Commercial uses of patient data

Thursday, 12 October 2017
QuintilesIMS, 210 Pentonville Road, London, N1 9JY

Summary of the day

"The use of my health data is infinitely more important than the possible misuse."

Patient Advocate & workshop delegate

Contents

Chair's welcome & overview of the day

Mike Birtwistle
Founding Partner, Incisive Health

Welcoming everyone, Mike highlighted that the day had been put together by use MY data members.

We tend to think of data as being in silos, which is not actually how the world is working e.g. companies collaborate with charities and this can generate concerns about the uses of data. It is important to get clarity, understanding and transparency right, in order for everything to work well.

The Leeds Institute for Data Analytics, QuintilesIMS and Understanding Patient Data were thanked for supporting the workshop.

| Session 1 | Why do commercial companies need health data? |

Nicola Perrin
Head, Understanding Patient Data

This session gave an overview of the different types of companies that access data. Commercial access is at the top of most people's minds when discussing concerns about the use of their data. It is understandable that people are nervous, as it is the scare stories make the headlines.

There are many companies currently accessing NHS data for a wide range of uses. There is variability amongst the public in terms of the acceptance of the use of patient data and some of this variation depends on the wording of the question.

Nicola referenced the Wellcome's Trust report *The One-Way Mirror: Public attitudes to commercial access to health data.* On balance, 54% of those surveyed supported companies accessing patient data. A significant minority, 17%, did not want patient data to be accessed for any purpose outside of the patient's direct care. The key issue for people was why access was wanted and what purpose the data would be used for; if there was a public benefit this was most important reason for allowing data be used.

The concerns were around the perceived harm of the data being passed to a third party, with two particular issues: harm to individuals and family, followed by concerns about the negative impact on society. The biggest concerns were about insurance companies having access to data.

Questions to address:
- **Why** do companies need patient data?
- Will companies **market** products to me because of my health condition?
- Will **insurance companies** discriminate against me?
- Does the **NHS** sell **patient data**?
- Can companies **make a profit** from patient data?
- Can companies **be trusted** to store the data safely?

The NHS by itself does not have the expertise or technology to develop what is necessary to improve health care, and needs support in this area.

Reasons for needing access to patient data:

- Individual care – electronic patient records are provided by a software company, the chemist can access the patient record for prescribing purposes, wearables and apps are used for collecting personal data
- Improving diagnosis – developing diagnostic tests and decision support tools through technology companies
- Treatment and prevention – recruiting for clinical trials, testing new treatments and devices by following people up through their data
- Patient safety – looking at the impact of side effects
- Planning NHS services – looking at patient pathways, identifying variation and designing more efficient services
- Evaluating policy
- Understanding disease – pharmaceutical companies want this understanding for developing drugs, the data can aid the development of personalised medicine and can help to understand the burden of disease and the potential size of the market
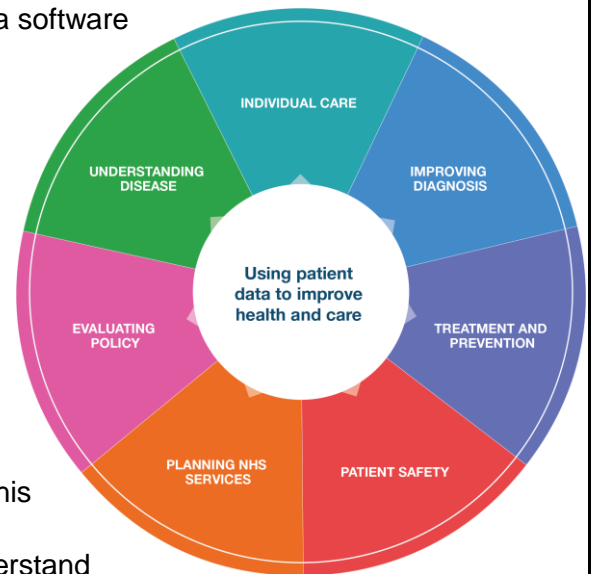
Insurance companies want access to data to help them decide appropriate cover charges. This can raise concerns amongst patients and the public as, unlike pharmaceutical companies, the insurance industry is not immediately part of delivering to healthcare.

There are two main purposes for insurance companies having patient data:
- individual applications for cover (personal identifiable data – can only be accessed with the patient's permission)
- setting insurance premiums (anonymised data).

Patient data could lead to the setting of higher or lower insurance premiums. Macmillan Cancer Support is doing some work in this area, looking at travel insurance costs for those affected by cancer as the costs seem to be inappropriately high.

Will companies market products to you because of your health condition?
- Companies do not receive access to the name or contact details of an individual, and they are unable to directly contact the person or market to them.
- It is more likely that an individual would receive targeted advertising because of their searches on Google – one in twenty Google searches are health related.

Questions and discussion

Q Can credit rating companies e.g. Experian access patient data?

A No, Experian do not have access to record level data from NHS Digital, but they do have access to anonymised group level or population level data.

Q Could the NHS get royalties from the use of data for commercial applications? Is the NHS realising the value of patient data?

A NHS Digital is not allowed to sell patient data, it operates a cost recovery only.

Q Should the NHS get a reduced price for services / products which are developed as a result of NHS patient data?

A There are lots of difference commercial business models and the right one for this has not yet been found.

Q What are the differences between depersonalised, anonymised, pseudonymised?

A The definition of 'de-personalised' is that it sits between identifiable and anonymised, so this would be likely to be individual level data but no personal identifiers. There is new legislation coming in about the ability to identify someone from pseudonymised data. Understanding Patient Data's website has helpful information on the categories of data identifiability - https://understandingpatientdata.org.uk/what-does-anonymised-mean

Q The NHS uses software for commercial companies to provide services – how are providers known to be secure?

A Providers go through an extensive procurement process. The company has to be able to demonstrate its security. There are a limited number of providers. The NHS should have the highest levels of protection, and this is always front of mind for NHS Digital.

Q Are opportunities to ensure ethical employment practices embedded right from the start?

A This question led to a short discussion on ensuring that private companies have good practices in terms of paying the living wage and that they do not operate 'off-shore'.

Session 2	How are patient data used to provide the insights and evidence that the NHS needs to deliver and evaluate services to provide better outcomes for patients? **Sue Beecroft** **CEO, Harvey Walsh Limited**

This session examined how a commercial company provides commissioning support to the NHS, describing which data they have access to, in order to undertake this work.

Sue gave an overview of Harvey Walsh, which is a healthcare informatics and patient outcomes consultancy, originally set up to support the implementation of national guidelines. Harvey Walsh works with the NHS, pharmaceutical companies and patients.

Within the healthcare system some parts have good data, but it is difficult to compare across areas. The company has to follow procedures set down by NHS Digital that are acceptable and work within the NHS N3 environment. They will approach NHS Digital for data including: Hospital Episode Statistics (HES) data, Quality and Outcomes Framework (QOF), GP prescribing and anonymised primary care data.

HES data is considered as pseudonymised; there is a random identifier which means someone can be tracked through the system, and allows all the records for one person to be linked together, without knowing who the person is. It is treated as record level data and everything is coded, although because there are so many data records for any person, it is not straightforward to analyse.

The data is received via a monthly electronic download from NHS Digital. After receiving this download, it is then further encrypted by Harvey Walsh.

Harvey Walsh uses the HES data to provide services for: a wide range of charities, Public Health England, pharmaceutical companies and academic health networks. These services must always show patient benefit.
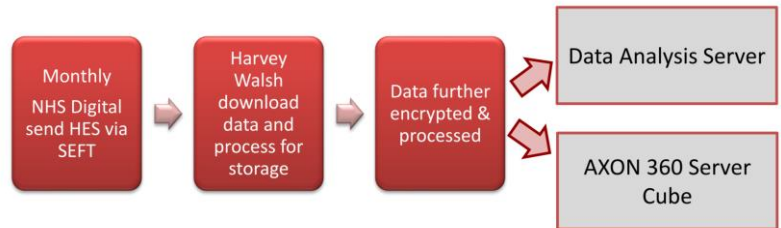
HES data is very strictly controlled. Last year the company had to take a data server, AXON, offline – as it was not recorded in their Data Sharing Agreement that the server was hosted in a server centre in Maidenhead. Harvey Walsh had to go through very strict NHS Digital audit before going back online. NHS Digital do a huge amount of work to ensure the correct use and control of data. The breach of the Data Sharing Agreement had a massive impact on Harvey Walsh: cost of lost business, lost people and reputational damage.

Sue referenced a series of case studies, which demonstrate benefits to the public.

- An oncology project in renal cancer, which described how there was a variance around the country in terms of access to treatment and time to treatment. The project helped identify local pathways and introduced education, training and support to reduce time lines. An interactive dashboard was produced, which is in its third year and improvements are starting to be seen. A working group has been convened around best practice for renal cancer.

- The Academic Health Science Network (AHSN) using data around stroke to enable GPs to see where they sit within their peer group in terms of cost of treatment, bed days etc. for their stroke patients.

- Working with the Royal National Institute of Blind People (RNIB) to address massive variation in cataract surgery. This led to analysis, report and a publication which highlighted variance and service disparities.

Questions and discussion

Q Why can't NHS Digital run the data to provide the same services?

A Harvey Walsh do not charge the NHS. Others such as pharmaceutical companies provide the payment and the outputs are provided to the NHS.

Q How are priority decisions made around what is analysed, who is driving this: the NHS or pharmaceutical companies?

A There are expert user groups including consultants, GPs and epidemiologists who may identify a need and approach a company for support, or it may come directly from a company. Sometimes Harvey Walsh may identify a need, sometimes clients will ask Harvey Walsh to look at something. Matching clients depends on who has a current need.

Q NHS N3 network – what it does and why you need it?

A N3 is the secure network that the NHS transmits patient data through. Data must be kept and secured within the NHS. The use of data is strictly controlled. Harvey Walsh & Public Health England might have access to N3 but, just having an N3 connection does not give them the right to access and exchange data. N3 just provides the connectivity where such uses are permitted.

Q	With two stage/elaborate coding, does it incur increased risk of data entry errors?
A	No, it's a security algorithm – encryption takes place through algorithms so that there is no fear of data entry errors.
Q	Why does a pharmaceutical company pay for the service for the NHS?
A	This is ultimately to improve patient outcomes. A pharmaceutical company does not have access to record level data; the data is aggregated.
Q	You lost business when your system was taken down – how many competitors do you have?
A	There are about 30 to 40, with a range of sizes.

Session 3	**How does a commercial company support the NHS and pharmaceutical industry in conducting clinical trials and real world evidence studies in disease areas?**
	Tim Sheppard
	General Manager, QuintilesIMS

This session explored how a commercial company uses patient data to support the NHS, looking at what types of data are needed alongside the information governance required to be able to access anonymised patient level data.

QuintilesIMS employs 50,000 people globally and is involved in 30% of the world's clinical trials. The data they analyse is anonymised. Pharmaceutical companies commission QuintilesIMS for global work, some of which takes place in the UK. QuintilesIMS's market is global as diseases are global; they want to improve access to good value medicines, to get the medicines doctors want to those patients who need it.

This is an important part of healthcare advancement which can be broken down into:
- Research and development – disease insights: prevalence, diagnosis, treatment patterns, unmet needs
- Medical affairs and safety – insight on how drugs are being used, patient safety and drug effectiveness
- Health economics – inform assumptions on disease prevalence, diagnosis, treatment, burden of disease
- Commercial insights – insight about how patients are diagnosed, monitored and treated.

As humans we generate a lot of data, especially when we are patients. As a scientific company QuintilesIMS is rigorous in its approach. They can also identify and source data from third parties, and combine with other datasets:
- Broad data – broad datasets allow them to look generally at what's happening in a vast population
- Deep data – the kind of very detailed data held in registries, hospitals

Tim highlighted a series of case studies to demonstrate how QuintilesIMS supports the NHS.

- Using patient data for rare disease detection. Globally 350 million people suffer from what are described as 'rare diseases'. On average, it takes 4.8 years to be diagnosed. There are more than 7,000 different conditions so they are all unusual for a doctor to see. HES data can be used to try to identify these. For example, it was estimated that in the UK there should be 250 cases of a specific disease but only 100 cases were found, meaning there could be 150 undiagnosed cases.

Tim referenced work on the rare genetic disease, Fabry disease. The pathway to detect rare disease:

- ➢ National coverage of all hospital episodes in England collected in a single data source
- ➢ Partnership with a specialist clinic to develop a risk stratification algorithm to find undiagnosed patients
- ➢ Alerts sent from a specialist clinic via email to physicians, with guidance to screen named patients for rare condition
- ➢ Physicians carry out a diagnostic test.

Challenges for clinical trials mean a new approach is needed.

QuintilesIMS use data and analytics to quantify patients for clinical trials. They received permission from NHS Digital to use data to do this. There is a lot of data around clinical trials;

| 48% of hospitals miss their patient targets[1] | 57% of trials have a protocol amendment[2] | 80% of trials are delayed, often recruitment related[3] | 61% increase in inclusion/exclusion criteria[4] |

how many people are approached to take part, how many trials miss their target numbers and have to amend protocols and change the inclusion and exclusion criteria. It is possible to use informatics to attract more trials.

- ▪ Working with Cancer Vanguard hospitals to improve care, four areas came to light:
    - ➢ Establish medicine utilisation – many patients are not using recommended drugs or are not taking them the way they are supposed to
    - ➢ Identify unwarranted variations in care across hospital sites
    - ➢ Drive citizen engagement – an app was developed to assess how hospitals were performing
    - ➢ Model potential savings – good care is usually cheaper than bad care.

- ▪ Using data QuintilesIMS can look globally at drug usage patterns. In some cases the UK has lower usage than other countries; this can then be examined regionally.

- ▪ New methods of pharmacovigilance – this is a direct to patient validation study, conducted with the European Medicines Agency. Its aim was to assess the extent to which data collected directly from pregnant women provides information on medication use and other potential risk factors throughout pregnancy. The results showed a large percentage (83%) were using non-pregnancy related medications during pregnancy.

For the work of QuintilesIMS, independent ethical approval committee is key and their work is often governed by multiple regulatory authorities.

Questions and discussion

Q Do you anticipate having access to DNA data to access genetic markers?

A Yes; we anticipate that we will have that at some point. It's really tricky though, as there is nothing more difficult than anonymising a genome. Colleagues in the US are working on how to do this.

Q As a patient, if I opt-out of my data being used, how would my data be extracted from your dataset? Can a patient opt-out during a project?

A QuintilesIMS uses anonymised data. NHS Digital upholds patient objections when data is identifiable but does not have to uphold patient objections when data is given in an anonymised form.

Q   For drugs for which the costs are huge, such as Fabry disease, is your case finding only related to high priced drugs – for a big rake-off?

A   There are tricky ethical issues. The US has less of these issues as money is often thrown at drugs 'at any price'. It is different here. QuintilesIMS has not done the work just for expensive drugs, but inevitably rare disease has high costs for research and development.

Q   Do you collect data on ethnicity and how does it impact on the use of medication?

A   As much as possible is collected because of the impact of ethnicity on disease prevalence. However, this data is often passed on from the GP record, so it may be inaccurate or incomplete. Clinical trial data usually has more accurate ethnicity data. Genome data may be helpful in deciding upon the levels of drugs to administer for the best results.

A discussion on clinical trials followed, referencing how some hospitals have good take up rates and have access to free medicines through the trial. Other hospitals don't have the resources, the set up or the interest. However, it is important to understand the patient's point of view and why they may choose not to take part.

The contribution this data and analysis can make to early diagnosis was discussed. Early diagnosis is paramount for many conditions, especially cancers such as pancreatic cancer. The Routes to Diagnosis study benefitted from being able to use the HES dataset.

Session 4	How does the pharmaceutical industry use patient data?

Dr Shahid Hanif
Head of Health Data & Outcomes, The Association of the British Pharmaceutical Industry

Tamsin Morris
Real World Evidence Lead, AstraZeneca UK Ltd

This session examined the types of patient data the pharmaceutical industry uses, how the data are obtained and what the controls are around the use of these data. It looked at how the data are used to better understand treatment patterns, burden of disease and outcomes.

There is a long process (life cycle) for a drug to come to market which involves discovery, development, market access, assessing safety and monitoring. The process can take over 12 years. As the drug goes through the lifecycle there is an increasing need for evidence and this is where data from the healthcare sector is needed.

The questions which the data answer are:
- Is the drug hitting an unmet need?
- Is it improving patient outcomes?
- What effect does this have on the value of the medicine?

Sources of patient data include electronic health records as well as data from pharmacies, disease registries and imaging data. The data tends to be in the pseudonymised or fully anonymised form.

The companies have to follow guidelines around data management and there are policies in place around data security. The access to the data is controlled and is considered as 'effective informed consent'. There is a balance involved between patient risks and benefits.

Other key considerations:
- Effective informed consent
- Balancing or communicating patient benefits and risks
- The ABPI code of practice
- Sharing clinical trials data
- Patient engagement / communication.
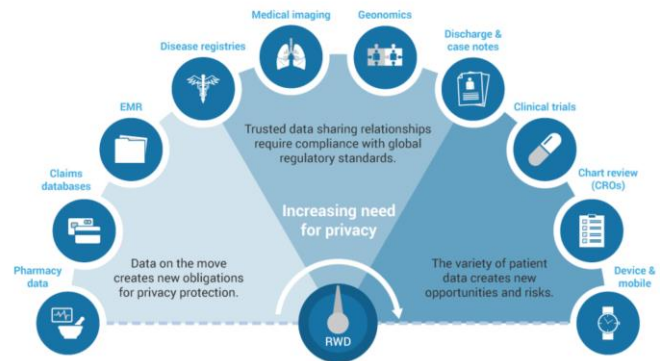
There is a move between companies to share clinical trials data but have to consider that all companies have different policies in place when they undertake trials. A key element to this is patient engagement and effective communication. In contrast to clinical trials data, is the data which is collected in the 'real world' known as Real World Evidence (RWE). It is known that clinical trials are run under optimal conditions with highly selected populations, so it is important to measure how the drug performs once it is being universally used in routine clinical practice.

RWE complements clinical trial data and is being increasingly used to support decisions and support patients.

There are several healthcare decision makers who impact the drug's use:
- Patients – need confidence that the drug is the right choice
- Healthcare professionals – need to believe it is right for their patients
- Payers – need to believe the drug is value for money
- Regulators – need to know whether the drug works and is safe
- System – need to know whether the drug is beneficial in terms of outcomes.

Several case studies were outlined, including:

- Monitoring the safety of the medicine, which may lead to licence changes if necessary.

- Understanding cancer diagnoses, outcomes & treatments – using the Simulacrum, an artificial dataset which models some of the properties of the Cancer Registry dataset, but does not contain real patient data. It will allow researchers to develop and define data queries, before submitting them to Public Health England analysts to be studied in the 'real' data. The researcher will then receive aggregated results, once approved by the Office for Data Release. The project has involved AstraZeneca, QuintilesIMS & Health Data Insight.

- Partnership with 'Patients like me' to create a community of patients which will help develop, support and establish which medicines are needed. AstraZeneca has a five-year strategy to investigate what patients like, how clinical trials should be developed, the impact of side effects and understanding the patient experience.

Questions and discussion

Q Referencing the Patients Like Me work, has AstraZeneca considered approaching other patient led charities e.g. brain tumour charities, who are already doing this work?

A Yes, we have and we do. One of the benefits of 'Patients like me' is that it is international and most drugs have an international target market; AstraZeneca is looking at initiatives to work with other patient groups / charities.

Q   When will Simulacrum be available?

A   The finalised simulated data will be ready to share with the public by the end of 2017, with the launch in early 2018.

Q   How can organisations, such as The Brain Tumour Charity, obtain analyst resources at Public Health England (when this is too costly for the organisation)?

A   The Association of the British Pharmaceutical Industry funds analysts at Public Health England and it could be possible to look at joint initiatives.

Q   If drugs get to market quicker, through better data access, will this bring the price down?

A   As we develop the use of Real World Evidence to get the drugs to market more quickly and efficiently, then this should lead to reduced development costs.

Q   Are obsolete drugs monitored?

A   There are drugs which are outside the patent. The process of NICE is to get better drugs to the patients and to remove the old ones, but it is also the responsibility of the NHS to do this.

Q   Both speakers have expressed how important patient data and its use is, so why are patients refused entry to some drug company events and meetings?

A   There are some communication problems around informing the patients about the outcomes of the projects where patient data has been used. Some meetings are not for the 'public', which is why entry may have been refused as it is not permissible to 'promote' prescription only medicines to the public. The Association of the British Pharmaceutical Industry has discussed this with the (then) Health and Social Care Information Centre, regarding clinical trial data.

AstraZeneca is committed to keeping patients involved in their clinical trials informed and has a website that participants can visit to see the outcomes of the trials they have taken part in - https://www.trialsummaries.com/Home/LandingPage.

The patient who asked this question followed up to say that, as patients provide the data. they are not 'the public'.

Q   What are the rules and regulations for access to Real World Evidence? Are there rules and regulations where, if you could push the limits just a little bit, you could add value to our healthcare?

A   Pharmaceutical companies are keen to push the boundaries so that they can get better drugs to market. The Life Science Industrial Strategy references pushing boundaries.

This led to a discussion about how patients are often considered to be quite low on the 'stakeholder' pecking order and that this can disengage patients. Pharmaceutical companies need to take a 'brave pill' to address this and find better ways to work with patients.

Q   Can the pharmaceutical companies influence how the NHS displays its data?

A   Pharmaceutical companies cannot directly influence, but can put time into the innovative presentation of data, as well as investing in analysis.

Session 5   What steps does a company need to go through to be able to access patient data?

Garry Coleman
Head of Data Access, NHS Digital

In this session we heard what NHS Digital needs to see from a commercial applicant, in order for the data to safely flow to their organisation, including the steps, checks and tests involved.

Garry began by addressing points that arose in earlier sessions:

- NHS Digital does not make money from giving out data but they do charge for the service. NHS Digital's approach is the less data they give out the better. Wherever possible, they provide routinely available aggregate data.

- The encryption of patient data is such that it is not possible to trace back to a patient's NHS number.

NHS Digital wants to ensure that the data they supply is used appropriately and all applicants must go through the Data Access Request Service. NHS Digital holds large quantities of data and their applicants include academia, researchers, the NHS and currently approximately 30-40 private companies.

Questions and discussion

Q   Can a researcher come back for more data, if they realise that is necessary?

A   It would depend on the purpose, but it is acceptable for the applicant to reapply if necessary.

Q   Can more detail on the process be given; help with checking forms?

A   Public Health England offers a service for checking the Office for Data Release forms. NHS Digital charge for the costs of accessing the data at the end of the application process. NHS Digital want to help people to get it right.

Q   If the applicant has consent from people to access their data, do they still need to have all the security checks?

A   Yes, definitely.

Q   Is the purpose to secure money for the NHS?

A   No, it is purely to benefit the health and social care system

A brief discussion followed on how private companies can employ people to make funding requests, but this is difficult for small charitable organisations. It is important to make sure that the results are put in the public domain.

Q   Can organisations be penalised if they fail an audit?

A   No, they are only charged for the work that was done by the auditors. All the audits are published on the NHS Digital website.

A discussion followed about the provision of aggregate data and how, if a data breach occurs, the offending company must destroy the data they have been given.

Session 6	Openness and transparency - could it be improved? What do patients want?
	Sam Smith **Coordinator, medConfidential**

The session was planned as a joint session with medConfidential and a Patient Advocate from use MY data. However, due to illness our Patient Advocate was unable to take part.

The session examined who checks that your data have been used properly, how a patient can find out where their data have been used and what choices patients have about their data being used. Can awareness, transparency and choice be improved?

Sam emphasised the importance of people needing to have information in order to make a decision about opting in or opting out of their data being used. There are questions around whether people really know what choices they have, the impact of their choices, whether those choices are actually respected and if their data are used appropriately.

medConfidential do not take a position on any particular pharmaceutical or commercial companies. Their position is – do you have the information needed to make an informed decision about consent?

The incentives for academics is to write papers and get them published. Commercial organisations have a different incentive: to make money for their shareholders.

Although data is reported as being anonymous it is possible to identify people from the dates they had treatments. There is commercial sensitivity and companies sometimes keep secrets. It is important that data is consensual, safe and transparent.

Do you know where your data goes? It comes down to secrecy. There must be full transparency over where your data goes.

Sam gave some examples of where he did not think there was enough transparency:

- Harvey Walsh and its data breach

- Public Health England & the Cancer Registry

- Health Data Insight.

Questions and discussion

Q I get the impression that you don't approve of collecting data? When researchers get patient data it hasn't handed over to just anyone. It is not in a researcher's interest to try to hack in and identify patients. NHS Digital don't just give it out to anybody, there has to be an approved protocol in place.

A Picking up on comments about commercial users, data doesn't just go to researchers. This is much more like a credit history that is really hard to replace when it's been screwed up. Are you sure that everyone will be perfect when they have the data?

Q As a cancer patient, I have never been asked to give my consent?

A The cancer registry has serious problems.

Nicola Perrin answered this question: A recent review by Macmillan Cancer Support and Cancer Research UK demonstrated how low awareness of the Cancer Registry is, and work is being done to raise awareness. Nothing is ever risk free (regarding reidentification) and there should be strong (criminal) sanctions if anyone deliberately reidentifies data. New regulations will address this.

Q Going back to the purpose of accessing/using data – you do accept that the use of data can advance medical care? We've seen a slow-down in the use of data. What are your reflections on that?

A The slow-down could have been resolved more quickly. Regarding the new criminal offence for reidentification of data – medConfidential has asked the Department of Health if this applies to HES data. The answers are unclear.

Q What would make Sam happy in terms of data protection?

A Ticks in all the boxes on the scorecard. Is Cancer Registry data going to be included in the booklet sent to everyone (about the National Data Opt-out?) There has to be fair processing.

	Consensual	Safe	Transparent
GPs - Direct Care	✔	✔	✔
GPs - local CCGs / councils	✔	Varies by recipient	Depends on GP
GPs - research copies	✔	Unknown	✗
Hospital - Direct Care	✔	✔	✔
Hospital - local sharing	By 2020	Varies by recipient	By 2020?
NHS Digital: SCR controls	✔	✔	In 2018
NHS Digital: Safe Setting	✔	✔	✔
NHS Digital: Sale of hospital records	✗ (opt outs ignored)	✗	Partial: now; More: late 2017; Full: Late 2018.
NHS Digital: Commercial reuse of hospital records	✗ (opt outs ignored)	✗	✗
NHS England: CSUs / councils / national	Variable	Unlikely	✗
DH family: https://medconfidential.org/for-patients/loopholes/			
PHE disease registries	✗ (no fair processing) ✗ (misleads patients)	✗	✗ (proposed as a postcode lottery)
CPRD @ MHRA	✔ (Type 1)	✗	Partial (unknown)

Q Who should be in the room next, with the same level of openness that both Harvey Walsh and QuintilesIMS have had today?

A Probably Public Health England and the Cancer Registry, who have refused to have a dialogue for two years. They published the data release register with justifying data as "depersonalised" for data releases that occurred over a year before the framework was published (and the term defined).

There are times you do need 100% of the data (as compared to 98%) and a database of all tumours is probably one of them. Our democracy has processes for deciding those things.

Q Where would you put the line?

A That's what we have the Confidentiality Advisory Group (CAG) for. We need a method to have a continuing conversation. The Opt-out should be statutory – so there is a democratic process for when the Opt-out doesn't apply. The Confidentiality Advisory Group was strengthened in the Care Act 2014, but the Regulations haven't been laid to implement that yet (they're (currently) awaiting the definition of the Caldicott Choice).

Session 7	What would patients like the next steps to be?
	Nicola Perrin **Head, Understanding Patient Data**

This concluding and interactive session sought feedback from delegates on the topics covered during the workshop and looked at next steps.

A quick overview of Understanding Patient Data was given. The organisation is funded by two research councils, the Wellcome Trust, Public Health England and the Department of Health. Understanding Patient Data works across the sectors, with more than 25 supporters.

Nicola gave an update on the resource that is being developed around commercial uses of data and asked delegates for feedback on key things they had learned during the day, what had surprised them the most and whether they felt more concerned or reassured about the use of their data.

Round table discussions

- There was a range of feelings about access to patient data, some quite polarized. Some delegates felt quite reassured about the use of their data and others felt data needs more protection.

- Transparency and awareness of data sources – who collects what and the reasons for collection.

- Need more diagnostic decision tools for GPs to be developed through the use of patient data.

- Needs to be information of this type for GPs to consider when they see patients.

- There are risks versus benefits.

- There are some parts of the health system where people may be more concerned about the confidentiality of their data.

- Transparency around the data – there are a number of organisations using and sharing data, what are the potential benefits of sharing data?

- What are the risks associated with using patient data, what issues do patients have?

- Need more from companies reporting back on how data is used. Presently studies using Hospital Episode Statistics (HES) data do not need to report back / publish.

- Would like better awareness around how QuintilesIMS uses data.

- Patients need to hear about how data is used; there are always issues of patients' access to journals.

Discussion points from delegates' questions, collected throughout the day

- Need clarity on the National Data Opt-out

- Information needed on where companies get data from

- NHS royalties (profits)

- Data given to the Home Office by NHS Digital.

- Patients feeling like bystanders.

- The work of analysts is missing: what are they actually doing with the data? Reassurance is needed about security and that they can be trusted to use the data safely when they have it.

- Weigh up risks versus benefits, these can be hard to quantify.

- Potential harms / perceived harms.

- Confidentiality – patients are often more concerned about those they know seeing their data and finding out information, than private companies.

- Emphasis on the value of the data.

- Controversy helps to define what the issues are. Shock and awe is very strong in the media.

- Important to include Sam in the discussion; it helps to define arguments. There is a very passionate side about data use and alongside that we also need a very dispassionate side – just the facts (risks and benefits) – so that patients and the public can make informed choices.

- In order to provide balance, challenge thinking, we need to have a scenario where people who are against having patient data used have to talk about the benefits, and those who are for data being used, have to speak about the risks.

- For patients with a poor prognosis – their data will help to improve the lives of others, not their own.

- Several patients referenced a marketing letter from a pharmacy delivery service, which had been sent to their home addresses. How were their names and addresses obtained?

- Not enough awareness that commercial companies, such as QuintilesIMS, have to publish results.

- Is there a particular part of the healthcare system where people are concerned about data being used? Collective data is really powerful and can move services forward.

- Good to hear lots of different perspectives.

Understanding Patient Data will develop further information into online resources and a leaflet to incorporate / address issues which were discussed in the workshop. They are working with the pharmaceutical industry to get more stories about how data are used.

Please see Appendix 1 for the complete list of the 'post-it' note questions asked by delegates.

Chair's closing summary

Mike Birtwistle
Founding Partner, Incisive Health

Mike thanked all delegates and speakers for their contributions to the day. He acknowledged once more the role of patients, relatives and carers and the contribution of supporters, who all enabled the workshop to take place.

Mike closed the day by emphasising that there is much value in what we can achieve together: collectively data are much more valuable than they are individually.

Acknowledgements

For their contributions to the workshop, use MY data gratefully acknowledges and thanks:

- Our workshop chair and speakers, for so generously giving their time

- Our delegates for their participation and time

- Jane Lyons for her assistance on the day

- Jennifer Yiallouros for her assistance with this summary

- Our supporters who enabled the workshop to take place:

  - Leeds Institute for Data Analytics

  - QuintilesIMS

  - Understanding Patient Data.

Appendix 1	Complete list of the 'post-it note' questions and comments from delegates

General questions

Can depersonalised data be shared overseas?

What about the data held by Public Health England in the ENCORE database obtained from cancer registration? Is this made available commercially?

Are data controllers so concerned about the security of data that research is being impacted?

How will we ensure data on cancer is still available after the National Data Opt-out comes in next year? We need a session on this please.

Who can have access to data: local Healthwatch? Individual patients?

Why do drug companies pay for systems such as AXON 360? Are we paying them to access patient data?

Harvey Walsh's reply: Companies pay to access AXON 360 so they can use the aggregated outputs with the NHS for purposes such as NICE submissions and local pathway analysis.

Examples (needed) of how the use of patient data has improved patient care i.e. directly attributable to collection of patient data.

How do you ensure data from rare conditions is de-identified? Particularly when combining datasets.

The National Cancer Patient Experience Survey has provided a useful source of data about the experience of cancer patients and areas where improvement is needed, but could be removed due to confidentiality issues. How can we deal with this?

As the NHS is splintered by privatisation, how can we guarantee that the owners of our data (GP, pharmacy) are not seeking commercial gain from selling our data?

Does ticking a terms and conditions box count as consent? (i.e. physical trackers, apps etc.)

How and what formats are used to get patients' consent? Confirm please.

The figure of 54% supporting the use of 'my health data' is appalling low. The default media reaction to the use and availability or worse, the loss of data, is uniformly negative. So, how can we better communicate the 'value versus risk' story? Why do I never see a 'good news' story involving data?

Discussion has centred around 'live data' – how does the situation change with respect to deceased medical records? What is their status? If they are of value in research how are they being used and, in which case, why are they apparently destroyed after ten years? If not why and, why are they being destroyed before a potential use has been ascertained? N.B. Scanned files/digital data require little storage space!

What minimum percentage of opt-outs result in a statistically significant skew in opt-in data analysis?

What is the proportion of opt-outs within available sample? Statistically, can this corrupt information?

Is the information you get from the NHS what you need? If you limit your request, what do you miss?

Do you anticipate having access to DNA data to access genetic markers? In this day of personalised medicine – yes.

The NHS has a need - it goes out to tender - tenderers need data. Tenderers ask/apply for varying levels of data for the same project. Surely the NHS can indulge in pre-assessment on the basis of applicants' requests? Should the NHS provide data on total requests to all?

This is just the start – the information/data has huge benefit in its use. In the future, do you see the prospect of patients adding to their own rewards of lifestyle? Exercise, nutrition etc.

With the increasing number of drug combinations to be tested are we running out of patients for these trials?

"Companies will never be given name or contact details" – will this condition be under a law that must be discussed in Parliament, or something that can be changed by a civil servant?

Process following release of data: what follow-up / progress / feed-back (is there), to take account of success / failure and then modify task or need for more data.

Why isn't the NHS working out partnership / patent percentage from commercial companies or academies using our data?

Do commercial companies have data from individual hospitals / NHS Trusts, or just NHS Digital?

Several patients referenced a marketing letter from a pharmacy delivery service, which had been sent to their home addresses. How were their names and addresses obtained?

Comments & information

The use of my health data is infinitely more important than the <u>possible</u> misuse.

Next year there will be a national 'opt-out' for patient data

Any company or body making a (reasonable) profit from the use of patient data:
- Must be business registered in the UK
- Pay full corporation tax in the UK
- Pay a living wage
- Profitability must be limited/capped
- Have a worker representative on the Board of Directors
- Profits not sent off shore.

The amount of money paid to hospitals / consultants etc. needs to be transparent for involving patients.

I think it is a shame that the companies are collaborating with GPs to help with their IT systems. This has led to different systems that are used, that are not able to 'talk to each other'. We need to stop this and try and develop 'one' system to be used throughout the NHS.

N3 = National NHS Network. This sits in parallel to the internet with similar protocols <u>but</u> it only accessible to organisations which meet high IT security standards, with firewalls between N3 and the internet. In addition, many Trusts use end to end encryption with encrypted/password protected attachments. The encryption used is based on military level standard with at least two factor authentication. N3 websites are nww.site.nhs.uk

Personal difficulty – only get Summary Care Record from those records held by the part of the NHS where treatment occurred. This means the patient has to go to all sources.

Questions for Harvey Walsh

Would Harvey Walsh be able to separate pancreatic cancer data more accurately from Upper GI data, for the benefit of patient services?

Harvey Walsh's reply: Yes, analysis can be undertaken on pancreatic cancer specifically.

Questions for QuintilesIMS

You need to persuade NHSE and individual CCGs (particularly those operating without NHSE involvement) about how you can involve patients more directly:
- Raising awareness and education of your work etc.
- How to work directly with GPs & PPGs – talking to them at combined meetings
- Finding out why patients may be reluctant to join trials.

Then you need to work more widely with other voluntary organisations simultaneously with CCGs – the multiplicity of connections/patients this will generate may surprise you!

Do you have patient representatives on your clinical studies teams?

What contribution is QuintilesIMS making to early diagnosis of pancreatic cancer (4th biggest cancer killer – 3% survival not changed in 40 years!)

Questions for NHS Digital

Garry Coleman eloquently described the steps companies need to go through to access patient data. How did the Home Office bypass these processes? Giving asylum seekers' addresses does not benefit health or social care.

Are Section 251 exemptions assessed very stringently? I have heard researchers say personal data is needed – if the patients will not consent, a Section 251 will be applied for. This sort of attitude does not engender trust. How can you ensure that trust is maintained?

How much money does NHS Digital receive for supplying data to pharmaceutical companies on a yearly basis?

Comment for medConfidential

I have on more than one occasion begged for more information to be taken from relatives who have been ill and have had to fight for this to happen. It is our responsibility to improve health for future generations and personally for my children, my children's children and so on.

medConfidential's comment: No one should need to beg for their medical record to be used in accordance with their wishes (whether that's more sharing, or none).

Appendix 2   Organisations to whom delegates will feed back

Academic Health Science Network for the North West Coast

Barnet Healthwatch Primary Care Group

Cancer Research UK - patient representatives

Cancer support groups

Clinical Trials Dispensary, Addenbrookes

Early Diagnosis Group, Department of Primary Care, Cambridge University

Empower Data4Health

Healthwatch volunteers

Independent Cancer Patients' Voice

Janssen

Local groups, friends, relatives and neighbours

London Transferring Cancer Services (NHSE) – patient advisory group

Macmillan Cancer Support - patient representatives

NIHR (National Institute for Health Research) Biomedical Research Centre, University College London

STP (Sustainability and Transformation Partnerships) Service User Advisory Group

Yorkshire and Humberside Consumer Research Panel

University

WH Cancer Network PV + I group

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