

Screening LOg Guidelines (SLOG): A standardised model for screening data: who should be included and which data should be collected?

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1. Title of Project

Screening LOg Guidelines (SLOG): A standardised model for screening data: who should be included and which data should be collected?

2. Abstract

The reporting of trials in health or social care research, involving participants, includes the number of participants assessed for inclusion into the trial. Such information is traditionally referred to as “screening data”. The CONSORT group¹ recommend that the number of people assessed for inclusion in a trial should be reported, but there is little guidance on what to record on screening logs, nor who to include on such a log.

With the requirement for unambiguous and prompt reporting of trial data, sites may be stretched to also address the recording of screening information. Without uniform guidance, the data obtained from screening logs may be inconsistent, and possibly misleading.

In some trials it may be possible to obtain more complete and representative data on potential participants from registries and / or NHS databases. In these trials the burden of recording trial screening data could be removed from trial sites. This project reviewed reporting of screening data in a selection of trials published during a recent ten year period. Surveys were used to collect information and opinion on current use of screening logs and data from trial personnel and health care professionals, a screening log template with user guidelines was defined and refined with input from a variety of stakeholders using Delphi Survey Rounds.

Guidelines and template are available <https://norwichctu.uea.ac.uk/slog/>.

3. Introduction

Reporting of trials in health and social care research involving participants typically includes information on participants assessed for inclusion into the study. Such information is usually referred to as “screening data” and is recorded on a “screening log”.

The Good Clinical Practice (GCP) guide² suggests reviewing screening logs to identify barriers to recruitment relating to inclusion or exclusion criteria. The CONSORT group recommend that participant flow (the numbers of participants who progress through the research study) should be included when reporting a Randomised Controlled Trial (RCT), and “if available, the number of people assessed for eligibility should also be reported”. The reporting of screening data is

also “a useful indicator of whether trial participants were likely to be representative of all eligible participants”³.

The SEAR framework (Screened, Eligible, Approached, Randomised)⁴ was developed to “document, understand, and improve the process of trial recruitment”.

However there is little consensus on what data should be collected on screening logs, nor at which point during the screening of potential participants should they be recorded on these logs.

Data collected on screening logs are typically limited to basic non-identifiable information such as sex, date approached, and, where applicable, reasons for non-inclusion. As the majority of these data are collected without consent, the recording of personally identifiable data is avoided. However in future there may be justification for the collection of additional data, such as ethnicity, to address concerns about inclusivity and / or generalisability of trial results.

Furthermore, in practice the completion of screening logs often varies between trials (even within the same CTU). Variation can also occur between sites undertaking the same trial. For example, without clear guidance some sites may incorrectly include every participant within a clinic (even those clearly ineligible for the study) whereas other sites may only include those participants handed a participant information sheet. There is no clear mechanism for the reimbursement of sites for time spent completing screening logs and it is unclear through the Attributing the cost of health and social care Research & Development (AcoRD) guidelines as to whether this is a research or service support associated cost.

Without uniform guidance, the data obtained from screening logs may be at best inconsistent, and even potentially misleading. This can have consequences as Trial Teams, Trial Management Groups and oversight committees rely on information obtained from screening logs when reviewing feasibility of recruitment during the trial. Inconsistent screening data also impact on the reporting of trials and could result in misleading CONSORT diagrams.

Finally, as increasing numbers of trials utilise routine data sets and existing data, there may be an opportunity to rethink how screening data are collected. Rather than relying on site staff completing a screening log, it may be possible to obtain more complete and representative data on potential participants from registries and / or NHS databases. If this were possible, then for some trials the burden of collecting and recording screening data would be removed from trial sites.

Screening data are clearly of great importance to clinical trial delivery but there remains very little guidance to underpin the quality, consistency or integrity of the information collected.

This work reviewed reporting of screening data in a selection of published trials. Surveys were used, to collect information and opinion from trial personnel and health care professionals on aspects of screening data collection, and to prepare a screening log template with user guidelines with input from trial personnel, health care professionals and stakeholders.

4. Methods

Ethics approval for the SLoG project was obtained from the University of East Anglia, Faculty of Medicine and Health Sciences “S-REC” Research ethics committee.

4.1 Literature review

We conducted a literature review to provide a snap-shot of the reporting of screening log data current practice for individually randomised trials published between 2011 and 2020. Using the Cochrane Library trial search facility we aimed to identify, for each year in the ten year period, ten publications presenting trial results, five from UK-based trials, the remainder from non-UK trials (published in an English language journal). Full details of the search strategy will be included in a planned peer-reviewed publication.

4.2 Survey 1: staff involved with design, management & analysis of trials

We surveyed staff with experience of screening logs, through their work in managing, analysing or supporting recruitment in clinical trials, to gain knowledge of opinion, and current trends in usage of screening logs.

4.3 Survey 2: health care professionals involved in collection & recording of screening data

We also surveyed clinical staff who use, or are impacted by, screening logs in the collection of trial data.

4.4 Delphi Survey

We conducted an online two-round (with the option of a third round) Delphi survey in an attempt to reach consensus on statements and questions for guidelines on the use of screening logs, and collection of screening data. Delphi participants comprised a broad range of stakeholders and we ensured that no roles or job types were over-represented. Participants expressed an interest following completion of either of the surveys detailed in 4.2 or 4.3, or contacted the SLoG team via our social media requests and articles in national trial group newsletters, websites, emails and forums, such as UKCRC, UKTMN, NHS R&D Forum, TMRP and PPI groups or our presentation of the SLoG project at the 2022 International Clinical Trials Methodology Conference, Harrogate.

5. Results and Conclusion

A summary of results is provided here, and full results will be published and made available upon request.

5.1 Results

Literature Review

In our literature review we identified 91 publications published between 2011 and 2020 fulfilling our selection criteria, representing 44 (48.4%) UK only trials, the

remainder were non-UK or trials which included UK sites. The majority 81 (89%) included a consort diagram, or reference to one, but crucially only 36 (40%) included a precise definition of the top line number on the CONSORT diagram “assessed for eligibility”.

Survey 1

The survey of staff working in the management, analysis or support of recruitment in clinical trials yielded 113 responses, up to 20th April 2022. Of the respondents, 80% were affiliated with a UKCRC registered Clinical Trials Unit; the remainder were based in university/public sector trials units (10%), NHS research departments (5%), non-registered academic CTU (4%) & industry/CRO (1%). Three quarters of respondents had a role in Trial Management (or similar), a further 10% identified as statisticians or data analysts; the remainder reported roles in trial support (4%), data management (4%), QA monitoring (4%) or trial leader/director (4%). The majority of respondents felt that screening logs provide useful information on trials (88%), but that current use of screening logs could be improved (84%).

Survey 2

Our survey of health care professionals working on clinical trials resulted in 37 responses from nurses (51%), NHS office-based staff (19%), other clinical research roles (16%), doctors (11%) & other HCPs (3%). The majority of respondents (85%) reported that screening data were requested in at least 50% of trials they worked on. Two thirds (68%) used screening logs but felt that the process could be improved.

Delphi Survey

Interest in involvement in the Delphi survey was expressed by 44, trial personnel, health care professionals or stakeholders, of whom 30 consented to participate. We wrote a participant information sheet to accompany the survey, comprising brief details on how a Delphi study operates, in addition to rules of participation, confidentiality statement and contact details. We circulated round one of the Delphi survey on 14th October 2022 to those consenting, with a closing date of Friday 4th November 2022. There were 26 responses to the first round of the Delphi Survey by the given deadline. The SLoG Delphi steering committee discussed responses to the first round of the survey, we excluded from the second survey statements for which consensus had been achieved, and either repeated or amended those statements for which consensus had not been achieved. We also added new statements where relevant, to better understand the first round results. We sent the second round of the Delphi survey on 8th December 2022 to participants who had responded to the first round of the survey on or before the deadline. As with the first round, reminders were sent to recipients of the second round, to respond on or before the 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. The SLoG Delphi Steering Committee met to discuss the second round of results 24th January 2023 and agreed that a third round of the Delphi Survey would not be required.

5.2 Conclusions

A draft of the guidelines has been written; the next stage will be to test them and invite broader review through their initial use, with further refinements in a second iteration.

We have attempted to raise awareness of our work as broadly as possible and within the limitations of the grant and time available. Throughout the process and during dissemination we have continued to receive more interest and are planning further collaborative work.

6. Dissemination

6.1 Presentation at Harrogate

Susan Stirling gave a 10 minute presentation focussing on the two SLoG surveys of trial personnel at the 6th International Clinical Trials Methodology Conference, Harrogate, UK, 3 – 6th October 2022

6.2 Presentation at Baltimore

Juliet High gave a 10 minute presentation of the SLoG project, including the development of screening log guidelines, at the 44th Annual Meeting of the Society for Clinical Trials, Baltimore, MD, USA, 21st – 24th May 2023.

6.3 Guidelines and Publications

The main output from this research is the Screening Log Guidelines and template log. These will be available to download from the CTU website here: <https://norwichctu.uea.ac.uk/slog/>. We also plan to make them available in other repositories along with the survey data and these will all be available upon request to the project team.

We are preparing a manuscript for an open access journal that will contain more details about the results. The Guidelines will focus on the findings.

7. Acknowledgements

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Contribution of Authors

Matt Hammond – Deputy Director, Norwich CTU, developed the grant application; wrote and reviewed final report and Guidelines, Chair of Delphi Steering group.

Juliet High, Research Lead – CTIMPS (Medicines) and Medical Devices, Norwich CTU, developed the grant application; applied for ethical approval, led the surveys of trial personnel and health care professionals; developed the Delphi Survey, Delphi Steering group member; wrote and reviewed final report and Guidelines.

Susan Stirling – Trial Statistician, Norwich CTU, developed the grant application; led the literature review; produced tables of results of surveys of trial personnel and health care professionals; produced reports of the two rounds of Delphi Surveys, Delphi Steering group member; wrote and reviewed final report and Guidelines.

8. References

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4. Wilson C, Rooshenas L, Paramisasivan S, Elliott D, Jepson M et al. Development of a framework to improve the process of recruitment to randomised controlled trials (RCTs): the SEAR (Screened, Eligible, Approached, Randomised) framework. *Trials*. 2018; 19: 50

9. Appendices

10. Conflict of interest declaration

The authors have no conflicts of interest to declare