Fixing the challenges in the diagnostic testing ecosystem post-COVID-19

Special Focus Dialogue
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Kindly supported by
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Moderated by

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Diaceutics
Fixing the challenges in the diagnostic testing ecosystem post-COVID-19

Susanne Munksted, Chief Precision Officer, Diaceutics
The dynamics at play in the delivery of test-dependent Precision Medicine therapies

Non-small cell lung cancer (NSCLC) reveals the complex dynamics at work today in Precision Medicine (PM), including:

- Delayed diagnosis
- New high-volume precision treatments
- Evolving understanding of disease
- Fragmented stakeholders
- Wasted and siloed investment
- Imperfect information flows
- The absence of a standard optimal approach to precision testing for all NSCLC patients

Global Impact

Our analysis suggests that the common pain points and practice gaps are evident in NSCLC in the US beleaguer precision testing globally
The advances in PM cancer care as illustrated by the US NSCLC landscape

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Testing</th>
<th>Biomarker</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>12 new</strong></td>
<td><strong>67%</strong></td>
<td><strong>11.3%</strong></td>
</tr>
<tr>
<td>targeted treatments have been approved during the past 2 decades for second- and first-line treatment options</td>
<td>of labs in the US offering EGFR testing (the most established NSCLC companion biomarker) are now using an NGS method</td>
<td>of patients with metastatic NSCLC were tested for PD-L1 expression prior to receiving nivolumab or pembrolizumab</td>
</tr>
<tr>
<td><strong>48%</strong></td>
<td><strong>14.5%</strong></td>
<td><strong>50%</strong></td>
</tr>
<tr>
<td>reduction in disease progression for patients with access to single and combination immunotherapy</td>
<td>of tests for patients who might otherwise miss out on treatment due to tumor sampling difficulties are now delivered by liquid biopsy tests</td>
<td>of the ~8800 oncologists comprising the main segment of HCPs treating patients with NSCLC tested at least one of their patients for PD-L1 expression</td>
</tr>
</tbody>
</table>

Real-world analysis of US NSCLC landscape illustrates the challenges in the clinical diagnostic testing ecosystem

As a result, the majority of NSCLC patients in the US today are still diagnosed in late stage (75%), with only 50% and 22% progressing to 2nd & 3rd-line therapy.
Recommendations to address hurdles in the US NSCLC landscape

1. Shared responsibility across stakeholders for addressing early diagnosis
2. Better lab support and education
3. Enhanced support to harmonize and guarantee best-in-class quality
4. Standardized guidance on biomarker inclusions
5. Multi-disciplinary practices integrated into the testing journey at community level
6. Peer-review assessment of economic benefit to address imbalance
Impact of COVID-19 on the NSCLC landscape: US and China data

**US**

- **31%* decline**

  Cancer testing rates dropped as much as 31%* between Feb 2020 and March 2020 - setting the stage for a cancer chain reaction in 2021

*Non-small cell lung cancer testing rates

**China**

- **~40% decrease**

  At the peak of pandemic in Feb 2020, the ~40% drop in overall hospital visits corresponded to a drop in the number of cancer patients tested

- **A gradual recovery in hospital visits began in March 2020**

Number of COVID-19 cases reported in the 9 provinces covered

**Figure 6. Diaceutics’ COVID-19 Oncology Tracker: Impact of COVID-19 on US NSCLC testing**

EGFR = actionable biomarker in NSCLC; NSCLC = non-small cell lung cancer; US = United States

COVID-19 impacted diagnosis of new cancer cases

% Change in average hospital visits and number of patients tested by cancer type: Q1/2 2020 vs Q1/2 2019

Change of biomarker testing rates: March vs February 2020

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Change in Biomarker Testing Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSCLC</td>
<td></td>
</tr>
<tr>
<td>KRAS</td>
<td>-7%</td>
</tr>
<tr>
<td>EGFR</td>
<td>-13%</td>
</tr>
<tr>
<td>BRAF</td>
<td>-11%</td>
</tr>
<tr>
<td>CRC</td>
<td></td>
</tr>
<tr>
<td>BRAF</td>
<td>-9%</td>
</tr>
<tr>
<td>MSI/MMR</td>
<td>-8%</td>
</tr>
<tr>
<td>RAS</td>
<td>-6%</td>
</tr>
<tr>
<td>AML</td>
<td></td>
</tr>
<tr>
<td>FLT3</td>
<td>-12%</td>
</tr>
<tr>
<td>IDH1</td>
<td>-11%</td>
</tr>
<tr>
<td>IDH2</td>
<td>-12%</td>
</tr>
</tbody>
</table>

Source: National Health Commission and Diaceutics Data Lake
A collaborative solution to the broken clinical diagnostic testing ecosystem

- Collaboration with multiple stakeholders working together to solve the real-world testing challenges to ensure every patient gets the treatment they deserve
- Greater data insights from laboratories to enable efficient decision-making
- Collaboration at biomarker discovery stage to unlock purpose-built testing solutions to solve real-world challenges together
- Enhancing the tracking and monitoring of test quality to improve outcomes
- In-lab solutions for test standardization, training, tech support, regulatory support, and quality assessment
Thank you

Susanne Munksted, Chief Precision Officer, Diaceutics
Challenges in Cancer Screening during COVID-19

Jody Hoyos, Executive Vice President
Foundation history

• Founded in 1985 by Carolyn “Bo” Aldigé in memory of her father, Edward Perry Richardson.

• Back then, everyone was looking for the “magic bullet” that would cure cancer. Prevention was not the mainstream.

• The Prevent Cancer Foundation remains the only U.S.-based advocacy organization that focuses solely on cancer prevention and early detection.

• Through research, education, outreach and advocacy we have helped countless people avoid a cancer diagnosis or detect their cancer early enough to be successfully treated.

preventcancer.org
Every year, 1.8 million Americans are diagnosed with cancer. More than 600,000 people die from these diseases each year. Imagine if all cancers could be prevented or detected early enough to be successfully treated.

50% of cancer cases are preventable.

50% of cancer deaths are preventable.

preventcancer.org
The challenge

• Data shows that appointments for screenings for cancers of the cervix, colon, and breast were down between 86% and 94% in March. (Stat News)

• Lung cancer screenings decreased 56% in April. (Avalere Health)
HIGHLIGHTS FROM MAY 2020 PREVENT CANCER SURVEY:

- 22% said their doctor’s or dentist’s office was open, but they wanted to minimize their risk of exposure to COVID-19.
- 24% expect their provider to contact them to reschedule missed appointments.

preventcancer.org/backonthebooks
Addressing the Challenges—Leveraging Community

- Reaching people through trusted communities
  - Churches and faith-based institutions
  - Gaming communities—Prevent Cancer Foundation and Awesome Games Done Quick

Invite community members to be advisors in outreach efforts
Project Echo-the ECHO Model™ connects groups of community providers with specialists at centers of excellence in regular real-time collaborative sessions.

+ MD Anderson Cancer Center program for cervical cancer screening training and case review in medically underserved areas of Texas and Mozambique
Addressing the Challenges—Leveraging Technology

- iBreast-handheld, radiation-free breast screening device that detects abnormal breast lumps as small as five millimeters that can be early signs of breast cancer. It allows health care workers to perform breast exams anywhere, determining within minutes who needs further testing or treatment.

  + Drs. Victoria Mango and Peter Kingham of Memorial Sloan Kettering Cancer Center clinical trial to evaluate the effectiveness of a new low-cost breast cancer screening device in Nigeria, where mammograms can be hard to obtain due to the expense, lack of access and lack of basic resources, equipment and radiologists.

  + The iBreast Exam is the biggest innovation in early breast cancer detection since the mammogram was widely introduced in 1963—and has already been used to screen more than a quarter million women worldwide.
Laboratory Challenges during COVID19 – Global perspective

Dan Milner, MD, MSc, MBA
Chief Medical Officer, ASCP
The Global Laboratory Response

• The initial response of LMIC laboratories to COVID:
  • Awaiting guidance from WHO, CDC
  • Governments enacting restrictions before testing was available

• What did laboratories do?
  • Received rationed supplies for testing initially
  • Received partial orders for testing workflow

• Why?
  • Market priorities, low incidence

• Real challenges created by pandemic pressure:
  • Strained infrastructure
  • Pressure on governments to “act”
  • Demand for testing platforms in countries without
    • specimen transport networks
    • Tracking
    • logistical efficiency
  • Decimation of fragile economy through restrictions on movement and travel
Africa Survey – March 2020
53 laboratories from 10 countries responded
- Rwanda
- Uganda
- Kenya
- Ethiopia
- Mozambique
- Tanzania
- Nigeria
- Madagascar
- Malawi
- South Africa
Africa Dashboard— Oct 2020

Rwanda – 10,000 tests/day (7/27)
Uganda – total tests = 264,162 (7/28)
Kenya – 55,074 tests with 1109 + (5/22)
Ethiopia – 400,000 tests per month (8/2)
Mozambique – Results in 72 hours (9/2)
Tanzania – 652 tests with 509 + (5/19)
Nigeria – 2549 tests/day, 509K in total (9/28)
Madagascar – 304 confirmed (5/19)
Malawi – Received 38,000 test kits (7/23)
South Africa – 3,726,721 tests done (9/2)
**Global Numbers (Oct 4 2020)**

**Incidence Rates**
- Rwanda – 37.46 per 100,000
- Uganda – 19.26 per 100,000
- Kenya – 73.32 per 100,000
- Ethiopia – 67.73 per 100,000
- Mozambique – 28.95 per 100,000
- Tanzania – 0.85 per 100,000
- Nigeria – 28.76 per 100,000
- Madagascar – 59.80 per 100,000
- Malawi – 30.23 per 100,000
- South Africa – 1146.06 per 100,000
- US – > 2500 per 100,000
Impact on Diagnostics from COVID19

- In a follow up survey, 57% of laboratories reported affects on their other laboratory services (especially AP):
  - Surgeries cancelled, medical staff infected, other medical staff afraid to work
  - Patients afraid to go to hospital
  - Hospital mission switched purely to COVID19
  - Costs of labs increase, volume decreased, massive loss of revenue
  - Further delays in supply chain
  - Performing post-mortems without proper PPE or clinical data
  - around 80% to 90% reduction in the incoming volume of both cytology and biopsy specimens

- More than 90% reported adequate hand sanitizer and cleaning supplies and more than 85% require mask to work in the lab (and hospital) beginning as early as March
Global Cancer Burden

Cervical Cancer and Prostate Cancer have the highest incidence and mortality in developing nations with specific risk factors being:

- HIV positivity
- Low income/poverty
- Black African origin

No infrastructure for screening prior to 2018

WHO Program for Cervical Cancer

Blossoming cancer programs in LMICS began between 2010-2015

HIV testing/treatment tied to cervical cancer screening through PEPFAR funding

-Bush Institute received $90M from 2018 – 2020 to cervical cancer screening in HIV+ women in 10 countries

With the advent of COVID... all programs ceased to function
Global Cancer Burden

Incidence (above) and mortality (below) for all cancers:

- US and Australia — Skin Cancer and access to screening and diagnosis overestimate the impact of cancer relative to other countries.

- A population of 1,000,000 people has, on average, 5,000 cancers per year (4500 to 5500).

- If you are diagnosed with cancer in LMICs, you are much more likely to die (75%) than if you are in the US (35%).

- Lack of infrastructure for screening, diagnosis, and treatment underestimates the burden of cancer in LMICS.

With the advent of COVID, what programs were functioning ceased as healthcare workers were task-shifted to COVID preparedness.

- No biopsies, no treatments, no surgeries.
Q&A session
Thank you