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Ethical Considerations: Assessing Risks, Benefits and Burdens during Health Emergencies

Urban Wiesing

WMA‘s Regional Expert Meeting in the Pacific
on the WMA Declaration of Helsinki
Tokyo, Nov. 30-Dez. 1 2023

Assessing risks, burdens and benefits during health emergencies

Distinction:

- Emergency in an individual case
- Emergency in the health care system

Emergency in an individual case

- Risks and benefits for the patient are more difficult to assess because of time constraints
- Informed consent not always possible
- Proxy consent not always possible

Emergency in the health care system

- High pressure to get new knowledge/therapies
- Benefits for society: urgently needed but probability of success more difficult to assess
- Risks and benefits for the participant more difficult to assess because of time constraints
- Therefore, Informed Consent more difficult

Emergency in an individual case and Emergency in health care system

Commonality:

- Time restriction, less accurate assessment of benefits and risks
- Informed Consent impossible or more vague

Assessing risks, burdens and benefits during health emergencies

- What is meant by "assess"?
- Structure of medical assessment:
  - The **possible** information that can be considered is always too much.
  - The **relevant** information is usually too little.
  - To keep searching for relevant information does not make sense, because at some point one must assess and decide in medicine.
  - In particular in emergencies

Assessing risks, burdens and benefits during health emergencies

- In most cases, assessments in medicine are 'to a degree' uncertain.
- These structures also apply to emergency situations, only the time for assessment is more limited.

Assessing risks, burdens and benefits during health emergencies

- Lack of relevant information ⇧
- Time to assess ⇩
- This characteristic can be **reduced** by expertise, experience, (and AI?) to a certain extent, but **not eliminated.**

Assessing risks, burdens and benefits during health emergencies

- Emergency represents the structures of life in a pointed way:
- ars longa, vita brevis
- There is always more to learn and to consider (“ars longa”) than the situation allows (“brevis”, short)
- In life, and dramatically in emergencies

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1st Hippocratic Aphorism

Ὁ βίος βραχύς,	life is short,
ἡ δὲ τέχνη μακρή,	the art long,
ὁ δὲ καιρὸς ὀξύς,	opportunity fleeting,
ἡ δὲ πεῖρα σφαλερή,	experiment treacherous,
ἡ δὲ κρίσις χαλεπή	judgment difficult

The DoH and emergencies

- How should the DoH react to these structural conditions?
- DoH cannot change the structures of assessments.
- Moral conditions of research in emergencies must be stated.

Emergency in the DoH?

- The risk-benefit ratio is more uncertain
  - higher risk of wrong assessment
  - higher risk of patients coming to harm
  - higher risk of insufficient informed consent
- Because the medical assessment is more uncertain in emergencies, adequate moral conditions must be defined.

Emergency in the DoH?

- Emergency is not mentioned in the DoH

- DoH refers in § 30 to the situation that informed consent cannot be given by the patient, no "representative is available and […] the research cannot be delayed".

- This is part of the typical situation of individual emergency medical research.

Emergency in the DoH?

- The DoH: “the study may proceed without informed consent
  - provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee.
  - Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.”

Individual Emergency in the DoH?

- Langlois et al. 2021: DoH (and CIOMS-Guidelines) should be “revised to include more specific provisions on emergency medical research”.

- Langlois, A., Armstrong, S., & Siriwardena, A. N. (2021). Do National and International Ethics Documents Accord With the Consent Substitute Model for Emergency Research? *Acad Emerg Med, 28*(5), 569-577

Individual Emergency in the DoH?

- Langlois et al. propose five conditions :

- "1) the research addresses the patients' urgent medical needs,
- 2) the risk–benefit ratio is favorable,
- 3) there are no known conflicts with patients' values or interests,
- 4) cumulative net risk is minimal, and
- 5) consent is given as soon as possible."

Individual Emergency in the DoH?

- Langlois et al. propose five conditions :

- "1) the research addresses the patients' urgent medical needs, ['urgent' is not in the DoH]
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Individual Emergency in the DoH?

Question:

- Shall the DoH add wording like
- “urgent medical needs” and/or
- “no known conflicts with patients’ values or interests”?

Health Care Emergency in the DoH?

- High pressure to get new knowledge/prevention/therapies
- Benefits for society: urgently needed but probability of success more difficult to assess
- Risks and benefits for the participant more difficult to assess because of time constraints
- Therefore, Informed Consent more difficult
- So far: DoH demands balancing of individual benefit, individual risk, benefit of groups affected

Health Care Emergency in the DoH?

- “16 Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.”

- “importance of the objective” in emergencies?

Health Care Emergency in the DoH?

- “17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.”

- “benefits to them and to other individuals or groups affected”: in emergencies or pandemics?

Health Care Emergency in the DoH?

- So far: Balancing risks/benefits is demanded!
- Are new ethical principles needed?
- Or only specifications of existing principles?
- The relevant ethical principles are mentioned in the DoH
- No new ethical principles are needed
- Specification?
- General problem: Character of the DoH!

Health Care Emergency in the DoH?

- In Corona Pandemic:
- **The most difficult question: early market approval**
- “pandemic exceptionalism”
- Market approval so far **not** addressed in the DoH.
- Shall the DoH add a paragraph on market approval?
- **No!**
- DoH addresses researchers, not market approval authorities!

New paragraph(s) on Emergency in the DoH?

- Research in emergencies: not mentioned in the DoH!
- Neither in an individual case nor in health care system
- The relevant ethical principles are mentioned in the DoH.
- No new ethical principles are needed.
- The explicit condition "no known conflicts with patients' values or interests" could be added.
- The potential for individual *and* group benefit as a legitimising factor should not be removed.
- Risk-benefit balancing should remain in the DoH
- (Early) market approval should not be addressed

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