Development of an all-in-one transportable clinical bacteriology laboratory: feedback from testing a Mini-Lab prototype

MSF Scientific Days 2019

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Antibiotic resistance (ABR) in the world

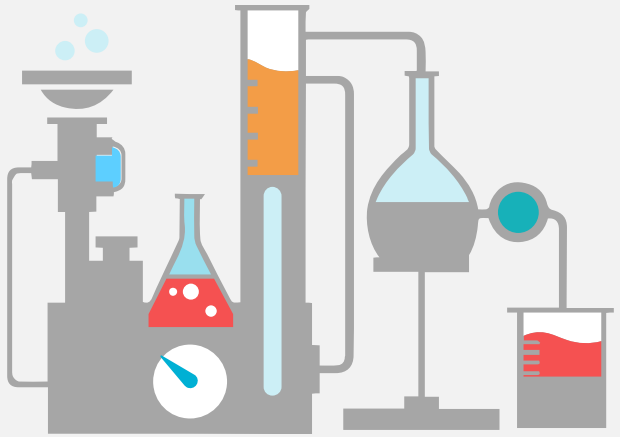
ABR is growing in severity; all regions of the world are affected to varying extents (Becker, J. U. *et al.* 2009)

- WHO has identified ABR as one of the major threats to global health (WHO, 2014)
- Many of the gaps in ABR surveillance exist where MSF operations are active
- ABR puts patient at risk and jeopardizes MSF and other humanitarian medical activities
- Sepsis emerged as new threat within MSF populations

01 Background

Clinical bacteriology lab: cornerstone to improve our medical interventions

- Today, the only way to diagnose sepsis and survey resistance trends in our population is by implementing clinical bacteriology laboratories (CBL).



- WHO recommends massive implementation of clinical bacteriology in Low Resource Settings (LRS). (WHO, 2014)

- MSF Medical Director platform supports the necessity to further invest in CBL

01 Background

Implementing CBL in LRS implies serious challenges:

Inherent limitations of infrastructure and budget

Power supply

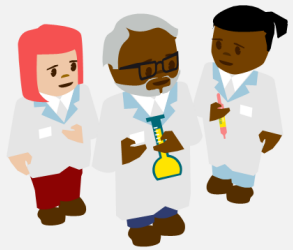
Climate, Humidity, dust control

Costly methods

Logistical problems

Steady supply, availability, quality assurance and cold-chain requirements for shipment and storage

Lack of skilled human resources

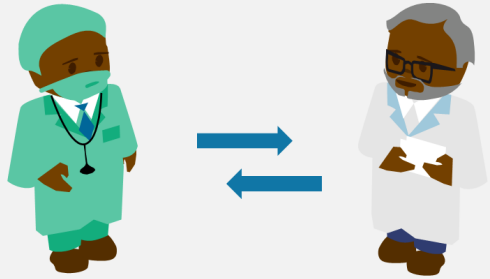


Conventional methods not adapted to low resources

Logistic constraints and complexity, etc.

Paucity of adequate reference sources and training materials

Too few RDTs exist (Strepto A, Salmonella, etc.) no multiplex RDTs



Difficulty to integrate microbiology into clinical practices

Ombelet, S. and Ronat, JB et al. (2018) 'Clinical bacteriology in low-resource settings: today's solutions', The Lancet Infectious Diseases, 3099, pp. 1–11. doi: 10.1016/S1473-3099(18)30093-8

01 Background

As the next-generation diagnostics adapted to LRS are unlikely to become available quickly,

MSF has decided to work on the **development** of a, quality-assured, cost efficient, all-in-one and transportable **clinical bacteriology laboratory**.

- Enabling **diagnosis of sepsis**, **antibiotic sensitivity testing** and **surveillance** of antibiotic resistance
- **Maximizing ease of use and clinical relevance** with harmonized and simplified manual techniques
- To be **used by trained but non-expert users**, and respond to clinical needs at MSF field sites.

02 Methods

Strong governance, mixed group of experts, key industrial partnerships

Steering committee

Chair: Clair Mills (DirMed OCP)

8 members from different MSF Operation centers, Internationnal office

Scientific committee

Chair: Olivier Vandenberg (LHUB-ULB)

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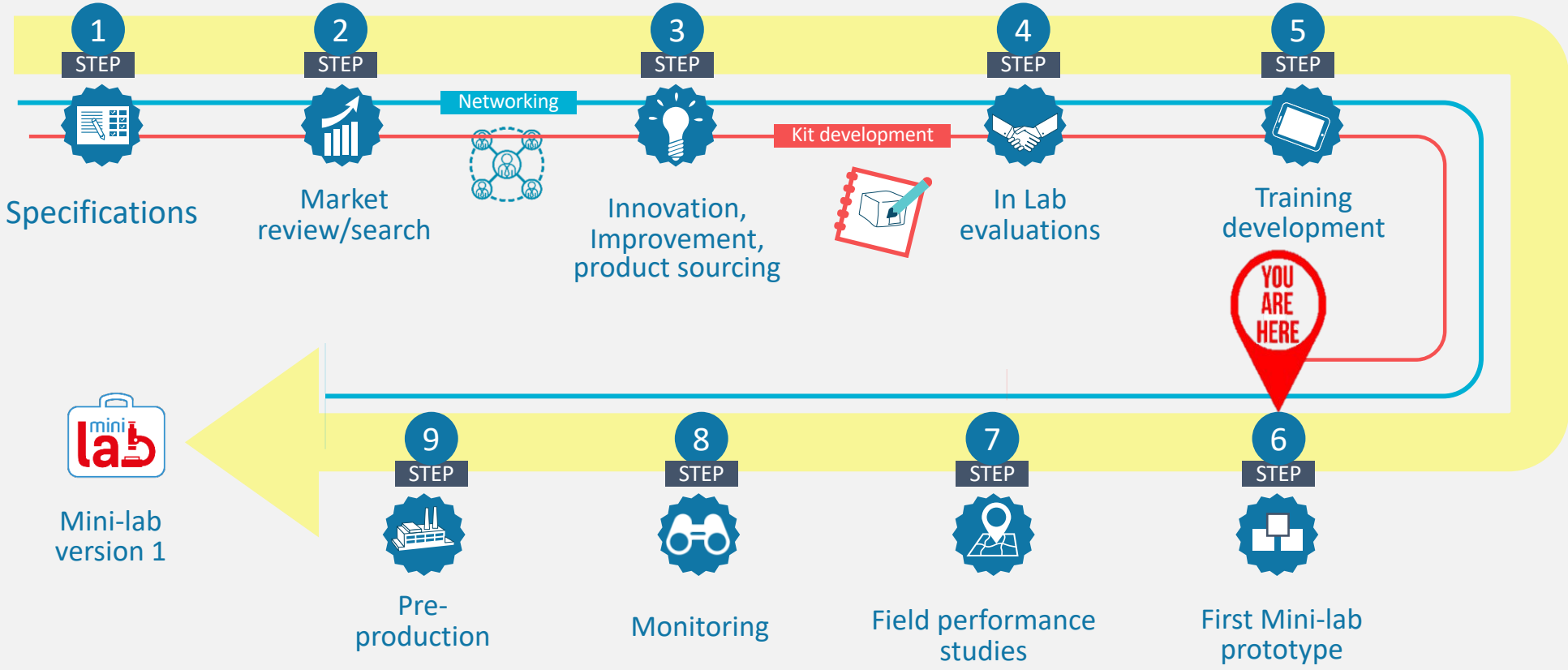
Expert from MSF and non MSF

- Microbiologist
- Epidemilogist
- Infectious diseases MD
- Bio-medical
- In-Vitro Diagnostic expert
- Ergonomist

Partners

02 Methods

A USER-CENTERED & ITERATIVE DEVELOPMENT PROCESS



02 Methods TESTING THE PROTOTYPE IN A LAB

Objective: Assessing ergonomics, appropriateness and user-friendliness of the setup, diagnostic testing and user guidance tools

Context:

- January 2019, assembled all components into full working prototype
- Installed at Laboratoire Hospitalo-Universitaire, Brussels.

02 Methods TESTING THE PROTOTYPE IN A LAB

Set-up:

- Simulation of routine laboratory work, with 3 non-microbiologist laboratory technicians and short training
- Carrying out sample processing and test procedures, on 17 simulated samples of known bacteria for 4 days
- Evaluator observation, user questionnaires and final group interview to collect feedback
- Using Likert scale *

* Likert, R. (1932) A technique for the measurement of attitudes. The Science Press

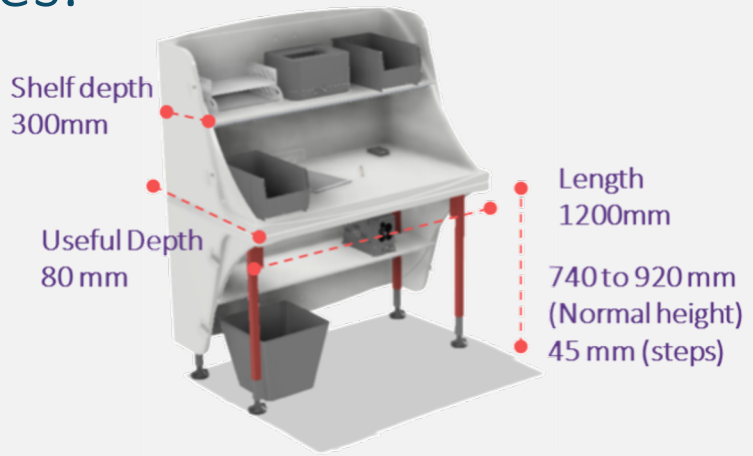
TESTING THE PROTOTYPE IN A LAB

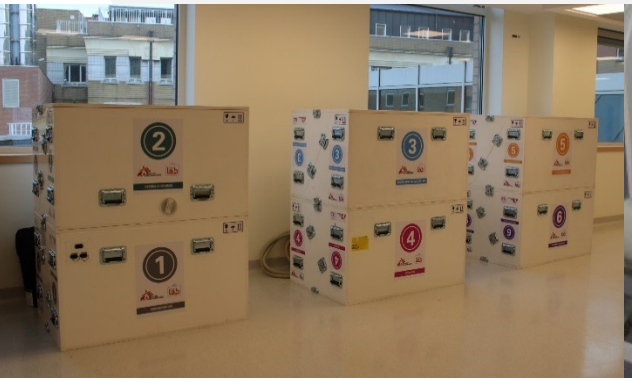
Ethics:

This innovation project did not involve human participants or their data; the MSF Ethics Framework for Innovation was used to help identify and mitigate potential harms .

03 Results ASSEMBLY OF THE KIT – BOX/BENCH FURNITURE

- 6 foldable, sturdy transport boxes (~120kg each)
- Transformable into standalone laboratory benches.
- With all materials packed inside boxes
- Plug and play modules, bench's with leveling features, washable surfaces
- Light integrated, fit into 20 m² room







03 Results SET UP OF THE LABORTORY SPACE

1. **Administrative Module**
   - Réception
   - Enregistrement
   - Communication clinicien
2. **Hygien and security Module**
   - Hygiène
   - Coloration
   - Sécurité
3. **Sample manipulation Module**
   - Pré-identification
   - AST/ID
4. **Incubation Module**
   - Incubation hémoculture
   - Incubation plaques
5. **Reading and Interpretation Module**
   - Observation au microscope
   - Lecture des plaques
6. **Waste management Module**
   - Élimination
   - Conservation

03 Results ASSEMBLY OF THE KIT – MATERIAL & EQUIPMENT

Tests / Consumables

- 35 reagents and ready to use tests, 45 consumables

Among them, 7 tests have been customized / developed

- Shelf life ≥ 12 months (except 3)
- 14 reagents/ tests under cold chain

Equipment/ IT

- 2 incubators, 1 table top autoclave, 1 camera based microscope, 1 digital micro-plate reader.

Among them, 2 have been customized / developed

- 20 small laboratory devices

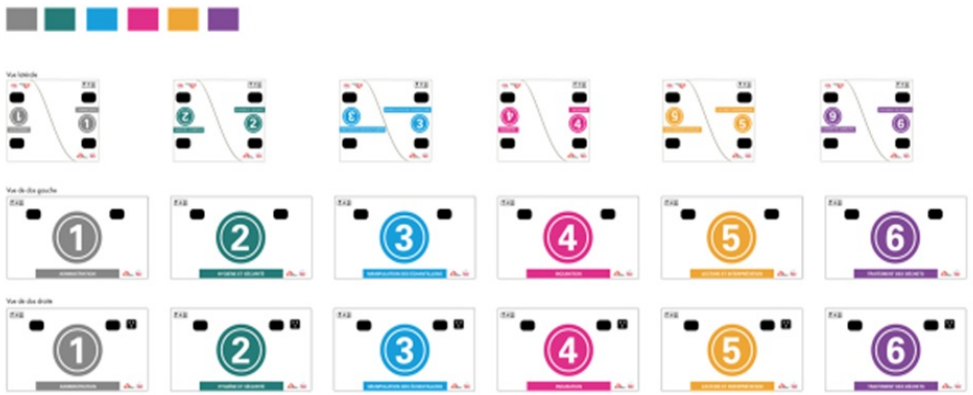
Among them, 3 were specifically developed / adapted

- User-friendly IT hardware (tablets, touch-screen)
- Tailor-made simple Laboratory Information System based on open source no-code platform – workflow management user support

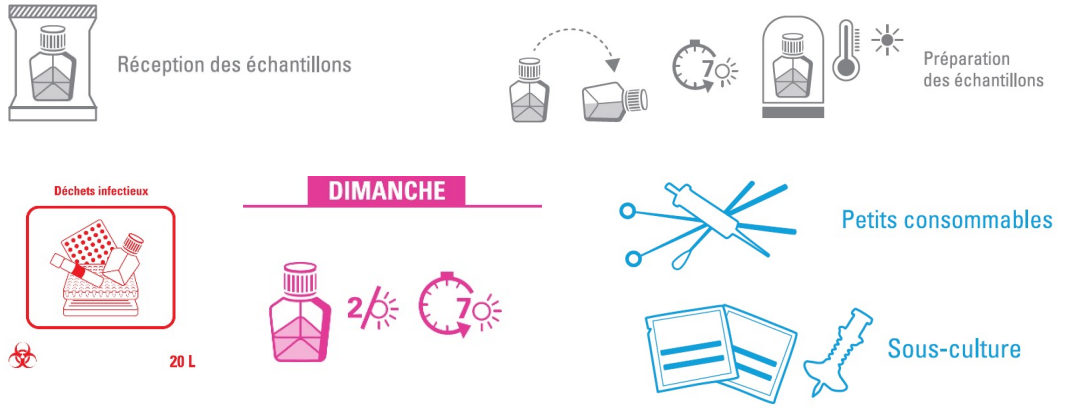
The devices were chosen or developed on the basis of 16 technical requirement / market reviews and 14 Scientific Literatures reviews.

GUIDING USER WITH GRAPHIC DESIGN

Graphic layout

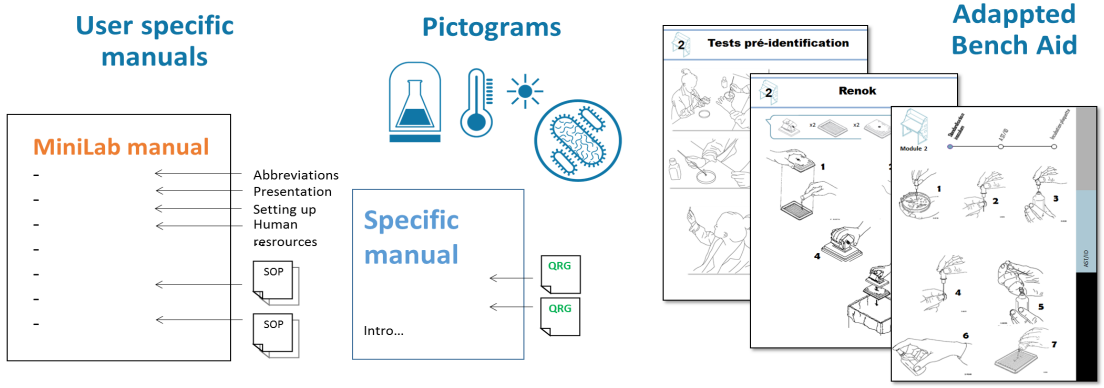


Pictograms guiding along the process

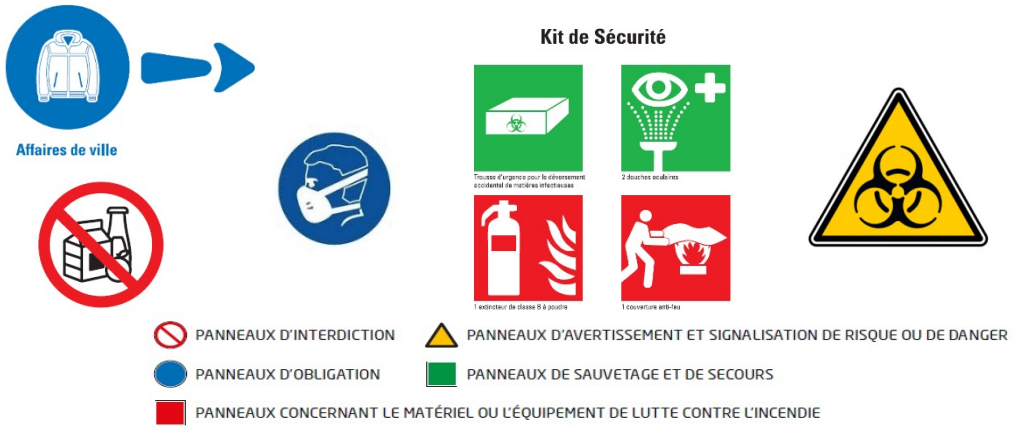


User manual

Following ISO 15189, SLIPTA and CLSI QMS



Security and obligations



03 Results USER EXPERIENCE FEED BACK – evaluations

- 135 observations
- 14 questionnaire administered (installation, comfort, use of devices, etc.) with 152 questions
  - ❑ Overal mean likert scale on **user experience** = 6 (scale of 1 strongly disagree to 7 strongly agree)
  - ❑ Poorest note of 2/7 on the capacity to work together within the lab space
  - ❑ Highest note of 7/7 on individual work comfort, design and intuitiveness of the different systems

03 Results USER EXPERIENCE FEED BACK - synthesis

Topic	Remarks	Actions
Assembly	• Outside surface - not easy to clean • Assembly process is quite intuitive	Change to be made in final product
Boxes/ bench design	• Weight is quite important. • Ergonomics of the bench is great, very comfortable	Change to be made in final product
Task organization	• Optimize workbench space if many tasks need to be done at the same time by different lab techs	Try a new setup for first field pilot
Sign posting	• Make writing bigger stickers. • Accompaniment with visual pictograms is really valuable	Adapted pictograms
Analytical process	• Adjustment of some part of the process to be made • High usability and user friendliness of the different devices	Adjustment made for field pilot

04 Conclusions

- Reached the testing phase of a prototype including all components.
- Test users have responded positively with regard to ergonomics of the bench and modules, tests and pictogram-based guidance.
- Module weight and task organization within a confine space has emerged as a constraint.
- Provided us critical information for our iterative design process.
- Feasible, useful improvements will be made before the first Mini-Lab field evaluation, planned at an MSF-supported burn centre in Haiti, June 2019.

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