Course material

Course:

Ethics in Emergencies

Video:

10d Ethical issues specific to the case study

Concepts (extracted from automatically generated subtitles):

Rapid diagnostic test. Potential benefits of the study. Implementation research. Ethics review. Ethical issues. Capacity building of the local researchers. High risk viruses. Fingerprick test. Risk of therapeutic misconception. Diagnostic tests. Such ancillary needs. Appropriate care. Dengue outbreak. Vulnerable groups. Research study.

to video sequence search
(within Ethics in Emergencies.)

to video



...

notes

summary

0m 0s

Potential benefits



TDR For research on diseases of poverty
UNICEF · UNDP · World Bank · WHO

We have now reviewed the overall approach to the ethics review. Let's go back now to focus more closely on some of the ethical issues that may be specifically relevant when implementation research is conducted during the dengue outbreak. The potential benefits of the study are clear. The

notes

summary

0m 3s

Potential benefits



- Quick diagnosis
- Early and appropriate care
- Reduced workload for laboratories

TDR For research on diseases of poverty

rapid diagnostic test should facilitate a quick diagnosis, permit early and appropriate care, should reduce the workload of the clinical laboratory, and may permit clinicians to work

notes

summary

0m 18s

Potential benefits



- Quick diagnosis
- Early and appropriate care
- Reduced workload for laboratories
- Diagnosis of small children
- Available in clinics without laboratories

faster and care better for other patients. The fingerprick test may also permit diagnosis in

notes

summary

0m 32s

Potential benefits



- Quick diagnosis
- Early and appropriate care
- Reduced workload for laboratories
- Diagnosis of small children
- Available in clinics without laboratories

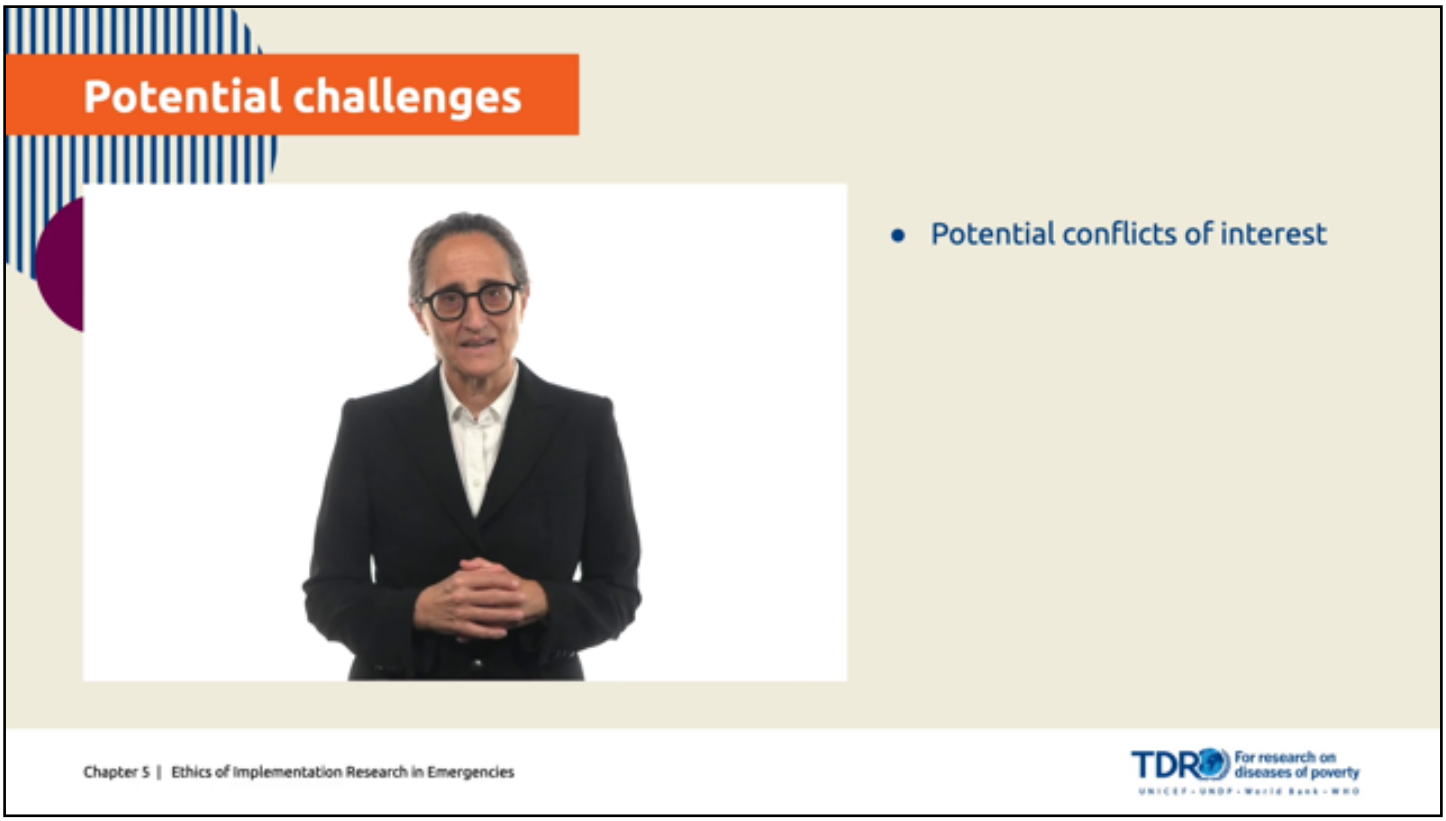
TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

small children from whom blood samples are hard to obtain. This test can permit diagnosis of dengue in primary care clinics where there are no laboratory services. Communities may be more satisfied with better clinical service and less need to travel for diagnosis. Implementation

notes

summary

0m 38s

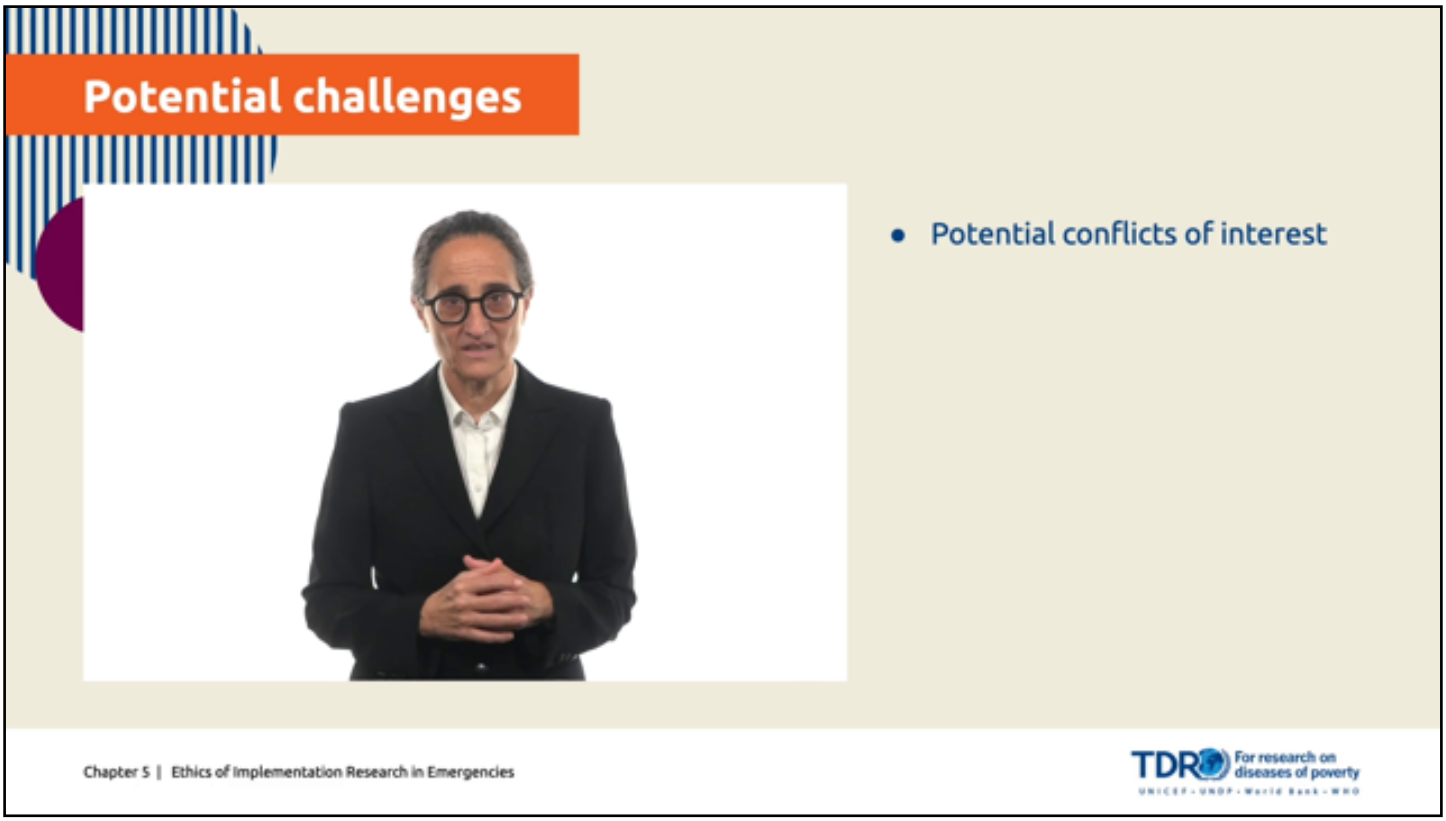


research conducted in emergencies, however, can not only focus on the potential benefit, the potential harms must also be closely scrutinised. To start with, given that the study is being driven by

notes

summary

0m 50s

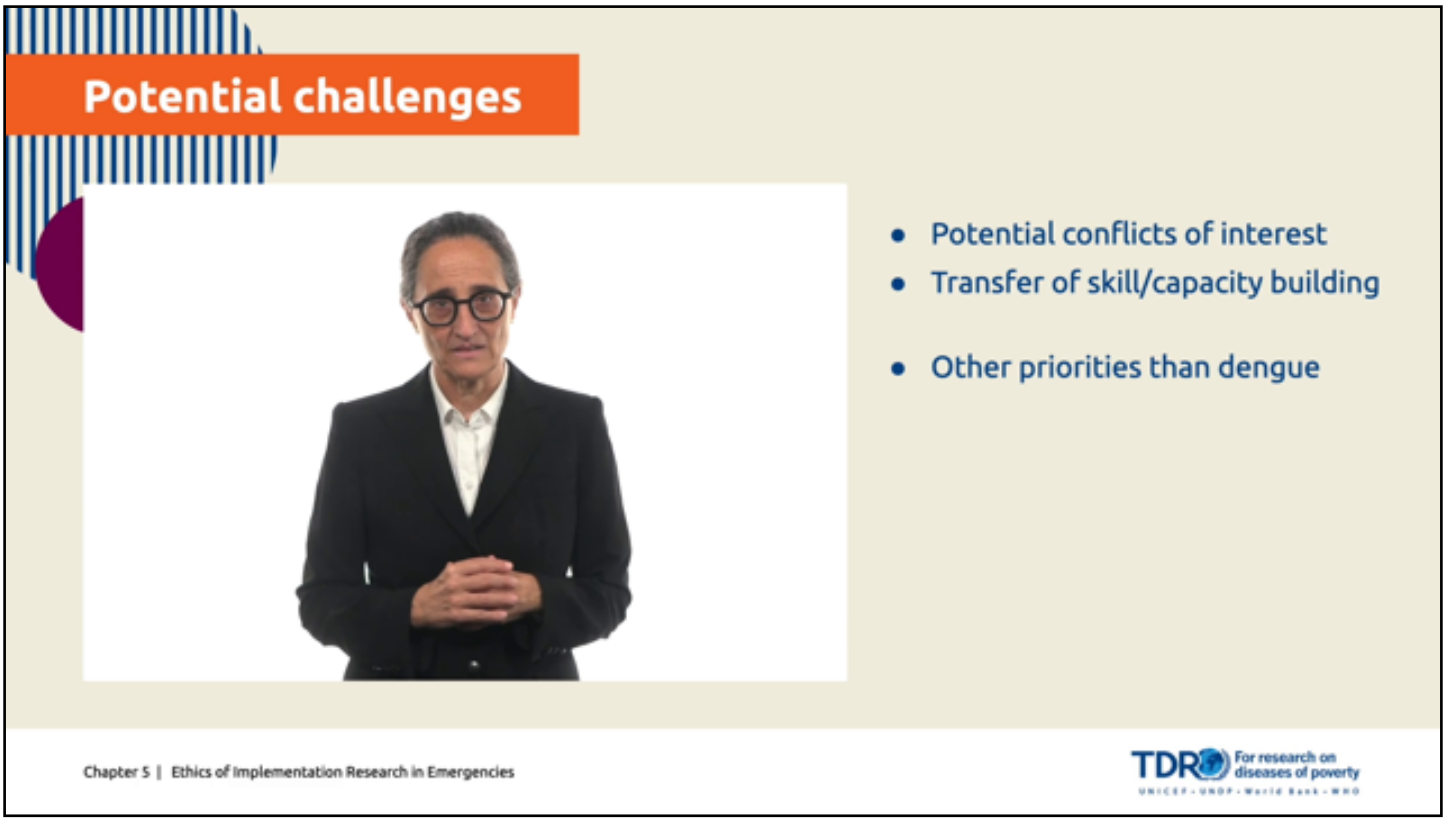


external funders and researchers, you, as a reviewer on the Research Ethics Committee, must consider whether there may be conflicts of interest, possibly for the researchers or for the

notes

summary

1m 2s

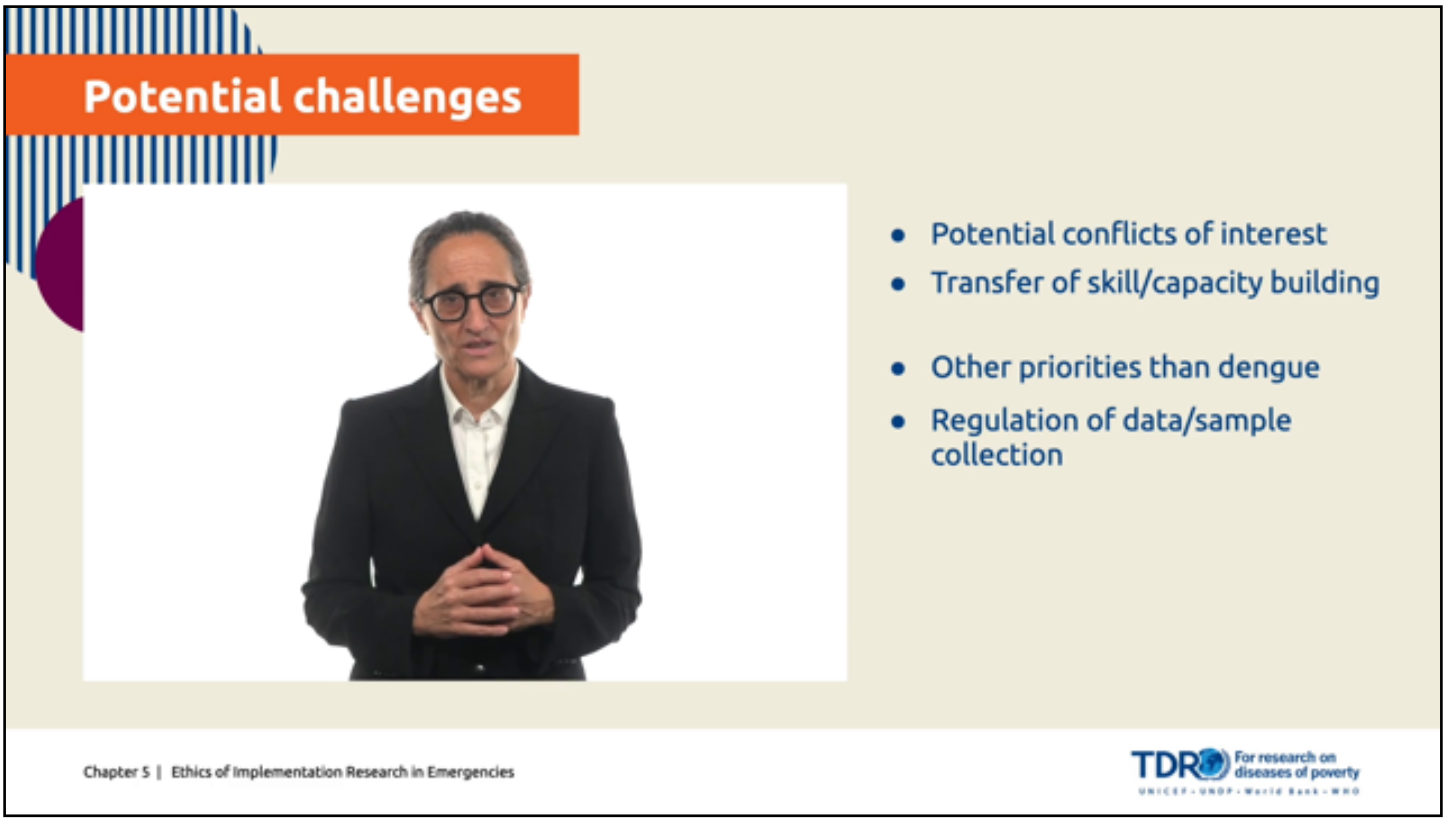


industry. Also, given all the external engagement, plans for transfer of skills and capacity building of the local researchers should be clearly laid out. As we've discussed earlier, community engagement is key to determine whether dengue is still a critical problem: there might be bigger problems happening in other areas. The hospitals may be struggling to access other diagnostic tests, which are needed more than a new dengue test, given that the existing test does not

notes

summary

1m 13s

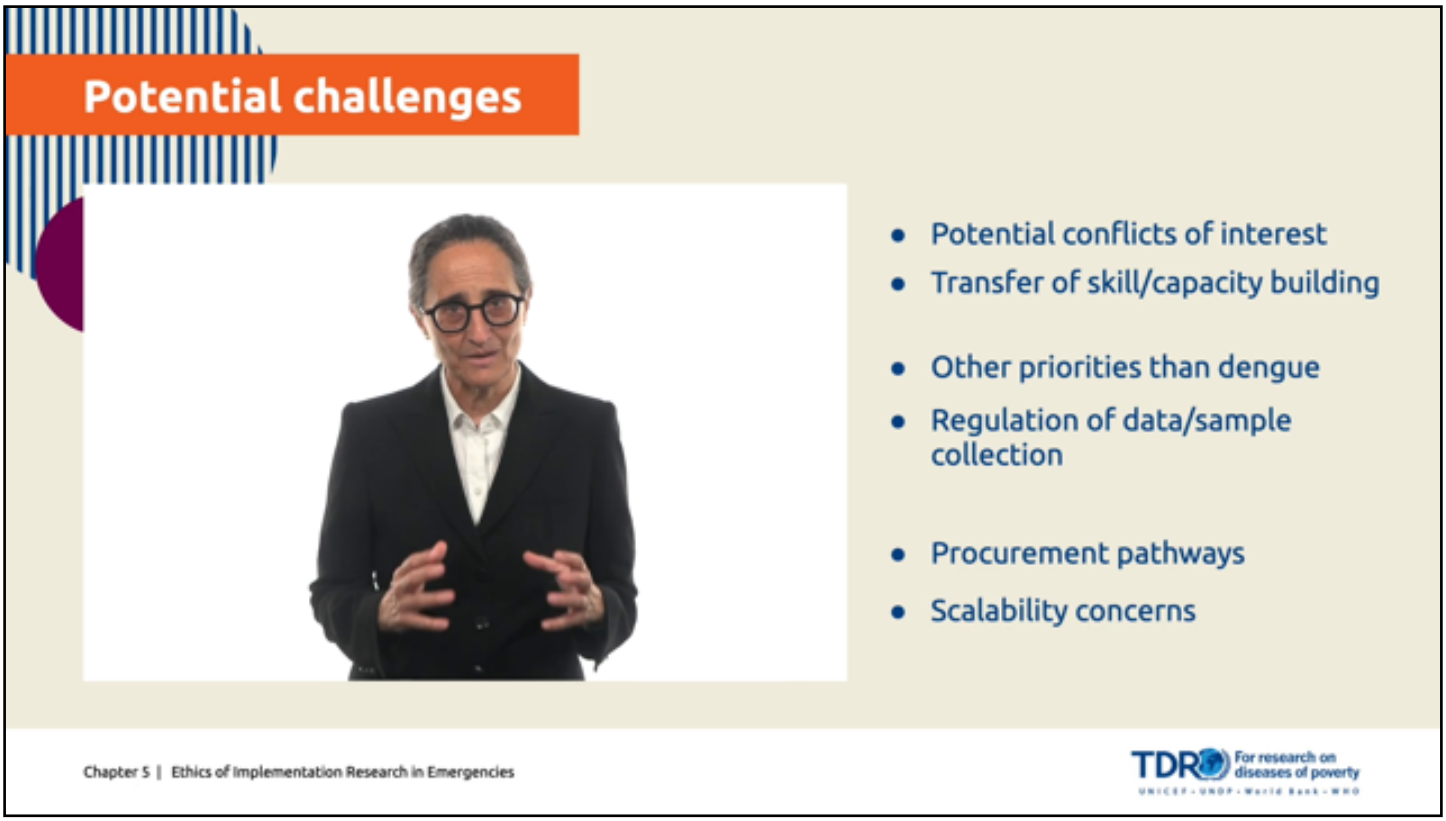


need to be immediately replaced. In emergencies, mistrust is high in communities, therefore, researchers should be transparent and explain the need for any sample or data collection activities.

notes

summary

1m 42s



Ethics review should ensure that researchers are only collecting the amounts of blood and the data that they need. The researchers must also have engaged with all the other potential stakeholders. For example, the study may require new procurement pathways, import duties may impact suppliers, and

notes

summary

1m 54s



the Ministry of Health must be involved to negotiate scalability concerns, including pricing,

notes

summary

2m 12s

Equity and access



TDR For research on diseases of poverty
UNICEF · UNDP · World Bank · WHO

if the rapid diagnostic test proved useful. Especially in emergencies when health and community services may be disrupted and vulnerable groups may become more marginalised, it is important that the implementation researchers have thought about equity and access issues. We

notes

summary

2m 16s



will consider a few examples here, and I'm sure you can think of others. An equity concern, which is also related to patient autonomy in the study, would be whether or not the dengue tests will be free. If yes, patients may feel coerced into participating in the study if the usual dengue test must be paid for out of pocket. Researchers should ensure that all tests are free to remove this

notes

summary

2m 33s

Equity and access



Standard of care

- **Same costs for all tests**
  Coercion if usual tests cost more than study tests

TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

coercion. Conversely, other patients may lie about symptoms to be eligible to get free blood tests

notes

summary

2m 49s

Equity and access



Standard of care

- **Same costs for all tests**
- **Same standard of care for all patients**

High risk of therapeutic misconception: clearly differentiate study from care

TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

or to be enrolled if they feel they may get better care within the study. This risk of therapeutic misconception is high in an emergency, especially if there have been significant health

notes

summary

2m 51s

Equity and access



Standard of care

- **Same costs for all tests**
- **Same standard of care for all patients**

High risk of therapeutic misconception: clearly differentiate study from care

TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

systems disruptions. It is important for researchers to be clear that this is a research

notes

summary

3m 6s



study and not clinical care. Researchers should also ensure that the standards of care for those enrolled and not enrolled in the study are the same to avoid this concern. It is very important that the implementation researchers identify that the basic standard of care is acceptable under

notes

summary

3m 14s

Equity and access



Standard of care

- **Same costs for all tests**
- **Same standard of care for all patients**
- **Treatment of dengue complications**

Responsibility of the researchers, appropriate referrals

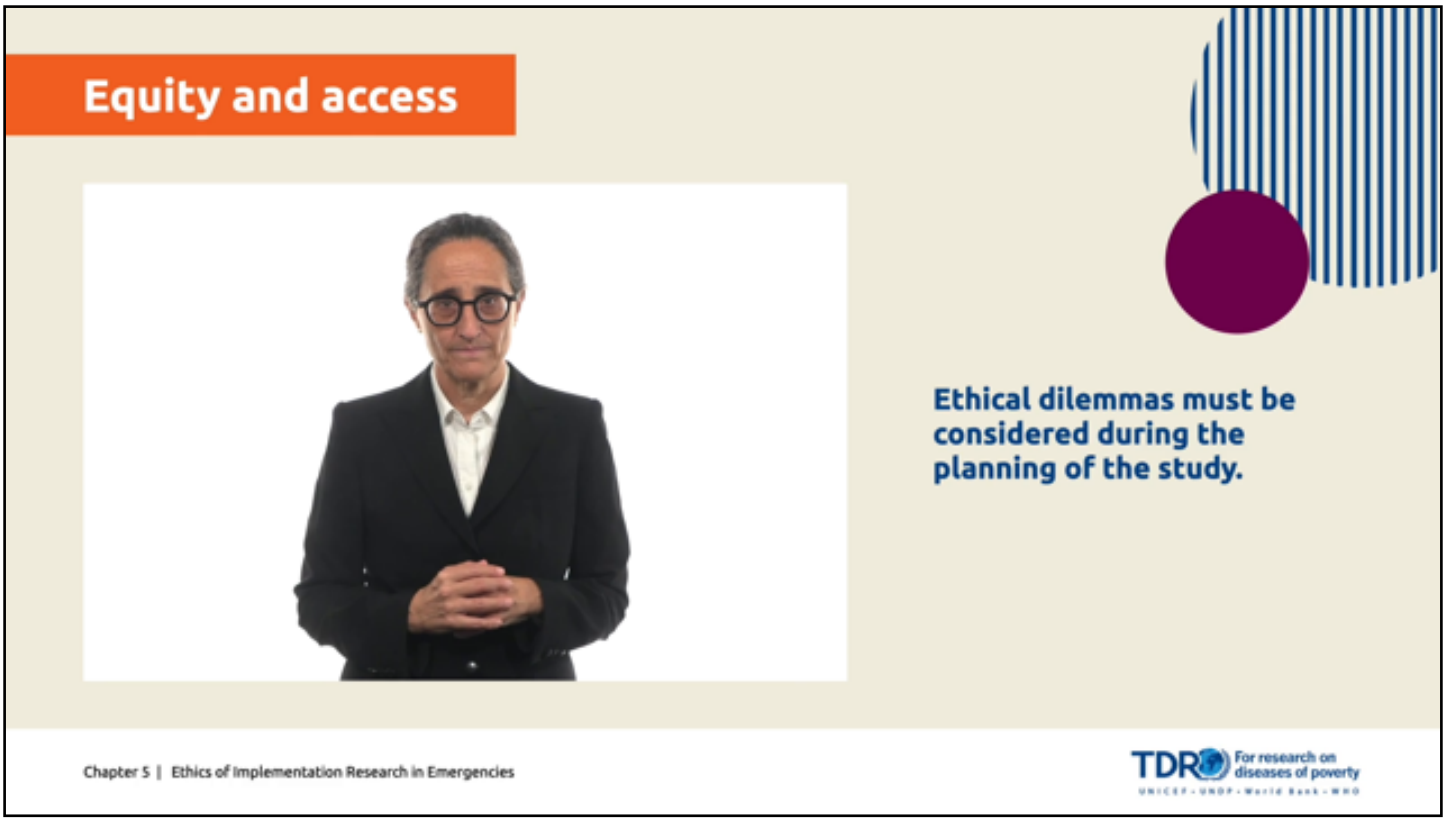
TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

the emergency conditions before the research can take place. In addition, the researchers must have considered their responsibilities towards patients enrolled in the study who may develop a related complication. For example, if a patient develops kidney failure from the dengue infection and dialysis is not available at the hospital, should the researchers be responsible to get the

notes

summary

3m 33s

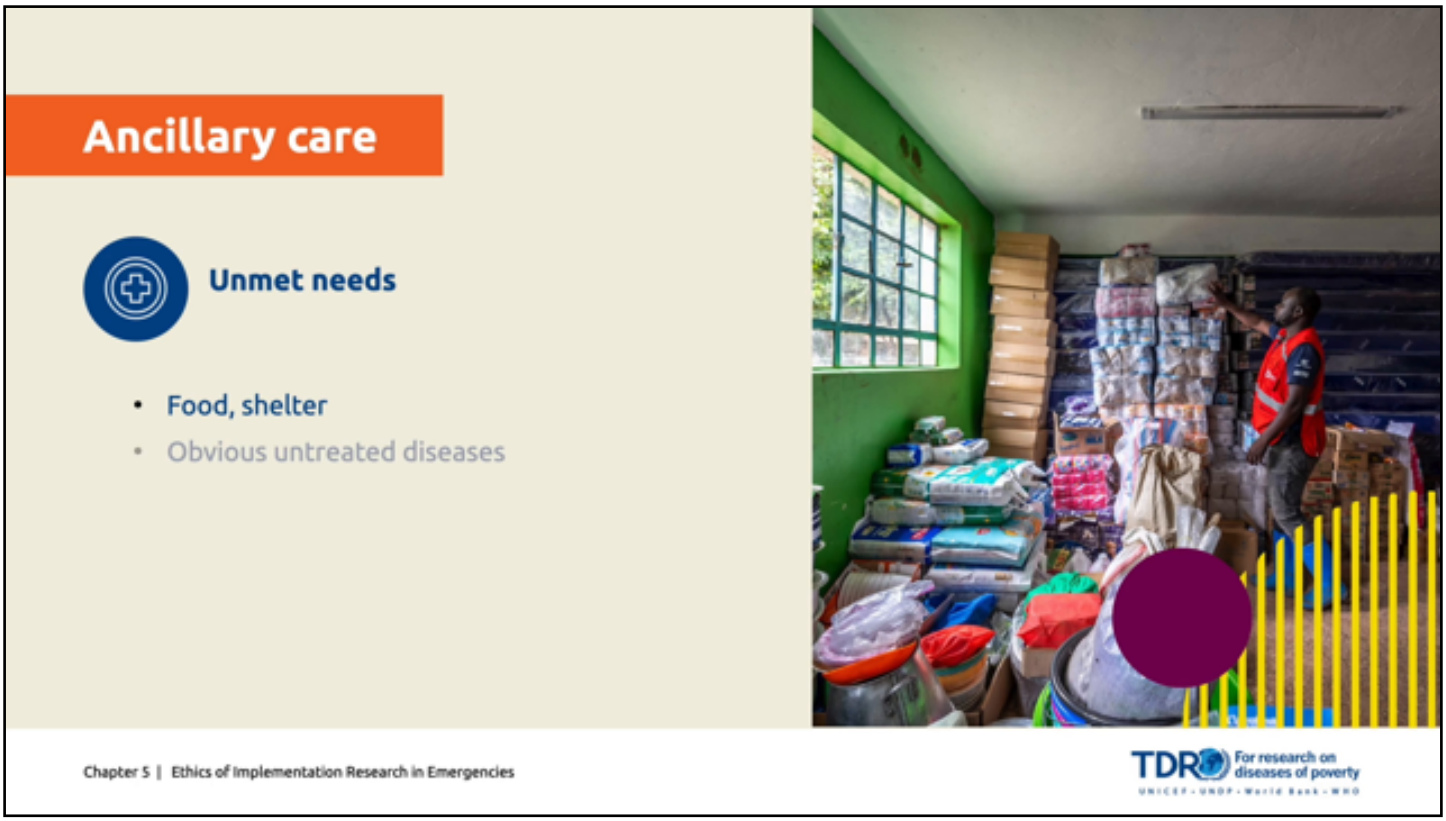


person to a place where dialysis may save their life? These ethical dilemmas must be considered during the planning of the study, especially in emergencies, a time when all resources are strained and services everywhere may also be disrupted. It is too late to consider these while the study is ongoing. However, unforeseen ethical challenges do arise during studies, and mechanisms

notes

summary

3m 53s



for dealing with them should be planned for. Researchers also need to take into account that when they are conducting implementation research in an emergency, that they are very likely to identify many other unmet needs in the hospital or the patients. For example, some patients may

notes

summary

4m 16s

Ancillary care

Unmet needs

- Food, shelter
- Obvious untreated diseases
- Problems with hospital functioning



TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

have no access to food or shelter, some may have other obvious untreated diseases such as leprosy

notes

summary

4m 33s



or heart failure. Researchers may also identify problems with staffing or overall hospital functioning. There is an ethical obligation that researchers be accountable and plan for strategies to address such ancillary needs, either themselves, as part of the study, or identify other

notes

summary

4m 38s



responsible parties. All clinical demands are likely to increase in an emergency. Implementation research conducted in an emergency may therefore negatively impact the local standard of care

notes

summary

4m 55s



through the increased workload and diversion of clinical resources. The risk of this may be higher, for example, if lengthy interviews must be conducted with research participants by the busy clinician researchers diverting their time from caring for other patients. Researchers must

notes

summary

5m 6s



clearly outline how they will support the local clinicians to handle the study and the clinical

notes

summary

5m 22s



needs, such that no patient groups are disproportionately disadvantaged. This situation may impose moral distress or burnout on the local clinical researchers. Researchers need to

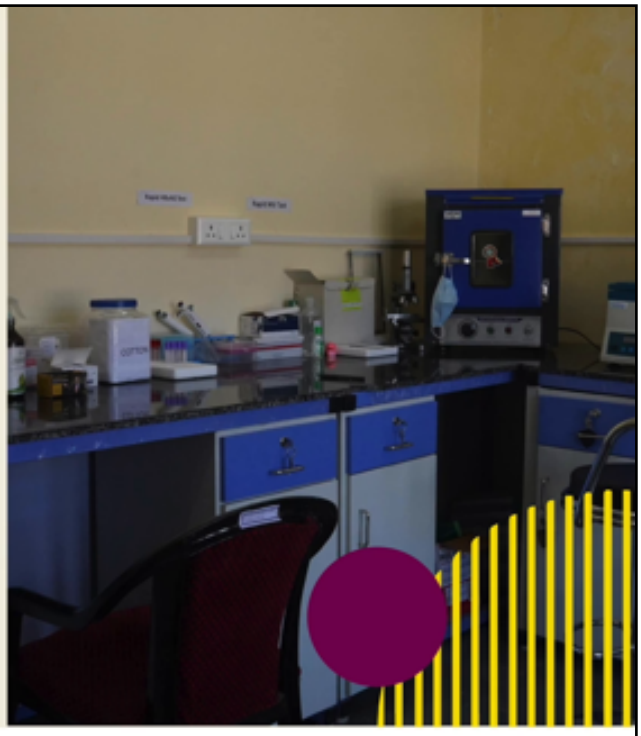
notes

summary

5m 25s

Hospital reputation

- Potential unreliability of local tests



TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

anticipate these and other potential harms and plan to prevent these. A potential further unintended harm of the study may be that when comparing the rapid diagnostic test to the hospital laboratory test and an external laboratory test, it may become apparent that the

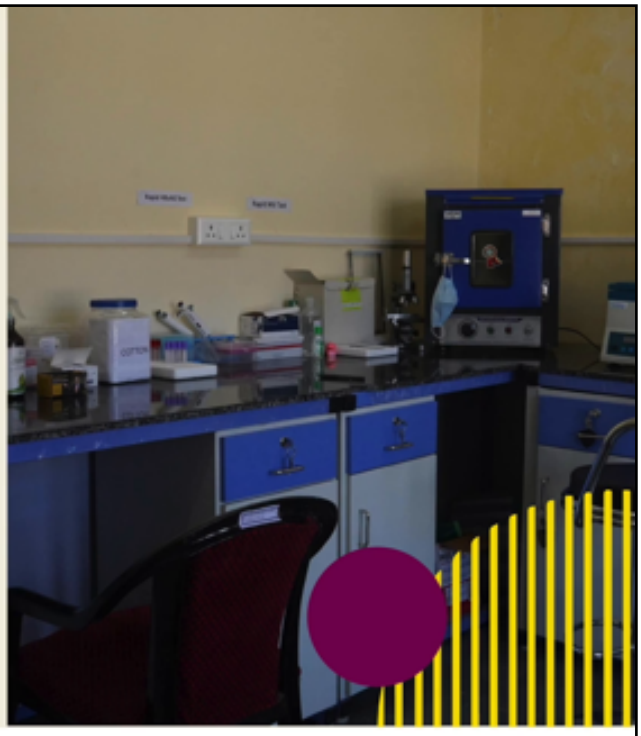
notes

summary

5m 42s

Hospital reputation

- Potential unreliability of local tests



Chapter 5 | Ethics of Implementation Research in Emergencies

TDR For research on diseases of poverty

local laboratory tests are very unreliable. The reporting back of this information may lead to reputational risk for the hospitals and blaming of the laboratory workers. These risks are all higher in implementation research conducted in emergencies, as privacy and confidentiality may be

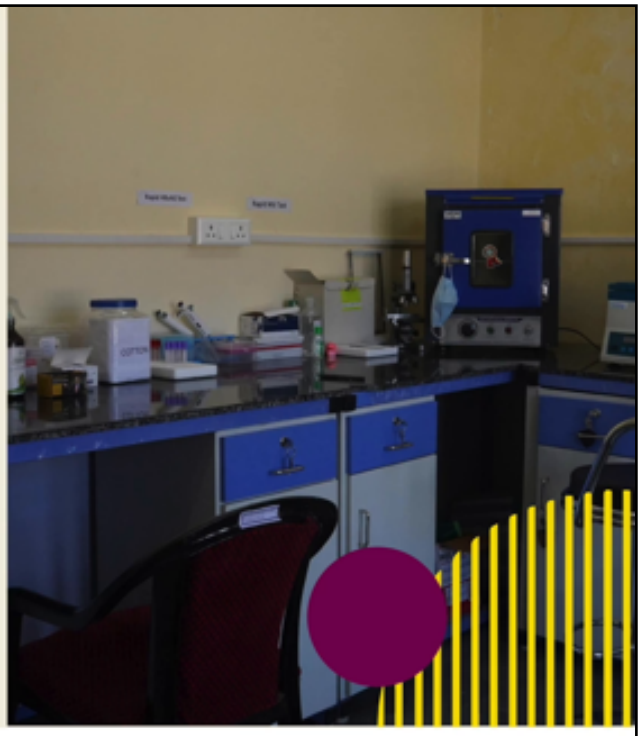
notes

summary

5m 54s

Hospital reputation

- Potential unreliability of local tests
- Strategy for feedback and capacity building



TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

more easily breached and everyone's performance may be below their usual standards. Researchers

notes

summary

6m 12s

Hospital reputation



- Potential unreliability of local tests
- Strategy for feedback and capacity building
- Strengthening laboratory services

TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

must have a careful strategy for feedback and capacity building in such cases, rather than simply reporting. As part of the goal of the dengue study, researchers will need to consider how the study will contribute to strengthening the laboratory services as a whole. Their

notes

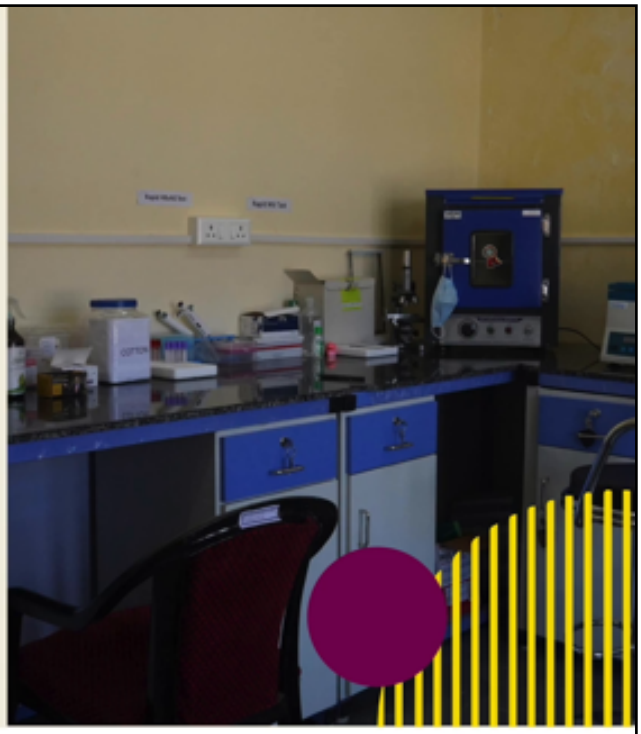
summary

6m 18s

Hospital reputation

- Potential unreliability of local tests
- Strategy for feedback and capacity building
- Strengthening laboratory services

- Acknowledgement of contributors



observations might point to more systematic deficits in the laboratory services, which would need to be identified and then improved. This would also fall under the researchers accountability to address ancillary care needs identified during the study. The ethics review

notes

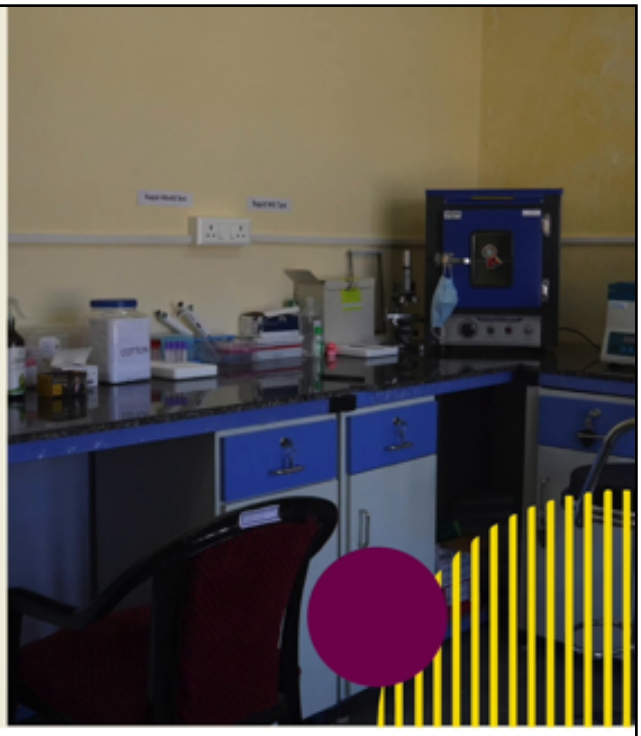
summary

6m 30s

Hospital reputation

- Potential unreliability of local tests
- Strategy for feedback and capacity building
- Strengthening laboratory services

- Acknowledgement of contributors



TDR For research on diseases of poverty
UNICEF · UNDP · World Bank · WHO

should also clearly understand the role of the local clinician researcher and what their role is

notes

summary

6m 46s

Hospital reputation



- Potential unreliability of local tests
- Strategy for feedback and capacity building
- Strengthening laboratory services

- Acknowledgement of contributors

TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

in the study. Have they had input into the study design? Is there some assurance that this person's

notes

summary

6m 49s

Hospital reputation

- Potential unreliability of local tests
- Strategy for feedback and capacity building
- Strengthening laboratory services

- Acknowledgement of contributors



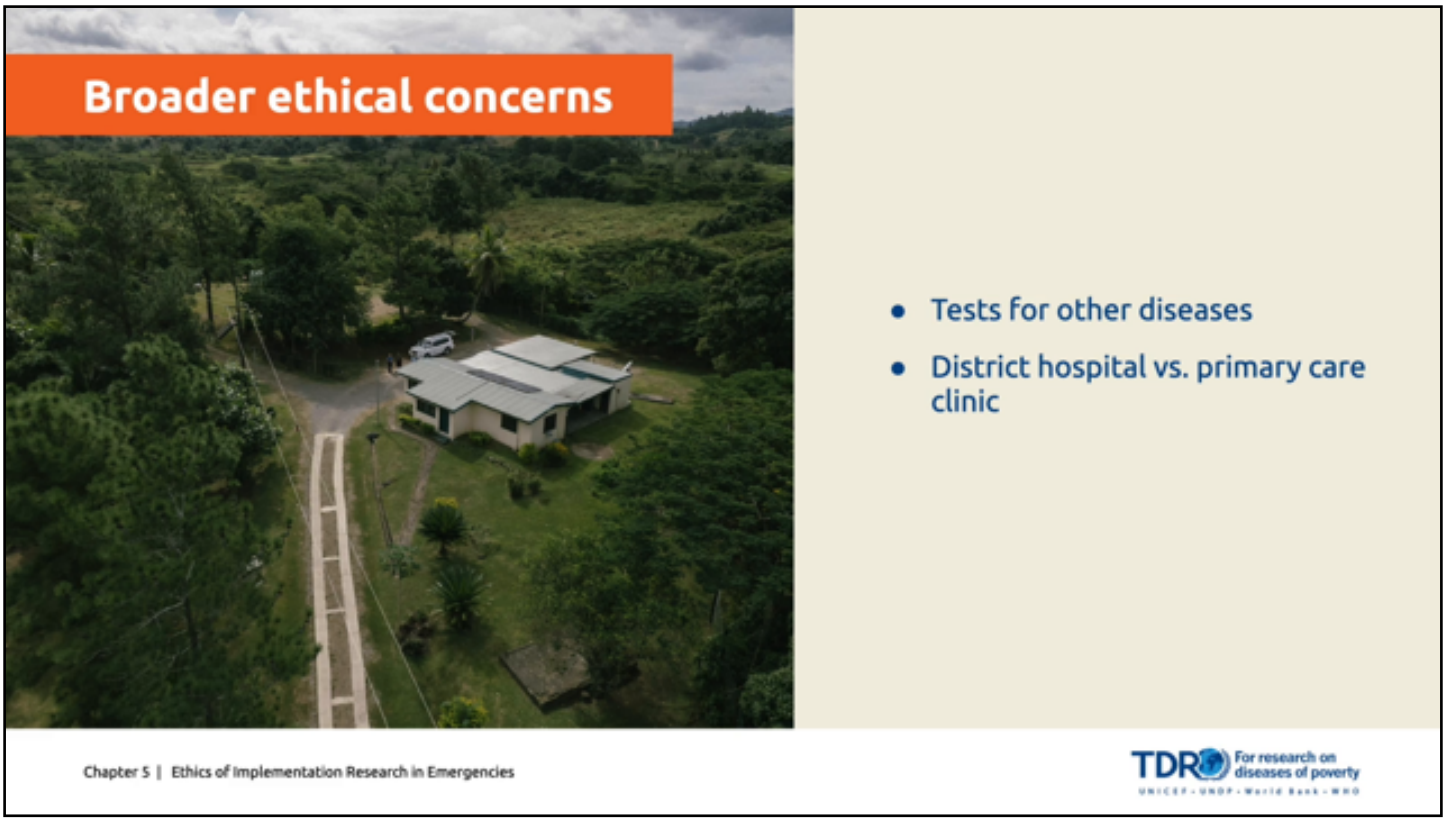
TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

contribution will be fairly acknowledged? Are they being remunerated fairly? Will this remuneration

notes

summary

7m 1s



drain clinicians and nurses from the health workforce? Now that we've gone through some examples of the more specific aspects of the study, we need to start thinking about equity and justice aspects at a broader level. Given that the number of serious outbreaks around the world are increasing as a consequence of climate change, natural disasters and conflicts, it may be worth considering that companies be encouraged to develop multiplex tests, which can simultaneously detect multiple high risk viruses, rather than focusing only on one disease such as dengue. Such a test would reduce inequities between those with dengue and those who receive a diagnosis, and others who do not. This may be included as a comment from the ethics reviewer, but may or may not be addressable by the researchers in the study. Focusing the study on district

notes

summary

7m 7s

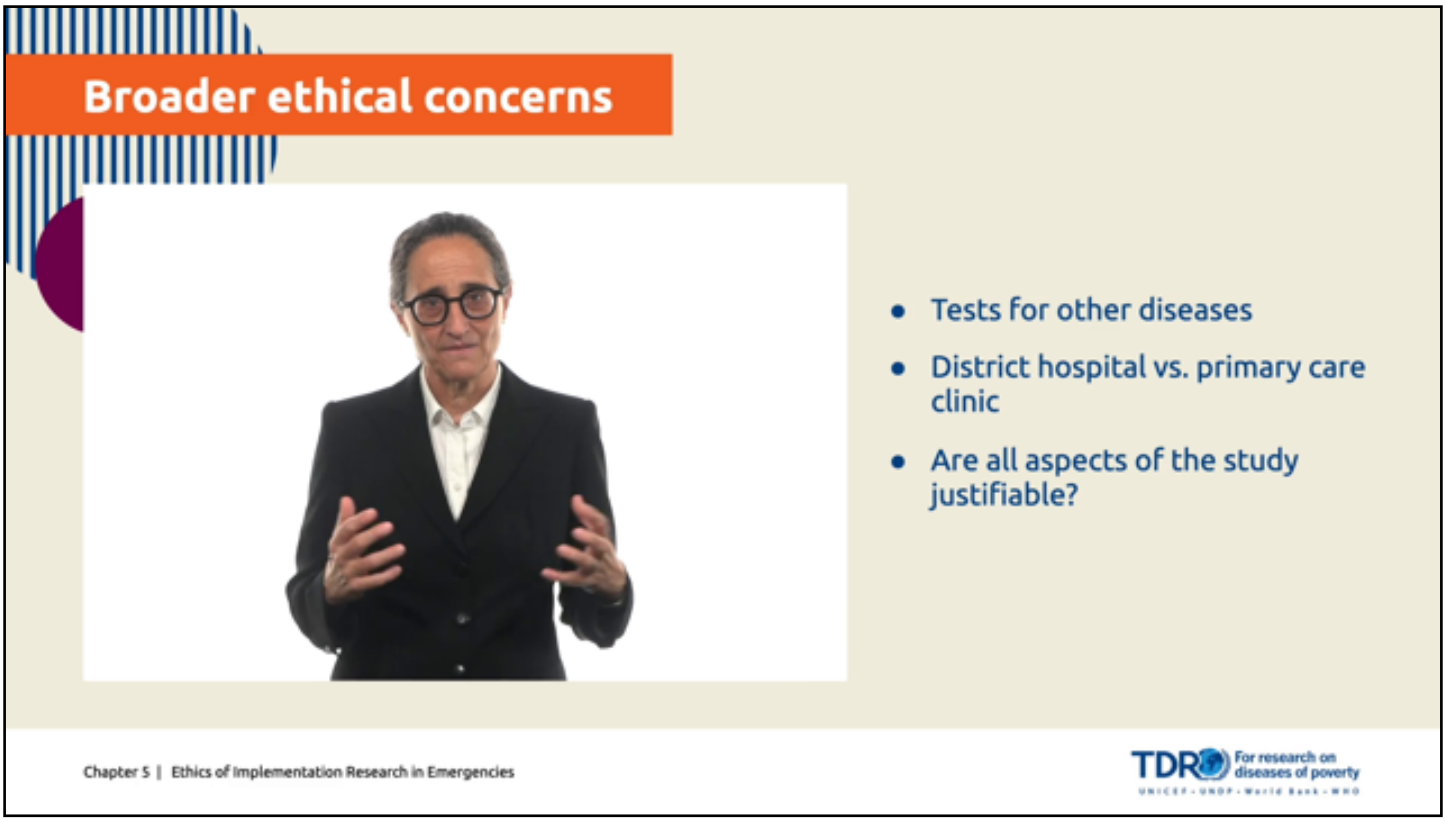


hospitals where it may be easier to conduct, is likely to leave out a large proportion of vulnerable patients who may not have had the means to get to the district hospital during an emergency, and may present instead to their primary care clinic. The rapid diagnostic test should be as feasible at primary care as it is at the district hospital. Justice concerns would demand that the study include these harder-to-reach populations and study sites, especially as the rapid test may have even more potential value there during an outbreak. This may be a

notes

summary

7m 56s

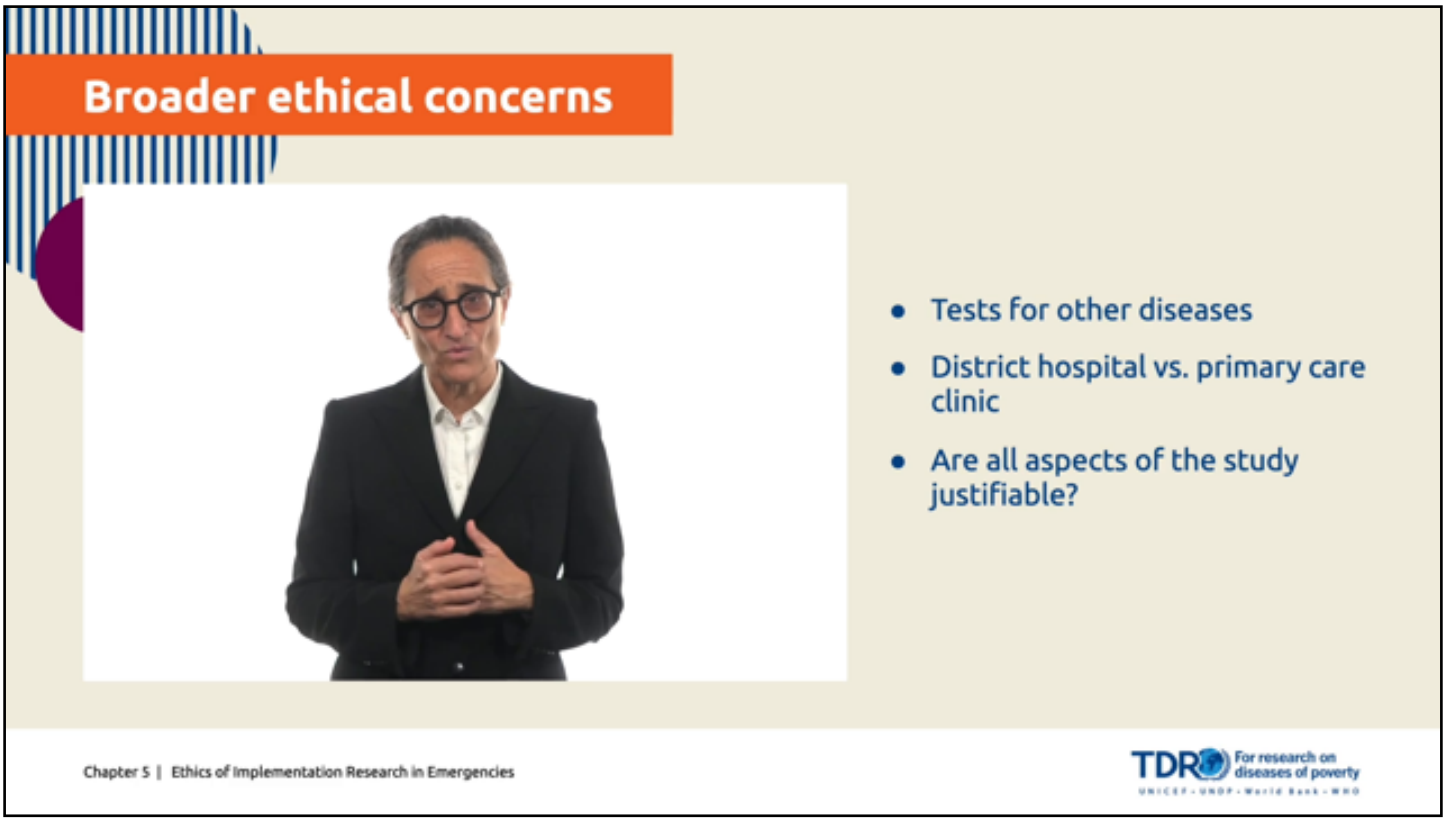


recommendation of the ethics review, and researchers may respond that they will begin in the hospitals given the time pressure, but amend the protocol to expand to the primary care clinics if the feasibility of the test seems promising. As a reviewer, you will also need

notes

summary

8m 25s



to consider individual aspects of the study, and if they are ethically justifiable. One could

notes

summary

8m 46s

Broader ethical concerns



- Tests for other diseases
- District hospital vs. primary care clinic
- Are all aspects of the study justifiable?

Scientific or contextual equipoise

TDR For research on diseases of poverty
UNICEF - UNDP - World Bank - WHO

question whether it's really necessary to determine the validity of the rapid diagnostic test during an emergency, where all risks are higher. Could this not be conducted elsewhere in a more safe setting? If the rapid diagnostic test is known to be valid, equipoise may dictate that researchers should not be taking advantage of the most vulnerable people in an emergency setting to

notes

summary

8m 50s

Broader ethical concerns



- Tests for other diseases
- District hospital vs. primary care clinic
- Are all aspects of the study justifiable?

Scientific or contextual equipoise

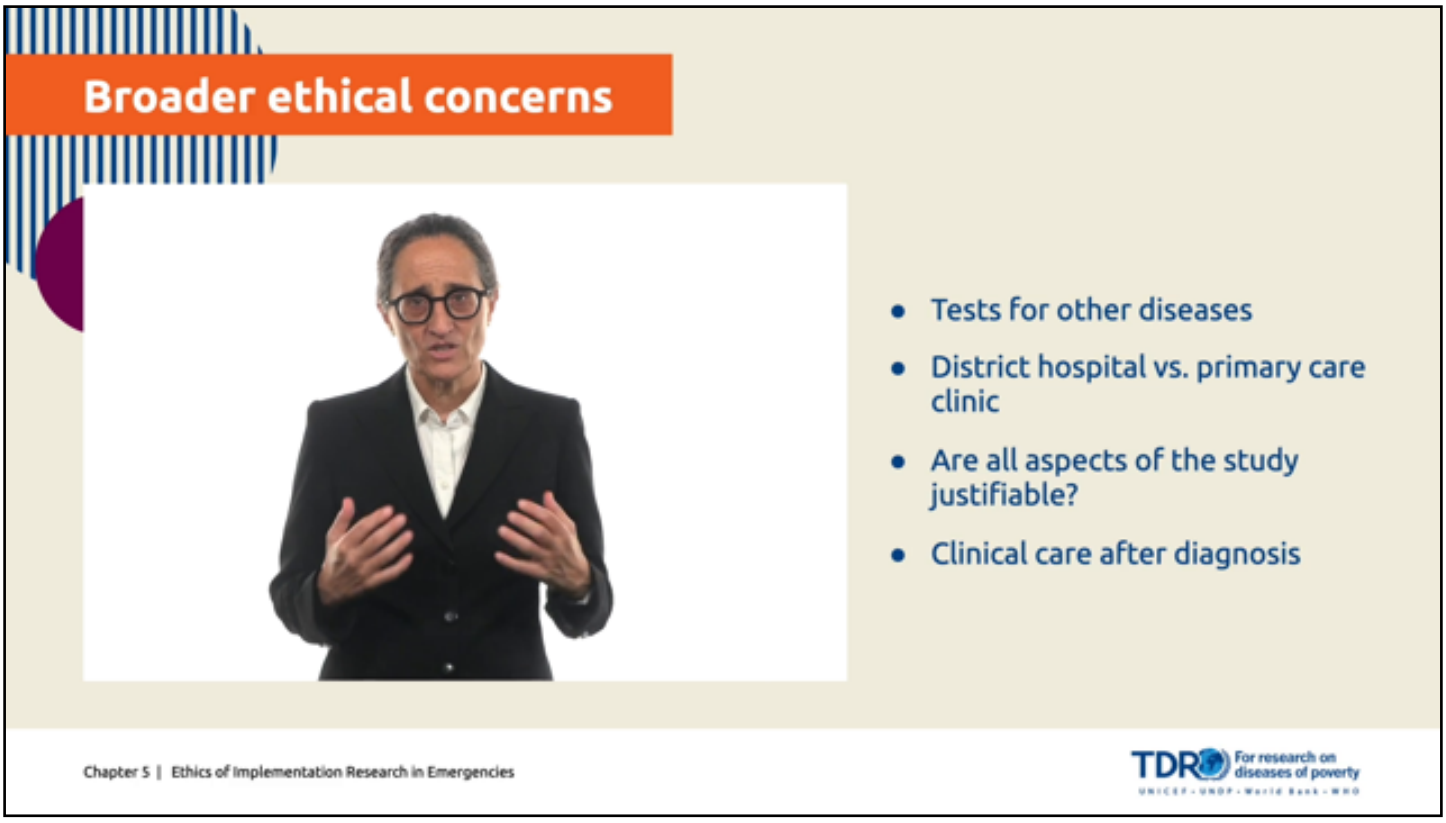
TDR For research on diseases of poverty
UNICEF · UNDP · World Bank · WHO

answer this question again. If, however, there is uncertainty on how the test or device may perform

notes

summary

9m 12s



under the hot research conditions over a 24-hour period when being used by clinicians under stress, then it may be justifiable to evaluate the validity in the specific emergency context, which

notes

summary

9m 14s

Broader ethical concerns



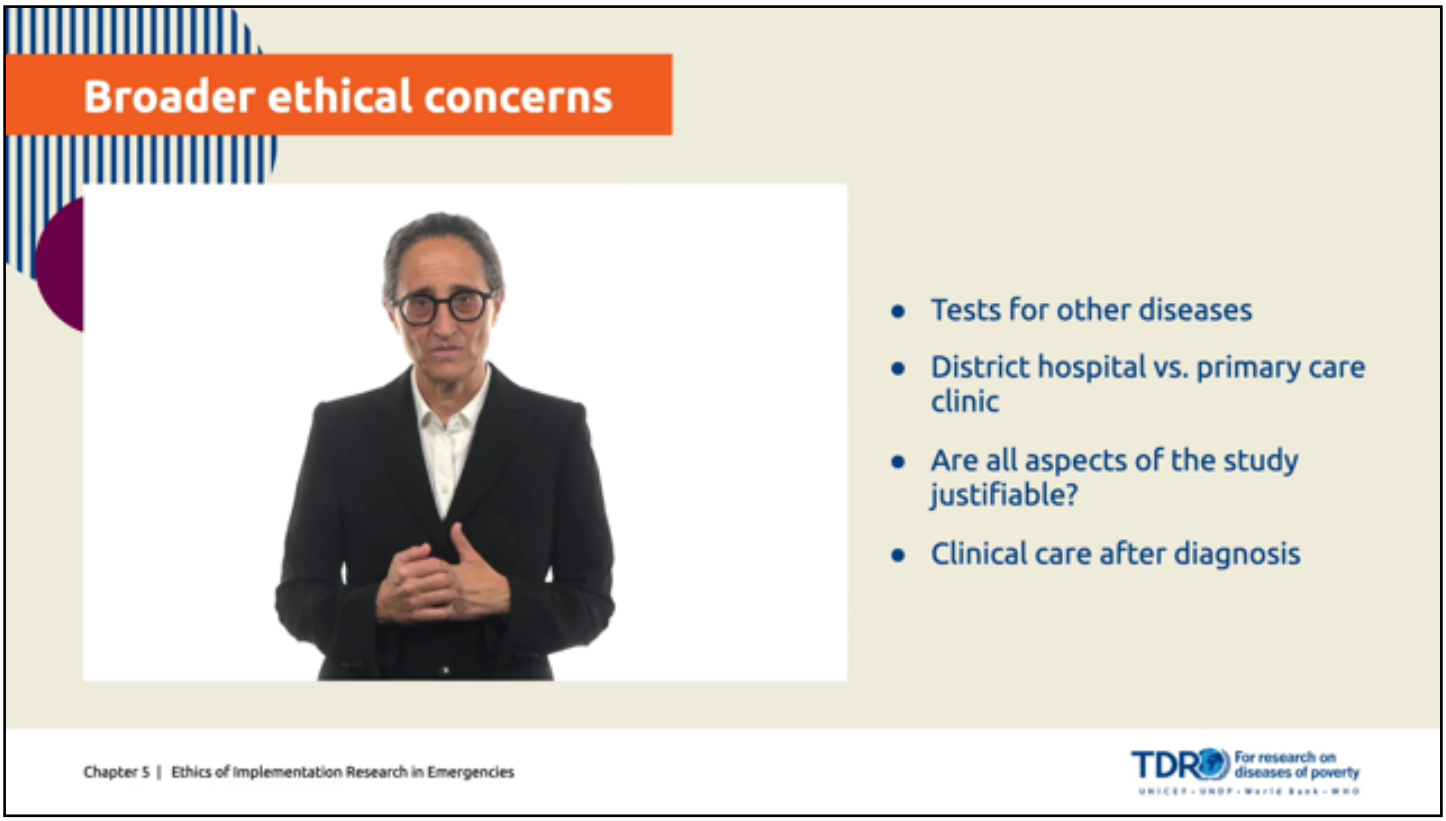
- Tests for other diseases
- District hospital vs. primary care clinic
- Are all aspects of the study justifiable?
- Clinical care after diagnosis

would qualify as contextual equipoise. You should consider whether the researchers have an

notes

summary

9m 32s

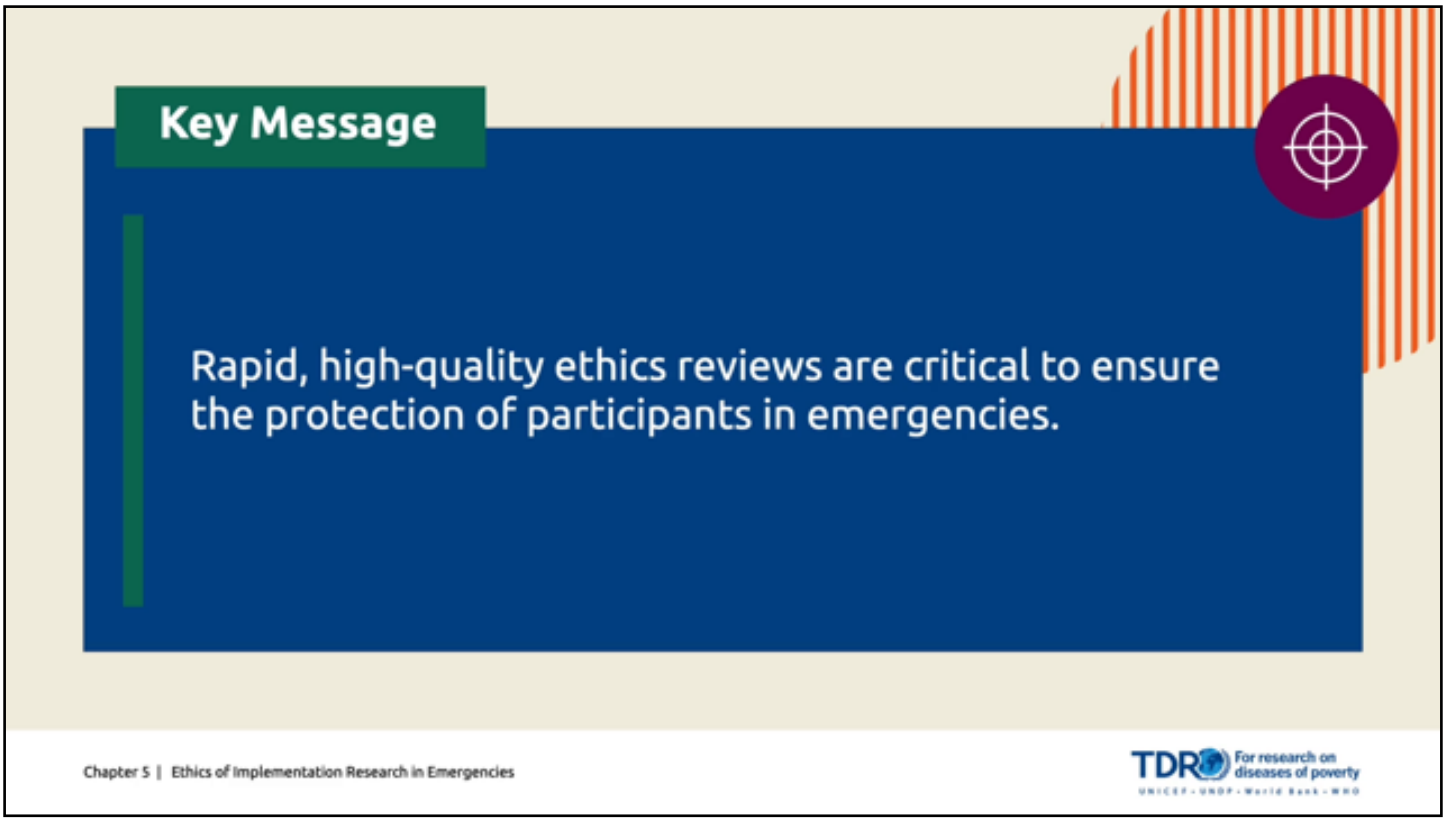


obligation to ensure clinical care after diagnosis is of an acceptable standard, as this is both clinically and scientifically very important. I'm sure if you consider this example at more length, you will be able to come up with other potential ethical concerns that might arise in your own work environment. Going through this exercise may help you to design and conduct your own implementation research better, and to be aware of the additional ethical concerns that may

notes

summary

9m 37s

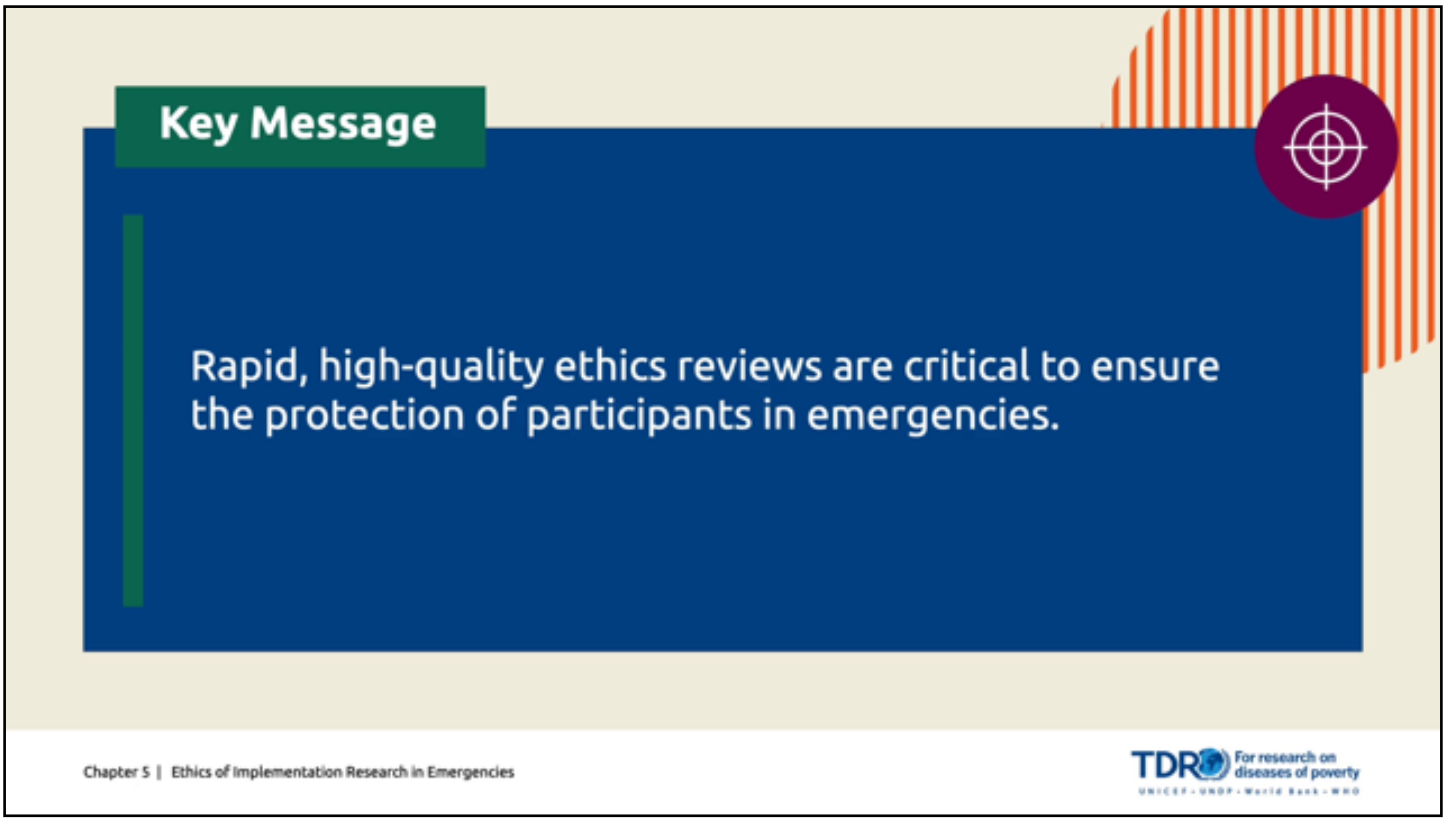


be greater in emergencies. It should now be clear to all of us that given the urgency, the unknowns and the high stakes in terms of protecting communities and vulnerable people in emergencies, there is an ethical imperative to do quality implementation research. It is, however, critical that this research is done ethically. Research ethics committees and institutional review boards

notes

summary

10m 1s

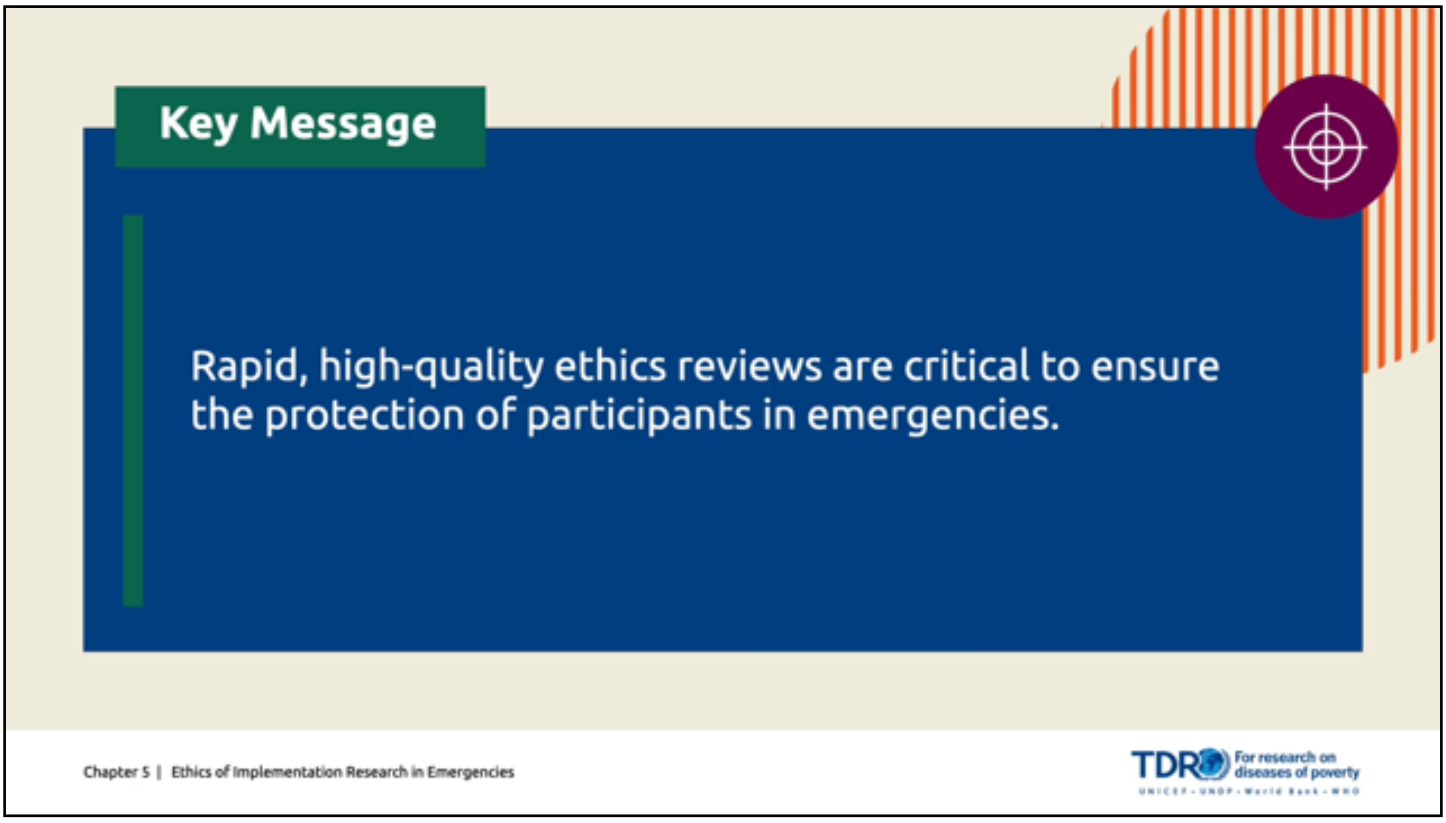


must be familiar with the ethical considerations which arise in implementation research in

notes

summary

10m 22s



emergencies, such that they can produce high quality reviews with a rapid turnaround time. Ethics review is essential to ensure that research participants will be protected and not

notes

summary

10m 26s



be taken advantage of in an emergency. We've now come to the end of this massive open online course on ethics in implementation research in emergencies. We hope that this has been of interest and of value to you. Various references are listed at the end which you can use to gain more information, should you be interested to learn more. Thank you for your participation.

notes

summary

10m 41s