Course material

Course:

Ethics in Emergencies

Video:

3b Scientific rationale and equipoise

Concepts (extracted from automatically generated subtitles):

Specific research question. Implementation research. Typical example. Randomised clinical trial. Principle of equipoise. Local context. Important justification. Rabies vaccinations. Clinical equipoise. Community engagement. Transparent stakeholder engagement. Proof of concept. Important role. Clinical effectiveness of bedaquiline. Emergency setting.



to video sequence search
(within Ethics in Emergencies.)



to video

CHAPTER 2A

Ethical considerations in planning implementation research in emergencies

Scientific rationale and equipoise

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

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notes

summary

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Scientific rationale



Once the researchers determined whether a specific research question in an emergency setting is indeed a priority in the local context, meaning that the

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study is worth doing, their next obligation is to ensure that the study will be scientifically sound. As we keep saying, the stakes in implementation research in emergencies are very high. Knowledge generated through research should lead to the rapid implementation and

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scaling up of effective interventions. If a proof of concept exists from

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elsewhere, this may support the scientific rationale. However, how

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to translate findings from elsewhere may itself be the core challenge and

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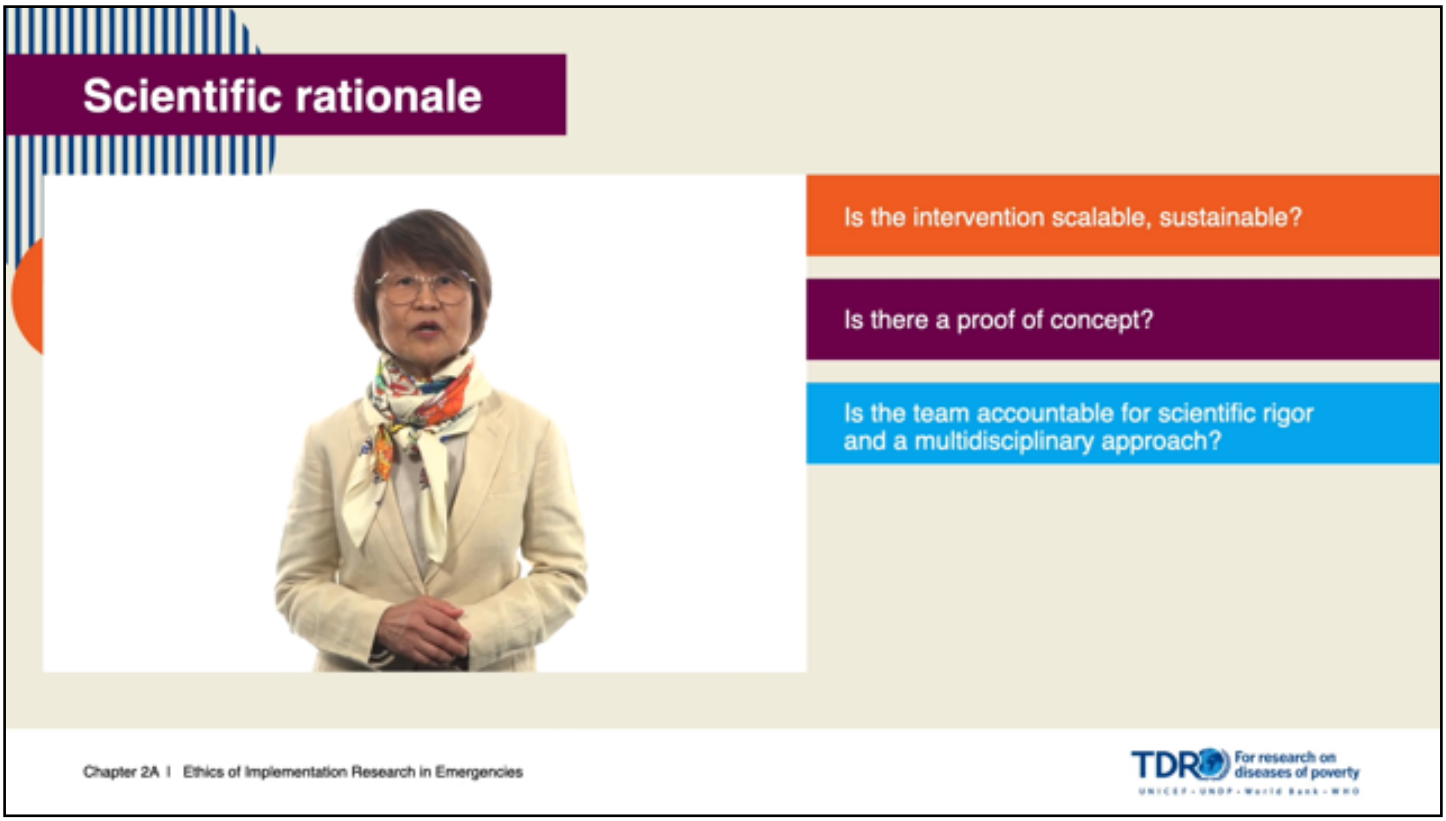


implementation research question. If the science was not done well, many resources will be invested into implementation that may not have the

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intended beneficial impact. Accountability for the scientific rigor of a project is therefore important,

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and this includes incorporating input from multiple disciplines to appropriately address implementation research questions. Identifying the right research

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1m 34s



question and determining the best scientific approach to answer the question are not enough,

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1m 46s



however. A study must be practically feasible with appropriate resources in place and acceptable to the community. This may be easier said than done in an emergency, where physically accessing communities or procuring supplies may be challenging,

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1m 52s



and where financial and human resources may be limited.

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2m 18s



Broad and transparent stakeholder engagement is therefore crucial here to identify any logistical barriers that may need to be overcome. We will discuss community engagement more thoroughly in a later chapter. An

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important justification for any research is the principle of equipoise. This means that there should be true uncertainty about whether an intervention or method is effective or not. The

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typical example we are all familiar with is a randomised clinical trial.

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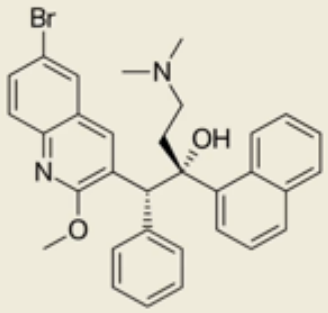
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Equipoise

True uncertainty about the effectiveness of an intervention

Clinical equipoise justifies clinical trial:



Bedaquiline, a drug against tuberculosis

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For example, bedaquiline was initially developed for

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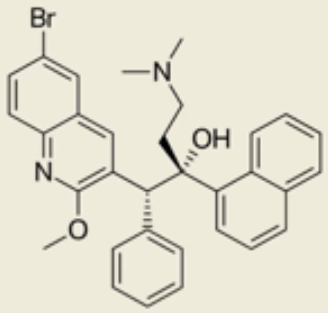
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Equipoise

True uncertainty about the effectiveness of an intervention

Clinical equipoise justifies clinical trial:

- Is bedaquiline effective against leprosy?



Bedaquiline, a drug against tuberculosis

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treating tuberculosis. However, given its properties, there was reason to believe it might be effective in treating patients with leprosy.

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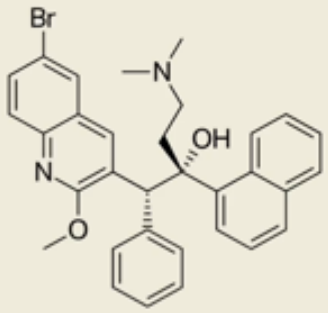
3m 25s

Equipoise

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Clinical equipoise justifies clinical trial:

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Bedaquiline, a drug against tuberculosis

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Given this hypothesis, clinical equipoise would justify a proof-of- concept clinical trial to test bedaquiline against standard leprosy therapy.

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Once the clinical effectiveness of bedaquiline is proven, there would no

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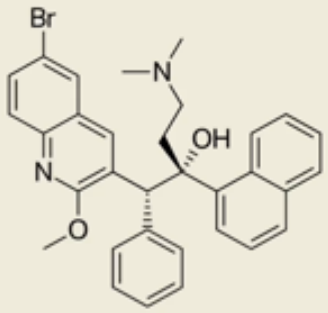
Equipoise

True uncertainty about the effectiveness of an intervention

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- Is bedaquiline effective against leprosy?
- Is bedaquiline effective against leprosy in children?

Contextual equipoise justifies implementation research:



Bedaquiline, a drug against tuberculosis

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longer be clinical equipoise to justify repeating such a study, unless there were other circumstances that may possibly impact its effectiveness or safety, such as inclusion of children. Given that

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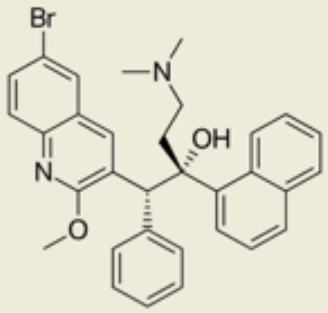
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bedaquiline is a drug that is used in multidrug-resistant tuberculosis. There

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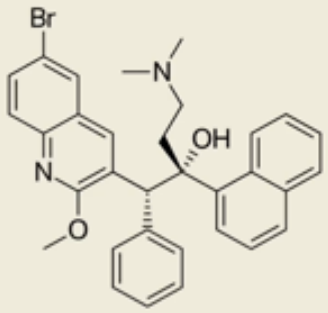
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Bedaquiline, a drug against tuberculosis

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may, for example, be stigma attached to its use in community, where MDR-TB prevalence is high and patients with leprosy might resist using

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Equipoise

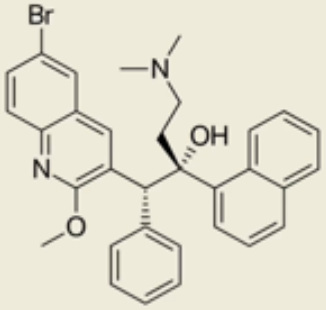
True uncertainty about the effectiveness of an intervention

Clinical equipoise justifies clinical trial:

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Contextual equipoise justifies implementation research:

- How can resistance to take bedaquiline against leprosy be overcome?



Bedaquiline, a drug against tuberculosis

it. Implementation research would therefore be required to try to understand the barriers to uptake in a community, and how this can be overcome. Such an implementation research study is justified because contextual equipoise, that is, the impact of the community's day-to-day realities, remain in this setting. A solution may turn out to be as simple

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Equipoise

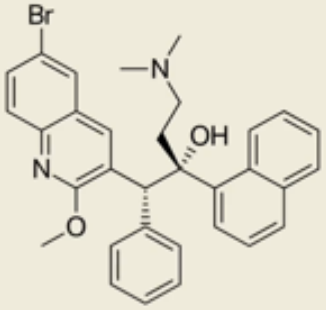
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Bedaquiline, a drug against tuberculosis

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as changing the packaging to make the medication less recognisable.

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Equipoise, therefore, is a fundamental principle which may justify investigating the

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5m 15s



potential clinical or physical effect of an intervention. In implementation research, it also is of paramount importance when

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5m 25s



considering the impact of the context and setting in which an intervention will be

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5m 37s



implemented. As we have just seen, then, if the clinical effectiveness

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of an intervention, that is proof of principle, is already known, then clinical equipoise will no longer exist. to think this through

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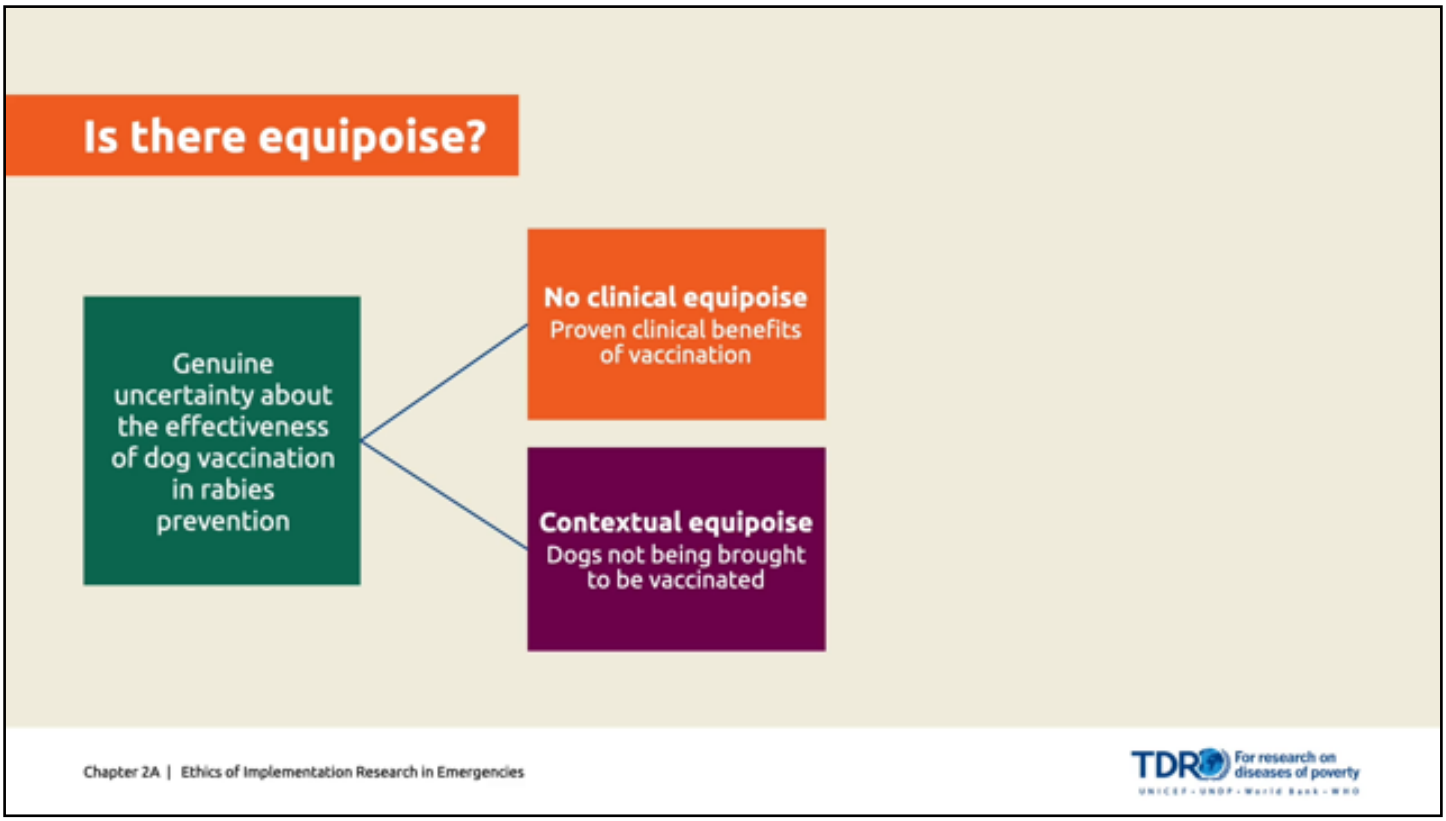


again, let us now go back to the rabies example we discussed earlier regarding the need for rabies vaccinations in humans and dogs in a refugee community in

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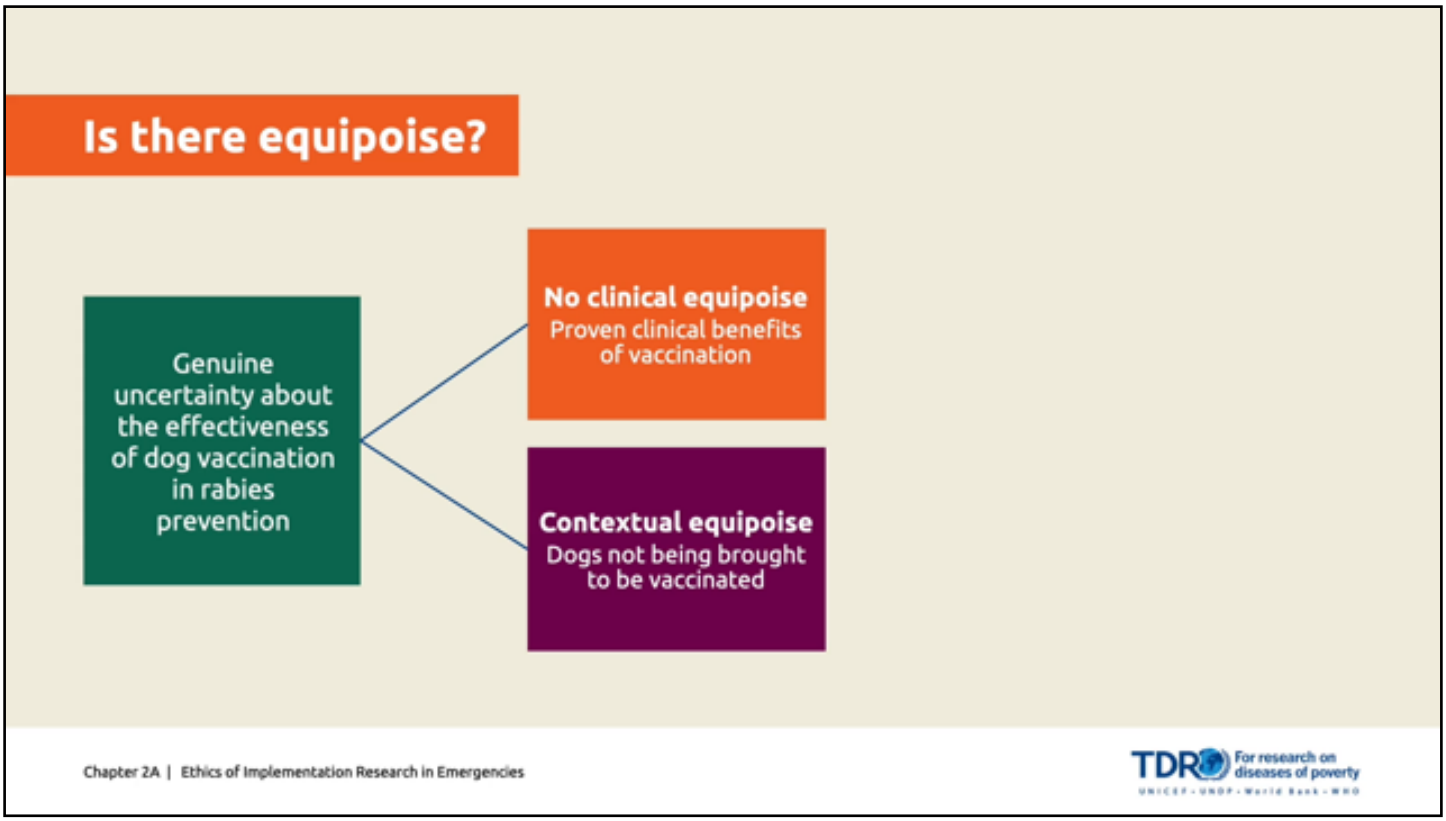


Uganda that fled the conflict in Sudan. We know that systematic dog vaccination prevents rabies transmission and is required to achieve the One Health goal of zero rabies death by 2030. Despite the seemingly

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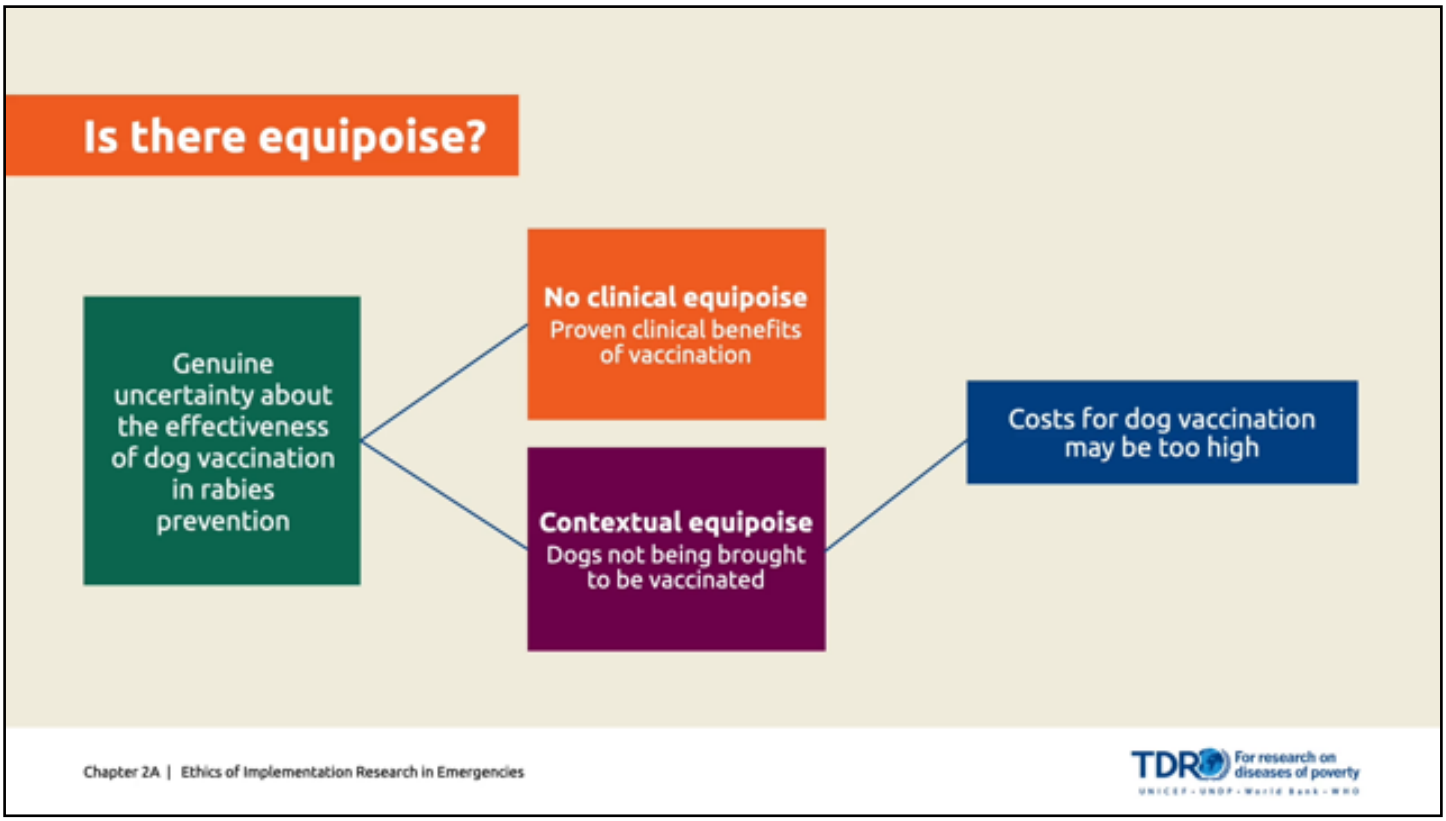


obvious benefit, dog owners in a large Sudanese refugee community in Uganda are not bringing their dogs for vaccination.

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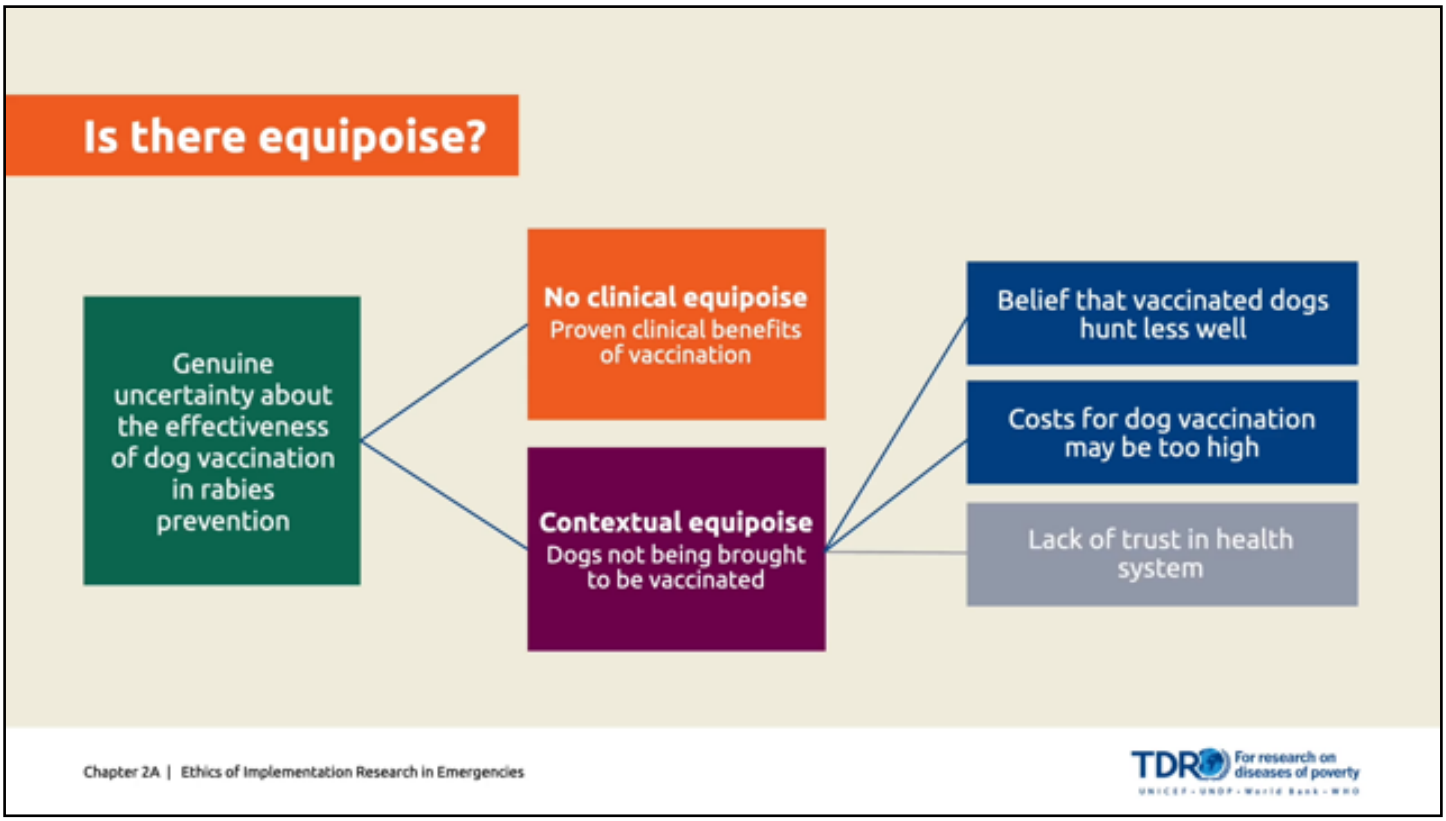


Implementation research is therefore needed to understand why the dogs are not being vaccinated. The justification for the research here would be contextual equipoise, that is, to understand the barriers within the local context that are hindering vaccine uptake. The study may

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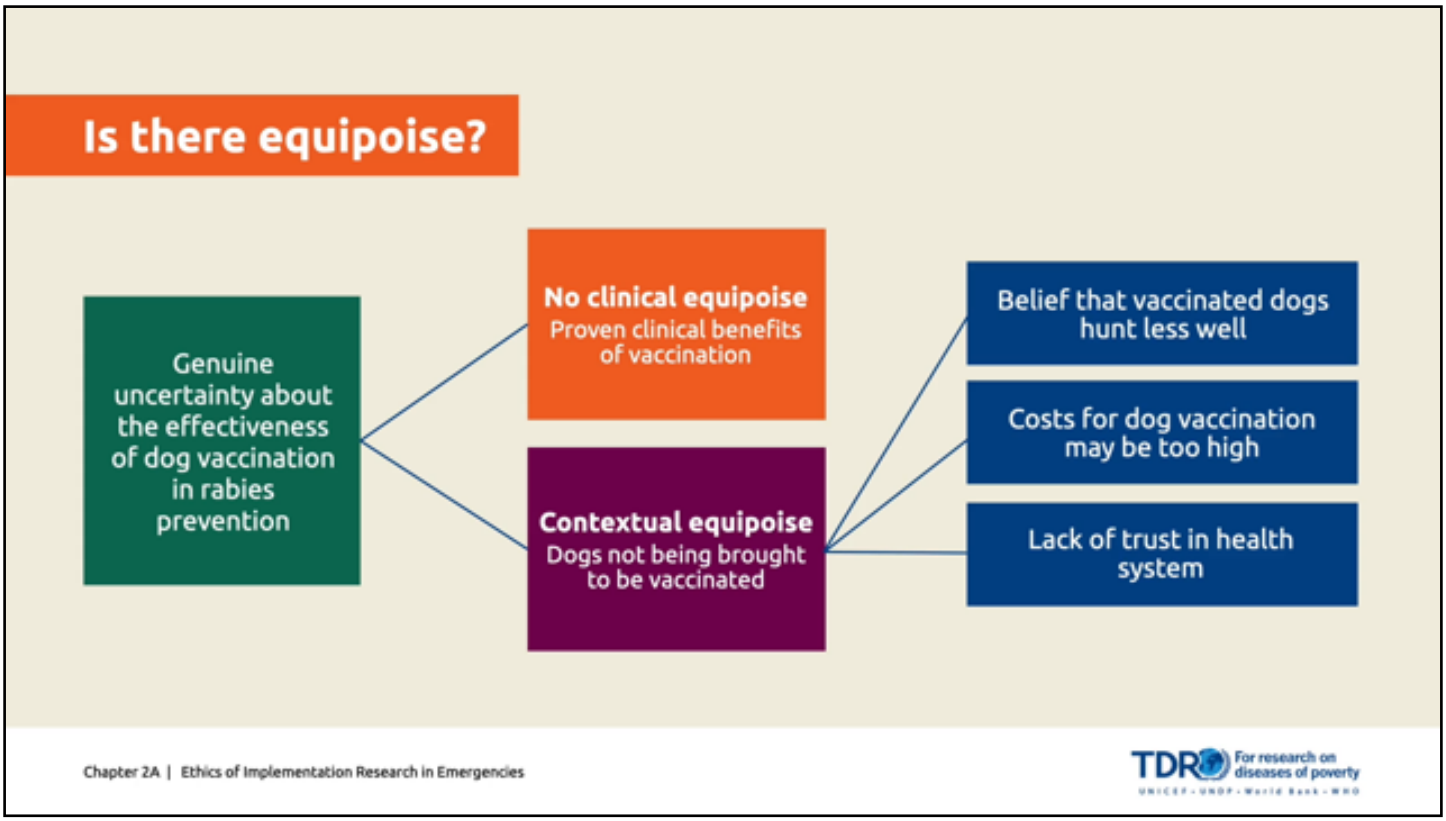


discover that the out-of-pocket costs for the vaccines are too high, or may uncover a belief that vaccinating the dogs against rabies makes them less

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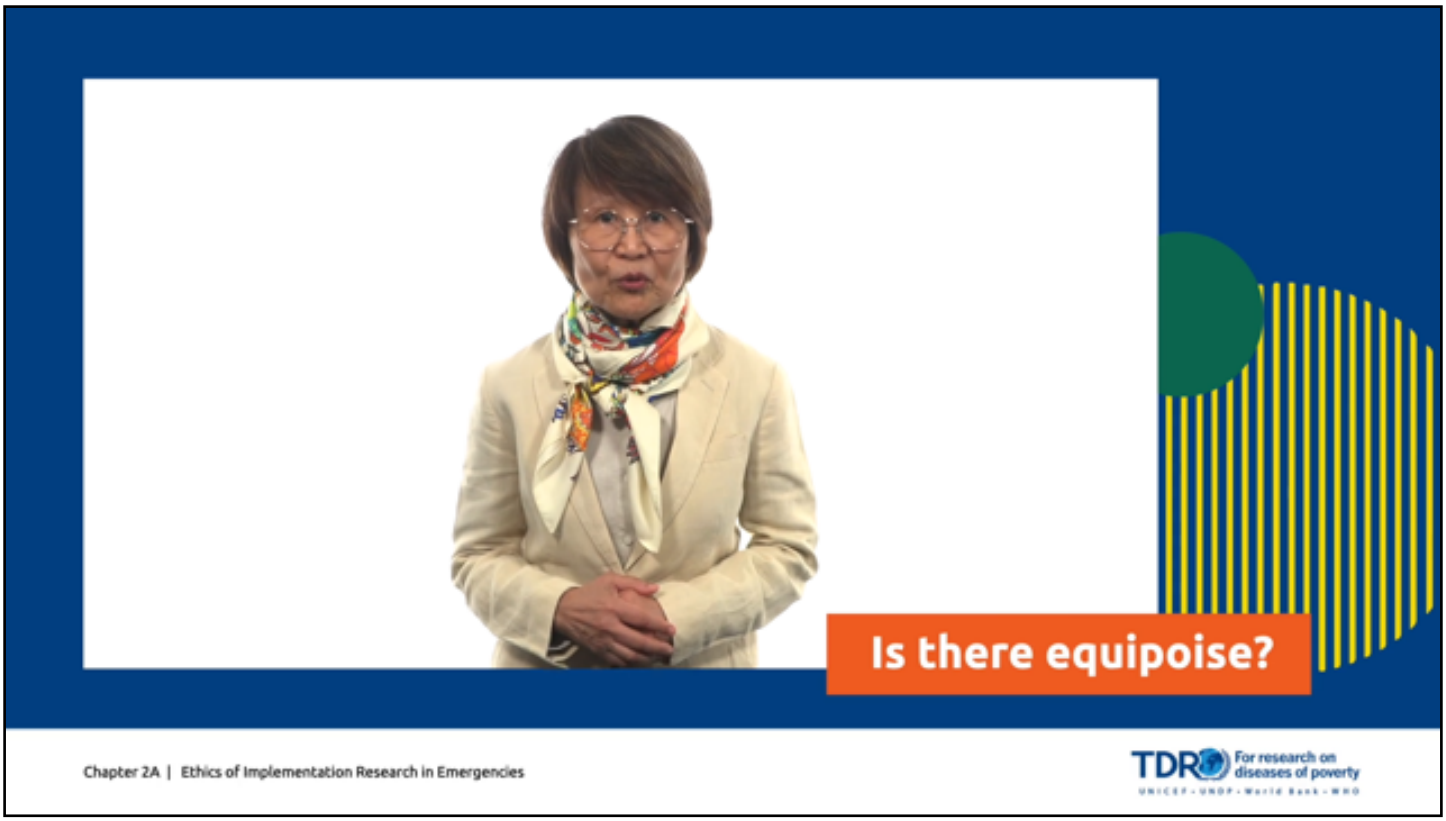


good hunters, or may simply reveal that the refugee community does

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7m 33s



not trust the health system. In an emergency context, like a refugee

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7m 40s



camp, the contextual issue may play an important role in impacting uptake of an intervention, as the displaced communities may not have prior experience within a specific health system. People may be more afraid,

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7m 49s



may cling strongly to their cultural beliefs, and there may be more misinformation and mistrust. Getting to the bottom of these factors is urgently needed,

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but requires a skilful and careful research approach based on the ethical norms of respect, transparency, solidarity and accountability.

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8m 18s



In the rabies vaccination example, open engagement with the community in a nonjudgmental manner would permit understanding of many barriers upfront and create opportunities to co-develop potential solutions to test in implementation research studies.

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