Course material

Course:

Ethics in Emergencies

Video:

10c Overall approach to the ethics review

Concepts (extracted from automatically generated subtitles):

Real need. Implementation researchers. Local community. Advantage of this new test. Responsiveness of the research question. Study question. Informed consent. Rapid diagnostic test device. Patient outcomes. Potential concern. Blood samples. Study. Major reasons. Emergency setting. Sustainability of all aspects of the research proposal.

to video sequence search
(within Ethics in Emergencies.)

to video

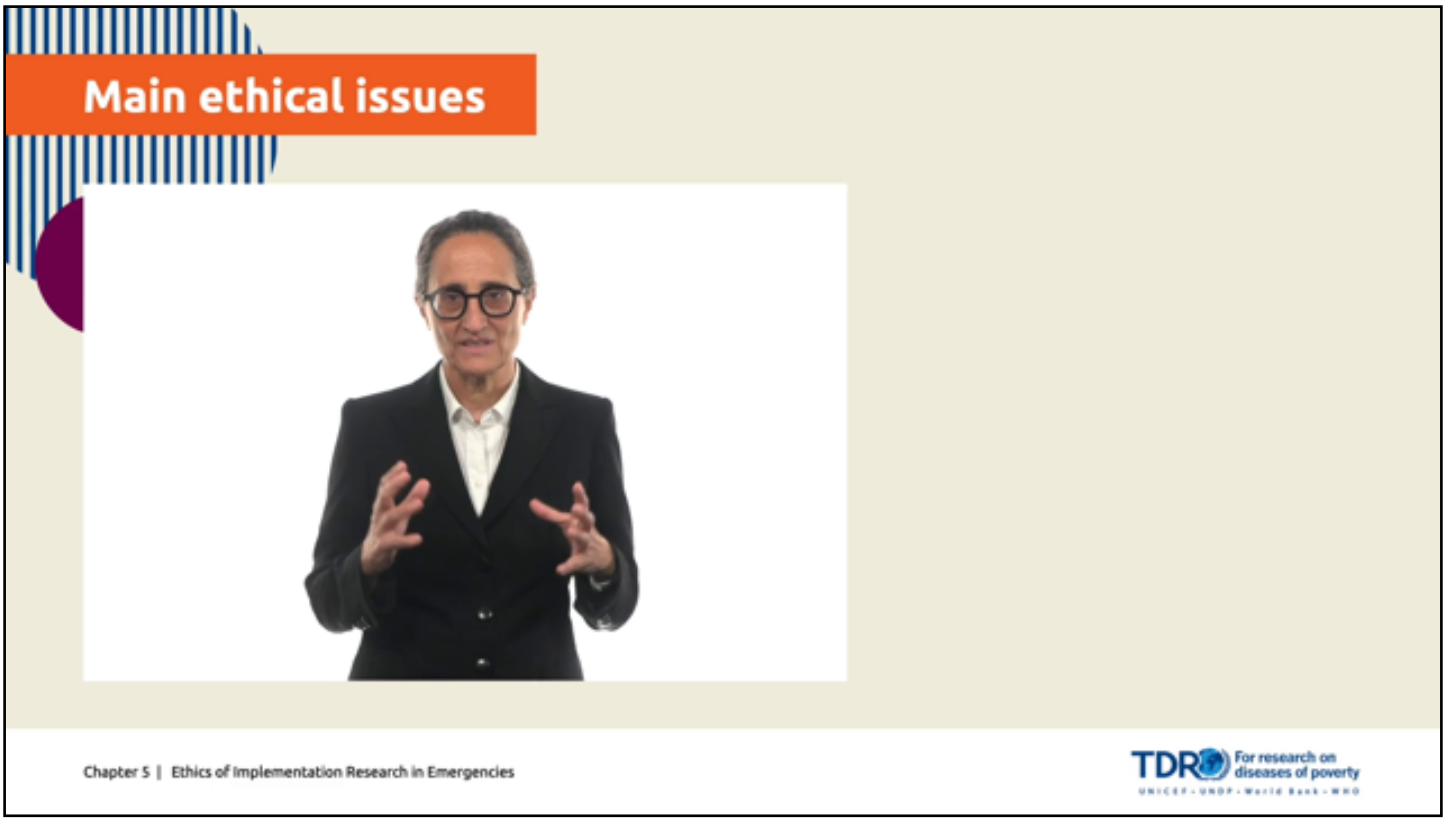


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notes

summary

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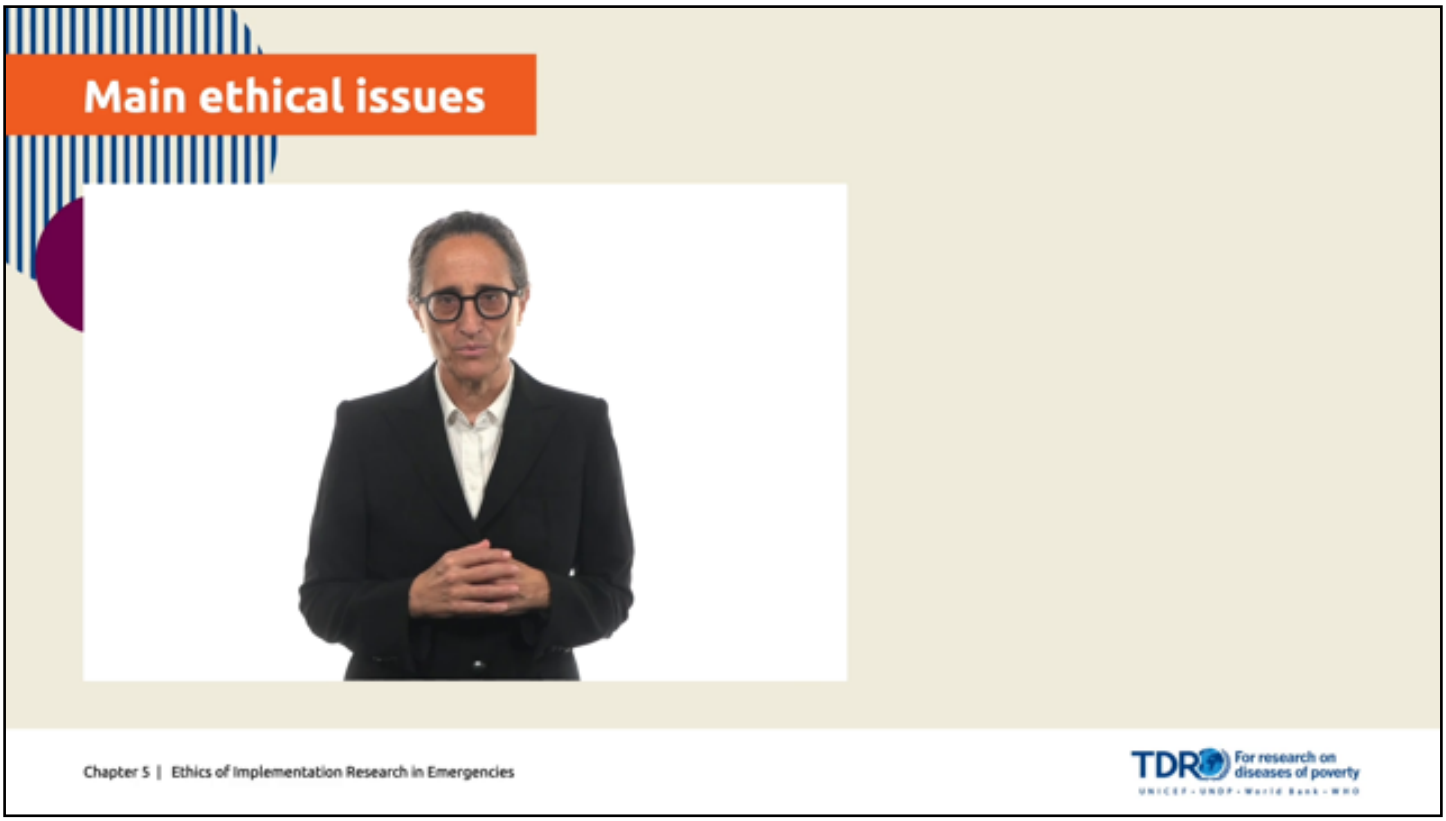


Now that we've considered your role and responsibilities as a member of the Research Ethics Committee, let us delve a bit more deeply into the ethical considerations you need to think about when reviewing the study. You will have to start at the beginning and ask yourself if the

notes

summary

0m 3s



study is being done because it's doable or because it's addressing a real need, especially in an emergency where resources are stretched and everyone is functioning under pressure. Implementation researchers must be accountable to the communities where they propose to conduct a

notes

summary

0m 20s



study. This accountability means that the study question must be one of high social value to the

notes

summary

0m 32s



local community, and that the study will be done well, which means it is scientifically

notes

summary

0m 38s



sound. In general, a scientific review should have been conducted and documented before an ethics review, but sometimes this does happen simultaneously. To answer all these

notes

summary

0m 49s



questions, let us take a look at these issues in the context of the dengue rapid diagnostic test

notes

summary

1m 1s

Social value and scientific rigor



Social value of the dengue RDT study

Improve clinical workflow and patient outcome

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study. In terms of social value, the advantage of this new test is that it has a very rapid turnaround time, which should improve clinical workflows and thereby patient outcomes. The study

notes

summary

1m 4s

Social value and scientific rigor



Social value of the dengue RDT study

Improve clinical workflow and patient outcome

Test feasibility and acceptability

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proposes to understand whether this test will be feasible to use and acceptable to the patients and clinicians in the district hospitals that are facing a protracted dengue outbreak. One potential

notes

summary

1m 15s

Social value and scientific rigor

Scientific rigor in the dengue RDT study

Keeping the device cold for optimal performance



concern in terms of scientific rigor, identified by the researchers, is that the rapid diagnostic test device itself must be kept cold, and this may pose a problem in an emergency setting, as the

notes

summary

1m 26s

Social value and scientific rigor



Scientific rigor in the dengue RDT study

Keeping the device cold for optimal performance

Possible erratic electricity supply

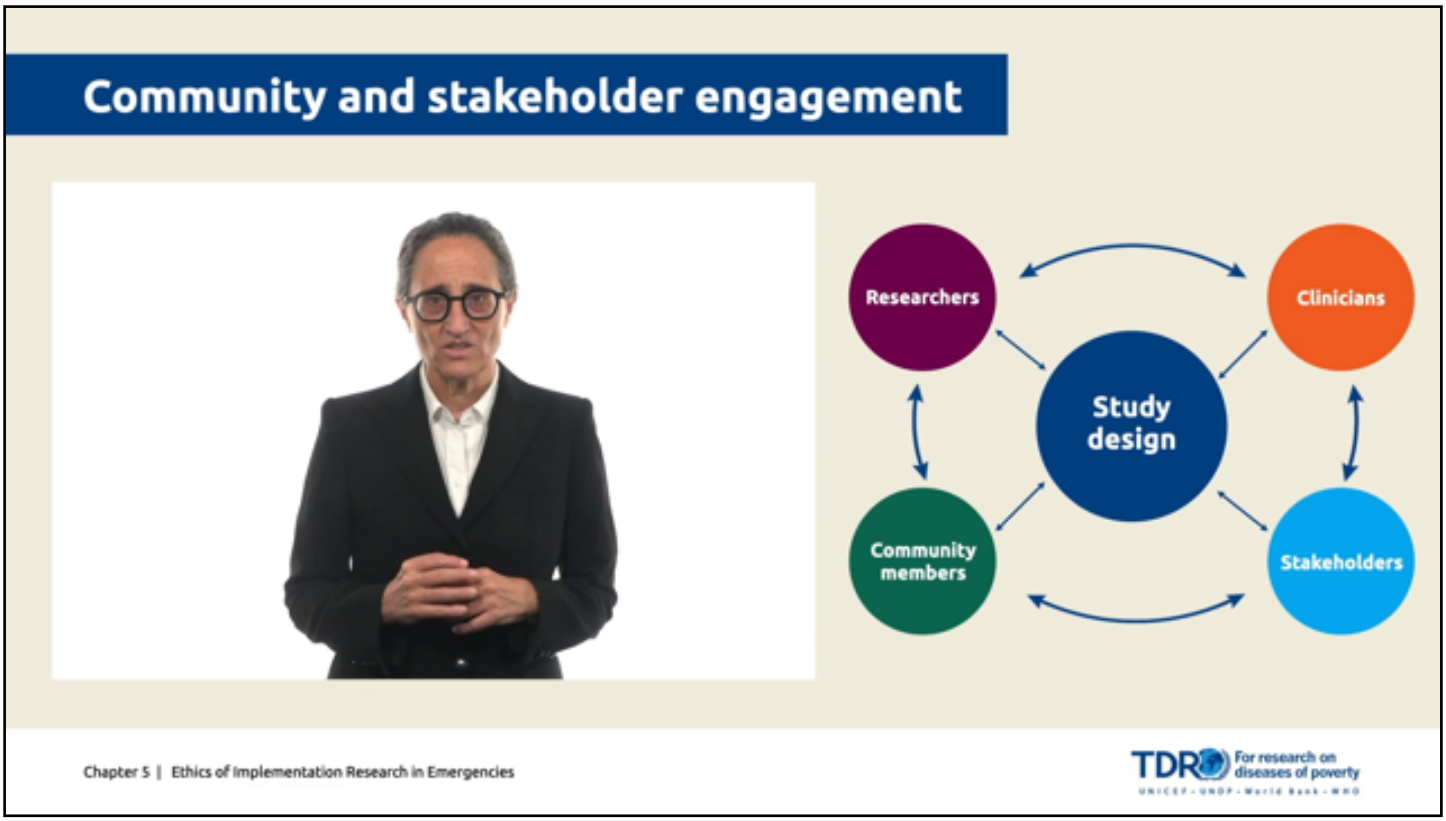
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device will be constantly in use in a hot environment and the performance may therefore decline. Keeping the devices and their cooling boxes charged could be problematic if the

notes

summary

1m 38s

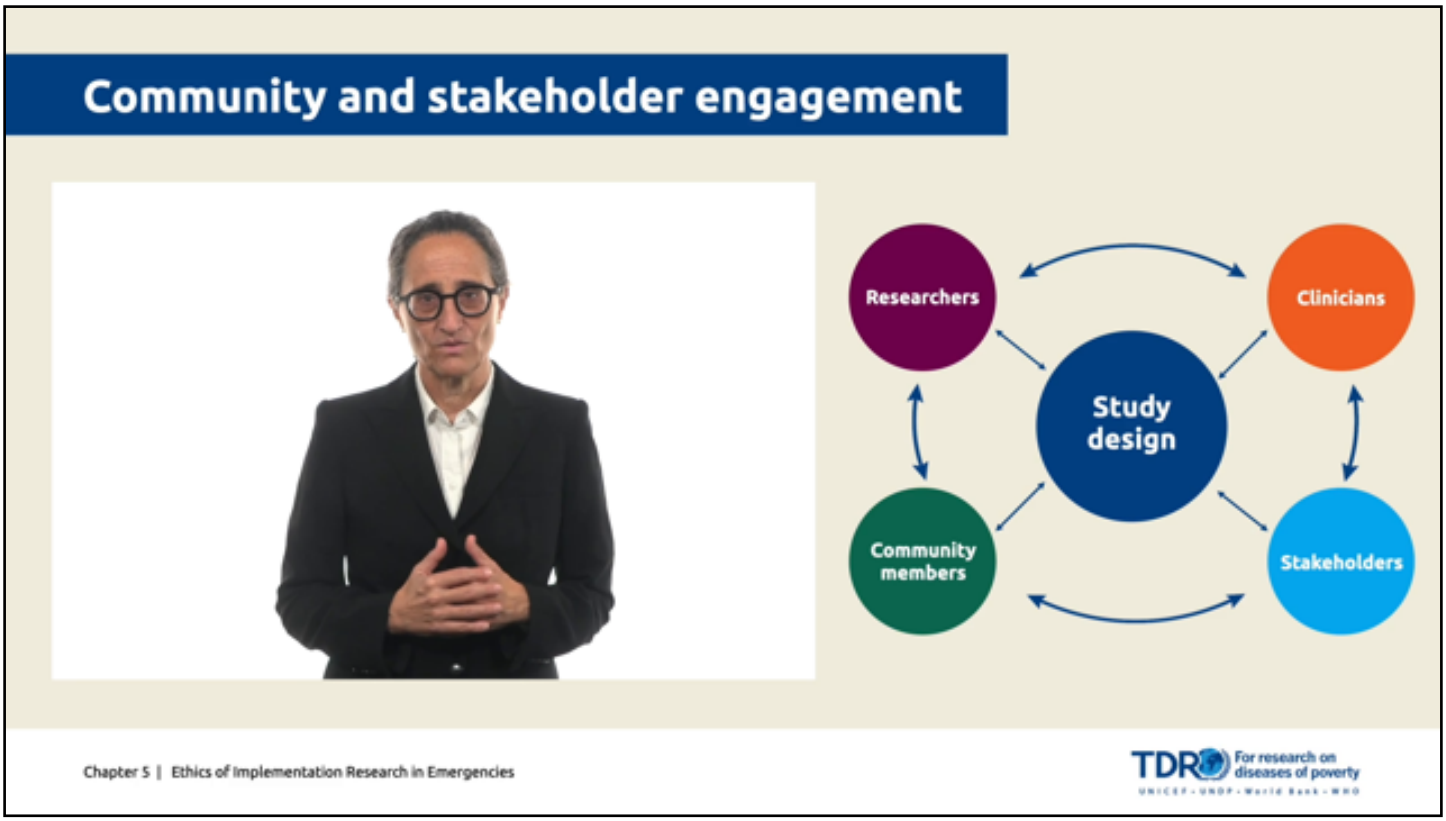


electricity supply is erratic because of the emergency. To understand the responsiveness of the research question to the local community in the emergency setting, as the ethics reviewer, you need

notes

summary

1m 52s



to be sure that the researchers have conducted careful community and stakeholder engagement locally. It is important that the researchers have engaged with the community in terms of the study

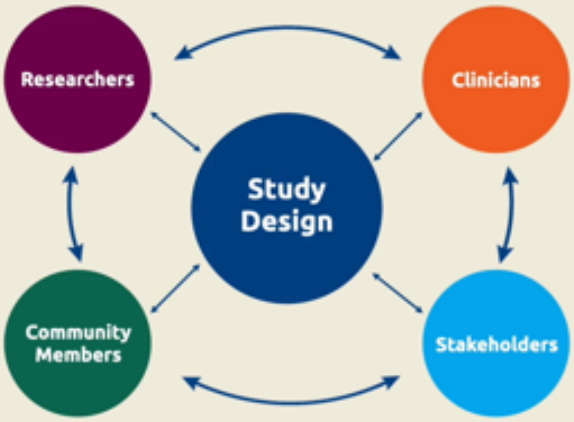
notes

summary

2m 1s

Community and stakeholder engagement

- **Priority for the community**



question and the study design, and that the study itself is acceptable to the community. The dengue outbreak has followed a massive flood and people have been displaced. The researchers need to justify that a diagnostic test for dengue is indeed a priority for the community. Their main

notes

summary

2m 14s

Community and stakeholder engagement

- **Priority for the community**
- **Acceptability: trust**



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concerns could actually lie elsewhere after a flood. For example, there may also be an outbreak of diarrhoea among the children because they are lacking safe drinking water. Relevant for the

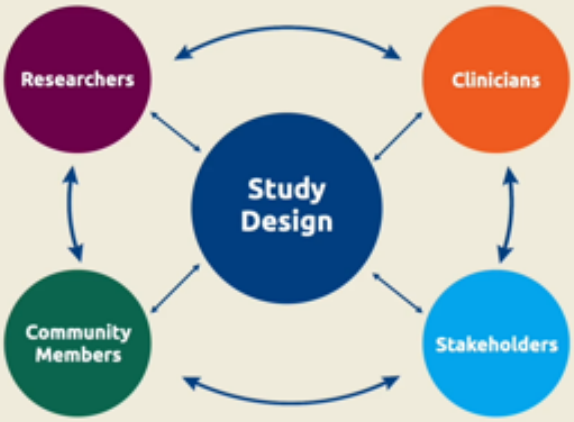
notes

summary

2m 29s

Community and stakeholder engagement

- **Priority for the community**
- **Acceptability: trust**



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ethics review is the acceptability of the proposed study to the community, which includes the health workers. For example, even if the community may agree that dengue is a priority problem, patients may be mistrustful of outside researchers obtaining their blood samples, especially if these are to be shipped somewhere else. The community may also be suspicious of a

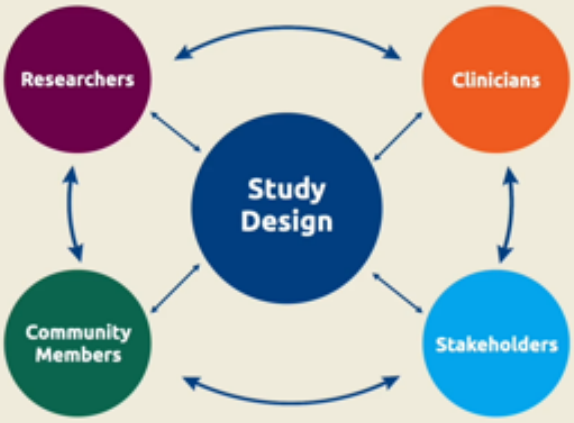
notes

summary

2m 38s

Community and stakeholder engagement

- **Priority for the community**
- **Acceptability: trust**



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new handheld device that reports results as a plus sign or a minus sign when they may be used

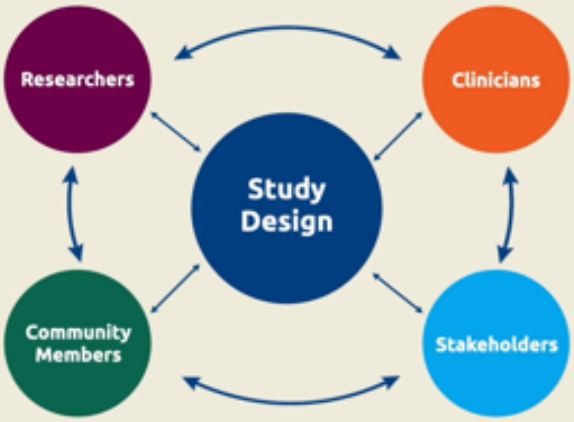
notes

summary

2m 58s

Community and stakeholder engagement

- **Priority for the community**
- **Acceptability: trust**
- **Stigma (similar to HIV tests)**



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to paying for laboratory tests and getting a paper printout at the hospital. This may also confuse them, because the study test might be similar to a test used for HIV years ago, which

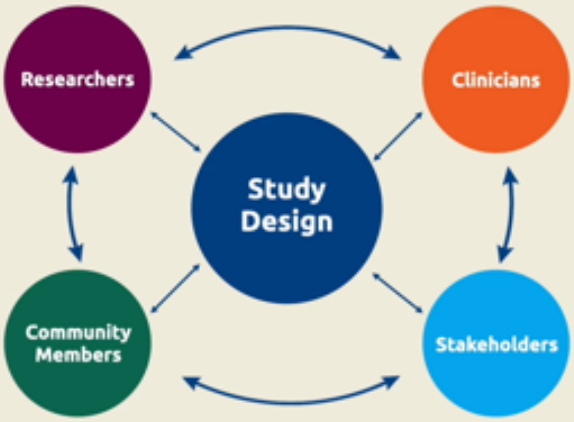
notes

summary

3m 1s

Community and stakeholder engagement

- Priority for the community
- Acceptability: trust
- Stigma (similar to HIV tests)
- Hospital reputation and clinician time



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brought a lot of stigma to those who tested with a positive plus sign in the community. The

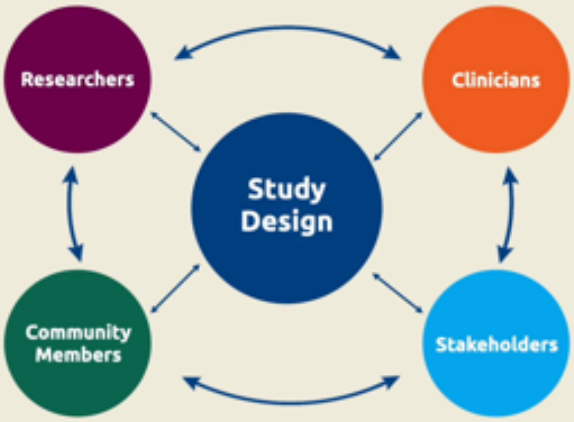
notes

summary

3m 13s

Community and stakeholder engagement

- Priority for the community
- Acceptability: trust
- Stigma (similar to HIV tests)
- Hospital reputation and clinician time



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clinicians or hospitals themselves may be afraid of being judged. Additionally, the need for interviews within the qualitative portion of the study may be a concern, as this will require clinician time that may pull them away from other responsibilities. All of these concerns should

notes

summary

3m 20s



have been identified by the researchers if they have conducted appropriate community engagement, including with the clinicians, and the study protocol should have been adapted and discussed with the community to find the most acceptable way to test the new device. Additional

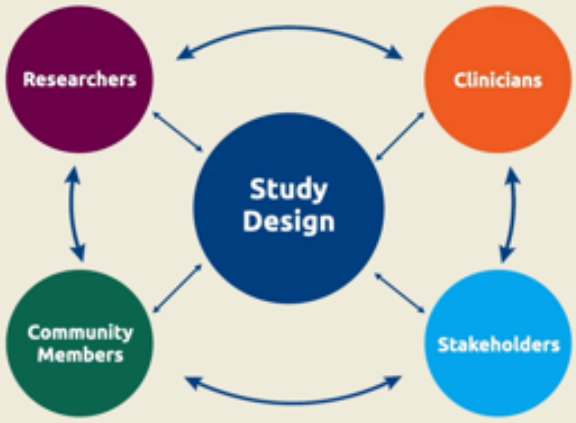
notes

summary

3m 34s

Community and stakeholder engagement

- Priority for the community
- Acceptability: trust
- Stigma (similar to HIV tests)
- Hospital reputation and clinician time
- Import taxes and customs problems
- Training and feedback from clinicians



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realistic concerns that may have arisen during stakeholder engagement may be high import taxes, and worries that new devices and test strips may get stuck in customs and delay or interrupt the study. These logistical issues should also have been addressed before the study begins. Training of the local clinicians about the study should also have taken place, and their feedback should

notes

summary

3m 50s



have been incorporated. The next big questions you need to consider as you approach your review relate to the four ethical principles which apply to all research autonomy, maximising benefit,

notes

summary

4m 13s

Participant autonomy



- Gatekeepers for participating hospitals
- Approach of participants
- Participants: patients and clinicians

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reducing harm, and ensuring justice and fairness. You now need to understand how participant autonomy will be upheld. Who are the gatekeepers? Who will be approached to agree for their hospitals to participate? How are individuals going to be approached? Will only patients need to consent to the study, or must consent also be obtained from the clinicians as their actions

notes

summary

4m 25s

Participant autonomy



- Gatekeepers for participating hospitals
- Approach of participants
- Participants: patients and clinicians
- Documentation of the consent
- Clarity of the consent forms
- Language of the consent process

will be tracked and they will be interviewed? How will the informed consent be documented during the chaos of the emergency? Do the consent forms transparently, clearly and understandably explain

notes

summary

4m 48s

Participant autonomy



- Gatekeepers for participating hospitals
- Approach of participants
- Participants: patients and clinicians
- Documentation of the consent
- Clarity of the consent forms
- Language of the consent process
- Verbal or written consent

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all the details of the study? In which language will the consent process take place? Who will

notes

summary

5m 0s

Participant autonomy



- Gatekeepers for participating hospitals
- Approach of participants
- Participants: patients and clinicians
- Documentation of the consent
- Clarity of the consent forms
- Language of the consent process
- Verbal or written consent
- Access to all who may benefit
- Consent for patients unable to consent themselves
- Storage of information

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obtain the consent, and how? Written or verbal? Do all who might benefit have the opportunity to participate? If some individuals who cannot provide consent are eligible for the study, such as children or patients who are unconscious, who will consent for them? It will be important to

notes

summary

5m 7s

Participant autonomy



- Gatekeepers for participating hospitals
- Approach of participants
- Participants: patients and clinicians
- Documentation of the consent
- Clarity of the consent forms
- Language of the consent process
- Verbal or written consent
- Access to all who may benefit
- Consent for patients unable to consent themselves
- Storage of information

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understand how and where consent forms will be stored because, especially in emergencies, pieces

notes

summary

5m 24s

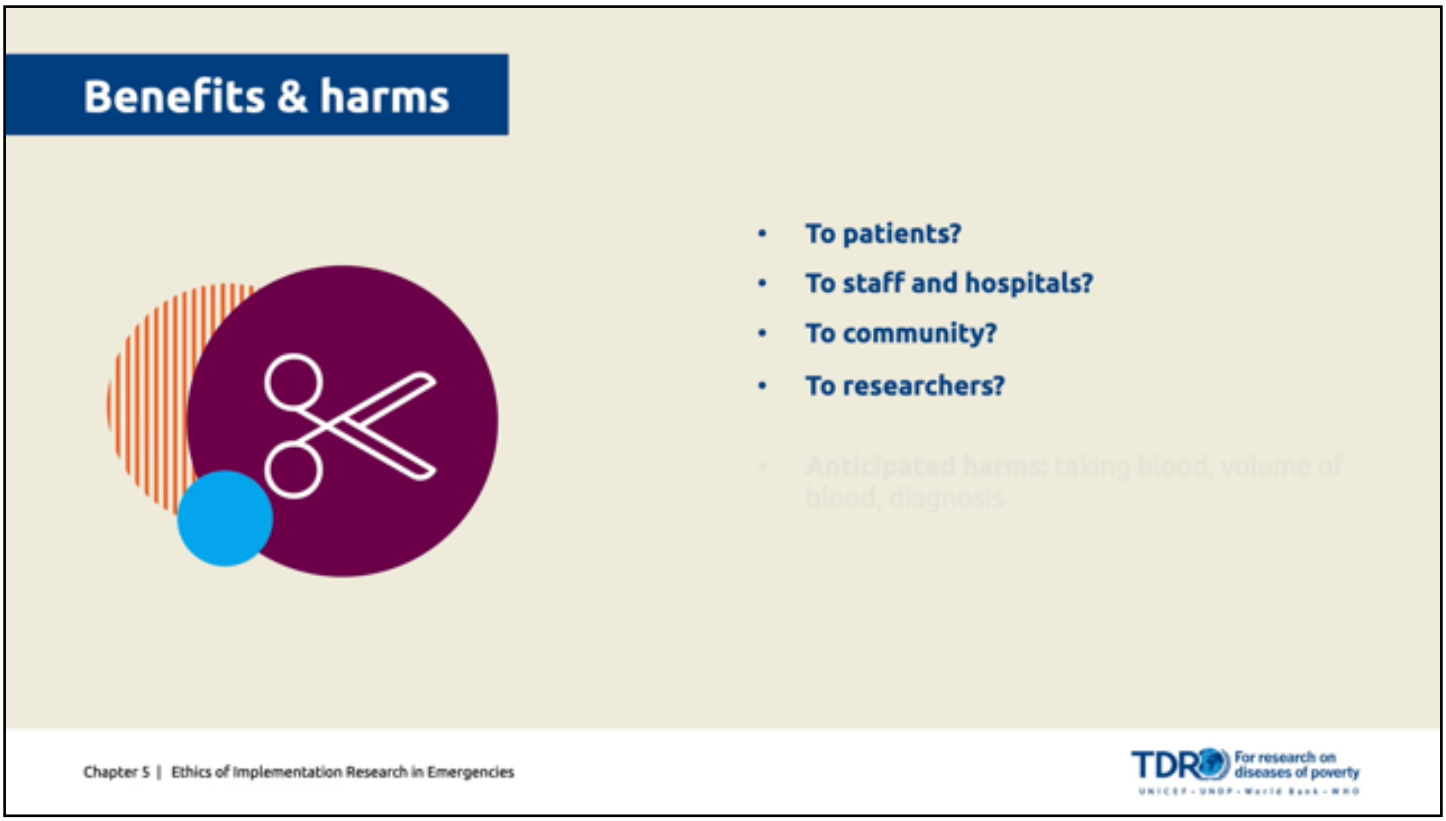


of paper can easily get lost and this can lead to very serious breaches of privacy and confidentiality. At the broader level, you will need to consider the risks and benefits of the

notes

summary

5m 25s



study. These should have been considered as they apply to the patients themselves, to the hospital staff, the hospitals, to the community, and even to the researchers. Especially in implementation

notes

summary

5m 37s

Benefits & harms



- **To patients?**
- **To staff and hospitals?**
- **To community?**
- **To researchers?**

- **Anticipated harms:** taking blood, volume of blood, diagnosis
- **Unanticipated:** therapeutic misconception, inequities, reputation of the hospital

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research done in emergencies, it is crucial that all the obvious anticipated harms are identified, such as the harm of taking a blood test, the volume of blood, the harm of a right or a wrong diagnosis. In addition, researchers must consider potential unanticipated harms such as therapeutic misconception, an exacerbation of inequities, reputational risk to the hospital, which we will

notes

summary

5m 48s

Justice and fairness



Highly relevant to the community

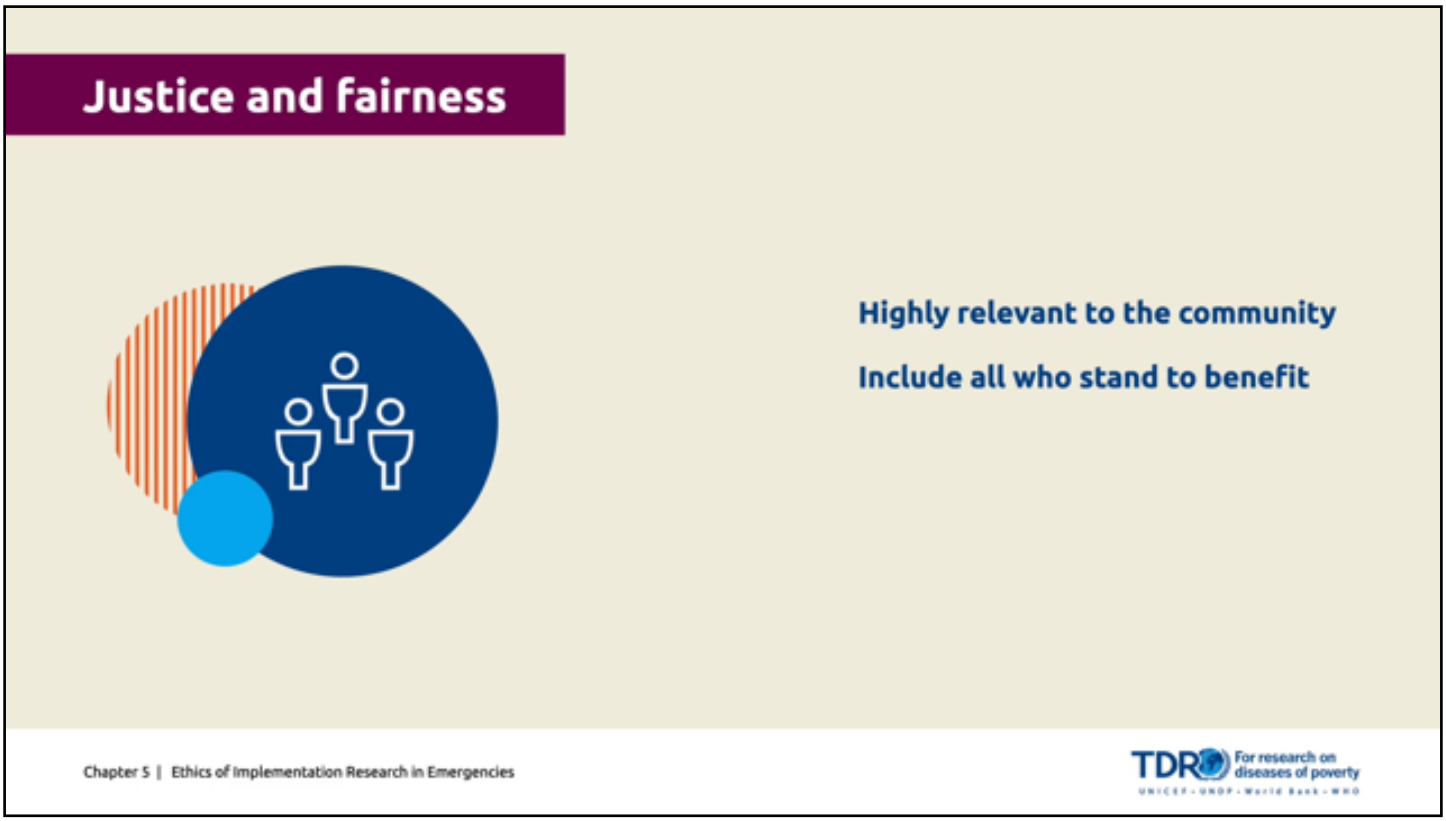
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discuss further a little later. Finally, you will need to be convinced about the justice and sustainability of all aspects of the research proposal, which are ultimately the major reasons

notes

summary

6m 13s



to perform implementation research. Especially in an emergency, research must be highly relevant to the local community at that moment, and must include all who may stand to benefit. This means that the researchers must have identified the most vulnerable groups in the community, and have

notes

summary

6m 25s

Justice and fairness



Highly relevant to the community

Include all who stand to benefit

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included strategies to ensure that these groups have the opportunity to participate. Obvious

notes

summary

6m 37s

Justice and fairness



Highly relevant to the community

Include all who stand to benefit

- Children: volume of blood

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vulnerable groups here may be children who may be excluded on the basis of safety because of the volume of blood required for the study. Researchers may need to consider using smaller blood samples or doing all the tests on one sample, as children would stand to benefit

notes

summary

6m 43s

Justice and fairness



Highly relevant to the community

Include all who stand to benefit

- Children: volume of blood
- Access for poorest community members

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significantly from this test, especially during an outbreak. Alternatively, if admission to the emergency room requires a user fee, for example, many of the poorest in the community may not even

notes

summary

6m 58s

Justice and fairness



Highly relevant to the community

Include all who stand to benefit

- Children: volume of blood
- Access for poorest community members

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come. This barrier may be even higher in an emergency. The researchers may need to negotiate a way around this without creating unrealistic expectations for the future if user fees are

notes

summary

7m 12s

Justice and fairness



Highly relevant to the community

Include all who stand to benefit

- Children: volume of blood
- Access for poorest community members

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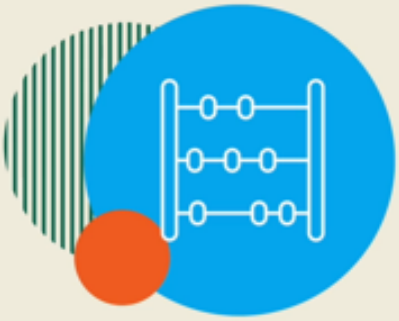
waived during the study and without creating inequities between eligible patients for the study and others, for example, who might be presenting with bone fractures or dog bites, who

notes

summary

7m 24s

Sustainability



If the intervention is successful and acceptable:

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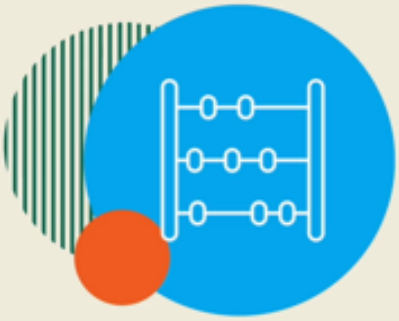
may not be eligible for a waiver of the user fee. If a study involves an intervention or a

notes

summary

7m 34s

Sustainability



If the intervention is successful and acceptable:

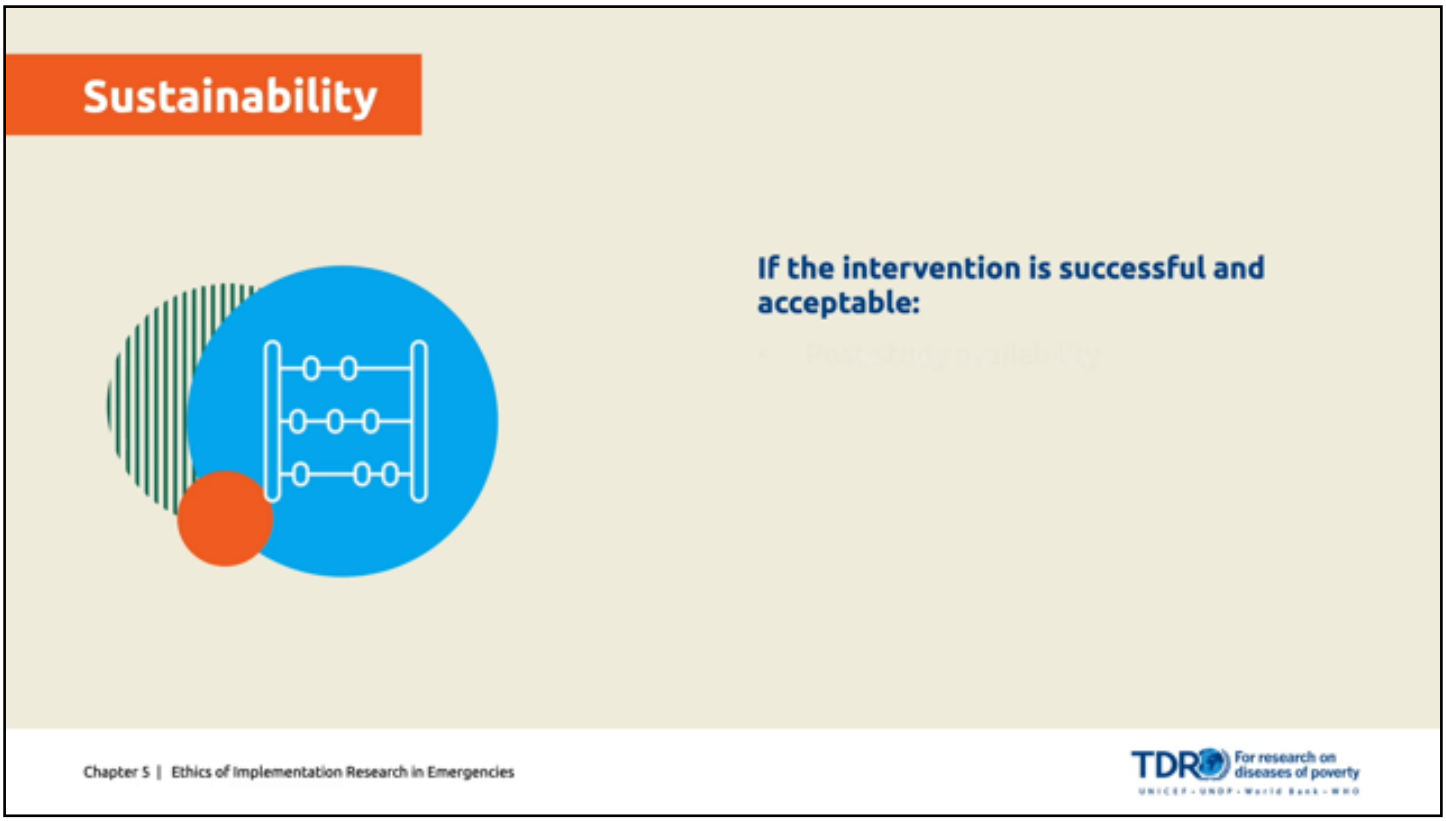
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technology such as integration of a new rapid diagnostic test for dengue into the clinical workflow, there must be a commitment that if the intervention is successful and it proves to be

notes

summary

7m 37s



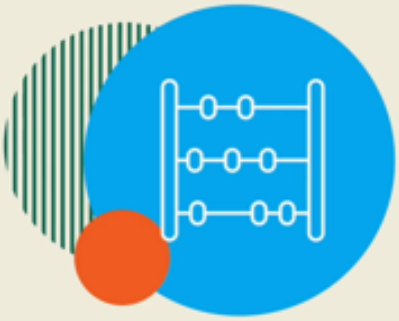
better than the existing interventions and is acceptable to the community, that it must be made

notes

summary

7m 49s

Sustainability



If the intervention is successful and acceptable:

- Post-study availability
- Affordability and scalability
- Equitable distribution

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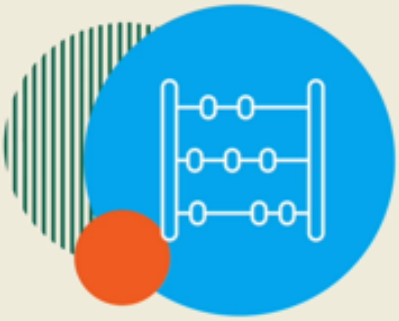
available and accessible rapidly after the study. The test should be affordable enough that it can be scaled up and equitably distributed, even to small primary care clinics as well as large

notes

summary

7m 52s

Sustainability



If the intervention is successful and acceptable:

- Post-study availability
- Affordability and scalability
- Equitable distribution
- Availability of therapeutics following diagnosis

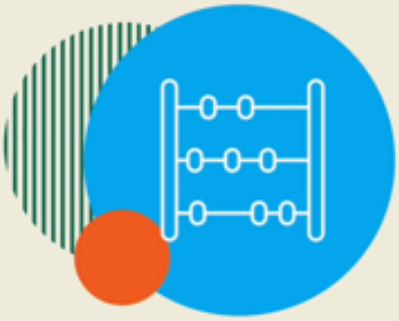
hospitals. Ultimately, also, the goal of a rapid test would be to permit rapid initiation of therapy. The researchers should have assured, through engaging local stakeholders, that the necessary therapeutic resources and training of health care workers are sustainably in place in

notes

summary

8m 6s

Sustainability



If the intervention is successful and acceptable:

- Post-study availability
- Affordability and scalability
- Equitable distribution
- Availability of therapeutics following diagnosis

the hospitals where the study is being conducted. Making a diagnosis without therapeutics being in

notes

summary

8m 20s



place is unethical. The implementation researchers will have to describe their plan to rapidly disseminate all study findings to ensure rapid scale-up during the emergency. This dissemination must include sharing both positive and negative findings with the local healthcare decision makers and all the stakeholders, the community, and the broader scientific and global health communities.

notes

summary

8m 28s