Cochrane EPOC Protocol

Providing medication adherence feedback to healthcare providers. The effect on care and outcomes.

Protocol for a Cochrane review update

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What's new

Date / Event	Description
31/03/2022	Edited following comments from AD, JH & RP.
30/05/2022	Removal of NRCT trial types as advised by EPOC (low volume returns)
17/08/2022	Edit of Grey Literature search sources: OpenGrey, NICE Evidence Search (no longer available), Grey Literature Report (stopped being updated in 2017)

ABSTRACT

This is a protocol for a Cochrane Review (update).

Background

Key barriers to effectively supporting adherence include poor awareness amongst healthcare professionals (HCPs), scarce clinical tools and interventions, and suboptimal patient-provider communication. A Cochrane review assessed the impact of feedback interventions amongst physicians published until 2016. Other HCPs are increasingly involved in supporting adherence.

Objectives

To assess the effects of providing healthcare providers with medication adherence feedback as a mechanism for improving patients' medication adherence. To assess the impact of the intervention upon clinical outcomes, patient-reported outcomes, economic/financial outcomes and processes of care.

Search methods

We will search RCTs and cluster RCTs on CENTRAL, CINAHL, Embase, MEDLINE, PsychArticles and PsychInfo, and grey literature sources.

Selection criteria

Inclusion criteria are any reported intervention providing adherence feedback to HCPs as a key component, for long term medication for chronic diseases.

Data collection and analysis

One author performs title and abstract screening. Four authors will review full texts, extract data, and assess risk of bias. We will assess intervention effects on medication adherence, clinical outcomes, patient-reported outcomes, economic/financial outcomes and processes of care. We will assess heterogeneity, sensitivity, and undertake meta-analysis where appropriate.

Main results

The search yielded 4415 articles (pending grey literature). Publication is anticipated Q1 2023.

Author's conclusions

Medication adherence feedback to HCPs could contribute significantly to reducing key barriers associated with poor adherence. The Cochrane review will provide evidence of effectiveness amongst HCPs whist updating that regarding physicians.

Contents

Background

Description of the condition

Adherence can be defined as "the extent to which a patient participates in a treatment regimen after he or she agrees to that regimen" (Balkrishnan, 2005). Adherence to medications is the process by which patients take their medication as prescribed (Vrijens et al., 2012)

Medication plays a vital role in the management and control of long-term conditions, including that of managing complications. It is thought that between a third and a half of all medicines prescribed for long-term conditions are not taken as recommended (Brown & Bussell, 2011; NICE, 2009).

Suboptimal medication adherence, that is not taking medication as agreed can have a serious impact upon health outcomes and increases healthcare costs. From the patient perspective it may limit the benefits of medicines, resulting in a lack of improvement, or deterioration, in health. Poor adherence is estimated to contribute to nearly 200,000 deaths in Europe every year (Khan & Socha-Dietrich, 2018). The cost to the NHS of suboptimal adherence in the England is estimated at £500 million per year (Langley & Bush, 2014), with a further £300 million attributable to wasted medicines (Trueman et al., 2010). The economic costs are not limited to wasted medicines but also include the knock-on costs arising from increased demands for healthcare if health deteriorates (NICE, 2009).

Description of the intervention

The intervention involves the provision of medication adherence feedback to healthcare providers regarding patients' medication adherence. The feedback may be based on various methods to measure adherence (e.g. measurement of drug/metabolite levels, prescription dispensing data, self-reported questionnaires, pill counts, electronic monitoring systems) and methods to provide feedback (e.g. paper based, electronic). It may also vary in timing or frequency (e.g. clinician feedback after each prescription dispensing or as trend over time, patient alert as a reminder when medication would be due).

How the intervention might work

A prior Cochrane systematic review (Zaugg, 2018) reported that the intervention may lead to improvement in processes of care. These included rates of medication changes, patient dialogue and satisfaction rates, and management of uncontrolled hypertension compared to usual process of care. The review noted possible mechanisms as improvement through increasing awareness on patients' behaviours, encouraging dialogue to tailor strategies to improve adherence, helping HCPs determine causes of non-adherence. This appears tentatively positive but was highlighted as something which needs addressed by future research. The review found little or no difference in

medication adherence, patient outcomes or health resource use. No firm conclusions were able to be drawn due to the low number of studies and a high risk of bias. A systematic review of the effects of audit and feedback on professional practice (Ivers et al., 2012) found that providing feedback led to small but potentially important improvements in professional practice though noted that this appeared dependent upon baseline performance and the manner of feedback delivery. A systematic review of the effects of feedback on adherence to treatment amongst patients (Seewoodharry, 2017) concluded that the provision of feedback guided by subjective or objective measures improved adherence and prevented adherence worsening over time. The limitations of this review were a limited number of studies (6), difficulties comparing studies due to variation in data collection and reporting, and that several studies used self-reporting as a measure (which can be subject to bias).

Why it is important to do this review

The previous review by Zaugg et al, 2018 provided useful insights regarding the intervention in question, and in terms of implications for further research. It examined the importance of adherence, the importance of targeting physicians, and the importance of simplicity when implementing this type of intervention. The search criteria stopped at December 2016 and therefore we propose to update this review.

We intend to identify and synthesise current evidence on medication adherence feedback to healthcare professionals.

The importance of other Healthcare Professionals

We will examine the evidence supporting the use of the intervention amongst a wider range of HCPs. Demands on health services mean that a range of health workforce strategies are required. One such strategy to help alleviate the burden on medical prescribers is the utilisation of other healthcare providers as prescribers. Recent years have seen increasing utilisation of non-medical prescribers (e.g. nurses, pharmacists, allied health professionals) who may have an active role to play in assessing medication adherence, an essential component of good clinical governance when prescribing. The previous review incorporated the search terms “prescriber* or provider* or physician* or clinician* or doctor*” and therefore potentially did not include other HCPs. It suggested in the ‘Implications for research’ section that there could be further work to determine the impact of feedback upon broader professional groups.

The importance of identifying new evidence

We intend to assess whether there is further research regarding the use of medication adherence feedback as a means to support the clinical decision making process. There has been, and will likely continue to be an increasing use of technology for clinical decision support systems (CDSS). The World Health Organisation (2003) cited the development of better information technology as one of the key principles for improving adherence and minimising the risk of failure. CDSS are typically integrated with clinical IT systems, including electronic medical records and workflows, and aim to support and augment clinicians in clinical decision making. Despite advances and the level of integration questions remain as to the effect CDSS systems have upon providers, patient outcomes and costs (Sutton et al., 2020).

We will assess whether further research has taken place and whether there is now information relating to the European context. In addition, the previous review only identified studies relating to the USA and Canada. Potential reasons cited were related to information governance and data sharing restrictions, and a lack of linkage between healthcare datasets. It concluded that there would be interest in assessing effects in the European context.

The importance of evidence quality

Finally, the review noted that providing clinicians feedback about medication adherence may improve processes of care but cautioned against firm conclusions due to variations in definitions of adherence, the small number of studies, and the risk of bias in those studies reviewed. It suggested adapting a more rigorous approach for further research. This update intends to determine whether there are more recent publications relating to the use of feedback in medication adherence and assess this considering any updated research.

Objectives

Main Objective

To assess the effects of providing prescribers with feedback about their patients' medication adherence on improving adherence.

Secondary Objectives

The secondary objectives are to assess the impact of the intervention upon:

- clinical outcomes (e.g. measures of morbidity and mortality such as survival, diabetic complications)
- patient-reported outcomes (e.g. a direct report from a patient regarding their health condition and its treatment such as symptoms, quality of life, adherence)

- economic/financial outcomes (e.g. estimates of medical and non-medical resource utilisation and costs)
- processes of care (e.g. medication dose escalation, discontinuation or dose adjustment, counselling)

Methods

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and cluster RCTs. For inclusion these studies must meet the Cochrane Effective Practice and Organisation of Care (EPOC) Group checklist (EPOC, 2016) study design criteria. We will include full-text studies, conference abstracts, and unpublished data. We will include studies irrespective of their publication status and language of publication.

Types of participants

We will consider a broad range of healthcare providers including medical, independent or supplementary non-medical prescribers (e.g. nurses, pharmacists, and other allied health professionals or categories not specifically mentioned). We will include prescribers classified as 'supplementary prescribers', that is those who tend to work in collaboration with a medical prescriber. This is a variation from Zaugg (2018) in that it only incorporated studies relating to physicians.

We will include all adults or children treated with any long term medication for any chronic disease condition.

Setting

We will include studies based in any primary, secondary or tertiary care setting.

Types of interventions

We will include studies where the intervention includes or relates to medication adherence feedback. This will be regardless of the method used to measure (e.g. based on prescribing data, electronic device alerts, self-report), the mode of delivery (e.g. paper based, via a web interface or application, face to face), and the timing (e.g. in advance or retrospective, routine ongoing or targeted). The intervention must include a component of medication adherence feedback but this can be as a single intervention or as part of a multifaceted intervention. Where delivered as part of a multifaceted intervention it must be as a key component rather than a minor component. Any studies whereby the feedback is deemed a minor component will be excluded.

Types of outcome measures

We will consider the following outcomes: medication adherence, clinical outcomes, patient-reported outcomes, economic/financial outcomes, and processes of care. We will include both quantitative and qualitative outcome data.

Primary outcomes

Medication adherence, including the additional related terms as defined within this protocol and regardless of the data source (e.g. pill count, patient reported, electronic databases, electronic monitoring), method of calculation (e.g. medication possession ratio (MPR), continuous multiple interval measure of medication acquisition (CMA)), or method of summarisation (e.g. dichotomous or continuous variable based).

Secondary outcomes

Clinical outcomes, including those measuring morbidity (e.g. incidence proportion or attack rate and risks, secondary attack rate, incidence rate, point prevalence, period prevalence) or mortality (e.g. crude death rate, cause-specific death rate, proportionate mortality, death-to-case ratio).

Patient-reported outcomes, those related to daily functioning (e.g. health related quality of life measures) and health outcomes (e.g. adherence, systematic response to treatment) from the patient's perspective.

Economic/financial outcomes, those estimates of medical resource utilisation (e.g. visits to general practitioner or specialists, bed days, accident and emergency attendance), non-medical resource utilisation (e.g. transportation, social services, patient time receiving care, family or caregiver time), and costs (e.g. related to treatment of disease or condition, treating adverse events, prescribing costs).

Processes of care, those which may serve as a proxy indicator of action or activity regarding medication adherence (e.g. medication dose escalation, discontinuation or dose adjustment, counselling).

Search methods for identification of studies

Electronic searches

The EPOC Information Specialist will develop the search strategies in consultation with the review authors. We will search the Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effects (DARE) for related systematic reviews.

We will search the following databases for primary studies, from inception to the date of search.

- Cochrane Central Register of Controlled Trials (CENTRAL; latest issue), in the Cochrane Library.
- MEDLINE Ovid (1946 to June 2022).
- Embase Ovid (1974 to June 2022).

- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1982 to June 2022)
- PsycArticles (2009 to June 2022)
- PsycInfo (2007 to June 2022)

Search strategies are comprised of keywords and controlled vocabulary terms. We will not apply any limits on language and we will search all databases from inception to the date of search. We will use methodology search filters to limit retrieval to appropriate study designs: a modified version of the Cochrane Highly Sensitive Search Strategy (sensitivity- and precision-maximizing version - 2008 revision; Lefebvre 2019) to identify randomised trials. See Appendix 1 for the MEDLINE search strategy, which we will adapt for other databases.

Searching other resources

Trial registries

- WHO ICTRP (Word Health Organization International Clinical Trials Registry Platform); www.who.int/ictrp; to August 2022).
- US National Institutes of Health Ongoing Trials Register (clinicaltrials.gov; to August 2022).

Grey literature

We will conduct a grey literature search to identify studies not indexed in the databases listed above.

- Grey Literature Report (New York Academy of Medicine; www.greylit.org; to 2017).
- Agency for Healthcare Research and Quality (AHRQ; www.ahrq.gov; to August 2022).
- Joanna Briggs Institute (www.joannabriggs.edu.au; to August 2022).

We will also review reference lists of all included studies and relevant systematic reviews for additional potentially eligible primary studies. We will contact authors of included studies/reviews to clarify reported published information and to seek unpublished results/data. We will contact researchers with expertise relevant to the review topic/EPOC interventions. We will conduct cited reference searches for all included studies in ISI Web of Knowledge and screen individual journals and conference proceedings (e.g. handsearch).

We will provide appendices for all strategies used, including a list of sources screened and relevant reviews/primary studies reviewed.

Data collection and analysis

Selection of studies

We will download all titles and abstracts retrieved by electronic searching to a reference management database and remove duplicates. Review author (RH) will independently screen titles and abstracts for inclusion. We will retrieve the full-text study reports/publication and review authors (RH, RP, BS,

VS, AD) will independently screen the full-text and identify studies for inclusion and identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreement through discussion or, if required, we will consult authors (JH, AM).

We will list studies that initially appeared to meet the inclusion criteria but that we later excluded in the 'Characteristics of excluded studies' table. We will collate multiple reports of the same study so that each study rather than each report is the unit of interest in the review. We will also provide any information we can obtain about ongoing studies. We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Liberati 2009).

Data extraction and management

We will use the EPOC standard data collection form and adapt it for study characteristics and outcome data (EPOC 2017a); we will pilot the form on at least one study in the review. Review authors (RH, RP) will independently extract the following study characteristics from the included studies and enter the data into Review Manager 5 (Review Manager 2014).

Following the methodology used by Zaugg et al., 2018 we will extract the following information:

1. Study characteristics: author name, publication year, journal name, type of study.
2. Methods: study design, number of study centres and location, study setting, withdrawals, date of study, follow-up.
3. Participants: setting, healthcare system, number of participants, speciality and training of the healthcare provider, age, socioeconomic status, disease, treatment, baseline medication adherence of the patients.
4. Intervention: description of the feedback, method used to measure adherence, delivery mode, duration, timing, auxiliary interventions, description of the control.
5. Outcomes: outcomes assessed, results and their measures of variance, outcome assessor, timing of the assessment.
6. Notes: funding for trial, notable conflicts of interest of trial authors, ethical approval.

Review authors (RH, RP) will independently extract outcome data from included studies. We will note in the 'Characteristics of included studies' table if outcome data were reported in an unusable way. We will resolve disagreements by consensus or by involving a review authors (AD, JH, AM, BS, VS).

Assessment of risk of bias in included studies

RH and RP will assess risk of bias using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions Section 8.5 (Higgins 2019), and the guidance from the EPOC group (EPOC 2017b). Randomized trials, cluster-randomised trials and crossover trials will be assessed using the Cochrane Review Risk of Bias tools (“Risk of bias”, 2021). Where an ITS has ignored secular

changes and performed a t-test of pre verses post intervention periods without further justification, we will contact the main authors for further information. If possible, we will perform a re-analysis. Where re-analysis is not possible the study will be excluded.

We will include an assessment of the individual studies included in a systematic review and that of meta-analysis or other synthesis of findings from included studies. We will additionally assess the risk of bias due to missing results. We will review any noted register of conflict of interest of study investigators.

We will judge each potential source of bias as high, low, or unclear and provide a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed. We will assign an overall 'Risk of bias' assessment (high, moderate or low) to each of the included studies using the approach suggested in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2019). We will consider studies with low risk of bias for all key domains or where it seems unlikely for bias to seriously alter the results, to have a low risk of bias. We will consider studies where risk of bias in at least one domain was unclear or judged to have some bias that could plausibly raise doubts about the conclusions, to have an unclear risk of bias. We will consider studies with a high risk of bias in at least one domain or judged to have serious bias that decreases the certainty of the conclusions, to have a high risk of bias.

We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient reported pain scale). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table. We will not exclude studies on the grounds of their risk of bias, but will clearly report the risk of bias when presenting the results of the studies.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome. Any disagreements will be resolved through discussion with the review authors (AD, JH, AM, BS, VS).
We will conduct the review according to this published protocol and report any deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will estimate the effect of the intervention using risk ratio/risk difference for dichotomous data, together with the appropriate associated 95% confidence interval and mean difference or

standardised mean difference for continuous data, together with the 95% appropriate associated confidence interval (Higgins 2019). We will ensure that an increase in scores for continuous outcomes can be interpreted in the same way for each outcome, explain the direction to the reader, and report where the directions were reversed, if this was necessary.

We will perform the analyses using Review Manager 5 (RevMan, 2014) and record data in a tabular format according to the Cochrane EPOC Group's data extraction template (EPOC, 2013).

Unit of analysis issues

We will assess whether appropriate adjustment has been made to account for unit-of-analysis errors for clustering in RCTs and CBA studies. If there is insufficient data for re-analysis we will attempt to correct by contacting the main authors for further information. Where such information is not available we will report measures or effect without precision.

Dealing with missing data

We will contact investigators in order to verify key study characteristics and obtain missing outcome data where possible (e.g. when a study is identified as abstract only). We will try to compute missing summary data from other reported statistics. We will follow the principles of intention-to-treat analysis (Sedgwick, 2013) as much as possible. Whenever it is not possible to obtain data, we will report the level of missingness and consider how that might impact the certainty of the evidence.

Assessment of heterogeneity

If we find a sufficient number of studies, where we judge participants, interventions, comparisons and outcomes to be sufficiently similar, we will conduct a meta-analysis (Borenstein 2009). We will use the I^2 statistic to measure heterogeneity among the trials in each analysis. We will assess low heterogeneity as an I^2 result between 0% and 30%, medium heterogeneity as 30% to 60%, and high heterogeneity as above 60% (Higgins 2019). If we identify substantial heterogeneity we will explore it by prespecified subgroup analysis.

Assessment of reporting biases

We will attempt to contact study authors, asking them to provide missing outcome data. Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results. If we are able to pool more than 10 trials, we will create and examine a funnel plot to explore possible publication biases, interpreting the results with caution (Sterne 2011).

Data synthesis

We will undertake meta-analyses only where this is meaningful i.e. if the treatments, participants, and the underlying clinical question are similar enough for pooling to make sense (Borenstein 2009). A

common way that trialists indicate when they have skewed data is by reporting medians and interquartile ranges. When we encounter this we will note that the data are skewed and consider the implications. Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons (e.g. intervention A versus usual care and intervention B versus usual care) must be entered into the same meta-analysis, we will halve the control group to avoid double-counting.

'Summary of findings' and GRADE

Review authors (RH and RP) will independently assess the certainty of the evidence (high, moderate, low, and very low) using the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias) Guyatt 2011. We will use methods and recommendations described in Section 8.5 and Chapter 12 of the Cochrane Handbook for Systematic Reviews of interventions (Higgins 2019), and the EPOC worksheets (EPOC 2017c), and we will use GRADEpro software (GRADEpro GDT). We will resolve disagreements on certainty ratings by discussion and provide justification for decisions to down- or upgrade the ratings using footnotes in the table and make comments to aid readers' understanding of the review where necessary. We will use plain language statements to report these findings in the review (EPOC 2017c).

We will summarise the findings in a 'Summary of findings' table(s) for the main intervention comparison(s) and include the most important outcomes:

- Medication adherence
- Clinical outcomes, including adverse effects
- Patient-reported outcomes
- Economic/financial outcomes
- Processes of care

If during the review process, we become aware of an important outcome that we failed to list in our planned 'Summary of findings' table(s), we will include the relevant outcome and explain the reasons for this is the section 'Differences between protocol and review'.

We will consider whether there is any additional outcome information that was not able to be incorporated into meta-analyses and note this in the comments and state if it supports or contradicts the information from the meta-analyses. If it is not possible to meta-analyse the data we will summarise the results in the text.

Subgroup analysis and investigation of heterogeneity

We will assess potential methodological and statistical sources of heterogeneity. We will consider explanatory variables or effect modifiers which may influence the intervention effects: study quality, baseline medication adherence, intervention type, healthcare provider type, and study population. We will explore the size of the observed effect in relation to the variable and modifiers and present

this data though the use of tables and visual display. We will apply a test for interaction to test for statistical significant differences between subgroups.

Sensitivity analysis

We will perform sensitivity analyses defined a priori to assess the robustness of our conclusions and explore its impact on effect sizes. This will involve the following:

1. Restricting the analysis to published studies.
2. Restricting the analysis to studies with a low risk of bias, as specified in section 'Assessment of risk of bias in included studies'
3. Imputing missing data.

Stakeholder consultation and involvement

Following Cochrane guidance (Pollock 2018) and in the interests of transparency, accountability, efficiency in research, and supporting the translation of this research into practice (CCN 2018), we will involve stakeholders in this systematic review.

We will undertake a stakeholder analysis exercise to identify key stakeholders as set out on the World Health Organisation guidance (Kammi, 2000).

We will convene a steering group representative of key stakeholders to act as a consulting body during the course of this review. The steering group will asked to provide feedback at key points:

- To comment on the draft protocol to support efficiency in research
- To support identification of priority review outcomes to support efficiency in research
- To encourage transparency and accountability throughout the process to provide confidence in the review
- To comment on the review to improve readability and/or quality
- To comment on the plain English summaries to improve their usefulness
- To support the process of evidence dissemination and awareness raising of evidence based healthcare to help make the information more accessible

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Declarations of interest

The review authors declare no known financial conflict of interest.

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Appendices

1 Medline search strategy

1 exp patient compliance/
2 ((medication? or pharmaceutical? or drug? or medicament? or medicine?) adj2 (adhere* or complian* or nonadhere* or noncomplian*)).ti,ab.
3 or/1-2
4 exp feedback/
5 (feedback or feed back or fed back).ti,ab.
6 or/4-5
7 (refill* adj2 (adhere* or complian* or nonadhere* or noncomplian* or feedback or data or persistence)).ti,ab.
8 ((prescriber* or provider* or physician* or clinician* or doctor* or pharm* or nurs* or ahp* or allied health professional*) adj5 (know* or furnish* or deliver* or fax* or email* or facsimile or share* or provid* or feed back or feedback or fed back or phone or telephone or alert* or notify* or notifi* or supply* or suppli* or inform* or report* or disclos* or result* or recei* or summar* or availab* or data) adj5 (complian* or adhere* or noncomplian* or nonadhere* or persistence)).ti,ab.
9 3 and 6
10 or/7-9
11 randomized controlled trial.pt.
12 controlled clinical trial.pt.
13 multicenter study.pt.
14 pragmatic clinical trial.pt.
15 (randomis* or randomiz* or randomly).ti,ab.
16 groups.ab.
17 (trial or multicenter or multi center or multicentre or multi centre).ti.
18 (intervention? or effect? or impact? or controlled or control group? or (before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or quasiexperiment* or quasi experiment* or pseudo experiment* or pseudoexperiment* or evaluat* or time series or time point? or repeated measur*). ti,ab.
19 or/11-18
20 exp animals/
21 humans/
22 20 not (20 and 21)
23 review.pt.
24 meta analysis.pt.
25 news.pt.
26 comment.pt.
27 editorial.pt.
28 cochrane database of systematic reviews.jn.
29 comment on.cm.
30 (systematic review or literature review).ti.
31 or/22-30
32 19 not 31
33 7 and 32

2 Cochrane EPOC data collection checklist

https://methods.cochrane.org/sites/methods.cochrane.org.bias/files/public/uploads/EPOC%20Data%20Collection%20Checklist.pdf

3 Risk of bias

Risk of bias tools