Course material

Course:

Ethics in Emergencies

Video:

3c Study design

Concepts (extracted from automatically generated subtitles):

Such study designs. Implementation research. Mobile phone app. Control group. Potential short term benefits. Efficacy of an intervention. Study design. Scientific quality of the research. Stepped-wedge. Emergency circumstances. Control intervention. Clinical trials. Ethical implications. Such studies. Clinical effectiveness of a new vaccine.



to video sequence search
(within Ethics in Emergencies.)



to video



...

notes

summary

0m 0s

Study design in emergencies

Control groups:

- Useful to assess efficacy



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As we have already seen, implementation research must rapidly provide highly relevant answers to important public health questions in emergencies. Despite the hassle, however, maintaining the scientific quality of the

notes

summary

0m 3s

Study design in emergencies

Control groups:

- Useful to assess efficacy



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research is imperative. As we know from clinical trials, a useful way to assess the efficacy of an intervention is to compare it to a control

notes

summary

0m 29s

Study design in emergencies

Control groups:

- Useful to assess efficacy
- Ethically questionable if life-threatening emergency



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intervention and to perform long term follow up. Under emergency circumstances, however, if faced with a life threatening outbreak such as Ebola, for example, including a control group in a study on the clinical

notes

summary

0m 40s

Study design in emergencies

Control groups:

- Useful to assess efficacy
- Ethically questionable if life-threatening emergency



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effectiveness of a new vaccine which is reasonably expected to be effective,

notes

summary

1m 0s

Study design in emergencies

Control groups:

- Useful to assess efficacy
- Ethically questionable if life-threatening emergency



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may be ethically questionable if the new vaccine utilises a new

notes

summary

1m 1s

Study design in emergencies

Control groups:

- Useful to assess efficacy
- Ethically questionable if life-threatening emergency



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technology, such as the new mRNA vaccines that were deployed during the

notes

summary

1m 13s

Study design in emergencies

Control groups:

- Useful to assess efficacy
- Ethically questionable if life-threatening emergency



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Covid-19 pandemic. The community may understand potential short term benefits, but there may be hesitation within the community about unknown long

notes

summary

1m 16s

Study design in emergencies

Control groups:

- Useful to assess efficacy
- Ethically questionable if life-threatening emergency



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term effects. Implementation research would therefore be required to

notes

summary

1m 36s



understand how best to improve uptake in a community. For example, various public education strategies may need to be tested against each other and against no education across similar communities or individuals.

notes

summary

1m 42s

Study design in emergencies



Control groups:

- Useful to assess efficacy
- Ethically questionable if life-threatening emergency
- Used to compare interventions in IR as well
- Study designs minimizing harms for control groups

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If a control group is imperative from a scientific perspective, careful

notes

summary

1m 59s

Study design in emergencies



Control groups:

- Useful to assess efficacy
- Ethically questionable if life-threatening emergency
- Used to compare interventions in IR as well
- Study designs minimizing harms for control groups

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consideration of the ethics of the possible study designs is required to

notes

summary

2m 10s

Stepped-wedge design



	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Sequence 1	Routine care	Interven-tion	Interven-tion	Interven-tion	Interven-tion	Interven-tion
Sequence 2	Routine care	Routine care	Interven-tion	Interven-tion	Interven-tion	Interven-tion
Sequence 3	Routine care	Routine care	Routine care	Interven-tion	Interven-tion	Interven-tion
Sequence 4	Routine care	Routine care	Routine care	Routine care	Interven-tion	Interven-tion
Sequence 5	Routine care	Routine care	Routine care	Routine care	Routine care	Interven-tion

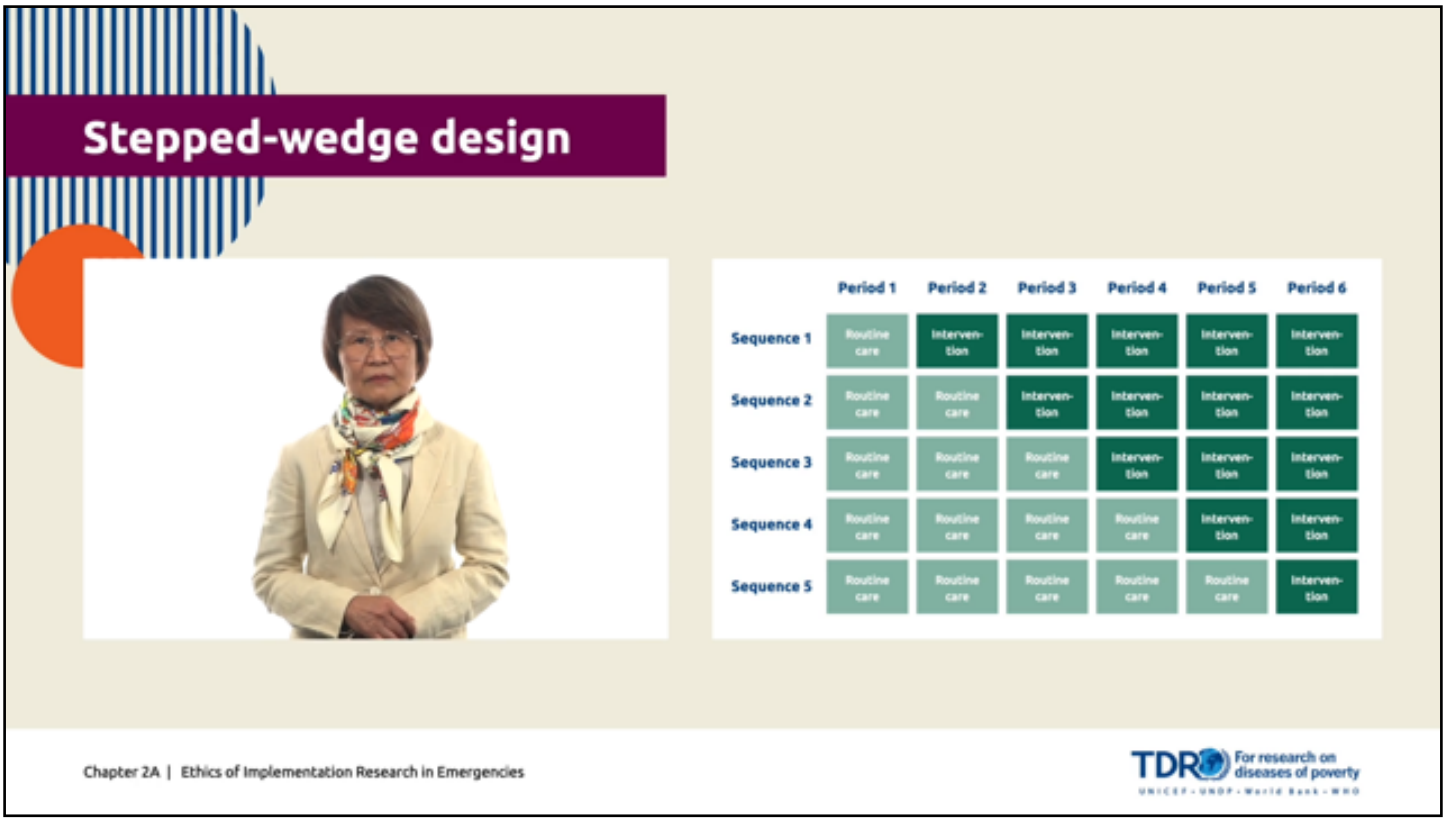
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minimise the potential harms. Such study designs have been termed «pragmatic trials÷. This may include various forms of sequential,

notes

summary

2m 13s



or stepped-wedge, cluster randomised trials, where successive communities are exposed to an intervention in a cumulative fashion, such as intervention to increase mask use in school, hand-washing promotion strategies, or vaccine uptake. In these designs, not all who may benefit have the opportunity to receive the intervention at the start,

notes

summary

2m 25s

Stepped-wedge design



	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Sequence 1	Routine care	Interven-tion	Interven-tion	Interven-tion	Interven-tion	Interven-tion
Sequence 2	Routine care	Routine care	Interven-tion	Interven-tion	Interven-tion	Interven-tion
Sequence 3	Routine care	Routine care	Routine care	Interven-tion	Interven-tion	Interven-tion
Sequence 4	Routine care	Routine care	Routine care	Routine care	Interven-tion	Interven-tion
Sequence 5	Routine care	Routine care	Routine care	Routine care	Routine care	Interven-tion

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but over time, successive communities or groups become included

notes

summary

3m 0s

Stepped-wedge design



	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Sequence 1	Routine care	Interven-tion	Interven-tion	Interven-tion	Interven-tion	Interven-tion
Sequence 2	Routine care	Routine care	Interven-tion	Interven-tion	Interven-tion	Interven-tion
Sequence 3	Routine care	Routine care	Routine care	Interven-tion	Interven-tion	Interven-tion
Sequence 4	Routine care	Routine care	Routine care	Routine care	Interven-tion	Interven-tion
Sequence 5	Routine care	Routine care	Routine care	Routine care	Routine care	Interven-tion

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such that all will eventually receive the potentially beneficial intervention.

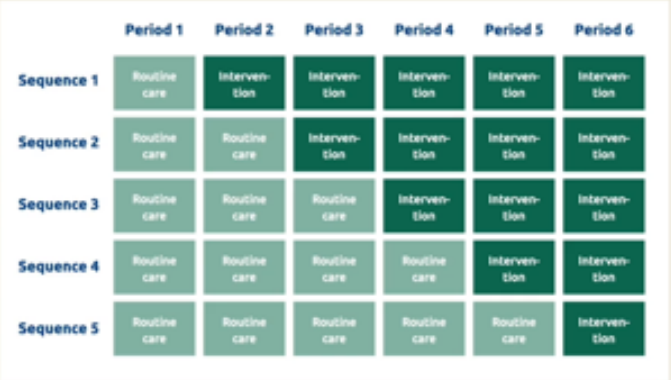
notes

summary

3m 11s

Example of stepped-wedge design

Problem: Improve the uptake of handwashing with an app to reduce an outbreak in 5 communities.



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This study design reduces the potential harm from being in the control group if the intervention is positive. To illustrate these concepts, let's consider another example where a rapidly scaled-up stepped-wedge study design may be ethically justifiable

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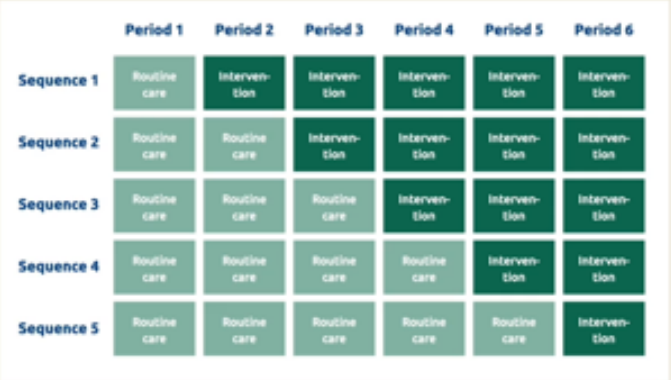
summary

3m 13s

Example of stepped-wedge design

Problem: Improve the uptake of handwashing with an app to reduce an outbreak in 5 communities.

Strategy: Test the acceptability and feasibility of the app to promote handwashing.



in an emergency. In a stepped-wedge study design, for example, five refugee communities in a district experiencing an outbreak would be randomised to receive a novel hand-washing intervention delivered via a mobile phone app, which also informs users of where supplies of hand sanitiser are currently in stock for purchase. It is unknown if the app is feasible and how it would be

notes

summary

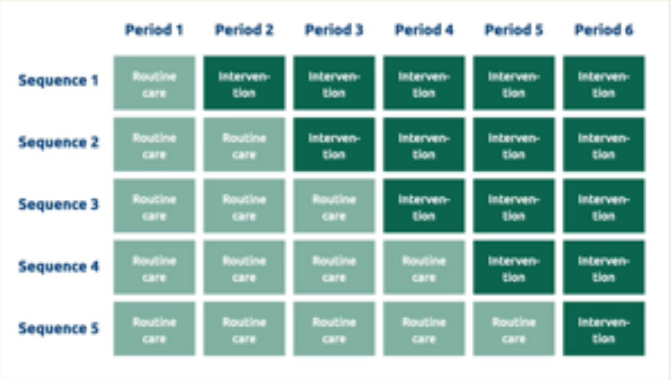
3m 37s

Example of stepped-wedge design

Problem: Improve the uptake of handwashing with an app to reduce an outbreak in 5 communities.

Strategy: Test the acceptability and feasibility of the app to promote handwashing.

Study design: Enroll one community at a time and wait to detect results.



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accepted by the communities. The app would be first rolled out

notes

summary

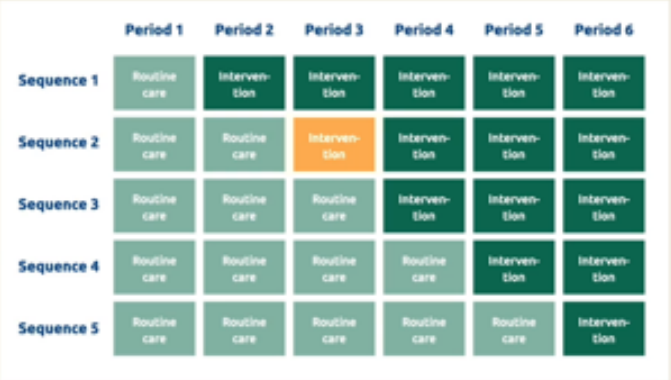
4m 12s

Example of stepped-wedge design

Problem: Improve the uptake of handwashing with an app to reduce an outbreak in 5 communities.

Strategy: Test the acceptability and feasibility of the app to promote handwashing.

Study design: Enroll one community at a time and wait to detect results.



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in one community, and compared to the impact of no app in the other four communities. In the next step, after a short time, which would be enough to detect a difference in target outcome, a second

notes

summary

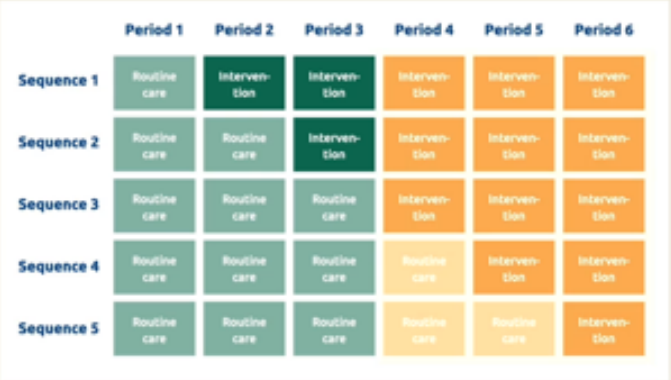
4m 13s

Example of stepped-wedge design

Problem: Improve the uptake of handwashing with an app to reduce an outbreak in 5 communities.

Strategy: Test the acceptability and feasibility of the app to promote handwashing.

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community would be enrolled into the app arm and the three other communities would remain as controls. This process would continue until all five

notes

summary

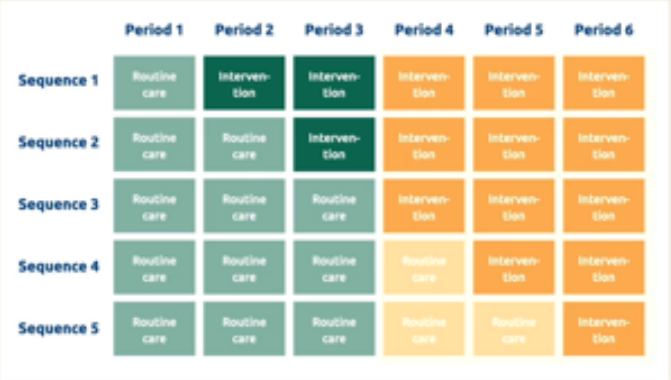
4m 37s

Example of stepped-wedge design

Problem: Improve the uptake of handwashing with an app to reduce an outbreak in 5 communities.

Strategy: Test the acceptability and feasibility of the app to promote handwashing.

Study design: Enroll one community at a time and wait to detect results.



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communities are enrolled, especially if there is an understanding over time that the

notes

summary

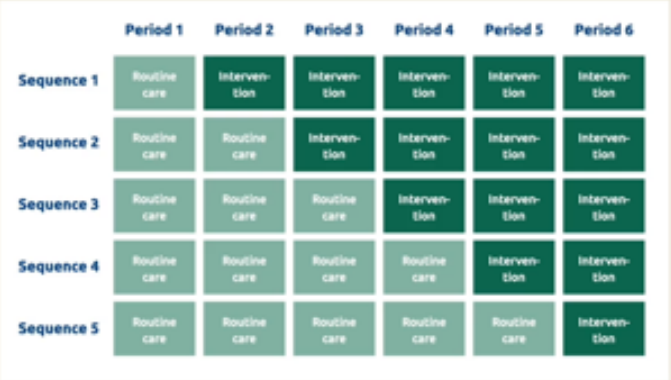
4m 49s

Example of stepped-wedge design

Problem: Improve the uptake of handwashing with an app to reduce an outbreak in 5 communities.

Strategy: Test the acceptability and feasibility of the app to promote handwashing.

Study design: Enroll one community at a time and wait to detect results.



app is being used and is effective. This sort of study design

notes

summary

4m 50s

Advantages of stepped-wedge studies

- Improves equity
- Reduces potential harm



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improves equity in opportunity to participate in the study, and reduces the potential harm done to a group that would remain as control

notes

summary

5m 1s

Advantages of stepped-wedge studies

- Improves equity
- Reduces potential harm
- No excessive resources used if unsuccessful



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without ever receiving the intervention. If the app was not feasible or acceptable, it would have permitted rapid understanding of this and avoided excessive resources being spent unnecessarily in a larger study from day one.

notes

summary

5m 20s

Advantages of stepped-wedge studies

- Improves equity
- Reduces potential harm
- No excessive resources used if unsuccessful
- Allows real-time improvement of intervention



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Importantly also, from a scientific perspective, such a

notes

summary

5m 38s

Advantages of stepped-wedge studies

- Improves equity
- Reduces potential harm
- No excessive resources used if unsuccessful
- Allows real-time improvement of intervention



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design may permit tweaking of the app with each successive community that is included, to allow real time improvement without starting a study from scratch

notes

summary

5m 49s



each time. Given that implementation research study design may be complex, the studies are often taking place in vulnerable communities and under unstable conditions in emergencies, designing such studies from scratch

notes

summary

6m 1s



in an emergency may not be practical. As such, building on prior experiences, Implementation research studies to be deployed in

notes

summary

6m 24s

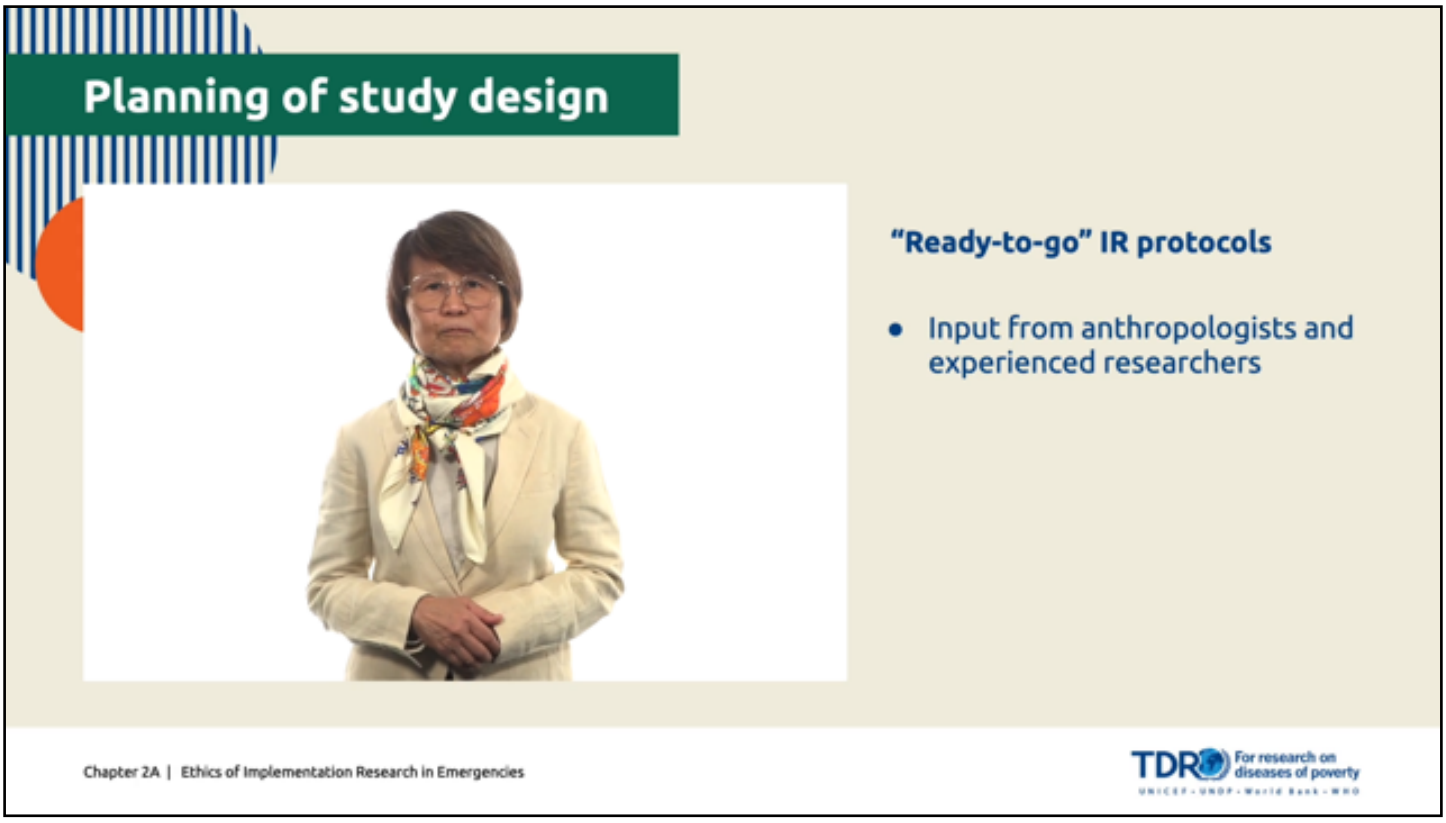


emergency should ideally be ready to go and planned ahead of time for

notes

summary

6m 33s

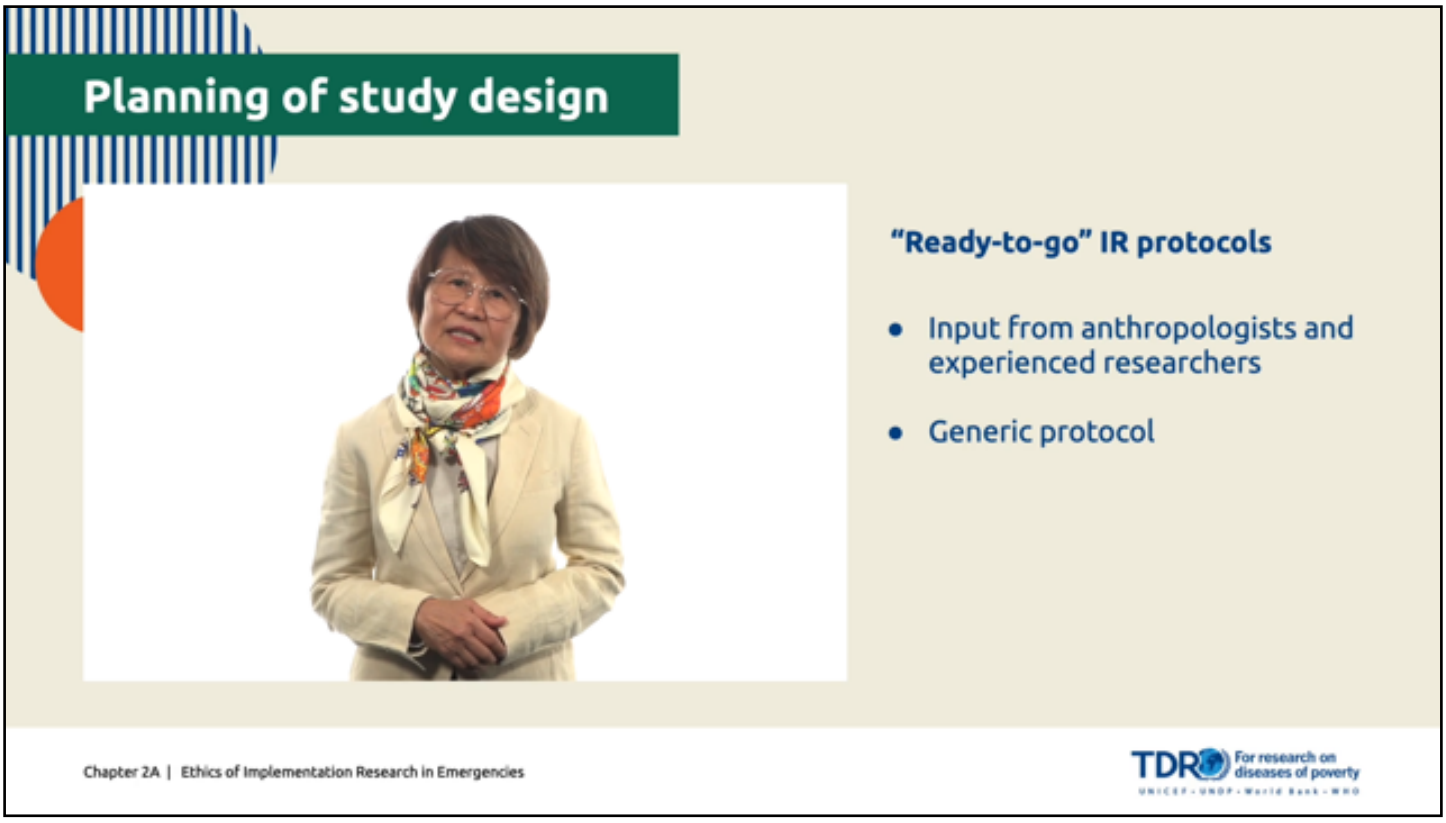


emergencies that may be predictable. These protocols should include input from anthropologists and others who have prior

notes

summary

6m 38s

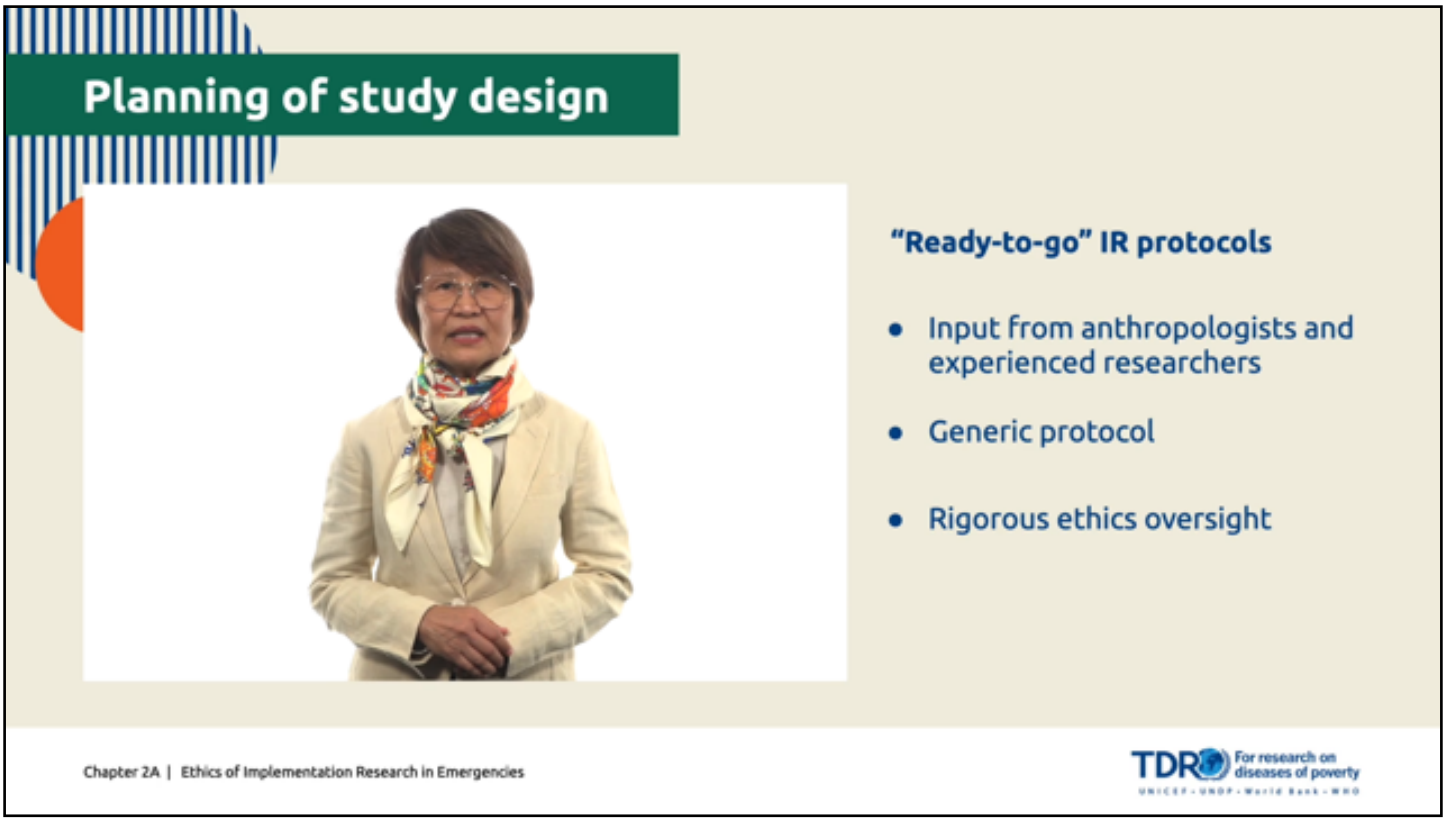


experience of conducting implementation research in emergencies. This

notes

summary

6m 58s



means a generic study protocol and design can be developed, which would undergo rigorous ethics oversight as a template protocol.

notes

summary

7m 1s

Planning of study design



"Ready-to-go" IR protocols

- Input from anthropologists and experienced researchers
- Generic protocol
- Rigorous ethics oversight
- Rapidly adaptable

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This template can then be rapidly adapted to fit the actual emergency

notes

summary

7m 13s

Planning of study design



"Ready-to-go" IR protocols

- Input from anthropologists and experienced researchers
- Generic protocol
- Rigorous ethics oversight
- Rapidly adaptable

circumstances and undergo an expedited, updated ethics review to permit the study to begin as early as possible without compromising on the ethics. Ethics review of implementation research in emergency will be discussed in more detail in

notes

summary

7m 22s

Planning of study design



"Ready-to-go" IR protocols

- Input from anthropologists and experienced researchers
- Generic protocol
- Rigorous ethics oversight
- Rapidly adaptable

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chapter five. Discussion of the individual study designs in implementation research and the ethical implications of each is beyond the scope here.

notes

summary

7m 44s



Awareness of the ethical implications, especially as they related to fairness

notes

summary

7m 55s



of opportunity to participate, and the potential balance between benefits and harms of the

notes

summary

8m 5s

Choice of study design



TDR training toolkit: https://adphealth.org/irtoolkit/

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intervention can help to determine the most appropriate study design to answer a research question rapidly, scientifically and ethically in an emergency. More

notes

summary

8m 13s

Choice of study design



TDR training toolkit: https://adphealth.org/irtoolkit/

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information can be found in the TDR training tool on the ethics of implementation research,

notes

summary

8m 25s

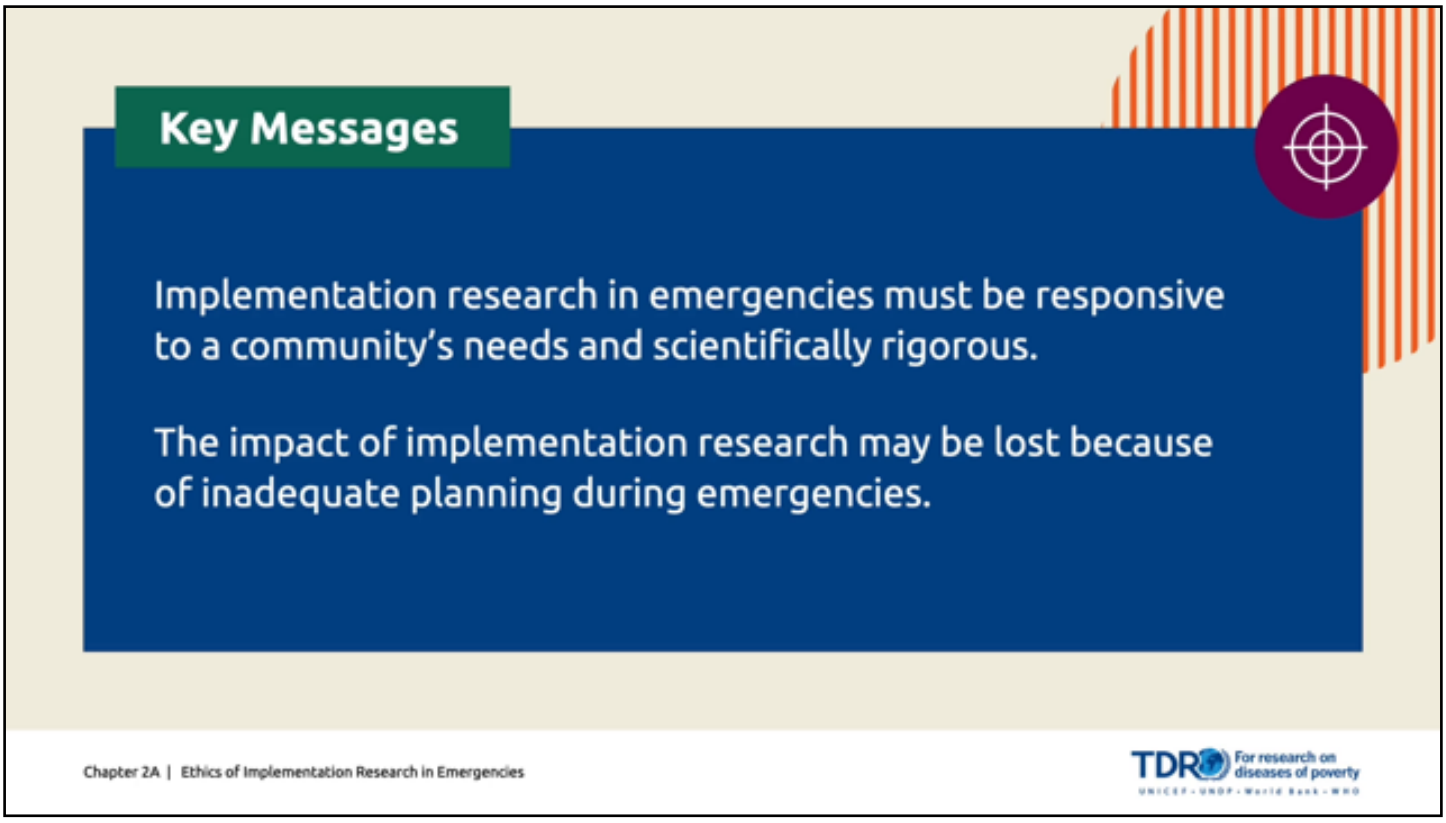


freely available through the link below the screen. To summarise this first section on the planning of implementation research in emergencies, it is important to remember that for implementation research to be justifiable, it must be responsive to the community's needs and scientifically rigorous.

notes

summary

8m 33s



These considerations are of crucial importance because the impact of research may be lost if planning is inadequate. The consequences in emergency can be severe. Now,

notes

summary

8m 56s



building on this foundation, in the next chapter, we will turn to consider the anticipation of potential benefits and harms as important ethical considerations associated with implementation research in emergencies.

notes

summary

9m 14s