UMN Grand Challenge State-wide Pharmacogenomics (PGx) Initiative

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Ex. of Clinical PGx Implementations

<table>
<thead>
<tr>
<th>INSTITUTION</th>
<th>PGx LAUNCHED</th>
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<tbody>
<tr>
<td>Icahn School of Medicine and Mount Sinai Medical Center</td>
<td>2007</td>
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<tr>
<td>Vanderbilt University Medical Center</td>
<td>2010</td>
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<tr>
<td>Duke University Health System</td>
<td>2011</td>
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<td>St. Jude Children's Research Hospital</td>
<td>2011</td>
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<td>Cleveland Clinic</td>
<td>2012</td>
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<td>Mayo Clinic</td>
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<tr>
<td>University of Florida and Shands Hospital</td>
<td>2012</td>
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<td>Mission Health System</td>
<td>2013</td>
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<td>NorthShore University HealthSystem</td>
<td>2015</td>
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<td>Children's Minnesota</td>
<td>2016</td>
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<td>Sanford Health</td>
<td>2016</td>
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CPIC’s goal is to create, curate, and post freely available, peer-reviewed, evidence-based, updatable, and detailed gene/drug clinical practice guidelines.

23 guidelines covering 47 drugs, >100 drugs with mention of importance of genetic variants in package insert

Despite guidelines and many implementation examples, many health systems, clinics and retail pharmacys lag in implementation across the USA.
About the Grand Challenge Research Initiative

• Provost Karen Hanson convened a team of 30 distinguished faculty members early in 2015 to recommend potential Grand Challenges areas and related interdisciplinary research strategies that would best align with the goals of the Twin Cities Campus Strategic Plan.

• The committee arrived at a final slate of five interrelated Grand Challenges where the University is positioned to have major impact on the most critical challenges of our state, nation, and world.
Minnesota Precision Medicine Collaborative

• Established in early 2017 by a Grand Challenge award in the first phase of funding
• Brought together faculty from Pharmacy, Medicine, Informatics, Law, and from both Twin Cities and Duluth campuses
• Pilot projects
• MPMC white paper articulated a vision for precision medicine at the University
• A second white paper identified pharmacogenomics (PGx) as an immediate opportunity for Minnesota
Survey of Pharmacogenomics Readiness in MN Healthcare Systems

Conducted August 21–September 5, 2018

INVESTIGATORS: SORENSEN, SEIFERT, JACOBSON

• Surveyed pharmacists-in-charge at health systems in Minnesota
• 113 participants invited via email to complete the survey; 30 responses received (26.6%)
• 50% of respondents were from a large, vertically integrated, multi-hospital health system with at least one hospital having more than 250 beds
• 63% of respondents do not have, or have not yet launched, a PGx program in their health system
Findings from PGx Survey

• 92% believe that patients served by their health system would benefit from application or increased application of PGx.

• 67% expect their organization will increase use of PGx testing services over the next three years.

• 96% expect it would be moderately to very difficult to develop PGx services in their health system.

• ~52% don’t believe their pharmacy team or their health system has the knowledge needed to implement or maintain a PGx program.

• At least 70% of respondents rank insurance reimbursement, patient out-of-pocket costs, clinical decision support systems, clinical expertise and integration into EMR as either moderate, significant or extreme barriers to PGx implementation.

• The two factors identified as most critical to implementing or expanding PGx services were a business plan and PGx education of clinicians.
Vision: PGx-Guided Care Statewide

• In January 2019, MPMC was awarded new funding in the Provost’s third phase of Grand Challenge:

  Toward Pharmacogenomics-Enabled Healthcare at Statewide Scale: Implementing Precision Medicine

• Objectives:
  • Create a framework and policies for PGx at statewide scale
  • Conduct the prerequisite work for implementation across the state
  • Show feasibility of PGx implementation through pilot projects
  • Develop a statewide shareable PGx CDS and a research platform for cutting-edge PGx-empowered discovery

• Dates: January 2019—January 2021
External Partners

- **Fellow researchers outside the University**
  - Essentia Institute of Rural Health
  - Mayo Clinic
  - HealthPartners Institute

- **Healthcare providers – from large multi-hospital systems to independent pharmacies and clinics**
  - Fairview Health Systems
  - Children’s Minnesota
  - Essentia Health
  - Goodrich Pharmacy
  - Northern Pines Mental Health Center
  - Mayo Clinic - Rochester
  - Minneapolis VA
  - Recent – Sanford Health

- **Biomedical industry**
  - OneOme, LLC
Structure and Approach

- **Six work groups each tackle a component integral to implementation.** The groups comprise contributing team members from the University and our partnering providers, researchers, and biomedical industry.

- **Demonstration projects**, in varied clinical/geographical settings, inform and test the development of our implementation ideas, tools and workflow.
Project Partner Locations

- Well representative of the diverse settings in which Minnesotans live and find their care:
  - urban, suburban, rural
  - large health systems, community clinics, and independent pharmacies
- Demo projects in mental health, oncology, and primary care
Work Groups

- Multi-institutional group has been established
- They will review and assess CPIC, Dutch Working Group and other guidelines and scientific literature
- Make recommendations for drug-gene pairs for adoption and payer reimbursement
- Make recommendations on actionable panel content
- Build an online queryable public database to house committee recommendations
Work Groups

- Engage with public and private payers through key informant interviews and surveys to ascertain status, barriers, and evidence needs for reimbursement of PGx testing
- Perform economic analyses of select drug-disease pairs where PGx provides high value
Work Groups

- Prototype a PGx Data Repository as a system separate from, but interfacing with, Electronic Health Record systems
- Establish a system for sharing of PGx test results among health systems, providers and available to the patient
- Establish an online system to query the data repository
- Establish and pilot a centralized, shareable clinical decision support (CDS) to providers
• Identify the PGx education needs of providers, workforce, students, payers, and policy makers
• Design educational programs tailored to the needs of the providers in the pilot projects
• Pilot the delivery of educational PGx programs to the implementation projects
Work Groups

- Establish an advisory ethics, law and social implications (ELSI) task force
- Conduct key informant interviews with health system leaders and clinicians to assess perceived ELSI barriers to PGx implementation
- Conduct analyses, formulate recommendations, and disseminate findings
Work Groups

- Identify PGx research needs for discovery, clinical utility evidence, etc
- Establish a system for sharing of PGx test results for research use
- Define data control privacy and digital rights
- Prototype a PGx electronic platform and pilot use cases for research
- Develop a PGx research infrastructure, with processes for transfer of data, data storage, access to data, privacy protections, patient/participant consent to sharing
Other Activities

• Legislative initiatives
  • In 2019 Session, 3 PGx bills introduced in MN House and Senate
  • Revising these based on feedback and will re-introduce in 2020
  • Continuing one-to-one meetings with legislators to educate on PGx

• Development of new external partnerships ex:
  • PGx industry
  • High throughput/sequencing partners
  • Other states i.e. North Carolina
IMPLEMENTATION OF PHARMACOGENOMICS INTO CLINICAL CARE

June 11-12, 2020
UNIVERSITY OF MINNESOTA TWIN CITIES CAMPUS

Hosted by the Department of Experimental and Clinical Pharmacology