

Safety of participants and research team during epidemics

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Introduction

- Clinical research is vital during epidemics and may include;
 - Research activities planned or ongoing prior to the epidemic
 - Epidemic-related specific research activities
- Epidemics especially with novel pathogens present an unprecedented challenge for research
 - Rapid development of new diagnostic, preventive and therapeutic strategies
 - Clinical and epidemiological studies to enhance understanding of the disease.
- As epidemics spread across the world, the critical importance of research and development in the response to such outbreaks is spotlighted.

Introduction

- Epidemics usually require a swift response from authorities to manage spread.
- Lockdowns in many countries are usually enforced quickly to try and slow the spread including restrictions to healthcare facilities.
- In such contexts, safety and principles of do-no-harm are critical for both research and clinical care.
- In research, safety of participants and staff should be the first priority

Response to epidemics

- Many institutions and regulatory agencies paused clinical research:
 - Eliminate non-essential contact to protect study participants and research staff
 - To shift focus to epidemic related research
 - To adapt to necessary changes in the hospital/research clinic operations to accommodate safety measures

Safety concerns

- Research participants and staff are affected by epidemics in many ways.
- Research participants and staff may feel stressed and need counseling.
 - Several negative psychological effects of quarantine including posttraumatic stress, confusion and anger.
 - Other factors like loneliness and isolation, especially for people living alone.
 - Worry that they or family members will contract the virus.
- Possibility of mental stress should be monitored and addressed
- Limited access to investigational products during lockdown and alternative arrangements may be needed to assist participants.

Safety concerns

- Risk of exposure or transmission which varies according to:
 - Types of interactions occurring during the research - both the amount of close contact and the number of different contacts between individuals
 - Use of personal protective equipment (PPE).
- Risk of having more severe disease which varies at individual level with certain characteristics clearly associated with greater risk
- Biggest challenge may not be not safety in the clinics/Lab but safety in getting to and from these sites - risks of public transportation
- Safety concerns related to new investigational products or unproven experimental therapies – potential toxicities

Considerations for continuing research

- Decision to continue clinical research during epidemics is usually a tough choice for principle investigators (PIs).
- Its the PI's responsibility to weigh up the risks and benefits in the context of the epidemic.
- PIs must provide a safe environment and address the psychological needs of participants.
- Community engagement is essential - a community, involved in the planning process of a study and informed of the risks and benefits, is more likely to trust the research process.

Some general guidelines

- **Staff and participant safety:** several regulatory agencies have stated that “safety of the participant is of primary importance, and risks of involvement in studies should be weighed against anticipated benefit for the participant and society.”
- **Protocol amendments:** Any hazards should be minimized or eliminated to protect research staff and participants
- **Study management:** alternative methods for communicating with participants should be considered in cases where physical visits are not essential. Where possible, study treatments should be delivered to participants’ homes to minimize travel
- **Communication:** Any trial conduct changes, and the implications thereof, must be communicated to research sites

What can be done

- All research participants and staff must be informed of the risks and educated regarding transmission routes and symptoms of infection.
 - important to provide the best and most transparent information possible.
- Vulnerable populations, such as those who are pregnant or have comorbidities are particularly at risk and should be protected
- Face-to-face meetings with participants should be conducted only when absolutely necessary, and where possible, be changed to phone calls or online meetings.
- Appropriate PPE is mandatory to help address some of these concerns.

Reduce density at research sites

- Making sure there are never a lot of people—whether researchers, participants, students or administrative staff—at one place at one time is key.
- Consider stretching participant appointments out to seven days a week to minimize the number of people in the building at one time.
- Shift from indoor to predominantly outdoor activities where possible – optimize ventilation

Revise your consent forms, if needed

- Reworking consent forms to make sure that participants can make informed choices about what they're comfortable doing
- Detail the potential risks as well as the measures you are taking to protect participants.
- Make sure participants understand they can withdraw from the study at any point.

Epidemic-related research

- These research activities raise specific safety concerns for research staff as the risk of exposure are particularly high
- Overall objective should be to reduce risk to the lowest reasonably practicable level by taking preventative measures, in order of priority
- Effective training and communication to ensure all staff understand related safety procedures
- Use of appropriate Infection prevention and control processes and PPE
- Workforce management – working in short shifts and in teams e.g. buddy system
- For participants, harms may result from breaches of confidentiality, violations of privacy, or discrimination or stigma as a consequence of participation

***“In the midst of chaos, there is also opportunity”
Sun-Tzu, The Art of War.***

Conclusion

- Guiding principles for conducting human research during epidemics:
 - The safety of research participants and staff is paramount
 - The risk of community spread, including spread to the researchers themselves, must be minimized
 - Policies and practices must be designed and implemented in a way that attends to inequities explicitly and proactively
 - Best practices need to be shared widely within the research community

THANK YOU