Interdisciplinary Research (IDR) Origination Awards

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Project Title

3D Printed Maternal-Infant Metabolic Screening Device for Lower Middle-Income Countries (LMIC)

Principal Investigator(s) (full-time faculty)

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Track

Track 1

Abstract

Maternal and infant health interventions often fall short when they are built on assumptions instead of lived local realities. In Winter 2025, interdisciplinary teams from FHSS Anthropology, Sidi Mohammed Ben Abdellah University, and BYU College of Nursing spent three months conducting observations and interviews with women and clinicians across hospitals, clinics, and homes in the Fez and Sefrou regions of Morocco. A consistent, actionable priority emerged: the absence of affordable, timely newborn screening for treatable metabolic and endocrine conditions, including congenital hypothyroidism and phenylketonuria, and the potential need to differentiate genetic causes of anemia such as thalassemia from nutritional iron deficiency.

In the U.S., routine newborn screening enables early treatment that prevents irreversible harm. In Morocco, limited access to centralized laboratories, long travel distances, and inconsistent follow-up can delay diagnosis until brain injury, developmental delay, or severe morbidity is no longer preventable. Hypothyroidism remains underdiagnosed but a preventable contributor to adverse childhood outcomes.

We propose exploratory proof-of-concept work to assess whether a low-cost, in-country lab-on-chip (LoC) hypothyroidism screening test can be developed and integrated into existing antenatal or early postnatal workflows. Leveraging BYU strengths in 3D-printed microfluidics and analytical chemistry, we will survey candidate LoC architectures, fabricate early prototypes, and identify the key technical and implementation uncertainties governing feasibility at a $1/test target. Funding supports three half-time PhD students, undergraduate nursing and ethnography partners teams, travel, and supplies, to de-risk a subsequent pilot and external proposal.

Summary of Plans for External Funding

Funding Source	Grant Name	Submission Goal
National Science Foundation	PD 23-5345	Dec 2026 (Rolling Sub.)
National Science Foundation	PD 20-7909	Dec 2026 (Rolling Sub.)
NIH NIBIB	PA 25-304	Oct 16, 2026
Wellcome Trust	Discovery Award (LMIC PI)	Mar 31, 2026
Wellcome Trust	Joint Global Health Trials	Mar 31, 2026

Project Narrative

1. Overview and Objectives

1.1. An on-demand locally manufactured inexpensive hypothyroidism screening device

Interventions to reduce maternal morbidity and mortality often fail when designed around assumptions rather than local realities. In Winter 2025, teams from the FHSS Anthropology Department and Sidi Mohammed Ben Abdellah University spent three months observing and interviewing women and clinicians across hospitals, clinics, and homes in Fez and Sefrou regions of Morocco, producing data on local needs and requests for eHealth solutions to improve maternal-infant health outcomes in a *preliminary study*. They were joined by two Nursing students and 2 Nursing faculty for one week to assist with the needs assessment.

A concrete and addressable issue came to the fore in this process: the lack of consistent country-wide available newborn metabolic, and endocrinal testing for known and treatable issues in Morocco, such as congenital hypothyroidism (CH), phenylketonuria, (PKU), and potentially thalassemia (a mediterranean relevant genetic rather than metabolic cause for anemia). While newborn screenings for PKU and CH are routine in the U.S., there are no low-cost point-of-care newborn blood tests to quickly address and treat infants for the potential brain damage and developmental delays of untreated CH, PKU or the anemia possible from thalassemia. We are seeking to address one disease: congenital hypothyroidism. *This work aligns with a newly expanded institutional commitment by the Church's Relief Society to identify and assist in maternal and infant healthcare and humanitarian outreach globally and fits BYU's motto to "Go Forth to Serve".*

Hypothyroidism, whether congenital or acquired, results from insufficient thyroid hormone production, leading to impaired brain development in neonates and progressive metabolic dysfunction in adults. **CH is the most common preventable cause of intellectual disability worldwide**, with Moroccan screening pilots identifying a birth prevalence of approximately 1 in 1,300 (roughly three times the global average), likely driven by persistent iodine deficiency affecting over 75% of rural Moroccan women [1], [2]. Acquired hypothyroidism in adults, predominantly from iodine deficiency and autoimmune thyroiditis, causes fatigue, cognitive impairment, cardiovascular complications, and adverse pregnancy outcomes, yet also remains largely undiagnosed in regions without routine laboratory access [3]. Treatment for both forms is straightforward and inexpensive (oral levothyroxine costs under $0.05/day) but is contingent on timely diagnosis. In rural settings, long travel distances, intermittent access to centralized laboratories, and limited follow-up infrastructure mean that many cases are never screened at all. **Even where neonatal screening exists, cumulative delays from sample collection through result reporting and follow-up can push treatment initiation well past the internationally recognized 14-day window associated with optimal neurodevelopmental outcomes** [4], [5].

Current techniques require a heel-prick blood sample from the individual, which is blotted and dried onto filter paper before shipping it to a centralized laboratory, introducing diagnostic delays of >14 days. Though there are currently six centralized laboratories in Morocco, **no sustainable newborn screening (NBS) program currently exists in the country** [6].

Our proposed solution to the problem is the development of an inexpensive open-source thyroid stimulating hormone (TSH) electrochemical biosensor manufactured in-country on demand using commercial-off-the-shelf (COTS) components and techniques to minimize costs. This will allow the creation of fast result (target of 15 minutes) decentralized screening tests that integrate into existing antenatal or early postnatal workflows that could substantially reduce the travel burden, out-of-pocket costs, and quality of life for rural families, those most at risk in the

Moroccan public health system. This technology is applicable to multiple diseases currently targeted by newborn screening tests. We will focus on CH as an example condition.

We believe the IDR award is the perfect mechanism to propose exploratory proof-of-concept work to evaluate whether lab-on-chip (LoC) CH screening can be realized as a low-cost, in-country device, leveraging BYU expertise in 3D-printed microfluidics, electronics, and analytical chemistry. Building on established approaches for quantifying small-molecule biomarkers, we will survey candidate LoC architectures, fabricate early prototypes, and identify the key technical and implementation uncertainties that determine feasibility at a $1/test price-point (a production price point imperative discovered during our initial research). Although current federal priorities may favor domestically focused health applications, the high CH prevalence in Morocco, our established institutional partnerships, and the interdisciplinary breadth of our team create favorable conditions for generating robust preliminary data, including field-validated requirements, proof-of-concept prototypes, and analytical performance benchmarks, that will strengthen applications to both federal agencies (framed around the underlying biosensor technology) and global health funders (framed around LMIC deployment).

Our interdisciplinary team, consisting of four BYU colleges and an external university is particularly well suited to achieve this task as much of it has been de-risked by earlier work of the grant applicants. PIs Greg Nordin and Adam Woolley have developed rapid 3D resin printing technologies and methods for microfluidics research over the past decade. To our knowledge there are no other microfluidic 3D printers in the world that can achieve the resolution of our printers at the same speed. This allows us to iterate quickly. While the printers developed at BYU are expensive, the learnings are extendable to less costly COTS units that are more appropriate for LMICs. The combined labs have created and published on devices and libraries enabling complex on-chip disease diagnostics, recently for preterm birth risk and chikungunya [7], [8]. The developed techniques for attaching antibodies to preterm birth risk biomarkers in 3D printed structures are readily extendable to CH. PI Preston Manwaring's lab has been developing microfluidic dielectric spectroscopy and electrochemical impedance spectroscopy (EIS) methods to detect differences between treated and untreated complex fluids. He also has extensive medical device design experience that will be leveraged to create a viable device. These learnings will be used to confirm detection electrically and produce a readable output (Aim 3). Critically, the techniques are in the process of being open sourced to make them available world-wide. *This vision aligns with the humanitarian and health-care priorities outlined by the Church for BYU's medical research.*

The long-term goal using the combined experiences from our technical labs, nursing, and anthropology will allow the creation and successful adoption of an inexpensive in-country printable CH detection device with a pilot launch in Morocco. Our short-term objectives de-risk this by leveraging the combined experience of our colleagues in the college of nursing and anthropology to inform and assess the acceptability of the proposed solution (Aim 2) after a down selection of options (Aim 1). The output of Aim 1 will be looks-like/works-like artifacts that can be taken to our Moroccan colleagues for evaluation. The output of Aim 3, which will run parallel to Aim 2, will be functional proof-of-concept devices and methods ready for further refinement with additional grant funding. This is in line with typical product development processes requiring iteration to ensure acceptance criteria are met.

This project will impact maternal and fetal welfare, global healthcare delivery, and contribute substantially to *scholarly works*. First, we are contributing an open-source product with early prototypes to diagnose CH in low-resource settings. Second, this research will contribute in-country options to print their own diagnostic tools, thus eliminating dependence on centralized manufacturing and international supply chains that historically ignore low-resource settings. Third, these novel techniques can be extended to other diseases for future low-cost LoC

diagnostic tools. Fourth, an interdisciplinary collaboration model integrating ethnographers, healthcare providers, chemists, and engineers will be documented and disseminated as a replicable framework for global health device development. *We anticipate a minimum of six peer-reviewed publications spanning microfluidic device methods, field-based human factors assessment, and interdisciplinary design methodology.* These will lead to subsequent federal and foundation funding applications (e.g. NSF CBET, NIH NIBIB, Gates Foundation, Wellcome Trust (with Moroccan PI)).

1.2. Interdisciplinary Team

The PIs are experts in chemistry and biochemistry, microfluidic devices, electrical and computer engineering, collaborative ethnography in Morocco, and nursing. Each plays a critical role in device development and deployment. PI Manwaring is a former medical device developer, having been part of teams that took several products through FDA clearance to market. He will work with teams on Aims 1-3 to ensure the customer needs in Morocco are met in the device under development. One outcome of this work will be an eventual miniaturized device able to be deployed. PI Adam Woolley is an expert in bioanalytical chemistry and will work primarily on Aims 1 and 3 to ensure practical choices are being made during down-selection and prototype construction. He will be responsible for the core functionality and accuracy of the diagnostic test. PI Greg Nordin is an expert on microfluidics and will work on the practical application of his 3D printer technology for rapid prototyping during development of the test (Aims 1 & 3). He will be key in determining how to translate the prototype device from BYU's precision 3D printer technology to less expensive lower-resolution devices readily available on the market. PI Becky Schulthies is an expert in collaborative ethnography in Morocco. She will lead a team of student ethnographers to Morocco to gather requirements and ensure the looks-like/works-like devices meet the needs of the users and to provide feedback for further iterations (Aims 1 & 2). PI Kristen Erekson is a practicing nurse practitioner with transcultural nursing experience on the global stage. PI Sarah Harmon Davis is a practicing nurse practitioner with precision health and clinical workflow design experience. They are experts in training HCPs and interfacing with patients. They, along with Becky Schulthies and our Moroccan colleagues, will provide insights into requirements, human factors, workflow, and practicability of the device in Moroccan clinical settings (Aims 1 & 2).

We have established a working relationship with a memorandum of understanding (MOU) between BYU, and the engineering and medical schools of Sidi Mohammed Ben Abdellah University (SMBAU) in Morocco. These are our colleagues and ultimate product owners driving requirements specifications and who will sustain device deployment. We are additionally working on an MOU with the public nursing institutes in Fez and Khenifra in the high mountains of Morocco (ISPITS-Fez, ISPITS-Khenifra). These will be in place in time for in-country trials.

2. Research Plan

2.1. Aim 1 – Define performance requirements and select a lab-on-chip architecture for CH screening

Rationale: Congenital hypothyroidism (CH) imposes substantial preventable morbidity when newborn screening and early intervention are limited, particularly in rural Morocco. Existing screening approaches for CH detection require centralized laboratories often >2 weeks of turn-around time thus missing a critical 14-day window for initial treatment. BYU's 3D-printed microfluidics platform offers a pathway to replicate core LoC functions with reduced fabrication cost and complexity, enabling rapid iterative design and a credible route to in-country manufacturing with eventual point-of-care diagnostics. Success will require guidance from HCPs, ethnographers, and in-country engineers.

Hypothesis: A structured technical and implementation-focused down selection of current technologies will identify one CH LoC method that can be adapted to 3D-printed microfluidics while preserving clinically relevant performance and minimizing per-test consumable cost. Interaction with nursing, anthropology, and colleagues in Morocco will help define what "good enough" and practicality look like.

Outcomes: We will (i) define a target product profile for rural deployment (analytical requirements, workflow, durability, training burden, and acceptable time-to-result), (ii) evaluate candidate CH LoC methods against feasibility criteria (analytical performance, manufacturability, robustness, instrumentation, and consumables), and (iii) down select one approach for prototyping and validation in Aims 2-3.

2.2. Aim 2 – Map technical and implementation unknowns and establish a feasibility and cost pathway toward deployable CH screening

Rationale: Even if analytical proof-of-concept is achieved, translation depends on practical constraints: consumables cost, supply chain availability, device shelf-life, user workflow, required instrumentation, maintenance, constraints of rural clinic settings, among others. These are known as "human factors". Identifying these constraints early prevents over-optimizing laboratory performance while avoiding barriers to deployment and sustainability. Success will require colleagues and students from BYU engineering, nursing, anthropology, and Sidi Mohammed Ben Abdellah University to travel and collaborate to identify these constraints. They will then propose solutions while iterating with BYU chemistry and engineering faculty and students on a proof-of-concept.

Hypothesis: A combined engineering, cost, and deployment assessment by nursing and anthropology will identify the dominant translation barriers and define a pathway that moves the CH approach from bench proof-of-concept toward a simplified, ruggedized device concept compatible with low-resource use.

Outcomes: We will deliver (i) a quantitative cost model and bill of materials highlighting primary cost drivers and plausible sourcing options for Morocco, (ii) an implementation plan addressing workflow, training, biospecimen handling, and equipment requirements for rural sites, (iii) iterative design inputs for milestones, subsequent optimization, and field evaluation, and (iv) a structured field verification plan using "looks-like/works-like" models that nursing students and ethnographers can deploy to confirm usability, acceptability, and real-world workflow fit (without requiring a fully field-ready device).

2.3. Aim 3 – Design, fabricate, and demonstrate proof-of-concept 3D-printed lab-on-chip prototypes for the selected CH assay, on a pathway toward device reduction

Rationale: Demonstrating that a TSH immunoassay can be implemented in a 3D-printed microfluidic format requires prototypes that integrate sample handling, antibody-based capture, and quantitative detection within a single disposable cartridge. Rapid prototyping, enabled by the Nordin lab's custom DLP-SLA printer capable of sub-100 µm channels with ~30-minute print cycles, will reveal which design elements drive assay performance, cartridge reliability, and manufacturability [9], [10]. The end-of-grant objective is not a finished field-ready device; it is proof-of-concept methods and prototypes that are actively being reduced towards a device guided by Aim 2 feasibility constraints. This will generate preliminary data for subsequent grants targeting clinical validation and deployment in rural Morocco, where hypothyroidism prevalence is elevated by persistent iodine deficiency [2].

Hypothesis: A quantitative TSH immunoassay can be implemented in 3D-printed microfluidic prototypes that demonstrate end-to-end assay function and quantitative readout consistent with screening needs (level-of-detection (LOD) ≤1.0 mIU/L, dynamic range 0.1–50 mIU/L, time-to-

result ≤15 minutes), and that can be iteratively simplified toward a field-compatible architecture. An initial back-of-the-envelope estimate suggests EIS, leveraging the Woolley lab's established expertise in electrochemical detection within microfluidic devices, could be a viable candidate. To that end, there are potentiostat reference design options to aid in implementation and risk mitigation [11], [12], [13]. This label-free approach requires the simplest biochemistry and yields the lowest per-test reagent cost. Capillary-driven flow through microfluidic channels and delay valves sequences plasma separation, electrode wetting, and incubation without external pumps. We note that while commercially validated TSH point-of-care devices (Finecare™, ichroma™) have to date relied on fluorescence-based detection rather than electrochemical methods, the Woolley lab's extensive track record integrating electrochemical sensors into microfluidic platforms provides a strong foundation for advancing this approach beyond what has been attempted commercially. As a secondary approach, we may evaluate fluorescence immunoassay. The fluorescence approach offers broader dynamic range and stronger commercial precedent for TSH point of care (POC) testing; however, it introduces additional reagent and instrumentation complexities that may not be appropriate low-resource settings.

Outcomes: We will produce and test prototypes demonstrating end-to-end assay function on relevant samples or appropriate surrogates, including (i) repeatable fabrication and assembly, (ii) measurable analytical performance (for example sensitivity, quantitative accuracy, and run-to-run reproducibility), (iii) identification of key design and chemistry parameters that must be optimized for robustness, and (iv) a device-reduction roadmap linking laboratory proof-of-concept to the next-stage ruggedized prototype requirements established in Aim 2.

2.4. Research Timeline

Our estimated timeline with program milestones is shown in the figure below. Key milestones are indicated with an asterisk and represent iteration closures. Final direction will be given to the engineering team at those key moments.

		Year 1				Year 2				
	Aim	2Q26	3Q26	4Q26	1Q27	2Q27	3Q27	4Q27	1Q28	Notes
Aim 1	Product CIRs Defined		*							Team in Morocco
	LoC options gathered									
	Down selection									
Aim 2	Cost model refined									
	Plan fleshed out									
	Development milestones set			*						
	Looks-like/Works-like evaluation				*					Team in Morocco
Aim 3	Prototype development									
	Repeatability assessed									
	Optimization/iteration									
	Device reduction plan								*	

2.5. Summary of Expected Research Outcomes

From our three aims, the project delivers (1) customer requirements for rural Moroccan CH screening that translates ethnography-backed clinical needs into measurable performance, workflow, durability, training, and time-to-result specifications; (2) a down-selection of existing CH lab-on-chip approaches to a single architecture that is most adaptable to low-cost 3D-printed microfluidics and compatible with in-country, on-demand manufacturing; (3) a feasibility package that maps the technical and human-factors unknowns, including a quantitative cost model and bill of materials, supply-chain assumptions, and an implementation plan for rural clinic workflows; and (4) proof-of-concept prototypes and or methods that demonstrate end-to-end CH assay function, with a device-reduction roadmap that links our bench prototypes to a simplified, “looks-like/works-like” usability and acceptability testing with Moroccan partners.