CLINICAL SAFETY OF SOFTWARE CLASSIFIED AS A MEDICAL DEVICE

ROSALIND CAUSEY FEB 2020
MY FIRST CLINICAL SAFETY EXPERIENCE

1983 – A potentially career breaking clinical safety challenge

I have dyspraxia, illegible handwriting but before being granted my registration, I faced an UKCC tribunal:

“is this nurse safe to practice if no one can read her records?”

Things looked bleak, until a panel member asked...

“have you tried to read Doctors handwriting?”

Panel agreed Drs not penalised for poor Prescriptions,

So Nurses shouldn’t be either

... His mitigation,

“Dr’s have Secretaries”.

Phew!
I LEARNED:

• to be tenacious, my handwriting doesn’t reflect my ability,

• the importance of clinical safety,

• to mitigate the risk so my practice is acceptably safe.

Became an early adaptor of all things digital –
Find new ways to write legible clinical records in client’s homes
THEN – I USED PSION ORGANISER FOR MY HV RECORDS

I could type and sign and date, share what I was writing with my client - they controlled the red book ... but I had to print and stick everything into the paper records! ....... yes it took AGES!

NOW, 37 years later
I use a smart phone full of Apps

Win95- Outlook as my diary, Excel as birth book to manage my workload.
1999 PCG IM&T - learned to programme & design databases whilst lead IG (FOI & DP), PRIMIS Data Quality improvement, GP net.

2005 Early CfH Safety training to increase clinician awareness

2006 set up Consultancy to support NPfIT
Delivered my first safety sign off for BT.

(BT developed its own risk management processes in parallel with CfH, based on aerospace standards.)

2018- MHRA experience of regulation of Software and Apps as Medical devices.
MY ROLE IN MHRA DEVICES SAFETY TEAM WAS TO:

Engage

• Understand local processes and safety challenges for MDSO’s
• Identify ways MHRA can better support its stakeholders?
• Facilitate peer to peer sharing of concerns, solutions and lessons learned

Improve

• Quantity & Quality of Reporting
  • MHRA need detail to follow up (serial numbers & manufacturer)
• MHRA’s feedback of:
  • Progress of investigations to those who reported them (capacity)
  • Early safety concerns (confidentiality constraints vs sharing)
CLINICAL SAFETY HAS COME A LONG WAY IN 15 YEARS:

- **Mandatory Compliance** with DCB0129 and DCB0160
  - Under the Health and Social care Act 2012.

- **Alignment** of NHS Digital clinical safety standards with MHRA Medical Devices Regulation

- Clinical Safety Community growing ...
  
  "...A lot of excellent work being done."

But challenging for Regulators to keep up with speed of change

from Apps in Abundance to the very different world of AI in healthcare
CHALLENGES FOR SOFTWARE SAFETY ASURANCE

• Changes in Regs’ for Software used as components or in conjunction with medical devices (2017- full force May 2020)

• Apps in Abundance on Super Smart devices.

• AI & Machine learning - a very different new world.

• Big Data - Ownership, Mining, Data Sharing & Do$h.

• World Wide Regulation required— Britain, Brexit and Regulating Software in a Global Economy.
CHANGES IN REGULATIONS

May 2020, new MDR will change the law and process of certification for medical software:

• **Software intended** to provide information used to take decisions with diagnosis or therapeutic purposes are now Class IIa.

• Software, where these decisions have an impact that may cause a serious deterioration of a person's state of health or a surgical intervention, are Class IIb.

• Software, where these decisions have an impact that may cause death or an irreversible deterioration in a person's health, are Class III.

• All other medical device software is Class I.

Many devices qualifying as class I under existing MDD likely to move up a class under the MDR
Any Instrument, apparatus, appliance, **software**, material or other article used on human beings for:

- **Disease**: diagnosis, prevention, monitoring, treatment, alleviation
- **Injury or Handicap**: diagnosis, monitoring, treatment, alleviation, compensation
- **Anatomy or Physiological process**: Investigation, replacement or modification
- **Control of conception**.

**THOUGHTS ON REGULATING APPS AS MEDICAL DEVICES?**
What people **actually** use an app for may not be manufacturers **intended** purpose? Could software not classified as a medical device be inadvertently used as one?
EXAMPLES OF SOFTWARE LIKELY TO BE CLASSIFIED AS A CLASS II MEDICAL DEVICE

• Dose calculators (e.g. insulin/general)
• Image diagnosis (e.g. melanoma)
• Algorithms calculating observations to signal a warning (e.g. in electronic patient records)
HEALTH APP’S ARE EVERYWHERE - BUT EVERY HEALTH APP ISN’T A MEDICAL DEVICE.
MHRA SUGGESTS:

Apps that **make recommendations** based on patient entered data = likely to be medical device

Apps intended to carry out further calculations, enhancements or interpretations of patient images or data = medical device.

An App is also a medical device if it carries out complex calculations, which **replace** the clinician’s own calculation.

**Software/apps that replace existing paper charts**

Are not usually considered to be a medical device, however, the addition of complex functionality to the product can make it a medical device.
 WHICH OF THESE APPS DO YOU THINK IS A MEDICAL DEVICE?

Not all medical devices. Not always easy to guess—need to assess content and function. Some free to user, some only for those who can pay. These all in NHS App Library, Many more on App store / google play.
DEVICE INCIDENT REPORTING HAS INCREASED OVER LAST DECADE

• 2018 MHRA received 20708 device incidents reports of which:
  • 13951 incidents from Manufacturers
  • 3653 incidents from Healthcare Professionals
  • 1039 incidents from Members of the Public

• In addition, MHRA also receives reports directly from
  • Northern Ireland – NIAC
  • Scotland – IRIC
  • England & Wales via NLRS

• **Freedom of Information requests also give us a sense of public concern**

BUT evidence suggests there is still significant under reporting
Common concerns about medical device software reported to MHRA

- App or physical device not CE marked.
- Concern whether risk associated with calculation has been properly assessed.
- Uses Units not standard in UK.
- Designed for internal use but no restriction on download.
- Incorrect patient identification.
- Upload problem from handheld device to server.
- Warning scores randomly miscalculated due to software error.

Important to share concerns so they may be addressed quickly.

Source of reports can be users, manufacturers, professionals, public or scientific papers.
HOW CAN WE BETTER SHARE SAFETY CONCERNS?

REPORTING

• MHRA – Device Incident Reporting via Yellow card, or contact Devices safety team.

• Local Risk Management systems - e.g. Datex- local policy?

• NLRS, or replacement PSIMS (directly or via a feed from NHS risk management systems)

• CQC?

DISCUSSION- Peer to peer

• **MDSO network**- monthly webinar & chat forum run by MHRA & NHS.

• NHS National Safety team – contact device safety lead.

• NHSD – Regular CSO Webinars- London, Leeds or Log in.

• Clinicals Safety Community.

• Other?

JOINED UP WORKING – Industry, Public & Healthcare Professionals
AI & MACHINE LEARNING
- A VERY DIFFERENT NEW WORLD

AI = “Software Algorithm which functions to replace human judgment.”

Machine learning = AI that can learn from its informational environment and structure its own learning to reach different or new conclusions from those it would have reached before the learning period.

This learning capacity distinguishes machine learning from other technology.

CULTURE CHANGING REWARDS - BUT GREAT RISKS

REQUIRES DIFFERENT SAFETY REGULATION & MONITORING
THE RISK IS THAT WE CAN PUT TOO MUCH TRUST IN SMART SYSTEMS...

....WITHOUT KNOWING EXACTLY HOW THE ALGORITHM CAME ITS CONCLUSION.

Machine learning works by training software to spot patterns in data. Once trained, it is put to work analysing fresh, unseen data. But when the computer spits out an answer, the logic isn’t obvious. Even those who wrote the algorithm don’t always know.

CASE STUDY: A system trained to learn which patients with pneumonia had a higher risk of death, so that they might be admitted to hospital, unexpectedly classified patients with asthma as being at lower risk. But because people with pneumonia and a history of asthma usually go straight to intensive care and therefore get the kind of treatment that significantly reduces their risk of dying.

The machine learning erroneously took this to mean that asthma + pneumonia = lower risk of death.

LICENSING AND POST-MARKET SURVEILLANCE, BACKED UP BY METHODS TO REMOVE UNSAFE SYSTEMS WILL BE NEEDED TO MITIGATE AGAINST THESE UNKNOWNS.
ACCOUNTABILITY?
Who is accountable for machine errors that lead to mismanaged care?

BUILT IN BIAS?
How do we eliminate pre-existing bias in data used for "training" AI? (melanoma)

INFORMED CHOICE?
Should patients be informed of reliance on AI in their treatment – and of its limitations?
What about quality of Apps they download for personal use?

Automation Bias? The risk is people tend to believe computers. Impacts CLINICIANS AUTONOMY? -Doctors who overrules the AI?

PUBLIC TRUST
AI makes accidental disclosure much easier. To what extent do the public trust global organisations with their private health data?
Cambridge Analytica?

How can REGULATORS achieve the right BALANCE between protecting the public, clinicians & the service and promoting growth and innovation.
GDPR may ‘hamstring’ innovation
AI CAN CERTAINLY FREE US TO DO MORE OF WHAT WE ARE GOOD AT

BUT will patients be as safe or safer?

There is great uncertainty about accountability, responsibility and the wider legal implications of the use of this technology.

Joined up regulation is key to make sure that AI introduced safely whilst realising the benefits.
BIG DATA MINING  AI REQUIRES ACCESS TO BIG DATA -
- The bigger and better the data, the more reliable the results

• The UK Government and its health and social care systems have a legal duty to maintain the privacy and confidentiality of its citizens.

• Europe’s 2018 General Data Protection Regulation (GDPR) offers additional privacy safeguards.

• However, the development of machine learning algorithms relies on the use of large datasets.

• The accuracy and evolution of these algorithms depend on the availability of high volumes of good-quality data.

WE NEED BALANCE BETWEEN PRIVACY & PUBLIC INTEREST
Who owns the data? does it belong to:

• each patient?
• the public as a whole?
• the NHS? MHRA?
• UK Government?
• Private sector including global players?

Who should provide consent and who should reap the rewards from any Monetisation?
ETHICS? SHOULD THERE BE WORLD WIDE REGULATION OF THE GLOBAL ECONOMY?

• Do high-income countries have a humanitarian duty to share data and technologies with resource-poor countries?

• Should the NHS fund or collaborate with private partners in exchange for data sharing - which may cross country boundaries?

• Is data a currency for trade deals or health provision?

• Impact of comparing data from differing sources across the world, with different population makeup, healthcare standards and quality of data?
THE CHALLENGES TO MEDICAL DEVICE REGULATION ARE DIVERSE

While many Apps and AI products will meet the definition of a medical device and would therefore fall under the regulatory jurisdiction of the MHRA, there are also implications for:

• **GMC, NMC etc** – clinicians need clear guidelines on the appropriate use of AI.

• **Medical defence organisations** – the nature of negligence claims may change as patients adapt to AI-generated decisions and recommendations.

• **CQC** – will need to consider how AI systems are embedded and used in healthcare organisations and their impact on quality of care.

• **NHS Digital** – will have a role in clinical risk management in the development of health IT

• **Everyone** – we all have a role.

We need to work together to develop relevant and appropriate regulatory frameworks to realise the benefits and manage the risks of Medical devices using this exciting new technology.
CLINICAL SAFETY OF SOFTWARE CLASSIFIED AS A MEDICAL DEVICE

DISCUSSION TIME.....

.... OVER TO YOU FOR YOUR QUESTIONS AND COMMENTS?

ROSALIND CAUSEY FEB 2020