**Co-creating social licence for sharing health and care data**

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**Abstract**

**Background**

Optimising the use of patient data has the potential to produce a transformational change in healthcare planning, treatment, condition prevention and understanding disease progression. Establishing how people’s trust could be secured and a social licence to share data could be achieved is of paramount importance.

**Methods**

The study took place across Yorkshire and the Humber, in the North of the England, using a sequential mixed methods approach comprising focus groups, surveys and co-design groups. Twelve focus groups explored people’s response to how their health and social care data is, could, and should be used. A survey examined who should be able to see health and care records, acceptable uses of anonymous health and care records, and trust in different organisations. Case study cards addressed willingness for data to be used for different purposes. Co-creation workshops produced a set of guidelines for how data should be used.

**Results**

Focus group participants (n=80) supported sharing health and care data for direct care and were surprised that this is not already happening. They discussed concerns about the currency and accuracy of their records and possible stigma associated with certain diagnoses, such as mental health conditions. They were less supportive of social care access to their records. They discussed three main concerns about their data being used for research or service planning: being identified; security limitations; and the potential rationing of care on the basis of information in their record such as their lifestyle choices. Survey respondents (n=1031) agreed that their GP (98%) and hospital doctors and nurses (93%) should be able to see their health and care records. There was more limited support for pharmacists (37%), care staff (36%), social workers (24%) and researchers (24%). Respondents thought their health and social care records should be used to help plan services (88%), to help people stay healthy (67%), to help find cures for diseases (67%), for research for the public good (58%), but only 16% for commercial research. Co-creation groups developed a set of principles for a social licence for data sharing based around good governance, effective processes, the type of organisation, and the ability to opt in and out.

**Conclusion**

People support their data being shared for a range of purposes and co-designed a set of principles that would secure their trust and consent to data sharing.

Key words: patient; big data; health records; barriers; co-design

**1. Background**

Data-driven scientific advances in healthcare is a key goal for healthcare providers1 and has the potential to produce a transformational change in healthcare planning, treatment, condition prevention and the understanding of disease progression. Rapid advances are possible through using intelligence from large-scale data sets to improve population health, enable better planning of services and a preventative approach by identifying and acting on trends.2

Linking patient data from different healthcare systems brings several clear benefits, including providing a comprehensive overview of care and treatment, and reducing unsafe care for patients.3 There is also the potential for patients themselves to obtain a comprehensive view of their care and highlight any errors in their records. It creates potential for innovation in data-driven technologies, such as mobile apps and wearables. Finally, it offers the potential for linked information about patients to be shared and used for population health management and healthcare research. The potential for data science and analytic technologies to draw inference from this type of data is vast and progressing at pace.

Despite being a publicly funded healthcare system, the UK NHS currently struggles to link and share data from different providers. With caveats, clinicians tend to support such data usage, although they have concerns about privacy and the potential to damage the clinician-patient relationship.4 Patients can be inconvenienced and confused that different members of the healthcare team cannot access their recent health information,5 and often experience the impact of the lack of connectivity through inconveniences and patient safety incidents.6

Patients and members of the public recognise potential benefits but have concerns about confidentiality breaches and data being used for other purposes.7 Lack of trust and poor communication led to NHS England’s care.data programme’s discontinuation in 2016 after failing to secure ‘social licence’ (trust and consent) for its aims.8 9

The COVID-19 pandemic has highlighted the advantages of a well-primed system of data collection and sharing to enable co-ordinated and evidence-based activity, for example through the Recovery trial,10 and modelling the differential effects of the disease on those with differing demographics.11 However, patient concerns about processes such a ‘test and trace’ echo those voiced more generally about data use, such as privacy, mistrust, fear of stigma and a lack of information about how data will be used.12 Consequently, establishing how people’s trust could be secured and a social licence to share data could be achieved is of paramount importance. A 2019 systematic review and ethical enquiry13 found that trust and willingness to share data for research could be secured through establishing infrastructure to make data access decisions, transparency about safeguarding processes, a system of penalties for misuse, a cap on profits from data use and control of third-party data access.

There is a clear need to develop – with the public – a set of principles that will engender trust in using health and care data for research and planning purposes. This study addresses this need by exploring the public’s willingness to contribute data for direct care and research purposes, how the concerns they have differ between data sharing for different reasons, and the principles that should apply when their data are used for different purposes.

**2. Methods**

**2.1 Design and setting**

The study took place across Yorkshire and the Humber, in the North of the England. It is a large region containing a diverse mix of urban, rural and coastal communities and it includes areas of high and low deprivation and populations with high rates of chronic health conditions, such as diabetes.14 We used a sequential mixed methods approach comprising focus groups, surveys and co-design groups. The study followed the tenet of the Declaration of Helsinki and ethics approval from the lead author’s research organisation was received.

**2.2 Data collection**

**2.2.1 Focus groups**

Twelve focus groups took place, involving between four and eight participants (n=80) with different life and employment experiences or health conditions, as shown in Table 1. Each lasted an hour and was facilitated by one of the authors (FF). Data were audio recorded, transcribed and analysed using deductive framework analysis15 in which we coded text and identified themes in two areas: Should health and care information be shared? and What concerns do people have about their information being used?

**Table 1: Focus group demographics**

|  |  |
| --- | --- |
| FG1 | People from black and minority ethnic communities |
| FG2 | Men who work in the local area |
| FG3 | Mums attending a community group that encourages physical activity |
| FG4 | Parents who attend the Central Family Hub. Parents were a mix of nationalities, reflecting the ethnic diversity of the local area |
| FG5 | People who attend a Multiple Sclerosis Society support group |
| FG6 | People who attend a community craft group |
| FG7 | People with long-term physical or mental health conditions who attend a council-run physical activity and leisure scheme |
| FG8 | People who work in or live near a large housing estate in an area of high deprivation |
| FG9 | People who attend a community group that supports people over the age of 60 to live independently |
| FG10 | People who live or work in a rural community. |
| FG11 | Parents and carers who attend a local Children’s Centre. |
| FG12 | Young people attending a charity that provides mentoring and specialist support, particularly for vulnerable and disadvantaged young people. |

**2.2.2 Survey**

Online data collection used a fieldwork panel and promotion using NHS social media and community groups (both leisure and health/condition groups). A paper version was distributed via community organisations. A total of 1,066 people started the survey and 1,031 completed it. More were female (63%) than male (37%), 10% reported having a disability, 18% reported having a long-term health condition and 11% a mental health condition. Respondents were mainly white (91%); higher than the 2011 census data for the region (86%). A range of ages was included: 14% were 18-24, 26% were 25-44, 39% were 45-64, and 21% were over 65. Data were analysed using descriptive statistics and 𝜒2 tests with a significance level of 0.05.

**2.2.3 Case study cards**

Six versions of the cards addressed a different type of data sharing: data accessed by Accident and Emergency (A&E), social care, community care, voluntary sector, data used for population health management planning, and data used to identify and contact high-risk individuals. Cards were used in 12 data collection events in public places. A total of 415 cards were completed.

**2.2.4 Co-creation workshops**

Four workshops reviewed the findings and developed a set of guidelines for how data should be used and shared. Each workshop included 7-10 members of the public (n=34), plus one or two participants from public health or the NHS. Participants worked in pairs and trios to review the study findings and then the whole group discussed their views and developed a set of guidelines that should be used for sharing health and care data, agreed using an adapted nominal group technique.16 Each workshop lasted two hours and discussions were audio recorded and transcribed.

**3. Results**

**3.1 Focus groups**

**3.1.1. Should health and care data be shared?**

Discussions about sharing health and care data showed differences between sharing with healthcare professionals for direct care purposes, sharing with social care professionals, and sharing data with research organisations. There was strong support for sharing health and care data for direct care. Participants discussed how it will improve patient-centred care, continuity of care, communication between different health and care teams, the accuracy of diagnoses and prescribing, and generally lead to a more efficient and cost-effective service. Many people were surprised that their health and care records are not already shared across the NHS.

The situation was less clear for sharing data with social care professionals and there was low awareness of the role that local councils play in planning and providing health and care services. Participants were concerned that care workers, social workers, etc. would misunderstand the information they access, or not have confidentiality requirements. Several participants suggested having an audit trail that would allow them to track who had accessed their information.

*“How would you be sure that people have accessed it for a legitimate reason not just thought yes, she lives down the street?”* (FG6)

Participants discussed whether their data should be used for research and planning purposes. While they appreciated that research provides important benefits, many had reservations. There was uncertainty about who conducts and owns the research and how it is used. Some discussed how commercial organisations could take advantage of the NHS.

*“I don’t mind anyone sharing my information within the NHS or within the local authority, but I would be extremely unhappy to find it been sold to third parties or even given to third parties because of the potential abuse.” (F12)*

*“If the NHS tells a private company, like a care home, where beds are needed, that is ok. But they shouldn’t get a commercial advantage.” (FG1)*

**3.1.2. What concerns do people have about their information being analysed?**

Participants were concerned that they might be identified from their health data, and some found it difficult to understand how individual records could generate aggregated data. Most were happy for aggregated data to be used but were more cautious about individual records being analysed, even when identifiable information is removed. Participants discussed being personally targeted by commercial companies trying to sell them products related to their health condition.

*“If pharmaceutical companies find out that you have got a heart condition and you are on a certain type of beta blocker before you know it you could be getting all sorts of leaflets, try this drug change to this drug, you could end up being targeted.” (FG9)*

They had concerns about cyber security, including data security breaches and computer viruses might affect NHS and local authority data, with several pointing to the “WannaCry” cybersecurity incident as an example of how their data is vulnerable to malicious attacks. Some also highlighted how staff members themselves may be the source of data leaks, either intentionally or unintentionally.

*“The NHS cannot afford to upgrade their security to the latest because they haven’t got the money to do so, so potentially it is at risk because they are using out of date technology which is more prone to be hacked then the latest operating systems.” (FG11)*

They also had concerns that information in people’s health and care records may be used against them, for example by rationing care on the basis of lifestyle choices. A few talked about how care is already restricted on the basis of age and wondered if the situation could be more extreme in the future, for example denying care to people who carry a genetic condition. Participants also talked about how they could be adversely affected if other organisations find out about their health condition, e.g. raised insurance costs or difficulties obtaining a mortgage. A few talked about how the NHS and local councils might share information from the records of people who are refugees or asylum seekers with government bodies, and these bodies might use this information to locate, detain or deport individuals.

*“At this present time I think the information would only be used for good but you can’t guarantee this will always be the case.” (FG10)*

**3.2 Survey**

Survey respondents were given a list of professionals and asked which should be able to see their health and care records so that they can help care for them (Figure 1). There was strong support GPs (98%), hospital doctors and nurses (93%), and clinical staff (61%). There was more limited support for pharmacists (37%), care staff (36%), social workers (24%) and researchers (24%). Very few believed housing officers (7%), employers (4%), or insurers (4%) should have access.

**Figure 1: The percentage of respondents who believe different professionals should be able to access their health and care records.**

They were asked how much they trust different organisations with information about them (Figure 2). There are statistically significant differences in how much these organisations are trusted, with GPs trusted more than the NHS in general, and both of these trusted significantly more than banks or building societies, the local council and Universities (all p<0.01). All these organisations are trusted more than insurance companies, and all of these are trusted more than health apps, store loyalty cards, Amazon and Google. Facebook is trusted less than all other organisations listed.

**Figure 2: How much people trust different organisations with their information.**

Most respondents reported that anonymous records should be used to help plan services (88%), to help people stay healthy or find cures for diseases (both 67%), and research for the public good (58%), but only 16% for commercial research. They were also given options for whether people should be identified and contacted as part of the process of analysing data: 81% reported that people at risk of a condition should be contacted to invite them for screening, 60% to give them health advice, and 46% to take part in medical research. There were very few demographic differences in the survey results. Males were more likely than females to believe that people should be contacted if they are at risk of a disease (𝜒2 = 11.8, p=0.003).

Most (79%) had at least one concern about their data being used: information might be sold to private companies (56%); it might not be stored securely (53%); it might be used to cut services (41%); they might receive more junk mail (33%); and they might be identified (31%).

**3.3 Case study cards**

There was support for data use across all the case studies (Table 2), although less support for patients identified as being high risk and contacted. Nevertheless, 84% of participants believed this is a good use of information and would be happy for their information to be used in this way. There were no significant differences between the case studies for it being a good use of data (𝜒2 (5) = 3.98, p = 0.11) or for information to be used in this way (𝜒2 (5) = 4.55, p = 0.47). There were no age differences in the pattern of responses for the case studies being a good use of data (𝜒2 (5) = 8.99, p = 0.55) or for their information to be used in this way (𝜒2 (5) = 3.71, p = 0.59).

**Table 2: The percentage of people who agree with each data use.**

|  |  |  |
| --- | --- | --- |
|  | Good use of information | Use my information this way |
| 1. Consultant accessed A&E data | 96% | 93% |
| 2. A&E accessed social care data | 94% | 92% |
| 3. Data shared with community care | 94% | 90% |
| 4. Data shared with the voluntary sector | 89% | 87% |
| 5. Data used to plan services | 95% | 93% |
| 6. Patient identified as higher risk and contacted | 84% | 84% |

**3.4 Co-creation workshops**

Participants developed a set of principles that different types of organisations with access to their data should adhere to.

**Private hospitals and clinics providing direct care**

* The NHS should own and control the data rather than private hospitals and clinics.
* Data sharing processes should be governed effectively.
* Data should not be shared with commercial or profit-making third parties.

**Organisations that help people stay healthy or live independently**

* People should be provided with the ability to opt in or opt out.
* Only current and relevant information should be shared and people should be able to check which aspects of their records have been shared.

**Organisations that develop new equipment and treatments**

* People should be provided with the ability to opt out and opt back in.
* Data should be anonymous unless people give consent.
* There should be clarity on what information is and isn’t shared.
* All research projects should go through an ethics review process.

**4. Discussion**

This research has identified the concerns that people have about their health and care data being used for direct care and for research and planning purposes and has co-designed a set of principles that would secure social licence (trust and consent) for data being used in different ways. People support their data being shared for direct care, and indeed, have concerns about the consequences of *failing* to share it, such as information being unavailable for clinicians, and duplicated tests. Their main concern is that their records may contain inaccuracies, and that only current and relevant information is shared. As with clinicians,4 there is strong support for this form of data sharing. Provided that people can opt in or out, data for direct care can be shared with the independent sector. People were concerned about being identified, as has been shown before.7,13 We explored *why* being identified is a concern: people do not want to be targeted by condition-related healthcare marketing, to have their future healthcare rationed because of their lifestyle choices, nor to experience financial or employment discrimination on the basis of their condition. Rather than identification occurring through linked datasets, they assumed that it would happen through intentional sharing with other organisations, or by NHS data systems being hacked.

People believed that NHS lacks IT security expertise and that systems are outdated. Publicity around large-scale public sector IT projects that fail could underpin this, together with the Wannacry incident,17 and people’s own experiences of NHS IT limitations. Despite this, there was support for data sharing as people believed the NHS only uses data for the public good, whereas private sector organisations are driven by their shareholders’ interests. This is in line with earlier research.13 The NHS was positioned as a naïve partner, being unaware of the value large organisations place on personal data, and easily taken advantage of by the pharmaceutical sector. These concerns have not been previously identified.

There is less support for allied healthcare professionals (e.g. pharmacists) accessing data, which needs to be addressed if the role of these services is to be expanded.18 Universities and local authorities are trusted less, which may be because people are unsure about their motives for accessing data. People have low understanding of the public health function of local authorities, and little familiarity with the role of University researchers. Our findings also provide insight into people’s responses to different organisations involved in the pandemic and how future systems should be designed. Our results suggest that a national private-sector test and trace organisation, as set up in the UK, would not engender trust, which means that compliance is likely to be low. While people have more trust in local authorities, they have low understanding of their role in public health, so even higher compliance could be achieved by involving NHS, and in particular GP practices.

Our results show that people support their records being used for population health management purposes, and most would be willing to be identified and contacted should data analysis identify them as being at risk. Higher support in males may be because it requires less engagement.19 Sharing data for population health management purposes could lead to more efficient services, focused on maintaining health and preventing disease, which are better tailored to the needs of the community they serve. It is therefore important that social licence is obtained from all groups in society, with no groups being more likely to opt out of sharing their data.

We found evidence of a trust-benefit ratio,20 21 which describes how if an individual perceives more benefit, they are willing to lend more trust and to provide more data. There is a need to help people to recognise the benefits they are, or could, benefit from; at present these benefits are too abstract to be influential. The invisibility of NHS data strategies acts as a barrier: the public is not aware of the NHS vision for data-driven healthcare.

Our co-designed principles for data sharing have few caveats on use of information for direct care; mainly that the NHS owns the data. Research organisations have additional requirements such as people being able to opt out, and consent being required if individuals are identified, that data use is overseen by an ethics process, and there is transparency over what is shared. This research demonstrates support for data sharing with the voluntary sector, with the additional requirement that people can check what is shared, and only current and relevant information is shared. This supports an expanded role for the voluntary sector, e.g. in social prescribing. Processes are needed to ensure data sharing meets these principles, and that there is sufficient governance.

The strengths of the study include that it took place in a series of community setting across a large region of the UK and involved a wide range of participants with different experiences. The combined use of quantitative and qualitative data is also a strength, and the qualitative sample was large. The co-design element involved participants from both the NHS and public health organisations. The limitations are that the survey sample under-represented Black and Minority Ethnic groups.

Our research predicts many of the public’s responses to data sharing during the UK’s response to Covid-19, but the public is likely to be more aware of the links between the NHS, public health and commercial research and further research is needed to explore the impact of Covid-19 on public perceptions of data sharing and how to achieve social licence.

**Authors’ contributions**

Both authors contributed to conception and design of the study, acquisition and interpretation of data, drafting, revising and approving the article.

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**Conflict of interest**: None

**Summary**

* Optimising the use of patient data has the potential to produce a transformational change in healthcare planning, treatment, condition prevention and understanding disease progression. We explored how to secure the trust required for social licence to use health and care data for research and planning purposes, as well as for direct care.
* There is strong support for sharing health and care data for direct care, although less so for social care access to records.
* There is also strong support for health and social care records being for research and planning, although little support for commercial research.
* Participants were concerned about being identified, security limitations, and the potential rationing of care on the basis of information in their record.
* Co-creation groups developed a set of principles for a social licence for data sharing based around good governance, effective processes, the type of organisation, and the ability to opt in and out.

**References**

1. The NHS Long-Term Plan, 2019. [Available from https://www.longtermplan.nhs.uk/ accedded 11/01/2021

2. Kruse CS, Goswamy R, Raval Y, et al. Challenges and Opportunities of Big Data in Health Care: A Systematic Review. *JMIR Med Inform* 2016;4(4):e38. doi: 10.2196/medinform.5359 [published Online First: 2016/11/23]

3. Fylan B, Marques I, Ismail H, et al. Gaps, traps, bridges and props: A mixed-methods study of resilience in the medicines management system for patients with heart failure at hospital discharge. *BMJ Open* 2019;9(2)

4. Hopf YM, Centre of Academic Primary Care UoA, Aberdeen, UK, Bond C, et al. Views of healthcare professionals to linkage of routinely collected healthcare data: a systematic literature review. *Journal of the American Medical Informatics Association* 2020;21(e1) doi: 10.1136/amiajnl-2012-001575

5. Edwards Z, Blenkinsopp A, Ziegler L, et al. How do patients with cancer pain view community pharmacy services? An interview study. *Health & Social Care in the Community* 2018;26(4):507-18. doi: <https://doi.org/10.1111/hsc.12549>

6. Fylan B, Armitage G, Naylor D, et al. A qualitative study of patient involvement in medicines management after hospital discharge: an under-recognised source of systems resilience. *BMJ Quality & Safety* 2018;27(7):539-46. doi: 10.1136/bmjqs-2017-006813

7. Kalkman S, Delden Jv, Banerjee A, et al. Patients’ and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence. 2019 doi: 10.1136/medethics-2019-105651

8. Carter P, Laurie GT, Dixon-Woods M. The social licence for research: why care.data ran into trouble. *J Med Ethics* 2015;41(5):404-9. doi: 10.1136/medethics-2014-102374 [published Online First: 2015/01/27]

9. Dixon-Woods M, Ashcroft RE. Regulation and the social licence for medical research. *Med Health Care Philos* 2008;11(4):381-91. doi: 10.1007/s11019-008-9152-0 [published Online First: 2008/07/18]

10. Group RC, Horby P, Lim WS, et al. Dexamethasone in Hospitalized Patients with Covid-19 - Preliminary Report. *N Engl J Med* 2020 doi: 10.1056/NEJMoa2021436 [published Online First: 2020/07/18]

11. Niedzwiedz CL, O'Donnell CA, Jani BD, et al. Ethnic and socioeconomic differences in SARS-CoV-2 infection: prospective cohort study using UK Biobank. *BMC Med* 2020;18(1):160. doi: 10.1186/s12916-020-01640-8 [published Online First: 2020/05/30]

12. Megnin-Viggars O, Carter P, Melendez-Torres GJ, et al. Facilitators and barriers to engagement with contact tracing during infectious disease outbreaks: A rapid review of the evidence. *PLoS One* 2020;15(10):e0241473. doi: 10.1371/journal.pone.0241473 [published Online First: 2020/10/30]

13. Stockdale J, Cassell J, Ford E. “Giving something back”: A systematic review and ethical enquiry into public views on the use of patient data for research in the United Kingdom and the Republic of Ireland. *Wellcome Open Research 2019 3:6* 2019;3(6) doi: doi:10.12688/wellcomeopenres.13531.2

14. Local Authority Health Profile 2019: Bradford: Public Health England; 2021 [Available from: <https://fingertips.phe.org.uk/static-reports/health-profiles/2019/E08000032.html?area-name=Bradford> accessed 06/01/2021.

15. Gale NK, Heath G, Cameron E, et al. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC medical research methodology* 2013;13(1):117-17. doi: 10.1186/1471-2288-13-117

16. McMillan SS, King M, Tully MP. How to use the nominal group and Delphi techniques. *Int J Clin Pharm* 2016;38(3):655-62. doi: 10.1007/s11096-016-0257-x [published Online First: 2016/02/06]

17. Mattei TA. Privacy, Confidentiality, and Security of Health Care Information: Lessons from the Recent WannaCry Cyberattack. *World Neurosurg* 2017;104:972-74. doi: 10.1016/j.wneu.2017.06.104 [published Online First: 2017/06/26]

18. Integrating care: Next steps to building strong and effective integrated care systems across England: NHS England and NHS Improvement, 2020.

19. Cook EJ, Sharp C, Randhawa G, et al. Who uses NHS health checks? Investigating the impact of ethnicity and gender and method of invitation on uptake of NHS health checks. *Int J Equity Health* 2016;15:13. doi: 10.1186/s12939-016-0303-2 [published Online First: 2016/01/23]

20. Kim KK, Sankar P, Wilson MD, et al. Factors affecting willingness to share electronic health data among California consumers. *BMC Med Ethics* 2017;18(1):25. doi: 10.1186/s12910-017-0185-x [published Online First: 2017/04/06]

21. Fylan F, Fylan Gwynn B, Caveney L. Joined up Leeds. Report for the Leeds NHS Informatics Team. Leeds, 2015.