themes that emerged within the discussion were healthcare staff's lack of consistent compliance or adherence to safe practices, trust of personal healthcare provider, greater awareness and education of patients regarding safe practices, as well as healthcare staff being more overstressed in a hospital.

After analyzing the participants' quantitative response associated with their perception of risk of getting an infection from an unsafe injection practice, their qualitative response, or reason

provided with their quantitative score was then assessed and compared. As shown in Figure 3, participants attributing their risk to chance ranged greatly in their quantitative responses (Range=2-5). However, these participants citing chance as the reason for their perceived risk were found to have statistically significantly higher quantitative responses (Median=3) than those that gave another reason (Median=2) ( $p<0.01$ ). Along with this, participants attributing their self-efficacy for their quantitative response ranged from 1-3 but they were found to perceive a lesser risk (Median=2) than those giving some other reason (Median=3) ( $p<0.01$ ). Those who commented that risk depends on how frequently healthcare services are utilized ranged greatly (Range=1-4) in their quantitative risk, while those citing other reasons such as greater patient awareness and education of safe practices, trust of personal healthcare provider, overstressed staff in a hospital, and healthcare personnel's lack of consistent compliance/adherence to safe practices had much less variation in their responses (Ranges=2, 2, 2.5, and 5 respectively).

#### *Patient Notification Letters*

One group in each city read a letter that was written by a healthcare facility where an unsafe practice had been identified yet there was no known disease transmission at that time, while the second group in each city read a letter that was written by a Health Department notifying patients that disease transmission had been identified as a result of unsafe practices. Participants were then asked to rate, on a scale of 1 to 5, with 1 being strongly disagree and 5 being strongly agree, whether the letter contained an appropriate amount of information about the incident/event/practice that put the patients at risk. Those who received the letter written by the healthcare facility indicating that no known disease transmission had taken place agreed that the letter contained an appropriate amount of information about the event (Mean=4.58, Median=5.00, Range=4-5) (Table 3). However, those who received the letter written by the

Health Department indicating that disease transmission had been identified were unsure about whether it contained an appropriate amount of information about the event (Mean=3.00, Median=3.00, Range=1-5). The difference between these two groups was highly significant ( $p<0.01$ ).

A statistically significant difference ( $p<0.01$ ) also was found between New York participants (Mean=3.28) and Atlanta participants (Mean=4.38) (Table 4). Additionally, in New York City, the group receiving the letter written by the healthcare facility indicating that no disease transmission had taken place were significantly more likely to agree (Mean=4.39) that the letter was adequate than those receiving the letter from the Health Department indicating disease transmission had taken place (Mean=2.17) ( $p<0.01$ ) (Table 5). Likewise, within the two groups of respondents in Atlanta, there was a statistically significant difference ( $p=0.02$ ) in that same direction in whether their letters contained an appropriate amount of information about the event.

The groups receiving a letter also were asked whether the letter contained an appropriate amount of information about the disease(s) the patient is at risk of acquiring. Using the same scale as previously described, those who received the letter written by the healthcare facility where no disease transmission had been identified agreed that an appropriate amount of information about the disease was presented (Mean=4.19, Median=4.50, Range=1-5) (Table 3). At the same time those who read the letter from the Health Department where disease transmission had been identified were less likely to agree that an appropriate amount of information about the disease had been presented (Mean=2.76, Median=3.00, Range=1-4). The difference in responses between the groups was statistically significant ( $p<0.01$ ).

When comparing participants in New York City and Atlanta who read a patient notification letter, there was no statistically significant difference between their mean agreement score when deciding whether the letter contained an appropriate amount of information about the disease the patient was at risk of acquiring ( $p=0.34$ ) (Table 4). However, when examining differences between the groups within both cities there was a significant difference found between the two groups within New York City with the group reading the letter from the healthcare facility with no disease transmission more likely to agree that it contained an appropriate amount of information about the disease (Mean=4.17) than the group reading the letter from the Health Department with disease transmission identified (Mean=2.44) ( $p<0.01$ ) (Table 5). The groups in Atlanta followed the same trend yet were not statistically different ( $p=0.07$ ).

#### *Examining the Letter/Content for a Letter*

A large component of the focus group discussion was geared towards determining information that should be included within a patient notification letter. Participants' responses to a number of questions were combined and analyzed. The questions included topics such as: initial reactions after reading the letter, information that should be included in a notification letter in general, key concerns after receiving the letter, feelings related to the wording used, information related to the incident/event/practice that put the patients at risk, information related to the disease the patients were at risk of acquiring, and additional information/suggestions for a letter. From this discussion emerged a variety of different themes (Table 6), while some participants highlighted things that were already found in the sample patient notification letters, others brought up items that were not already contained by the letters shared with the participants.

The most prevalent theme was participants wanting to see a description of the corrective actions that had been taken by the facility. Included in this theme were the actions the healthcare facility was taking to resolve the incident, actions the facility was taking to prevent similar incidents from happening in the future, as well as corrective action for the healthcare staff directly involved in the event. One participant said: “What kind of things are the hospital or clinic going to be doing? How they're going to resolve it. I would want details on how it occurred, and what plan they're going to implement to prevent this from happening.” The second most common theme that emerged from the focus group discussions was a suggested course of action for the patient affected by the unsafe practice. Receiving answers to the questions “what do I do now” and “what’s going to happen to me” were very important to participants as one stated: “A course of action plan, you know you’ve been potentially exposed to this, this is what you should do, lay it out for me exactly, and I want to know exactly what they suggest I should do.”

The next two themes were of equal importance to the participants: assurance of medical coverage and how it happened/reason for the incident. Participants felt very strongly that the letter should provide assurance of coverage for medical costs and services, such as testing and follow-up care, that would be needed because of the unsafe injection practice. As one participant stated, “Are they going to provide me with healthcare? Cause they caused me to have the disease. Take some responsibility because this happened due to no fault of my own, I do not know why it should be at my expense.” At the same time, participants felt they deserved to know exactly how the unsafe practice occurred and the reason behind the incident that caused the notification of patients: “I would like to know how it happened, what occurred to put me in jeopardy.”



Participants also requested including a point of contact within the letter as a means to get more information. This theme included a 24-hour hotline where patients could reach a knowledgeable staff member along with a website patients could use to find out more information about the event and the diseases he/she was at risk of acquiring. One participant added, “I think it should have some kind of assurance where you can contact immediately or as soon as possible. Having someone on the phone 24 hours a day. I think it would put me at ease knowing that as soon as I get home, if I get home at 9 o'clock at night and I'm reading this letter, I would be at ease knowing that I could make that phone call right there and then.”

Participants often stated that the letter should highlight the importance of getting tested along with providing a referral for medical care and any follow-up that may be needed. As one participant suggested, “How about something where you say very important. Just to emphasize how important it is to come and not to give room to spread the disease.” In addition, information about the course of the possible diseases/duration was an important piece that emerged from discussion. Participants wanted to be informed as to what they could expect in relation to the disease, “I also would like to know if whatever it is I have acquired in this unsafe practice, are there long-term affects? Or can I expect to have a course of antibiotics and get over it?” Another aspect highlighted in the discussion was that participants wanted to see some sort of acknowledgement of responsibility for the event, as well as an apology, from the healthcare facility. When asked what should be in a notification letter, one participant simply stated: “It should start off with an apology. If they know they're wrong start off saying it. Don't let legal get you caught all off guard with we can't attribute the blame here. If you know it's a problem, there is blame, so state it clearly and apologize for it, so the people can be more at ease about their reactions to it and their ability to take action about it.”

Other essential information to be included in a notification letter was the risk to patients involved in the incident such as risk he/she was actually exposed to one of the diseases as well as the risk of contracting one of the diseases after being potentially exposed. One participant implied: “The odds, you injected me unsafely, is it a 10% I’m going to react to it, or a 100%?” Similarly, participants also requested the inclusion of whether the diseases were contagious and how to prevent the spread of infection. As one participant explained: “Advice on what to do. Is it going to affect my everyday activity? Is it going to affect people I am around?” Participants also thought it was important to know the symptoms of the diseases in order to “know what to look for.” “I would like to know what symptoms I might have if I am one of those affected.” The legal rights of those receiving the notification letter also was another common theme within the discussion. Many participants wanted to know: “What if I did come back positive, what are my rights? Am I allowed to sue? Who is liable for this?” Also important to be included within a letter was some form of verification of exposure. This verification included things such as the location and date of the injection, and some type of personal identification besides a name, such as a birth date or the last four digits of his/her social security number as indicated by a participant: “I think that one of the resources would be to check that the name is not a duplicate, the date of birth so it’s got the same name and the same birthday, so probably relating the last four digits of their social, also indicating that I’m trying to make sure this is you that they are talking about and talking to.”

Another concept that was brought up during the discussion was including information within the letter about how many people were affected by the unsafe injection practice. “I’d probably want to know, I mean the other people this happened to. How many people did it occur to?” Including information about the kinds of infections the patients were potentially exposed to

was an important issue as well. They wanted to know exactly what they were exposed to in addition to HIV and Hepatitis B and C as one participant remarked, “I’d like to see written verification of what viruses or whatever may have been in that area that I could be exposed to, it could be anything from the Ebola virus where it is fatal, to just a common cold. Tell me what could have been here.” Similarly, participants wanted to know the severity of the disease(s) and whether or not they were fatal, “I’d like to know some assessment of how serious the problem is from a health point standpoint. One of those things that there’s no cure for them. Is it going to be fatal?”

In addition, participants requested that the letter be signed by someone at the leadership level (i.e., CEO) as well as someone the patient had direct contact with during his/her visit to the healthcare facility. One participant voiced concern saying, “The bottom says sincerely CEO, Medical Center. I do not know those particulars, the CEO of the company who does not know you from Adam signing off on this. It maybe needs two signatures, one from the CEO because it is that important but also if there is a personal contact or a person at that center to see what happens. That could give you another signature line.” Furthermore, participants requested information about whether the event has happened in the past. “I wonder how many times this kind of thing happened at that facility or practice. Is this a onetime deal, was it just me, was it 10 people, is this a once a month thing, or is this a safe practice that occasionally had a slip up?”

Participants also stressed the importance of including how long it would take to receive the results after undergoing testing. Concern was expressed by a participant who stated, “How long the tests would take or when you should expect results. Is it two days or two weeks?” In addition to the basic information within the notification letter, participants also wanted to see the letter translated into other languages (i.e., Spanish) as well as offer a support line/group in order

to cover the emotional needs of all who might be receiving the letter. Likewise, participants requested a number of other things such as the affiliations of the facility, assurance of notification of test results, assurance to testing family/contacts, and confidentiality.

During the discussion of what content should be included in the letter, many participants mentioned numerous characteristics that would be featured in their preferred letter. Participants were split between wanting the letter to be comprehensive, including all possible information, and including only basic information. Those believing the letter should be comprehensive wanted it to include as much information as possible upfront so he/she could have all of the information at his/her disposal before making any further decisions. Participants stated that they would like “Every last little detail” and “As much as possible. Educate me to the fullest extent.” On the other hand, those wanting the letter to be basic requested only minimal information to be placed in the letter in order to avoid overwhelming the recipient with information. One participant conveyed this by saying, “I want to know the symptoms; I want to know the immediate concerns, but I’m not going to be ready for the details yet. I’m not sure the letter is the place to overly explain it.”

Aside from describing the preferred letter as either comprehensive or basic, participants stated a variety of other characteristics. They requested the letter to be “more personal/less businesslike” as well as more “empathetic” stating “I want a little bit of sympathy, a little compassion.” Participants expressed other characteristics such as the letter being “factual,” “reassuring,” “apologetic,” “confidential,” and showing a “neutral tone.” Others wished that the facility would be “proactive” including in the letter something similar to “We are being proactive in something that we are responsible for and we want you to know that we are on your side.”

Finally, participants suggested that the notification letter should “convey urgency” to the patient, as well be “tactful/diplomatic” in tone.

#### *Actions Taken after Receiving a Letter*

Participants were asked what actions they would take after receiving a patient notification letter. Thirty-three percent of the participants said they would contact his/her personal doctor while 28% would contact the facility where the incident occurred with one participant stating, “I would call the center which is where the infection came from in the first place.” Eleven percent stated he/she would research on his/her own with a participant explaining, “I would definitely go to the Internet and start researching and understand it before I just call a doctor, because I probably wouldn’t believe everything it was going to tell me so I want to become educated so that I know more.” Other responses included schedule a lab appointment, contact a lawyer, “panic/collapse,” obtain an independent expert, “page Dr. Sanjay Gupta,” and pray.

When asked how likely it would be that participants got tested after receiving a patient notification letter on a scale of 1 to 5, with 1 being not at all likely and 5 being very likely, only one participant said likely (4), all else (N=52) stated very likely (5) (Mean=4.98). Participants also were asked where they would prefer to be tested. The most common response was with his/her personal doctor. Other less common responses were obtaining a second opinion, finding a specialized/neutral/independent facility, and using the testing center in the letter. When receiving those test results, participants stated they would prefer to receive them via phone call, letter/mailling, email, and face-to-face.

## Discussion

In recent years, there have been over 40 separate outbreaks involving HBV and HCV within numerous types of healthcare settings, resulting in the exposure and notification of thousands of patients.<sup>19, 20</sup> This study was a secondary data analysis utilizing the Health Belief Model (HBM) as a framework to examine preferences for receiving health information, knowledge of safe injection practices, and responses to and preferences for a patient notification letter. The following four research questions were asked: (1) What are the general perceptions regarding patient communication following a breach of patient safety?, (2) What are the public's perceptions of the problem of unsafe injections (knowledge of safe injection practices)?, (3) What is the public's perceived risk of infection due to an unsafe injection practice?, and (4) What information should be included within a patient notification letter?

According to HBM, in order to have perceived threat or perceived expectations, one first must be aware of and/or knowledgeable about the event (i.e., unsafe injections). When asked if participants had ever heard of the term "safe injection practices," only two participants out of the 53 total responded that they had heard the term used before. Despite the growing number of patient notifications in recent years,<sup>23, 27, 32</sup> this sample of the general public was mostly unaware of the concept "safe injection practices." This provides evidence of the need for public health entities as well as healthcare facilities to highlight the importance of safe injection practices, allowing for increased patient awareness by becoming more familiar with the terminology and examples of safe practices of healthcare staff. Thus, in a situation where potential unsafe injections could occur, patients may be more aware and potentially less likely to receive an unsafe injection. Injection safety messages also should be integrated into other patient safety

efforts in order to further increase awareness and knowledge of these important public health issues.

Many of the participants' levels of knowledge were in line with the WHO/CDC definitions<sup>1, 3, 4</sup> when asked to give examples of what they believed to be unsafe injection practices as well as diseases that could be transmitted from unsafe injections, citing themes such as improper disposal of injection equipment, reuse of injection equipment, and using unsterilized equipment. Others provided themes more general to unsafe healthcare practices such as improper use of gloves and lack of hand hygiene; while a few cited things such as "the temperature of the room" and "doctors wearing ties" as being examples of unsafe injections. These results are encouraging because despite never hearing the term "safe injection practices" used before, after being provided with a short explanation, most participants were able to respond with an accurate example of an unsafe practice. While participants may be aware of what is safe/unsafe, they were not familiar with the specific/exact terminology used, something that could be corrected with education along with dissemination of promotional health materials. Likewise, while participants were able to give examples of diseases associated with unsafe injections, it is unclear whether they understood that these same diseases could be transmitted as one of the many risks associated with unsafe practices or if they were simply answering the question with diseases that are prominent in the media spotlight such as HIV and hepatitis.

When disseminating health messages to the public, it is important to take into account the preferred methods of communication of the target audience. The focus group participants within this study preferred to receive information in many different ways depending on the situation. The most common responses to the three different scenarios (general health information, exposed to infectious disease, and unsafe injection practice identified) were phone call,

letter/ mailing, face-to-face, and email which supports previous research.<sup>35, 37, 39</sup> Throughout the discussion of these questions, participants often gave two or more different methods they would prefer to receive information. Because health communication materials, in this case patient notification letters, are often used as a cue to action, more direct forms of communication such as face-to-face meetings and phone calls may convey a sense of greater urgency leading to quicker action while at the same time allowing patients the ability to ask any questions they may have. When faced with something that may need immediate attention, such as being exposed to an infectious disease, participants overall preferred the use of more direct forms of communication.

Furthermore, it is important to note along with multimodal communication, participants also requested being contacted multiple times after an unsafe injection practice had been identified. When asked, all but one participant agreed that attempts should continue until the patient has been reached, possibly realizing the potential danger caused by unsafe injections. This is consistent with prior research demonstrating that the more warnings a person receives and the greater the threat, the more likely the individual is to take action.<sup>56</sup>

Aside from preferred means of health communication, it also was important to assess the commonality and perceived risk of receiving an unsafe injection. When examining themes that arose from the discussion of why unsafe injection practices were more common in one healthcare setting verses another, a general theme of personalized/individualized healthcare (or lack thereof) within a hospital setting emerged. Participants compared the workload within the two healthcare settings, stating that at any given time within a hospital there is often a greater patient to staff ratio than in a doctor's office. Many participants felt that because of the stresses of dealing with a large number of patients from day to day, unsafe injections were relatively common. This is congruent with prior research conducted by Weissman et al. which states that an increase in the



occupancy at a hospital as well as increases in the ratio of patients to nurse staff increased the rate of adverse events.<sup>57</sup> Also encompassed within the theme of greater workload was the belief that patients are more likely to have multiple healthcare providers within a hospital rather than just one personal provider as in a doctor's office, thus leading to a perceived increase in unsafe practices. Because of this, patients may lack the connection they are able to develop with their personal healthcare provider. Previous research on this topic found that some individuals have greater perceived feelings of not being safe if there was a discontinuity of care from their primary healthcare providers.<sup>58</sup> This issue then leads to an increased feeling of risk of unsafe injections because patients may believe healthcare staff invested in patient care would be more likely to strive to use only safe injection practices. Findings from another study suggest that personal care in the relationship between the healthcare provider and the patient fosters a sense of trust and confidence, puts the patient at ease, and promotes open communication.<sup>59</sup> Patients who perceive a good communicative relationship with their provider are more likely to view a medical error as a mistake or complication, while those who were dissatisfied with their communication with the healthcare provider were more likely to view it as incompetence or with malicious intent.<sup>60</sup> Additionally, this same study explained that patient-provider communication was critical to whether patients perceived adverse events as a "mistake" or "malpractice." Therefore, it is important for healthcare staff to develop and maintain an open and honest relationship with patients in order to foster a sense of safety and trust. This idea applies regardless of the setting, but is especially important for hospital-based healthcare staff that are already at a disadvantage for developing relationships due to potentially high patient turnover. For this reason, more research is needed to investigate ways for hospital-based healthcare

providers to develop meaningful relationships with patients despite the potential discontinuity of care provided in that atmosphere.

On the other hand, participants perceived unsafe injections to be slightly less common at a doctor's office than at a hospital. Fascinatingly, the most common theme accounting for unsafe injections in a doctor's office was chance. Participants seemed to possess a mindset that there was always a chance of unsafe injections and that they "just happen" due to human error. Many times participants stated that all people make mistakes so "slip-ups" are bound to happen anywhere. Because the main reason for unsafe injections in a doctor's office is related to human error, participants may seem to alleviate some of the blame from their personal healthcare providers. However, when speaking about a hospital setting, participants seem to place blame on the hospital healthcare system as well as the healthcare staff saying that they are more careless than staff within a doctor's office. These thoughts also tie into a general feeling of carelessness from the healthcare staff within a hospital among participants. Previous research showed that the most common reasons for needle stick injuries cited by healthcare staff were stress/being overburdened and carelessness.<sup>61</sup> Therefore, facility wide efforts to reduce the perceived overburden of healthcare providers should be implemented in order to avoid unsafe injection practices by increasing staff numbers and decreasing patient loads for each provider where/when possible.

Continuing to assess participants' perceived susceptibility to unsafe injections, they were asked to rate the risk they felt in regards to getting an infection from an unsafe injection. Interestingly, there was a stark contrast between the two main themes that emerged from this discussion: unsafe injections "just happen"/patients have no control and self-efficacy. A large number of participants responded that there is always a chance that something could go wrong and therefore expressed a greater perceived risk than those citing other reasons. This theme

encompassed those that believed unsafe injections just happen with one participant conveying, “you can’t be 100 percent sure of stuff;” as well as those that felt he/she had “no control over the practice.” Another participant stated, “It is not totally in my control in terms of their safe practices. If I’m relying on them, something can happen.” It is important to address the issue of patients feeling like they have no control in their medical care. Providing patients with educational materials to increase their awareness and empower them to be an active participant in their healthcare is an important aspect of patient safety. Such measures have already been taken with increasing hand hygiene compliance as well as diabetes and chronic disease management, and could be adapted to include safe injection practices as well.<sup>62-64</sup>

On the opposite end of the spectrum, those that cited self-efficacy as their reasoning behind their perceived risk expressed a lesser perceived risk than those citing other reasons. These participants felt much more empowered and demonstrated feelings of minimal risk. One participant aptly stated, “If I saw someone doing something that I felt uncomfortable with I would speak up.” While another declared “I will stop anybody if I see that they are unsafe. I will tell them ‘no you are not doing that, you have to do it this way’.” Further exploration should examine what, if any, differences there are between those that feel they have no control over their healthcare and those that feel empowered to speak out against unsafe practices.

In addition to chance and self-efficacy, another main theme that appeared in the discussion of risk was infrequent use of healthcare services which in turn led to lower perceived susceptibility. This group, comprised of 19% of participants, felt that because they did not use healthcare services they were not at risk for unsafe injections. One participant stated, “I don’t get sick. I’ve been to the hospital only twice to give birth.” While another added, “I go to the doctor to get a flu shot and give blood that is it.” However, it is unknown whether these people

believe that they will be at risk when they do choose to use healthcare services at some point in their lives. It may be helpful to target this group of individuals with programs of patient awareness and empowerment to increase their perceived susceptibility as well as their perceived control. Because these people do not frequent healthcare facilities, messages aimed at increasing susceptibility and control also should be conveyed from other sources such as the media to reach those in need of this information.

As equally important as increasing knowledge and empowering patients, this study examined what elements would best serve patients receiving a patient notification letter, motivating them to get tested without causing undue emotional stress. When asked generally what information they believed should be included within a patient notification letter participants' responses fell into over 25 different themes, providing further support for previous research.<sup>27, 40, 41</sup> The most requested piece of information within the notification letter was the corrective actions being taken by the facility where the incident occurred. Participants wanted to know what the facility was doing to rectify the situation. When participants were given one of two actual de-identified patient notification letters, those that read the letter that pointed out corrective actions taken and mentioned that the "unacceptable practice" was immediately corrected, were more likely to agree that the letter contained appropriate information about the incident. Additionally, another aspect of this theme that was discussed was what will be done in the future (i.e., policies implemented) to prevent unsafe injection practices from happening again. Along those same lines, participants requested information on the corrective actions taken with the person(s) associated with the incident. Including information within the notification letter about what the facility is doing (going to do) in order to fix/prevent something similar from happening again is very important to the reader for a number of possible reasons. Often, after a

mistake the people affected usually request an apology along with information about how the incident will be prevented in the future.<sup>40, 60, 65, 66</sup> This not only shows the reader that the facility is dedicated to improving patient care, but also preventing these unfortunate events from happening to other people.

As stated within the American College of Physicians Ethics Manual, in order to make informed healthcare decisions, patients have the right to all information surrounding “his or her situation, possible treatments, and probable outcomes.”<sup>67</sup> It is important to note that the participants wanted more details on what happened potentially putting them at risk for disease. Participants reading the notification letter that was much more direct in explaining the incident pinpointing who (a nurse), what happened (re-used medical supplies), and when (date range) were more likely to agree that the letter contained an appropriate amount of information about the incident. Similarly, when asked later in the discussion what elements would be important to have in a letter, participants wanted to know how the incident occurred/reason, how many people were affected, as well as if it has happened in the past. As a patient, it also is important to know exactly what happened to put you at risk so you can avoid similar unsafe situations and practices in the future. Therefore, as public health professionals it is important to include these aspects within a patient notification letter in order to best fit patients’ needs.

Another very important piece of information requested by participants was a course of action for the patients receiving the notification letter. The majority of the time, the patient notification process will be a novel experience for those involved. As stated in an article focused on risk communication for public health emergencies, patients need clear guidance, specific information, and actionable messages on what to do ensure their safety.<sup>56</sup> Including this information should not only decrease patient fear and anxiety, but also help them be active

participants in protecting themselves against any further harm. Because the course of action involves getting tested, it also is important to include an assurance of medical coverage. This includes providing information about who will be conducting the testing, who will be paying for testing, and some mention about who will be paying for treatment if the patient was found to have the infection. Information such as assurance of medical coverage (of services and costs) is important to include within a patient notification letter in order to show recipients that the facility is taking responsibility for the unsafe practice. Furthermore, assuring the patient of medical coverage could potentially relieve some of the anxiety and frustration associated with the event since many patients may not be able to afford additional healthcare costs and/or feel that the facility is obligated to provide coverage since the incident occurred there.

In order to develop patients' sense of perceived threat and further assist with determining a course of action, patients also must be provided with information regarding the infection/disease they are at risk of acquiring. When asked, participants requested information about the diseases patients were at risk of acquiring such as: the course of disease/duration, risk to patient, how to prevent infection/contagiousness, symptoms, and the kinds of infections. All of this information would help to inform the patient on what to look for/expect if he/she actually contracted the infection. This relates back to the belief that patients must be aware of their situation before they can appropriately act upon it. Future efforts should engage patients in determining what level of knowledge is most appropriate for the situation leading to an increased level of perceived threat but cause the least amount of undue stress. Along with this, it is necessary for public health professionals to discuss how to accurately assess patient risk as well as how best to convey within a notification letter.

Perhaps one of the most important aspects in handling a notification event, participants requested including a point of contact within the letter to answer any additional questions they may have.<sup>34</sup> Participants requested a non-automated hotline they could call at any time to request more information about their case specifically and the next steps that needed to be taken. Some also suggested including a website where more information could be found about the diseases the recipients were at risk of acquiring (i.e., signs, symptoms, and treatment options). Many times patients are going to want more details than what can be expressed in a brief letter, highlighting the importance of a staffed call center. The recipient may or may not be able to process the information without the assistance of a knowledgeable healthcare provider. Furthermore, given the emotional impact of receiving such a letter, it is important to have additional resources (i.e., non-automated hotline) available to patients to help relieve some of the stress and anxiety brought on by the notification.

Further supporting these findings, when asked who or what organization would be trusted most for information after being potentially exposed to an infectious disease, participants responded that they would trust their personal physician first and foremost. Often times, patients have developed a personal relationship with their primary care provider over the course of many years of care administered. This relationship builds trust and therefore a sense of safety within the patient. Interestingly, the second most prevalent theme in this discussion was the CDC. This trend may be attributed to the fact that half of the participants were from Atlanta, the city in which the CDC headquarters are located, potentially making them more aware of the CDC than the rest of the general population. However, after examining the data, it was found that almost half of respondents mentioning CDC were from New York. The Internet did not prove to be a common response despite the fact that early data from the 2009 National Health Interview

Survey found that 51% of adults had used the Internet to look up health information within the last year.<sup>68</sup> This further highlights the need to tailor communication materials to the intended audience because receiving information from a trusted source could lead to a quicker response from the patient.

At the same time, just as important as what is in the letter, is who the letter is coming from. Over half of the respondents wanted to be notified from a caregiver at the facility where the incident occurred. Some participants even stated things like “it should come from whoever administered the injection” and “whoever provided the care,” indicating that they wanted to hear directly from the person that was involved in the incident. This may stem from patients’ desire for an acknowledgment of or apology for the error from the wrongdoer.<sup>65, 66, 69</sup> Overall, most people (81%) wanted to hear from the facility where the incident occurred, whether it was the person specifically involved in the incident, someone in a leadership position, or a staff member in general. This finding is particularly important because, investigations are often conducted and notification letters are sent by local, state, and federal health departments/agencies. Therefore, more research is needed to explore just how important receiving notification from the facility where in the incident occurred is to the affected patients.

Despite the different types of information that could be included within a patient notification letter, perhaps the most important function of the letter is to lead patients to get tested. When participants were asked what actions they would take after receiving the notification in the mail, the majority cited that they would first call their personal healthcare provider followed by the facility where the incident occurred. Again highlighting patients desire to speak with someone they know and trust. Along with that, all participants responded that they would likely get tested, with all but one respondent saying it was “very likely” that he/she would



get tested. These results provide for optimistic enthusiasm because, despite the fact that many participants did not believe that the notification letter contained an appropriate amount of information about the incident that put them at risk nor the diseases they were at risk of acquiring, most participants said their first reaction would be to seek out medical care through either their primary healthcare provider or the facility where the incident occurred. Therefore, despite participants' concern with the notification letter, the letter itself was adequate enough to prompt a response from the reader. However, it also is important to note that a few participants cited emotional responses such as panic/collapse and pray. For that reason, further development and evaluation of patient notification letters is needed to reduce the amount of stress and anxiety felt by the reader.

Beyond the content participants requested to include in a notification letter, they also identified several descriptors that would add to the overall quality of the letter. Interestingly, participants were almost equally split between those wanting the notification letter to be comprehensive and those wanting it to be basic. Those wanting the letter to be comprehensive wanted as much information in the letter as possible in order to make an informed decision about next steps. These participants wanted all of the information so they had time to calmly absorb the information and develop their own questions before speaking with their healthcare provider. On the other hand, those wanting the letter to include only basic information conveyed that they would not be emotionally ready for all of the details during that initial letter. Many of these participants stated that receiving this type of information in a letter was "too cold" and expressed interest in the letter only containing "just enough information to make me take action." These people would prefer to get the details over the phone or in person so that they could ask questions while the information was still fresh in their minds. Future research in this area is

important in order to see if there are underlying differences (i.e., age, gender, educational status) between those people that would prefer a comprehensive versus a basic letter.

Besides being either basic or comprehensive, participants came up with numerous other descriptors to distinguish an ideal letter. Readers wanted a letter to feel more personal, empathetic, reassuring, and apologetic. These characteristics would all lead to lessening the feelings of anger, anxiety, and stress felt by the patient receiving the notification letter. Others suggested that a letter should be proactive, convey urgency, factual, and tactful. These characteristics would conceivably make it easier for readers to comprehend the seriousness of the situation; therefore, leading patients to take action by getting tested. As shown by the numerous descriptors used in articulating an ideal patient notification letter, there is still much to be learned about these modes of health communication in order to best serve the patient population. However, these findings demonstrate that patient notification letters are not “one size fits all.” They must be tailored to different audiences for different situations and contexts further highlighting the need for future research in this area.

As an example, within this study, the two audiences (New York City vs. Atlanta) highlighted differences and similarities in knowledge and awareness based on exposure status. The New York City groups were able to identify a real life example in which patients (and the media) were notified of the occurrence of an unsafe injection practice. Despite this, these participants rated the commonality of unsafe injections at a level similar to that of Atlanta participants. Along those same lines, participants in both cities rated their perceived risk of getting an infection from an unsafe injection practice at similar levels. This piece of information is important for public health professionals planning programs to increase patient awareness of safe injection practices because, despite the increasing commonality of patient notification

events, many people are still unaware of the magnitude of the problem regardless of the area in which these events are occurring.

There were several limitations to this study, the first of which being the small sample size. This sample size may affect the how generalizable the results are to a broader population. Along with that, New York City and Atlanta residents were chosen to represent participants living in environments “exposed” and “unexposed” to patient notification letters. These residents may not be representative of the whole US population, especially those living in rural areas, again limiting the generalizability of the results. In addition, when surveyed, not all New York City residents were aware of the patient notifications that had taken place; therefore, these participants could potentially be considered “unexposed.” Additionally, due to the average age of the participant groups (Mean age=54) as well as the requirement of having health insurance, the results may not be generalizable to a younger population nor those without healthcare coverage.

Another limitation of this research lies within potential self-report biasing due to the nature of this formative qualitative research. Along with that, there is no way of discerning whether participants were affected by groupthink, being more focused on specific answers from dynamic individuals potentially leading to a lack of individualized responses. Also, because focus group participants read sample notification letters that had nothing to do with their personal medical situation, only behavioral intention could be measured. While some may argue that behavioral intention does not always translate into action within real life, due to the nature of the focus groups, actual behavior was not able to be assessed.

As shown by the results of this study which used HBM as a framework for examining knowledge of injection safety issues, it is vitally important to provide appropriate information on

safe and unsafe injection practices to patients receiving healthcare to increase their awareness of safe practices. Patients not only need to become more aware of examples of unsafe practices and diseases that can be contracted from them, but also the commonality of unsafe injections and the risks associated with them. After providing necessary information, patients will be able to take a more proactive role in protecting their safety when using healthcare services. Therefore, it is important to take information provided by researchers and apply it to educational programs and patient outreach initiatives in order to increase patient safety within healthcare.

Furthermore, the results show that a general patient notification letter is not going to be adequate for all patients; one size does not fit all. Therefore, the information obtained from these focus groups should help to facilitate discussion as to which elements should be included within a patient notification letter. Again, it is important to note that much of the information requested within a patient notification letter was already in the given letter. Therefore, it would be important to examine whether readers were not understanding the information in the sample letter or just glossing over it without allowing time to process the information.

While it is apparent that opinions vary on what information to include within a notification letter, further research should seek to identify which elements are most effective and essential to appease the largest number of recipients. Along with that, developing a template that lists important characteristics to be included within a notification letter is necessary to make the process of patient notifications as timely and effortless as possible for all involved (i.e., patients, healthcare facilities, health departments). Just as a general patient notification letter does not fit all people, it also does not fit all situations and contexts. For that reason it will be important to modify and tailor letters to fit within each context and intended notification population. It is clear that what is called for by patients may not be realistically possible for all healthcare

facilities, but it will be important to remedy these differences as much as possible to avoid unnecessary stress and legal ramifications from dismayed patients.

Perhaps the most important thing to note is that receiving a patient notification letter is a frightening, anxiety producing event. As one participant aptly stated, “If it would have been real I would be scared to death right now, fell over at the mailbox, this is serious stuff.” As a field living by the idea that patient health and wellbeing should come first, public health professionals should seek to understand how to best present this information to patients in order to cause the least amount of harm. Future patient safety initiatives should include information on unsafe injection practices and the infections they are often linked to, increasing patients’ knowledge and awareness therefore increasing their perceived susceptibility and perceived severity. Notification letters should contain information to not only increase the patient’s awareness and knowledge of the event, but also highlight the benefits and decrease the barriers to testing. Ultimately, in future notification events, it will be imperative that patient notification letters contain the appropriate amount information to motivate patients to obtain testing without causing them undue psychological and emotional stress.

## Tables

**Table 1.** Demographic Characteristics for All Participants (n=53).

	Overall (n=53)	Atlanta (n=26)	New York City (n=27)
Age (Mean years)	54.9	55.8	54.1
Gender			
Male	50.9%	50.0%	51.9%
Female	49.1%	50.0%	48.2%
Ethnicity			
Caucasian	35.9%	46.2%	25.9%
African American	22.6%	26.9%	18.5%
Hispanic	20.8%	19.2%	22.2%
Asian	13.2%	7.7%	18.5%
Other/Multiracial	7.6%	0.0%	14.8%
Employment			
Full-time	52.8%	42.3%	63.0%
Part-time	20.8%	19.2%	22.2%
Other	26.4%	38.5%	14.8%
Insurance Type			
PPO	45.3%	53.9%	37.0%
HMO	32.1%	30.8%	33.3%
Medicare	9.4%	11.5%	7.4%
Medicaid	1.9%	0.0%	3.7%
Unknown	11.3%	3.9%	18.5%

PPO= Preferred Provider Organization

HMO= Health Maintenance Organization

Columns/rows may not equal 100% due to rounding

**Table 2.** Perceptions of Commonality and Risk of Unsafe Injection Practices between Atlanta and New York City Respondents, Comparison of Means<sup>a</sup>

	Overall (n=53)	Atlanta (n=26)	New York City (n=27)	p-value <sup>b</sup>
Commonality of unsafe injections				
Doctor's Office	2.13	2.26	2.04	0.3894
Hospital	3.30	3.35	3.27	0.7775
Risk of unsafe injections				
Risk of getting an infection from an unsafe injection practice	2.75	2.90	2.59	0.3701

<sup>a</sup> Likert-scale from 1(not at all common) to 5 (very common)

<sup>b</sup> T-test

**Table 3.** Respondents' Perceptions of Information regarding the Incident and the Disease within the Patient Notification Letter, Comparison of Means by Letter Group<sup>a</sup>

	Healthcare Facility (no disease) (n=18)	Health Department (disease) (n=17)	p-value <sup>b</sup>
Letter contains an appropriate amount of information about the <u>incident/event/practice</u>	4.58	3.00	<0.0001
Letter contains an appropriate amount of information about the <u>disease</u>	4.19	2.76	0.0002

<sup>a</sup> Likert-scale from 1 (strongly disagree) to 5 (strongly agree)

<sup>b</sup> T-test



**Table 4.** Respondents' Perceptions of Information regarding the Incident and the Disease within the Patient Notification Letter, Comparison of Means by City<sup>a</sup>

	Overall (n=35)	Atlanta (n=17)	New York City (n=18)	p-value <sup>b</sup>
Letter contains an appropriate amount of information about the <u>incident/event/practice</u>	3.81	4.38	3.28	0.0078
Letter contains an appropriate amount of <u>information about the disease</u>	3.50	3.71	3.31	0.3389

<sup>a</sup> Likert-scale from 1 (strongly disagree) to 5 (strongly agree)

<sup>b</sup> ANOVA

**Table 5.** Respondents' Perceptions of Information regarding the Incident and the Disease within the Patient Notification Letter by Letter Types within Cities, Comparison of Means<sup>a</sup>

	Atlanta		p-value <sup>b</sup>	New York City		p-value <sup>b</sup>
	Healthcare Facility (no disease) (n=9)	Health Department (disease) (n=8)		Healthcare Facility (no disease) (n=9)	Health Department (disease) (n=9)	
Letter contains an appropriate amount of information about the <u>incident/event/practice</u>	4.78	3.94	0.0212	4.39	2.17	<0.0001
Letter contains an appropriate amount of information about the <u>disease</u>	4.22	3.13	0.0721	4.17	2.44	0.0003

<sup>a</sup> Likert-scale from 1 (strongly disagree) to 5 (strongly agree)

<sup>b</sup> ANOVA

**Table 6.** Content for a Patient Notification Letter after the Identification of an Unsafe Injection Practice<sup>a</sup>

Theme	Example Quotes
Corrective Actions Taken (for facility)	<ul style="list-style-type: none"> <li>• What kind of things are the hospital or clinic going to be doing? How they're going to resolve it. I would want details on how it occurred, and what plan they're going to implement to prevent this from happening.</li> <li>• I liked the fact that the provider was taking responsibility of their miss deeds and they have already corrected the problem.</li> <li>• I would like for them to tell me that they have implemented procedures to prevent this from happening again.</li> </ul>
Course of Action (for patient)	<ul style="list-style-type: none"> <li>• What's going to happen to me? And what do I do now?</li> <li>• At least give an epic to the next step, what do I do from here? I want to know if it will be laid out step by step, very explicit.</li> <li>• A course of action plan, you know you've been potentially exposed to this, this is what you should do...lay it out for me exactly, and I want to know exactly what they suggest I should do.</li> </ul>
Assurance of Medical Coverage (cost & services)	<ul style="list-style-type: none"> <li>• I would want a guarantee that they will cover any and all costs of whatever tests I would need to have wherever I needed to have them.</li> <li>• Are they going to provide me with health care? Cause they caused me to have the disease. Take some responsibility because this happened due to no fault of my own.</li> <li>• Who is going to be picking up the tab? Financially, I don't want to see a bill behind all this. I'm not going to want to see a bill because of the mistakes that they made.</li> </ul>
Information about the Event: How it Happened/Reason	<ul style="list-style-type: none"> <li>• I would like to know how it happened, what occurred to put me in jeopardy.</li> <li>• I would just like to know how I got it, why, what happened exactly.</li> <li>• I think I would like to know a little more about how they think this may have happened.</li> </ul>
Point of Contact for More Information	<ul style="list-style-type: none"> <li>• I think it should have some kind of assurance (emergency number) where you can contact immediately or as soon as possible. Having someone (an on call physician) on the phone 24 hours a day. I think it would put me at ease knowing that as soon as I get home, if I get home at 9 o'clock at night and I'm reading this letter, I would be at ease knowing that I could make that phone call right there and then and know that the person's going to answer, they can answer my questions.</li> <li>• The letter should be vague but with an urgency to contact, and there should be a 24-hour number where you should be able to call someone, and after you speak to that person, depending upon the severity of the matter, either they can tell you over the phone or ask you to come in.</li> <li>• You want a live voice. I want to call this person at this number and be able to talk to them about my situation and not some hotline. Make it more personal.</li> </ul>

Importance of Testing/Referral for Medical Care/Follow-up	<ul style="list-style-type: none"> <li>• The letter should go out signaling the person's critical information and then what's at stake, that is to say, if it's something that's contagious or what's going on generally and a proposed date to come in.</li> <li>• Telling me to come in as soon as possible. And for me to see a doctor, and not to see, I wouldn't want to see a receptionist or an aide or something like that. I would like to see the doctor.</li> <li>• How about something where you say very important. Just to emphasize how important it is to come and not to give room to spread the disease.</li> </ul>
Information about Disease: Course of Disease/Duration	<ul style="list-style-type: none"> <li>• With the disease, if I was infected with the timeframe, exactly what stage could I be at? How long will it last?</li> <li>• I also would like to know if whatever it is I have acquired in this unsafe practice, are there long-term affects? Or can I expect to have a course of antibiotics and get over it?</li> <li>• I would like to know how long I would have it in my system. What is the time frame we are talking about?</li> </ul>
Acknowledgement of Responsibility/ Apology	<ul style="list-style-type: none"> <li>• I liked the fact that the provider was taking responsibility of their misdeeds.</li> <li>• Well, they told you what you needed to know and they gave you the dates. They are giving you location to go to and they are responsible of the cost and said that this was an unacceptable practice.</li> <li>• It should start off with an apology. If they know they're wrong start off saying it. Don't let legal get you caught all off guard with we can't attribute the blame here. If you know it's a problem, there is blame, so state it clearly and apologize for it, so the people can be more at ease about their reactions to it and their ability to take action about it.</li> </ul>
Information about Disease: Risk to Patient	<ul style="list-style-type: none"> <li>• What the potential risks are.</li> <li>• What are the likelihoods of these from where I was tested, that any of these types of diseases or infections, the likelihood of them happening?</li> <li>• The odds, you injected me unsafely, is it a 10% I'm going to react to it, or a 100%?</li> </ul>
Information about Disease: How to Prevent/Contagiousness	<ul style="list-style-type: none"> <li>• If it's contagious. I want to protect my family.</li> <li>• Advice on what to do. Is it going to affect my everyday activity? Is it going to affect people I am around?</li> <li>• Steps I can take to protect myself personally from this happening in the future and steps to take to minimize any risk of infection.</li> </ul>
Information about Disease: Symptoms	<ul style="list-style-type: none"> <li>• What symptoms am I going to expect. What I should be looking for.</li> <li>• I would like to know what symptoms I might have if I am one of those affected.</li> <li>• What happens if the symptoms do occur, what's the next step, what are we to do?</li> </ul>
Legal Rights	<ul style="list-style-type: none"> <li>• What if I did come back positive, what are my rights?</li> <li>• Am I allowed to sue?</li> <li>• Who is liable for this?</li> </ul>

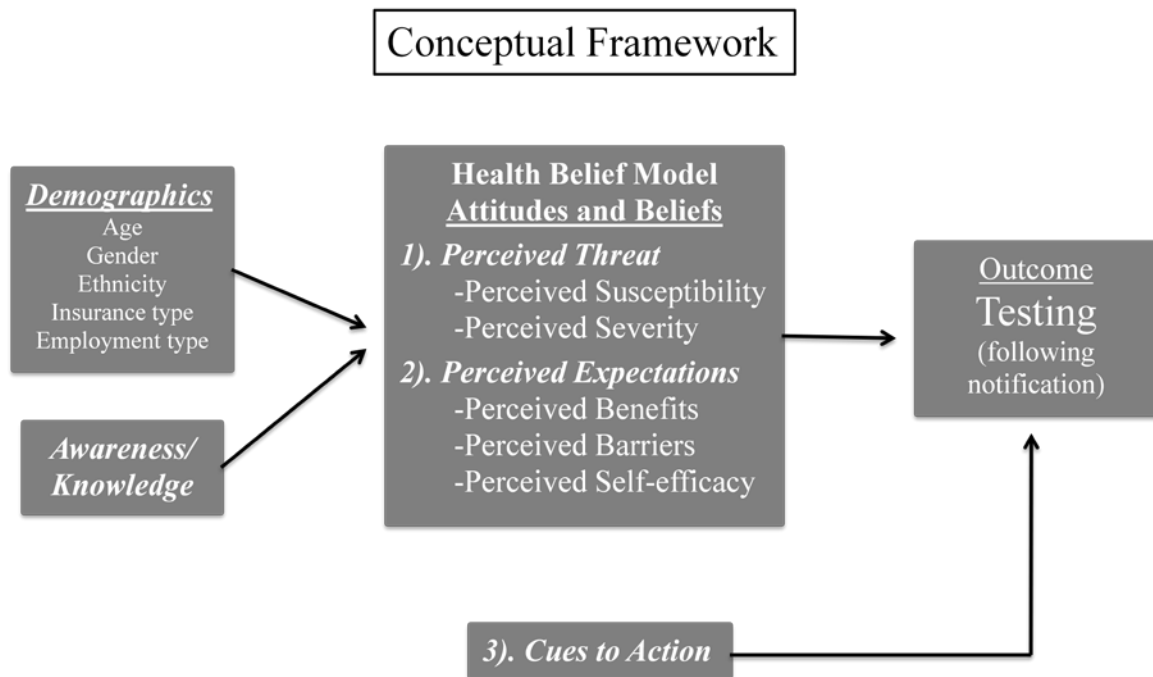
Verification of Exposure	<ul style="list-style-type: none"> <li>• The date of the injection, just so they don't confuse you with someone else. I have someone with the same name, and for many years I would get phone calls that were meant for her not me. So, the date, the place, date of birth.</li> <li>• I think that one of the resources would be to check that the name is not a duplicate, the date of birth so it's got the same name and the same birthday, so probably relating the last four digits of their social, also indicating that I'm trying to make sure this is you that they are talking about and talking to.</li> <li>• They gave you the dates. They told you if it was before you didn't need you didn't need to do it. If it was after you still need to do it.</li> </ul>
How Many People Affected by the Event	<ul style="list-style-type: none"> <li>• I'd probably want to know, I mean the other people this happened to. How many people did it occur to?</li> <li>• I think I would like to know how many patients between this timeframe, about how many patients are affected by this.</li> <li>• Testing population, is it 25% of the people that they treated got, were infected with whatever (or more)?</li> </ul>
Information about Disease: Kind of Infection	<ul style="list-style-type: none"> <li>• I would like to know what exactly is it that I potentially have.</li> <li>• My concern would be what is it that I got. You know what infection.</li> <li>• I'd like to see written verification of what viruses or whatever may have been in that area that I could be exposed to, it could be anything from the Ebola virus where it is fatal, to just a common cold.</li> </ul>
Information about Disease: Severity (seriousness, fatal)	<ul style="list-style-type: none"> <li>• I'd like to know some assessment of how serious the problem is from a health standpoint. One of those things that there's no cure for them.</li> <li>• If it's fatal or if it's not.</li> <li>• Am I going to sneeze? Or am I going to die?</li> </ul>
Signature Line	<ul style="list-style-type: none"> <li>• The bottom says sincerely CEO, Medical Center. I do not know those particulars, the CEO of the company who does not you from Adam signing off on this. It maybe needs two signatures, one from the CEO because it is that important but also if there is a personal contact or a person at that center to see what happens. That could give you another signature line.</li> <li>• Their name should have been on it, and then you could have the CEO and everybody, because that was the contact. I need somebody I can contact.</li> <li>• I do not know who this letter is from? I do not know, is Dr. Smith a city health officer, a federal health officer? Is he the health officer for the center? Where is this coming from?</li> </ul>
Information about Event: Has it Happened Before	<ul style="list-style-type: none"> <li>• Have you had this happen before? And if yes, what was the outcome before?</li> <li>• The only thing that I would be interested in knowing is it an epidemic or is it an isolated incident.</li> <li>• I wonder how many times this kind of thing happened at that facility or practice. Is this a onetime deal, was it just me, was it 10 people, is this a once a month thing, is their liability through the roof now or is this a safe practice that occasionally had a slip up?</li> </ul>

Time until Result Notification	<ul style="list-style-type: none"> <li>• How long the tests would take or when you should expect results. Is it two days or two weeks?</li> <li>• How long the test takes to get back the results.</li> <li>• I think that they should also say (since HIV is included) that your results may not show up next week you may have to keep getting tested for awhile I'm not sure about (Hepatitis) whether it takes six weeks or what to get it but I know that (HIV) can be dormant for a long time.</li> </ul>
Translated into other Languages	<ul style="list-style-type: none"> <li>• You might want to consider putting it in a language other than Spanish.</li> <li>• If I were a person who my language was Spanish I would be concerned where it says if you need this information call this number but I don't know what this information is about so I would be concerned. It doesn't even address what the situation is in Spanish just if there is a problem call this number.</li> <li>• Should be sent to me in Spanish also, one side English, one side Spanish.</li> </ul>
Other	
Affiliations of Facility	<ul style="list-style-type: none"> <li>• I want to know who this particular place is affiliated with, who they do business with because I do not want to go there either.</li> </ul>
Assurance of Notification of Test Results	<ul style="list-style-type: none"> <li>• It doesn't say that they were going to tell you the results.</li> </ul>
Assurance to Testing Family/Contacts	<ul style="list-style-type: none"> <li>• I would like to see that they also are going to test my immediate family and anybody that you have come in contact with.</li> </ul>
Confidential	<ul style="list-style-type: none"> <li>• Obviously I wouldn't want to see a lot of confidential information. So basic information and then just enough to trigger communication.</li> </ul>
Support Group/System	<ul style="list-style-type: none"> <li>• A support group. They should tell you, especially if you're in a group that is exposed to something serious, there should be something telling you where you can talk about it, other than just calling your doctor.</li> </ul>

<sup>a</sup> Presented in order of frequency from most frequently stated to least frequently stated

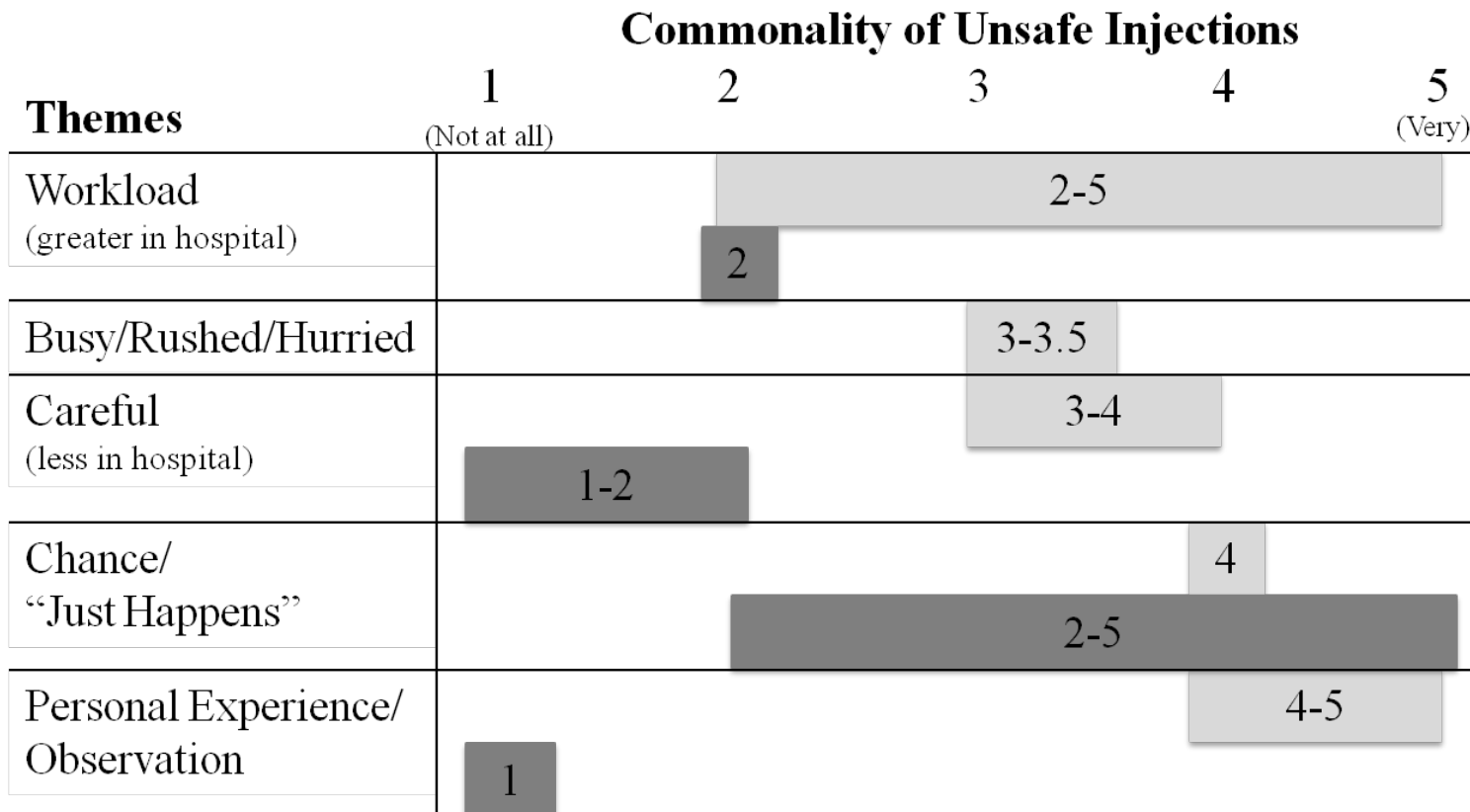
## Figures

Figure 1.



**Figure 2.**

Comparison of Qualitative Themes associated with Quantitative Scores for Commonality of Unsafe Injections in a Doctor’s Office and a Hospital

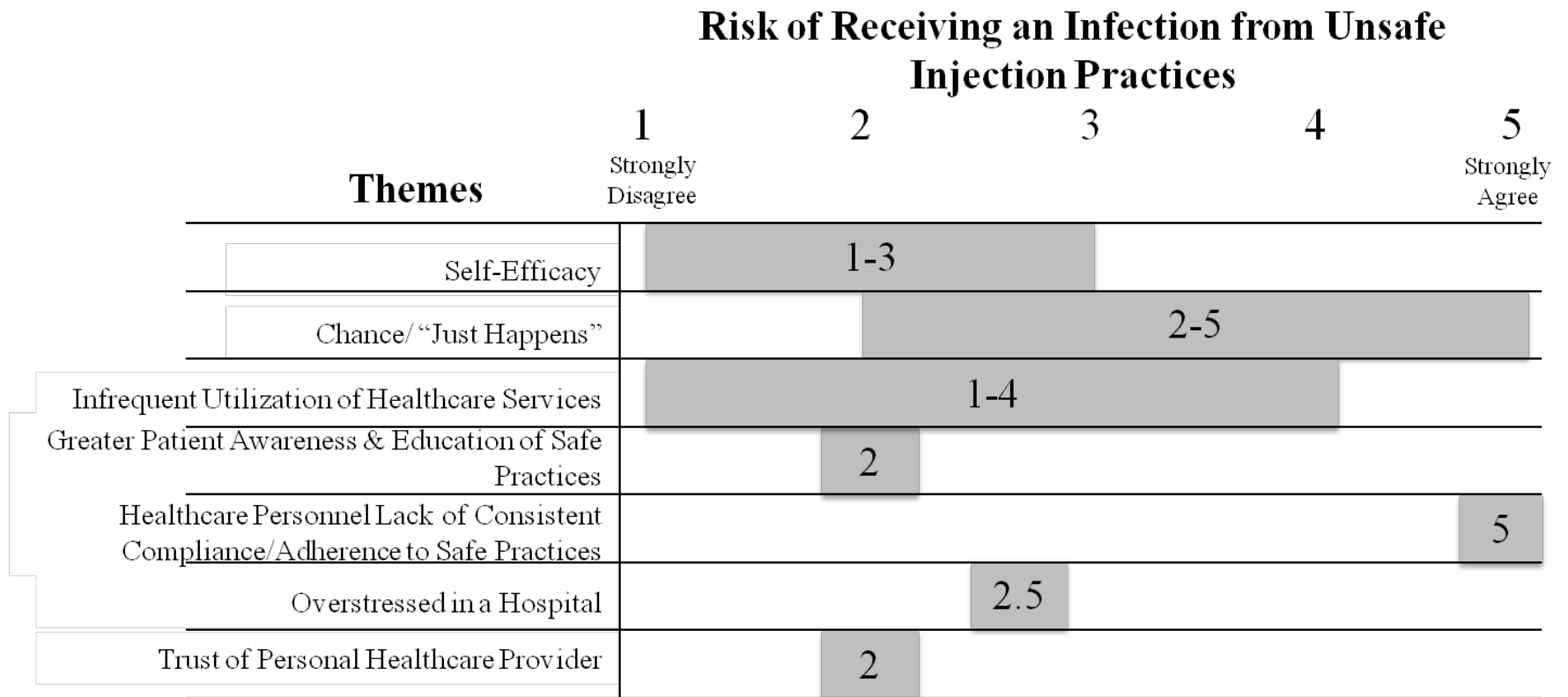


Hospital values are shown in light grey. Doctor’s office values are shown in dark grey.



**Figure 3.**

Qualitative Themes associated with Quantitative Scores for Risk of Receiving an Infection from Unsafe Injection Practices



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## Appendix<sup>a</sup>

*Letter written by Health Department indicating that disease transmission had been identified*

February 27

Dear Sir or Madam,

In January the Any Where Health District began investigating reports of recent hepatitis C infection among several people who had undergone procedures at the Endoscopy Center of Any Where USA, located at 1234 Main Street, Any Where. Through the investigation, we identified the use of unsafe injection practices which may have exposed patients to the blood of other clinic patients.

This letter serves as notification that you have been identified in clinic records as a former patient of the clinic who was placed at risk for possible exposure to bloodborne pathogens. **As a precaution, and in order to take appropriate steps to protect your health, we recommend you get tested for hepatitis C, hepatitis B, and HIV.**

It is not possible to determine specifically which people were exposed, but **all patients who received injected anesthesia at the center** have been placed at increased risk for exposure. As a result, we are notifying all people who received injected anesthesia medications between March and January 11. Our investigation has identified that the infections were associated with the unsafe injection practices and **not** with the procedures themselves.

People infected with viruses such as hepatitis C and HIV typically do not have symptoms for many years, so you may have been infected and not know it. Even though you may not feel ill or remember getting sick, you should get tested in order to safeguard your health. Although testing cannot determine if you were infected at the clinic or by another source, knowing that you are infected is important, as there are treatment options available if you do test positive.

We recommend that you be tested at your own doctor's office, as he or she will be able to best advise you on what to do if you test positive. If you do not have a regular doctor, a list of resources is available on the health district website at <http://www>. Wherever you choose to be tested, be sure to bring this letter with you and give it to your doctor. Information for your doctor is printed at the end of this letter.

We understand that you and your family may have many more questions or concerns with the information you have received. To help answer them, we have established a hotline at 800-555-1212. The hotline will be available starting Wednesday, February 27. You may also obtain additional information on the health district website at <http://www>.

NOTA: Para obtener esta información en español llame al 555-1212 o visite el sitio web  
www.

Sincerely,  
Dr Steve Smith, MD  
Chief Health Officer



*Letter written by healthcare facility indicating that no disease transmission had occurred*

DATE

Name field for mail merge

Address field for mail merge

Dear \_\_\_\_\_:

We are sending this letter because you had a cardiac chemical (pharmacological) stress test at No Name Medical Center, 1600 Main Street, Anywhere USA, between DATE and early DATE. During this test, a nurse caring for you may have inappropriately re-used medical supplies. Although we do not know whether this action has caused any illness, it is possible that this action may have exposed you to infections. **As a precaution, we are asking that patients get tested for hepatitis C virus, hepatitis B virus and human immunodeficiency virus (HIV).**

All of us at No Name Medical Center understand that this is alarming and may be frightening. We want to assure you that we will assist you in every way possible, including paying for you to receive necessary tests. **We recommend that you get tested**, as there are treatment options available if you do test positive for one of the above infections.

No Name Medical Center understands that this is an unacceptable practice that once discovered was immediately corrected. We are working with public health authorities to conduct a thorough investigation. We have no reason to suspect that patients who had chemical stress tests before DATE are at risk. The concern lies only in patients treated during this time by one particular nurse.

We have made arrangements with Lab Company X, an independent network of clinical laboratories, to provide free blood testing for you. No Name Medical Center will be responsible for the cost. Enclosed is a form for the testing. Please take this form to a Lab Company X Patient Service Center location convenient to you. Fasting before the test is not necessary, and Lab Company X recommends arriving after 11 a.m. for the tests. We have enclosed a list of local Lab Company X centers, and a complete listing of locations is available by visiting WEBSITE.

Additionally, if you received a chemical stress test after DATE, you will need to be tested now and will require a repeat test six months after the date of your procedure.

The physician specified on your No Name Medical Center medical record for this procedure will also receive a letter of explanation including which tests are required.

We realize that you turn to No Name Medical Center to get better. This event is unacceptable to us as well, and we are trying to be as proactive as possible to ensure the safety and well-being of our patients. If you have additional questions or concerns, please call the dedicated, 24-hour hotline at NUMBER or refer to the following website: WEBSITE

Sincerely,  
**CEO**  
**No Name Medical Center**

<sup>a</sup>Letters were originally 1 page each but due to formatting were made to fit on two pages each