

**This year thousands of men
will die from stubbornness.**

NO WE WON'T

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American Heart Association





Medication Adherence Initiatives

International Association of Providers of Aids Care

2013 Meeting in Miami

June 3, 2013

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Conflicts & Disclaimer

- No personal or financial conflicts to disclose
- Views and opinions are my own and do not reflect those of AHRQ or DHHS



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CERTs Collaborative Project Steering Group



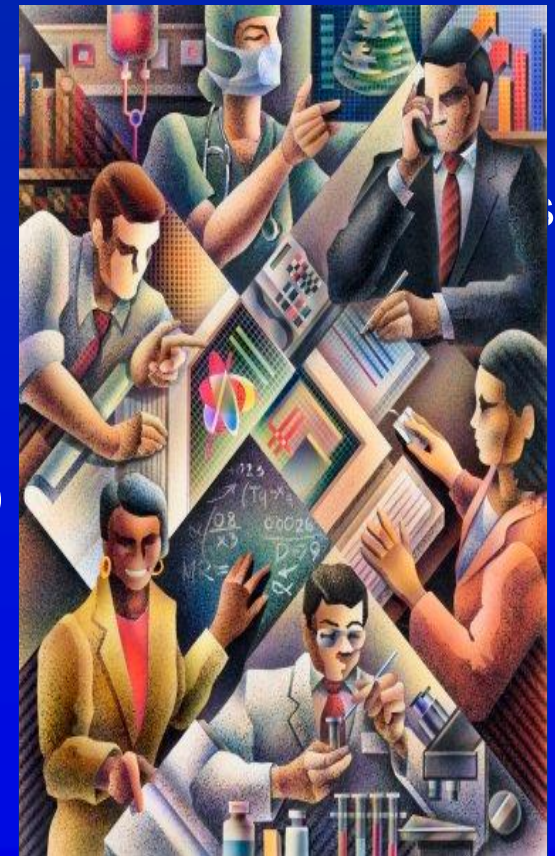
Presentation Outline

- AHRQ
- Adherence and its significance
- Adherence Highlights
 - Systematic Review Comparing Interventions
 - Ongoing work of the Centers for Education and Research on Therapeutics (CERTs)
- Resources and Follow-up



AHRQ Background

- Research & dissemination to promote the quality, safety, effectiveness and efficiency of health care for all Americans
- ~350 employees, ~\$380 M/yr funding
- Diverse portfolios of research &
 - Effective, evidence-based health care & Preventive services (USPSTF)
 - Patient Safety (med error & HAI prevention)
 - Data systems to assess patterns, costs, and satisfaction with care (MEPS, HCUP, CAHPS)
 - Health Information Technology
 - Knowledge transfer & outreach





Adherence & its Importance in Health Care

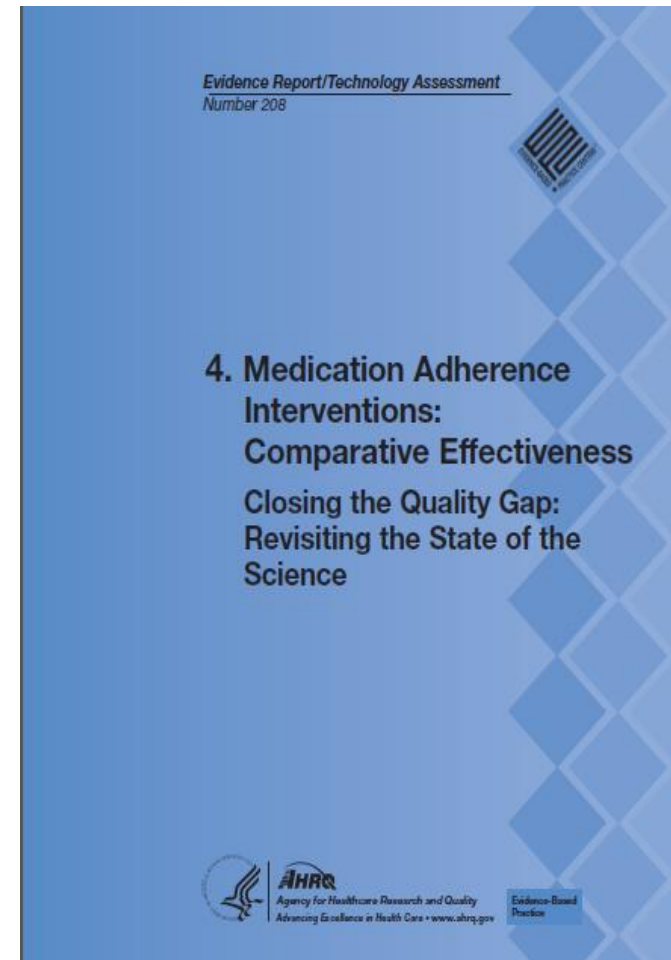
- 20 . 30% of Rx never filled; 50% not taken as prescribed
- Leads to 10% of hospitalizations and 125,000 deaths annually
- Estimated \$100-289 billion annually



An opportunity to improve patient outcomes, quality of care, and health care costs

Adherence Activities of AHRQ

- Since 2012, more than 50 investigator-initiated grants, conferences, or projects within programmatic grants like the CERTs
- Initial funding of National Consumers League development of %Script Your Future+campaign
- Recent systematic review on the Comparative Effectiveness (CE) of Medication Adherence Interventions





Scope of Medication Adherence Interventions Examined for CE

- Focus on self-administered medication for chronic diseases
 - Excluded infectious conditions (e.g. PID, TB, HIV), mental illness involving psychosis, mania, or bipolar disorder, and medications for substance abuse
- Examined 2 types of interventions
 - Directed at patients, providers, and systems
 - Directed at policy
- Examined 3 areas of impact
 - Medication adherence
 - Patient outcomes: biomarkers, morbidity, mortality, quality of life, satisfaction
 - System outcomes: health care utilization, quality of care



Systematic Review Approach

- Rigorous, public methods to assure quality, transparency, objectivity, and credibility of the review process *
- Evaluates the strength of evidence based on its consistency, directness, precision, and risk of bias
- Strength of evidence reflects the degree of confidence that the effect seen is true and that its estimate is
 - . Unlikely to change with more research HIGH
 - . May change with more research MODERATE
 - . Likely to change with more research LOW
 - . No evidence or cannot estimate INSUFFICIENT

*<http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=318&pageaction=displayproduct>



Findings: Medication Adherence Comparative Effectiveness

- 33 of 62 trials of patient, provider, & systems interventions found statistically significant improvements in medication adherence but
 - No one magic bullet
 - Limited evidence on long term adherence or changes in health outcomes
 - Taxonomy of interventions was poor
 - Standardized, objective measures of adherence were lacking

Poor taxonomy & standardization weaken the overall body & achievable strength of evidence



Findings: Medication Adherence Comparative Effectiveness

- Most interventions had low/insufficient evidence, but a select few had moderate SOE of effectiveness
 - Asthma self-management had improved short-term adherence
 - Depression
 - case-management benefited adherence and symptom improvement
 - Collaborative care helped adherence but only with phone + in-person efforts and NOT in depressed HIV patients; moderate benefit seen in patient satisfaction with quality of care



Findings: Medication Adherence Comparative Effectiveness

- Direct comparison of shared decision-making versus clinician decision-making in 1 study of asthma found low strength of evidence for
 - Improved medication adherence
 - Improved biomarkers

Insufficient /no evidence seen for differences in asthma morbidity and mortality

Policy Interventions

- Improved Rx drug coverage policies show moderate SOE to benefit adherence
- One RCT of no copays (MI FREEE) found improved patient outcomes, reduced patient spending, and total cost neutrality to the insurer



Time for a New Approach to Adherence ?

- Most interventions are knowledge-based and aimed at changing patient behavior to follow prescribers' orders+
- Patients' perspectives missing or secondary to providers'
- Relative success of more interpersonal approaches, such as shared decision-making raised a hypothesis:

Would a patient-centered approach offer fresh ideas and opportunities for improvement?



Patient-Centered Medical Home and Care

- PCMH under active exploration as a means to improve the coordination, quality, and patient experience of health care
- Defined by IOM: Care that is respectful of and responsive to individual patient preferences, needs and values, and ensures that patient values guide all clinical decisions





A New Opportunity for Innovation in Adherence?

- Improving adherence offers promise for improving outcomes, quality, and costs at the same time
- Data suggest that personalized approaches to adherence hold special promise
- Growing interest in patient-centered care and medical homes
- Many interested organizations (NCL, CMS, NCPIE, NEHI, PQA, others) for partnerships and synergy
- A network of therapeutics researchers seeking to collaborate, contribute, and partner with others to optimize therapeutics use

Enter the CERTs...

Centers for Education and Research on Therapeutics



CERTs in Brief

- A research and education grant program legislated by Congress since 1999 with a mission to conduct research and provide education that will advance the optimal use of drugs, medical devices, and biologic products
- Funded by public and private sources with core AHRQ support
- Consists of 6 research centers, a Coordinating/Scientific Center or Forum, and a Steering Committee with diverse representatives from industry, government, the health care sector, and patients/consumers





CERTs 2011-2016

Research Centers

- Brigham & Women's Hospital: *Health Information Technology*
- Cincinnati Children's Hospital Medical Center: *Quality Pediatric Care*
- Duke Clinical Research Center: *Cardiovascular Disease (HF, Afib, HTN, ACS)*
- Rutgers University: *Mental Health Therapeutics*
- University of Alabama, Birmingham: *Arthritis and Musculoskeletal Disorders*
- University of Illinois, Chicago: *Tools for Optimizing Medication Safety*

Scientific Forum/Coordinating Center

- Kaiser Permanente Center for Health Research: *Scientific Forum and Coordinating Center*
 - Responsible for leading/supporting CERTs-wide collaborative project



CERTs Aims



- **To increase awareness** of both the uses and risks of new drugs and drug combinations, biological products, and devices, as well as of mechanisms to improve their safe and effective use.
- **To provide clinical information** to patients and consumers; health care providers; pharmacists, pharmacy benefit managers, and purchasers; health maintenance organizations (HMOs) and health care delivery systems; insurers; and government agencies.
- **To improve quality while reducing cost of care** by increasing the appropriate use of therapeutics and by preventing their adverse effects and consequences of these effects (such as unnecessary hospitalizations)



Initiation of CERTs Collaboration on Medication Adherence

- Group brainstorming and priority-setting of potential collaborative activities
- Shaped by expertise and feasibility of contributions by research centers & the Scientific Forum Center
 - Many Centers pursuing independent projects on or related to adherence projects
- Adherence offered special opportunities to
 - Build upon gaps identified in the CE Evidence report
 - Engage multiple, diverse partners to improve outcomes and lower costs of care
 - Meld social science, epidemiology, & health services expertise of the CERTs



Collaborative Project Steering Group

Patients + members of CERTs Centers representing

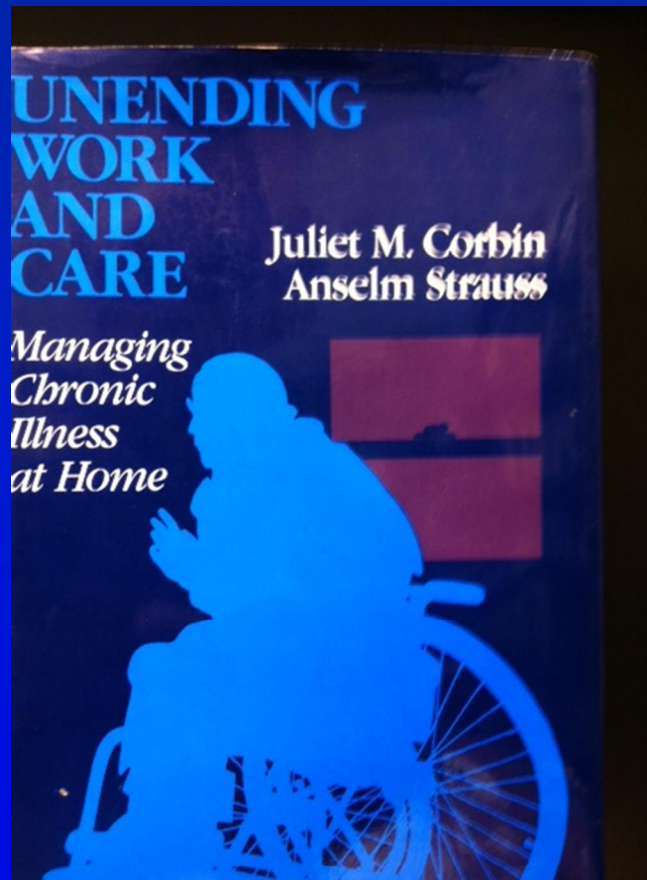
- Medical anthropology
- Community psychology
- Research psychology focusing on self-management behaviors
- Pharmacy and pharmacoepidemiology
- Economics and health services research
- Medical informatics
- Clinical care of complex patients involving shared decision-making about medications



Development of CERTs- Wide Medication Adherence Project

- Redefined the topic as %Patient-Centered Medication Management+ to avoid pejorative connotation of %adherence+
 - Developed a 4 component framework for organizing literature review and discussions
- Used ethnographic accounts of chronic illness to challenge & expand the concept of %patient-centeredness+
- Organized and convened an October 2012 agenda-setting workshop of diverse stakeholders, experts
- Now preparing a publication and follow-up activities

Two Foundational works on the Ethnography of Chronic Illness



Both by Corbin & Strauss
(1988 book and 1987 paper in
Res Sociology Health Care)
describe chronic illness in
terms of

- Defining characteristics
- Work of care
- Integrated psychosocial aspects of illness/health %BC Model+

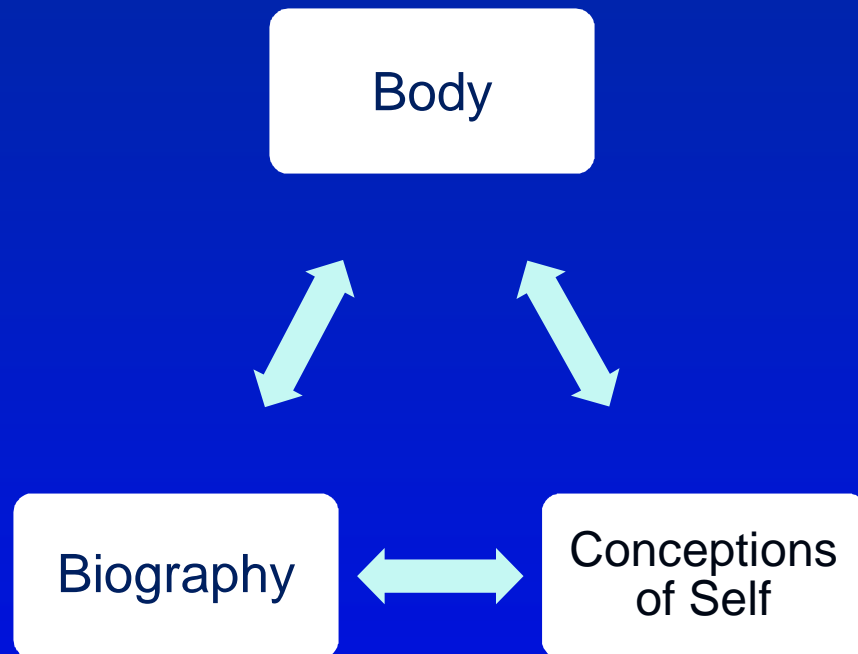


Defining Characteristics of Chronic Illness (Corbin & Strauss)

1. Home
 2. Quality of life
 3. Lifelong Work
 4. Phases
 5. Variability of work by phase
 6. Illness, household and biographical work
 7. Arrangements
 8. Variability of arrangements
 9. Continuous rearrangement
 10. Work of health professionals only part of overall work
 11. Articulation of lay and professional work
 12. Concept of trajectory
- In short, paying attention to medication taking is a very small part of a patient's chronic illness experience**

BBC Chain of Self-Regulation

(Corbin and Strauss)



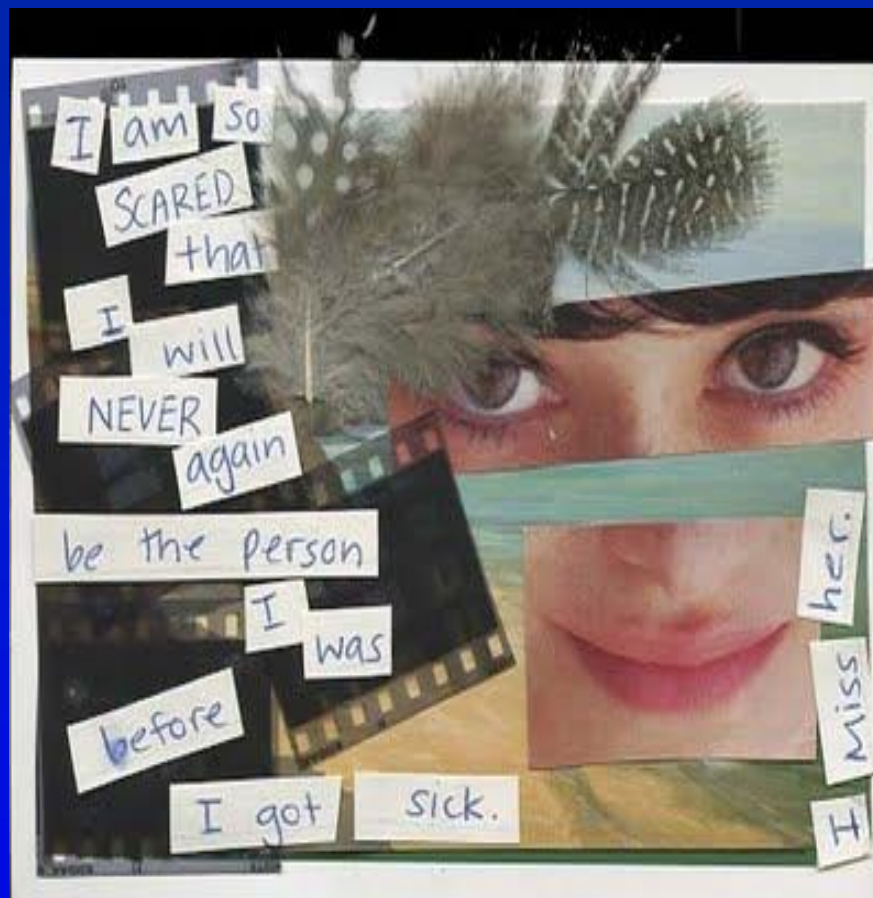
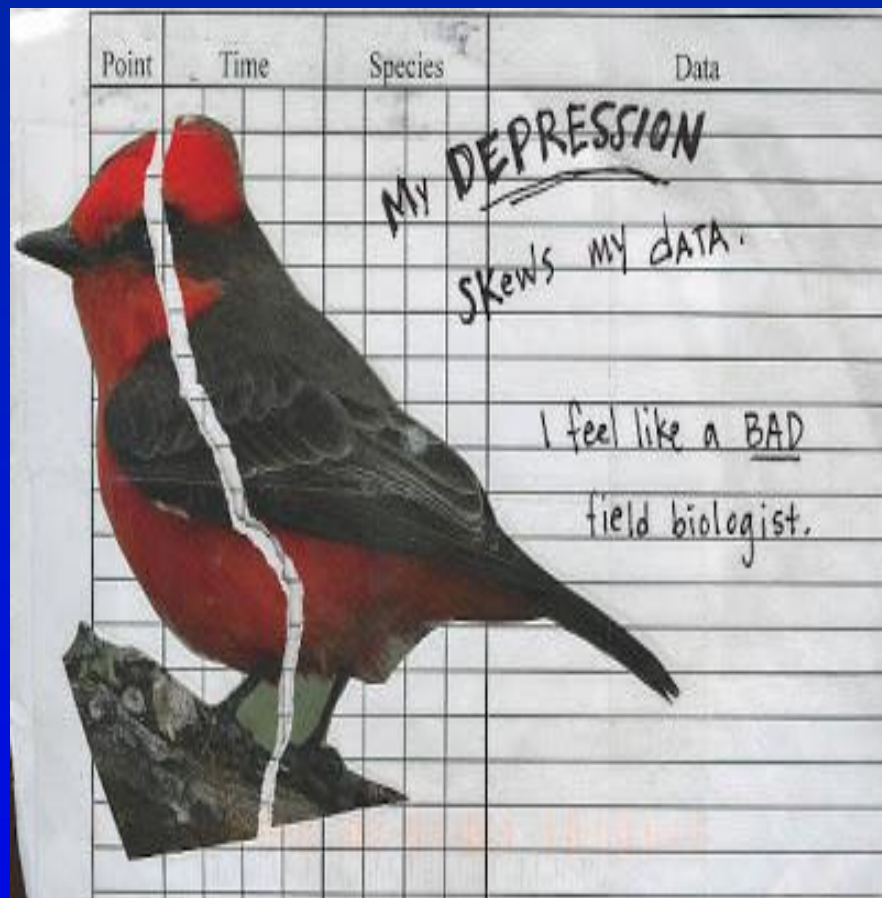
Alignment & stability are major drivers in illness and in health

“Biography: your story (job or profession, schooling, family structure, relationships, etc.)

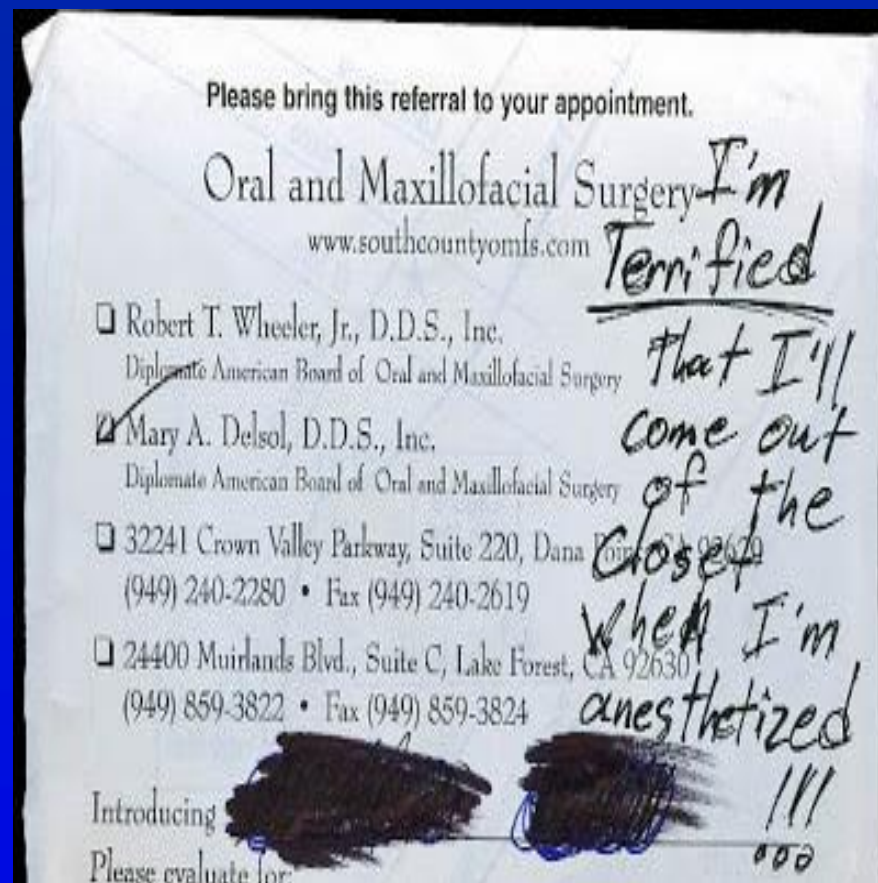
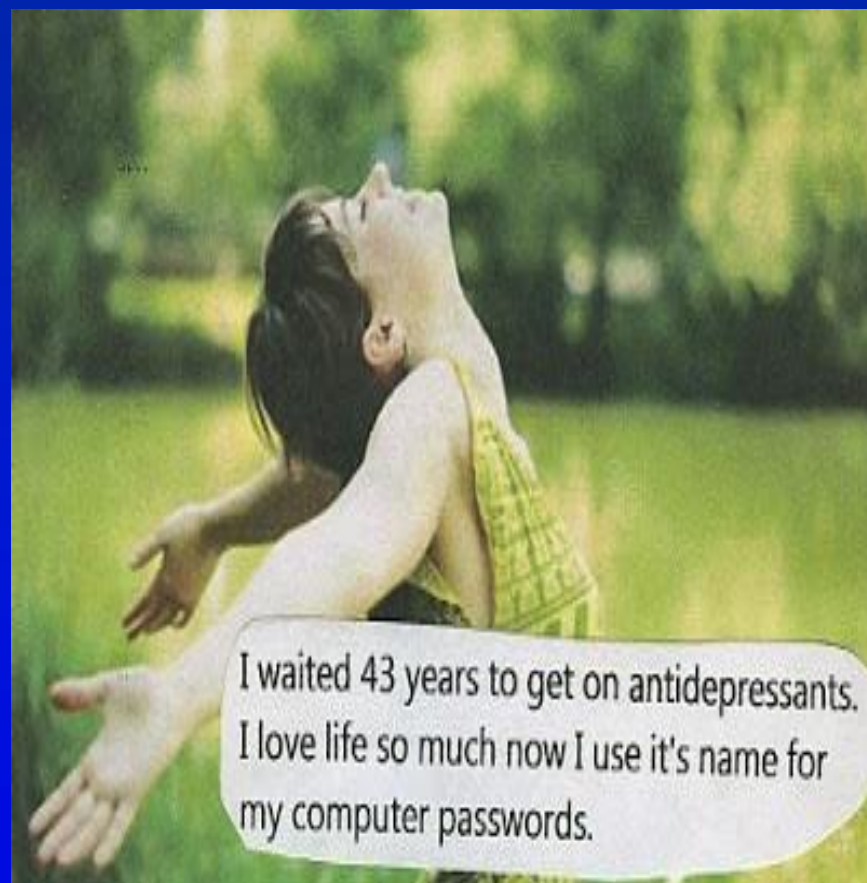
“Self-concept: the kind of person you believe yourself to be (personality, values, autonomy, etc.)

“Disruption of any component is destabilizing

Illness Can Affect Biography and Self-Conception



Medication Also Affects Biography and Self-Conception





Illustrative Case Study

- Dr. Suzanne Koven in Boston Globe 4/22/13
<http://www.bostonglobe.com/lifestyle/health-wellness/2013/04/21/practice-why-patients-don-always-follow-orders/6HRxBeEuLf7jCk2pu7ilKP/story.html>
- Well-educated, capable man who for many years avoided taking medications for his HBP and did not manage his multiple risks to develop diabetes
- Went on to develop diabetes and symptoms but still non adherent with meds and weight loss
- Later changed, lost weight, took his meds, brought DM and HBP under good control, and when asked what changed, wrote " .



Case Study: Behind resistance...

- %Taking a pill everyday to solve a health problem feels like a defeat, while solving the problem through behavior/diet feels like a success+
- %A basic mistrust [of] large marketing effort trying to push a drug on me.+ related to mistrust of pharmaceutical companies.
- %A regimented routine+ %feels confining and defeating+to my %spontaneous, creative, streak.+



Case Study: Overcoming resistance...

- Symptoms finally caught up with me, in the form of extreme fatigue—circulatory problems— even impacting my ability to think clearly+
- Above + knowledge of DM in my family (including a relative with both legs amputated) started making me have anxiety over what was in store. I had a vivid dream of a guy with no legs in a wheelchair. When I work up, I realized this was me in the future if I didn't do something drastic.+
- Gained a more balanced perspective on my distrust of pharmaceutical companies and—marketing. There is truth in my concerns, but it doesn't mean the profit motive doesn't also have a desirable effect, i.e. creating medications that actually solve problems. %



Ethnography Implications for Addressing Adherence

■ Chronic illnesses

- Are burdensome to manage with other life tasks and responsibilities
- Vary in their impact and burdens over time
- Show medication taking to be a minor component in the larger context of the chronic illness experience

■ Body/Biography/Conception of Self

- Alignment of these is a driver of behaviors
- Chronic illness often disruptive; meds can disrupt or stabilize

- Hypothesis: Effective self regulation, including medication management, will be positively influenced by regimens that restore or maintains the integrity of the BBC chain



October 2012 Workshop Preparation

- Developed a 4 component framework for patient-centered medication management that encompassed provider behaviors, including their communications with patients
- Reviewed literature for studies using patient-centered medication management framework
- Planned and convened presentations and small group brainstorming sessions in a 2 day workshop with patients, representatives of health plans, insurers, researchers, pharmaceutical industry, & others
- Small group suggestions were arrayed, voted upon, and prioritized and workshop discussions analyzed for content and themes

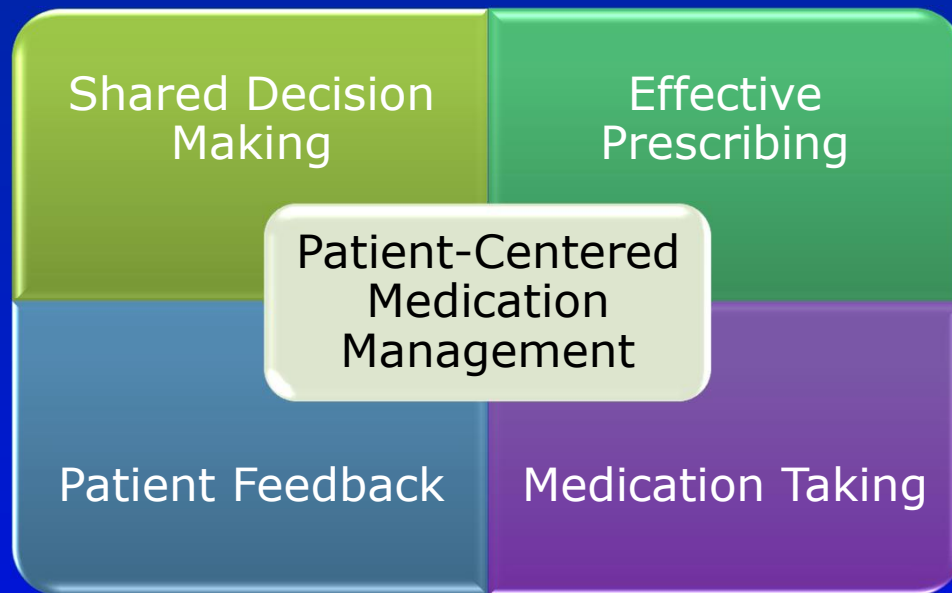


Workshop Consensus and Potential Research Directions

- All patient representatives wholeheartedly supported the authenticity of the ethnographic picture of chronic illness
 - Medicines part of a much larger picture & can contribute challenges in coping and self-management
- Patient-centered approaches to taking medicines need to consider patient beliefs, values, goals, and other concerns
 - Cultural changes in health care delivery will be necessary
 - Measures are needed to capture the critical interpersonal aspects of health care that drive patient choices and behaviors
 - Medication adherence needs expand its focus beyond the patient's act of taking a medication or not



Patient Centered Medication Management Model



MT: Extends adherence to include health system, provider, & other interventions to assist patients in medication-taking

SDM: Patient-specific values and mutuality used in weighing therapeutic choices and prescribing decision

EP: Knowledge transfer & communication to assure patient's ability & confidence of what to do & expect with a drug

PF: Patient Feedback: Means and ability for patient to contact provider with questions, unanticipated problems or side effects that may modify the treatment plan if necessary



Initial Workshop Recommendations for Patient-Centered Medication Management

- **All:** Educate clinicians and patients on the value and skills of PCMM
 - To appreciate the context, complexities, and personal challenges of illness & its management
 - To enhance provider-pt communications & trust
 - To foster a supportive healthcare system for patients
 - To communicate information in a meaningful way
- **Patients:** incorporate peers, family, and social networks in medication management
- **Non-patients:** A toolbox of personalized approaches to use in improving PCMM



Next Steps for CERTs

- Submit a manuscript for publication on the workshop proceedings and recommendations
- Disseminate findings to other adherence efforts and initiatives
- Further development of PCMM with partners



Follow-up/Resources

- Medication Adherence Interventions: Comparative Effectiveness Systematic Review
Manuscript <http://annals.org/article.aspx?articleid=1357338>
Full Report <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-andreports/?pageaction=displayproduct&productid=1249>
Webinar to be posted soon at
http://obssr.od.nih.gov/scientific_areas/health_behaviour/adherence/webinars.aspx
- Patient-Centered Adherence is an Oxymoron: Self-Regulation of the Lived Experience of Chronic Illness (ethnography)
http://obssr.od.nih.gov/scientific_areas/health_behaviour/adherence/webinars.aspx
- Interest in CERTs development of patient-centered medication management
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Thank you! Questions?



Backup Slides



AHRQ Grants in Adherence - 2012 to present

- Targeting medication nonadherence using mobile phone based tailored messaging
- Promoting Adherence to Improve Effectiveness of Cardiovascular Care
- Tools to Reduce Infant RSV Morbidity and Asthma: Use, Adherence and Effectiveness
- Predictors of Medication Adherence Among African Americans With Hypertension
- Drug Insurance, Medication Adherence, and Subsequent Outcomes Among Seniors
- Randomized Study of a Depression Decision Aid on Patient Knowledge, Patient Involvement in Decision-making and Decision-making Quality, and 6-month Measures of Medication Adherence and Mental Health