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MEDICINE

Navigating the Future: Strategies for Managing Emerging Technologies at the Point-of-Care

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November 12, 2025

Disclosures

- None.

Objectives

1. Describe the current POCT landscape, including existing technologies and methodologies

2. Identify challenges for implementing point-of-care testing within interdisciplinary teams

3. Formulate strategies for efficiently managing a growing POCT program

Essential Functions of Point-of-Care Testing Programs

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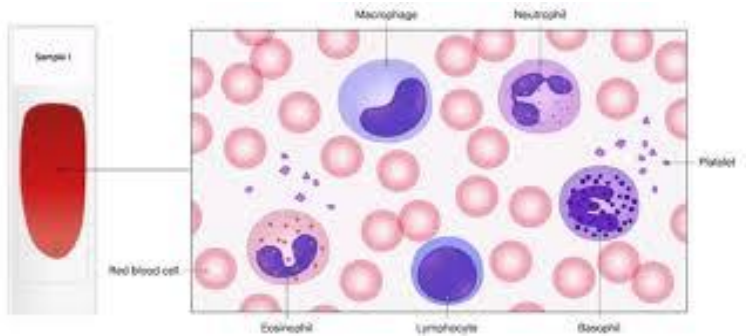

Challenges in a Rapidly Evolving Landscape

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Pre-Analytical

- Appropriate test selection
- Specimen handling
- Contraindications for testing

Analytical

- Number of devices and methods
- Diversity of testing
- Heterogeneity of verification procedures

Post-Analytical

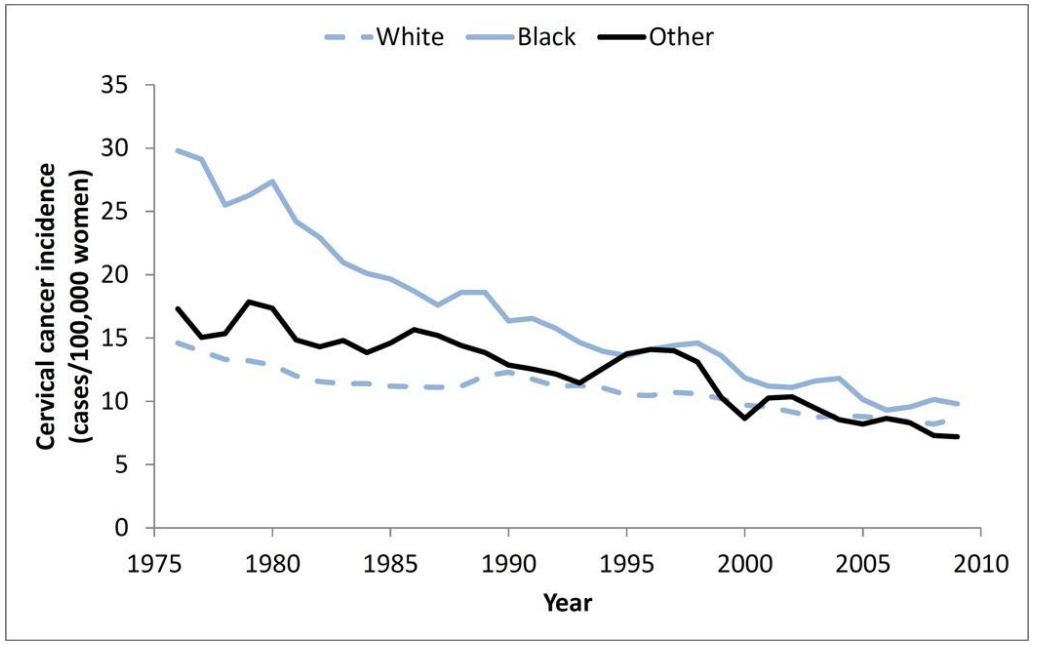
- Manual vs. Automatic entry into the EHR
- IT connectivity
- Result interpretation

Rapid Expansion of Point-of-Care Diagnostics

- In 2024, the POCT industry had an estimated market share of 31.5 billion USD
  - The North American POCT market represents nearly half of that market share
  - Projected to grow to over 50 billion by 2032
  - In 2032, self- or at-home testing market is project to approach an additional 15 billion
- Expansion has been driven by advancements in technology and updated regulations that support and encourage point-of-care and at-home testing
- How do technological, regulatory, and medical advancements impact POCT?

Cervical Cancer Screening: A Case Study for Emerging POCT

- Human papillomavirus (HPV) is responsible for >99% of all cervical cancer cases
- Over 80% of cervical cancer cases globally occur in regions without significant healthcare infrastructure
  - Even in the US adherence and access may be challenging
- Traditionally, cervical cancer screening was done by obtaining cervical scrapings for cytological evaluation (Pap smear)
  - In the early 2000s HPV testing was added to the screening program
  - Addition of HPV testing to pap smear testing can increase the sensitivity from 50-85% to 100%
  - In 2021 it was estimated 25% of women were not up to date with cervical cancer screening
- More recently, there have been large clinical trials that demonstrate equal or improved screening with HPV testing alone



Yang et.al. Am J Clin Oncol 2019

HPV Testing and POCT

- HPV testing is more accessible than traditional Pap smears
  - Can self-collect vaginal “swab” and send to the lab
  - Well suited to low resource settings
- Although self-collection for HPV testing is allowed, there are ongoing conversations about where and how testing should occur
  - In 2024, FDA announced approval of self-collected samples in healthcare settings
  - Shortly thereafter, FDA also approved teal, which is intended to be an at-home self-collection kit
- How would self-collected specimens be regulated and managed?
  - Should/could these samples be tested on a POCT device? At home or in a healthcare setting?
  - Some POCT HPV tests are already available with others in development
- Should screening frequency be impacted by self vs. provider collected specimens? Or by the analytical method?

Examining Emerging Technologies: What to Watch For in HPV Testing

- Clinical
  - Updated screening guidelines
    - Inclusion of factors which may change recommendations
    - Vaccination status, family history, sexual history
  - Guidelines describing the role and cadence of HPV vs. HPV + Pap testing
- Analytical
  - Examination of methods for HPV testing and clinical performance
  - Ensure methods and technologies are fit for purpose
- Practical
  - Design systems aligned with best practices
    - Ex. Utilization of POCT HPV testing in rural areas and those with a high rate of patients lost to follow up
  - Ordering algorithms that reinforce safe screening based upon the method and technology
    - Ex. Self-collect and POCT with HPV testing only may be prudent every 2 years rather than every 3 years
- Special Populations
  - Employ trauma informed care to ensure everyone has access to a screening program
    - Tailoring these algorithms for women that would only be comfortable self-testing

Challenges for Addressing Novel Point-of-Care Testing

1. Identification of clinical need and best practices
2. Understanding the analytical method
    - Focus on molecular techniques and how the method impacts quality assurance
3. Use of algorithms and risk scores in emerging technologies
4. Digital health and integration of information systems

Unpacking Novel POCT

1. Molecular POCT: A Focus on Infectious Disease

2. Algorithms in POCT: High sensitivity troponin

3. Digital health and integration of information systems
   - At home monitoring, wearables, connectivity, and AI

Molecular POC Diagnostics

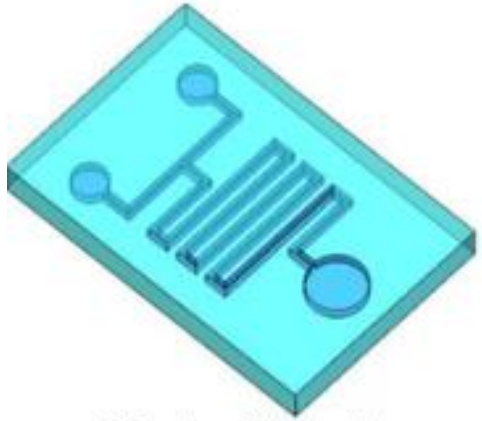
- Respiratory virus testing
  - Flu, strep, RSV, COVID-19
- Sexually transmitted infections
  - Chlamydia, gonorrhea, trichomonas vaginalis
- Non-transmissible vaginal infections
  - Bacterial vaginosis, candida group assessment
- Targets in development
  - Emergency and critical care medicine
    - Molecular sepsis biomarkers
  - Oncology
    - Circulating tumor DNA for disease progression and recurrence
  - Global health
    - Antibiotic resistance markers
    - *HIV viral load*

Managing Molecular POCT

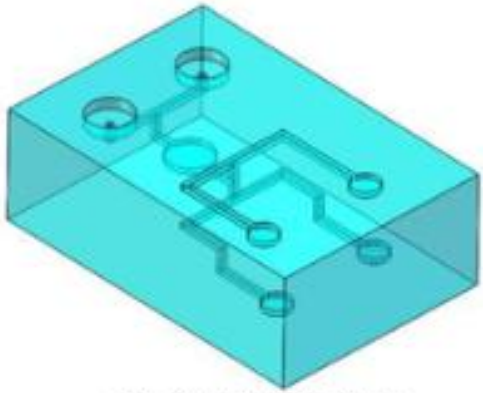
Roadmap for Molecular Testing

Sample Processing

- Point-of-care devices use crude samples
  - Any "processing" happens within the device or the extraction is performed directly on specimen
- Processing within a device
  - Nanopore membranes
    - Filter out larger components (erythrocytes) or specifically enrich for a specific target (E. Coli)
  - Microfluidic sedimentation
    - Allow the sample to flow through a series of small, tortuous chambers within a microchip to filter components by size
  - In development:
    - Centrifugal force (magnetic particles) and acoustic separation



2D microfluidic chip



3D microfluidic cube

He et. Al. Electroanalysis. 2016

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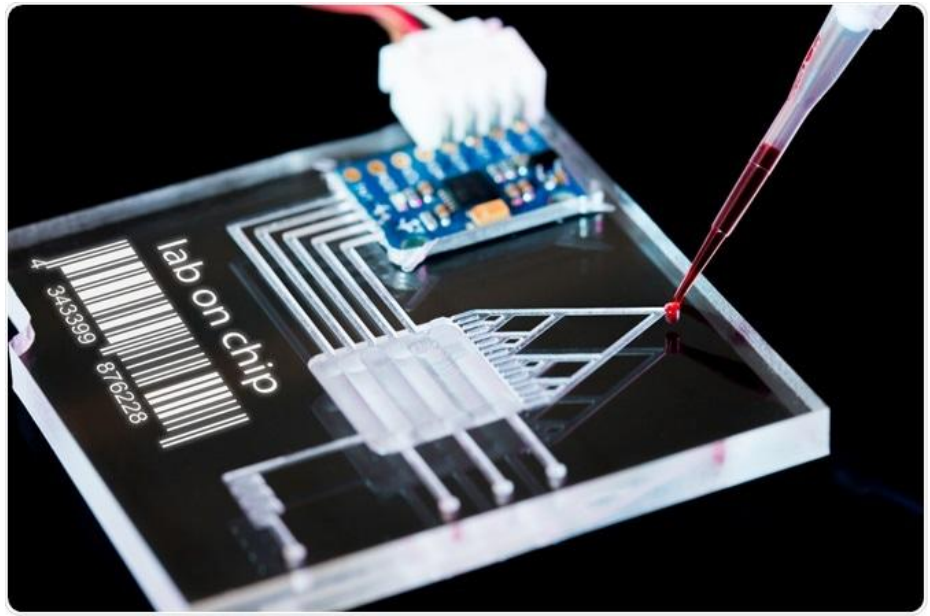
Operational Considerations:

1. Processing time
2. Compatible specimen sources
3. Does this mean the device could clog? Does this impact the cartridge or the entire device?
4. Failure rate

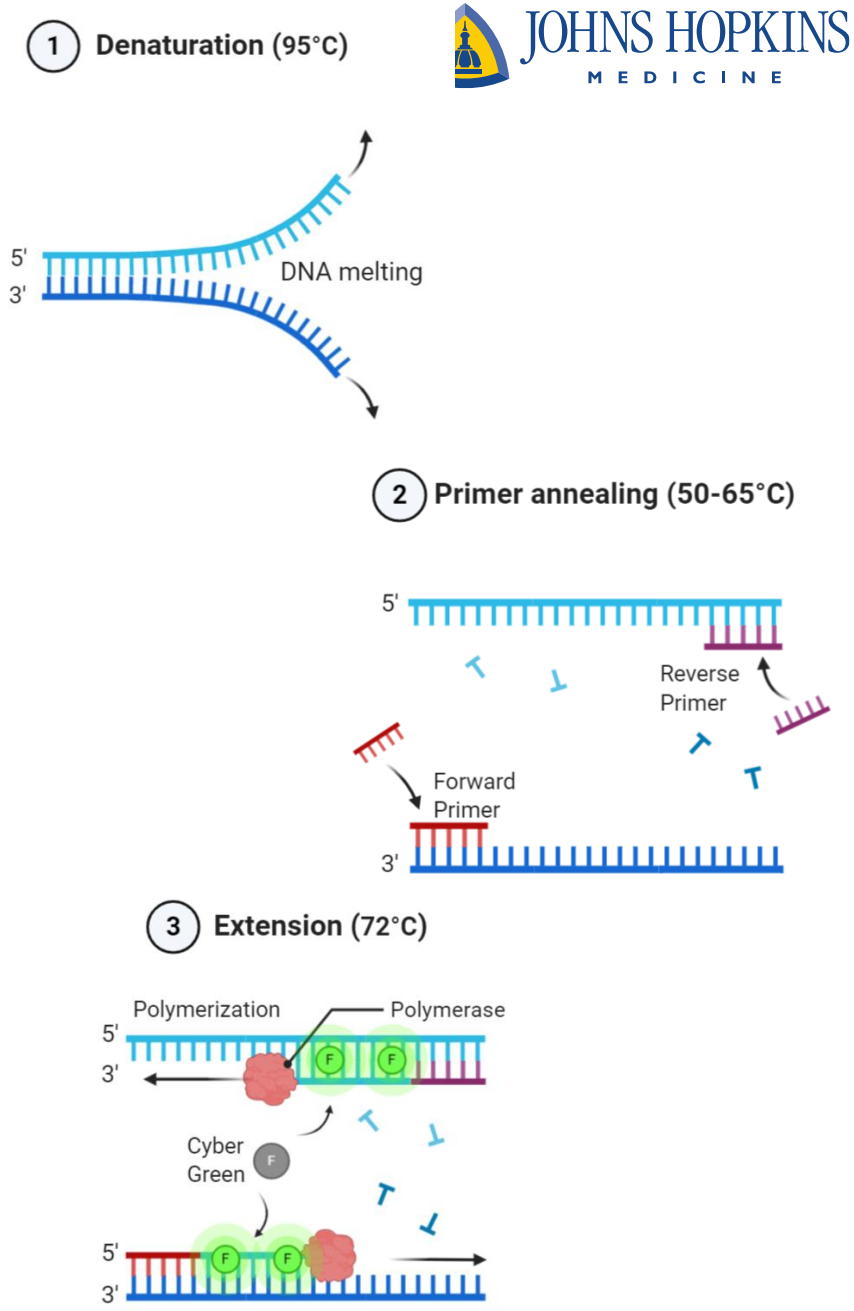
Extraction of Nucleic Acids

- Samples are lysed
  - Mechanical, chemical, electrochemical, thermal
- After lysing, product may be filtered through a column or series of pores to increase selectivity for the target
  - Filter based on size, charge, pH to yield a cleaner sample
- Sample flows through a series of buffers to extract nucleic acids
  - Buffers often held within the device in "blister packs" that may be punctured or dissolved upon contact with other liquids
  - May also include centrifugation
- Yields extracted DNA or RNA



Target Detection

- Molecular targets (specific DNA/RNA fragments) are traditionally detected by gently melting paired DNA strands
  - Primers, which are made to specifically bind to the target on each strand of DNA, are introduced
  - These primers will specifically bind to the target on the single strand of DNA
  - We can then give nucleotides and enzymes to extend the target
    - Now instead of 1 copy we have 2 copies of our target
    - Return the temperature to cool the DNA, allow it to come back together
    - Increase the temperature so we can repeat this cycle and continue to amplify (20-40 cycles)
  - When the primers are introduced, we can also introduce a fluorescent tag so we can count how often we "see" the target with our primers
    - This is proportional to the number of targets in the sample



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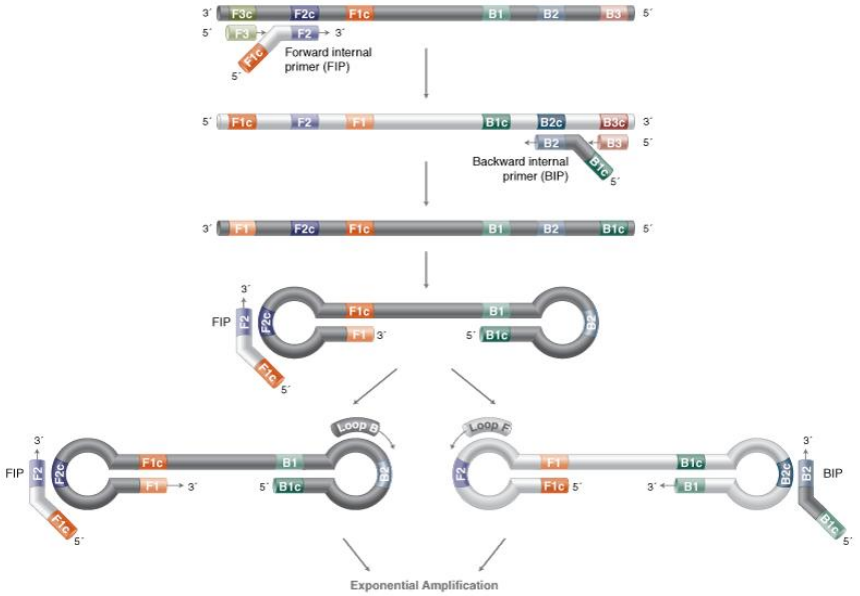
Operational Considerations:

1. What type of temperature control is needed externally? Does it require external power?
2. Is there temperature control in the device?
3. Does this make the device immobile? Or require it to be plugged in?
4. What does it look like when this process fails?

Emerging Methods of Target Detection: LAMP

- LAMP: Loop-mediated **isothermal** amplification
- LAMP operates based on specific primer design
  - Make primers that bind to double stranded DNA
    - The LAMP primer binds competitively and forces out one of the strands
    - Other single strand primers come in to search for and extend the target
  - All of this is done at a standard temperature and with several additional primers (typically 6-8 primers)
    - Makes the process faster, easier and eliminates need for power source
    - Increases specificity because of additional primers
    - Other endpoint approaches can be used (color, turbidometry, end-point etc)



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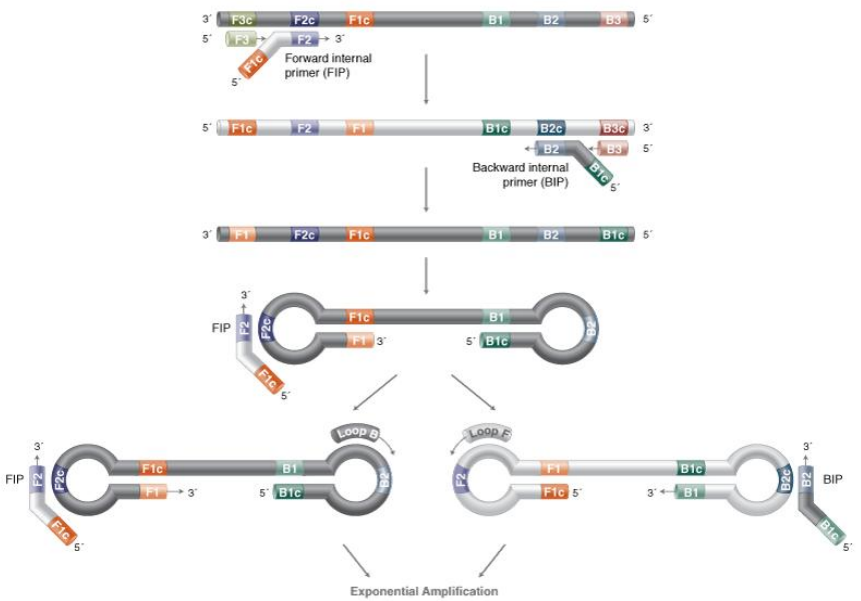

Molecular POC Diagnostics

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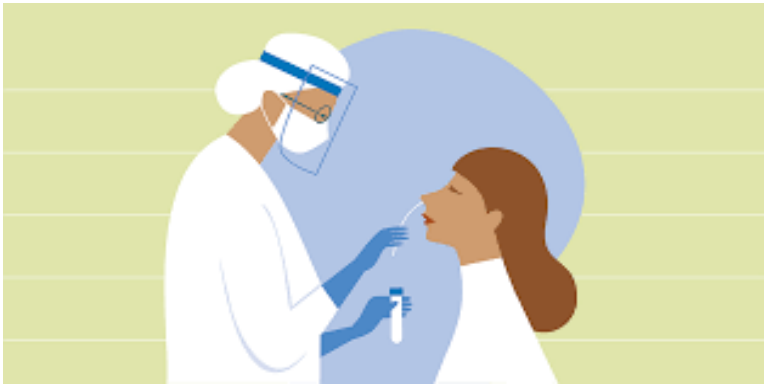
How a Working Knowledge of Molecular Assists in POCT Implementation



- Pre-Analytical
  - Who is collecting the specimen?
  - How is it being stored/covered before it is tested?
    - Maintain DNA integrity, minimize risk of cross-contamination
    - To ensure surfaces and testing areas are clean swipe testing should be performed and included in audits
- Analytical
  - Ensure appropriate temperature monitoring is in place
  - How is the sample being introduced to the instrument?
    - Is PPE needed to prevent cross-contamination?
    - Swipe testing should also be completed
  - What are the potential errors? What are next actions for the user? When do these occur (immediately or 30 minutes after sample introduction)?
    - Cartridge versus instrument errors
    - Temperature or power failures
- Post-Analytical
  - What is the frequency of an inconclusive result?
  - How are results reported? Is training needed to understand results?
    - If semi-quantitative, is an evaluation of the cut-off threshold needed?
  - Is confirmatory testing required?

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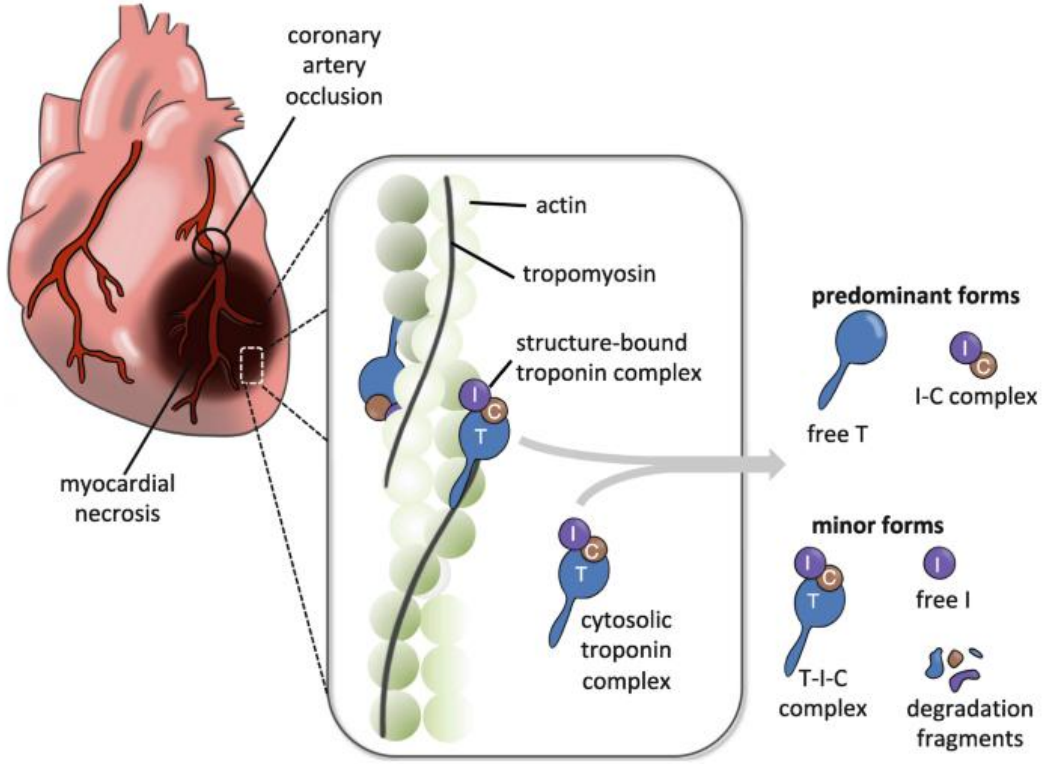
Introduction to Troponin

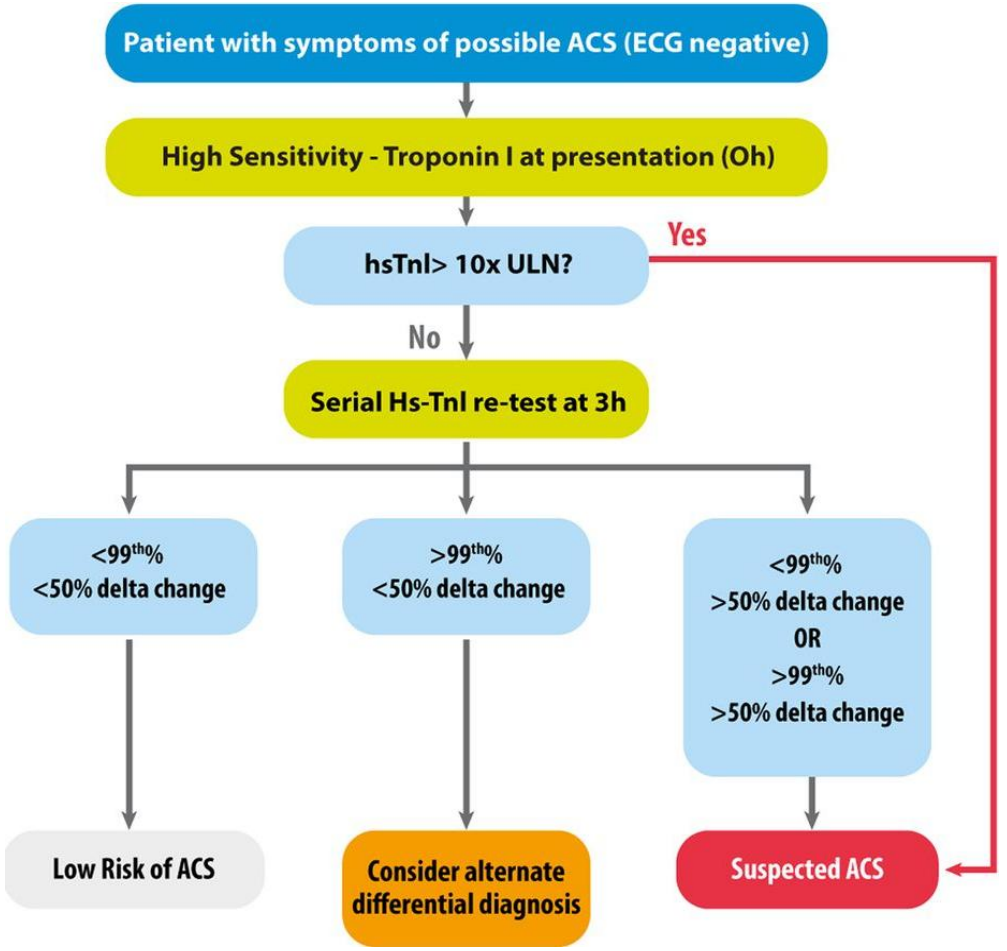
- The troponin complex binds muscle fibers (actin) to coordinate regulation of muscle contraction
- The troponin complex is highly flexible and changes conformation to help regulate calcium as actin and myosin contract
  - Low level of troponin secretion in healthy individuals
  - Troponins undergo structural changes when there is significant muscular effort or a sudden cardiac event, releasing increased concentrations into blood
- Troponins are components of all muscle fibers, but troponin complex components I and T both have cardiac specific isoforms
  - This is what we measure in the laboratory
- Troponin is a critical metric for evaluation of acute myocardial injury



Hof et al. Methods in Molecular Biology. 2019.

High-Sensitivity Troponin (Hs-Tn)

- High sensitivity troponin assays are designed to have a very low limit of detection
  - Must have a %CV of ≤10% at the 99th percentile upper reference limit
    - 99th percentile is how the reference range is made
  - Must be able to measure troponin for at least 50% of all healthy individuals
- Enables earlier identification of AMI
  - Compared to that individual's baseline
- While the actual troponin result is important, trending the valuable
  - Are the values increasing over time, suggesting damage is ongoing?
  - Is this resolving?
- How (often) should we test? For what types of patients?



Implementation of hs-Tn Algorithms

- Hs-troponin measurements have improved clinical performance if serial measurements are performed
- Traditional testing cadence is to order troponins at 0, 3, and 6 hours
  - Depending on the result, the 6 hour measurement may not be needed
  - In this paradigm that fastest workup would be 3 hours
- More recently many studies have been conducted to try to optimize these algorithms
  - More rapid rule-in/rule out
    - 0, 1, and 2-3 hour collections
  - Incorporation of additional clinical variables
    - Medical history, age, sex, ECG findings, blood pressure, risk factors
  - Addition of other laboratory values
    - Glucose, lipids

Evaluation of Rapid Troponin Algorithms

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- Careful examination of troponin algorithms is critical for patient safety
  - Want to be very certain in our rule-out
  - Likely over-cautious in our rule-in
- While ultra rapid (0-1 hour algorithms) still show room for improvement, algorithms using 0, 1, and 2/3 hour timepoints show excellent performance and are utilized clinically
  - To improve performance we now need to integrate more data...

Table 3. Test Characteristics of the European Society of Cardiology 0/1-Hour High-Sensitivity Cardiac Troponin T Algorithm for 30-Day Cardiac Death or MI and MACE in Patients With and Without Known CAD

	% (95% CI)			
	30-d Cardiac death or MI		30-d MACE	
Characteristic	Known CAD	No known CAD	Known CAD	No known CAD
Rule out				
Sensitivity	93.2 (85.7-97.5)	92.6 (85.4-97.0)	86.5 (78.4-92.4)	90.9 (83.4-95.8)
NPV	96.6 (92.8-98.8)	98.9 (97.8-99.6)	92.1 (87.1-95.6)	98.6 (97.4-99.4)
Rule in				
Specificity	90.0 (86.5-92.9)	95.1 (93.5-96.5)	89.6 (85.7-92.6)	95.1 (93.5-96.4)
PPV	59.1 (48.1-69.4)	57.8 (47.7-67.6)	59.1 (48.1-69.5)	57.8 (47.7-67.6)

Abbreviations: CAD, coronary artery disease; MACE, major adverse cardiovascular event; MI, myocardial infarction; NPV, negative predictive value; PPV, positive predictive value.

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Rapid algorithms pose challenges for ED staff and Core labs

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Hs-Tn at the Point-of-Care

- Several hs-Tn assays are on the market and in development
- POCT can significantly reduce TAT, decrease the workload for nursing (less venipuncture), and allow for more rapid algorithms
  - Supports efficient workflows in the ED
  - Potential to decrease time to treatment and reduce ED wait times
- So we should all just switch to POCT?

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Considerations for (current) Implementation of hs-Tn at the POC

1. Verify performance; ensure test meets the clinical need
   - Will it be used alongside Core lab results? How do the POCT results compare to Core lab results? Are the reference ranges the same?
   - **Assays are not standardized and mixing Core lab with POC results is not recommended**
   - How is the change over time reported?
2. Are there contraindications or interferences?
   - Troponin results may be impacted by hemolysis
3. Will single event testing be allowed?
   - Some patient populations will have higher troponin results at baseline; without proper clinical interpretation this could lead to unnecessary workup/medical intervention
   - Higher baseline: severe infection, chronic kidney disease, and myositis
4. Will testing be deployed in a way that will yield excellent clinical performance?
   - Evidence based implementation strategies
   - Easy to interpret in the medical record
5. Critical action values

Considerations for (future) Implementation of hs-Tn at the POC

1. What is the best approach for hs-Tn testing based on clinical need?
   - Core lab? POCT? Both?
   - Assay standardization would be a game changer
2. How should results be presented?
   - At minimum show result and a delta value to communicate the change between specimens
   - Should this be done for both POCT and Core testing? Together or separately? How would these be presented?
3. How would an appropriate algorithm be established?
   - What if these algorithms incorporated other clinical factors? How would these be integrated? How are these models verified?
   - Work ongoing to establish risk scores and interpretation for these models
     - Does this fall within the scope of point of care programs?

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Digital Health: Point-of-Care Testing

- The COVID-19 pandemic sparked significant growth in digital health and point-of-care testing
- Healthcare systems were overwhelmed with test orders and the number of devices available
- Rapid development and deployment meant test performance characteristics were highly variable
- Portals were established to deliver results for those who were tested outside of a traditional healthcare setting
- Lack of understanding about how the test is intended to work

DECEMBER 19, 2023 | 6 MIN READ

Do Fainter Lines on Home COVID Tests Mean You're Getting Better?

The colors of lines on COVID tests can show whether you're getting healthy or staying sick—if they're interpreted the right way

BY SAM JONES EDITED BY JOSH FISCHMAN

Digital Health Movement

- The digital health movement aims to leverage new technology to make healthcare accessible, personalized, and integrated across devices and platforms
  - Telemedicine
  - At-home testing
  - Wearable devices
  - At-home or remote monitoring
- Digital health initiatives have the potential to increase compliance, support healthcare literacy, and increase access to care while potentially decreasing cost
- Integrate algorithms, risk scores, and artificial intelligence into healthcare
  - Either to prompt an action (ex. Take blood sugar measurement) or integrate multiple results to make recommendations

Digital Health and Acute Myocardial Injury

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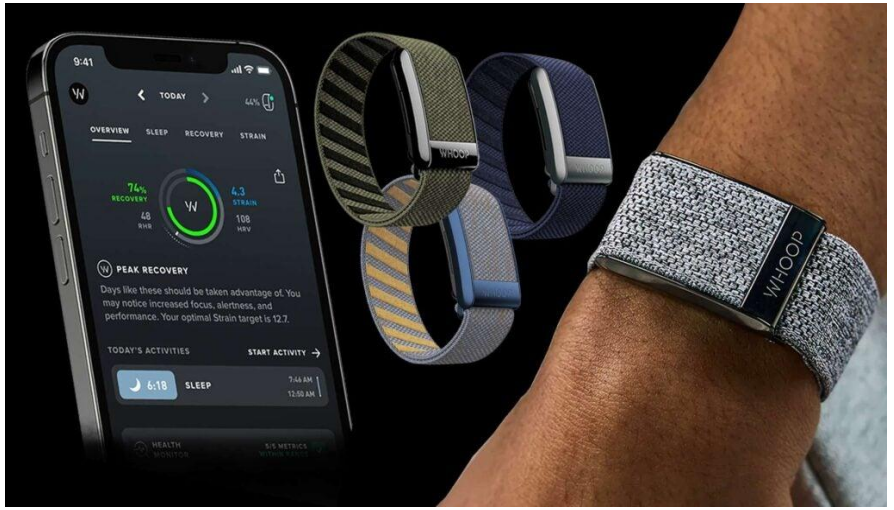
- Several smartwatches have been cleared by the FDA to perform a single lead ECG
  - Not the same as full ECG, but may provide insight into health status and symptoms
    - Under investigation for clinical utility
- Other companies are trying to integrate additional information
  - Blood pressure, glucose monitoring
- At some point, could this data be integrated into the medical record?
  - Could this be used to track cardiac history prior to presentation at an ED or urgent care?

Other Wearable Devices Entering the Healthcare Market

- Sleep and sleep apnea
  - Breathing rate
  - SpO2
- Cardiac health
  - VO2
  - Heart rate and heart rate variability
  - ECG/atrial fibrillation
- Metabolic health
  - Glucose (biosensor needed)
  - Food intake by photos
- Reproductive health
  - Ovulation alert
  - Fertile window prediction
  - Additional interpretation for pregnant women
- Stress
  - Stress monitoring and prediction tools (glucose, body temperature, heart rate)

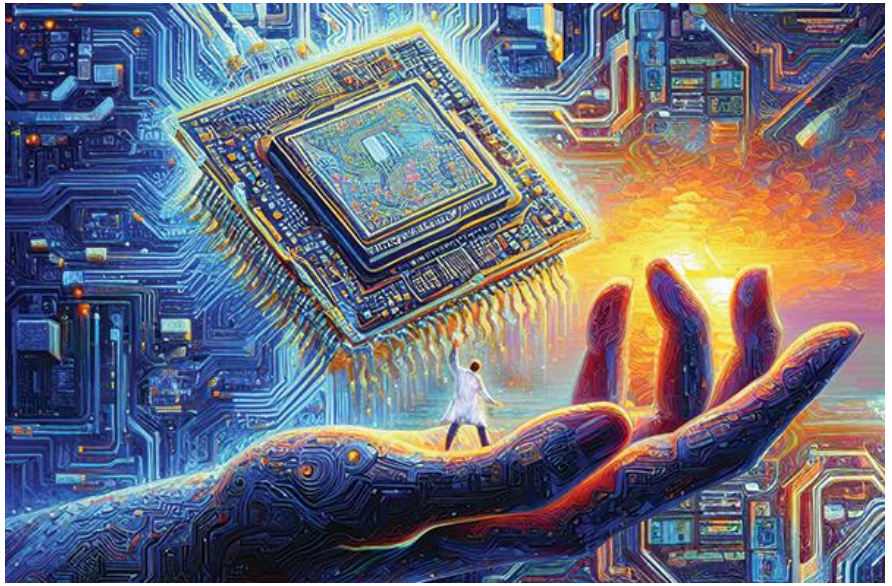


Challenges of the Digital Health Era

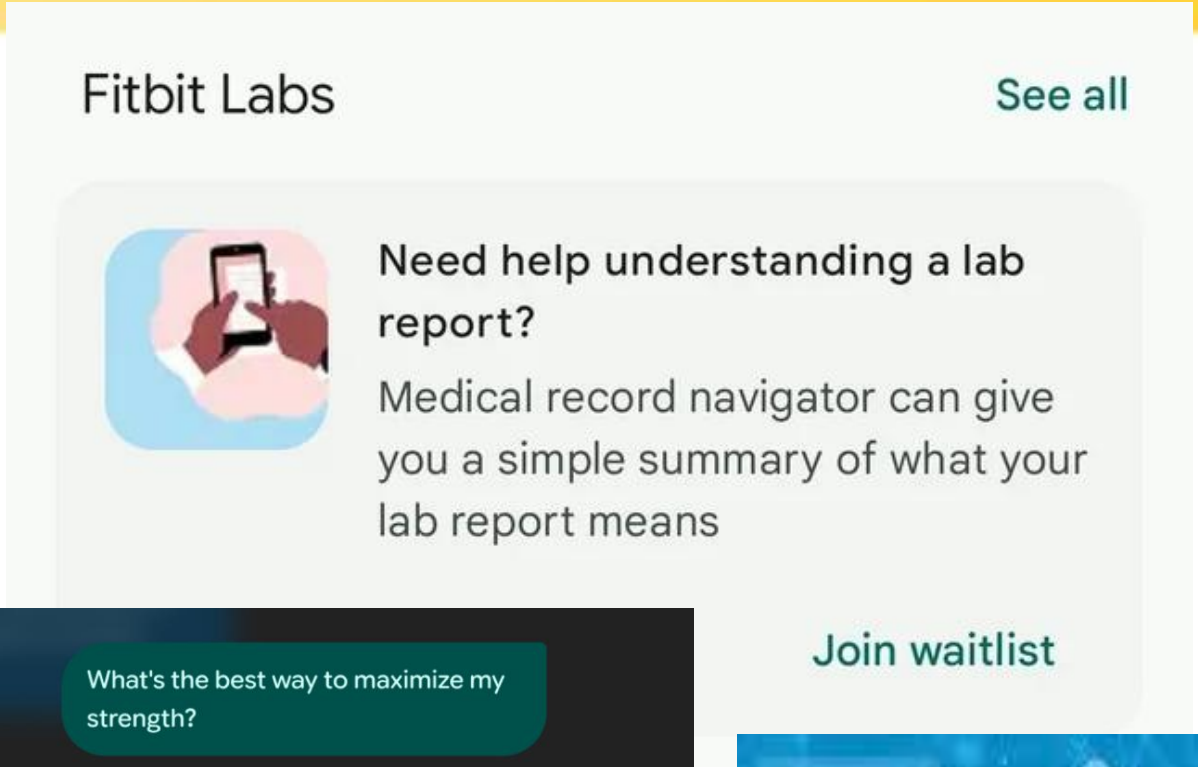
1. Data security
   - How are these platforms evaluated/vetted?
   - Who is responsible for maintaining these platforms?
   - Who has access to identified and de-identified results?
   - Is HIPAA maintained? Who is responsible for this evaluation?
2. Device functionality
   - How is device performance evaluated?
3. Interfacing
   - Is there a middleware system?
   - How are these results communicated to the provider?
   - Where are results documented?
4. Health equity
   - Who has access?
   - At what cost?

Unpacking Novel POCT

- Understanding the analytical method is critical to properly verify and manage new POC technologies
  - Protection from environmental contamination
    - Perform swipe testing
  - Identify infrastructure needs
  - Anticipate concerns
    - Indeterminant results, TAT, confirmatory testing, suitable collectors and POCT users for the technology



Questions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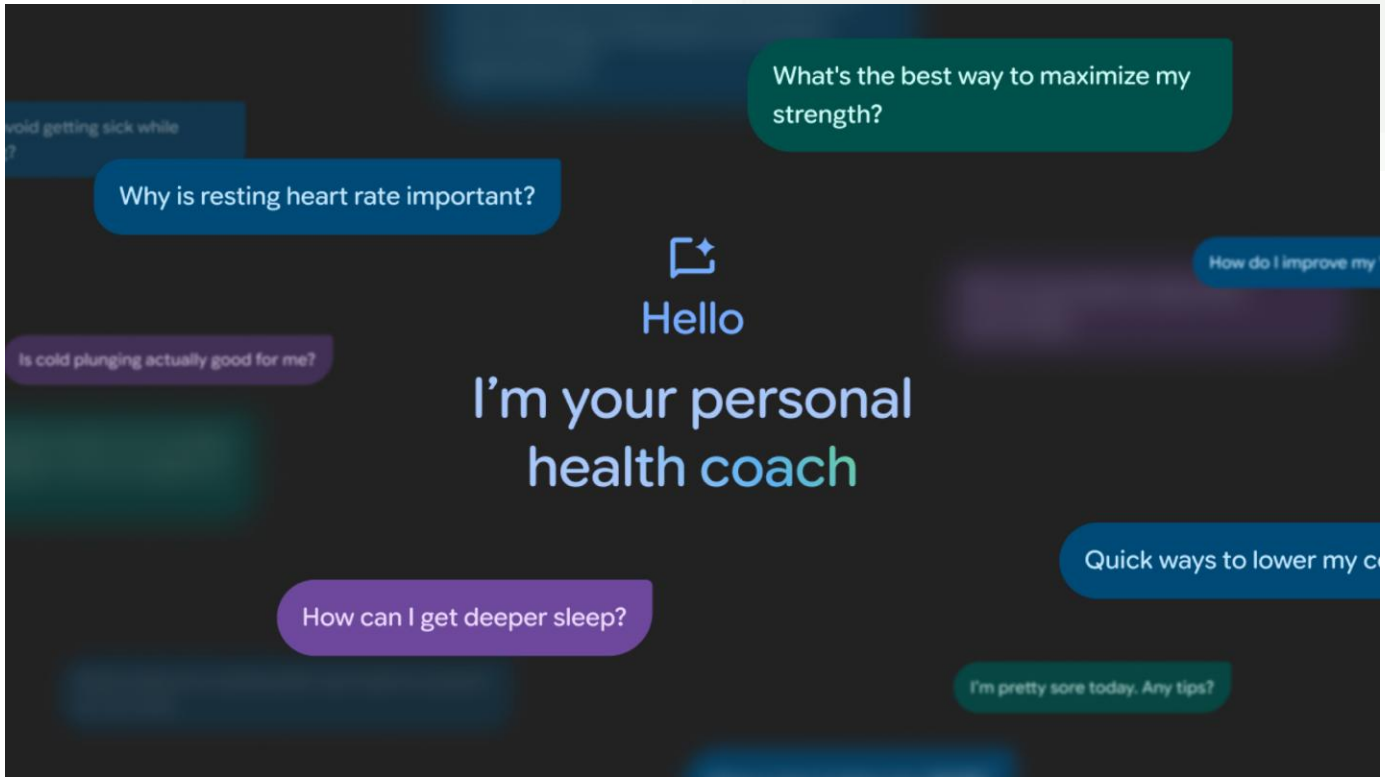
What's the best way to maximize my strength?
Why is resting heart rate important?
How do I improve my
Is cold plunging actually good for me?
Hello
I'm your personal health coach
Quick ways to lower my c
How can I get deeper sleep?
I'm pretty sore today. Any tips?