

MEDICATION ADHERENCE MEASURES, INTERVENTIONS AND MOBILE TECHNOLOGY

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Disclosure

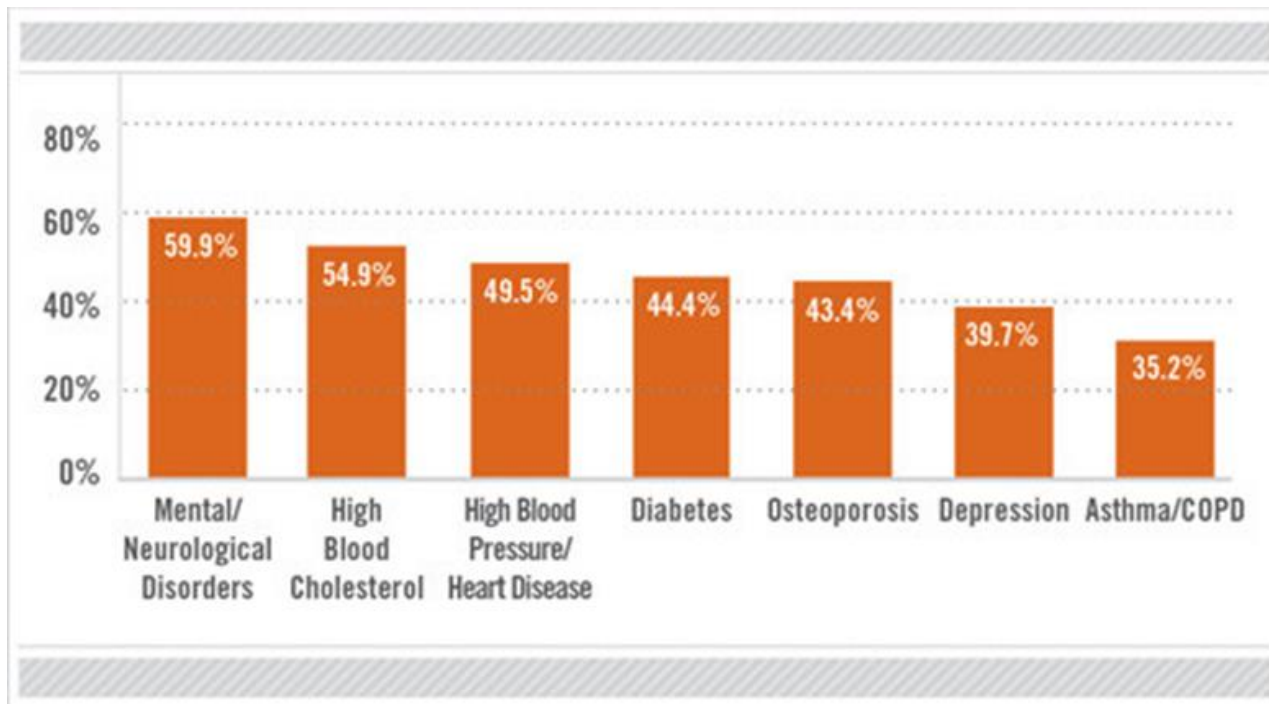
- ❑ Consult and collaborate with private technology companies to design and develop mHealth programs
- ❑ No financial ties: decline any personal payments, honoraria, gifts or stock (will accept funds for conducting research)
- ❑ I often pay them for customization



The Problem



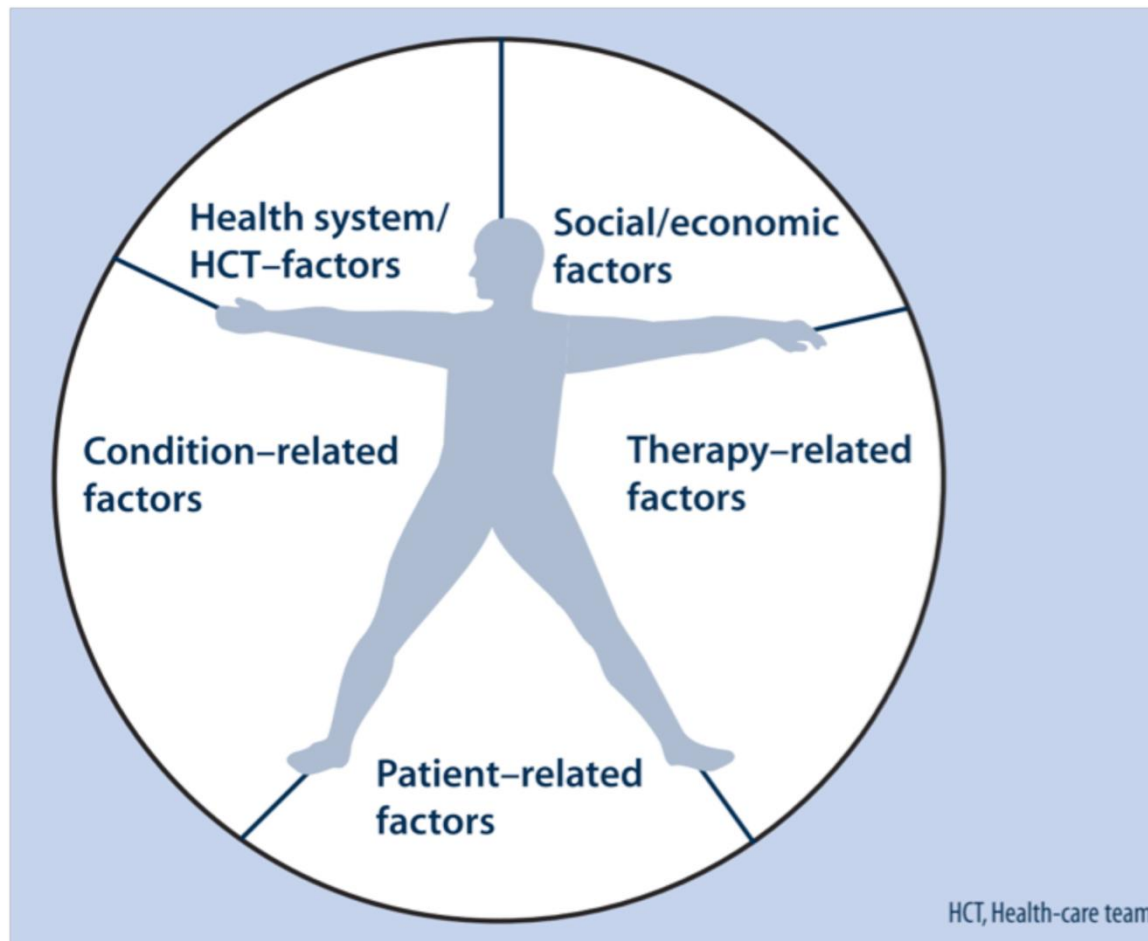
- 3.2 billion annual Rx USA
- 50% not taken as prescribed
- 125, 000 deaths yearly
- \$300 billion yearly



Adherence for the top Medicaid drug classes 2011 Express Scripts Data (80% Medication Possession Ratio)

Multi-factorial Problem

Five Dimensions of Adherence



Challenges of Measuring Adherence

Method	Advantages	Disadvantages	Comments
Provider assessment	<ul style="list-style-type: none">▪ Simple, cheap, requires no structured tool	<ul style="list-style-type: none">▪ Subjective, communication varies, inaccurate, estimates affected by doctor-patient relationship	<ul style="list-style-type: none">▪ May over/under estimate adherence▪ Accurate ~40%
Patient self-report	<ul style="list-style-type: none">▪ Simple, cheap, qualitative assessment possible	<ul style="list-style-type: none">▪ Subjective, inaccurate, poor recall, limited responses for nonadherence	<ul style="list-style-type: none">▪ May overestimate adherence▪ Most widely used
Pill counts	<ul style="list-style-type: none">▪ Simple, cheap, objective	<ul style="list-style-type: none">▪ Pill dumping, pill sharing, timing of doses unknown, bottles needed, time	<ul style="list-style-type: none">▪ May overestimate adherence

Challenges of Measuring Adherence Cont.

Method	Advantages	Disadvantages	Potential Bias
Pharmacy records, Claims data	<ul style="list-style-type: none"> ▪ Objective 	<ul style="list-style-type: none"> ▪ Pill dumping, pill sharing, timing of doses unknown; good records and patient tracking needed 	<ul style="list-style-type: none"> ▪ May overestimate adherence
Drug level monitoring	<ul style="list-style-type: none"> ▪ Objective 	<ul style="list-style-type: none"> ▪ Expensive, requires lab, invasive, unknown timing of doses; PK profile of population needed 	<ul style="list-style-type: none"> ▪ May over/under estimate adherence; depends on behavior prior to test; genetic variations in drug metabolism
Electronic Medication Packaging (EMP)	<ul style="list-style-type: none"> ▪ Objective, timing of doses, monitor long periods 	<ul style="list-style-type: none"> ▪ Pill dumping, pill sharing, limited to the specific system 	<ul style="list-style-type: none"> ▪ May underestimate adherence; taking out multiple doses for later use

Examples of Various Medication Adherence Scales Based on Condition of Interest

Therapeutic Area

Medication Adherence Scales

Metabolic Disorders:
hypertension, dyslipidemia,
diabetes

MAQ (shortest to administer)
SEAMS (assesses self-efficacy)
BMQ (diabetes only)
Hill-Bone Compliance Scale
(hypertension in predominantly
black populations)

Mental Health:
schizophrenia, psychosis,
depression

MARS (schizophrenia and
psychosis)
BMQ (depression)

Abbreviations used:

BMQ = Brief Medication Questionnaire

MAQ = Medication Adherence Questionnaire (also known as the Morisky-4 or MMAS-4 scale)

MARS = Medication Adherence Rating Scale

SEAMS = Self-Efficacy for Appropriate Medication Use Scale

Source: Lavsa SM et al. J Am Pharm Assoc. 2011

Limitations of Measuring Adherence

- ❑ **NO GOLD STANDARD**
- ❑ Specific measure varies by:
 - ▣ Provider: communication, time/access, literacy, empathy, relationship
 - ▣ Patient: demographics, literacy, understanding, attitude, belief, complexity, disease/condition, side effects/benefits, access/cost, social factors
 - ▣ System: access and continuity of care, insurance, records
- ❑ Difficulty choosing the right measure of adherence
- ❑ Identify nonadherence vs. *reasons for nonadherence*

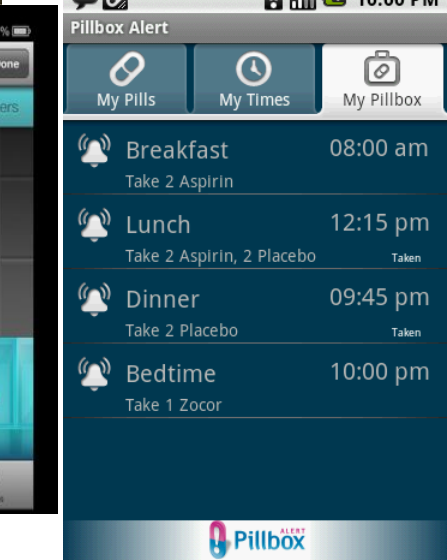
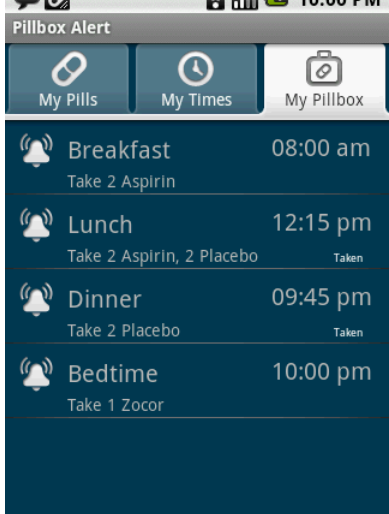
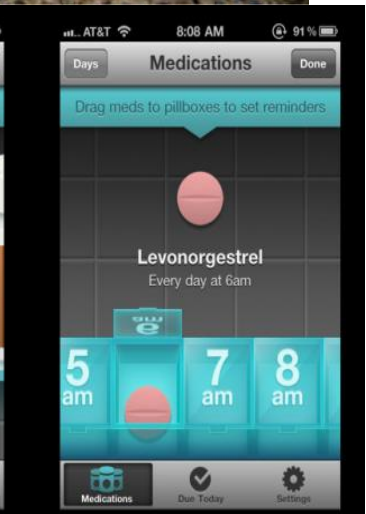
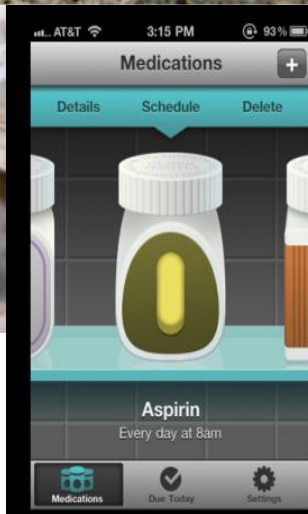
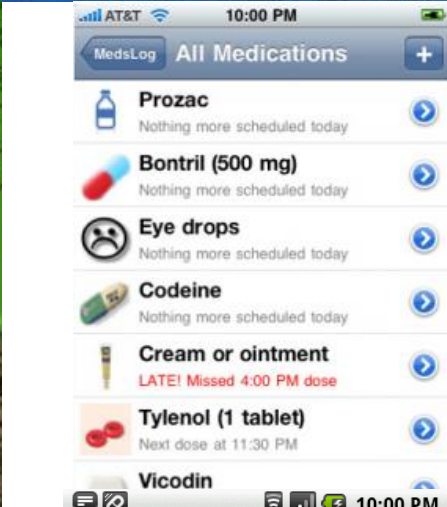
Effective Interventions for Improving Medication Adherence

- **Complex**
- Often delivered by pharmacists, nurses and other allied health care providers
- Intense education, counseling, monitoring and motivational interviewing
- Designed to overcome multiple barriers
- Tailored to support individual patient needs
- Frequent interaction with patients focusing on adherence

Limitations of Interventions for Medication Adherence

- Not fully understanding the details of non-adherence
- Heterogeneity of:
 - ▣ Disease or condition
 - ▣ Patient populations
 - ▣ Interventions
 - ▣ Measures of adherence
 - ▣ Clinical outcomes (or lack thereof)
- Inconsistent effects (higher quality studies needed)
- Coordination between patient, provider and system
- Intervention must be maintained for duration of therapy, integrated into the care system and be cost-effective

Medication Tools and Technology



adoption of technology is accelerating

radio

38 yrs

tv

14 yrs

internet

4 yrs

facebook

3.6 yrs

iphone

2.8 yrs

android

2.2 yrs

google+

88 days

ipad

80 days



What is Mobile Health?

- **Mobile health or mHealth** is a term describing the use of mobile communication devices and multimedia technologies for health services and information (e.g., computers, tablets, mobile phones, communication satellites, monitors and sensors)

Common mHealth Applications

- ❑ Collection of clinical health data (record, send)
- ❑ Providing health information to patients & providers
- ❑ Real-time monitoring of patients (vital signs)
- ❑ Direct provision of care (telemedicine, helpline)
- ❑ Social support and networking (facebook, twitter)
- ❑ Improve medication

mHealth Potential Benefits

- Reduce healthcare costs
 - ▣ Improve communication and efficiency in healthcare systems
 - ▣ Promote prevention through behavior change communication
- Improve health outcomes
 - ▣ Increased access to healthcare and health information
 - ▣ Increase ability to diagnose, manage and monitor conditions

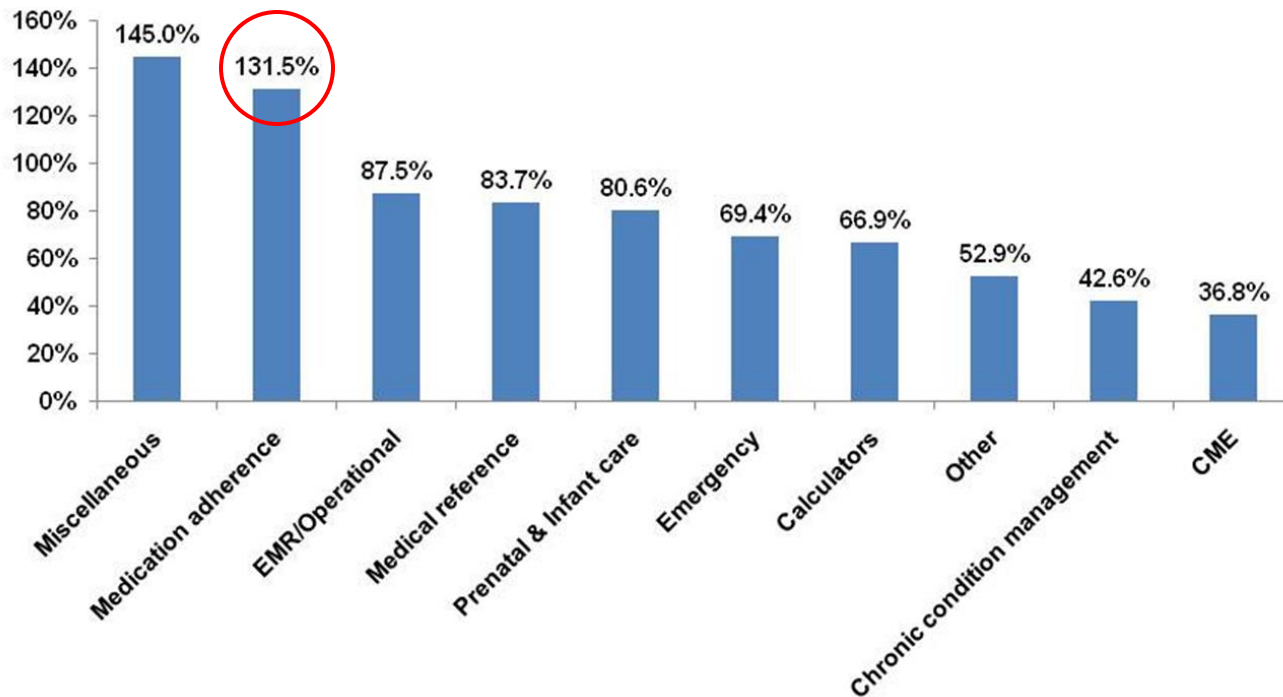
VIEWPOINT

Can Mobile Health Technologies Transform Health Care?

JAMA Published online October 24, 2013

What's Out There?

Medication Adherence Apps Grew Quickly in 2010; EMR, Reference & Babies Also Fast-Growing *% Growth of iPhone Medical Subcategories*



Source: *The Fastest Growing and Most Successful Health and Medical Apps*, MobiHealthNews, November 2010

Patient Perspectives on mHealth

Patient Factors:

- Forget
- Complex/difficult regimen
- Lack of understanding
- Literacy/language
- Motivation
- Clinical outcomes/feedback
- Side effects
- Cost
- Easy, minimal data entry
- Communicate with provider
- Security/privacy
- Technical support

What's Out There:

- Reminders, alarms, calendars
- Pill boxes, blister packaging
- Education, information, pill ID
- Mostly English
- Incentives (\$, social, gaming)
- Self-report, sensors
- Self-report, sensors
- Drug info, education
- Bar code, sensors, QR code
- Limited: text, email, print, none
- SSL, encryption, password
- Limited

Provider Perspectives on mHealth

Provider Factors:

- Interoperability (EMR, Pharmacies, SmartPhone)
- Easy, minimal data entry
- Security (PHI, HIPAA)
- Track medications
- Track clinical outcomes
- Formulary/cost information
- Communicate with patients

What's Out There:

- Software, CCD/HL7, limited HIE agreements
- Limited interoperability, med lists, bar code, sensors
- SSL, encryption, passwords
- EMR, self-report, sensors
- EMR, labs, self-report, sensors
- Drug info, education
- Email, text, phone

Current Limitations and Concerns with mHealth for Medication Adherence

- ❑ Lack of evidence demonstrating benefit (very few evaluations mostly about usability, not outcomes)
- ❑ Security of personal health information
- ❑ Slow adoption (too many choices), poor usability/content
- ❑ Lack of integration within healthcare system
- ❑ Costs, limited resources and technical support
- ❑ Adherence to the app itself
- ❑ Disparities in the use of mHealth by racial/ethnic minorities, older adults and persons with lower health literacy or depression

Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on February 9, 2015.



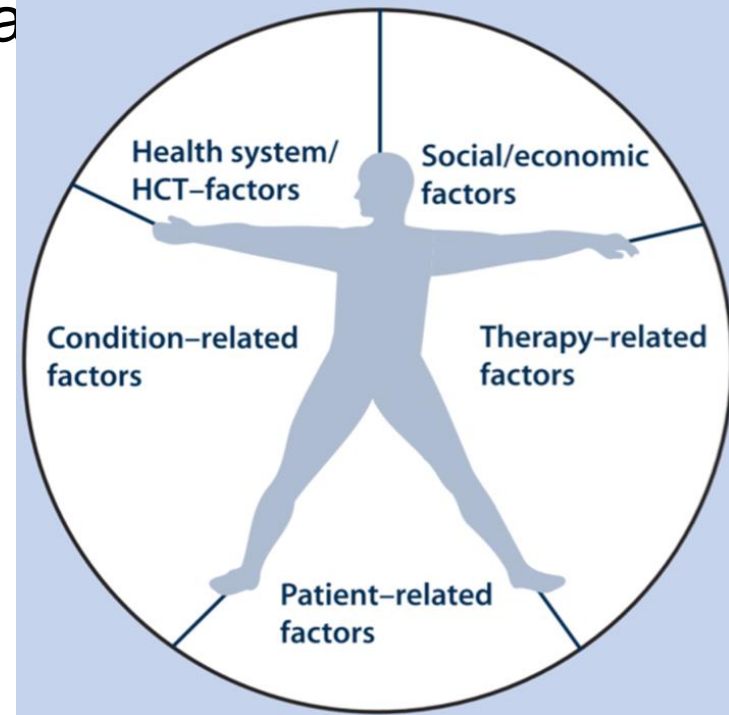
**U.S. Department of Health and Human Services
Food and Drug Administration**

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Opportunities for mHealth

- Patients have multiple factors that need to be addressed
- Providers need interoperability, minimal data entry, securely track medications and clinical
- Patient-provider communication AND engagement
- Behavior change and sustained use
- Part of a multi-factorial intervention
- Simple, customizable, affordable
- Support
- Success!





Questions?