A Pragmatic Work Flow for Manual Medical Chart Review: A Systematic Literature Review

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A PRAGMATIC WORK FLOW FOR MANUAL MEDICAL
CHART REVIEW: A SYSTEMATIC LITERATURE REVIEW

INTERNERSHIP PRACTICUM REPORT

Presented to the Graduate Council of the Graduate School of
Biomedical Sciences
University of North Texas Health Science Center at Fort Worth

In Partial Fulfillment of the Requirements
For the Degree of

MASTER OF SCIENCE IN CLINICAL RESEARCH
MANAGEMENT

By

Taoran Qiu, B.S.
Fort Worth, Texas
November 20
ABSTRACT


There has been a lack of detailed description of the manual medical chart review process with standardized steps for data abstraction. The aim of this practicum thesis is to develop a pragmatic and systematic work flow for the manual reviewing of medical records. The thesis is conducted by systematically reviewing publications from the last twenty years. The end product of this practicum report is series of twelve steps work flow for manual medical data abstraction.
ACKNOWLEDGEMENT

I would like to express my sincere appreciation to Dr. Patricia Gwirtz, PhD, for her valuable and constructive suggestions throughout this entire project. Her willingness to give time so generously have been very much appreciated. The success of students are always her concerns and she truly have the most sincere and best wishes for all her students. I am also grateful to my committee member, Dr. Kunlin Jin, MD, PhD, for his valued opinions and advice in completing this report.

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Last but not least, I would like to thank my family for never-ending support and encouragement that they have given me throughout years of education. It is virtually impossible to pursue my career goals with their support, I am always in debt to their generosity.
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CHAPTER I – INTRODUCTION

With the advancement of technology and the introduction of Electronic Health Record (EHR) systems, the health care providers are able to record and maintain a large set of data with ease. These tremendous amounts of data provide an inexhaustible source of information that is extremely valuable for various research interests, for example: quality improvement, health service research, epidemiology, comparative effectiveness and clinical research. Such data, when analyzed with appropriate statistical methods, can give insights to the quality of care, patient safety and clinical outcomes. One advantage of conducting research using the EHR is that the data are already collected and researchers can use the technique of retrospective medical chart review to assess utilization, appropriateness, process and outcome of care at a minimal cost. As a result, medical chart review is a very popular methodology in health care research.

The relevant data are usually buried deeply within the EHR systems; therefore, data need to be extracted before they can provide meaningful indications. Chart review, essentially, is the process of obtaining useful information from medical records and it is usually the first step in conducting research using the information contained in EHR. The name, chart review, may sounds simple yet the actual procedure is very complicated especially when trying to obtain high quality data.

When it comes to research, data quality is paramount since it serves as a crucial foundation to all analyses. Chart abstraction, historically, is conducted manually. It is rather
labor-intensive and often associated with risks of having high error rates and data inconsistency.\textsuperscript{6} Previously, there have been attempts at streamlining the manual chart abstraction process\textsuperscript{7, 8}; however, a systematic review of these methods is lacking. Having an establish, standardized work flow when conducting retrospective chart review can ensure higher quality data hence solid research results.

This practicum report examines the advantages and disadvantages of manual chart review when conducting retrospective chart review studies using EHR. The purpose of this practicum is to offer a best-practice guide or a pragmatic workflow for manual chart review or manual data abstraction in order to extract quality data from the wealth of information hidden within the elaborated medical record systems.
CHAPTER II – BACKGROUND

Electronic Health Record: Application and Implication

Clinicians started to record clinical episodes and care information into the so-called electronic health record (EHR) as early as the 1960s.\(^9\) EHR, as suggested by International Organization for Standardization (ISO), is a repository of patient medical data in a digital form, stored, exchanged and accessed in a secure manner by multiple authorized personnel.\(^{10}\) Therefore, EHR systems are designed and should be able to support clinical care, billing and other functions such as quality improvements and audits, education for clinicians, patient reported outcomes, shared decision-making, patient safety and self-management especially for chronic diseases.\(^{11-13}\)

Because EHR has a diverse role, it naturally incorporates multidisciplinary and multifunctional data, for instance: billing documents, laboratory results, reports from different departments, vital signs, medication records and communication or notes associated with patient care.\(^{11}\) Hence, the information contained in the EHR are extensive and its heterogeneity allows researchers to investigate not only clinical care but also quality, patient centeredness, billing information and adequacy and appropriateness of the care.\(^{14}\) Besides being voluminous, the information contained in the EHR are much more reflective because they are the real-time record
of clinical care. This particular aspect of EHR data enables clinicians and researchers to have a holistic view of the patient and caring process.

The increase in EHR system adoption has augmented the amount of clinical data and transforming these data into indicative findings is an important component for many biomedical researches. There has been an increase of interest in doing research using EHR data since it is associated with potential lower study start-up costs when compared to prospective pharmaceutical trials. Data are already collected as part of daily clinical practice, it has minimal burden on the budget; thus, the secondary use of EHR data has been encouraged in recent years. Also, the breadth of EHR data provides versatility and broader spectrum for various disciplines such as epidemiology, health informatics, health service research, quality and safety of clinical care, patient-centered care and clinical research. As a result, the data that can be obtained from EHR hold great promise to healthcare delivery, policy implementation and clinical research.

The successful transformation, utilization and management of knowledge obtained from EHR data is potentially beneficial to both clinicians and patients. However, transforming this massive amount of data hidden in EHR systems into useful knowledge is not a simple task. One common method to transform these disparate data from EHR into a cohesive concept is medical chart review.
The secondary use of EHR data as the primary source of information requires significant investments of time, effort and human resources.\textsuperscript{11} The data collection process can be extremely complicated due to inconsistent location of data, missing data, conflicting data and many other challenges.\textsuperscript{16} Therefore, it is necessary to understand the approach to medical chart review or the data collection process in general.

Medical chart review is commonly employed in research to extract useful information out of the EHR. The process itself is associated with many different expressions, for example: medical chart audit, medical chart review, medical record review, medical record abstraction and medical record audit. Some published articles\textsuperscript{24,25} distinguish the difference between these terms; however, there is still a lack of general consensus on the differentiation, specification and standardization on the definition and usage of these terms. It is beyond the scope of this practicum report to discuss the subtle differences between these terms. For this practicum report, medical chart review will be used to refer to the activity of using pre-recorded, collected for non-research purpose clinical information as the primary source of data to answer a research question.\textsuperscript{26} Medical chart abstraction, on the other hand, is the process of collecting specific variables or data from the medical record and it is a component of the medical chart review.

Medical chart review can be done either retrospectively or prospectively.\textsuperscript{27} The difference between the two study designs is the existence of patient records.\textsuperscript{29} For retrospective chart review, the patient data has already been collected and ready for use at the time the project is submitted to the Internal Review Board (IRB) for initial review.\textsuperscript{30} Besides the aforementioned two study designs, there are two approaches to chart review: explicit and implicit.\textsuperscript{31} For explicit
chart review, it focuses on the objectivity of the abstraction process in which a trained abstractor will extract specific data from a medical record following detailed instruction and a data collection template. Implicit chart review, on the other hand, focuses on the subjectivity of the abstraction process in which a nurse or physician will review the medical charts based on clinical experience.

Traditionally, medical chart abstraction is done manually with trained abstractors. Depending on the research topics, number of variables, availability of the records and data collection modes, the manual medical chart abstraction process can be labor-intensive and may potentially take longer time to complete. Besides time, staff compensation may be another consideration when it comes to medical chart review studies. Many chart review studies employ nurses, physicians or other clinicians to abstract data from the medical records and this method may increase the cost of research. However, two studies have indicated that non-clinical personnel, upon ample training, are able to abstract accurately and efficiently; therefore, employ well-trained non-clinical personnel may reduce the budget constrain.

EHR Data Quality: Concerns and Cautions

Retrospective medical chart review utilizes patient data that are collected in advance and usually not intended for research purpose. Similar to other data, EHR data are also subjected to accuracy and quality checks. Even though patient’s clinical information is recorded in the EHR, it does not indicate accuracy Therefore, it is necessary for researchers to review the raw material and ascertain pertinent data specific to the research question before transforming these data into
useful knowledge.\textsuperscript{8,30} The data extracted from voluminous EHR system have a direct impact on the future analysis of the study and may potentially influence the conclusion of the study as well.\textsuperscript{8,37} As a result, having good quality data is essential.\textsuperscript{38}

Since data came from EHR, it would be advantageous to know the various limitations, considerations and issues regarding to EHR data. According to Bayley et. al\textsuperscript{16}, researchers should consider inherited data quality issues such as missing data, erroneous data, uninterpretable data, inconsistent data and text notes/non-coded data when working with EHR. When these issues are not addressed or mishandled, they can increase the data error rate which, in turn, decrease study reliability and validity.\textsuperscript{39-43} The data abstracted from the EHR is only good as the initial documentation; therefore, there is a need to streamline and standardize the medical chart abstraction process to limit additional error.\textsuperscript{44}

In order to complete medical chart review studies within a reasonable amount of time, multiple abstractors are usually used in order to meet the deadline. However, this approach may introduce even more error to studies.\textsuperscript{45} Measurement such as inter-rater reliability (IRR) should be performed for medical chart review study to assess the agreement between multiple abstractors and in order to achieve high IRR, an efficient and standardized work flow should be available.\textsuperscript{46,47}

Having a systematic and standardized medical chart review or data abstraction protocol may increase the efficiency of abstraction process and ensure the quality of the data. The purpose of this practicum is to systematically review literature from the past twenty years in order to develop a pragmatic work flow for manual medical chart abstraction. It is only one component of the medical chart review study design; however, it is extremely crucial to have a best-practice guideline in order to guarantee the quality of the data extracted EHR.
CHAPTER III – SPECIFIC AIMS

The specific aims of this practicum project are:

1. To describe the process of manual chart review and to explore its advantages and disadvantages

2. To systematically review the literature on the methodology of conducting manual chart review

3. To develop a best-practice guideline or a pragmatic work flow for manual chart review
CHAPTER IV – SIGNIFICANCE

There has been an influx of technology into the field of healthcare and clinical research. This increase in technology utilization has aided the data capturing process, which, in turn created a substantial amount of data. As healthcare systems entered the era of “Big Data”, data obtained from electronic health records, billing information, administrative records and many more has become a rich source for answering critical questions in the medical fields. These electronic health data provide a wealth of resources, yet it cannot be utilized until the relevant data have been extracted or parsed out of the large selection pool.

Data abstraction is an important process for any research utilizing EHR data. Traditionally, data abstractions are done manually without consistent documentation of the actual extraction process. Due to lack of clarity in this step of research, it often introduces errors into the data. High error rates would increase variance, which in turn would diminish the statistical power of a study. Since the scientific validity of research depends largely on the data quality and data accuracy; it is extremely important to obtain good quality data at the forehand.

In order to achieve higher data quality and attain reproducibility, the actual process of manual chart abstraction should to be described and documented in detail. Although having a “cook-book” approach might not work for each retrospective chart review study, there are still essential steps to take in order to ensure the quality of the data. This practicum project provides some of the essential procedures synthetized from different literature on manual data abstraction.
Moreover, the focus of this practicum report is to develop a pragmatic workflow for chart abstraction in order to improve the accuracy of the data and the efficiency in the abstraction process.
CHAPTER V – METHODOLOGY

All specific aims will be addressed by conducting a literature search and specific aim 2 will be accomplished by using systematic literature review following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. PRISMA is a detailed, checklist of items that should be reported for formal, systematic literature reviews. The specific sections suggested by PRISMA guidelines have been modified in order to fulfill formatting requirement of practicum thesis. Appendix C lists the corresponding sections and contents between this practicum report and the PRISMA sections.

Search Strategy

Student researcher will utilize PubMed to identify potentially eligible publications. Search terms for this practicum project include: medical chart review, medical chart audit, medical chart abstraction, medical record review, medical record audit, medical record abstraction, manual, methodology, retrospective, inter-rater reliability, data collection and data quality. Various combinations of these key terms will be used since there is no standard use of language or terms for medical chart review studies. Examples of possible term combination are:

• “Data collection/methods” [MAJR] AND “Medical Records*/classification” [MAJR] AND “Reproducibility of Results” [MeSH Terms]
• Retrospective chart review AND considerations AND methodology AND medical record
• Medical record review AND data collection AND method AND abstraction
• “Data collection/methods” [MeSH Term] AND “Medical Records” [MAJR] AND “Retrospective Studies” [MeSH Term]
• Medical chart review AND data collection AND method AND interrater reliability

Study Selection

Titles and abstracts of publications obtained by using the above search strategy will be reviewed while applying the inclusion and exclusion criteria. Table I lists the inclusion and exclusion criteria for this practicum report. Student researcher also examine the references or bibliography of eligible publications to identify additional sources in order to enhance the electronic researching process. A detailed diagram denoting the included and excluded publications will be provided in Chapter VI of this practicum report and Appendix B has the comprehensive list of excluded publications with justification for exclusion.
### Table I – Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Full Text</td>
<td>• No detailed abstraction mechanism and/or no description of abstraction/review work flow</td>
</tr>
<tr>
<td>• In English Language or Translated into English Language</td>
<td>• Usage/methodology/discussion on specific tool, database or collection mechanism. For example, manual for certain website utilization.</td>
</tr>
<tr>
<td>• Publication date from 1994 to 2014</td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER VI – RESULTS AND DISCUSSIONS

Specific Aim 1: to describe the process of manual chart review and to explore its advantages and disadvantages

The process and general overview of the manual chart review process has been described in Chapter II – Background, subsection: medical chart review: history and science. One advantage of medical chart review (MCR) studies commonly discussed across the literature is the potential lower cost or rather lower budget constraint.\textsuperscript{26,44,51,54,56} Besides lower cost, MCR allows for a relatively quick and conditional easy access to medical records, thus, enabling investigators to have ample amount of historical information.\textsuperscript{2,26,51,56,59} Therefore, MCR is generally good for addressing research questions that contain a historical component.

Since medical recordkeeping is not intended for research, it is often subject to poor quality documentation, in addition to inaccurate information and incomplete or missing documents.\textsuperscript{44,50,51} Also, due to the large volume, MCR study process is often labor intensive, time consuming and may be subjected to potential abstraction disagreement and bias.\textsuperscript{44,51,56}

Table II provides a short summary of the advantages and disadvantages associated with medical chart review studies synthesized from the included publications.
<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Real time clinical records</td>
<td>• Subject to poor quality initial data</td>
</tr>
<tr>
<td>• More reflective information</td>
<td>• Inaccurate information, incomplete documentation and other inherited data issues</td>
</tr>
<tr>
<td>• Relatively Accessible</td>
<td>• Labor intensive and time consuming</td>
</tr>
<tr>
<td>• Potential lower cost compared to prospective trials</td>
<td>• Abstractor disagreement or bias</td>
</tr>
<tr>
<td>• History information which allows longitudinal inspection</td>
<td>• Abstractor associated error, for example: abstractor fatigue, poor training or incompetence</td>
</tr>
<tr>
<td>• Data ready to be used</td>
<td>•</td>
</tr>
<tr>
<td>• Large volume</td>
<td>•</td>
</tr>
<tr>
<td>• Versatility and customization</td>
<td>•</td>
</tr>
</tbody>
</table>

Specific Aim 2: to systematically review the literature on the methodology of conducting manual chart review

Upon applying search terms following the search strategies proposed in Chapter V – Methodology, 346 publications were identified. Five additional publications are identified via cross-referencing the bibliographies from the eligible, included publications. Since this practicum report aims to develop a generic yet pragmatic work flow for manual medical chart review, many publications with methodological discussions were included. These articles did not have the traditional lay out of research study. Instead of having sample size, bias and formal methodology, these publications had methodological considerations and concerns. Therefore,
table of characteristics of include publications is omitted for this practicum report. Figure I outlines the detailed exclusion process following declared inclusion and exclusion criteria.
Figure I – PRISMA literature inclusion and exclusion diagram
A significantly portion of the identified publications did not report detailed work flow or provided specific abstraction mechanism. Roughly 71.23% of identified publications did not report the actual abstraction process. The abstraction process was referred by using only vague and non-reflective statements, for instance: abstractors were trained, structured data collection tool is used, and inter-rater agreement has been assessed.

Approximately thirty-three publications employed specific database or specialized data collection tool during the chart abstraction process. A portion of the abstraction is done manually and the remaining task is completed by direct electronic acquisition process. Figure II shows the percentage of excluded publications in each category against total number of identified publications.

![Figure II – Percentage representation of excluded publications](image-url)
Specific Aim 3: to develop a best-practice guideline or a pragmatic work flow for manual chart review

After reviewing all eligible publications according to inclusion and exclusion criteria, a series of twelve steps with one optional procedure have been synthesized from the sources. Figure III contains a diagrammatic representation of the workflow. Table III elicits a detailed listing of included publications and which step of the pragmatic work flow is mentioned. Finally, Figure IV contains a graphic representation of the percentage of each step in the pragmatic work flow mentioned in the included publications.

Below is a detailed description of each of the steps in the pragmatic workflow for manual data abstraction of medical chart review studies.

1. Formulating a research question

   Research question should be specific, clear and focused.\textsuperscript{4,26,49,50,53} It should not be too narrow or too broad.\textsuperscript{3} Investigators can conduct literature review on the question of interest in order to develop a well-defined hypothesis.\textsuperscript{56} Having a clear defined research question and hypothesis allows the investigators to determine the feasibility of medical chart review.\textsuperscript{53,55}

   Moreover, investigators should seek expert opinion on the question of interest and consider various pitfalls as early as possible. Inputs from clinicians, data management team, project management team and technical staff may affect the study design and it may have significant influence on later steps.\textsuperscript{53}
2. Pre-pilot phase

There are three distinct components in the pre-pilot phase: record identification, variable categorization and sample size determination. A few medical charts or records should be examined in order to fully execute these components.\textsuperscript{49}

2.1 Record identification

Depending on the research question, the pre-pilot phase should also determine which record, which part of the record and any supplementary documents to be included in order to extract useful information.\textsuperscript{7,26,50} Location and specific document should be discussed during this step of the workflow. Moreover, strategies to handle missing records, inconsistent documentation, erroneous records, uninterpretable records and other poor documentation issues should be addressed among the research team. A consensus of treatment should be done in this step. In case multiple documents are needed in order to address the research question, a hierarchy of documents should be established in order to deal with conflicting data existed across the different documents.\textsuperscript{7}

2.2 Variable categorization

Variables pertaining to specific research question should be identified during this step.\textsuperscript{7,26,50,53} Also, the variable categories need to be determined, for instance, should variables be captured as nominal, ordinal, interval or ratio. Besides variable categorization, ways to handle missing data, conflicting data, inconsistent data, data with multiple entries, un-interpretable data and erroneous data should be addressed in this step.\textsuperscript{7,50}
2.3 Sample size determination

Also, a pre-sampling step is recommended in this step in order to have a better estimate of the actual sample size.\textsuperscript{2} After choosing a desired confidence interval, sample size can be determined by the investigators using a reliable statistical formula or determined by consulting a statistician.

3 Designing data collection form (DCF)

Designing the data collection form may require extensive collaboration since clinical expertise is needed in order to answer specific knowledge questions.\textsuperscript{4,53} Data collection forms need to include all variables in a logical order and they should be standardized.\textsuperscript{4,7,49,58} It is preferable to have the DCF structure corresponds with the document or medical records. Variables can be broken into sections for ease of capturing. Also, the layout of the form and variable categorization should include appropriate handling for missing data, erroneous data and other data issues.\textsuperscript{49} Presentation should be clear for example: a check box for options, lines for free-text information or coded entry. Below is an example of a section in a DCF.

<table>
<thead>
<tr>
<th>Past Pregnancies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Month/Year:</strong></td>
</tr>
<tr>
<td><strong>Pre-term labor:</strong></td>
</tr>
<tr>
<td><strong>Length of labor:</strong></td>
</tr>
<tr>
<td><strong>Multiples:</strong></td>
</tr>
<tr>
<td><strong>Birth weight:</strong></td>
</tr>
</tbody>
</table>
4 Create DCF completion manual

A DCF completion manual can be accomplished concurrently with step 3. Ideally, step 3 and step 4 should be performed immediately after step 2 in order to fully address all concerns, rules and regulations formulated during the pre-pilot phase of the pragmatic work flow.

A DCF completion manual or abstraction protocol should include detailed capturing mechanism for each variable with agreed rules between multiple abstractors. Also, it should reflect the various ways that a variable can be recorded in the EHR system. If there are multiple expressions or synonyms, DCF completion manual should explain how to capture the data. In addition, a DCF completion manual should also provide examples whenever appropriate in order to help the abstractor to understand the abstraction process.

If multiple documents will be used for research studies, then the DCF completion manual or abstraction protocol should denote which variable can be abstracted from which document and which specific entry of the variable will be captured. If multiple entries of a variable exist, then the investigator and abstracting team should agree on which specific entry or all entries will be captured.

Furthermore, a hierarchy of records should be established. The most powerful record or the most decisive document should be the most relevant to a research study. It should be determined based on expert opinion and the results from step 2. Below is an example of DCF completion manual.
Principal Document Sources:

1. Prenatal record
2. Qs document
3. Face sheet
4. Mother’s worksheet for birth certificate
5. Maternity progress summary report
6. Delivery System

Hierarchy of document usage:

1. **Use prenatal record to fill out the form, should there be any conflict of information across the documents, prenatal record always win!**

General rules:

1. Prenatal record is the most authoritative source, should there be a conflict of information, capture the data from prenatal record
2. For medical history, infectious disease history, and family history, if there is a ‘yes’ recorded in any of the five principal documents sources, capture as yes.
3. For other entries, please use the table below for reference
4. For laboratory/diagnostics tests, please capture the value of the latest date

<table>
<thead>
<tr>
<th>Categories</th>
<th>Specific Items</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic</td>
<td>Account #</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Use “mother’s worksheet for birth certificate” if needed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• If no records found, capture as U (unknown)</td>
</tr>
<tr>
<td>Past Pregnancies</td>
<td>Weeks Gestation</td>
<td>• If recorded as full term, capture as 40 weeks</td>
</tr>
<tr>
<td></td>
<td>Pre-term Labor</td>
<td>• Capture as Y if the weeks of gestation if anything less than 36 weeks unless the record shows otherwise</td>
</tr>
<tr>
<td></td>
<td>Birth Weight</td>
<td>• Capture in lb and oz, please convert if recorded in any other measuring units</td>
</tr>
<tr>
<td>Last Physical Exam</td>
<td>Presentation</td>
<td>• Vertex position can be recorded as ‘cephalic’. Capture as ‘vertex’</td>
</tr>
<tr>
<td>Laboratory Test</td>
<td>Diabetes Screen</td>
<td>• If multiple entries exist, capture the latest one</td>
</tr>
</tbody>
</table>
5 Pilot phase

Once the DCF and the DCF completion manual are finished, a pilot phase should occur to test the feasibility of the DCF, the DCF completion manual, sample size, percentage of missing documents, variables, and over-all design of the protocol.\(^7,^{50}\) Pilot testing can assess the appropriateness of sample size since this step allows the investigators to examine percentage of missing records or missing data.

A larger sample of charts should be used to see if the DCF, the DCF completion manual and sample size are reasonable, representative and inclusive. When choosing the records or documents for pilot test, convenience sampling and non-convenience sampling can be employed depending on the sample size.\(^2\)

The DCF should be evaluated for its structural layout, variable inclusion, variable categorization and usability. The DCF completion manual should be reviewed for its completeness, inclusive, rules and the ability to facilitate explicit data abstraction. Examples of few questions to consider during this step of the pragmatic work flow is listed below.

- Is exclusion percentage is too high or too low?
- Should study increase sample size?
- Should inclusion and exclusion criteria be modified?
- Does the study have enough number of variables?
- Are variables accurately and appropriately categorized?
- Is the DCF completion manual complete?
6 Revision

After pilot phase, DCF and DCF completion manual can be revised in order to address additional questions and concerns. The DCF and the DCF completion manual, after revision, ideally should be optimized to facilitate efficient usage and avoid abstractor fatigue.4,50

7 Training

Investigators should carefully choose abstractors base on qualification and experience.4,49 Investigators or other research team members need to train the abstractors on how to use the DCF and the DCF completion manual.2 A few medical records may be used as examples.49,50,51

One optional procedure that can occur during this phase of the pragmatic work flow is masking or blinding. Abstractors can be masked or blinded in order to decrease bias and subjectivity while abstracting.2 If the investigators wish to mask the abstractors, the hypothesis or research question should not be revealed to the abstractors. Among the nineteen included publications, five publications mentioned this step.2,25,49,51,55 Since the effect of masking has not been fully explored, the effect and usage of this step remains inconclusive.

8 Abstraction

This step is the most important and crucial step of medical chart review studies and it contains two major components: monitoring and quality assurance (QA).4
8.1 Monitoring

Investigators or designated quality officers can monitor the abstraction process. Regular conference and double review should be performed while abstraction takes place. Bi-weekly phone conference and/or webinar should be scheduled for the abstractors in order to address any abstraction concerns, questions, discrepancies and dis-agreements.49,51,52,59

Abstractors are advised to take breaks periodically in order to eliminate abstraction fatigue and investigators should consider flexible working hours in addition to quite, private abstraction locations for the abstractors.4

8.2 Quality Assurances

Investigators or designated quality officers should periodically review abstracted records to assess the inter-rater reliability between the abstractors. Inter-rater reliability (IRR) examines the percent of agreement when multiple abstractors ascertain the same medical records.4 A higher IRR indicates that abstractors are extracting the information consistently and indirectly attests the validity of the DCF and the DCF completion manual.49,50

There are numerous statistical analysis for IRR measurement; however, the two most common measurements are kappa and percent agreement.2 It is beyond the scope of this practicum report to discuss which analysis is appropriate and statisticians can be consulted in this matter.7

9 Building database

Depending on the research, availability and team dynamics, a database can be built in order to enter those data extracted from medical records.50 Programmer and
database personnel should design the database and build it according to the DCF. An ideal database may include the following features:

- Drop-down, coded lists using standardized, agreed terminology
- Auto-prompt for completion of required fields
- Tab function (allowing tabbing to the next field)
- Auto-Saving or other saving functions

10 Testing the database

Once the database has been built, abstractors and investigators should test the database. Examples of few questions to consider while testing the database is provided below.

- Does the database have all variables?
- Can the variables be entered in the correct format?
- Are there any default values for any variables?
- How big is the text field?
- What is the upper and lower limit on numerical values?
- Does the database have any editorial functions?

11 Revision

After testing the database, programmer should modify the database according to the results obtained from step 10.
12 Data entry

After step 9, 10 and 11, data entry can take place. Continuing quality assurance (QA) process should be considered during this step. Investigators should monitor the data entry process and randomly check on the data been entered.
Figure III – Pragmatic Work Flow for Manual Data Abstraction for a Medical Chart Review Study
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Figure IV – Manual data abstraction steps mentioned in included publications
CHAPTER VII – SUMMARY AND CONCLUSION

Medical chart review is a convenient, accessible, and potentially low cost research method especially when EHR data are available. It is beneficial to use on research questions that have a historical nature for example: epidemiological studies, quality improvement, comparative effectiveness, patient safety and outcome measurement. Having a pragmatic, streamlined and standardized manual data abstraction process can ensure better quality of data and increase the reproducibility of a search study. Also, medical chart review can provide golden standards or function as quality assurance measurement for studies that utilize direct electronic acquisition techniques such as natural language process to collect data or variables from a larger sample of charts.

After reviewing a total of 351 publications, 19 are identified as relevant for inclusion for review by this practicum project, these publications contain essential information pertaining to abstraction workflow and detailed methodology. From these included publications, student researcher synthesized a 12 step workflow designed form manual data abstraction for any medical chart review studies (Figure III). It is intended that this workflow be generic; therefore, articles that offer tips and methodology on specific database and/or data capturing tool are excluded. The generic
format of the 12 step work flow allows more applicability and adoption for different research studies.

Each included publication lists different steps, with some overlapping or omitted. However, 7 steps are considered essential and included in over 50% of the included literature (Figure IV). These 7 steps are:

1. Cleary defined research question
2. Pre-pilot phase
3. Designing data collection form
4. Data collection form completion manual
5. Pilot study
6. Training
7. Abstraction

Three steps in particular, designing data collection form, training and abstraction with monitoring, and QA (Figure IV), are mentioned highly by the included publication. Considering these three steps are the core of manual chart abstraction, it is not surprising to see these steps have high mentioning rate. It is interesting to observe that step 11 – revision (of database) is mentioned in only one article. Since the responsibilities of this task generally belong to programmers or database builder, it is normal to have low inclusion rate among publications focus on methodology of manual data abstraction.

Among the excluded publications, 70.98% of them have no detailed abstraction methodology or lack a description of abstraction work flow (Figure II). It highlights the need for detailed description of manual data abstraction for medical chart review studies.
Documentation and specific protocol should be developed in order to bridge the gap between manual data abstraction and retrospective chart review study.

One limitation of this practicum thesis is the lack of an additional literature reviewer. Having another reviewer would not only ensure the student researcher reviewed the articles in a systematic fashion in accordance with the inclusion and exclusion criteria, but also would allow for the publications to be summarized in similar manner. Furthermore, having an additional reviewer may increase the number of publications reviewed and shorten the review period.

The student researcher has tested the feasibility of the proposed, 12 steps work flow on two particular studies at the internship site. It would be beneficial to test the scalability of this pragmatic work flow for manual data abstraction in order to develop system wide standard operating procedures.
CHAPTER VIII – INTERNSHIP EXPERIENCE

I have completed my six month internship at the Baylor Scott and White Health (BSWH) system, Center for Clinical Effectiveness in the department of the Office of the Chief Quality Officer. The Center for Clinical Effectiveness focuses on developing and investigation methods or innovations that will improve health care quality and efficiency across the BWSH system in order to address constant changes in health policy. The strategy to successfully integrate, modify and improve health care delivery system lies within the idea of STEEP which stands for safety, timely, effective, efficient, equitable and patient centered. In order to achieve the goal of STEEP, the staff has a dynamic profile ranging from health services researchers, epidemiologists, medical economists and people with various specialties in order to design, conduct and implement qualitative health care. Under the leadership of Dr. Andrew L. Masica, the center oversees various research activities ranging from health services research, clinical trials, and comparative effectiveness researches.

The purpose of participating in the internship is to gain knowledge and practical experience of clinical trials management with the focus of human subject protection. The aim of my internship was to function as an assistant to project managers and clinical research coordinator (CRC) in order to understand the work flow of clinical trial, health service research and quality improvement initiatives. My on-site mentors were Dr. Andrew L. Masica, Jessica Harbor and Louann Cole. They have involved me in multiple
studies ranging from shared-decision-making projects, ED workflow study, C-Section predictability model, behavior health evaluation implementation, COPD study and ICU delirium assessment bundle study.

This internship experience has provided insights into various aspects of clinical research management such as coordination, implementation, designing study, administrative enforcement, regulatory affairs, IRB communication, and corresponding between multiple parties. Some of my direct duties are: coordinator – sponsor correspondence, subject survey delivery, data entry, data collection, informed consent development and delivery, interview subjects, follow up activities with different study personnel and IRB interactions. Some of my indirect duties include maintaining and testing the database, designing data collection form or case report forms, schedule meetings and phone calls, cross verifying documents for multiple studies and maintaining study or regulatory binder. Specific activities and experiences are explained in the following sections. A detailed listing of daily activities is enclosed in Appendix A.

Training and Certification:

In order to participate in clinical research involving human subjects and have access to patient information, I completed the training and lessons offered by Baylor Learning Network (a division of the Baylor Research Institute) targeting specifically to human subject protection, IRB regulation and Health Insurance Portability and accountability Act (HIPPA). It is necessary to understand the nature of research involving human subjects and how to take preventive measures to ensure the
confidentiality of the human subjects. I have also completed Collaborative IRB Training Initiative (CITI) prior coming to the site.

There has been continual training and webinars for the studies that I was involved. The online training focused on protocol implementation, procedural ramification, project management and utilization of electronic data capture (EDC) systems. My on-site mentors and I have daily sessions to discuss the progress of various projects and training on the current status, updates and information regarding to each projects.

Subject Recruitment, Screening and Retention:

For most of the projects that I have worked on during this internship, the screening process was conducted by the clinical professionals such as, nurse or therapists, since they have direct contact with the subjects and it is often easier to have them enroll the subjects while the subjects are visiting. However, we maintain the enrollment logs and screening logs. We also conduct additional verification of the subjects according to the defined inclusion and exclusion criteria.

Many projects have multiple surveys issued at different stages of the study. It is our duty to ensure that the surveys are sent, delivered and returned to our office in order to accurately document the process. Keeping track of the survey is another way that we detect subject adherence or retention. If the subject has been constantly not completing certain follow up surveys, contacts will be made by the clinical professionals to discuss if the patient would still like to participate in the trial.
For retrospective studies, Louann Cole, MHA and I audited numerous medical charts or patient’s medical records in order to determine the eligibility of the subjects based on study-defined inclusion and exclusion criteria. All identification, account numbers or linkers are always removed or masked in order to ensure the confidentiality of the patient’s records.

Implementing the Study Protocol Procedures:

During my internship, I was fortunate to actively participate in the development of informed consent. Depending on the nature of the research, there are different kinds of informed consent with various lengths. I helped Louann Cole, MHA in preparing the informed consent that will be submitted for IRB approval and also involved in addressing the stipulation of this informed consent.

There are certain cases when informed consent is not necessary, a cover letter will be used in order to explain the study to the subjects. I was fortunate to observe the cover letter development process for different projects and was able to gain the experience of delivering the cover letter to the subjects.

I helped Jessica Harbor, MS to constantly re-enforce the definition of study concepts and review the qualification criteria with the clinical professionals. Also, I helped coordinated multiple meetings and phone calls in order to discuss the study protocol, procedures and implementation details regarding to different studies during my internship.
Regulatory and Administrative Duties:

I was involved in preparing and maintaining the study binder (or regulatory binder) for two studies. This activity allowed me to understand different components of the study and give clear classification of the massive volume of paper works. Also, having a working, properly documented regulatory binder can ease the regulation of the study and ensure the efficiency of the work flow. Moreover, it allows better transitions if other study personnel need quick reference to certain documents.

Some trials were already approved by the IRB when I joined the center. However, I was able to work on the continuing review process.

Meetings:

During the course of my internship, I had the chance to attend most of the team, department, institutional, study sponsor and coordinator meetings. Sometimes there seems to be an abundance of meetings; however, it is essential to attend these meetings since they gave exposure to the topics and allow beginners to understand the whole picture a lot faster. Despite the fact that meetings may be overwhelming for beginners, I believe attending them can give insights and essential updates to the study. During these meetings, I learned the challenges, lessons and tips associated with different study designs and how to properly address these concerns.
APPENDIX A – INTERNSHIP DAILY JOURNAL


Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Mrs. Jessica Harbor, MS

Dr. Andrew L. Masica, MD, MSCI

Monday 6/2/2014

- Basic set up, introduction into the systems
- Discuss projects with Mrs. Jessica Harbor and Mrs. Louann Cole
  - CMMI – Patient engagement/Shared Decision making (CMMI-SDM)
  - Patient activation measure (PAM)
  - C-section predictability
  - Behavior health study
- Read materials on categories of IRB review process

Tuesday 6/3/2014

- Start reading materials + watching videos on CMMI – SDM
- Start read materials on patient activation project
- CMMI – SDM update – introduction to the iRIS system
- Continue reading materials on PAM
- Read the protocol for Behavior Health Evaluation

Wednesday 6/4/2014

- Finish reading materials on PAM
- CITI training with Baylor Research Institute added
- UNT HSC IRB website for guidance on filling out various forms and how certain components of the trial needed to be followed
- PAM data entry training with Mrs. Jessica Harbor using Flourish
- Looking through various examples of research proposal

Thursday 6/5/2014

- Literature searching on the topics of PAM – more literature
- Conference call – CMMI – weekly implementation meetings
- Conference call – PAM meeting
- Start working on research proposal, basic set up structure
Friday 6/6/2014

- Data entry of PAM for the Heart Hospital Baylor Plano (THHBP)
- HVHC conference call
- Meeting with Dr. Andrew Masica
- Discuss projects with Mrs. Louann Cole

Approved by: [Signature]

Site: Baylor Research Institute – Center of Clinical Effectiveness

On site Mentors: Dr. Andrew L. Masica, MD, MSCI

Mrs. Jessica Harbor, MS  Mrs. Louann Cole, MHA

Monday 6/9/2014

• Review IRB, different review forms, necessary forms and requirements
• Markov Logic – associated with C-section predictability study
• Conference – HVHC diabetic team meeting
• Video on electronic reporting system
• Reading through various IRB forms + protocols for CMMI

Tuesday 6/10/2014

• Study protocols and IRB applications for HVHC Hip and Knee and HVHC CHF
• Research on different care systems ➔ better picture to understand HVHC and different collaboration
• Start constructing background information section of the PAM study protocol

Wednesday 6/11/2014

• Meeting with Dr. Jenny Adams
• Discuss projects with Mrs. Louann Cole
• Comparing the differences of handing out survey at two different cardiac rehab sites + schedule meeting
• Review C-section predictability grand proposal

Thursday 6/12/2014

• BLN training courses
• CMMI weekly implementation meeting
• SDM training – Medprovider
• C-Section Predictability meeting

Friday 6/13/2014

• Data entry for THHBP
• CMMI monthly report – observe Mrs. Jessica Harbor (partially)

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS        Mrs. Louann Cole, MHA

Monday 6/16/2014

• HVHC – Diabetes baseline survey – start
• HVHC – Diabetes follow up survey – start
• Discuss potential research proposal with Ms. Louann Cole
• Research proposal topic consolidation
• Literature research for research proposal

Tuesday 6/17/2014

• Meeting with Mr. Tim Bilbrey
  o Update Julie/Tim PAM excel
• HVHC – Diabetes baseline + follow up survey  ➔ develop paper form (using template and SAT tool)
• Literature search for research proposal
  o Begin writing for research proposal (Summary, Aims, Significance, Limitations + Chapters)

Wednesday 6/18/2014

• CMMI – SDM project meeting
• HVHC – Diabetes baseline + follow up survey  ➔ complete paper form
  o Send to Mrs. Jessica Harbor for review
• Research proposal (Background + Methodology)

Thursday 6/19/2014

• CMMI weekly implementation meeting – conference call
• Research proposal  ➔ editing
• Meeting with Mrs. Harbor + Mrs. Cole to discuss research proposal

Friday 6/20/2014

• Data entry at THHBP
• Research proposal finish

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 6/23/2014

• HVHC – CHF baseline survey – start
• HVHC – CHF follow up survey – start
• Research proposal writing up ➔ Change focus

Tuesday 6/24/2014

• HVHC – CHF baseline + follow up survey ➔ develop paper form (using template and SAT tool)
• Committee meeting with Dr. Gwirtz, Dr. Jin, Dr. Mascia, Mrs. Harbor held at the site
• Editing research proposal: grammatical editing, version feature added, search pattern refined
• Work with Mrs. Louann Cole on C-Section Predictability

Wednesday 6/25/2014

• Conference call with Laurell Lawson – CHF/ICD set up
• Start working on IRB submission and develop protocol for C-section predictability with Louann

Thursday 6/26/2014

• C-section predictability protocol development with Louann
• HVHC – Knee survey development with

Jessi Friday 6/27/2014

• HVHC Conference Call – HF/ICD/SAT discussion
• C-section predictability protocol development with Louann
• Discuss goals for C-section project for the next weeks with Louann

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 6/30/2014

• HVHC – Knee Baseline + 3 month follow ups
• HVHC – Diabetes Baseline + 3 month follow ups
• HBHC – CHF/ICD Baseline + 3 month follow ups
• Data collection sheet clarification
• Developing data abstraction guide/instructions
• Editing research proposal – methodology portions

Tuesday 7/1/2014

• HVHC IRB updates with Jessi
• HVHC – survey updates
• Discuss research methodology with Jessi
• Edit research proposal

Wednesday 7/2/2014

• Start developing search patterns and keywords combination for research project
• C-section predictability protocol editing

Thursday 7/3/2014

• Start initial literature review process
• Sending research proposal to Dr. Gwirtz for initial review

Friday 7/4/2014 – Independence Day
Weekly Log 7/7/2014 – 7/11/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI

Mrs. Jessica Harbor, MS

Mrs. Louann Cole, MHA

Monday 7/7/2014

• Start filling Form 15 for C-Section Predictability
• Updating IRB (online system) for C-Section Predictability
• Finish Hip baseline survey + testing on the beta site
• Finish Hip 3 month survey + testing on the beta site
• KCCQ scoring calculation ➔ email tagging HVHC

personnel Tuesday 7/8/2014

• C-Section Predictability meet up with Louann and Dr. Elisa Priest, DrPH
• Work on diabetes, CHF, PROMIS, KCCQ and SPORT ODI slides
• Informed Consent development for ED Workflow project with Louann
• Start PAM protocol again (lost initial ones)

Wednesday 7/9/2014

• C-Section predictability data collection sheet editing ➔ send to Louann for further review
• Follow ups for C-section predictability
• Continue HVHC IRB update with Jessi
• Follow protocol updates with Dr. Elisa Priest

Thursday 7/10/2014

• CMMI implementation weekly meeting
• COPD and BHEG meeting with Dr. Elisa Priest
  o Start up meeting for COPD
  o Data Collection for BHEG
• Data entry for HVHC June report part 1

Friday 7/11/2014

• PAM data entry at THHBP (The Heart Hospital Baylor Plano)
• Data entry for HVHC June report part 2
  o E-mail both Lee and Cynthia for notification and clarification

Approved by: [Signature]
Weekly Log 7/14/2014 – 7/18/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 7/14/2014

• C-Section predictability protocol update with data retention
• Follow up with Dr. Stecher for C-section project (form 35)
• HVHC quarterly report continue update
• HVHC diabetes team meeting
• Follow up with Cynthia on HVHC quarterly report status (number verification)

Tuesday 7/15/2014

• HVHC master IRB annual update due today → update changes
• HVHC update form 15
• BHEG screening form data completion guide development
• Record retention guideline development
• C-Section Predictability regulatory binder start up

Wednesday 7/16/2014

• BHEG medication matrix start up
• HVHC Hip and Knee continuing review start up
• Edit research proposal – With Dr. Gwirtz’s notes
  o Send it to Jessi, Louann and Dr. Jin for review

Thursday 7/17/2014

• CMMI weekly implementation conference
• Research proposal editing – with Louann’s notes
• Sample chart abstraction for C-Section Predictability
• Training with Louann to use Allscripts – EMR application

Friday 7/18/2014

• Data entry at THHBP
• Town Hall meeting in Baylor regional medical center at Plano
• HVHC CMMI paper survey group conference 1

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 7/21/2014

• Organize meeting minute ➔ send to Jessi ➔ share with paper survey group once approved
• C Section predictability data collection form updates
• Continue research proposal edit ➔ discuss with Louann
• COPD with PAM protocol study

Tuesday 7/22/2014

• Continue review process for HVHC hip and knee ➔ work with Jessi
• HVHC Access database set up
• COPD /PAM study regulatory binder start up

Wednesday 7/23/2014

• IRB conference with center for clinical effectiveness team
• Research proposal discussion with Louann
• SAT running weekly report training with Jessi
• SAT report running for 3 sites
• SAT data back entry
• HVHC patient satisfaction conference
• Paper group survey meeting minute follow ups

Thursday 7/24/2014

• CMMI weekly implementation meeting
• SAT report running and data back entry for all sites
• Regulatory binder maintenance for COPD/PAM

Friday 7/25/2014

• Systematic literature review – work on research project
Weekly Log 7/28/2014 – 8/1/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI

Mrs. Jessica Harbor, MS

Mrs. Louann Cole, MHA

Monday 7/28/2014

- HVHC orthopedic condition weekly report
- HVHC orthopedic condition – back entering data
- Maintaining COPD/PAM regulatory binder (electronic)
- Create “delegation for authority” log
- Filed “intend to graduate” with Dr. Amanda Griffith
- HVHC Hip + Knee continuing Review – Lit Search
- Research proposal signature obtained from

Jessi Tuesday 7/29/2014

- C-Section predictability next step meeting with Louann and Dr. Elisa Priest
- C-Section predictability data collection sheet revision
- Literature search for shared decision making
- Reading articles on differentiation between quality improvement project and research projects

Wednesday 7/30/2014

- Work on research project – systematic literature review
- C-Section predictability data collection sheet revision – route for review
- Work on PAM protocol
- Obtain signatures from Dr. Masica and run to Fort Worth to obtain signatures from Dr. Jin and Dr. Gwirtz → filing research proposal

Thursday 7/31/2014

- COPD/PAM project meeting with Dr. Elisa Priest and Rachel Brown
- PAM protocol development
- Run for signatures

Friday 8/1/2014

- THHBP PAM data entry
- HVHC Spine – Herniated Disc and Stenosis baseline survey and 3 months follow up survey development

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors:  Dr. Andrew L. Masica, MD, MSCI
                     Mrs. Jessica Harbor, MS  Mrs. Louann Cole, MHA

Monday 8/4/2014

• SAT – Ortho conditions weekly reports
• HVHC hip and knee continuing review – meeting with Jessi
• Back entry for SAT – Terrell/Lee clinics
• Running Terrell weekly reports – training with Jessi
• PAM protocol (aiming to finish by the end of Tuesday)
• BHEG data collection sheet – sorting out the errors, classify sheets, pulled administration time
• BHEG data management meeting with Louann and Elisa

Tuesday 8/5/2014

• HVHC qualitative training
• COPD study meeting – Rachel
• BHEG database user testing
• PAM protocol development

Wednesday 8/6/2014

• BHEG weekly meeting – conference
• PAM protocol development – send to Jessi for review
• BHEG database testing – data entry and field reports
• BHEG data rough counts
• BHEG data collection form review for accuracy and errors

Thursday 8/7/2014

• COPD update meeting with Elisa, Rachel and Louann
• SAT Terrell Clinic data back entering
• HVHC weekly implementation meeting
• Finish the surveys and send spine surveys to Cynthia for review

Friday 8/8/2014

• PAM data collection THHBP + Systematic literature review

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 8/11/2014

• SAT weekly report – Ortho conditions
• SAT weekly report – Terrell conditions
• BHEG database testing – testing v1.1
• Developing online survey questions for HVHC paper survey group
• Systematic literature

review Tuesday 8/12/2014

• ABCDE – ICU delirium qualitative interviews meeting
• HVHC monthly report – July’s status ➔ data from Ortho + Terrell
• BHEG protocol revision – initiation of the process ➔ sending form 35
• BHEG revision – IRB portions

Wednesday 8/13/2014

• BHEG weekly conference
• BHEG data collection sheet re-classification
• Patient report outcome measure conference
• PAM Protocol review with Jessi
• Continue PAM Protocol development – Specific aim review for Jenny
• C-Section Predictability – Protocol revision

Thursday 8/14/2014

• CMMI weekly implementation meeting
• BHEG data entry meeting with Shanni

Friday 8/15/2014

• Data entry at THHBP
• Systematic literature review
Weekly Log 8/18/2014 – 8/22/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS          Mrs. Louann Cole, MHA

Monday 8/18/2014

• CMMI Ortho weekly report
• CMMI FMC diabetes weekly report
• Conference call – health coach ortho definition clarifications
• CHF survey questions verification and validation
• PAM data back entering
• BHEG protocol driven IRB submission

Tuesday 8/19/2014

• ED workflow meeting with PI
• Literature review and searching for practicum project

Wednesday 8/20/2014

• GSK study folder assembly
• IBID mock interview and note taking, testing database and data collection tool
• Continue literature review and searching for the practicum project

Thursday 8/21/2014

• CMMI weekly implementation meeting
• PAM Protocol fine tuning with the researchers
• Continue working PAM protocol
• DSMB Cover Letter development ➔ use it for HVHC Hip and Knee continuing review

Friday 8/22/2014

• PAM data entry at THHBP
• Systematic literature review

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
			Mrs. Jessica Harbor, MS
			Mrs. Louann Cole, MHA

Monday 8/25/2014

- Generate CMMI weekly report – Ortho condition
- Generate CMMI weekly report – FMC
- Back entry contact information for FMC health coaches
- Systematic literature review
- Follow up with Co-PI for C-section predictability study → BLN lessons

Tuesday 8/26/2014

- Practice IBID interview
- Request access for interview projects
- Systematic literature review – search for literatures, different combination of keywords
- Follow up with FMC health coach on contact log

Wednesday 8/27/2014

- ABCDE interview @ BUMC – Truett 4 X 1 people
- Post interview – data collection + notes cleaning + files establishment

Thursday 8/28/2014

- ABCDE interviews @ Garland X 4 people
- Post interview – data collection + notes cleaning + files establishment

Friday 8/29/2014

- PAM data entry
- Systematic literature review
Weekly Log 9/1/2014 – 9/5/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 9/1/2014 – Labor Day

Tuesday 9/2/2014

• Data back entering for Family Medical Clinic at Terrell (FMC) – contact logs
• Generating weekly report for ortho conditions
• Generating weekly report for FMC
• Practicum Project – X 4 articles examined + sorted into files accordingly
• Updating paper surveys for CMMI projects and send them to David – Central divisions

Wednesday 9/3/2014

• IBID qualitative interviews – BUMC 2 S ICU X 3
• IBID qualitative interviews – BUMC RT department X 5

Thursday 9/4/2014

• IBID qualitative interviews – BUMC 4 T X 3
• BHEG data collection meeting with Shinny
• Collecting and classifying BHEG data forms – old ones

Friday 9/5/2014

• Organizing and correcting IBID qualitative interview notes
• C-Section predictability Form 15 discussion and filling out

Approved by: [Signature]
Weekly Log 9/8/2014 – 9/12/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 9/8/2014

• Generate weekly report for CMMI – Ortho condition
• Generate weekly report for CMMI – FMC – Diabetes
• BHEG data collection tool conference meeting with Brandy + Louann
• Systematic literature review – background literatures revisit
• HVHC Diabetes Team meeting – conference call
• PAM protocol definite discussion with Jessi and future game plan for PAM

Tuesday 9/9/2014

• Systematic literature review – background literatures revisit part II
• BHEG database – sorting and going through questions
  o Coordinating discussion time with another project manager
• IBID qualitative interview 4 T X 2

Wednesday 9/10/2014

• Generate monthly report for CMMI – Ortho
  o Report numbers and completion status
  o Double check with the health coach and conference call
• Meeting with Briget da Graca to discuss practicum project
  o Redirecting and narrowing the research questions
• Continue literature search – literature digging phase I

Thursday 9/11/2014

• BHEG data collection and entry discussion with Shinny
• ED workflow quick briefing meeting with Louann and Dr. Xiao
• Literature search and related citation features employed

Friday 9/12/2014

• PAM data entry at THHBP – network connection issues
• BHEG data – new forms and re-numbering ➔ ready for entry
• Continue to work on CMMI monthly action report

Approved by: [Signature]
Weekly Log 9/15/2014 – 9/19/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 9/15/2014

• Complete CMMI monthly action report – Ortho condition
• Complete CMMI monthly action report – Diabetes condition
• Complete CMMI weekly report – Ortho condition
• Complete CMMI weekly report – diabetes conditions
• PAM data entry completion
• BHEG data collection forms – administrative business
• Start working on HVHC – Spine conditions – IRB continuing reviews
• Start working on thesis

Tuesday 9/16/2014

• IBID Interviews at Baylor Plano ICU Nurses X 5

Wednesday 9/17/2014

• BHEG data collection forms meeting with Shinny
• BHEG data entry
• Interview notes and database re-collection and organization and data entry
• Coordinating a solution for oral defense – time and schedule conflict

Thursday 9/18/2014

• CMMI weekly implementation meeting
• IBID interviews at Baylor Plano X 4
• IBID interviews at Baylor Garland RT X 2
• Interview notes, data collection and data entry
• Coordinating a solution for oral defense – time and schedule conflict

conflict Friday 9/19/2014

• IBID Interview notes, data collection and data entry
• Update Dr. Gwirtz on oral defense solutions
• PAM data entry at THHBP
• Start putting together regulatory binders for HVHC conditions
• HVHC Spine continuing review

Approved by: [Signature]
Weekly Log 9/22/2014 – 9/26/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors:  Dr. Andrew L. Masica, MD, MSCI
                  Mrs. Jessica Harbor, MS        Mrs. Louann Cole, MHA

Monday 9/22/2014

- Generate and Complete weekly report for CMMI – Ortho conditions
- Generate and Complete weekly report for CMMI – Diabetes conditions
- Practicum project – refocus
- C-Section Predictability – Sample abstraction X 4

Tuesday 9/23/2014

- BHEG data form/collection meeting with Shinny + Louann
- CMMI – Diabetes/CHF team core meeting
- Inter-rater reliability with Louann

Wednesday 9/24/2014

- HVHC Spine continuing review application submission – attach all forms and craft language
- Maintaining HVHC Spine regulatory binder
- Re-draft C-Section predictability data abstraction form
- Re-draft C-section predictability data abstraction guide
- IBID interviews at Baylor Irving X 4

Thursday 9/25/2014

- CMMI weekly implementation meeting
- Practicum project meeting with Jessi
- Inter-rater reliability with Louann X 2 charts
- C-section predictability data abstraction form correction
- C-section predictability data abstraction guide development → reformatting

Friday 9/26/2014

- PAM data entry
- Article re-organization and regrouping them according to chapters in the report
Weekly Log 9/29/2014 – 10/03/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 9/29/2014

• Generated CMMI weekly report for FMC
• Hold off on the CMMI weekly report for ortho conditions
• HVHC Spine continuing review (continue working on it)
• C-Section Predictability chart abstraction X 15
• Literature revisit and regrouping

Tuesday 9/30/2014

• Practicum project – background literature regrouping
• Start going to the 25 chart abstraction and flag the questionable ones

Wednesday 10/1/2014

• Fill intend to defend form
• IBID qualitative interviews at Baylor All Saints X 4

Thursday 10/2/2014

• CMMI weekly implementation meeting
• Follow up with new BHEG forms
• Re-checking on the chart abstractions for C-Section Predictability
• HVHC Spine continuing review → route it to Jessi
• C-Section Predictability → IRB revision and add additional Co-PI to the study

Friday 10/3/2014

• PAM data entry
• Practicum project
Weekly Log 10/6/2014 – 10/10/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Ms. Jessica Harbor, MS Ms. Louann Cole, MHA

Monday 10/6/2014
- CMMI – weekly report for diabetes
- Continue to follow up with the “intend to defend” form
- HVHC – CHF paper survey complete updating and generate the paper form
- C-Section predictability chart abstraction X 10
- Practicum thesis writing

Tuesday 10/7/2014
- Update HVHC Diabetes paper surveys (baseline, 3 month and 6 month) ➔ send them out to the health coach
- Coordinate and trouble shoot a solution for patient entries issues of SAT tool (HVHC project)
- C-Section predictability chart abstraction X 6
- Practicum thesis writing

Wednesday 10/8/2014
- Follow up BHEG data collection sheets
- HVHC Hip and Knee adding another key study personnel
- C-Section predictability ➔ re-examine excluded patients + organize data entry forms
- C-Section predictability chart abstraction X 15
- Follow up on HVHC patient entries issues

Thursday 10/9/2014
- Follow up with BHEG data collection sheets
- HVHC Hip and Knee change of key personnel IRB stipulation
- C-Section Predictability change of key personnel re-submission
- C-Section Predictability chart abstraction guideline development
- C-Section Predictability chart abstraction X 10
- Practicum thesis writing

Friday 10/10/2014
• Meeting with Dr. Elisa Priest to discuss details regarding to practicum
• C-Section Predictability chart abstraction X 5
• C-Section Predictability database pilot testing
• Practicum thesis writing

Weekly Log 10/13/2014 – 10/17/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 10/13/2014

• Generate CMMI weekly report for Diabetes
• Generate CMMI monthly action tracking report
• C-Section predictability database testing X 10
• Making SDM folder X 14
• HVHC Diabetes Conference call
• C-Section predictability chart abstraction X 10

Tuesday 10/14/2014

• C-Section predictability chart abstraction X 5
• Literature search for practicum report
• HVHC Hip surveys coordination with another personnel
• Follow up with IRB on the status for continuing review of a study

Wednesday 10/15/2014

• IBID interviews at Baylor All

Saints Thursday 10/16/2014

• BHEG data collection and data entry
• C-Section predictability chart abstraction X 10
• Literature re-classification

Friday 10/17/2014

• C-Section predictability chart abstraction X 15
• Literature review and work on practicum report
Weekly Log 10/20/2014 – 10/24/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS
Mrs. Louann Cole, MHA

Monday 10/20/2014

- Generate weekly report for CMMI – Diabetes
- Follow up with health coach on paper survey status
- Testing C-section predictability database
- C-section predictability chart abstraction X 5
- Practicum report

Tuesday 10/21/2014

- C-Section predictability chart abstraction X 5
- Practicum report

Wednesday 10/22/2014

- C-Section predictability chart abstraction X 5
- BHEG follow up coordination
- Practicum report – systematic review

Thursday 10/23/2014

- Town Hall Meeting
- BHEG database verification and missing data handling
- Practicum report

Friday 10/24/2014

- PAM data entry at THHBP
- BHEG follow up discussion with data management team members
- C-Section predictability chart abstraction X 5
- Follow up with the PI for the C-section predictability study
- Practicum report

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors: Dr. Andrew L. Masica, MD, MSCI
Mrs. Jessica Harbor, MS  Mrs. Louann Cole, MHA

Monday 10/27/2014
• Generate and send out weekly CMMI diabetes report
• C-Section predictability chart abstraction X 5
• BHEG data form carination
• Practicum report – literature

log Tuesday 10/28/2014
• C-Section predictability chart abstraction X 10
• Practicum report – continue literature review and prepare to write the summary and conclusion portion of the thesis
• Comparison table between PRISMA and the practicum thesis

Wednesday 10/29/2014
• Practicum thesis
• Chart abstraction X 5

Thursday 10/30/2014
• Practicum thesis
• Chart abstraction X 5
• PAM conference phone call

Friday 10/31/2014
• PAM data entry
• Chart abstraction
Weekly Log 11/03/2014 – 11/07/2014

Site: Baylor Research Institute – Center of Clinical Effectiveness

On-site Mentors:  Dr. Andrew L. Masica, MD, MSCI

Mrs. Jessica Harbor, MS

Mrs. Louann Cole, MHA

Monday 11/03/2014

• BHEG phone conference
• Weekly report for CMMI projects
• Chart abstraction X 15
• Practicum thesis
• Send meeting notes to BHEG team
• Paper Survey double check, re-editing and referencing

Tuesday 11/04/2014

• Data entry for patient contact
• Paper survey follow up on question clarification
• Chart abstraction X 5
• Practicum thesis
• Send off paper survey to couple patients

Wednesday 11/05/2014

• Chart abstraction X 5
• Practicum thesis – final editing
• Follow up actions on hip paper survey

Thursday 11/06/2014

• Send practicum thesis to committee members for review

Friday 11/07/2014

• PAM data entry
## APPENDIX B – LITERATURE EXCLUSION LOG

<table>
<thead>
<tr>
<th>Title</th>
<th>Exclusion Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bae, A., Elbert, Y., Burkom, H. S., Holtry, R., Lombardo, J. S., &amp; Dunchin, J. S. (2011).</td>
<td>No detailed abstraction mechanism and/or</td>
</tr>
</tbody>
</table>


No detailed abstraction mechanism and/or no description of abstraction/review work flow


<table>
<thead>
<tr>
<th>Year</th>
<th>Title</th>
<th>Authors</th>
<th>Abstract Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>Validity and reliability of retrospective assessment of disease activity and flare in observational cohorts of lupus patients.</td>
<td>FitzGerald, J. D., &amp; Grossman, J. M.</td>
<td>No detailed abstraction mechanism and/or no description of abstraction/review workflow.</td>
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<tr>
<td>2009</td>
<td>Researching labor and birth events using health information records: methodological challenges.</td>
<td>Flood, M., &amp; Small, R.</td>
<td>No detailed abstraction mechanism and/or no description of abstraction/review workflow.</td>
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<tr>
<td>1997</td>
<td>Comparing claims data and self-reported data with medical record for Pap smear rates.</td>
<td>Fowles, J. B., Fowler, E., Craft, C., &amp; McCoy, C. E.</td>
<td>No detailed abstraction mechanism and/or no description of abstraction/review workflow.</td>
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<tr>
<td>1989</td>
<td>Methodological issues associated with an audit of stillbirth in a family medicine practice in Israel.</td>
<td>Furst, A. L., &amp; Shamba, E.</td>
<td>Not in 20 years</td>
</tr>
<tr>
<td>2013</td>
<td>Identifying and collecting pertinent medical records for centralized abstraction in a multi-center randomized clinical trial: the model used by the American College of Radiology arm of the National Lung Screening Trial.</td>
<td>Gareen, I. F., Sicks, J. D., Jain, A. A., Moline, D., &amp; Coffman-Kadish, N.</td>
<td>No detailed abstraction mechanism and/or no description of abstraction/review workflow.</td>
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<tr>
<td>2012</td>
<td>Transitioning from a legacy EHR to a commercial, vendor-supplied, EHR: one academic health system's experience.</td>
<td>Gettner, A., &amp; Csatari, A.</td>
<td>No detailed abstraction mechanism and/or no description of abstraction/review workflow.</td>
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68
<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Title</th>
<th>Journal</th>
<th>Year</th>
<th>Notes</th>
</tr>
</thead>
</table>


| Kim, Hw. (2004). Perimenstrual symptoms of Korean women living in the USA: applicability of the WDHID (Women's Daily Health Diary) on prospective report. *Taehan Kanho Hakhoe Chi*, 34:8, 1395 - 1401. | No detailed abstraction mechanism and/or no description of abstraction/review work flow |


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<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Year</th>
<th>Abstract Details</th>
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<tbody>
<tr>
<td>Mitchell, R. J., Bambrick, M. R., Mescatello, D., McKenzie, K., &amp; Balogh, Z. J. (2013).</td>
<td>Can SNOMED CT as implemented in New South Wales, Australia be used for road trauma injury surveillance in emergency departments? HIM J, 42:2, 4 - 8.</td>
<td>No detailed abstraction mechanism and/or no description of abstraction/review work flow</td>
<td></td>
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<tr>
<td>Norquist, G., Wells, K. B., Rogers, W. H., Davis, L. M., Kahn, K., &amp; Brook, R. (1995).</td>
<td>Quality of care for depressed elderly patients hospitalized in the specialty psychiatric units or general medical wards. Arch Gen Psychiatry, 52:8, 695 - 701.</td>
<td>No detailed abstraction mechanism and/or no description of abstraction/review work flow</td>
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</table>


<table>
<thead>
<tr>
<th>Prim Care Update Ob Gyns, 5/4, 207.</th>
<th>flow</th>
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<tbody>
<tr>
<td>Tu, K., Wang, M., Young, J., Green, D., Ivers, N. M., Butt, D., Jaakkimainen, L., &amp; Kapral, M. K. (2013). Validity of administrative data for identifying patients who have had a stroke or transient ischemic attack using EMRALD as a reference standard. <em>Can J Cardiol</em>, 29:11, 1388 - 1394.</td>
<td>No detailed abstraction mechanism and/or no description of abstraction/review work flow</td>
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<tr>
<td>Source</td>
<td>Details</td>
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</table>
APPENDIX C – PRISMA CHECKLIST

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist item</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
<td>Title Page</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
<td>Abstract Page</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
<td>1</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
<td>2</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
<td>N/A</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
<td>11 + Table I</td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
<td>12</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
<td>11-12</td>
</tr>
<tr>
<td>Section/topic</td>
<td>#</td>
<td>Checklist item</td>
<td>Reported on page #</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>-----</td>
<td>-------------------------------------------------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
<td>11-12</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td>12</td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</td>
<td>11-12 + Table III</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
<td>N/A</td>
</tr>
<tr>
<td>Summary measures</td>
<td>13</td>
<td>State the principal summary measures (e.g., risk ratio, difference in means).</td>
<td>N/A</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>14</td>
<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I²) for each meta-analysis.</td>
<td>N/A</td>
</tr>
<tr>
<td>Risk of bias across studies</td>
<td>15</td>
<td>Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
<td>N/A</td>
</tr>
<tr>
<td>Additional analyses</td>
<td>16</td>
<td>Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**RESULTS**

<p>| Study selection                       | 17  | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | 15 + Fig. 1        |
| Study characteristics                 | 18  | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | 15                 |
| Risk of bias within studies           | 19  | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | N/A                |
| Results of individual studies         | 20  | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence | N/A                |</p>
<table>
<thead>
<tr>
<th>Section</th>
<th>Steps</th>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synthesis of results</td>
<td>21</td>
<td>Present results of each meta-analysis done, including confidence intervals and measures of consistency.</td>
<td>N/A</td>
</tr>
<tr>
<td>Risk of bias across studies</td>
<td>22</td>
<td>Present results of any assessment of risk of bias across studies (see Item 15).</td>
<td>10</td>
</tr>
<tr>
<td>Additional analysis</td>
<td>23</td>
<td>Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**DISCUSSION**

<table>
<thead>
<tr>
<th>Section</th>
<th>Steps</th>
<th>Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Summary of evidence</td>
<td>24</td>
<td>Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).</td>
<td>32-33</td>
</tr>
<tr>
<td>Limitations</td>
<td>25</td>
<td>Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).</td>
<td>33-34</td>
</tr>
<tr>
<td>Conclusions</td>
<td>26</td>
<td>Provide a general interpretation of the results in the context of other evidence, and implications for future research.</td>
<td>34</td>
</tr>
</tbody>
</table>

**FUNDING**

<table>
<thead>
<tr>
<th>Section</th>
<th>Steps</th>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding</td>
<td>27</td>
<td>Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.</td>
<td>N/A</td>
</tr>
</tbody>
</table>


*For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org).*
BIBLIOGRAPHY


