Analysing two serious incidents in clinical research from a systems theory perspective

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THE WORK IN CONTEXT

Effectively ensuring the safety of volunteers that participate in clinical trials involving healthcare products (drugs, medical devices) is a subject of debate in clinical research. This is especially so when healthy volunteers choose to enter Phase I (first-in-human) trials where any serious incident is unacceptable and undermines the confidence in the whole healthcare industry. As in other industries, safety management of clinical trials rely mainly on a traditional view that aims to avoid serious incidents by the identification of hazards, the development of safety barriers (technological barriers, procedures, regulation, laws) to prevent and mitigate risks, and the strict compliance of operators with these safety barriers. This traditional view of safety management is recognised as no longer sufficient to maintain safety in a dynamic, complex, and competitive environment where changes and perturbations are permanent, and the pace of technological innovations is high. In that respect, a group of individual pharmacology and clinical professionals have argued for the need to introduce the principles and methods from human factors and systems theory into the process of safety investigations following serious incidents occurring in clinical research. In this perspective, an international, interdisciplinary and multi-stakeholder collaboration was established to explore the feasibility to transpose human factors and systems theory methods to the specific context of investigation of serious incidents that occurred during phase I-trials. The Causal Analysis using System Theory method was applied to two emblematic serious incidents, one in London (United Kingdom) in 2006 and one in Rennes (France) in 2016. These two serious incidents have benefited from extensive investigations by both stakeholders and authorities afterwards to identify their root-causes and propose remedial actions to avoid their recurrence.

KEYWORDS

CAST method, human clinical research, human factors, serious incidents, volunteer safety

A brief outline of the work carried out

The two serious incidents were analysed by our interdisciplinary group following the Causal Analysis using System Theory method from Leveson (2012). Data used were those collected during official investigations that have followed these serious adverse incidents and that were subsequently made available in official regulatory inspection reports. These data were expanded by information gathered from the scientific articles that have been published on the topic, and from experts in pharmacology and human clinical trials. Based on the information available in these reports, our results have highlighted the safety control structure in place to minimise the risk of harms to volunteers during the two first-in-human clinical trials and the weaknesses in this safety control

structure that allowed these two serious incidents to occur. Systemic changes and constraints that could explain the emergence of these serious incidents are suggested.

Findings/solutions (the outcome)

No explicit method of accident analysis and prevention model or method from safety science was indicated in the official investigation reports. Each investigation focused mainly on the identification of failures from frontline operators and latent failures in the organisation.

For the two serious incidents, not all the reasons that led to the identified unsafe control actions could be explained due to lack of information on the context in which they were carried out, in particular, the mental model of the operators at the time of the event. Such information was not sought or reported in the official reports. Our exploratory study suggests inadequate situational and contextual information in the investigation reports of serious incidents occurring during clinical trials.

Impact

Our results suggest the need to investigate serious incidents that occur during human clinical research involving healthcare research from both human factors and systems theory perspectives.

References

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