

INCORPORATING INTEGRATED DIAGNOSTICS INTO PRECISION ONCOLOGY CARE

SESSION 7 PANEL DISCUSSION

Opportunities to Advance Integrated Diagnostics in Cancer Care

SESSION MODERATOR

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SESSION 1

VISION AND STATE OF THE SCIENCE FOR INTEGRATED DIAGNOSTICS IN CANCER CARE

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- Diagnostics is moving toward **Data Science** and there is a need for **Data Integration**
- Definition/Clarity for Integrated Diagnostics
 - Integrated Diagnostics is not CDS
 - Dashboards are not Integrated with Diagnostics
 - Remain flexible in the scope of Integrated with Diagnostics
 - Fundamental Patient-driven goals for Integrated Diagnostics
- Return on Investment
 - Difficult to demonstrate P&L in short term
 - Long-term multifaceted benefits difficult to demonstrate (e.g. PACS)
 - Incentives

SESSION 1

VISION AND STATE OF THE SCIENCE FOR INTEGRATED DIAGNOSTICS IN CANCER CARE

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

Opportunities

1. Need for:

- **Interoperability of the systems**
- **Standards**
- **Synoptic reports/Certainty lexicon** (radiology, pathology, surgery, clinical notes - diagnosis, staging, follow-up)
- **Annotations/segmentation** – moving away from the manual to augmenting with the ultimate goal: **Automate**
- **Data Equity**

2. **Culture:** Partnership and Data Sharing

3. **Reimburse diagnoses** and the not procedures

4. Precision diagnostics **scaled the population level** for the impact an individual level

5. **Governance**

Patient-Centered Approach!

SESSION 2

EXAMPLES OF EFFORTS TO DEVELOP, IMPLEMENT, AND USE INTEGRATED DIAGNOSTICS

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- **Issue 1: Need for integrated activity to eliminate silos—a common theme between academia and industry**
 - Results communication and management
 - Billing systems that reward patient benefit
 - Incentive alignment for all stakeholders including payors
 - Cost effectiveness models
- **Issue 2: Training a new generation of integrated practitioners**
- **Issue 3: What can be learned from ongoing integrated systems like VA and University of California Health—example of UC Health and COVID-19 efforts**

SESSION 2

EXAMPLES OF EFFORTS TO DEVELOP, IMPLEMENT, AND USE INTEGRATED DIAGNOSTICS

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- **Opportunity 1:** Structured reporting to facilitate horizontally integrated curated multimodal inputs
- **Opportunity 2:** Diagnostic decision support systems
- **Opportunity 3:** Patient centricity
- **Opportunity 4:** Self supervised learning from artificial intelligence
- **Opportunity 5:** Ticket closure and feedback loops
- **Opportunity 6:** Engineering technologies to measure biomarkers in real-time
- **Opportunity 7:** Reinventing training for a new type of specialist in integrated diagnostics

SESSION 3

IMPROVING EVIDENCE GENERATION FOR INTEGRATED DIAGNOSTICS

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- **EMRs** can be used to evaluate integrated diagnostics
 - **Pragmatic study designs** with data collected as part of routine clinical documentation.
 - **Prospective clinical trials management** with **minimum intentional data collection** beyond standard of care documentation and embedded into providers workflows.
- **Novel AI driven diagnostics** require significant investment in **evidence generation** for analytic validity, clinical validity and clinical utility.
- The **culture of data sharing** for discovery remains strong.

SESSION 3

IMPROVING EVIDENCE GENERATION FOR INTEGRATED DIAGNOSTICS

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- HIPAA and consent:
 - Data donors and data repositories continue to struggle to interpret regulations related to **consent** requirements for sharing de-identified somatic genomic data for research.
 - Policy level clarity is needed to decrease barriers to data donation and secondary use.
- Structured documentation:
 - Regulations, policies, and guidelines that recommend **minimum structured documentation standards** for diagnostic reporting do influence documentation practices that can enable evidence generation for integrated diagnostics.
- Need **common terminology for diagnostic procedures** to ensure interoperability across systems to enable discovery and clinical decision support for integrated diagnostics.
- Continue to engage EMR vendors to advance and disseminate use cases for integrated diagnostics workflows and evaluation.

SESSION 4

OVERSIGHT AND COVERAGE OF INTEGRATED DIAGNOSTICS

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- **Issue 1:**
 - AI/ML algorithms need to be tested against diverse and inclusive populations from the beginning.
- **Issue 2:**
 - Integrative Diagnostic Management Teams benefit from focusing on specific therapeutic areas. One should not try to boil the ocean at the beginning of the process.
- **Issue 3:**
 - AI/Integrative Diagnostics are being evaluated according to traditional approaches by the FDA.
- **Issue 4:**
 - Payers are loath to cover Integrative Diagnostics as a standalone part of medical care and believe the issue will be solved once bundled payments for oncology care are implemented.

SESSION 4

OVERSIGHT AND COVERAGE OF INTEGRATED DIAGNOSTICS

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- **Opportunity 1:**
 - Promote diversity and inclusion in the accrual to clinical trials that test Integrative Diagnostics.
- **Opportunity 2:**
 - Have NIH/NCI pilot a mechanism to fund the development of Diagnostic Management Teams focused in specific areas.
- **Opportunity 3:**
 - Meet with FDA Leadership to propose the development of a regulatory pathway for AI/ML/Integrative Diagnostic software and devices.
- **Opportunity 4:**
 - Medicare for All

SESSION 5

PATIENT CARE AND WORKFLOW CONSIDERATIONS

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- **Issue #1:** Investment in data engineering is important to provide scale, automation and standards
- **Issue #2:** The following key issues must be addressed when implementing integrated diagnostics: Trust, Understanding, Accountability, Timing, Options, Prioritization, Adjudication / Annotation, and Actionability
- **Issue #3:** EHR integration - Need to consider the following elements: data visualization, machine learning for workflow and diagnostics, and multi-level modeling
- **Issue #4:** Talent is a bottleneck to recruiting data scientists to work on the challenges we face
- **Issue #5:** Need to follow risk communication principles, such as use numbers not words, simple data visualization of risk, keep consistent denominators, use absolute not relative risks, etc.

SESSION 5

PATIENT CARE AND WORKFLOW CONSIDERATIONS

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- **Opportunity #1:** After initial validation of an algorithm, ongoing implementation and testing requires a focus on the principles of High-Reliability Organizations to ensure reliability and reduce unwanted variation.
- **Opportunity #2:** For sustainability and scale-ability, open source protocols for algorithms and inter-institutional sharing and testing are critical
- **Opportunity #3:** For integrative diagnostics (ID), we need a code of conduct with criteria that govern implementation
- **Opportunity #4:** Redesign EHR user interfaces to integrate diagnosis and treatment into holistic modules that guide decisions rather than forcing clinicians to hunt for different diagnostic components across the EHR
- **Opportunity #5:** Use decision aides and communication tools to improve the patient/clinician decision making processes around integrated diagnostics
- **Opportunity #6:** Innovative clinical trial designs, such as hybrid implementation-effectiveness designs, can help facilitate the simultaneous testing of novel ID methods/tools, processes and implementation strategies.

SESSION 6

ENSURING PATIENT ACCESS AND HEALTH EQUITY

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- Opportunity 1:
 - Equity needs to be a part of all we do!
 - AI can worsen health disparities (although they are already there)
 - Predictions come from complex algorithms and data. This is beyond human abilities
 - Need to have validation across institutions and populations
 - Data splits are often not done with the care they need to address biases
 - Explainable AI is a challenge when we do not understand how to explain these tasks (how does a microwave work? When are alerted when there is a problem)

SESSION 6

ENSURING PATIENT ACCESS AND HEALTH EQUITY

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- Opportunity 2:
 - 85% of people get their cancer care in the community (Distributed across the US)
 - Care is provided in academia, community practice, small/private, government (service and staff are different): Moving research to the continuum of care
 - Movement from academia to community is a slow process (50 Year War)
 - Who will do this? Which labs, staff and resources?
 - Translation from research to practice is very slow (17 years)
 - Need to increase caregiver capacity, patient experience and clinical efficiency and effectiveness - Leverage technology to provide effective integration and communication.

SESSION 6

ENSURING PATIENT ACCESS AND HEALTH EQUITY

KEY ISSUES IDENTIFIED BY SESSION SPEAKERS

- Opportunity 3:
 - New technologies automatically create disparities (Some get it, some do not)
 - The US spends more than other countries, but our disparities are worse (mortality)
 - Diversity covers many different sociopolitical vectors (e.g., gender, race, geographic, culture, etc)
 - Racial minorities and the poor more likely to have poorer outcomes (e.g., the machines are lower quality)
 - Many people receive unnecessary care because they are treated in resource poor settings.
 - There are differences in implementation & dissemination are key!
 - Need more diverse genomic data to reduce ineffective treatments and to create better treatments
 - Some common interventions need to be retired
 - Make sure to study markers across more than race

SESSION 6

ENSURING PATIENT ACCESS AND HEALTH EQUITY

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- Policy #1
 - Integrated diagnostics require interdisciplinary teams
 - Make sure that biases and fairness are addressed in development of AI and diagnostics
 - More diverse data helps reduce biases across populations
 - Algorithmic fairness can be forced
 - Data splits are important often should be a focus of research
 - Develop diagnostics to alert us when we cannot trust outcomes (uncertainty quantification)
 - Include the different types of care providers when developing new tools
 - Build in dissemination and implementation research as a part of research on tool development
 - Build infrastructure to share knowledge and resources across settings.
 - Build a national network (hub and spoke). The network model needs support to encompass the full range of care (expand networks around NCI Cancer & Academic Med Centers)
 - Factor in disparities when adopting new technology: distribute to resource-poor settings to enhance quality of care and reduce unnecessary care
 - More diverse genomic studies are required, markers should go beyond race

SESSION 6

ENSURING PATIENT ACCESS AND HEALTH EQUITY

POLICY OPPORTUNITIES TO ADVANCE PROGRESS

- Policy #2
 - Data deserts - Need datasets that are less biased, including those we would not usually think about (out of distribution allows us to find things we do not know)
 - Do not expect health care to solve disparities on its own. Some issues go beyond health care. Social needs undermine what we can do in healthcare.
 - Need to continue to effectively distribute evidenced-based practice
 - Put sufficient resources in AI systems that work across populations.
 - Create tomorrow's workforce to reduce data deserts and enhance quality across systems.
 - Ensure we have the appropriate technologies to reduce disparities (not a two-tiered system)
 - Advance the speed of research so we are not building the plane as we fly it!
 - Do we need integrated diagnostics for prevention and screening? Risk assessment should increase efficiency and effectiveness. Create more complex, integrate models for risk