The quality of mHealth apps: research and practical approaches from the UK

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Overview

What should a safe app look like ?

- **Examples of studies examining safety**

What should an effective app look like ?

- **Examples of studies examining effectiveness**

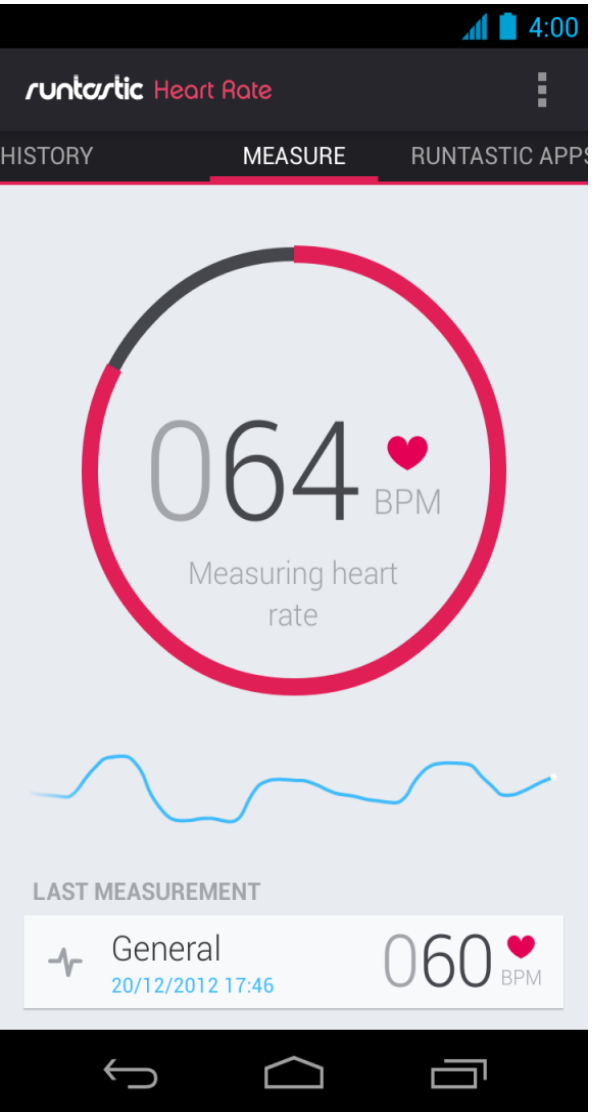
Should we evaluate safety & effectiveness for *every* mHealth app ?

Conclusions

A safe mHealth app should…

1. Respect the privacy of sensitive user data
2. Be based on sound evidence (not just opinion)
3. Be usable & behave predictably
4. Give accurate output or advice

Privacy and mHealt



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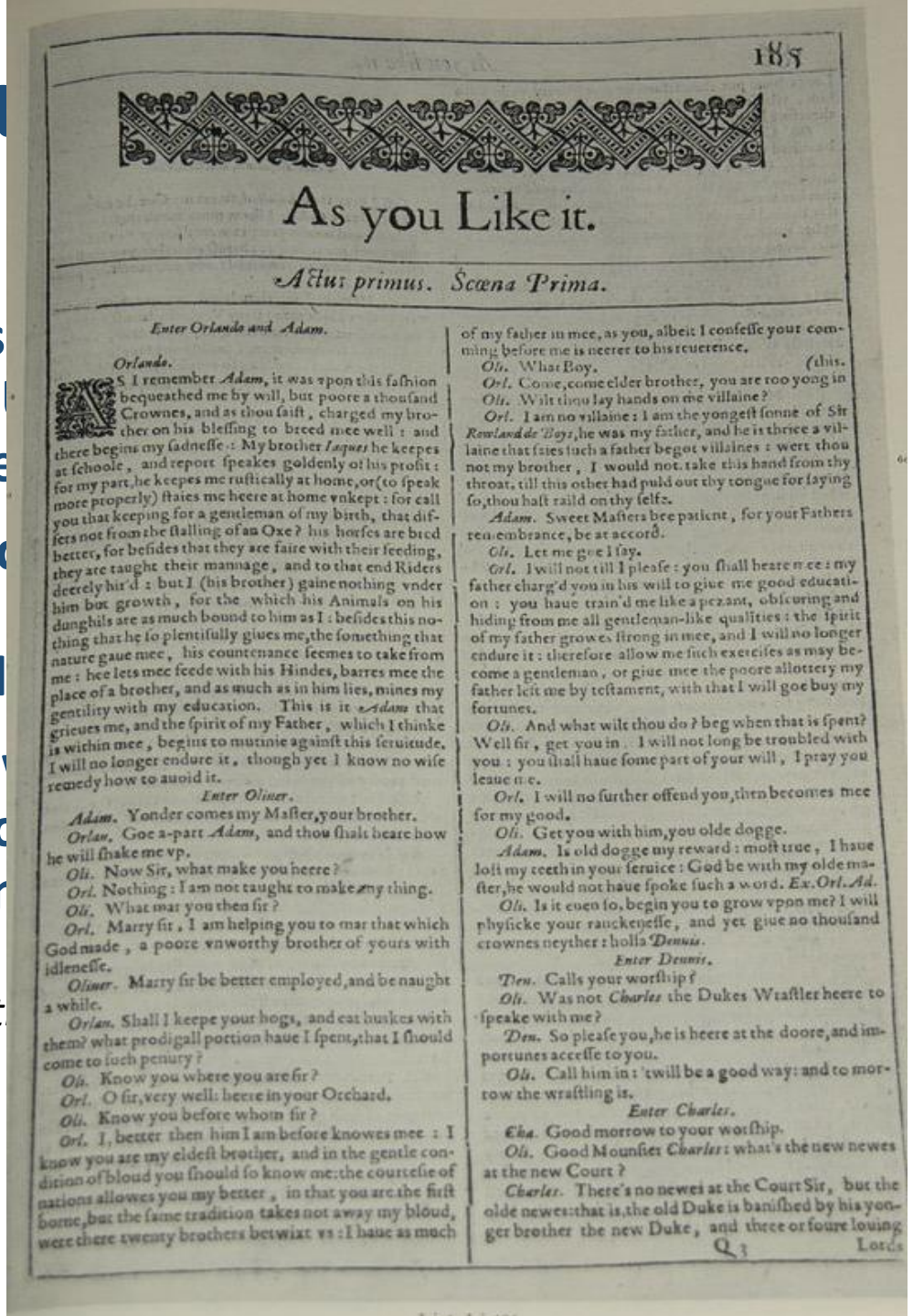
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As you Like it.

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 report 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: hee 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 pull'd 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, than 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.

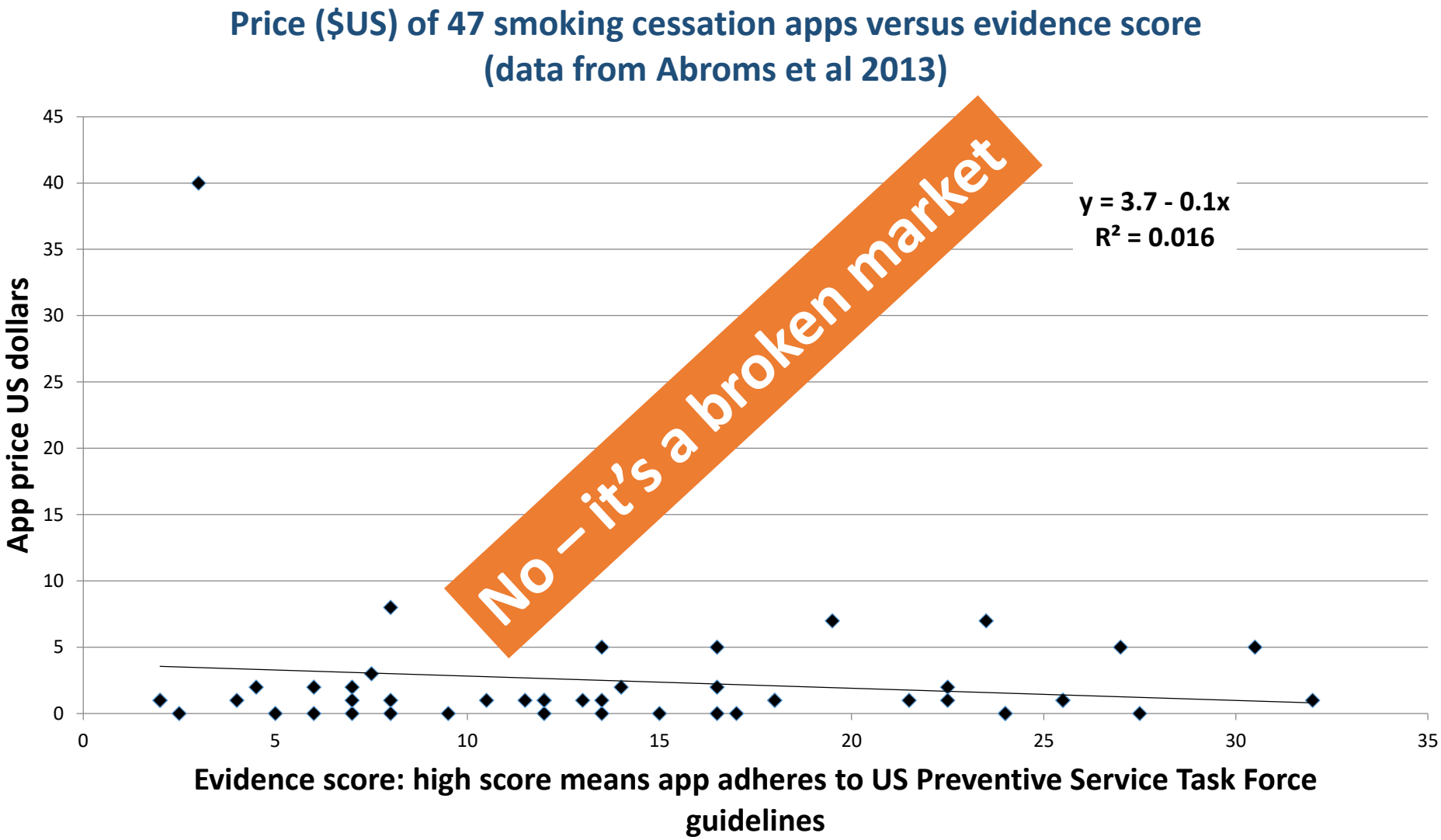
Oli. Good Mounsier *Charles*: what's the new newes at the new Court?

Charles. There's no newes at the Court Sir, but the olde newes: that is, the old Duke is banished by his younger 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

Does higher price correlate with sound evidence base for mHealth apps ?



Other evidence on app safety

Apps for insulin dosage adjustment (n= 46, Huckvale 2015):

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

Only 1 app was free of issues

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

Asthma apps (Huckvale 2015):

Number doubled from 93 in 2011 to 191 in 2013

23 (25%) of the first group withdrawn; 147 new apps in 2 years

Newer apps **not** more evidence based: only 75 (50%) of 147 gave basic info on asthma, 36 (24%) had diary functions

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

Accuracy of CVD risk apps for public

We located 21 apps: only 19 (7 paid) gave figures

All 19 communicated risk using percentages (cf. Gigerenzer, BMJ 2004: use numbers)

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

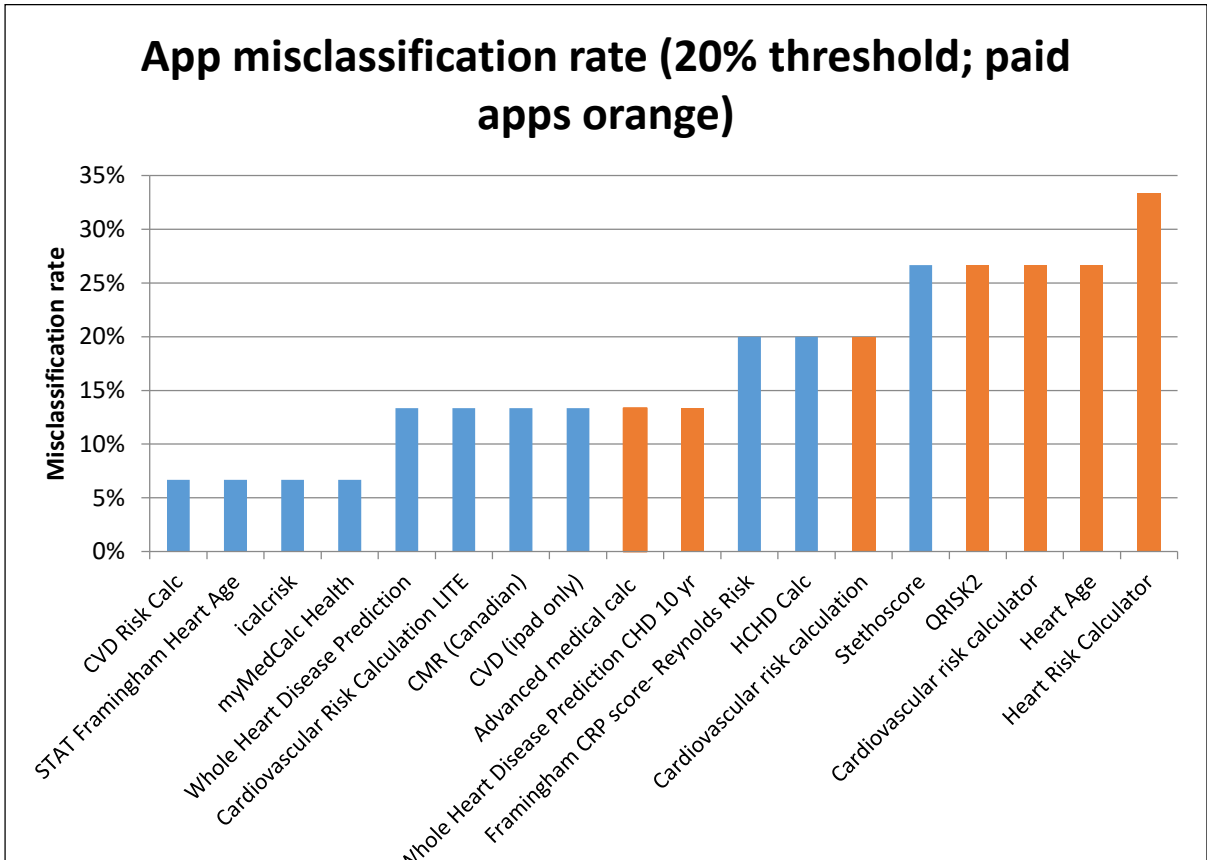
Heart Health App

Error rates

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

Of 19 apps, 8 (42%) misclassified at least 20% of scenarios

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



Assessing app accuracy

1. Only applies to apps that give advice, calculate a risk, drug dose etc.
2. Need a representative case series, or plausible simulated cases
3. Need a gold standard for the correct advice / risk [QRisk2 in our case]
4. Ideally, users should enter case data – or their own data
5. How accurate is “accurate enough”:
   - Accurate enough to get used ?
   - Accurate enough to encourage user to take action ?

Study of the accuracy of NHS Blood & Transplant PBM app

(Slides from Aman Dhesi)

Methods

A multidisciplinary team with junior and senior clinicians, transfusion practitioners, digital healthcare and biomedical scientists developed the App script.

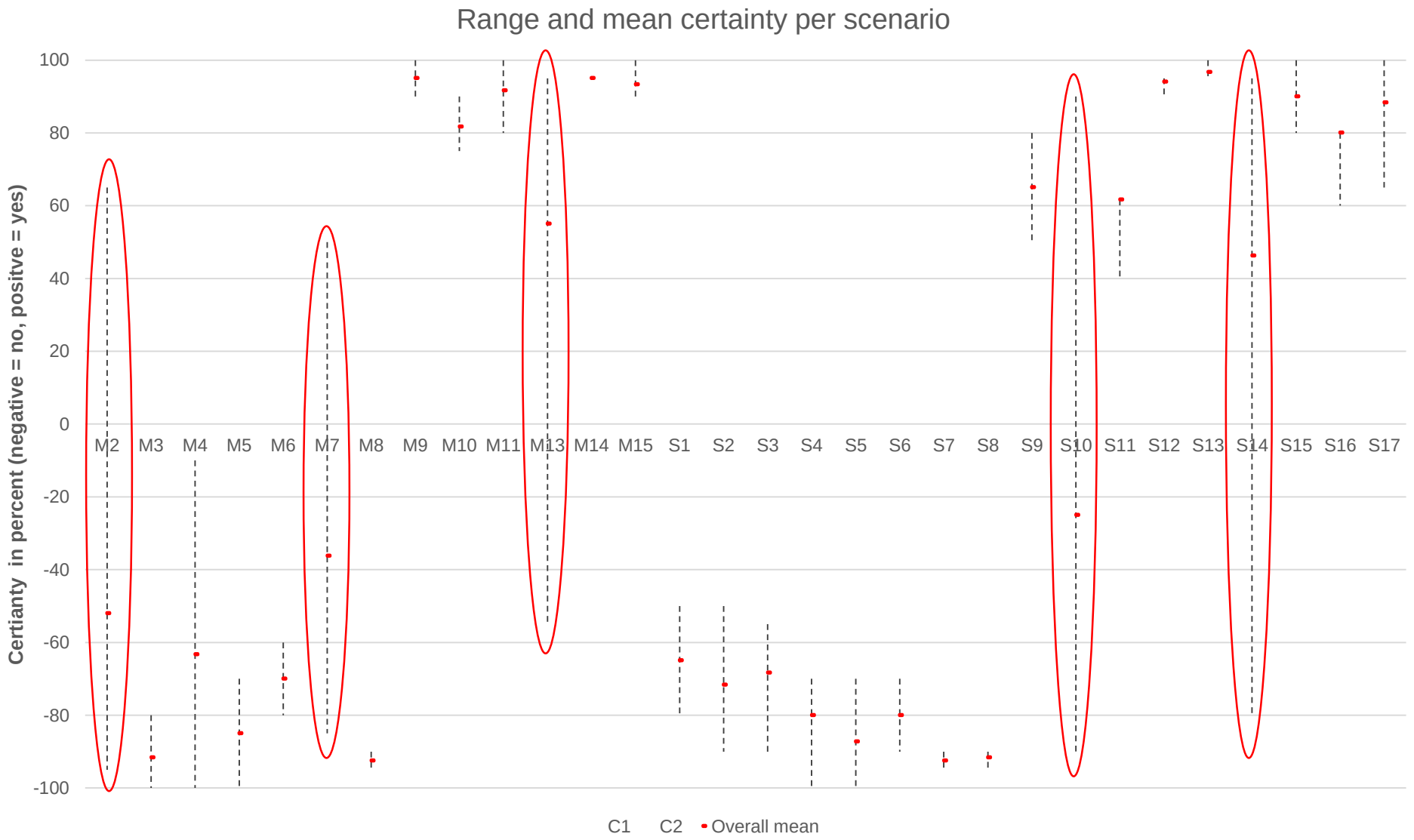
To test accuracy of the App we developed 30 scenarios based on medical or surgical patient cases with a recommended outcome based on PBM principles on whether or not transfusion was indicated.

To eliminate ambiguous scenarios we compared consultant clinical decisions and decision certainty using a visual analogue scale for each scenario.

These were sent to 24 consultant haematologists with expertise in Transfusion Medicine (aim of minimum 3 consultants per scenario).

The clinical decision was then compared with the guidance obtained using the App. We also asked consultants to provide feedback on or suggest changes to the supporting information provided by the App in response to each scenario.

Results of study to determine gold standard for each scenario



An effective app should…

1. Deliver on its claims
2. Offer the user more benefits than harms
3. EITHER:
    a) Be equivalent to current alternatives but less costly, OR
    b) Be better than alternatives, and the same cost

and therefore be prescribable…

Options for evaluating effectiveness

1. **Psychological experiments:** within user change in knowledge / views / decisions / certainty
2. **Exploiting big health data:** instrumental variable, regression discontinuity etc designs
3. **Engineering methods:** SMART, A-B testing; testing generic design principles, not apps
4. **Or online or face-to-face randomised trials !**

Trials of app effectiveness

In 2016 there were 21 published randomised trials of apps used by patients / the 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 trials*:

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

5 studied clinical processes: 3 positive, 2 equal

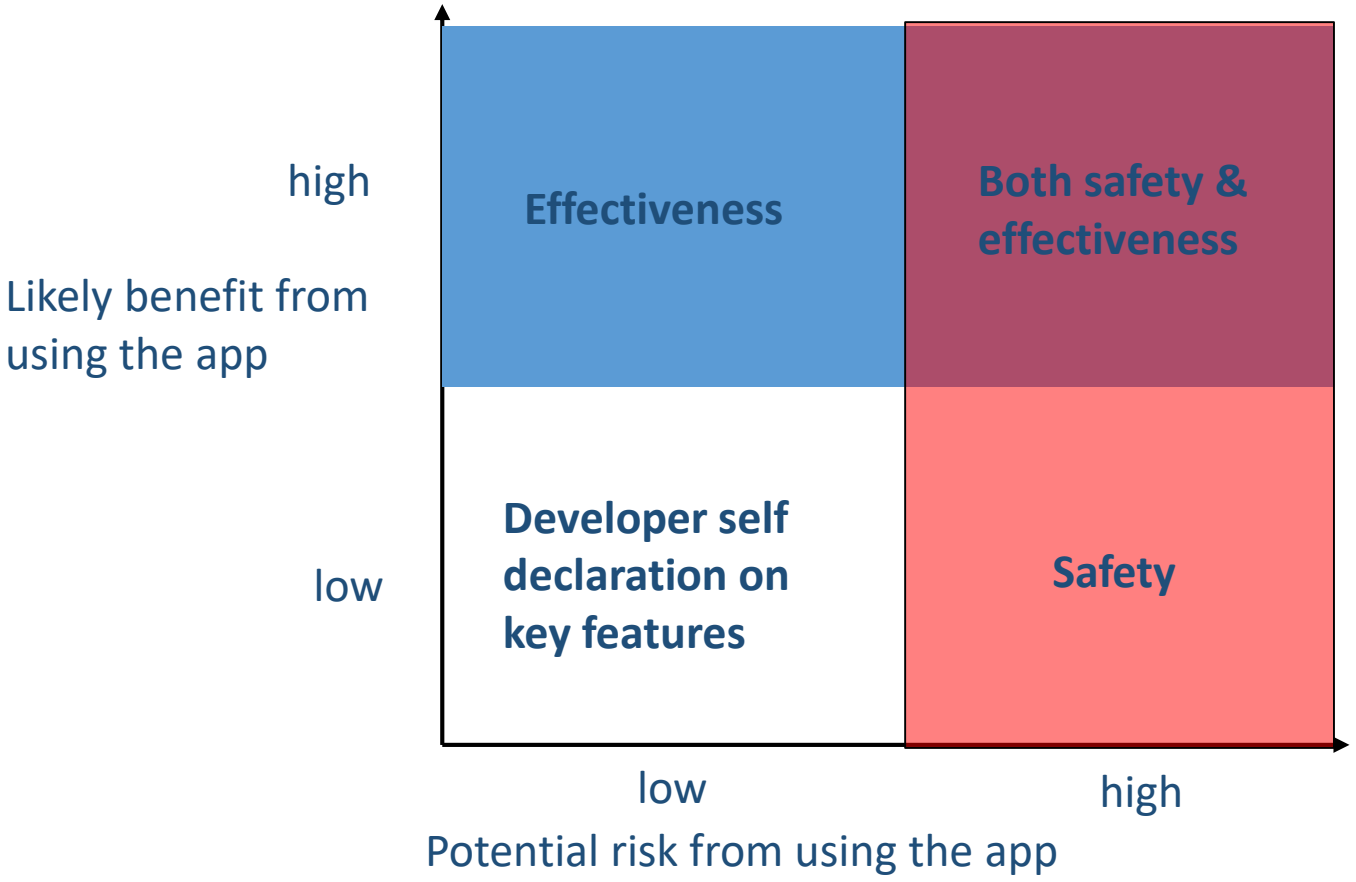
5 studied patient outcomes: 3 positive, 2 equal

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

- 3 studies measured more than one of these

Now there are about 180 trials…

What to evaluate, for which apps?



A proposed evaluation cascade for mHealth Apps

Area	Topics	Methods
Source	• Purpose, sponsor • User, cost	Inspection
Safety	• Data protection • Usability	Inspection HCI lab / user tests
Content	• Based on sound evidence • Proven behaviour change methods	Inspection
Accuracy	• Calculations • Advice	Scenarios with gold standard
Potential impact	• Ease of use in the field • Understanding of output	Usability type studies
Impact	• Knowledge, attitudes, self-efficacy • Health behaviours, outcomes	Within-subject expts Field trials

Conclusions: good evaluation practice for digital health interventions

1. **Know why you are evaluating:** who are the stakeholders, what decision do they face ?
2. **Understand stakeholder questions** and the level of evidence they need to answer them
3. **Design your study with:**
   - Enough participants of the right kind
   - The right intervention
   - The right control
   - Validated outcome measures
4. **Check for biases and confounders** & that you will learn something if study negative
5. **Run the study & report your results**

See: Murray E et al. Design & evaluation of digital interventions. **Am J Prev Med** Nov 2016

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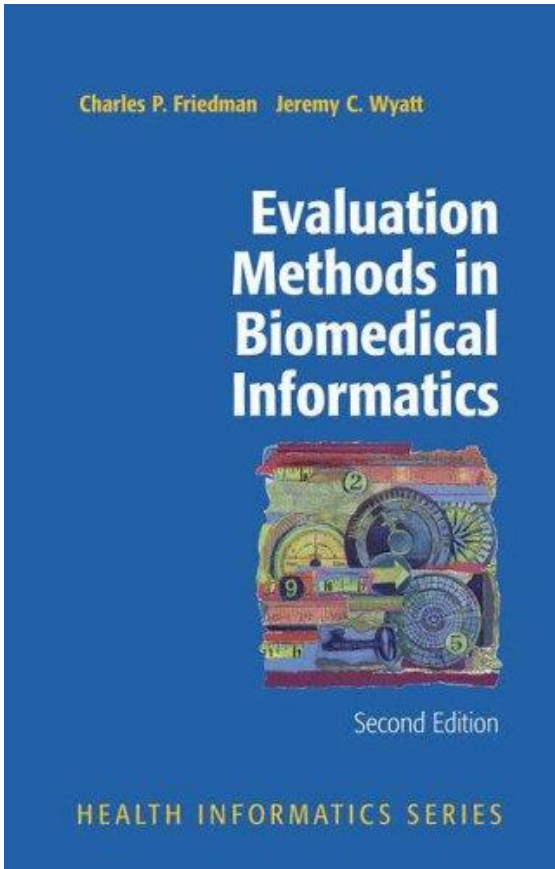

Spare slides

Online RCT to measure impact of Fogg's persuasive technology theory on NHS organ donation register sign up rates

Result: 900 participants recruited to RCT in 5 days; no difference in NHS organ donation register sign-up rates (38% both groups)

Persuasive features:

1. URL includes https, dundee.ac.uk
2. University Logo
3. No advertising
4. References
5. Address & contact details
6. Privacy Statement
7. Articles all dated
8. Site certified (W3C / Health on Net)

Source: Nind, Sniehotta et al 2010