Life Sciences Ontario
Ontario's Readiness for Genomic Medicine:
Recommendations for Health System Preparedness

Workshop Facilitator

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Panel Discussion Featuring:

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Introduction:

Following the **Life Sciences Ontario** (LSO) Annual Policy Forum held in Toronto on November 2nd, 2023, a post-forum workshop was organized to delve deeper into evaluating the value of genome-based medicine and Ontario's preparedness to implement this crucial approach to patient care. The workshop took place on February 21st, 2024, at JLABS and aimed to address the rapidly advancing science around genome-based medicine and its potential to revolutionize healthcare delivery in Ontario. Despite the significant benefits it offers, there are notable challenges hindering its integration into routine care within the Ontario healthcare system. The workshop brought together vested stakeholders, across the system, including administrators, clinicians, and patients to discuss Ontario's readiness, identify barriers to implementation, and explore potential solutions.

Current State of Readiness:

- **Potential Benefits and Cost Savings:** Participants recognized the significant potential of genome-based medicine not only to improve healthcare outcomes, targeted therapeutics and enhance patient care but also to generate substantial cost savings for the health care system. It was acknowledged that genome-based medicine could contribute to societal benefits such as economic productivity and scientific research.

- **Infrastructure Challenges:** Concerns were raised regarding Ontario's infrastructure inadequacy to support the rapid pace of genomic innovation. Participants highlighted the need for improved information sharing systems (i.e. test order placing and test order tracking) and seamless integration of genomic testing data with patient health records.

- **Genetic Testing Disparities:** Ontario's genetic testing program lags behind other jurisdictions (i.e. the United States), leading to patients seeking testing outside of the province. Addressing this gap presents an opportunity to attract economic investments and enhance healthcare quality in Ontario.

- **Genomic Information Management Challenges:** Managing and interpreting genomic information presents significant challenges within healthcare systems. Integrating this vast amount of data into patient records while ensuring accuracy, accessibility, and confidentiality requires robust information management systems. Additionally, healthcare providers need tools and resources to effectively interpret and utilize genomic data to inform clinical decision-making.

    - "Simple" genomic results data integrated into the EMRs so that clinical decision-making can take place (i.e. the health record should show biomarker positivity data and tests related to metrics).

    - Analysis of vast amounts of genomic data is a significant problem, but one that should be solved for the whole province, following most up-to-date guidelines.

- **Access Disparities:** Disparities in patient access to genetic testing were noted, with rural and remote patients facing greater challenges compared to urban counterparts.

- **Oncology Perspective:** The lack of formal recognition of cancer as a genetic disease was highlighted. Participants stressed the urgent need for timely access to genetic testing in oncology to improve patient outcomes. Current and future oncology drugs require timely genetic testing.

- **Clinical Trials and COVID-19 Impacts:** The influx of cancer patients, compounded by the COVID-19 pandemic, has strained the healthcare system's capacity to provide timely care. Decentralizing clinical trials was suggested as a means of improving rural access to genomic medicine and testing.

- **Staffing Challenges:** The healthcare staffing crisis, particularly the shortage of pathologists and oncologists with expertise in genetic testing, poses a significant barrier to Ontario's readiness for genomic medicine.

- **Funding Transparency:** Concerns were raised regarding the lack of transparency and timelines in Ontario's funding system for genetic testing development.

- **Operational Challenges:** Operational hurdles, including turnaround time for testing and staffing shortages, pose significant barriers to implementation. Additionally, lack of standardization and centralization in policymaking further complicates the landscape.

Barriers to Implementation in the Ontario Health System:

- **Educational Gaps:**
  Limited understanding and awareness of genomic testing among both patients and healthcare providers hinders its uptake and integration into clinical practice. Comprehensive education and awareness initiatives are crucial to address this gap.

- **Lack of Timely Reporting of Results:**
  Significant challenges, starting from delays in testing initiation and carrier delays in transmitting results between hospitals. This issue is further compounded by delays in opening packages sent by the original hospital. Moreover, running the test and interpreting the report can be complex, with many oncologists encountering details they may not fully understand.

- **Infrastructure Limitations:**
  Insufficient infrastructure and technology impede the scalability of and efficiency of genomic testing. Addressing this requires investment in information systems and data integration to support the demand for comprehensive genetic analysis.

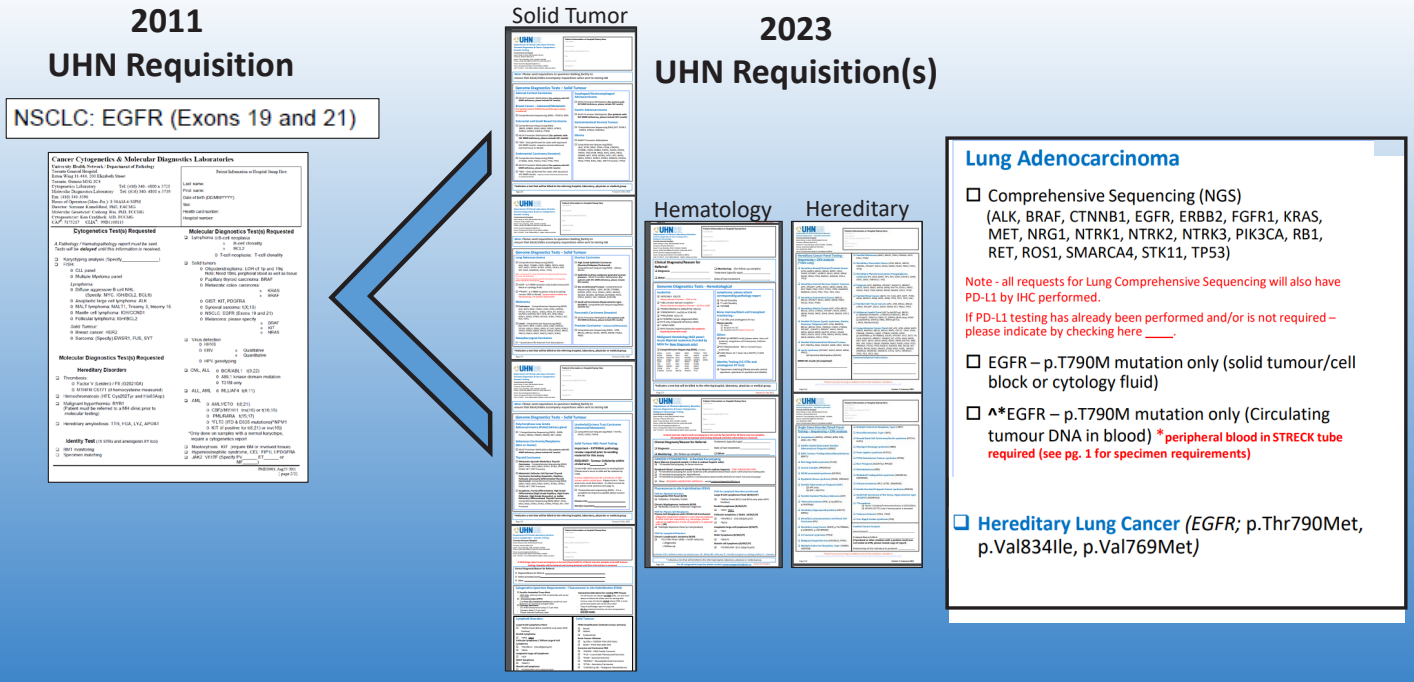
- **Inherent Barriers with Current Technology:**
  Issues of turnaround time largely due to the current technology. Depending on the type of test, it can take up to 14 days to get results.

- **Access and Equity:**
  Disparities in access to testing, particularly in rural areas, underscore the need for equitable distribution of resources and services. Additionally, financial constraints and lack of reimbursement for genetic testing limit accessibility for certain patient populations.

- **Regulatory and Policy Challenges:**
  Policy fragmentation and lack of standardization hinder the development and implementation of genomic medicine initiatives. Clear guidelines and regulatory frameworks are essential to navigate ethical, legal and social considerations.

- **Laboratory Limitations:**
  The demand for genetic testing continues to rise steadily due to its growing importance in various fields, reflecting the increasing recognition of its value and potential benefits. In 2011, the requisition was 1 page (very targeted), fast forward to 2023 the requisition is now 8 – 9 pages, making it more comprehensive for many different genes. (See diagram below)

An Insatiable Appetite for Genomic Testing in Ontario



The testing portfolio of the genome diagnostic laboratory at University Health Network has grown significantly over the last 10 years. In 2011, the available testing was limited to one page and primarily focused on targeted mutations, such as discreet mutations only in a portion of the EGFR gene, for treatment options in patients with lung adenocarcinoma. In 2023, the available tests grew to 8 separate pages with far more comprehensive analyses including simultaneous detection of genomic alterations in 19 different genes for lung adenocarcinoma.

Opportunities and Solutions for Real Change and Progress:

- **Education and Awareness Campaigns:**
  Implement comprehensive education and awareness programs targeting local governments, hospitals, patients, and healthcare providers to foster understanding and promote uptake of genetic testing.

- **Infrastructure Investment:**
  Allocate resources to enhance healthcare infrastructure, including information systems and laboratory capabilities, to support the scalability and efficiency of genomic testing.

- **Mandatory Lab Representation on Advisory Committees:**
  Advisory committees guiding genomic medicine initiatives should include mandatory representation from laboratory professionals. This ensures that the expertise and insights of laboratory staff, who possess in-depth knowledge of genomic testing procedures and implications, are integral to policy development and decision-making processes.

- **Policy Alignment and Standardization:**
  There is a need for standardized requirements for genomic targets to ensure consistency and quality in genomic testing practices across healthcare settings. Establishing clear and uniform criteria for genomic targets enhances the accuracy, reliability, and comparability of genomic testing results, ultimately improving patient care and outcomes.

- **Regular Reimbursement Reviews:**
  Recognizing the rapid pace of innovation in genomic medicine, participants stressed the importance of conducting regular reviews of reimbursement policies. These reviews are essential to ensure that reimbursement practices remain aligned with technological advancements and evolving clinical evidence, facilitating equitable access to genomic testing for all patients in Ontario. Funding for testing needs to be realigned to allow for laboratories to reinvest in themselves, update equipment as needed, conduct non-patient facing activities like Proficiency Testing, etc.

- **Adoption of Technology:**
  Recognizing the importance of integrating new genomic technologies into clinical practice, it is essential to prioritize comprehensive staff training and allocate sufficient time for healthcare professionals to familiarize themselves with these advancements. Allocating resources for technology adoption programs and fostering a culture of innovation can help healthcare professionals confidently integrate genomic medicine into practice.

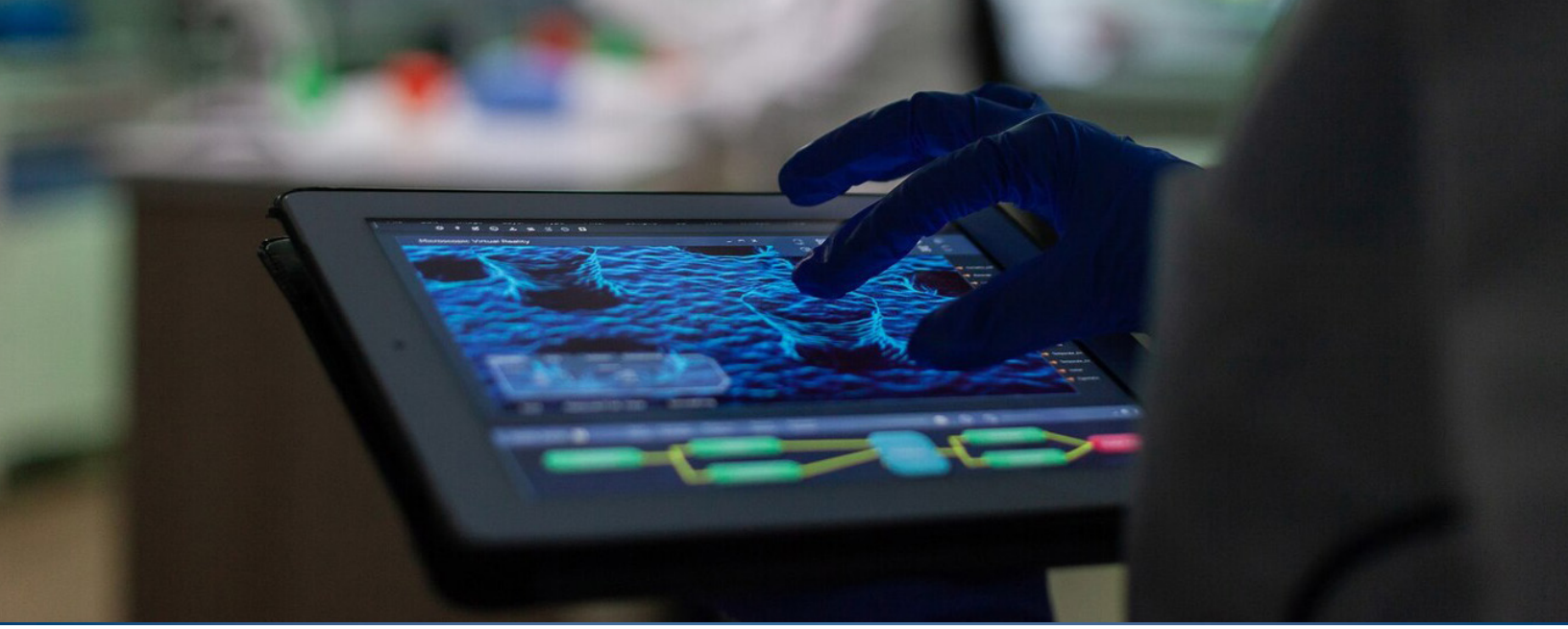
- **Collaborative Partnerships:**
  Foster collaboration among stakeholders, including government agencies, industry partners, and healthcare institutions, to address barriers collectively and drive innovation in genomic medicine.

- **Patient Empowerment and Advocacy:**
  Empower patients with knowledge about genomic testing options and advocate for their access to equitable and affordable testing through partnerships with patient advocacy groups and healthcare organizations.

- **Linking Genomic Data to Clinical Trials:**
  Genomic testing plays a significant role in shaping economic and investment opportunities. When industries contemplate the placement of clinical trials, they carefully consider jurisdictions equipped with the necessary infrastructure to support such endeavors. Additionally, they assess the availability of sufficient patient population to ensure the success of these trials.

- **Opportunities for Clinical Trials:**
  Over the past four decades, the number of rare disease drugs has quadrupled, with the orphan drug industry now valued at $217 billion in the US, indicating a surge in clinical trials. These trials represent a substantial market and bring both health advancements and employment opportunities to the regions hosting them.

- **Seizing Ontario's Opportunity in the Rare Disease Clinical Trials Market:**
  If Ontario aims to position itself as a hospitable jurisdiction for Clinical Trials, investment in genomic testing is imperative. The federal rare disease strategy has allocated $1.4 billion to the provinces, a significant portion of which will be directed towards therapies, early diagnosis, and screening. This presents an opportunity for the province to strategize on maximizing benefits for Ontario patients through collaborative efforts and leveraging this funding source effectively.

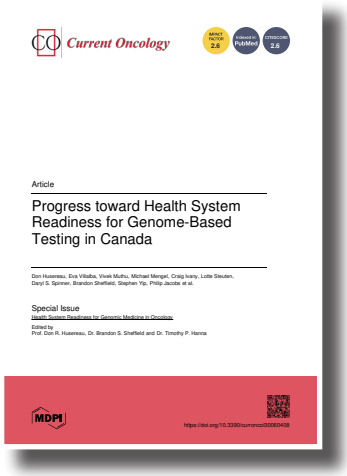


Conclusion:

The workshop served as a valuable platform for stakeholders to assess Ontario's readiness for genome-based medicine, identify key barriers to implementation, and to explore potential solutions. The discussions underscored the significant benefits that genome-based medicine offers in terms of improving healthcare outcomes, enhancing patient care, and cost-savings for the healthcare system.

Several barriers were identified that hinder the seamless integration of genomic medicine into routine care. From lack of education to disparities in access and regulatory hurdles, Ontario faces multifaceted challenges in realizing the full potential of genomic medicine. Workshop participants offered opportunities and solutions for real change and progress towards addressing these challenges and advancing the implementation of genomic medicine in Ontario. Addressing these barriers demands concerted efforts from all stakeholders, including policymakers, healthcare providers, industry partners, patients, and laboratories.

Further Reading



Progress toward Health System Readiness for Genome-Based Testing in Canada

https://www.mdpi.com/1718-7729/30/6/408

2023 Ideas to Action Forum - Summary Report

https://lifesciencesontario.ca/wp-content/uploads/2024/02/2023-Ideas-to-Action-Report-2024-02-13.pdf

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