

A Qualitative Study of Screening Logs in Clinical Trials: How Can We Improve Current Practice?

Juliet High

j.high@uea.ac.uk

University of East Anglia <https://orcid.org/0000-0003-2555-2349>

Matthew Hammond

University of East Anglia <https://orcid.org/0000-0002-0739-3412>

Susan Stirling

University of East Anglia <https://orcid.org/0000-0001-6663-7846>

Research Article

Keywords: Screening, log, clinical trial

Posted Date: October 15th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-11350823/v1>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Additional Declarations: The authors declare no competing interests.

Abstract

Introduction:

Screening data, comprising the number of individuals assessed for clinical trial inclusion, provides useful information. Efficient, consistent collection of relevant, high-quality data remains challenging. This work aimed to analyse current practices and opinions and develop draft guidelines.

Methods:

Literature reviews examined inclusion of screening data in trial results papers and papers that mentioned this type of methodology work. Surveys of current practice, sent to a range of stakeholders, included those who request and those who provide screening data. A Delphi survey defined and refined sections of relevance to include in the draft guidelines. Alternative methods of data collection and potential new sources of screening data were reviewed.

Results:

89% of reviewed, published trials included a CONSORT diagram, only 40% gave the definition of those included in the figure “assessed for eligibility”. Publications about screening data methodology are scarce and all concluded that data collection is challenging and further research is needed.

88% of survey respondents acknowledged the usefulness of screening data, 84% felt current implementation could be improved. This work has highlighted recurring themes, with concerns regarding data quality and lack of standardisation.

Conclusions:

Widespread use, and necessity, of screening logs is recognised in clinical trials. Improvements are needed in data collection practices to address observed variability in data quality. Despite its frequent publication, screening data often lacks scrutiny. Resource constraints and lack of funding are contributing to poor data collection. Development and implementation of guidelines are essential to enhance consistency, improve data quality, and elevate the focus of this under-researched methodological area.

INTRODUCTION

The reporting of healthcare research typically includes information on the number of participants assessed for inclusion into a clinical trial or other study. This is often referred to as screening data.

Justification for collecting screening data is well documented [1, 2, 3]. It is a valuable opportunity to understand whether patient groups are under-(or over) represented and determine if the trial population accurately reflects the real-world population of interest [4]. It can identify potential barriers to recruitment from both individual and trial delivery perspectives [1].

The CONSORT (Consolidated Standards of Reporting Trials) group [4] recommend that participant flow (the number of participants who progressed through the research study) should be included when reporting a Randomised Controlled Trial (RCT), and that “if available the number of people assessed for eligibility, and reasons for exclusion [5], should also be reported”.

The SEAR framework (Screened, Eligible, Approached, Randomised) was developed “to document, understand and improve the process of trial recruitment”[2]. This built on work from the QuinteT Recruitment Intervention [3], optimising recruitment and informed consent into RCTs and further describing the importance of screening data.

Whilst the potential uses of screening data are clear, acquiring quality data efficiently remains challenging. Elm et al [6] consider whether the financial cost of collecting screen data is justified, in part due to inability to centrally monitor screening data in the same manner as other trial data. They conclude “the efforts required to centrally collect high quality data on an extensive number of screened patients may outweigh the scientific value of the data. Moreover, the lack of a standardised definition of ‘screened’ and the challenges of collecting meaningful characteristics for patients who have not signed consent limits the ability to compare across studies and to assess generalizability and selection bias as intended”.

The authors of this paper have had similar experiences when publishing a variety of trials. Pressure from reviewers to include a “number screened” box at the top of a CONSORT diagram could result in some trial teams publishing a figure that has not been scrutinised in the same way as other trial data. Reported screening numbers in some papers can be misleading, offering little to no assistance in assessing potential bias or representativeness of the trial population.

Significant variation in practice persists, with little consensus on key aspects of screening logs. These include: when they should be used, what data should be collected, who should be included, and at what stage of the screening process. Furthermore, the potential for collecting this data through alternative methods remains largely unexplored.

Without clear guidance, published screening data will continue to be of variable quality, collected inconsistently and sometimes unnecessarily, and at the risk of considerable variation between sites recruiting to the same trial. Opportunities to understand recruitment bias and representation in trials may be lost. Improvements in practice could save time and resource, improve recruitment and make research findings more relevant.

The Screening Log Guidelines project (SLoG), funded by the National Institute for Health and Care Research (NIHR135423) [7], conducted a study into current practices, decisions, and opinions related to screening data collection and publication. This involved surveying a range of stakeholders and exploring digital and novel data collection methods, with the goal of producing screening log guidelines.

We hope this work will foster further discussion on screening data, including the drivers behind publication of this data, the methods, rationale and optimal timing for its collection, its quality and assessment, maximizing its potential applications.

METHODS

Literature reviews

General searches (“Literature review 1”) were conducted prior to receiving funding for this project (April 2021), and updated April 2024. PubMed and other databases were searched using keywords such as “screening log” to obtain a list of relevant publications. These broadly fell into two categories; methodology of screening log use and examples of trials that have published and reviewed their screening data.

A literature review (March 2022) provided a snap-shot of current practice for individually randomised trials published between 2011 and 2020. This search focussed on publications reporting trial results (“Literature review 2”).

The Cochrane Library trial search facility was used to identify, for each year in the ten-year period 2011–2020, up to ten publications presenting results from individually randomised trials, aiming for five from UK-based trials, the remainder from non-UK trials (published in an English language journal). Search terms were “individually randomised controlled trials” in the all text box, for each publication year of interest. Meta-analyses, HTA monographs, conference abstracts, cost-effectiveness analyses, non-phase II/phase III trials and any trial described as pilot/feasibility were excluded. The following details were collected: whether a CONSORT diagram was included, whether a screening figure was included on the CONSORT and any details on how this figure was calculated, and whether screening logs were mentioned.

Surveys of current practice

Following the review of past screening log work, two surveys were designed aiming to explore current views and practice on screening data. Surveys (see Supplementary materials A and B) were developed by JH and SS, tested locally and revised following feedback. Patient and Public representatives were involved in the initial scoping work.

Ethical approval

from the University of East Anglia Faculty of Medicine and Health Sciences research ethics sub-committee (S-REC) was gained (ETH2122-0915) for this work.

Survey 1 was sent to those involved in the design/analysis of screening logs, we invited people to participate using networks such as the UK Clinical Research Collaboration (UKCRC), UK Trial Managers

Network (UKTMN) and Trials Methodology Research Partnership (TMRP), social media channels, and included both commercial and non-commercial sectors.

Survey 2 was sent to healthcare professionals (HCPs) and others who typically complete screening logs, using pre-consented mailing lists from existing trials and projects, local NHS Trust R&D departments and the NHS Research and Development Forum newsletter.

In both surveys a broad range of specialisms from responders was sought. Results were summarised where possible as frequency and percentage; free text responses were reviewed.

Delphi Method

We had planned to use focus groups in the development of screening log guidelines, however early feedback advised that the Delphi method would be more suitable.

A protocol (supplementary material C) was developed, alongside information sheets and consent forms. These were sent to those expressing an interest in further work, following the surveys and scoping exercises. Invitations were sent to those representing a broad range of job roles and geographic locations, and pre-determined rules decided who to include if there was over-representation from any group.

The aim of the Delphi rounds was “To reach consensus on statements and questions that will lead to the development of guidelines on the collection of screening data, that are relevant to a variety of trials at a national level and to develop a template screening log”.

A Steering Group was convened to facilitate Delphi rounds, agree when consensus was reached for items and consider dropping items from future rounds. The group agreed new wording as necessary or how to adapt or drop items with no consensus and agreed outcomes for qualitative items where consensus definition was difficult.

To mitigate against dropouts impacting the validity of the results, a £30 voucher for completion of all rounds was offered and 2 email reminders were sent.

Each Delphi item was rated from 1 (meaning total disagreement or unimportant) to 9 (complete agreement or extremely important). The meaning changed depending on the item wording and was made clear within each item. “Consensus in” was defined as an item scoring 7–9 by 70% or more panellists, and scoring 1–3 by fewer than 15% “consensus out” was defined as item scoring 1–3 by 70% or more, and 7–9 by fewer than 15% of panellists.

For each item in Round 1 we reported the percentage distribution of scores and summary statistics. Results were shared with the Steering Group. As a Delphi Survey is an iterative process, Round 2 was devised, excluding items achieving consensus (in or out) in Round 1, and retaining those for which consensus had not been achieved previously. Wording of some items was amended, and new items

were added. Descriptive statistics were sent to participants (written summaries or basic tables), with the participants' own score for each item. Results of excluded items for which consensus was achieved in Round 1 were also included in the summary for Round 2.

For qualitative questions and statements, such as definitions, where similar themes did not emerge after each round, the Steering Group agreed a decision based on the answers provided. This was provided to panellists and they were asked whether they agreed with the definitions.

The Steering Group concluded that a third round was not required.

Exploring other sources of screening data

Following survey feedback and discussions with a range of stakeholders, other sources of screening data were considered and the project team reviewed each for suitability and accessibility in providing screening data.

Development of draft guidelines

Delphi survey results were used to develop draft guidelines.

To inform the project, stakeholders in screening work were identified from a range of institutions, as well as NHS Ethics committees and policy makers such as the HRA. Public and patient involvement was sought via existing channels in the Norwich Clinical Trials Unit.

RESULTS

LITERATURE REVIEWS

Literature review 1 (the general review) identified 10 publications relating to trials publishing their screening data. One publication [2] published general considerations for use of screening logs and 9 publications were trial specific, although some of these [6, 8, 9] also drew general conclusions about the use of screening logs/screening methodology. The full list of papers is included in supplementary material D.

Table 1
Quoted findings from papers that published screening data

Findings of relevance from published screening data	Author
"Central collection of screening logs can identify reasons for patients declining trial participation and help monitor trial activity at sites; however, obtaining complete data can be challenging" and "The use of screening logs may not be appropriate for all trials and they should be carefully considered in relation to the associated workload"	[8] Lewis et al, 2020
"Screening logs at a recruiting site may underestimate the trial's target population and overestimate recruitment [...] This may affect the generalizability of the trial's reported findings."	[9] Sundaresan et al. 2014
"Although the rate of return of screen failure logs was high overall (95%) there were a considerable number of logs that were returned with 'no data to report' (23%)" and "The lack of a standardised definition of 'screened' and the challenges of collecting meaningful characteristics for patients who have not signed consent limits the ability to compare across studies and to assess generalizability and selection bias as intended".	[6] Elm et al. 2014

Taylor et al [10] considered the problem of screening log completion in 1984, by asking physicians (via a questionnaire) why they were not completing screening logs. The questionnaire achieved a 97% response rate and a variety of reasons for not offering the trial to eligible individuals. Many of the reasons remain today.

Literature review 2 (reported screening data in main trial publication) identified 91 publications published between 2011 and 2020 fulfilling the selection criteria: 44 (48.4%) UK only trials, the remainder being non-UK or trials which included UK sites. (89%) included a consort diagram, or reference to one, but only 40% included a precise definition of the top line number on the CONSORT diagram "assessed for eligibility".

Screening logs were mentioned for only three trials, either in the main publication or an associated document. A summary of our findings by publication year is presented in supplementary material E, a list of publications reviewed is available from the authors.

Hopewell et al. 2011 [11] completed a similar literature review, looking for "participant flow diagrams in published reports of randomised trials". The review was more comprehensive but not exclusive to investigating those reporting numbers screened and what that figure comprised. Results were similar to our findings, noting "81% reported overall number assessed for eligibility and 71% the number excluded prior to randomisation" [11].

SURVEYS OF CURRENT PRACTICE

Survey 1

Full results are provided in supplementary material A.

There were 113 responses (20th April 2022).

Demographics: The majority (80%) were affiliated with a UKCRC Clinical Trials Unit, and 75% of respondents had a role in Trial Management (or similar), 10% statisticians or data analysts and 4% in each of trial support, data management, QA monitoring and trial leader/director.

Most respondents felt that screening logs provide useful information (88%), but current use could be improved (84%).

Table 2
Do you think current use of screening logs could be improved? (A24 and B9)

I think the data could be obtained in different ways	No (%) of responses	No (%) of responses
	Survey 1	Survey 2 (HCPs)
	7 (6.2%)	4 (10.8%)
I use them but I wish we didn't need to	5 (4.4%)	4 (10.8%)
No I'm happy with the way they are used/they generate useful data	6 (5.3%)	2 (5.4%)
Yes I use them but they could be improved	95 (84.1%)	25 (67.6%)
I don't use them and don't see a need for them	0	1 (2.7%)
Not answered	0	1 (2.7%)

86% of respondents always use a screening log in trials, with a variety of situations given for not doing so.

Among trial staff who felt screening logs could be improved, multiple ways in which they were not helpful were selected, including not seen as a priority (64.2%) and not clear why screening data is important (57.9%) (Table 3).

Of those using a screening log for phase 2 or 3 trials, or all trials, 52% design the log themselves and 25% sometimes design it, suggesting little consistency but scope to be trial-specific. Respondents often don't require logs to be reviewed or tested before use (41% sought no approvals at all, 25% sometimes and 47% did not ask others to test it, 32% only sometimes). However 59% of all respondents (S1) said their organisation has a template screening log (9% were not sure and 32% do not). Of those in an organisation that has a template log, or were not sure (n = 77), 68% use the same template for all trials but only 3% said they were not permitted to adapt it; additionally only 17% felt that data collected was of high quality (if a template screening log used), with a further 73% responding high quality "sometimes" (S1).

Trial staff recognise that screening logs are often not used consistently if they provide a template to recruiting sites. Most common reasons for this; lack of time or resource, and misinterpreting who to record on the log including variation in the definition of “screened”/“pre-screened”. Other themes included lack of training, local policy or forgetting to complete it. (S1)

Table 3

If you think screening logs could be improved, why do you think they are sometimes not helpful?
(multiple answers permitted)

Not properly funded data collection ie: lots of funding models pay per recruit randomised, not per person screened	No (%) of responses	No (%) of responses
	Survey 1	Survey 2 (HCPs)
	47 (49.5%)	19 (76.0%)
Poorly designed	42 (44.2%)	8 (32.0%)
Not seen as important or a priority	61 (64.2%)	7 (28.0%)
Not made clear why the data is important	55 (57.9%)	11 (44.0%)
Site perceive it only as a tool to review how many participants they have “missed” (Survey 1) or only used by the sponsor to assess targets (Survey 2)	48 (50.5%)	11 (44.0%)

Another common theme in around half the free text comments was inconsistent use driving poor data quality. This could be considered along with “poor design” but it may also be related to all the other factors in Table 3. A respondent commented “Research staff do not always have access to the data required for the logs”, this is a further factor that needs consideration.

There is variation in the way screening data is recorded and returned to those who are analysing it (A17, A18, supplement A), this process would benefit from further research. Many said obtaining screening data can be challenging and is resource heavy both on site and trial management staff, with one responder commenting “sites do not always comply”.

Some offer a choice of paper or electronic versions (35%), though increasingly the trial database is used for this purpose and many acknowledged the benefits if collected this way in future.

69% of Survey 1 responders reported providing instructions; given the concerns about who is put on a screening log there is a need for logs to be accompanied by detailed instructions.

A key consideration is what to record on screening logs. Table 4 shows the responses from each survey. The project group reflected that the way these questions were asked may have led to inconclusive results, therefore these results were explored further in the Delphi rounds.

Table 4
What anonymised data do you think should be collected /reported?

What anonymised data do you think should be collected /reported? For this question please keep in mind that we mean data collected prior to consent, which would be separate from any identifiable data the site requires to manage their local screening process.¹		
	No (%) of responses	No (%) of responses
	Survey 1	Survey 2 (HCPs)
<i>Age</i>		
Collect this information already	56 (49.6%)	NA ⁴
Should be collected	25 (22.1%)	21 (56.8%)
Not answered	32 (28.3%)	16 (43.2%)
<i>Sex</i>		
Collect this information already	49 (43.4%)	NA
Should be collected	29 (25.7%)	16 (43.2%)
Not answered	35 (31.0%)	21 (56.8%)
<i>Ethnicity</i>		
Collect this information already	19 (16.8%)	NA
Should be collected	52 (46.0%)	5 (13.5%)
Not answered	42 (37.2%)	32 (86.5%)
<i>Co-morbidities</i>		
Collect this information already	NA	NA
Should be collected	NA	21 (56.8%)
Not answered	NA	16 (43.2%)
<i>Consent to trial²</i>		
Collect this information already	87 (77.0%)	NA
Should be collected	18 (15.9%)	30 (81.1%)
Not answered	8 (7.1%)	7 (18.9%)
<i>If not consented, reason for non eligibility or reason declined³</i>		
Collect this information already	91 (80.5%)	NA

What anonymised data do you think should be collected /reported? For this question please keep in mind that we mean data collected prior to consent, which would be separate from any identifiable data the site requires to manage their local screening process.¹		
	No (%) of responses	No (%) of responses
	Survey 1	Survey 2 (HCPs)
Should be collected	18 (15.9%)	27 (73.0%)
Not answered	4 (3.5%)	10 (27.0%)
<i>Prohibited concomitant medications that the participant is taking (for the specific trial)</i>		
Should be collected	NA	22 (59.5%)
Not answered	NA	15 (40.5%)
<i>Exclusion criteria tick -box</i>		
Should be collected	NA	31 (83.8%)
Not answered	NA	6 (16.2%)
¹ Wording for Survey 2 respondents differed slightly: “Which of these do you consider are valid things to collect prior to consent?”		
² Wording for Survey 2: Consent status (did or did not proceed to trial)		
³ Wording for Survey 2: Reason if consent declined		
⁴ NA – question not asked		
Note: Healthcare professionals and those collecting data were not asked about information collected already, just whether they think this information should be collected. It is likely that the way these questions were answered varied slightly between each survey. Eg: Some Survey 1 staff chose “collect already” OR “should be collected” when they had the option to say both.		

68% (n = 75) routinely include screening data when publishing trial results. The main reasons for not publishing it were when it’s only used to assess recruitment, and concerns over poor data quality. One responder stated “CIs often don’t see the value of screening data as it can be unreliable. For a previous phase II CTIMP we only reported from consent onwards in the CONSORT diagram”.

A common theme when designing this project was the disagreement between site (healthcare staff) and trial management staff over why the data is collected. Site staff were more likely to consider screening logs as a tool to assess work done to identify participants. Trial Management staff agree the logs can be used for that purpose, but their top reason for using screening logs was “to look at reasons why people are being excluded” (98.2%).

Question A32 (supplementary material A) asked respondents to comment on screening logs in general. Many supported further work into their use and agreed that a more standardised approach is required.

Survey 2

37 responses were received (April 2022) from: nurses (51%), NHS office-based staff (19%), other clinical research roles (16%), doctors (11%) and other HCPs (3%).

Most respondents (86%) reported that screening data were requested in at least 50% of trials they worked on.

68% used screening logs but felt that the process could be improved.

HCPs find the data fairly burdensome to collect and only 5% are happy with current screening log use (see Table 1), so other approaches would be welcomed by healthcare staff.

Many healthcare providers keep separate logs of screening data (43.2%, B4), so streamlining the process could lead to efficiencies. This was also a major theme in comments from this survey, concluding current processes are repetitive and time consuming.

One respondent commented “we are not consistent in the data we collect, so currently not useful. if the processes were the same for each project this would save time and enable much more clean data”.

Standardisation, collecting less detail and reducing burden were also the most common themes to the question “how do you think screening logs could be improved?”

Cost was also raised as a barrier, this data collection is not currently costed as part of research and is another disincentive to its collection.

DELPHI

Interest in the Delphi survey was expressed by 44 trial personnel, HCPs or stakeholders, of whom 30 consented to participate.

Round one of the Delphi survey was circulated on 14th October 2022 to those consenting, with a closing date of Friday 4th November 2022. 26 responses to the round were received by the deadline. Following review by the Steering Group in which statements were removed, amended or added. The second round of the Delphi survey was circulated on 8th December 2022 to participants who had responded to the first round on or before the round one deadline, with a deadline of 6th January 2023; in addition participants were sent a summary of their responses to the first round of the survey. 23 participants responded to the second round of the Delphi Survey.

Full results of both Delphi rounds are shown in Supplementary material F, a summary of some key results are shown here.

Table 5

Summary of occupational roles and response rates of respondents Respondents were asked to rate 59 items relating to screening logs in round 1 of the survey, and 22 items in round 2. Items were sub-divided into categories, for ease of completion. Categories and number of items in each, for both Rounds are listed (Table 6).

Sent (n)	Consent	Round 1	Round 2
	44	30	26
Responded in time (n)	30	26	23
Responded, out of time	0	1	0
Did not respond	14	3	3
Respondent Roles			
HCPs	7 (23.3%)	5 (19.2%)	4 (17.4%)
NHS R&D	1 (3.3%)	1 (3.9%)	1 (4.4%)
Trial management staff	9 (30.0%)	9 (34.6%)	8 (34.8%)
Statistician	6 (20.0%)	4 (15.4%)	4 (17.4%)
Data Management	2 (6.7%)	2 (7.7%)	2 (8.7%)
National policy group	1 (3.3%)	1 (3.9%)	1 (4.4%)
Other role	4 (13.3%)	4 (15.4%)	3 (13.0%)

Table 6
Categories and numbers of items in each Delphi round

Category	Number of items	
	Round 1	Round 2
Definition of a screening log	3	2
Who to record on a screening log	12	7
Assessing the important of a screening log in different situations	12	2
Concerns re absence of screening data	4	-
Consort diagrams	-	2
Alternative sources of screening data	3	2
Information to record on a screening log	9	5
Inclusion in screening log: Example A	4	-
Inclusion in screening log: Example B	4	-
Frequency of return of screening logs	5	-
Other items about screening logs	3	2
Total	59	22

Participants were first presented with our proposed definition of a screening log:

A record of all people assessed by a site for inclusion in medical research

Participants were asked whether this i) was a suitable definition; ii) was suitable for a broad range of trial types involving human participants and iii) clearly identified the people who need to be listed on the log. Consensus was not obtained, free-text comments suggested the definition was “vague”, and greater clarity concerning “assessed” was required. (Supplementary Material, F1).

The definition of a screening log was modified for Round 2 as:

A list of potential participants and their screening outcomes, assessed using eligibility criteria as per study protocol

The revision achieved consensus.

Participants were asked to decide whether persons described in twelve scenarios (Supplement, F3) and seven scenarios (Supplement, F25) should be recorded on a trial screening log. The only items achieving consensus for recording on a trial screening log in Round 1 were: “potentially eligible person....given an

information sheet”, “person attends a specific “trial screening visit” and “person signs consent form but when further assessed is found to be ineligible”.

Delphi respondents were asked to assess the importance of a screening log in twelve situations (Supplement, F5) achieving consensus/almost consensus for nine of these in Round 1 and after amendments 2 further situations achieved consensus in Round 2.

Rounds 1 and 2 considered alternative sources of screening data. Consensus was not achieved on any item in either round (Supplement, F10, F12, F30).

Round 1 asked participants whether items such as sex, age in years, year of birth, ethnicity, overall eligibility, individual inclusion/exclusion criteria, willingness to consent, reason for declining participation, were of sufficient importance to be included on a screening log, and to indicate whether each should be considered as identifiable information. Consensus for the importance of the following to be recorded was achieved: individual inclusion/exclusion criteria, willingness to consent and reason for declining participation, but not for any demographic items. (Supplement F13).

For the items not achieving consensus, the introduction to this section of the survey was amended in Round 2 specifying that ethical approval would be gained to hold this information without consent, and the log could be adapted if storing such detail could result in identification of an individual. Respondents achieved consensus that sex, age in years (but not year of birth), ethnicity and overall eligibility were items critical for inclusion on a screening log (Supplement, F32) and this followed the same trends from the surveys.

Suggestions such as monthly returns, more frequent returns during the early stages of a trial or targeting poorly recruiting sites for more frequent return of screening logs did not achieve consensus. Respondents were in agreement that frequency of return of screening log data is trial specific (Supplement, F18).

DEVELOPMENT OF SCREENING LOG GUIDELINES

The results of our Delphi Survey Rounds were used to inform the development of draft Screening Log Guidelines (Supplementary material G, separate document).

EXPLORING OTHER SOURCES OF SCREENING DATA

Encouragingly, some respondents already collect screening data from other sources, but less than half.

Table 7

Do you collect equivalent data from other sources? (*Eg registries/HES or directly reported via the hospital's internal data system*) (Supplement, A9)

Do you collect equivalent data from other sources?	No (%) of responses
No	79 (69.9%)
Sometimes	23 (20.4%)
Yes	11 (9.7%)

Comments in Survey 1 were in support of exploring this, agreeing that it could be more efficient in time and money and lead to more robust data.

See supplementary data F10, Delphi round 1 was fairly evenly split for and against collecting screening data in other ways and neither round reached consensus (see F30, F31).

The project team reviewed the suitability of various existing health and social care datasets for collection of screening data with the following results:

Table 8
Summary of datasets reviewed for collection of screening data

Name	Details
NHS Digitrials Feasibility Service	https://digital.nhs.uk/services/nhs-digitrials “Works out if there are enough suitable people in England to take part in a particular trial but does not identify individuals”.
HES* - Hospital Episode Statistics from NHS Digital	https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics “Details about admissions, outpatient appointments and historical A&E attendances at NHS hospitals in England”.
CPRD* - Clinical Practice Research Datalink	https://cprd.com/ “Collects anonymised patient data from a network of GP practices across the UK”
ICNARC – Intensive Care National Audit and Research Centre	https://www.icnarc.org/ Specifically intensive care patients
NCIN – National Cancer Data Repository	http://www.ncin.org.uk/collecting_and_using_data/national_cancer_data_repository/ Specifically cancer patients
NDRS – National Disease Registration Service	https://digital.nhs.uk/services/national-disease-registration-service
NHFD – National Hip Fracture Database	https://www.nhfd.co.uk/ Specifically hip fracture patients
*Can be accessed as part of NHS Digitrials service	

DISCUSSION

Screening logs are widely used and there is a clear need for the data they can provide, but the way data is collected needs improving.

There was some variation in what is considered important in screening data use and collection methods, but overall consensus was reached that this is valuable data.

Further research into more efficient collection of the data is needed but this is an emerging area of interest and is likely to change as electronic data collection and availability increases. Where the same data can be collected from other sources, site level data collection should be avoided. Collection of

screening data and the challenges therein is not new [10], collection techniques have changed little in 40 years yet demand for what it could show (bias, generalizability of results etc) is appropriately increasing.

Collecting screening data is time consuming and that time is rarely funded or considered, this has a direct impact on quality and attitude towards the data collection. If funders consider the data important this should be reflected in trial costs.

More quality control is needed and greater awareness raised of the issues and pressure to publish data that has had less scrutiny than other trial data points. In a multicentre trial, a consistent definition of who to record on the screening log must be followed if total “number screened” is to be reported. This definition requires agreement by a multidisciplinary team for each trial, but this work concluded that people “approached” is a good place to start and less ambiguous than other definitions such as “number assessed”. Inherent bias was noted as a reason for not using the definition “assessed” and such biases have been noted historically and would benefit from further qualitative work.

Declarations

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval from the University of East Anglia Faculty of Medicine and Health Sciences research ethics sub-committee (S-REC) was gained (ETH2122-0915) for this work.

CONSENT FOR PUBLICATION

Not applicable

COMPETING INTERESTS

The authors have no interests to declare.

FUNDING

This project was funded by the National Institute for Health Research (NIHR) CTU Support Funding scheme. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

AUTHOR CONTRIBUTIONS

Juliet High: Conceptualisation, methodology, validation, investigation, data curation, writing- original draft, writing- review and editing, visualisation, supervision, project administration, funding acquisition.
Susan Stirling: Conceptualisation, methodology, validation, investigation, data curation, formal analysis,

writing- review and editing, visualisation, supervision, project administration, funding acquisition.
Matthew Hammond: Conceptualisation, writing- review and editing, supervision, project administration, funding acquisition.

ACKNOWLEDGEMENTS

The authors are very grateful to the following for their contribution, time and efforts in ensuring the success of this project: UKCRC, HTA, UKTMN, INHALE PPI panel (the INHALE trial, ISRCTN16483855 and <https://norwichctu.uea.ac.uk/inhale/>).

We would like to thank the following staff members of Norwich CTU for their help with this project: Polly-Anna Ashford and Erika Sims (routinely collected data); Erica Berardi and Martin Pond (REDCap database programming); Tom Conway (survey programming, literature search, Delphi steering group member); Jean Craig (literature review); Thando Katangwe-Chigamba (Delphi Survey methodology; Delphi steering group member) ; Stacey Smeaton-Small (literature search)

The authors would like to thank all trial personnel and health care professionals who participated in our surveys and/or Delphi rounds, most of whom are listed and some requested to remain anonymous:

AVAILABILITY OF DATA AND MATERIALS

The data underlying this article are included in the supplementary information will be shared on reasonable request to the corresponding author.

References

1. Medicines and Healthcare Products Regulatory Agency (2012) Good Clinical Practice guide. TSO, Norwich
2. Wilson C, Rooshenas L, Paramasivan S et al (2018) Development of a framework to improve the process of recruitment to randomised controlled trials (RCTs): the SEAR (Screened, Eligible, Approached, Randomised) framework. *Trials* 19:50. <https://doi.org/10.1186/s13063-017-2413-6>
3. Donovan JL, Rooshenas L, Jepson M et al (2016) Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI). *Trials* 17:283. <https://doi.org/10.1186/s13063-016-1391-4>
4. Butcher NJ, Monsour A, Mew EJ et al (2022) Guidelines for Reporting Outcomes in Trial Reports: The CONSORT-Outcomes 2022 Extension. *JAMA* 328(22):2252–2264. 10.1001/jama.2022.21022
5. Hopewell S, Chan AW, Collins GS et al (2025) CONSORT 2025 Statement: Updated Guideline for Reporting Randomized Trials. *JAMA*. Apr 14. 10.1001/jama.2025.4347. Epub ahead of print. PMID: 40228499

6. Elm JJ, Palesch Y, Easton JD et al (2014) Screen failure data in clinical trials: Are screening logs worth it? Clin Trails 11(4):467–472. 10.1177/1740774514538706
7. <https://fundingawards.nihr.ac.uk/award/NIHR135423>
8. Lewis R, Todd R, Newton M et al (2020) The implementation and utility of patient screening logs in a multicentre randomised controlled oncology trial. Trials 21:629. <https://doi.org/10.1186/s13063-020-04559-w>
9. Sundaresan P, Turner S, Kneebone A et al (2014) Do Screening Trial Recruitment Logs Accurately Reflect the Eligibility Criteria of a Given Clinical Trial? Early Lessons from the RAVES 0803 Trial, Clinical Oncology. 26(6):348–352. <https://doi.org/10.1016/j.clon.2014.02.012>
10. Taylor KM, Margolese RG, Soskolne CL (1984) Physicians' reasons for not entering eligible patients in a randomized clinical trial of surgery for breast cancer. N Engl J Med. ;310(21):1363-7. 10.1056/NEJM198405243102106 PMID: 6717508
11. Hopewell S, Hirst A, Collins GS et al (2011) Reporting of participant flow diagrams in published reports of randomized trials. Trials 12:253. <https://doi.org/10.1186/1745-6215-12-253>

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Supplement1forSLoGpublicationFinalv1.002.05.25.docx](#)
- [Supplementary2SLoGGuidelinesv1.0FINAL.docx](#)