Information About You

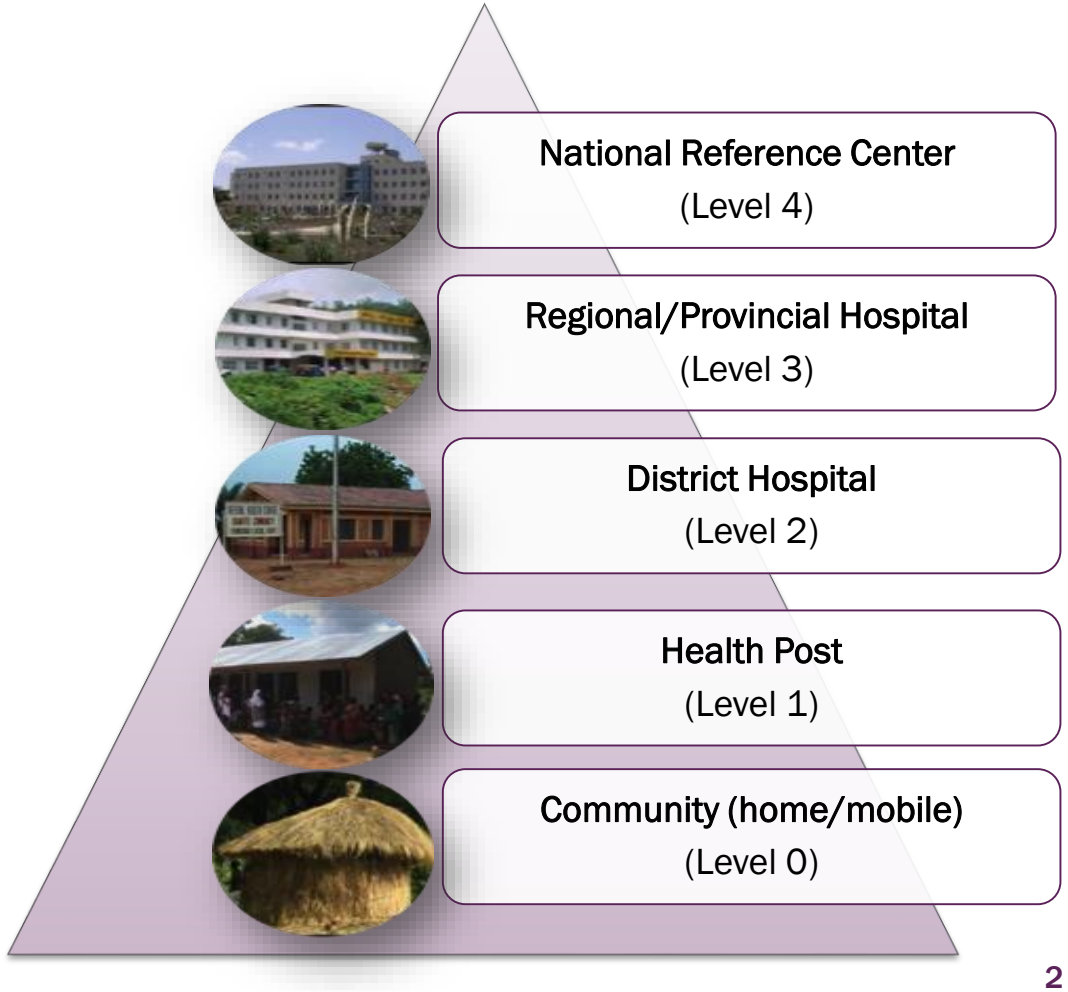
- What is your title/role?
- Background?
- Time in your field?
- Where do you work?

Purpose

- ***Enable the Development*** – of a simplified blood culture system fit for purpose to low resource areas by developing an appropriate Target Product Profile

- Support fever management to allow targeted treatment and reduce morbidity associated with sepsis.
  - What level do you think is achievable now?
  - What level would it be ideal to have blood culture available?

Health System Levels



Target Product Profiles

- The purpose of a TPP is to inform product developers of key characteristics and the performance specifications of a test that are required to meet the end user's needs for a defined use case.

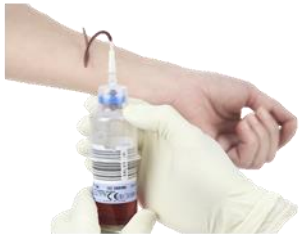
- A systematically developed TPP can **ensure alignment** of objectives across company departments, accelerate development timelines, minimize development risks, and eventually **lead to an optimal product** that meets user needs.
  - The TPP document is therefore an important communication tool between users and product developers

- TPPs often include an ***optimal*** and ***minimal*** definition for each test performance characteristic.
  - Ideally, products should be designed to achieve as many of the optimal characteristics that are feasible, while still satisfying the minimal criteria for all defined features.

Goal: Support fever management to allow targeted treatment and reduce morbidity associated with sepsis.

Potential case identified

Sample collection



Sample transport to lab

Test procedure

Test results

Patient outcomes

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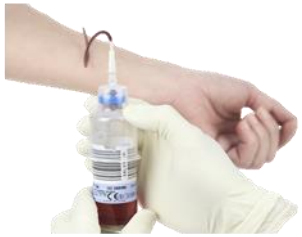
Potential case identified → **Sample collection** → **Sample transport to lab** → **Test procedure** → **Test results** → **Patient outcomes**



- What are the patient populations of interest (adult, pediatric, immunocompromised)?
- What level of the health system would use a simplified blood culture system and who would use it?

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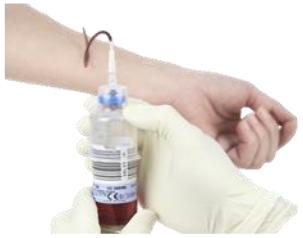

- How do you currently test for suspected bacteremia/sepsis? (Manual/Instrument, bottles, blind subculture, identification, Susceptibility testing)
- What are the challenges? What is stopping you from doing better than you are? What is stopping you from performing BC now or using it more frequently?
- What is a typical patient load/bottles per week?

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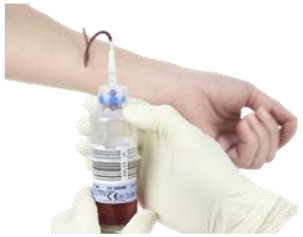

- Who would collect the sample and what would be their typical level of training?
- Blood volumes typically collected; other sterile body fluids collected?
- How is a blood culture sample typically collected? What supplies are required?

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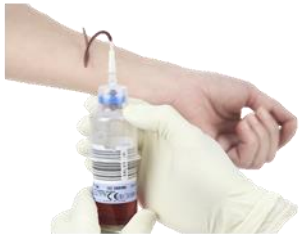
Potential case identified → **Sample collection** → **Sample transport to lab** → **Test procedure** → **Test results** → **Patient outcomes**



- What is the typical time between sample collection and transport to the lab?
- How is the sample stored during this time? Distance between sample collection and lab?
- How is this influenced by patient load at the clinic or the time the patient arrives at the clinic (e.g., batching?)
- How are patient ID's tracked from collection to test result?

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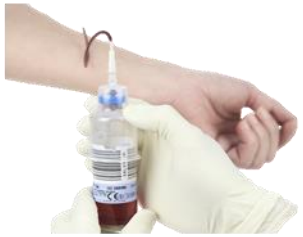

- What is the laboratory environment like where the test would be run? (e.g. Temperature, floor space, power, dust, humidity, connectivity, AC, windows open)
- What is the level of training of the staff performing blood cultures?
- What kind of quality control for blood culture do you do? How often is it done?
- How often can you order bottles and how long can they be stored (and how)? Shipping conditions / transport of supplies to the site?
- How many bottles/week? (If using instrument, what is the bottle capacity of your instrument?)
- Any critical biosafety concerns- (pos / neg bottles), value of alerts

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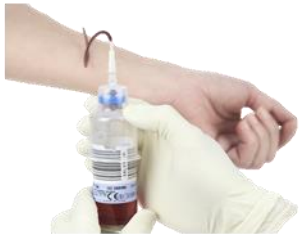

- How are results reported and to whom, timing? Are results stored? If so, how long?
- What happens if a positive result is identified? Gram stain/morphology? Identification? What method? Antimicrobial susceptibility?
- What is your percentage of contaminated blood cultures?
- What categories of pathogens would be useful for guiding treatment? E.g., GNR, Enterobacteriaceae? Etc.
- What are the most common, pathogens that you encounter? “Unusual” or regional pathogens of interest? Most important? Are anaerobes important?
- In your lab, what are the problems in terms of identification: -- e.g. Typhoid v. non-typhoidal Salmonella; Strep pneumo v. viridans or other strep, Pseudomonas v. Burkholderia?

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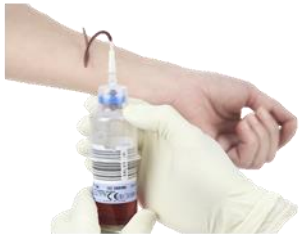


- What information do clinicians request to inform patient management?
- What treatment guidelines are used? Are the drugs available for treatment?
- What is the current turnaround time from sample collection to result? What would be ideal?
- What would be an acceptable cost?
  - (cost of bottle, cost of instrument)
- Who generally pays for such a tests (e.g. patient, MoH, funder?)

Current Pathway for Blood Culture in High Resource Countries

Sepsis indicated

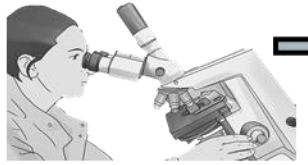
Prepare paper work, bottles

Blood draw

Broad spectrum antibiotics administered

Transport bottles to lab

Detection in blood culture instrument
8 to 12 hours if positive

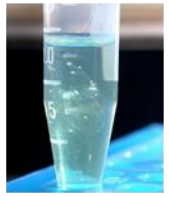


Gram status

Inoculate on plates

Grow in incubator
Overnight
>18 hours

Pick colonies



Prepare sample

Identification and Susceptibility
6 to 12 hours

Lab report

Physician chooses targeted antibiotic

Proposed Pathway for Simplified Blood Culture

Sepsis indicated

Prepare paper work, bottles

Blood draw

Broad spectrum antibiotics administered

Transport bottles to lab

Detection, Gram status and Identification in blood culture instrument
8 to 12 hours if positive

Physician chooses targeted antibiotic

- What would the idea blood culture system look like for you?
- Would a simplified blood culture system, as described above, be helpful?
  - Why or why not?