INTRODUCING MOBILE APPLICATIONS INTO CLINICAL PRACTICE

NATIONAL DIALOGUES ON BEHAVIORAL HEALTH 2018 CONFERENCE

Brian Grady, MD Psychiatrist October 28, 2018

DISCLOSURE INFORMATION

- The views expressed are those of the author and do not reflect the official policy of the Department of Defense, Department of Veterans Affairs or the U.S. Government.
- Disclosure of Relevant Financial Relationships
 - I have no financial relationships to disclose.
- Disclosure of Off-Label and/or investigative Uses
 - I will not discuss off label use and/or investigational use in my presentation.

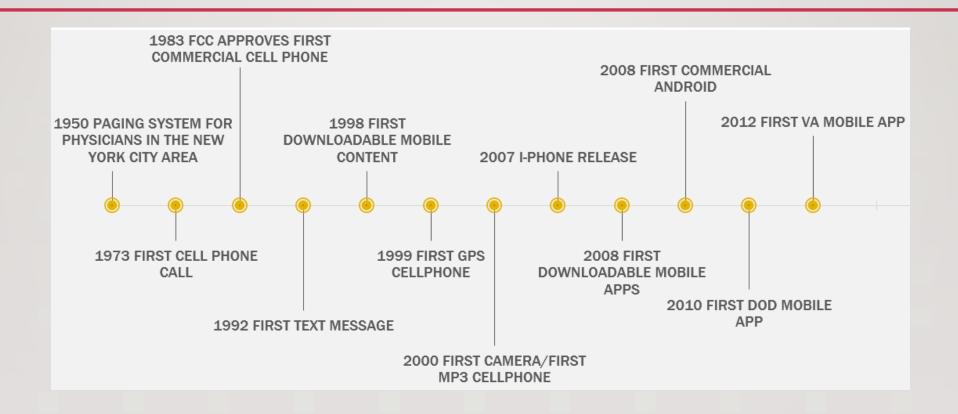
OBJECTIVES

- Reviewing the Pros and Cons of mobile application use in clinical practice
- Identifying some introductory mobile applications for clinical practice
- Demonstrating some introductory clinical mobile applications

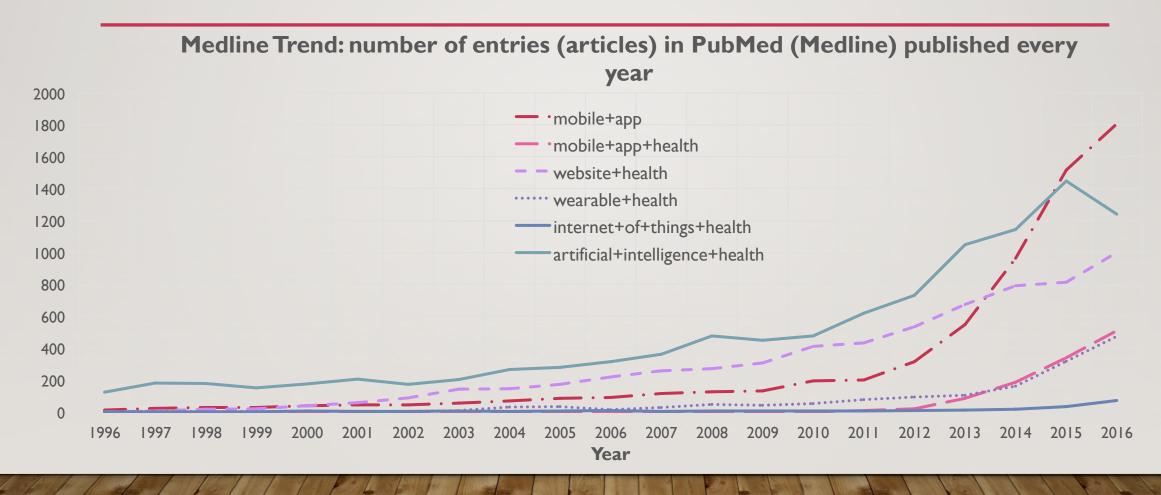
BLUF (BOTTOM LINE UP FRONT)

Keep your eye on the horizon and your feet on the ground.

MOBILE TECHNOLOGY TIMELINE



MEDLINE TRENDS



PROS AND CONS OF MOBILE APPLICATION USE IN CLINICAL PRACTICE

- Pros
 - White Space
 - Access
 - Clinical Care Multiplier
 - Client/Patient Engagement
 - Self Management/Empowerment
 - Momentary Ecological Assessment/ Intervention (in vivo, in silico)
 - •

Cons

- Security, Privacy, Confidentiality
- Which Apps to Use?
- Vetting of Mobile Apps
- Provider, staff, patient learning curve
- Effect and changes in workflow
- Ethical use, storage, and transmission of personal data
- Continuous App Updating

LEVERAGING THE "WHITE SPACE"



GETTING MOBILE HEALTH IN CLINICAL CARE: FIVE CORE COMPETENCIES*

- Evidence Base
- Clinical Integration
- Security and Privacy
- Ethical Issues
- Cultural Considerations

EVIDENCE BASE*

To evaluate the level of evidence to support a particular mobile health app, the following questions should be asked:

- Is the content of the mobile app based on evidence based practices? If so, what is the level of the evidence base?
- What is the level of the research on the efficacy of treatment with and without the mobile app to augment clinical practice?

FIRST DO NO HARM

- Mobile Apps for Bipolar Disorder: A Systematic Review of Features and Content Quality. In general, the content of currently available apps for BD is not in line with practice guidelines or established self-management principles.
 Apps also fail to provide important information to help users assess their quality, with most lacking source citation and a privacy policy. Nicholas, Jennifer, Mark Erik Larsen, Judith Proudfoot, and Helen Christensen. "Mobile apps for bipolar disorder: a systematic review of features and content quality." Journal of medical Internet research 17, no. 8 (2015).
- "There's a Pain App for That": Review of Patient-targeted Smartphone Applications for Pain Management. Currently available pain self-management apps for patients are simplistic, lack the involvement of health care professionals in their development, and have not been rigorously tested for effectiveness on pain-related health outcomes. Lalloo, Chitra, Lindsay A. Jibb, Jordan Rivera, Arnav Agarwal, and Jennifer N. Stinson. ""There's pain app for that": Review of patient-targeted smartphone applications for pain management. "The Clinical journal of pain 31, no. 6 (2015): 557-563.
- A systematic review of smartphone applications for chronic pain available for download in the United States. Overall, most of the pain-related apps included within our review not only lacked evidence of HCP input regarding development but also contained few evidence-based pain management features. Wallace, Lorraine S., and Lara K. Dhingra. "A systematic review of smartphone applications for chronic pain available for download in the United States." Journal of opioid management 10, no. 1 (2014): 63-68.

CLINICAL INTEGRATION*

- Workflow
 - How to think through how your clinic workflow may be impacted
- Introduction
 - How to introduce an app to clinical care
- Prescription
 - How to prescribe an app to a patient to support a treatment plan
- Data Review
 - How to review the data collected on the app with the patient
- Documentation
 - How to document the use of an app in the patient's records

SECURITY AND PRIVACY

There are four key questions regarding security and privacy that providers need to ask when selecting mobile health apps*:

- **Source:** Is the app coming from a trusted source?
- Permissions: What permissions is the app asking for?
- Data protection: How can I help patients protect their health data on their device?
- Data transmission: How will data be shared with providers?

ETHICAL ISSUES

American Psychological Association

- Ethical Principles of Psychologists and Code of Conduct, especially:
 - Competence
 - Human Relations
 - Privacy and Confidentiality

American Psychiatric Association

- Mental Health Apps
 - Why Rate Apps
 - App Evaluation Model
 - Help with Rating Apps

National Association of Social Workers, Association of Social Work Boards, Council on Social Work Education, & Clinical Social Work Association

Technology Standards in Social Work Practice

ETHICAL ISSUES – IDENTIFYING PROBLEM USE/ RISKS

Screen for Technology Use

Habits:

- Smoking
- Alcohol
- Caffeine use
- Pain Medications
- Recreational drug use
- Nutrition/Diet
- Technology Use

Areas of Concern:

- Phubbing
- FOMO Fear of Missing Out
- Gaming
- Dieting
- Inactivity
- Pornography
- •
- Suicide Prevention Apps

SUICIDE PREVENTION APPS

Larsen et. al.

- 123 apps referring to suicide were reviewed
- 49 contained at least one interactive suicide prevention feature
 - Obtaining support from friends and family (n=27)
 - Safety planning (n=14)
- All reviewed apps contained at least one evidence based or best-practice strategy
- Apps tended to focus on a single suicide prevention strategy (mean = 1.1)
- Potentially harmful content was also identified
 - Listing lethal means
 - Encouraging risky behavior in a crisis

CULTURAL CONSIDERATIONS

There are five steps to addressing cultural issues when integrating mobile apps and other technologies into clinical care*:

- Understand the cultural variables
- Identify your own potential biases
- Use a framework to better understand how you experience these differences
- Increase cultural competency
- Determine your patient's relationship with technology.

IDENTIFYING SOME INTRODUCTORY MOBILE APPLICATIONS FOR CLINICAL PRACTICE

- Classification
 - Education
 - Self monitoring
 - Self Management
 - Treatment Companion
 - References
 - Resources
 - Social Connectivity

HOW DO "HEALTH" APPS MAKE IT TO MARKET?

H.R.34 - 21st Century Cures Act - 12/13/2016 Became Public Law No: 114-2551

• Clarifying Medical Software Regulation - SEC. 3060.(a).(o).(1) The term device, as defined in section 201(h), shall not include a software function that is intended—(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

The FDA then developed the Digital Health Innovation Action Plan²

- focused oversight on mobile medical apps to only those that present higher risk to patients, while choosing not to enforce compliance for lower risk mobile apps;
- confirmed intention to not focus our oversight on technologies that receive, transmit, store or display data from medical devices;
- chose not to focus oversight on products that only promote general wellness; ...

"GENERAL WELLNESS" POLICY FOR LOW RISK DEVICES

• For purposes of this guidance, CDRH defines general wellness products as products that meet the following two factors: (I) are intended for only general wellness use, as defined in this guidance, and (2) present a low risk to the safety of users and other persons. General wellness products may include exercise equipment, audio recordings, video games, software programs and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded), when consistent with the two factors above.

Terms

- Software as a Medical Device or SaMD (The term Software as a Medical Device is defined by the International Medical Device Regulators Forum (IMDRF) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.") e.g. Mobile EKG or Wearable Watch EKG
- Software in a Medical Device or SiMD, e.g. •Software used to "drive or control" the motors and the pumping of medication in an infusion pump or software that enables clinical communication such as video, etc.

VETTING MOBILE APPS

- FDA partially
 - Apps for diabetes, eye conditions, ekg, ...
 - App for alcohol, cocaine, marijuana and stimulant SUDs
 - Most recently granted the marketing authorization for contraception mobile app
 - Examples of <u>FDA Pre-Market Submissions</u>
- Research Few RTCs
 - Minimum based on EBP
 - Moderate one RTC
 - High Multiple RTCs
- You are responsible for vetting the resource

LOCATING MOBILE APPS?

Emergency Medicine Example

- We found a total of 7,699 apps from the 21 search terms, of which 17.8% were clinical, 9.6% were based on a book or published source, 1.6% were non-English, 0.7% were clinically relevant patient education resources, and 4.8% were study tools. Most significantly, 64.9% were considered not relevant to medical professionals. Clinically relevant apps make up approximately 6.9% of the App Store's "Medical" Category and 0.1% of the overall App Store
- Clinically relevant apps represent only a small percentage (6.9%) of the total App volume within the Medical section of the App Store. Without a structured search-and-evaluation strategy, it may be difficult for the casual user to identify this potentially useful content.

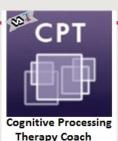
VA/DOD MOBILE APPS





VAHealth Caring 4 Women Veterans















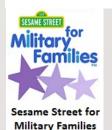
















t2mood tracker

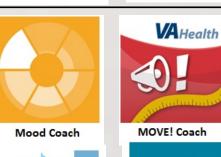














VetChange



Available only in the AppStore (Apple iOS)

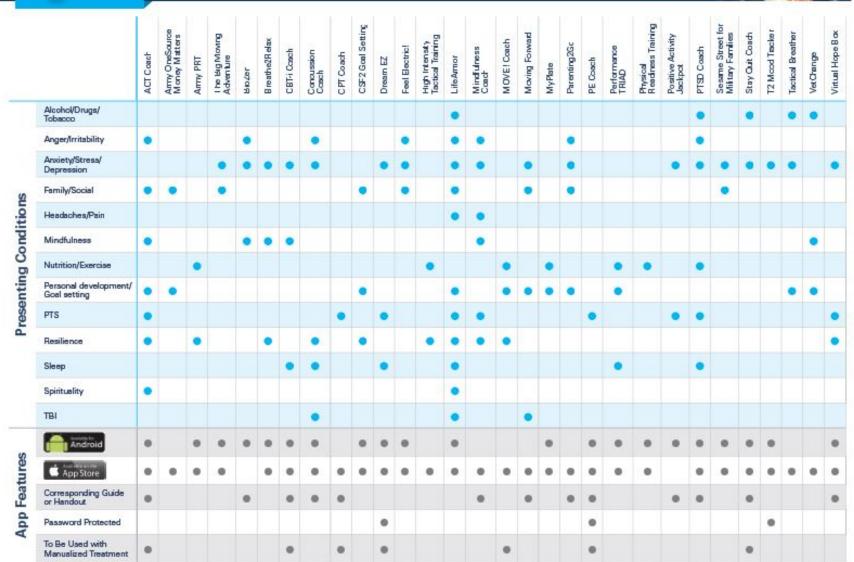
Available only in the Play Store (Android OS)



STAIR Coach



DoD and VA Mobile Health Apps for **PATIENTS**



"GATEWAY" MOBILE APPLICATIONS

For Individuals:

- Breath2 Relax
- Mood Tracker
- Virtual Hope Box
- Some FDA approved Apps



- PTSD Family Coach
- Sesame Street for Military Families
- The Big Moving Adventure













CALLING FOR HELP - FREE

ANDROID – IN CASE OF EMERGENCY ICE



IOS - MEDICAL ID



DEMONSTRATING SOME INTRODUCTORY CLINICAL MOBILE APPLICATIONS

• One or more of the "Gateway" Mobile Apps will be demonstrated

CHECK IN - PROS AND CONS OF MOBILE APPLICATION USE IN CLINICAL PRACTICE

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