

Problem statement

When a pandemic breaks out it is crucial to have a clear and executable plan ready. Usually a **mass vaccination campaign** is initiated by the government. However, a pandemic vaccine goes through a shorter process. This causes the **safety information to be incomplete**. Therefore the monitoring is really important.

Therefore, the policy implemented by Lareb during the last pandemic in 2009 needs to be assessed, in order to enhance safety surveillance of influenza vaccines in a future pandemic.

The *aim* of this study is to contribute to the **improvement of the safety monitoring of vaccines** by Lareb when a **pandemic** breaks out, by analyzing **stakeholder insights** regarding their experiences during the **pandemic of 2009**.

Theoretical background

HACCP framework

The studies of MacLehose et al (2001)¹ and Krumkamp et al (2009)² used the HACCP approach to evaluate a pandemic preparedness process.

The HACCP approach is a method to identify hazards and solve these through CCPs (critical control points). The method itself is the theory, that by identifying hazards in the process, these hazards can be prevented and risk minimized. If hazards are identified, they can be controlled with complementing action and monitoring.

The framework consists of the following principles:

Principle I: setting up a flowchart of the pandemic preparing process and identify possible **hazards**.

Principle II: Identify **CCPs** to minimize or prevent the hazards.

Principle III: establish **critical limits** for these CCPs → formulate recommendations.

Study design

Qualitative research approach

9 semi-structured interviews were conducted with respondents from **Lareb, RIVM, CBG** and the **Ministry of Health**.

Data analysis: open coding and axial coding in ATLAS.ti

Key Results

CCP: influencing external decision making

"Choices made somewhere else on the vaccination strategy, do have impact on where we have to invest our time and attention to. But also what can we do with the data, or how difficult or easy we can interpret the data."

Respondent 8

CCP: cooperation between organizations

"Actually, from day one on, there was a team set up with the most important professionals, which came together, daily, weekly. To gather all the information which was available and also to discuss of what we knew, what do we want to know to be better prepared, it changed from day to day and from week to week."

Respondent 2

CCP: work capacity

"You have to think about, aside from the vaccine, what if a lot of people become sick and half of the department is sick and tasks still need to be fulfilled, which tasks do you prioritize?"

Respondent 8

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Discussion/Conclusion

- Decisions that were made externally, had influence on the pharmacovigilance tasks of Lareb. → It is recommended to **convey knowledge on pharmacovigilance** to key decision makers by establishing a **knowledge transfer strategy framework**
- To enhance and improve the cooperation between organizations. → **Frequent and timely meetings** should be set up between organizations.
- As the work capacity is also an important aspect to maintain the safety monitoring → it is recommended to set up a **business continuity plan** in case of crisis.

Limitation: The pandemic of 2009 was mild, therefore no major problems were found. As the last pandemic was a decade ago, this has influence on the recall ability of the respondents.

Strength: The framework effectively identified minor hazards which led to CCPs and eventually to recommendations for this study.

References

1. MacLehose, L., Brand, H., Camaroni, I., Fulop, N., Gill, O., Reintjes, R., et al. (2001). Communicable disease outbreaks involving more than one country: systems approach to evaluating the response. *BMJ*, 861-63.
2. Krumkamp, R., Ahmad, A., Kassen, A., Hjarmoe, L., Syed, A., Aro, A., et al. (2009). Evaluation of national pandemic management policies - a hazard analysis of critical control points approach. *health policy*, 21-26.