RESPONSE TO THE CONSULTATION ON THE NATIONAL DATA GUARDIAN FOR HEALTH AND CARE’S REVIEW OF DATA SECURITY, CONSENT AND OPT-OUTS

Submission from the Association of Medical Research Charities (AMRC)

7th September 2016
EXECUTIVE SUMMARY

- Health information is vital for medical research; it enables researchers to prevent, diagnose and treat disease, as well as improving patient care.

Consent/opt-out model

- **AMRC supports the right to opt-out;** we believe that the public and patients must have the option to choose whether their identifiable health information is used for purposes beyond their direct care.
- **AMRC members support the proposal that anonymised data and national registries of disease will not be subject to opt-outs.**
- The clear consensus from our members is in favour of a **single consent/opt-out question** rather than a two-part question that separates care planning and research, for the following reasons:
  - Attempting to differentiate between care planning and research reflects a false choice. Research and care planning are closely intertwined; and there is no clear divide between data used for care planning and that for research. (See Annex 1 for case studies from our members illustrating where health information has been used for both research and care planning purposes).
  - A two-part opt-out question could have a severely damaging impact on medical research as there is a significant risk that the public may opt-out of research due to a lack of information about how research uses data.
  - A single opt-out question helps to simplify the question for patients and the public.
- We urge the Government to produce a comprehensive plan for the implementation of the opt-out question, which should be communicated transparently with an appropriate timescale.
  - Further user testing should be undertaken to ensure the language, format and style of the consent/opt-out model supports public understanding.
  - **AMRC strongly recommends that healthcare professionals communicate the consent/opt-out question.** We believe this is an important decision and the public need to be able to make an informed choice. It should not be left to leaflets and letters alone to explain the opt-out question.
  - **AMRC calls for a thorough communications plan for healthcare professionals and other related staff to ensure they are able to support and inform patients with the consent/opt-out choice.**
- AMRC is supportive of the independent taskforce on patient data hosted by the Wellcome Trust, and we encourage the Department of Health to engage with the taskforce.

Data security standards

- **AMRC welcomes the new data security standards for every organisation handling health and social care information;** they are essential for building trust in the system. If the public do not trust the system, they will be unwilling to share health information for
medical research and this will seriously hinder progress on new treatments and cures of diseases such as cancer, dementia, rare conditions and many more.

About AMRC
The Association of Medical Research Charities (AMRC) is a membership organisation of the leading medical and health charities funding research in the UK. Working with our 133 members, we aim to support the sector’s effectiveness and advance medical research by developing best practice, improving public dialogue about research and science and influencing government to ensure the best research can go ahead and be translated into new treatments. Medical research charities exist because the public choose to donate their money to support research to develop new treatments and cures; 10 million people donated to medical research charities last year. In 2015, AMRC members invested over £1.4 billion in health research in the UK and funded a quarter of non-commercial research in the NHS.

- Our members fund research focussed on the needs of patients for better treatments, therapies and interventions designed to improve the quality of life and ultimately prevent or cure their condition. This includes funding for rare and neglected diseases, for which other public funding is limited.
- We provide an authoritative advice on what matters to patients and the public. AMRC members represent charities big and small, covering acute and chronic conditions, both rare and common.

Health information is vital to enable researchers to prevent, diagnose and treat disease, as well as improving patient care. Our members have a dual interest in health and care services data – both as funders of a significant amount of medical research for which the use of data is essential and as champions for the views of patients and the public who support them. Some of our members also have an interest from a care provider perspective.

Introduction

Question 1: Please tell us which group you belong to?
The Association of Medical Research Charities (AMRC)

Question 2: If you are a member of an organisation or profession, please tell us if you are responding in a personal or private capacity
Responding on behalf of AMRC and its 133 member health and medical research charities

Question 3: If the Department of Health or other organisations were to create further opportunities to engage on data security and the consent/opt-out model, would you be interested in attending? If so where would you find it helpful an event to be held?
Yes, and in Central London

Data security standards

Question 4: The Review proposes ten data security standards relating to Leadership, People, Processes, and Technology. Please provide your views about these standards.

The ten data security standards proposed in Dame Fiona Caldicott’s ‘Review of Data Security, Consent and Opt-Outs’ are sensible, coherent and comprehensive. AMRC is supportive of the data security standards; we recognise the importance of having clear standards in place to improve data security across health and social care organisations to build trust in the system. As Dame Fiona points out in her review, trust is essential.
The public need to feel that they can trust health and social care organisations to handle their information with care and competence, and respect their wishes. If the public do not trust the system, they will be unwilling to share health information for medical research and this will seriously hinder progress on new treatments and cures of diseases such as cancer, dementia, rare conditions and many more. For this reason, AMRC welcomes the data security standards and embedding them fully and consistently across every organisation handling health and social care information.

Whilst we welcome the standards we have comments and suggestions on how the data security standards could be improved in detail below.

The scale of the organisations that will need to embed the data security standards is significant. Greater detail is needed on the timeline for implementation, along with the resource available to support implementation. A phased implementation where organisations ‘evolve towards’ the standards could be considered initially. AMRC would also strongly recommend stress testing the standards against real-life situations to resolve unintended barriers and to ensure that the information governance requirements are proportionate and feasible in everyday practice.

**Standards one to three** are applicable to “all staff”; our members would like further clarity on who is covered under this definition. AMRC recommends that “all staff” includes temporary staff and staff from other third-party organisations. Findings from the Wellcome Trust’s research into commercial access to data report\(^1\) and focus groups from the Review found the public need reassurance about data security when data is moving outside the NHS. For this reason, AMRC proposes that the standards apply to third-party organisations (IT operators, service providers, etc.) and that this is clearly communicated to all relevant stakeholders.

**Standard three** proposes “All staff complete appropriate annual data security training and pass a mandatory test”. Adequate staff training is essential to support and develop understanding of data security; building confidence and consistency amongst the workforce. AMRC believes it is crucial to delivering cultural and process change with regards to data security. However, we are concerned that providing training once a year may not be sufficient and recommend that additional support and resources are made available. Clear guidance on who to ask for advice is also key; staff should be able to ask questions and raise concerns.

The level of training should be proportional to the level of access staff have to data and their level of responsibility in handling that data. Consideration should be given to how training will work for new starters and temporary staff, such as bank and agency medical staff. Finally, we would suggest that training is revised to reflect ‘near misses’ and breaches of data security.

We support **standard four** and welcome the inclusion of “data on IT systems can be attributed to individuals”, this will help ensure people act responsibly and provide confidence to patients and the public.

**Standard eight** specifies that no unsupported operating systems, software or internet browsers are to be used within the IT estate. Further clarification is needed as to whether this standard is applicable to third party organisations. We would also like to understand whether other organisations (research centres, local authorities, etc.) have operating systems in place that are compatible with the NHS and social care systems.

Further consideration must also be given to the impact of the data security standards on clinical research staff and academics. For example, open source software is very useful for research; it is important that researchers are able to continue to access and work with health data.

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\(^1\) Ipsos MORI (2016) *The One-Way Mirror: Public attitudes to commercial access to health data*  
Question 10: Do you agree with the approaches to objective assurance that we have outlined in paragraphs 2.8 and 2.9 of this document?

AMRC is in favour of both the CQC and NHS Digital’s extended roles. The proposed approach will ensure that high standards for data security are met, helping to build public trust in the system. It is important that both organisations are adequately resourced and have the relevant expertise to take forward these duties.

Proposed consent/opt-out model

Question 11: Do you have any comments or points of clarification about any of the eight elements of the model described above? If so please provide details in the space below, making it clear which of the elements you are referring to.

AMRC supports the right to opt-out; we believe that the public and patients must have the option to choose whether their identifiable health information is being used for purposes beyond their direct care. Health information is vital for medical research; it enables researchers to prevent, diagnose and treat disease as well as improving patient care. We want to ensure that patients and the public are able to make an informed choice about sharing their data.

Our members have a number of concerns and questions regarding the consent/opt-out model, which are set out below, along with comments on the eight elements of the model.

The consent/opt-out model

The consensus from our members is in favour of a single opt-out question rather than a two-part question, for the reasons stated below. We have used the term ‘care planning’ to mean the running of the health and social care system.

- Attempting to differentiate between care planning and research reflects a false choice. Research and care planning are extremely closely intertwined; and there is no clear divide between data used for care planning and that for research. It would be confusing and inaccurate to suggest such a divide exists. See Annex 1 for a number of examples of where data has been used for both research and care planning purposes. The examples cover a wide range of research into different disease areas including using medical records to assess the provision of a heart attack treatment across the UK; using data to understand the patterns of hospitalisation of dialysis patients which have resulted in important implications for how the dialysis services and clinical pathways are designed.

- Medical research charities are concerned that a two-part opt-out question could have a severely damaging impact on medical research, as there is a significant risk that the public may opt-out of research due to a lack of information about how research uses data. The Wellcome Trust Monitor, a survey of the UK public, found that 20% of participants said they would be unwilling to share their anonymised health information.2 In a scenario in which 20% of the population chose to opt-out of sharing data for the purposes of research, it would have a detrimental impact on medical research.

- Evidence suggests that members of the public are concerned about commercial access to their health information.3 A two part-question may provide false assurance that by opting out of the research option they are also opting out of commercial access.

- Applying opt-outs as a two-part question model would be extremely confusing for data holders, which may increase the risk of making mistakes and further damaging public trust. The two-part question will add an extra layer of complexity to an already complex system.

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The review heard that people find the current type 1 and type 2 objections difficult and confusing. The public would like a clearer choice that is easier to understand. A **single opt-out question helps to simplify the question for patients and the public.**

In addition, AMRC would advise that further user testing is undertaken to ensure the language, format and style of the consent/opt-out question support public understanding. The consent/opt-out model and related information must take into account social, cultural and educational differences in the population. Terms such as “personal confidential data” may not be easily understood by all. We would also recommend input from behavioural experts on the consent/opt-out model and its implementation.

Further deliberation must also be given to the examples included in the proposed consent/opt-out model. Our members have suggested that some of the examples given are unrealistic and inappropriate, such as the illustration of research as “a researcher writing to an individual to invite them to participate in a specific approved research project.”

**Implementation and communication of the opt-out question**

Making the case to the public for sharing personal health information (choosing not to opt-out) is critical for the future of medical research. AMRC and our members are extremely concerned that an opt-out system will be introduced without the public really understanding the value of data sharing and the consequences of opting-out. The public must be given the opportunity to make an informed decision about the use of their health information.

Careful and considered implementation of the opt-out question is therefore vital. **We urge the Government to produce a comprehensive plan for implementation, which should be communicated transparently with an appropriate timescale.** It is important going forward that lessons are learnt from the implementation of the care.data programme.

The Department of Health must set out how the consent/opt-out question will be presented; it is unclear if the question will be communicated by person or by other means. **AMRC strongly recommends that healthcare professionals communicate the consent/opt-out question as they are well-suited to helping the public make an informed choice. We believe this is an important decision and it should not be left to leaflets and letters alone.**

**AMRC calls for a thorough communications plan for healthcare professionals and other related staff to ensure they are able to support and inform patients with the consent/opt-out choice**, including highlighting the importance of personal health information for research and care planning services. The Department of Health and its arm’s length bodies will need to work with the relevant professional bodies to develop appropriate training materials and supporting information. Consideration should also be given to what constitutes an appropriate time to discuss the question with patients.

AMRC is supportive of the independent taskforce on patient data hosted by the Wellcome Trust. It is important that the Department of Health engages with the taskforce on issues of communication with patients, healthcare professionals and the broader public.

On a different but related note, it is important that the new opt-out/consent model does not damage this country’s unique data environment, which provides exceptional opportunities for medical research. The rich data setting of a cradle-to-grave NHS is strength for the medical research environment and of particular importance as the UK exits the European Union. Continuing to enable unique research opportunities in our data rich NHS will help support and secure medical research in this country in future.

**Eight elements of the consent/opt-out model**

AMRC is broadly supportive of the new opt-out model’s eight statements. We would like to provide comments on a selection of the eight statements:
1. You are protected by law

AMRC proposes that the eight principles should more clearly communicate that the opt-out question only applies to identifiable data, and that anonymised data will not be subject to opt-outs.

With regards to the statement “Your personal confidential information will never be used for marketing or insurance purposes, without your consent”; we would like further assurance that this statement is accurate under all circumstances. In addition, in the proposed examples on pages 40 to 41 of the Caldicott review, the words “without your consent” should be added to the section relating to marketing and insurance. This information should be made more prominent as it is likely to be the greatest concern to patients.

4. You have the right to opt-out

As stated above, AMRC members welcome the right to opt-out; we believe that the public and patients must have the option to choose whether their personal confidential information is being used for purposes beyond their direct care.

Further clarity is needed on circumstances where a person may not have the capacity to make a choice, for instance after brain injury or a stroke, or as a consequence of dementia or certain severe mental health conditions. It is also unclear how the consent/opt-out choice will be implemented in relation to children and young people. Parents, guardians and carers should have clear information about any choice they need to make for children and young people.

It is important that the opt-out/consent questions works for vulnerable members of the public that may not be able to provide consent. Those that are the most vulnerable often have the greatest health and social care needs, and thus it is critical that researchers and care planners have access to their health information, as is deemed appropriate. Allowing carers and family members to give consent on behalf of vulnerable people will enable researchers to continue to prevent, diagnose and treat ill health, as well as improve patient care.

6. Explicit consent will continue to be possible.

We would welcome further detail on how a patient will be able to give explicit consent for a specific research study if the patient has chosen to opt-out of data sharing.

It is important that any changes from the current system are communicated clearly and transparently. Further clarity is needed on how researchers will be able to access data, recruit patients on to clinical trials and communicate with patients.

8. The opt-out will not apply in certain exceptional circumstances

We would like to understand who will be responsible for identifying and deciding what an ‘exceptional circumstance’ is.

AMRC members support the proposal that anonymised data and national registries of disease will not be subject to opt-outs.

Sanctions

Question 12: Do you support the recommendation that the Government should introduce stronger sanctions, including criminal penalties in the case of deliberate or negligent re-identification, to protect an individual’s anonymised data?

AMRC supports the National Data Guardians’s recommendation for tougher sanctions for “malicious or intentional security breaches”. The NHS, safe havens and all users of data should be held to account for their handling and use of the data. Governance requirements need to be clear.
and adherence monitored effectively and thus sanctions need to have real teeth and be applied transparently to those who have broken the rules. This will give the public greater confidence that firm action will be taken as necessary to protect their personal identifiable health information. We would welcome further specific detail on the proposed sanctions, both financial and criminal.

There is a need to ensure the level of punishment is proportional to the breach (deliberate vs negligent) and that individuals are not held accountable for system error (e.g. IT). It would be useful to have clear definitions and distinctions between the different types of data security breaches. To encourage a culture in which individuals are willing to report breaches and near-misses in order to learn from them.

However, we are concerned that issuing financial sanctions to NHS trusts that are already in financial difficulty may have unintended negative consequences on healthcare for patients. Furthermore, it should be noted that current sanctions that are in place, such as for long waiting times, are not always being enforced\(^4\). Any enforced sanctions should be in line with current regulations and guidelines.

**Current opt-outs**

**Question 15: What are your views about what needs to be done to move from the current opt-out system to a new consent/opt-out model?**

The Review does not recommend any changes to the existing arrangements until there has been a full consultation on the proposed opt-out model.

It is important that the transition from the current opt-out system to a new opt-out model is considered, measured and timely, with minimal disruption and thorough user-testing. NHS and social care organisations will need to be given sufficient notice to implement the new question and develop appropriate training materials.

For those patients that have already opted-out of sharing their information under the existing framework, these decisions should be respected. Clear communication about any decision made on previously-registered type 1 and 2 objections is essential, and we would welcome clear guidance from NHS Digital for all organisations sending data to them or requesting data from them. Finally, in order to support understanding of the organisations that collect and store health information, AMRC would welcome a diagram that illustrates how health information flows through the system and where patients’ opt-out preferences will be stored and enacted.

ANNEX 1

The following pages set out a number of case studies from our members demonstrating some of the ways researchers are using health information to inform both research and care planning, and how their aims are closely linked.

Using medical records to assess the provision of a heart attack treatment across the UK
Funded by: British Heart Foundation

A ten year research project at the University of Leeds has revealed that the use of a heart attack treatment, which drastically improves a patient's chances of survival, has rapidly increased.

Emergency stenting treatment (PPCI) involves opening a blocked artery to restore blood flow to the oxygen-starved part of the heart and has helped save thousands of lives since becoming available in the early 2000s.

Using medical records from across the NHS, researchers found that the use of PPCI increased from 0.1 per cent in 2003 to 86 per cent in 2013. Despite such rapid uptake, the study also discovered vast differences in the provision of treatment between hospitals in England, highlighting the need to ensure that all heart attack centres, regardless of location, are equipped to deliver the best possible care.

Using patient data from the UK Renal Registry and Hospital Episode Statistics data to measure quality and drive change in renal services
Funded by: Kidney Research UK

In the UK around 3,000 people a year die while on dialysis and more than 250 people a year die while waiting for a kidney transplant. That equates to five people every week.

To better understand the pattern of hospitalisation of patients undergoing dialysis, researchers linked patient data from the UK Renal Registry with Hospital Episode Statistics data.

Researchers found that hospital admissions were 69% higher, and deaths were 33% higher, in patients who had a two-day break in their dialysis treatment. Patients receiving renal replacement therapy (dialysis or a transplant) in some centres were four times more likely to be admitted than similar patients treated in other centres.

These findings have important implications for how dialysis services and clinical pathways are designed. Health services can now take action to plan dialysis services to reduce the risk of health complications or even death.

Using patient data from the MRC National Survey of Health and Development to better understand the lifetime risk factors for developing dementia, and detecting some of the earliest signs of diseases like Alzheimer's
Funded by: Alzheimer's Research UK, Iceland Foods Charitable Foundation, the Medical Research Council (MRC) Dementias Platform UK and the Wolfson Foundation

The MRC National Survey of Health and Development (NHSD), the oldest of the British birth cohort studies, is unique in having data from birth on the health and social circumstances of a 5,362 men and women born in England, Scotland or Wales in March 1946.

The unique cohort has contributed to almost seven decades of pioneering research shedding light on infant development, educational attainment and cognitive function in midlife. As volunteers now approach later life, a multi-disciplinary team of researchers based at UCL are studying 500
members of the unique MRC National Survey of Health and Development, to gain crucial insight into Alzheimer’s and other dementias.

The UCL team is using brain scanning along with memory and thinking tests to help shed more light on the lifetime risk factors for dementia as well as looking for some of the earliest signs of diseases like Alzheimer’s.

This research will provide the platform for the UK to undertake pre-symptomatic trials to test therapies aimed at preventing the development of impairments due to Alzheimer’s disease. This collection of data may have important implications for the provision of care, services and possibly treatments for people living with dementias and their families, now and in the future.

Using patient data to deliver high quality care for people with Parkinson’s

*Funded by: Parkinson’s UK*

Many people with Parkinson’s report that the care they receive when admitted to hospital is unsatisfactory. People with Parkinson’s often find their medication is delayed or not given at all when admitted into hospital.

Researchers found that where medication was missed, a reason was recorded in about 3 out 4 instances. The top reasons recorded included the patient not being able to take medication by mouth, the drug not being available or the patient refusing to take the medication.

Identifying reasons for medication errors will help to develop strategies that reduce missed medication doses. This will benefit people with Parkinson’s when admitted to hospital and help in the delivery of high quality care.

This research has helped inform what best practice in hospitals may look like. The researchers recommend all hospitals have guidelines for what to do when someone with Parkinson’s cannot swallow their medication. They also recommend an accessible stock of Parkinson’s medication in key areas such as admissions units, and a substitution policy should be considered when a drug is not available but a similar drug is in stock.

Using patient reported outcome measures (PROMs) to assess and improve treatment planning for men with prostate cancer

*Funded by: Prostate Cancer UK and Movember UK*

Life after prostate cancer diagnosis (LAPCD) is a patient reported outcome measures (PROMs) project, designed to identify the outcomes of prostate cancer diagnosis and treatment that really matter to men across the UK. The response rate from men diagnosed with prostate cancer is very good (circa 60%).

The research can help to understand what men think about the treatments that they received and their effectiveness, how their quality of life changes as they live with prostate cancer and the consequences of treatment over time, and how these health outcomes compare to a wider group of men without prostate cancer.

The data from this survey will be published nationally and therefore individual trust results will be available, but data will remain anonymous. The information generated from this study will highlight areas of treatment and experiences that show patterns of poor care. This will subsequently allow work towards better treatment planning and also provides improved evidence for future research calls.
The role of the Cancer Registry is vital for the project to work towards the goal of improving men’s lives, by identifying the patients and using that data in order to know if they are eligible for the study and subsequently inviting them to take part in the study.

**Using routine NHS datasets with newly captured patient reported outcomes and diagnostic profiles to robustly quantify the quality of hospital services and colorectal cancer outcomes across Yorkshire**

*Funded by Yorkshire Cancer Research*

This study involves linking routine NHS datasets (such as Hospital Episode Statistics, cancer registrations, screening, radiotherapy and chemotherapy) with newly captured patient reported outcomes and diagnostic profiles to robustly quantify the quality of hospital services and colorectal cancer outcomes across Yorkshire. This information will be fed back to the multidisciplinary teams, used to identify improvement areas and education initiatives delivered to achieve optimal practice. Hospital performance will then be re-audited and the cycle of improvement repeated. Colorectal cancer care in Yorkshire will, consequently, be significantly improved above that of hospitals not participating. The project aims to achieve a 10-15% improvement in outcomes, saving around 120 to 150 deaths from bowel cancer each year. National rollout could lead to even greater improvements in bowel cancer survival.