Course material

Course:

Ethics in Emergencies

Video:

6b Challenges in emergencies

Concepts (extracted from automatically generated subtitles):

Participant autonomy. Implementation research. Strong community engagement. Individual consent. Emergency setting. Research participants. Potential risks. True informed consent. Ethical implications. Such cases. Wrong hands. Study question. Communication barriers. Benefits of an intervention. Community engagement.



to video sequence search
(within Ethics in Emergencies.)



to video



...

notes

summary

0m 0s

Informed consent: challenges in emergencies



Chapter 3A | Ethics of Implementation Research in Emergencies

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Respect for participant autonomy requires transparent disclosure of all information, but as one can imagine, many challenges arise in an emergency setting. These challenges may impact how

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summary

0m 3s

Informed consent: challenges in emergencies

Geographical, cultural, language barriers

Individual consent



Mystakidou K et al. Ethical and practical challenges in implementing informed consent in HIV/AIDS clinical trials in developing or resource-limited countries. *SAHARA J*, 6, 46-57 2009. https://doi.org/10.1080/17290376.2009.9724930

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informed consent is obtained and if and whether it is meaningful. Some barriers to obtaining true informed consent for implementation research in an emergency can be geographical, cultural and communication barriers, and they should be addressable with good planning and strong community engagement. To overcome concerns of literacy or confidentiality, variable forms of documentation of consent may need to be considered, depending on the population and the

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summary

0m 19s

Informed consent: challenges in emergencies

Geographical, cultural, language barriers

Individual consent

- Size of community, migration, risk of infection



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potential risks involved. Requiring research participants to provide signed informed consent may not be logistically feasible in an emergency. For example, if the community is very large or is on

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0m 49s

Informed consent: challenges in emergencies

Geographical, cultural, language barriers

Individual consent

- Size of community, migration, risk of infection



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the move, or there is an infection risk. In such cases, verbal consent documented by

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summary

1m 1s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality



Mystakidou K et al. Ethical and practical challenges in implementing informed consent in HIV/AIDS clinical trials in developing or resource-limited countries. *SAHARA J*, 6, 46-57 2009. https://doi.org/10.1080/17290376.2009.9724930

researchers could be implemented if approved by the local ethics committee. When pertinent, ethics committees will need to determine whether individual consent may be waived, which will depend on the study question, the level of risk and the context. This will be discussed further in a later chapter. Privacy and confidentiality are terms that are often used interchangeably. They are, however, different, and the ethical implications may differ when one

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1m 6s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality



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considers individual or public matters. Both are also relevant for implementation research

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summary

1m 36s

Informed consent: challenges in emergencies

Geographical, cultural, language barriers

Individual consent

Privacy and confidentiality

- **Confidentiality**: no data sharing with third parties



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conducted in emergencies. Confidentiality reflects the ethical duty on the part of the researcher to

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summary

1m 38s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
  - **Confidentiality**: no data sharing with third parties



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ensure that data and information are not shared with third parties. Researchers should clearly explain in the protocol the process that will be followed to maintain confidentiality – for example,

notes

summary

1m 49s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
  - **Confidentiality**: no data sharing with third parties
  - **Privacy**: freedom from intrusion



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where records will be safely kept, who will have access to them, when they will be destroyed.

notes

summary

2m 1s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
  - **Confidentiality**: no data sharing with third parties
  - **Privacy**: freedom from intrusion



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Privacy is the right of a research participant to freedom from intrusion into their personal

notes

summary

2m 8s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
  - **Confidentiality**: no data sharing with third parties
  - **Privacy**: freedom from intrusion
  - Lost or misplaced forms



Mystakidou K et al. Ethical and practical challenges in implementing informed consent in HIV/AIDS clinical trials in developing or resource-limited countries. *SAHARA J*, 6, 46-57 2009. https://doi.org/10.1080/17290376.2009.9724930

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affairs. Respecting privacy and confidentiality in the process of obtaining informed consent may be challenging in an emergency. Researchers must put mechanisms in place to protect study data, documents, recordings and others, and avoid, for example, that consent forms that include

notes

summary

2m 14s

Informed consent: challenges in emergencies

Geographical, cultural, language barriers

Individual consent

Privacy and confidentiality

- **Confidentiality**: no data sharing with third parties
- **Privacy**: freedom from intrusion
- Lost or misplaced forms
- Privacy of phone or telehealth



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signatures are lost or get in the wrong hands, which may violate participant confidentiality and

notes

summary

2m 34s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
  - **Confidentiality**: no data sharing with third parties
  - **Privacy**: freedom from intrusion
  - Lost or misplaced forms
  - Privacy of phone or telehealth



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put individuals at risk. Obtaining consent by phone or telehealth may violate the individual's

notes

summary

2m 42s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
- Mistrust, misinformation and misunderstanding
- Transparency



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privacy if this is overheard or tracked. Alternative means of obtaining and documenting informed consent may therefore be required in emergencies to minimise potential harms. More challenging are the barriers of mistrust, misinformation, and misunderstanding, which may be more common in emergencies. Community engagement, along with transparent and consistent

notes

summary

2m 49s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
- Mistrust, misinformation and misunderstanding
  - Transparency
  - Explaining uncertainties



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communication about the research, will be key to mitigate these. Uncertainties about risks and benefits of an intervention may be greater in an emergency. Communication about these uncertainties related to a novel intervention may be challenging, especially when communities are mistrustful or do not have high levels of health literacy. Uncertainties cannot be shied away from, but must be clearly explained within the emergency context. The optimal methods for communication about risks and uncertainty may indeed be the topic of implementation research in

notes

summary

3m 10s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
- Mistrust, misinformation and misunderstanding
- Coercion
- Hope



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such a setting. Some individuals or communities may be more willing to accept risks in an

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3m 45s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
- Mistrust, misinformation and misunderstanding
- Coercion
  - Hope
  - Fear, stigma



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emergency if the intervention offers the only hope. The risks that participants may be coerced to participate in implementation research may therefore be higher in emergencies driven by fear

notes

summary

3m 49s

Informed consent: challenges in emergencies

- Geographical, cultural, language barriers
- Individual consent
- Privacy and confidentiality
- Mistrust, misinformation and misunderstanding
- Coercion
  - Hope
  - Fear, stigma



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or stigma, which undermines autonomy. Researchers should be aware of these pressures and try to

notes

summary

4m 1s

Challenges for informed consent



At the community level:

- May impact the individual autonomy of participants

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mitigate against them through clear and transparent communication. Also relevant for participant autonomy in implementation research is the fact that interventions may be studied at community or district levels. This may impact the autonomy of individuals in those communities as

notes

summary

4m 2s

Challenges for informed consent



At the community level:

- May impact the individual autonomy of participants
- Consent given by a "gatekeeper" for the whole community
- Identifying a gatekeeper may be challenging
- Objectivity may be difficult

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permission to run the study may be given by a gatekeeper or community leader. Identification of these leaders may be challenging in an emergency, as the traditional leaders may be sidelined or may have fled or died. Objectivity may be also harder for these individuals to maintain if they perceive themselves to be under threat, or a sector of the community being blamed in an

notes

summary

4m 25s

Consent for communities

Intervention: Add chlorine bleach to only water source during diarrhoeal outbreak



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emergency. To illustrate the role of the gatekeepers in informed consent, let us consider an implementation research study assessing the acceptability of adding chlorine bleach to

notes

summary

4m 49s

Consent for communities

Intervention: Add chlorine bleach to only water source during diarrhoeal outbreak

Gatekeeper: District health decision maker

Consent: No individual informed consent required since individuals cannot opt out

Community engagement: Feedback and adaptation according to needs



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disinfect the only water source in a drought stricken community during an outbreak of diarrheal illness. Permission for community participation would have been obtained from a district health decision maker as the gatekeeper. Individual informed consent in this case would

notes

summary

5m 2s

Consent for communities

Intervention: Add chlorine bleach to only water source during diarrhoeal outbreak

Gatekeeper: District health decision maker

Consent: No individual informed consent required since individuals cannot opt out

Community engagement: Feedback and adaptation according to needs



not be required, as it may not be meaningful in practice. However, communities are to be involved from the beginning, consulted about the intervention, and be able to give feedback to

notes

summary

5m 20s

Consent for communities

Intervention: Add chlorine bleach to only water source during diarrhoeal outbreak

Gatekeeper: District health decision maker

Consent: No individual informed consent required since individuals cannot opt out

Community engagement: Feedback and adaptation according to needs



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modify and adapt the intervention as per the values and needs. As with any other study, the

notes

summary

5m 28s



local ethics committee should approve the project. Fundamental to agreeing to participate in a study is the possibility to opt out. In this case, in practice, if someone did not want to participate

notes

summary

5m 37s



in the study, they would not be able to opt out without moving to another community. This may be impossible in an emergency if movement is restricted. Such examples may be more likely in

notes

summary

5m 49s



emergencies where the interventions for the greater good may be tested, but which may be perceived to override individual autonomy. The imposition of these interventions on individuals

notes

summary

6m 1s

Consent for communities



- More likely in emergencies
- Override of autonomy may damage trust
- Participants should still be fully informed, independent of consent

may risk losing the trust of individuals within the community. To mitigate against this,

notes

summary

6m 12s



regardless of whether informed consent is feasible or meaningful, all potential participants impacted by the study must still be fully informed. In emergencies, however, especially if communities are large, this may require thinking out of the box to ensure transparent and clear

notes

summary

6m 22s

Consent for communities



- More likely in emergencies
- Override of autonomy may damage trust
- Participants should still be fully informed, independent of consent

communication while maintaining trust. Implementation research may be needed to determine how best this may be achieved through community notice boards, WhatsApp groups, radio

notes

summary

6m 37s



broadcasts, to name a few examples. To summarise this chapter, before we move on, it is important to recognise that respect for participant autonomy is fundamental to any research activity, ensuring

notes

summary

6m 49s

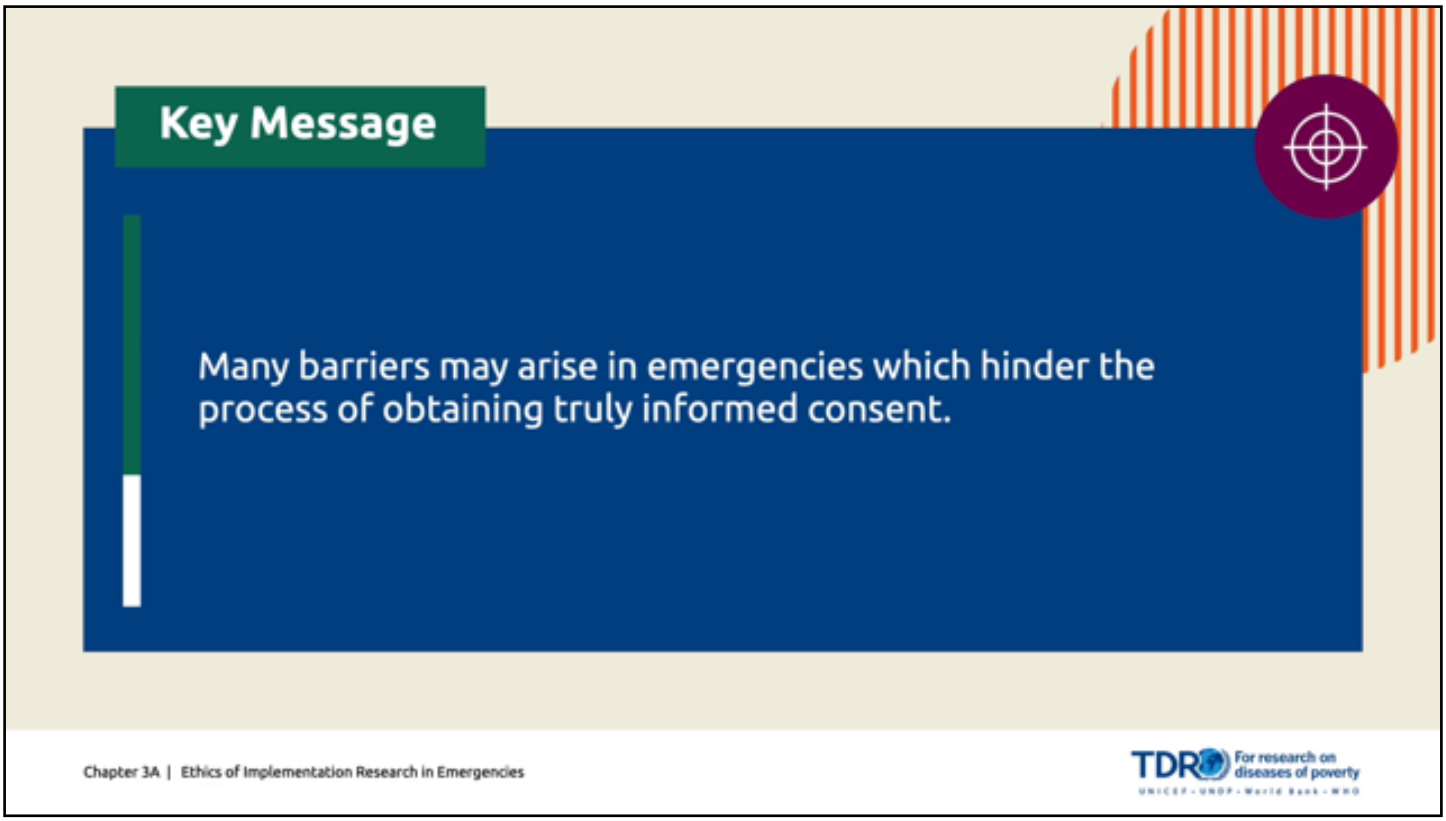


such respect goes hand in hand with informing participants and obtaining consent for research

notes

summary

7m 1s

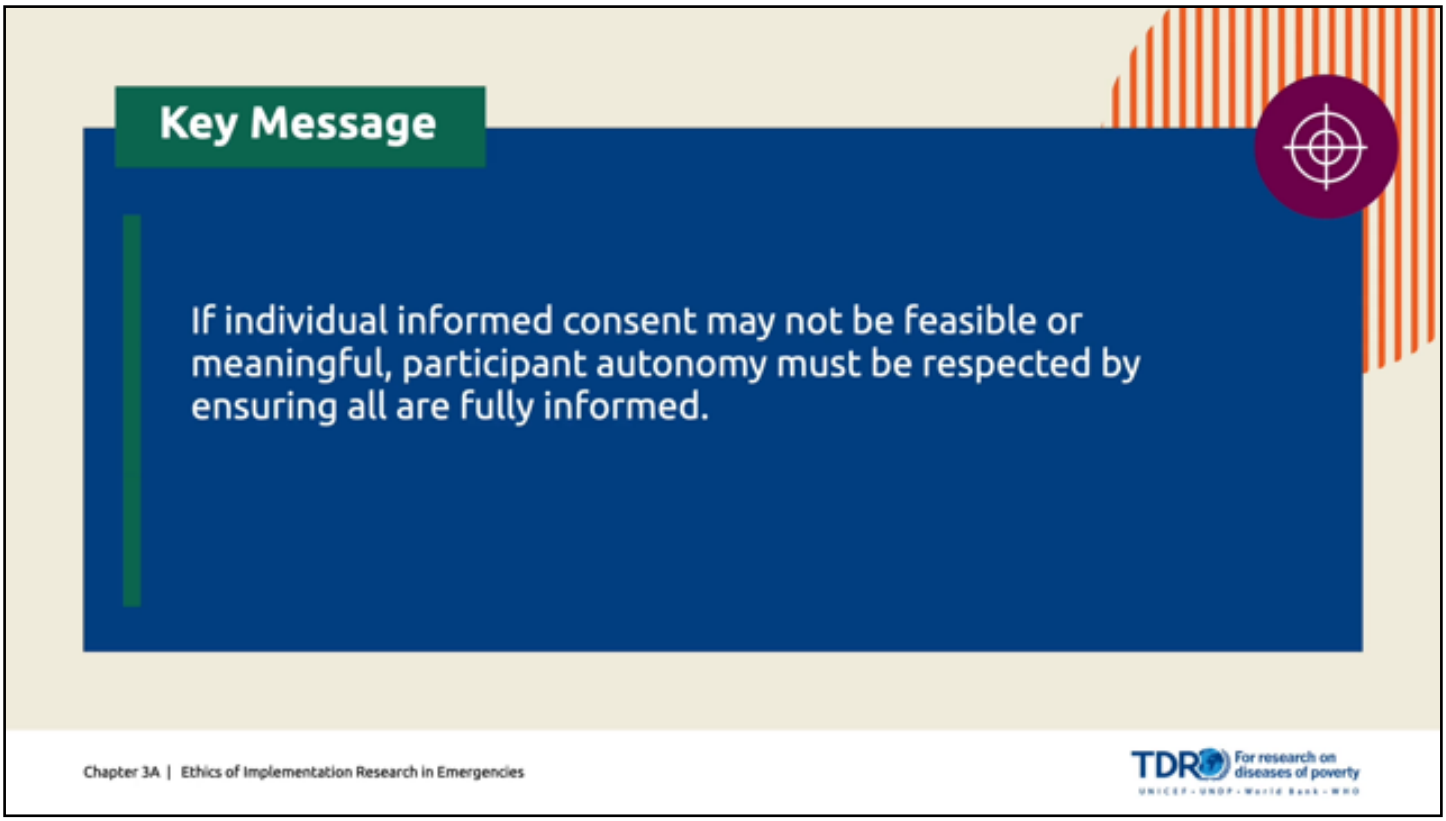


participation. This process in emergencies may be impacted by several barriers, including significant time pressure, populations being hard to reach at various levels, and overall fears and

notes

summary

7m 11s



misconceptions. When interventions are conducted at institutional and community levels, if individual informed consent is not feasible or meaningful, participant autonomy may still be

notes

summary

7m 22s



respected through clear, transparent, and understandable information. Now that we have understood the importance and implications of respecting participant autonomy, in the next chapter, we will turn to the ethical questions that relate to justice in the conduct of implementation research in emergencies.

notes

summary

7m 32s