VA GLA Health Services Genomics Program

NHGRI Genomic Medicine Meeting
December 6, 2011

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Veterans Health Administration

- Largest integrated delivery system in US; $36 billion dollar annual budget; $580 million for research
- Provides inpatient and outpatient care to Veterans
- Comprehensive care in multiple settings:
  - 152 hospitals/medical centers
  - 784 community clinics
  - 126 nursing home units
  - 35 domiciliaries
  - Home-based care programs
  - Rehabilitative care programs
VA Office of Research & Development

- Biomedical Laboratory R&D service
- Clinical Science R&D Service
  - Cooperative Studies
- Rehabilitation R&D Service
- Health Services R&D Service
  - Quality Enhancement Research Initiative
Research-implementation pipeline

1. Basic Science
2. Translational Pre-Clinical Research
3. Clinical Science
4. Health Behavior
5. Clinical
6. Health Behavior
7. Health Services
8. Health Services Research
9. Effective-ness Studies
10. Implementation Research
11. Improved Health Processes, Outcomes
VA Health Services Genomics Research Priorities in 2007

- **Capacity** - Building a foundation for research that examines all aspects of translation of genomics information into the clinical setting

- **Informatics** - Development of new systems of information retrieval and knowledge management

- **Education** - Development of genomic educational interventions that link practice patterns to patient outcomes data

- **Implementation** - Development and evaluation of implementation models; disseminate and implement interventions

Courtesy, Pauline Sieverding, VA HSR&D

Informed by systematic review: Scheuner et al., Delivery of genomic medicine for common chronic adult diseases. JAMA 2008;299:1320-1324.
VA Health Services Genomics
Priority Solicitation 2008

To encourage innovative research for evidence-based planning of Veteran health services in genetics and genomics, and to begin the development of tools and models for genomic translation within the Veterans Administration integrated health system

Courtesy, Pauline Sieverding, VA HSR&D
### HSR&D FY 2008-2009 Genomic Center Supplements

<table>
<thead>
<tr>
<th>Location</th>
<th>Project Description</th>
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<tbody>
<tr>
<td>Minneapolis</td>
<td>Pilot instruments to measure veterans’ &amp; providers’ knowledge &amp; attitudes about genetic issues re: SPMI</td>
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<tr>
<td>Ann Arbor</td>
<td>Establish models to translate clinical genomics to health care delivery systems</td>
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<tr>
<td>Durham</td>
<td>Evaluate health services genomics in primary care interventions</td>
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<tr>
<td>Palo Alto</td>
<td>Develop pharmacogenomic decision support tools</td>
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<tr>
<td>San Francisco</td>
<td>Qualitatively &amp; quantitatively document VA genomics services; develop an evidence-based conceptual framework</td>
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<tr>
<td>San Antonio</td>
<td>Understand provider &amp; patient barriers to applying genomics information to clinical care</td>
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<tr>
<td>Greater LA</td>
<td>Develop and evaluate genomic medicine delivery models that incorporate family history &amp; genetic tests into CPRS</td>
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VA GLA Health Services Genomics Research Program

Within the Center of Excellence for the Study of Healthcare Provider Behavior

- Capitalize on the Center’s methodological and content area strengths in:
  - Provider behavior theory
  - Quality improvement
  - Implementation science
  - Medical Genetics
Mission

To conduct health services and implementation research that will promote adoption and implementation of effective delivery of evidence-based genetic/genomic medicine to improve the health and healthcare for Veterans.
VA GLA Health Services Genomics Team

Maren Scheuner - medical genetics
Elizabeth Yano - healthcare management
Alison Hamilton - medical anthropology
Brian Mittman - implementation science
Ann Chou - organizational theory
Lisa Rubenstein - quality of care, PCP
Stuart Gilman - CME, PCP
Paul Shekelle - evidence-based medicine
Caroline Goldzweig - informatics, PCP
Colletta Austin - CPRS programming
Martin Lee - statistical analysis
Andy Lanto - programmer, analyst
Barbara Simon - survey development

Alissa Simon - survey design
Jane Peredo - research associate, genetic counselor
Taylor Sale - research associate, genetic counselor
Shannon Rhodes - program management, epidemiology, analyst
Nell Marshall - program management, health services research, CEA
Angela Cohen - program management
Diane Schoeff - program management
Claudia Vaughn - research coordination
Cynthia Gammage - research coordination
Zebada Brown - research assistance
<table>
<thead>
<tr>
<th>Projects</th>
<th>Funding source</th>
<th>Period</th>
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<tr>
<td>2. Family History Education to Improve Genetic Risk Assessment for Cancer</td>
<td>CDC OPHG</td>
<td>10/2008 - 9/2012</td>
</tr>
<tr>
<td>3. Adoption and Delivery of Genomic Medicine in VHA</td>
<td>VA HSR&amp;D</td>
<td>10/2009 - 9/2012</td>
</tr>
<tr>
<td>4. Evaluation of an Educational Program that Features Model Genetic Test Reports</td>
<td>CDC LS&amp;S</td>
<td>10/2010 - 9/2013</td>
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</table>
Family History Education to Improve Genetic Risk Assessment for Cancer
Goal

To develop a multi-component education program that improves recognition and referral of patients at risk for hereditary cancer syndromes.

*Implement USPSTF, NCCN and CDC EGAPP recommendations*
Components of Our Education Program Grouped As:

- Informational interventions
- Clinical interventions
- Behavioral interventions

Continuing medical education objectives as defined by Mazmanian and Davis, 2002.
Multi-component Education Program

GENETICS

7-Part, CME Lecture Series

What to Expect from a Genetic Consultation

The goal of a genetic consultation is to learn about a possible inherited condition and how it may affect your health and healthcare.

Indications for a Cancer Genetics Consultation

Family History is Important To Your Health

GCAT

Genetics Curriculum and Tools
Family History Red Flags for Hereditary Cancer

For Males:
1. Have you ever had breast cancer (includes invasive ductal or lobular carcinoma, or DCIS)?
   - If no/unknown ➔ Question 7
   - If yes ➔ [document details in text box] possible HBOC, consider referral for genetic evaluation (stop)

For Females:
2. Have you ever had breast cancer (includes invasive ductal or lobular carcinoma, or DCIS)?
   - If no/unknown ➔ Question 5
   - If yes ➔
     • Have you ever had ovarian or pancreatic cancer?
       o If no/unknown ➔ next question
       o If yes ➔ [document details in text box] possible HBOC, consider referral for genetic evaluation (stop)
     • Was your breast cancer diagnosis before age 50 yrs?
       o If no/unknown ➔ Have you ever had another primary breast cancer (ipsilateral or bilateral but not LCIS)?
         • If yes ➔ [document details in text box] possible HBOC, consider referral for genetic evaluation (stop)
         • If no ➔ next question
Focus Group Feedback

- Not useful
- As primary care providers, we need to document complete family history
- Once history is documented, we can recognize the red flags
- Tool should have a few stem questions that can be completed quickly for most patients
CANCER FAMILY HISTORY TOOL

Purpose: To facilitate documentation and interpretation of cancer family history and referral for genetic consultation.

Due: Every two years unless the patient declines to provide family history, then the reminder will be due in 6 months. Or if the patient has limited life expectancy, the reminder will be turned off.

If you have any questions or comments about this reminder, e-mail maren.scheuner@va.gov

Complete questionnaire today

- Female
- Transgender female to male
- Male
- Transgender male to female

- Patient declines to provide family history.
- Limited life expectancy and patient uninterested in completing history

Clear | Clinical Maint | Visit Info | < Back | Next › | Finish | Cancel

Cancer Family History Questionnaire:
CANCER FAMILY HISTORY TOOL

<No encounter information entered>
1. Are you adopted?
- Yes  (Please provide information about biological family members or "blood relatives" if known)
- No
- Don't know

2a. Have you ever been diagnosed with any kind of cancer?
- Yes
- No
- Don't know

2b. Have you ever had 10 or more colon polyps?
- Yes
- No
- Don't know

3. Were any first-degree relatives (parents, siblings, children) affected with cancer?
- Yes
- No
- Don't know

4. Were any second degree MATERNAL relatives (grandparents, aunts or uncles) affected with cancer?
- Yes
- No
- Don't know

5. Were any second degree FATHERAL relatives (grandparents, aunts or uncles) affected with cancer?
- Yes
- No
- Don't know
3. Were any first-degree relatives (parents, siblings, children) affected with cancer?

- Yes

Please select the relative(s) affected and the cancer history for each including the age at onset.

- Mother
- Father
- Sister #1
- Sister #2

- 10 or more gastrointestinal polyps
- Breast
- Colon or rectal
- Gastric, small bowel, or bila duct
- Kidney or ureter
  - Age at onset < 50 years
  - Age at onset 50 years or older
  - Age at onset unknown
- Melanoma
- Ovarian
- Pancreatic
- Thyroid
- Uterine (not cervical)
- Other cancer

- Sister #3
- Brother #1
- Brother #2
- Brother #3
- Daughter #1
- Daughter #2
- Daughter #3
- Son #1

Cancer Family History Questionnaire:
CANCER FAMILY HISTORY TOOL
Health Factor: CANCER RISK ASSESSMENT COMPLETED

*Indicates a Required Field
6. Have there other relatives with cancer?
   - Yes
   - No
   - Don't know

   SKIP items 7 and 8 if there is no personal or family history of cancer.

7. Were any of your grandparents of Jewish ancestry (some forms of hereditary cancer are more common among Jewish people)?
   - Yes
   - No
   - Don't know

8. Have you or anyone else in your family had genetic testing for cancer predisposition?
   - Yes
   - No
   - Don't know

   **** INFORMATION ONLY ****
   Check the box below to review the indications for cancer genetic consultation.
   - Indications for cancer genetic consultation

   >>> GENETIC CONSULT? [response required]
   - Request genetic consultation for cancer. (Order screen will open when you click on the 'Finish' button below)
   - Genetic consult is indicated; however, patient declines referral for genetic consult.
   - Genetic consultation for cancer not indicated.

The algorithm supporting this reminder dialog is based on the:
- USPSTF guidelines for BRCAl/2 testing:

- NCCN guidelines for risk assessment of hereditary breast & ovarian cancer:


For additional information about risk assessment for hereditary cancer syndromes go to
Assessing Implementation

- Pre/Post design:
  - Pre-implementation Oct - Dec 2009
  - Post-implementation Apr 2010 - Sep 2011

- Monthly monitoring of health factors generated by cancer family history reminder

- Abstraction of random 10% of progress notes each month. Assessed change in documentation of:
  - Cancer family history
  - Referral for genetic consultation

- Pre/Post knowledge and attitudes survey

- Mid- and post-implementation interviews
Cancer Family History Reminder, April 2010 - September 2011

Cancer family history reminder due
N=4,716

Family history completed
N=1,275
27%

Strong familial risk
N=170
13%

Referred
N=112
66%

Not referred
N=58
34%

Moderate familial risk
N=349
27%

Referred
N=65
19%

Not referred
N=284
81%

Weak familial risk
N=756
60%

Referred
N=25
3%

Not referred
N=731
97%
Cancer Family History Documented in Progress Notes

By text | By Template | Previously By Template

Pre-implementation

Post-implementation

Oct-Dec 2009: n = 76
-Apr-Jun 2010: n = 101
-Jul-Sep 2010: n = 109
-Oct-Dec 2010: n = 112
-Jan-Mar 2011: n = 120
-Apr-Jun 2011: n = 113

30% 41% 39% 45% 50% 52%

Post-implementation
## Quality of Cancer Family History Documentation in Progress Notes with Cancer Family History

<table>
<thead>
<tr>
<th></th>
<th>Pre-implementation (n=21)</th>
<th>Post-implementation (n=117)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st degree relatives, %</td>
<td>76</td>
<td>81</td>
</tr>
<tr>
<td>2nd degree relatives, %</td>
<td>48</td>
<td>62</td>
</tr>
<tr>
<td>Lineage of relatives, %</td>
<td>14</td>
<td>62</td>
</tr>
<tr>
<td>Age of cancer onset, %</td>
<td>19</td>
<td>43</td>
</tr>
<tr>
<td>Jewish ancestry, %</td>
<td>0</td>
<td>45</td>
</tr>
</tbody>
</table>

Pre-implementation: Oct 2009 - Dec 2009
Post-implementation: Apr 2010 - Dec 2010
# Knowledge and Attitudes

<table>
<thead>
<tr>
<th>Domains</th>
<th>Knowledge, % correct</th>
<th>Attitudes, scale 1-4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
</tr>
<tr>
<td>Basic genetic concepts, terminology</td>
<td>82</td>
<td>82</td>
</tr>
<tr>
<td>Familial/genetic risk assessment</td>
<td>48</td>
<td>55</td>
</tr>
<tr>
<td>Recognizing hereditary cancer syndromes</td>
<td>51</td>
<td>69</td>
</tr>
<tr>
<td>Genetic testing</td>
<td>33</td>
<td>71</td>
</tr>
<tr>
<td>Management of hereditary cancer, including referral</td>
<td>67</td>
<td>86</td>
</tr>
<tr>
<td>Ethical issues for patients and clinicians</td>
<td>71</td>
<td>90</td>
</tr>
<tr>
<td>Overall</td>
<td>59</td>
<td>73</td>
</tr>
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</table>
"I have gained in so many ways by participating in this project. For one, I have refreshed and expanded my knowledge about genetics in general, and I’ve gained substantial new knowledge about hereditary cancers in particular. As a result of my participation, I now feel quite confident in recognizing “red flag” patterns of cancer in my patients’ family histories. I don’t necessarily identify exactly which syndrome a patient may have, but I can ascertain when further evaluation is needed, can understand what the results of tests mean for a patient, and understand my obligation to follow through if additional surveillance or referrals are needed."
Post-Implementation Comments

- Cancer family history reminder was most influential
- All would like the reminder to remain in CPRS, but no need to make mandatory
- All value availability of genetic consult service
- All would like expert review of health factors generated by reminder with feedback regarding indication for referral
- Most want additional lectures
- Most want patient-administered family history questionnaire and information materials to remain
- Few use GCAT website and practice-feedback reports
Logic Model

- Strategies to Increase Genetics Referrals
- Genetic Consultation
- Preventive Services Utilization
- Morbidity & Mortality

Population

- Family Hx Documentation
- Strategies to Increase Familial Risk Assessment
- Strategies to Increase Risk-Appropriate Interventions

Interventions
Outcomes
Thank You
Types of Evaluation

Formative evaluation

– *Rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts*

Summative (impact) evaluation

– *Systematic process of collecting and analyzing data on impacts, outputs, products, outcomes and costs in an implementation study*

How do we measure success?

Formative evaluation

Measures of implementation success

Intervention

Implementation strategies

Clinical Innovation

Process Outcomes

Health Outcomes

Other factors affecting progress and success

Need for Formative Evaluation in Implementation Research

- Captures information on factors that hinder or facilitate successful implementation

- Helps explain why implementation strategy does or doesn’t work.
# Formative evaluation according to implementation

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<th>Implementation</th>
<th>Post-Implementation</th>
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<td><strong>2. Implementation-focused</strong></td>
<td><strong>4. Interpretive</strong></td>
</tr>
<tr>
<td>Identify determinants of current practice</td>
<td>Assess discrepancies between implementation plan and execution, exploring issues of fidelity, intensity, exposure</td>
<td>Assess intervention usefulness/value from stakeholders perspectives</td>
</tr>
<tr>
<td>Identify barriers and facilitators</td>
<td>Understand and document nature and implications of local adaptation</td>
<td>Elicit stakeholder recommendations for further intervention refinements</td>
</tr>
<tr>
<td>Assess feasibility of proposed intervention</td>
<td>Monitor impacts and indicators of progress toward project goals</td>
<td>Assess satisfaction with intervention and implementation process</td>
</tr>
<tr>
<td>Integrate findings into intervention design, and refinement prior to implementation</td>
<td>Use data to inform need for modifying original strategy</td>
<td>Identify additional barriers / facilitators</td>
</tr>
<tr>
<td></td>
<td>Provide positive reinforcement to high performers; negative reinforcement to low performers</td>
<td></td>
</tr>
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<td>Pre-Implementation</td>
<td>Implementation</td>
<td>Post-Implementation</td>
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Assessment Methods / Tools for Formative Evaluation

Quantitative
- Structured surveys / tools
- Instruments assessing organizational culture, readiness to change, provider receptivity to evidence-based practices
- Intervention fidelity measures
- Audit / feedback of clinical performance data

Qualitative
- Semi-structured interviews with clinical stakeholders (pre-/post-)
- Focus groups
- Direct observation of clinical structure and processes in site visits
- Document review

Mixed methods (i.e., quantitative + qualitative)
Usefulness of Theory

In terms of…

– Planning the implementation strategy
– Conducting evaluations
– Helping to understand findings, including relationships between domains or constructs
– Identifying unanticipated elements critical to successful implementation, but may be unexplained by selected theory
– Gaining additional insights about the theory
Figure 1. Conceptual Model of Factors Associated with Adoption & Delivery of Genomic Medicine. Adapted from the provider behavior model (Rubenstein et al., 2000), Rogers' diffusion theory (Rogers, 1995), and organizational factors related to implementation (Yano, 2008).
Types of Theories

Multiple theories often needed

- **Explanatory theories** (aka descriptive, impact)
  - Hypotheses and assumptions about how implementation activities will facilitate a desired change as well as the facilitators and barriers for success

- **Process theories** (aka prescriptive, planned action)
  - How implementation should be planned, organized and scheduled

- **Mixed theories**
  - Elements of both
Choosing Theory

- Consider nature of the theory
  - Process vs. explanatory
  - Context (e.g., policy, organization)
  - Discipline (e.g., social science, psychology)

- Consider level at which it will be applied
  - Individuals
  - Teams
  - Organization
  - System

- Consider previous findings, experience

- Consider greatest potential for adding to the knowledge-base
HSR&D Genomic Center Supplements

- HSR&D Program Announcement for Center Supplements to build Health Services Genomics research capacity within the Centers
- The strongest Center applications showed collaboration between bio-lab, clinical, & health services researchers within the VAMCs
- 7 supplements funded for FY 08 and FY 09

Courtesy, Pauline Sieverding, VA HSR&D
Comments from Primary Care Providers

“My documentation of cancer family history has improved... I had a template I was using and it was limited to the colon, breast, uterine and ovarian cancer, so now it’s expanded because we have all those other options.”

“Now my documentation is very detailed, whereas before I would just mainly ask about mom and dad.”

“I probably wasn’t doing that in-depth of a family history before, especially not focused on cancer.”
Healthcare Systems Exist within Networks