Report on the Health Archives and Records Group (HARG) workshop on wearable medical device data

King's College London | Great Hall (K0.64) | Strand | London WC2R 2LS
Monday 23 July 2018, 10:00 to 16:00 (BST)

Morning session

Speaker presentations: summaries (full slides are available to view at healtharchives.co.uk)

"Making sure data from wearable devices is used properly and people's confidentiality is protected: the Caldicott Guardian's perspective"
– Tim Kendall (Caldicott Guardian for tmwk Limited, Chair of London Caldicott Guardian Regional Group)

- There can be a challenge getting senior staff (e.g. Chief Medical Officer/senior management) to buy into the importance of data
- Duty to share data as much as duty to confidentiality
- Privacy by design should be considered at the planning/build stage
- Information Governance Toolkit is important and you may need a Data Protection Impact Assessment for contentious records
- Google Deep Mind/Bart's shows the danger of a lack of transparency in publicity around collection/use of data – always important that people can 'see the workings' of the data and the rationale behind the collection
- Summarised GDPR principles: portability of data; only justified retention; right to be forgotten; need for a Data Protection Officer
- Reminder of the Common Law Duty of Confidentiality – privacy is not new
- Highlighted the National Data Opt-out Programme (https://digital.nhs.uk/services/national-data-opt-out-programme); also refer to the UKCGC manual for advice
- 3 key obligations which TK highlights: leadership (all staff need to exercise responsibility with data); transparency; keep data legal, secure and safe.

"How patient adherence data helps patients and clinicians improve condition management"
– Chris Robson (CEO, Living With Limited)

- Living With Limited is a company which develops technology that helps people suffering from long-term conditions
- To get the best out of patients, everyone needs to benefit, including both doctor and patient
- Self-management tracking data systems are well used but clinical monitoring is more highly valued
- If clinicians are actively involved then this generally saves time and improves outcome

- Only 1/5 women seek help for bladder/incontinence problems. Only 20% do PFME to improve strength
- Living With have developed Squeezy, a pelvic floor exercise app, one of the most top rated in the UK with 30,000 users per month. 25% use it for more than 10 months
- Adherence data is critical – are people keeping up use over time?
- Key finding is that the patient values being monitored and these apps work best if they are closely related to a condition and are clinician-led, not DIY
- 25% improvements to outcomes and fewer DNAs
- Important that clinicians can monitor adherence and intervene
- The app is helping to drive behavioral change.

"The GLOVE Project: Remote data-capture in hand-care, the implications for IT governance of routine-monitoring by patients"
– Professor Patricia Grocott (Professor of Nursing Technology and Innovation, King's College London)

- The GLOVE project focuses on the management of a skin condition that is difficult for clinicians to monitor and leads to a cycle of surgery and deterioration
- Phase 1 of the GLOVE project has been completed and a disposable dressing glove and with sensors and splints have been developed
- Heavy emphasis on co-design with clinicians and patients
- Data is sent to clinicians and an archive is maintained that requires sharing
- It is a crucial feature that data integrates with the NHS electronic patient record system.
- Highlights the importance of the NHS Health Research Authority Research Information Governance Process (https://www.hra.nhs.uk/about-us/governance/information-governance/)
- Highlights the value of data 'pots' and ability to share data for the management of a condition across projects
- Trust in the data is crucial as is how it is shared, so relationship management is important
- How will the data be aggregated to spot trends?

"Bourbon. Lamp posts. And a Sense of Understanding." (Perspectives on the Meaning, Value and Integrity of Information)"
- Russell Joyce (Director and Principal Consultant, Heath Barrowcliff Consulting Ltd and Health Sciences Records and Archives (HSRAA) Conference Programme Organiser)

- There is very little regulation around records management of wearable data
- Highlights the importance of the MHRA Data Integrity Guidelines for clinical trials (https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity) used in pharma, and similar WHO guidelines
- RecommendS the use of the ALCOA framework/principles used since the 1990s for the pharma data lifecycle – data that is Attributable, Legible, Contemporaneous and Accurate
- Importance of rules, technology, policies, people and training

- True meaning and traceability of data requires an understanding of context
- Warns about the 'data tsunami' and the methodology for excluding data
- Dangers of making upload of data safe and how to transfer data effectively so it remains accurate. Similarly, validation of devices: be clear on what you are measuring and planning for the collection of analytics and its re-use.

Questions from floor to all speakers

Geoff Browell: What major lessons do you take and from whom?

Patricia: GLOVE collaborates with design sciences, HRA, clinical groups
Chris: Clinicians often don't know what patients want, so you need people who can think laterally. Data has value to patients and clinicians, but only if both pay attention to the historic data which has been recorded. So how do you get clinicians and patients to engage with historic data rather than start from scratch each time? It's also important to pay attention to trend data and to be more transparent on both sides.
Russell: Take the opportunity to be involved at the design stage to understand and represent those needs.
Patricia: We define the data/measurable at proof of concept (e.g. we know what the qualitative measurables are at the outset).

Question from Adam Spinks: Interested in two directions, e.g. starting from research into development (with heavy regulations) into daily management. How to maintain this regulatory aspect the context of day-to-day use?

Patricia: This can be part of a stage process of implementation and hand-over. It is the responsibility of clinical teams to take this on as part of a managed process.
Russell: Things like the anonymisation of data can be straightforward as part of normal clinical process.
Tim: How far does data go and how is it anonymised?
Chris: Regulations for commercial companies and are very difficult to deal with. Formal RCTs 'incredibly painful'.

Discussion session on the topic of data integrity (Chair: Russell Joyce)
Scenario: Sponsor clinical trial into sleep disorder requires the development of wearable tech to measure sleep patterns. What considerations need to be made in the following four areas?

Group 1: Technology

- Ensure devices measure accurately what you want to measure and up to 'gold standard'
- Granularity of data
- Scaleability of storage
- Data retrieval
- Metadata

- Contextual knowledge
- Rationalise across devices
- Proprietary software? Compatibility
- Audience – to whom is it valuable?
- Who needs access? Audit trails
- Retention
- Authenticity and control
- Data transfer from device to CRO and back to sponsor (migration and conversion)
- Ensure against tampering
- Add archivists in from beginning of process
- Accountability

Group 2: Policies and procedures

- Work out where responsibilities lie – data controller/processor/combination of sponsor and research centre or other?
- Data Protection/confidentiality policy
- Records Management policy
- Work details into contract
- Would need more details of scenario to be specific

Group 3: People

- What are we evaluating?
- Who will take part and how to join
- What info will they require
- How adept are they at using tech?
- Breakdown/troubleshooting procedures
- What different groups will they interact with?
- How to translate issues around data integrity in a way which is understandable
- Consent, criteria to take part
- Risk management
- Control of use of devices to ensure data integrity (eg. other users getting hold of the device)
- Gender/age/cultural device

Group 4: Training

- Without training, devices/software is useless
- Identify main groups for bespoke training
- Patients – how to use/wear device
- What format of training (eg. booklets, online guides, in-person, etc)
- Opportunities for feedback to sponsors
- Information security
- CRO – how to process, store, use data, backup
- Deliver exactly what was agreed to sponsor in contract
- Sponsor – protecting patient info, management, storage, preservation of data, maintain training records

12.45-13.15: Product demonstrations from event sponsors Max Communication and Preservica

Afternoon session

Speaker presentations: summaries (full slides are available to view at healtharchives.co.uk)

"We need to talk about data: trust, transparency and talking to the public"
– Dr Natalie Banner (Understanding Patient Data Lead, Wellcome Trust)

- AI is poorly understood with little recent research on impact
- Commercial access to health data leads to a drop off in public support for collection
- People often don't understand what is being done with their data due to lack of guidance/proper explanation
- Terminology of engagement with public/patients is often opaque
- Identifiability is a worry for patients
- Trustworthiness is crucial and requires: early conversation; use of examples to illustrate; human interaction to teach/reassure; meaningful transparency, and accountability (who controls the data in the short/medium/long term?)
- Fairness and equity in access to the data is important
- Above all, context changes meaning and needs to be clear and understood.

"Quantified lives: Putting digital data in context"
– Dr Rebecca Lynch (Assistant Professor in Medical Anthropology, London School of Hygiene and Tropical Medicine)

- Fear of technology and surveillance limits take-up
- Wider cultural context is ignored
- Key areas: what is being measured? What are the underlying assumptions? What other technology is needed, for example a telephone/wireless? Who is measuring? How is data interpreted?
- The way data is collected shapes things fundamentally and behaviorally
- What is not recorded might be important
- What are the values and aims behind the tools and assumptions being tested?
- The human dimension is critical, such as the actual way people live their lives
- The social aspect is also important and will affect data
- Data and technologies are never agnostic.

"Machine learning tailored to textile-embedded sensors"
– Dr Matthew J.W. Howard (Senior Lecturer in Informatics (Robotics), King's College London)

- Provides example of smart sensors in textiles

- Issues of working around how people really move naturally
- Shows potential importance of patient motion-capture through conductive sensors
- Too much is limited to the laboratory and is impractical
- Major potential in sub Saharan Africa where data capture in the field is very difficult
- 80% of disabled people live in developing countries
- Such sensor initiatives can help capture meaningful data from a very large number of people.

Questions for speakers

Geoff: Picking up on the idea that 'data is not neutral' – it is about integrity, trust etc. How would you respond to that?

Natalie: We're increasingly aware of ourselves as data subjects. A one-off conversation is not sufficient: researchers need to demonstrate what they're doing differently to demonstrate trustworthiness.
Rebecca: People often find it hard to conceptualise what happens to data when it leaves its original context. We need to think about different groups with different needs.
Matthew: There's a trade-off with commercial technology companies. There could be benefits to using computational resources of, say, cloud platforms vs. personal devices.
Patricia: We need to work with industry. The potential commercial use of data is anathema to some patients, but researchers often rely on commercial partners. How to get around this?
Natalie: Openness and honesty is important here: we can't avoid work with commercial partners.
Rebecca: Idea of commercial gain is indeed anathema to the general public, many of whom are committed to ideas around 'greater good' and free NHS. There's a question about transparency – how do we trust what happens to data after it leaves us?
Natalie: NHS Digital/national data opt-out has helped, in terms of providing more resources for clinicians and healthcare professionals to deal with some of these questions. It is hard to get an overall picture of data landscape in UK, so having a big level of detail many not be that useful.

Question from unidentified speaker: Data science is built on finding value for data collected for other purposes (eg. pharma background) – how does this square with transparency around use and purpose?

Natalie: This is a harder case to make, but the only way is to be transparent and clear on governance and the information security framework. The approach "We want all this data but we can't tell you what we want from it" is going to be problematic.
Rebecca: People are generally happy to help but it depends on the context.
Matthew: You can't just throw data at an algorithm: you need to know what you are measuring. But it does help to specify what kinds of things you could get out of the data and what that might be useful for.

Introduction to and data visualisation from the project RADAR-base team (RADAR-base & PHI Data Lab, Institute of Psychiatry, Psychology & Neuroscience)

- Can collect data from third-party API, device middleware or smartphone/apps/wearables
- Data is stored and analysed via open source tools
- Management and visualisation (data streaming)
- Data source integration – how do we create data archives that make trends and meaningful intervention possible?

Discussion session on 'Next steps for dealing with medical device data'

- Engaging participants
- How to define/apply best practice
- Compatible standards for data export, particularly for archives
- Methods to integrate all groups (archivists, patients, IT backgrounds) at the beginning of a project
- Functionality of data
- Appraisal of technology
- Define what data is and for what area
- Transparency of data
- Define how data is shared with other parties
- Transparency
- Auditable systems and processes
- Interface of data management is often the weakest point
- Educations of all parties needed
- Standardisation of data, not technology
- Should patients be in control of who accesses their data?
- Standards
- Compare output of one sensor/device to another
- Data quality
- Raw data access
- Proprietary algorithms
- Different types of medical validation
- Identifying relevant features/types from medical data – of what to store
- Use of software stack and what you validate
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Take away points:

- Variety of devices – DIY, GP/consultant-led, research-focused and trend is upwards
- Need for transparency about who is collecting, why and what is being collected. Who will ultimately be able to use it – danger of Facebook/Google type situation?
- Trust: patients value the input and direction of clinicians and engagement with the public is important. Avoidance of jargon. Mixed views on the desirability of private sector leading

collection, and their motives. Credibility is important, as are real world examples and demonstrable impact

- Desirability of data sharing/archive pools for maximum impact, so structure, governance and interoperability need to be designed-in to avoid silos
- Context is important: lifestyle, circumstances, behaviour. Data is rarely neutral. Custodians need the contextual data to permit meaningful re-use of ones and zeros in a year/ten years, and facilitate appraisal/destruction
- Universities: research data management and clinical data management often divorced from archives/records management, so long term value of retention is not being recognised/existing skills utilised. Danger of rick aversion meaning data is destroyed. This is an advocacy issue/political issue within hospitals/universities
- Need for better advice and training, sharing between sectors and audiences/actors such as universities, clinicians, researchers re-using data, data managers/archivists
- Data guidelines are well developed and have often have been in use for years – how do they overlap and are used in practice, especially in situations with high staff turnover when institutional memory/continuity is lost?