



INTRODUCTION

Background

Children are particularly susceptible to trauma in a humanitarian crisis given their dependence on social structures and developing coping skills. For this reason, it is important to understand comprehensively how humanitarian crises affect children in order to provide effective therapeutic interventions. But beyond assessing the effects of disasters on children, little is known about their coping after disasters, resulting in a current lack of evidence-based therapies¹.

A Vulnerable Population

As a vulnerable population, children require special considerations when participating in research in the areas of obtaining informed consent, minimizing risks, and considering their best interests. Disasters often erode normal functions of every day life and thus make it difficult to navigate these conditions in children and research.

Yet over-protections for children may understate rather than impress the need for research in children following a traumatic event. On the other hand, downplaying children's special considerations presents the potential for significant harm and adverse consequences².



The Therapeutic Orphan

In 1963, pediatrician Dr. Harry Shirkey coined the term "therapeutic orphan" and a few years later explained in an editorial its significance. By overlooking pediatric populations in clinical drug and device research, children were denied access to effective, safe treatments widely available to adult populations³.

Considering the lack of research to directly benefit children in the context of a humanitarian crisis, this project was carried out to determine:

1. What lessons can be learned from clinical research in children?
2. What is the ethical dilemma when this research is not conducted?

AIM

The Case for the Therapeutic Orphan

The aim of this project was to consider and compare children as therapeutic orphans in clinical research and determine, by means of a literature review, if children in humanitarian research are also therapeutic orphans. To date, no literature has considered children in humanitarian research as therapeutic orphans.

Elements of clinical therapeutic orphans was analyzed to reveal at least three key components:

- Adult-centric research
- Off-label treatment
- Neglect of childhood conditions

Though children in a humanitarian crisis do not present with unique or rare diseases, they often will express distinct psychological symptoms with a strong correlation to the disaster event⁴. It becomes important to understand what the moral imperative is to conduct this research in children given the risks and trauma involved⁵.

Elements of the Therapeutic Orphan		
Key Elements	Clinical Research	Humanitarian Research
Adult-centric research	Drug manufacturing and clinical research	Trauma research following a disaster crisis
Off-label treatments:	Children prescribed drugs tested for safety and efficacy in adult populations only	Psychological interventions used not tested for efficacy in context of humanitarian crisis ¹
Childhood-specific conditions:	Children present unique diseases or rare conditions	Impaired autonomy, limited by childhood, further exacerbated by loss of social structures

Table 1. Comparing the elements of the "therapeutic orphan" in clinical research and humanitarian research.

METHODS

Exploring Evidence for Ethical Research

Designating children in humanitarian crises as therapeutic orphans propels the need for ethically justifiable conditions of research. A **literature review** was performed, and the following elements were studied:

- Natural disaster research, refugee research, and community emergency research
- Qualitative methodologies
- Studies in which an ethical examination occurred prior, during, or after the conduct of research
- Considerations of autonomy in children

A **principlism approach** was used to evaluate the literature on the principles of:

- Respect for autonomy
- Beneficence
- Nonmaleficence
- Justice

Finally, studies that were conducted for children populations following a disaster event were evaluated for perceptions of advocacy on behalf of the children and the considerations of autonomy.

RESULTS

Justifying Research

Beneficence	Non-maleficence	Respect for autonomy	Justice
Research designed as a benefit		Promoting autonomy as a form of advocacy	
Research as a trust-building initiative			
Risks mediated collaboratively with participants			

In general:

- The research design itself should be designed as a benefit, rather than only supplying extemporaneous benefits.
- Ethical issues arise during the research process, and protocols need to emphasize the ways in which researchers will include participants to resolve these issues.
- Participatory methods, narrative data collection, and iterative consent models serve to promote autonomy.
- Research must additionally serve the goal of trust-building with the specific population.

For the therapeutic orphan:

Participating in research allows the opportunity for children status-post a humanitarian crisis to alleviate adjustment challenges by engaging in active self-determination.

CONCLUSIONS

By failing to engage in research of children who experience traumatic events, not only do their health and social needs go unmet, but they also lose an opportunity to give voice to their own self-determination the midst of distress and insecurity.

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