Course material

Course:

Ethics in Emergencies

Video:

10a Study overview

Concepts (extracted from automatically generated subtitles):

Example of a research study. Rapid diagnostic test. Study overview. Local hospitals. Principal investigator. Ethical issues. Number of patients. Rapid rise. Emergency room. Relevant issues. Diagnostic test. Post-research phases of implementation research. Emergency services. New rapid diagnostic test. Finger prick.



to video sequence search
(within Ethics in Emergencies.)



to video

CHAPTER 5

Ethics oversight of implementation research in emergencies

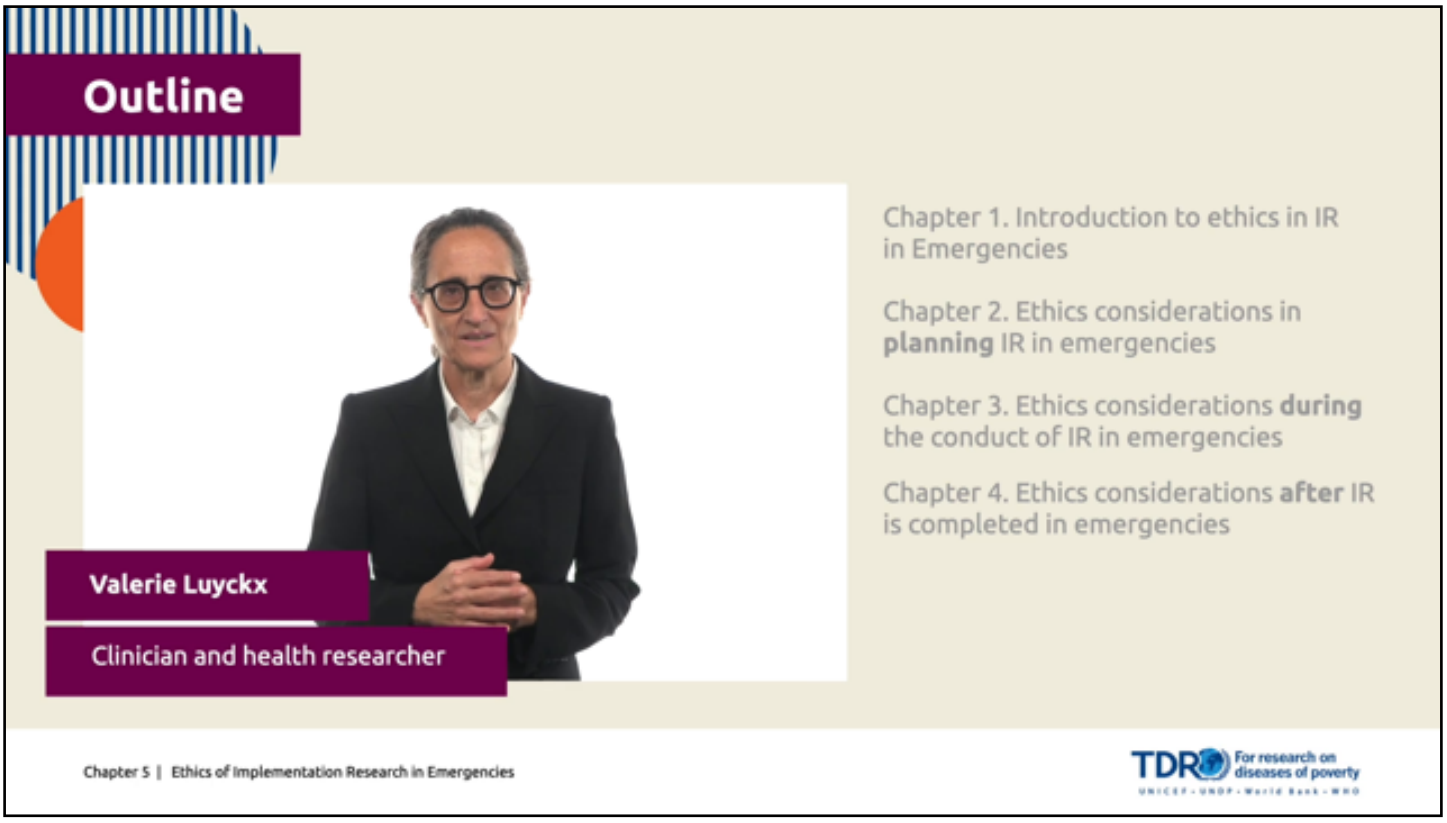
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notes

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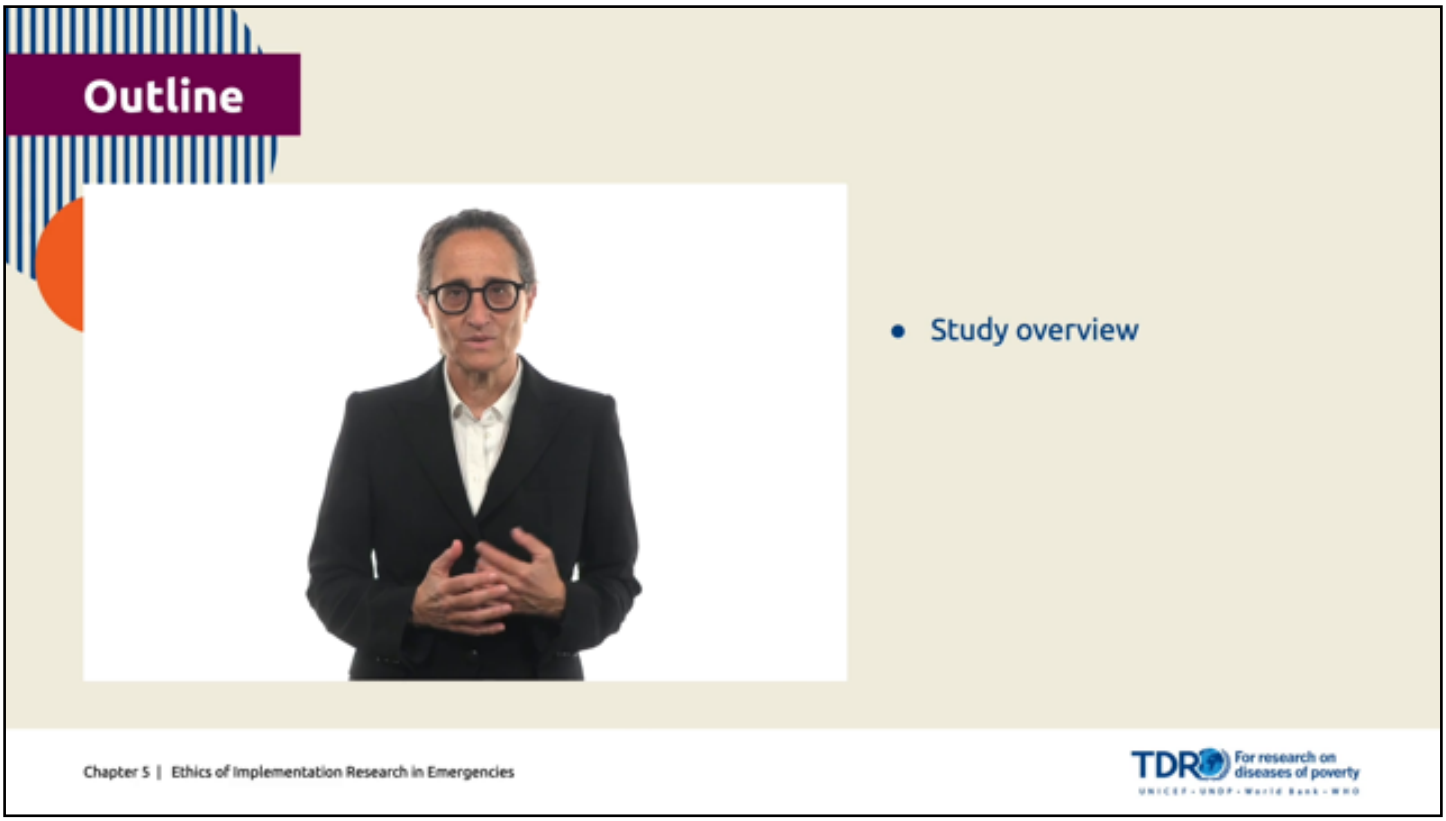


Now that we've covered the ethical issues that are relevant in terms of the planning, research

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and post-research phases of implementation research conducted in emergencies. We will now go through an example of a research study to identify the relevant issues, as if we were one of the ethics review committee members. This chapter is divided into three parts. We will start with a

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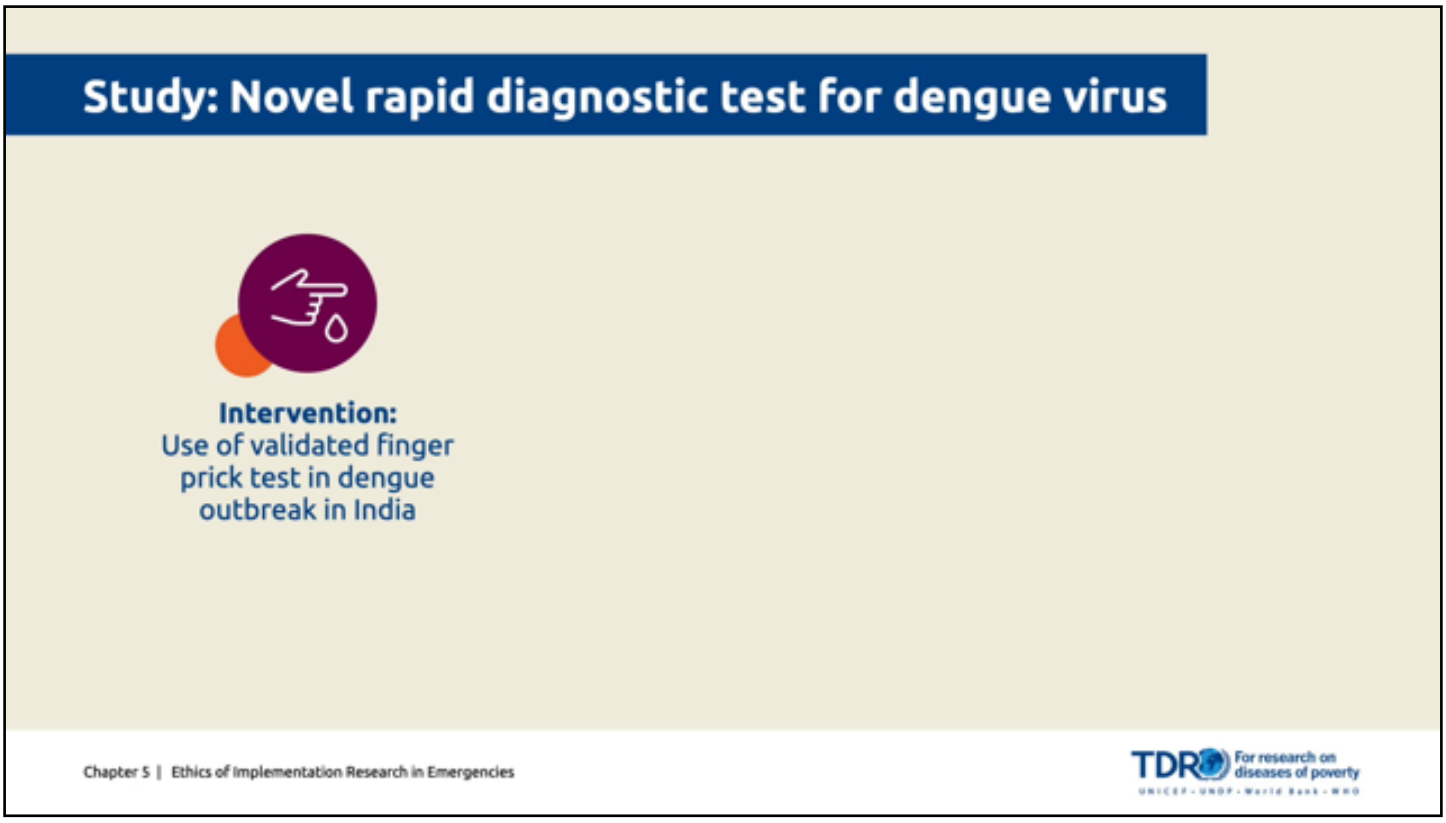


study overview, then think about your roles and responsibilities as a reviewer, and then go

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through the ethical issues relating to the protocol in some detail. An implementation

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summary

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Study: Novel rapid diagnostic test for dengue virus



Intervention:
Use of validated finger prick test in dengue outbreak in India

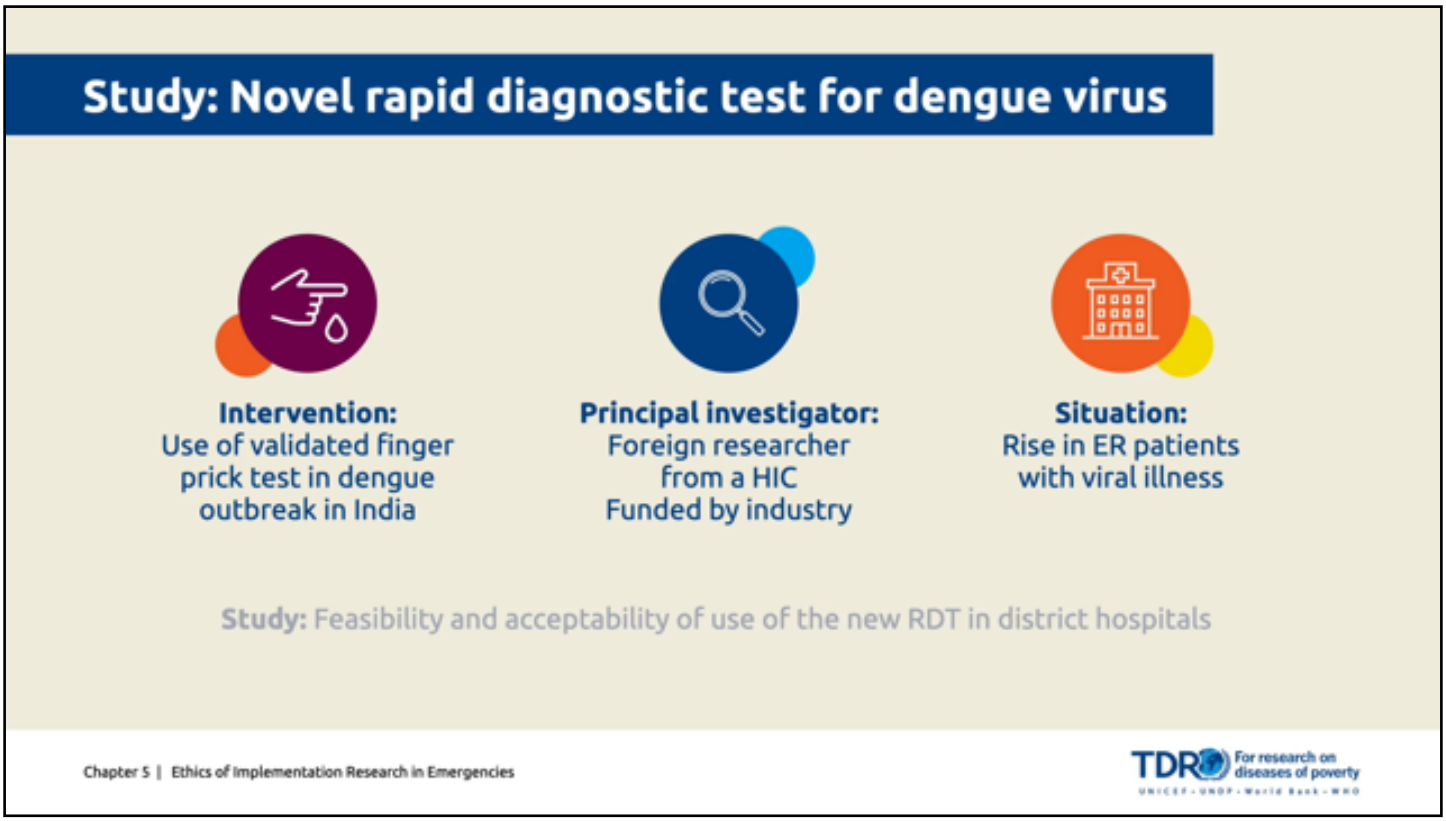
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research protocol to study a new, previously validated finger prick rapid diagnostic test for dengue, in an ongoing outbreak in a state in India, has been submitted urgently. The funders and

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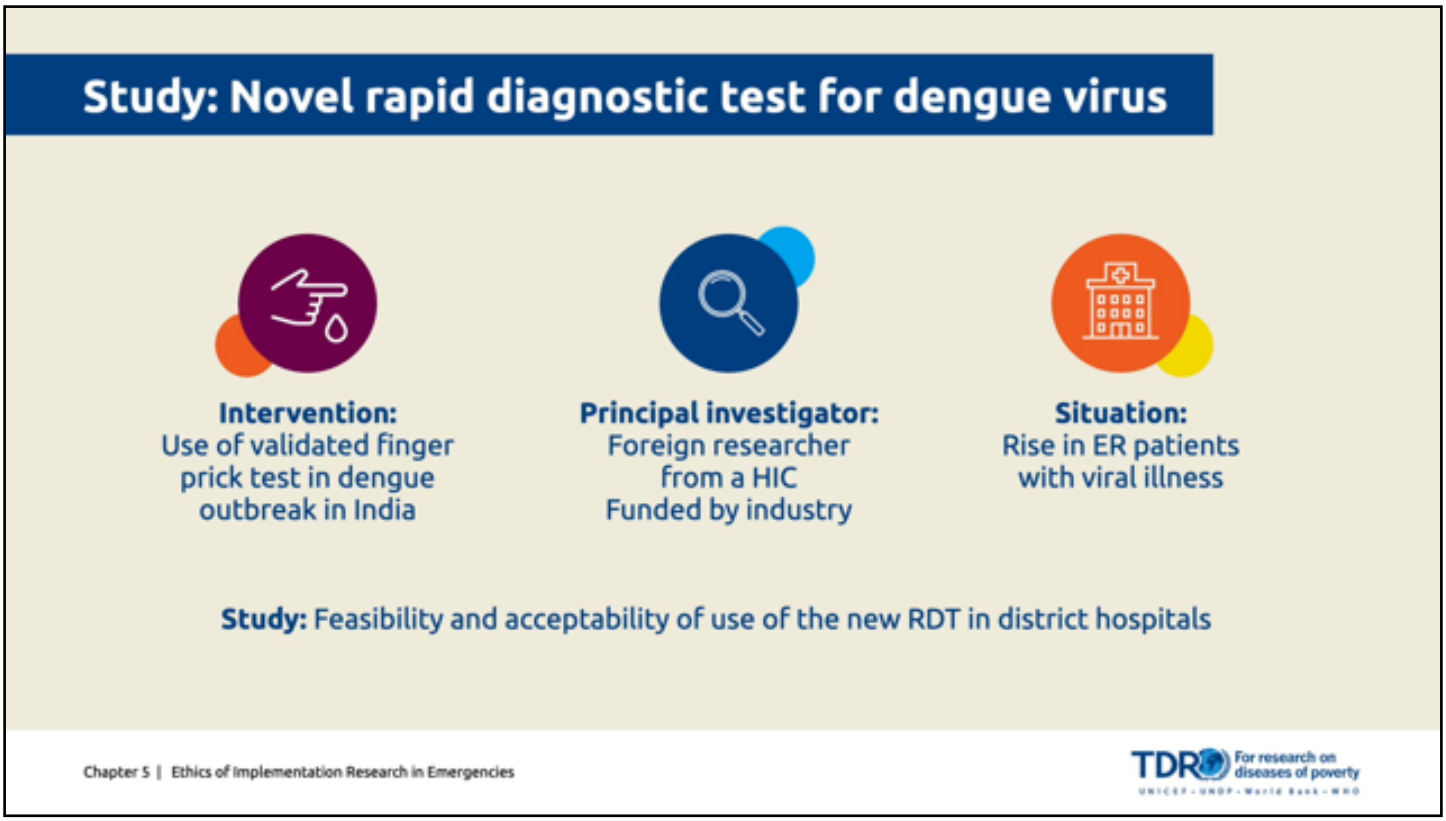


researchers are pushing to begin the study as soon as possible. The principal investigator is a foreign researcher from a high income country, and the study is being funded by a US company that develops diagnostics. In this hypothetical example, the local hospitals are seeing a rapid rise in

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the number of patients presenting to the emergency room. The study proposes to assess the

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feasibility of use and acceptability of use of the new rapid diagnostic test in several district hospitals in the outbreak region. For the purpose of this study, the diagnostic company explains that patients presenting to the emergency services with fever and a clinical syndrome

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suggestive of a viral illness will be eligible to participate. The study will be supervised in the

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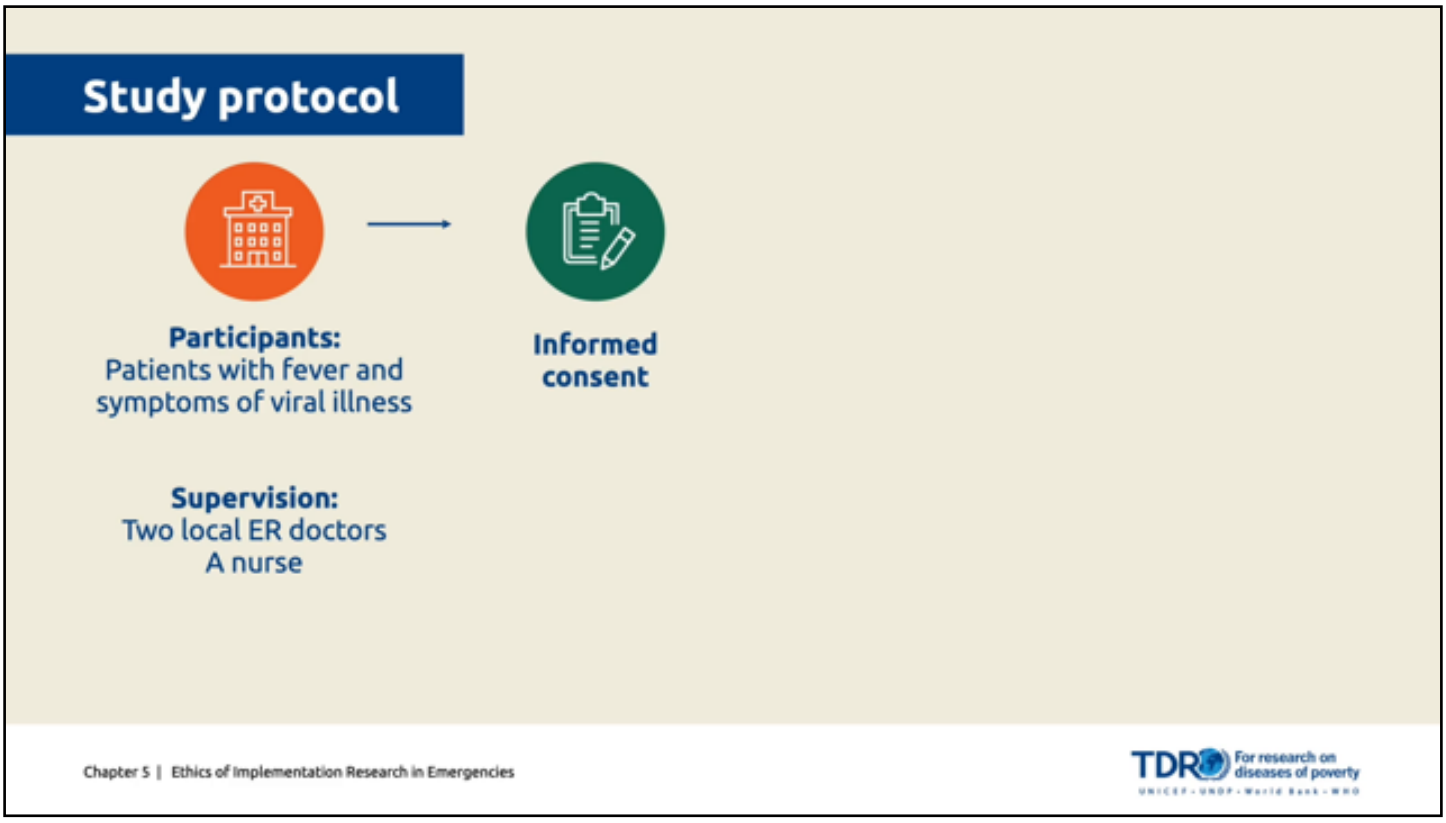


local setting by two local emergency room doctors, who cover the local hospitals, and will employ a

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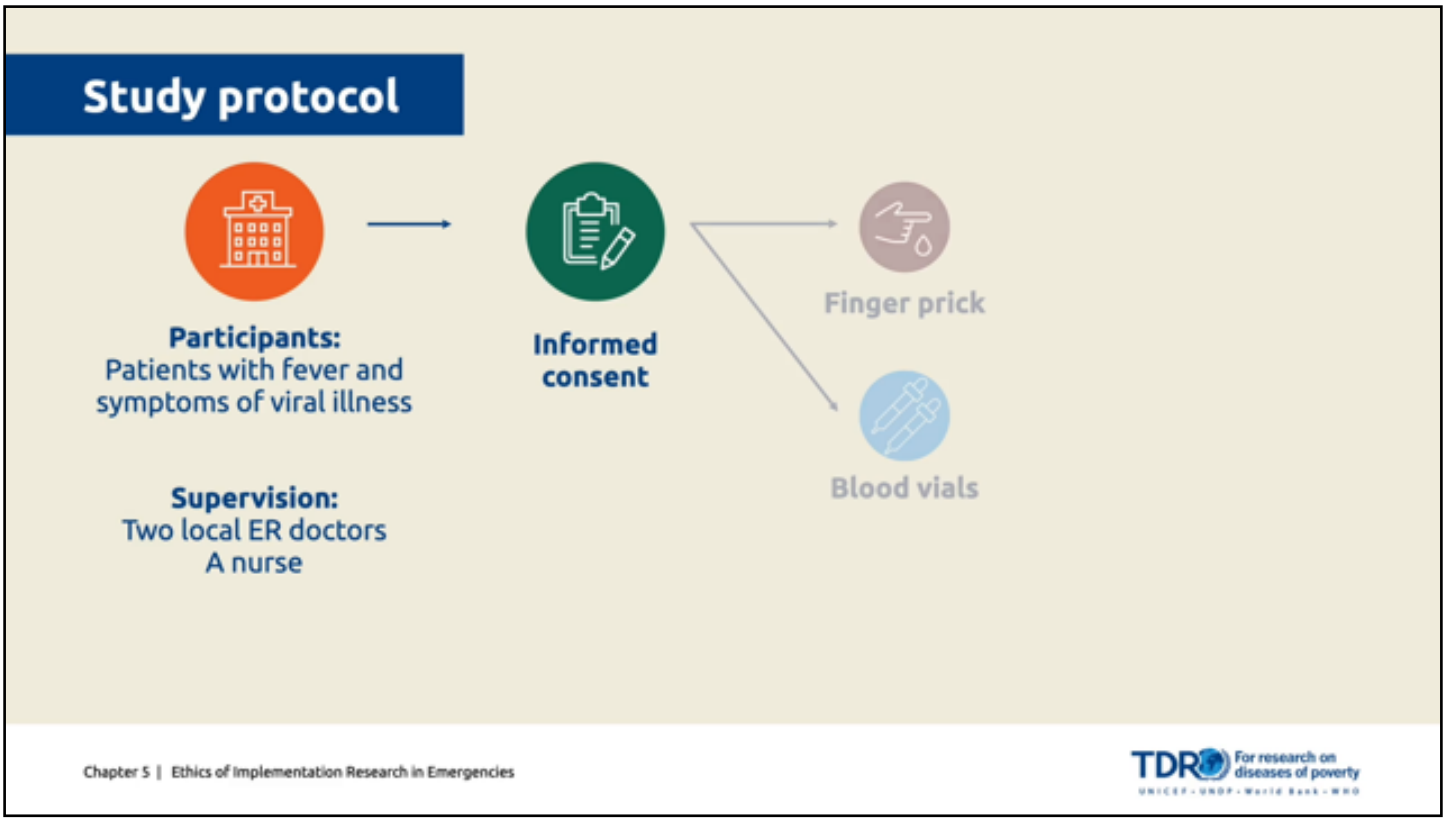


study nurse. These individuals will oversee the study and will be responsible to ensure appropriate patient enrolment and data collection by the emergency room staff. When a

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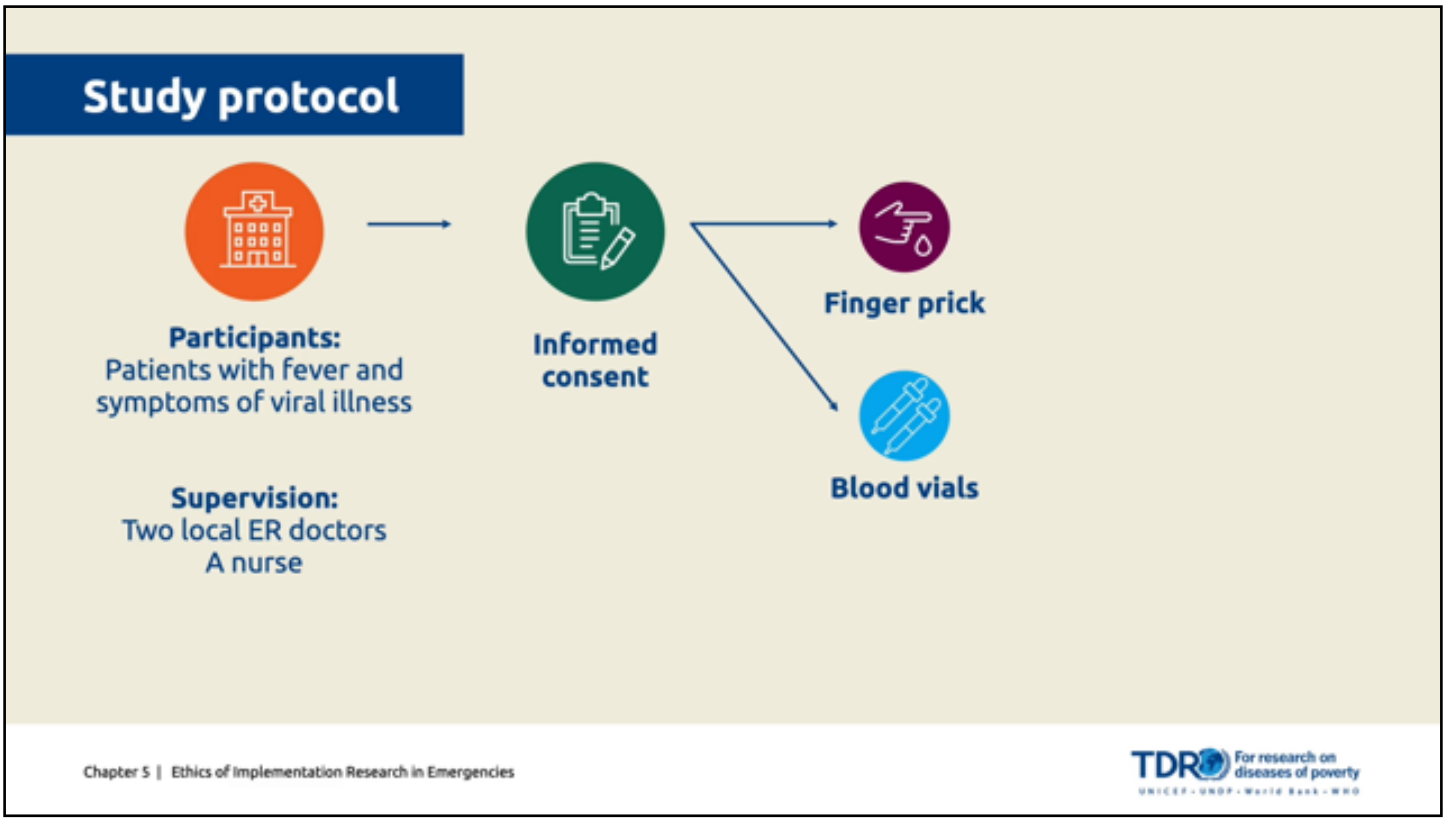


patient has been identified as eligible for the study, they will be asked by the clinician seeing

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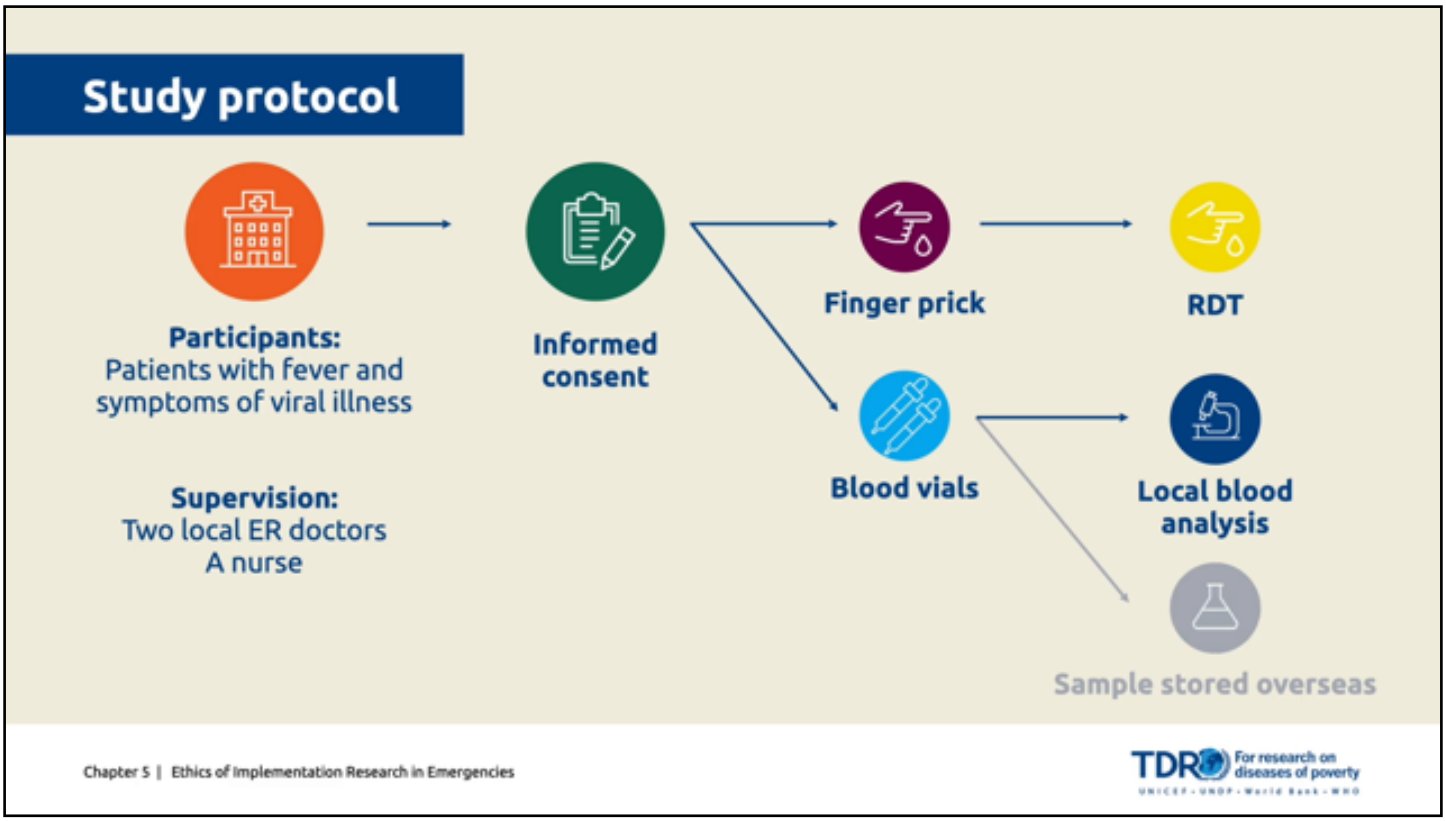


them to sign an informed consent form, after which the finger prick and two extra blood vials will

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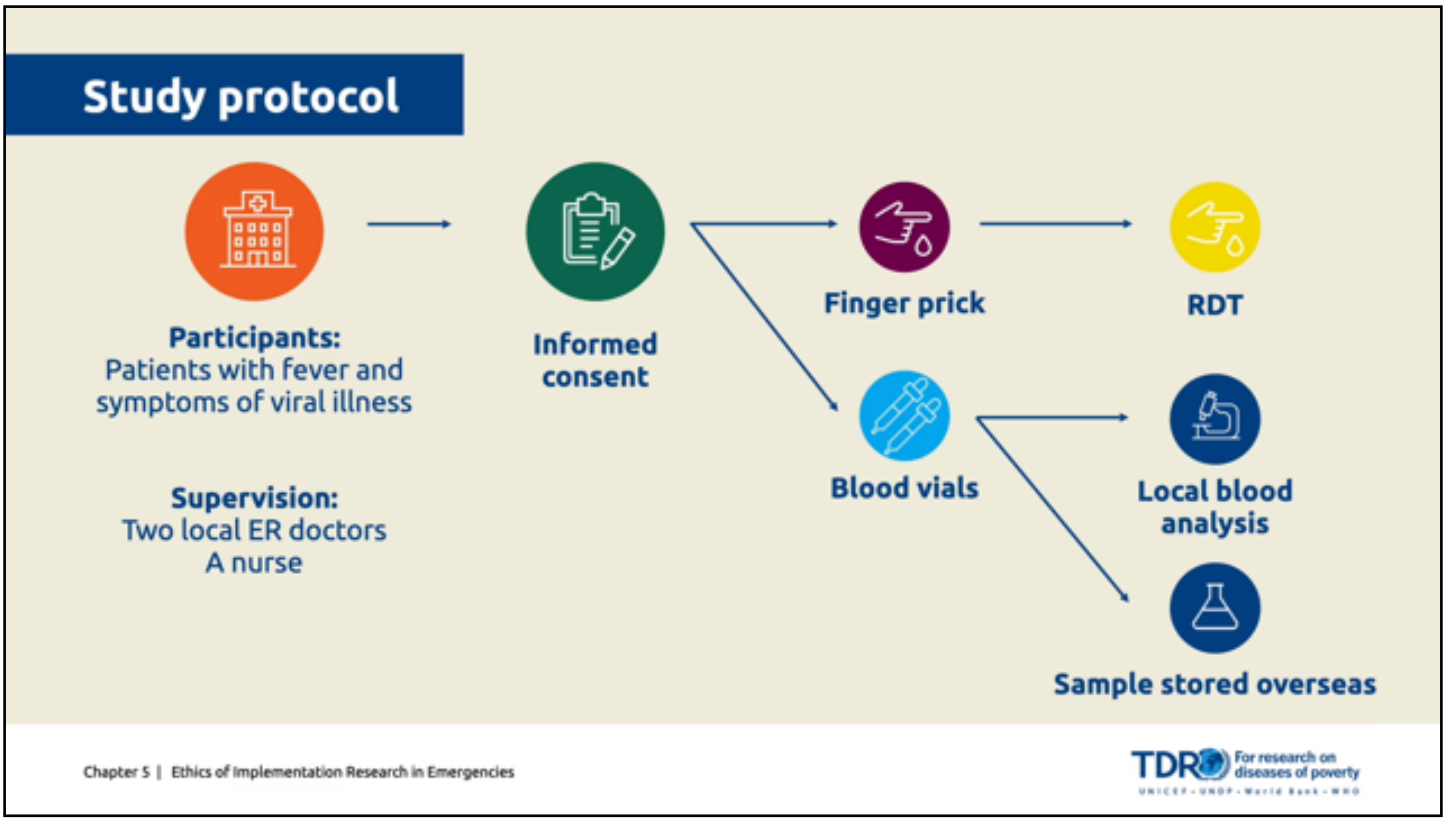


be taken. The finger prick samples will be subjected to the new rapid diagnostic test at the bedside, one of the vials of blood will be sent to the hospital laboratory for the usual dengue

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diagnostic test, and the third vial will be shipped in batches to a referral laboratory in the researchers home institution overseas, and the samples will be stored for future use. Each emergency department will have one dengue rapid diagnostic test device and a supply of test

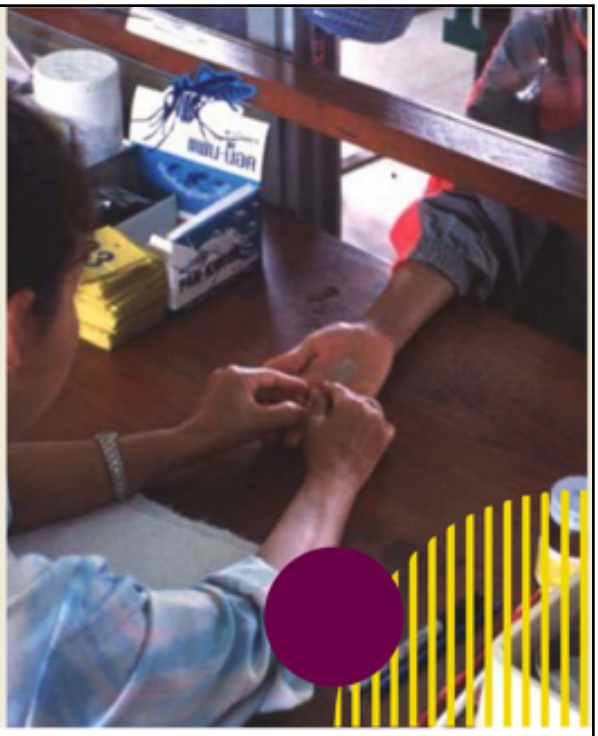
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Outcomes of the study

- Rapidity of diagnosis
- Impact on clinical workflow



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strips, which have a shelf life of one month. The main study outcome will be the rapidity with

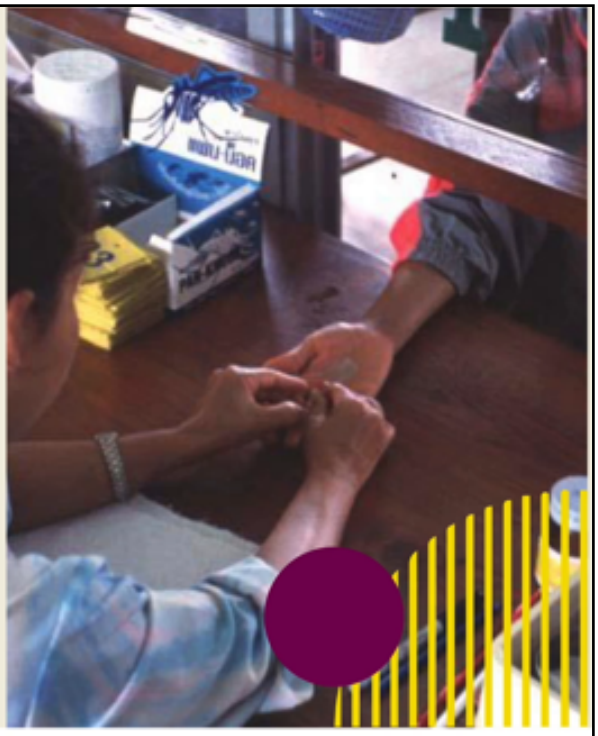
notes

summary

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Outcomes of the study

- Rapidity of diagnosis
- Impact on clinical workflow
- Experience of patients and staff



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which a diagnosis of dengue will be made or ruled out, and the impact on the clinical workflow, which is already overwhelming for the clinical staff in the emergency room. In addition, selected patients and clinical staff will be interviewed about their experience of the use of the rapid

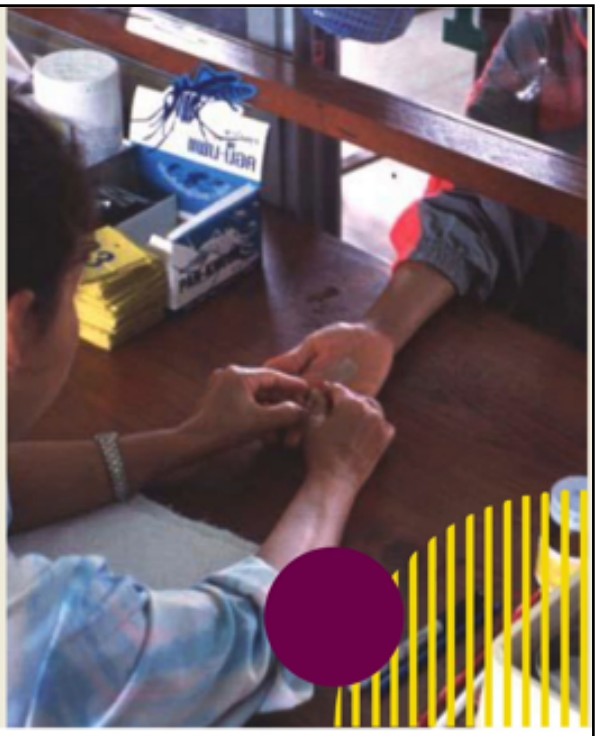
notes

summary

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Outcomes of the study

- Rapidity of diagnosis
- Impact on clinical workflow
- Experience of patients and staff
- Validity compared to laboratory tests



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diagnostic test. As a built in quality control measure to ensure appropriate processes are followed, tests are interpreted correctly, an appropriate functioning of the test device will be necessary, as it is known that this device is temperature sensitive. The validity of the rapid diagnostic test results will be determined against the standard laboratory test that was in

notes

summary

2m 50s

Outcomes of the study

- Rapidity of diagnosis
- Impact on clinical workflow
- Experience of patients and staff
- Validity compared to laboratory tests
- Impact on mortality



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place before the study began in the hospital and the overseas laboratory test. A secondary outcome

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3m 13s



will assess whether the rapid diagnostic test impacts mortality in patients with dengue on the premise that this may reduce time to diagnosis and permit more proactive early therapy. The cost and potential savings of the use of this test will also be determined.

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