

A short proposal to deliver on the Secretary of State's promise to patients, address NHS England's care.data fiasco, consider opt-in, and allow HSCIC to deliver a consent-based data infrastructure for a 'digital' NHS.

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Proposal

A single Spine¹-based consent setting: **"Dissent from disclosure of individual-level data for uses other than my care and treatment"**

When applied wherever the NHS number is known, a Spine-based consent setting will deliver on Secretary of State Jeremy Hunt's April 2013 promise to patients²:

"We're not going to cancel the opting out that has already happened.... we will respect the people who have already said they wish to opt-out of any data sharing."

Such an opt out would, of course, still permit the use of data in exceptional circumstances allowed by law, such as a public health emergency.

¹ Implemented via an attribute on the new 'Spine2'. This was not feasible when the care.data programme was originally conceived, but the long delays to care.data and the success of the new Spine mean that a 'universal' secondary uses consent flag in Spine2 is now a viable option.

² When accepting the Caldicott2 review, at 14:46: <https://www.youtube.com/watch?v=Udpaijg3nE>

Executive Summary

To have privacy, a citizen should not have to learn how the NHS works.

The problems with the details of the opt-out that is offered to every patient as part of the discredited care.data scheme, and the resolution of the mistake with 9Nu4 are both symptoms of the same bigger problem: the unaddressed “data trust deficit” in the NHS for secondary uses of patient data.

That deficit has grown and been substantiated due, in large part, to the commercial re-use of Hospital Episode Statistics (HES) and other datasets since 2005/6 and the origins of the NHS Information Centre. To resolve it, there must be a cultural change around secondary uses, as called for by Dame Fiona Caldicott.

Patients must be offered a comprehensible choice that covers the whole NHS - and ultimately the whole health and social care system - not just the bits that are easy to do.

HSCIC, as the ‘institutional memory’ of the NHS, can start with the three long-standing large datasets that cause most public concern: HES, Maternity and Mental Health (MHMDs), and show evidence that it continues the cultural shift that IIGOP’s annual report acknowledges has occurred only in some places since last April. Full implementation across all data flows will clearly take time; targeted implementation in areas of major concern can be done first.

The choice we detail below can be implemented in a coherent and consensual fashion, reflecting and acknowledging past problems, but moving on from the various catastrophes of governance that have occurred.

Proper implementation will require respect for patient choice, medical ethics, good communications and a clear understanding that past decisions by NHS England have made the public more suspicious, not less.

This being the case, Personalised Data Usage Reports must be operational before the public are written to. The National Data Guardian must be on a statutory basis, and operational, in order for the public to be told, not what *might* be in the future, but what the new governance framework actually is - a framework which patients can examine without unanswered questions.

We propose the creation of a new field on Spine2, which is **“Dissent from disclosure of individual-level data for uses other than my care and treatment”**.

Given all the existing problems, and as a definitive act to demonstrate that patient choices will be respected now and in the future, this would initially be set for all those who have opted out of data leaving their GP practice (9Nu0), all those who have used the flawed HSCIC code (9Nu4), and also the Summary Care Record and other relevant opt outs.

Such a clear public statement of an abundance of caution would be a significant confidence building measure - especially as all those people will be contacted, irrespective of which opt out they had (or how many). If this new consent setting is going to be ‘forever’, it cannot afford to go down in flames.

There is not a blank space for this proposal; it is emerging into a complex world, with pre-existing decisions, choices and beliefs. A point that NHS England seems to have ignored in its control of the programme so far; is it eager to rush into its next mistake?

We understand that NHS England's internal timescale is still to send out communications to GPs and patients in the pathfinder areas prior to the general election³. This appears to be precisely the sort of arbitrary deadline that it has said should not happen. The whole process cannot, and must not, be rushed. Each component must be put in place only when it is ready, with clearly-defined published roadmaps and interim procedures for those elements that cannot be delivered straight away.

The rest of this paper details the implementation of the full proposal, and interim measures that should be taken until it is in place.

To have privacy, a citizen should not have to learn how the NHS works.

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medConfidential
January 2015⁴

³ The regular paper detailing timescales has not been shared with the care.data Advisory Group this month. CDAG has had papers indicating timescales throughout the last 5 months (see Annex D); this January that paper was curiously missing.

⁴ The latest version of this paper can be found at <https://medconfidential.org/information/towards-every-flow/>

Implementation details

Specific actions can be taken to deliver a practicable, system-wide consent mechanism for secondary use of NHS patients' individual-level information, in the near future.

A choice to offer patients

The current care.data leaflets (diagram from version received on 22nd January 2015 in Annex B, Part 2) could be amended by inserting "hospitals and" before each mention of "GP practices", thereby **extending the single opt out to cover all secondary uses⁵ of patient data.**

In terms of communications, this would have substantially the same effect as combining the two options from last year; it is comprehensible to patients, and we detail below how it could be implemented. It is also in line with the version of the leaflets shown to patients at the care.data Advisory Group public meeting in Manchester in November 2014⁶, and can be extended as more data sources are added to the Care Episode Histories⁷ programme.

We appreciate this extremely simple proposal may provoke opposition from NHS England, which prefers giving patients more difficult choices - or no choice at all - to avoid administrative inconvenience. We look forward to engaging with HSCIC on the details.

As many patients have already opted out, they must clearly all be contacted with regard to the ongoing implementation of their existing choices. Whatever the content of that communication, the promise of "no impact on direct care" must be honoured, and the choice they made ("to prevent confidential information about you from being shared or used for any purpose other than providing your care"⁸) must be respected.

That the 9Nu4 code used to implement 'Type 2' objections was mis-specified is not patients' mistake. To presume after the fact that they didn't understand⁹ the choice they were making is perverse; the choice people made was clear enough - it just wasn't true.

(If it is the intention to offer patients a means to opt out entirely from the 'digital' NHS, then of course the mechanism to do so should be made clear as well.)

⁵ We appreciate that the language and presentation in the leaflet must be simplified. "Hospital" in this instance should be understood to mean all settings outside the GP practice, e.g. clinics, pathology labs, etc.

⁶ Annex B, Part 1

⁷ While NHS England calls the output (linked GP data + HES) of care.data, 'Care Episode Statistics' - imitating 'Hospital Episode Statistics' - it is important to note that these are not actually statistics in the common use of the term. They are raw data, linked by individuals across time, without any form of protection of the events or dates within. As such, to call them 'Statistics' is misleading. 'Histories' is a much clearer and more accurate description of what is included.

⁸ As stated in the leaflet sent out in Jan/Feb 2014. On the website and in other literature, the opt-outs were stated in varying ways, e.g. "if you do not want information that identifies you from being shared outside your GP practice" and "You will also be able to restrict the use of information held by other places you receive care from. However, this will not affect the care you receive."

⁹ Letter from Kingsley Manning to Select Committee, 20/1/15: "...it has been hard for the public to understand the objection policy in the context of care.data."

Interim consent measures

While this discussion continues, and while letters to patients are in the post, the NHS will continue to deliver care and generate data, and HSCIC will continue to collect and send data to their commercial users. What happens during that time must be safe.

Therefore, interim measures cannot be limited to care.data alone, but must apply across data flows for secondary uses in, around and out of the NHS. This means the initial Spine consent code has to be set not only for those who have 9Nu0 / 9Nu4 codes, but also if the individual has opted out of any other data sharing.¹⁰

We include in this patients who opted out of the Summary Care Record because of the significant confusion caused between the care.data and SCR opt-outs last year, and because it is reasonable to assume that those who have opted out of medical staff having access to an extract of their GP record for direct care purposes would not want much larger portions of their medical history made available to commercial third parties.

People should be contacted out of an abundance of caution, not in a panic because what is being done while they are being contacted is reckless.

As we said above, given that those people who are being (re)contacted will have expressed a preference in the past for their data not to be shared - in most cases having been told that it “does not affect your direct care” - then it must be made clear that their existing choices will continue, and that any interim and ongoing consent measures will not affect this.

Once those interim measures are in place, and assuming the status quo is safe, the recontacting process may take place. It would be far preferable for Personalised Data Usage Reports and a statutory National Data Guardian to also both be up and running, i.e. when consent is based on a new system that is in place *and can clearly be seen to be in place* - not something dependent on promises that may be broken in the future as easily as promises have been broken in the past.

¹⁰ e.g. a partial list, given in medConfidential's letter to the Secretary of State, 29/4/13:

- 93C3 Refused consent for upload to national shared electronic record
- 93C1 Refused consent for upload to local shared electronic record
- 9Ndo Express dissent for Summary Care Record dataset upload
- 9Nd1 No consent for electronic record sharing
- 9NdH Declined consent to share pt data with specified 3rd party
- 9q2 Declined consent for Electronic Prescription Service
- 9M1 Informed dissent for national audit
- 9M10 Informed dissent for diabetes national audit

Before (re)contacting patients

Research by the Royal Statistical Society has shown that trust in organisations' use of personal data is lower than the trust in those same organisations more generally.

Beyond the NHS, the RSS found that few people have *“a high level of trust in these organisations to use data appropriately, compared with 36% trusting the NHS, and 41% trusting their GP. Nearly all institutions also suffer a “data trust deficit”, whereby trust in them to use personal data appropriately is lower than trust generally.”*¹¹

This deficit must be addressed, and the level of trust in the NHS shows that it can be addressed, if consent is taken seriously and applied consistently throughout the system. This is an opportunity to do precisely that.

If, as we propose, consent were to become a Spine-based setting across the system, the processes of the Secondary Uses Service (SUS, newly in-house at HSCIC¹²) can honour these settings; SUS being the primary data source for HES, which is the main cause of concern for existing data flows.

While not all hospitals - and certainly not all care providers - can honour patient dissent for secondary uses immediately, the implementation of a Personalised Data Usage Report would allow patients to know precisely which of the care providers that have received their data may not be capable of honouring their wishes¹³. A Personalised Data Usage Report would also allow a patient to verify care providers' statements, as if a provider says one thing and does another, that will be immediately apparent to the patient in their Report.

A Spine-based setting would also recognise that - as some GP practices expand their services to those traditionally offered by hospitals, and some hospitals experiment with providing GP services - distinctions between contexts in a single “NHS-wide” choice on secondary uses are likely to become increasingly flawed.

If it chooses not to take an approach like this, the NHS faces a tremendous problem and will be forced to recontact up to a million people or more - all of whom have already demonstrated they have strong concerns about the use of their medical information - to explain what it is now doing about consent. This is an opportunity for the NHS to demonstrate a comprehensive commitment to consent in secondary use of patients' data, and to show through action the cultural change that Dame Fiona Caldicott has called for.

While there may be some residual potential for embarrassment, such an approach would mitigate even greater reputational damage and provide all patients with a strong, future-proofed option that does what they intend:

“Dissent from disclosure of individual-level data for uses other than my care and treatment”

¹¹ <http://www.statslife.org.uk/news/1672-new-rss-research-finds-data-trust-deficit-with-lessons-for-policy-makers>

¹² <http://www.computerweekly.com/news/2240238422/NHS-to-bring-two-IT-systems-in-house-away-from-BT-next-month>

¹³ This could also be indicated at a high level in the NHS Choices information shown about care providers - so patients, in advance of treatment, have some measure of the IG of an institution.

Patient communications

We propose using work already done for the communications around the care.data pathfinders, trivially modified to cover all secondary uses as we mention above, but needing to take account of the fact that some patients quite reasonably believe they have been opted out already. If the interim arrangements reflect the best IG available, then the pathfinders also become a test of the communications to go forward on a wider basis, under a comprehensive consent model.

There will be patients in the pathfinder areas who have opted out already, whose choice must be respected. We see no alternative but for them to be written to, explaining how this is to be done.

But if the care.data programme specifically, or wider NHS data programmes more generally, are to engender public confidence and trust moving forwards, it is simply unacceptable for patients who have already opted out to be sent a communication asking them to opt out again - effectively ignoring their past choices. The patient communications as currently drafted read as if last year and the choices they made never happened. A single sentence saying, "Ignore this if you've opted out already" is both dangerously ambiguous¹⁴ and dismissive to the point of contempt.

These communications must be done properly. Patients should receive just one letter, depending on their circumstances. The presence or absence of particular codes can be determined by a single, properly authorised extraction.

- As there is no way to tell who received a copy of the junk mail leaflet sent last January / February, it must be assumed that everyone did. Communications to this Group (1) must explain that this is another opportunity for them to choose to opt out or do nothing.
- Group (2) comprises those patients who have just an 9Nu0 code, or any of the specified previous opt-out codes, on their GP record. It should be explained to this group that the Spine dissent code has been set for them, based on their previous choice(s), and could offer them a chance to opt in - i.e. withdraw dissent - if they so wish.
- Group (3) comprises those patients who have a 9Nu4 code on their GP record, either by itself or in combination with other codes. It should be explained to them that there was a mistake with 9Nu4, that it has been rectified, and that the Spine dissent code that has been set for them will meet the choice(s) they made in 2014.

NHS England currently seems to be suggesting that the solution relies on a paper-based, largely hidden HSCIC process, a version of the form previously described as "phrased like a threat" by the Committee. We sincerely hope that whatever is said to patients is not phrased as a threat either - "You won't be called for screening" already comes pretty close. We address this further below.

We feel strongly that the patient's GP must be involved - especially if choices made relating to HSCIC, a faceless arm's-length body of the Department of Health, may impact on the GP's capacity to provide care. Single-choice consent delivered via GP communications would also allow practices or CCGs to decide for themselves whether they wish to make a "Local Choice" and run an local opt-in process, as medConfidential detailed to the BMA in summer 2014¹⁵.

¹⁴ Previous experience demonstrated significant confusion in both patients and GP practice staff between care.data and other opt outs, notably the Summary Care Record. Including one practice that had a "Summary Care Data" opt out form!

¹⁵ <https://medconfidential.org/wp-content/uploads/2014/06/2014-06-11-Achieving-local-choice-and-consensual-research-use.pdf>

Steps in implementing consent in existing flows

Until legislation requiring care providers to use NHS numbers as the mandatory identifier for patients - the Health and Social Care (Safety and Quality) Bill 2014-15, currently in the Lords - is passed and enforced, there will need to be a form of 'lookup table' between the identifiers used in a data flow, and the NHS Number used by the Spine.

For providers that use NHS Numbers, this is entirely straightforward.

For providers that do not, some form of lookup table - between the local identifiers and the NHS number - will be required for every patient in the NHS. Such a 'Patient Identifier Table' is a necessary, interim step.

The three datasets that should be prioritised are all under the control of HSCIC: Hospital Episodes Statistics, the Mental Health Minimum Dataset (MHMDS) and the Maternity dataset. While the many other datasets supported by HSCIC should be included in the medium term, the greatest immediate public concern is with these three.

While HSCIC itself has no powers to force care providers to use the NHS Number, for these three critical datasets, it may publish a list of organisations which are not supporting the consent flag via either Spine or the HSCIC Patient Identifier Table. A public list would help provide the necessary impetus for those organisations to respect patient consent.

For datasets that can be linked via a pseudonym, or via any one of the Patient Identifier Table, the Spine consent flag or the NHS number, we propose that - in the medium term - these datasets be available exclusively within a safe setting (in the first instance, HSCIC's Secure Data Facility). For permanence, this would require legislation.¹⁶

Meeting such a requirement would allow for reconsideration of the original "Care Episode Statistics" [sic] proposal; a single research dataset covering all aspects of the NHS and patient data. With the addition of the Secure Data Facility, Personalised Data Usage Reports, consistent consent processes and statutory governance oversight, a coherent discussion could finally be had with all interested stakeholders.

The principle and benefits of such a dataset are widely supported; the question has been whether the implementation is fit for purpose. Quite clearly, care.data has not.

¹⁶ Absent legislation, this would be a side-effect of the implementation of our "CLASSIFIED when complete" proposal

There is need of a replacement code for 9Nu4

Due to the misspecification of the 9Nu4 code and subsequent confusion, existing 9Nu4 codes on people's records will need to be 'copied across' to the new dissent code on the Spine, and then 9Nu4 itself should be withdrawn from use.

The new Spine dissent code cannot however be solely based on 9Nu4; it should also reflect 9Nu0, SCR and other existing patient choices, as mentioned above. This new, comprehensive approach can be seen as an expression of a (hopefully new-found) respect for Information Governance and consent, acknowledging the existence of the data trust deficit, and committing to concrete steps towards addressing it.

As an additional a confidence-building measure for a digital NHS¹⁷, a new code - say '9Nu8' - could be created, reflecting the choice currently defined by the broken 9Nu4. For if a patient wishes to opt out of all digital services from the NHS, they should be able to do so. Patients such as Helen Wilkinson¹⁸, whose case has been raised repeatedly in Parliament, would be provided a reassuring backstop; even if they wished to entirely dissent from electronic transfer of their records, they could do so. As even completely destroyed trust can be rebuilt with care and attention over time, it would also form a route back.

This would be an acknowledgement by HSCIC that the trust placed in them must be earned, and maintained - and cannot be taken for granted as cavalierly as it was for a period up until early 2014. It also means that patients need not make the choice, as has been implied, between protecting their and their family's privacy or using a digital health service.

The use of a new 9Nu8 code at the GP practice - rather than the "phrased as a threat" forms that have to be posted to a PO Box, accompanied by copies of ID documents that will be saved for 7 years for bureaucratic paperwork reasons - means such a choice could be discussed in a setting where patients are more likely to feel safe, can have the implications explained to them and possibly be provided with a cooling off period, but with a personal guarantee from their GP that the right thing will happen.

We understand HSCIC's expectation that a long, complex form with multiple signatures is the only way to approach the problem, but this reflects the perspective of an arm's-length body of the Department of Health - not the perspective of a citizen, viewing the NHS as a single entity.

To have privacy, a citizen should not have to learn how the NHS works.

¹⁷ [Simon] Stevens calls for digital NHS front door. E-Health Insider. January 2015.

<http://www.ehi.co.uk/news/EHI/9818/stevens-calls-for-digital-nhs-front-door>

¹⁸ <http://www.theyworkforyou.com/debates/?id=2005-06-16b.495.0>

Updating specifications over time

Patients must know how things can change. The update process is key to that.

While Tim Kelsey said to the Committee that the specification of the codes to be extracted for the pathfinder phase would not be updated, we are not certain this is entirely true. We understand¹⁹ there is still an update pending, which was due to be published last November - although it is possible this may not be implemented until after the pathfinders. The update in question would not include musculoskeletal conditions; it would be fixing mistakes, and contains no substantive additions.

In short, the continued lack of transparency and substance is likely disappoint everyone.

Either way, there needs to be an ongoing process for updating the specification of the programme and dataset over time. As care.data - or whatever will replace care.data (which we refer to above as 'Care Episode Histories') - these changes must be subject to an appropriate public consultation process.

We welcome Tim Kelsey's commitment in evidence to consult on the first update, but this falls far short of the proposal we published in September as "no back door changes".²⁰ A far more robust process such as this should be adopted by NHS England, and preferably be reinforced (and enforced) by regulation or a mandate from the Secretary of State.

If patients are to trust the process by which collections may change, they must know how.

¹⁹ We were told it would be published in November 2014. It wasn't. It has been confirmed as still pending.

²⁰ <https://medconfidential.org/2014/expanding-the-scope-of-care-data-no-back-door-changes/>

Screening must, and can, be unaffected by privacy choices

If historically confused processes are deconflated, screening can be entirely safe for people who have opted-out in this proposed model.

Screening, including calling patients for any form of screening, can be addressed by a slightly modified version of the approach we outline in our risk stratification paper²¹, that has been clarified and updated since we originally published it in response to DH's 'Accredited Safe Havens' consultation in summer 2014.²²

In practice, a commissioner could say: "Contact all *women over 65* who *haven't* been screened in the past 3 years", knowing only a count of how many people this would be; the GP can then contact the relevant patients. Similarly, a second rule could be: "Contact *women* with this *particular diagnosis* who *haven't* been screened in 12 months", or: "Contact *all men* who *haven't had this test* in the *last decade*". A list of standard best practices should likely exist, though commissioners would have some flexibility to address local variations in their areas.

Publication of such lists would allow very simple natural Randomised Control Trials on the effects over time, by examining the impacts of defined differences, and also assist in removing unintended differences.

It is differences such as these that care.data was expecting researchers to find - by matching parts of one broken research needle buried across 211 different CCG haystacks, containing many different bits of needles. A better approach may be needed.

²¹ <http://medconfidential.org/2015/towards-protecting-data-in-secondary-uses/>

²² pp4 & 5, 'A substantive proposal for safe settings': <https://medconfidential.org/2014/the-department-of-health-protecting-personal-health-and-care-data/>

Opt-in as a Local Choice²³

It is a simple question, but what exactly are people consenting to?

Details are important and at the very least, for example, this needs to be a system where all individual-level data is only ever accessed via a safe setting.

NHS England has committed to the safe setting solely for the pathfinders, but says nothing about what will happen beyond then. While we expect any teething problems with the HSCIC's Secure Data Facility will be resolved, and while we understand NHS England's newfound concern to only tell patients things that are actually true, the fact is that for a fundamental safeguard such as this to be presented to patients and to mean anything, it must be applied consistently, universally - and remain in place.

Any significant change in the rules, processes or data hierarchy must require the re-consenting of those who have already opted in. While superficially opt-in may seem sensible, a once-in-a-lifetime opt in to a system that evolves over time is completely unacceptable; in order to be valid, consent must be properly informed.

As such, opt-in practices may wish to defer their inclusion at least until the medium-term structure of the programme is clear and the governance protections - such as a statutory National Data Guardian, a Personalised Data Usage Report and overarching consent across all HSCIC secondary use data flows - are fully implemented. These would demonstrate to patients that specific new governance frameworks are in place, rather than making promises that may not be fully met.

In order for Local Choice to work, NHS England must be explicit that no GP who chooses opt-in as the best choice for their patients will be subject to contractual penalties. While carrots may be used to incentivise the pathfinder volunteers, there must be no sticks against sceptics in a national roll-out.

The mechanics of a local opt-in process is effectively to perform a mass opt-out of the GP's entire list, then to contact every patient with an opportunity to opt in - reversing the current process of contact, then opt-out. Patients' existing choices should, of course be respected. Given that many patients across the country will have already opted out, the materials used in the pathfinders to contact patients who have already opted out may prove appropriate, with some modification. We expect the BMA would advise on this.

²³ <https://medconfidential.org/wp-content/uploads/2014/06/2014-06-11-Achieving-local-choice-and-consensual-research-use.pdf>

Implement Personalised Data Usage Reports

Patients must be able to check that their choices have been recorded properly.

One of the failings of NHS England's previous attempts was the absence of any receipt or acknowledgement when a patient opted out, which in some cases wasted GP and practice staff time and contributed to further confusion.

Given NHS England's commitment to making patients' GP records available via "Patient Online", a copy of their consent settings must be included there. This would be entirely consistent with the proposed approach, where consent for secondary uses becomes an option within the Spine, managed by the GP.

Similarly, Personalised Data Usage Reports²⁴ should detail the patient's current consent settings, so those who cannot or will not access their GP record online can still get a printout to take home.

A Personalised Data Usage Report would answer Dr Sarah Wollaston's question from last February²⁵: *"so HES data uploaded to 'google's immense army of servers', who consented to that @hscic ?!"* and many other patients' questions as well.

Such a report would provide detailed accountability and, where there is a breach, the ability to tell a patient what happened, and what has been done about it. If the latter were still cause for public concern, this would generate pressure for policies to evolve in response - as the decision makers responsible will not be lost in an alphabet soup of committees.

We have confidence that, in general, NHS committees perform their remit with dedication, but as was seen with the Dr Foster fiasco in 2005²⁶, and with the commercial re-use problems in 2014 which were a direct descendant of those decisions, individual's remits may sometimes be constrained in order to deflect or evade responsibility and blame.

A Personalised Data Usage Report, to each patient about their own data, is a necessary prerequisite to narrow and close the data trust deficit in the long term; with such a report, patients do not need to take everything on trust - they will have knowledge. When trust is neither forced nor demanded nor presumed, it is easier to obtain.

²⁴ <https://medconfidential.org/wp-content/uploads/2014/11/personalised-data-usage-report.pdf>

²⁵ <https://twitter.com/drwollastonmp/status/440275592655949824>

²⁶ <http://www.parliament.uk/business/committees/committees-archive/committee-of-public-accounts/pac0607pn070206/>

Other recommended actions:

- Secretary of State to direct NHS England to conduct a formal, public, 12 week consultation prior to issuing any future Directions utilising HSCA 2012 s259 “require any person to provide...”
- SROs of NHS England patient data programmes, and the Chair of the Department of Health’s National Information Board, must be individuals registered with the GMC.²⁷
- National Data Guardian / IIGOP to be on a statutory basis and operational with appropriate budget and staffing.
- Resolve the question of whether the Hospital Episode Statistics and similar individual-level pseudonymised datasets are “personal data”²⁸. HSCIC currently says they are not. See attached paper - “CLASSIFIED when complete”.²⁹

²⁷ We note the Health Select Committee has asked the GMC about publishing a public conflict of interest register for doctors. Such registration should also require managers of programmes to covered by the same rules.

²⁸ This, really, deserves it’s own section, but the status quo is so entirely ludicrous, that this should suffice.

²⁹ <https://medconfidential.org/wp-content/uploads/2015/01/2014-01-07CLASSIFIEDwhencomplete-classifymedicalrecordsatrest.pdf>

Appendices

Annex A: Copy of patient leaflet and NHS England / HSCIC opt out form from 2014

Introduction

We want to improve the quality of care and health services for all. By using information about the care you have received, those involved in providing care and health services can see how well they are doing, and where improvements need to be made.

NHS organisations share information about the care you receive with those who plan health and social care services, as well as with approved researchers and organisations outside the NHS, if this will benefit patient care. As a patient, you may receive care and treatment from a number of places such as your GP practice, hospitals and community services. By bringing this information together from

all the different places, we can compare the care provided in one area with the care provided in another, so we can see what worked best.

We will use information such as your postcode and NHS number to link your records from these different places. Records are linked in a secure system so your identity is protected. Details that could identify you will be removed before your information is made available to others, such as those planning NHS services and approved researchers.

We sometimes release confidential information to approved researchers, if this is allowed by law and meets the strict rules that are in place to protect your privacy.

What are the **benefits** of sharing my information?

Sharing information about the care you have received helps us understand the health needs of everyone and the quality of the treatment and care provided.

It also helps researchers by supporting studies that identify patterns in diseases, responses to different treatments, and the effectiveness of different services.



Your choice will not affect the care you receive.

How information about you helps us provide better care

If you do not want information that identifies you to be shared outside your GP practice, you can ask your practice to make a note of this in your medical record. This is called an objection. An objection will prevent your confidential information being used other than where there are exceptional circumstances or where the law allows your information to be shared.

Remember, if you are happy for your information to be used for planning health services and for research then you do not need to do anything.

What kinds of information sharing can I object to?

There are two types of information sharing you can object to:

- **Section A:** You can object to information containing data that identifies you from leaving your GP practice. This type of objection will prevent the identifiable information held in your GP record from being sent to the HSCIC secure environment. It will also prevent those who have gained special legal approval from using your health information for research.

I wish to exercise my right to object as described in section A

Signature

- **Section B:** You can also object to any information containing data that identifies you from leaving the HSCIC secure environment. This includes information from all places you receive NHS care, such as hospitals. If you do not object, information that identifies you will only leave the HSCIC in limited circumstances where there is special legal approval, for example for medical research. If you object, confidential information will not leave the HSCIC and be used in this way, except in very rare circumstances for example in the event of a civil emergency.

I wish to exercise my right to object as described in section B

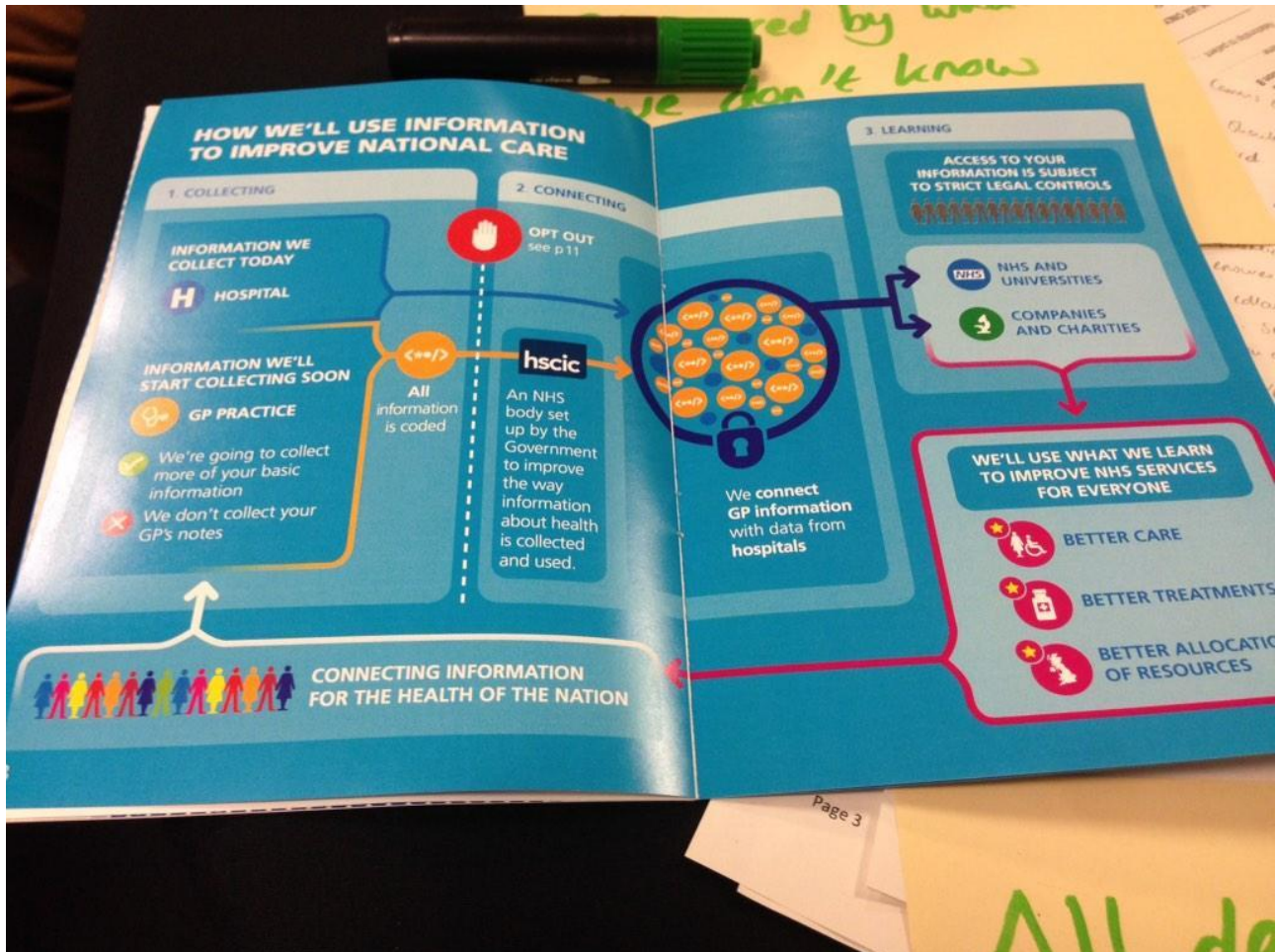
Signature

Name	Address
Today's date	Date of birth

Annex B: Draft patient communications

Part 1: care.data diagram as shown in public in Manchester in November 2014³⁰:

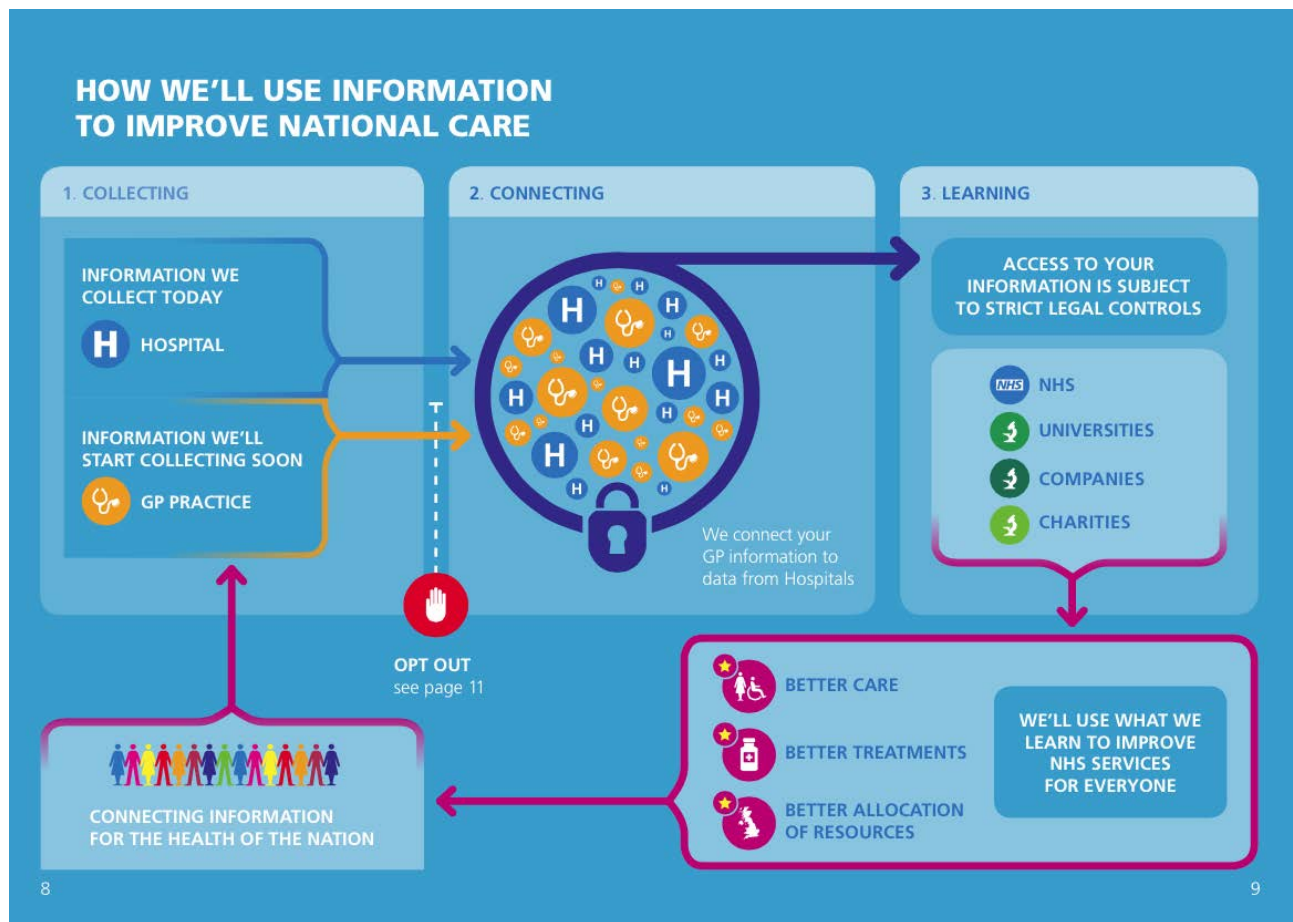
Note the reach of the dotted opt-out line, running down from the stop sign, reflecting a full opt out:



³⁰ <https://pbs.twimg.com/media/B3ZFjgGIMAIP4OW.jpg:large>

Part 2: care.data diagram as shown privately to care.data Advisory Group in January 2015:

This removes the “hospital” opt out that has been offered to patients throughout 2014:



medConfidential's comments on this draft of the patient communications are included as a separate document, for information.

We note that this draft also conflicts with Tim Kelsey's evidence to the Committee about who will have access to patient data in the pathfinders.

Annex C: Timeline of “hospital” opt-out

2013: March: As one of its final acts, NIGB raises concerns about consent for the care.data plan. 9Nu4 (the “hospital” opt out) is created - with a mistake in it - in addressing Dame Fiona Caldicott's concerns.

2013: 1st April: NIGB abolished by HSCA 2012.

2013: August: GP practice-only posters and leaflets distributed, as a first attempt at care.data communications.

2013: October: ICO calls a halt to first attempt due to concerns about fair processing.

2013: October: GPES IAG notices the 9Nu4 problem after considering the care.data addendum request.

2013: November: IIGOP formed at the request of the Secretary of State.

2013: December: NHS England notifies IIGOP of the content of the next version of the leaflets, which were sent to the printers before IIGOP replies within days.

2014: 6th January: Leaflets sent out, second attempt at communications.

2014: January: 9Nu0 / 9Nu4 opt out forms (see Annex A) sent to GPs, mid-late January.

2014: February: Programme suspended

...

2014: November: Comms materials for care.data Advisory Group public meeting - opt out covers hospitals.

2014: December: care.data Advisory Group (private) meeting - opt out does not cover hospitals. Gets queried

2015: January 20th: NHS England has updated comms materials ready.

2015: January 21st: At Health Select Committee, Tim Kelsey comments on what he has seen, which had not been shown to the care.data Advisory Group members giving evidence.

2015: January 22nd: NHS England sends care.data Advisory Group comms materials for “final comments”

2015: March-May: NHS England sends out letters?

Annex D: care.data programme timetables

The lack of progress is striking; note the dates change as time goes on.

(The following slides are excerpts from a slide deck which changes in content each month, hence the number in the slide headings will vary.)

care.data Advisory Group papers, early September 2014:



(1) Key Milestones

Task/Milestone	Date
Pathfinder CCGs Confirmed	12/09/2014
Formal Start CCG Pathfinder Projects	15/09/2014
MOUs Signed (including scope and success criteria)	29/09/2014
Patient Objection Lines Agreed with SofS	30/09/2014
Start of Fair Processing with patients / public	03/11/2014
Business Case Endorsed by Programme Board	30/11/2014
Programme Board Approval to extract	22/12/2014
Technical Platform Available	31/12/2014
Secure Data Facility Available	19/01/2015
Data Extracts available for viewing in Secure Data Facility	30/01/2015

2. High level timeframe

Milestone	Forecast
Pathfinder CCGs Confirmed & Formal Start CCG Projects	October 2014 ✓
MOUs Signed (including local governance and outline project plans)	November 2014
Local Sign off of materials	December 2014
Central Sign off of materials (Department of Health, NHSE CEO, SofS)	December 2014
Participating Practices confirmed, and Mailing data for patients received	December 2014
Local Agreement to proceed to mail-out	December 2014
IIGOP Assessment / Report	December 2014
SofS Approval to enter Fair Processing	January 2015
Programme Board Approval to enter Fair Processing	January 2015
Materials delivered to practices	January 2015
Personalised comms to patients (incl. patient letters)	February 2015
Start of Fair Processing with patients / public	February 2015
Data extracted from practices	March 2015



Above: care.data Advisory Group papers, November 2014.

Below: care.data Advisory Group papers, December 2014:

1. High level timeframe

Milestone	Forecast
Pathfinder CCGs Confirmed & Formal Start CCG Projects	October 2014 ✓
MOUs Signed	December 2014
IIGOP Assessment / Report	December 2014
Local Sign off of materials	Dec'14 / Jan'15
Central Sign off of materials	Dec'14 / Jan'15
Participating Practices confirmed, and Mailing data received	January 2015
Local Agreement to proceed to mail-out	January 2015
SofS Approval to enter Fair Processing	January 2015
Programme Board Approval to enter Fair Processing	January 2015
Materials delivered to practices	February 2015
Personalised comms to patients (incl. patient letters)	February 2015
Start of Fair Processing with patients / public	February 2015
Data extracted from practices	May 2015

