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Dear Commissioners,

We are writing to you with regard to a number of issues, including the upcoming care.data 'pathfinders', some of which may significantly affect patients and healthcare providers within your Clinical Commissioning Group in coming months.

medConfidential is an independent, non-partisan organisation campaigning for confidentiality and consent in health and social care. We seek to ensure that every flow of data into, across and out of the NHS and care system is *consensual, safe and transparent*. Founded in January 2013, medConfidential works with patients and medics, service users and care professionals and draws advice from a network of experts in the fields of health informatics, computer security, law / ethics and privacy. We believe there need be no conflict between good research, good ethics and good medical care. Further information is available on our website at www.medconfidential.org

1) care.data 'pathfinders'

We are aware that, rather than writing openly to all CCGs inviting them to volunteer as care.data 'pathfinders', NHS England has chosen to approach CCGs via internal networks in an attempt to meet its publicly-stated target number of care.data 'recruits'. We have heard that some of these approaches have been felt to be not entirely appropriate. That NHS England has chosen not to write publicly to all CCGs, sharing information and facts on the current state of care.data, suggests it is reluctant to provide details or firm assurances on which it may be held to account.

In February 2014, when the *second* attempt to introduce care.data was delayed amid public controversy¹, NHS England officials said they would listen to stakeholders as to what they should do next. After a number of publicly-minuted meetings of the care.data Advisory Group² we are no clearer as to what NHS England is proposing, beyond making the responsibility for significant decisions entirely yours. We would hope that NHS England is proactively providing you all information necessary to inform your decisions, but have seen no evidence of this to date.

While care.data is still quite evidently being driven by NHS England, officials seem to want to devolve responsibility for the impact on patients and liability of GP practices to individual CCGs. No substantive changes to the scheme have been announced as yet, and significant decisions may be passed on to you, but the constraints under which you will be operating are not in the

¹ BBC, "Care.data: How did it go so wrong" <http://www.bbc.com/news/health-26259101>

² <http://england.nhs.uk/ourwork/tsd/ad-grp/>

public domain. Your CCG is unlikely to have been involved in the lengthy discussions about what could be handled differently, yet it will be held publicly responsible for any - or indeed no - changes by NHS England.

If you are considering participating as one of the 2-4 pathfinder CCGs, we include some questions below - the answers to which may help inform your decision:

a) If your CCG wishes to write to every patient in the area / each 'pathfinder' practice with details of care.data and an opt-out form, will that be fully funded by NHS England?

We don't know the answer; you may wish to ask. medConfidential, the BMA and others have been advocating for a letter and opt-out form direct to each patient as a bare minimum requirement since care.data first came to public attention.

b) Who will write and approve the text of any such letters, and take responsibility for the information that patients are given? How could CCGs be certain they have all the information they need? What, for example, will patient communications say about future use of "free text" in their records, DNA / genomic data or where and by whom data will be used? Who will be responsible when patients are effectively misled by planned changes to NHS England policy? What is a CCG's recourse when NHS England changes rules it assured patients were in place?

c) Who will guarantee that any and all commitments made to patients are accurate and will be fully met, not only during the 'pathfinders' but in any future roll-out? For example, undertakings that patient information gathered from GP records for commissioning purposes will never leave the Health and Social Care Information Centre (HSCIC) or the fact that NHS England has said it intends widening the collection process in due course. How will the promises a CCG makes to patients be kept in light of NHS England's choices?

d) If future changes to NHS England policy alter patient information / fair processing requirements, who will bear the responsibility and cost of re-contacting patients? Who ultimately decides what is necessary or appropriate for your patients?

e) As the purpose of the pathfinders is to learn what works and what doesn't; if any element of care.data is found to be problematic in any way for your CCG, what support will NHS England commit to giving in order to rectify this for patients in your area? Though care.data is currently only approved for commissioning uses, other secondary uses are intended - including controversial ones such as commercial re-use by 'information intermediaries'. Does your CCG want one of its first communications to every patient in its area to be associated with a "toxic" programme?³

f) Will there be 'opt-in' practices in your area? NHS England has said it wishes skeptical practices to be included in the pathfinders. **If GP practices in your CCG wish to follow BMA policy and make care.data an opt-in choice for their patients, will NHS England support that in the same way as for those offering opt-out?** Have the various arms of NHS England been consistent in the information they have given, e.g. on incentives for participating CCGs?

³ <http://www.ehi.co.uk/insight/analysis/1260/a-bad-week-in-the-bunker-for-care.data>

Before signing up as a care.data 'pathfinder', we would expect such a significant decision to be referred for consideration by the CCG Governing Body and others responsible for democratic oversight. Given intense public interest in this programme, such input would seem wise.

Other issues

Besides the national care.data programme, it has been brought to our attention that some CCGs have inherited data sharing agreements from previous bodies which have a variety of information management and governance issues:

2) Storage of patient objections: in at least one instance we are aware of, when a GP practice's management software was upgraded to the newer "web" version, the consent / dissent settings from patients for a county-wide data sharing programme were wiped – i.e. all patients who had opted out had their dissent 'forgotten'. More concerningly, the GP assured the patient that it had been corrected by the CCG, which was not true. Further investigation has shown lines of responsibility are confused at best.

If any practices in your CCG have upgraded software in the recent past, or will do so in the future, you may wish to confirm that any dissent codes for data sharing were correctly copied and applied in the new system, and explicitly confirm where responsibility for transfer and verification lies.

As part of ongoing work by NHS England and HSCIC on dissent or "patient objection management" it may be worth considering a migration path to phase out local dissent codes, instead using appropriate national Read codes - such as the broad-scope '9Nu0' code for care.data.

3) Respecting patient dissent: some system suppliers have invited GPs to participate in their programmes for making of large amounts of individual-level data available to third parties⁴ with variable public oversight.

If any practices in your CCG are involved in these systems, are patients aware that their data is being released in this way? When data is being extracted, is the patient dissent code '9Nu0' being respected, preventing any individual-level (thus identifiable) patient data leaving the GP practice for those patients who have objected to that happening?

4) Coerced 'consent': some non-NHS service providers, including private MRI providers and commercial pharmacies, are requiring signed consent forms from patients in order to provide services. These forms go far beyond basic approval, and have in some instances required the patient to consent to data sharing for a variety of secondary purposes in order to receive the service.

⁴ e.g. TPP has developed a database called [ResearchONE](#) in partnership with the University of Leeds and the UK Government's Technology Strategy Board; INPS, in collaboration with market research company Cegedim Strategic Data Medical Research, has one called [THIN](#); EMIS and the University of Nottingham jointly own [Qresearch](#), a database derived from the pseudonymised records of over 13 million patients. Data is also gathered from all 4 main GP IT systems by the [Clinical Practice Research Datalink](#) (CPRD), a joint venture between the Medicines and Healthcare Products Regulatory Agency (MHRA) and National Institute for Health Research (NIHR).

Forcing patients to sign away secondary use of their medical information in order to receive an MRI scan is not only in conflict with their rights under the NHS Constitution, it is unethical and open to challenge under the law. (Data collected, processed or retained in such circumstances is quite clearly 'excessive' for the specified purpose, i.e. delivery of care.)

Your CCG may wish to remind its suppliers that patients must not be coerced or misled into releasing their confidential medical information for purposes beyond their direct care.

Furthermore, all services must respect the '9Nu0' code, which is the dissent code for data sharing beyond a GP practice⁵, or equivalent national codes. While a proposal for patients to be able to explicitly consent to research but dissent to other purposes is in circulation⁶, the circumstances in which patient dissent may be overridden are very rare and involve specific legal exceptions such as a public health emergency.

medConfidential is happy to discuss any and all of the issues raised above and how they may relate to your CCG and the GP practices within it, including any further questions you have around the care.data pathfinders. For information on the care.data scheme that you may not have received from NHS England, please see www.medconfidential.org or get in touch.

Yours sincerely,



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cc: CCGs, Healthwatches, & NHS Regional Directors of Intelligence.

⁵ Question 23: <http://www.england.nhs.uk/wp-content/uploads/2014/03/cd-gp-faq-03-14.pdf>

⁶ <https://medconfidential.org/wp-content/uploads/2014/06/2014-06-11-Achieving-local-choice-and-consensual-research-use.pdf>