Abbott

Current & Future Applications of Point-of-Care Testing

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Clinical Diagnostics

Definition of Clinical Diagnostics: Medical and clinical diagnostics is the practice of detecting, identifying and monitoring a disease or medical disorder.

Location is not part of the definition,

Centralized: Laboratories enable high throughput, complex, and critical care testing consolidating diagnostics from numerous access points

Decentralized/Near Patient: Point-of-care testing enables decentralized access points and immediate healthcare interaction

Why Not?

BOTH ARE REQUIRED TO ACHIEVE THE BEST HEALTHCARE OUTCOMES

Healthcare Access Points Are Overwhelmed And Disparately Available

CHALLENGES PRIOR TO COVID PANDEMIC

- Pressures to reduce costs and improve quality pushed healthcare systems to their limits

- Acknowledgement that change needed to occur

- Accessibility and quality of healthcare aligned to zip code

- Medicine was transitioning from activity-paid decisions and treatment to quality-based decisions looking at access, outcomes, satisfaction with care, care pathways and the financial measures of providing care

- Changes were being driven by consumerism, government payment changes, and an increase in care settings networked through digital platforms

CHALLENGES GOING FORWARD

- U.S. healthcare system underperformed in healthcare *access, quality, and cost* resulting in some of the poorest health outcomes among comparable countries[*]

- Inadequate access to healthcare is an issue in the US, particularly in rural areas[*]

    - Too few providers exist to meet population health needs, and fragmented communication impairs rural health systems' ability to function

- *Healthy People's* progressive goals include:

    1. Reduce and ultimately eliminate health disparities

    2. Achieve health equity–expand focus of "health equity" to consider social determinants of health (the conditions in which people are born, grow, live, work, and age that shape health), health literacy, and well-being.[#]

*Coombs NC, Campbell DG, Caringi J. A qualitative study of rural healthcare providers' views of social, cultural, and programmatic barriers to healthcare access. BMC Health Serv Res. 2022;22:438. Published 2022 Apr 2. doi:10.1186/s12913-022-07829-2

#Salmond S, Dorsen C. Time to Reflect and Take Action on Health Disparities and Health Inequities. Orthop Nurs. 2022;41(2):64-85. doi:10.1097/NOR.0000000000000828

COVID-19 Disrupted the Access and Infrastructure of Healthcare

LESSONS LEARNED TO DATE FROM THE PANDEMIC RESPONSE

Early COVID overwhelmed central lab capabilities which limited the public health benefit of testing due to long wait times for results (days not minutes)

Access to healthcare was increased at novel points, not replacing traditional healthcare

- Increase in CLIA Waived Sites

- Infrastructure- Telehealth continues to account for ~30% of healthcare engagement

- Approach-multi-layered healthcare engagement, healthcare sites, urgent care, alternative sites, etc.

Diagnostics were an essential component of data

- Quality high trusted diagnostics are critical to patient treatment as well as situational awareness

Patient Perspective:

- Isolating due to respiratory illness symptoms increased due to continual awareness

- Testing at home became commonplace and is a useful tool in managing the pandemic

- Parents/Caregivers are hesitant to expose those in care

Implications to Healthcare and Diagnostics

ABBOTT DIAGNOSTICS FUTURE APPROACH

- Patients access across a continuum of care, too often an individual event is the model

- Access to Diagnostic Testing is not an *OR* but rather an *AND* discussion

- Not all diagnostic questions/technologies lend themselves to decentralized access points; understanding the multi-layered diagnostic infrastructure is important.

- Build **Trusted** point-of-care Diagnostics through holistic approaches with appropriate clinical performance

  - Alignment of Point of Care and Centralized Laboratory across the patient journey

  - "Fisher Price simple" approaches mitigating and containing use failures

  - Utilize technology to support novice users and decrease failure rate

  - Connected Health Information

Healthcare Considerations

Access

Hospital and primary care testing can be a tradeoff between healthcare and taking time off from work. Access is on a continuum and only extended through the pandemic. Access should not imply moving beyond the healthcare infrastructure

Affordability

Diagnostics are an essential tool within healthcare. Over 70% of healthcare decisions utilize diagnostics. The turn around time often impacts the ability to initiate treatment.

Clinical Impact

Healthcare scenarios like pharyngitis are usually time sensitive for young children to get the necessary relief. Untreated pharyngitis can lead to complications.

Near Universal Diagnostic Access Success

COVID-19, MULTI-TIERED ACCESS TO DIAGNOSTICS

Clinical Impact

- As laboratories were consumed with COVID-19 testing, it was difficult to get other essential testing done

- Point-of-care testing allowed individuals to avoid exposing other risk groups in medical centers such as those that were elderly or undergoing chemotherapy

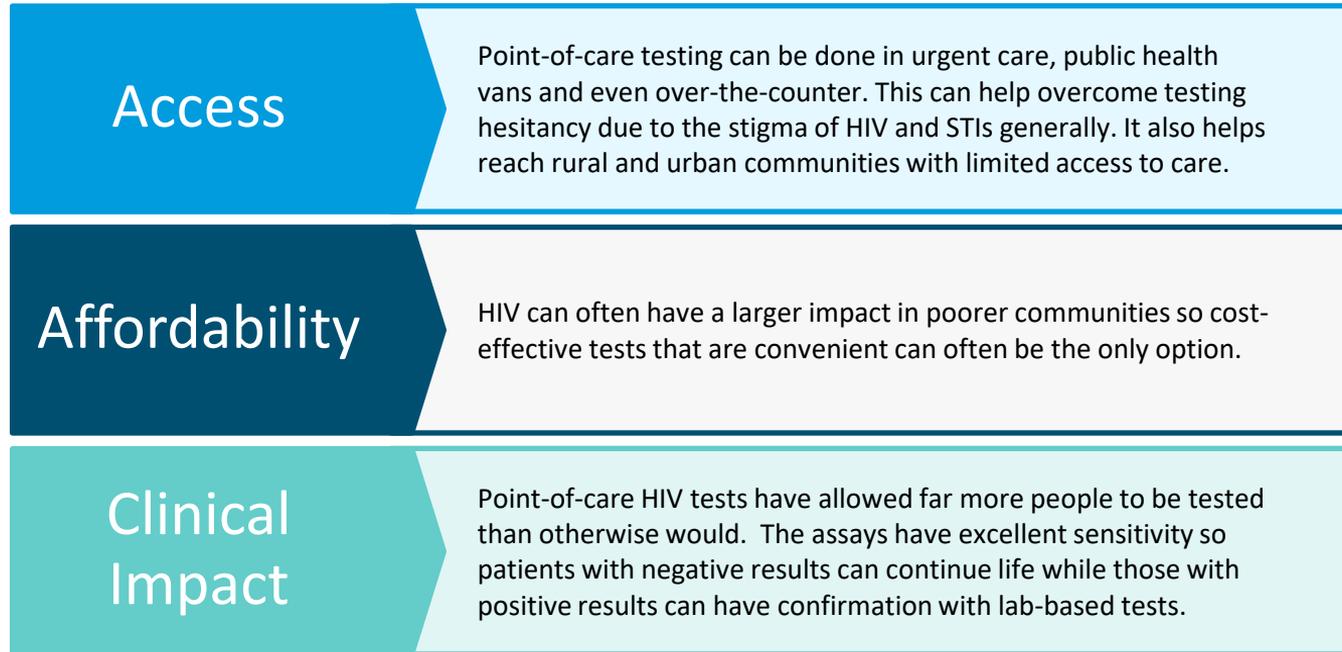- Observed increase value of information for situational analysis

Access

- Pandemic response reinforced the need for healthcare multi-tiered access points

- Beyond the healthcare system, novel access points evolved to further mitigate spread of infection

- Rapid Diagnostic tests enabled schools and business to return to face-to-face activities as well as piece of mind

While not perfect, the diagnostic infrastructure for COVID demonstrated the advantages of a multi-tiered diagnostic infrastructure.

Successful Continuum of Access Lessons Learned

HIV SCREENING EXPANDING ACCESS AND MINIMIZING LOSS TO FOLLOW UP

Access	Point-of-care testing can be done in urgent care, public health vans and even over-the-counter. This can help overcome testing hesitancy due to the stigma of HIV and STIs generally. It also helps reach rural and urban communities with limited access to care.
Affordability	HIV can often have a larger impact in poorer communities so cost-effective tests that are convenient can often be the only option.
Clinical Impact	Point-of-care HIV tests have allowed far more people to be tested than otherwise would. The assays have excellent sensitivity so patients with negative results can continue life while those with positive results can have confirmation with lab-based tests.

Near-Term Pervasive Diagnostic Access Opportunity

INFLUENZA LIKE ILLNESS- RESPIRATORY PRESENTATION

Situation

RESPIRATORY

- The symptoms overlap from influenza, SARS CoV 19, severe colds and mild pneumonias

- Antivirals for influenza are good only if given within 48 hours from onset of symptoms and people often don t come in on the first day

- Time to treat is limited

Opportunity

RESPIRATORY

- Increased awareness of respiratory disease

- Difficult to discern by symptoms alone

- Many publications exist on the cost/benefits of rapid respiratory testing as they save on unnecessary antibiotics as well as direct the appropriate use of antivirals

INFLUENZA LIKE ILLNESS- RESPIRATORY PRESENTATION

Situation

- Sore throats are common in children

- Due to timing and personal trade offs many parents are concerned if sending to kids to school and going to work is the correct decision

Opportunity

- Only 30% of children with pharyngitis have Group A Streptococcus and 10% of adults

- Trusted POC diagnostics can be used to enable Test and Treat algorithms

- Assumed increase in Antibiotic Stewardship as well as reduction in healthcare infrastructure consumption

Patient engagement is a journey, not a singular event

Patients access healthcare along a continuum and the goal is to provide trusted and clinically impactful diagnostics at all access points.

- Success of **Increased Access** cannot be underestimated
  - Patients engage healthcare along a journey which will utilize both centralized and point-of-care diagnostics
  - Future point-of-care tests that have the appropriate performance at the point of access
- **Affordability** and **Overall Impact** to patient and healthcare must be considered
  - Point-of-care testing enables Test and Treat algorithms for targeted clinical scenarios
  - Centralized diagnostics play a critical role for more complex—and less time constrained—diagnosis
- Understanding the **Clinical Impact** for the patient at the point of access is essential
  - Complex/high order clinical diagnostics should be centralized
  - The medical provider is an essential component when accessing healthcare
- **Golden Questions:**
  - » Why is this patient accessing healthcare here?
  - » What is needed to make appropriate healthcare decisions for them at the point of access?