A letter from CRISP

Welcome!

Mobile health (mHealth), the use of mobile technologies in the delivery of health care, is a field that is rapidly expanding. Many mHealth tools are being implemented commercially without prior evaluation to assess their effectiveness. There is growing recognition that more research is needed to examine health outcomes related to mHealth interventions as well as the potential use of mHealth tools in collecting and sharing data in order to improve health outcomes.

In this workshop, we will introduce participants to concepts related to developing, evaluating, implementing and researching mHealth tools, with a focus on web-based tools, text messaging and social media. Participants will learn from local and national experts, various applications for mHealth tools, how to effectively design user interfaces, best practices for mHealth content development, and how to apply mHealth tools to various clinical settings and problems. In addition, throughout the workshop, participants will learn key issues to consider in designing and implementing their own mHealth projects.

This workshop is designed to be relevant to clinicians and public health practitioners with an interest in applying existing mHealth tools, and researchers and developers interested in designing and evaluating new mHealth interventions.

We are excited about the national and local mHealth experts who are part of the workshop. We look forward to your feedback and the mHealth research community we are forging together in Colorado!

Allison Kempe, MD, MPH                                   Amanda F. Dempsey, MD, PhD, MPH
Center Director, CRISP                                      Associate Professor of Pediatrics, ACCORDS

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Planning Faculty: Mandy Dempsey, Sheana Bull, Lisa Schilling, Susan Moore, Dennis Gurfinkel, and Ally Kempe

Collaborating Agencies:
   Center for Research in Implementation Science and Prevention (CRISP)
   Adult and Child Center for Outcomes Research and Delivery Science (ACCORDS)
   Colorado School of Public Health (Colorado SPH)
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Amy J. Barton, PhD, RN, FAAN
Dr. Amy Barton, Professor and Daniel and Janet Mordecai Endowed Chair in Rural Health Nursing, earned a BSN from the University of Toledo, an MSN from the Medical College of Ohio, and a PhD from the University of Florida. As Associate Dean for Clinical and Community Affairs at the University of Colorado, College of Nursing she is responsible for faculty practice and development of community partnerships. She provided the vision and strategic initiative to create Sheridan Health Services, a nurse-managed federally qualified community health center, serving low-income residents in an urban area southwest of Denver, Colorado.

Her publications focus on faculty practice, patient outcomes, quality and safety, and informatics. Her work in national quality and safety initiatives include the Quality and Safety Education for Nurses initiative and the Institute for Healthcare Improvement/Josiah Macy Jr. Foundation initiative on “Retooling for Quality and Safety.” Dr. Barton is a member of the 2005 cohort of the Robert Wood Johnson Executive Nurse Fellows. She is currently chair of the Board of the National Nursing Centers Consortium. She is a member of Sigma Theta Tau International, the American Nurses Association, and the American Medical Informatics Association. She is a Distinguished Practitioner in the National Academies of Practice, and is a Fellow in the Western Academy of Nursing, and the American Academy of Nursing. She received the University of Colorado Denver Chancellor’s Recognition for Promoting and Supporting Diversity as well as alumni awards from the University of Toledo and the University of Florida.

John Bennett, PhD
John Bennett is the Associate Vice Chancellor for Innovation Initiatives at the University of Colorado Denver, where among other responsibilities, he leads the inWorks, a new initiative of the University of Colorado Denver | Anschutz Medical Campus that draws together faculty, staff and students from across the two campuses, as well as entrepreneurs and leaders from industry, government, education and the community, to address problems of importance to human society. The inWorks seeks to create innovative solutions to some of the world’s most challenging problems, while in the process creating life-long innovators.

Bennett was formerly the Archuleta Professor of Computer Science at the University of Colorado Boulder, where he directed the ATLAS Institute, a campus-wide initiative that explores ways in which information and communication technology (ICT) can benefit human society. Prior to directing ATLAS, Bennett was the Associate Dean of Engineering for Education in the College of Engineering and Applied Science. He joined the CU-Boulder faculty in 2000, after serving on the faculty of Rice University for 11 years. Bennett holds MS and PhD degrees in Computer Science from the University of Washington Seattle, and BSEE and MEE degrees from Rice University. After almost two decades of research in distributed and parallel computing, Bennett’s current research interests focus on innovation within the academy, ICTD and STEM education.

Bennett is the past president of the national Governing Board of Engineers Without Borders USA, and is a current member of the Board of Directors of the National Center for Women and IT. He has received several teaching awards, including the Keck Foundation National Award for Engineering Teaching Excellence. Prior to his academic career, Bennett founded and led two successful technology start-ups, and was an Officer in the US Navy. In spare time he almost never has, Bennett restores vintage BMW motorcycles and weaves weft-face tapestries in traditional Rio Grande style.
Sheana Bull, PhD, MPH
Dr. Bull is a Professor and Chair of the Community and Behavioral Health Department in the Colorado School of Public Health. She has spent the past 17 years exploring linkages between the use of technology and health behaviors and health outcomes. Her work includes development and evaluation of programs using the Internet, cell phone text messaging, social media and apps primarily to improve sexual and reproductive health. Currently she directs the mHealth Impact Lab, intended to facilitate a more rapid and responsive evaluation process for digital health developers to build the evidence base for mHealth and digital health.

Amanda (Mandy) Dempsey, MD, PhD, MPH
Dr. Dempsey is an Associate Professor of Pediatrics at the University of Colorado Denver, in the Children’s Outcomes Research program. She has studied pediatric immunization delivery for the last 11 years. She completed a combined MD-PhD program at Vanderbilt University. She then moved to Seattle where she did her Pediatric residency followed by the Robert Wood Johnson Clinical Scholars Program. Her research interests have focused since 2003 on HPV vaccination, parental vaccine hesitancy, agent-based modeling of different vaccine policies and implementation strategies, and developing and assessing interventions to improve vaccine delivery and utilization.

Henry Fischer, MD
Dr. Fischer practices internal medicine at Westside Family Health Center, one of Denver Health’s eight federally qualified community health centers. He has served as Westside’s “diabetes champion” since 2003 and has been the Director of Denver Health’s Diabetes Collaborative since May of 2010. After seeing some of the shortcomings firsthand of the traditional approach to managing chronic disease, Dr. Fischer has focused his endeavors on exploring new modalities for chronic disease management, including the use of text messaging, RN-based algorithmic care, and the use of Health Information Technology. He is currently over-seeing the use of text messaging for appointment reminders, weight loss, flu vaccination outreach, and tobacco cessation as part of Denver Health’s Center for Medicaid and Medicare Innovation grant. As part of an AHRQ infrastructure grant, he is also participating in a project which compares the impact of text message support with a modified Diabetes Prevention Program in patients with pre-diabetes.
Dennis Gurfinkel, MPH
Dennis is a research assistant working with ACCORDS at the University of Colorado, Denver, where he also received his MPH in 2012. He has worked on various health projects at CU and the Colorado Department of Public Health and Environment, including a text messaging program geared at reducing STI and unwanted pregnancies in at risk youth, and has also done work in rural Peru educating local lay health workers.

Alain Labrique, PhD
Dr. Alain Labrique is the founding director of the Johns Hopkins University Global mHealth Initiative, a multi-disciplinary consortium of over 130 projects engaged in mHealth innovation and research across the Johns Hopkins system. An infectious disease epidemiologist, with training in molecular biology and over a decade of field experience running large population-based research studies, Dr. Labrique holds joint appointments in the Department of Epidemiology, Bloomberg School of Public Health, the Department of Community-Public Health in the School of Nursing and the Division of Health Informatics at the School of Medicine. He is lead investigator in several research projects measuring the impact of mobile information and communications technologies on improving maternal, neonatal and infant outcomes in resource-limited settings, primarily in South Asia. Dr. Labrique was recognized as one of the Top 11 mHealth Innovators in 2011. Labrique serves as an mHealth and Technical Advisor to several international and global health agencies, including the World Health Organization, Unicef, USAID and the mHealth Alliance.

Patrick Leonard, CTO
Patrick is responsible for the overall technology vision and strategy for Aetna Innovation and Digital Products. This includes architecture, innovation, security, operations, platform engineering and agile practice for iTriage and Aetna-branded digital products. To this role, Patrick brings a broad range of software and technology leadership in software applications and infrastructure in healthcare and other industries. His experience includes software design and development, architecture, product management, international markets, public policy, professional services and product marketing. He is a recognized expert in the areas of web & mobile application development, parallel programming and SOA, and has written and spoken in publications and events for U.S. HHS, Sun, Intel, Microsoft and IEEE/ACM Supercomputing among others.

Patrick led the architecture and delivery of iTriage technologies from the startup phase through acquisition and the growth phase of the company. Before joining iTriage, he headed technology at Axion Health and Rogue Wave Software. Prior to that, Patrick led the creation of the world’s first web-based ERP system at J.D. Edwards (now part of Oracle) and designed and built custom enterprise systems for Accenture (formerly Andersen Consulting).

He serves on the Public Policy Committee for the Colorado Technology Association (CTA) and advisory boards for No Barriers and 10.10.10 Health
Susan Moore, PhD, MSPH
Susan L. Moore is the Assistant Director of Health Services Research at Denver Health, where she has been involved in research projects concerning the use of health information technology (IT) to improve public health emergency preparedness, patient safety, and care for chronic conditions. Prior to joining Denver Health, Dr. Moore worked in the IT industry for ten years, focusing primarily on implementation and support for software systems and technical education, training, and evaluation. Her ongoing research interests include consumer health informatics, clinical decision support, the application of mixed methods to health systems research, and the use of mobile health technology to deliver patient-centered care.

Jeffrey Nathanson, CEO
Jeffrey is a serial entrepreneur. He is the CEO of Strategic Catalysts a business development advisory service focused on monetizing healthcare innovation.

He currently leads the Colorado Digital Health Ecosystem, through the PrIME Health Collaborative a growing community of more than 500 health care executives, clinicians, technologists, academics, entrepreneurs and investors improving health care outcomes and reducing cost through the commercialization of emerging digital health technologies. He also serves as the Chairman of the Industrial Advisory Board for the University of Colorado CITI-DHC (Center for Information Technology Innovation-Digital Health Consortium). He has co-developed two digital Health companies. FitLogix®, an internet based weight management program utilizing a biometric weight and activity monitoring system & telephonic coaching for National Jewish Health. The business unit currently generates millions of dollars in revenue for the hospital. He also co-created the Emmy award-winning children’s TV show Big Green Rabbit focused on reducing childhood obesity viewed on PBS stations nationwide.

He is currently a member of the steering committee for 10.10.10 Health-ten proven entrepreneurs from around the US; ten market pain points –wicked healthcare problems and opportunities; spending ten days to wrestle down the problems, ending with a few extraordinary, fundable startups.

Jeffrey holds a B.A. degree in Environmental Studies from the University of California, Santa Barbara, and an M.S. Degree in Environmental Management and Communications, from the University of Michigan.
Donald E. Nease, Jr., MD
Dr. Nease is Associate Professor of Family Medicine at the University of Colorado – Denver, where he is Director of Community Engagement and Research for the Colorado Clinical and Translational Sciences Institute, Vice Chair for Research in the Department of Family Medicine and Director of the SNOCAP PBRN Collaborative at the Colorado Health Outcomes Program. He completed medical school at the University of Kansas, residency at the Medical University of South Carolina in Charleston and a Faculty Development Fellowship at the University of North Carolina. Dr. Nease’s work is dedicated to improving health from the level of individual doctor-patient interactions to community and population-based interventions. His research is conducted largely within communities and their primary care practices, most notably in the areas of Chronic Illness and Systems Change.

Steve Ross, MD
Dr. Ross is Associate Clinical Professor in the University of Colorado Division of General Internal Medicine, and a physician informaticist at Health Language, Inc. in the Denver Tech Center. Prior to joining Health Language in 2012, Dr. Ross was the principal investigator in studies of patient-centered health information technology and health information exchange. Dr. Ross’s research projects include open access to clinical notes (SPPARO), which led to studies of a patient portal to assist in diabetes self-care (Diabetes-STAR), and a tablet to assist older adults with transitions of care (Colorado Care Tablet).

Lisa Schilling, MD, MSPH
Lisa Schilling is an Associate Professor of Medicine at the University of Colorado, School of Medicine. She is a practicing general internist, who is also board-certified in clinical informatics. Her research interests are at the intersection of informatics and health services research. She is the PI and Director on the AHRQ-funding Scalable Architecture for Federated Therapeutic Inquires (SAFTINet) project, a distributed research network. She is also directs the Clinical Informatics Core for Adult and Child Center for Outcomes Research and Delivery Science (ACCORDS) and Center for Research Implementation Science and Prevention (CRISP). Her research interests focus on the use of health information technology to improve the quality, safety and efficiency of medical care at the individual patient-, practice-, and population-level. Her informatics interests include standardized terminologies and data interoperability, data modeling, data quality, and the use of integrated data sources to impact health outcomes. She was active in establishing the Colorado’s health information exchange and co-directed the evaluation of the Colorado’s health information exchange project.
Ida Sim, MD, PhD
Dr. Sim is a primary care physician, health information technology researcher, and entrepreneur. She is a Professor of Medicine at the University of California, San Francisco, where she co-directs Biomedical Informatics at UCSF’s Clinical and Translational Sciences Institute. Her research work focuses on computational methods for data sharing and decision making for clinical research and for mobile health. She is also co-founder of Open mHealth, a non-profit organization bridging academia and industry to bring clinical meaning to mobile health data. Other major projects that Dr. Sim is a member of include the Mobile Data to Knowledge NIH Center of Excellence, and the Health eHeart study. Dr. Sim has served on multiple advisory committees on health information infrastructure for clinical care and research, including committees of the National Research Council and Institute of Medicine.

In 2005, Dr. Sim was the founding Project Coordinator of the World Health Organization's International Clinical Trials Registry Platform, where she led the establishment of the first global policy on clinical trial registration, including the development of the Trial Registration Data Set, the common 20-item data set that all registers worldwide adhere to.

Dr. Sim is a recipient of the United States Presidential Early Career Award for Scientists and Engineers (PECASE), a Fellow of the American College of Medical Informatics, and a member of the American Society for Clinical Investigation.

Donald E. Zimmerman, PhD
Donald E. Zimmerman, research professor, Library, Colorado State University, Fort Collins, Colorado, holds a Ph.D. in mass communication research, University of Wisconsin-Madison; and an M.S. in Technical Journalism and B.S. in Biology Sciences, Kansas State University. His research focuses website design; usability testing; environmental, health, and risk communication; and technology transfer. He has been investigator or co-investigator on more than $4 million in grants from EPA, Hewlett Packard, IBM, NIAAA, NCI, National Park Service, and other organizations.

While a professor in CSU’s Department of Journalism and Technical Communication (1976 to 2012), he provided the lead in developing CSU’s Master of Science in Technical Communication and assisted in developing the Ph.D. in Communication and Technology. He served as co-director of CSU’s Center for Research on Writing, Communication, and Technology for 16+ years.

Don has authored or co-authored 125+ referred journal articles and presentations at regional, national, and international conferences; 4 books; and 6 book chapters.

Don has taught technical and science writing, editing, and communication; information design; communication management; and research methods. He has served on more than 125 master’s and doctorate committees in 25 different CSU departments. Prior to joining academia, Don worked in university residence halls, as a newspaper reporter, an Army Signal Officer, and information specialist with the Pennsylvania Game Commission.
Getting the Message Across

Don Zimmerman, Ph.D.
Research Professor
Colorado State University

Objectives

1. Suggest “best practices” for mHealth messages.
2. Provide a framework to consider mHealth message production
3. Introduce key concepts of message design driven by research, theory, & practice
4. Provide references

Framework—1

Communication science develops empirically testable theories to help understand the
- Production
- Processing
- Effects of messages.
(Berger & Chaffee 1987, p. 17).

Framework—2

- Observe & empirically test how
  - Messages are produced
  - Transmitted—i.e., what media/channel
  - Interactions with messages
- Effects of messages
  - How they change or fail to change
    - Behaviors
    - Information levels
    - Attitudes

Framework—3

- Crosses disciplines—i.e., interdisciplinary
  - Psychology
  - Sociology
  - Social psychology
  - Education
  - Linguists
  - Statistics
  - Medical

Framework—4

- Research on how users’ interaction with mobile technology is just beginning
- Research on online information
  - HCI—human computer interaction
  - 1990s
  - [www.usability.gov](http://www.usability.gov) (U.S. Dept. of Health & human Services, National Cancer Institute, 2014)
  - Concepts apply to mobile technologies
Iterative Design: Developing & testing of mHealth Campaigns

- Identify target audience(s)
- Identify key characteristics of target audience(s)
- Select content & design campaign
- Develop, test, revise, test messages
- Use research-based formative evaluations
- Launch mHealth campaign
- Conduct summative evaluations

Team Approach

- Interdisciplinary/ transdisciplinary
- Need diverse skillsets
  - Behavioral science research
  - MDs & medical/ content specialists
  - Communication & education specialists
  - Designers
  - Programmers

Why Use Theory to Guide Research & Development?

- Identifies what works
- Identifies what doesn’t work
- Provides suggestions for
  - Selection of mHealth technologies
  - Message design—i.e., layout, fonts, graphics
  - Message content & slanting
- Learn from others
- Don’t “re-invent the wheel”

Selected Theories—1

- Communication Functions
  - Informational
  - Educational
  - Persuasional
  - Entertainment
    (Schramm, 1972)
- Added function
  - Documentation

Selected Theories—2

- Health Belief Model (Rosenstock, 1974)
- Social Cognitive Theory (Bandura, 1986)
- Diffusions of Innovations (Rogers, 2003)
- Extended Parallel Process Model (Witte, 1995)
- Theory of Reasoned Action/Planned Behavior (Fishbein & Ajzen 1980)
- Message tailoring (Krueger, et al., 2000)
- Education/Entertainment (Singal, et al., 2003)
Role of mHealth Devices—1
• What mHealth devices are part of a health information campaign?
• Who is the target audience?
• Will the target audience
  – Have mHealth devices?
  – Have the needed Internet connection?
  – Be skilled in using the mHealth devices?
  – Will they use vertical or landscape format?
• Where will they use the device?

Role of mHealth Devices—2
• Role of mobile devices
  – Provide information
    • What information?
    • How much information?
  – Encourage/ change behaviors
  – Change attitudes
  – Link to full website
  – Provide opportunity for interactivity?
  – Combination of strategies

mHealth Technology Issues
• Rapidly changing technologies
  – Size of technology
  – Screen sizes
  – Screen resolution
• Programming approaches
  – Individual sites for specific devices
• Responsive design
  – Fits multiple devices

Responsive Design—1
• One website program for
  – Desktop
  – Tablets
  – Smartphones
  – Watches
  – Ubiquitous computing
• Programming reformats screens

Responsive Design—2
• Key programming
  – HTML 5
  – Cascading style sheets
  – Java scripts
• Program
  – Top down—Desktop website to smartphone
  – Bottom up—Smartphone to desktop website
Responsive Design—4

- Content developers and programmers need to work together
- Key issues
  - Advocate for the user
  - Arrangement of screens to be download
  - Placement of copy
    (Peterson, 2014)
  www.lynda.com
  www.usability.gov

Target Audiences: Challenges—1

- Divides
  - Digital—i.e. broadband access
    - Economic levels
    - Ethnicity/cultural differences
    - Urban vs. rural
- Smartphone ownership in households about $75K
  - 90% 18-29 year olds
  - 87% 30-49 year olds
  - 72% 50-64 year olds
  - 43% 65+ year olds
    (Pew, Smith, 2013)

Message Design Rec’d—1

- Check for latest surveys on adoption & use of Internet technologies
- Pew Research Internet Project
  http://www.pewinternet.org/
- Survey target audience(s)?
- Interviews?

Message Design Rec’d—2

- Usability testing
  - Personas
    - Create description of “typical” user
    - Key characteristics
    - Their where they use mHealth devices
    - When they use mHealth devices
    - Their information needs
    - Tasks they need to complete
      (NCI, www.usability, Persona 2014)

Message Design Rec’d—3

- Use theory to develop key messages
- Think about key variables and lessons learned
- Target—i.e., write content with key variables in mind.
Message Design Rec’d—4

- Example:
- Diffusion of innovation, selected key variables:
  - Relative advantage
  - Complexity
  - Compatibility
  - Observability
  - Trailability
  (Rogers, 2003)

Target Audience: Challenges—2

- Expectation of Smartphone users
  - Mobile mind shift
  - Mobile moments
    (Forrester Research, Schadler, Bernoff & Ask 2014)
- Information convenience
  - What they want
  - Wherever they are using mHealth devices
  - When they want the information

Target Audiences: Challenges—3

- Users make quick decision to use or not to use a website based on studies:
  - 50 milliseconds (University students, Lindgard, et al., 2006)
  - 1-2 seconds (18-24 year olds, Akamai, 2010)
  - 3 Seconds (Shoppers, Akamai, 2010)
  - 10 seconds (Diverse users, Nielsen, 2010)

Target Audience: Challenges—4

- Download speeds
  - Hardware
  - Programming, size of website
  - Graphics, audio, video
  - Quality of images (resolution)
  - Location where used/accessed
  - Weather
  - Quality & intensity of signal
    (Everts, 2013)

Message Design Rec’d—5

- Design for fast download speeds
- Design for visual appeal
  - Legible text and easy to scan
  - Graphics—selected use
  - Font selection
  - White space

Message Design Rec’d—6

- Factors influencing download time
  - Interactivity
  - Photographs
  - Audio
  - Video
- Navigation
- Design consistency
- Visual appeal—graphics
- Legible and easy to read
- Font selection
Message Design Rec’d—7

- Place the key message at the top on the Website
- Place the key message in the left or middle.
- Consider the “F” pattern from eye tracking of Websites
  (Nielsen & Pernice, 2010)

Target Audience Challenge—5

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Message Design Rec’d—8

- Simple Smartphone interfaces—positive influence on user satisfaction
  (Cho & Lee, 2012)
- Higher aesthetic features, judged higher credibility
  (Robins & Holmes, 2008; Lin et al., 2013; Gastou, et al., 2011)

Target Audience: Challenges—6

- Text legibility: Shape of words & text
  - 38-42 years old bifocals (Batteman, personal communication, 1982)
  - About 25% college students report trouble reading screens
    (Zimmerman, personal observation)

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Message Design Rec’d —9

- Legibility
  - Contrast between text & background
  - Fonts:
    - Sans-serif over serif fonts
    - Cleartype Consolars & Cambria, Verdana vs. Times New Roman
      (Chaparro, Shaiukh, Chaparro & Merkle, 2010)

Target Audience Challenge—5

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Message Design Rec’d –10

- Text—Selected Research Findings
  - Preference white background/black text
  - No pattern background
    - (McClinotch, 2000)
  - Reading time increased as contrast decreased (Saito, Saito, & Saito, 2010)
Message Design Rec’d—11

• 12 point, functional equivalent  
  (Saito et al., 2010)

Formatting
– Ragged right margins
– Keep paragraphs short
  • 3 to 5 lines
– Use bullet lists  
  (NCI, 2014)

Target Audience Challenges—7

• Cognitive abilities
  – Reading skills?
  – Math skills?
  – Visual processing skills?
  – Health literacy?

• National US Adult Reading Statistics
  – 14% Scored below basic prose skills (30 Million)
  – 25% Scored at basic literacy skills (63 Million)
  (National Assessment of Adult Literacy, 2003)

Message Design Rec’d—12

• Key writing concepts
  – Organization
  – Prose—i.e., body copy
  – Formatting
  – Readability (Comprehension)

Message Design Rec’d—13

• Organize by users’ perceptions
• Usability testing--Card Sorting  
  – “Applied focus group”
  – 75 or so ideas for website
  – Individual cards
  – Have individuals sort into piles
  – Add labels  
  (NCI, 2014; Zimmerman & Akerelrea, 2002).

Message Design Rec’d—14

• Writing—much like writing advertising copy
• Short & tight
  – Writing web content.  
  (Chapter 15, Guidelines, www.usability.gov)  
  (Reddish, 2007)
• Plain Language
  • Plain Language.gov  
  (http://www.plainlanguage.gov/)

Message Design Rec’d—15

• Testing prose/body copy
  – Readability—i.e., comprehension
  – NCI: 8th grade level
  – Readability formulas  
  • Regression formulas
  • Dependent variable (Comprehension, grade level)
  • Independent variables
    – Sentence length—number words
    – Complexity of words—number of syllables
    – Difficult words
Message Design Rec’d—16

- Microsoft Word
  - Using MS Word Help
  - Search for
    - "readability scoring"
  - Readability scoring must be turned on under "Options," then "Proofing"

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Target Audience Challenges—8

- Icons
  - Users may not recognize icons
  - Detailed & concrete icons interpreted correctly (Pappachan & Ziefle, 2008)
  - Younger users prefer visual icons
  - Older users prefer text buttons (Gatsou, Politis, & Zevgolis, 2011)
  - Will icons scale (vector graphics)?
  - Visible on smaller screens?

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Message Design Rec’d—17

- Provide detailed & concrete icons interpreted correctly (Pappachan & Ziefle, 2008)
- Younger users prefer visual icons
- Older users prefer text buttons (Gatsou, Politis, & Zevgolis, 2011)

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Message Design Rec’d—18

- Formatting (scannable)
- Website
  - Wide vs. deep (Parushy & Yulviler-Gavish, 2004)
  - Short paragraphs
  - Ragged right margins
  - Bullet lists
  - White space (Reddish, 2007; Ziefle, 2010)

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Message Design Rec’d—19

- Links
  - Write “high scent”, i.e. descriptive (Warcup, 2002; Zimmerman et al., 2004)
  - Obvious in the design
    - Placement
    - Color (Holtze, 2006)

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Message Design Rec’d—20

- Use formative evaluations
  - Readability scoring
  - Experiments with different messages
  - Usability testing
    - Fraught with pitfalls for the unwary
    - Expert review
    - Protocol analysis
      - Triangulation on data collected

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mHealth Technologies: Regulations and Considerations

Amy J. Barton, PhD, RN
Professor
University of Colorado College of Nursing

Objective
- Examine the regulatory environment for m-health applications in health care.

What is m-Health?

NIH Consensus Definition

What is mHealth?
mHealth is the use of mobile and wireless devices to improve health outcomes, healthcare services and health research.

Food and Drug Administration Statutory Authority
- Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321)

Categories of Health IT Functionality

m-Health Regulation

- Mobile Platform
  - Handheld computing platforms

- Mobile Application
  - Software application that can run on a mobile platform

- Medical Mobile App
  - Used as an accessory to a regulated medical device; or
  - Transforms a mobile platform into a regulated medical device
**When is a mobile app a “device”?**

**Intended Use**

Labeling Claims, Advertising Materials, Statements by Manufacturers or their Representatives

- Diagnosis of disease
- Cure, mitigation, treatment, or prevention of disease
- Affect the structure of any function of the body of man

**What is NOT a mobile medical app?**

- Electronic “copies” of reference materials, teaching aids
- Solely used to log, evaluate, make suggestions about general health and wellness
- Automate office operations
- Generic aids, not marketed for medical purposes
- Electronic health records/Personal health records

**Mobile Medical Apps**

- Display, store, transmit patient-specific medical device data in its original format
- Control the intended use, function, modes, or energy source of the connected medical device
- Transform the mobile platform into a regulated medical device
- Create alarms, recommendations or new information by analyzing or interpreting medical device data

**Device Classifications determine level of regulatory requirements**

- **Safety**
- **Innovation**

“FDA seeks to strike the right balance by providing a risk-based, focused approach to the oversight of a small subset of mobile medical apps that present a potential risk to patients if they do not work as intended.”


**Regulatory Requirements**

- **Class I devices:** General Controls
- **Class II devices:** General Controls, Special Controls, Premarket Notification
- **Class III devices:** General Controls and Premarket Approval

**Legislative Developments in the 113th Congress**

- **H.R. 3303**
  - SOFTWARE
  - Sensible Oversight for Technology which Advances Regulatory Efficiency Act of 2013
- **S. 2007**
  - PROTECT
  - Preventing Regulatory Overreach to Enhance Care Technology Act of 2014
Further Clarification Needed...

- Clarify difference between medical app and wellness app
- Clarify difference between diagnosing and monitoring
- Establish risk-level threshold
- Define limits of FDAs rule on apps that serve as device accessories
- Plan for how to handle "modular" apps

Risk Assessment Framework
Lewis & Wyatt, 2014

New Developments from the Private Sector

FDASIA Recommendations for a Risk-Based Framework

- Promote the Use of Quality Management Principles
- Identify, Develop, and Adopt Standards and Best Practices
- Leverage Conformity Assessment Tools
- Create an Environment of Learning and Continual Improvement

Lessons Learned

1. The current regulatory framework applies to a very small number of mobile medical apps.
2. Providing users with trustworthy apps that are well suited for their purpose is very important (Becker et al. 2014)
Ready to Build a Healthcare App?
You sure?

Patrick Leonard
Denver Startup Week
9.17.14
@patrickleonard

Me in 2009

Me in 2014

What's different about building a healthcare app?

Security, Privacy, Compliance

Combining Different Skill Sets & Languages
Lining It All Up

- **Process**: Agile / Lean
- **Organization**: Vertical / Cross-functional
- **Engineering Practices**: TDD / CI / CD
- **Software Architecture**: Modular / SOA
- **Ops Architecture**: CI / CD / Containerized
- **Culture**: AMP

We’re Hiring

- Mobile Apps Developers (iOS and Android)
- Software Engineer in Test
- Full-Stack Developers (RoR/JS)
- Node.js
- UX/UI Designer with mobile application design experience
- Digital Marketing Specialist
- Engagement Marketing Specialist
- and more...

More Info

- @patrickleonard
- technology.itriagehealth.com
Beyond "There's an App for That"

Ida Sim, MD, PhD
Professor, UC San Francisco
Co-Founder, Open mHealth

www.ucdenver.edu/implementation

Beyond "There's an App for That"

- mHealth shows great promise for reducing health care costs and improving health outcomes
- This promise requires that mHealth data and technologies be used in frontline clinical care
- Current approach focuses on developing and marketing stand-alone apps to consumers, insurance companies, health care organizations, and/or physicians
- This "There's an App for That" approach hasn't worked and won't, because it
  - cuts against the dominant pattern of how clinicians use technology
  - difficult to adapt to patients with multiple conditions
  - locks users in to a self-contained approach that is too rigid for a new and fast-moving field and market

Guiding Principles and Key Terms

- Guiding Principles
  - Open approaches promote the most innovation and rapid exploration for efficacy
  - Data standards are critical for open systems, but cannot be imposed
  - Best approach starts with principled technical design and is pragmatic in defining and demonstrating clinical value
- Key Terms
  - syntactic data interoperation
  - semantic data interoperation

With 6 billion phones in people's pockets worldwide, and 56% of the US owning a smartphone....

...we've seen an explosion of health apps being developed, with >50K apps now in the market place

- most Americans will need more than one app
- need to bring together many different kinds of data, outside of any one app
Clinical Data Visualization and Decision Support

For mHealth data to be clinically useful, clinicians must be able to access that data through the EHR. However, clinicians cannot be expected to sort through different data coming from different apps and sensors in different formats.

Hypertension

- In 2010, HTN was projected to cost the United States $93.5 billion in health care services, medications, and missed days of work.\(^1\)

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Minutes of Moderate Activity

- American Heart Association, American College of Cardiology, Centers for Disease Control and World Health Organization clinical guidelines state:
  - substantial health benefits are obtained from accumulating, in bouts of 10 minutes
    - 150 minutes per week of moderate-intensity (i.e., ≥ 3 METS) or
    - 75 minutes per week of vigorous-intensity (i.e., > 5 METS) aerobic activity or
  - an equivalent combination of both

Physical Activity

FitBit

RunKeeper

Moves
Minutes of Moderate Activity

<table>
<thead>
<tr>
<th>Device</th>
<th>Data Element Name</th>
<th>Data Type/Value List</th>
</tr>
</thead>
<tbody>
<tr>
<td>FitBit</td>
<td>Fairly active minutes</td>
<td>Number</td>
</tr>
<tr>
<td>Movers</td>
<td>Activity</td>
<td>walk, cyc, run or trp</td>
</tr>
<tr>
<td></td>
<td>Distance (in meters)</td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td>Duration (in seconds)</td>
<td>Number</td>
</tr>
<tr>
<td>RunKeeper</td>
<td>Type</td>
<td>Running, Cycling, Mountain Biking,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Walking, Hiking, Downhill Skiing,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cross-Country Skiing, Snowboarding,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skatting, Swimming, Wheelchair,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rowing, Elliptical, Other</td>
</tr>
<tr>
<td></td>
<td>Total_distance (in</td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td>meters)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Distance (in meters)</td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td>Duration (in seconds)</td>
<td>Number</td>
</tr>
</tbody>
</table>

Need to convert duration and distance to METS (ml/kg/min) and add up minutes at >=3 METS

Is the silo problem going away?

Need an Open Systems Approach

1. Open source data schemas: give 3rd party data clinical meaning
2. Open source API wrappers: (e.g. Fitbit, Jawbone, Withings, etc)
3. Open source data storage, processing and dataviz modules

1-stop toolkit! Coming soon!
openmhealth.org/developers

Estrin D, Sim I. Science 2010; 330:759-760

Deja Vu

SNOMED

ICD-10

ICD-9

RxNORM

CPT

LOINC

syntactic data interoperation

data needs to get from one source or device to another (aka the "pipes")
- e.g., from FitBit to Epic, from glucometer to your nutrition app

http://openmhealth.org/developers/overview/

Data aggregators serve as bigger pipes
semantic interoperation

semantic interoperation is preserving the meaning of data when they are shared across applications
- it’s not the pipes, it’s what’s in the pipes

is a blood glucose a blood glucose?

in health care, critical that the clinical meaning of the data be clear
- e.g., random glucose versus fasting glucose

is enhanced if applications say the same things the same way
- unambiguous and understandable
- available (and computable) to 3rd party users far and wide

philosophical approach to data interoperation

imposed standards are difficult to get adopted

Open mHealth provides a common "language" (API spec) for describing the meaning of mHealth data at the atomic data level

our architecture and community is designed to enable best practices to emerge and to be shared

free-for-all schema

in JSON Schema

```json

{  "type": "object",  "fields":  [ { "name": "blood_sweetness", "type": "number" } ] }
```

binding to a standard vocabulary

schema ID: omh:mydomain:FastingGlucose

```json

{  "type": "object",  "fields":  [ { "external_id": ["http://purl.bioontology.org/ontology/LNC/1558-6"], "name": "fasting_glucose", "type": "number" } ] }
```

Standard clinical vocabularies (e.g., for EHR data exchange)
- SNOMED for diagnoses, signs, and symptoms
- LOINC for lab tests
- RxNORM for medications

1A Robust Health Data Infrastructure. JASON Report, 2014.
all using the same dictionaries

best practice schemas

best practice representations of clinically useful measures
- not steps/day but minutes of moderate activity per week
- servings of USDA food groups per day

best practice representations of generic concepts
- time (point and interval based), units, dates, part-of-day, average/min/max, etc.
- metadata
  - UID
  - data origin (self-report or measured)
  - acquisition time

metadata registry

any data source that is Open mHealth compliant guarantees
- atomic data in OmH-compliant JSON
- accessible via OAuth 2.0
- data schema available at registry.openmhealth.org (pending)
- descriptions of meaning needed for clinical sensemaking will be available and computable

new sciences of digital health

Analytics to extract value out of data requires
- definition of clinically useful measures (e.g., mins mod activity)
- data interoperation of clinically useful measures
  - syntactic interoperation (the pipes)
  - semantic interoperation (the meaning)
- support for scientific inferencing and decision support
- data sharing and privacy/security architecture

Physical activity data using Open mHealth

metadata: UID, data origin, acquisition time

omh:mins_mod_activity:
value, external reference to minutes schema
http://purl.bioontology.org/ontology/SNOMEDCT/408581006
Integration into Care Flow

- Device-agnostic access to atomic data, enabling modular data processing and data visualization
- see linqhealth.co

Key Questions to Ask

- What is your clinical use case? Whose problem are you trying to solve (patient, doctor, other)?
  - if for patients, will it work for patients with more than just your target condition?
- Have you tested your solution idea with real clinicians in real care settings? Are you supporting team care (doctors, nurses, patient, family)?
- Are you providing data, an intervention, or both?
  - what data do you need to import or export? from where?
  - what is your approach to sharing data using the fewest development resources possible?
- Are you supporting a learning health care system?

Need New Clinically Useful Measures

- cadence (steps/min)
  - working with RunKeeper
- pulmonary congestion
  - RF sensor with Ohio State
- physical activity correlate of chronic pain
- gait speed for morbidity prediction
- etc.

Connect with Open mHealth

- What kind of researchers should work with Open mHealth?
  - If you are integrating data from commercial sensors
  - If you are defining and testing new measures for physical activity, nutrition, mood/depression, pain, sleep
  - If you want to position your data to be interoperable with the rest of healthcare
- Why should researchers work with Open mHealth?
  - Join a public-private initiative to break down silos in mHealth
  - Help keep focus on clinical value for patients and clinicians
  - Help keep focus on and help advance the science of digital health through high quality and pragmatic informatics and research methodology
  - www.openmhealth.org
  - @openmhealth
  - email@openmhealth.org
Issues to consider in implementing and evaluating mHealth

Sheana Salyers Bull, PhD, MPH

Objectives

• To consider strategies for
  – Recruitment
  – Engagement
  – Implementation management

Gaps in mHealth evidence

• How does it work?
  – Population
  – Modality
  – Length
  – Frequency
  – Engagement

Gaps in mHealth evidence

• How does it work?
  – Technology based data collection tools

Recruitment

• Who is your audience?
• Are there people with disparities facing the condition you are addressing?
• How do people with disparities utilize technology?
  – Internet access? Social Media? Mobile Phones?

Online Recruitment
Getting the **right** target audience

- Internet as adjunct—recruit face to face in community, clinic settings and direct participants to program (“infomediary”)
  - Advantages—can target enrollment, can be systematic in recruitment
  - Disadvantages—doesn’t capitalize on Internet potential for speed and efficiency

- Online panels
  - Harris Interactive has multiple panels of diverse groups
  - Considerations: survey fatigue, “professional” research participant, possible selection bias

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Getting the **right** target audience

- Consider using respondent-driven sampling online
  - RDS could allow you to tap into social networks and have individual participants facilitate recruitment
    - Identify a ‘seed’ and recruit them; then ask them to recruit X number of friends (wave 1) each of these friends can subsequently recruit X friends (waves 2, 3 etc).
    - You need to determine what X will be (3-5) and how many waves (up to 5?)

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Recruitment in social media

- Develop profiles on Facebook and My Space and Twitter
- Establish site for your program
- Recruit friends
- Deliver intervention on social media

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Just Us Tracking Respondent Driven Sampling

Networks generated by seeds randomized to the control arm
Networks generated by seeds randomized to the intervention arm

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Getting the **right** target audience

- Online panels
  - Harris Interactive has multiple panels of diverse groups
  - Considerations: survey fatigue, “professional” research participant, possible selection bias

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Additional Considerations—a preview on retention

• Treat your participants well!
• Touch base often but not too often
• Establish rapport

Things to consider for recruitment

Where?
• Where are you recruiting?
  – Community? Online? Word of mouth?
• How often in each spot?
• What does each different place yield in terms of enrollment?
  – Not only numbers but effectively recruiting the WHO that you want

Who?
• Who is participating?
  – If you want teens, are they enrolling?
  – Adults?
  – Males/Females?
  – Race/Ethnicity?
  – Health Condition?
Recruitment on Facebook

Orientation to TOP® 4ME

• Hybrid SMS program
• An effective pregnancy prevention program (TOP®)
• Implemented with 200 youth aged 14-18 in 8 Boys and Girls Clubs in Metro Denver annually for four years (N=32 clubs; 800 youth)
• Text message component to teens in four clubs with 100 youth annually (N=16 clubs; 400 youth exposed to the “intervention” called TOP®4ME
  • Text messages supplement, enhance and intensify material offered through TOP each week

Engagement

• What are all the elements of your program?
  – Text messaging
    • How many texts? Times of day? Days of week?
    • Do they require a response?
    • Do different text messages generate differential response?

Just/Us
Engagement with Just/Us content

- Average of 43 unique visitors per week—high of 101 during week discussing multiple sex partners
- There were 93 loyal visitors (10% of those enrolled in intervention)
- Average time spent 3.16 minutes—high of 7.3
- 589 posts by peer staff; 277 comments by fans
- Most content viewed through RSS feed

Additional implementation measures

- User satisfaction
  - Qualitative assessments
  - Quantitative assessments

  What did you like? What did you dislike? What would you do differently?

Additional implementation measures

- Numbers of errors
- Time to resolve errors
- Numbers affected by errors
- Any associated impacts on the program
- All unsolicited user feedback

Implementation Management

- What to track once your trial begins

Like · Comment · Share · 😊
Implementation Management

- What to track once your trial begins
  - Page views
  - Amount of time spend on a page/element
  - Click trail
Aitken, M. 2013. Industry report from IMS Institute for Healthcare Informatics

Executive Summary
Little is currently understood about the diverse array of healthcare apps available to consumers, their role in healthcare, the barriers to increasing their recommendation and support from providers, and the requirements for mobile apps to move into the mainstream of healthcare.

This study includes the analysis of the 40,000+ healthcare apps available for download from the U.S. Apple iTunes app store and an assessment of the potential value they provide throughout a patient’s journey. This clearly demonstrates that to date most efforts in app development have been in the overall wellness category, with diet and exercise apps accounting for the majority available. Further an assessment of functionality of available apps finds that healthcare apps available today have both limited and simple functionality - the majority do little more than provide information.

There is a significant skew in download volume for healthcare apps, with more than 50% of available apps achieving fewer than 500 downloads. Conversely, 5 apps account for 15% of all downloads in the healthcare category. The reason behind the limited downloads, and hurdles to improved uptake, span all stakeholders. Patients currently face a dizzying array of healthcare apps to choose from, with little guidance on quality or support from their doctors. Some efforts are underway to help provide professional healthcare guidance in both the U.S. and the U.K. but these are limited in scope and impact to date. Furthermore, apps developed to date do not fit well with the greatest areas of spend in healthcare – those patients facing multiple chronic diseases and typically over the age of 65. These patients are likely to be among the top healthcare spenders but smartphone penetration is lowest among this group, with only 18% of the U.S. population using them, compared to 55% of those aged 45-54 years.

Physicians can see the potential benefits of mobile healthcare apps but remain wary of formally recommending apps to patients without evidence of their benefit, clear professional guidelines regarding their use in practice, and confidence in the security of personal health information that may be generated or transmitted by the app. Payers and employer wellness programs also want clear evidence of benefit before considering reimbursement or promoting the use of apps.

Over time, the app maturity model will see apps progress from being recommended on an ad hoc basis by individual physicians, to systematic use in healthcare, and ultimately to an end goal of being a fully integrated component of healthcare management. There are four key steps to move through on this process: recognition by payers and providers of the role that apps can play in healthcare; security and privacy guidelines and assurances being put in place between providers, patients and app developers; systematic curation and evaluation of apps that can provide both physicians and patients with useful summarized content about apps that can aid decision-making regarding their appropriate use; and integration of apps with other aspects of patient care. Underpinning all of this will be the generation of credible evidence of value derived from the use of apps that will demonstrate the nature and magnitude of behavioral changes or improved health outcomes.

Meeting these preconditions will accelerate the movement of apps use from that of a novelty into the mainstream of healthcare – and realizing their full potential in the years ahead.


Center for Research and Implementation Science and Prevention (CRISP)
CRISP brings together expertise in implementation of preventive services, practice-based research networks (PBRNs) and national authorities in innovative health information technology (HIT). You can find this as well as other workshops and information on their monthly Seminar Series on the CRISP website.

www.ucdenver.edu/implementation

University of Colorado inWorks
A new initiative that draws together faculty, staff and students from across the CU campuses, as well as entrepreneurs and leaders from industry, government, education and the community, to address problems of importance to human society by fostering collaborative innovation and providing extensive facilities for rapid prototyping.

www.inworks.org

Colorado Clinical and Translational Sciences Institute (CCTSI)
The CCTSI is a collaborative enterprise between University of Colorado, Colorado State University, six affiliated Hospitals and health care organizations, and multiple community organizations with a goal to accelerate the translation of research discoveries into improved patient care and public health. Resources include protocol submission reviews, information on financial support policies, regulatory knowledge and support, and forms, tools, checklists and templates.

http://cctsi.ucdenver.edu/Pages/index.aspx

FDA Regulations on Mobile Health Technologies
Information on the FDA’s emerging regulatory framework for mHealth tools and devices, recent reform proposals, and policy recommendations.


Section 508
Provides accessibility guidelines to comply with Federal laws and regulations

www.section508.gov

Usability.gov
Resource for user experience (UX) best practices and guidelines, serving practitioners and students in the government and private sectors.

www.usability.gov

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grants
Application information for the National Institutes of Health’s SBIR/STTR grant opportunities.


w3schools
Provides free tutorials of HTML and other programming

www.w3schools.com

Lynda
Fee-based tutorials for hundreds of software

www.lynda.com

Open mHealth
Nonprofit bringing clinicians, data scientists, developers and designers together to build tools and products that transform the way personal, digital data can be used in health care.

www.openmhealth.org


Rempel, H. G., & Bridges, L. (2013). That was then, this is now: Replacing the mobile optimized site with responsive design. Information Technology and Libraries, 32(1), 8-24.


Amy Barton, PhD, RN – References

Barton, A. J. The regulation of mobile health applications. BMC Medicine, 2012;10, 46. URL: http://www.biomedcentral.com/content/pdf/1741-7015-10-46.pdf


Ida Sim, MD, PhD – References


“A Robust Health Data Infrastructure”. AHRQ Publication No. 14-0041-EF April 2014

http://www.openhealth.org

http://md2k.org