



*Web-RADR: Use of mobile applications for
ADRs reporting & social media data mining*

François Houyez

Treatment Information & Access Director @ Eurordis

PCWP-HCPWP meeting, 4 March 2015, EMA

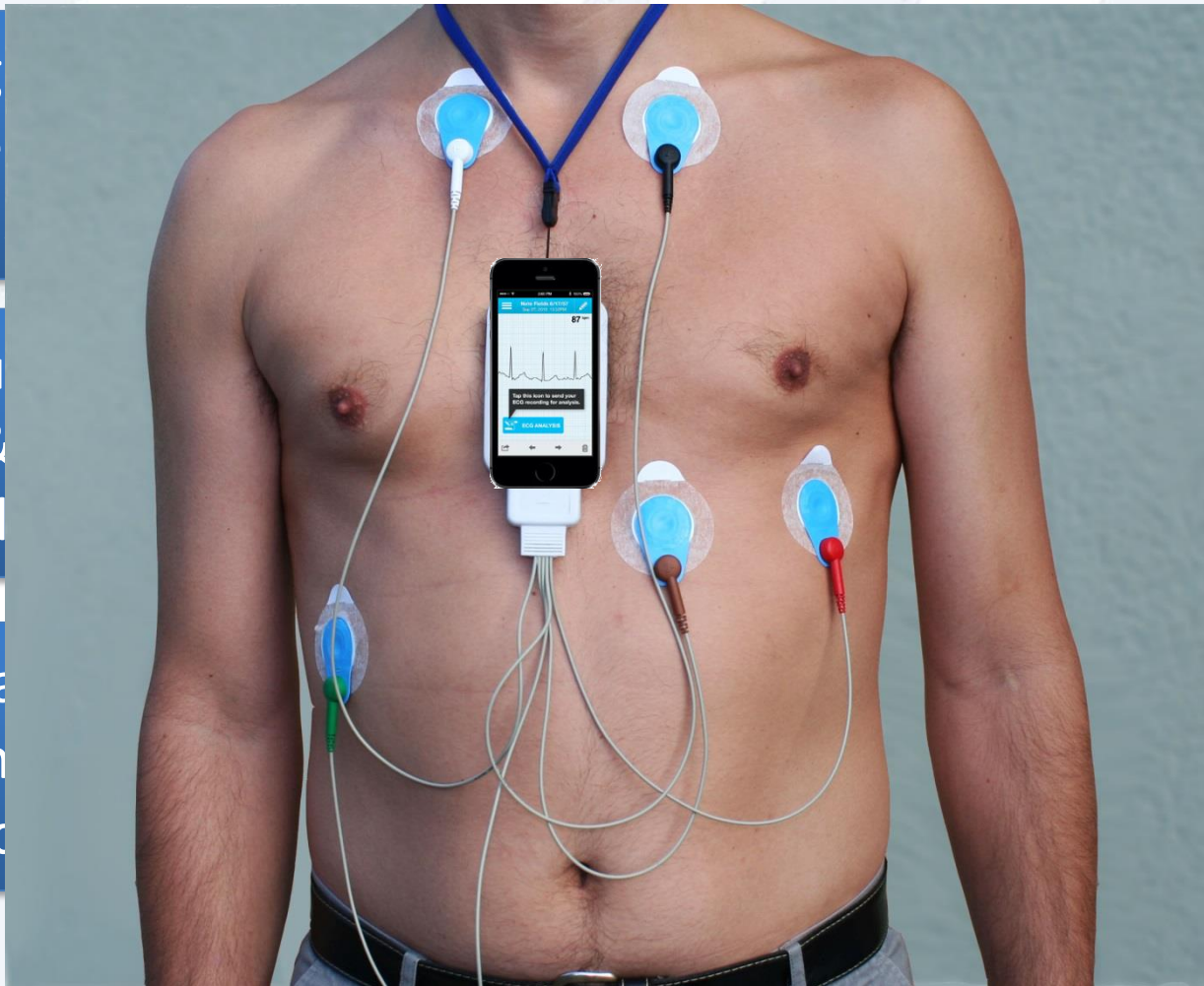
Opportunities

08 Aug
97,000 he
app

To distinguish

- Health &
- Med

A medical
provides in
not a med



onals

os that
device
f 08/2014

ser's own
cal device
smartphone
onitor)

Limits

Most of the time: data sent to a HCP
Are HCPs ready to receive millions of data with real-time action?

Actual use of these med apps by patients is low

Can healthcare apps be trusted?
In other words, are they regulated? Or are regulators involved in their design, use?

Many app developers have little or no formal medical training and do not involve clinicians in the development process

Lewis TL, Wyatt JC. mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use
J Med Internet Res 2014;16(9):e210. URL: <http://www.jmir.org/2014/9/e210>

FDA regulation
Mobile Medical Applications
[Here](#)

See Mike Brown
Mobile App Testing Blog
www.mobileapptesting.com

Potential to do harm

Diagnostic Inaccuracy of Smartphone Applications for
Melanoma Detection

Even the most accurate of the apps that used algorithms missed 18/60 lesions diagnosed as melanoma and deemed them low-risk for cancer

Joel A. Wolf et al, University of Pittsburgh Medical Center,
JAMA Dermatol. 2013;149(4):422-426. doi:10.1001/jamadermatol.2013.2382

Possible features of an app to report ADRs

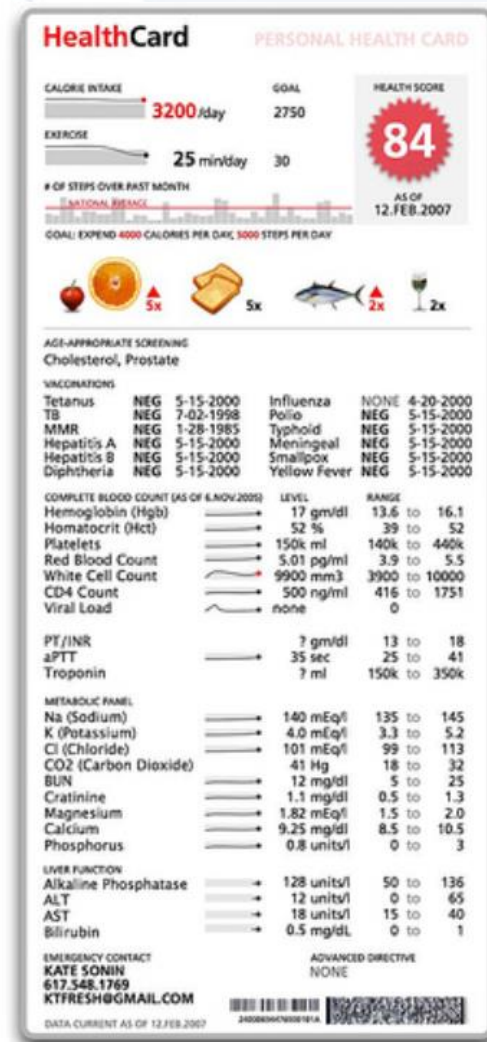
Need for a
choose M
preferred



Envir



Questions



Issues (1)

- A medical app to report suspected ADRs
 - In a patient's life, how many times do we report ADRs?
 - Do we need a specific app, or a reporting system embedded in other med app we may use?
- Elderly and med apps/smartphones
- Who's receiving the report?
 - Health authorities? Industry as well?
 - Response: pharmacovigilance experts, national authorities
- Patient ID or not?
 - Do we want to be called/emailed/texted back?

Issues (2)

- Which immediate feedback? www.adrreports.eu
 - Other similar reports, same product, same type of reaction
- Geolocation: opportunity or intrusion?
 - To detect counterfeit medicines
 - To report shortages
 - To report other environmental data
- In Web-RADR: EU funding only for UK and Croatia
 - What about adaptation for other MS?
 - Their own resources?
- If app developer acquired by third party, what about governance, guidelines, rules of use?

Issues (3) on the data mining tools

- Which social media?
 - Principle: only exchanges which are publicly accessible will be monitored (to the exclusion of private messages 1-to-1)
- Monitoring? Surveillance? Big Brother?
 - Do we feel comfortable our posts are scrutinised and automatically analysed?
 - Health authorities are interested by what we say, excellent!
It's only normal
- Will social media access the results?
 - During the research phase of Web-RADR?
 - As usual practice afterwards?
- An opportunity for two-way communication: DTCl-like risk?

YOUR VIEWS? QUESTIONS?