

Methodological issues in personalized health care and research

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Objectives

Explore “personalized health” in research methods & practice

Describe methodological approaches to study the “personal” in health research

Apply mixed methods to specific research questions in personalized health research

Not everything
that can be
counted
counts, and not
everything that
counts can be
counted

-Einstein



“Personalized” health care

A coordinated, strategic approach to care combining concepts of systems biology, and personalized, predictive, preventive, and participatory care

- **Customized plan of care developed collaboratively between patient & provider**
- **Shared goals**
- **Tracking measures**

Simmons et al (2014). Patient engagement as a risk factor in personalized health care: a systematic review of the literature on chronic disease. *Genome Medicine*, 6, 16.

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Challenges to personalized health care

Provider knowledge gaps

Availability /reliability of genomics, pharmogenetics, & other “-omics” tests

Ethical challenges

Data dispersion, lack of cooperation, & suboptimal achievements

Ever evolving personalized medicine

Cohen et al (2013). Overcoming barriers in the implementation of personalized medicine into clinical practice. IMAJ, 15, 599.

Challenges to personalized health care

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Barriers for Integrating Personalized Medicine into Clinical Practice: A Qualitative Analysis

Mehdi Najafzadeh,¹ Jennifer C. Davis,² Pamela Joshi,³ and Carlo Marra^{4,5*}

The negatives are like opening a Pandora's box and not knowing what to do with it. If you tell somebody, you are going to have an illness down the road and you can't do anything about it, is the person willing to know? (Pediatrician, Focus Group in Langley, BC)

Challenges to personalized health care

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Challenges to personalized health care

Availability /reliability of genomics, pharmacogenetics, & other “-omics” tests

- **Poor timing & sequencing of tests**
- **Reimbursement issues**

Challenges to personalized health care

Availability /reliability of genomics, pharmogenetics, & other “-omics” tests

TIMING OF TEST

- Obtaining authorization
- Outside laboratories
- Delayed results
- Delayed counseling on treatment decisions

Weldon et al (2012). Barriers to the use of personalized medicine in breast cancer. *Journal of Oncology Practice*, 8, e24.

Challenges to personalized health care

Availability /reliability of genomics, pharmogenetics, & other “-omics” tests

REIMBURSEMENT (disincentives)

- Tests might result in reduced drug or procedure reimbursement
- Decreased revenue when chemotherapy avoided
- Preoperative BRCA testing might forego surgical reimbursement

Challenges to personalized health care

Ethical challenges

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Challenges to personalized health care

Ethical challenges

WHO decides on its use in practice ...

- **patient?**
- **provider?**
- **payor?**

Birmingham et al (2013). Patient and provider attitudes toward genomic testing for prostate cancer susceptibility: a mixed method study. *BMC Health Services Research*, 13, 279.

RESEARCH ARTICLE

Open Access

Patient and provider attitudes toward genomic testing for prostate cancer susceptibility: a mixed method study

Wendy C Birmingham^{1*}, Neeraj Agarwal^{2,3}, Wendy Kohlmann², Lisa G Aspinwall⁴, Mary Wang³, Jay Bohoff⁵, Christopher Decher^{2,3} and Anita Y Krimley^{2,3}

“To take the time to understand this report, which is not something that I’m going to have seen on a regular basis, is going to take more time than I have and I would be quite annoyed if a patient brought this in.”

Challenges to personalized health care

Data dispersion, lack of cooperation, & suboptimal achievements

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Challenges to personalized health care

Data dispersion, lack of cooperation, & suboptimal achievements

- Unleashed public information/access
- Guarding of data
- Mutual cooperation of data sharing
- More research

Challenges to personalized health care

Ever evolving personalized medicine

- **Managing emergent evidence**
- **Rapid & reliable information for all settings**
- **Consistent & coherent framework linking community health services and hospitals**

Cohen et al (2013). Overcoming barriers in the implementation of personalized medicine into clinical practice. IMAJ, 15, 599.

The future ...

- 1. Establish national/international bio-repositories & data banks**
- 2. Determine roles for shared access**
- 3. Create financial incentives for data sharing**
- 4. Support collaborative scientific networks for analyzing, integrating, and updating molecular and “omics” data to be integrated into electronic health records**

Cohen et al (2013). Overcoming barriers in the implementation of personalized medicine into clinical practice. IMAJ, 15, 599.

“Personalized” health care

“The role of patient engagement in risk and outcome prediction may well be among the most important and modifiable risk factors for chronic disease outcomes --- it needs to be further elucidated.”

Simmons et al (2014). Patient engagement as a risk factor in personalized health care: a systematic review of the literature on chronic disease. *Genome Medicine*, 6, 16.

“Patient engagement”

- 1. Recognizing & understanding the importance of taking an active role in one’s health/health care**
- 2. Having knowledge, skills, & confidence to manage health**
- 3. Using knowledge, skills, & confidence to engage in health-promoting behaviors to obtain greatest benefit**

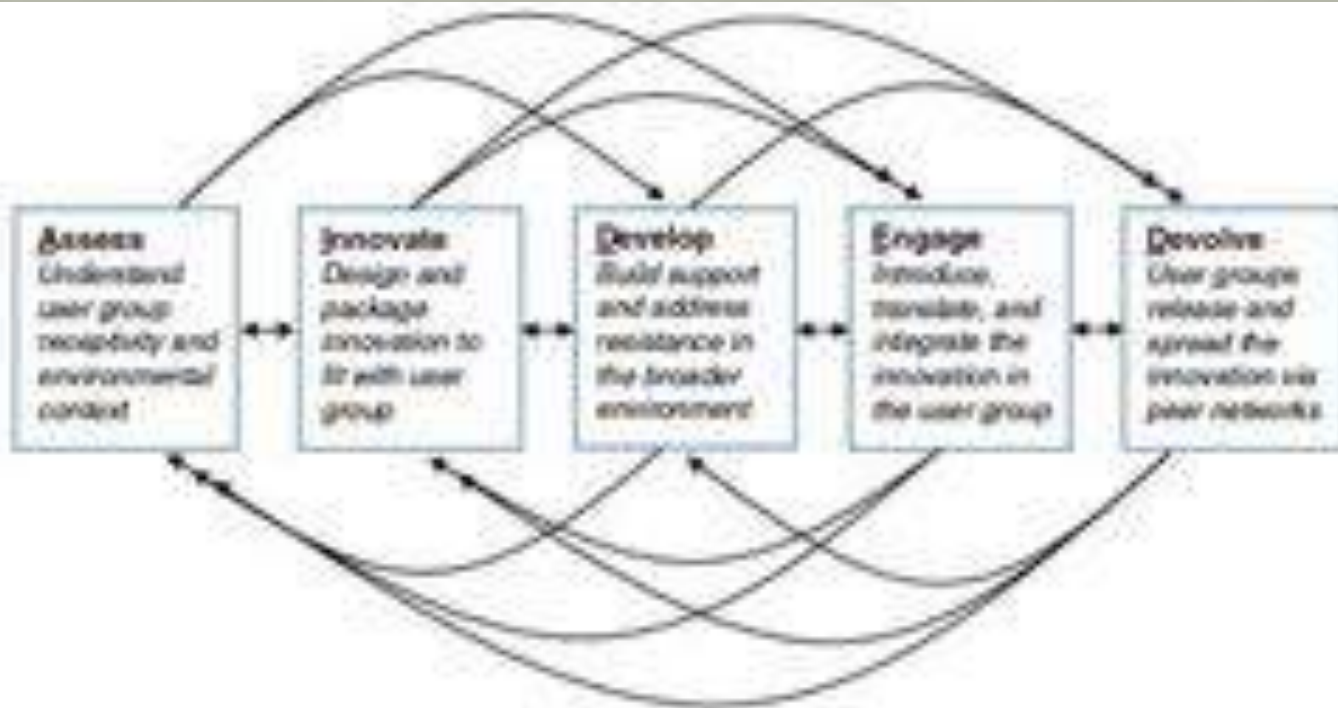
Simmons et al (2014). Patient engagement as a risk factor in personalized health care: a systematic review of the literature on chronic disease. *Genome Medicine*, 6, 16.

Understanding the impact of personalized health must be considered from the perspectives of those who receive it and those who provide it.

Researching & integrating personalized medicine

- **The challenges of integrating personalized medicine require systematic planning, training, & evaluation**
- **Future research must include multiple lenses – triangulation of data & methods**

The Aided Model



Curry et al (2013). Scaling up depot medroxyprogesterone acetate (DMPA): a systematic literature review illustrating the AIDED model. *Reproductive Health*, 10, 39.

The Aided Model

ASSESS: understand user group receptivity & environmental context

INNOVATE: design & package innovation to fit with user group

DEVELOP: build support & address resistance in the broader environment

ENGAGE: introduce, translate, & integrate the innovation in the user group

DEVOLVE: user groups release & spread the innovation via peer networks

Curry et al (2013). Scaling up depot medroxyprogesterone acetate (DMPA): a systematic literature review illustrating the AIDED model. *Reproductive Health*, 10, 39.

Mixed Method Research

... especially important in underserved populations or areas of science poorly understood

What are the patient and provider experiences of integrating personalized medicine in the immediate context and over time?

MIXED

- Quality of phenomena
- Inductive
- Natural setting
- Purposeful sampling
- Depth
- Text based

METHODS

- Quantity of phenomena
- Deductive
- Experimental setting
- Random sampling
- Breadth
- Numeric



Contents lists available at ScienceDirect

Medical Hypotheses

Journal homepage: www.elsevier.com/locate/mh



The EPIC hypothesis: Intrapartum effects on the neonatal epigenome and consequent health outcomes

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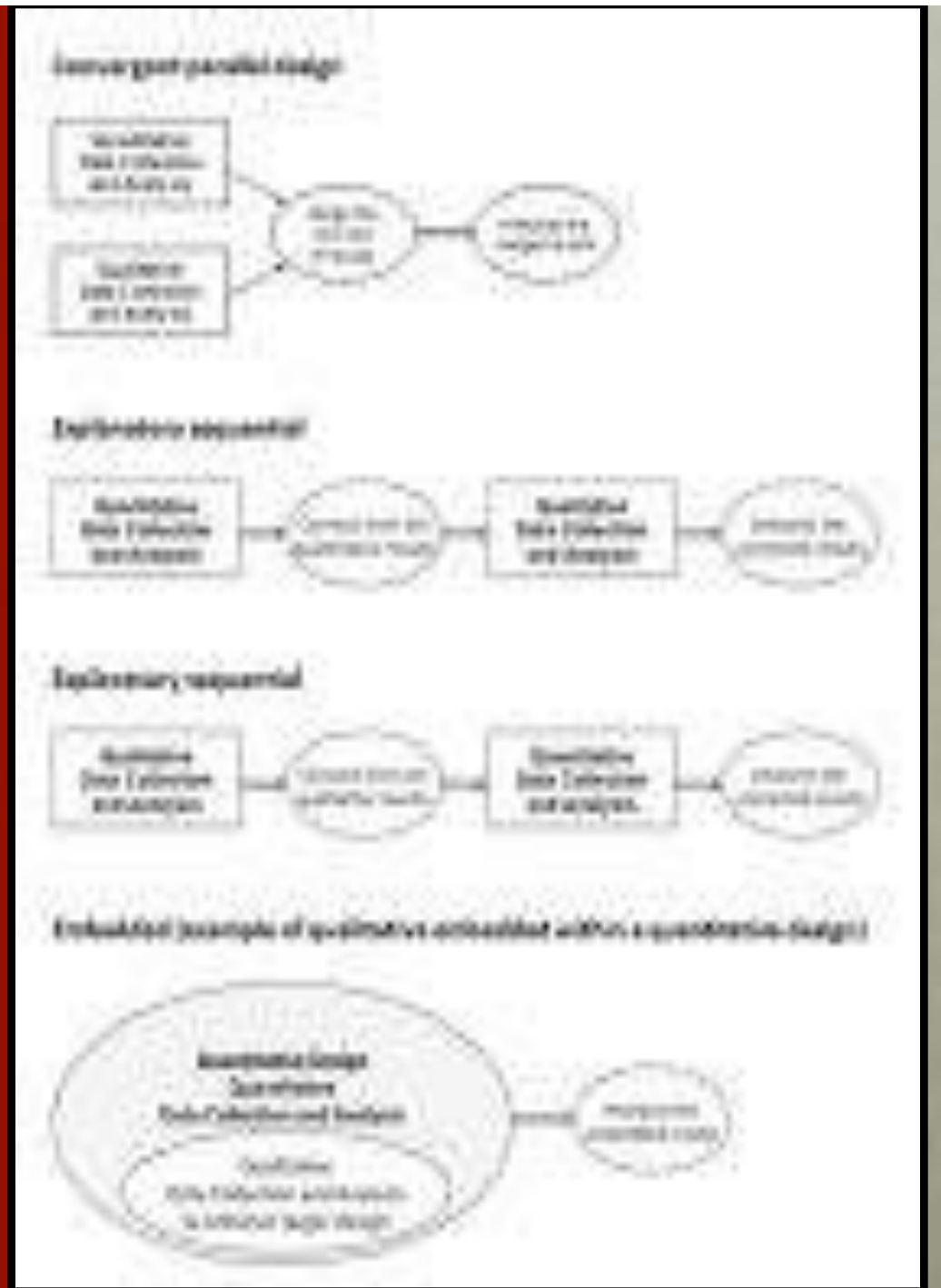
⁸University of Central Lancashire, Preston, Lancashire PR1 2BE, UK

Characterize patterns, interactions or perceptions, inductive hypothesis development

Dahlen, Kennedy et al 2013
Medical Hypotheses

Major mixed methods research designs & approaches

Curry et al (2014). Mixed methods in biomedical and health services research. *Circulation* 6d Cardiovascular Outcomes, 15, 119.



Summary

- **Preparation & training**
- **Triangulation of data and methods**
- **Engagement of patient & family – requires investment of time, tolerance of uncertainty**
- **Systematic creation of practice frameworks for personalized health care and networks to assist clinicians & patients manage the growing knowledge for clinical decision making**
- **Ongoing evaluation**

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Curry et al (2013). Mixed methods in biomedical and health services research. *Circulation: Cardiovascular Quality & Outcomes*, 6, 113.

Dahlen et al (2013). The EPIIC hypothesis: Intrapartum effects on the neonatal epigenome and consequent health outcomes. *Medical Hypotheses*, 80, 656.

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