Short communication

Planning for the unexpected: Strategies for maintaining a robust clinical trial program

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ABSTRACT

During our entire history, Puerto Rico has suffered from being in the path of Hurricanes. The implications of these events during the conduction of clinical trials present a great challenge. On September 20, 2017 Puerto Rico suffered its most devastating hurricane in decades. We identified four main challenges faced as a result of the natural disaster: infrastructure damage, shortage of basic necessities, transportation difficulties and communication failure. By assessing the needs of each participant, we were able to aid with food, water and medicine. Protocols were resumed shortly after the disaster, participants were located and transportation to the research center was arranged for participants. Development of emergency plans within research protocols, allocation of emergency budgets, including transportation and communication costs, may overcome some of the challenges created by a natural disaster.

1. Background

As researchers engaged in conducting clinical trials, maintaining the wellbeing of our participants is our outmost priority. Clinical research studies incorporate multiple safety evaluations such as laboratory and physical examinations to ensure the participant’s health. Similarly, research protocols have delineated participant and sponsor communication plans. However, plans for unforeseen disasters, such as those caused by natural disasters or political unrests, are limited or unavailable to help researchers deal with those kinds of events during the span of a clinical study. These unexpected events may cause vast damage to infrastructure and affect the day-to-day of research staff and participants. Cyclic events, such as the hurricane season, allows for the development of contingency plans to ensure continuity of the research study, effective communications among all parties and safety of the research participants. These protocols and procedures provide a roadmap for participants, investigators and sponsors for the continued operation of the study protocol.

Hurricane Maria devastated Puerto Rico on September 20, 2017 as a Category 4 hurricane (sustained winds of 155 mph [2]) causing significant infrastructure damage across the island (Fig. 1A). All basic necessities in Puerto Rico were severely compromised, including access to clean water, access to medicine and electricity. Reestablishing the needs of the population was a daunting task not only because of the extensive damage but also because of our geographical isolation as an island. Federal Emergency Management Agency (FEMA) reported that during the first 30 days after Hurricane Maria only 61% of the population had cellphone service, 69% had clean drinkable water and 21% had electricity [1].

In addition, transportation was severely impaired as the integrity of the roads and accessibility were largely disrupted (Fig. 1). Due to the very limited communications across the island, relief efforts were significantly compromised. As an island located in the path of atmospheric events, national and institutional contingency plans have been developed to prepare for different scenarios, such as loss of power and shortages of food and water. However, even with contingency plans in effect, failure in communications and limited supply of basic items interrupted the normalcy of our participants’ life.

2. Challenges

Challenges related to management of research studies during natural...
disasters have been previously reported in mainland USA [3]. However, coordinated efforts among professionals, government and private citizens, may overcome limited disaster preparations [4], to ensure the research participant’s life are protected and the continuance of the research study. Hurricane Maria reminded us that our duties as clinical investigators extend beyond the immediate research protocol to include supporting our research participants in their immediate needs. We identified four main challenges faced as a result of the natural disaster: (1) damage to buildings/roads, (2) shortage of basic necessities (water, fuel, food, medications, etc.), (3) transportation difficulties; and (4) communication failure. However, communication failure was critical as it was key to determine immediate needs for the staff and research participants and to receive instructions from the sponsors. At the Puerto Rico Medical Center and other large metropolitan areas phone landlines were restored quickly; however, cell phones and Internet services took several weeks to months to be reestablished.

3. Strategies

After the immediate emergency passed, we first assessed the status of our research team by using house phones and visiting those we could not reach by phone. Then, we started to communicate with study participants. Some of the participants could be reached by analog phones lines; however, most participants only had cellphones and could not be reached as wireless communications towers were offline. Our standard operating procedures included obtaining the name and telephone number of a relative or friend we could reach out to in case of an emergency. In addition, we also asked participants for a physical home and work address and permission to visit them in case we cannot establish contact with them by phone. This proved to be an asset for reestablishing contact with our participants. We had a total of 27 participants enrolled on three different active protocols. Of these, eleven had to be contacted the week after Hurricane Maria as per protocol guidelines. Nine participants (82%) were contacted via phone calls within the first two weeks after the emergency. The other two participants (18%) were not contacted by phone, but home visits were done to establish contact. We issued temporary cellular phones to follow-up on the participants progress and to establish contact as needed. Thus, we were able to retain all of our participants active in the protocols.

After contacting every participant, we assessed their basic needs and that of their families. We assisted participants by providing help with water, food, medicine or information on how to get disaster relief through the government or private institutions. For those research participants who were having trouble with telephone communications, we provided prepaid cellphones that had good coverage in their geographical area. This would help them to communicate with the authorities, their relatives and our team. Help was given to each participant regardless of his/her continued participation in the study. Our research facilities, as most healthcare facilities, had contingency plans that allowed for an adequate environment with emergency water supply and power for participants, study agents and any other medical supply. For those participants who needed assistance with transportation, we contacted a private contractor and our research team members also volunteered to personally help with the transportation. Furthermore, with permission of the sponsors we accommodated schedule changes to facilitate the transportation arrangements and delivery of the study agent to the participant’s home if needed (Fig. 2). Most of the schedule changes we established for our participants were done before treatment was administered. Thus, data collection was not compromised because treatment schedules were maintained per protocol. These measures allowed us to retain 100% of our participants thus allowing us to maintain the retention rates established for each protocol.

Fig. 1. Images of the aftermath of Hurricane Maria after making landfall on Puerto Rico on September 20, 2017. a) Image of Hurricane Maria starting to cover the island of Puerto Rico. b) Image of destruction in the streets of San Juan. c) Image of a demolished house in rural part of Adjuntas. d) Image of destruction in the streets of Las Piedras.
4. Discussion

Surviving hurricane Maria has given us a unique perspective on planning for emergencies, developing redundant systems, emergency operating procedures and protocols that incorporate loss of infrastructure support in an island. Moreover, funds to support transportation and communications costs during natural disasters or other unexpected events should be incorporated in the initial study budget. In addition, research protocol should have clear algorithms for emergencies (pre-approved with Sponsors and approved by IRBs) including periods of extended loss of communication. Emergency preparedness is essential in the design and conduction of clinical research, and results in a robust research infrastructure, protection of participants and upholds the science. Furthermore, if previously approved schedule changes consider emergency situations within the study design, data collection and maintenance of the protocol will be minimally affected. Future clinical trials should consider how a natural disaster might affect them and adjust treatment schedules to accommodate these situations without affecting the study and the results.

In conclusion, we are indebted to our study participants for their commitment to the research studies during and after the emergency, they truly inspired us. We are also indebted to our sponsors including the National Cancer Institute and the Cancer Prevention Network at Mayo Clinic for their guidance, unyielding support and encouragement during the recovery phase.

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