NIH Collaboratory

Health Care Systems Research Collaboratory

Incorporating Research Driven Changes into Health Care System's IT Operations: A Multi-Perspective Panel Discussion

Grand Rounds Webinar

January 10, 2014

Rethinking Clinical Trials

What to expect

Presentation (30 Minutes)

- Introductions
- Overview of a common issue that those conducting pragmatic clinical research must address
- Presentation of a hypothetical scenario
- Researcher/data user, health system IT decision maker and clinician perspectives

Open Discussion (30 Minutes)

Eric B. Larson, MD, MPH

- Chair, Health systems interaction core, Co-PD NIH Collaboratory
- Co-Lead, Health systems interactions task force, PCORnet
- Executive Director, Group Health Research Institute
- Vice President for Research, Group Health Cooperative
- General Internist, University of WA Medical Center

Today's role

- Introductions
- Topic overview
- Discussion facilitation

Amy P. Abernethy, MD, PhD

- Co-Chair, Patient-reported outcomes core, NIH Collaboratory
- Lead, Patient-reported outcomes task force, PCORnet
- Director, Duke Center for Learning Health Care
- Director, Duke Cancer Care Research Program
- Medical oncologist & palliative medicine physician, Duke University Medical Center

Today's role

- Scenario presentation
- Discussant

Jeffrey Brown, PhD

- Co-Chair, Electronic health records core, NIH Collaboratory
- Co-Lead, Data standards, security & network infrastructure, PCORnet
- Director, Scientific Operations Center, FDA Mini-Sentinel
- Assistant Professor, Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School

Today's role

- Perspective panelist: Researcher / data user
- Discussant

Gwendolyn O'Keefe, MD

- Vice President, Delivery System Support, Group Health Cooperative
- Chief Medical Information Officer, Group Health Cooperative
- General Internist

Today's role

- Perspective panelist: Health IT decision-maker
- Perspective panelist: Clinician / EHR end user
- Discussant

Research advances through HCS IT

Pragmatic Clinical Trials (PCTs) typically rely heavily on the electronic health systems (EHRs) and other electronic data resources of the health plans with whom they partner, e.g.:

- Identifying patients for targeted enrollment in the trial
- Gathering routinely collected HCS data for research analysis (e.g., EHRs, patient portals, insurance coverage and enrollment, pharmacy fills, laboratory tests, etc.)
- Delivering or documenting an intervention
- Measuring patient outcomes post-intervention

HCS IT creates huge opportunities for health-related research.

Data collection and consistency

- Health care systems collect data for care delivery and business operations –not to support rigorous research.
- Not all the data needed for a pragmatic trial may be collected by the health system - including patient reported outcomes, patient preferences, language and ethnicity data, and other information.
- Some data may be collected - but not consistently. Researchers may find that data they thought were available are often missing.
- Other data may not be collected in a standard way across different health systems - or even within a single system.

BUT – better than administrative data and more realistic and practical than traditional clinical research.

Complications and challenges

- Health systems have limited IT staff and resources. Business and patient care priorities related to IT can directly compete with IT change requests from researchers.
- Even if a researcher successfully negotiates a change with a partnering health system, a different solution may be needed for other partnering systems.

  - EHR installations are typically customized, not 'out of the box'

  - Patient portals may be separate or integrated with EHRs
- Both technical and logistical challenges arise when building a new functionality into an EHR or patient portal - then limiting its use to only research subjects, certain settings, time periods, etc.

Change management challenges

Examples:

- Clinicians may already be getting multiple reminders and EHR prompts at every visit. 'Alert fatigue' is a constant challenge.
- Changes that aren't in the "right place" in the EHR may also be missed or ignored simply due to poor timing within visit flow.
- Researchers may need to work with the health systems to provide training on the use of new features or elements added for research purposes.

Building partnerships

Increasingly, practice changes will be based on technology, researcher-learning health system collaborations, and be patient-centered. Researchers need to build stable relationships with operations staff, as both a journey and partnership with the goal of solving problems and spreading good solutions.

- Get to know the health plan people and processes for requesting, prioritizing, and resourcing IT changes.
- Partner with clinical operations early on to think through workflow issues to maximize usability and action-ability.
- Work up front to ensure what you propose can/will be utilized as intended by end users, and if appropriate enduring

Facilitating your success

- Clearly articulate the use case, structure, and specifications of what you are planning.
- Understand exactly how you plan to use the data. **Don't build in more than is needed.**
- Consider building and piloting separately (if possible) both to reduce the impact and test utility. Integrate later based on your findings.
- If building items into patient portals, assess the patient experience and consider their perspective. For example: Will it impact their care? Is it too long? Is it well formatted? Are the questions clear?

Next: Scenario presentation

Amy P. Abernethy, MD, PhD

SurvivorCare:
A Hypothetical Psychological Support Model for Cancer Patients and Caregivers

Amy Abernethy, MD, PhD

January 10th, 2014

SurvivorCare

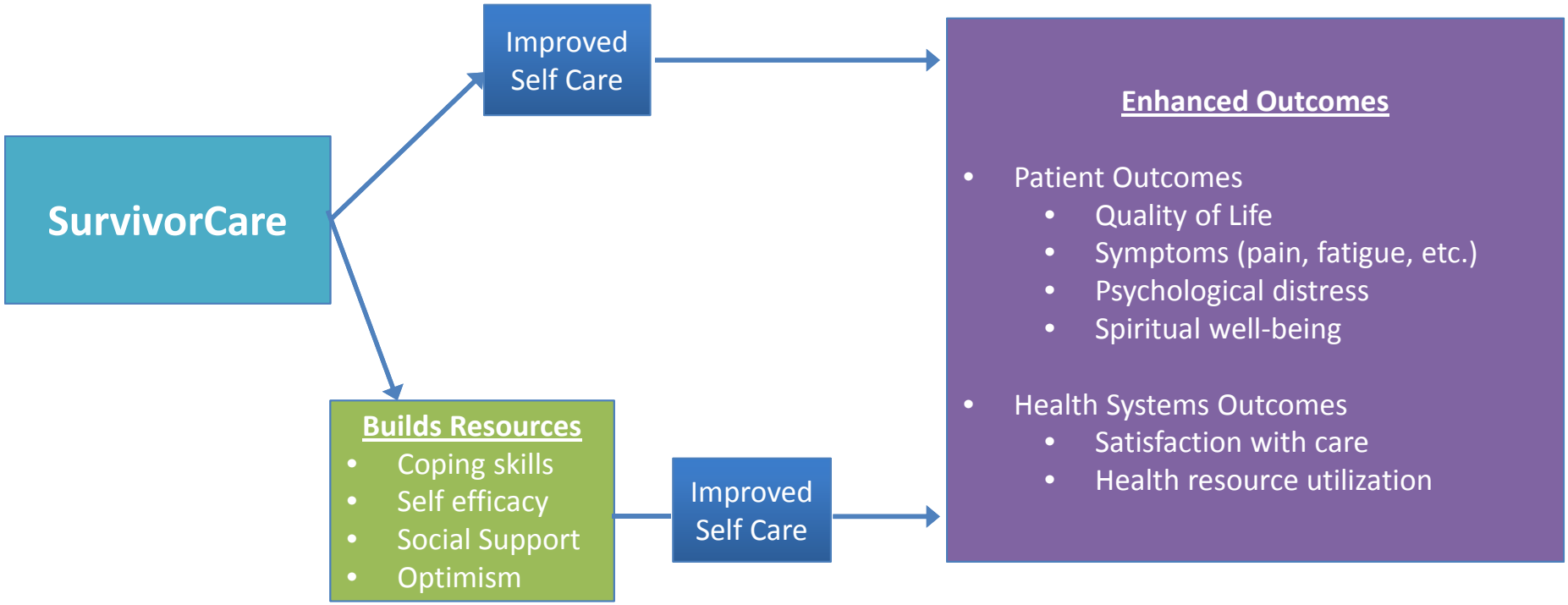
- People with cancer suffer from persistent psychological distress, symptoms, reduced quality of life (QOL), and PTSD symptoms for years after diagnosis, even when the cancer is not active.

- SurvivorCare
  - Psychosocial support model
  - Developed for people with cancer and caregivers
  - Derived from social work and family counseling program developed and tested in Colorado for 7 years
  - Manualized and delivered by licensed therapists

Pilot Program Evaluation

- SurvivorCare underwent evaluation at a large cancer clinic Bridgewater Health Care System (BHCS)
  - People with metastatic breast cancer were included
- BHCS routinely collects patient reported data as a part of the cancer clinic visit
  - Standardized reporting of symptoms & satisfaction with care
  - Can ask additional questions as needed, including specific PRO instruments
- BHCS has an electronic health record and enterprise data warehouse
- Supplemental data collected as needed by research personnel using case report forms

Conceptual Model for the Evaluation Program



Mediators of Outcomes

This model is hypothesized to improve care by…

- ✓ *Supporting sense of self-efficacy*
- ✓ *Reinforcing social support*
- ✓ *Supporting spirituality and coping*
- ✓ *Promoting optimism*
- ✓ *Incorporating advanced care planning and life review*
- ✓ *Reducing health care costs by reducing unnecessary treatment and creating bridge to early palliative care*

The Process

All patients complete clinical review of symptoms (ROS) and satisfaction survey

Clinicians received ROS reports in real time

SurvivorCare participants also complete:

- QOL (FACT-B)
- Fatigue (FACT-F)
- Anxiety/depression (PHQ-9, GAD7)

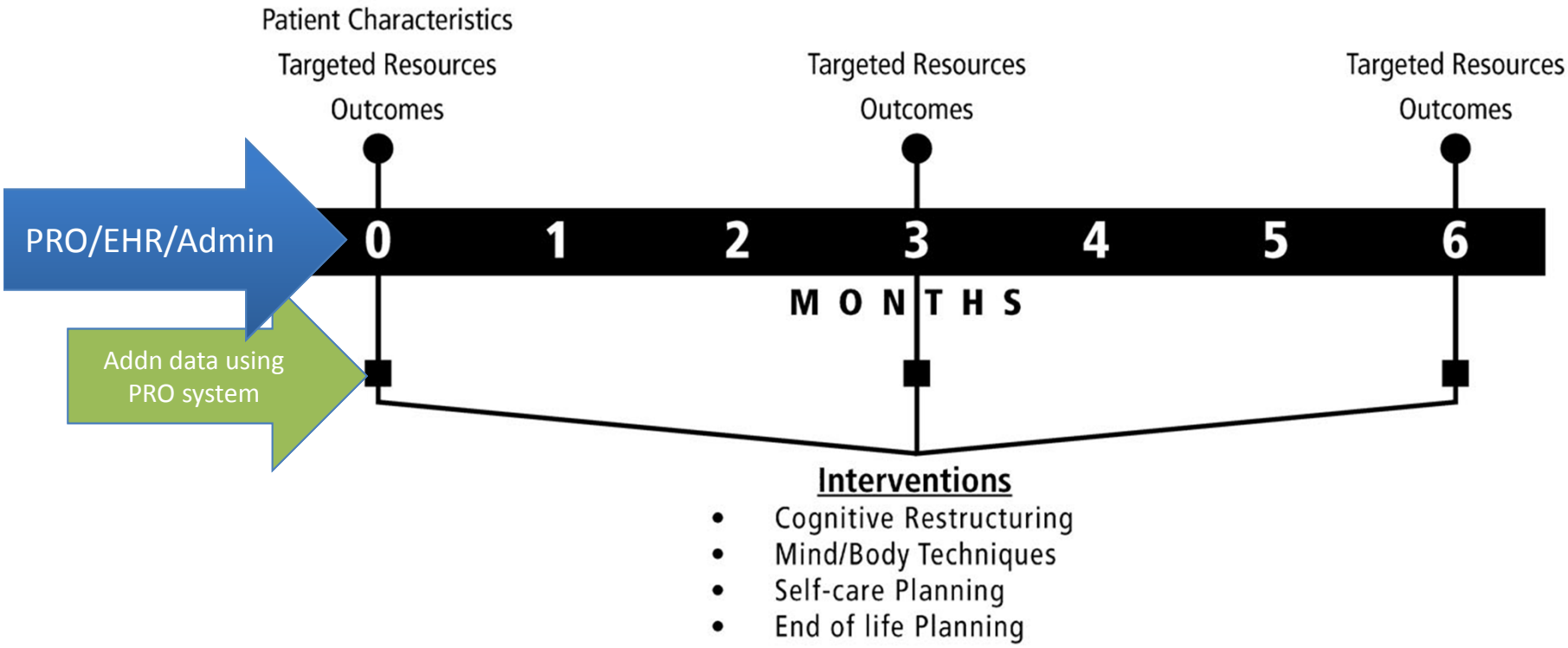
Additional assessments completed at intermittent time points:

- Social Support
- Self-efficacy
- Optimism
- Coping
- Spirituality

EHR/Admin Data

- Performance Status
- Weight
- Survival
- ED, Hosp. admin/discharge
- Palliative care

Aggregated study database supports assessment of planned outcomes



Longitudinal Enterprise Data Warehouse

Patient reported data

- Symptom (e.g. fatigue)
- Quality of Life
- Distress
- Satisfaction

EHR Data

- Performance status
- Weight

Administrative Data

- Health care utilization
- Palliative care
- Survival

Pilot Study Results

- Metastatic breast cancer patients had statistically significant improvement in psychosocial distress, fatigue, and QOL after 3 months
- Patients who had positive changes in distress, despair and QOL were more likely to have demonstrated improvement in self-efficacy, social support and optimism
- SurvivorCare improved overall patient and family satisfaction against historical controls
- Information on survival and health resource utilization was available, but without a control group data were difficult to interpret

Support Care Cancer
DOI 10.1007/s00520-010-0823-z

SHORT COMMUNICATION

Phase 2 pilot study of Pathfinders: a psychosocial intervention for cancer patients

Amy P. Abernethy · James E. Herndon II · April Coan · Tina Staley · Jane L. Wheeler · Krista Rowe · Sophia K. Smith · H. Kim Lyerly

Psycho-Oncology
Psycho-Oncology (2010)
Published online in Wiley InterScience (www.interscience.wiley.com). **DOI**: 10.1002/pon.1770

Brief Report

Correlates of quality of life-related outcomes in breast cancer patients participating in the Pathfinders pilot study

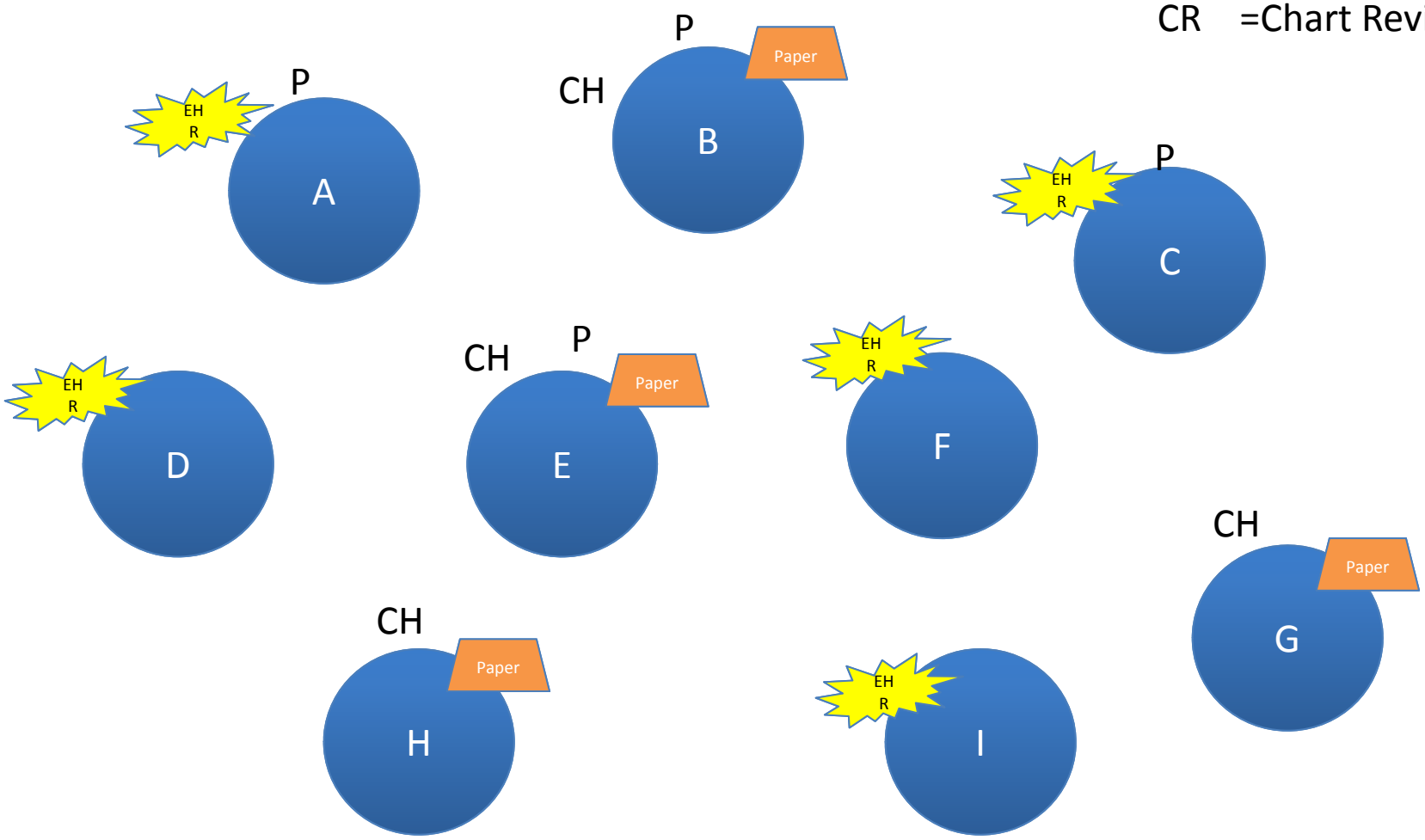
Sophia K. Smith[1,2], James E. Herndon[1,3], H. Kim Lyerly[1,4], April Coan[1], Jane L. Wheeler[5], Tina Staley[1] and Amy P. Abernethy[1,2,5]*

Evaluation: Next Steps

- Multi-site pragmatic design
  - Cluster-randomized trial vs.
  - Iterative longitudinal pre-/post- design with iterative optimization of intervention
- Site-level study requirements:
  - ✓ Mechanism to collect PROs
  - ✓ Understanding of availability of electronic data at each site (EHR, data warehouse, PROs, tumor registry other)
  - ✓ Ability to supplement with data collected on paper when needed
  - ✓ Institutional buy-in for project, intervention, provision of data, etc
  - ✓ [?consent]

Data collection across multiple sites: Planning for various scenarios

P =PRO collection
EHR = EHR present
Paper =Paper PRO
CR =Chart Review



Additional considerations……

1. Will data collected be considered standard of care or part of the trial process?
2. What processes should take place to ensure data collection is embedded in care?
3. Define conceptual model and data dictionary
4. Determine PRO instruments for use, based on pilot results. What if the PROs used at sites do not match?
5. Analyses must accommodate erratic time points
6. Intervention is likely to undergo iterative enhancement over time
7. Other data linkage opportunities (e.g. tumor registries, SSDI, geospatial mapping, etc.)

Next: Perspective Panelists

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Summary and Open Discussion