Concerns about trust, security & safety in mHealth: are they justified, and what to do about them ?

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Agenda

Why bother with mHealth ?

Why do mHealth safety, trust and security matter ?

What is the evidence about these ?

What to do to alleviate these problems ?

Conclusions

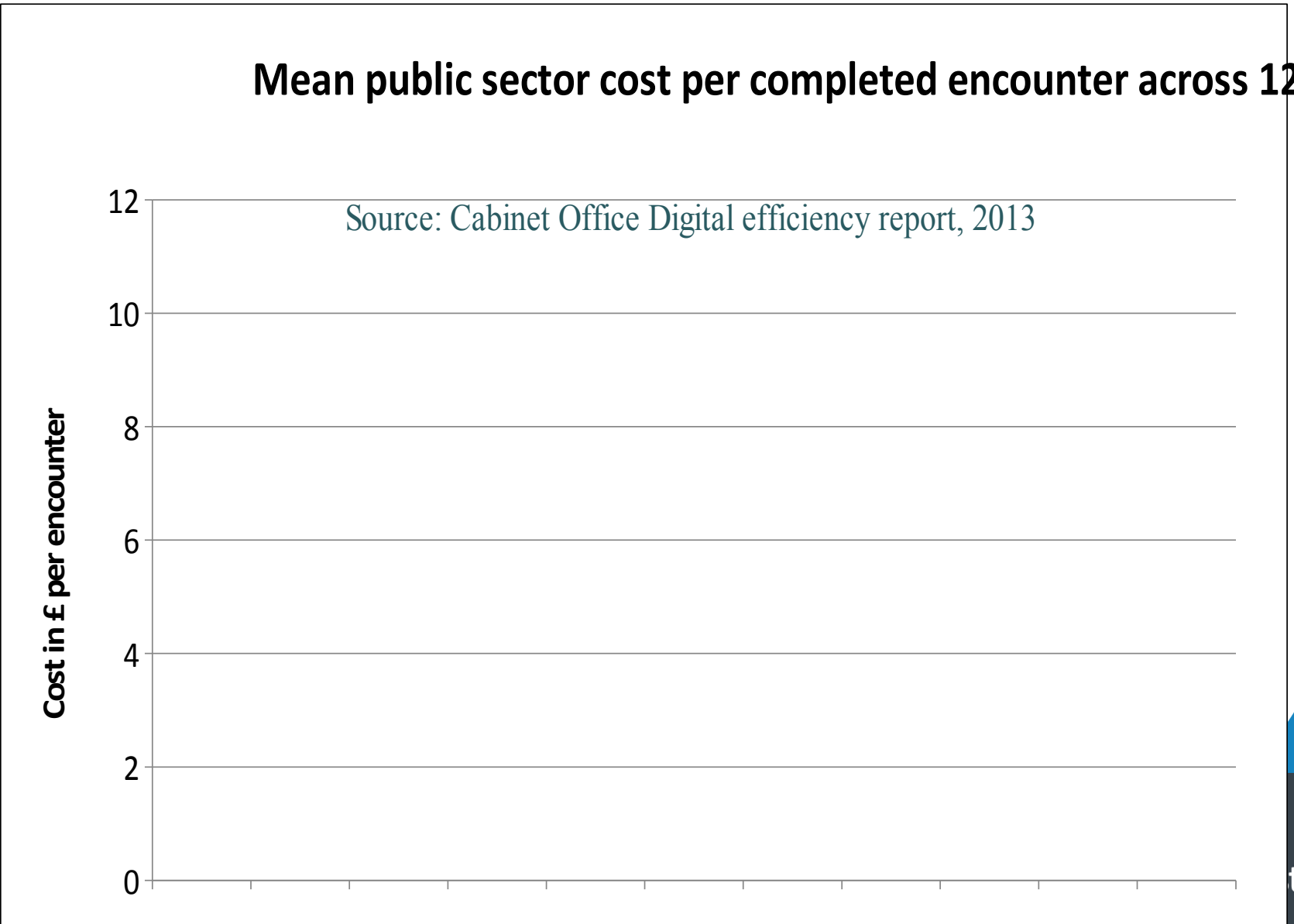
Why bother with mHealth ?

1. Face-to-face contacts do not scale

2. Smart phone hardware used by 75%+ of adults:
   - Cheap, convenient, fashionable
   - Inbuilt sensors / wearables allow easy measurements
   - Multiple communication channels: SMS, voice, video, apps…

3. mHealth software enables:
   - Unobtrusive alerts to record data, take action
   - Incorporation of Susan Michie's behaviour change techniques (eg. present in 96% of drug adherence apps)
   - Tailoring, which makes behaviour change more effective (d=0.16, Lustria, J H Comm 2013)

Why digital channels ?



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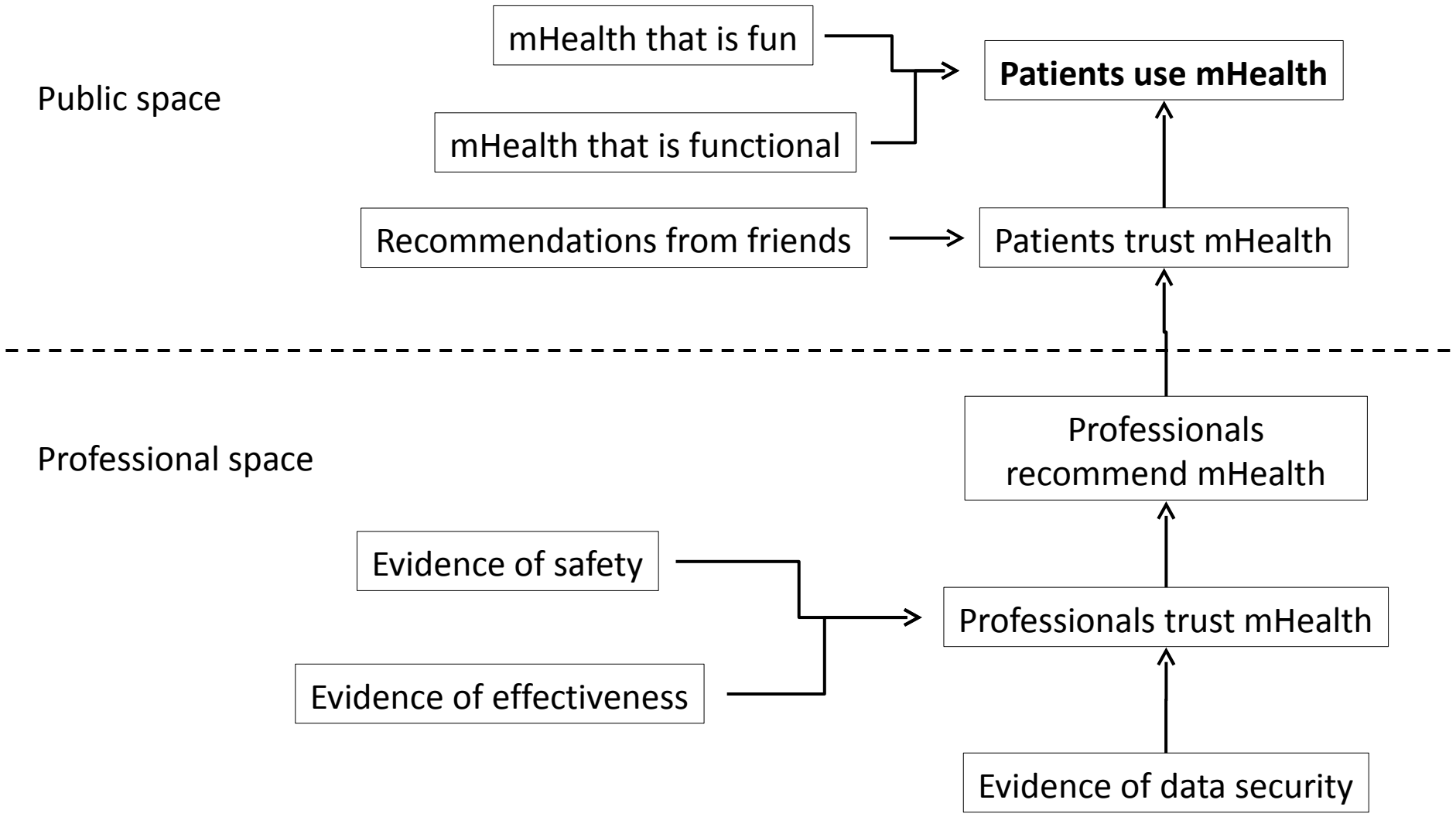
Trust, security and safety



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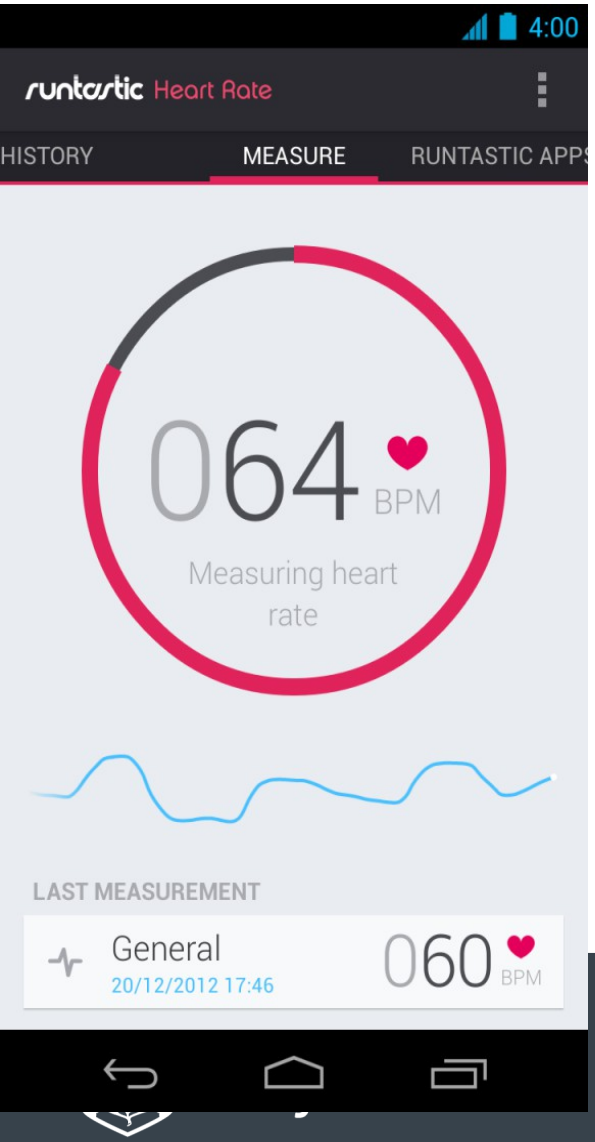

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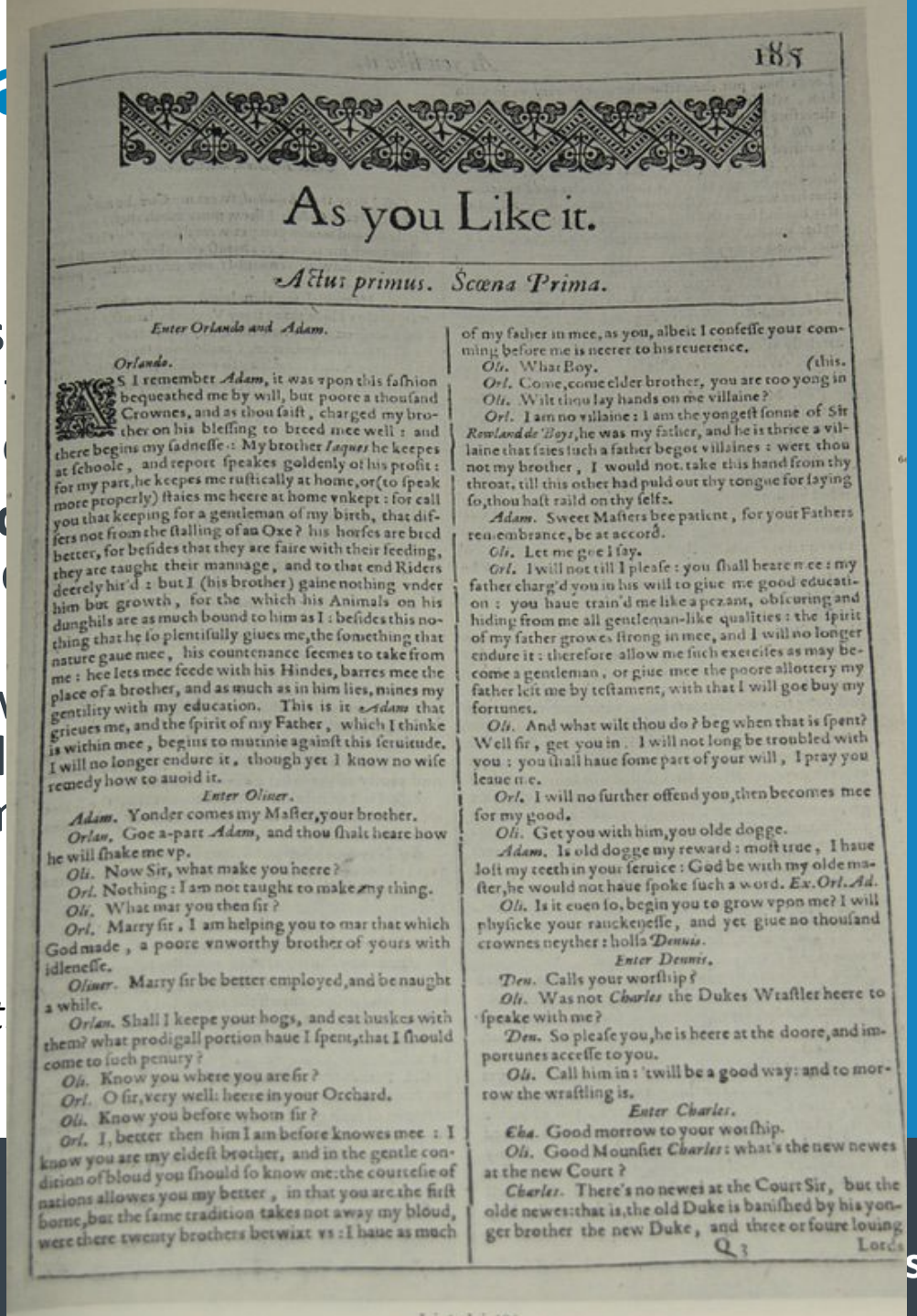

185

As you Like it.

Actus primus. Scœna Prima.

Enter Orlando and Adam.

Orlando.

AS I remember Adam, it was vpon this fashion bequeathed me by will, but poore a thousand Crownes, and as thou saist, charged my brother on his blessing to breed mee well: and there begins my sadnesse: My brother Iaques he keepes at schoole, and reports speakes goldenly of his profit: for my part, he keepes me rustically at home, or (to speak more properly) staies me heere at home vnkept: for call you that keeping for a gentleman of my birth, that differs not from the stalling of an Oxe? his horses are bred better, for besides that they are faire with their feeding, they are taught their manage, and to that end Riders deerely hir'd: but I (his brother) gaine nothing vnder him but growth, for the which his Animals on his dunghils are as much bound to him as I: besides this nothing that he so plentifully giues me, the something that nature gaue mee, his countenance seemes to take from me: he lets mee feede with his Hindes, barres mee the place of a brother, and as much as in him lies, mines my gentility with my education. This is it Adam that grieues me, and the spirit of my Father, which I thinke is within mee, begins to mutinie against this seruitude. I will no longer endure it, though yet I know no wise remedy how to auoid it.

Enter Oliuer.

Adam. Yonder comes my Master, your brother.

Orlan. Goe a-part Adam, and thou shalt heare how he will shake me vp.

Oli. Now Sir, what make you heere?

Orl. Nothing: I am not taught to make any thing.

Oli. What mar you then sir?

Orl. Marry sir, I am helping you to mar that which God made, a poore vnworthy brother of yours with idlenesse.

Oliuer. Marry sir be better employed, and be naught a while.

Orlan. Shall I keepe your hogs, and eat huskes with them? what prodigall portion haue I spent, that I should come to such penury?

Oli. Know you where you are sir?

Orl. O sir, very well: heere in your Orchard.

Oli. Know you before whom sir?

Orl. I, better then him I am before knowes mee: I know you are my eldest brother, and in the gentle condition of blood you should so know me: the courtesie of nations allowes you my better, in that you are the first borne, but the same tradition takes not away my blood, were there twenty brothers betwixt vs: I haue as much of my father in mee, as you, albeit I confesse your coming before me is neerer to his reuerence.

Oli. What Boy. (this.

Orl. Come, come elder brother, you are too yong in

Oli. Wilt thou lay hands on me villaine?

Orl. I am no villaine: I am the yongest sonne of Sir Rowland de Boys, he was my father, and he is thrice a villaine that saies such a father begot villaines: wert thou not my brother, I would not take this hand from thy throat, till this other had pulld out thy tongue for saying so, thou hast rail'd on thy selfe.

Adam. Sweet Masters bee patient, for your Fathers remembrance, be at accord.

Oli. Let me goe I say.

Orl. I will not till I please: you shall heare mee: my father charg'd you in his will to giue me good education: you haue train'd me like a peazant, obscuring and hiding from me all gentleman-like qualities: the spirit of my father growes strong in mee, and I will no longer endure it: therefore allow me such exercises as may become a gentleman, or giue mee the poore allottery my father left me by testament, with that I will goe buy my fortunes.

Oli. And what wilt thou do? beg when that is spent? Well sir, get you in. I will not long be troubled with you: you shall haue some part of your will, I pray you leaue mee.

Orl. I will no further offend you, then becomes mee for my good.

Oli. Get you with him, you olde dogge.

Adam. Is old dogge my reward: most true, I haue lost my teeth in your seruice: God be with my olde master, he would not haue spoke such a word. Ex. Orl. Ad.

Oli. Is it euen so, begin you to grow vpon me? I will physicke your rankenesse, and yet giue no thousand crownes neyther: holla Dennis.

Enter Dennis.

Den. Calls your worship?

Oli. Was not Charles the Dukes Wrastler heere to speake with me?

Den. So please you, he is heere at the doore, and importunes accesse to you.

Oli. Call him in: 'twill be a good way: and to morrow the wrastling is.

Enter Charles.

Cha. Good morrow to your worship.

Oli. Good Mounsier Charles: what's the new newes at the new Court?

Charles. There's no newes at the Court Sir, but the olde newes: that is, the old Duke is banished by his yonger brother the new Duke, and three or foure louing

Q 3 Lords

First Folio As You Like It Public Domain Photo taken by Cowardly Lion - Folio Society edition of 1996

Recent evidence on privacy & mHealth apps

Huckvale et al 2015 study of 79 accredited lifestyle apps from NHS Apps library:

Only 53 (67%) had a privacy policy: policies vaguely worded, many did not explain what types of data were being shared

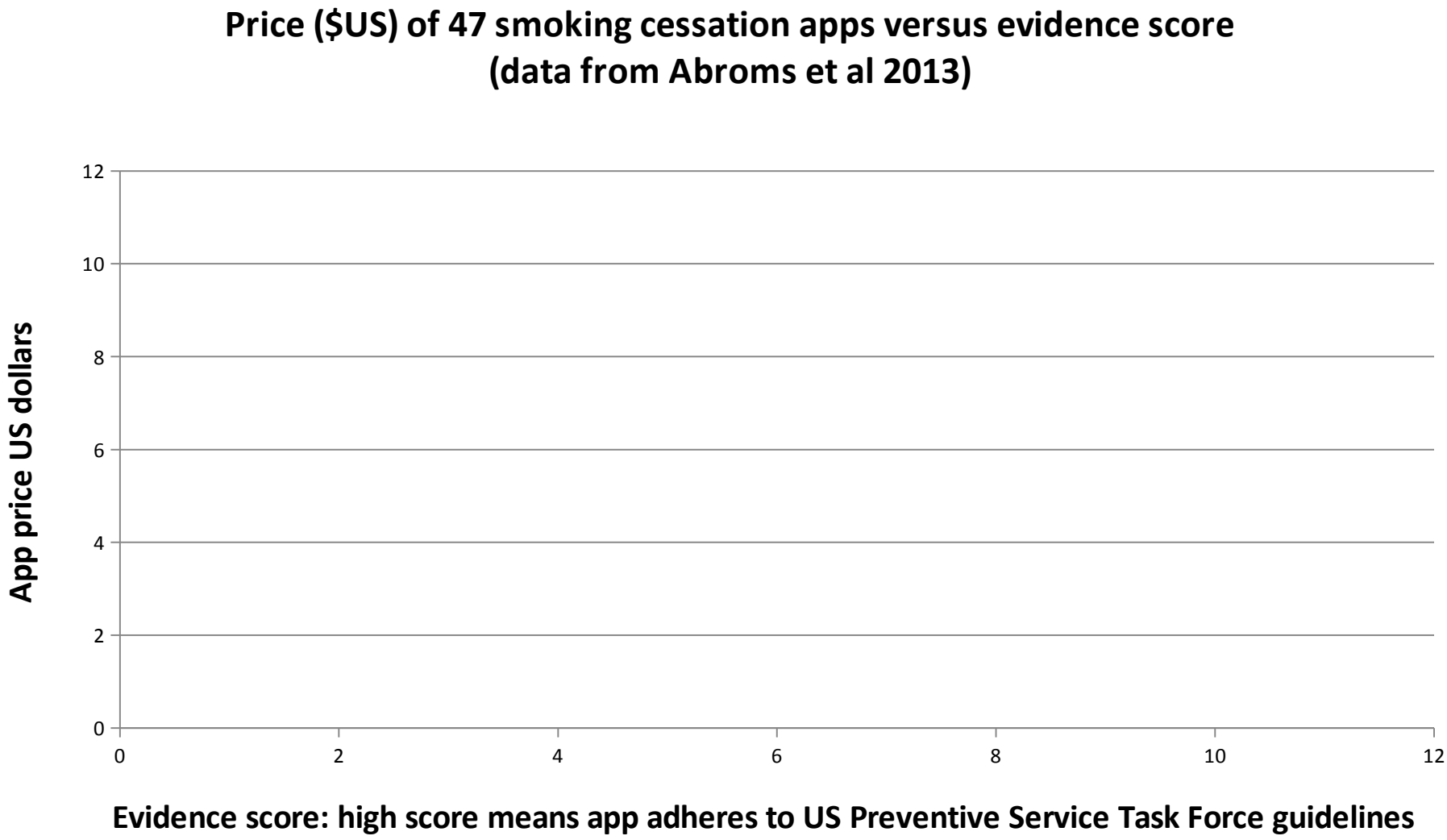
No app encrypted data held on the device

70 (89%) leaked confidential data over network

35 included identifiers, 23 sent IDs without encryption

4 apps sent **both** IDs and health information without encryption

Are apps based on sound evidence ?



Current evidence on app safety

Apps for insulin dosage adjustment (Huckvale 2015):

14 (30%) of 46 declared source of algorithm, 3 (9%) of 46 validated input data, 27 (59%) allowed calculation with missing data

17 (37%) did not update when input data changed

1 app was issue free

Asthma apps (Huckvale 2015):

Number doubled from 93 in 2011 to 191 in 2013

23 (25%) of the first group withdrawn, leaving 147 new apps

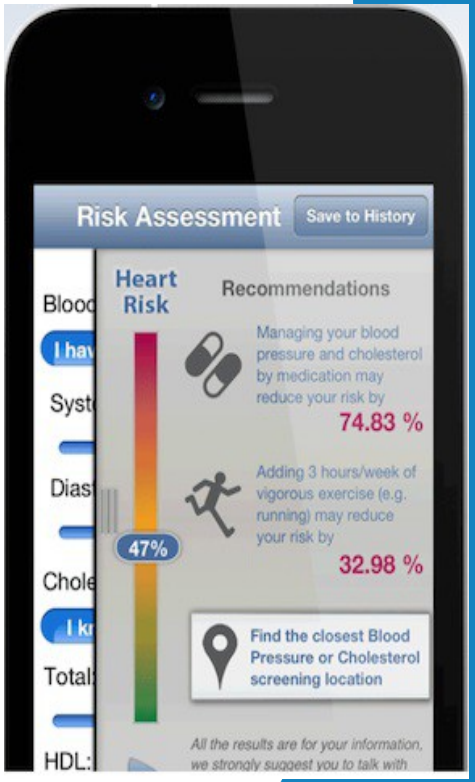
Newer apps no more likely to include EB advice: only 75 (50%) of 147 gave basic info on asthma, 36 (24%) diary function

Only 4 (17%) of 23 advising on asthma management were consistent with guidelines

CVD risk apps

Overall results

- Located 21 apps, only 19 (7 paid) gave figures
- All 19 communicated risk using percentages (cf. advice from Gigerenzer, BMJ 2004)
- One app said see your GP ***every*** time; none of the rest gave advice
- Some apps refused to accept key data, eg. age > 74, diabetes



Heart Health App

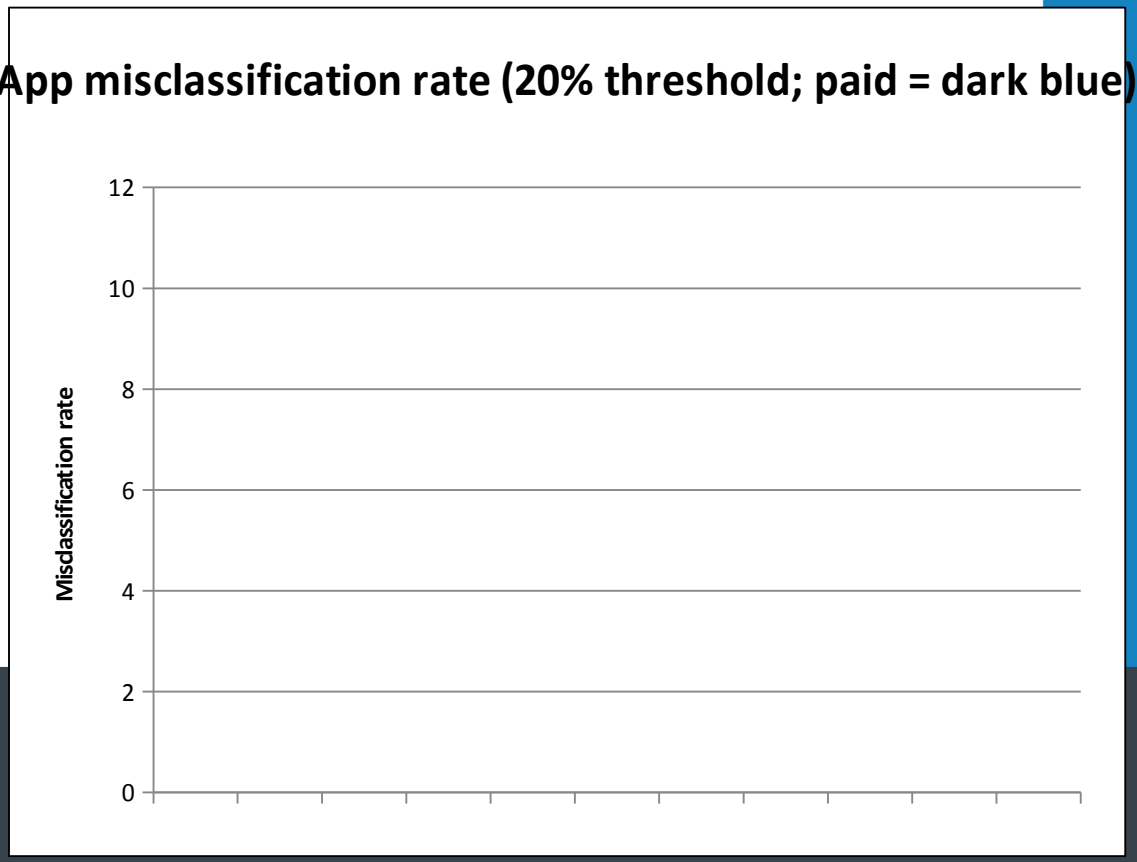
Misclassification rates

Rates varied from 7% (safe ?) to 33% (unsafe !)

Of 19 apps:

- 5 (26%) misclassified 25% or more scenarios
- 8 (42%) misclassified at least 20% of the scenarios

Median error rate free 13%, paid 27% (p = 0.026)



Current evidence on app effectiveness

21 RCTs of apps used by patients / public:

3 studies were confounded (used app + much else besides)

3 were *equivalence studies (*does app save resources, but with same outcomes ?): 2 were positive

Of the remaining 15 studies*:

8 studied health behaviours: 7 positive, 1 worse (compared to SMS for smoking cessation)

5 studied clinical process: 3+, 2 equal

5 studied patient outcomes: 3+, 2 equal

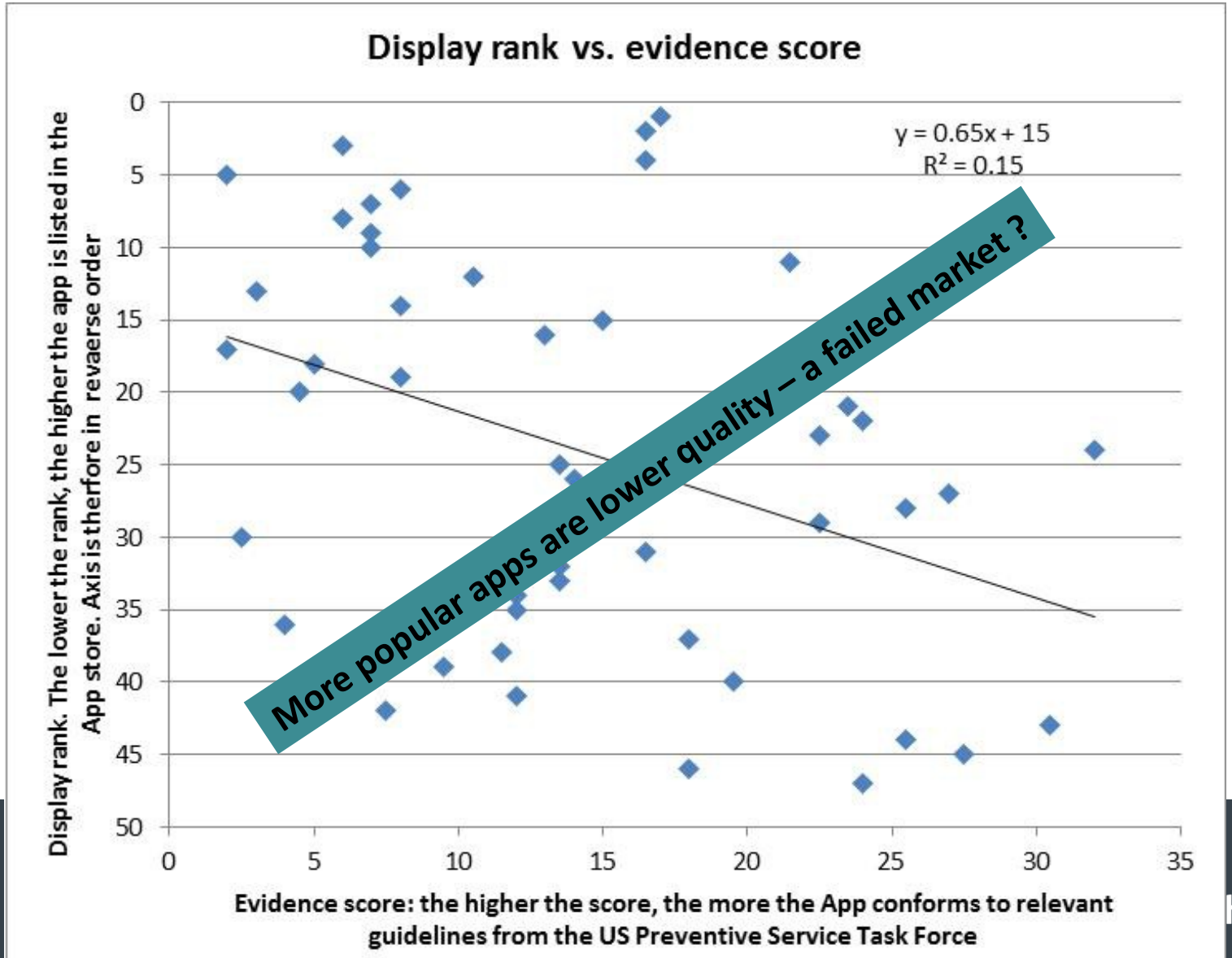
Overall (inc. equivalence trials): 15 positive, **4 equal**, 1 worse

* 3 trials measured more than one of these

Possible quality approval processes to improve mHealth

Methods	Advantages	Disadvantages	Examples
Wisdom of the crowd	Simple user ranking	Hard for users to assess quality; click factory bias	Current app stores MyHealthApps
Users apply quality criteria	Explicit	Requires widespread dissemination; can everyone apply them ?	RCP checklist
Classic peer reviewed article	Rigorous (?)	Slow, resource intensive, doesn't fit App model	47 PubMed articles
Physician peer review	Timely Dynamic	Not as rigorous Scalable ?	iMedicalApps, MedicalAppJournal
Developer self-certification	Dynamic	Requires developers to understand & comply; checklist must fit apps	HON Code ? RCP checklist
Developer support	Resource light	Technical knowledge needed Multitude of developers	BSI PAS 277
CE marking, external regulation	Credible	Slow, expensive, apps don't fit national model	NHS App Store, FDA, MHRA

User ratings: app display rank versus adherence to evidence



Study of 47 smoking cessation apps (Abroms, 2013)

Regulation of medical apps by FDA, FCC

If classified as a medical device by FDA a product must demonstrate efficacy, but:

- Only 100 apps so far classified as a medical device
- Decision to exercise "*enforcement discretion*" on most medical apps

So, FDA has not actually banned any apps, yet

However, the Federal Communication Commission **has** banned some apps with misleading claims, eg. "Acne Cure" (no evidence of claimed benefit of iPhone screen backlight)

Sharpe, New England Center for Investigative Reporting, Many health apps are based on flimsy science at best, and often do not work. Washington Post, November 12th 2012

Some criteria for an mHealth quality approval process

1. Empower patient & professional choice ?
2. Use criteria that make sense to patients / profs / the NHS / industry ?
3. Scalable to thousands of apps ?
4. Proportionate to clinical risk ?
5. Promote useful innovation and a vigorous apps marketplace, with survival of the fittest ?
6. Fit with the rapidly evolving apps market ?
7. Resistant to manipulation & auditable ?

We need to think differently…

Old think	New Think
Paternalism: we know & determine what is best for users	**Self determination: users decide what is best for them**
Regulation will eliminate harmful Apps after release	**Prevent bad Apps - help App developers understand safety & quality**
The NHS must control Apps, apply rules and safety checks	**Self regulation by developer community Consumer choice informed by truth in labelling**
App developers are in control	**Aristotle's *civil society** is in control**
Quality is best achieved by laws and regulations	**Quality is best achieved by consensus and culture change**
The aim of Apps is innovation (sometimes above other considerations)	**App innovation must balance benefits and risks**
An Apps market driven by viral campaigns, unfounded claims of benefit	**An Apps market driven by *fitness for purpose* (ISO) & evidence of benefit**

· *The elements that make up a democratic society, such as freedom of speech, an independent judiciary, collaborating for common wellbeing*

Our draft quality criteria for apps based on Donabedian 1966

Structure = the app development team, the evidence base, use of an appropriate behaviour change model etc. …

Processes = app functions: usability, accuracy etc.

Outcomes = app impacts on user knowledge & self efficacy, user behaviours, resource usage

Wyatt JC, et al. Clinical Medicine December 2015

Labelling of apps

Analogy: legally required food labels listing ingredients, allergens etc.

Q: What fields for a health app label ?

A: Intended user; app functions;
privacy policy; source of content; results of accuracy / impact studies

Conclusions

1. The quality of mHealth tools varies too much
2. User & professional reviews, developer self-certification and regulation are not enough
3. To help reduce "***apptimism***" and strengthen other strategies, we need to agree quality criteria, evaluate apps against them, & label app with results
4. We have the evaluation methods (eg. rating quality of evidence, accuracy studies, RCTs)
5. This will support patients, health professionals, health systems and app developers to maximise the benefits of mHealth