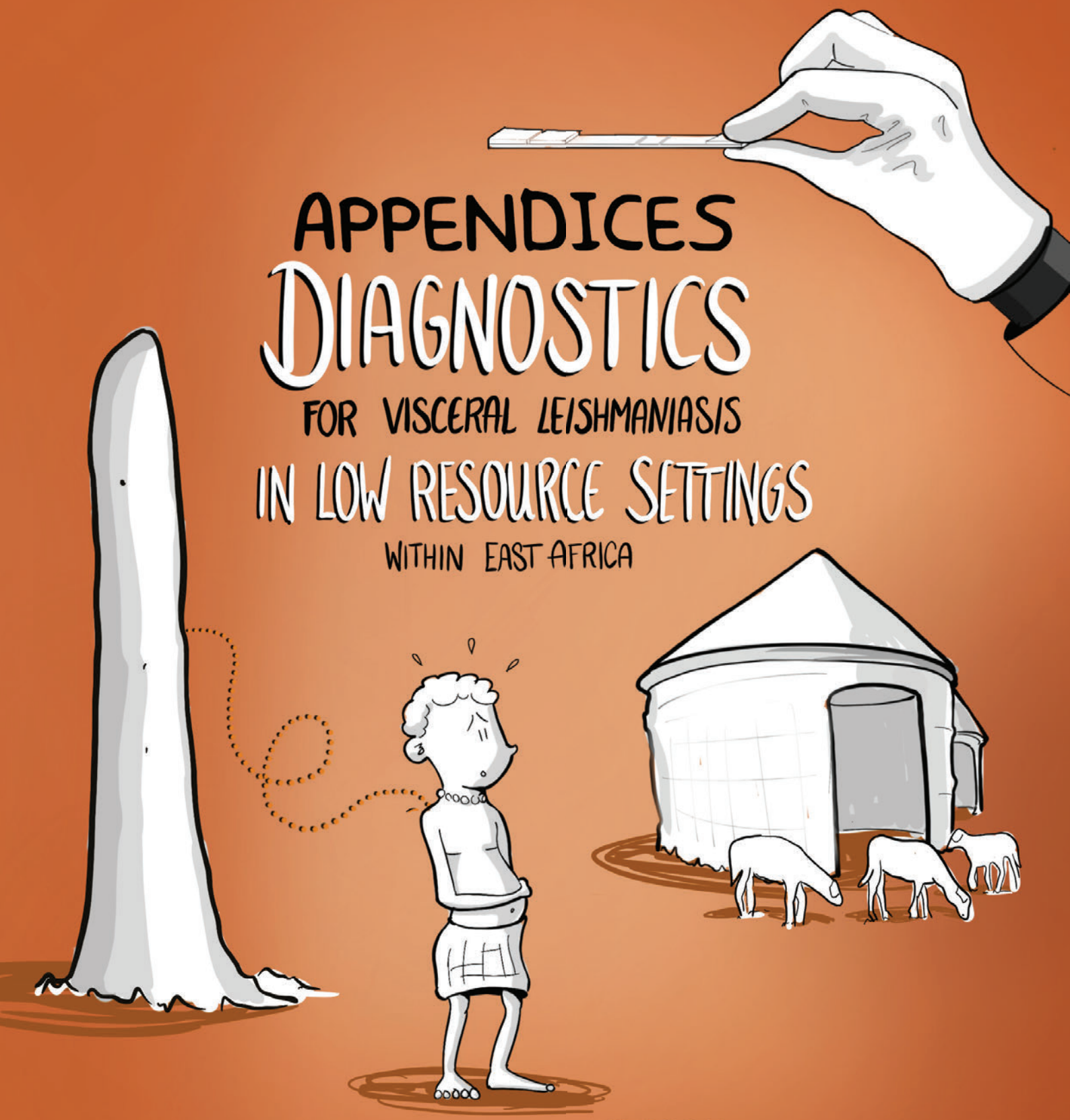
APPENDICES

DIAGNOSTICS

FOR VISCERAL LEISHMANIASIS IN LOW RESOURCE SETTINGS

WITHIN EAST AFRICA



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Appendices

This is the Appendix Report which contains supporting material of the Final Thesis.

APPENDICES THESIS

A-1
Field trip preparation

MATERIALS PREPARED PRIOR TO THE FIELD-TRIP

The field-trip preparation can be split up into 3 elements, which each help to understand the context of VL. These three elements are discussed here. and are supported with materials (FIgure 1 - 6).

1 Journeys

What is the current (diagnostic) context of VL like? What are the liminations and challenges?

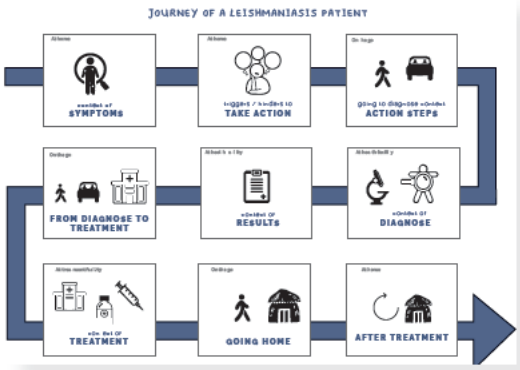


Figure 1: Interview patient journey

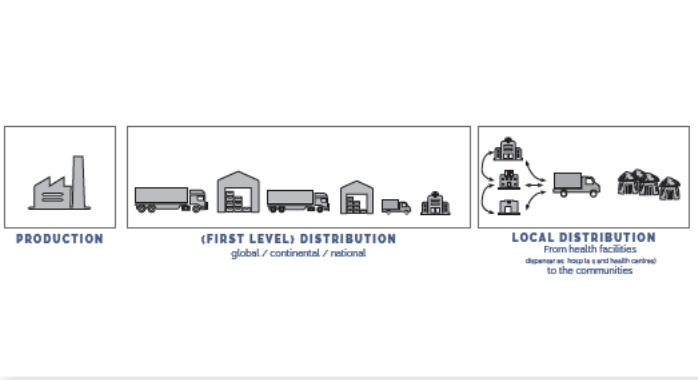


Figure 2: Interview logistics journey

2 Interviews on Access to diagnostics

What is the current (diagnostic) context of VL like? What are the liminations and challenges?

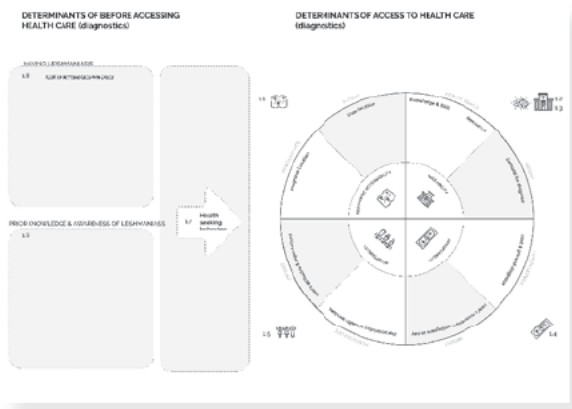


Figure 3: Framework accessing VL care.

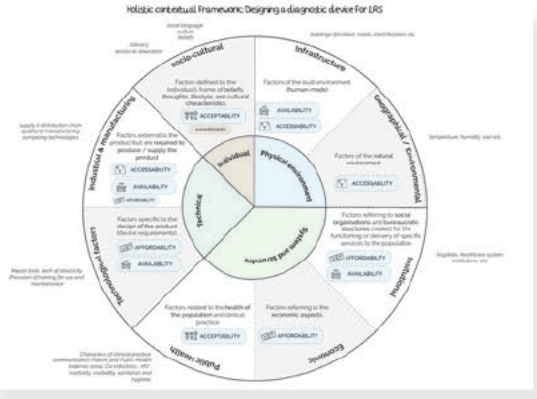
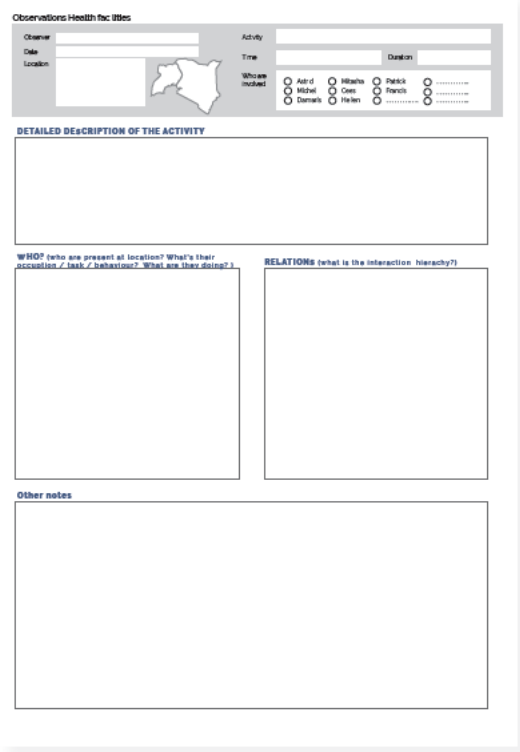


Figure 4: Holistic contextual framework.

3 Observations

What is the current (diagnostic) context of VL like?

Observations at communities and health care facilites.



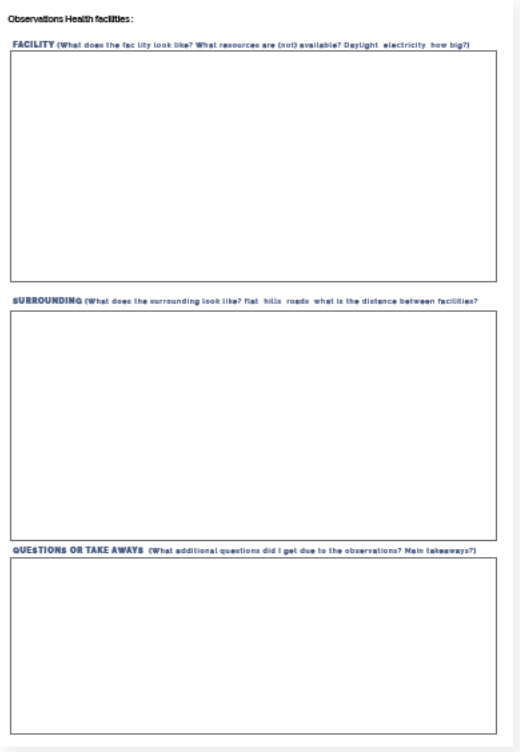
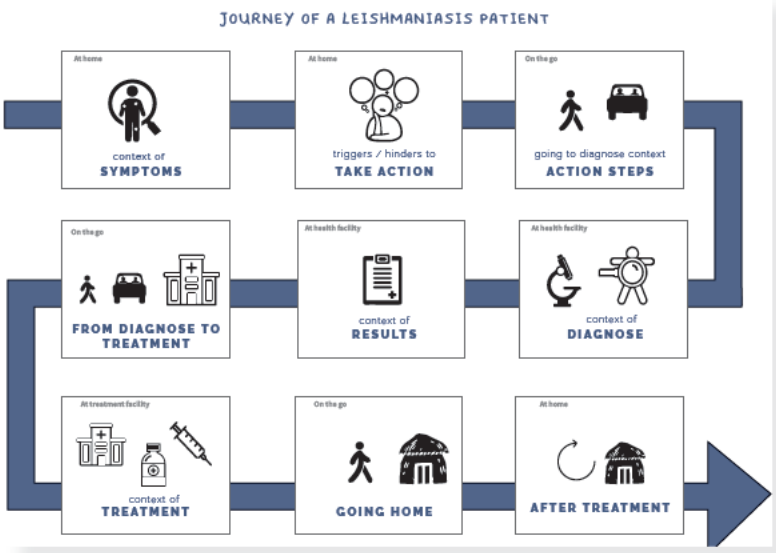


Figure 5: Observation templates.

PATIENT

1 Journey To understand the journeys of VL patients



interview preparation about patient journeys

Interview with health care expert

context of SYMPTOMS

1) What is the context of symptoms like?

a. What are the first symptoms patients have?
b. Whais the most common age / age group for people with leish?
- ◊ What's their gender?
- ◊ What is their daily living look like?

c. Are patients or their surrounding familiar with Leishmaniasis?
- ◊ Is there confusion with other diseases?
- ◊ Why?
- ◊ Is the patient aware of being sick (symptoms) or mostly the surrouding? (Especially concerning children)

d. What is the local name?

triggers / hinders to TAKE ACTION

1) What is the context of symptoms like?

a. When does a patient decide to take action?
- ◊ After how much time?
- ◊ After which symptoms?

b. What aspects influence the time it takes to take action?
c. Are there other people who are involved in considering the options and deciding to go to a health facility?
d. What are the main hinders which stop someone to go for a diagnose?
- ◊ Money
- ◊ Culture?
- ◊ Short term thinking
- ◊ Afraid of consequences
- ◊ Not beig able to work

ACTION STEPS

3) What are the action steps from home to diagnose (facility)?

a. What are the action steps someone sick needs to take to get diagnose?
b. How often does a patient ake someone with him?
c. Where can you get a diagnose?
- ◊ How do people know where to go? (information)
- ◊ How far do people have to travel?
- ◊ What are the ways of transport?

d. Do people actively seek healthcare? (why or why not?)
e. What do they do with their current obligations (work, family)?
f. What does it costs to go to diagnose location? Who pays?

context of
DIAGNOSE

At Health facility

4) What are the action steps from home to diagnose?

a. When a patients comes in, what is the first that happens?
- ◊ By whom?
- ◊ What are the most common symptoms patients present when arriving?
- ◊ What is the number of patients seen every day?

b.How is Leishmaniasis diagnoses currently done?
- ◊ Which test(s) are done? (rk39, bone)?
- ◊ What sample is used (blood, urine, tissue)
- ◊ By whom? Who is involved in diagnosing (doctor, nurse, dwb)
- ◊ WHat kind of education, skills do you need to do the tests?
- ◊ What other tests are done? (blood..)
- ◊ What are the costs and who pays?

c.Where are the main diagnose facilities?
- ◊ How may diagnostic facilities are available? and how distributed?

d. What is the average waiting time for patients to get a diagnose?
e. What information is documented from the patient?
- ◊ How is this information documented?
- ◊ Is this information shared with other health facilities?

f. How much time is spend with a patient for each diagnosis? (incl patient history, check fever, evaluate symptoms and perform test)
g. What are most challenging factors when doing diagnoses in the field?
h. Do co-infections complicate the diagnosis? How?
i. MISDIAGNOSING: How often are patients treated for Malaria while in fact they suffer from Leishmaniasis?

context of
RESULTS

At Health facility

5) What are the action steps from home to diagnose?

a. How long does the patient have to wait for results?
b. How is the result delivered?
- ◊ Who explains the result to the patient?
- ◊ How many of the patients understand the results and/or concequences?
- ◊ Are there support tools to help explain the results or procedure? (posters, flyers)
- ◊ How are next steps communicated when patient gets a postive result,

c. What is the response of patients? and surrounding
d. What happens with patient when receiving a negative result? (home? Other tests?)
e. Do patients have a say in when the treatment starts? & Are there patients who can't or don't want to be treated?
f. How are the results reported or documented!

ACTION STEPS

On the go

6) What are the action steps from diagnose to treatment?

a. How does the patient go to the treatment facility?
- ◊ What is the distance to the treatment facility?
- ◊ How to get there?
- ◊ Who pays for the transport?

b. Who pays for the treatment?
c. Is there a waiting time?
- ◊ How long is the waiting time?
- ◊ What do the patients do in the meantime?
- ◊ Why is there a waiting time?

Case:
Sub-county Hospital in CHemolingot
Diagnose but not treatment

Patients have to go to Kimalel Health centre (70 km).

TREATMENT

At treatment facility

7) What is the context of treatment?

a. What are the treatment facilities like?
- ◊ How does it look?
- ◊ What resources are available?
- ◊ Which experts are available?
- ◊ Where are the treatment facilities?

b. What's the procedure when the patient gets in?
c. What is the treatment process like?
- ◊ How long does it take?
- ◊ How painful for patient?
- ◊ Does patient have contact with family?
- ◊ How much hours staff?
- ◊ How much does it cost?

After treatment
ACTION STEPS

On the go — Being home

Relapse?

8) What are the action steps after treatment (to go home)?

a. When is the treatment sucessful?
- ◊ How many of the treatments are successful?

b. How is their physical wellbeing after treatment?
- ◊ Can they walk?
- ◊ Can they go home by themselves?

c. How do people go home?

d. Is it necessary to schedule a (new) check-up?
e. Are patients more aware of Leish now?
- ◊ Is there education about the symptoms so they are able to recognize it in an earlier stage?
- ◊ Will they recognize symptoms of people around them?
- ◊ Will they ducate their surrounding or at least make their surrounding aware of Leishmanaisis?

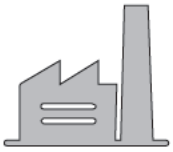
DISTRIBUTION

1 Journey understanding the current distribution chain

interview preparation about distribution of diagnostic tests.

Interview about logistics of RDT's and medicines

context of PRODUCTION



1. What is the context of production of medicines and RDT's like?

- Where are RDT's for African use produced?
- Where are medicines for African use produced?

context of DISTRIBUTION

2. What does the distribution chain of medicines and RDTs look like?

- What are the distribution stages which are passed? (what vehicle, where to?)
  - ◊ How much time does it take to get the medicines or RDTs from production to point-of-care?
- Where do medicines and RDT's enter the country?
  - ◊ What needs to be checked before products can enter the country?
  - ◊ Regulations?
- Where are the medicines / RDTs stored?
- How do the storage facilities look like?
- When are they transported to a next facility?
- Do different organisations (government, private care, NGO's), make use of the same distribution channel of medicines? Or do they have their own channel and medicines?

- Some medicines or test need to be kept cool (below 30). How are these medicines kept cool?

context of

LOCAL DISTRIBUTION
(from hospital to community)

3. What does the local distribution chain look like?

- How do medicines get transported between health centres and dispensa ies in the county or region?
  - ◊ What kind of vehicle?
  - ◊ How often?
  - ◊ Between which facilities?
  - ◊ Where are they stored in the facilities?
- What happends when there is a short of medicines or RDT's in a health facility?
  - ◊ How is this short of medicines communicated?
  - ◊ To whom is it communicated?
  - ◊ How quick can a new order be placed?
  - ◊ Who is responsible or takes responsibi ity?
  - ◊ How often are medicines or RDT's unavailable at the moment of need (care)?
- Do poor roads influence the time it takes for medicines to get to a faci ity?
  - ◊ How long does it take to reach communities?
  - ◊ Where are medicines stored in the rural ares?
  - ◊ How are they stored?
- Do different organisations (government, private care, NGO's), make use of the same distribution channel of medicines? Or do they have their own channel for medicines?

context of

STORAGE

4. What is the context of Storage of medicines and RDT's?

- What are the main storage faci ities?
- What is a storage faci ity ike in a rural area?
  - ◊ Where are they located?
  - ◊ How big are these storage faci ities?
  - ◊ How many RDT's are usually stored at these faci ities?
  - ◊ What is the temperature of the storage spaces?
  - ◊ How often are they checked on expiration date?
- Are all medicines stored at some point or can they be transported straight to the point-of-care?
- Is there a (accurate) database of where medicines and RDT's are stored or how many are in stock?
- What happens when things are out of stock?
- How do people in communities know if there are available medicines?

2 Interviews on Access to diagnostics

Method: interviewing Time: Who:	Need: • Interview questionnaire • Access templates • Pen & paper • Camera • Voice recorder

GEOGRAPHIC ACCESSIBILITY

The physical distance or travel time from the diagnosis facility (health facility) to the patient.

SQ1.1: What is the current geographic accessibility to diagnostics for Leishmaniasis?

- What is the average distance (km) between a community (patient's habitat) and a health facility (to diagnose)
- What makes it difficult for patients to get to a health facility (to get a diagnosis)?
  - Poor infrastructure:
    - How does the climate influence the accessibility for the people to go to a health facility?
  - Road quality: How does road quality / transportation / owning a vehicle / distance influence the geographic accessibility?
  - To what extend does lack of transportation make it more difficult for patients to get to health facilities?
- In what way do the distances have influence on health seeking behavior of patient?

- How do health care workers or community health workers reach these remote areas of the communities?
  - What kind of transportation do they use?
  - How much time does it take?
  - How often do they go?
  - How do they know they have to go? (regular basis or do they get information when they are needed?)

- How are medicines or equipment needed at the health facility transported here?
  - Is it difficult to get medicines or tools to the facilities ? Why?
  - How long does it usually take to distribute medicines to these facilities?
  - Who are involved in the distribution of medicines and RDT's?
  - Does the climate (rain) influence the delivery of medicines to the health facility?
  - What are the main requirements that medicines have to meet to be distributed in the supply chain?
  - What are the pitfalls of the current system?

- Does the remoteness of the area influence the number of health care workers?

AVAILABILITY

Having the right type of care available to those who need it that meet demands of those who would use care, as well as having the appropriate type of service providers and materials.

SQ1.2: What is the current availability of resources to diagnose Leishmaniasis?

- What are the current facilities (health centers, hospitals, clinics) in this region where patients can get a diagnose of Leishmaniasis?
- Which of these facilities get the most patients?
  - Why do they get most patients?
- Do patients know there are multiple facilities in the region?
- Do people choose for a specific facility (health care center or hospital) or do they just go to the closest one?
- What tools are the available in *Kimalel Health Centre / Chemolingot Sub-County Hospital / Amudat Hospital /* ..... to diagnose Leishmaniasis?
  - How do they do tests for VL at these facilities?
  - Microscopes, Lab
  - Does it happen that tools are unavailable at the facilities (they are out of stock or broken)?
  - What happens then?
- What tools are available outside of the health centers or hospitals?
  - Do community health workers have tools or medicines they bring along when visiting the communities?

SQ1.3: What is the current availability of knowledge and skills to diagnose the disease?

- Who carry out the diagnoses of Leishmaniasis?
  - Is this always the same person or does it differ?
  - Who are allowed to carry out diagnoses?

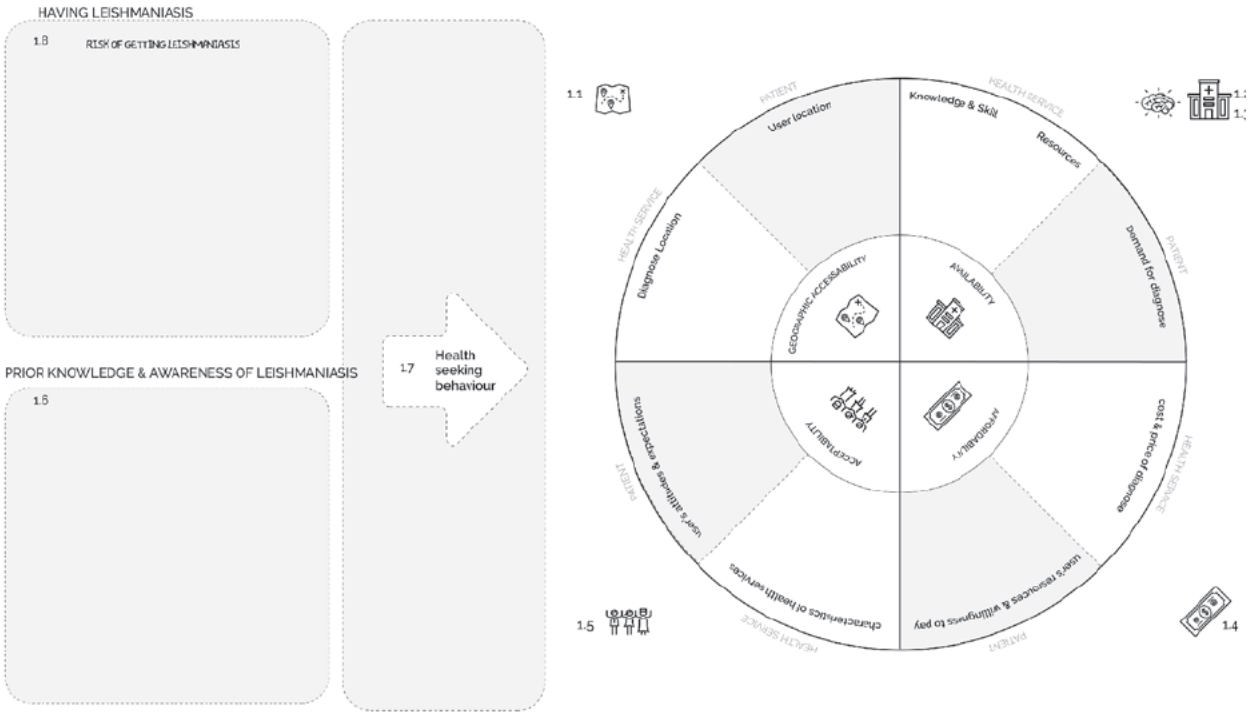


Figure 6: Access to diagnostics framework

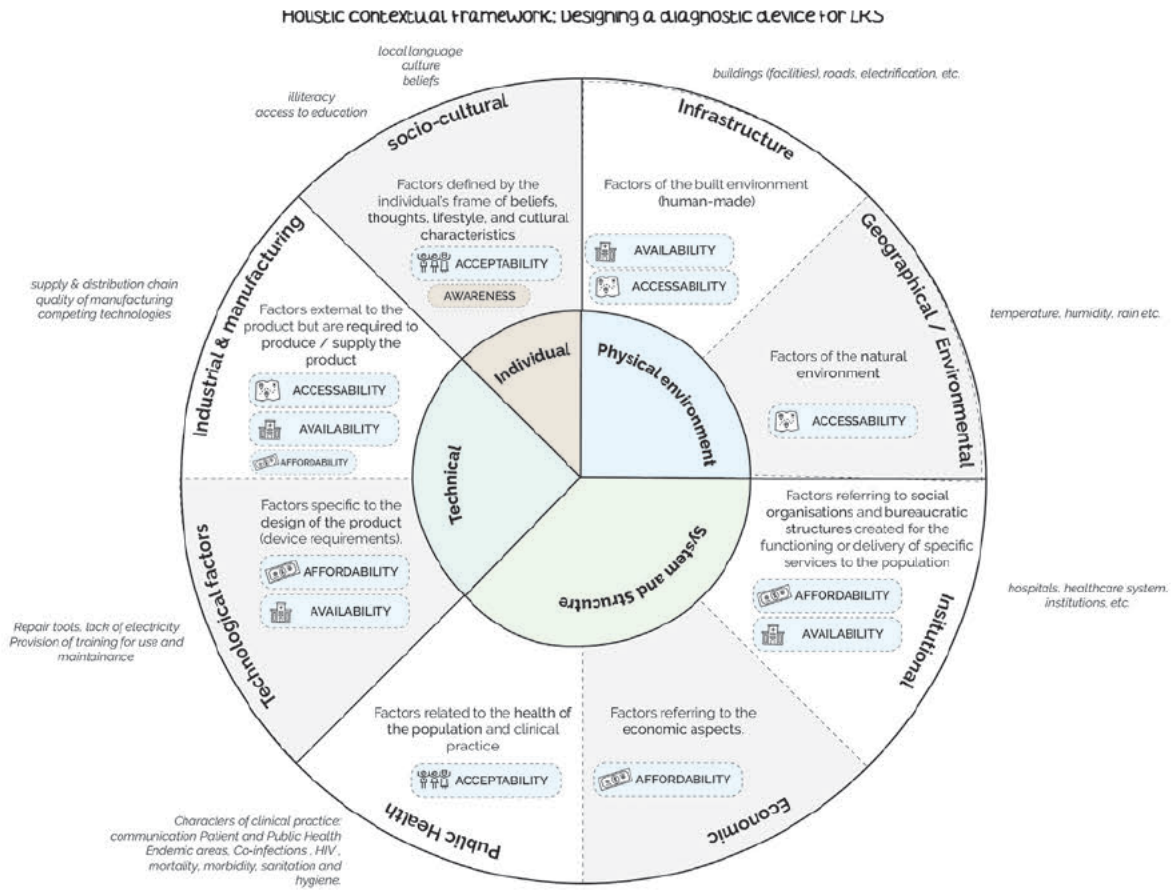


Figure 7: Holistic contextual framework

- How? Which tools are used?

- Did these _____*(people who diagnose)* have an education or training to carry out diagnoses?
- Is there sufficient staff at _____ **health facility** to meet the demand (number of patients and urge?)

Awareness:

- What do *doctors / healthcare workers (nurses) / Community health workers* know about the disease Leishmaniasis?
  - Are there people who don't know about the disease?
- How do patients perceive doctors, health care workers (nurses), community health workers?
  - Do patients trust a doctor/ nurse / community health worker?
- Do *health facilities* make estimations of the demand (number of patients and urge?)
  - Do they collect data / process data to estimate the number of patients (outbreaks)?
  - Why (not)?
  - Does this (lack of) estimation result in out of stock of/sufficient diagnostic tests or medicines?

AFFORDABILITY

The relationship between the price of health services and the willingness and ability of users to pay for those services

SQ1.4: What is the current affordability of diagnosing the disease?

- Who pays for the diagnosis? (patients, hospital, government, non-governmental organization?)
  - What % do patients have to pay the diagnosis / treatment?
- How much does it cost to get a diagnosis (in hospital, clinic)?
  - How is this price established? / build up?
  - Is there a difference in price between health facilities?
- Who are involved in determining the costs of the diagnosis?

- When a patient seeks help, are they aware of the price (they need to pay) of diagnosis and treatment *before they go to the facility / when they are at the health facility?*
- Are patients willing to pay this?
  - Why (not)? (The urge? The age of patient? Costs? Trust in treatment or diagnosis?)
  - Do previous experiences (positive or negative) with health care influence the willingness to pay for diagnosis?
- What happens if they cannot pay it (when at the facility?) (at home?)?
- Besides paying for the diagnosis / treatment, are their other expenses patients have to make to get a diagnosis (For example transportation costs or work they cannot do in the meantime)
- How often is money a hinder for patients to seek care (diagnosis)?

ACCEPTABILITY

The match between how responsive health service providers are to the social and cultural expectations of individual users and communities.

SQ1.5: What is the current acceptability of the disease and diagnostics?

- Do you know what kind of expectations patients have when going to a health facility for a diagnose?
  - No -> Do you think they have expectations before they go? For example about who do they expect they will speak to? Who will treat them?
  - What disease do they expect they have?
- What attitude do people in communities have towards health (care) and diagnostics?
  - Do they trust it?
  - Do they like or dislike it? / are they positive or sceptical?
  - Do people in communities seek care from a traditional healer?
    - What is the role of a traditional healer in the community?
    - Who do they trust more: a traditional healer or doctors or nurses at a health center?
- Do patients trust the result of a diagnose test? // Do you trust malaria tests?
- Who do patients trust most when getting a diagnosis: a doctor / nurse/ healthcare worker
  - What is the social status of doctors, healthcare workers, community volunteers?
- Do traditions or culture have an influence on acceptability of health care?

- Do the health facilities meet the expectations of patients?
- What are current health facilities like? (*Observations*)
- What are the procedures (JOURNEY) ?

AWARENESS

**PEOPLE* = Doctors, nurses, health care workers, community health workers, people in communities (patients)*

SQ1.6: What is the current level of awareness of Leishmaniasis?

- Are **PEOPLE** aware of Leishmaniasis? Do they know the disease?
- How did **PEOPLE** get aware of Leishmaniasis? (information, documents, education, experience)
- Are **PEOPLE** familiar with the how people can get leishmaniasis?
- Are **PEOPLE** more familiar with Malaria than with Leishmaniasis? (or Schistosomiasis)
- Are **PEOPLE** aware of the symptoms?
- Are **PEOPLE** aware of the course / fatality of Leishmaniasis?
- Is there confusion of symptoms between Leishmaniasis and other diseases?
  - Which disease do they often confuse it with?
  - Does this result in wrong diagnose or treatment?

SQ1.7: What are the most important influencers/hinders for health seeking behavior of patients towards diagnostics?

- What are the main hinders why people who are sick do not go to a doctor or hospital (or go for a diagnosis)
  - What do patients consider before they decide to get (or not get) a diagnosis?
  - *(Money,time, distance, family)*
  - Is this different for sick children compared to sick adults?
- How does the culture influence these considerations?
  - Would they go to a traditional healer first? (why (not)?)
  - Are they pro-public health or con?
- How sick are patients usually when they decide they need care (diagnose and treatment)?
- Is the government or public health doing something to improve the health seeking behavior of people in these remote areas (low resource settings)
  - What are they currently doing to improve the health seeking behavior of people in remote areas?

SQ1.8: What factors influence the risk of getting Leishmaniasis?

- What factors increase the risk of getting Leishmaniasis?
    - Living conditions -> How?
    - Occupation or daily activities? How?
    - Co-infections (HIV, Malaria) How ?
    - Age?
- Are people in communities aware of the increased risk?
- Who has most risk to get Leishmaniasis?

RAPID DIAGNOSTIC TESTS

SQ1.9: What are pains and gains from currently used RDT's?

- Are Rapid Diagnostic tests (FE malaria or rK39) currently used by community health workers in communities / in the field?
    - Which ones?
    - Is there a follow-up test after the RDT to confirm? Why (not)?
- Who are using these RDT's (CHW's, MSF, Red cross, health facilities)?
- Are people who are sick diagnosing themselves to test if they have malaria?
    - Why or why not?
    - What is the risk with people (without medical background) diagnosing themselves?
- At what levels (of health care) / facilities are these RDT's used?
- What are the advantages of such tests?
- What are the disadvantages of such tests?
- What do you think of RDT's?
    - Do you know how to use it?
    - What do you think about the instructions?
    - Packaging?
    - The amount of elements needed to do the test? / Usability?
- How often are misinterpretations of test results occurring with Rk39 or Malaria RDT's?

SQ1.0: What is the current situation of Leishmaniasis?

- How many cases of Leishmaniasis?
- What is the impact of Leishmaniasis on the patient?
- What can be done to reduce the impact?
- What is currently done to reduce this impact?
- What are the current activities done to reduce spread of disease, vector control et cetera?

What are the levels of health facilities in areas:?

3 Observations

An observation template was used in the field trip. This tempate facilitated making quick notes immediately after the visit (See Figure 8).

Observations at:	Need:
• Communities • Hospital facilities • Health centres • Landscape	• Observation templates • Charged Camera (+SD's) • Tripod? • Pen & Paper & clipboard (Post-its) • Mobile phone

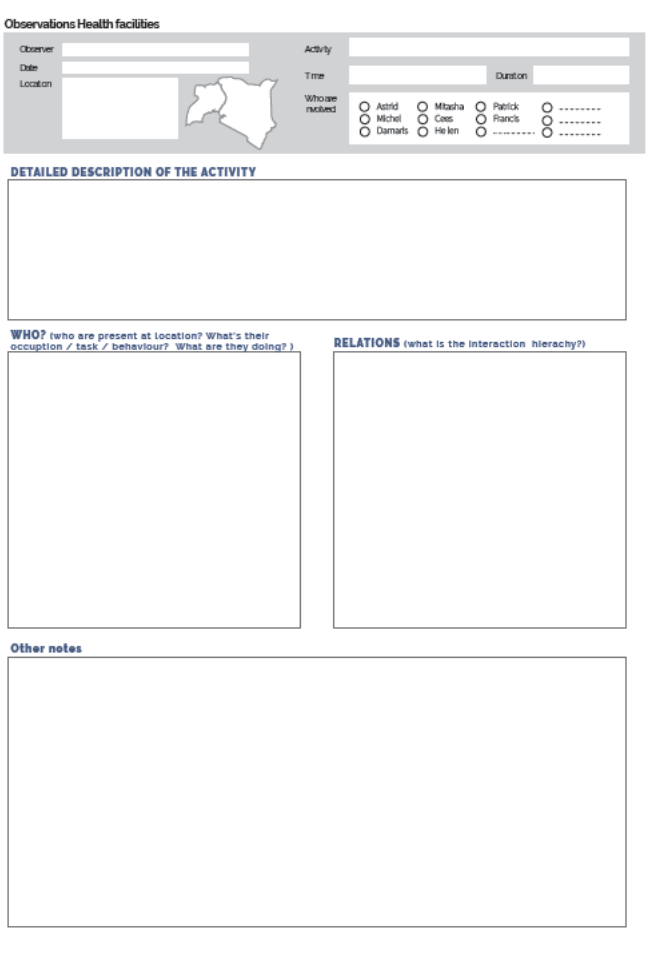


Figure 8: Observation templates.

A-2
Field trip itinerary

TWO WEEKS IN THE FIELD

A 2-week field trip is done to Kenya and Uganda. The field-trip took place between the 19th of November and 1st of December. (See Figure 9).
From the two weeks, 10 days were spend in the field, visiting several organisations and health care facilities.

Itinerary and locations visited

1. **Day 01, Nov 19th**

   Day star University, Nairobi.
   Key informant : Dr. Martha Kiarie.

2. **Day 02, Nov 20th**

   KEMRI, Nairobi.
   Key informants: Dr. Joseph Wangombe, Dr. Daniel Masiga and Ms. Hellen Nyakundi.

3. **Day 03, Nov 21st**

   Rift valley resort, Kabernet
   Key informants: Johnstone Ingonga, Biochemist (technician) and Anyona, (student) KEMRI, Nairobi

   Baringo county health administration, Kabernet
   Key informants: Moses Mulamba (County-PHO), Leah Cherutich (County-Health promotion), Salinah Labatt (County-Reproductive HO), Samuel Ruto (County-Community Health services), Zachariah Kimwetich (County-In-charge special program)

   Kimalel Health center, Kimalel
   Key informants: Dr. Abass Ali, Med. Superintendent since 2016 and Ms. Mercy, Lab Technician.

4. **Day 04, Nov 22nd**

   Chemolingot Health center, Chemolingot
   Key informants: Dr. Kipasang Marichi (Med. Superintendent), Samali Joel, (sub-county clinical officer) and Mr. Elijah Plilan (PHO sub-county community strategy) and Ms. Jane, CHV.

5. **Day 06, Nov 24th**

   Mbale Resort Hotel, Mbale, Uganda
   Key informant: Dr. Patrick Sagaki, in-charge of Amudat hospital, Uganda

6. **Day 08, Nov 26th**

   Amudat Hospital, Uganda
   Key informants: Dr. Andrew (on-site physician), Dr. Lorenz (trials physician), Ms. Jane (lab Technician) and Mr. Francisco Masaai, Trainee CHW.

7. **Day 09, Nov 27th**

   Rupa, Health center II
   Key informants: Mr. Korobe Fontiano, Lab technician, Rupa H C II, Ms. Sara and Ms. Martha (mid wives)

   Sub-county administration, Rupa.
   Key informant: Mr. Godfrey Lotuk, the sub-county chief

8. **Day 10, Nov 28th**

   Kacheliba Kala azar Treatment center, West Pokot, Kenya
   Key informants: Dr. Jane Mbui, Centre For Clinical Research, KEMRI and Dr. Mark Riongota, Clinician Kacheliba Sub-District Hospital

Figure 9: The route through Kenya and Uganda during the field trip.

Figure 10: The team which went to the low resource settings in Kenya.

A-3
Field trip notes

FILLED OUT TEMPLATES AND INSIGHTS GATHERED

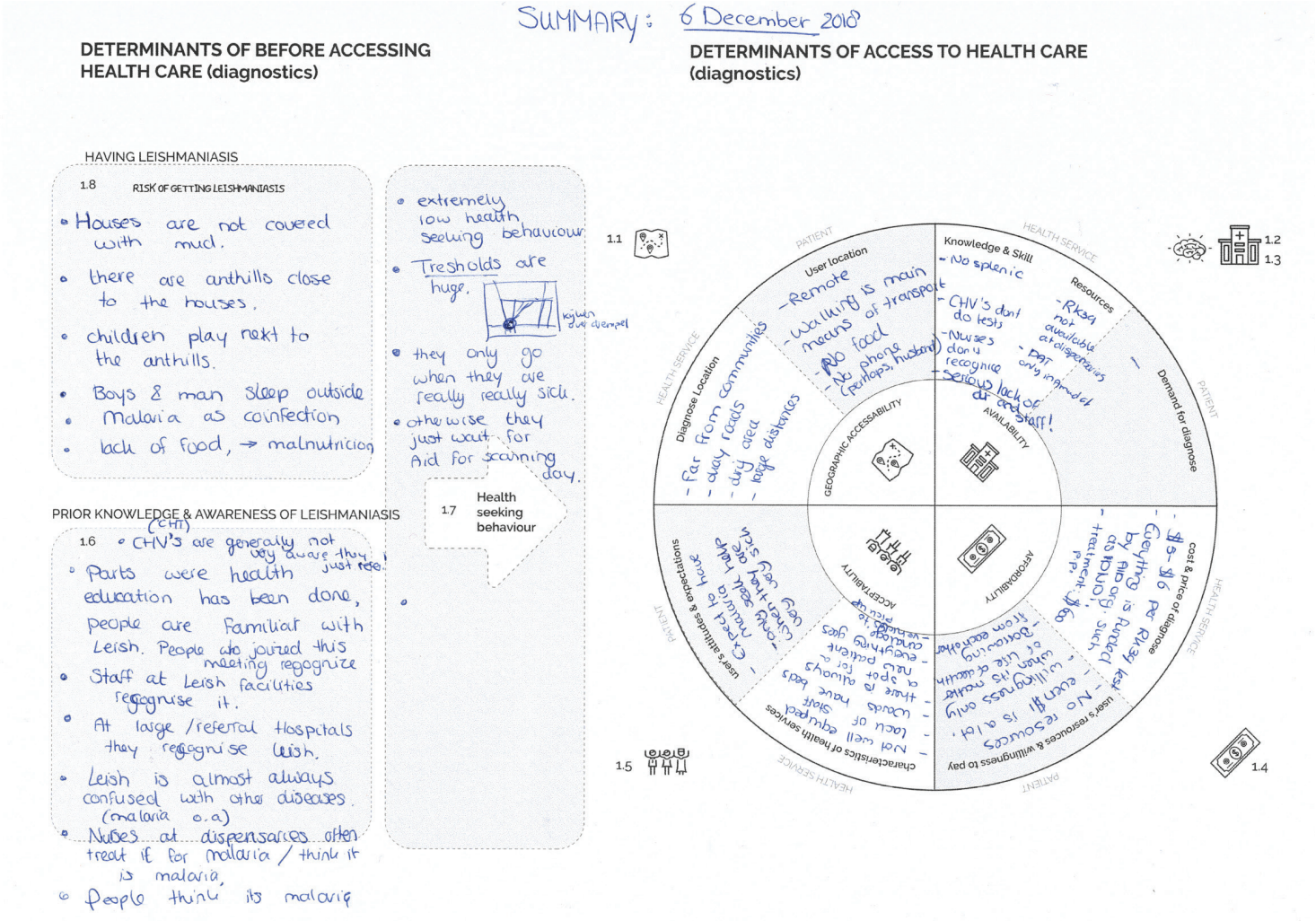


Figure 11: Holistic contextual framework filled out after field trip

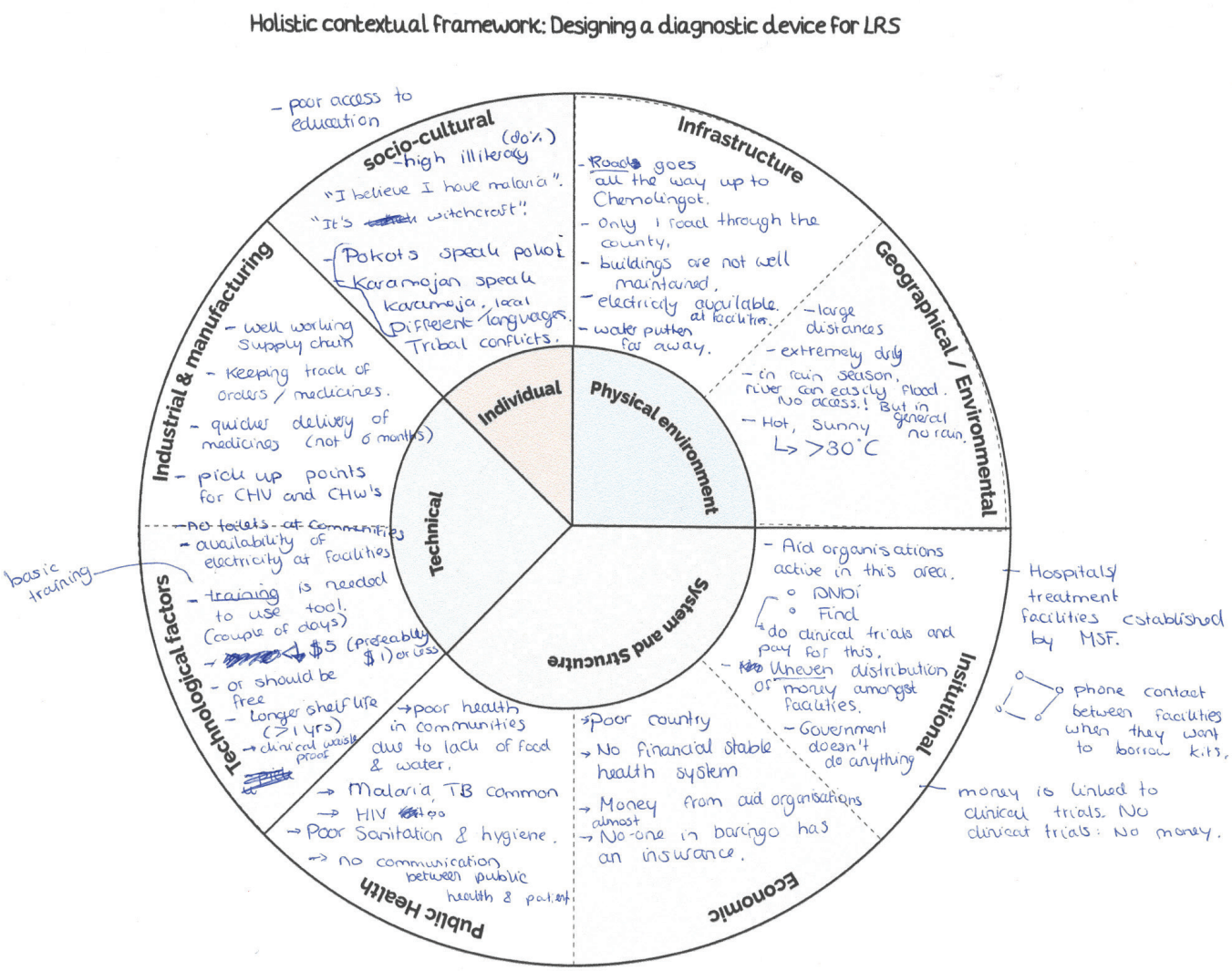


Figure 12: Holistic contextual framework filled out after field trip

B-1
Patient stories

SEVEN FICTIONAL STORIES OF VL PATIENTS

Seven patient stories are created which illustrate the barriers that patients face to receive VL care. (Figure 13).

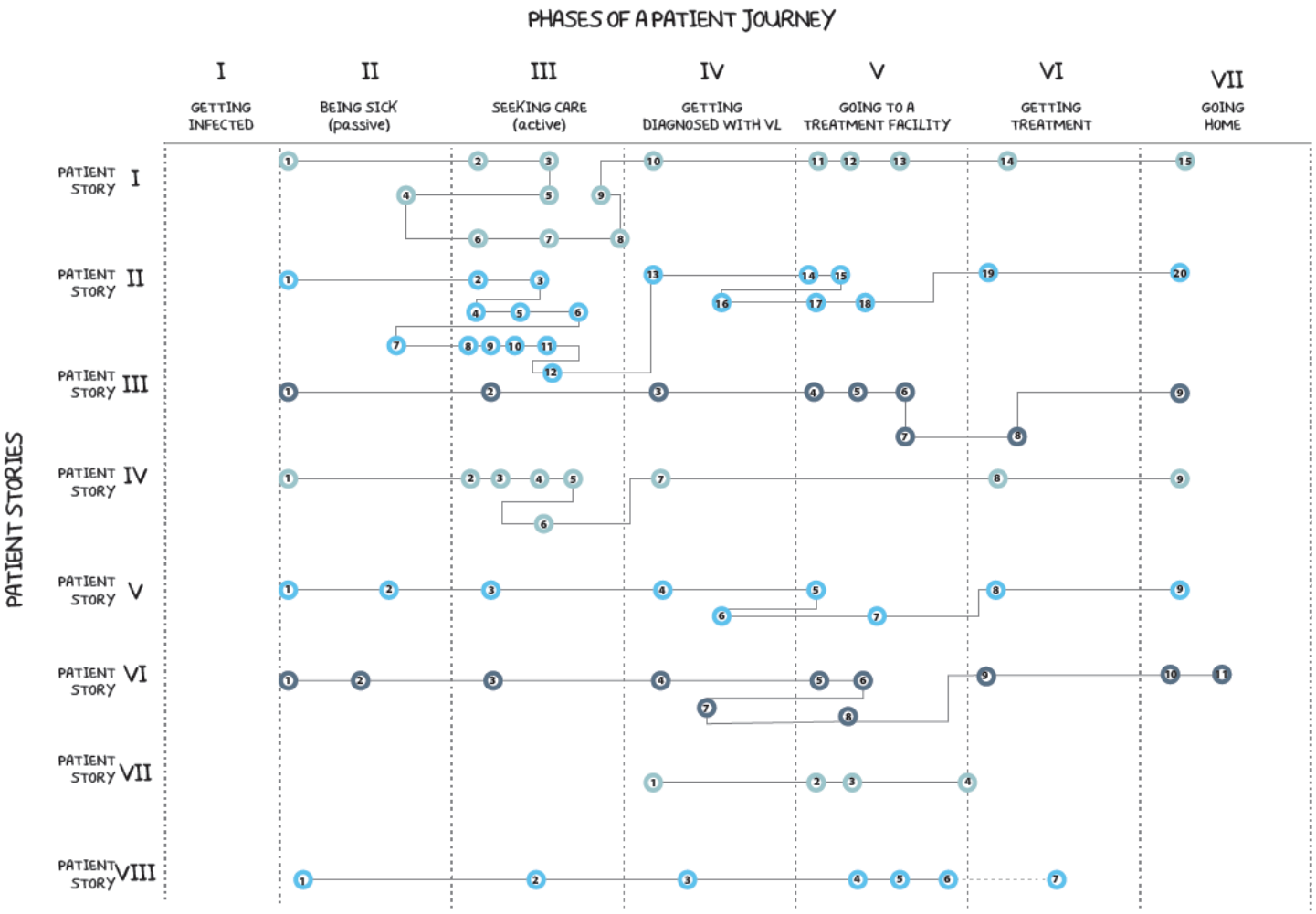


Figure 13: Patient stories

Story I: Vl patient who is misdiagnosed with Malaria

1. Someone is feeling sick
2. The CHV recommends that the sick person goes to the dispensary to check himself
3. At the dispensary, the nurse or Community Health Extension Worker thinks it is malaria and give him anti-malaria drugs
4. The person goes back home
5. After a few weeks, he still doesn't feel better
6. He goes back to the dispensary and they test for Malaria and other things. Nothing comes out
7. They refer him to the hospital in Kabarnet to get a diagnose
8. At the hospital the doctors suspect VL, but they don't test there.
9. So they refer him to Kimalel
10. At Kimalel he is tested by the lab technician with Rk39. He is tested positive.
11. However, before getting the treatment he needs a blood transfusion. His HB value is so low that he needs a transfusion
12. So they send him to Kabarnet for transfusion
13. This takes about a week.
14. He comes back at Kimalel and can start treatment
15. After the treatment, he is brought back home

Story III : Chemolingot to Kimalel (active health seeking behaviour)

1. 1) Someone in the village is ill. The boy has an enlarged spleen, fever, anaemia.
2. 2) One day the VHT identifies the sick boy. She thinks it might be Malaria and goes to the nearby Health Facility II Rupa to get a malaria test. The VHT tests the boy on Malaria in the community. The result of the test is negative, but the boy is very sick. So the VHT refers the boy to the next level health facility.
3. 3) The VHT walks with the boy to the next level health facility
4. 4) Here the boy is again tested for malaria and other diseases (TB et other)
5. 5) All of them give a negative result. In the meantime, the boy is very sick
6. 6) The healthcare workers at this facility don't know what it is and send the boy to Moroto Hospital.
7. 7) At Moroto hospital they query VL and they call Amudat Hospital for a suspected case.
8. 8) One driver and one Community health worker come and pick up the boy to bring him to Amudat (100 km drive)
9. 9) At Amudat Hospital the boy is indeed diagnosed with VL through Rk39, DAT and Splenic aspiration.
10. 10) 17 days later, the boy is cured and brought back with the vehicle of Amudat Hospital.

Story II: 5 year old referred and referred

1. Someone is not feeling well for a while. This young girl is 5 years old and has a fever and general malaise for quite some time now.
2. Her mother assumes it is malaria and goes to the counter to get malaria drugs
3. She takes the medication for a couple of weeks but doesn't get better
4. Mom asks the neighbour what she thinks it is. But she doesn't know. So weeks pass by
5. Now she gets really sick. Her spleen starts to swell. So mother decides to take her to the dispensary
6. At the dispensary, they check her on malaria. They test and the results are negative. However, they are sure it is malaria, "I mean, all the symptoms are those of malaria". So they prescribe another dose and send the girl home.
7. She is not feeling better at all. She gets sicker and sicker
8. Mom takes her again to the dispensary and tells them: "this cannot be malaria, I need help"
9. The nurse agrees that it cannot be malaria and tests the girl on all kind of things (TB, ….) All of them give a negative result
10. So she is referred to the health facility. Mom takes the girl to the health Centre on foot.
11. At the Health Center, the girl is again tested for several things including malaria. But the nurse queries that it might be VL. So the patient is referred to Chemolingot to test.
12. Mom carries the child to Chemolingot which is 20 km further, so hours of walking.
13. When they arrive at Chemolingot, the girl gets tested and indeed she has VL. She is referred to Kimalel to start treatment
14. The staff calls to Kimalel and they send a car to come to pick up this sick 5-year-old. The mom goes back home as the kid can be taken by car.
15. The car comes and brings the girl to Kimalel.
16. When she arrives at Kimalel, she is again tested on VL with Rk39. The result is positive so she gets all other tests such as liver function et cetera before starting treatment.
17. However, her HB value is so low (less than 4.0) that she is sent to Kabarnet to get a blood transfusion before starting treatment.
18. She is brought to Kabarnet by car to get a blood transfusion. This takes about a week before she is back at Kimalel to start the treatment.
19. After a week, she is brought back at the Kimalel facility and starts treatment.
20. 17 days later she is brought back to her family, treated.

Story IV : From VHT to Moroto to Amudat

1. Someone is not feeling well for some time
2. He decides to go to Chemolingot. This is 20 km walking.
3. Here they test him for Malaria which his negative. After this, they test him for VL. The results are positive and the patient is referred to Kimalel.
4. Now, a vehicle is called who can take the patient for 2000 KES to Kimalel
5. The patient goes home to borrow money and returns to Chemolingot.
6. A car comes and picks up the patient to bring him to Kimalel.

Story V: Screening day in Kenya (passive)

1. A young boy of 10 years old is sick in the village
2. The CHV spreads the news that on Saturday there will be a screening day at a central place in the community.
3. The mother of the boy who is sick decides to go there to get her son tested.
4. They test the boy on Malaria, dehydration, TB and VL. He gets a positive VL test result.
5. The organization arranges a vehicle to come to pick up the boy to bring him to Kimalel
6. The boy is tested again at Kimalel health centre on VL.
7. After receiving positive diagnose, they do several other tests before starting treatment.
8. The boy is treated for 17 days
9. After the treatment, he is brought back by car to his family.

Story VIII: Pastoralist relocation, □ year old

1. A 7-year-old was very sick.
2. The child was tested positive during a screening day.
3. The staff told the mother that the child needs to be taken to Kimalel.
4. The mother said she has no time to take the boy to the hospital.
5. The staff from Chemolingot followed it up, see how it was with the boy
6. At some point, the family just relocated, so the staff has no idea what happened to the boy.

Story VI: CHW from Amudat (passive)

1. A 17 years old boy is sick for a while but has taken malaria drugs which didn't help.
2. At one day, a CHW from Amudat Hospital arrives at the community.
3. He looks around the people in the community and notices that the boy has a swollen spleen. He asks the boy if he is sick, and the boy describes his symptoms: fever for weeks, swollen spleen, anaemic.
4. The CHW queries VL and takes his IT LEISH kit to test the boy. The boy is indeed VL positive.
5. The CHW makes a call to Amudat hospital to communicate the found case.
6. A vehicle is coming with one driver and one Health worker to pick up the boy from the community. The boy is taken to Amudat hospital
7. When arriving, he is again tested with IT LEISH (rk39) and DAT by the lab technician at Amudat.
8. After receiving a positive result, they do splenic aspirate and test his kidney functioning among other tests
9. He can now start treatment for 17 days.
10. After the boy is finished with the treatment he has to wait 2 days to be taken back to the community by a vehicle from Amudat.
11. He is brought back.

Story VII: Pregnant lady during screening day

1. During screening day, a pregnant lady is tested positive for VL.
2. She is told to go to Kimalel for treatment by the staff during the screening day.
3. However, she says she cannot go because her husband won't allow her. She said: "I even sneaked out because I'm not feeling well".
4. The staff at the screening day tell her that she needs to go or she (and the baby) will die. So they write a letter to her husband explaining the condition of the pregnant lady and just explain that she needs treatment. And that if he cannot make arrangement to take her, then the staff will do this. They emphasize the fact that the treatment is free.
5. The staff never heard from the pregnant lady again. Kimalel was called to found out if there was a pregnant lady, but no. She didn't have a phone number, her husband had one but she didn't give this number because she was scared.
6. She hasn't been treated

C-1
Session I

How to combine the technical principle into the context?

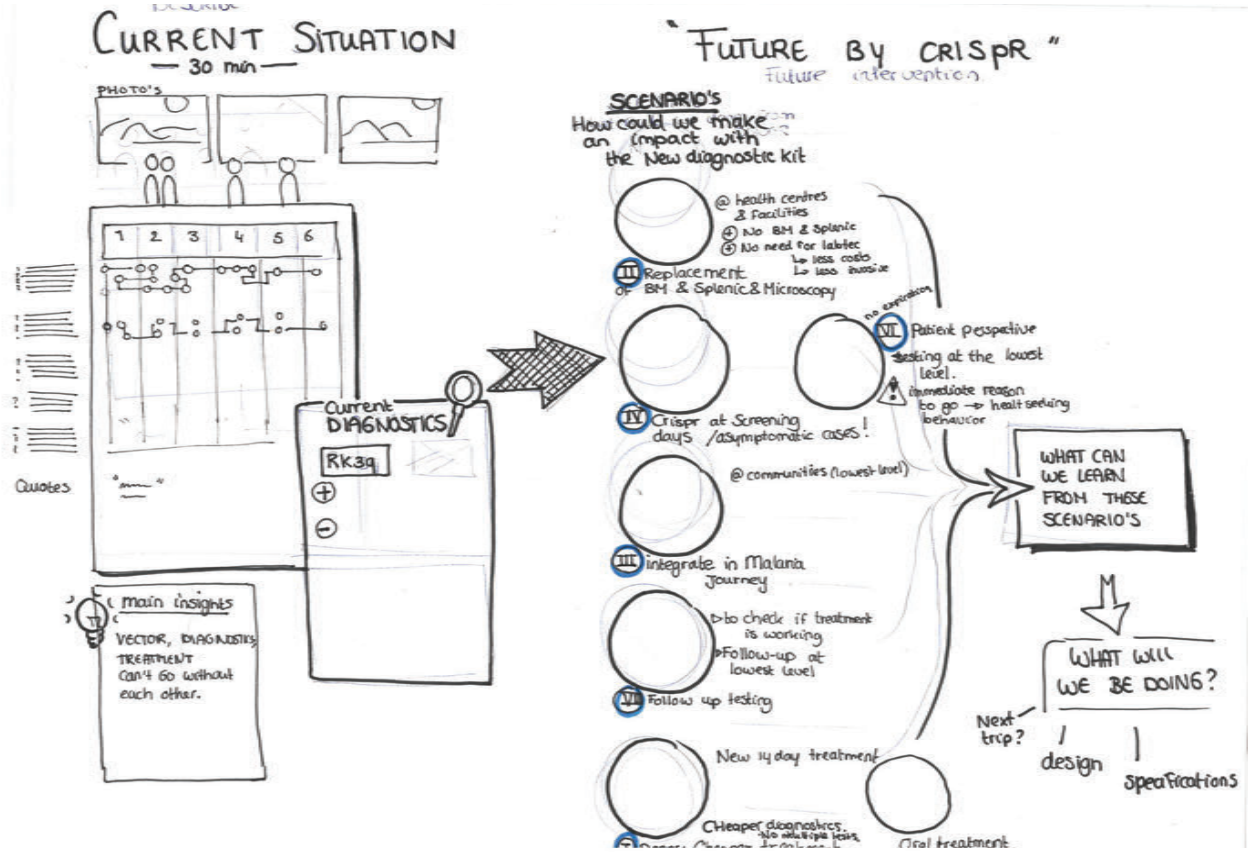


Figure 14: Preparation of the session.

The session is divided into two parts, which are visible in Figure 14 and 15. One part focusses on the current VL context as seen during the field trip, and part two focusses on the future of the technical principle in that context.

Thus, part one (visible on the left) prepared by selecting images which reflect the living conditions as well as the health care situation in the visited VL endemic areas. Besides pictures, this part is supported by using patient stories. These patient stories described in SECTION III Chapter 4.2 and Appendix B-1, are used as a summary of the field trip, displaying the variation between patient journeys along the way from being sick to treatment.

This part is used as the starting point of the session and be used as a summary of all the insights gathered from the field trip.

The second part of the session is prepared by preparing several scenarios where the technical principle could make an impact. During the session, the prepared scenarios were further detailed and facilitated conversations about the

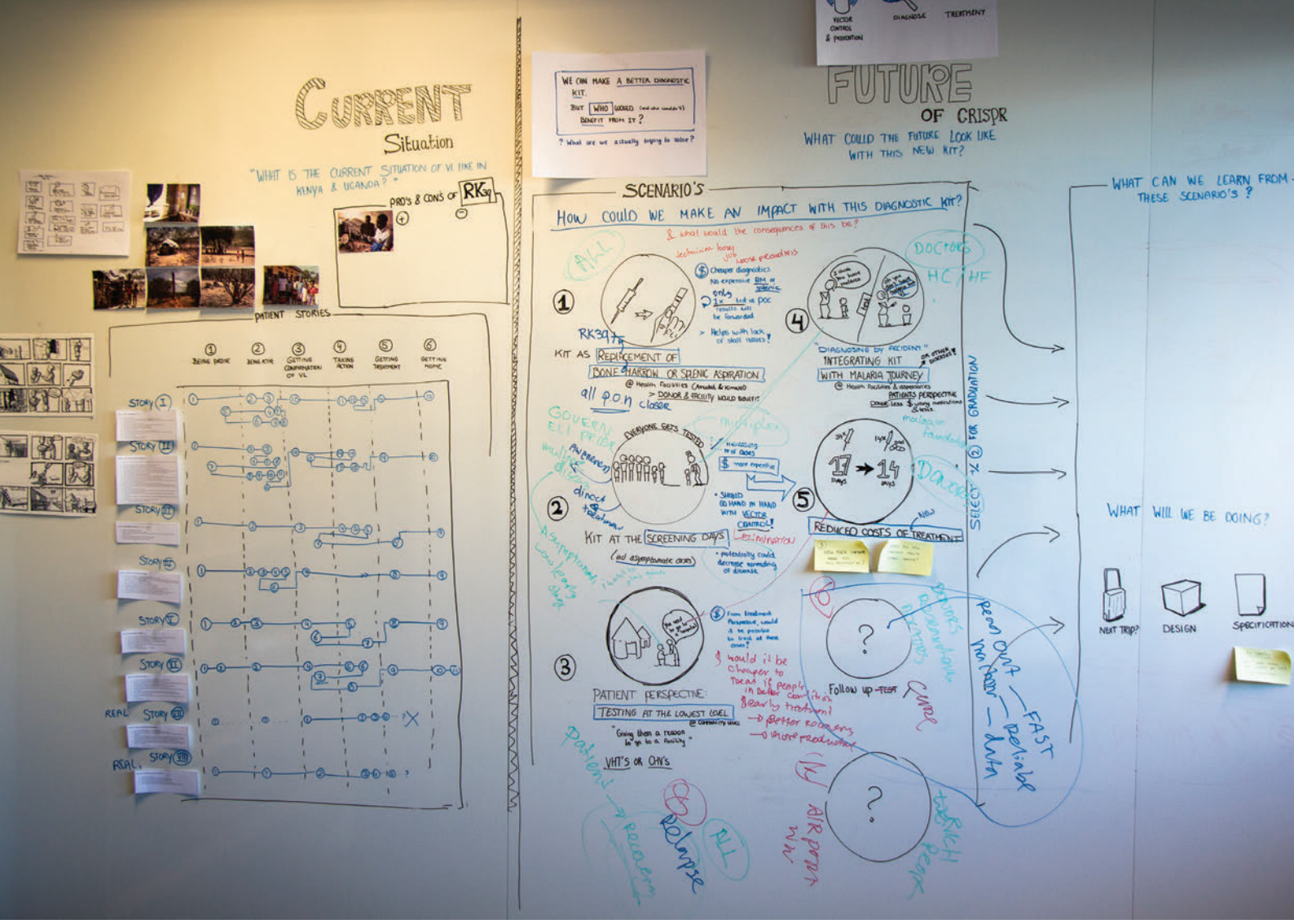


Figure 15: Session results.

applicability of the technical principle in the VL context.

The overall goal of creating these scenarios is to envision where the technical principle could make an impact in VL disease management and thus get a more clear understanding of where the technical principle could be implemented and who would be interested in it.

After the session, the scenarios are detailed and can serve as visual support and conversation triggers throughout the project.

After the session, the scenarios are detailed and can serve as visual support and conversation triggers throughout the project.

C-2
Session II

What is the diagnostic setting of the two scenario like?

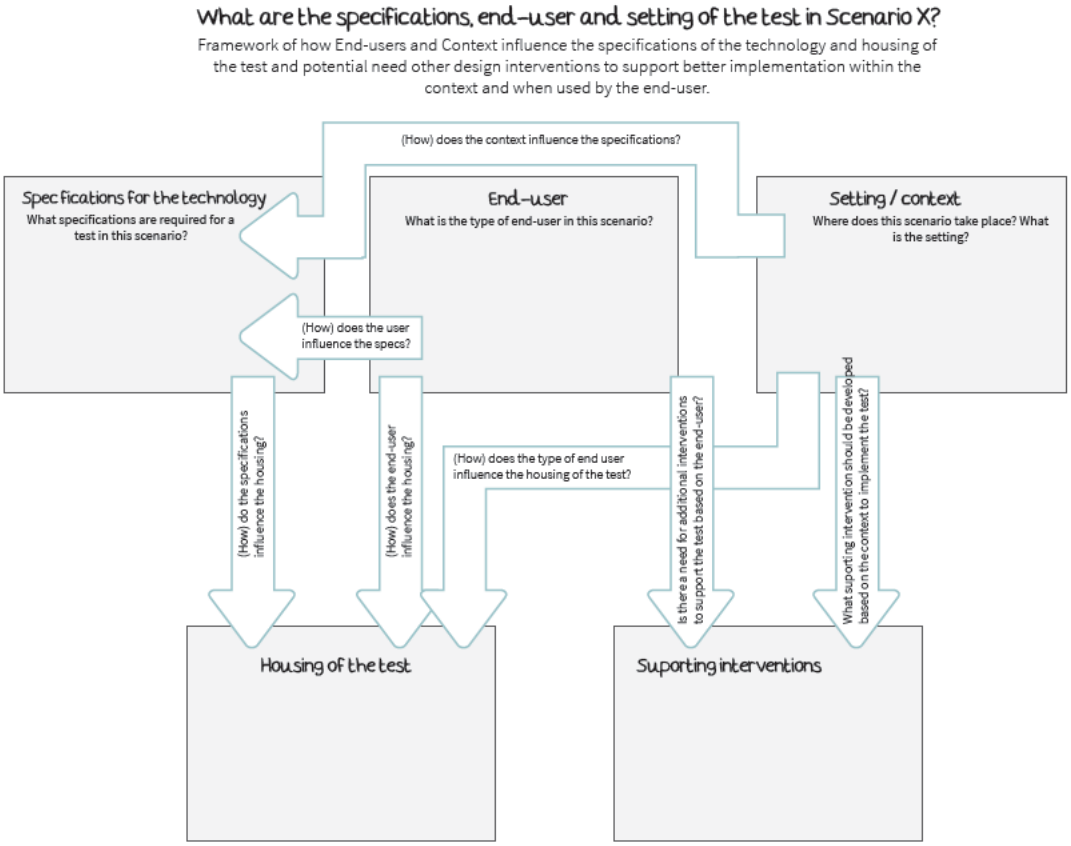


Figure 16: Framework which helps to detail the two selected scenarios.

The goal of this Session was to specify the "Screening & Confirming" and the "Test-of-cure" scenario together with the team of IDE and Applied Sciences.
Based on specifying the End-user and the setting in which the scenarios take place, requirements can be composed for the technical principle and the housing of the diagnostic test. See Figure 16 for the framework which was composed prior to this session.

This session resulted into detailing the two selected scneario (See Figure 17).
By detailing the scenarios it became clear that they can take place in different settings.
Based on the end result of the session (Figure 17), the scenarios are described in more detail (Figure 18 -20).

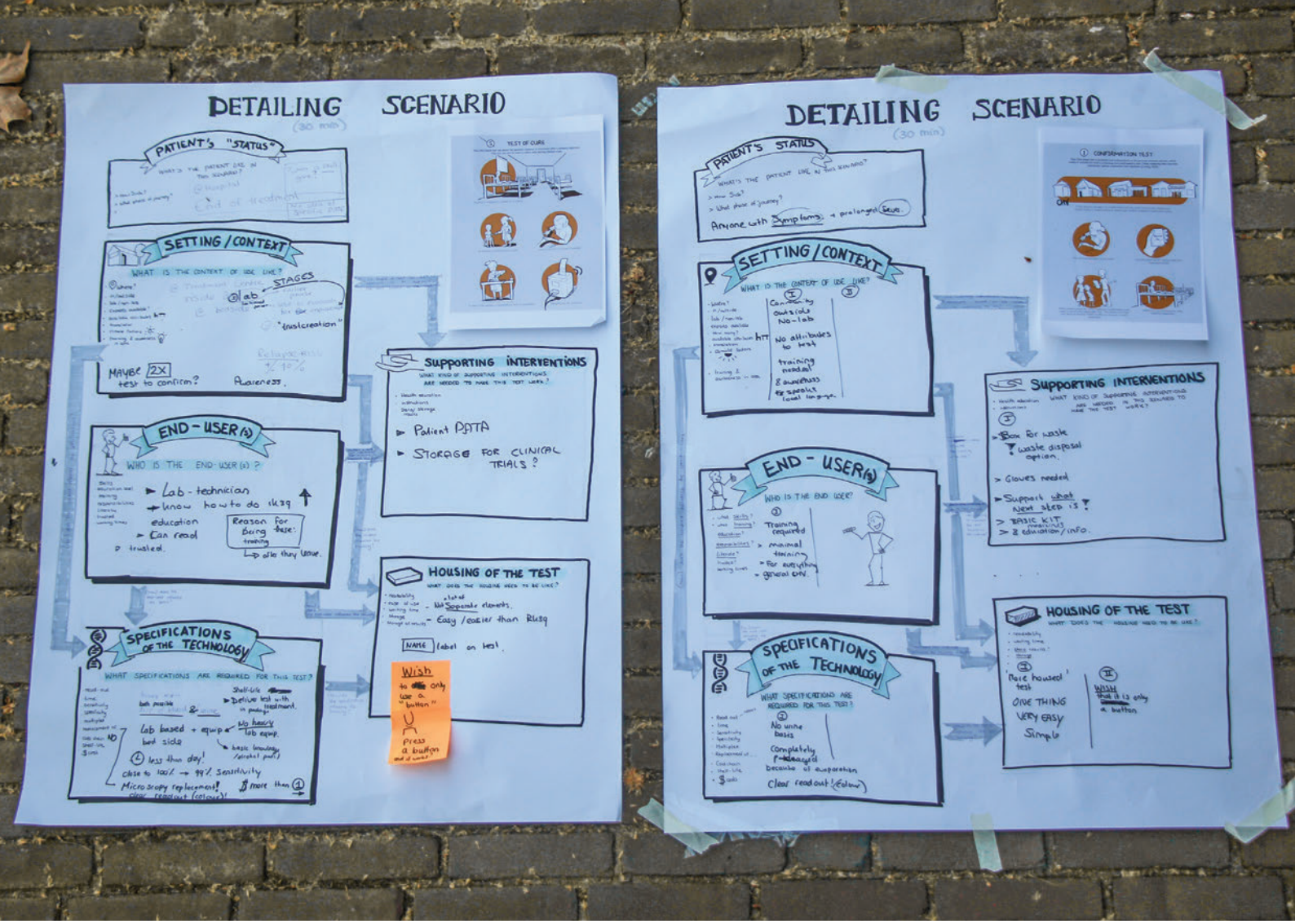


Figure 17: Detailed scenarios based on the Setting and End-user.

Figure 18: Detailed "Screening & confirmating" Scenario at sub-county level.

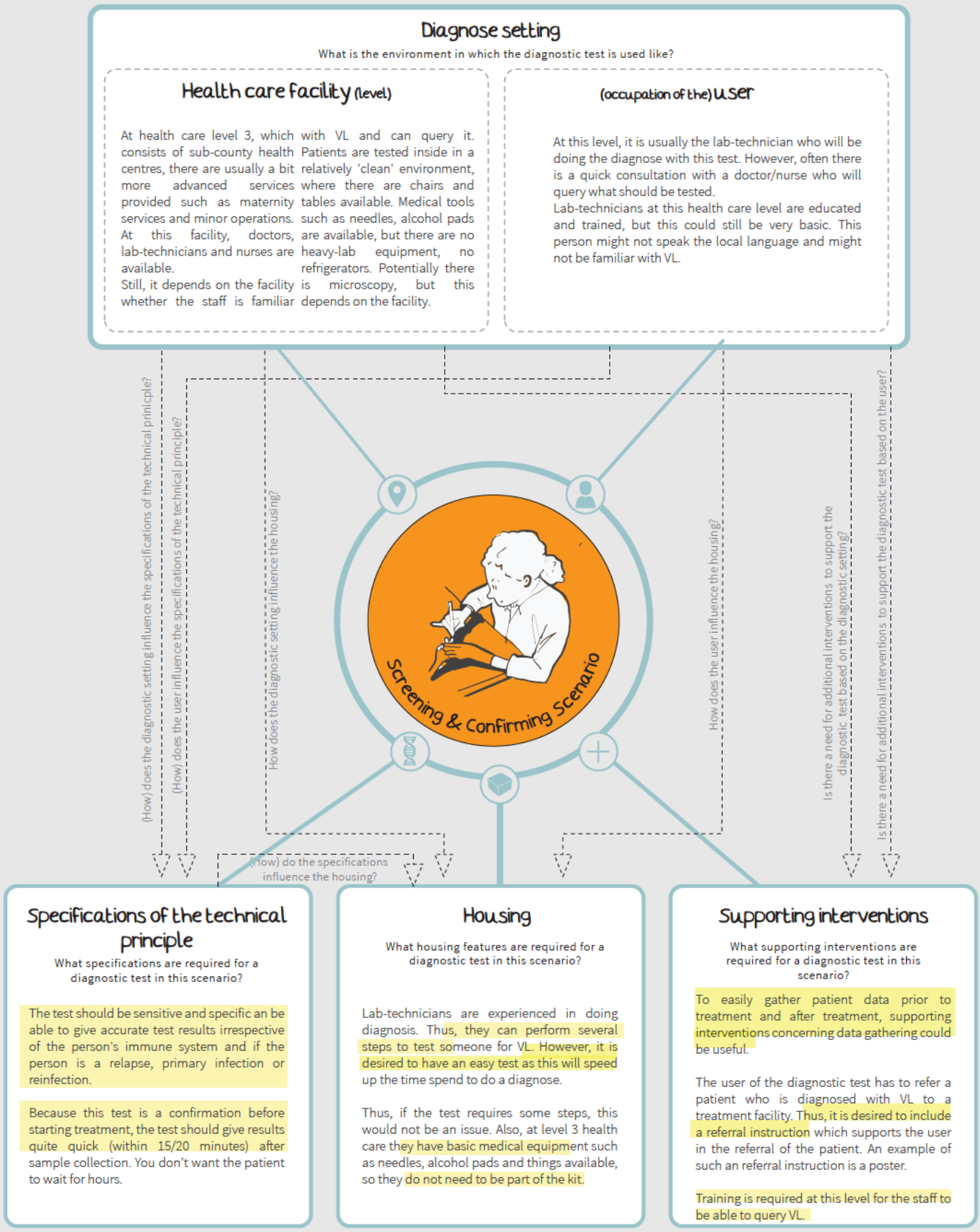


Figure 19: Detailed "Screening & confirmating" Scenario at a VL treatment centre.

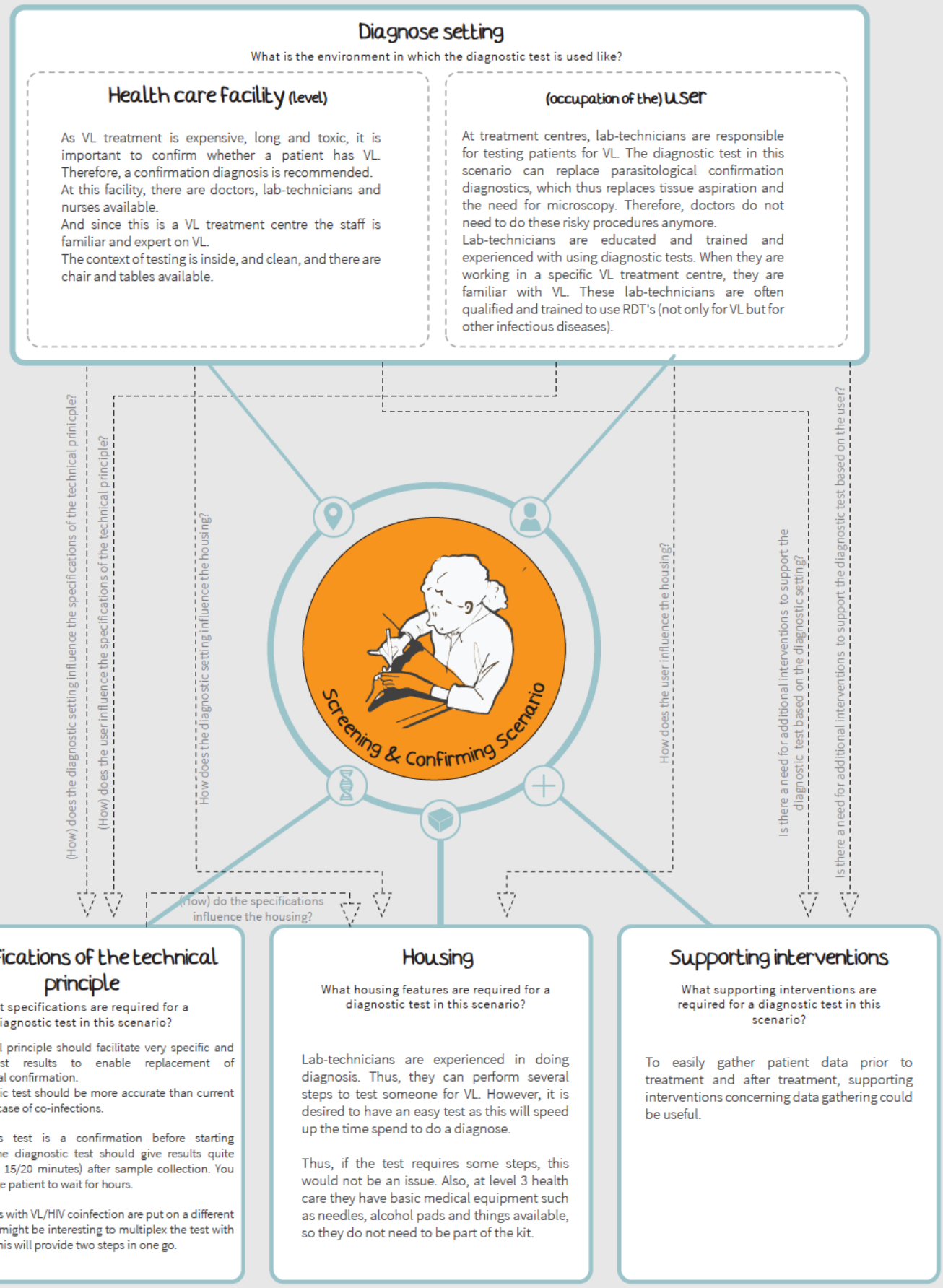
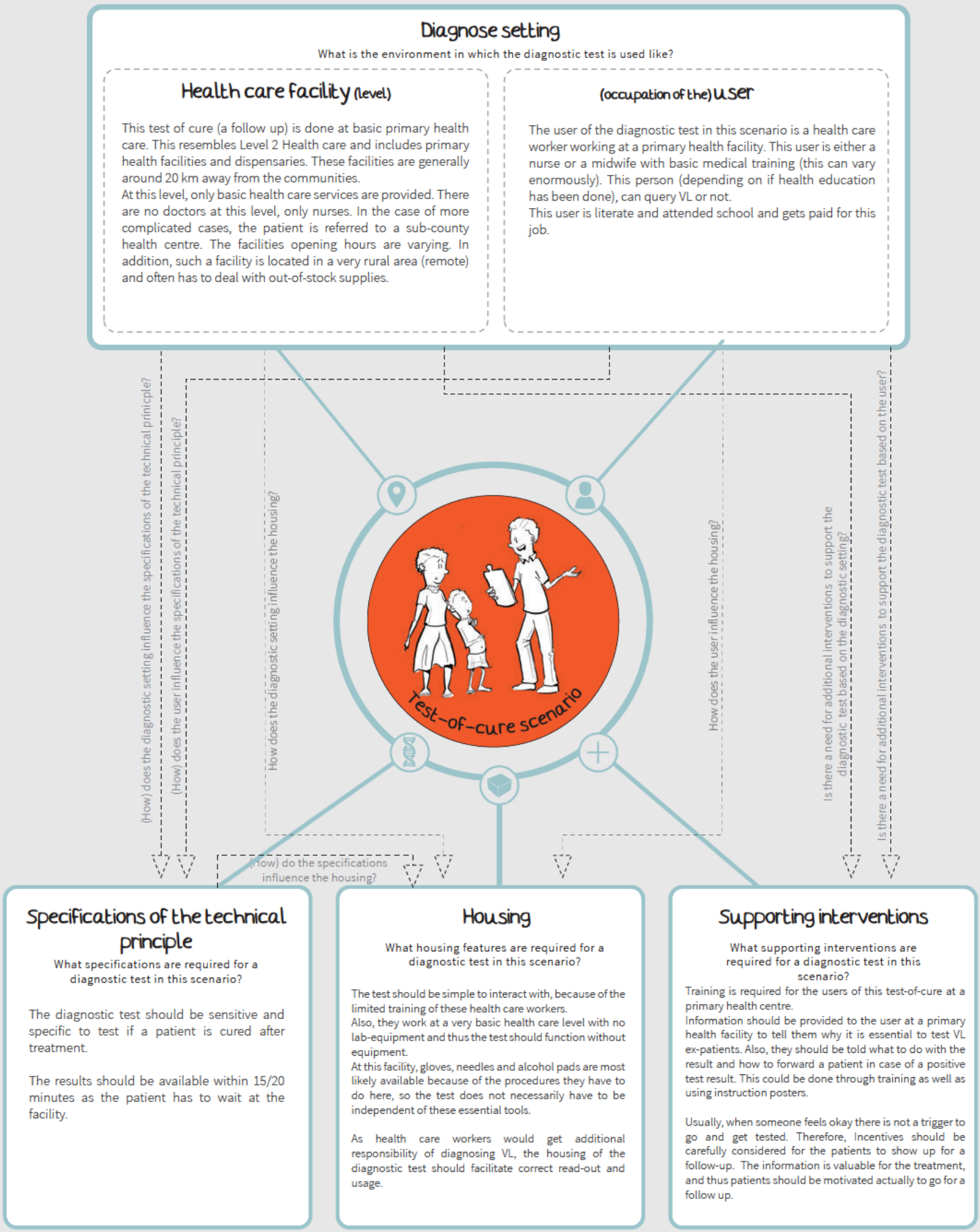


Figure 20: Detailed "Test-of-Cure" Scenario at primary health facilities.




STAGES
MAYBE 2X test to confirm?
Awareness.
"trustcreation"
END - USER(s)
WHO IS THE END-USER (s) ?
Lab - technician
know how to do rt-sg
education
Can read
trusted.
Reason for being these: training
after they leave.
SUPPORTING INTERVENTIONS
WHAT KIND OF SUPPORTING INTERVENTIONS ARE NEEDED TO MAKE THIS TEST WORK?
Patient DATA
STORAGE FOR CLINICAL TRIALS?
TEST OF CURE
DETAILING
(30 min)
PATIENT'S STATUS
Anyone with symptoms + prolonged cough.
SETTING / CONTEXT
WHAT IS THE CONTEXT OF USE LIKE?
Community outside No-lab
No attributes to test
training needed!
& awareness
SPECIFICATIONS OF THE TECHNOLOGY
HOUSING OF THE TEST
WHAT DOES THE HOUSING NEED TO BE LIKE?
a lot of
Not Seperate elements.
Easy / easier than RT-sg
NAME label on test
END - USER(s)
WHO IS THE END USER?
Training required
minimal training
For everything
general env.
SUPPORTING INTERVENTIONS
Box for waste
waste disposal option.
Gloves needed
Support what
Next step is?

C-3
Session II

What should the diagnostic test be like based on the diagnostic setting?

The goal of this Session was to idenfity the layers that connect the technical principle at the core to an entire disease context.
Therefore, the researchers from Applied Sciences where asked to fill out a 'booket' with the different layers (See figure 21 and 22).
Both researchers were asked to come up with requirements of a diagnostic test, but for a different scenario.

This helped to clarify the influence of a diagnostic setting on the features of a diagnositc test (technical principle, housing and usability guidance).

Figure 21: Booklet with the different layers which connect a technical principle in a diagnostic setting.

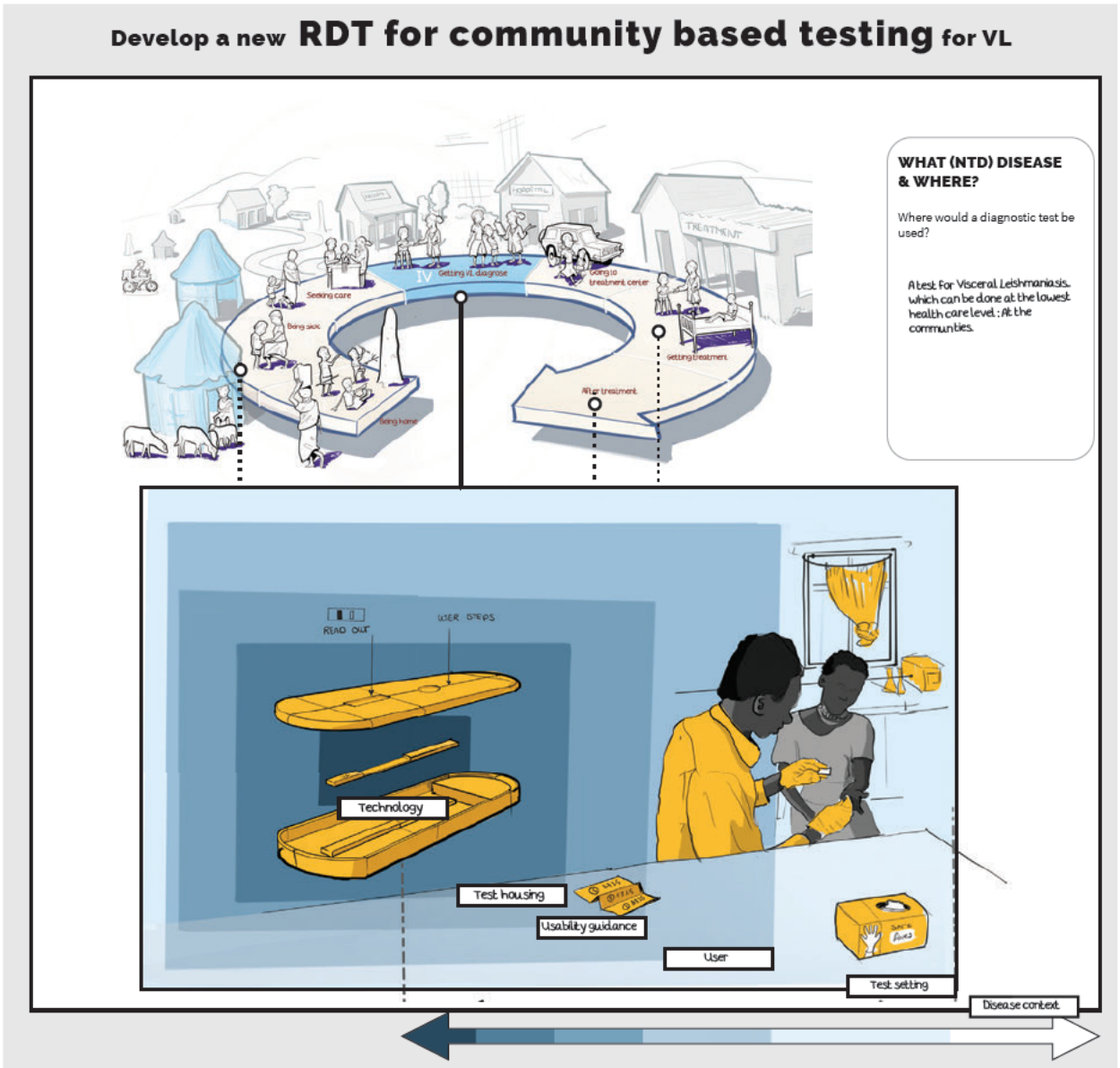


Figure 22: Overview of diagnostic setting and diagnostic test

D-1
Scenarios
Feedback from MSF on Scenarios

Scenario I: Screening & Confirming

The setting where the diagnostic test is used, influences the case management one test as confirmation is not a problem. However, it is essential to consider where the test will actually be used and who would use it. For example, in a hospital, there will be a trained doctor who can deal with more scenarios. However, a CHV is generally trained to identify malaria, malnutrition and maybe something else, but therefore is trained for a limited number of scenarios (Charity MSF, 2019). This can become rather complex in case of co-infections. When a patient has both malaria and Kala-azar, but the CHV can query Kala-azar, see the symptoms and the test is positive, the person will be referred to a treatment centre for Kala-azar. Then this patient will not get diagnosed with malaria, while at the hospital they would treat the patient for both malaria and kala-azar. So there is a risk: even if you would diagnose a patient with VL while this patient also has Malaria, there is a risk that the patient might die of Malaria with a VL diagnose. It is possible to have a Community health volunteer/worker with the final confirmation test. But it is important what they do after diagnosing the patient positively. Thus the instructions given to the CHV's is crucial. Repetition of tests is not a bad thing and will inevitably happen. Therefore, aiming for only 1 test in the entire journey is aiming for the impossible. It is not that much about suspicion between health care levels about the results, but more about the assurance you want before you put a patient on treatment. You want to be sure someone indeed is a VL patient before putting someone on a toxic, long and expensive treatment. Of course, a patient should not be tested 6 times, but a couple of times would not be a problem. As long as the test is cheap enough so you can do the tests multiple times. Charity: We repeat tests all the time even within the same health centre to rule out clerical or procedural errors, independent of performance of test because if you are going to put a patient on toxic, expensive and potentially life long drugs, you want to be sure (e.g. DNA PCR for HIV in infants is repeated). So we can operate on the assumption it will happen and it is not a bad thing (obviously it shouldn't be 6 times per patient) and we need to make the test affordable enough to enable this.

Scenario II: Test-of-cure

A test of cure is very important. Not only during clinical trials, but even without. During clinical trials there are a lot of questionable responses to the treatment, and thus a test-of-cure would be useful to know whether the treatment worked. Besides, patients who are part of a clinical trial, a test-of-cure is also useful for patients that are in high risk of relapse. A test-of-cure can be used to make sure they are cleared and thus successfully treated. All immune-compromised patients, such as HIV co-infected patients, pregnant woman and children below 5 have a higher chance or relapse. According to Koert,

between 5 – 10% of the cases do end in relapses. Koert: the main constraint we have now with the current serological tests is that we cannot confirm relapses.

Scenario III: Screening day

During a screening day, it is not possible to test everyone on every possible disease as there are simply too many different diseases. Also according to Charity from MSF, ethically it is not possible to test people who are not sick for diseases. Therefore, it is better to screen everyone on clinical symptoms and then only test the symptomatic people. According to Koert Ritmeijer from MSF, there are fever camps in India where everyone with a fever is asked to come to a central place to get tested on multiple diseases. So people with fever are tested on all fever related diseases. However, the number of fever-related diseases in these areas (fever meaning 7 days or longer) is around 20. Screening days are challenging Screening days are not easy. It is difficult to get the people there as they have better things to do. People would rather work than go to a screening day. Therefore, there should be a benefit for the people to come. Koert Ritmeijer mentioned that a screening day on fever related diseases would be useful at farms in North Ethiopia. In this region farmers will only seek health care when they are very sick. Thus organizing screening days at the farms would be useful. Besides the risk that people are not showing up, the costs are also high. Screening days are very expensive and the cost effectiveness is questionable (Koert). The disadvantage of screening days is that they are restricted to a 'day'. Therefore, there is a risk that someone has a fever the day after but not on the screening day. Detection of asymptomatic cases Asymptomatic patients are a reservoir and carry the disease. How many asymptomatic VL cases are existing is not known. At the moment it is not useful to diagnose asymptomatic cases as there is no suitable treatment for them. According to Koert Ritmeijer, 'if you want to treat asymptomatic people you need a treatment which is safe, short and doesn't cause any inconvenience for the patients.' Only in the context of elimination of VL would it be useful to diagnose asymptomatic cases. However, in East-Africa elimination of VL is still out of the picture.

Scenario IV Community testing

A technical consideration came forward after meeting with MSF. Charity and Koert were wondering how well the multiplex test could be to differentiate between all kind of fever-related diseases. So, therefore, if this scenario is feasible is strongly dependent on the specificity of DNA detection. Besides that, the same comment was given by charity as in Scenario 1. Even if someone at a lower level diagnoses someone with VL or VL and a co-infection, what happens then. The instructions around the diagnostic test are extremely important (Charity). Would you give these people the responsibility to refer patients and how do they know what to do after a diagnosis? Koert Ritmeijer, MSF mentioned that a test would be best used at the health centre level.

Scenario V: Integration with malaria journey

Multiplexing malaria & VL test In the past, there was the duo-test from DIAMED for Malaria and VL. Both diseases have fever symptoms, only with malaria, it is an acute fever and with VL a persistent fever. In most cases, if someone presents with an acute fever you want to do a malaria test and not test the patient on VL. In that case, testing with a dual test would be much more expensive. According to Koert, it would make sense to use a dual-test for a patient who presents with persistent fever, but even then you are cheaper to have two separate tests.

D-2
Feedback form

A feedback form was prepared to get feedack from staekholders met during the dfield trip.
This feedback form can be found here.

First of all, thank you very much for filling out this feedback form.
This feedback form contains 7 scenarios in which a new diagnostic tool for Kala-azar could make an impact.

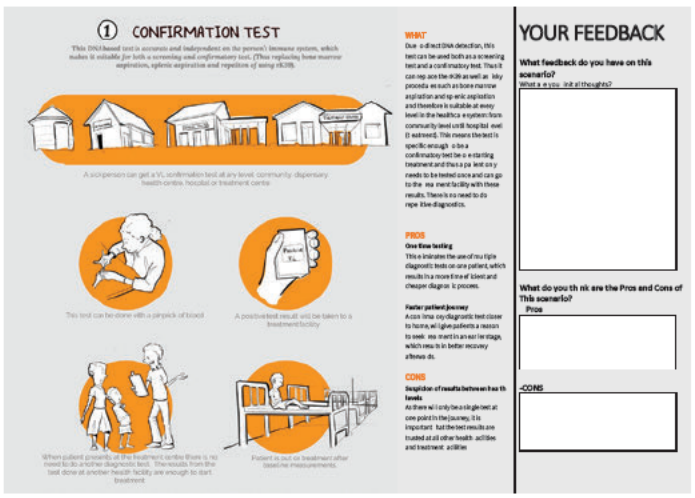
Each of these scenarios will be explained on a separate page.
It would be great if you could give some feedback on each scenario and in the end rate which scenarios you think are most **feasible** to implement and which are can have the most **impact** on disease management of Visceral Leishmaniasis.

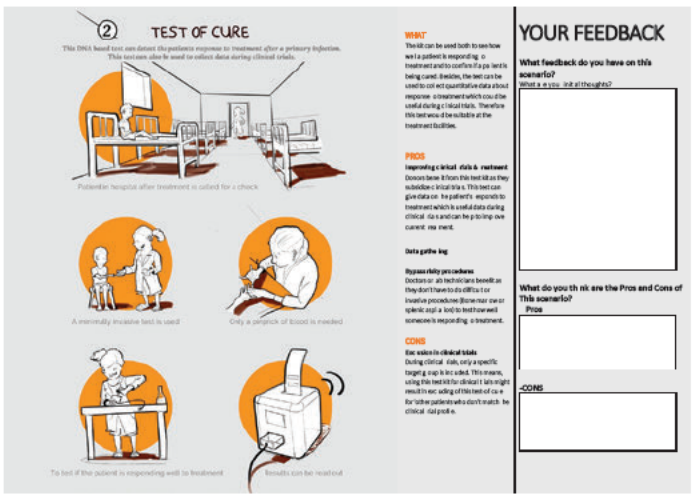
Again, thank you for participating, your feedback will be of great help!
You can type your answers in this document, and can you save it and send it back to me when you are finished? (to astridtenbosch@gmail.com)

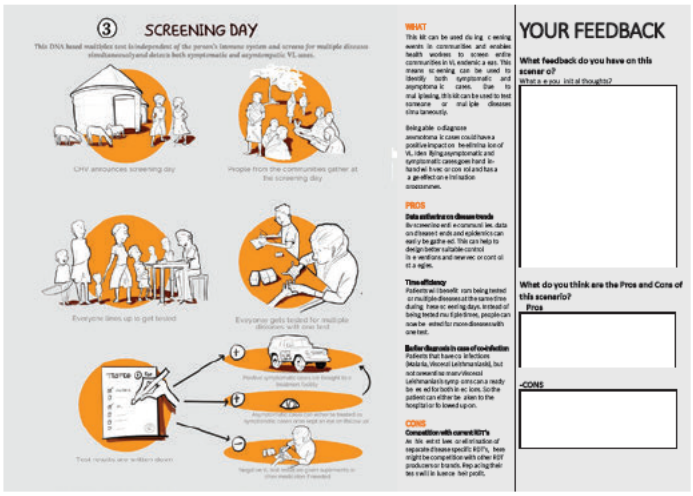
If you have any questions, don't hesitate to contact me at:
astridtenbosch@gmail.com

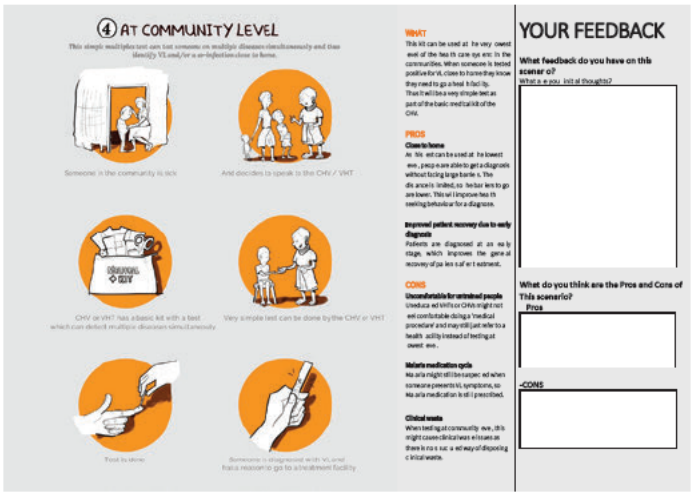
Best regards,

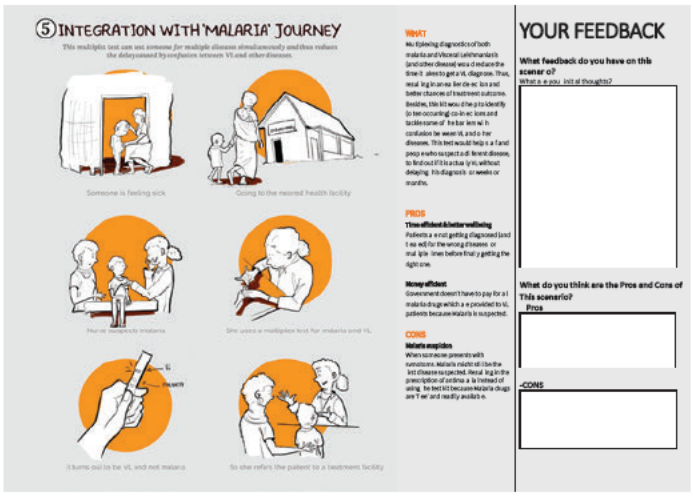
Astrid on behalf of the TU Delft Team

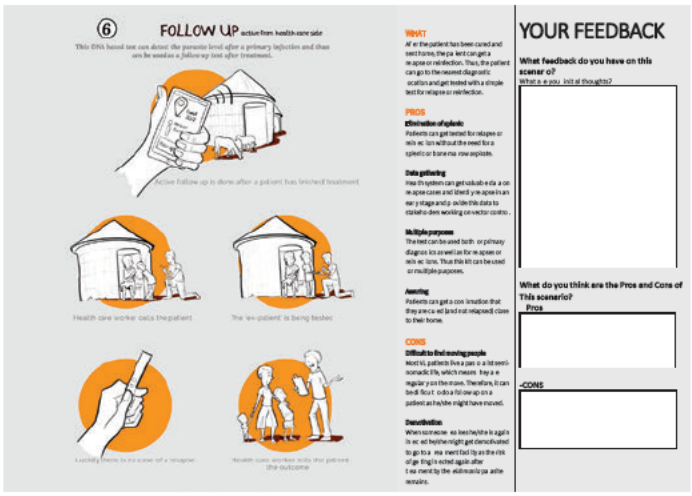












What are the 3 most feasible scenarios?

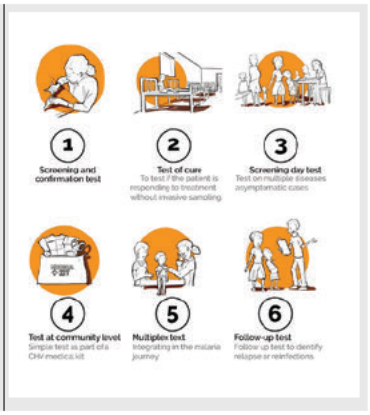
FEASIBILITY

What scenario is the most feasible to implement in the context?

1 most feasible - 3 least feasible

1
2
3

Why these three?



What are the 3 most Impactful scenarios?

IMPACTFUL

What scenario is the most impact on disease management of Visceral Leishmaniasis?

1 most impactful - 3 least impactful

1
2
3

Why these three?

D-3
Feedback from stakeholders

the feedback of stakeholders on the scenarios.

Five people met during the field trip responded to the feedback form. They provided feedback on the scenarios, which can be read here.
The condlusions of these feedback are described in the main report.

	RESPONDENTS TO THE FEEDBACK FORM
NR	WHO? The occupation of the user
1	Junior researcher at KEMRI
2	Lab-technician at Rupa Health centre
3	Biochemist at KEMRI
4	Public health officer (university of Nairobi)
5	Molecular biologist at KEMRI

RESPONDENT 1
JUNIOR RESEARCHER AT KEMRI

SCENARIO I

The diagnosis and treatment of Kala-azar is a Challenge in Kenya. This is because of the cost and duration of treatment and the definitive diagnosis by rK39 require tissue specimen conventionally obtained through the organ needle aspiration for microscopic demonstrations of amastigotes seen on stained smears. The examination of samples obtained as spleen and bone marrow aspirates have varying sensitivity to test. Organ aspiration requires technical experience which are not uniformly and readily available at rural settings where the disease burden is most impactful.
DNA based testing will improve parasitological yields and offers definitive confirmatory diagnosis towards eliminating Kala-azar in the developing countries.

+pros

It will take some time for the KIT to be trusted in a level of handling it as confirmatory test without repeating after doing the single test. The assimilation will also depend on the bpriuce of the KIT since most of the Tests are government sponsored and people targed are very poor and sensitive to all prices

SCENARIO II

The Success of the assimilation and the number of times a KIT can be used will depend on the Price and the Availability, Health Financing options available (Insurance covers and National health funds) Quality of the KIT, technical Skills required and the personnel to run the tests.

+pros

It can be less invasive but sensitivity to Samples obtained matter.

+Cons

Reasons for exclusion needs to be prominent and satisfactory. If used on screening, what factors to considers since the DNA sample can be detected during before the disease start showing symptoms. The stage will not be Symptomatic, it is asymptomatic.

SCENARIO III

+pros

It can be VL endemic and not Malaria endemic at the same time. Testing Malaria when not necessary can also be resource wasting. Unless it comes out as optional basis or some KITs with Multi-tests and some single for VL only.

+cons

Replacement of the RDTs is based on the assimilation rate and marketing strategies. Furthermore, will depend on the support from the government.

SCENARIO IV

The Health Seeking behaviours cannot be based on positive tests only. Cost of medication and the duration of being in the hospital during treatment can influence the decision of seeking help from the health facilities.

+pros

..

+Cons

The combination of VL and Malaria has to be supported by the current Data suggesting high rates of Co-infection. What informed this combination might be varying regionally and interventions or control strategies

SCENARIO V

+pros

Co-infections has to be based on Data or evidence per regions.

+cons

Only applicable on Malaria Endemic areas.

SCENARIO VI

The Elimination of additional Spleen or Bone Marrow aspiration will depend on the options available and the costs implications.

+pros

This accurate less invasive and field-test is suitable to Kenya rural areas, only to make it rapid to circumvent the preceding limitations of rK39.

+Cons

Demotivation due to re-infection is not influenced by the KIT, thus not a constraint as per say.SELECTION OF SCENARIOS

SELECTION OF SCENARIOS

Most feasible?

1: Screening and Confirmation test, Test of Cure, Screening day test
2: Test at the Community Level
3:Multiplex test, Follow-up test

Why these three?

Before initiating treatment, its important to confirm what to treat. After treatment, its satisfactory to confirm cure by testing to get the negative. At most of times, testing asymptomatic cases to get positives enables one to initiate treatment early before the patients immune gets knockdown.

Most impactful?

1: Screening and Confirmation test
2: Test of Cure
3: Screening day test

RESPONDENT 2

LAB-TECHNICIAN AT RUPA HEALTH CENTRE IN UGANDA.

SCENARIO I

First, this is the way to go, most patients have expressed invasiveness of some management procedures such as bone marrow aspiration, spleen punctures /aspirates.

+pros

Time saving
Promotes quick recovery of clients
No invasive procedures done to clients
Decisions on patient management are made timely
Reduced complications from the patient
Reduced mortality rate attributed to kala-azar and its complications and morbidity
Improved overall treatment outcomes
Cheaper
No need of highly educated people
Can be appoint of care procedure

+cons

Forgery of results from the screening /diagnosing facility.
Unknown specificity and sensitivity
Recommendation:
Let us also cater for specificity and sensitivity of this tests.
The diagnosing facility to refer the client with the positive test results and positive strip to the treatment facility.

SCENARIO II

This is too another technology I do conquer with, only that this is more of hospital based and may not be sustainable in rural African countries such as Uganda for example with no sustainable power supply and its complexity in terms of needing power supply and, technology and human resource for health

+pros

Very instrumental in finding cases, confirming, and even monitoring the patients response to care

+Cons

Very expensive
Requires power supply
Cannot be a point of care test except at hospital level
May not be sustainable in the current rural Africa

SCENARIO III

This kit is very important in screening the entire community in endemic areas however depending on the specificity and the sensitivity I do have reservations on multiple diagnosis of conditions for example HIV/Syphilis duo test kit which gives many false positives
It is the way to go because this helps a lot in eradicating VL as even the asymptomatic cases can be diagnosed
Recommended one for mass screening campaigns

+pros

Early diagnosis and management
Multiple disease detection
Time required to test for many conditions is reduced
.

+cons

Increased false positives
May require repeat tests
Expensive as it will require resources to take health workers out of the health facility

SCENARIO IV

This is very good for the Ugandan setting and much more applicable since we already have the community structures such as the village health team (VHT)

+pros

Time saving
Reduced distance
Minimal barriers to access service
Early diagnosis and referral
Improved treatment outcomes
Minimal mortality and morbidity related to VL

+Cons

Illiteracy levels of most VHTs in Karamoja may affect its effective utilization

SCENARIO V

This is also good except the specificity and sensitivity must be taken care off

+pros

+cons

SCENARIO VI

+pros

+Cons

LECTION OF SCENARIOS

SELECTION OF SCENARIOS

Most feasible?

1:screening and confirmatory test
2:testingat the community level
3:follow-up tests

Why these three?
As discussed earlier, the screening and confirmatory test is very good for the reasons above and could be used in Ugandan context
The testing at the community level will be for VHTs to screen and diagnose but this can also be used in mass screening in endemic prone areas.
A follow up test then can be used to diagnose for a re-infection and avoid treating even those already cured from VL

Most impactful?

1:screening and confirmation test
2:test at the community
3:follow-up test
Least impactful

1. Screening day test
2. Multiplex text
3. Test of cure

Follow up test is adequate to check for cure than having to do test for cure
Multiple text and Screening day can be affected by the sensitivity and specificity levels of the test and a lot of wasting as you screen everyone.

RESPONDENT 3:
BIOCHEMIST AT KEMRI.

SCENARIO I
This will be great diagnostic tool which will improve false diagnosis during early stages of the disease.
It also looks to be user friendly sustainable in the hash endemic areas.
Could be helpful in early detection during normal random testing.
I highly recommend the idea for the development of the tool for it will improve the control of the dIsease.

+pros
Very true for it targets DNA and not antibodies. Could also have less incubation period during diagnosis.

+cons
Since it is developed as confirmatory tool challenges will be during referrals to health facilities that are far. Suspicion can only arise depending on the level of different facilities and health workers in the facilities

SCENARIO II
This is quite true for there is no tool currently to monitor response to treatment or resistance. The current tool which is spleenic aspiration is done after the full dose of the treatment is done and its dangerous to the patient.
Very good instrument during clinical trials to monitor drug response during trails.

+pros
Improve diagnosis and early detection of the disease and user friendly.

+Cons
Cost of the kit might be a problem to the effected community.
Proper training the health workers in the most remote area which have no electricity which will affect storage

SCENARIO III
rk39 is the most common and user friendly to community workers in this areas. However it has its short fall for it based on antibody antigen rxn this tool could improved diagnosis and monitoring drug response because its DNA based

+pros
This is true for this will enable vector teams to identify areas of high infections since communities also leave nomadic life. This area has also different types of vectors documented for spreading different types of leishaniases. Multiple infection could be experienced and thus giving the tool recommendable..

+cons
..

SCENARIO IV
Referral hospitals are so far from these communities and the health centres might not be having sufficient diagnostic tools. This will offer great solutions to these challenges.

Will also improve early detection during random testing

+pros
Through training this scenario can be over come

+Cons
Some communities are not comfortable during blood samples collection. This can be improved through public health initiatives.

SCENARIO V
Both this diseases present similar symptoms this will truly be useful to diagnose for both since both diseases are endemic in these areas.

+pros
Facilities do not offer diagnostic services due to access and mostly disease diagnosed based on symptoms. High chances of wrong diagnosis.

+cons
Malaria drugs readily accessible than VL wrong treatment is highly possible

SCENARIO VI
This will detect recurrence infections in endemic areas which will guide also vector intervention
Will also help to detect resistance
Make sure data is available in the real endemic areas and not in referrals which might not be endemic.
It could also be used as both diagnostic and confirmatory tool for the disease.

+pros
Outreach programmes would be key to access nomadic areas

+Cons
Endemic areas are nomadic communities and with poor

road network. a bit of a challenge

SELECTION OF SCENARIOS

Most feasible?

1:
4:
5:

Why these three?

1. This offers improved diagnostic tool as this a key priority in this area, this will also improve control measures of the disease
2. Currently diagnosis for the VL is in the referral hospital which is miles away from the affected community, a kit that will be accessed on the community level is highly welcomed
3. The area is endemic to other disease like malaria which has similar initial symptoms; multiplex test could offer proper distinction of the two.

Most impactful?

1:
2:
4:

Screening is key to during initial stages which will eventually lead to proper medication to the community level. This will have great impact on the control of the disease which is also affecting the economy of the residents.

RESPONDENT 4:
PUBLIC HEALTH OFFICER.

SCENARIO I

This is the best-case scenario.
The rK39 is not 100% sensitive or specific.
Aspirates are invasive and need highly skilled personnel.

+pros

-Once confirmed a patient can be started on treatment immediately
-Shorter hospital stay
-Quick recovery period

+cons

Repeat tests may be done to dispel suspicion at the beginning but time will take care of this if repeat procedures constantly yield the same result

The need to bring treatment services closer to the patient so that all services; diagnostics and treatment are all under one roof

SCENARIO II

This is a positive outcome as antigens stay in the body long after the patient is healed and current tests cannot test for cure, So this feels a critical gap

+pros

A less skilled person like a CHV can perform the test thus less resources are required to train personnel.

+Cons

SCENARIO III

If the cost is not prohibitive, the test can be used for sero prevalence studies.

Identification of asymptomatic cases will help reduce burden an transmission of the disease significantly; we can stop talking about control and focus on elimination

SCENARIO IV

This improves access to VL services and addresses geographical and socio-economic barriers to health care

In Baringo, Kenya, the main reason for patients not seeking care is distance to the nearest VL treatment centre, which is over 100 km away. Supporting facilities to diagnose has improved the index of those getting these services

This will improve health seeking behaviour and treatment outcomes

+pros

Malaria medication is prescribed only when someone tests positive for Malaria (this point is not clear. You don't treat on suspicion; you treat once suspicion is confirmed)

-Correct disposal of medical waste might be a big issue; unless the waste is stored in a safebox and periodicaly taken to the nearest health facility for proper disposal

+cons

Repeat tests may be done to dispel suspicion at the beginning but time will take care of this if repeat procedures constantly yield the same result

The need to bring treatment services closer to the patient so that all services; diag

SCENARIO V

As mentioned earlier, testing for multiple disease ensures proper management of patient and appropriate medication for co-infections like HIV that require specialized treatment.

+pros

If the current Malaria policy on testing all cases is followed, we will not have clinicians treating patients based on clinical diagnosis.

The test is welcome as the reason most patients are treated without confirmation is due to lack of test kits. Again this is mostly a case of making these kits available

+cons

SCENARIO VI

This will fill a gap; most patients are not followed up and those with reLAPSE only come back when they are in critical condition.

With this test we can monitor replaces and reinfections

+pros

Mechanisms and resources for follow-up especially for nomadic communities might prove challenging

Only patient on clinical trials are followed up after 6 months.

+cons

Health education on prevention and vector control is key-alongside treatment. The patient is likely to get re-infected if they go back to the same environment without knowledge of how to reduce exposure.

SELECTION OF SCENARIOS

Most feasible?

1:Screening and confirmation
2: Screening day test
3: Test at community level

Why these three?

The most important step towards control and elimination of VL is identification and management of cases. Therefore; screening; both passive (1) and active (3) are critical.

Most of those infected and affected are marginalized poor populations. Bringing the test closer to them will ensure uptake of the service. If these services are not easily accessible then we will not achieve our goals

Most impactful?

1:Screening and confirmation
2: Test at community level
3:Screening day test

The reasons I have stated above of confirming cases and but most important ensuring these services actually reach the intended beneficiaries

RESPONDENT 5:
MOLECULAR SCIENTIST

SCENARIO I

A good idea! The kit can be used at home which will assist in reaching most who are not able to visit the health facilities for diagnosis

+pros

The easy to use, minimal training needed

+cons

Misuse of the kits, patients might use them even when they not suspecting to have leishmaniasis

Will need lot's of health education, some might test at home and avoid visiting the health facilities for treatment considering treatment needs hospitalization.
Still invasive….a none invasive will be good e.g use of saliva or urine

SCENARIO II

Great that it can be used for monitoring patient treatment outcome something which the current kits can't do

+pros

Good for research e.g use in monitoring of clinical trials

+Cons

NONE

SCENARIO III

Good, however the diagnosing of both symptomatic and asymptomatic cases might not be an advantage since we don't have guidelines on what to do with asymptomatic at the moment. Do you treat or leave them? This might exaggerate the number of cases.

+pros

This can help on determination of whether humans are disease reservoirs or identify transmission dynamics

+Cons

Asymptomatic cases during community screening might add to the numbers and make cases unmanageable

SCENARIO IV

Use at home, an awesome idea

+pros

Early diagnosis

+cons

No clear how coinfection will be detected

SCENARIO V

Considering the level misdiagnosis and mistreatment associated with malaria, leishmaniasis and other febrile illnesses, the kit being a multiplex is a noble idea and will help in reducing cost, morbidity and mortality related to these diseases which can be attributed to promptness of diagnosis.

+pros

Able to diagnose malaria and leishmaniasis infections

+cons

Other febrile illness are left out e.g typhoid, brucellosis, arboviruses. Consider including them sisnce they are common in these areas

SCENARIO VI

Great idea of testing of relapse or reinfection

+pros

Better method for testing relapses/reinfection, not as invasive as Splenic or bone aspirates

+Cons

NONE

SELECTION OF SCENARIOS

Most feasible?

1: Multiplex test
2: Test at Community level
3: Screening and Confirmatory testing

1: Multiplex test
The ability to diagnose malaria and leishmania at the same time, which is important

2: Test at Community level
There is need for this since the populations to be reached are far from the health facility

3: Screening and Confirmatory testing
The current kits in use can diagnose however for confirmatory splenic or bone barrow aspiration has to be done which requires technical expertise, the proposed kit will overcome this challenge.

Most impactful?

1: Multiplex test
2: Test at Community level
3: Screening and Confirmatory testing

1: Multiplex test
The ability to diagnose malaria and leishmania at the same time, which is important. This will help in earlier treatment of the right infection

2: Test at Community level
Reaching the unreached or difficult to access thus increasing population screening coverage. Most people infected with are nomads/pastoralists who live far from the health facility.

3: Screening and Confirmatory testing
The current kits in use can diagnose however for confirmatory splenic or bone barrow aspiration must be done which requires technical expertise, the proposed kit will overcome this challenge.

E-1
list of requirements

what are the requirements that the diagnostic tests needs to fulfill?

Technical requirements	
1.01	The test should be able to test people on Visceral Leishmaniasis and give accurate test results irrespective of the patient having a primary infection, relapse, reinfection or co-infection.
1.02	The test should be able to give a correct diagnose for VL in an early (possibly asymptomatic) stage of the infection.
1.04	The test should be able to give correct test results (no false positives or negatives) independent on a person's immune system.
1.05	The test should be able to detect if a patient is cured (or not) after treatment independent of the patient's immune system.
1.06	The test should be able to detect the patient's response to treatment during treatment. (quantitative readout)
1.07	The test should have a high accuracy (specificity and sensitivity) to function as a confirmatory test (final test before putting a patient on treatment).
1.08	The test should work with a direct unprocessed blood sample.
1.09	The test should minimise or avoid false negatives.
1.10	The test should have a low false positive rate.

Equipment requirements	
2.01	The test should function independently of basic medical equipment (lancet, capillary tube).
2.02	The test should function independently of heavy lab-equipment (f.e. centrifuges, cooling boxes).

Usability requirements	
3.01	The test should be easy to use for someone with no prior knowledge of doing diagnostic tests after attending a basic training (this includes CHV's, VHT's and primary health care workers)
3.02	The test should be easy to use for a user with a medical background and some experience in doing diagnosis after attending a basic training (such as lab-technicians).
3.03	The test should be easy to use for a minimally trained health care worker after attending a basic training.
3.04	The test does not require a specialized or technical training.

3.05	The test should be the easier to use (require less steps) than the current rK39.
3.06	The test should require a limited number of steps (5 max)
3.07	The test should be understandable when being illiterate.
3.08	The test should be a fully automized and self-contained test with limited steps for the user to execute.
3.10	The test should facilitate correct usage of the test and minimize the risk of human errors when performing a diagnose.
3.11	Test housing should facilitate writing the patient name on it.
3.12	The test should facilitate the user to take a blood sample from the patient safely, thus avoid blood to blood contact.
3.13	The test should facilitate an easy way to get a blood sample.
3.14	The test should be usable without the presence of a chair for the patient to sit on and table to put the test kit on.
3.15	The test contains a quick reference instruction sheet written at the educational level of the user.
3.16	The test contains a quick referral instruction written at the educational level of the user to advice the user what to do with the patient after testing.
3.17	The test should be able to stand in a stable position (for the capillary working) until read out.
3.18	The test should be able to be in a stable position (for the capillary working) until read out when there is no table to put it on.

Read out requirements		
4.01	The test should facilitate easy and correct read-out by a user who has no prior knowledge of doing diagnostic tests.	
4.02	The test should facilitate easy and correct read-out by a user who has basic knowledge of doing diagnostic tests (and basic medical background).	
4.03	The test should facilitate easy and correct read-out by a user who has a medical background and experience with doing diagnoses.	
4.04	The test should facilitate correct read-out of the results when being illiterate.	
4.05	Test results should be available within 20 minutes after sample collection.	
4.06	Test results should be available within a day after sample collection.	
4.07	Test results should be readable by the naked eye outside.	
4.08	Test results should be readable by the naked eye inside.	
4.09	The results should prevent errors in subjective interpretation (f e. produce a clear presence or absence of a line or gradient in colour to indicate either a positive or negative result.)	
4.10	The results do not require calibrations or calculations.	
4.11	The test should notify the user when test results are not valid (f e. due to expiration date or human error)	
4.12	The test should be able to deal with human errors in such way that incorrect usage results in unavailable results instead of incorrect results.	A human error should not result in an incorrect diagnose (incorrect results), but unavailable results.
4.13	The test results should be trusted by the user when used correctly.	
4.14	The test results should be collectable as data.	
4.15	The test results should be collectable as data and send to the treatment facility.	

Robustness requirements		
5.01	Test should be able to withstand the supply chain (temperature, humidity, time delays, mechanical stresses) without requiring additional transport and storage conditions.	
5.02	The test should be able to sustain well during storage at 30 degrees for as long as the expiration date is valid.	
5.03	The buffer/liquid should be completely packaged so it does not evaporate when exposed to temperature above 30 degrees.	
5.04	The test (and reagent) should be able to withstand large fluctuations in temperature (from 40 to 10) during transportation and storage.	
5.05	The test should be able to withstand the mechanical stresses it is exposed to during transportation and storage.	
5.06	The test should have an expiration date of at least x years.	
5.07	All test components (including needle, buffer, capillary tube, alcohol swab) should be part of the test kit to make sure the user has all the tools available when doing a diagnosis.	
5.08	All test components that might be unavailable at the health facility should be part of the test kit to make sure the user has all the tools available when doing a diagnosis.	
5.09	The test should be packaged in such a way that it can be distributed and delivered efficiently.	
5.10	Every test should be packaged separately (so it can be used for per patient without opening other tests).	
5.11	A more sustainable supply system should be considered to decrease the risk of out of stock of tests.	Disease context
5.12	A notification should be send to the supplier when the tests are almost out of stock.	Disease context
5.13	The test should be retrievable at primary health facilities (dispensaries or health care centres) by the user in case of testing at community level.	
5.14	The test should be delivered to primary health facilities based on request from the treatment centre.	

Affordability requirements	
6.01	The test should be affordable for donors to fund it.
6.02	The test costs should be affordable enough to enable repetition of testing between staff and health care levels to rule out errors.

Environmental requirements		
7.01	The test should not cause environmental harm in the context due to poor waste management (of clinical waste).	
7.03	The tests should not cause risk of being left and being burned and causing toxic fumes.	
7.04	The test kit should include an instruction written at the educational level of the user which explains the correct way to dispose clinical waste.	

7.02	The environmental impact of disposable, chemical reagents, and biohazardous materials should be considered.	Process requirement

E-2
Prioritising requirements

What can be concluded from the coding the requirements to find priority?

To define a priority in the requirements established, all requirements have been coded in Atlas software and a quote list has been generated with all matches of these codes from all theory, field data, meeting insights and design process. Based on this quotation list, all pros and cons of each requirements have been sorted and selected (based on ALTAS.ti). The priority is defined by a hierarchy of 1 to 6, with 1 being the highest priority requirement and 6 the lowest. Requirements were set up in 6 groups as mentioned earlier which are: 1) Technical principle 2) Equipment 3) Usability 4) Read out 5) Robustness 6) Affordability 7) environment. For every group of requirements the most important insights based on the quotation list are summarized.

Group 1: Technical principle requirements

Most of the requirements which are part of this group are crucial for the technical principle to distinguish itself from current diagnostic practices thus have a high priority (1). Most of the requirements in group 1 are the fundament of the working of the test so without these requirements it would not make sense to develop a new POC RDT.

Group 2: Equipment free

From Literature and the field trip it becomes clear there is a serious lack of equipment in low resource settings where VL is endemic. Therefore, it is crucial that the test will function independent of equipment. This results in one of the requirements in this group being a general requirement which is applicable in all test settings (2.2). Therefore, this is a high priority requirement and can be seen a guideline as WHO ASSURED criteria emphasis that it should be E-Equipment free. The other requirement about equipment is applicable at the lowest test settings (2.1). Still important, but not as important thus receives a lower priority (3).

Group 3: Usability

Almost all requirements in this category are context-user-specific, with only few of the requirements being general and applicable for every test setting. Clearly, this is not a surprise as the background of the user defines how this person is able to interact with the test. By analysing the pros and cons for each usability requirement, it becomes clear that lack of trained staff and high staff movements in these LRS are important triggers to develop a test which is easy to use. Lack of trained staff is a serious problem and might even affect users who already have some experience with diagnose testing. Hence, almost all usability requirements are high priority requirements (1 and 2). Only 3 requirements in this group are less important.

Group 4: Read out

Only few of the requirements in this group are general and applicable for every test setting. The majority of requirement in group 4 are user specific. Similar to group 3 the way to read out the test result is very much dependent on the background of the user. The read-out time is a crucial and important requirement, similar ot

requirements based on correct read-out.
On the contrary, even though illiteracy levels are high in these VL endemic areas, requirements based on making tests suitable for illiterate people (4.4) is less priority because this is only applicable in case putting the test in the hands of the very least educated and illiterate people. However, only when the test is in the hands of a VHT or CHV, does the test have to deal with illiteracy of these users. Thus, an important requirement if you specifically want to make these ppl the users. However, as Charity said, if you look from the perspective that you will put the test in hands of a lay person with basic math and reading skills, this is not such an important priority.

Group 6: Affordability

The requirements in group 6: affordability are all high priority, as affordability is a crucial factor in Low resource settings. Especially as the affected people are not able to pay it for themselves and the entire VL treatment and diagnose is donor dependent. Thus affordability of the test is crucial and careful consideration needs to be taken to this. Therefore, both requirements about affordability of the test are high priority requirements (1).

Group 7: Environment

All of the requirements that are part of the group Environment, are crucial, therefore all of them are general requirements and thus get a priority 1.

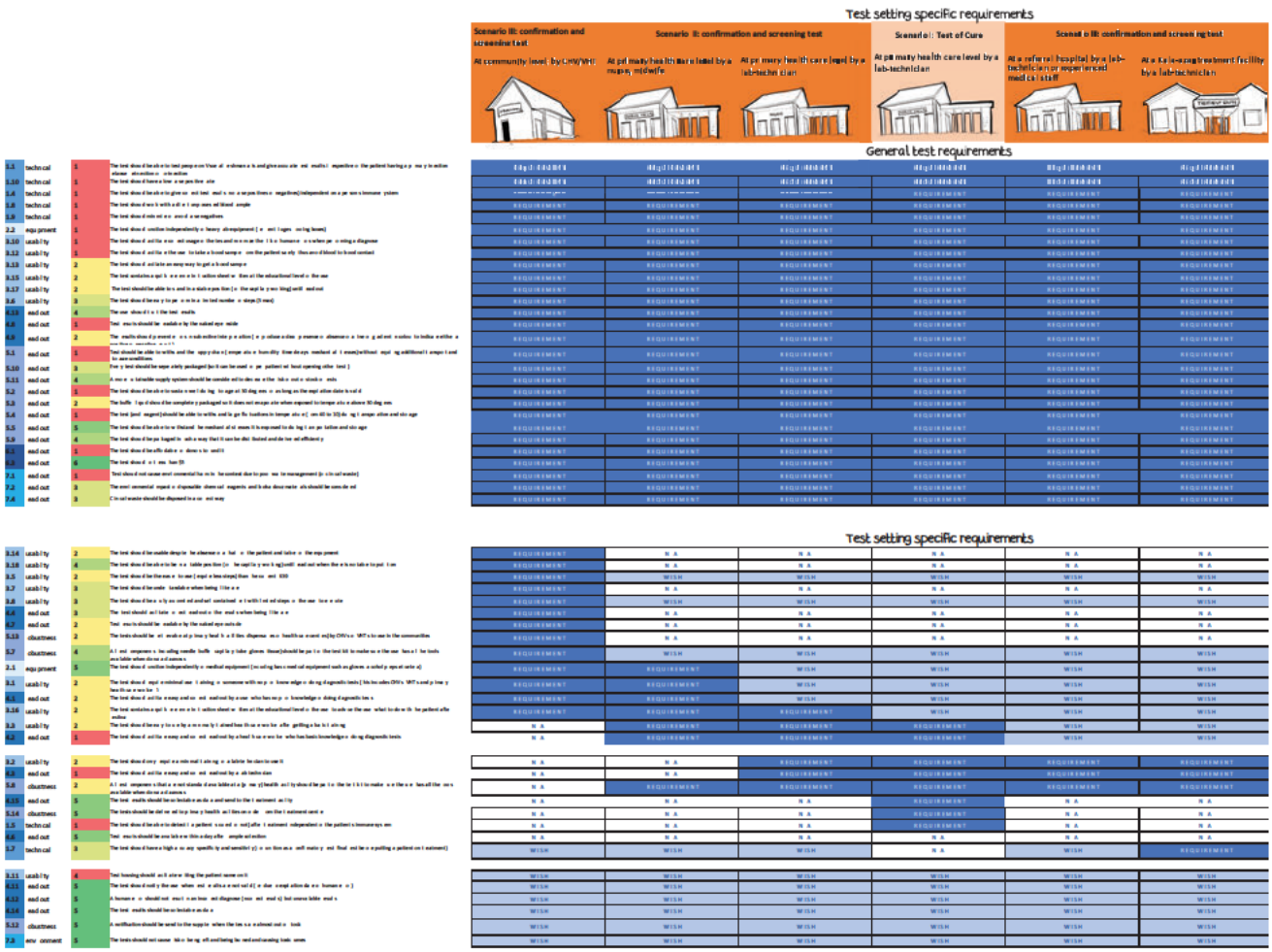
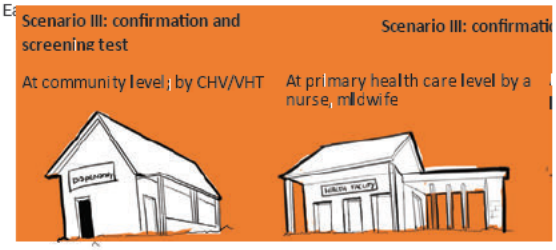


Figure 23: Requirements and their priority based on the health care level.



1.1	technical	1	The test should be able to test people on Visceral Leishmaniasis and give accurate test results irrespective of the patient having a primary infection relapse, reinfection or co-infection	REQUIREMENT	REQUIREMENT
1.10	technical	1	The test should have a low false positive rate.	REQUIREMENT	REQUIREMENT
1.4	technical	1	The test should be able to give correct test results (no false positives or negatives) independent on a person's immune system.	REQUIREMENT	REQUIREMENT
1.8	technical	1	The test should work with a direct unprocessed blood sample.	REQUIREMENT	REQUIREMENT
1.9	technical	1	The test should minimise or avoid false negatives.	REQUIREMENT	REQUIREMENT
2.2	equipment	1	The test should function independently of heavy lab-equipment (f.e. centrifuges cooling boxes).	REQUIREMENT	REQUIREMENT
3.10	usability	1	The test should facilitate correct usage of the tes and minimize the risk of human errors when performing a diagnose.	REQUIREMENT	REQUIREMENT
3.12	usability	1	The test should facilitate the user to take a blood sample from the patient safely thus avoid blood to blood contact.	REQUIREMENT	REQUIREMENT
3.13	usability	2	The test should faciliate an easy way to get a blood sample.	REQUIREMENT	REQUIREMENT
3.15	usability	2	The test contains a quick reference instruction sheet written at the educational level of the user.	REQUIREMENT	REQUIREMENT
3.17	usability	2	The test should be able to stand in a stable position (for the capillary working) until read out.	REQUIREMENT	REQUIREMENT
3.6	usability	3	The test should be easy to perform in a limited number of steps (3 max)	REQUIREMENT	REQUIREMENT
4.13	read out	4	The user should trust the test results.	REQUIREMENT	REQUIREMENT
4.8	read out	1	Test results should be readable by the naked eye inside.	REQUIREMENT	REQUIREMENT
4.9	read out	2	The results should prevent errors in subjective interpretation (f.e. produce a clear presence or absence of a line or gradient in colour to indicate either a positive or negative result)	REQUIREMENT	REQUIREMENT
5.1	read out	1	Test should be able to withstand the supply chain (temperature humidity time delays mechanical stresses) without requiring additional transport and storage conditions	REQUIREMENT	REQUIREMENT
5.10	read out	3	Every test should be seperately packaged (so it can be used for per patient without opening other tests).	REQUIREMENT	REQUIREMENT
5.11	read out	4	A more sustainable supply system should be considered to decrease the risk of out of stock of tests.	REQUIREMENT	REQUIREMENT
5.2	read out	1	The test should be able to sustain well during storage at 30 degrees for as long as the expiration date is valid.	REQUIREMENT	REQUIREMENT
5.3	read out	2	The buffer/liquid should be completely packaged so it does not evaporate when exposed to temperature above 30 degrees.	REQUIREMENT	REQUIREMENT
5.4	read out	1	The test (and reagent) should be able to withstand large fluctuations in temperature (from 40 to 10) during transporation and storage	REQUIREMENT	REQUIREMENT
5.5	read out	5	The test should be able to withstand the mechanical stresses it is explosed to during transportation and storage.	REQUIREMENT	REQUIREMENT
5.9	read out	4	The test should be packaged in such a way that it can be distributed and delivered efficiently.	REQUIREMENT	REQUIREMENT
6.1	read out	1	The test should be affordable for donors to fund it	REQUIREMENT	REQUIREMENT
6.3	read out	6	The test should cost less than $5.	REQUIREMENT	REQUIREMENT
7.1	read out	1	Test should not cause environmental harm in the context due to poor waste management (of clinical waste).	REQUIREMENT	REQUIREMENT
7.2	read out	3	The environmental impact of disposable chemical reagents and biohardouz materials should be considered.	REQUIREMENT	REQUIREMENT
7.4	read out	3	Clinical waste should be disposed in a correct way.	REQUIREMENT	REQUIREMENT
3.14	usability	2	The test should be usable despite the absence of a chair for the patient and table for the equipment.	REQUIREMENT	N.A.
3.18	usability	4	The test should be able to be in a stable position (for the capillary working) until read out when there is no table to put it on.	REQUIREMENT	N.A.
3.5	usability	2	The test should be the easier to use (require less steps) than the current rK39.	REQUIREMENT	WISH
3.7	usability	3	The test should be understandable when being illiterate.	REQUIREMENT	N.A.
3.8	usability	3	The test should be a fully automized and self-contained test with limited steps for the user to execute.	REQUIREMENT	WISH
4.4	read out	3	The test should facilitate correct read-out of the results when being illiterate.	REQUIREMENT	N.A.
4.7	read out	2	Test results should be readable by the naked eye outside.	REQUIREMENT	N.A.
5.13	robustness	2	The tests should be retrievable at primary health facilities (dispensaries or health care centres) by CHV's or VHT's to use in the communities.	REQUIREMENT	N.A.
5.7	robustness	4	All test components (including needle buffer capillary tube gloves tissue) should be part of the test kit to make sure the user has all the tools available when doine a diagnosis.	REQUIREMENT	WISH
2.1	equipment	5	The test should function independently of medical equipment (including basic medical equipment such as gloves alcohol preps et cetera).	REQUIREMENT	REQUIREMENT
3.1	usability	2	The test should require minimal user training for someone with no prior knowledge of doing diagnostic tests (this includes CHV's VHT's and primary health care workers)	REQUIREMENT	REQUIREMENT
4.1	read out	2	The test should facilitate easy and correct read-out by a user who has no prior knowledge of doing diagnostic tests.	REQUIREMENT	REQUIREMENT
3.16	usability	2	The test contains a quick reference instruction sheet written at the educational level of the user to advice the user what to do with the patient after testing	REQUIREMENT	REQUIREMENT
3.3	usability	2	The test should be easy to use by a minimally trained health care worker after getting a basic training.	N.A.	REQUIREMENT
4.2	read out	1	The test should facilitate easy and correct read-out by a health care worker who has basic knowledge of doing diagnostic tests.	N.A.	REQUIREMENT
3.2	usability	2	The test should only require a minimal training for a lab-technician to use it.	N.A.	N.A.
4.3	read out	1	The test should facilitate easy and correct read-out by a lab technician.	N.A.	N.A.
5.8	robustness	2	All test components that are not standard available at a (primary) health facility should be part of the test kit to make sure the user has all the tools available when doine a diagnosis	N.A.	REQUIREMENT
4.15	read out	5	The test results should be collectable as data and send to the treatment facility.	N.A.	N.A.
5.14	robustness	5	The tests should be delivered to primary health facilities on order from the treatment centre.	N.A.	N.A.
1.5	technical	1	The test should be able to detect if a patient is cured (or not) after treatment independent of the patient's immune system.	N.A.	N.A.
4.6	read out	5	Test results should be available within a day after sample collection.	N.A.	N.A.
1.7	technical	3	The test should have a high accuracy (specificity and sensitivity) to function as a confirmatory test (final test before putting a patient on treatment).	WISH	WISH
3.11	usability	4	Test housing should facilitate writing the patient name on it.	WISH	WISH
4.11	read out	5	The test should notify the user when test results are not valid (f.e. due to expiration date or human error)	WISH	WISH
4.12	read out	5	A human error should not result in an incorrect diagnose (incorrect results) but unavailable results.	WISH	WISH
4.14	read out	5	The test results should be collectable as data.	WISH	WISH
5.12	robustness	5	A notification should be send to the supplier when the tests are almost out of stock.	WISH	WISH
7.3	environment	5	The tests should not cause risk of being left and being burned and causing toxic fumes.	WISH	WISH

Test setting specific requirements

nation and screening test	Scenario I: Test of Cure	Scenario III: confirmation and screening test		Scenario I: Test of Cure
a At primary health care level by a lab-technician	At primary health care level by a lab-technician	At a referral hospital by a lab-technician or experienced medical staff	At a Kala-azar treatment facility by a lab-technician	At a Kala-azar treatment facility by a lab-technician
				

General test requirements

REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT
REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT
REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT
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REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT
REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT

Test setting specific requirements

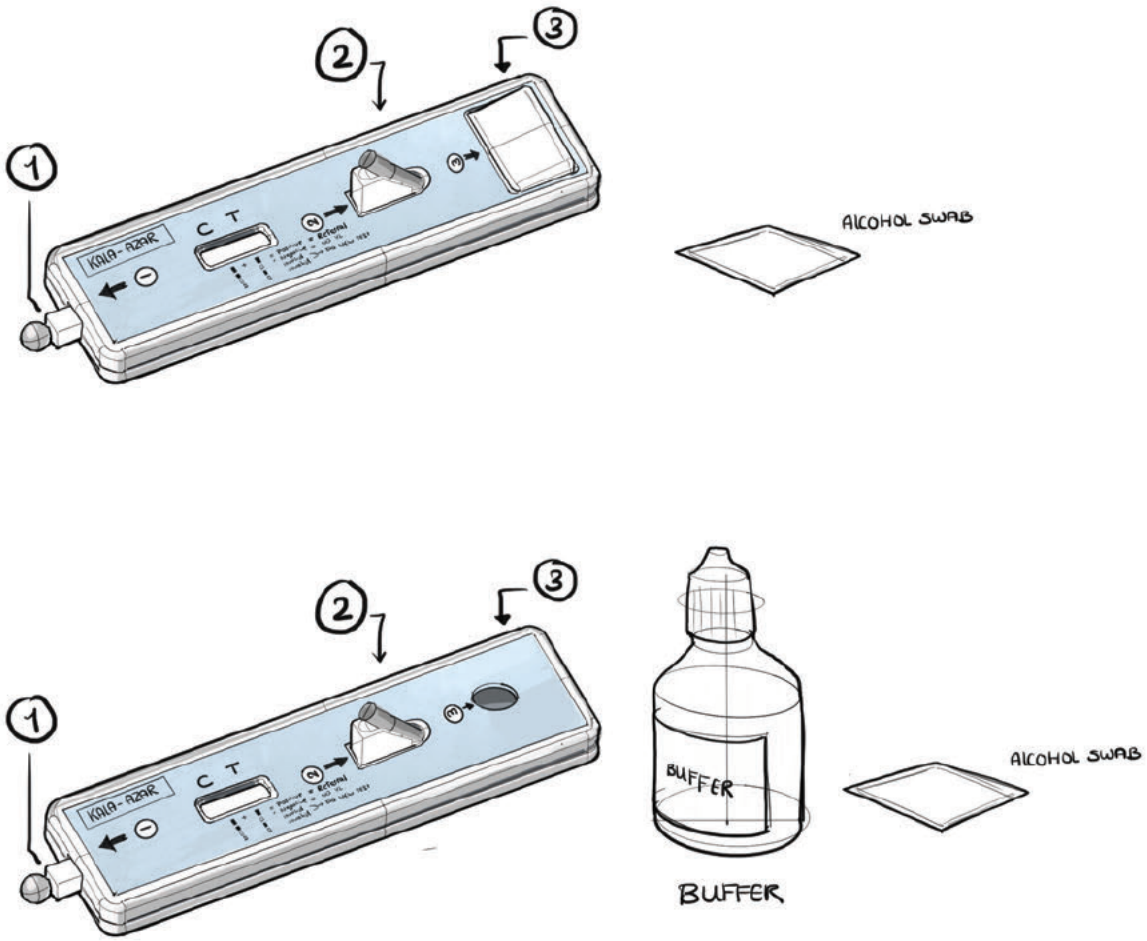
N.A.	N.A.	N.A.	N.A.	N.A.
N.A.	N.A.	N.A.	N.A.	N.A.
WISH	WISH	WISH	WISH	WISH
N.A.	N.A.	N.A.	N.A.	N.A.
WISH	WISH	WISH	WISH	WISH
N.A.	N.A.	N.A.	N.A.	N.A.
N.A.	N.A.	N.A.	N.A.	N.A.
N.A.	N.A.	N.A.	N.A.	N.A.
WISH	WISH	WISH	WISH	WISH
WISH	WISH	WISH	WISH	WISH
WISH	WISH	WISH	WISH	WISH
WISH	WISH	WISH	WISH	WISH
REQUIREMENT	WISH	WISH	WISH	WISH
REQUIREMENT	REQUIREMENT	WISH	WISH	WISH
REQUIREMENT	REQUIREMENT	WISH	WISH	WISH

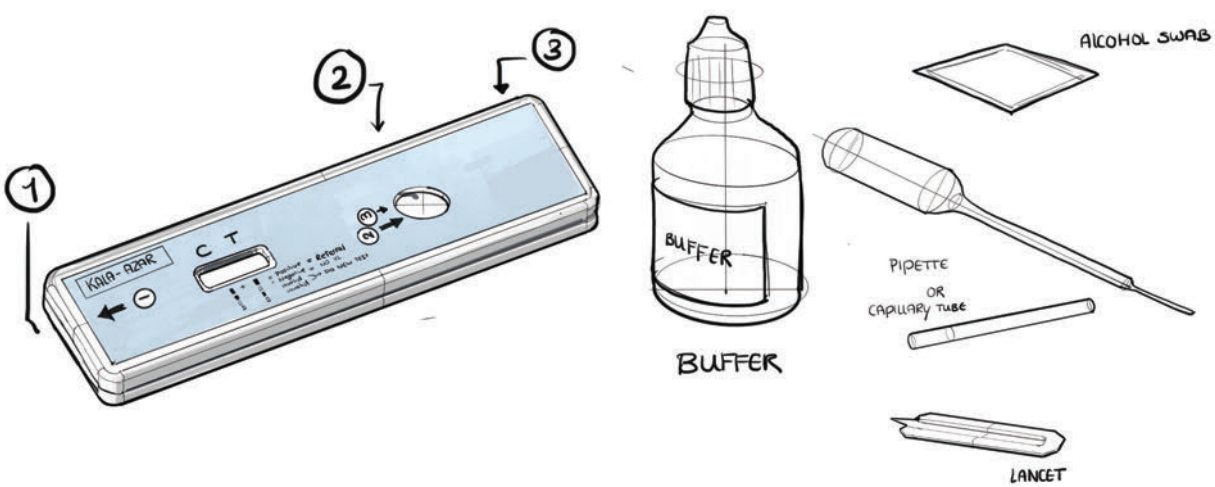
REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT
REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT
REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT	REQUIREMENT
N.A.	REQUIREMENT	N.A.	N.A.	N.A.
N.A.	REQUIREMENT	N.A.	N.A.	N.A.
N.A.	REQUIREMENT	N.A.	N.A.	REQUIREMENT
N.A.	N.A.	N.A.	N.A.	REQUIREMENT
WISH	N.A.	WISH	REQUIREMENT	N.A.

WISH	WISH	WISH	WISH	WISH
WISH	WISH	WISH	WISH	WISH
WISH	WISH	WISH	WISH	WISH
WISH	WISH	WISH	WISH	WISH
WISH	WISH	WISH	WISH	WISH
WISH	WISH	WISH	WISH	WISH

F-1
Draft diagnostic tests

Housing drafts based on requirements.




1
2
3
KALA- AZAR
C T
BUFFER
BUFFER
ALCOHOL SWAB
PIPETTE
OR
CAPILLARY TUBE
LANCET

F-2
Usability of rK39

How 'usable' is the current rK39?

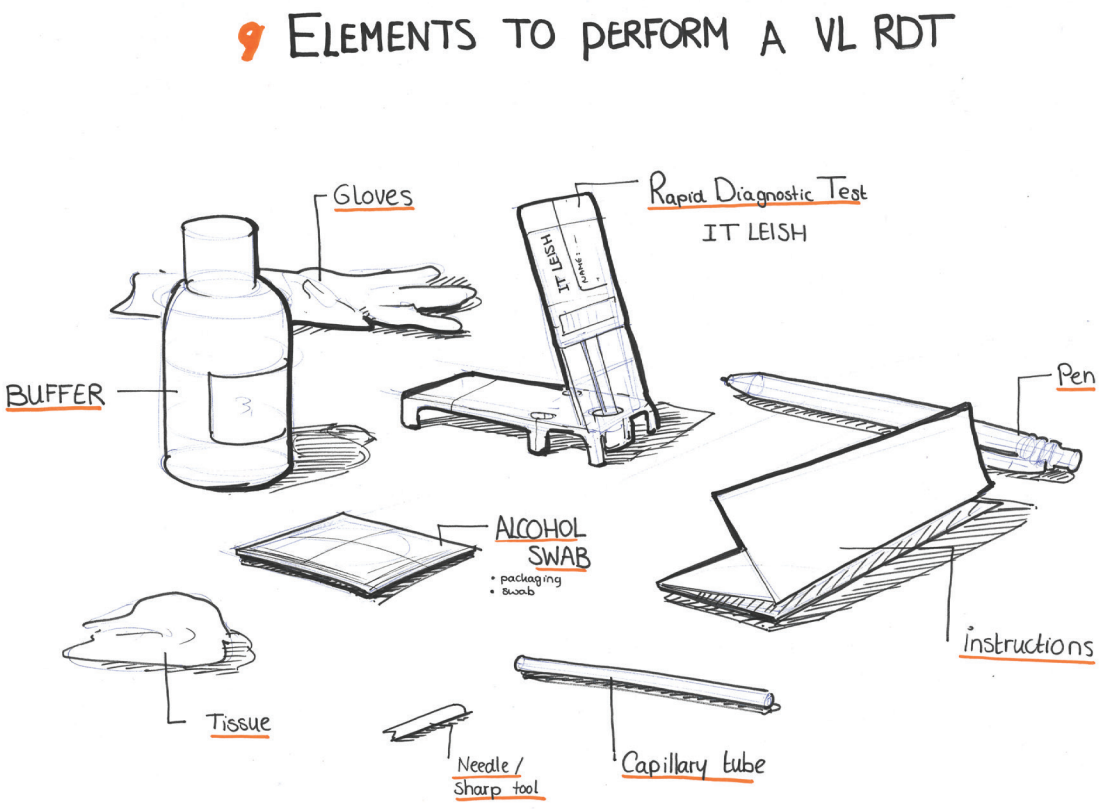


Figure 24: Elements of the rK39.

By analysing the usage of the rk39 in the field (by a lab-technician and CHW in training), several insights were found considering the usability.

The IT Leish rk39 version consists of a lot of components (see Figure 24).

Even though this diagnostic test claims to be 'easy' to use, in reality, this is not the case.
o The rK39 has quite many components (see Figure 24) which makes it complicated to use this diagnostic test at communities, where there are no tables or chairs.
o During a phone call with Charity Kamau from MSF, it became clear that mistakes in the execution of this diagnostic test are frequently occurring. When asking her what can go wrong, she mentioned that everything goes wrong.

This includes mistakes such as
- the collection of the wrong sample

- the alcohol (of the alcohol swab) is still present on the finger and thus messes up with the blood sample
- the wrong amount of sample
- wrong buffers
  too much or too little of the buffer, losing the buffer or switching buffers
- incorrect read-out.

Training:

During endemic seasons, MSF regularly trains people from communities to perform this rapid diagnostic test. According to MSF, teaching someone to use an rK39 diagnostic test takes approximately 3 days. However, this training is no guarantee that the diagnostic test is used correctly (at all times).

In the field, from own observations, it became evident that someone needs quite some training to be able to use an rK39 test. A CHW needs to be trained for months to be able to test people for VL responsibly.

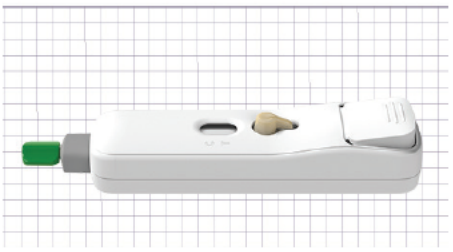
The current rK39 is not that 'easy to use' as Literature claims. The number of interventions which the user needs to perform often result in usability errors (MSF, 2018).

Usability errors can be risky when incorrectly taking a blood sample. Usability errors can lead to contamination of the sample or blood-to-blood contact between the patient and the user. This can have enormous negative consequences. Therefore, it is important for future diagnostics to guarantee a safe way to use a blood sample.

Usability errors of current tests

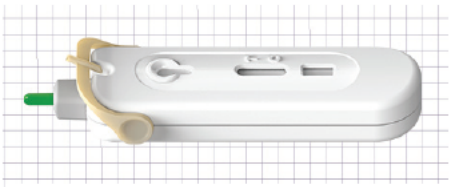
Interestingly and in contrast with the positive reactions of the IT Leish test in the field, Charity Kamau mentioned that usability errors occur often. Not only with the IT LEISH rk39 RDT but also Malaria tests everything can go wrong. Every possible thing that can go wrong, in reality, goes wrong. Interestingly, according to Charity Kamau, it does not matter if the test is executed at a lower health care level or a higher health care level, mistakes in the execution of these tests are still common.
Only correct results are produced when every step is done correctly, and in reality, this seems to be rather difficult.

F-3
Reference diagnostics
Existing diagnostic tests



Atmo HIV test

There are multiple versions. It depends on the version which components are integrated.
For example in case of the upper one (self-test), the buffer and capillary tube and needle are integrated.



In case of the lower one, the buffer is not integrated. However the other components are.


Lance Finger


Collect Blood


Deliver Buffer


Read Results


Lance Finger


Collect Blood


Deliver Blood


Add Buffer


Read Result

http://atomodiagnostics.com/oem/our-rdt-platforms/elion-rdt-platform/

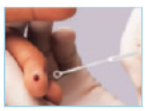
OraSure HIV test
This test is usable. However, it should stand up straight and thus requires an extra (reusable) stand.

Can be used with wholeblood, saliva.

Simple Testing Procedure

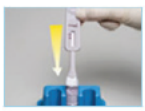
Fingerstick

Step 1 - Collect sample.



Step 1b - Mix sample in buffer.

Step 2 - Insert the device into the buffer.



Step 3 - Read between 20 and 40 minutes.

Non-Reactive
Line in the C Zone

Reactive
Line in the C and T Zones

http://www.orasure.com/products-infectious/products-infectious-oraquick-self-test.asp

F-4
The new diagnostic tests in action
A well-handled diagnostic test procedure

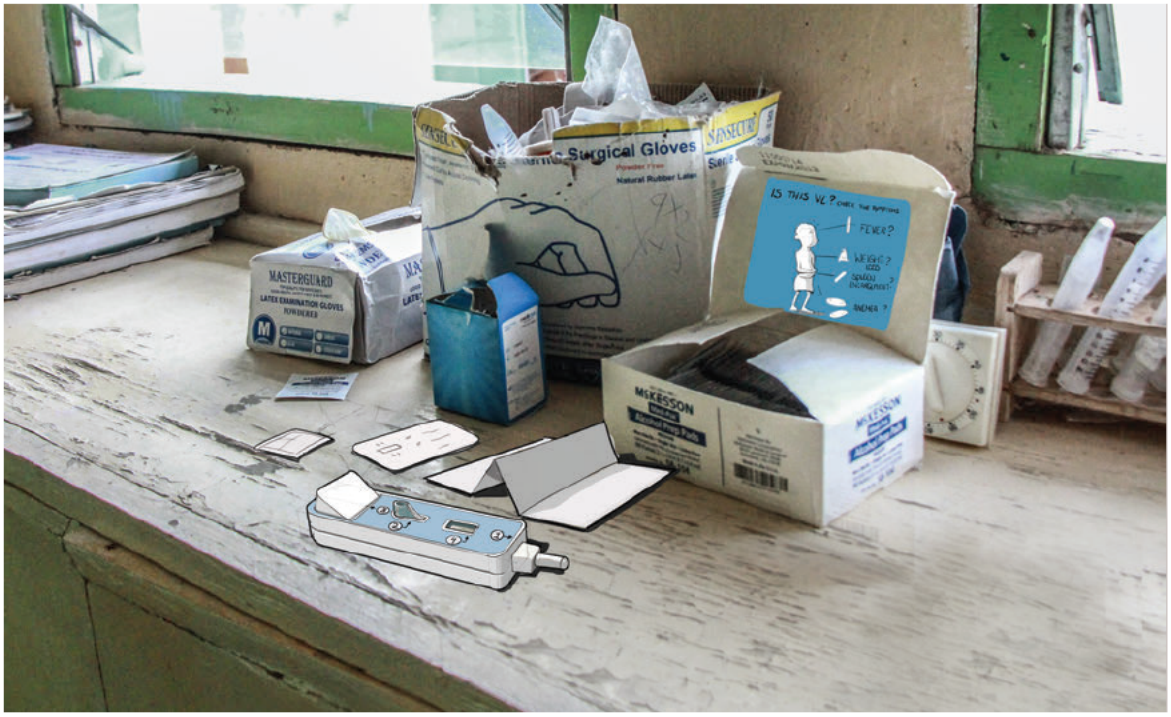


Figure 25: Diagnostic test kit with 'querying instruction' on the inside of the primary packaging.

A well-handled diagnostic test procedure includes more than being able to use a diagnostic test. Therefore, each diagnostic test should facilitate the user through three steps:

1) **Query VL**
2) **Use** the diagnostic test
3) **Conclude** the test result (and either refer to a treatment facility or test for another disease)

1) Query

The users can be guided by providing 'querying instructions' as part of the diagnostic test kit. This will help users to query VL, which is especially important among users without a medical background.

- As can be seen in Figure 26, the primary packaging of the diagnostic tests includes a 'querying instruction'. This instruction enables users to check if the symptoms of the patient match which the intention of the diagnostic test before opening it. It is important that the user can distinguish VL from other fever-related diseases. Ideally, this instruction would not only be applied at the packaging of VL diagnostic tests but at all other RDT packages.

    - Note: Querying VL can be rather complicated in case of co-infections even for trained health care workers. Therefore it is recommended to include an instruction

which guides the user in distinguishing the most important symptoms between VL and other common symptom-related diseases. This could, for example, be printed on the package (see Figure 26).

- It is not that easy to design a 'querying' instruction which supports the user in distinguishing VL from other endemic diseases. Especially in the presence of co-infections, recognising VL can be rather complicated. Therefore, for future development of the diagnostic test, it is recommended to further look into ways to support a user in the querying process.

2) Use the diagnostic test

The diagnostic tests are designed in such a way that they will guide all users through the usage of the diagnostic test as much as possible.

- Integration of components
  The required level of integration of the components in a diagnostic test depends on the experience of the user and the resources available at a diagnostic setting. When a user has no medical background (and no prior knowledge of doing diagnostic tests), and the resources at the context are limited, more components need to be integrated into the diagnostic test. When the diagnostic test is used by a well-trained health care worker components (such as buffer and lancet) can be separate. Similarly, the number of steps needs to be as small as possible when the user has

3) Draw conclusions from test results

The background of the user influences the ability to draw (correct) conclusions from the diagnostic test. In other words, the level of medical background of a user affects whether or not someone can read out the results and draw conclusions from them. Readout support and referral support are especially important for users without a medical background. Therefore, the diagnostic tests B, C and D include a read-out/referral instruction. This instruction supports the user to read out the result and either refer (in case of a positive test result) or test the patient for another disease (in case of a negative test result). When a medical professional (level 4 background of the user) uses the diagnostic test, there is no need for this readout/referral instruction as this user can conclude without additional support.

G-1
Envisioned application

BASELINE MEASUREMENTS WITH APPLIED SCIENCES

To get an idea of what the researchers from Applied sciences are envisioning the application of the technical principle will be like when developed, a baseline measurement is done before the field trip. This baseline measurement is done by asking the Cees Dekker, Michel Bengtson and Mitasha Bharadwaj separately what they would envision the test would be like in 2025 (6 years from now). The main insights from this baseline measurement are described here. However, it is essential to keep in mind that there are differences between the answers of the researchers.

Automated self-test:

In general, the ideal test described and envisioned would be a self-test thus enabling patients to test themselves. In addition, this self-test would be purchase by patients themselves. Therefore, they mentioned that the test should have a low price. During the conversations, the pregnancy test was often set as an example for the envisioned test in terms of usability. Thus, the envisioned test should be completely automated to facilitate self-usage by a patient. The way the envisioned test is used would have much resemblance with the steps which are taken when you suspect to be pregnant. First, if you suspect to be sick, you go to a pharmacy to buy a test and do the test yourself at home. If the result is positive, you make an appointment to go to a doctor. Thus, the test is (similar to a pregnancy test) used as a first indication that you are pregnant but will be combined with further consultation with a professional (going to a doctor).

Ideally, the test should be usable outside the walls of the health care facility and into the homes of the people. Of course, the researchers also realised that this is ideal and the question is whether this is feasible in low-resource settings.

Sample

As became clear from the baseline measurements, the envisioned test is very much focussed on non-invasiveness. Therefore, urine is mentioned as the ideal sample source due to its non-invasive character.

However, both urine and blood-based tests are currently being developed.

Applicable for all diseases and VL seen as case study

From the researcher's point of views, logically, the technical principle is the central element. During the baseline measurement it became clear that the researchers are very much looking at the project from the technical principle point of view and thus (Visceral) Leishmaniasis is seen as a case study. When the technical principle works for one disease, it can be used for other diseases as well. During the baseline measurements, it became clear that the emphasis of them is on developing the technical principle first and then see for which diseases it can be applied.

Start-up / business model

The baseline measurement showed that the researchers also envision a business model in this technical principle. They see a commercial side of the technical principle such as turning the technical principle into a start-up. For example, it was mentioned that the technical principle could even be usable as a self-test for western people who have been travelling to endemic areas.

DESIGN FOR our future

H-1 Project Brief

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name
initials given name
student number
street & no.
zipcode & city
country
phone
email

Your master programme (only select the options that apply to you):

IDE master(s): ★ IPD ○ DfI ○ SPD

2nd non-IDE master:

individual programme: - - (give date of approval)

honours programme: ○ Honours Programme Master

specialisation / annotation: ○ Medisign
○ Tech. in Sustainable Design
○ Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Dr. ir. Diehl — dept. / section: DE/DfS

** mentor: Prof. dr. ir. van Engelen — dept. / section: DE/DfS

2nd mentor: Michel Bengtson

organisation: TU Delft (Faculty of Applied Sciences)

city: Delft — country: The Netherlands

comments (optional): Dr. ir. Diehl has a lot experience in design for sustainability and did a lot of Base of Pyramid and healthcare projects before. Prof. dr. ir. van Engelen is expert in Business development and has a medical background.

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

TU Delft

Procedural Checks - IDE Master Graduation

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Dr. ir. Diehl date 10 - 11 - 2018 signature jdiehl Digitally signed by jdiehl Date: 2018.11.10 22:34:34 +01'00'

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 30 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 30 EC

List of electives obtained before the third semester without approval of the BoE

(X) YES all 1st year master courses passed

( ) NO missing 1st year master courses are:

name date 23 - 11 - 18 signature

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: (V) APPROVED ( ) NOT APPROVED

Procedure: (V) APPROVED ( ) NOT APPROVED

comments

name A Kuwae date 11 - 12 - 2018 signature

Point-of-care diagnostic tool for low resource settings in East-Africa

project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 05 - 11 - 2018 22 - 04 - 2019 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

This project focusses on the neglected disease Leishmaniasis in East-African countries such as Kenya and Uganda. Leishmaniases are a group of diseases which are caused by parasites from more than 20 different Leishmania species. The disease is transmitted to humans by the bite of infected female sand-flies (Figure 1). Worldwide, there are 2 million new cases each year and 556 million people are at risk of acquiring the infection (Handman, 2001). Leishmaniasis occurs in two forms: Viscular Leishmaniasis (VL) and Cutaneous leishmaniasis (CL) (African Health Observatory, 2016). CL is a skin infection which may cause a large number of lesions, which can cause serious disability. When the ulcers heal, they invariably leave permanent scars, which are often the cause of serious social prejudice. VL is the most severe form of the disease. VL is curable but still causes high morbidity due to its low index of suspicion by health care providers, late diagnosis and case management. Therefore, the fatality rate in developing countries such as Kenya and Uganda for Visceral Leishmaniasis is as high as 100% in two years. Most cases of VL occur in Brazil, East Africa and in South-East Asia. In East Africa, outbreaks of Leishmaniasis occur frequently (WHO, n.d.). Poor housing and sanity conditions can also have an influence on the increase of sand-fly and their access to humans. This can result in higher risk of Leishmaniasis. Therefore, Leishmaniasis is strongly related to poverty and often associated with malnutrition, population displacement, poor housing, a weak immune system and lack of financial resources (WHO, n.d.)

Treatment for VL is available, but especially in low resource settings it is difficult to diagnose the disease in an early stage due to limited facilities, health care workers and doctors. Besides that, the symptoms of VL are pretty similar to other diseases and therefore it is often confused for other diseases.

Current rapid diagnoses tests exist but often detect antigens in the body which differ from person to person and even between countries and therefore is less consistent. Besides that, these tests cannot distinguish between previous and current infections. More specific and reliable diagnostic tests exist, but require microscopes, sterile environments or other advanced tools which are simply not available in these low resource settings. Therefore, PhD candidate Michel Bengtson from Applied Sciences at the TU Delft is performing research as the Cees Dekker lab to develop a technology which involves a CRISPR/Cas9 system which can be used to detect pathogenic DNA in a drop of blood ("Testing of parasitic DNA", n.d.). This detection of DNA of the pathogen will be more consistent and will work independent of the person's immune response. Besides that, it can distinguish between current and previous infections, unlike current rapid diagnostic tests. This technology is the start of developing a point-of-care tool to diagnose infectious diseases such as Leishmaniasis in an early stage in low resource settings (Figure 2).

To develop a suitable diagnostic tool for these low resource settings in Kenya and Uganda, it is important take into account both the direct users (doctors and patients) of the diagnostic tool as well as other stakeholders involved. Therefore, developing a product for such low resource settings in East-Africa involves multiple other stakeholders such as governmental and non-governmental organisations, aid and knowledge institutes with different backgrounds and interests (Delft Design Guide, 2013).

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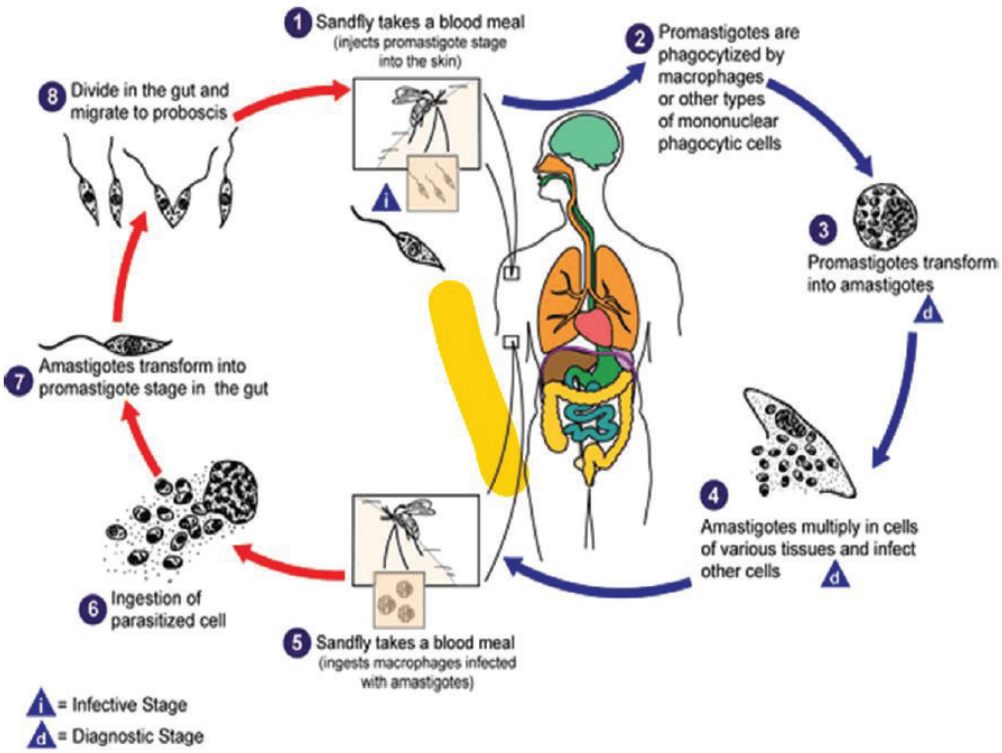


image / figure 1: Life cycle of Leishmania (Republic of Kenya, Ministry of Health 2017)

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

As mentioned before, Leishmaniasis is curable when diagnosed and treated in time. Unfortunately, especially in low resource settings it is difficult to diagnose the disease (in early stage). There is a lack of facilities and technical expertise to do diagnosis through microscopic confirmation of the parasite in tissue aspiration. Even though current rapid diagnostic tests require minimal training they are not ideal as they cannot distinguish between previous and current infections. Therefore, it is important to develop an effective diagnostic tool to diagnose Leishmaniasis which is suitable for low resource settings of Kenya and Uganda.

The Pathogenic DNA technology that is now being developed at Applied Sciences is expected to be used in a diagnostic tool that probes for (neglected) infectious diseases in resource limited settings. Integrating this Pathogenic DNA technology into a potentially low-cost diagnostic tool is a highly promising alternative to current diagnostic approaches. For successful integration of the technology and product in this resource limited context, it is essential to know more about the current (diagnosis) context (healthcare system, stakeholders, patients, climate and infrastructure) as well as the desired future context to diagnose Leishmaniasis (from the perspective of the different stakeholders). However, there is a lack of knowledge about the context of these resource limited settings in Kenya and Uganda in which the product (system) should work.

An understanding of the context will help to develop product specifications for smart diagnostics considering local knowledge and experience. Thus, a clear understanding of the journey of Leishmaniasis patients, healthcare system and facilities, diagnosis procedure and climate and infrastructure is needed. The aim is to set technical product (system) requirements and specifications from the context analysis which will help develop a product system which is suitable for its context in terms of logistics, materials, expiration date, cooling system and usability. Thus, the focus will be on balancing the desirability of the users in context, feasibility and viability into a suitable product system which can be implemented into the local healthcare systems of Kenya and Uganda.

ASSIGNMENT **

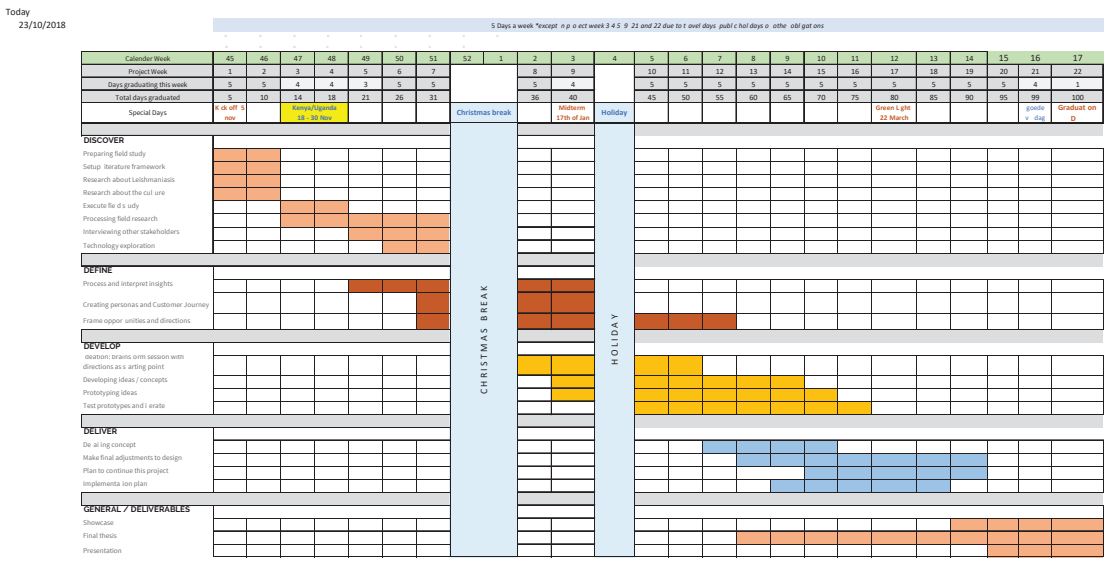
State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

Further develop a point-of-care infection diagnostic tool based on the technology principle of Applied Sciences which is desirable (for direct users and stakeholders) and suitable for resource limited settings in Kenya/Uganda to diagnose Leishmaniasis. This with the aim to diagnose patients with Leishmaniasis in an early stage in low resource settings.

At the end of this project a product system will be delivered. This means that the outcome of this project will not purely be a diagnostic tool (product), but rather a diagnostic tool and distribution chain to the last mile within a healthcare (governmental) system involving a broader range of stakeholders. For the product part of the product system, a final prototype or step-by-step approach will be delivered. The delivered product system will integrate the technology of Applied Sciences. In addition, the project will provide guidelines and recommendations for further development of both the technology and product.

meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 5 - 11 - 2018 22 - 4 - 2019 end date



The project will be divided in four stages based on the Double Diamond model (Design Council, 2004). Parallel to those 4 stages there is the lab development from Applied Sciences, which means there will be exchange of information throughout the project. This graduation project will directly influence the distribution chain.

o Phase I: DISCOVER: This phase is all about gathering information and familiarizing with the context of Leishmaniasis, the diagnosis process and the culture and health system of Kenya / Uganda. Thus, this phase involves a 2 week fieldtrip to East-Africa. In addition this phase will be about getting to know the stakeholders involved in this project and exploration of the DNA CRISPR technology (development at the lab) and its potential future implications.

o Phase II: DEFINE: In this phase it is all about trying to make sense of all insights and interpret the meaning. All information gathered in Phase I will be used to (re)frame fundamental opportunities or directions to tackle ad develop ideas upon.

o Phase III: DEVELOP: In this phase it will be about the development of solutions or concepts through ideation, prototyping, testing and iterating. In creative sessions with design students and other stakeholders (doctors, doctors without borders and perhaps potential users) quick ideas can be generated and discussed. Simple prototypes can be on created to valuate early ideas/concepts and iterate upon. Usability tests of the interaction can be done both in the Netherlands as well as the actual context (Kenya/Uganda) depending on the planning.

o Phase IV: DELIVER: In this phase, the designed solution(s) will be detailed and refined to come up with a final product system. Besides that the focus is on coming up with guidelines to implement the solution(s) in the actual context/system. This phase ends with a thorough reflection on the project and recommendations for further development.

Throughout this project there will be continues loops back and forth between phases to reflect/iterate. It also requires a continuous movement between zooming in and out between the product/context details and system as a whole.

Initials & Name A.P. ten Bosch Student number 4296753

Title of Project Point-of-care diagnostic tool for low resource settings in East-Africa

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

Throughout my entire studies I have been interested in doing meaningful projects which I would contribute (even if it is in a very small way) to a positive improvement of people's lives. This project appeals to me as it includes several areas of my interest such as design for Base of pyramid context, health care (systems), user centeredness, context analysis during a fieldtrip and the combination both system and product design.

I am a curious person who enjoys diving into new projects or topics and gather, cluster and structure information. The master IPD has taught me a lot about integrating all kinds of elements into a whole (system or product) and finding relations between the elements. Unfortunately in previous projects (in IPD) there was usually less focus (and time) on the exploration of the context and the interpretation of insights found from the context. In this project the context analysis is crucial for further development and direction of the diagnostic technology. At the same time, this context is extremely unfamiliar to me which makes this project exciting and challenging at the same time.

This project enables me to use the knowledge about integrating a wide variety of elements/aspects into a proposal and requires continues zooming in and out between product & technology and a system. This continues switching between the 'bigger picture' and details within the context or product appeal to me. Throughout my graduation I want to prove that I am capable of diving into a completely unfamiliar topic and context and use the insights into a meaningful design.

During my in-house project at Unilever and the cases from various companies in Brazil during Flightcase, I figured out that I enjoy working with people with different expertise areas (in terms of other master students as well as engineers, scientists and marketeers). Communicating thoughts, finding common ground when working together with people with a different skillset is something I find interesting. It is challenging and interesting to find an effective way to collaborate with people who do not have a similar background. This project enables me to work together with a research team of Applied Sciences and apply my knowledge and skills to contribute to their project while learning from such a collaboration.

Throughout my graduation I would like to develop my facilitation skills when having meetings or doing creative sessions. Besides that I want to experience how I am able to contribute in a project with a completely new context and topic. Thus, pushing my boundaries as a designer and designing for a target group and context that is completely new to me.

I want to further develop my visual communication skills throughout the project and use them to improve communication with stakeholders. This will be especially valuable to explain my project to other stakeholders and gain understanding, communicate my capabilities as a designer, but also make a complex system more tangible. Besides that, I want to effectively use my visualisation skills to communicate complex elements within this project.

Lastly, I want to consciously enjoy the graduation time. As perfectionistic as I am, I want to be specific on what I want to be perfectionistic about instead of trying to be perfectionistic about everything. Also, I want to embrace 'failure' or doing something wrong during the project as trial-and-error is a great way to learn.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.