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Principles of evidence in designing educational programs

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Improving Genetics Education in Graduate and
Continuing Health Professional Education

Disclosures

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Generating evidence for genetics education: Implementation Research

“... the study of methods to promote the integration of research findings and evidence into healthcare policy and practice.”

Implementation Science Information and Resources, Fogarty International Science for Global Health. www.fic.nih.gov. Accessed August 10, 2014

“...scientific investigations that support movement of evidence-based, effective health care approaches (e.g., as embodied in guidelines) from the clinical knowledge base into routine use.”

Rubenstein & Pugh, 2006.



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How do we measure implementation success?

- Formative evaluation
 - *Rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts*
- Summative 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.



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Usefulness of theory

In terms of...

- Planning the implementation strategy
- Conducting evaluations
- Identifying unanticipated elements critical to successful implementation (that may be unexplained by selected theory)
- Gaining additional insights about the theory
- Helping to understand findings, including relationships between domains or constructs



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Types of Theories

- 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 explanatory and process theories
- Often multiple theories useful



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IMPLEMENTATION CASE STUDY

To illustrate:

- Use of theory
- Formative evaluation
 - pre-implementation
 - Implementation
 - post-implementation
- Summative evaluation



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CDC OPHG Genomics Translation Programs

(Oct 2008 – Sep 2011)

- Goal: Promote evidence-based clinical and public health practice in genomics
- Focus: Genetic testing applications with evidence of clinical utility (e.g., CDC EGAPP reviews, USPSTF recommendations)
- Supported activities: education, policy, surveillance



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***“Family History Education to Improve Risk
Assessment for Hereditary Cancer”***

**Translating Clinical Guidelines for
Family History Risk Assessment into Practice**

Goal

To develop an education program for primary care clinicians that improves recognition and referral of patients at risk for hereditary cancer syndromes.

CME Theory: Informed our interventions

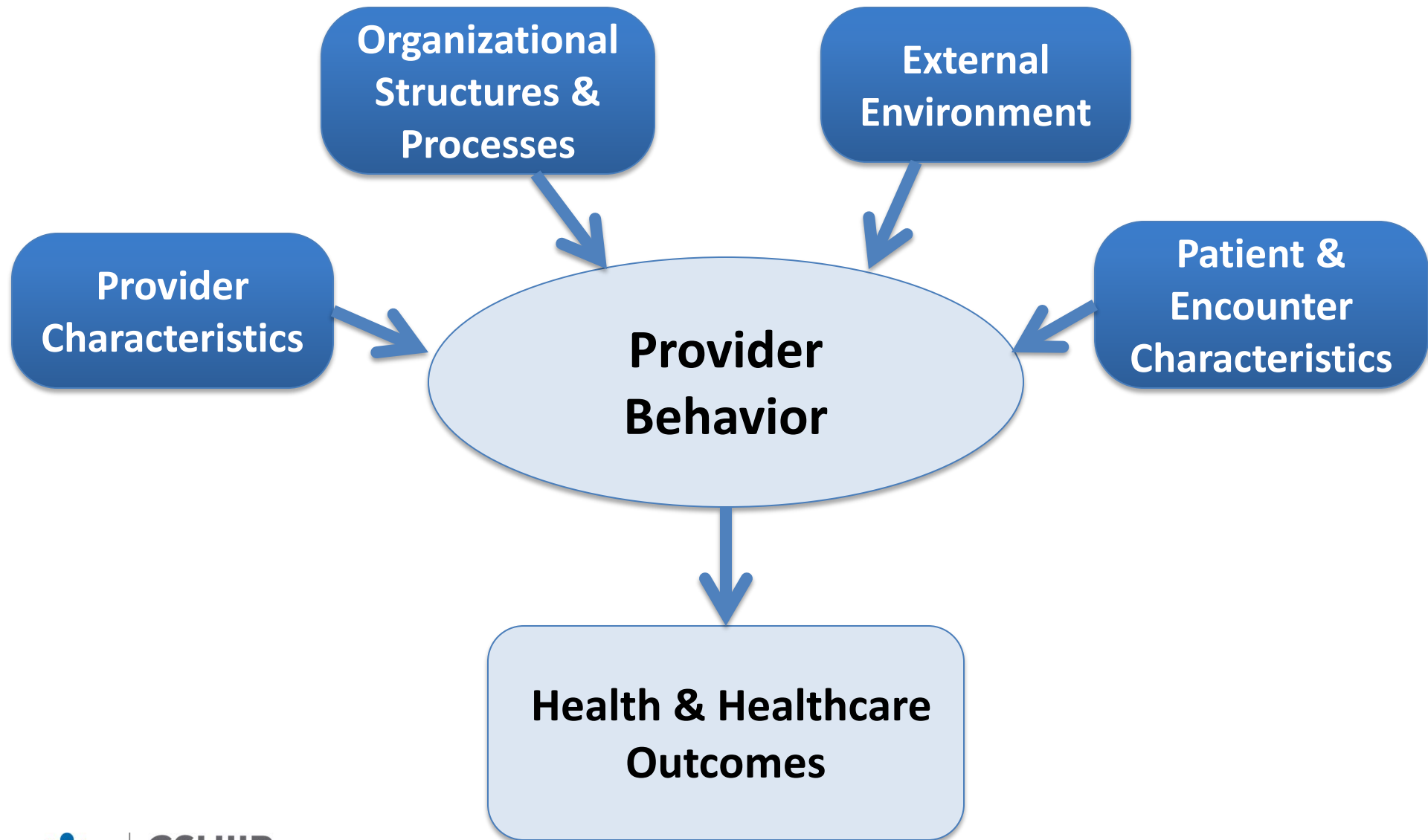
- Sequenced, continuous and multifaceted activities can lead to change in practice.
 - Mazmanian PE, Davis DA. Continuing medical education and the physician as a learner: Guide to the evidence. JAMA 2002;288:1057-1060.
- Passive interventions are generally ineffective...
Multifaceted interventions targeting different barriers to change are more likely to be effective than single interventions.
 - Grimshaw JM et al. Changing provider behavior. Medical Care 2001;39:II2-II45.
- CME interventions: Educational materials, conferences, outreach visits, local opinion leaders, patient-mediated interventions, audit and feedback, reminders.



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Theory: Determinants of provider behavior



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Donabedian A, Health Administration Press; 1980;
Rubenstein et al., *Med Care*, 2000;38(6):129-141.

Formative Evaluation: Pre-implementation Phase

- ✓ Identify determinants of current practice
- ✓ Identify barriers and facilitators
- ✓ Assess feasibility of the proposed intervention
- ✓ Integrate findings into intervention design, and refinement prior to implementation

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.



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EHR lacks standards for family history documentation

- 1,416 progress note templates (2007 – 2008)
 - Family history mentioned in 8%
 - Disease checklist most common format, 46%
 - Family history open text box, 38%
 - List of first-degree relatives with text box, 14%
- None captured information about specific diseases in specific relatives.



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Key informant interviews

- Routine family history collection of limited scope occurring primarily on initial visits.
- To improve documentation of family history, primary care providers wanted:
 - Template for family history in the EHR
 - Better organization of the family history in EHR
 - Pre-visit, patient-provided data (through kiosk or personal health record)

High Ratings for Clinical Reminders

- To help with documentation
- To recognize inherited conditions
- To prompt referrals for consultation or testing
- Reasons for high ratings:
 - Lack of knowledge, familiarity and confidence in genetic risk assessment, diagnosis and testing



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First draft: 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,

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



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Reminder Dialog Template: RISK ASSESS HERED CA TEST

Risk Assessment for Hereditary Cancers

☒ Male or transgender male to female

1. Are you adopted?

- ☒ Yes (Please provide information)
☐ No
☐ Don't know

2. Have you ever had cancer or 10 or more

- ☐ Yes
☒ No
☐ Don't know

3. Were any first-degree relatives (pa

- ☐ Yes
☒ No
☐ Don't know

4. Were any second degree MATERNAL rel

- ☐ Yes
☒ No
☐ Don't know

5. Were any second degree PATERNAL rel

- ☐ Yes

Risk Assessment for Hereditary Cancers
 Patient is adopted.
 Patient reports no personal history of c

Health Factors: ADOPTED, NO PERSONAL HX CANCER

* Indicates a Required Field

Reminder Dialog Template: RISK ASSESS HERED CA TEST

3. Were any first-degree relatives (parents, siblings, children) affected with cancer?

☒ Yes

Please select the relative(s) affected

☒ Mother

- ☐ 10 or more gastrointestinal
☒ Breast
☒ Age at onset <50 years
☐ Age at onset 50 years or older
☐ Age at onset unknown
☐ Colon or rectal
☐ Gastric, small bowel, or biliary
☐ Kidney or ureter
☐ Melanoma
☐ Ovarian
☐ Pancreatic
☐ Thyroid
☐ Uterine (not cervical)

☒ Father

- ☒ 10 or more gastrointestinal
☐ Age at onset <50 years
☐ Age at onset 50 years or older
☒ Age at onset unknown
☐ Breast

Risk Assessment for Hereditary Cancers
 Patient is adopted.
 Patient reports no personal history of cancer
 Mother history breast cancer, age at onset
 Father history 10 or more gastrointestinal

Health Factors: ADOPTED, FATHER HX 10+ GI POLYPS, RISK ASSESSMENT HEREDITARY CA TEST

* Indicates a Required Field

Reminder Resolution: Cancer Family History Questionnaire

6. Were there other relatives with cancer?

- ☐ Yes
☒ No
☐ Don't know

SKIP item #7 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

**** INFORMATION ONLY ****

Check the box below to review the indications for cancer genetics consultation.

☐ Indications for cancer genetics consultation

>>>> GENETICS CONSULT? (response required)

- ☐ Request genetics consultation for cancer. (Order screen will open when you click on the "Finish" button below)
☐ Patient declines genetics consultation for cancer.
☐ Genetics consultation for cancer not indicated.

The algorithm supporting this reminder dialog is based on the:

USPSTF guidelines for BRCA1/2 testing:

<http://www.portal.gla.med.va.gov/sites/Research/HSRD/Genomics/Delivery%20of%20Genomic%20Medicine/USPSTFG>

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

<http://www.portal.gla.med.va.gov/sites/Research/HSRD/Genomics/Delivery%20of%20Genomic%20Medicine/ClinPrac>

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://www.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

* Indicates a Required Field

Family history toolkit: A Multifaceted implementation strategy

- **Clinical interventions**
 - Cancer family history reminder in EHR with links to information interventions
 - Self-administered, patient questionnaire
- **Information interventions:**
 - 7-part CME lecture series on cancer genetics
 - Information sheets for providers
 - Information brochures for patients
 - Web site
- **Behavior interventions**
 - Real-time review of family history generated by reminder with feedback by opinion leaders
 - Practice-feedback reports each quarter

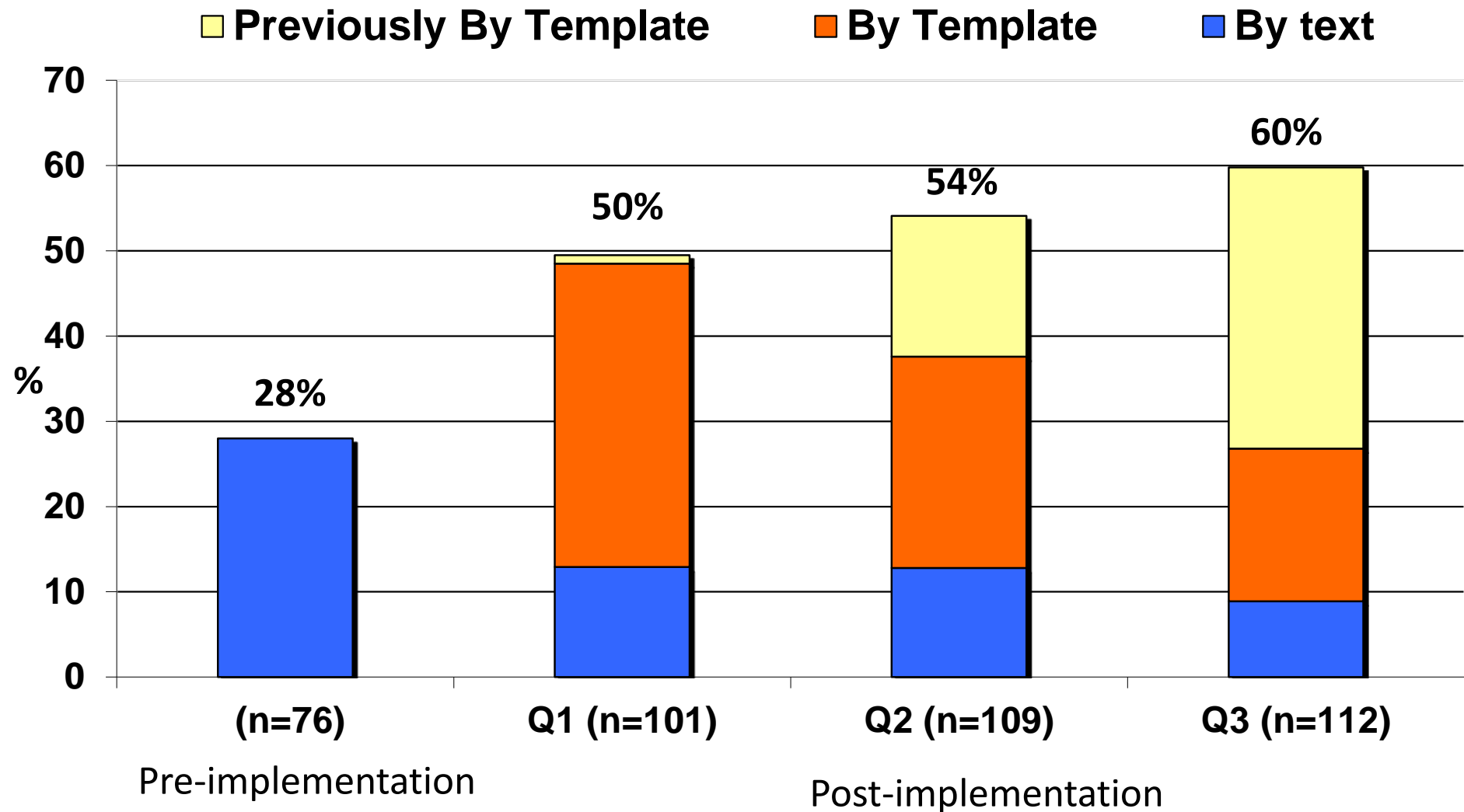


Formative Evaluation: Implementation Phase

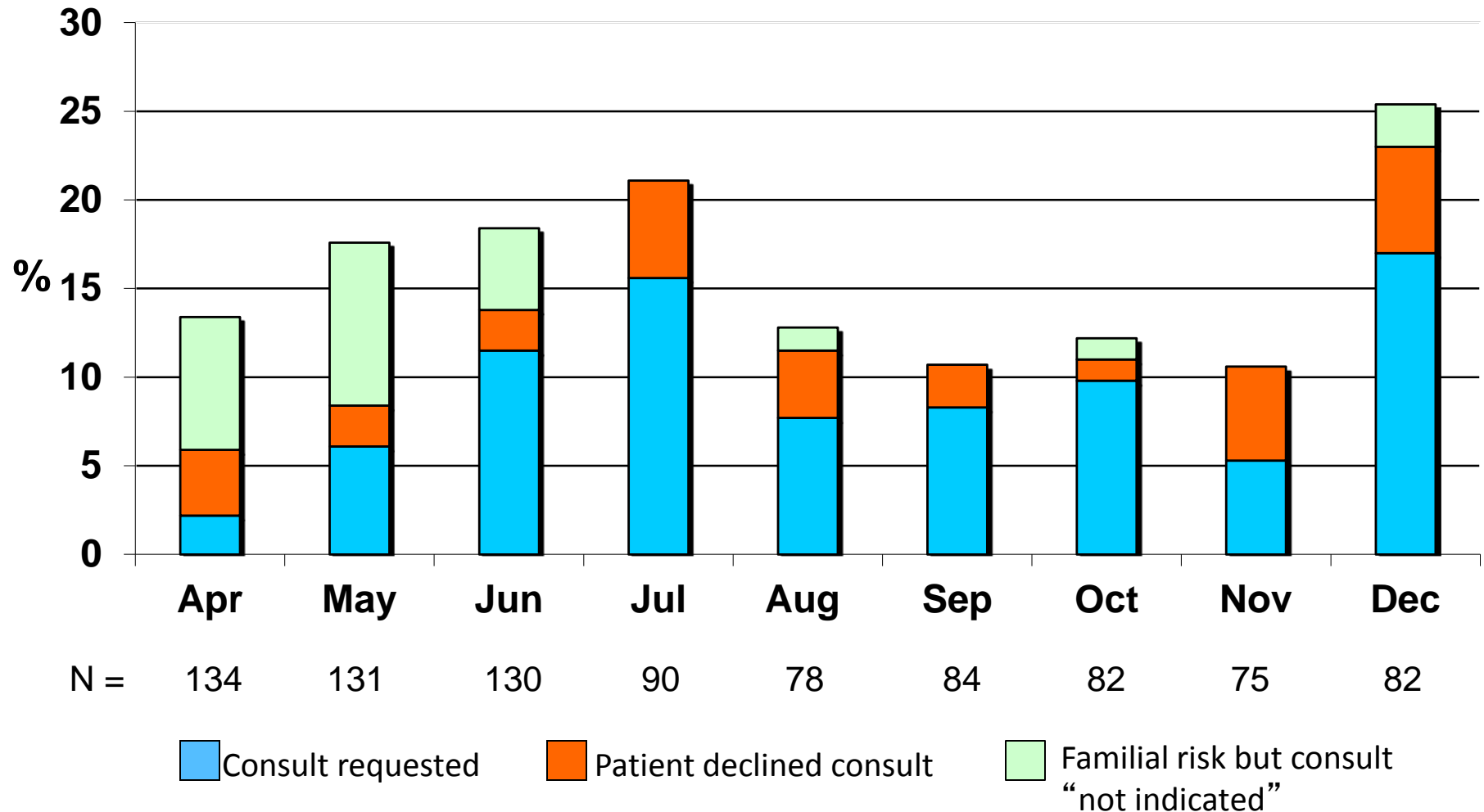
- ✓ Assess discrepancies between implementation plan and execution, exploring issues of fidelity, intensity, exposure
- ✓ Understand and document nature and implications of local adaptation
- ✓ Monitor impacts and indicators of progress toward project goals
- ✓ Use data to inform need for modifying original strategy
- ✓ Provide positive reinforcement to high performers; negative reinforcement to low performers



Cancer Family History Documented in Progress Notes



Trends in genetics referral generated by template: Missed opportunities decreased over time



Individualized reinforcement provided

February 10, 2011

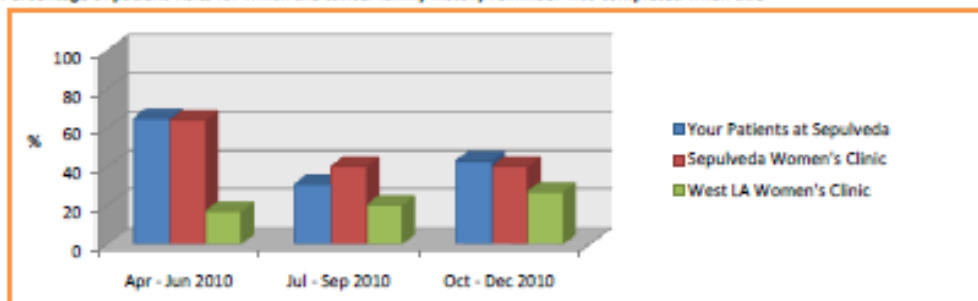
Dear Participant 101,

Thank you for participating in the CDC-funded project, "Family History Education to Improve Genetic Risk Assessment for Cancer." Below we have summarized your individual activity related to the use of the Cancer Family History Reminder in CPRS that was developed for this project. A table with more detailed information is also attached.

We hope this feedback is useful to you. If you have any questions, please contact Erin Schalles, MS, CGC by phone at (818) 891-7711 x5279 or by email at Erin.Schalles@uva.gov.

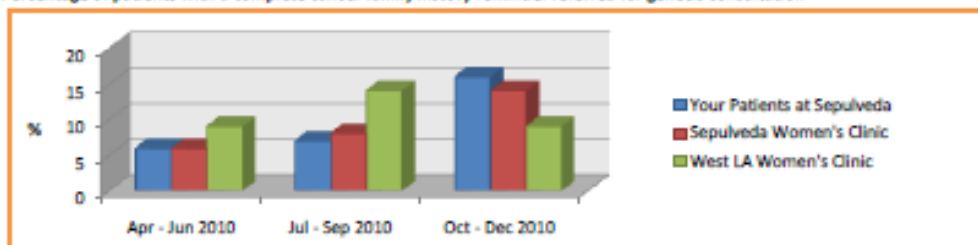
For the last three quarters, beginning in April 2010, you completed the template for 63%, 31% and 43% of patient visits. Corresponding percentages for the Sepulveda Women's Clinics were 64%, 40% and 40%, respectively.

Percentage of patient visits for which the cancer family history reminder was completed when due



For the last three quarters, beginning in April 2010, you referred 6%, 7% and 16% of your patients for a genetic consultation. Percentages of patients referred from the Sepulveda Women's Clinics were 6%, 8% and 14%, respectively.

Percentage of patients with a complete cancer family history reminder referred for genetic consultation



Sincerely,

Erin Schalles, MS, CGC

Sepulveda Ambulatory Care Center & Nursing Home • West Los Angeles Healthcare Center
• University of California, Los Angeles • RAND Health Sciences Program



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Formative Evaluation: Post Implementation Phase

- ✓ 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

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.



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Interviews with Primary Care Providers

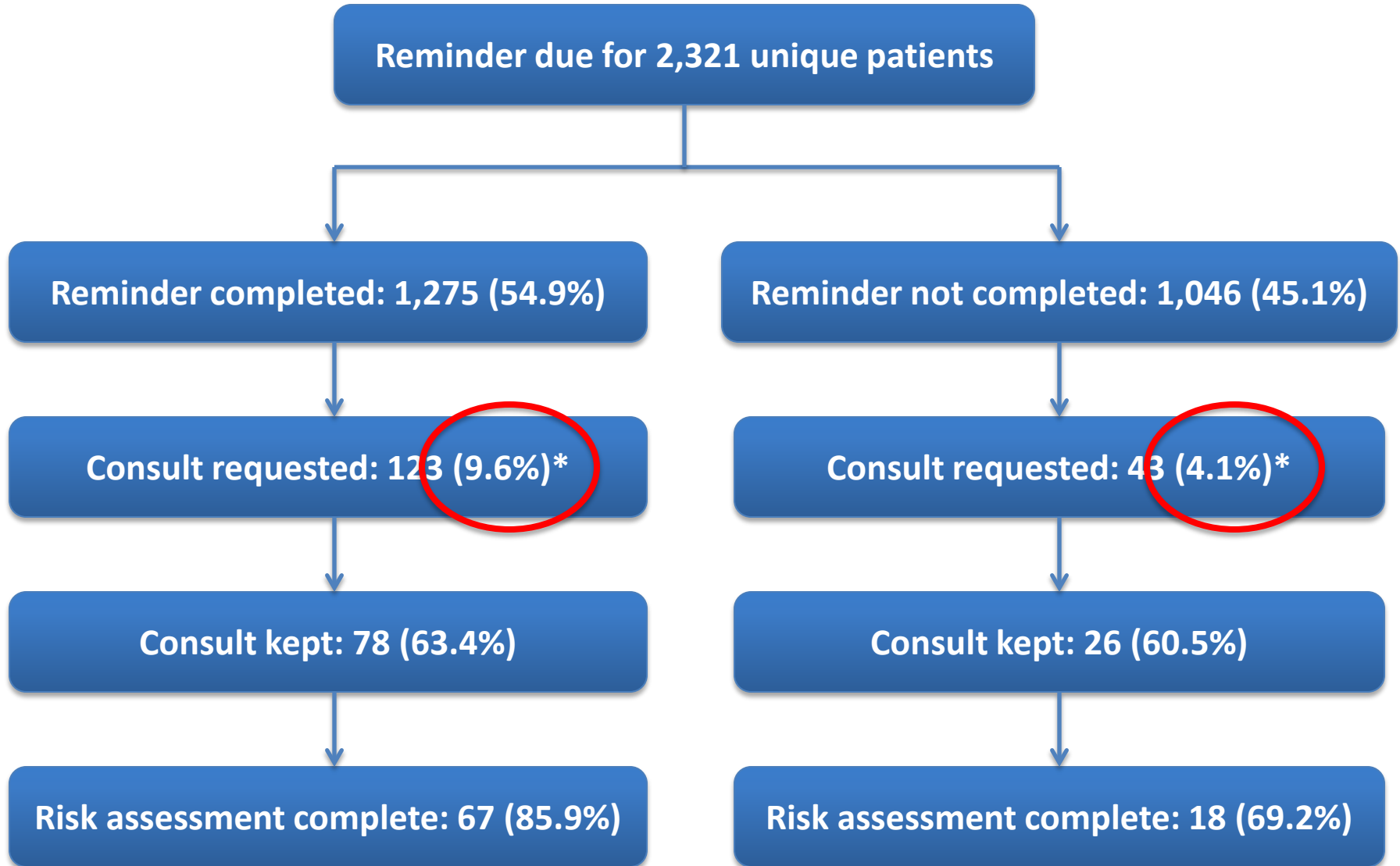
- “My documentation of cancer family history has improved... I had a template I was using and it was limited to the colon, breast, uterine and ovarian cancer, so now it’s expanded because we have all those other options.”
- “Now my documentation is very detailed, whereas before I would just mainly ask about mom and dad.”
- “I probably wasn’t doing that in-depth of a family history before, especially not focused on cancer.”
- “The template is much broader and more detailed than what I probably would have gotten before. I don’t know if I would have gone down to all those relatives..., and it certainly triggered a number of consultations in some people who probably deserved it a long time ago. So I think this has greatly improved my history-taking.”



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Summative Evaluation



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$P < 0.001$

Summary

- Develop implementation strategies for your genetics education programs and generate evidence regarding effectiveness.
- Effective education programs are multifaceted and on-going.
- Use a theoretical model(s) to inform the development, implementation and evaluation of genetics education.
- Conduct formative evaluations to measure implementation success.
- Conduct summative evaluations to assess health and healthcare outcomes.



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Thank You!

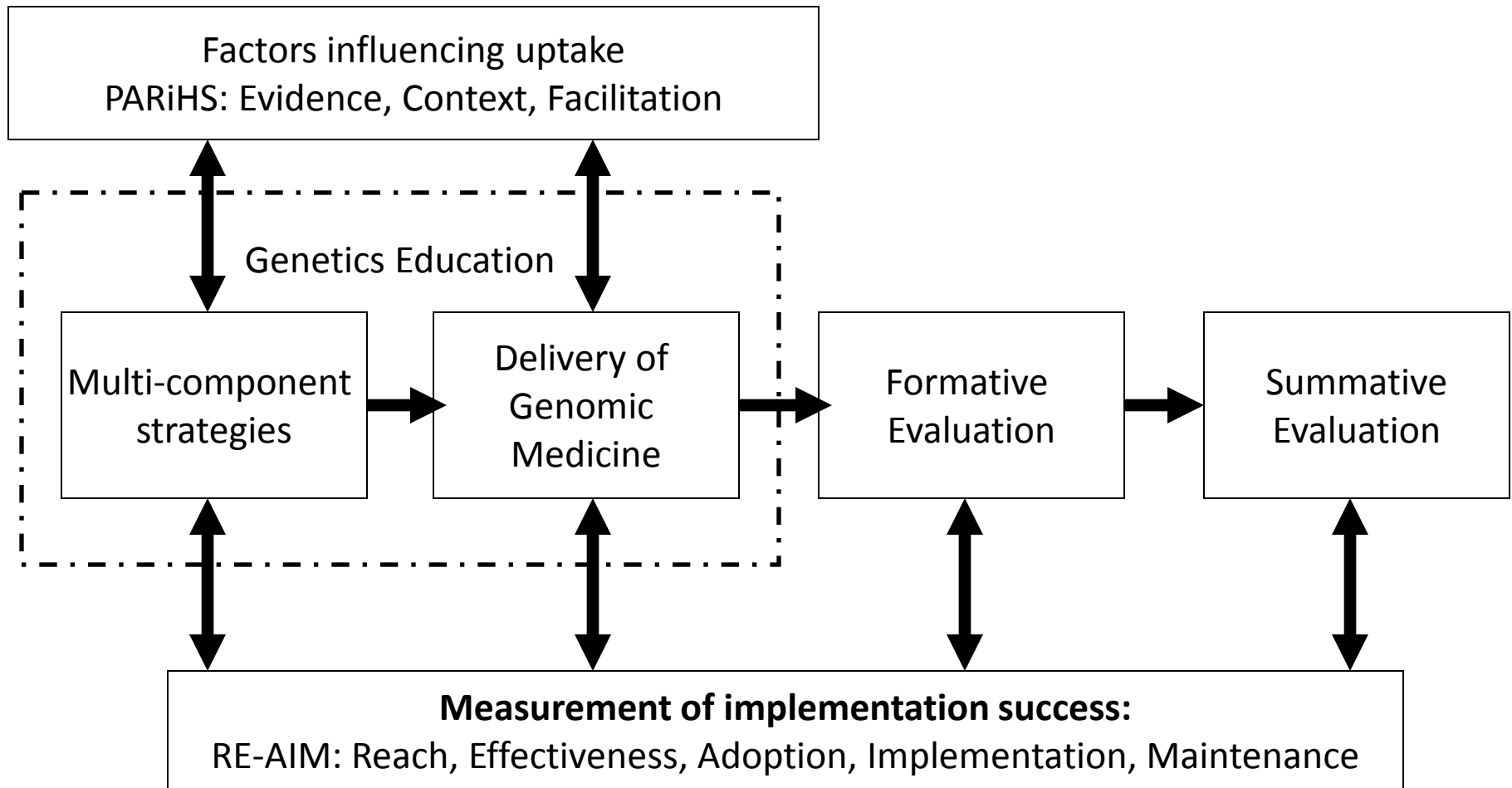
maren.scheuner@va.gov



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Interaction of PARiHS and RE-AIM Frameworks



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

Formative Evaluation Methods

- 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
 - Focus groups
 - Direct observation of clinical structure and processes in site visits
 - Document review
- Mixed methods (i.e., quantitative + qualitative)



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