device developer perspective:

mHealth and the mobile transformation of healthcare

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BCS Manchester & Health Northern Specialist Group, 3 June 2014
agenda

- introductions & quiz
- motivation for connected healthcare
- mHealth case studies: standalone software & connected medical devices
- regulation: why it’s important
- regulation: US & European frameworks
- ways forward for new product concepts
- Q&A & discussion
audience quiz

1. what is a medical device?
2. what is ISO13485?
3. what is IEC62304?
4. who are the FDA?
5. who are the MHRA?
6. what are the main differences between Class I, II and III?
7. what is fragmentation in the context of mobile?
introduction – Antony Rix

- Manchester Grammar School, Cambridge University (M Eng) & Edinburgh University (Ph.D. in Engineering applications of psychoacoustics)

- twice BCS Programming Competition winner

- Bronze medallist, International Olympiad in Informatics then co-founder of the British Informatics Olympiad

- worked in telecommunications at BT then Psytechnics

- at TTP since 2004, focusing on developing and applying wireless & communications technology to new markets
TTP is a leading independent technology, product development and consultancy company, part of the *Cambridge Phenomenon* since it was founded in 1987.

active in a very wide range of markets, TTP works with its customers worldwide to develop devices, products, services, systems and supply chains to create new business from technology.
motivation: health economics

countries are spending a growing proportion of national income on health

% of GDP spent on healthcare

life expectancy at birth

as life expectancy increases and birth rates fall, many countries will find it increasingly difficult to care for aging populations, especially given rising incidence of chronic conditions & obesity

medication adherence remains poor

number of new drugs approved by FDA per $Bn R&D (inflation adjusted) is roughly halving every 9 years

source:
Diagnosing the decline in pharmaceutical R&D efficiency
Jack W. Scannell, Alex Blanckley, Helen Boldon & Brian Warrington
Nature Reviews Drug Discovery 11, 191-200 (March 2012)
doi:10.1038/nrd3681
FIGURE 1 | Erroom’s Law in pharmaceutical R&D.
motivation: market opportunity

- “A new report from research analyst firm GBI Research predicts that by 2019 the remote patient monitoring market in the US will reach $296.5 million, up from $104.5 million in 2012.
- ... estimated savings per patient per year of more than $900 and more than $140 per person per year in saved transportation costs.”

- “According market data from GfK, the number of mobile-connected blood pressure monitors purchased last year rose by 42% across Great Britain, Germany, France and the Netherlands, compared to 2012, while connected personal weighing scales rose by an enormous 88%.
- Despite this strong growth, connected devices account for only a small percentage of the overall market at present.”

- “Remote patient monitoring will save the world’s healthcare systems up to $36 billion by 2018, according to a new projection by Juniper Research.” (picture)
mobile is a key touchpoint for healthcare

- a majority of adults in the developed world own smartphones, providing a compelling opportunity to connect with users

- 56% of US adults now have a smartphone

- 59% use the Internet for health information

Pew Research Centre: Health Online 2013
http://www.pewinternet.org/Reports/2013/Health-online.aspx

Pew Research Centre: Smartphone Ownership 2013

Pew Research Centre: Mobile Health 2012
http://www.pewinternet.org/Reports/2012/Mobile-Health.aspx

- however, technology fragmentation remains a challenge
mHealth app case studies

Vocel Pill Phone
FDA 510(k) Class I, 2006
Medication reminder

Mersey Burns
EU Class I, 2012
Treatment calculator

iAsthma GPS Tracker HD, presume
Class I exempt, 2013
Log & avoid asthma attacks

OATBook
patient-developed (EU Class I?), 2012
Log anti-coagulation compliance

US pharmacy Walgreens: investing heavily to own customers via mobile and web presence, offering adherence tools as a driver of customer loyalty and refills
case study: Mersey Burns

- calculator for use by HCPs to determine fluid treatment of severe burns victims

- reported to be the first CE marked standalone app in UK (2012), although MyGlucoHealth may have been the first app/accessory combination (2010)
  - Class I; freely available to download

- an excellent case study that shows how:
  - a tiny team (1 student developer, 2 clinical advisors) can produce a fully regulated app in a short time
  - error-prone manual processes can be performed faster and more accurately using an app
  - warranty and liability issues can be practically overcome

http://www.merseyburns.com/
NHS adoption – apps now mainstream?

Safe and trusted apps to help you manage your health

Welcome to the Health Apps Library
- Discover apps to help you manage your health
- Reviewed by the NHS to ensure they are clinically safe
- Rated by you and the health care community

Latest apps

- MyDirectives
  - Decision aids
  - Not yet rated
  - Free
  - 
- The Immunisation App
  - Drugs
  - Not yet rated
  - Free
  - Android
- Headache Diary
  - Manage your health
  - Paid
  - Android, Windows
- Mindlogr
  - Manage your health
  - Free
  - "
- FibroMapp
  - Body parts
  - Paid
  - Android, Apple
- Whizz-Kidz mob.
  - Service information
  - Free
  - Android, Apple
app/device/data platform combinations

Asthmapolis: clip-on adherence monitor for inhalers

Proteus: ingestible placebo pill read by stomach-worn patch to verify that the medication set was taken

MyGlueHealth blood glucometer paired with phone app – first CE Marked app/device combination (2010)?

Agamatrix: following the success of its iBGStar with Sanofi, this new product is an app & connection cable supporting several other glucometers
**why regulation is vitally important**

Dear Doctor,

[Company] would like to inform you of an error in the [AppName] app which was available to download from [AppStoreName] during the period [LaunchDate] to [WithdrawalDate].

[Company] recently became aware that the app may produce [insert description of dangerous result] or [potentially expose patient data to attackers] and immediately withdrew it.

As a result, if you have obtained a copy of the app it must not be used and must be deleted. Any [insert why you would have used the app] derived from the app must be reviewed.

Yours sincerely,

Chief Medical Officer

[Company]

- several mHealth apps launched by major healthcare organisations have been withdrawn from the market when errors were discovered

- at least one case is understood to have involved a dosage calculator that incorrectly estimated dose

- on the plus side, this indicates that pharmacovigilance programmes can work for mHealth

- but these mistakes should not have been made, are costly, and have delayed wider adoption of mHealth by industry
why regulation is vitally important

- it’s not just apps that can expose patients to new dangers

- medical device developers unfamiliar with new technologies may have built generations of products over the last decade with substantial security weaknesses

- famously, the late hacker Barnaby Jack demonstrated live, potentially fatal remote wireless attacks on an insulin pump and then a pacemaker from a leading manufacturer
what is a **medical device**?

**EU (Directive 2007/47 EC)**
- any **instrument**, apparatus, appliance, **software**, material or other article ... together with any accessories ... **intended** by its manufacturer to be used specifically for ...
  - diagnosis, prevention, monitoring, treatment or alleviation of disease
  - diagnosis, prevention, monitoring, treatment or alleviation of or compensation for an **injury or handicap**
  - investigation, replacement or modification of the anatomy or of a physiological process
  - **control of conception**

**US (section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act)**
- an **instrument**, apparatus, implement, machine, **contrivance**, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - ... intended for use in the diagnosis of disease or other conditions, 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 of man or other animals ...

In both the US and EU, devices are classified by risk, from Class I (lowest risk) to Class III (highest risk) – details differ substantially between regions, and there are important sub-divisions.
mobile medical apps: FDA view

Mobile medical apps (MMA)

- Patient self-management apps
- Tools to organize and track their health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple health care providers tasks

Enforcement Discretion

MMA

Lower risk mobile apps that meet “device” definition but not considered “MMA"

Mobile apps not considered “medical devices"

focus of oversight

Mobile apps that meet “device” definition that are either intended
- To be used as an accessory to already regulated medical device,
  or
- To transform a mobile platform into a regulated medical device.

source: Bakul Patel, FDA, presentation to mHealth SIG, American Telemedicine Association, 12 Nov 2013
do I need regulatory approval for the US?

US Food and Drug Administration, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, September 25, 2013

FDA RF wireless & mobile medical app guidance overview, source: TTP
note: process can differ significantly between countries, and is changing; expert advice recommended
do I need regulatory approval in Europe?

European Commission, DG Health & Consumer, Guidelines on the Qualification and Classification of Standalone Software Used in Healthcare within the Regulatory Framework of Medical Devices, MedDev 2.1/6, Jan 2012

MHRA: Guidance on medical device stand-alone software (including apps), March 2014

note: process can differ significantly between countries, and is changing; expert advice recommended
US Food and Drug Administration, Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff, August 14, 2013

Many systems processing patient data may also be subject to data protection and in some cases other limitations: EU Data Protection Directive, US HIPAA

FDA RF wireless & mobile medical app guidance overview, source: TTP
note: process can differ significantly between countries, and is changing; expert advice recommended
future trends in regulation & mHealth

- regulation related to mHealth is still developing: expect change!

European regulators are working to clarify the position, but the update to the Medical Device Directives will be delayed by the May 2014 European Parliament elections.

EC Green Paper on mHealth is an important step:

USA: 2013 mHealth guidance threatened by PROTECT & SOFTWARE Acts, and under review by the FDASIA working party.

other countries following – even leading!
China reported to be world’s second-largest mHealth market
so you want to develop an mHealth concept?
reality checks

- “There are more than 43,000 healthcare apps available from the US iTunes store, but only about 16,275 of those are patient-facing apps with “genuine” health content, according to a new study from the IMS Institute for Healthcare Informatics”

- “…50 percent of health apps are downloaded fewer than 500 times and just five apps account for 15 percent of all health app downloads”

- just under 2,000 apps deal with specific therapy areas (figure)

http://mobihealthnews.com/26836/ims-half-of-android-health-apps-have-fewer-than-500-downloads/
there are gorillas in this market
questions (a non-exhaustive list)

is it legal?

is it safe?

do you have (or can get) the resources?

are you ready to be a medical manufacturer?

will your insurance cover it?

does it work (in clinical study/trial)?

do you know the (route to) market? etc. etc.

do you have the right range of skills, or can you buy them in?

do you have the quality systems?
steps on the mHealth journey

1. Identify viable target
2. Identify all stakeholders and benefits for each of them
3. Build sustainable business model
4. Design for Success
5. Acquire/build/deliver
6. Measure and improve

source:
6 Steps to mHealth success, Tony Kane, May 2014
www.tonykaneconsulting.com
TTP can help you deliver this vision

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see also my recent article:
New FDA wireless and mHealth guidelines
an overview for medical device developers, Nov 2013