GM5-GM10: Mission Health’s Personalized Medicine Program - Implementation, Challenges and Lessons Learned

GM10
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The Mission Health Experience.

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www.mission-health.org/personalized-medicine.php
Who is Mission Health?
Non-profit rural health care system, Western NC
The Mission Health Footprint

18 counties (~1 million residents)

1. Asheville Surgery Center
   Cancer Care of Western North Carolina
   Carolina Spine and Neurosurgery Center
   Fullerton Genetics Center
   Hope Women’s Cancer Centers
   Mission Hospital
   Mission Children’s Hospital
   Mission Medical Associates
   Regional Surgical Specialists
   Victoria Urological Associates

2. Angel Medical Center

3. Blue Ridge Regional Hospital

4. McDowell Hospital

5. Transylvania Regional Hospital

Western NC
Mission Health System

Mission Hospital
- Flagship, tertiary care regional referral center
- 750 bed hospital

Five smaller hospitals
- Throughout mountains
- Add’l 400 beds

Patient demographic
- Largely underserved
- Increase in retirees
- Mostly caucasian
- Stable population
- Payor mix: 75% CMS, self

Highly rated quality care:
- Truven/Thomson Reuters: Top 15 health care system (6 yrs)
- Mission Hospital
  - Truven: Top 100 hospitals

Excellent resources:
- Innovative leadership
- HIT/EMR/CDS
- Fullerton Genetics
- New Cancer Center (2010)
- Highly rated cardiology
- Primary care network
- 2015: New ACO (MHP)
Mission’s Personalized Medicine Program
Vision and Focus 2013-present

• Utilize genetic and genomic information to minimize adverse drug response and maximize drug effectiveness.
  – **Cancer**: focus on predicting response to anti-cancer drugs, where testing is already standard of care.
  – **Non-Cancer**: focus on addressing drug–gene associations with highest level of evidence, where testing is emerging as a best practice (FDA black boxed drugs/CPIC).
### Strategy: FDA Black Box Drugs

#### Implications for Genetic Testing to Prevent ADRs*

<table>
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<th>Intended use for gene-drug test</th>
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*PharmGKB and FDA websites*
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Personalized Medicine Implementation in Cardiology -Challenges-

**Challenges 2013/2014**
- No clinical problem identified by cardiologists
- Literature controversial
- Variable uptake in academia
- AHA does not endorse routine testing
- Other efforts:
  - Ginsburg grand rounds
  - Cost analysis shows savings
  - Research Project Identifies ~4% of ACS/PCI patients may be Plavix “failures” based on re-admissions due to MACE (MI, Stroke, Thrombosis, Stenosis)

**Revisit in 2016/2017**
- New cardiology leadership
- Stouffer, UNC: grand rounds; UNC implementation for all ACS/PCI, IGNITE data, discharge on drug
- Mission Physician experience: stent thrombosis observed 8 days post discharge-CYP2C19 PM
- In process of reconsidering position on testing
- Simplified ordering CYP2C19
- Cost benefit analysis redux
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Strategic Approach:  
-A work in progress-

• Raise awareness

• In-patient (Mission Health System):
  – Point of care clinical decision support (ordering test, drug alternatives, results interpretation)

• Outpatient (throughout region):
  – Pre-emptive testing: pilot studies
  – POC CDS for those on Mission EMR
Current PM Services/Team

Program Services
- Education/training/resource
- Policy /Best practices
- EMR Clinical decision support
- QI/Outcome Studies
- Clinical research
- Clinical consultation

Personalized Medicine Team:
- VP, Jonathan Bailey, MHA
- Director, Lynn Dressler, Dr.P.H.
- Clinical Pharmacist, Gillian Bell, PharmD.
- Coordinator: Paige Krug, B.S.
- Part time:
  - Research Nurse (Pearl Abernathy, RN);
  - Peds Pharmacist (Karl Ruch, PharmD)
- Trainees: Students, Residents, Fellows
- Consultants:
  - Howard McLeod (Moffit Cancer Center, Tampa)
  - Mark Dunnenberger (North Shore, Chicago)
- Partners: UNC, Duke, Vanderbilt, St Jude, UFl, Innova Health,
PM Program Major Projects: Cancer

2013-Present:

Developed first integrated tumor marker program at Mission Cancer Center

• Meet/exceed national guidelines for tumor markers
  – Working groups: internal guideline development (oncology, pathology, genetics, others)
• Instituted first QI studies for tumor markers to ensure compliance with evidence-based guidelines
• Streamline process/communication of test ordering, sample submission and results interpretation-interdisciplinary problem solving

2014-2015: Enhanced access to genomic profiling:
  – Partnership with Inter-Mountain Health; Foundation Medicine

2016: Provision of clinical consultation/interpretation for genomic profiling:
  - Comprehensive genomic profiling results; matching to drugs/trials;

2015-2016: In-house testing for Leukemia (coordination)

2017: Pilot: PGx and Supportive Care Study in Cancer Patients

2017: CDS: TPMT and Thiopurine: Pediatric ALL
### Implementation in Oncology
- **Current State**-

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<th>Services</th>
<th>Project Accomplishments</th>
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| Meeting national guidelines       | **Lung:** Stage IV NSCLC ADC: EGFR, ROS, ALK  
**CRC:** Stage IV, NRAS, KRAS, BRAF; CRC somatic LS testing  
**Breast:** Oncotype Dx  
**Endometrial:** somatic LS testing  
**Head and Neck:** HPV | -Coordination  
-Communication  
-Integration across disciplines                                                                                                                 |
| QI studies                        | **Lung:** 62% tested; 38% good clinical justification;  
**GI:** KRAS and BRAF, not NRAS  
**LS:** excellent in CRC  
**Breast:** improved compliance with use of OncoDx scores | -Lack of discrete fields in EMR;  
-Manual data abstraction;                                                                                                                              |
| Best Practices                    | Comprehensive Genomic Profiling-Operations, Consultation, Interpretation)                                                                                                                                              | -Access to data by pathology-EMR issue;                                                    |
Major Projects: Non Cancer

• **2015-2016:** Removed codeine from MHS pediatric formulary to minimize risk of lethal response due to genetic variations; developed CDS alerts inpatient and outpatient system-wide; NC Medicaid office to adopt Mission policy (2016).

• **2016:** Pilot feasibility study to bring PGx to primary care: Awarded ~$50K Presidential Award from NC Biotech Center

• **2016:** Development of Personalized Medicine clinic for adults with non-cancer conditions at the Fullerton Genetics Center.


• **2016/2017:** CDS/DIGITIZE: TPMT and ped ALL, near completion; abacavir in process.

• **April 2017:** Adding tramadol to pediatric alert; submission to P &T in process.
# Implementation in Non-Cancer -Current State-

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<td>HIT/CDS for Drug/Gene pairs</td>
<td><strong>Codeine</strong> removed from pediatric formulary; tramadol next; alerts and alternatives</td>
<td>- No PGx subcommittee; - Alert averse; - MD champion needed from each service line.</td>
</tr>
<tr>
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<td><strong>Tegretol /HLAB1502/Asians</strong></td>
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<td><strong>Thiopurine/TPMT:</strong> <strong>ped ALL</strong></td>
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<td>Personalized Medicine Clinic</td>
<td>Started, April 2016: 21 referrals from 17 different practices in region.</td>
<td>- Pt driven - Lack of uptake - Lack of awareness - Out of pocket patient expenses</td>
</tr>
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<td>Pilot Feasibility Studies</td>
<td>PGx in Primary care-funded PGx in cancer-funded Planned: PGx in behavioral health, elder care, employee</td>
<td>Funding</td>
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Integrating Personalized Medicine into Primary Care

- **Ongoing community education talks**: Patients starting to request testing from PCP
- **Educational Conference**: Fall 2015
- **Research demonstration project**: Spring, 2015
  Barriers when cost and education not an issue.
- **Defacto**: increased marketing of PGx testing to PCP and pediatricians
- **PMP as resource and consultation center to educate, train, (we’ve got your back)**
PM Pilot in Primary Care Preliminary Update: 4 27 17

- **Number of practices:** 4 Practices, 10 clinicians recruited
- **Number of patients:** 32 patients with PGx testing completed
- **Changes recommended for current drugs:** 12/32 (38%)
- **Clinician pre test surveys** (n=10)
  - 100% SA/A: *I would be more inclined to use PGx testing if I had access to an expert consult service I could rely on to help interpret and evaluate difficult cases.*
  - Top 4 barriers to implementing testing in their practice:
    - Out of pocket expense for my patient (80%)
    - Lack of comfort with interpreting and applying results (80%)
    - Lack of expertise to address complex cases (80%)
    - Lack of time to spend with patient to explain results (50%)
- **Patients expect disease susceptibility** in addition to drug response.
PCP Pilot Study: Barriers and Relevant solutions

- **Testing services:**
  - Lacking in NC at a reasonable price that bills patient’s health insurance
  - Software translation for phenotype-genotype translation and report generation

- **Consultation services:**
  - Practices want access to expert consultation for difficult cases
  - Clinical pharmacists, health educators, NPs,

- **Clinical decision support for each practice:**
  - Within PCP EMR; point of care app--what to do with result

- **Data storage and bioinformatics:**
  - Automatic updates for new guidelines, other drug-gene associations, push into EMR for alerts

- **Result sharing approaches:**
  - Interfacing EMRs to allow result sharing among clinicians and hospitals
  - Different CDS software interface needed for retail pharmacy
  - Create “chips” for patients to “carry” results
Lessons Learned

• “Top Down” and “Bottom Up” MD support needed
• Solve existing clinical problems
• Timing:
  – Responding to (national, regional) concerns that have leadership support is critical
  – Education, awareness, marketing aligned with new professional guidelines, popular press
• Pilot “try it”: a research approach first (vs clinical integration), when physician uncertain of clinical utility
• Apply Innovation Theory, Implementation/Diffusion Science and Behavioral Economics up front!
• Know what motivates your organization, community and clinicians
MISSION HEALTH AIM:
“Getting each person to their desired outcome,
Without harm, without waste,
And with an exceptional experience for
the person, family and care team.”

Thank You!
Questions and Comments?

lynn.dressler@msj.org
Mission Personalized Medicine Program