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11<sup>th</sup> June 2015

## Complaint about objections to dissemination of data from the HSCIC

Dear Information Commissioner,

In the late summer of 2013, NHS England attempted to launch its care.data programme using posters and leaflets in GP surgeries. While some patients may have opted out,<sup>1</sup> your Office intervened and determined that the communications and method did not meet fair processing requirements. You recommended an individually-addressed letter to each patient, as was done for the Summary Care Record.

In January 2014, NHS England sent out an unaddressed leaflet to households across England. Some people received or read a copy of that leaflet, others didn't – but hundreds of thousands of people went to the internet, downloaded forms for themselves and/or family members, printed them off and filled them in, ticking two boxes<sup>2</sup>, and either posted them back to their GP practice or delivered them in person. The Health and Social Care Information Centre (HSCIC) now estimates that "700,000" people did so<sup>3</sup>.

That at least 700,000 people had to follow such an *ad hoc* process would have caused significant issues, even had there not also been problems with the underlying definitions and specification of the processes.

This complaint is about the effect of decisions made about those individual patients who filled in a form in January / February 2014, or before or since, who – on the basis of what they were told – had a reasonable expectation that information about them and their medical events would not be included in the Hospital Episode Statistics (HES) or other data releases<sup>4</sup>; data that, to this day, continue to be sold by HSCIC.

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<sup>1</sup> Which may have included using the 'Type 2' objection / 9Nu4 code, to which we refer below.

<sup>2</sup> If they used a copy of medConfidential's form, they effectively 'ticked' both boxes at the same time. The form we eventually saw from HSCIC and NHS England required two separate 'ticks':

<https://medconfidential.org/wp-content/uploads/2014/04/2014-01-16-NHS-England-opt-out-form.pdf>

<sup>3</sup> Letter to the Health Select Committee from the Chair of HSCIC <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-committee/handling-of-nhs-patient-data/written/18661.pdf>

<sup>4</sup> For example, the release of identifiable patient information under Section 251.

## Grounds for complaint

Given the large number of patients who have contacted medConfidential, we believe the main ground for complaint is breach of the First Data Protection Principle – unfair processing. We ask the ICO to determine whether flowing data from patients' hospital records and other contexts by one part of the NHS (HSCIC), after a patient has recorded their objection to this action to another part (their GP), is a breach of fair processing or any other part of the Data Protection Act. We, and many of the patients who continue to contact us, believe it is.

In short, were the fair processing requirements under the Data Protection Act met by the NHS in England telling patients one thing, and then doing (or not doing) another?

It was repeatedly emphasised in January / February 2014 that opting out would not affect a patient's direct care - indeed, page 2 of the 'junk mail' leaflet<sup>5</sup> explicitly states: "*Your choice will not affect the care you receive*". We now know that NHS England was aware of the 'Type 2' / 9Nu4 problem by October 2013 (see below) and that it knew that, in the way the code was specified at the point it sent out the leaflets, choosing this option could impact on certain aspects of patients' direct care.

On the point of misleading the public, we also wish to draw attention to repeated and ongoing incidents where – in discussing patient objections or opt outs – Ministers and NHS England / Department of Health officials misleadingly conflate or confuse the two types of opt out. For example, when asked about 'Type 2' / 9Nu4 opt-outs, they assert that 'no GP data is flowing'<sup>6</sup>. This is as true as it is entirely irrelevant. 'Type 2' opt outs are to do with the release of hospital and other non-GP data by HSCIC, so these public answers – from people who must by now know better – are misleading.

That NHS England made egregious errors is one thing<sup>7</sup>; that it has refused or is unwilling to correct them, and that it continues to allow the public to be misinformed, means we must ask you to determine whether a breach has taken place and, if so, to use your powers to enforce the necessary steps that, despite over a year of "listening", NHS England has not taken – and which HSCIC cannot legally do alone.

HSCIC has said to Parliament<sup>8</sup>: "*We are extremely concerned that the implementation of individuals' wishes with respect to their data has been significantly delayed, although we are confident that this delay has not had any detrimental impact on their clinical care.*"

While this may be true with regard to patients' clinical care, does it also meet "the NHS's" obligations under DPA? And, if considering only clinical interests and the Department's priorities has caused this problem, can ensuring that Data Protection is properly included in the framing of this and all future programmes and initiatives generate a solution satisfactory to all?

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<sup>5</sup> NHS England has continued to provide the public with its misleading leaflet on its website since January 2014, on a page to which the [www.nhs.uk/caredata](http://www.nhs.uk/caredata) URL publicised in the leaflet resolves. It is still there at the time of writing: <http://www.nhs.uk/NHSEngland/thenhs/records/healthrecords/Documents/better-information-means-better-care.pdf>

<sup>6</sup> <http://www.theyworkforyou.com/lords/?id=2015-06-01a.154.2#g154.3>

<sup>7</sup> That it continues to make them in drafts of care.data communications (that your Office has seen) shows the problem remains unsolved, though we appreciate the ICO cannot enforce on the basis of hypotheticals and drafts.

<sup>8</sup> Letter to the Health Select Committee from HSCIC Chair, Kingsley Manning, sent 9 February 2015:

<http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-committee/handling-of-nhs-patient-data/written/18661.pdf>

## ***Dramatis Personae***

Given the complexity of the current situation, this complaint necessarily relates to a number of different parties: primarily NHS England, the Department of Health and the Health and Social Care Information Centre, but it also involves – as third parties, who could be considered data controllers for one objection code (9Nu0) and data processors for the other (9Nu4) – every GP in England who has received one or more patient “objections” to the release of their data for ‘secondary uses’.<sup>9</sup> While there are no official figures, it is likely that many (if not most) GPs will have received hundreds, possibly thousands, of such objections.

While the NHS Commissioning Board (“NHS England” being a title of convenience, not its legal designation) initiated and is responsible for creating the problem, since doing so it has decided that it should not be part of the solution.

The only logo that appeared on the leaflet sent to households who had not opted out of junk mail is the “blue NHS” logo / trademark. No organisational affiliations were included alongside it, as in previous communications. The Department of Health is the owner of the NHS trademark; any use of it in England must be authorised by NHS England.



To the extent that an amorphous “NHS” exists as a single entity, the only logo used in national care.data communications since January 2014 (and in the all draft communications seen at meetings of the care.data Advisory Group<sup>10</sup>) is the logo owned by the Department of Health.

Patients were encouraged by the January 2014 leaflet to contact their GP to opt out and it is on GP practice IT systems that these opt-outs remain, after the NHS bureaucracy got stuck. Absent any effective public action on the part of the responsible bodies in over a year to attend to the problem, enforcement action on the part of the ICO is now urgently required to get the system working if we are to avoid a repeat of the public outcry that occurred last year. In January 2014, the problem was largely theoretical; this year, over 700,000 people who had significant concerns and took action about them are directly involved.

Recent press attention<sup>11</sup> has focussed blame on the HSCIC. This is not wholly accurate nor entirely fair. When you are considering what action to take to ensure HSCIC does what it must to resolve this incident, a separate consideration should be actions to prevent NHS England and the Department of Health blocking the solution or causing a repeat.

As a ‘creature of statute’, HSCIC may only do what it has been Directed, required or requested to do by a competent body. HSCIC is required to release Hospital Episode Statistics (HES) and other data, including identifiable patient data under Section 251 (for which it is legally bound to honour objections), but it can only honour objections of which it is aware.

As it has not yet been Directed to collect 9Nu4 objection codes from GP systems, it is not and cannot be aware of them.<sup>12</sup> So HSCIC will continue to release and sell the data from other non-GP

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<sup>9</sup> This would also cover GPs who, given the level of confusion between care.data, SCR and other data-sharing initiatives last year, may still believe they have received none.

<sup>10</sup> Which the ICO attends.

<sup>11</sup> e.g. <http://www.telegraph.co.uk/news/health/news/11655777/Nearly-1-million-patients-could-be-having-confidential-data-shared-against-their-wishes.html>

<sup>12</sup> This is the reason that the figure for opt-outs given by HSCIC is an estimate – they don’t know.

care contexts of patients who have opted out using 9Nu4, until it is Directed to collect those opt out codes<sup>13</sup>.

Had it been Directed to do so in a proper and timely fashion, medConfidential is confident that HSCIC would have appropriately enacted those Directions to meet patient wishes. Had NHS England and the Department of Health respected the importance of fair processing and Information Governance, and taken appropriate action, then patients (and GPs) would not find themselves in the situation they are currently in.

## **Focus of the complaint: the ‘Type 2’ / 9Nu4 opt out**

Two types of objection or opt out were offered in early 2014, and are still available in 2015, both of which appeared on forms used by patients.

In discussion of care.data, the opt-out most frequently referred to is the one by which patients can prevent their data leaving their GP Practice for purposes other than their direct care<sup>14</sup>. This is variously referred to as a “Type 1” objection, or by its Read code designation “9Nu0”, but it only affects patient data under the data controllership of the GP.<sup>15</sup>

As care.data was “stopped”<sup>16</sup> in February 2014, no data has been extracted from GP practice systems to the HSCIC under the programme, and hence patients’ GP data has not been passed onwards to anywhere else. While this fact is highlighted repeatedly in official answers to questions, this is not the subject of this complaint.

This complaint is about the second opt out – the “Type 2”, or “9Nu4” objection – which covers all flows of data out of HSCIC which it has received from sources other than GPs.

The January 2014 leaflet and other public communications told patients they could object to the use of “*information from other places where you receive care, such as hospitals and community services*” for purposes beyond their direct care - that is, their individual-level<sup>17</sup> health data sourced from all the non-GP health providers across the NHS. When the care.data programme was suspended, the collection of these 9Nu4 opt-outs was suspended as well – but the flows of those data to and from<sup>18</sup> HSCIC were not.

As a result, where a patient registered an objection with their GP to their data being used for purposes beyond their direct care, due to the suspension of the care.data programme, HSCIC has not collected the list of patients who have objected in order to honour their objections – and so

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<sup>13</sup> It was noted by the Health Select Committee that, though an opt-out has been offered to patients, this remains within the gift of the Secretary of State and, as it will only be manifested in tertiary legislation (i.e. Directions), it could in principle be revoked at any time.

<sup>14</sup> With a small number of statutory exceptions, such as in a public health emergency.

<sup>15</sup> Nothing in this complaint should be taken to say there are no other issues of interest to the Commissioner around 9Nu0.

<sup>16</sup> NHS England’s Senior Responsible Owner for care.data, Tim Kelsey, October 2014: <https://www.omidyar.com/blog/health-data-transparency-and-trust>

<sup>17</sup> In confirming that the ‘Type 1’ / 9Nu0 opt-out would prevent any individual-level coded / clinical data being extracted from GP systems (as HSCIC was originally Directed to do for care.data by NHS England, even for patients who had opted out) the Secretary of State acknowledged that even de-identified, dated, linked episodes are inherently identifiable - as has been the understanding within the NHS since Caldicott1 in 1997.

<sup>18</sup> Data releases continue to flow; see DAAG minutes / papers.

patients' hospital and other data has continued to be released by HSCIC as if those objections did not exist. We note that Hospital Episode Statistics (HES) and other data are released monthly.

### **How many people are affected? How accurate is the “700,000”?**

The 700,000 figure is an estimate provided by HSCIC to the Health Select Committee's Inquiry into the Handling of NHS Patient Records in February 2015.<sup>19</sup> We do not know exactly how it was formulated, but believe it may be an estimate based on an extrapolation from a count of 9Nu4 codes inadvertently captured by one GP IT provider. We have heard the figure referred to as “a million” by informed individuals, and this is the headline figure that appeared in some media articles this last weekend.

medConfidential was one of three primary download sites<sup>20</sup> for the opt-out form<sup>21</sup> used by a large percentage of those patients who exercised their right to opt out. While we never stored any information relating to individual downloads, and were forced to serve the static PDF form from multiple locations due to the volume of traffic we were getting, we estimated that between 750,000 and 1.2 million patients have opted out – a range we also derived using reports of the number and distribution of forms returned to a selection of practices.<sup>22</sup> The exact figure is still unknown.

Over the last year, we have had reports from patients registered in well over 10% of GP practices in England, that the handling of care.data objections was sub-optimal.

In the vast majority of cases, this was down to busy and multitasking practice reception staff insisting that a Summary Care Record (SCR) form opted patients out of “care data”<sup>23</sup>, though in some cases forms created by practices themselves presented the two ‘care.data’ opt-out codes as mutually exclusive<sup>24</sup>.

As such, there will be patients with an objection to SCR on their GP record from 2014, despite having been told by practice staff<sup>25</sup> that they had “filled in the objection for care data” – both 9Nu0 and 9Nu4. Confusion about what “care data” is actually for is pervasive<sup>26</sup>, unpredictable and uncorrected. The many patients affected by this - the number of which cannot be calculated, but which will clearly not be included in HSCIC's “700,000” – must not be forgotten.

Almost all patients who used the various publicly-available opt out forms will have requested both types of opt out. As such, it is reasonable to assume that patients with a 9Nu0 code on their GP record are likely to have also requested 9Nu4. The existence of the two codes was for the convenience of NHS England – which, by Directing HSCIC, has determined the purposes and

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<sup>19</sup> Page 3: <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-committee/handling-of-nhs-patient-data/written/18661.pdf>

<sup>20</sup> At the time we upgraded our web services to cope with the traffic, the form had passed 300,000 downloads. Several other websites hosted copies of our form, and other sites hosted various versions of other forms.

<sup>21</sup> [https://medconfidential.org/wp-content/uploads/2015/05/caredata\\_trifold.pdf](https://medconfidential.org/wp-content/uploads/2015/05/caredata_trifold.pdf)

<sup>22</sup> medConfidential did not store any information about individual downloads of the opt-out form we provided, and only has a count of the number of PDFs served from our site at certain times.

<sup>23</sup> In one case, a practice referred patients to a “Summary Care Data” form: it was in fact an SCR opt out form.

<sup>24</sup> [https://medconfidential.org/wp-content/uploads/2015/06/2014-02-17-BGGP\\_opt-out-form-OR.doc](https://medconfidential.org/wp-content/uploads/2015/06/2014-02-17-BGGP_opt-out-form-OR.doc)

<sup>25</sup> including a staff member at MedConfidential.

<sup>26</sup> “That is exactly right” - Baroness Chisholm of Owlpen being exactly *wrong* on the purposes of care.data to the House of Lords. HL Deb, 1 June 2015, c156. <http://www.theyworkforyou.com/lords/?id=2015-06-01a.154.2>

manner in which patients' data was to be processed – rather than for the convenience of data subjects. Discussions on a single “comprehensive” consent setting which simply merges the two have been ongoing.

### **The second problem with the second opt out...**

All throughout the care.data debacle, and even now<sup>27</sup>, the NHS line has been that consent choices beyond direct care “will not affect the care you receive”. That is, fundamentally, the point of “beyond direct care”. It is the basis on which patients will have felt safe objecting to their data being sold – that their objection does not affect their care.

NHS England's code definitions, as given to GP practices<sup>28</sup> for honouring patient choice, are as follows (emphasis original):

- **Prevent PCD leaving the GP practice** – where a patient objects to PCD leaving the GP practice use the **'Dissent from secondary use of GP patient identifiable data'** code (Read v2: 9Nu0 or CTV3: XaZ89 or SNOMED CT 827241000000103).
- **Prevent PCD leaving the HSCIC** – where a patient wishes to prevent PCD gathered from any health and social care setting from leaving the HSCIC use the **'Dissent from disclosure of personal confidential data by Health and Social Care Information Centre'** code (Read v2: 9Nu4 or CTV3: XaaVL or SNOMED CT 8815610 00000100).

While the bold parts at the *start* of each statement are the same, it is quite clear that the GP practice definition has a “secondary use” limitation clause, whereas the HSCIC definition does not.

As such, despite NHS England's public statements and communications to patients, the 9Nu4 code is not restricted to purposes other than direct care. It applies to all data flows of the HSCIC, which include, for example, calling patients for screening at various routine stages throughout the course of their lives – which HSCIC does on behalf of various bits of the NHS, e.g. as data controller of the Personal Demographics Service (PDS).

Throughout 2014, and even now, NHS England repeatedly told patients that opting out “will not affect the care you receive”. That must be true for patients, and that must be made true by the NHS. The underlying problem is that NHS England didn't ensure it was true in 2013 when the 9Nu4 code was created and it still hadn't made it true by the second time it started nationwide care.data communications.

It is for this reason that neither NHS England nor the Department of Health can simply Direct HSCIC to extract objections. That definitional problem has never been rectified. NHS England seems quite capable of making mistakes, but incapable of admitting or correcting them. And, even were HSCIC to have a Direction which allowed it to extract the objections – given that it requires a legal basis to do so – there is a problem with the 9Nu4 code as defined which would have implications should it do so in an overly-simplified way.

In discussions, HSCIC has shown a strong commitment to solving this problem in a way which is legal, ethical and fair to patients – were it able to do so. The causes of this current situation are not

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<sup>27</sup> <http://nhs.uk/caredata>

<sup>28</sup> <http://www.england.nhs.uk/wp-content/uploads/2013/08/cd-guide.pdf>

entirely the fault of HSCIC, as we have detailed. While we suggest enforcement action may be required to break the current impasse, HSCIC's informed and engaged contributions to the solution will be absolutely necessary.

We would have hoped to be able to provide documentary evidence to back up some of these assertions, but – despite a promise to publish in June 2014, and a decision to publish in November 2014 – only 3 months of care.data Programme Board papers have been published.<sup>29</sup> While it is a different area of the ICO's work, this lack of transparency of the Board is reflected in a Freedom of Information Act appeal currently being handled by your Office.<sup>30</sup>

### **Third parties in the firing line: GPs**

As data controllers, data processors and as the direct recipients of patient requests to opt out, this issue involves GPs. They are in no way responsible for this mess but, while under the definitions of the Data Protection Act they may not be considered data controllers in relation to 9Nu4, in moral and ethical terms – and in patient perception – they are seen as the data custodians. GPs are the individuals who meet with patients, who assuage their concerns, who type sensitive medical information into their computer systems, and who make promises about what will or will not happen to that information.

Under the programme as currently formulated, it is with the GP that the patient lodges their objections, because the patient has a relationship with the GP in a way that does not exist with the NHS Commissioning Board (NHS England), HSCIC or other bodies. medConfidential appreciates that registering opt outs with the GP may be eminently practical, and a way to avoid a wide range of problems. But the continued mishandling of care.data puts GPs in an invidious position.

It is pertinent to compare the form that HSCIC requires patients to fill in if they wish to opt out directly with HSCIC<sup>31</sup>, with the form / information given via the GP practice. The HSCIC form requires copies of two forms of ID, multiple tick boxes for a number of different data flows (but not a comprehensive list), and includes a checklist to ensure the form was filled in correctly. The GP equivalent is a simple form which asks for just enough details to identify the patient, with the practice then able to confirm any idiosyncrasies of competence and/or authority through their individual connection and knowledge.

While registering objections with a body most of the public has not heard of might be more complicated from a bureaucratic perspective, and would clearly be more annoying and less convenient for patients, from the perspective of Data Protection and public comprehension, such an approach (which could still be facilitated by practices) would make things much clearer.

Thus far, the patient side of this process has worked – albeit imperfectly – but now the various Government bodies must deliver on their promises to patients. Unfortunately, they have failed to do so voluntarily, and their actions and inactions have repeatedly made the problem worse – to the point that we believe enforcement action in the interests of patients is now necessary.

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<sup>29</sup> [https://www.whatdotheyknow.com/request/caredata\\_programme\\_board\\_minutes](https://www.whatdotheyknow.com/request/caredata_programme_board_minutes)

<sup>30</sup> e.g. Case Reference Number FS50570344.

<sup>31</sup> [http://www.hscic.gov.uk/media/14700/Preventing-the-use-of-your-information-for-health-and-or-social-care-purposes-other-than-direct-care/pdf/Pt\\_health\\_information\\_form\\_June\\_14.pdf](http://www.hscic.gov.uk/media/14700/Preventing-the-use-of-your-information-for-health-and-or-social-care-purposes-other-than-direct-care/pdf/Pt_health_information_form_June_14.pdf)

## Specific questions

The question underlying this complaint is, does the continued flow of hospital records by “the NHS” (HSCIC), after a patient has reported an objection to “the NHS” (their GP), breach fair processing requirements?

To make a determination, we believe several other questions should be asked, the answers to which – even given medConfidential’s close involvement with the programme through our membership of the care.data Advisory Group (CDAG) – we are unable to cite in evidence. We have asked these ourselves, some of them repeatedly, but have never been given answers:

1. What was the genesis and process by which the ‘Type 2’ / 9Nu4 objection was defined and specified by NHS England and HSCIC?
2. When did (a) HSCIC, and (b) NHS England first<sup>32</sup> become aware of the problem with the definition of 9Nu4?
3. What meetings were held when, by and between which relevant bodies, regarding the definition of 9Nu4, the collection of the 9Nu4 opt-outs, and the impact on data releases including HES and Section 251 releases?
4. Who was responsible for the implementation of the opt-outs and any problems with the 9Nu4 definition at each of the following points, and what capability did they have to correct those problems?
  - a. August 2013, when NHS England sent care.data letters and guidance<sup>33</sup> to GPs;
  - b. January 2014, when NHS England began sending out the junk mail leaflets;
  - c. 18 February 2014, when NHS England “stopped” the care.data programme;
  - d. 20 November 2014, the day before HSCIC accepted responsibility from NHS England;
  - e. 9 December 2014<sup>34</sup>, after HSCIC had accepted responsibility from NHS England;
  - f. 6 June 2015, following questions in the House of Lords on 1/6/15

Given the ongoing nature of the problem, and with HES and other data continuing to flow, we ask that you consider urgent enforcement measures to protect patient confidentiality.

## Avoid solutions that may be worse than the status quo

While this complaint relates to fair processing and consent for the release and sale of patient data, a simple enforcement action preventing any data leaving HSCIC until the problem is resolved would likely not make the problem better – and would not resolve the issue of data that has already flowed. HSCIC must be compelled to reissue the relevant datasets, which it can do under contract

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<sup>32</sup> We have provided evidence that the issue was known as far back as September 2013; we do not know if it was known before that.

<sup>33</sup> Letter <https://t.co/bTecVAkAFO> and GP guidance <https://t.co/0Bw1rgbt5T> which are quite clear on who is calling the shots.

<sup>34</sup> This is the date that HSCIC first informed medConfidential of the scale of the problem and the actions it was taking as a result of taking responsibility for it, seeking to act fully in line with professional and medical ethics.

to all of its customers once objections have been honoured, but this can only happen after GPs have provided a list of the NHS numbers of patients who have already opted out to HSCIC.

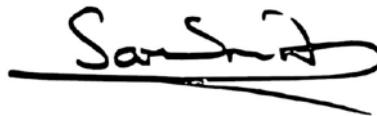
We appreciate this is not the permanent “end state” desired by HSCIC and others, but it will allow the Department of Health, NHS England and HSCIC to meet their obligations, it will protect the confidentiality of the 700,000 or more patients, many of who opted out over a year ago, and hopefully move the current impasse towards a solution.

We are happy to provide any further information you require, and look forward to a swift and decisive resolution.

Yours sincerely,

A handwritten signature in black ink that reads "Phil Booth". The letters are cursive and somewhat stylized.

Phil Booth, medConfidential

A handwritten signature in black ink that reads "Sam Smith". The signature is written in a cursive style with a long horizontal stroke underneath.

Sam Smith, medConfidential