Use of Mobile Medical Applications in Clinical Research

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Objectives

• Review the recent FDA Guidance on Mobile Medical Applications
• Identify which mobile apps are considered medical devices
• Outline regulatory requirements of doing research with mobile apps that are also medical devices (i.e. mobile medical apps)

Outline

• Background
• Definitions
• General Regulatory Approach (3 categories)
  – Mobile apps that are not medical devices
  – Mobile apps that may be medical devices for which the FDA will exercise enforcement discretion (lower risk)
  – Mobile medical apps (MMA) that require FDA oversight (higher risk)
• Examples for Practice
• Use of MMAs in Clinical Studies
The mobile medical apps market is fast growing

• It is estimated that 500 million smartphone users worldwide will be using health care applications by 2015.
• By 2018, there will be 3.4 billion smartphone/tablet users and 50% of them will have downloaded mobile health applications.


The FDA has a public health responsibility to oversee the safety and efficacy of medical devices – including mobile medical apps (MMAs)
• The Agency issued final guidance titled “Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff” on 9/25/2013.
  – The guidance explains the agency’s oversight of mobile medical apps as devices and their focus only on the apps that present a greater risk to patients if they don’t work as intended and on apps that cause smartphones or other mobile platforms to impact the functionality or performance of traditional medical devices.

Definitions

Mobile Platform
- “...defined as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as smartphones, tablet computers, or other portable computers.”

Definitions

Mobile Application (Mobil App)
- “...defined as a software application that can be executed (run) on a mobile platform... or a web-based software application that is tailored to a mobile platform but is executed on a server.”

Definitions

Mobile Medical Application (MMA)
- “…is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and either is intended:
  • to be used as an accessory to a regulated medical device; or
  • to transform a mobile platform into a regulated medical device.”
Definitions

Device
– It is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article or component, part, or accessory, which is:
  • Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  • Intended to affect the structure or any function of the body
  • And which does not achieve its intended purpose through chemical action and which is not dependent on being metabolized for the achievement of its primary purpose

FDA’s Risk Based Regulatory Approach for Mobile Apps

MAs that do not meet the definition of a medical device
MAs that meet the definition of a medical device, but are lower risk
MAs that meet the definition of a medical device and are higher risk
Not medical devices
Focus of Regulatory Oversight

Mobile Apps that are not medical devices

Mobile Apps that could be used in a healthcare environment, in clinical care or patient management, but are not considered medical devices.

1) Mobile apps that are intended to provide access to electronic “copies” (e.g., e-books, audio books) of medical textbooks or other reference materials with generic text search capabilities.

Ex. Medical Dictionaries or eCopies of medical reference texts (PDR, DSM); translations of medical terms across multiple languages
Mobile Apps that are not medical devices

Continued...

2. Mobile apps that are intended for health care providers to use as educational tools for medical training or to reinforce training previously received.
   Ex. Interactive anatomy diagrams or videos; surgical training videos; medical board certification preparation apps

3) Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information.
   Ex. Apps that help match patients to appropriate clinical trials; apps that provide information about gluten-free products; apps that provide tutorials on how to administer first aid

4) Mobile apps that automate general office operations in a health care setting.
   Ex. Apps that generate appointment reminders; apps that manage shifts for nurses; apps that help patients review, track and pay bills online
Mobile Apps that are not medical devices

Continued...

5) Mobile apps that are generic aids or general purpose products.

Ex: Use of a mobile platform as a magnifying glass (but are not specifically intended for medical purposes)

FDA’s Risk Based Regulatory Approach for Mobile Apps

Mobile Medical Apps: Focus of FDA Regulatory Oversight

Mobile Apps that meet the definition of a medical devices and can pose potential risks to public health.

Note: Oversight authority only to apply to those mobile apps whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.
Regulated Mobile Medical Apps (cont.)

1) Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data (i.e. an accessory to a regulated medical device).
   • MAs that alter the function or settings of an infusion pump.
   • MAs that calibrate, control, or change settings of a cochlear implant.
   • MAs that connect to a central nursing station and display medical device data to a physician’s mobile platform for review.

Regulated Mobile Medical Apps (cont.)

2) Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.
   • MAs that use a sensor attached to the mobile platform to:
     – Record eye movements for use in the diagnosis of balance disorders
     – Measure the degree of tremor caused by certain diseases
     – Measure physiological parameters (limb movement, EEG) during sleep and are intended for use in diagnosis of sleep disorders
     – Measure and display ECGs
   • MAs that use an attachment (e.g. laser) to remove hair.
   • MAs that present donor history questions to blood donors and record-transmit the responses to a collection center for determining donor eligibility prior to collection.

FDA’s Risk Based Regulatory Approach for Mobile Apps

Focus of Regulatory Oversight

MAs that meet the definition of a medical device and are higher risk

“Enforcement Discretion”

MAs that meet the definition of a medical device but are lower risk

MAs that do not meet the definition of a medical device

Not medical devices
Mobile Apps that may meet the definition of a medical devices for which the FDA intends to exercise ‘enforcement discretion’

1) Mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.

Example: "Apps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity, and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, . . . by simple prompting."

2) Mobile apps that provide patients with simple tools to organize and track their health information.

Example: Apps that provide simple tools for patients with specific conditions or chronic disease (e.g., obesity, diabetes, heart disease) to log, track, or trend their events or measurements (e.g., blood pressure measurements, drug intake times, diet) and share this information with their health care provider as part of a disease-management plan.

3) Mobile apps that provide easy access to information related to patients’ health conditions or treatments (beyond providing an electronic “copy” of a medical reference)

Example: Apps that are drug-drug interaction or drug-allergy look-up tools.
Enforcement Discretion

Continued . . .

4) Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions

Example: Apps specifically intended for medical uses that utilize the mobile device’s built in camera or a connected camera for purposes of documenting or transmitting pictures to supplement or augment what would otherwise be a verbal description . . .

Enforcement Discretion

Continued . . .

5) Mobile apps that perform simple calculations routinely used in clinical practice.

Example: Medical calculators for BMI, APGAR scores, NIH stroke scale, delivery date estimator

6) Mobile apps that enable individuals to interact with PHR systems or EHR systems

Example: An app that provide patients and providers with mobile access to health record systems.

FDA’s Risk Based Regulatory Approach for Mobile Apps

- MMA
- "Enforcement Discretion"
- Not medical devices

Focus of Regulatory Oversight

MAs that meet the definition of a medical device and are higher risk

MAs that meet the definition of a medical device but are lower risk

MAs that do not meet the definition of a medical device
Let’s Practice . . .

Example 1

• A mobile app which is a game that simulates various cardiac arrest scenarios to train health professionals in advanced CPR skills.
  - Not a medical device
  - Regulated MMA
  - Enforcement Discretion

Example 2

• A mobile app which uses electrodes and sensors attached to the mobile platform to measure physiological parameters during CPR and provides feedback about the quality of CPR being delivered.
  - Not a medical device
  - Regulated MMA
  - Enforcement Discretion
Example 3

- Mobile apps which use an attachment to the mobile platform to measure blood glucose.
  - Not a medical device
  - Regulated MMA
  - Enforcement Discretion

Example 4

- Mobile apps that use video and video games to motivate patients to do their physical therapy exercises at home.
  - Not a medical device
  - Regulated MMA
  - Enforcement Discretion

Example 5

- A mobile apps that allows users to input pill shape, color or imprint and displays pictures and names of pills that match this description.
  - Not a medical device
  - Regulated MMA
  - Enforcement Discretion
Example 6

- Mobile apps that control the inflation or deflation of a blood-pressure cuff.
  - Not a medical device
  - Regulated MMA
  - Enforcement Discretion

Example 7

- Mobile apps that use GPS location information to alert asthmatics of environmental conditions that may cause asthma symptoms.
  - Not a medical device
  - Regulated MMA
  - Enforcement Discretion

Using MMAs in Clinical Studies

- From the guidance:
  “Persons who manufacture mobile medical apps solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution. We note that while persons conducting research using mobile medical apps involving human subjects are exempt from registration and listing, they may instead be subject to investigational device exemption regulations.”

(21 CFR Part 812)
If the objective of your study is to test the safety and effectiveness of an investigational MMA, then your study is subject to the investigational device exemption regulations (IDE).

These studies will be treated just like any other device trial.

So, get your IDE checklists ready!
Thank You!

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