

Informing Patients About the Use of Their Healthcare Systems Data in RCTs: Insights from Information Leaflets

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Abstract

Background

Patient Information Leaflets (PILs) provide potential participants with the information needed to make an informed decision about joining a randomised controlled trial (RCT). The growing use of healthcare systems data (HSD) adds complexity to documents already under pressure to remain concise. While regulatory requirements exist for transparency about data use, no specific guidance prescribes the level of detail or wording required to describe HSD in PILs. This study examined how PILs from NIHR-funded RCTs communicate HSD use to potential participants.

Methods

A document analysis was conducted using a cohort of RCTs. Eligibility was determined by NIHR-HTA funding, active trial status in 2022, and planned use of HSD, resulting in 51 eligible RCTs. PILs were obtained through online searches and direct contact with trial teams. Data were extracted using a form based on HRA data protection disclosure requirements. Questions examined, data access, linkage, confidentiality and regulatory compliance. PILs were assessed against trial protocols to evaluate completeness of HSD source disclosure. A three-category scale (Vague, Clear, Detailed) captured variation in level of detail. Informed consent forms (ICFs) were reviewed where available.

Results

PILs were obtained for 43 of the 51 trials (84%). 33(77%) mentioned at least one HSD source, but of these only 22(67%) mentioned all sources planned in the protocol[GC1] . Only 7(16%) PILs described what specific data would be accessed from HSD. Three ICFs requested consent for HSD use not previously explained in the PIL, raising concerns about informed consent adequacy.

HSD detail varied across PILs, from vague references of medical records to detailed descriptions of data linkage and access procedures.

Most PILs were in a paper format, referencing additional websites through links. Seven (16%) were presented using a multimedia format, allowing for dynamic explanations of the trial.

Conclusion

Patients have identified data explanation as a high-priority feature of PILs, yet the level of detail provided about HSD is often insufficient to support informed decision-making. There is an absence of guidance for HSD-specific PIL content. The introduction of ICH E6(R3), which strengthens patient rights and data governance related to external data sources, highlights the need to address this gap and support trialists and patients.

Background

Patient Information Leaflets (PILs) are provided to patients who may be eligible to participate in a clinical trial. The PIL aims to provide important information about what may be expected if they agree to take part in the study such that they can make an informed decision on whether to participate. This document details the need for the trial, the condition under study and possible treatments, the expected commitment from the participant and risks (1, 2). The PIL needs to provide sufficient information about the nature of the data collected and its planned use, in order to ensure fair and transparent processing of data. (3)

Freely given informed consent has been a foundational principle of Good Clinical Practice since its inception (2). Potential participants should be given pertinent information about the trial as well as ample time to inquire about its details, presented in language that is as non-technical as practical. The International Council for Harmonisation, Guideline for Good Clinical Practice, Revision 3 (ICH E6(R3)) (4) places greater emphasis on risk-based and proportionate trial oversight, data integrity, and guidance suited to modern trial designs. Notably, it introduces a dedicated Data Governance section and acknowledges advances in trial conduct, including the use of electronic methods for obtaining informed consent.

Within the Health Research Authority (HRA) guidance (5), it is stipulated that participants must be informed that data about their health and/or treatment will be collected. This includes the need to clarify the type of information to be collected, and the rights they can exercise in relation to their data. Additionally, collection of information from other sources should be disclosed to patients as this may represent a potential risk to their confidentiality. While these requirements outline the categories of information to be disclosed, no guidance is provided on the level of detail or specific wording required for each item.

Regarding data confidentiality, patients should be informed if their data, either as is or anonymised, is to be kept or shared beyond the trial, both within and outside the UK, how the data will be kept secure and information about the data controller (5).

In addition, the GDPR, which came into effect in May 2018, introduced requirements for how personal data is processed in research, with trials commencing after this date required to inform patients of the lawful basis under which their data will be processed (3). Participation in a clinical trial requires the patient's freely given informed consent, which allows them to decide whether they wish to take part. However, the processing of their data does not always rely on consent as the lawful basis. Depending on the applicable data protection framework and the sponsor's responsibilities, personal data may instead be processed under another lawful basis, such as the performance of a task carried out in the public interest or compliance with legal obligations (6).

Underpinning these statutory requirements is the common law duty of confidentiality, which obliges healthcare providers to protect patient information obtained in the course of care (7). Where HSD is accessed for research purposes, this duty must be addressed through either the participant's explicit consent or a recognised legal gateway, such as approval under Section 251 of the National Health

Service Act 2006 in England (8), which permits the use of identifiable patient data without consent where it would not be reasonably practicable to obtain it. Patients should therefore be informed not only that their data will be accessed, but on what basis the confidentiality of that data is being managed. This makes the PIL a critical instrument for ensuring patients can meaningfully assess the implications of HSD use for their privacy and data rights.

Research has been conducted regarding the structure of the PIL. However, balancing the required volume of information to adequately explain all areas of the trial within the PIL while keeping the information concise and understandable is an on-going challenge (9–11). While there are no exact length limitations, better understanding may be attributed to shorter PILs (12, 13). The HRA and Information Commissioner's Office (ICO) recommend that project-specific information, such as that provided in a PIL, forms only one layer of a broader information framework, complemented by organisational and departmental level disclosures (14). PIL content therefore represents one component of a wider approach to patient-facing transparency.

Informed consent

is based on the patient's understanding of the PIL and additional discussions with care providers as appropriate (1). Therefore, vague or incomplete information in the PIL compromises fully informed consent. Moreover, previous research regarding PILs focused on the patient's understanding, especially on issues related to the complexity, readability, and the length, rather than the quality and accuracy of the content.(15) A recent study (16) asked patients to evaluate different PILs to identify sections of heightened interest. The findings showed that the significant topics relate to the clear explanation of the necessity of research, the method of collecting the data, and the background provided for the project.

A patient's decision regarding participation is recorded using an informed consent form (ICF). The ICF asks the patient to acknowledge understanding the information in the PIL and agree to the proposed uses of their data. The signed and dated ICFs need to be preserved at least for the duration of the trial.

Traditional data collection methods for randomised controlled trials (RCTs) involve asking participants to attend trial-specific assessments, at predefined time points, in specific medical or community based settings, and to complete self-reported questionnaires. Healthcare systems data (HSD) refers to medical information collected without having a specific research question formulated in advance. This can be provided either by individual medical facilities or by central sources like the National Health Service (NHS), the Office for National Statistics (ONS) or disease-specific participant registries. HSD sources contain large amounts of data, allowing for heightened interest in the possible efficiency gains, by having access to a larger population and reducing the burden imposed on participants.

The examination of a cohort of NIHR funded RCT protocols has shown the continuous interest in using HSD (17) demonstrating a 14% increase (from 47% to 61%) in the number of trials planning to use HSD, compared with 2019. The demand for using HSD as the sole data source for at least one outcome has remained similar.

Regarding accessing HSD, the current requirements are to include in the PIL the information resources that are intended to be accessed, to inform patients about issues related to confidentiality and to include a statement within the consent form using the following suggested wording : “I understand that the information held and maintained by The Health and Social Care Information Centre (or amend as appropriate) and other central UK NHS bodies may be used to help contact me or provide information about my health status.”. (5)

Despite the growing use of HSD in RCTs and increasing regulatory requirements for transparency, little is known about how HSD is currently communicated to patients in PILs. The current work aims to describe the level of detail in the information regarding HSD currently available in clinical trial PILs within a previously established cohort (17) in comparison with the information provided in their protocol.

Methods

The identification of the cohort of trials has been described in a previous publication (17). On-going NIHR-HTA funded RCTs were identified through a search of the NIHR Journals Library conducted in June 2022. Of these, 51 trials were planning to use HSD and formed the cohort for the current analysis. All trials within the cohort had start dates after October 2019. Therefore, the PILs were required to convey important information pertaining to GDPR and data privacy.

Online searches were conducted in early 2024 to obtain the PILs for each trial within the cohort. This included identifying trial-specific websites, CTU websites and NIHR documentation. Where the PIL was not located, trial teams were contacted by email. Where multiple versions were available, the latest full version was used. Informed consent forms (ICFs) were also collected where available online or requested alongside the PIL when trial teams were contacted for this purpose.

The trial protocols were used to identify planned use of HSD sources. This included the nature and use of data being extracted from each source. The PILs were examined to identify whether this use and any linkage required were clearly described to potential participants. ICFs were also reviewed to identify any use that was not described in the PIL and whether consent was being requested for HSD access consistent with HRA expectations.

A data extraction form, containing 12 questions, was designed to capture the information available in the PILs and ICFs. The form was piloted and amended prior to use across the cohort. Questions covered the following categories:

- The HSD sources and the specific data to be accessed
- Data storage, privacy and confidentiality
- HSD and bespoke data linkage
- HSD access in case of trial withdrawal
- Data controllers and Data Protection Officers

- Compliance with current regulations
- Information regarding complaints

Results were summarised as frequencies and percentages (Table 1). As the HRA requirements do not prescribe the level of detail or specific wording for each item, a three-category scale – Vague, Clear or Detailed – was developed to capture information that could not be quantified, with examples presented in Table 2. This scale does not necessarily reflect whether the comprehensiveness of information provided by PILs is sufficient but rather showcases the current information available. All extraction questions were derived from the HRA data protection disclosure requirements, with additional questions included to capture good practice beyond the minimum requirements.

To ensure consistency, a subset of PILs were independently reviewed. Any discrepancies were resolved through discussion.

Results

PILs were obtained for 43 out of the 51 RCTs in the cohort (84%). Of these, 34 (79%) had made their PIL available online, two on the NIHR website, 13 on their individual trial website and 19 on their CTU or institution's website. The 17 trials without publicly accessible PILs were contacted, of whom 9 (53%) responded and provided a PIL. 18 ICFs were collected (14 were sourced online and four via email correspondence).

Table 1
presents the HSD-related information provided in the PILs.

No	Question	Yes (% of <i>n</i> , unless stated otherwise)
1.	Are any HSD sources mentioned? ^a	33 (77%)
2.	Are all the data sources mentioned? * ^a	22 (67%*)
3.	Does it state what data is to be collected from HSD sources? ^a	7 (16%)
4.	Does it state clearly how long the data will be kept for? ^a	39 (91%)
5.	Is the information related to HSD in the ICF explained in the PIL? ** ^b	15 (83%**)
6.	Are the data controllers specified? ^a	27 (63%)
7.	Is the Data Protection Officer specified? ^a	35 (81%)
8.	Is there a link to the HRA website for the regulations? ^b	26 (60%)
9.	Is there a statement about GDPR compliance? ^b	8 (19%)
10.	Is there information about how to lodge a complaint? ^a	41 (95%)
11.	Is contact information given for the Information Commissioner's Office (ICO)? ^a	7 (16%)
12.	Is the lawful basis for data processing stated? ^a	8 (19%)

Table 1 - *Availability of information in the PILs.*

*Percentage calculated based on the number of PILs who mentioned any HSD source (n = 33)

**Percentage calculated based on the number of available ICFs (n = 18)

^a Questions derived from HRA data protection disclosure requirements.

^b Questions included to capture good practice beyond the minimum HRA requirements.

Within the 10 PILs that did not mention their HSD source, two used statements such as “We will need to use information from your medical records” and did not clearly reference any HSD source or use the HRA proposed statement, while the remaining eight did not mention HSD. According to their protocols, the planned HSD sources for these 10 trials included NHS data (n = 5), primary care data (n = 2), registries (n = 1) and other sources (n = 2). Planned uses included health economics analyses (n = 8), data collection in case of withdrawal (n = 4) and secondary outcomes (n = 3).

While only 16% (n = 7 out of 43) of the PILs included information about the data to be collected from HSD sources, 66% (n = 28) provided a statement vaguely identifying the possible categories of data, for example “This will give researchers information that is routinely collected during your visits to your GP and hospital, and let researchers find out about your use of NHS services and about your health after the study has ended without contacting you further.”.

Only two (5%) PILs contained no vague responses across all items. However, 53% of PILs (n = 23) had at least 75% of items rated as clear or detailed, and 86% (n = 37) had at least 50% rated as clear or detailed.

Three of the 18 ICFs identified used vague language regarding the data to be collected from HSD sources and did not mention it in the PIL. Examples of the text used include “relevant sections of my medical notes” or “provide information about me”. The additional 15 ICFs contained clear statements referencing HSD, such as “I agree to the information held and maintained by The Health and Social Care Information Centre, NHS Digital and other current and future NHS bodies being used in the future to provide information about my long-term health status and health care.” in addition to the information supplied in the PIL.

The topics used to identify the level of detail in the PILs are presented in Table 2. Examples of the average amount of information displayed, alongside what has been considered vague or detailed are presented below.

Table 2 - Examples of information in PILs

Discussion

The key findings of the current research relate to the limited information provided to patients about the data to be collected from HSD. Only 77% of all the PILs examined mentioned using HSD, and an additional third did not present all the HSD sources to be accessed relative to their protocol.

The information covered in the PIL is limited to essential knowledge required for a patient to consider their involvement in the trial. Patients have rated a clear explanation of the data to be collected as the second most important feature of a PIL, after the need for the research (16). Therefore, this research shows that information about data collected from HSD, important to the decision to participate, is only available in 16% of the PILs.

Beyond the PIL itself, ICFs should not introduce concepts or terminology not previously presented, as they are tools used to gather consent informed by the PIL. Three ICFs in this cohort requested consent for HSD use not previously described in the PIL, raising concerns about the adequacy of the patient-facing information.

The complexity of PILs has been shown to impact patients’ willingness to take part in the study, as “excessive complexity is likely to intimidate potential participants and impair comprehension” (18). Therefore, the content is usually examined for information related to supporting decision making (19),

rather than completeness of study related concepts. It may be assumed that the information in Table 2 is currently considered sufficient to support the decision-making process. However, as data sources use and linkage continues to expand in use and complexity, on-going discussions need to take place with patients to ensure that their preferences regarding the level and type of information provided are met and how best to communicate this information.

The patient's ability to read and comprehend the information in the PIL is of high research interest due to its importance in the informed consent process. The appropriate reading age of such information has been debated in several papers, with the result being determined based on the literacy of the population explored and the study-specific features (20–22). Within the UK, the recommended minimum reading age is 9, regardless of the age or characteristics of the population being recruited. (23)

The length of a PIL is also a topic of interest. It has been shown that patients are less likely to read longer documents, which leads to a lack of understanding and to poorer retention (13, 24–26). It has been shown that patients are unlikely to fully read a document if it is longer than 1,000 words (13). The size of the document influences the amount of detail that can be included related to HSD, therefore necessitating consideration of the balance between the amount of information necessary to offer the required understanding whilst keeping to reasonable word limits. Additionally, offering patients the option to choose the amount of information they would like to read related to specific aspects of the PILs can alleviate this issue. A recent study has shown that having additional information available in the format of layered PILs, each building on the more succinct version, was well received by patients. (27)

Of the 43 PILs, 7 (16%) were presented either using a website or video format, which allowed for animations and interactive explanations of the study. Depending on the target population of the study, these approaches may help ease the complexity and increase the comprehensiveness of the study. Interactive PILs may also allow patients to obtain as much information as they prefer, offering the option to get more details about certain aspects that are initially summarised. As an example, the ADEPP study interactive PIL (<https://adepp-information.digitrial.com/> (28)) walks patients through the information summary, while offering videos and additional details if the patient is interested in finding out more about particular sections.

There is increased interest in using multimedia information within trials, as patients consider it easier to understand and it supports higher levels of engagement (29) (30) (31). Beyond the trial specific ones, the number of interactive resources is expanding, with video and animated resources being available online, explaining different concepts related to trials(32, 33). This content can be reused for different contexts, complementing trial-specific PILs, and potentially minimising the effort required to offer a comprehensive understanding of the trial. A similar resource explaining the possible uses of HSD in RCTs might be a useful tool for informing patients while avoiding increasing the word-count in the PIL.

There is guidance available which provides recommendations on the minimum amount of information to be described in the PIL. (4, 34–36) These sources of guidance do not offer an exhaustive list but rather note the key elements to be presented. Within the guidelines, the level of detail is not presented, and the

use of specific wording is not mandated, enabling a range of interpretations to be inferred within the PIL. The extraction questions used in the current study were derived directly from HRA data protection disclosure requirements, with additional questions included to capture good practice beyond the minimum requirements, reflecting this lack of specificity in current guidance. This highlights a gap that warrants further development. Furthermore, the current study examined only the project-specific layer of patient information provision. The HRA and ICO recommend a broader tiered framework (14), and future research could examine how these layers align and whether organisational-level information adequately complements what is provided in the PIL regarding HSD.

Within the examined cohort, 81% of the PILs analysed excluded a specific statement regarding the lawful basis for data processing. Under GDPR, the lawful basis must be disclosed to participants and documented prior to the start of data processing, with the appropriate basis determined by the nature of the trial (3, 6). This raises concern that a substantial proportion of trials may not be meeting minimum disclosure requirements.

The ICH E6(R3) guideline (4) introduced a dedicated Data Governance section representing a significant evolution of the GCP framework. This section establishes a formalised approach to data integrity, traceability and security across the full trial data lifecycle, and introduces the previously not required mandatory management of trial metadata. Of relevance to HSD use, R3 requires that clinical practice systems such as hospital electronic health records be formally assessed for fitness for purpose within the trial context, and that system validation be proportionate to the potential impact on participant rights and safety. These provisions strengthen the governance infrastructure surrounding external data sources used in trials. However, such frameworks are directed at sponsors and investigators and do not address patient-facing communication requirements. As data governance requirements become increasingly formalised, the gap between how data is managed and how it is communicated to patients becomes increasingly important to address.

The need for guidance related to PIL development has been described in various papers (11). Several frameworks for PIL development have been published over the years(12, 15, 19), but there is no evidence of any resources specifically designed for PIL information relating to HSD. The existing frameworks tend to expand on the regulatory needs and offer a tool for PIL design and evaluation.

In addition to the frameworks currently available, many organisations have publicly available templates (37–41) for PILs that can be customised for individual RCTs, but the amount of information regarding HSD to be included is not usually detailed.

It is common practice for some information, including details about how participant data is being used and ICO contact information, to sometimes be stored outside the PIL, on public websites, and referenced through a link. While this method is efficient in keeping the word count low, there can be possible accessibility issues, especially when the PIL is presented to patients in a printed format. Some websites disclose the publication date and version; however, this is not a frequent practice, which means that information may be updated and therefore no longer apply. This may present issues as rules and

regulations might be subject to change. Additionally, as websites are expanded or updated, the links included might not be accessible for the entire duration of the RCT. For the purpose of this research, we have only taken into consideration the information available within the PIL. In over half of the PILs examined, regulatory information was provided solely via a link to the HRA website ("<https://www.hra.nhs.uk/information-about-patients/>" (42)). However, this link currently returns an error, rendering the referenced information inaccessible and providing a concrete example of the accessibility risks associated with externally hosted content.

Versioned and dated extension documents to be stored on the trial's website, or other domain managed by the research team, might be a suitable alternative for information referenced in the PIL, as the content is controlled by the trial team. While there are no current regulations regarding the length of time PILs should be available, the information should be accessible by participants for at least three years after the end of the trial, in order to allow for claims (43). The cost of maintaining these online documents should be taken into consideration from the trial outset.

These methods may provide a good option for reducing the word count in the PIL while offering the option for additional details but may not be appropriate for all cohorts of patients. When the target demographic includes older patients, offering both summarised and extended versions of the printable PIL may be more appropriate alternatives. Within the UK, approximately 13 to 19 million people live in digital poverty, meaning that they are not able to fully interact with the online world (44). Therefore, alternative options to online resources should be considered.

The strengths of the current research include the use of a previously established cohort of RCTs, with access to their published protocols, allowing for comparison between the planned use of HSD and the details given to patients. Also, as all the RCTs in the cohort are primarily UK based, and have a start date after October 2019, this ensured that similar regulations apply, as GDPR was in effect before their onset.

We acknowledge that the current research was limited by the availability of PILs which were sought using the online search and requests from the trial team. Also, the sample of RCTs has been previously chosen as all the NIHR-funded RCTs on-going on June 6th 2022, and therefore might not be an accurate representation of all RCTs. NIHR-funded trials are considered of higher quality due to their rigorous funding guidelines and strong focus on transparency and evidence sharing, therefore the lack of adequately conveyed information in the PILs, may suggest the overall standard to be lower. Additionally, the trial protocols were used as the reference point for planned HSD use. While protocols should document all planned data sources, it is possible that some planned uses were not fully captured within them, which may have affected the comparison between planned and reported HSD use. Lastly, the three-category scale used to assess level of detail was developed for the purpose of this study and has not been independently validated.

The increasing interest in HSD use in RCTs, combined with the current lack of frameworks or templates for HSD-specific PIL content, highlights the need for such guidance to be developed. Future research is

needed in order to explore what information regarding HSD data is of interest to patients, as well as the preferred extent of information to be included regarding data protection and processing compliance.

Conclusion

PILs are designed to equip patients with the knowledge required to inform appropriate consent. Current regulations, frameworks, and templates available do not offer guidance regarding the information to be included in the PIL regarding HSD, despite patients rating a clear explanation of the data to be collected as highly important. Given the strengthened data governance requirements introduced by ICH E6(R3), addressing this gap is increasingly important.

Research to date has focused predominantly on the readability and comprehension of PILs rather than the accuracy and depth of their content. Research informed by patient views is needed to determine what information about HSD should be included and how it should be communicated, to better support both trialists and patients.

The use of HSD in RCTs expands the sometimes already overwhelming amount of information in the PIL, especially as people are increasingly interested in how their data is being used and shared. The balance between the need to convey all important information and an acceptable length of documentation requires further research and consideration. The use of multimedia solutions has the potential to alleviate the issue, while offering an engaging alternative to the written documentation.

However, the use of public weblinks in PILs may not always be appropriate, as the information provided in such sources is externally controlled and therefore may change over time, as well as potentially representing a barrier to information access in cases of digital exclusion.

Abbreviations

CTU	Clinical Trials Unit
GDPR	General Data Protection Regulation
HRA	Health Research Authority
HSD	Healthcare Systems Data
ICF	Informed Consent Form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICO	Information Commissioner's Office
NHS	National Health Service
NIHR	National Institute for Health and Care Research
ONS	Office for National Statistics
PIL	Patient Information Leaflet
RCT	Randomised controlled trial

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analysed during the current study are available at

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Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

A-MT conducted the search, analysed the results and wrote the first draft of the manuscript. CLG and SD supervised the work, edited the draft manuscript and approved the final manuscript.

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