VA GLA Health Services Genomics Program

NHGRI Genomic Medicine Meeting

December 6, 2011

Maren T. Scheuner, MD, MPH, FACMG

Chief, Medical Genetics, VA Greater Los Angeles Healthcare System

Director, Clinical Genetics Service, VISN 22

Associate Professor, Department of Medicine,

David Geffen School of Medicine at UCLA

VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

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 HSR&D Center for the Study of Healthcare Provider Behavior

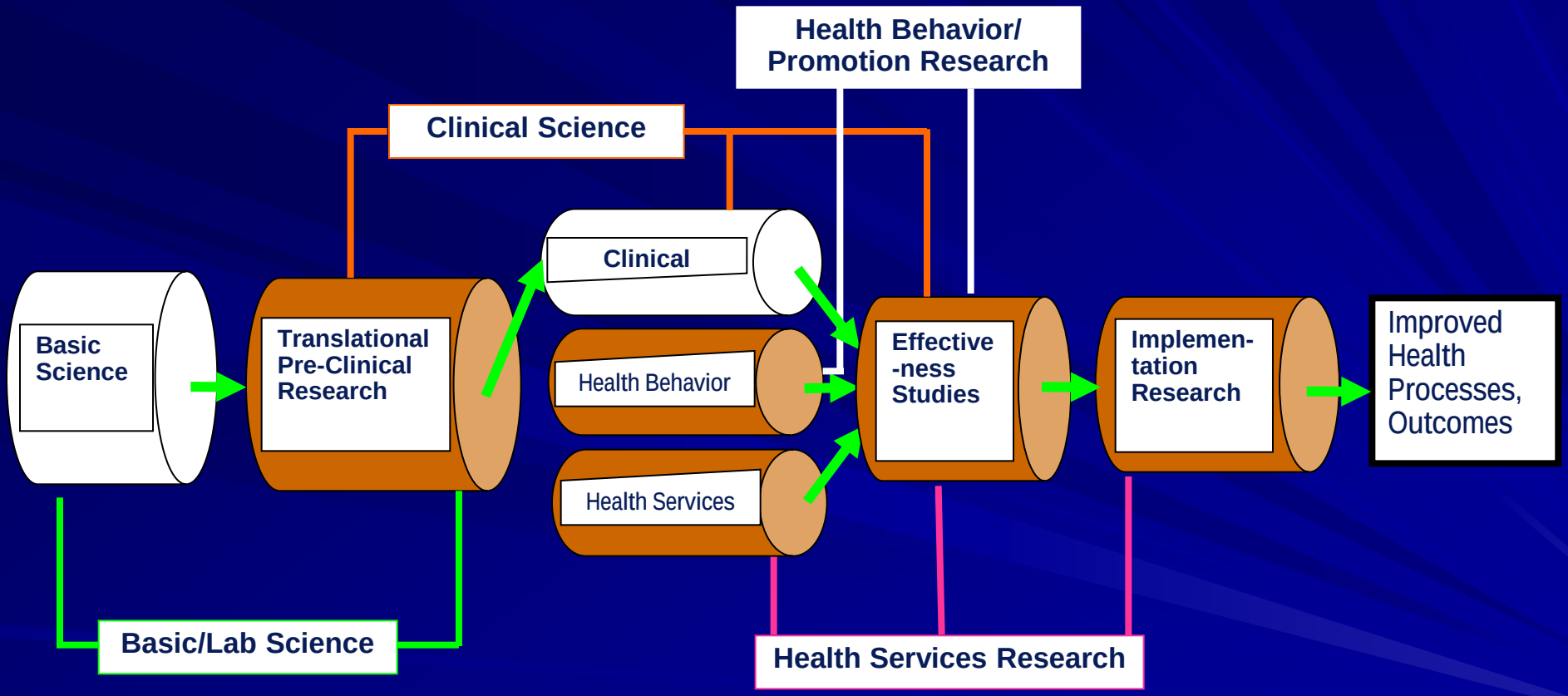
VA GREATER LOS ANGELES HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

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



CIPRS
Center for Implementation Practice & Research Support

VA QUERI

Veterans Health Administration
R&D
www.research.va.gov

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 HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

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

VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

HSR&D FY 2008-2009
Genomic Center Supplements

Minneapolis	Pilot instruments to measure veterans' & providers' knowledge & attitudes about genetic issues re: SPMI
Ann Arbor	Establish models to translate clinical genomics to health care delivery systems
Durham	Evaluate health services genomics in primary care interventions
Palo Alto	Develop pharmacogenomic decision support tools
San Francisco	Qualitatively & quantitatively document VA genomics services; develop an evidence-based conceptual framework
San Antonio	Understand provider & patient barriers to applying genomics information to clinical care
Greater LA	Develop and evaluate genomic medicine delivery models that incorporate family history & genetic tests into CPRS

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

VA GLA Health Services Genomics Program

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

VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Funded Research

	Projects	Funding source	Period
1.	Genomics Pilot Projects	VA HSR&D	3/2007 - 9/2008
2.	Family History Education to Improve Genetic Risk Assessment for Cancer	CDC OPHG	10/2008 - 9/2012
3.	Adoption and Delivery of Genomic Medicine in VHA	VA HSR&D	10/2009 - 9/2012
4.	Evaluation of an Educational Program that Features Model Genetic Test Reports	CDC LS&S	10/2010 - 9/2013
5.	Barriers and Facilitators to Lynch Syndrome Testing in VISN22	VA QUERI	6/2011 - 5/2012

Family History Education to Improve Genetic Risk Assessment for Cancer

VA HSR&D Center for the
Study of Healthcare
Provider Behavior

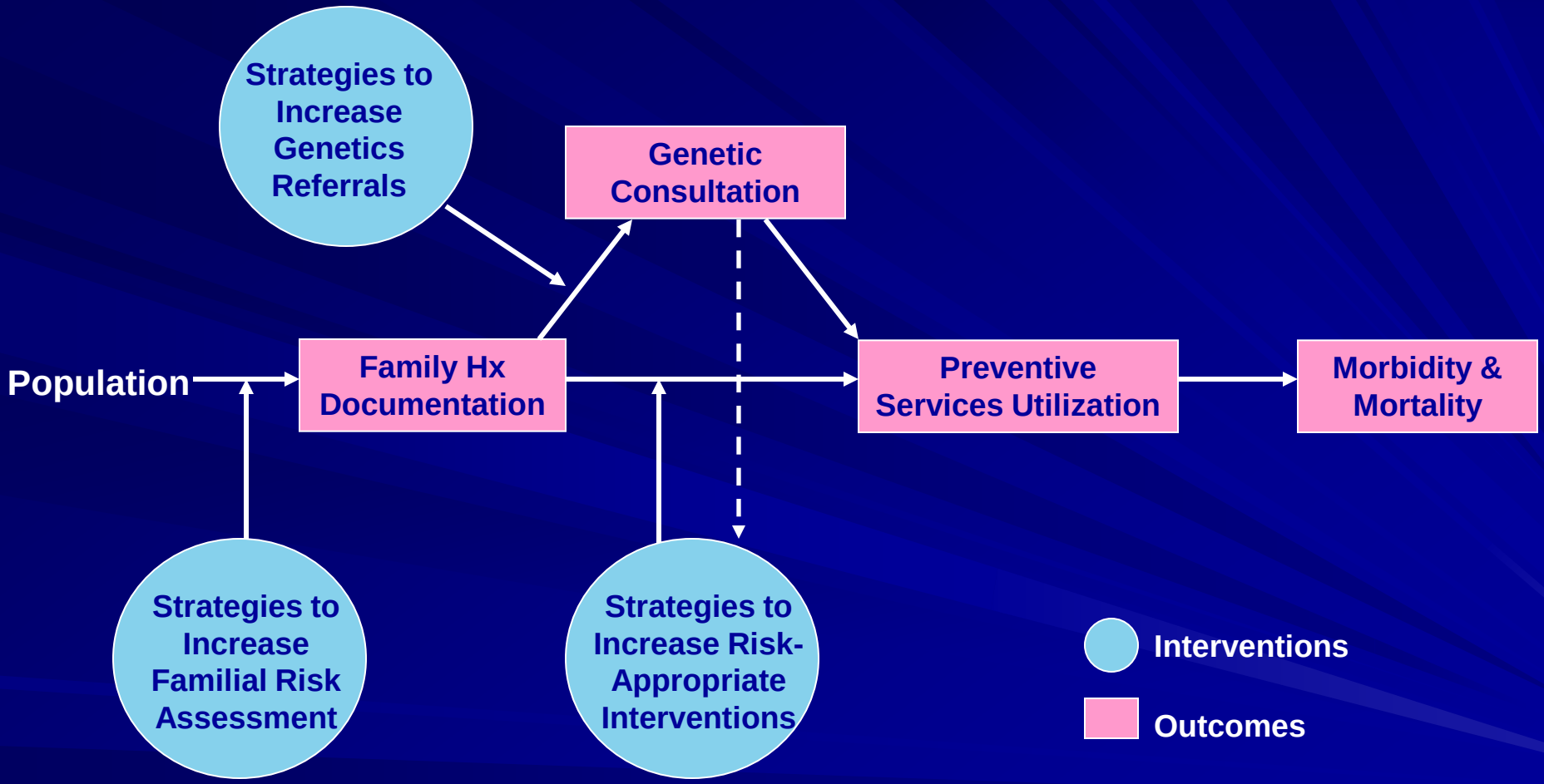
VA GREATER LOS ANGELES
HEALTHCARE SYSTEM

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

Logic Model



VA HSR&D Center for the Study of Healthcare Provider Behavior

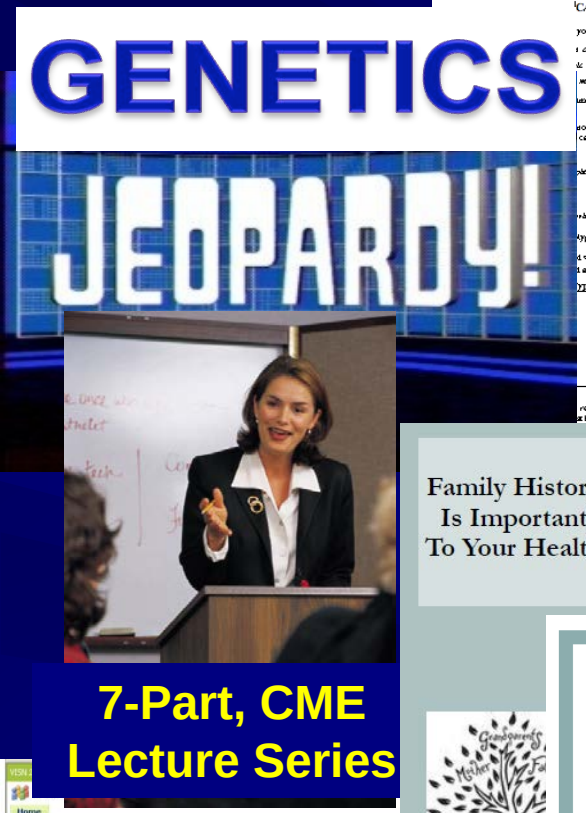
VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Components of Our Education Program Grouped As:

- Informational interventions
- Clinical interventions
- Behavioral interventions

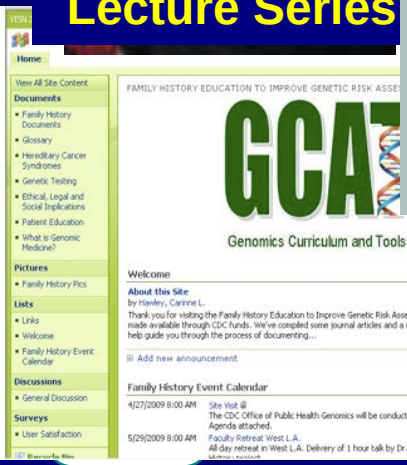
Continuing medical education objectives as defined by Mazmanian and Davis, 2002.

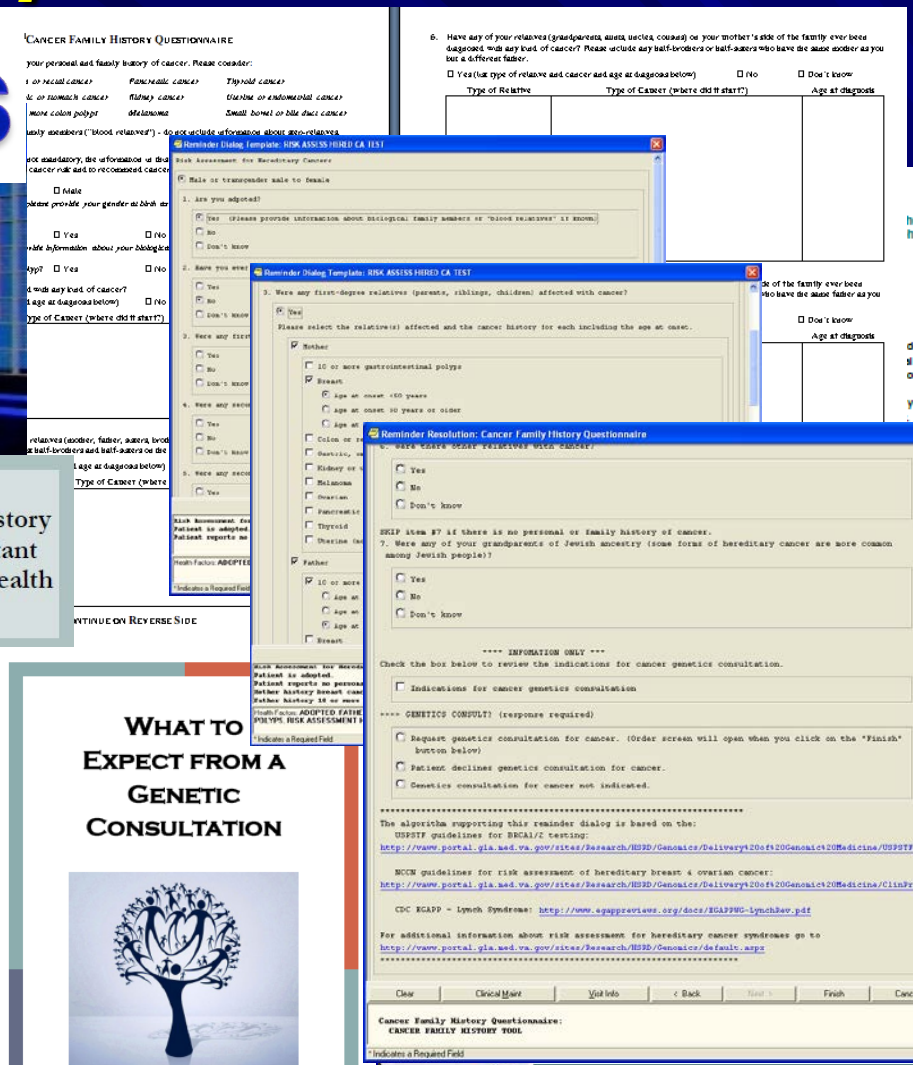
Multi-component Education Program

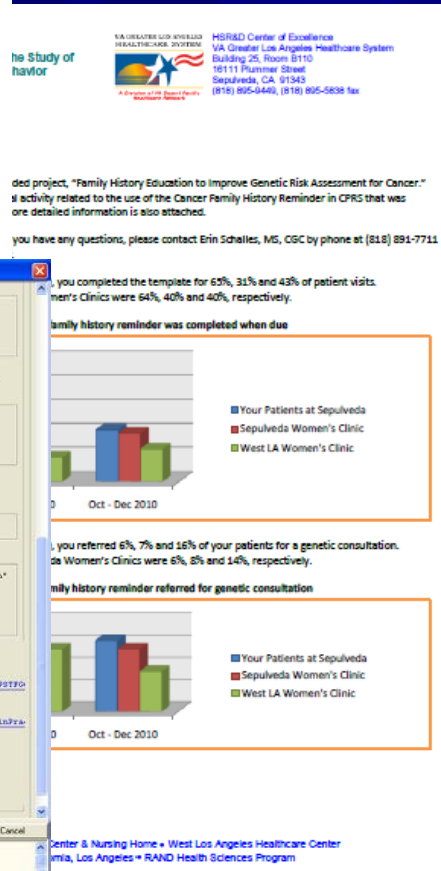


7-Part, CME Lecture Series

Family History Is Important To Your Health







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

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Family History Red Flags for Hereditary Cancer

For Males:

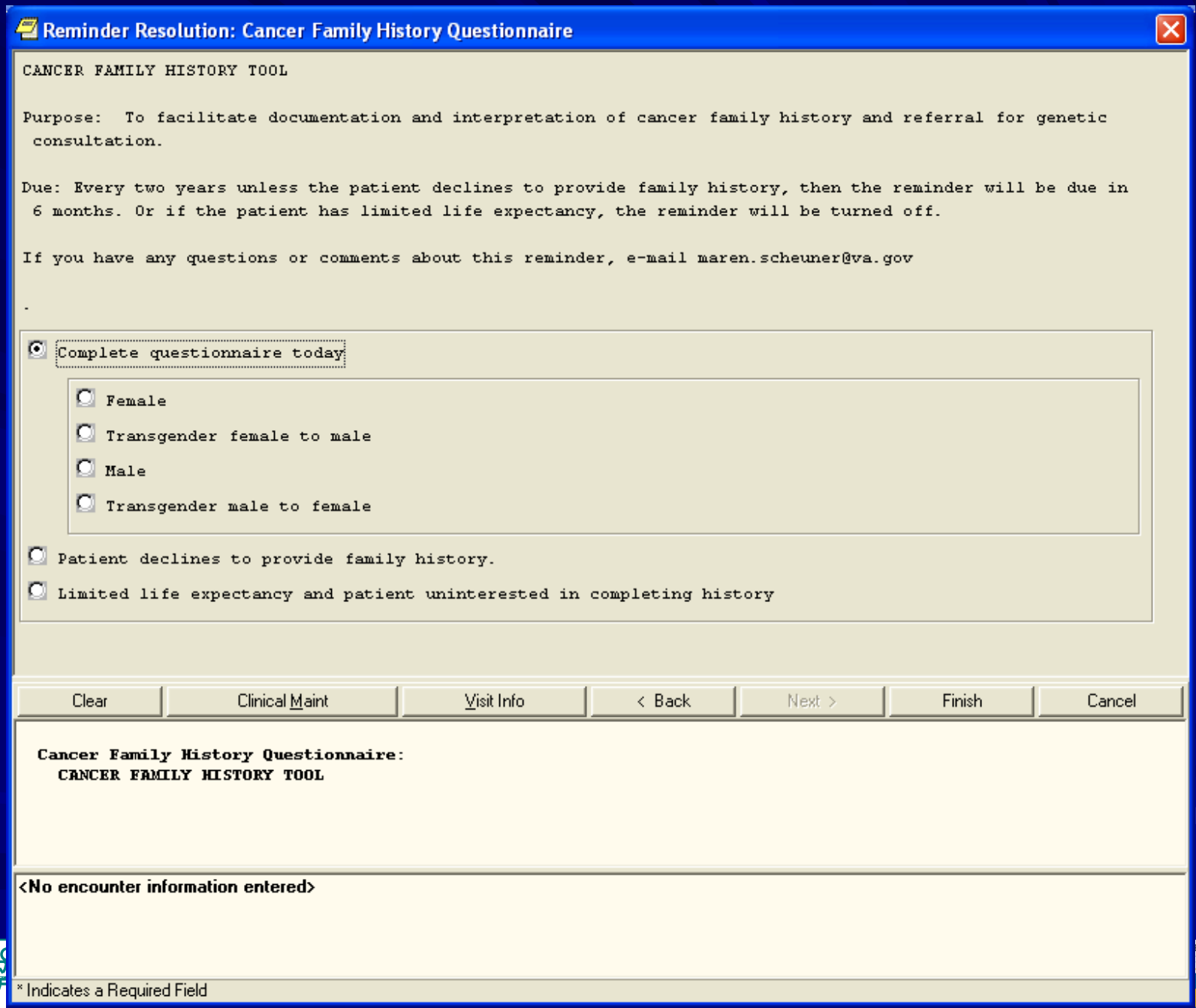
1. Have you ever had breast cancer (includes invasive ductal or lobular carcinoma, or DCIS)?
   - If no/unknown → Question 7
   - If yes→ [document details in text box] possible HBOC, consider referral for genetic evaluation (stop)

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?
       - If no/unknown→ next question
       - If yes → [document details in text box] possible HBOC, consider referral for genetic evaluation (stop)
     - Was your breast cancer diagnosis before age 50 yrs?
       - 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)

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


Reminder Resolution: Cancer Family History Questionnaire
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>
* Indicates a Required Field

Reminder Resolution: Cancer Family History Questionnaire

Complete questionnaire today

Female

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 PATERNAL relatives (grandparents, aunts or uncles) affected with cancer?

- Yes
- No
- Don't know

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

Cancer Family History Questionnaire:
CANCER FAMILY HISTORY TOOL

Health Factors: CANCER RISK ASSESSMENT COMPLETED

* Indicates a Required Field

VA HSR&
Study of
Provider

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

VA HSR
Study of
Provider

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Reminder Resolution: Cancer Family History Questionnaire

6. Were 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

**** INFOMATION 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 BRCA1/2 testing:
http://vaww.portal.gla.med.va.gov/sites/Research/HSRD/Genomics/Delivery%20of%20Genomic%20Medicine/USP

NCCN guidelines for risk assessment of hereditary breast & ovarian cancer:
http://vaww.portal.gla.med.va.gov/sites/Research/HSRD/Genomics/Delivery%20of%20Genomic%20Medicine/Clir

CDC EGAPP - Lynch Syndrome: http://www.egappreviews.org/docs/EGAPPWG-LynchRev.pdf

For additional information about risk assessment for hereditary cancer syndromes go to
http://vaww.portal.gla.med.va.gov/sites/Research/HSRD/Genomics/default.aspx

****

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

Cancer Family History Questionnaire:
CANCER FAMILY HISTORY TOOL

Health Factors: CANCER RISK ASSESSMENT COMPLETED

VA HSR&D
Study of He
Provider Be

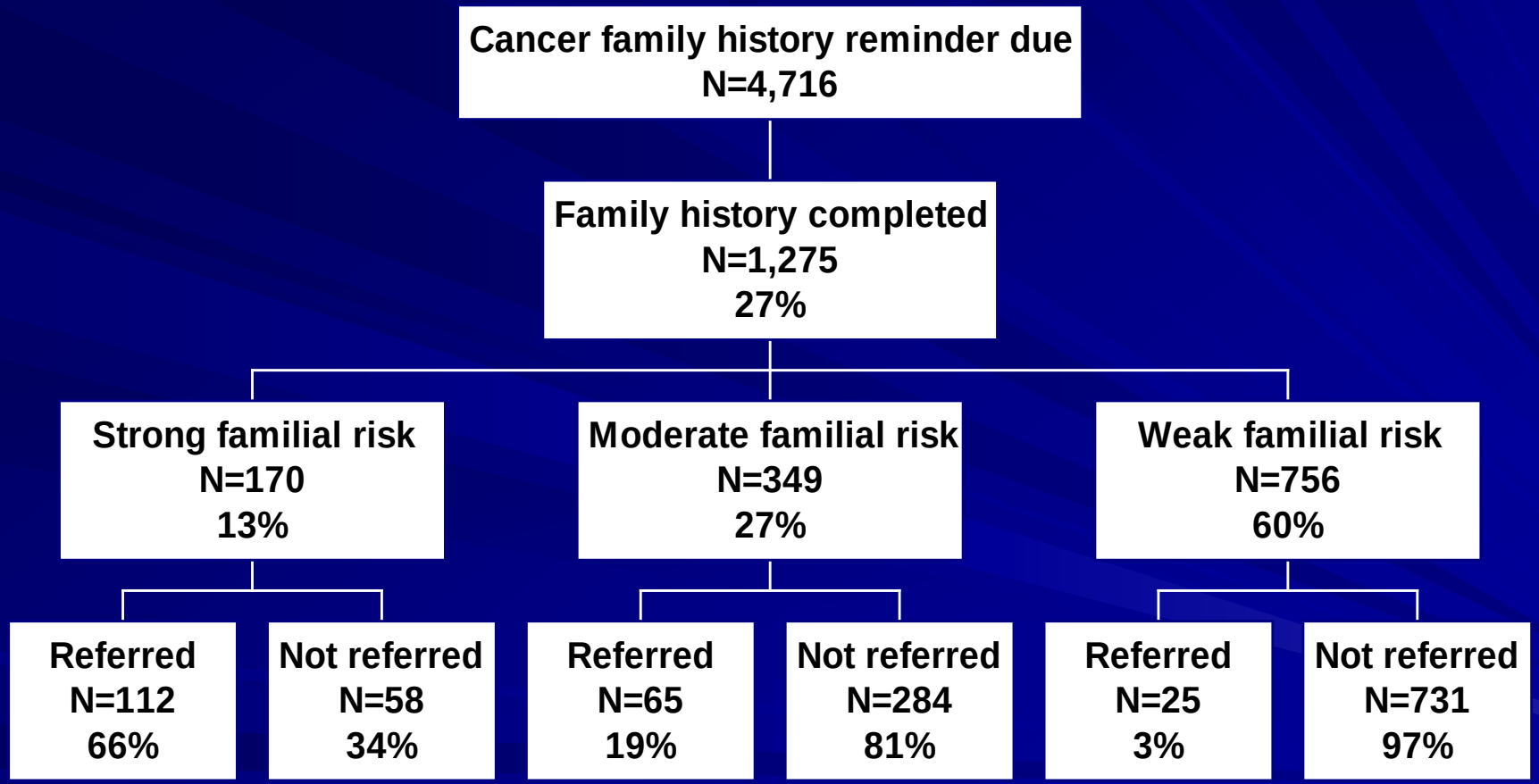
VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

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

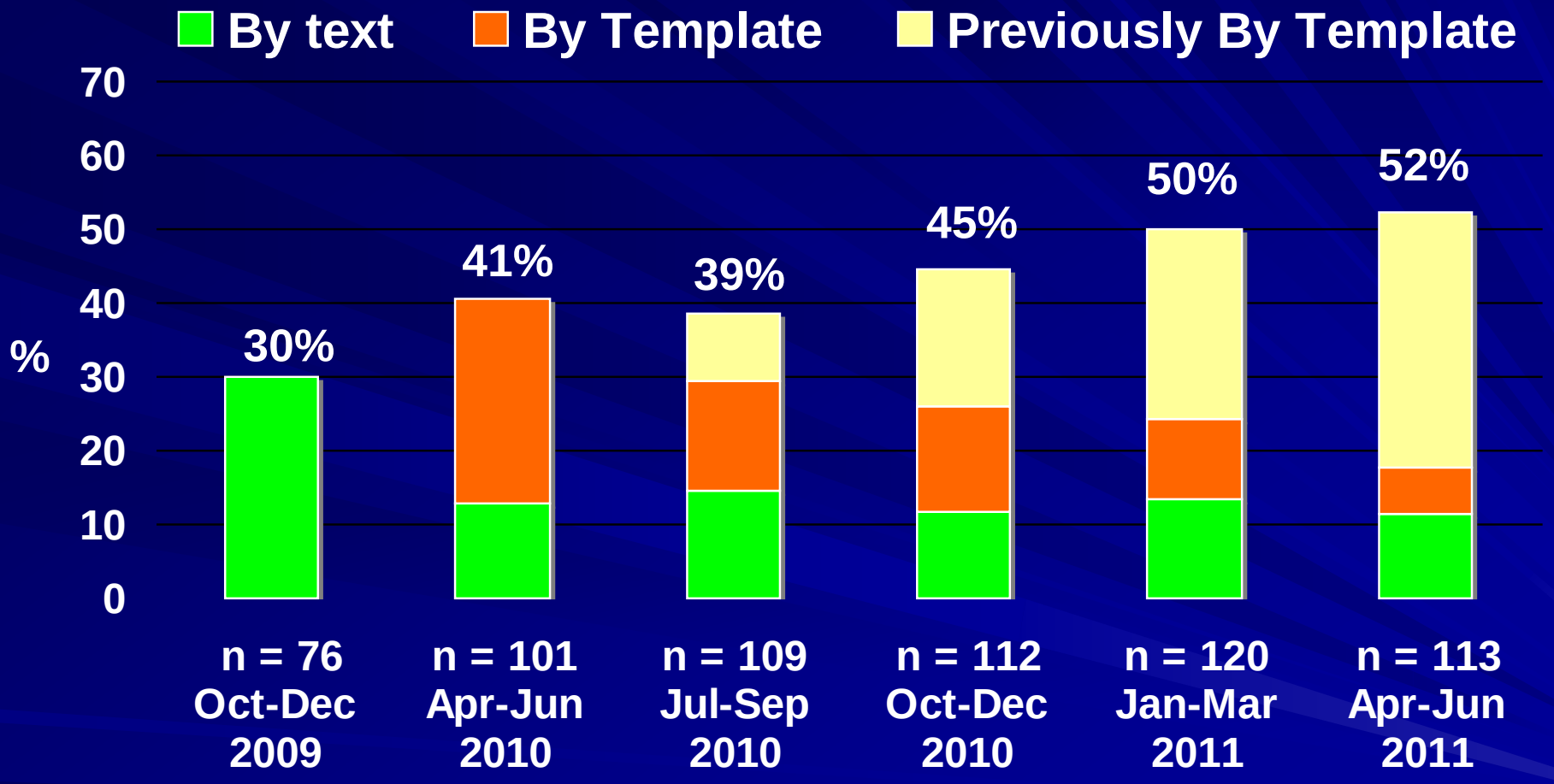
Organization Chart Title



VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Cancer Family History Documented in Progress Notes



Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Quality of Cancer Family History Documentation in Progress Notes with Cancer Family History

	Pre-implementation (n=21)	Post-implementation (n=117)
1st degree relatives, %	76	81
2nd degree relatives, %	48	62
Lineage of relatives, %	14	62
Age of cancer onset, %	19	43
Jewish ancestry, %	0	45

Pre-implementation: Oct 2009 - Dec 2009
Post-implementation: Apr 2010 - Dec 2010

Knowledge and Attitudes

Domains	Knowledge, % correct		Attitudes, scale 1-4	
	Pre	Post	Pre	Post
Basic genetic concepts, terminology	**82**	**82**	**2.86**	**2.71**
Familial/genetic risk assessment	**48**	**55**	**3.48**	**3.19**
Recognizing hereditary cancer syndromes	**51**	**69**	**3.57**	**3.14**
Genetic testing	**33**	**71**	**2.67**	**2.43**
Management of hereditary cancer, including referral	**67**	**86**	**3.64**	**3.21**
Ethical issues for patients and clinicians	**71**	**90**	**3.71**	**3.29**
Overall	**59**	**73**	**3.32**	**3.00**

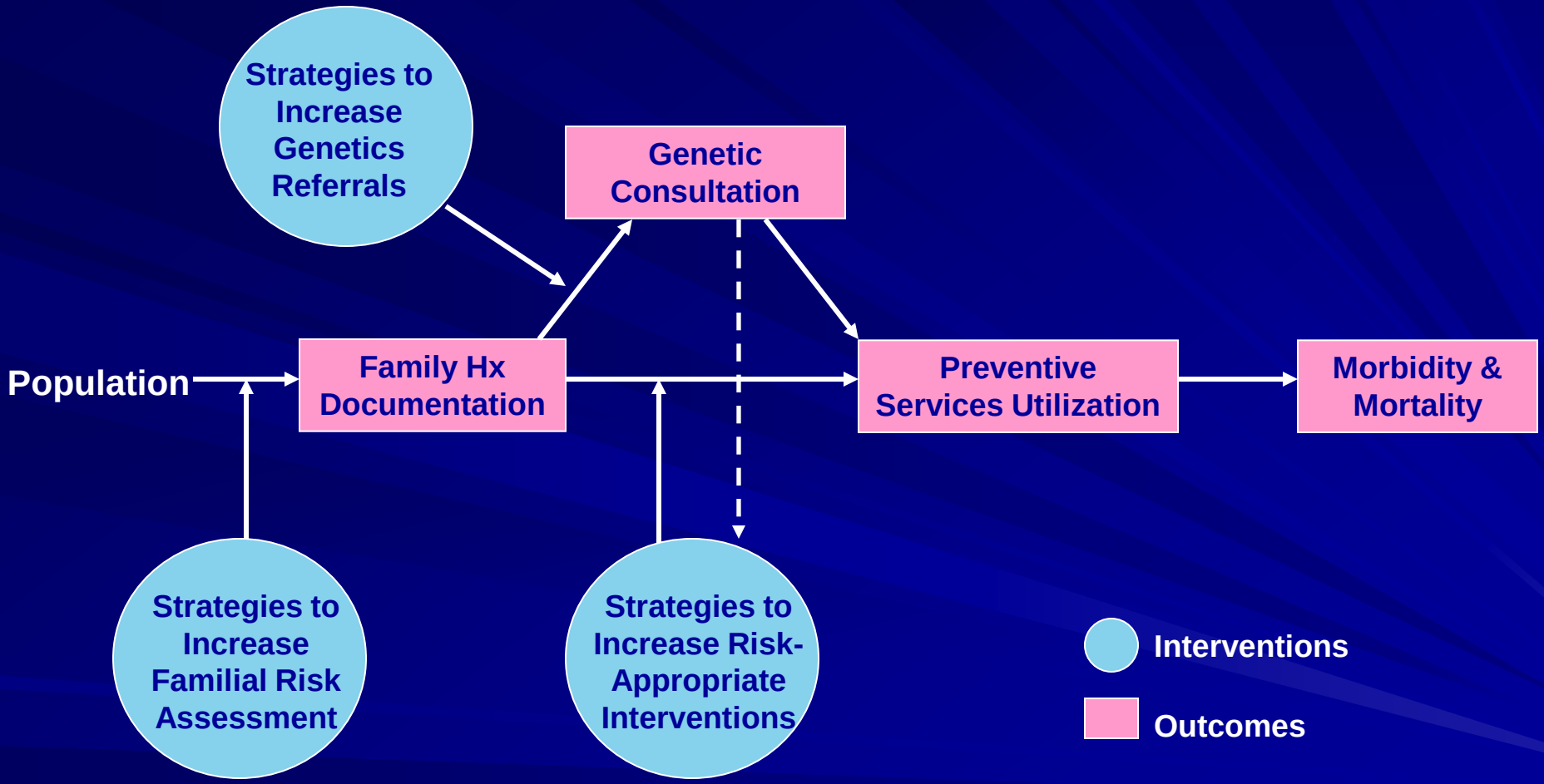
Comment from Primary Care Provider

"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



VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Thank You

VA HSR&D Center for the
Study of Healthcare
Provider Behavior

VA GREATER LOS ANGELES
HEALTHCARE SYSTEM

A Division of VA Desert Pacific
Healthcare Network

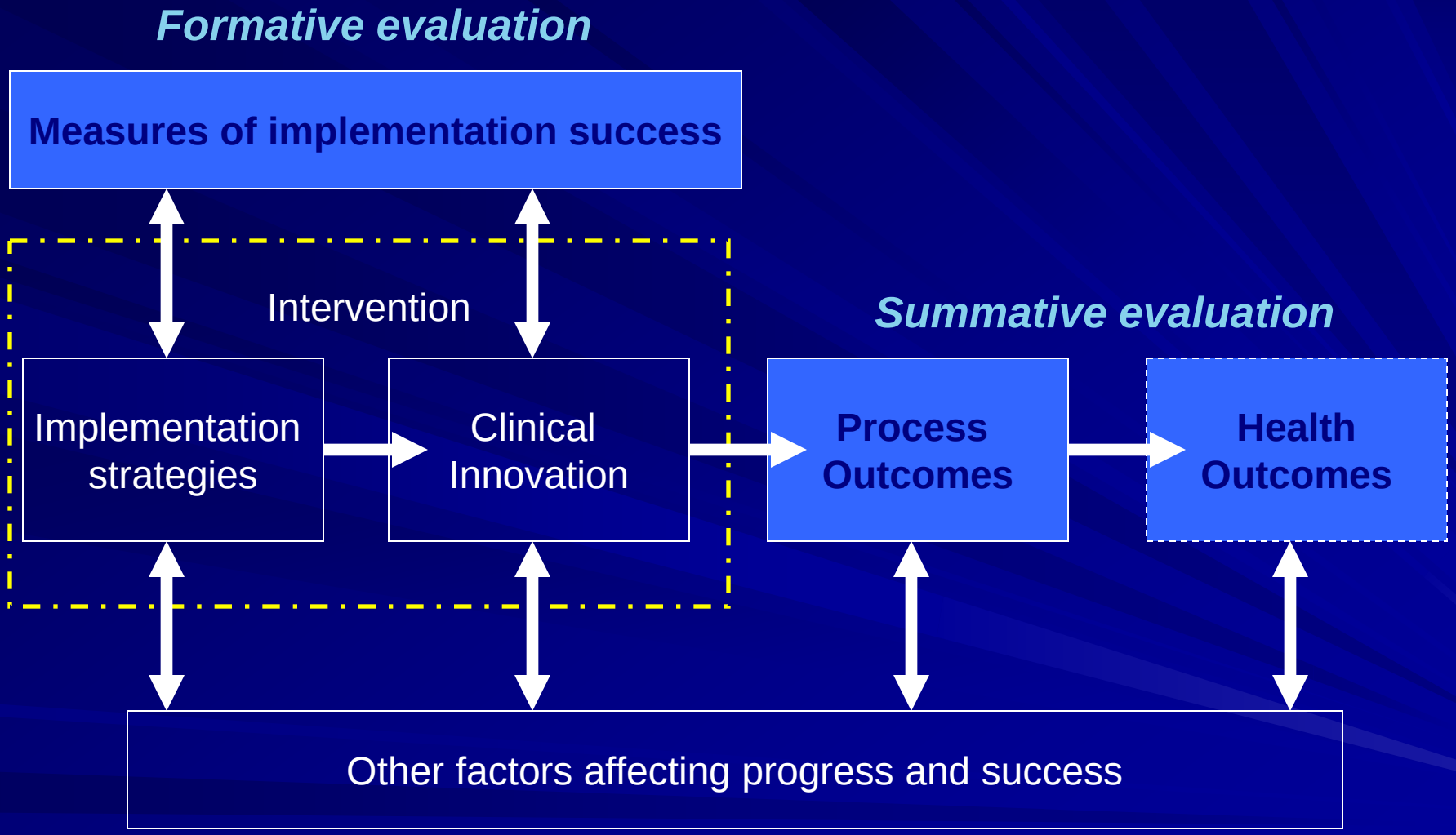
Types of Evaluation

- 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*

Stettler CB, Legro MW, Wallace CM, et al. The role of formative evaluation in implementation research and the QUERI experience. J Gen Intern Med 2006;21(Suppl 2):S1-8.

How do we measure success?



Adapted from: Luska CV, Hall C. Challenges in measuring implementation success. 3rd Annual NIH Conference on the Science of Implementation and Dissemination. Methods and Measurement. March 15-16, 2010, Bethesda, MD

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

Pre-Implementation | **Implementation** | **Post-Implementation**

1. Developmental

Identify determinants of current practice

Identify barriers and facilitators

Assess feasibility of proposed intervention

Integrate findings into intervention design, and refinement prior to implementation

2. Implementation-focused

Assess discrepancies between implementation plan and execution, exploring issues of fidelity, intensity, exposure

Understand and document nature and implications of local adaptation

3. Progress-focused

Monitor impacts and indicators of progress toward project goals

Use data to inform need for modifying original strategy

Provide positive reinforcement to high performers; negative reinforcement to low performers

4. Interpretive

Assess intervention usefulness/value from stakeholders perspectives

Elicit stakeholder recommendations for further intervention refinements

Assess satisfaction with intervention and implementation process

Identify additional barriers / facilitators

VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Formative evaluation according to implementation

Pre-Implementation	Implementation	Post-Implementation
Developmental	***Implementation-focused***	***Interpretive***
Identify determinants of current practice	Ass…	Assess intervention usefulness/value from stakeholders
Identify barriers and facilitators	…explori… …ensity, ex…	…erspectives
Assess feasibility of proposed intervention	…derstand and do… nature and implicati… adaptation	…licit stakeholder …ecommendations for further intervention refinements
Integrate findings into intervention design and refinement prior to implementation	***Progress-focused*** …ects and indicators …toward pr… …nform p… …ginal… …t to high performers, negative reinforcement to low performers	Assess satisfaction with …ntervention and …plementation process
		Identify additional barriers / facilitators

VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

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

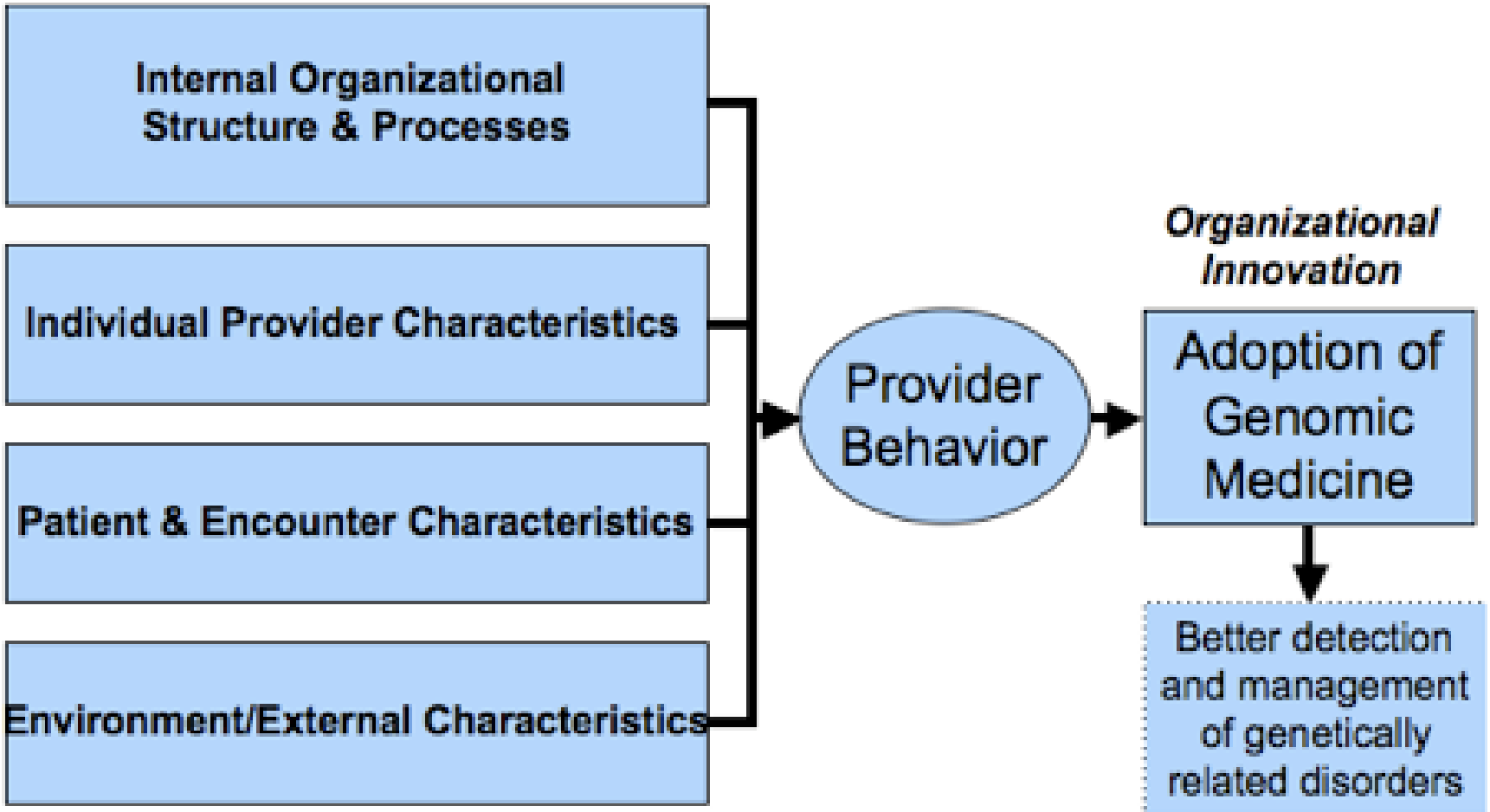


Figure 1. Conceptual Model of Factors Associated with Adoption & Delivery of Genomic Medicine. Adapted from the provider behavior model (Rubenstein et al., 2000), Rogers' diffusion theory (Rogers, 1995), and organizational factors related to implementation (Yano, 2008).

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

VA Service for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

HSR&D Genomic Center Supplements

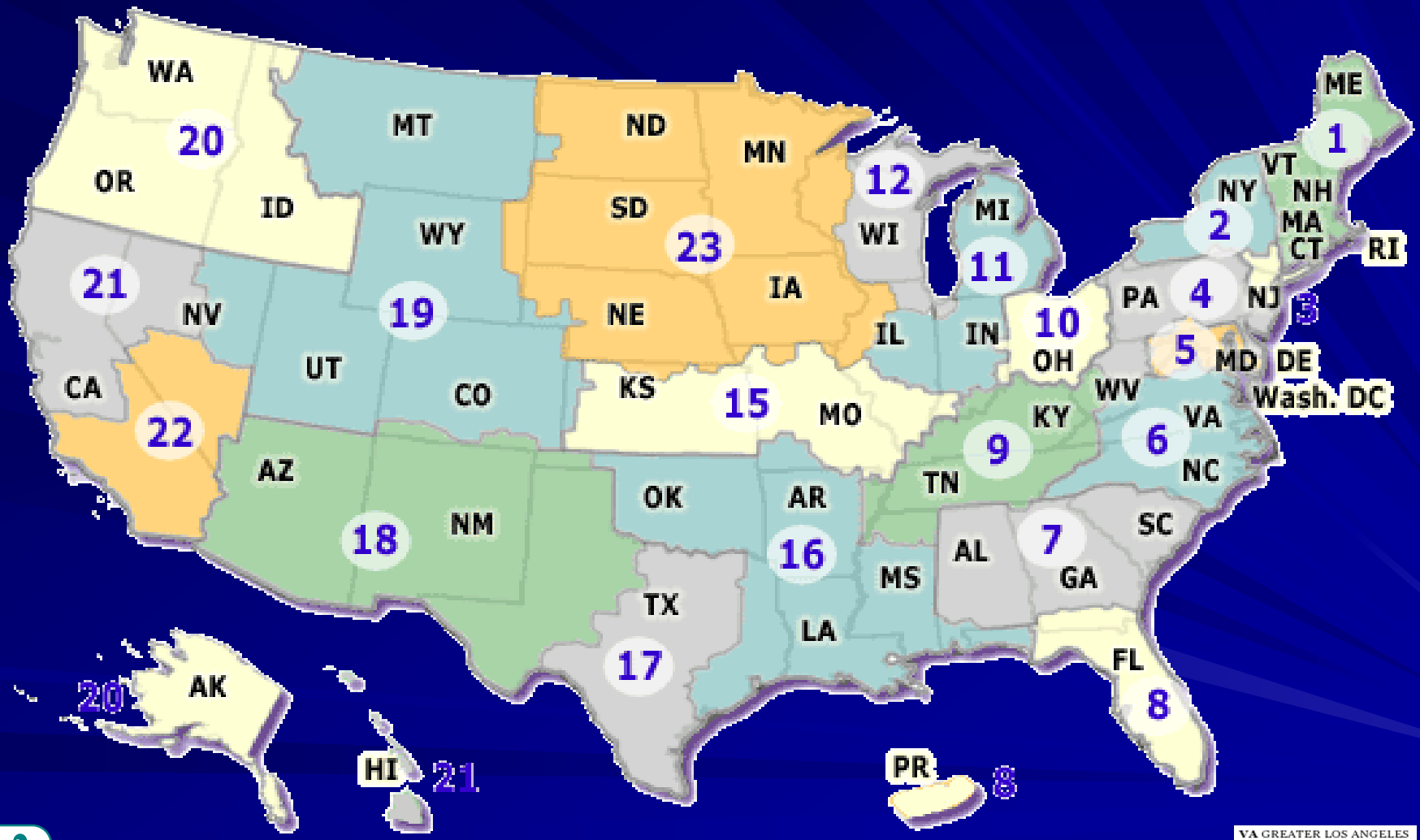
- HSR&D Program Announcement for Center Supplements to build Health Services Genomics research capacity within the Centers
- The strongest Center applications showed collaboration between bio-lab, clinical, & health services researchers within the VAMCs
- 7 supplements funded for FY 08 and FY 09

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



VA HSR&D Center for the Study of Healthcare Provider Behavior

VA GREATER LOS ANGELES HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

HSR&D Centers