RESEARCH NEWS
Washington University in St. Louis

The United States drug supply chain has been deeply affected by Hurricane Maria's devastation of Puerto Rico. Pharmaceuticals represent more than two-thirds of Puerto Rico's exports. There are approximately 50 pharmaceutical manufacturing plants in Puerto Rico and it is unknown how many of those have been structurally impacted. We do know that the overall infrastructure of the island has been devastated causing problems with transportation and electricity which has resulted in decreased production capacity at the manufacturing facilities.

The most impacted pharmaceutical products to date have been the small-volume parenteral solutions (SVPs), including 50 ml and 100ml bags of normal saline and dextrose that are used to dilute medications for intravenous administration. The manufacturer estimates that due to limited production it will not be able to produce 100% of historical supply levels until the end of the first quarter of 2018. The manufacturer and FDA have taken measures to allow importation of mini-bags from outside the United States, however, this is not thought to raise the supply level above a 30% allocation level.

These national shortages have had an impact on the BJH pharmacy, including the BJH investigational drug pharmacy that supports some Washington University clinical trials. Please note that the BJH pharmacy and the Washington University pharmacy are different entities which have been impacted differently. Specifically, the small IV fluid bags for the BJH pharmacy come from a supplier (Baxter Pharmaceuticals) which receives much of its supply from hurricane affected areas, while the Washington University pharmacy utilizes different suppliers which have not been as significantly affected.

Our main priority is to be able to avoid interruptions for research subjects that are actively receiving treatment under an IRB approved protocol. How can you help? We are asking that each principal investigator reach out to the study sponsor and determine if IV fluids can be provided by the study. Additionally, the pharmacy team has been actively working with the sponsors to determine if there is any opportunity to have flexibility in the diluent or concentration of the final study drug preparation to allow us the opportunity to modify how we make the drug based on what fluids are available at any given time.

Although we cannot say with confidence that currently active study participants will not be affected, the best way to prepare for this is to have principal investigator and research teams partner with the investigational drug pharmacy to understand your individual study needs. If the study sponsor is unable to provide a supply of small volume parenteral solutions, one of the following measures may need to be implemented:

1. Pause enrollment on any studies that utilize small volume IV fluids for compounding study medication.
2. Hold on any new studies that would require small volume IV fluids that are not currently open until the time that small volume IV fluids are readily available.

Again, our overall goal is to ensure that we provide the best possible care to our patients and your involvement is critical to this effort's success.

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