Short communication

Mitigating the impact of disasters and emergencies on clinical trials site conduct: A site perspective following major and minor unforeseen events

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ABSTRACT

Internationally, the frequency of emergencies and disasters affecting the built environment is increasing. Clinical trials sites that experience an event that affects their clinical trials research infrastructure and site functionality, may find their ability to follow optimal clinical trials conduct is compromised. There is however minimal published information on how clinical trials sites should best undertake emergency planning and develop resilience. We provide a description (case study) from a site perspective of two unforeseen events, one major and one minor, and discuss ‘lessons learnt’.

International collation of post-event information about what worked and what did not, collected across a spectrum of disasters and emergencies affecting facilities undertaking clinical trials, would provide a repository of shared knowledge and help inform the development of strategies aimed at enhancing the resilience of clinical trials sites to extreme events.

1. Introduction

Internationally, the risk of occurrence of disasters and unforeseen events and also the likelihood that events will impact on the built environment, is increasing [1–3]. Clinical trials sites affected by these events may struggle to adhere to study protocols [4,5]. Examples of the impact of even a minor event might include difficulties accessing the site for participant visits within a pre-specified time window, reduced retention of clinical trial participants and also problems with storage of IP (investigational product) [4,5]. Although there are multiple publications about generic emergency preparedness and disaster risk reduction in hospital and community health settings [3,6], there is minimal information that focuses specifically on enhancing clinical trials site preparedness and resilience [4,5]. A major natural or human-made disaster that occurs without warning may be a once-in-a-lifetime event for the site research team and their study participants. In contrast, local minor unforeseen events and emergencies that disrupt clinical trials site infrastructure, for example as a result of climate change [7], are likely to become increasingly common.

The case study outlined below describes one major and one minor event experienced at our clinical trials site. We compare our clinical trials site’s ability to respond to these two unforeseen events and describe some ‘lessons learnt’ from these emergencies.

2. Setting of case study

A small clinical trials site within a public healthcare facility, focusing on Phase II and III (human) diabetes and metabolic pharmaceutical trials, in an ambulatory environment.

3. Description of two local events

Our facility has been forced to close its doors for several weeks without notice, twice over the last 10 years. The first closure followed a series of earthquakes in 2011, which caused loss of life and extensive damage to regional infrastructure [8]. Most of the buildings in the hospital campus were damaged [8]. This included our clinical trials site, which was in a modern building that was nevertheless deemed non-repairable. These earthquakes had an impact on our site’s environment that led to a long-term reduction in function.

The second, shorter period of closure occurred in 2019, shortly after moving into a newly built outpatient building. A human-made flooding event occurred in relation to the building’s sprinkler system [9]. After two weeks’ closure, the building was repaired to a partly functional
state. The flooding caused extensive damage to infrastructure, including information technology infrastructure. These two events represent two extremes of a spectrum of business interruption and are compared in Table 1. While the magnitude of these two events differed, shared characteristics of these (and perhaps all survivable) emergencies, include trying to ‘make do’ in a suboptimal work environment and also living with uncertainties around recovery timelines, which makes detailed post-event planning a near impossibility.

4. Combining a top-down with a bottom-up approach to the management of emergencies

Multiple websites and also some academic publications outline checklists (emergency risk management plans) related to managing clinical trials during and after an emergency [4,10,11]. These lists include excellent practical advice such as having backup trial documentation and also backup contact details for participants, staff and key CRO (clinical research organisations) and Sponsor personnel. When considering individual clinical trials sites, sponsors and CROs commonly ask questions of the PI (principle investigator) and their staff about their local risk management and disaster recovery plans. This approach may be regarded as a ‘top down’ approach.

Following an unanticipated emergency, some of this generic ‘top down’ advice will prove to be of low relevance, ‘on the day’. As an example, although back-up sources of power may be available, equipment that relies on power (electricity) may not be fully functional after a flooding. The general disaster and emergency management literature recognises that a ‘top down’ organised approach that is integrated with a ‘bottom up’ community approach that allows responsiveness to local conditions, is likely to be the most effective way of dealing with unforeseen emergencies [2,12].

5. The impact of implementing disaster preparedness standard operating procedures (case study)

After the major earthquake event in 2011, our clinical trials site increased our focus on routine disaster preparedness SOPs (standard operating procedures). These included; i) having up-to-date lists of participants and their contact details located on different media (paper, electronic), plus multiple methods of making contact with participants (land line telephone, cell-phone, e-mail where applicable), ii) ensuring that, wherever possible, data are available in an electronic format and also accessible remotely, with a preference for cloud-based data storage when permissible, iii) ensuring paper records are secured safely (in our setting the focus has been on minimising earthquake-related damage), iv) developing relationships with local sites undertaking the same study, with a view to combining resources following unforeseen events, v) ensuring that onsite storage of bio-samples is minimised, with a preference to storing bio-samples at locations within our health campus with well-developed back-up plans for power cuts, vi) back-up of temperature sensors and finally, vii) ensuring that study participants have a self-management plan for emergencies. (Admittedly, this is easier to do in our disease speciality of diabetes, than it might be in specialities where discontinuation of IP might lead directly to life threatening scenarios).

Additional changes to research site staff behaviour that occurred following the 2011 major event, that are not usually considered as part of disaster preparedness SOPs, include an enhanced awareness of Sponsor-Host institute’s contractual obligations during and after emergencies. The urgency implied within the Force Majeure clause in particular, helped discussions around prioritising access to the clinical trials site’s built environment.

After the second minor event in 2019, the above approaches allowed our clinical trials site staff to work remotely and remain in contact with study participants during the time period when our built environment

| Post-event activity or consideration | Example of a disaster (major earthquake) | Example of a localised emergency event (internal flooding of a single building) | Lessons learnt, regarding planning for resilience, adaptability and recovery |
|-------------------------------------|----------------------------------------|-------------------------------------------------------------------|-----------------------------------------------------------------|
| Ability to access clinical site (built environment) | Prolonged restrictions on site access – major impact on trial activities. | No short-term access; limited access after a couple of weeks. | Undertake an early on-site stocktake where possible; what equipment is functioning; what documentation is retrievable? |
| Availability of alternative sites | Low: Widespread destructive nature of the disaster left few alternative sites available. | High: Destruction confined to a localised area of the health campus. | Scope alternative study sites, including sharing of sites and equipment, before and after the emergency. |
| Transfer of study participants to alternative sites unaffected by the event, may be necessary | Reduced infrastructure and staff necessitated permanent transfer of some participants. | Temporary site relocation of some patients. | Investigator awareness of alternative sites prior to an emergency, is important. |
| Viability and security of paper documentation | Documents may be destroyed, non-retrievable or non-secure. | Slight damage, but able to relocate documents to an alternative, temporary secure environment. | Retrieval and relocation of paper documentation to a secure environment is a priority. |
| Effect of event on participants | Participants may suffer loss of; domestic power, water, accommodation. Also, potential issues with food security. Safety of participants is a priority. | Participants are not affected directly. | Make early contact with the CRO/Sponsor, describing the site’s strategy to mitigate participant-related protocol deviations and violations. |
| Research staff | Directly affected (see above), safety of research staff is a priority. | Not directly affected, but working in an unfamiliar, temporary environment. | Anticipate that the functional efficiency of staff will be reduced. |
| Onsite storage of investigational product and biological samples | Affected. | May be viable. | Consider environmental (temperature) monitoring with both wireless and stand-alone technology. |
| Participant access to IP (investigational product) | Partially interrupted. | Not interrupted. | Aim to minimise the consequences of unplanned interruption of IP. |
| Functionality of communications technology and ability to communicate with CRO/sponsor | Compromised but CRO/Sponsor aware of problems, through news media reports. | No major barriers to communication. Updating the CRO/Sponsor to indicate the seriousness of the disaster and ability to undertake contingency planning, is a priority. | Scope how communication will be maintained even if communication is compromised (prolonged power shortage, damaged devices.) |
| Anticipated time to recovery | Months/years. | Weeks/months. | Estimation of the time and resources needed to clear work backlog within a disrupted physical environment, should be realistic. |
was inaccessible. We were able to arrange participant visits at an alternative local trial site with relative ease, thus participant visits remained ‘in window’. Details of local ‘lessons learnt’, are outlined below.

6. Bottom-up approach: Local ‘lessons learnt’

Reflections from our own operational debriefing following the minor flooding emergency, may add some nuance to the traditional tasks listed as part of emergency preparedness and responsiveness for clinical trials sites. Four observations about what went well, are outlined below. There is however always capacity to improve site preparedness. For example, increased use of cloud based electronic documentation, either as primary or backup documentation, would have provided additional resilience.

1. Redundancy (backup) planning may include small, low cost technology items. Redundancy within an engineering or systems thinking context can be used as a strategy to improve responsiveness to emergencies [13]. Redundancy is especially useful when planning for foreseeable or predictable events. In unforeseen emergencies it is however more difficult to predict which features of a redundancy approach may prove to be most valuable ‘on the day’. In the case of the flooding emergency, a key element of the backup plan proved to be duplication of temperature sensors. Water damage affected local computing servers, which in turn affected data transfer from wireless sensors to the offsite monitoring station. Fortunately, use of a simple stand-alone temperature sensor device enabled high quality documentation of IP storage conditions in the period immediately after the emergency was declared. The lesson learnt was that if it is possible to access low cost backup technology, consider using it.

2. Leverage institutional attention towards the clinical trials site’s emergency response. In an emergency affecting health care facilities, acute clinical care inevitably takes precedence over research activities, including clinical trials [4,5,14]. This is especially true after a major disaster where healthcare priorities need to be triaged [4,5,8]. However, in the localised flooding emergency, a discussion with local management about the Force Majeure sections of relevant sponsor-host institution CTAs (clinical trials agreements) proved a useful mechanism for directing institutional attention towards effecting a speedy return to clinical trials activities.

3. Obtain as much on-the-ground information as possible. The more information the clinical trials team are able to obtain about the site’s infrastructural damage and how this might relate to future clinical trials activities, the better. If it is possible (that is, if it is permissible and safe), for the clinical site staff to undertake early site inspection, then the detailed information (‘intelligence’) provided by this inspection will help with planning for the immediate future.

4. Place a high value on internal social networks. Finally, a clinical trials environment that builds on strong social networks provides resilience and adaptability during and after an emergency. While a major disaster will by definition require external (national, international) input from emergency agencies, in the more common scenario of a disaster where healthcare priorities need to be triaged [4,5,8], the clinical site staff to undertake early site inspection, then the detailed information (‘intelligence’) provided by this inspection will help with planning for the immediate future.

7. The case for international pooling of experiences

In contrast to hospital disaster preparedness and resilience [6], there is a paucity of published literature focusing on clinical trials sites’ emergency responsiveness. The extent to which operational debriefing occurs at clinical trials sites following an emergency (‘what have we learnt?’), is also unclear. Our own descriptive case study lacks breadth, for example it does not encompass the effects of extreme weather events. Also, it reflects the experience of a small clinical trials site, which lacks the organisational complexity of a larger site. Systematic collation of post-event information, done across a spectrum of disasters and emergencies affecting clinical trials facilities (and also other research facilities), would provide a useful repository of shared knowledge, highlighting what works in terms of building a resilient clinical trials environment, that allows rapid post-event recovery.

8. Conclusion

A resilient and adaptable institutional recovery environment, facilitated by the nurturing of collaborative institutional networks, is likely to minimise disruptions to the clinical trials environment after emergency events. This, together with a local ‘check list’ for clinical trials site preparedness completed prior to an event occurring, will facilitate recovery after an emergency. Ideally, knowledge about optimising the resiliency of the clinical trials environment should be obtained through systematic international research, covering a broad spectrum of disaster and emergency events.

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Declaration of competing interest

Nil.

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