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INTEGRATING RESEARCH FOR DESIGN (RFD) AND DELPHI VALIDATION: A FRAMEWORK FOR PH-RESPONSIVE MATERNITY WEARABLES

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ABSTRACT

Preterm prelabour rupture of membranes (PPROM) remains a leading cause of neonatal mortality, yet accessible screening tools are scarce in low-resource settings. Existing solutions, such as single-use Nitrazine pads or biomarker kits, often fail to balance affordability, sustainability, and diagnostic accuracy. This study proposes a comprehensive design framework for a reusable, pH-responsive maternity underwear system designed for early PPROM detection. Adopting a Research for Design (RfD) methodology, we synthesized material constraints of sol–gel indicators with clinical requirements to develop an initial prototype concept. Crucially, this concept was refined through two rounds of qualitative expert validation involving obstetricians and midwives. The first round identified key risks in user compliance and interpretation ambiguity, driving the iteration of a dual-criterion decision rule. This rule combines a pH threshold (pH ≥ 7.0) with a time-persistence check to mitigate false positives. The final output is a validated framework that integrates material performance, user interaction logic, and service design principles. This study contributes a practical, expert-verified pathway for developing sustainable, low-cost wearable diagnostics suitable for resource-constrained maternal care.

KEYWORDS: pH-responsive sensor; Nitrazine; amniotic fluid leakage; maternity safety underwear; low-resource settings; sol–gel.

1. INTRODUCTION

Preterm birth remains a leading cause of neonatal morbidity and mortality, accounting for nearly one million neonatal deaths annually worldwide (Liang et al., 2024). A considerable proportion of these cases are associated with preterm prelabour rupture of membranes (PPROM). When leakage is not recognised promptly, the risk of maternal infection increases; yet in many low-resource settings, clinic-based tests are difficult to access, delaying referral and care. There is therefore a clear need for a simple, private, and low-cost home screening method (Ghafoor, 2021; Ronzoni et al., 2022).

Existing pH-based methods, such as Nitrazine paper and disposable panty-liner devices, are inexpensive and easy to use, while biomarker assays can be highly sensitive (Ali & Ali, 2024). However, single-use pads are prone to false positives from urine, semen, or infection, whereas biomarker tests are costly, supply-dependent, and often require laboratory facilities. Importantly, neither approach is designed for continuous, comfortable wear in daily life (Birgisdottir et al., 2024).

To address these limitations, we propose a pH-responsive maternity underwear system composed of a washable base garment with low-cost replaceable sensing strips. The core concept leverages a sol–gel window designed to immobilise a Nitrazine indicator, aiming for a clear and stable colour change (from yellow to blue) upon exposure to alkaline fluid (pH ≥ 7.0). As shown in Figure 1, hydrogel and sol-gel matrices have been reported as effective hosts for rapid and reversible colorimetric response. However, the translation of these material properties into a reliable wearable device requires rigorous validation of the user scenario and decision logic, rather than material synthesis alone (Łabowska et al., 2024).

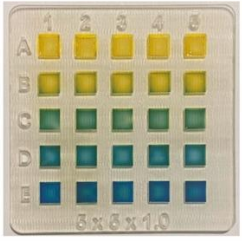

Figure. 1. hydrogel pH sensor substrate (a) used for pH-responsive sensing.

Source: Adapted from Łabowska M.B., Krakos A., & Kubicki W. (2024). 3D Printed Hydrogel Sensor for Rapid Colorimetric Detection of Salivary pH. Sensors, 24(12), 3740. https://doi.org/10.3390/s24123740 (CC BY 4.0).

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Therefore, this study adopts a Research for Design (RfD) approach to bridge the gap between material potential and clinical application. Unlike pure material studies, our methodology integrates a two-round Delphi validation process to establish a robust design framework. In the first round, we engaged a panel of experts to validate the clinical necessity and identify potential usability risks in home settings. The second round focused on refining the decision logic, leading to the adoption of a dual-criterion rule (combining pH threshold with time persistence) to mitigate false positives.

We then translate clinical and material constraints into design rules and testable targets, outline the prototype architecture, and specify bench protocols to quantify switching point, colour contrast, and response time (e.g., $\Delta E^*ab \geq 10$ between pH 6.8–7.2; $T_{90} \leq 30$ s; final read ≤ 60 s) (Wiorek et al., 2020). User and environmental risk factors are mapped to design mitigations, and a staged validation pathway is proposed for laboratory and simulated-use testing (Ray et al., 2015). Using a Research For Design (RfD) approach, we integrate these findings into a visual framework that links material performance, usability, and production feasibility (Frayling, 1994). This framework provides a structured pathway for developing and refining pH-responsive wearable devices that support early detection of PROM in resource-constrained settings(Wang et al., 2018).

Moreover, the system follows a sustainable design principle: it requires no large instruments or power supply, uses washable base garments with small replaceable sensing strips, and can be produced with simple local textile processes. These features reduce waste, extend usability, and make the approach adaptable for broader applications in low-cost, eco-friendly maternal health care.

By synthesizing these expert insights with material constraints, we present a comprehensive framework that outlines the prototype architecture, detection protocols, and validation steps suitable for resource-limited environments. Moreover, the system follows a sustainable design principle: it requires no large instruments or power supply and uses washable base garments to reduce waste. This framework provides a structured, expert-verified pathway for developing low-cost, eco-friendly maternal health monitoring devices.

2. RESEARCH METHODOLOGY

This study follows a Research for Design (RfD) approach, integrated with a two-round Delphi validation process. The methodology is positioned as a generative framework study that prioritizes clinical validity and user-centric logic over immediate physical manufacturing (Frayling, 1994). RfD was selected because it allows for the rigorous synthesis of material science constraints and clinical protocols into a validated design proposal, even in the absence of a physical prototype at this stage (Wiorek et al., 2020). To ensure the proposed solution is not merely theoretical but clinically viable for low-resource settings, the research design is structured into three distinct phases:

2.1 PHASE 1: EVIDENCE SYNTHESIS AND CONCEPTUALISATION

Initially, a comprehensive review of existing literature was conducted to define the material boundary conditions. We analysed the chemical properties of sol–gel stabilisation and the physiological parameters of amniotic fluid leakage. This phase identified the critical safety priorities for pregnant users—specifically the need for non-irritant, biocompatible materials —and informed the initial "Conceptual Model" (including the preliminary draft of the sensing strip architecture and user instructions).

2.2 PHASE 2: EXPERT VALIDATION (TWO-ROUND DELPHI STUDY)

To bridge the gap between theoretical material science and clinical reality, the initial concept underwent a two-round Delphi study involving a multidisciplinary panel of experts, including designers, material scientists, product managers, and medical professionals. In the exploratory first round, the panel evaluated the initial concept (Fig. 4 and Fig. 5) to isolate usability risks and potential failure points in home-use scenarios, with feedback primarily highlighting the potential for misinterpretation due to variable lighting and the complexity of the user journey under high stress. Building on these findings, the second round focused on consensus and iteration, leading to the refinement of design decision rules, specifically the introduction of the dual-criterion rule (combining pH threshold with time persistence), before the revised framework was re-submitted to the panel to verify consensus on its safety and feasibility.

2.3 PHASE 3: FRAMEWORK SYNTHESIS

The final phase involved integrating the validated clinical logic with the material production feasibility. This resulted in the final Design Framework (Fig. 8), which links material performance targets (e.g., response time, stability) with the expert-verified user decision pathways. This structured output provides an evidence-based roadmap for future laboratory prototyping and clinical pilot studies.

3. MATERIAL PRINCIPLE: PH-RESPONSIVE SOL–GEL SYSTEM FOR AMNIOTIC FLUID DETECTION

A Nitrazine dye is fixed within a porous sol-gel matrix that acts as the sensing core. The sol–gel holds the dye in place and therefore reduces wash-off during use (Wencel et al., 2009). It also allows the sensitivity point to be adjusted by changing the composition of the gel (Thapa et al., 2022). Under normal acidic vaginal fluid with pH between 4.5 and 6.0, the indicator

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stays yellow. When alkaline fluid with pH of 7.0 or higher reaches the sensing layer, an acid–base reaction then causes the colour to shift to green or blue. The colour change appears within 1 minute (≤ 60 s) under normal light and can be seen clearly by eye. To limit short-term false readings, a time-persistence rule is added: the signal must reach the colour threshold and remain visible for at least 10 minutes to be considered positive.

3.1 SUMMARY COMPARISON TABLE

Table 1: Comparison of amniotic fluid vs. common confounders for pH-responsive (Nitrazine) detections

Source: Author

Fluid / Scenario	Typical pH Range	Expected Nitrazine Colour*	Likely Interferents / Notes	Misclassification Risk	Design Implication
Amniotic fluid (Olarinoye et al., 2021)	7.1–7.3	Blue-green to blue (≥7.0)	May mix with vaginal secretions; read within 60 s	Low (vs. acidic baseline)	Trigger threshold ≥7.0; add time-persistence check
Vaginal secretions (Baev et al., 2023)	3.8–4.5	Yellow	Lactobacilli maintain acidity	Low	Avoid false positives < pH 6.8
Maternal urine (Baev et al., 2023)	4.6–8.0 (avg ~6.0)	Yellow → green/blue if alkaline (>7)	Diet/UTI can raise pH to ≥7–8	Medium	Add timed re-check or secondary criterion
Blood (Baev et al., 2023)	7.35–7.45	Blue	Alkaline; visible masking possible	Medium	Use area/pattern logic or add a secondary/orthogonal marker
Semen (post-coital residue) (Cooper et al., 2010)	7.2–8.0	Blue	Transient alkalinity	High (short-term)	Require time-persistence (e.g., sustained signal ≥10 min)
Bacterial Vaginosis (BV)(Aldunate et al., 2015; Y. Lin et al., 2021)	≥4.5 (often 5.0–6.0)	Yellow-green → green/blue-green†	Elevated vaginal pH due to BV/trichomonas	Medium	Pair with guidance: persistent leakage + symptoms
Sweat / Water (bathing) (Hemalatha et al., 2013; Y.-P. Lin et al., 2021)	Sweat: ~4.0–6.8; Water: 6.5–8.5	Yellow to light green (context-dependent)	Dilution from sweat; tap/shower water near-neutral to alkaline	Low	Hydrophobic base & flow-limiting to reduce dilution

Table 1 summarises the reference pH values and corresponding Nitrazine colour changes for amniotic fluid and common confounders ((Bennett et al., 1993). The colour descriptions refer to a typical Nitrazine readout; interpretation should follow the specific product chart and be made within 60 seconds (Bennett et al., 1993). As indicated, the exact shade varies slightly with dye brand and pH, and bacterial vaginosis (BV) can elevate vaginal pH above 4.5 but not necessarily into the amniotic range of 7.1–7.3 (Olarinoye et al., 2021).

Amniotic fluid generally presents a higher and more stable pH, producing a persistent blue response, while semen and alkaline urine may cause short-term colour shifts (Iqbal et al., 2022). Blood or BV may increase apparent pH or obscure the reading. Based on this comparison, we established preliminary detection rules: the trigger is set at pH ≥ 7.0, the readout is standardised at 60 seconds, and a positive result is defined only when the colour remains for ≥ 10 minutes (Olarinoye et al., 2021). To reduce false readings from dilution or transient wetting (e.g., sweat or bath water), the proposed textile architecture incorporates a hydrophobic base layer and controlled wicking pathways. These operational criteria are reflected in the draft Instructions for Use (IFU) and embedded within the conceptual design framework.

3.2 PH / NITRAZINE TEST

The sensing architecture (figure 2) relies on a halochromic transduction mechanism, wherein a Nitrazine indicator is physically entrapped within a porous sol–gel silicate network (Trovato et al., 2018). This immobilization strategy serves a dual function: it anchors the dye molecules to prevent leaching during fluid exposure critical for safety, while preserving the porous channels necessary for ionic diffusion. Upon contact with fluids exceeding the neutrality threshold (pH ≥ 7.0), the protonation state of the indicator shifts, triggering an immediate chromatic transition from yellow to a distinct blue-green spectrum (Trovato et al., 2018). Unlike transient wetting on standard cellulose paper, the sol–gel matrix modulates

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the fluid interaction, allowing for a stabilized readout window. To standardise interpretation, we define a "valid signal" not merely by the immediate colour shift (≤ 60 s), but by the stability of the hue over a ten-minute observation window, thereby filtering out transient alkaline spikes common in non-amniotic contaminants (Puoci et al., 2020).

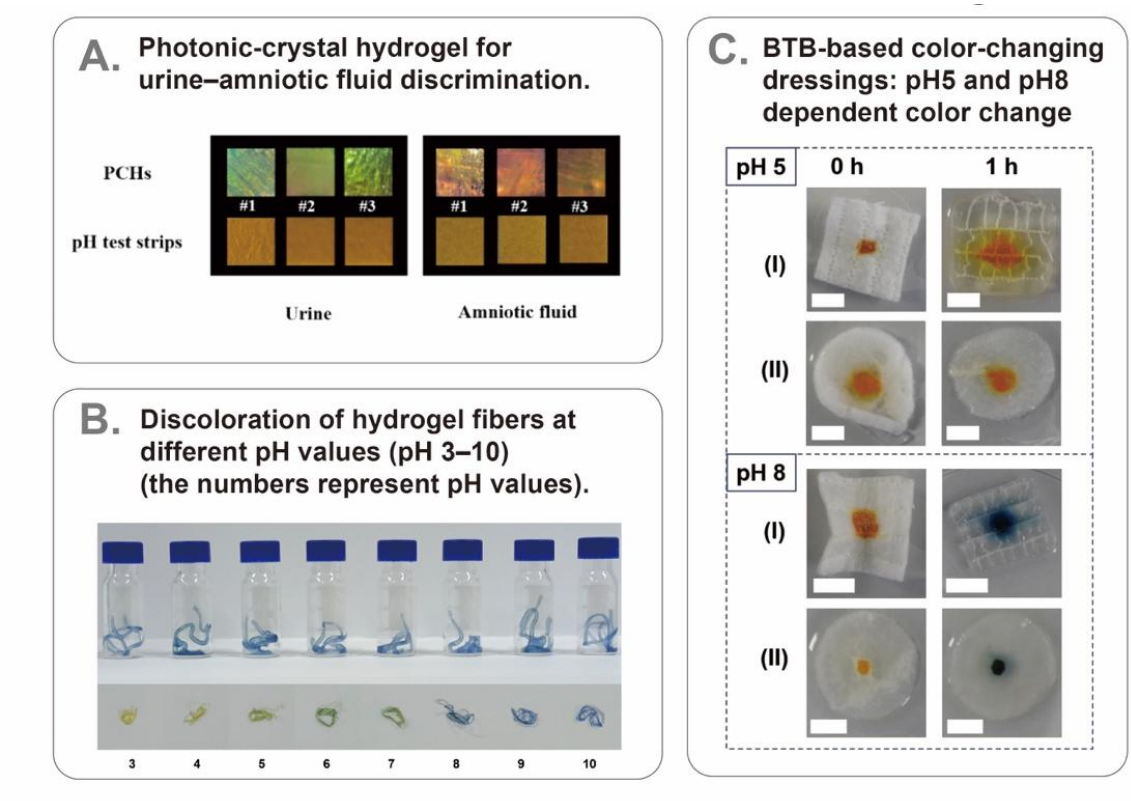

Figure. 2. Examples of hydrogel-based pH-responsive sensing materials reported in the literature.

(A) Photonic-crystal hydrogel for urine–amniotic fluid discrimination (Li et al., 2024). (B) pH-dependent discoloration of hydrogel fibers with wide-domain pH color-changing nanocapsules (Hou et al., 2022). (C) BTB-based color-changing dressings responding to infection-related pH shift (Brooker & Tronci, 2024).

Source: Li, Y., Wang, X., Li, L., Wang, J., Dong, X., Meng, Z., & Xue, M. (2024). Real-time and high-sensitive colorimetric sensor based on photonic crystal for amniotic fluid identification. Microchemical Journal, 202, 110691. Hou, X., Zhao, H., Zhang, K. Q., & Meng, K. (2022). Preparation of wide-domain pH color-changing nanocapsules and application in hydrogel fibers. Materials, 15(24), 8787. Brooker, C., & Tronci, G. (2024, May). Infection-responsivity of commercial dressings through halochromic drop-casting. In AIP Conference Proceedings (Vol. 3158, No. 1, p. 160002). AIP Publishing LLC.

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4. APPLICATION OF PH-RESPONSIVE NITRAZINE-BASED MATERIAL IN MATERNITY SAFETY UNDERWEAR

4.1 DESIGN CONCEPT AND PROTOTYPE DEVELOPMENT

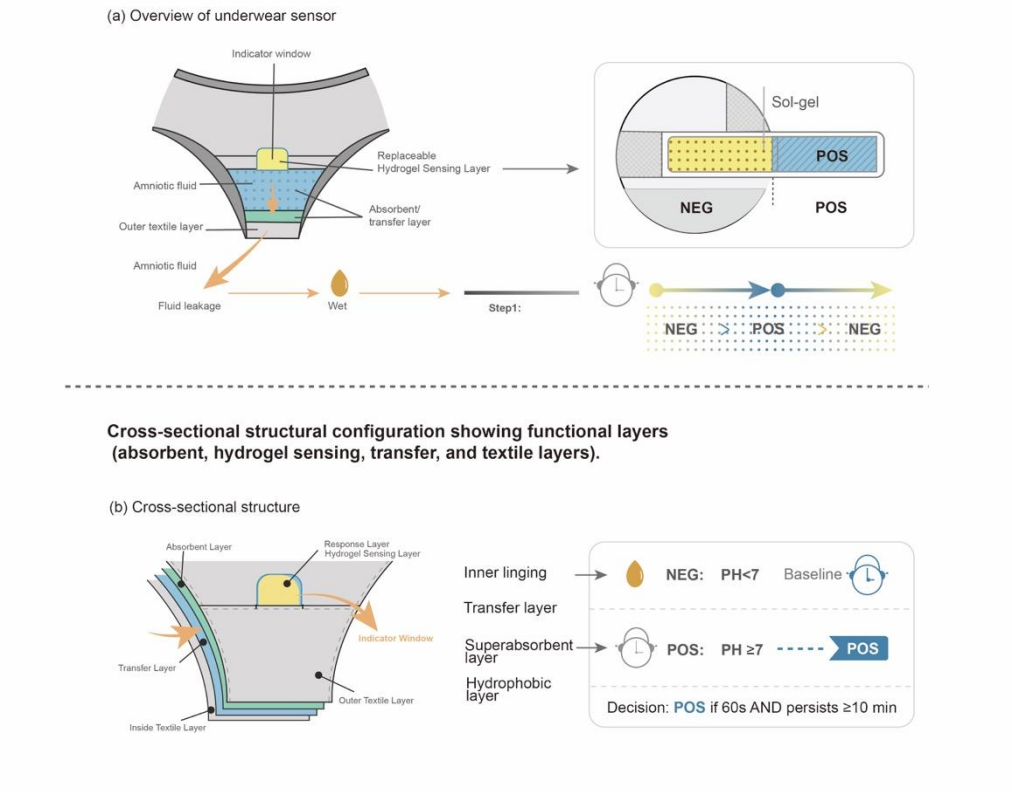

Figure. 3. Layered architecture and color-change mechanism of the proposed pH-responsive maternity safety-underwear sensor.

Source: Author

To operationalize the design framework (figure 3), a stratified textile configuration is proposed to resolve the conflict between sensing accuracy and wearer comfort. The architecture integrates three functional zones: a hydrophilic, biocompatible top sheet designed to facilitate rapid fluid uptake while maintaining a dry skin interface; a central sensing core where the Nitrazine indicator is entrapped within a porous sol–gel matrix to ensure selective alkaline detection without dye leaching; and a hydrophobic backing that simultaneously limits retrograde fluid flow and provides a high-contrast, non-absorbent background for improved readability. To further mitigate interpretation errors caused by ambient lighting, a comparative calibration index is integrated directly adjacent to the sensing window, while the strip's geometry is optimised to align with the anatomical flow path to capture both micro-leaks and significant fluid loss. In terms of system modularity, the design envisions a "consumable-insert" model where the sensing element is secured via skin-safe adhesives or a garment pouch, allowing the base underwear to be washed and reused, representing a critical feature for sustainability. It must be noted that this description represents the validated conceptual model derived from the RfD process, establishing the architectural logic for future prototyping.

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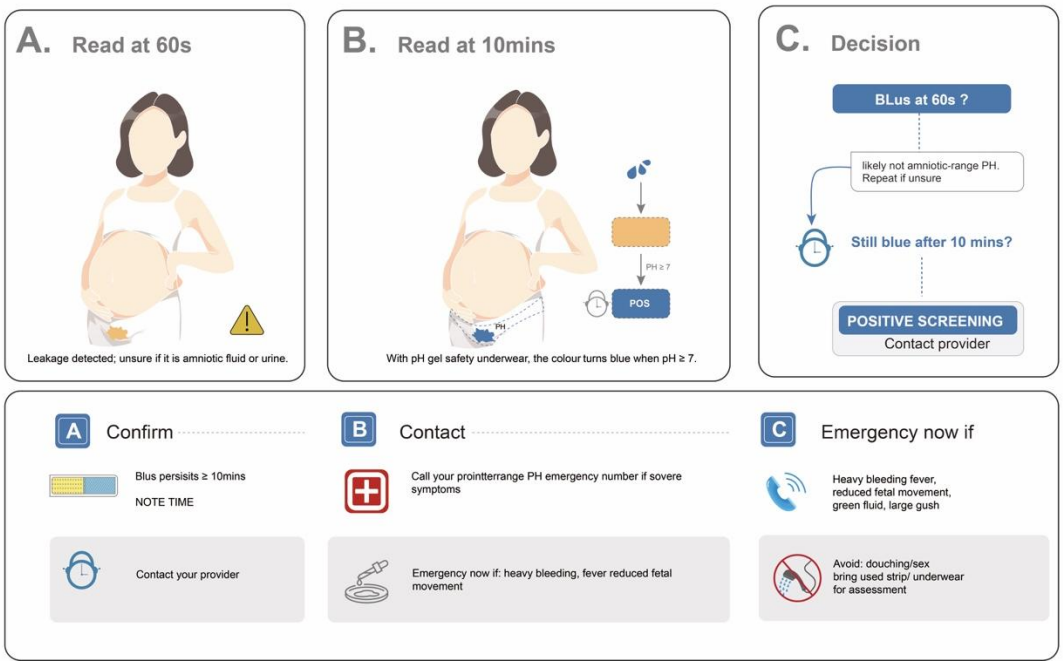

Figure. 4. Home-use user journey and dual-criterion decision rules for the laboratory-scale pH-gel safety-underwear prototype.

Source: Author

To operationalize the detection logic, a comprehensive user journey map (Fig. 4) was developed to guide the behavioral response to suspected leakage. The workflow initiates with the recognition of fluid loss (Panel A) and progresses to the sensing interface (Panel B), where a chromatic shift to blue indicates exposure to alkaline fluid (pH ≥ 7.0) at the 60-second mark. Crucially, Panel C integrates the expert-validated dual-criterion rule, requiring users to confirm that the signal persists for a minimum of 10 minutes before initiating clinical contact. The triage protocol is then stratified by gestational urgency, mandating immediate notification for pregnancies under 34 weeks, prompt consultation for those between 34 and 36 weeks, and direct hospital attendance for terms exceeding 37 weeks. Furthermore, the instruction set includes essential safety precautions, such as the avoidance of vaginal intercourse and the preservation of the used strip to facilitate subsequent clinical verification.

4.2 EVIDENCE SYNTHESIS AND FEASIBILITY VALIDATION FOR PH-RESPONSIVE DESIGN

Previous studies have shown that the pH difference between vaginal fluid and amniotic fluid is large enough to be used as a simple indicator for early rupture of membranes (Olarinoye et al., 2021). Nitrazine paper and hydrogel sensors have both been tested in laboratory settings, and most results report a clear colour shift within one minute when the pH rises above 7.0 (Iqbal et al., 2022). Some experiments also found that sol–gel materials can make the colour more stable and reduce fading during drying (Trovato et al., 2018). Based on these findings, our design combines a fixed pH threshold with a time rule to avoid short false signals from urine or semen (Baev et al., 2023). The validation roadmap embedded within the framework mandates a phased technical assessment starting with colorimetric kinetic verification in standard buffer solutions. Subsequent stages require stability testing within simulated physiological environments containing confounders such as urine, blood, and vaginal secretions. Ultimately, the protocol calls for simulated wearer trials utilizing a saline surrogate for amniotic fluid to verify that the signal meets the ten-minute persistence criterion while maintaining ergonomic comfort, ensuring the system is sufficiently robust for pilot deployment.

Complementing this pathway, Figure 5 presents a typological mapping of current pH-based colorimetric systems deployed in PROM detection, ranging from single-indicator and dual-dye hydrogels to more complex architectures involving photonic crystals, conductive polymers, and hybrid nanomaterials. Each modality is analyzed regarding its trade-off between diagnostic sensitivity, mechanical durability, and manufacturing complexity. This comparative taxonomy identifies a strategic opportunity for silane-stabilised indicator layers to bridge the gap between low-cost disposable pads and high-complexity smart materials, thereby substantiating the material selection rationale underpinning our design framework.

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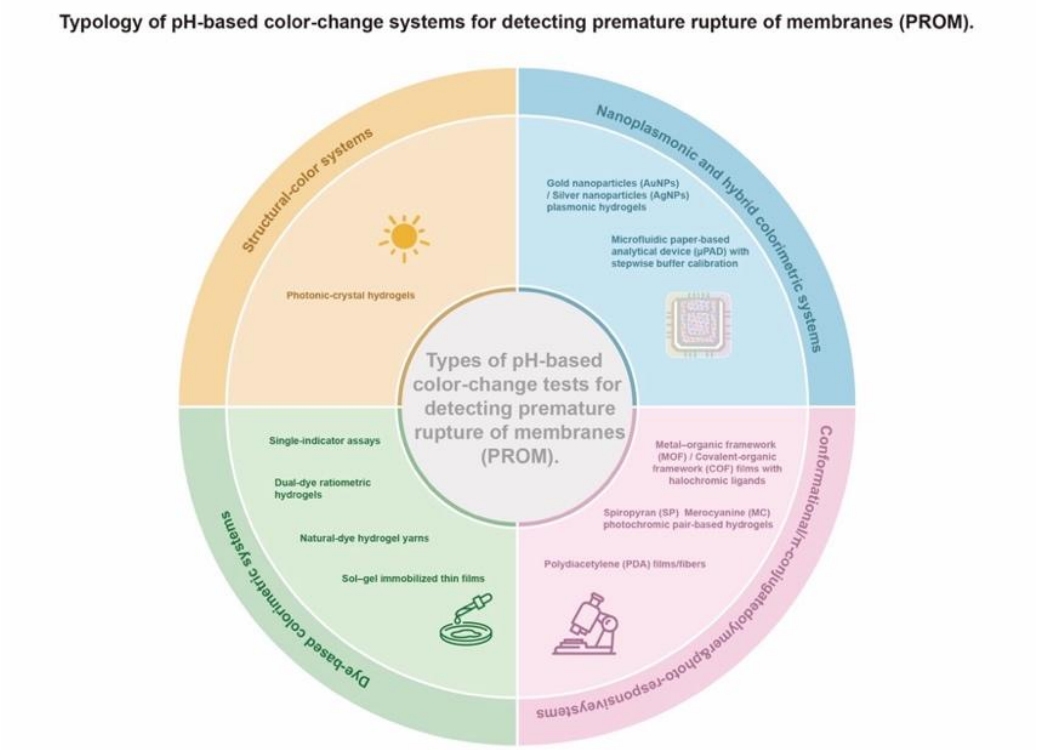

Figure. 5. Author-Synthesized Evidence Supporting the pH-Responsive Detection Design.

Source: Author

5. CHALLENGES AND LIMITATIONS IN THE APPLICATION OF PH-RESPONSIVE NITRAZINE-BASED MATERIALS

5.1 MATERIAL AND PERFORMANCE CHALLENGES

The development of a pH-responsive Nitrazine-based sensing strip presents several material and performance challenges that must be addressed before clinical validation. While prior studies confirm the halochromic stability of silane-tethered dyes and demonstrate clear colour transitions around pH 7 (Trovato et al., 2021), the behaviour of the sensing film under real conditions—such as mixed fluids, repeated wetting, and varying humidity—remains uncertain (Caldara et al., 2016).

Achieving uniform dye immobilisation is critical to prevent leaching and to maintain consistent colour intensity over time (Guido et al., 2014). Similarly, the thin-film structure must balance rapid wetting for response speed with sufficient barrier control to avoid over-spreading or signal dilution (Makote & Collinson, 1999).

From a materials perspective, sensitivity may vary with batch composition, curing temperature, and solvent residues, which can affect the switching point and optical contrast. Mechanical durability, especially during washing or friction, also influences reusability and safety for wearable applications (Elveren et al., 2022).

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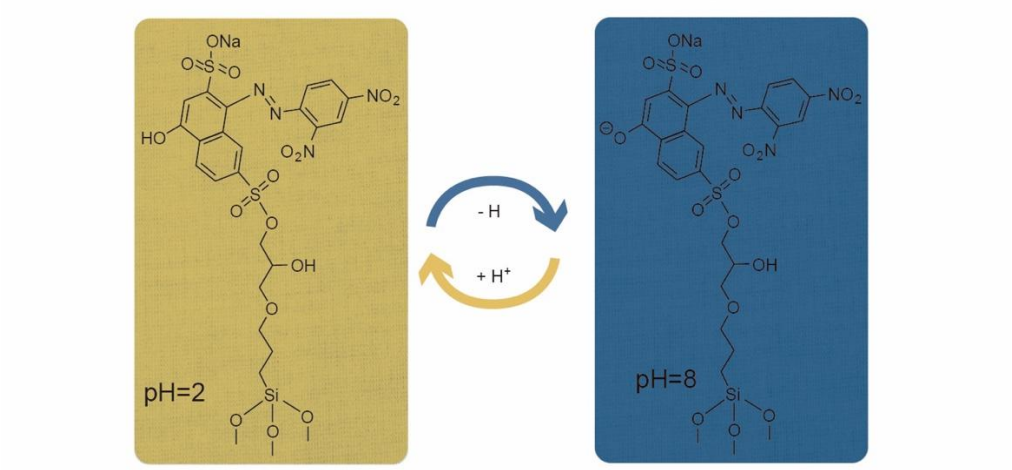

Figure. 6. Conceptual illustration of the pH-responsive mechanism of Nitrazine Yellow immobilised through a silane-based (GPTMS) coating on cotton fabric.

Source: Author illustration based on Trovato et al. (2022), Molecules, 27(17), 5709.

Figure 6 shows the colour-changing behaviour of a silane-tethered azo dye within a crosslinked silane network. When the surrounding pH is low (around 2), the molecule is protonated and appears yellow (Trovato et al., 2022). As the pH rises to approximately 8.0, the deprotonation of the azo group triggers a chromatic shift to blue. This reversible transition exemplifies the halochromic effect, wherein the molecular structure provides a visible optical response to fluctuations in hydrogen-ion concentration. Crucially, the silane-based matrix stabilizes the dye orientation while permitting sufficient ionic exchange to facilitate a distinct and repeatable color change. Collectively, this underlying chemical mechanism and the supporting material evidence validate the technical feasibility of the proposed design for reliable pH-responsive sensing in wearable applications.

5.2 USER AND ENVIRONMENTAL CHALLENGES

From a design perspective, the user context introduces complexities that transcend the mere chemical responsiveness of the material. The system must ensure safety, comfort, and acceptability for pregnant individuals, a demographic where physiological skin sensitivity and emotional vulnerability may exacerbate anxiety or physical discomfort (Liu et al., 2024). Consequently, the structural integration of the sensing strip is engineered to minimize contact irritation, reduce cognitive load regarding visual interpretation, and mitigate the stigma often associated with medical self-monitoring. Furthermore, the readability of the colorimetric signal constitutes a critical design challenge, requiring that the optical contrast be immediately discernible under standard ambient lighting without reliance on digital analysis, thereby ensuring the signal is sufficiently intuitive to prompt accurate decision-making.

Environmental constraints within low-resource or remote settings impose rigorous stability requirements, particularly where infrastructure for climate control or hermetic sealing is compromised. Consequently, the device architecture must prioritize chemically robust materials capable of maintaining functional integrity without reliance on cold-chain logistics or external power sources. Concurrently, the integration of a reusable base garment with modular, replaceable sensing elements addresses the imperative for environmental sustainability, minimizing bio-medical waste in alignment with green healthcare principles (Dulal et al., 2024). These ecological and logistical considerations extend beyond immediate usability, structurally informing the broader system framework regarding localized production, supply chain distribution, and responsible end-of-life disposal.

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6. FRAMEWORK

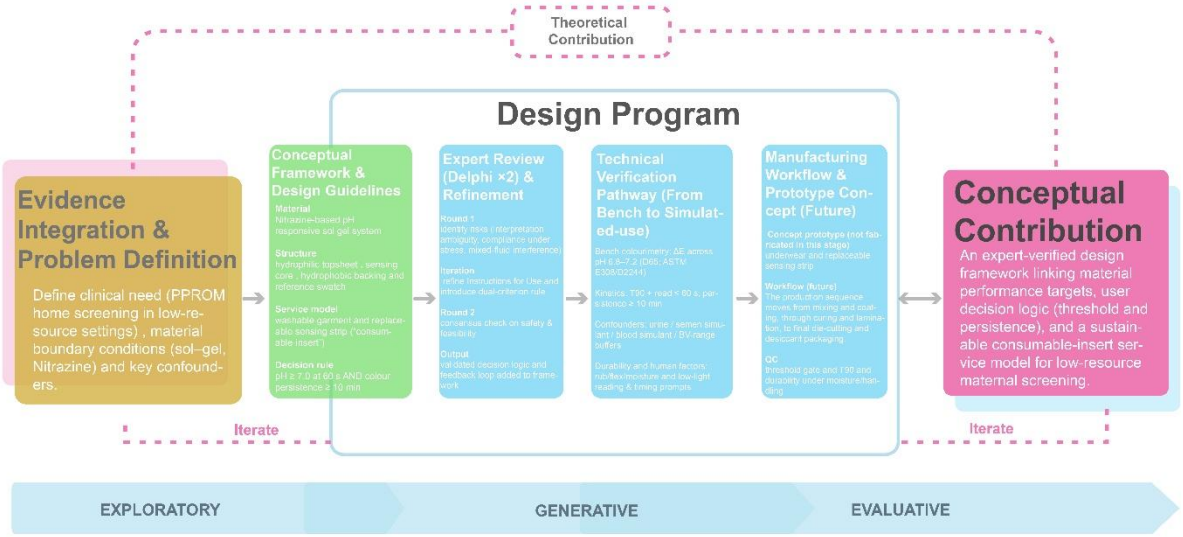

Figure. 7. Integrated Framework: Design Direction, Validation Strategy, and Production Workflow.

Source: Author

6.1 DESIGN DIRECTION

The translation of clinical requirements into a wearable form factor necessitated a departure from traditional "test-strip" logic. Our framework prioritizes specific user-centred criteria: discretion, reversibility, and sustainability. Rather than integrating complex electronics, the "consumable-insert" architecture was selected to decouple the sensing element from the garment, thereby reducing the economic and environmental cost per use. The decision to enforce a dual-criterion rule (Threshold + Persistence) was not arbitrary but emerged as a necessary design mitigation against the high "noise" of biological variables (e.g., urine/sweat) inherent in uncontrolled home environments. This approach shifts the reliance from pure chemical specificity, which is often unattainable with simple dyes, to a procedural logic that users can reliably execute.

6.2 VALIDATION STRATEGY

We follow a stepwise evaluation from bench to early human use. First, we run bench colourimetry to set objective acceptance limits. We use colourimetry defined by the International Commission on Illumination (CIE) under the standard illuminant D65 with the ten-degree standard observer, following the American Society for Testing and Materials (ASTM) standards E308 and D2244. We report the colour difference (ΔE*ab) across the decision region from pH 6.8 to 7.2 and set the corresponding pass criteria based on this threshold window. Then we measure response and persistence: the time to reach ninety per cent of the final colour and the stability of the signal for at least 10 minutes under controlled humidity and temperature. Next, we test a confounder panel that includes urine with pH from 6 to 8, a semen simulant at ten percent by volume, a blood simulant at one to five percent by volume, and buffers in the range typical of bacterial vaginosis, and we compute the misclassification rate under the dual rule of threshold and time persistence. In parallel, we assess durability and stability using methods from the American Association of Textile Chemists and Colorists（AATCC） for water, perspiration, and crocking, the International Organization for Standardization(ISO) for abrasion and flex, and the American Society for Testing and Materials F1980 for accelerated ageing. We then run formative human-factors studies with timing prompts, low light reading, and placement guides, and we iterate the instructions for use. Finally, after benchtop and simulated-use success, we proceed to small observational studies under ethical review, focusing on readability, comfort, and agreement with clinical assessment.

6.3 PRODUCTION WORKFLOW

This study does not include manufacturing; however, a future pathway (figure 7)is outlined to support a pilot study if the prototype progresses to the next stage. In the proposed process, the sensing film would be prepared by mixing the Nitrazine indicator with a sol–gel solution and coating it onto a nonwoven textile, followed by curing to immobilise the dye. A multilayer laminate would then be constructed with a wicking top layer, a hydrophobic base layer to prevent strike-through, and a neutral reference swatch, before die-cutting into sensor shapes. Assembly options would be explored, including a small replaceable sensing strip that can be inserted into a washable base garment, with skin-safe adhesive for stable placement. Quality control would focus on the colour transition at the decision threshold, the time to reach ninety percent

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of the final colour, and durability under moisture and handling. Additionally, sealed foil packaging with a desiccant and clear Instructions for Use would ensure performance stability and clarify that the product is intended to support, rather than replace, clinical diagnosis.

7. EXPERT VALIDATION

To verify the coherence and feasibility of the proposed design framework, a qualitative validation study was conducted with a panel of five multidisciplinary experts. The panel included specialists in Clinical Medicine, Textile Engineering, and Design Research/Human Factors, with experience ranging from junior practitioners (<5 years) to senior experts (>10 years). The validation results are summarized in Table 2.

Table 2: Summary of Expert Validation Feedback

Source: Author

Field of Expertise	Experience	Assessment Outcome	Key Validation Insights & Critical Feedback
Clinical / Medical	5–10 Years	Valid (High Agreement)	Confirmed alignment with clinical safety requirements. No logical breaks in translating medical needs to the conceptual model.
Design Research	> 10 Years	Valid (Strong Agreement)	Validated methodological progression and linkage between material constraints and user interaction logic.
Textile Engineering	< 5 Years	Valid (Strong Agreement)	Verified feasibility of laboratory-scale prototype and structural logic for smart-textile integration.
Design Research	> 10 Years	Conditional (Critical Revision Required)	Methodological gap identified: missing iterative feedback loop; linear progression ignores prototype failures. Usability risk: 10-minute wait rule may reduce compliance under high-stress anxiety.
Textile Engineering	5–10 Years	Conditional (Critical Revision Required)	Ecological validity issue: no validation for mixed-fluid interference. Feasibility challenge: color reversion via ammonia vapor may cause false positives if inhibited by contaminants.

7.1 ANALYSIS OF EXPERT FEEDBACK

The feedback from the expert panel revealed a distinct divide between conceptual validation and operational feasibility. Validation of Design Logic: Experts E1, E2, and E3 confirmed the structural coherence of the framework. There was strong consensus that the proposed "consumable-insert" architecture and the sol–gel material integration are theoretically sound and clinically relevant. The progression from exploratory research to generative design was deemed logical and appropriate for a laboratory-scale study.

Identification of Critical Risks: Conversely, the senior experts (E4 and E5) identified significant ecological and behavioral challenges that necessitated refinement of the framework: User Behavioral Constraints: Expert E4 emphasized that the "10-minute persistence rule," while chemically sound for differentiating ammonia, imposes an excessive cognitive load on anxious users. This suggests that the final device instructions must prioritize immediate "seek care" protocols over home-diagnosis confirmation to ensure safety.

Environmental Interference: Expert E5 highlighted that the initial framework focused heavily on pH sensitivity but lacked sufficient rigor regarding "physiological interference" (e.g., bacterial vaginosis or mixed fluids) and mechanical durability under shear forces.

Iterative Process: The critique regarding the linear nature of the design program (Expert E4) prompted a revision of the framework visual (Figure 3) to explicitly include a feedback loop, acknowledging that prototype failure is a generative part of the research process.

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7.2 REFINEMENT OF THE RESEARCH FRAMEWORK

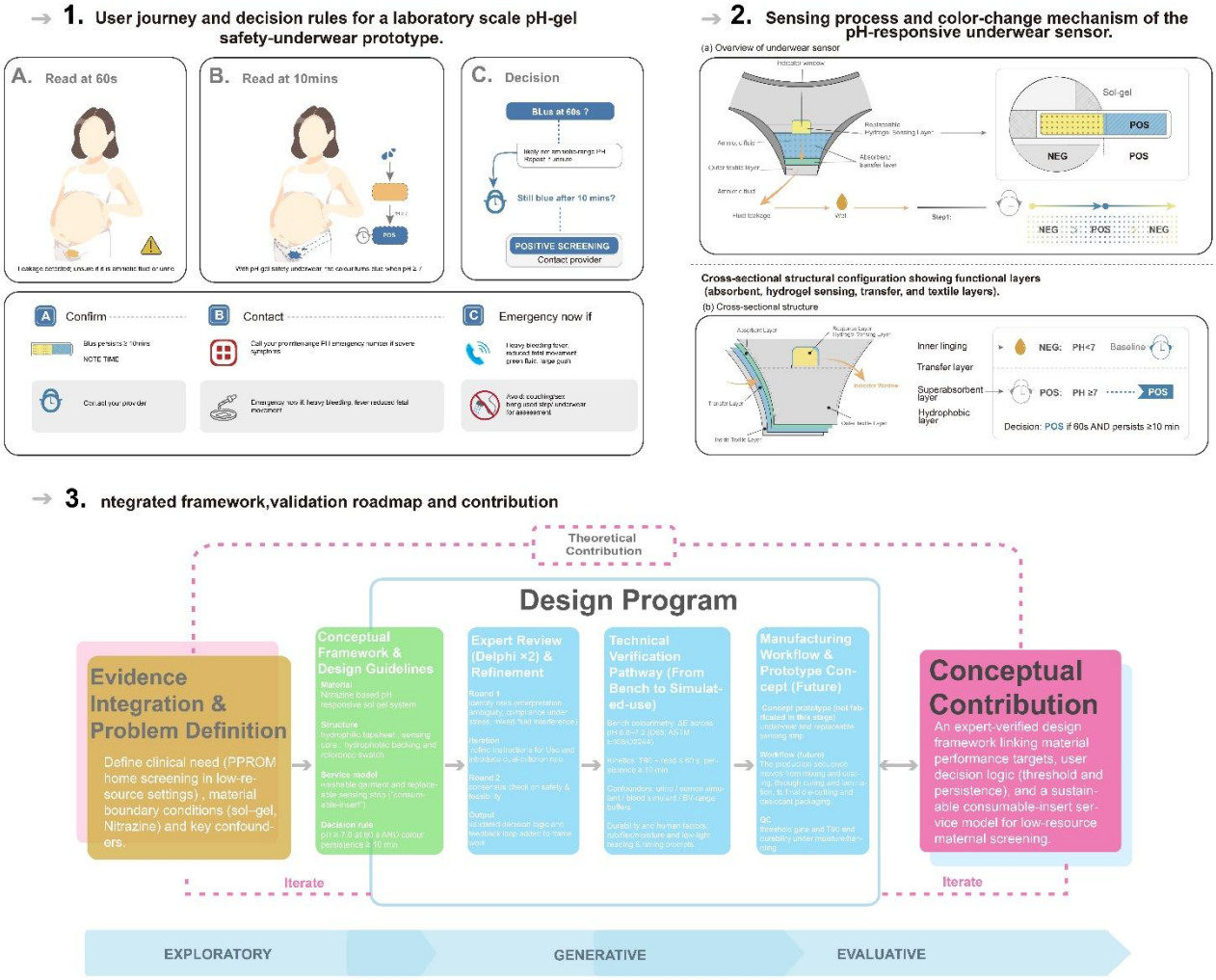

Fig. 8. The Integrated Research for Design (RfD) Framework, linking evidence synthesis, iterative expert validation (Delphi), and the technical roadmap for low-resource maternal care.

Source: Author

Following the refinement of the framework, specifically the introduction of the "Emergency Now" triage pathway and the "Dual-Criterion" decision logic—the revised design was re-submitted to the expert panel for a second round of validation. Unlike the exploratory nature of Round 1, this round utilized a structured 5-point Likert scale (1 = Strongly Disagree to 5 = Strongly Agree) to quantify consensus on the safety, technical validity, and methodological integrity of the final framework. The results from the second round demonstrated a high degree of convergence among the experts (Table 2). The panel reached unanimous agreement (Mean = 5.0) on the effectiveness of the Emergency Triage Pathway (Q1), confirming that separating high-risk symptoms from the pH testing workflow effectively mitigates the "user anxiety" risks raised in Round 1.

Similarly, the Dual-Criterion Rule (combining pH threshold with time persistence) and the proposed Confounder Testing Scope (including BV and semen simulants) received strong validation (Mean = 4.8), with experts confirming that these measures establish a clinically acceptable balance between home-use accessibility and diagnostic rigor. The methodological update, which explicitly visualized the iterative feedback loops between technical validation and problem framing, also received a perfect consensus score (Mean = 5.0), validating the RfD approach. In the final "Go/No-Go" assessment, 100% of the experts (n=5) voted to proceed to the next phase. The panel (table 3) concluded that the revised framework demonstrates sufficient theoretical robustness and safety safeguards to justify the transition from conceptual design to physical laboratory prototyping.

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Table 3: Summary of 2nd Expert Validation Feedback

Source: Author

Validation Criteria	Description of Revision	Mean Score (n=5)	Expert Consensus Outcome
Clinical Safety	Emergency Triage Pathway: Immediate care for bleeding/fever without testing to reduce decision delay.	5.0	Strongly Validated (Addressed Round 1 anxiety concerns)
User Logic	Dual-Criterion Rule: pH ≥ 7.0 + 10-min persistence to filter transient noise.	4.8	Validated (Acceptable burden/accuracy trade-off)
Ecological Validity	Confounder Scope: Mandatory testing for Urine, Semen, Blood, and BV buffers.	4.8	Validated (Sufficient for low-resource risks)
Technical Logic	Ammonia Rejection: Using signal fading vs. persistence to distinguish urine vapor.	4.8	Validated (Scientifically sound)
Methodology	Iterative Loops: Explicit feedback links between material tests and concept framing.	5.0	Strongly Validated (Correct use of RfD)
Overall Verdict	Go / No-Go Decision	100% Go	Proceed to Laboratory Prototyping

8. DISCUSSION

8.1 SHIFTING FROM DETECTION TO TRIAGE

Mitigating User Anxiety A primary finding from the first round of expert validation was the risk of "decision paralysis," where the complexity of home-testing could exacerbate maternal anxiety. The unanimous consensus (Mean = 5.0) achieved in the second round for the "Emergency Triage Pathway" validates our strategic shift from a purely diagnostic tool to a safety-first triage system. Unlike traditional commercial kits that focus solely on the chemical reaction (color change), our framework prioritizes clinical symptoms (e.g., heavy bleeding, reduced fetal movement) before the user engages with the device. This "safety-gate" mechanism ensures that high-risk cases are referred immediately to hospital care without the delay of testing, effectively resolving the ethical concerns raised by Expert E4 in the preliminary study. This suggests that for low-resource wearable diagnostics, the design of the decision protocol is as critical as the sensitivity of the sensor itself.

Specifically, enhancing Specificity through the Dual-Criterion Rule While Nitrazine is a well-established indicator, its application in home settings has historically been limited by false positives from urine, semen, and infection (BV). The strong expert validation of our "Dual-Criterion Rule" (combining pH threshold ≥ 7.0 with >10-minute signal persistence) confirms that procedural logic can effectively compensate for inherent material limitations. By exploiting the temporal instability of ammonia (which fades) versus the stability of amniotic fluid, the framework filters out transient noise without requiring expensive, lab-grade biomarkers. This finding is significant for low-resource contexts, as it demonstrates that high diagnostic specificity can be achieved through cost-effective sol–gel materials when paired with rigorous user interaction design.

Furthermore, the Value of Research for Design (RfD) in De-risking Prototyping The perfect consensus score (Mean = 5.0) regarding the iterative feedback loops underscores the efficacy of the RfD methodology in "de-risking" medical product development. Traditional engineering workflows often rush to physical fabrication, only to discover usability failures during late-stage testing. By contrast, our approach utilized the "generative failure" of the Round 1 concept to refine the system architecture before a single prototype was manufactured. The resulting framework, now verified by a multidisciplinary panel, provides a robust, evidence-based foundation for future laboratory prototyping. It ensures that subsequent physical testing can focus on optimizing material kinetics (e.g., response time, color contrast) rather than revisiting fundamental questions of clinical safety or user utility.

Moreover, sustainability and Service Model Beyond clinical functionality, the validated "consumable-insert" architecture offers a sustainable alternative to single-use plastic diagnostics. By decoupling the sensing element from the washable base garment, the framework addresses the economic constraints of low-resource settings while minimizing biomedical waste.

This aligns with emerging trends in green healthcare, suggesting that future maternal monitoring devices must balance diagnostic accuracy with environmental responsibility.

8.2 LIMITATION

It must be acknowledged that this study presents a validated design framework rather than clinical trial data. While the theoretical logic and material constraints have been expertly verified, the physical performance of the sol–gel strip depends on precise manufacturing variables (e.g., curing temperature, coating thickness) that remain to be tested. Future work will focus on the fabrication of the laboratory prototype according to the specifications defined in this framework, followed by benchtop colorimetry and simulated-use testing with surrogate fluids as outlined in the Validation Strategy.

9. CONCLUSION

This study presents a validated design framework for a pH-responsive maternity underwear system, addressing the critical gap in accessible PPROM screening for low-resource settings. By adopting a Research for Design (RfD) methodology, we successfully bridged the disconnect between material science capabilities (sol–gel Nitrazine stabilization) and the complex realities of home-based maternal care.

A key contribution of this work is the establishment of the "Dual-Criterion Decision Rule" (pH threshold ≥ 7.0 combined with >10-minute signal persistence). This logic, rigorously refined through two rounds of Delphi expert consultation, was confirmed to effectively mitigate the risks of false positives from physiological confounders such as urine and semen. Furthermore, the unanimous expert consensus (100% agreement) in the second validation round confirms that the integration of an "Emergency Triage Pathway" sufficiently addresses user anxiety and clinical safety concerns.

While physical fabrication was intentionally reserved for the subsequent phase, this study delivers a "Go-decision" ready roadmap. The resulting framework provides future researchers with a verified set of material performance targets, user instructions, and ecological validation protocols. Ultimately, this system proposes a sustainable, scalable, and clinically safe solution that empowers women in resource-constrained environments to manage pregnancy risks with greater autonomy and dignity.

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