Department of Biosystems and Agricultural Engineering
MICHIGAN STATE UNIVERSITY

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Biosystems Design Projects

Implementing a gMNP Tuberculosis Biosensor in Peru

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engineeringworldhealth

Background

TB in Peru

Peru has one of the highest TB rates in the Americas, with Belén reporting 106 cases per 100,000 people. Yet only 32% of cases are detected and treated. Since one undiagnosed person can infect 10–14 others each year, accurate diagnosis is crucial to stopping the spread.

Current Testing Methods

TB testing occurs in TB-specific clinics. Current methods include Sputum Smear Microscopy (SSM) and Lowenstein-Jensen (LJ) culture. However, SSM is unreliable, and LJ is time-consuming providing patients inaccurate results and forces them to return to the clinic. The team proposes a gMNP biosensor to improve testing.

Table 1: Comparison of TB Testing Methods

Test Method	% Sensitivity	Test Time
Sputum Smear Microscopy (SSM)	25 – 65	20 min
Lowenstein-Jensen (LJ) Culture	Gold standard	Weeks
gMNP Biosensor Test	99.7	20 min

Problem Statement

To develop procedural guidelines to safely and efficiently integrate a gMNP TB test into a TB clinic in Peru.

gMNP Biosensor

Glycan-coated magnetic nanoparticles (gMNP) bind with *Mycobacterium tuberculosis* (Mtb)[1] and a simple magnet is used to separate the gMNP-Mtb complex. When subjected to a Ziehl-Neelsen stain and viewed under a light microscope, Mtb is identified by red-stained clumps of bacteria surrounded by brown gMNPs. Biosensor sensitivity was verified by 1008 tests in Peru by Dr. Briceno.

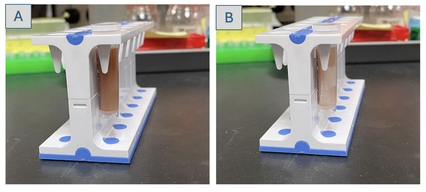

Fig. 1: gMNPs (A) Before and (B) After Magnetization

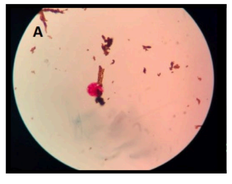

Fig. 2: Positive TB Result Under Microscope

Objectives

- Maintain 99.7% TB test sensitivity
- Individual test cost < $1.75 USD[2]
- Diagnosis results within 30 minutes of sampling

Constraints

- No ventilation
- No biosafety cabinets
- 11th grade education
- Patients must not leave the clinic
- Must be alternative to file sharing

Design Alternatives

There were 6 decision matrices for all design components. There were 3-4 design criteria for each matrix weighted in terms of importance for the design to meet. Each design alternative was given a score from 1-10 on how well they met the criteria. Those scores were summed up and the alternative with the highest score was chosen as the final design.

Table 2: Waiting Area Decision Matrix

Category	Weight	TB-specific outdoor waiting area	TB-specific indoor waiting room	Patients wait at home
Safety	50	8	3	4
Efficiency	30	7	7	6
Organization	20	5	5	6
Total	100	710	460	500

Clinic

2 decision matrices were performed for the clinic design. The clinic refers to the patient-facing aspect of the TB clinic from patient arrival to results notification. Each selected design prioritizes safety to reduce the risk of TB transmission[3] to TB-negative patients and staff as well as minimizes patient wait time within the clinic.

Table 4: Clinic Design

Design Category	Final Design	Selecting Factors
Patient Intake	Symptoms assessment with clinic staff	Separation accuracy, personnel requirement
Patient Waiting Area	TB-specific outdoor waiting room	Low TB transmission
Symptoms Assessment	TB symptoms assessment	N/A
Sputum Sampling	Sputum collection procedure	N/A

Patient Management

Patients proceed in a unidirectional flow path through the clinic to limit TB transmission. Symptoms assessment and sample collection are performed in separate rooms.

There are 2 symptoms assessment rooms and 3 sample collection rooms ensuring that if 3 patients arrived to the clinic at the same time, the third patient will receive their result within 1 hr 10 mins of arrival including symptoms assessment, sample collection, and sample processing time.

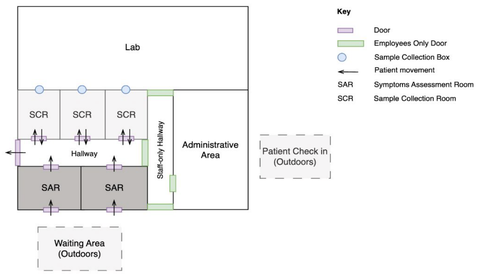

Fig. 6: Optimized Clinic Layout

Laboratory

We designed 4 components of a TB laboratory. TB testing needs to conform with a biosafety level 2 lab. Our final designs helped meet those regulations[4]. We chose on final designs for mode of ventilation, biosafety cabinet alternative, disinfection mode and biosensor SOP format.

Table 3: Selected Clinic Design Choice and Factors

Design Category	Final Design	Selecting Factors
Ventilation	Mechanical ventilation (exhaust fans)	Meets required ACH
BSC Alternative	GermGuardian AC500E air purifier	High bactericidal ability, long-lasting
Disinfection	Alcohol-based solution	High bactericidal ability, inexpensive
Biosensor SOP Format	Poster	Visuals, inexpensive

Fig. 4 & 5: GermGuardian AC500E and Mechanical Ventilation

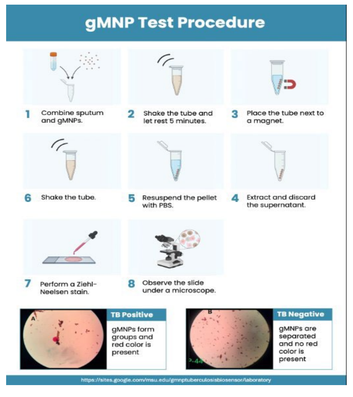

Fig. 7: gNMP Biosensor Test Poster

Deliverables

Standard Operating Procedures

The guidelines for implementation include 5 SOPs to ensure consistency in procedures to maximize efficiency. The SOPs include extensive information about the procedures.

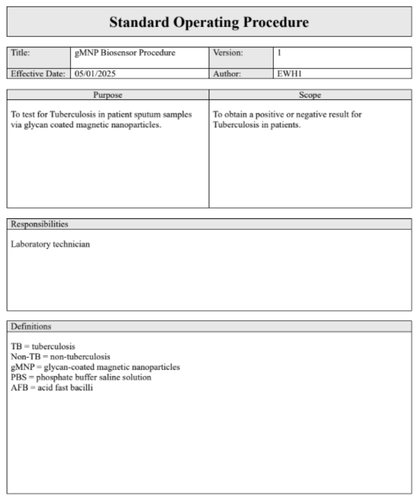

Fig. 8: First page of gMNP SOP

Website

A website was selected for its accessibility and ability to compile documents in one place. Google Sites was selected for simplicity.

Fig. 9: Website QR code

The website includes information about the biosensor test, our lab designs, our clinic designs, flowcharts of the processes, downloadable versions of the SOPs and references for further information.

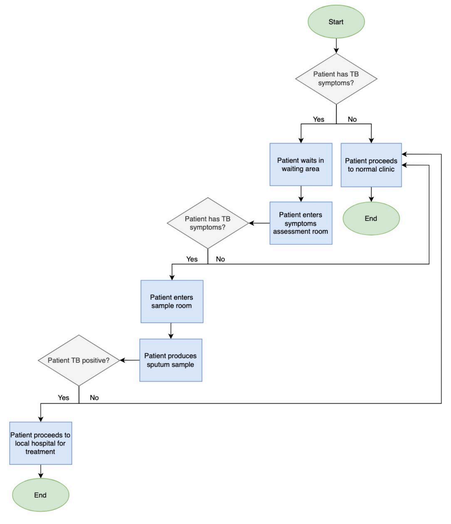

Figure 10: Patient Management Protocol Flowchart

Economics

Patient Test Cost

The cost patients pay per test is based on an estimated 334 TB tests per year[5]. The cost calculation includes test inputs, human resources costs, and equipment costs.

Table 5: Patient Test Cost

	Cost per test (USD)
Inputs	$ 0.84
Human Resources[6]	$ 1.28
Equipment	$ 0.16
Total	$ 2.28

The test cost exceeds the objective test cost of $1.75. The Peruvian government has TB funding to help finance the test cost. This will increase citizens' willingness to test.

Other Costs

- gMNP Biosensor costs are $280.56 per year.
- Implementation cost is $732.35.

Table 6: Biosensor Test Yearly Bill of Materials

Inputs	Unit value	Quantity /yr	Cost /yr (USD)
gMNP	$ 0.10	334	$ 33.40
Pipette tips	$ 0.03	2672	$ 80.16
Microscope slides	$ 0.22	334	$ 73.48
Microcentrifuge tubes	$ 0.06	334	$ 20.04
Carbol Fuscin stain	$ 0.05	668	$ 33.40
Acid alcohol	$ 0.04	668	$ 26.72
Methylene Blue stain	$ 0.02	668	$ 13.36
		Total	$ 280.56

Table 7: Initial Implementation Cost

Equipment	Unit value	Quantity	Cost (USD)
Germ Guardian AC500E Air Purifier	$ 149.99	2	$ 299.98
2000 CFM Exhaust Fan	$ 175.96	1	$ 175.96
Chairs	$ 28.49	9	$ 256.41
		Total	$ 732.35

Select References

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