

Webinar Questions (and threads)

COPI Regulations and Notices, the Law

1. The "Control of Patient Information" notices mentioned in the announcement is presented as if it were something new. In fact, Statutory Instrument 2002/1438 has been in force for 18 years, without substantive change. Has the government actually changed the law, as the announcement suggests? In particular, has it lifted the "opt-out"?
 - The National Data Opt-out is not applicable to data gathered under COPI notices (although it may be applied in some situations even though it does not have to be)
 - "If it helps I wrote an easy to read summary on the significance of the COVID-19 COPI notice: <https://theconversation.com/coronavirus-researchers-no-longer-need-consent-to-access-your-medical-records-138567>"
 - Well worth a read.
2. Do you actually mean The Health Service (Control of Patient Information) Regulations 2002? (Statutory Instrument 2002/1438)?
3. Is "confidential" data the same as "anonymised" data? Who is supposed to obey which law or regulation and when? How does anybody make sense of any of it??
 - "Anonymous" means you cannot identify an individual from the data, "confidential" means you can identify someone but you will limit/protect how the data is used. It's amazing how many researchers and clinicians do not understand this really important difference.
 - Although anonymous is not necessarily the same as anonymised (anonymised means there may be potential for re-identification)
 - Thanks Paul - I think there is a sliding scale for both anonymity and confidentiality, but the important thing to note is that these are two entirely different things/scales.
 - Agreed!
4. Our government is about to break international law, DHSC has already admitted breaching the NHS Act, so how can we trust ANY of this?
5. Regulation 3 is used for communicable diseases more broadly within the public health landscape.
6. WHY the need for new legislation? the Statutory Instrument (regulation 3) already says:
Communicable disease and other risks to public health 3.—(1) Subject to paragraphs (2) and (3) and regulation 7, confidential patient information may be processed with a view to— (a) diagnosing communicable diseases and other risks to public health; (b) recognising trends in such diseases and risks; (c) controlling and preventing the spread of such diseases and risks; (d) monitoring and managing—
(i) outbreaks of communicable disease;
(ii) incidents of exposure to communicable disease;

(iii) the delivery, efficacy and safety of immunisation programmes; (iv) adverse reactions to vaccines and medicines;

(v) risks of infection acquired from food or the environment (including water supplies);

(vi) the giving of information to persons about the diagnosis of communicable disease and risks of acquiring such disease."

7. I think you need to define confidential patient data as this is very specifically defined in section 251(10) and (11) of the National Health Service Act 2006

The Exit Options

8. When COPI notices expire will all data gathered and disseminated under them have to be deleted?
 - Is a switch to a different legal basis actually possible?
 - There could be a switch to, eg, s251 support, but that arguably won't help cure data collected under emergency legislation (cf routinely collected data in established datasets).
9. How can we maintain the positive aspects of data sharing, after COVID, whilst allowing opt outs to return? Ignoring opt-outs (as COPI does) will cause long term data to patient and public trust.
 - Or abolish opt-out? Move to a Danish-style system where private data relating to public services is used to improve those services.
10. The data should be retained. Everyone should be required to opt-in. We are all in it together. It's our NHS and we should all contribute our data just as we contribute our NI and our tax. The key is then to make sure it is used in ways we accept and by people we trust. Put real people on CAGs and make them data-access groups. Don't guard it, USE it!!
 - I could not agree more. The opt-outs resulted indirectly from the breach of public trust in the ability of government agencies to use patient data safely. That is what led to the collapse of care.data. That is an anomaly - and the opt-outts DISABLE truly population-based insights into trends and outcomes in disease - not just COVID-19
11. Long term covid understanding will need long term access to COPI data so urgent action to permit that must happen surely? So a Policy decision by NHSE and NHSX leading public debate purposefully is needed
 - The point about the wider benefits of extending COPI beyond CV19 to other serious conditions was well made as surely it will benefit our knowledge and in turn lead to improved healthcare
12. On the question of who has data - Will sensitive patient information about clinical vulnerability that has been disseminated to retailers and local authorities during COVID for food delivery access and support be required to be deleted by these groups?
13. The COPI regulations apply to cancer as well as to communicable diseases - that is why they were prepared. Chris Carrigan's point on applying the same approach to other disease makes sense

Wider data questions

14. I'd be interested in NHSX views on sharing of blood test results between primary and secondary care. I have blood tests for chronic conditions taken in both. When I see the secondary care consultant I have to provide him with the blood test results by taking my iPad logged into Patient Access. Equally, blood tests he initiates are not in my GPs database and thus not available for his or my graphical analysis. Is it an aim of NHSX to improve this situation?
15. What is NHSX's view on use of unstructured data (free text typed notes) in research for the benefit for patients or public health beyond the COPI notice expiring in March 2021
16. do wales operate similar process
17. Do we really need all these different organisations? Are they adding to confusion not improving clarity? If they want to abolish red tape how about abolishing all the silos?
 - I agree, but now that devolution has occurred and the NHS isn't really N anymore this will be difficult to fix.
18. What are the top 3 things that the public need to be concerned about or aware of relating to any changes?

Role of the GP

19. Can a GP now audit who has accessed their patient records through the HTML Shared view in GP Connect?
 - A commitment in the Care Record Guarantee, which is a contractual duty and the NHS has a legal duty to pay regard under the NHS Act 2009
20. Is the move to remote and especially phone consultations affecting the quality and even availability of data?
21. The issue about GP audit is CAN they find out who has used data, not HOW can they do it.
 - Yes, my question was ensuring that a GP can audit access through GP Connect to who has accessed the data as when GP Connect was implemented under COPI this wasn't available.

Transparency

22. The COPI notices require a record to be kept of where data went and what it was used for. Will you publish the lists of projects and what happened as a result?
23. No surprises is the key. The public should be able to find out what their sensitive data is used for, and there need to be robust mechanisms for ensuring this is the case.
24. An information graphic of a patients data journey (opt in and opt out) would be very useful for the public.

The National Data Opt-out

25. Who is opting out of what, if the opt-out doesn't work? Am I the only non-professional listening who is baffled by what the speakers are saying?
26. What proportion of the 1.65 million opt-outs were applied by GPs to their entire lists rather than as a result of individuals submitting their opt-out? What is the legality of opt-outs being submitted in that way? PHE claims not to know.
27. Why is a GP allowed to opt-out patients without asking or even telling the patients?
 - Exactly so
 - Have the GPs been given any access to the national data opt out yet?
28. The opt out only applies to data collected using the Health Research Authority/Confidentiality Advisory Group approach, not to that gathered under COPI Regs

The Red Tape Challenge

29. Will the National Data Guardian be involved in reviewing this guidance during the red stop challenge?
30. Please ask the speakers to use English not jargon!! And explain acronyms!! Is this webinar for patients or NHS staff?
31. How many patients will be at the red tape workshop?
32. I think Chris's question was whether patients are actually involved in the workshops mentioned? Not just reading the output!
 - Hi John - definitely we're involving patients in the 'red tape challenge', e.g. we'll be reaching out for suggestions of where there's confusion in current guidance. Initial workshop is mainly to bring the guidance producing orgs on board - point taken about getting involvement early though and we'll look at broadening the invite for the initial workshop
 - Will GPs be represented at the workshop as they have to interpret a lot of this guidance from multiple organisations.

NHS COVID-19 Data Store

33. The Foundry clearly creates a great resource for patient data research which would be of value after 31 March. Is it going to be lost with the expiry of COPI?
34. Uses of NHS data, whether COPI or otherwise, must follow s251(7) of the NHS Act, (leaving aside that DHSC has admitted breaching it,) what can you say to give patients confidence that the rules on patient data aren't being broken "in a very specific and limited way" by you bodies or commercial entities, which result in uses that patients were told wouldn't happen. Given the characterisation of IG as red tape, will the breaches of contracts or law be enforced in any way?

- I am concerned about IG being characterised as Red Tape by NHSX and NHS Digital, as good IG and data protection needs to be in place to ensure that data is shared in a safe, appropriate and legal way to provide assurance to data controllers and to patients. Red tape gives the impression that it is an irritant rather than a safe enabler.

35. Is it possible for a Charity that represents Extremely vulnerable patients get access to a subset of that data, and how would we go about it?

Other points

36. Will the next NDG be closer to the public and to real life or another Westminster Bubble Usual Suspect? (Baroness Harding maybe??)

- Are any clinicians involved in the recruitment of the next NDG?
- This talks to another comment about trust and trustworthiness. When DHSC admits breaking the law without penalty, how could anyone trust them with free access to confidential data?

37. Include patients in all discussions! They should be sitting at every single table.

- "The Confidentiality Advisory Group is currently recruiting for lay members:
<https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/become-cag-member/>"

38. What is CAG?

- <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/> CAG stands for Confidentiality Advisory Group
- Confidentiality Advisory Group. Similar in concept to a Caldicott Guardian; a group to advise a data holder whether or not they should keep the data confidential and thus not release it (eg for research). A well-intentioned idea that has held up a lot of research for many months in the UK, because our emphasis is on guarding privacy and until Covid, that trumped public benefit.

On the questions asked in the Polls

39. Sorry far too many caveats to respond authentically to the poll from my perspective. Ie. Q1 needs 'better' defined

- Turn the questions around; do we have the wrong culture around data (secrecy, privacy, guardians) as opposed to one of access and usage for public benefit. Do we believe that the rights of the individual outweigh the benefits to the many? I suggest our data regs and structures say yes, but most patients - and the public too - would say no.

40. Use of the word 'better' may result in leading questions.

41. Why would you need confidential data for planning?