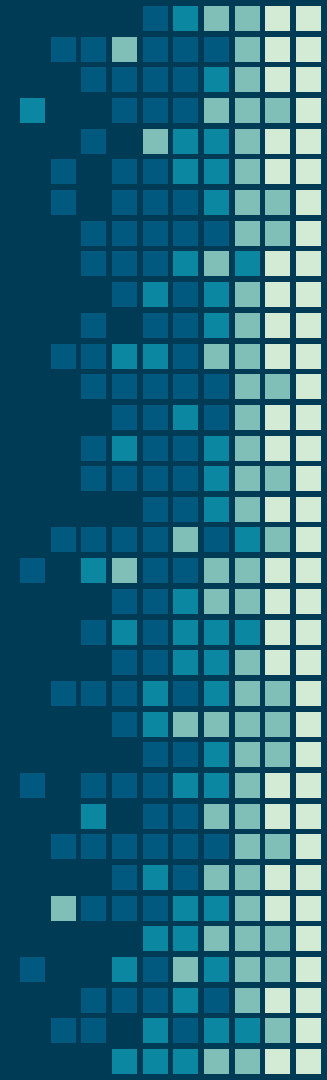# Raise your hand if you use/ have ever used a mobile health application!

Well, if your hand went up (or not), this presentation is for you!

Esther, Kenya

Used a mobile health app that diagnosed her with HIV simply by analyzing her fingerprint on the touch screen.

Esther, Kenya

Socioeconomic

Psychological

Emotional

"And she wasn't the only one, there were others that came to us worried about the app and those were just the ones that were willing to speak out."

-Laura de Reynal

http://www.bbc.com/news/technology-39371100

SafeHealthApps

Safety Concerns with Consumer-Facing Mobile Health Applications and their Consequences

Background

- A vast amount of mobile apps on the market

- 325,000 health apps currently available on IOS and Android[1]

- Consumer use of mobile health apps is rapidly growing

- Not independently evaluated, regulated or built to any common safety standard

- Limited examination of safety risks and harms posed by health apps
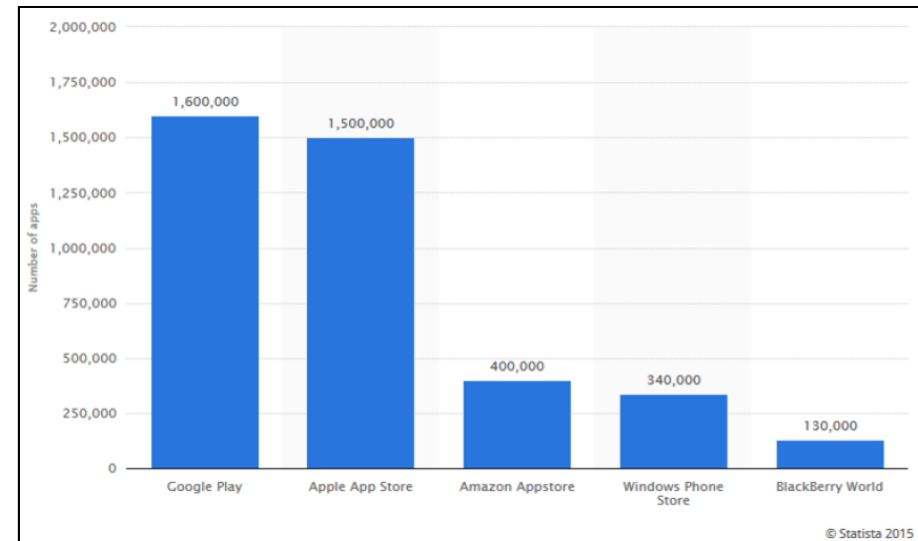
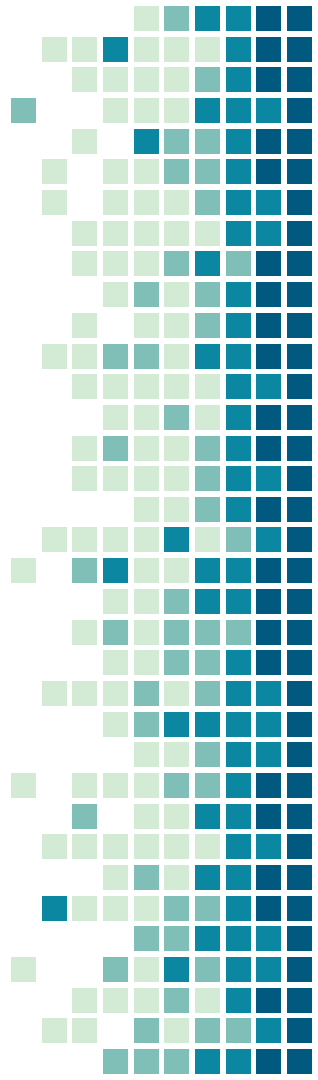The number of applications available at leading App stores (Statistica, 2015).

1. Research 2 Guidance. MHealth app economics 2017. 2017. Retrieved from: https://research2guidance.com/wp-content/uploads/2017/11/R2G-mHealth-Developer-Economics-2017-Status-And-Trends.pdf

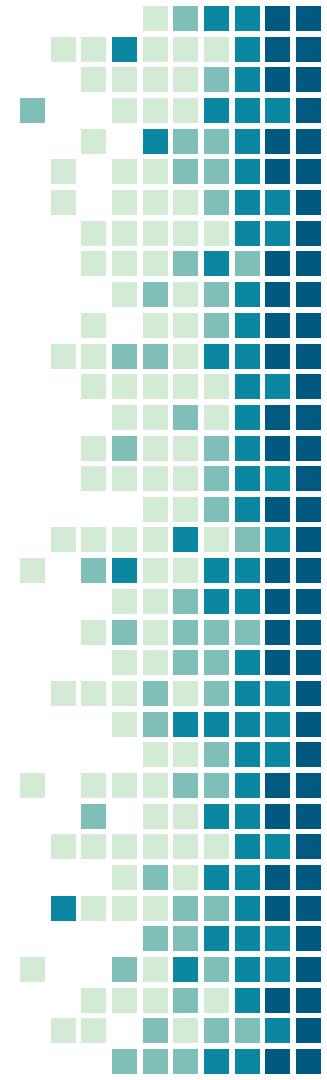# FDA GUIDELINES

Medical Devices

Intermediate

Wellness

SafeHealthApps

1. Scoping Review of Literature

2. Qualitative Analysis of Safety Reports

- Categorization of Safety Concerns

- Classification of Consequences

Classification of Consequences

Harm category[1]	Definition
Actual or potential harm	Adverse event - clinical consequence.
Arrested or interrupted sequence	Near miss – Error detected before it could harm the user.
Noticeable consequence but no harm	Problem that affected care delivery but involved no harm to the user.
No noticeable consequence	No affect on care delivery.
Hazardous event	A problem or circumstance that could eventually lead to an adverse event.

1. Kim MO, Coiera E, Magrabi F. Problems with health information technology and their effects on care delivery and patient outcomes: A systematic review. J Am Med Inform Assoc. 2017 Mar 1; 24(2): 246-250.
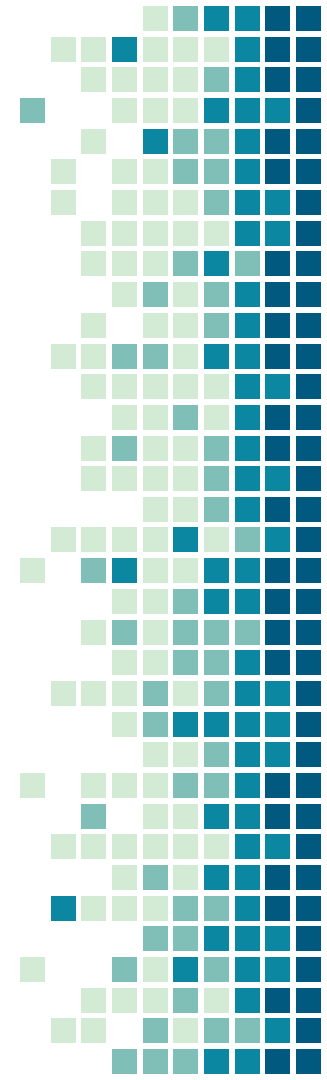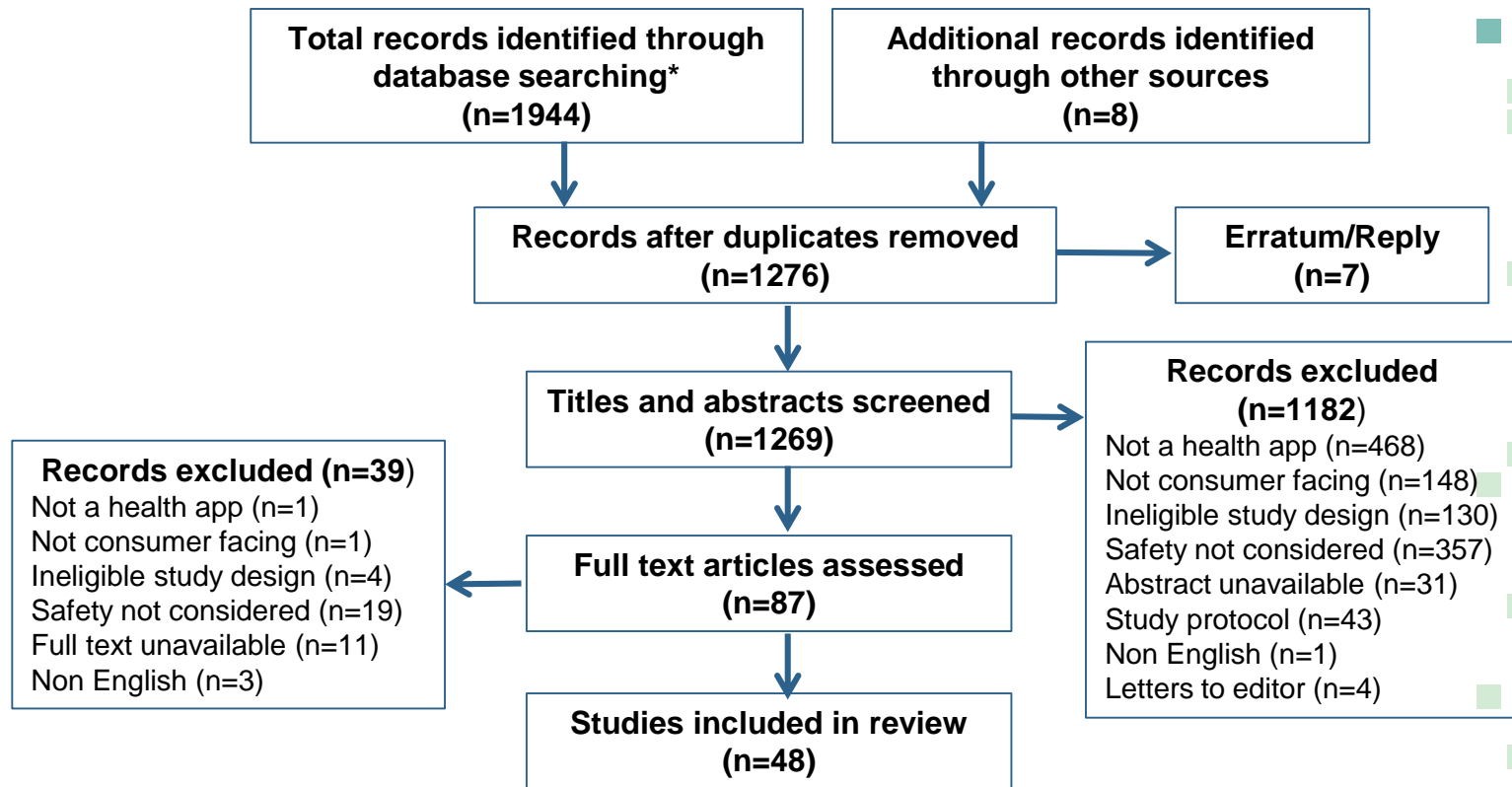
Scoping Review

Objectives

To review studies about health apps and to identify the types of safety concerns and their consequences.

Inclusion Criteria

- 2013 onwards (searched in Jun, 2017)
- Featuring consumer facing mobile health app
- Study design: Systematic reviews, RCTs, Analysis of health apps, Pilot tests
- Safety risk/ adverse event outcome considered

Identificatio

Screening

Eligibility

Included

Total records identified through database searching*
(n=1944)

Additional records identified through other sources
(n=8)

Records after duplicates removed
(n=1276)

Erratum/Reply
(n=7)

Titles and abstracts screened
(n=1269)

Records excluded (n=1182)
Not a health app (n=468)
Not consumer facing (n=148)
Ineligible study design (n=130)
Safety not considered (n=357)
Abstract unavailable (n=31)
Study protocol (n=43)
Non English (n=1)
Letters to editor (n=4)

Records excluded (n=39)
Not a health app (n=1)
Not consumer facing (n=1)
Ineligible study design (n=4)
Safety not considered (n=19)
Full text unavailable (n=11)
Non English (n=3)

Full text articles assessed
(n=87)

Studies included in review
(n=48)

*PubMed (n=631), Web of Science (n=385), Scopus (n=808), Cochrane (n=120)

Frequently Reported Concerns

κ=0.79 (p<0.001, 95% CI 0.70 to 0.88)

38%
of the studies reported
absence or lack of sufficient scientific evidence to support the information content of the app.

23%
of the studies reported
variation in content quality, particularly in clinical information.

23%
of the studies reported
Diagnostic or calculation errors yielding wrong output.

31%
of the studies reported
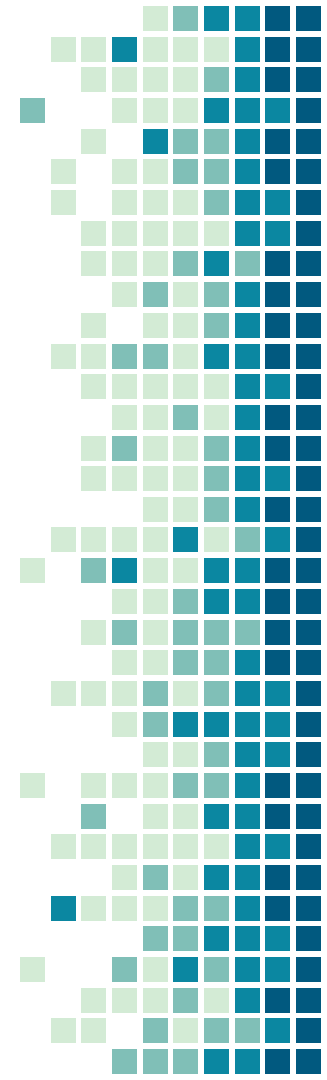that the apps provided incorrect or incomplete information.

21%
of the studies reported
Lack of medical professional involvement, in the process of app development.

Others	
Inducing unintended negative harms	4
Lack of regulatory evidence	1
Anxiety provoking information	1
Insufficient scope	1
Inappropriate response to consumers' needs	1

Consequences (n=22, 46%)

Harm category[1]	Frequency	Examples
Actual or potential harm (Adverse event)	5	Increased alcohol consumption due to competitive drinking games offered by apps.
Noticeable consequence but no harm	14	Inability to accurately monitor step count.
Hazardous event	3	Substituting a visit to a medical professional with the use of diagnostic apps that were found to be erratic.

1. Kim MO, Coiera E, Magrabi F. Problems with health information technology and their effects on care delivery and patient outcomes: A systematic review. J Am Med Inform Assoc. 2017 Mar 1; 24(2): 246-250.
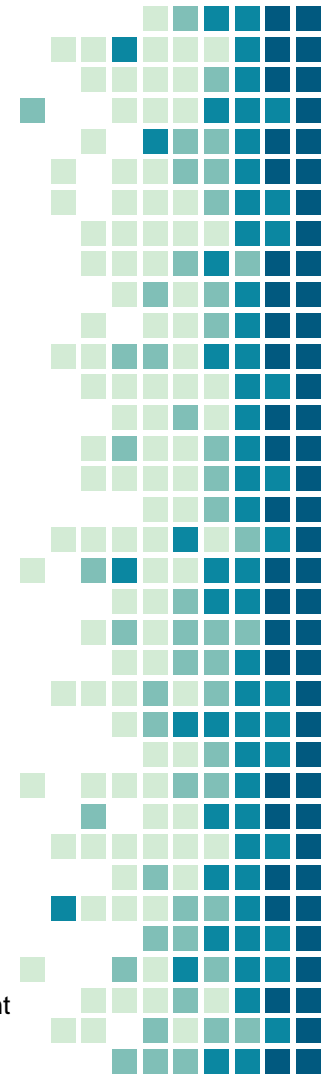
Safety Report Analysis

Objectives

To identify the types of safety concerns with consumer-facing mobile health apps in the hands of users, and their consequences.

Design

- Consumers reported safety concerns
- Aug'17 – Nov'17

Participants and setting

- Consenting Adults (18 years or over)
- Consumers of mHealth apps
- Voluntary participation
- Macquarie University

Tool

- Online Survey
  - Health app
  - Purpose of use
  - Response of app
  - Outcome
  - Demographics

Analysis

- Categorization of concerns by two independent reviewers
- Consequences analyzed using the standard approach[1]

1. Kim MO, Coiera E, Magrabi F. Problems with health information technology and their effects on care delivery and patient outcomes: A systematic review. J Am Med Inform Assoc. 2017 Mar 1; 24(2): 246-250.

17
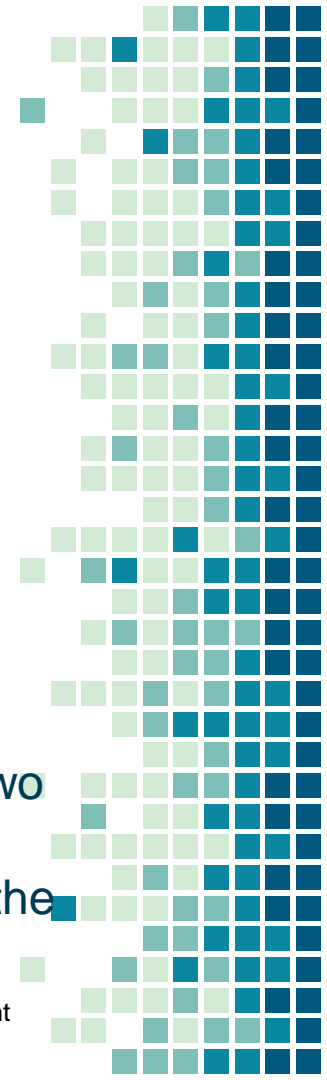
Reported Safety Concerns

25

Reports were related to

Errors in information tracking

E.g. inaccurate step count and sleep time

17

Reports were related to

Incorrect or incomplete information

E.g. misleading caloric count and absence of exercise instructions

Safety Concern	Number of incidents
Insufficient scope	6
Difficulty in accessing content	6
Lack of geographic customization	5
Complex or demotivating interface	5
Inability to interact with other devices	5
Inappropriate alerts	4
Addictive in nature	4
Variation in content quality	3
Information loss	2
Errors in calculation	2
Difficult retrieval of personal information	2

Reported Consequences

62 safety concerns (72%) were associated with a consequence.

| Harm category[1]	#	Examples
Actual or potential harm (Adverse event)	12	Undesired weight loss, sprain injury, over and under eating, missed medicine dose, risk of self-diagnosis, and inaccurate calorie count resulting in excess consumption. (Minimum Harm[2])
Arrested or interrupted sequence (near miss)	20	Google search solved confusion in calorie requirement, user created their own excel sheet to keep record of activity.
Noticeable consequence but no harm	15	Need to restart tracking, activities not counted towards team goals.
Hazardous event	6	Inaccurate sleep tracking, inability of the app to address special groups such as dwarfs, and wrong data output.
No noticeable consequence	11	Need to reboot the hardware, excessive battery consumption

1. Kim MO, Coiera E, Magrabi F. Problems with health information technology and their effects on care delivery and patient outcomes: A systematic review. J Am Med Inform Assoc. 2017 Mar 1; 24(2): 246-250.
2. NSW Health Incident Management Policy Directive, Quality and Safety Branch. 2007.

Consumers' Reactions

- 45 participants (70%) contacted a national authority

- 24 participants (37%) discontinued using the app

Study limitations

- Self-reporting

- Limited to university setting
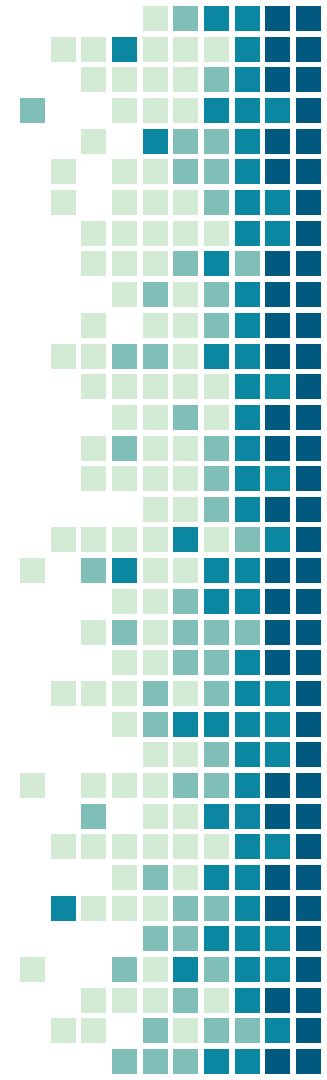
Conclusion

● Safety of health apps is an emerging issue in public health informatics.

●Incorrect or incomplete information is a commonly reported concern – both in literature and by consumers

● Need to address gaps in current process of app development.
○ regulatory framework
○ Involvement of HCPs
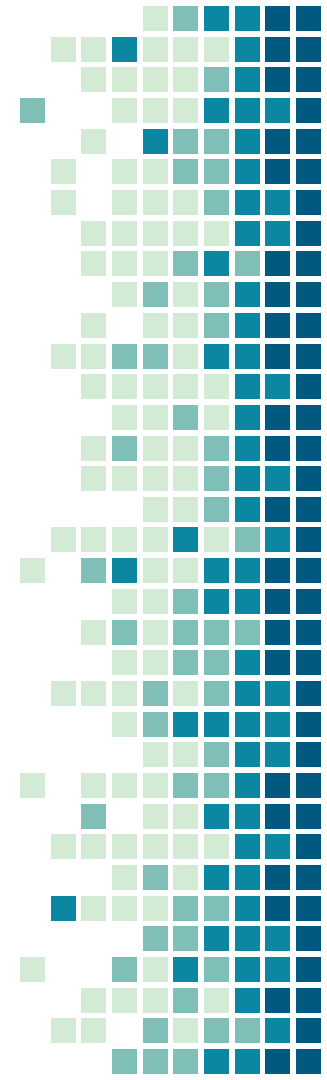○ Recency check

● Consumer awareness about safe use of apps.

Acknowledgement

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- Mi Ok Kim
- Ying Wang
- Denise Tsiros
- Samantha Morris
- Isabella Bozzi
- Study participants

Questions & Comments

"YO DOC! I'VE GOT A HEALTH APP, HOW ABOUT YOU EXAMINE MY PHONE WHILE I WAIT IN THE PUB?"

THANKS!

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