INPLASY's guidance for registering systematic review protocols (2022)

1. Introduction

Registering a systematic review protocol is considered crucially important to improve the transparency, quality and reduce duplication of systematic reviews.[1, 2] The protocol defines the scope and the methods that will be applied to conduct the review, providing the ability for authors to track what studies are taking place.[3] The most popular way to publicly a systematic review protocol is to register it in PROSPERO[4]. However, the popularity of PROSPERO as well as the rapid increase in the number of systematic reviews in the last 10 years, cause an unprecedented number of protocols submitted to PROSPERO. Consequently, a major delay in registrations was reported before the COVID-19 pandemic period. Puljak[5] reported waiting for more than six months to have a protocol published on the PROSPERO website.

In addition to the PROSPERO, other available methods to register systematic review protocols include the Cochrane Reviews, Joanna Briggs Institute, or the Campbell Collaboration, which provide quality assurance and many other benefits for accepted protocols.[6] However, these methods are very restricted, and only a small number of selected protocols can be registered with them. Additionally, these organisations produce only a minority of all published systematic reviews.[7]

INPLASY is an international platform of registered systematic review and meta-analysis protocols launched in March 2020.[8] Protocols registration in INPLASY increased rapidly, reaching on May 2022 more than 3300 records from 45 countries.

INPLASY accepts systematic review protocols of **interventions**, **diagnostic accuracy**, **prognostic factors**, **epidemiological characteristics**, **preclinical studies**, and **etc**. Additionally, systematic reviews assessing **sports performance** as an outcome also be accepted.

To avoid duplication effort, it is important to identify evidence syntheses that already exist and ongoing systematic reviews before starting a new project. Although registration on PROSPERO was the first available method, a single platform cannot register all systematic review protocols developed around the world. Solla et al.[9] showed that even PROSPERO registration does not prevent double review registration on the same topic. Thus, the authors are responsible for searching ongoing systematic reviews that are in the pipeline before submitting their protocols. COVID-END[10], a time-limited network group formed by more than 50 of the world's leading evidence-synthesis, indicated that before starting a new COVID-19 evidence-synthesis project, the researchers should seek ongoing reviews not only on PROSPERO, but on INPLASY, National Collaborating Centre, Centre for evidence Based Medicine, and VA Evidence Synthesis Program.[11]

One important aspect takes into account is that PROSPERO is funded by the National Institute for Health Research (NIHR). Therefore, all registrations from the UK are prioritized during the editorial process. **INPLASY database is not funded by any University, Institute, or Government agency, and all available sources of funds to support the platform are derived from the publication fees paid for the authors after protocol submission**. INPLASY does not prioritize protocols from any country, providing the same waiting time for all researchers, regardless of their nationality. Additionally, INPLASY protocols are published within 48h, reducing the time interval during which the public is unaware of this pending registration. This approach has a high potential to reduce duplication of effort once the longer the time interval, the greater the chances of duplicated protocols exist.

This report aims to describe a comprehensive list of items for systematic review protocol registration on INPLASY database, providing detailed descriptions for all required items. INPLASY develops the following guideline based on the most important recommendations reported in the scientific literature for protocol registration.[4, 12-17] The guideline will benefit authors of systematic reviews allowing accurate protocol registration. Ultimately, our recommendations report the standard items for developing systematic review protocols guiding peer-reviewers to evaluate submitted systematic review protocols in peer-reviewed journals.

2. What types of studies are accepted on the INPLASY?

INPLASY accepts systematic review protocols assessing interventions, prognostic factors, diagnostic accuracy, methodological reviews, epidemiological reviews, and systematic reviews of animal studies. Additionally, **INPLASY accepts systematic reviews assessing sports performance as an outcome**, methodological reviews that evaluate the quality of reporting, pedagogical reviews, and **scoping reviews**. Although **it is possible to register protocols retrospectively on INPLASY**, we do not recommend retrospective registration unless the authors explain the reasons that

prevented prospective registration. **ATTENTION: Some Peer-reviewed Journals could not accept protocols registered retrospectively.**

3. Requirements for registration

Registration form must be filled in English;
Publication fees should be paid after the submission;
Mandatory fields must be filled;
Authors must identify existing and ongoing reviews to avoid duplication of efforts.

4. Guide to completing a protocol registration

The following items provide guidance to authors for the preparation of systematic review protocols on the INPLASY register. Please, state ‘not applicable’ or ‘none' when the fields are not appropriated to your methodology design.

Item 1 - Title

The title should be as informative as possible and describe the main content of the review regarding the types of participants, types of interventions, the types of comparators, and the outcomes. Usually, titles do not include outcomes, although these can be included in some situations, for example, when the review will focus on the intervention's effectiveness. The sentences "protocol for a systematic review" or "systematic review protocol" should be included in the protocol title because it may improve protocol identification and retrieval. Additionally, the planned quantitative analysis should be included in the protocol title. The inclusion of terms, such as meta-analysis, network meta-analysis, individual participants data, and meta-analysis, can help readers understand how the evidence will be synthesized in the systematic review. Finally, if you will conduct an update of a previous systematic review, it should be clearly described in the protocol title.
Titles examples for
Interventions: "[Intervention A] versus [Intervention B] for [health problem] in [type of patients]: A protocol for a systematic review"
Diagnostic Test Accuracy: "Diagnostic test accuracy of [type of test] used to [diagnostic field] in [type of patients]: a systematic review protocol"
Prognostic: Prognostic value of [the variable associated with the risk of a subsequent health condition] in [particular health condition]: a systematic review protocol"

Note: Titles should be written in sentence case (capitalize only the first word of the title, and any proper nouns and genus names).

Item 2 - Corresponding author

The corresponding author is the guarantor for the accuracy and integrity of the information. Frequently, this author is responsible for conducting the review team, maintaining the protocol updated, and developing the review. They should provide the following additional information to facilitate their identification: email address, ORCID number, and institutional affiliation.

Item 3 - Support

Authors must report all financial support or sponsor in the protocol stage. Readers of a systematic review occasionally need to reflect on whether conflicts of interest have influenced the study and support information that can disclosure some potentials conflicts of interest.

Item 4 - Review Stage

This item refers to the stage of review progress at the time of registration. Although **it is possible to register protocols retrospectively on INPLASY**, we do not recommend retrospective registration unless the authors explain in detail the reasons that prevented prospective registration. We believe that prospective registration promotes transparency and helps decrease the potential for bias. The review stage options are: 1) The review has not yet started; 2) Preliminary searches; 3) Piloting of the study selection process; 4) Formal screening of search results against eligibility criteria; 5) Data extraction; 6) Risk of bias assessment; 7) Data analysis; 8) Other. For retrospective registration, authors must choose option eight and justify why the protocol was not registered prospectively.

Item 5 - Organisational affiliation of the systematic review

The organisational affiliation should reflect the organisation or institution where the more significant portion of the research will take place. Usually, the first author's affiliation is informed in this item. If more than one organisational is involved in the study, authors can add the second affiliation's name in item 27 (Other relevant information). Affiliations will be published as they appear in the submission form. Do not include Postal Codes, street addresses, or building numbers.
INPLASY recommendation: Authors should include the following information in item 5: (Department, Division, Section, Institution, City, State, Country) and do not use abbreviations (e.g. Dept.).

Item 6 - Conflicts of interest

The existence of a potential conflict of interest may affect the research integrity. Competing interests include financial and non-financial competing interests, such as personal, academic, political, or religious. Many researchers fail to declare a conflict of interest because they are confident that the conflict has not caused them to conduct the review in a different way. We would encourage authors to disclose any potential source of conflicts of interest that might unduly influence judgments made in the review.

Item 7 - Phone number

The phone number is an optional item. If added, the phone number must include the country and area codes.

Item 8 - Review question/ objective

A well-documented protocol begins with a well-formulated question that will guide many aspects of the review process, such as eligibility criteria and searching strategy. Authors should define in advance the objectives of the review, which can often be encapsulated by the PICO mnemonic (Population, Intervention, Comparison, and Outcome). The review question can be presented in the protocol and refined as other steps in the process are developed. Before starting, authors should certify the feasibility of the review question, avoid asking a question that will find insufficient quantities of information. There is no need for additional subquestions when the main review question sufficiently addresses the review objective. However, the exact number of questions for each systematic review depends on the health condition and the scope of the review. For authors can include multiple research questions in the same systematic review. The protocol review questions should not prevent the exploration of unexpected issues in the final analysis, but it is important to avoid bias changing questions. Any modification in the review questions must be reported in the review as 'differences between the protocol and the review'. Finally, authors should check for pre-existing systematic reviews and also for ongoing reviews before beginning their own systematic review.

Objective/ Review question template

"The aim of this systematic review is to compare [Intervention A] and [Intervention B] in terms of efficacy and acceptability in the [Health problem] to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce [Outcome] in [Population], [Intervention A] or [Intervention B] ?".

Item 9 - Rationale

The rationale for performing a systematic review should be well established in the protocol. Systematic reviews are important for healthcare providers, consumers, researchers, and policymakers. A new research should be started only if it does not unnecessarily duplicate an existing study. The authors should describe in item 9 what are the specific gaps in the knowledge or topics where the evidence is lacking, seeking to identify what is know and not know about each of those. In case of a systematic review already exists, authors should explain the reasons for conducting a new systematic review about the same issue.

Item 10 - Condition being studied

A short description of the condition should be included in this section to help the readers to understand what is the health condition or disease of interest. Authors should state clearly what factors or events of interest will be addressed by the systematic review.

Item 11 - Search strategy

In this item, authors can include the full electronic search strategies for each included database. We recommend authors describe all search interfaces used in the search

strategy. For instance, authors can search in MEDLINE using different interfaces, such as PubMed or Ovid. A detailed description including the standardized subject terms is extremely important to ensure methodology reproducibility. When more than one electronic database is used to screening eligible studies, authors should describe each search strategy separately because the controlled vocabulary search terms and the structure of the search are not always identical in different bibliographic databases. Searching for studies should seek high sensitivity through an objective search, using free-text terms and standardised search terms (Called MeSH in MEDLINE and Emtree in Embase). All boolean operators used to combine the search terms should be described as well as all applied filters.

Item 12 - Participants or population

Who are the authors interested in studying in their systematic review? Authors should describe clearly the types of participants which will be addressed in the review, including the most important characteristics that describe the target population. The included population should be based on a scientific justification. It is useful to report the age ranger, gender, ethnicity, the diagnosed condition, setting, and any other specific characteristic which can be relevant for the research. The precision of the description should always be detailed enough to identify which studies will be included or excluded from the review. Review authors might find studies that include patients who would be eligible and some who would not in the same study. Therefore, authors should specify how they plan to deal with these studies containing a mixed population (when only some of the participants meet the eligible participants). For instance, review authors would exclude studies involving both adults and pediatric populations unless the primary study reported results separately for each population. Finally, ineligible participants should be included in this section.

“Women enrolled in studies of thyroid cancer screening will be eligible for this review, with no exclusions based on ethnicity or age.”

Item 13 - Intervention

If applicable, authors will describe the intervention or group of interventions that they want to evaluate in the review, as well as what variations on interventions are acceptable is. It is essential to describe details of the intervention, ensuring that readers can distinguish the intervention of interest from those not eligible for the review question. The same detailed information should be specified for all comparators (Item 14). In many studies, the supplementary interventions will be important and can be added in this section. Although the four "PICO" elements are all important, the "I" element should be emphasized in systematic reviews of interventions. Authors may include in item 9 (Rationale) the theoretical reasoning for the potentially beneficial effect of the studied intervention.

Item 14 - Comparator

Traditional meta-analysis aims to compare two interventions at a time, while a more complex quantitative analysis, such as network meta-analysis, authors can compare

multiple interventions. If applicable, authors should define which comparative intervention will be applied to the target population. It is essential to describe details of the comparator, ensuring that readers can distinguish the intervention of interest from the comparator intervention(s). The two most common comparisons are the comparison of two active interventions and the comparison between intervention and placebo/ control intervention (e.g., placebo drug or no intervention).

Item 15 - Studies design to be included

Authors need to consider a priori what study designs will be included to address the objective of their systematic review (randomized controlled trials, controlled trials, cohort studies, case series, etc.). In the hierarchy of evidence, RCTs are more robust than the others designs in determining the validity and reliability of the review results. However, the study design to be included depends on the review objective and not only depends on the hierarchy of evidence. For example, a systematic review addressing adverse events will frequently include case-control studies. Finally, the risk of developing an empty review should be considered to select the study design during the protocol elaboration.

Item 16 - Eligibility criteria

The eligibility will guide which studies will be selected for inclusion in the review and ensure that the review question will be addressed correctly. Eligibility should be based on the PICOS elements and describe how the author will pre-specify the most important characteristics of the primary studies. Authors should report and explicitly justify any **additional inclusion or exclusion criteria not defined in the PICOS section**, such as exclusion based on language, time frame, country, publication status, setting, or other factors. However, arbitrary restrictions must be avoided because this practice increases the risk of bias while reducing the validity of the systematic review results. It is the best practice for systematic reviews to follow all pre-specified eligibility criteria stated in the protocol; authors must not make modifications to the eligibility based on the findings of the studies. If an unexpected issue arises after protocol registration and the eligibility criteria need to change, a clear rationale should be presented. If necessary, eligibility criteria changes should be accompanied by sensitivity analyses to ensure that the post hoc modification had no effect on the results.

Item 17 - Information sources

Authors should report all bibliographic databases that will be searched for the systematic review, such as MEDLINE, EMBASE, CENTRAL, CHKD-CNKI, CINAHL, WANFANG, etc. Additional sources, including dissertations and theses databases, grey literature databases, and other non-bibliographic database sources (e.g., hand searching, conference abstracts, web searching), should be reported in this section. A subjective specific database should be included for searching depending on the topic of the review. The strategy used for searching must be reported in item 11.

Item 18 - Main outcome(s)

Authors should define in advance what types of outcomes are most relevant for the review question and how the outcomes will be measured, both in terms of the timing of measurement and type of scale. This will reduce bias when the authors complete the review. Common types of data encounter in systematic reviews include patient-relevant outcomes, such as survival, quality of life, pain, anxiety, depression, continence, tumor response, etc. In addition, surrogate outcome measures should be avoided because they may not always correspond to true clinical outcomes. For instance, some interventions might reduce the risk for a surrogate outcome but do not affect true clinical outcomes. Finally, undesirable outcomes should always be considered in systematic reviews of interventions.

Item 19 - Additional outcome(s)

The additional outcomes arise from any secondary aim and may also be described and specified in this section. Additional outcomes are particularly helpful if they lend supporting evidence for the main outcomes. Usually, review authors should consider outcomes less important than primary outcomes but useful for explaining the intervention effect. The inclusion of additional outcomes in this section needs to be justified; large numbers of additional outcomes can make the review unfocused, potentially misleading readers, and prone to selective outcome reporting bias.

Item 20 - Data management

Authors should plan what data will be collected for their systematic review and develop a priori strategy for collecting them. Authors should report the number of reviewers that will be involved in selecting studies for inclusion and how disagreements will be handled. It is more advisable that at least two authors are selecting studies; one is knowledgeable in the review topic, and the other is a methodology expert. Several programs support the steps in the systematic review process; authors should describe all the software systems used for recording decisions. Additionally, software tools for conducting data extraction and statistical analyses should be reported in this section.

Item 21 - Quality assessment /Risk of bias analysis

The assessment of methodological quality is a critical step in the review process. There are many checklists or tools to assess the methodological quality of the included studies; authors should describe which tool they plan to use to determine the risk of bias, inconsistency, publication bias, imprecision, etc. Methods for assessing the quality of the evidence should include the GRADE system. GRADE is a sensible and transparent method to grading quality or certainty of evidence in systematic reviews, which is now considered the standard for rating the quality of evidence in systematic reviews.

Item 22 - Strategy of data synthesis

Ideally, authors should plan how the data will be analysed, mainly if the synthesis will involve only qualitative analysis or a quantitative analysis using one formal statistical

technique. The type of outcome data which will be synthesised (e.g., dichotomous data, continuous data, ordinal outcomes, counts, time-to-event, etc.) should be described in this section, as well as the planned method to synthesise them. Additionally, authors should report what effect measure will be applied. For instance, when the review authors compare the chances of an event between two different groups to decide which of the two groups has a better outcome, risk ratio, odds ratio, or risk difference may be used to report an overall effect measure. Similarly, for expressing and comparing continuous outcomes, mean difference or standardized mean difference can be applied. Authors can include the planned statistical method in this item to calculate the weighted average in pairwise comparisons (e.g., Inverse variance, Mantel-Haenszel, Peto). One other important choice to make about quantitative analysis is whether a fixed effect model or a random-effects model will be performed; this is particularly connected to the heterogeneity. Considerations about missing data, indirect comparisons, Bayesian/ frequentist approaches, consistency, and hierarchical methods, such as SUCRA or P-scores, should be described in this section.

Item 23 - Subgroup analysis

The authors should report in advance the subgroup analysis, including the pre-specified factors (explanatory variables), which will be investigated for their possible influence on the effect of the intervention. To reduce the likelihood of spurious findings and avoid a false positive result, we recommend selecting a small number of characteristics.

Item 24 - Sensitivity analysis

The sensitivity analyses can be pre-specified in the review protocol. Suppose authors explore the impact of arbitrary decisions on the results, including or excluding studies in the final analysis based on methodological quality. In that case, they should report it in this section. When the results remain consistent across different sensibility analyses, the results can be considered more robust.

Item 25 - Language

Authors should report whether language restriction will be imposed or not in the search strategy (e.g., only randomized clinical trials published in English will be considered for inclusion).

Item 26 - Countries involved

Describe the country in which the systematic review is being carried out. For multi-national authors, inform all the countries involved (e.g., Switzerland, China).

Item 27 - Other relevant information

This item provides a place for any supplementary information. The authors can include the list of references cited in the protocol in this item. The references must be included in the author-date style or Vancouver style as outlined in the ICMJE sample references.

Contributorship: If you would like to describe equal contributions in the first author, indicate here the authors' names followed by the sentence "These authors contributed equally to this work".

Item 28 - Keywords

The keywords will help readers find your review on the INPLASY website. Authors should report all the relevant words for the topic to facilitate online searches. INPLASY recommends 4-8 keywords (or phrases) to accompany a systematic review. Please, separate keywords with a semicolon.

Item 29 - Dissemination plans

In this section, the authors should give a brief description of the plans for disseminating the systematic review results.

Item 30 - Number of authors/ Email / ORCID / Contributions

Author names will be published exactly as they appear in the submission form. Please double-check the information carefully to make sure it is correct. Do not include titles (Dr., PhD, Professor, etc.). Initially, authors must specify the number of authors included in the review. After this, additional fields will appear in the form. Authors can include the following information of each author: name, email, ORCID, and the contribution. The contributions of the authors to the protocol or review should be described in this item (e.g., conceiving the review; designing the review; coordinating the review; data collection; data management; analysis of data; interpretation data; writing the protocol or review; providing funding; etc.).

Item 31 - List all authors in the correct order

Provide the author's surname(s) followed by the initials of their given name(s). Please, remember to list authors according to the order they appear on the protocol; include a comma after every surname and a semicolon between different authors' names (e.g., Lee, L; Wang, G; Parker, U).
Abbreviation of Chinese names: Li Xiwen, Li Xi-wen, or Li Xiwen all become **Li, XW**.

Item 32 - Email

Insert the email address to which you would like to receive information about your billing and payment confirmation. After the payment, we will send an email within 24h.

Item 33 - Current Review Status

The authors should indicate the stage of the review at the time of this submission. Authors must update the current review status when the study is discontinued, completed, or published. There is no charge in this process.

5. Updating a published protocol

It is possible to update or amend INPLASY protocols anytime; this will create a new version, but the first version will remain unchanged and permanently available. The

modifications are published within 48h after the submission, if not sooner. Go to service https://inplasy.com/services/ read, and follow the instructions (Item 4) on the page.

6. Publication fees

The protocol processing charge on INPLASY.com is **$20.00**. No additional taxes are applied to publish the protocol. Authors will be charged **$9.00** to update your protocol. You can send us the modifications any time using our INPLASY form. This will create a new version of the protocol and the 1st version will remain unchanged.

7. Publication embargo

7.1 What is an embargo? It is when a time delay is applied to INPLASY protocol before it can be officially made publicly available. In other words, an embargo is a request by a researcher to delay the publication of their protocol until a specified time to avoid methodological plagiarism.

7.2 How to avoid methodological plagiarism using INPLASY services? Publish some items of your protocol under embargo using our premium form; then the information can be held in confidence until the review has been completed. When the embargo period is passed, and the data is released, the full version of the protocol will be published accordingly to the original submission. Any restrictions on the availability of information must be disclosed at the time of article submission. **For example**, the detailed search strategy can be hidden until the review is completed or submitted to a peer-reviewed journal.

7.3 Publication fees using INPLASY premium form - The publication fee using our premium form is **$49.** Observe that no additional charge will be applied to make the full protocol version publicly accessible after the embargo. Authors can hide some parts of the text until the review is completed. However, INPLASY recommends hiding only essential information to avoid methodological plagiarism. The administrative information must not be hidden. Furthermore, the title, keywords, and all essential information to avoid unnecessary duplication of efforts by other reviewers should be available. If further clarification is required to avoid unnecessary duplication of efforts, readers should contact the corresponding author by email to know more about the study. INPLASY will not share any information protected by the embargo period.

7.4 How can authors protect methodological information until the review is completed? The author can use our premium INPLASY form **(https://inplasy.com/premium-inplasy-form/)**

8. Bibliography

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