Medical Product Safety Network (MedSun) Final Survey Report
Topic: Personal Protective Equipment Follow-up Survey
Year Conducted: 2015

Introduction

Personal Protective Equipment (PPE) refers to specialized clothing and equipment worn by health care providers to protect them from infectious diseases. The clothing and equipment include products such as isolation and surgical gowns, masks, coveralls, gloves, hoods, goggles, face shields, aprons, boot covers, and powered air purifying respirators (PAPRs). In fall of 2014, the FDA became aware that there may be shortages of PPE in response to the Ebola Virus Disease (EVD) and wanted to learn more about the availability of PPE from the perspective of healthcare workers. The information was a part of FDA's ongoing efforts to ensure an adequate supply of PPE for the nation's hospitals, and was considered very useful to the FDA team that was working with other federal agencies on Ebola Preparedness activities.

In May 2015 FDA staff needed to obtain additional information from the same sites surveyed in 2014 if possible, adding other hospitals if needed to substitute for those sites not available for the follow-up survey. The follow-up survey focused on whether the supplies needed for Ebola Preparedness had been obtained, what measures hospitals had to use to obtain them, how hospitals determined the protective level to use in ordering PPE products (especially gowns and coveralls), staff confidence in the protective value of gowns/coveralls, the monthly drawdown on hospital gowns/coveralls obtained for Ebola Preparedness, any failures seen with the protection provided by gowns/coveralls that they had been using for various purposes, and suggestions for encouraging reports to manufacturers/FDA concerning problems seen with consumable products.

Methodology

A small sample of health care providers from hospitals that participate in FDA's MedSun Program were queried to obtain detailed and in-depth information about the availability of personal protective equipment (PPE) used by healthcare workers in the event they are treating a patient with suspected or actual Ebola Virus Disease. Health care providers from nine different hospitals (located in the West, Midwest, Northeast, and Southern regions of the U.S.) participated in the voluntary survey. Eight of the nine hospitals had been included in the earlier PPE survey, and one had not been surveyed at that time.

Three hospitals in the survey have over 400 beds, four have between 100 to 400 beds, and two hospitals have less than 100 beds. One hospital is a stand-alone pediatric facility.

Survey respondents generally included both staff from Infection Prevention/Control and from Materials Management or Supply Chain operations including specialists in purchasing, distribution and/or central supply. It was a priority to have a leader from Infection Prevention/Control on the call, if possible, and that was the case for almost all of the calls completed.

Overview of Responses:

Receipt of PPE for Ebola Preparedness

The majority of respondents report having made significant strides in obtaining the PPE they ordered for Ebola Preparedness, although most of the sites indicated that they still had difficulty obtaining what they needed (such as cowls for use with gowns and tall boot covers). Over half indicated they are still waiting on certain supplies ordered in the fall of 2014 (such as PAPRs that cover the shoulders). Almost all of the sites indicated that they needed to tap alternate suppliers/sources that they did not normally use in order to obtain specific supplies for Ebola Preparedness that they had not ordered previously. They often needed to go to sources they had not used before (e.g., certain third party vendors). One large hospital indicated that they used supplies provided by their County Health Department and County Emergency Medical Services while they were waiting for their own supplies to arrive. Some hospitals indicated that they could only obtain large sizes of certain products (e.g., gowns), which would not fulfill their PPE needs.

The hospitals indicated that they made some decisions about the products to stock based on what they were training their staff with and ease of doffing/donning. For example, at least two hospitals decided not to use coveralls for Ebola Preparedness because they thought the coveralls are not easy to don and doff safely. In some cases, certain staff (such as those in the ER) considered the coveralls to be safer given the information they had about what was being used with actual Ebola patients (e.g., in the Nebraska hospital, at Emory, and by Doctors Without Borders working in West Africa), and those staff needed to be convinced of the effectiveness of the PPE selected by Infection Prevention/Control staff at the hospital.

Drawdown of PPE for Ebola Preparedness:

One hospital in this survey commented that they had drawn down their EVD PPE supply for training purposes, despite not seeing any patients suspected of having EVD. Another hospital in the survey had a patient that was suspected of having EVD, but it was subsequently ruled out. During that rule-out process, they did draw down their supply of their PPE for Ebola Preparedness for use by the staff who had contact with that patient.

Most of the hospitals indicated that they avoid drawing down upon their supplies that were obtained for Ebola Preparedness (and for preparedness with similar types of highly infectious diseases), except for certain items that they find fairly easy to replace as needed (such as gloves or some boot covers). One hospital indicated that it found many of these supplies useful for staff when it recently had a patient suspected of having MERS (which was subsequently ruled out). This hospital indicated that the PPE it needed for MERS and MERS rule-out cases was between the very protective level that was needed for Ebola Virus Disease and the less protective level needed for Tuberculosis.

Use of AAMI Barrier Protection Level Information and Other Sources of Information Concerning Protection Levels for PPE

In most of the interviews, the hospital respondents indicated familiarity with the AAMI Barrier Protection Levels, but they did not consider themselves well-versed in the clinical implications of the AAMI Levels or other standards (such as ASTM standards or their European equivalents) that are often used in association with the PPE gowns and coveralls to show their protection level. An Infection Prevention/Control physician specialist from a large hospitals asked that FDA or another qualified agency/organization create and disseminate a table or other document showing the ways that clinicians should interpret the various AAMI Levels and other standards to assist clinicians in understanding these labels much better and thereby help them use this information effectively. (This work began during the survey period as a response to this suggestion.)

Staff Confidence in PPE Provided:

Respondents indicated that the training provided to staff in recent months has helped lower the anxiety level considerably ("50% less anxiety among staff, especially for ICU nurses and OR staff" according to one hospital) regarding PPE for use with Ebola Preparedness and similar purposes, since staff have seen that they are provided with assistance in the process of donning/doffing and are more familiar with the processes involved. These respondents said that if there were a patient presenting at their hospital with suspected Ebola, there would still be fear among the healthcare providers, but with a greater confidence level that they are protected by the PPE and procedures developed for use of PPE.

Instances of Failures of Gowns, Coveralls used for PPE

Although at least two hospitals mentioned instances of rips/tears (especially at the seams) for PPE gowns/coveralls, other types of failures were seen as rare. Only one hospital mentioned cases of fluid penetration with protective gowns (from two years ago, with two staff), and the details were obtained about those instances.

Another hospital mentioned that they had two cases of bodily fluid "strike-through" in their ER/Trauma Unit but later learned that they had inadvertently purchased the wrong type of gowns to provide to the staff there. They worked with the manufacturer on a different choice for that area, with a higher level of protection. It is notable that only when the Infection Prevention/Control specialist went to that area and asked staff directly about any problems with gowns or other PPE that they learned of the problem and investigated the types of gowns provided. This specialist pointed out that healthcare staff rarely come forward to complain about such matters unless the problem is more serious than blood/bodily fluid strike-through with a gown, and that staff generally accept the products provided without questioning them. This site suggested that gowns be color coded for protection level, which the Infection Prevention/Control specialist endorsed strongly, and/or marked with the level of protection (i.e., AAMI 1,2,3,or 4). This would allow the Infection Control staff and the staff who were knowledgeable about the appropriate levels to easily observe and point out when someone was wearing PPE that was not at a high enough protection level for that area.

None of the nine hospitals' respondents knew of any health care worker illnesses at their hospitals that were associated with PPE failure.

Ways to Encourage Reporting about Consumable Products such as PPE Gowns/Coveralls, Gloves, Disposable Tubing:

Respondents from all of the hospitals in the survey had ideas about how FDA could encourage reports about problems with consumable products such as gowns and gloves. The suggestions were generally centered on educational efforts with staff such as Materials Managers/Purchasing, and through professional associations such as ARHMM, ASHRMM, and APIC (e.g., using messages in APIC's weekly educational newsletter, journal articles, and presentations at conferences).

An Infection Control clinician mentioned that there is an organizational liaison from APIC to FDA who may be helpful in spreading the word about FDA's interest in reports about PPE products including gowns and other disposable products. One Infection Control professional with a laboratory background suggested having information about FDA's interest in problems seen with these products included prominently in or on product packaging. The work of the MedSun Representatives/reporters was mentioned as helpful in encouraging reports for five of the hospitals surveyed. In several cases, respondents indicated that they do not think that healthcare professionals know about FDA's interest in medical product failures that do not involve adverse events. One hospital indicated that although they have reported on a number of medical devices, they have not thought about reporting regularly on consumable/disposable products such as gowns or IV tubing. They also suggested that manufacturers be required to provide them with feedback about their complaints regarding PPE products, as some but not all manufacturers do now.

Summary

Respondents to the follow-up survey express significant challenges involving obtaining the PPE they needed for Ebola Preparedness and responding to the changing recommendations from CDC during the fall of 2014. Hospital staff from one-third of the sites we spoke with indicate that they are still waiting for their orders of certain types of PPE ordered in the fall of 2014, while others were fully stocked within approximately 8-12 weeks, and all were stocked earlier for certain easy-to-obtain PPE products. Generally the respondents consider their hospital's staff to be fairly confident in the PPE that is supplied for their use, with some differences among the departments and types of staff. Sites mentioned OR staff as familiar with how to put PPE on and off when used for different situations.

The respondents indicated that they were at least somewhat familiar with the AAMI protection levels, and less so with other standards. One hospital indicated they would appreciate FDA or another knowledgeable agency providing a detailed comparison of the clinical implications of the various AAMI levels and other standards often used in reference to PPE.

Generally the hospitals we spoke with have not seen problems with bleed-through with gowns/coveralls, although one hospital provided details about two incidents involving bleed-through with gowns. The sites had a variety of suggestions for encouraging reports about problems with consumable medical products such as gowns and gloves, including educational efforts, reminders in newsletters from professional associations such as APIC and AHRMM.

Survey Limitations

Although the findings add to FDA's knowledge of hospitals' purchases and uses of Personal Protective Equipment, there are several limitations to the survey methodology. These include the small convenience sample of

respondents and the challenge with obtaining specific product information from hospitals including quantities on hand of PPE. In view of these limitations, the respondents' perspectives may not represent the perspectives of all device users.

Therefore, these findings represent only one piece of information. No conclusions can be made about PPE based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, clinical trials, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

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Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.

The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary action.