Patient Safety in Digital Healthcare:
Ensuring the intangible

Ciarán McInerney, PhD.

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"to digitise the entire NHS by 2024"

"ensuring that digital systems are designed to meet the needs of their users"

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Use digital; don't live digitally

Power cut?

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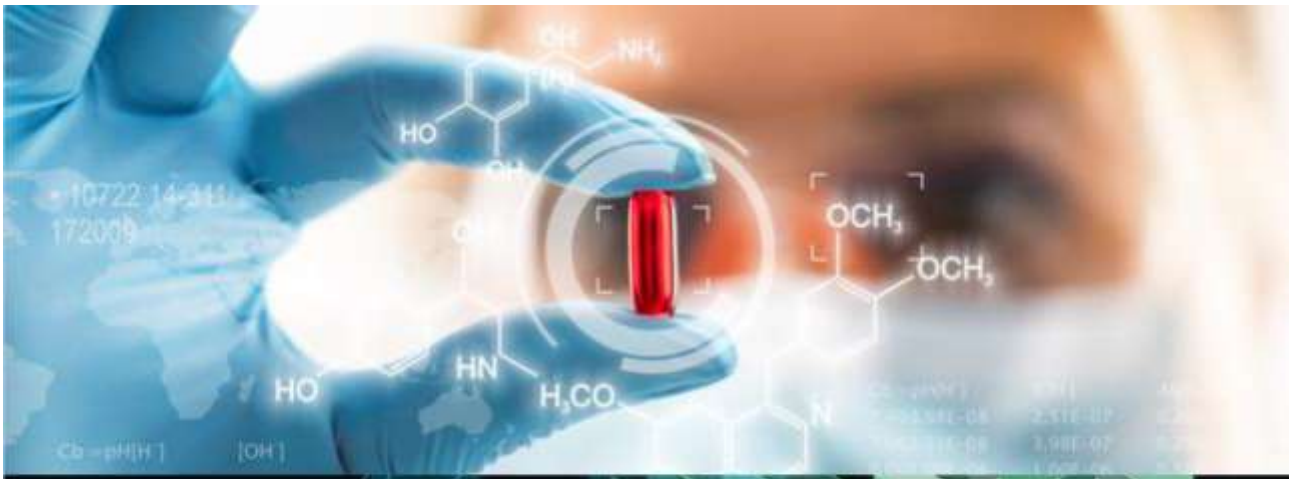

Patient Safety in Digital Healthcare:
Ensuring the intangible

Headingly Café Scientifique - 13th Sept 2021

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What is safety?

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£100,000,000

Safety 1

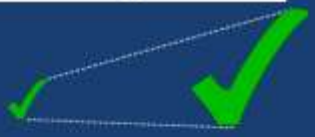
Discourage Bad

?

a. More to discourage
b. More to encourage
c. Same to both

Safety 2

Encourage Good



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Safety in Numbers

https://safety-in-numbers.co.uk/

Case studies

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ROBEAR

Constipation	Diarrhoea	Rectal bleeding	Loss of weight	Abdominal pain	Abdominal tenderness	Abnormal rectal exam	Haemoglobin 10–13 g dl^{-1}	Haemoglobin <10 g dl^{-1}	
0.42 0.3, 0.5	**0.94** 0.7, 1.1	**2.4** 1.9, 3.2	**1.2** 0.9, 1.6	**1.1** 0.9, 1.3	**1.1** 0.8, 1.5	**1.5** 1.0, 2.2	**0.97** 0.8, 1.3	**2.3** 1.6, 3.1	PPV as a single symptom
0.81 0.5, 1.3	**1.1** 0.6, 1.8	**2.4** 1.4, 4.4	**3.0** 1.7, 5.4	**1.5** 1.0, 2.2	**1.7** 0.9, 3.4	**2.6**	**1.2** 0.6, 2.7	**2.6**	Constipation
	1.5 1.0, 2.2	**3.4** 2.1, 6.0	**3.1** 1.8, 5.5	**1.9** 1.4, 2.7	**2.4** 1.3, 4.8	**11**	**2.2** 1.2, 4.3	**2.9**	Diarrhoea
		6.8	**4.7**	**3.1** 1.9, 5.3	**4.5**	**8.5**	**3.6**	**3.2**	Rectal bleeding
			1.4 0.8, 2.6	**3.4** 2.1, 6.0	**6.4**	**7.4**	**1.3** 0.7, 2.6	**4.7**	Loss of weight
				3.0 1.8, 5.2	**1.4** 0.3, 2.2	**3.3**	**2.2** 1.1, 4.5	**6.9**	Abdominal pain
					1.7 0.8, 3.7	**5.8**	**2.7**	**>10**	Abdominal tenderness

AI AND ANALYTICS

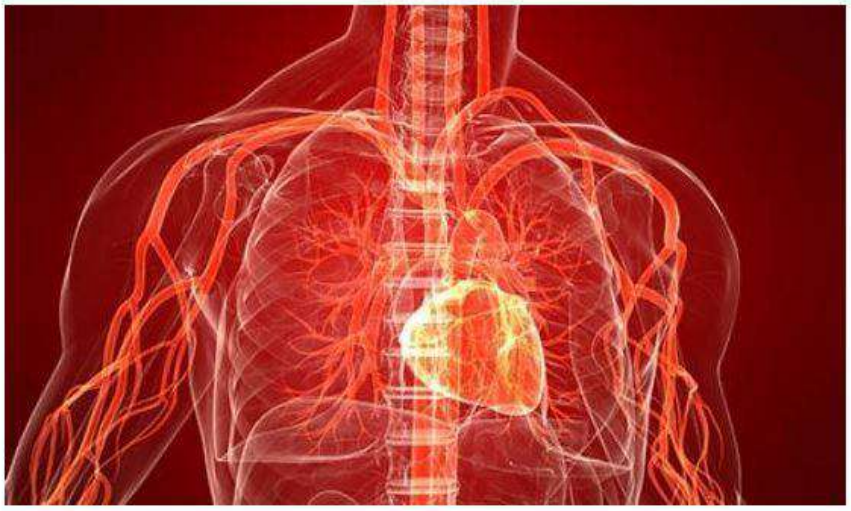
Decision support | MHRA | QRISK | TPP

QRisk2 in TPP "fixed" but up to 270,000 patients affected

Ben Heather

10 June 2016

Share this...



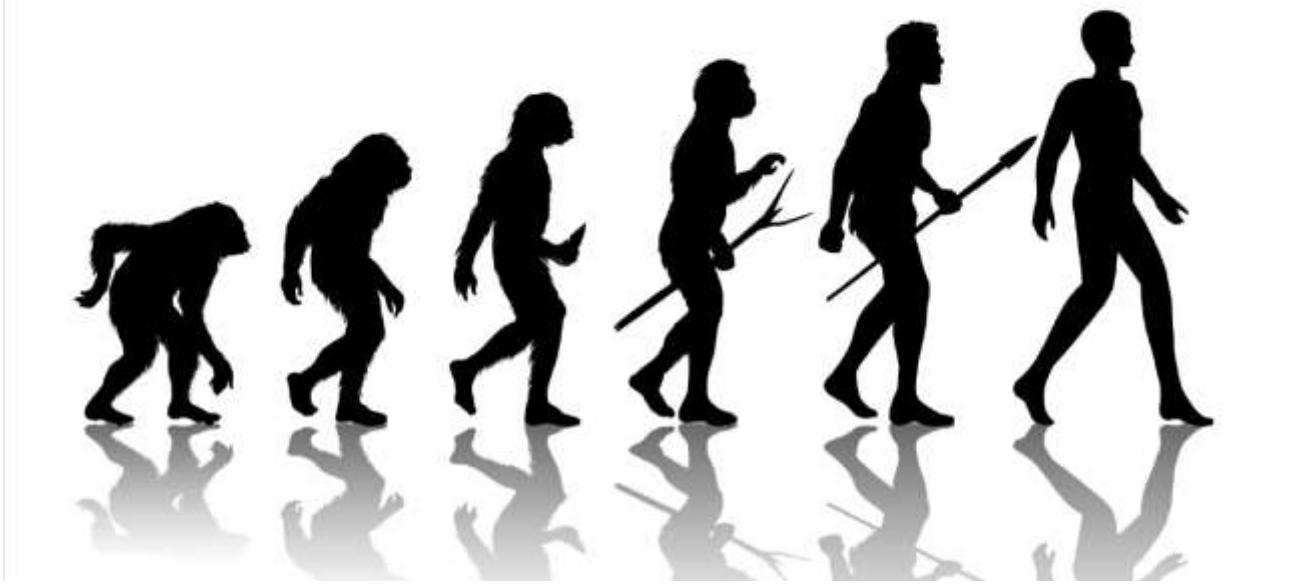
Up to 270,000 patients have been affected by errors in a cardiovascular disease risk digital calculator, which is being blamed on a "code mapping" issues.

intelligence

Trusts:

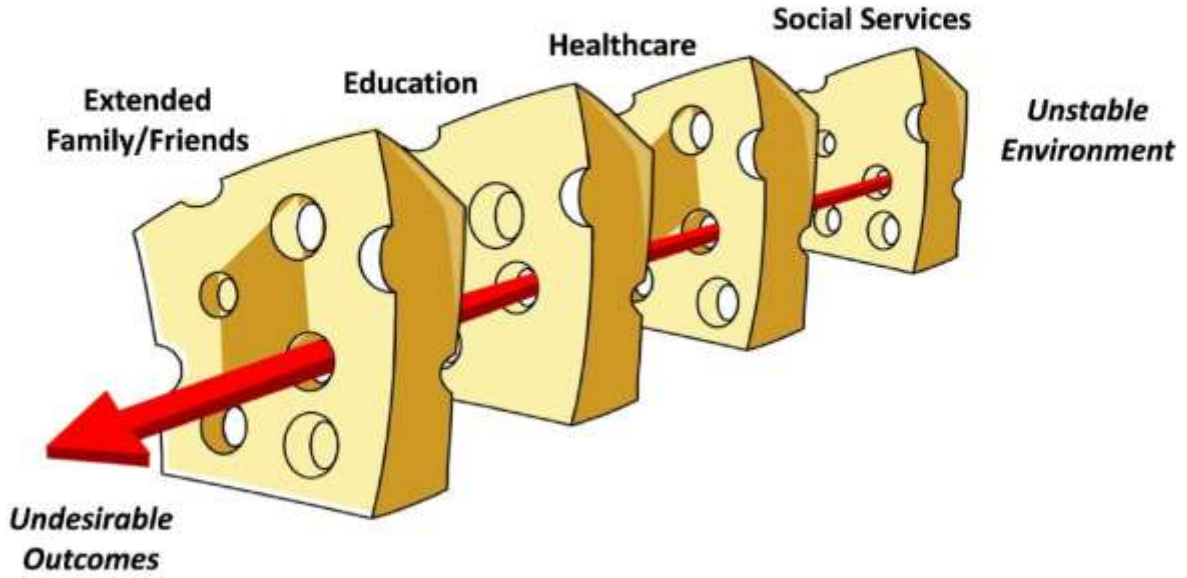
Suppliers:

Evolution of safety theory…in games



Safety-1: Whack-a-mole

Safety 1.5: Swiss cheese



Safety-2: Pretend

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WHAC-A-MOLE
Educa
ded
riends

Avoiding Risk
Managing Risk
Embracing Risk
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Avoiding Risk

Department of Health & Social Care

Policy paper

Annex A: about Exercise Cygnus

Updated 5 November 2020

Contents

Exercise Cygnus was a cross-government exercise to test the UK's

<u>Attitude</u>

No acceptable risk

<u>Need</u>

Competent regulators and supervisors

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Managing Risk

<u>Attitude</u>

Minimise damage

<u>Need</u>

Competent teams

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Photo by Jay Heike on Unsplash

Embracing Risk

Attitude

Inevitable danger

Need

Competent individuals

Photo by Super Straho on Unsplash

Risk vs. Uncertainty

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JCO® Clinical Cancer Informatics
An American Society of Clinical Oncology Journal

Enter words / phrases / DOI / ISBN / authors / keywords / etc.

SPECIAL ARTICLES

Are Regulations Safe? Reflections From Developing a Digital Cancer Decision-Support Tool

Check for updates

Ciarán D. McInerney, PhD[1]; Beverly C. Scott, MSc[2]; and Owen A. Johnson, MSc[1]

Show More

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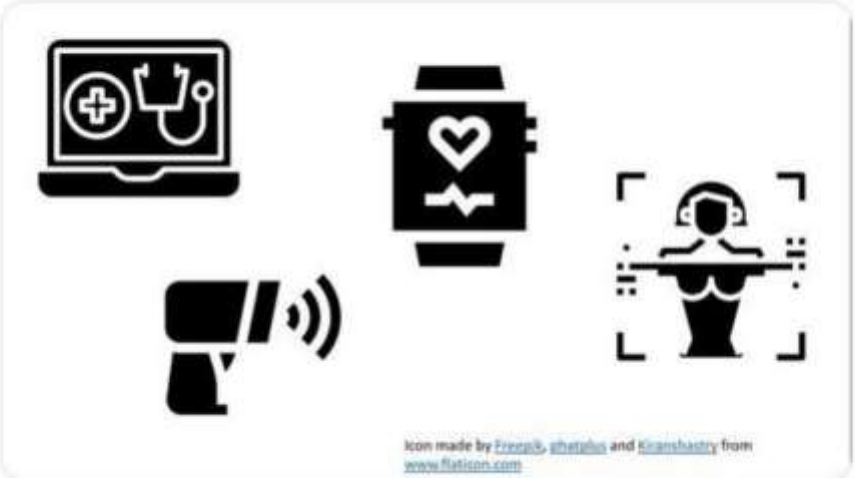
Ciarán
@CMc_PhD

Replying to @CMc_PhD

Digital technology has revolutionised healthcare but the changes have not all been positive.

In this thread, I will speak about three blind-spots of digital health innovations, with particular focus on regulation and on patient safety.



10:32 AM · Jul 15, 2020 · Twitter Web App

#1

Regulators do not control access and use of what they regulate.

Icon made by Freepik, Smashicons and Vitaly Gorbachev from www.flaticon.com

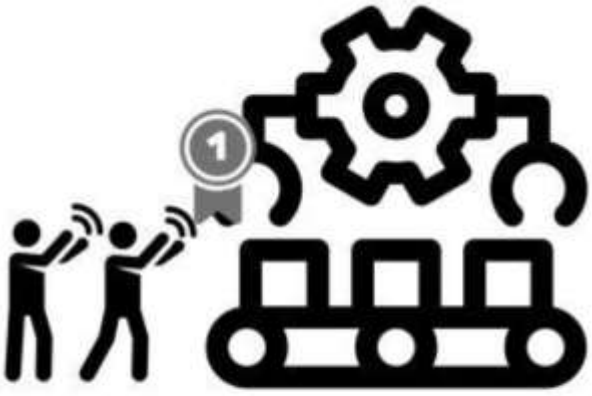
#2

Safety regulators will always play catch-up because innovation is not regulated.

Icon made by Freepik and Pixel perfect from www.flaticon.com

#3

Busy ≠ Productive.
Not all innovation is useful.



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How can we improve our sense making, and decision making when it comes to safety?

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EU AND MEMBER STATE MEDICAL DEVICES REGULATION

Christa Altenstetter
City University of New York

EU regulation of medical devices grew out of the adoption in the mid-1980s of so-called *new approach* legislation, which affected 17 industrial sectors, including medical devices. The adoption of this new approach was a historic move made at the highest political levels. While this move was not free of conflict, EU members accepted the entire new approach legislative package in order to set in motion the single market, which was perceived to be in the national interest of each country. But once the package was enacted, conflict resolution in the medical devices sector shifted from the "high politics" level to highly specialized and technocratic committees, working groups, and issue networks (18).

Under old approach legislation, technical standards and specifications were written into directives. New approach legislation, by contrast, institutionalized a separation between law and technical standards. Instead, directives would rely on essential requirements[2] and the use of voluntary standards. However, at the demand of France and a few other coalition part-

BMJ 2016;353:i2372 doi: 10.1136/bmj.i2372 (Published 9 June 2016)

ANALYSIS

IDEAL-D: a rational framework for evaluating and regulating the use of medical devices

High profile device failures have highlighted the inadequacies of current regulation. **Art Sedrakyan and colleagues** call for a move to a graduated model of approval and suggest a framework to achieve this goal

Art Sedrakyan *professor*[1], Bruce Campbell *professor*[2], Jose G Merino *clinical research editor*[3], Richard Kuntz *chief scientific, clinical, and regulatory officer*[4], Allison Hirst *researcher*[5], Peter McCulloch *professor*[5]

PERGAMON

Safety Science 42 (2004) 237–270

SAFETY SCIENCE

www.elsevier.com/locate/ssci

A new accident model for engineering safer systems

Nancy Leveson*

Systems Approach and Systems Engineering Applied to Health Care: Improving Patient Safety and Health Care Delivery

Alan D. Ravitz, Adam Sapirstein, Julius C. Pham, and Peter A. Doyle

Risk Analysis, Vol. 29, No. 12, 2009

On the Complex Definition of Risk: A Systems-Based Approach

Yacov Y. Haimes*

Risk Analysis, Vol. 29, No. 4, 2009

On the Definition of Resilience in Systems

Yacov Y. Haimes*

Safety in Numbers

https://safety-in-numbers.co.uk/