Pharmacogenomics Education Task Force

Jacob T. Brown, PharmD, MS

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Pharmacogenomics: New Advances in Pharmacy Practice, New Regulatory Challenges

Pharmacogenomics, once a hypothetical, someday-in-the-future ideal, promising optimal medication usage and improved treatment outcomes, is increasingly becoming a reality – with the notable involvement of pharmacists. Often abbreviated PGx, this marriage of pharmacology and genomics gives pharmacists and other health care practitioners patient-specific information about how a person’s genes will affect the way he or she responds to a particular medication. The United States Food and Drug Administration (FDA) currently includes PGx information on the labeling of more than 200 therapeutic products, encompassing medications used in diverse medical areas, from oncology (the most common) and psychiatry to infectious disease and cardiology, to name a few. While PGx by itself does not explain all variability in patients’ response to medications, it nonetheless provides important data that can inform clinical decision making and has the potential to improve medication-related outcomes in a number of ways, including better selection of appropriate therapies, reduction in adverse drug events, improved medication adherence, and decreased treatment costs. As pharmacology experts and trusted, easily accessible health care professionals, pharmacists in numerous practice settings are well placed to assist patients and other health care providers in accessing and navigating the continually evolving PGx field. Nonetheless, barriers still exist that impede the easy spread of pharmacist-provided PGx care services, even as a recent regulatory change allowing the sale of direct-to-consumer PGx tests has raised new questions about how consumers will choose to use the resulting data, and where and how they might turn for professional assistance.

Pharmacists as PGx Experts

Many members and observers of the pharmacy profession, including numerous academics and professional associations such as the American Society of Health-System Pharmacists (ASHP) and the American Pharmacists Association, have recognized that pharmacists’ medication expertise and easy accessibility make them ideal candidates to help lead, shape, and participate in the still nascent world of PGx. Furthermore, these stakeholders have publicly advocated for the development of such services. Commonly recognized barriers for pharmacists, however, include the need for PGx education, the ability to easily incorporate PGx data into electronic health records and workflow systems, insurance coverage of PGx testing,
University of Minnesota Grand Challenges

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Team Members

- Jeffrey Bishop, University of Minnesota
- Jacob Brown, University of Minnesota
- Timothy Curry, Mayo Clinic
- Julie England, OneOme
- Christine Formea, Mayo Clinic
- Jyothsna Giri, Mayo Clinic
- R Stephanie Huang, University of Minnesota
- Pamala Jacobson, University of Minnesota
- Edris Kosar, Banadir Pharmacy
- Tiana Luczak, University of Minnesota
- Catherine McCarty, University of Minnesota
- Natasha Petry, Sanford Health
- Erica Schnettler, OneOme
- Randy Seifert, University of Minnesota
- Marilyn Speedie, University of Minnesota
- David Sperl, Essentia Health
- David Stenehjem, University of Minnesota
- Robert Straka, University of Minnesota
- Paul Takahashi, Mayo Clinic
- Brian Van Ness, University of Minnesota
- Stephen Waring, Essentia Health
- Dianne Witten, Essentia Health
- Jessica Wright, Mayo Clinic
PGx Education Task Force Goals

- **Sub-goal 1**: Launch multi-disciplinary, multi-institutional PGx education task force
- **Sub-goal 2**: Identify PGx education needs of providers, workforce, students, health systems, payers and policy makers through surveys and key informant interviews
- **Sub-goal 3**: Design educational programs, interventions and offerings tailored to the needs of Sub-goal 2
- **Sub-goal 4**: Pilot delivery of educational programs and offerings of Sub-goal 3
• Adoption of Pharmacogenomic Testing by US Physicians: Results of a Nationwide Survey
  – Stanek et al. 2012
  – The majority of responders had heard of PGx testing and anticipated these are or would soon become a valuable tool
  – Only 13% indicated they felt comfortable ordering PGx testing, nearly 25% reported not having any PGx education

• Physicians Report Being Unprepared to Use Pharmacogenomics in Their Practice
  – Haga et al. 2012
  – 97.6% of responding physicians agreed that genetic variations may influence drug response, but only 10.3% felt adequately informed about PGx testing
• Essentia Prescribing Clinicians Attitudes and Knowledge
  – Olander et al 2018
  – 90% somewhat or very uncomfortable ordering PGx testing for patients
  – 78% somewhat or very uncomfortable applying PGx test results to patients
  – 78% somewhat or very interested in making PGx testing available through MTM
  – 95% somewhat or very interested in a decision support tool for a potential drug-gene interaction

• Essentia Pharmacists Attitudes and Knowledge
  – Manuscript in preparation
  – 75% reported no formal training and/or education
  – Nearly 20% reported having a patient or provider bring them a PGx test
  – 58% of respondents felt that pharmacists are the best suited clinician to implement PGx testing
Development and Evaluation of a Pharmacogenomics Educational Program for Pharmacists

- Results suggest that the complex topic of pharmacogenomics requires a large educational effort in order to increase pharmacists’ knowledge and comfort level
Education Task Force Activities

• Monthly education task force meetings
• Communicate with the demonstration projects to establish PGx education needs
  – Essentia
  – Fairview
• Identify online PGx education materials/resources
• Work with other UMN education colleagues to plan for a PGx certification and recertification program
Education Task Force Findings

• There is broad need of PGx education at all levels
• First target population should be Pharmacists
• Propose different tiers of PGx education for pharmacists with different practice
  – With different format of PGx education – online video, in person seminar, online point-of-care knowledge support
• Areas require education:
  – When to order PGx test(s)?
  – What will PGx tell them or not tell them?
  – How to read/interpret the PGx results/report?
Education Task Force Planned Activities

• Compile and edit existing PGx education materials
• Disseminating PGx education
• Create drug-gene specific content based on the identified pairs on collaboration with IT and the expert group
• Continue working with UMN education colleagues to develop PGx certification and recertification program
  – Tier 1: basic knowledge education (through either one of many national programs or local program in development)
  – Tier 2: PGx implementation think tank (online membership to join team, monthly conference to share implementation experience from different sites, potentially combine with precision medicine seminar series)
  – Tier 3: Statewide expert advisory committee for case by case questions on practice and implementation and education at the point of care (online education tool for gene-drug pair)
Essentia PGx Education

• Development of a credentialing framework
  – Define the levels of education that should go to each level of professional, e.g.
    • Nursing: Level 1
    • General practice physicians: Level 1
    • Relevant specialty physicians: Level 2
    • Retail pharmacist/acute care pharmacist not covering consults: Level 2
    • Ambulatory care/Acute care pharmacists handling PGx consults: certificate program and review of cases (Level 3)
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• **Sub-goal 4**: Pilot delivery of educational programs and offerings of Sub-goal 3

Launched and continued to determine membership

Ongoing, will be an iterative process

Identify and leverage existing educational programs

Work with implementation teams to educate implementation sites

Create additional educational program (e.g., online gene-drug pair info) to support education at the point of care