IMPLEMENTING EFORM-BASED BASELINE RISK DATA EXTRACTION FROM HIGH QUALITY PAPERS FOR THE BRISKET DATABASE AND TOOL

IMPLEMENTING EFORM-BASED BASELINE RISK DATA EXTRACTION FROM HIGH QUALITY PAPERS FOR THE BRISKET DATABASE AND TOOL

By ANAND JACOB, B.Sc.

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# List of Abbreviations and Symbols

**BRiskeT:** Baseline Risk eTool

**CAP:** McMaster University’s Critical Appraisal Process

**CI:** Confidence Interval

**CPGs:** Clinical Practice Guidelines

**CT:** Computed Tomography

**FP:** Family Practice

**GP:** General Practice

**HiRU:** McMaster University’s Health Information Research Unit

**HR:** Hazard Ratio

**LB:** Lower Bound

**MORE:** McMaster University’s McMaster Online Rating of Evidence

**MRI**: Magnetic Resonance Imaging

**OR:** Odds Ratio

**PLUS:** McMaster University’s Premium LiteratUre Service

**RCT:** Randomized Control Trial

**RR:** Relative Risk

**SNOMED:** Systematized Nomenclature of Medicine

**UB:** Upper Bound

# Declaration of Academic Achievement

The concept behind the BRiskeT tool is unique. If successful, a multitude of users seeking prognostic information on diseases and conditions may stand to benefit from having a large proportion of extracted data from the best articles in one place rather than spread across several journals. This thesis stands as a testament to the effect of technology on research and medical literature as the use of the new online extractor interface not only sped up the process of data extraction, but will also significantly increase the proportion of articles from which data are successfully extracted with minor alterations in the future.

# Abstract

This thesis was undertaken to investigate if an eForm-based extractor interface would improve the efficiency of the baseline risk extraction process for BRiskeT (Baseline Risk e-Tool). The BRiskeT database will contain the extracted baseline risk data from top prognostic research articles. BRiskeT utilizes McMaster University’s PLUS (Premium Literature Service) database to thoroughly vet articles prior to their inclusion in BRiskeT. The articles that have met inclusion criteria are then passed into the extractor interface that was developed for the purpose of this thesis, which has been called MacPrognosis. MacPrognosis displays these articles to a data extractor who fills out an electronic form which gives an overview of the baseline risk information in an article. The baseline risk information is subsequently saved to the BRiskeT database, which can then be queried according to the end user’s needs.

One of the goals in switching from a paper-based extraction system to an eForm-based system was to save time in the extraction process. Another goal for MacPrognosis was to create an eForm that allowed baseline risk information to be extracted from as many disciplines as possible. To test whether MacPrognosis succeeded in saving extraction time and improving the proportion of articles from which baseline risk data could be extracted, it was subsequently utilized to extract data from a large test set of articles. The results of the extraction process were then compared with results from a previously conducted data extraction pilot utilizing a paper-based system which was created during the feasibility analysis for BRiskeT in 2012.

The new eForm based extractor interface not only sped up the process of data extraction, but may also increase the proportion of articles from which data can be successfully extracted with minor future alterations when compared to a paper-based model of extraction.

# Introduction

### The Search For Clinical Answers, The Information Overload And Some Proposed Solutions.

Knowledge is a commodity within the medical field (Wyatt, 1991). Over the course of a standard 10-minute healthcare consultation, it is estimated that a doctor is asked at least one question to which he or she does not know the answer (Smith, 1996). To answer these questions, a doctor or other clinician may turn to a multitude of sources if he or she does not already know the answer. They may turn to trusted colleagues, in fact it is estimated that one third of hospital costs are associated with personal and professional communication (Wyatt, 1996). The health professionals may also turn to the news, wherein seemingly important discoveries are announced regularly but not in great detail. Lastly, they may choose to turn to primary research, which they must critically appraise and synthesize in their own time before application. The problem with turning to primary research is the number of articles and lack of quality of a large proportion of articles that are published every day.

In recent decades, the rate of publication of medical literature has grown exponentially. When the precursor to Medline was formed in the 1800s, it contained just 1600 references, by the year 2006, the number of citations had grown to over 10 million (Bastian, 2010) and is now over 20 million (National Library of Medicine, 2014). Keeping up to date with all of the published research, even within a particular specialty, is an impossible task (Fraser, 2010). In the early 1990s Dr. David Sackett (one of the founders of evidence based medicine) claimed that a doctor would have to read seventeen articles every day of the year in order to keep pace with the rate of publication in internal medicine (Smith, 2010). In 2010, it was estimated it would take a trainee in cardiac imaging reading forty papers a day, five days a week over a decade just to catch up with the publications in his or her own field. By the time they had caught up, however, they would have another 82,000 papers to read which would have been published over the previous decade, requiring them to read on for another eight years. It is important to note that these estimates were made assuming that the trainee only read about his or her particular discipline, when in reality it is often necessary to stay up to date with a much wider scope of disciplines (Smith, 2010).

The issue with medical literature now, as it has been for centuries, is not just the sheer quantity of publications, but the quality of those that are published. Andrew Duncan, a Scottish physician born in 1773, noted that information of value “is scattered through a great number of volumes, many of which are so expensive, that they can be purchased for the libraries of public society only, or of very wealthy individuals.”(Bastian, 2010). Meanwhile, within recent years Dr. Brian Haynes, a leading researcher in clinical epidemiology and information sciences has shown that less than 1% of published studies meet “stringent scientific standards” (Haynes, 1993). Doctors must be able to filter out articles that have little potential to provide strong evidence for clinical applications. These articles that are not ready for clinical application make up over 99% of publications.

McMaster’s Premium LiteratUre Service (PLUS) aims to do just that—identify only those articles with data that are appropriate for changing clinical care. Utilizing a multi-step selection process, the people involved in the production of PLUS are able to filter out up to 99.6% of articles that fail to meet the most stringent criteria for research methods, newsworthiness and clinical relevance for clinical care (Holland, 2005). PLUS is continuously fed via the McMaster knowledge refinery, whose readers scan more than 120 of the most important medical journals for articles that meet the Knowledge Refinery’s standards. These 120 journals publish over 50,000 articles a year on average. This article list is initially pruned from 50,000 to about 3,500 articles per year by McMaster’s Health Information Research Unit (HiRU) staff, who critically appraise each article to ensure that a study’s methods are rigorous, pertain to a list of suitable topics, and culminate in clinical endpoints. If the articles meet the aforementioned criteria, they are passed onto the McMaster Online Rating of Evidence (MORE) database for further appraisal. Once in the database, the MORE panel, which is composed of over 10,000 clinicians (5000 doctors and as many allied professionals), submit their ratings and comments pertaining to each article to which they are assigned. Here, several raters grade each paper on a scale of 1-7 on its newsworthiness and clinical relevance. Only articles which rate a 3 or higher on both scales are permitted in the PLUS database, which reduces the number of articles to about 20 a year per medical discipline (Holland, 2005). Therefore, the PLUS database is able to filter the large quantity of articles that are not ready for clinical application to a much smaller number of only the most important clinical articles available.

Even with these significantly shortened reading lists, some doctors are unable to find the time to read medical literature, in spite of understanding the task’s importance. In Smith’s 2010 paper on the role of eHealth, he recounts a survey he conducted:

*“Some 10 years ago I asked around 100 doctors how much of what they should read to do their job better they actually read. About 80% said less than 50%, and 10% said less than 1%. More than half felt guilty about this, and when asked to describe in one word how they felt about their information supply it was mostly negative (impossible, overwhelmed, crushed, despairing, depressed), with just a few answering “challenged.”* (Smith, 2010)

In one study, Dr. David Sackett discovered that the median time a new graduate in medicine spent reading per day was 0 minutes. Even more astonishing was the finding that senior clinicians in the United Kingdom only spent a median time of 30 minutes reading per day, and among this group about 40% admitted reading nothing (Smith, 2010).

In spite of the inability of some doctors to find the time to stay up to date with medical research, keeping current does have its benefits. In a 2013 study conducted with 56 medical libraries serving 118 hospitals, three quarters of the clinicians who responded to a survey reported a “definite or probable handling of patient care differently due to library information”. Respondents cited health research information provided by library staff as the reason they changed their medical diagnosis (25%), changed the prescription of a drug (33%), or changed clinical advice (48%) (Siemensma, 2014). From these results it is evident that reading medical literature has an effect on how doctors practice medicine.

### Searching Prognostic Information

A main reason why clinicians turn to medical research articles is to find answers to difficult questions. Some of the most difficult questions pertain to prognostic information. Prognosis is an estimation of how a disease or condition will progress and its possible outcomes over a period of time. Physicians are often asked to predict a patient’s prognosis. However, clinicians’ constant worry is that their assessment will be inaccurate (Justice, 1999). Accurate prognosis information can lead to more effective choices of treatment, and possibly a better overall outcome. Clinicians must use information pertaining to both baseline risk and potential treatment effects to ascertain a patient’s individual risk and subsequently prescribe an appropriate and acceptable treatment.

The best way to determine a course of treatment for a patient is to combine data on both the effect of a certain treatment and an individual’s baseline risk information for a given or several outcomes while also taking into account patient risk factors. By taking into consideration the individual’s baseline risk as well as the effect of treatment, a doctor can calculate the individual’s risk of an event occurring more accurately than with solely using baseline risk or treatment benefit information. This combination of information is then used to better understand the potential effect that a treatment will have on an individual patient and allows medical professionals to recommend a better selection of treatment choices to their patients. The medical professional then describes the benefits and risks that each treatment poses for the patient and the patient ultimately decides whether he or she will follow through with the treatment or not.

Randomized control trials (RCTs) are used to estimate the effect of an intervention. To quantify the effect of a treatment, individuals who are selected for a study are randomly allocated to two or more different groups. In the simplest RCT design, one group is given a treatment to alleviate symptoms of an illness while another receives no treatment, or a placebo (control group). The two groups are followed to determine the effect of the treatment by comparing rate of events in the two groups. The results of the trial allow the investigator to estimate baseline risk (in the control group) and the effect of treatment (in the treatment group). The issue with the RCT study design is that the results of the trial are largely dependent on the inclusion and exclusion criteria that are imposed to select participants in the study. Often, the inclusion and exclusion criteria are so strict that the selected samples of participants are not representative of the population as a whole. This may lead to inaccurate estimates of baseline risks, which can negatively affect the choice of treatment doctors give their patients (Thompson, 1997).

Systematic reviews of RCTs go some way to alleviate the issue of bias due to stringent inclusion and exclusion criteria imposed on the participants of trials in the included studies. Systematic reviews gather studies related to a topic or question and synthesize all the available information. The results of the source studies are combined and the merits and issues of each study are taken into account when conducting a systematic review. Each study which is added to a systematic review potentially dilutes the selection bias of that specific study within the overall pool of studies, thereby potentially improving the overall estimate of baseline risk. While the reduction in the risk of significant selection bias effect is likely, systematic reviews of treatment trials may introduce bias through the application of strict inclusion and exclusion criteria for included trials. Systematic reviews can also impose stringent criteria on the individual studies to be included, thereby leading to a more homogenized pool of studies, therefore allowing for the possibility of bias.

While systematic reviews of RCTs may dilute bias found in the source studies, the reviews inevitably contain some degree of heterogeneity. Heterogeneity measures the differences found between source studies. This heterogeneity may present itself in the way the outcome is evaluated, a difference in methodology, or difference in study participation criteria. It is important that the level of heterogeneity does not lead to a conclusion that is difficult to apply due to the sheer variation of the source studies.

It is also difficult to keep systematic reviews up to date (Bastian, 2010). An important source of clinical systematic reviews is the Cochrane Collaboration. The Collaboration and their published reviews are widely renowned as being “the highest standard in evidence-based health care” (Cochrane Collaboration, 2014.) The Cochrane Collaboration was founded in 1993 with a mission to provide “high-quality, relevant and up-to-date synthesised research evidence”. Unfortunately even the Cochrane Collaboration has been unable to keep its systematic reviews up to date. In 2006, it was noted that “still less than half of the Cochrane reviews are up to date” (Koch, 2006). Also, and more relevantly to our topic, the Cochrane Collaboration does not host or maintain reviews about baseline risk.

For all these reasons, information about baseline risk is more productively sought in observational trials conducted to assess prognosis and in systematic reviews of such trials. These observational trials (and systematic reviews of them) are more difficult to retrieve and to appraise than RCTs (and their systematic reviews). The difficulty to retrieve them is largely due to the fact that there are so many more observational studies when compared with systematic reviews. The difficulty in appraising observational trials is mostly due to the much higher complexity of appraising non-randomized trials, for which, additionally, there are no commonly agreed upon risk of bias assessment tools. This large number of studies leads to an increasing amount of work that needs to be done simply sorting through articles while looking for high quality and clinically relevant research. Luckily, the use of the PLUS database alleviates the workload of retrieving, appraising and sorting through articles, and provides users with a collection of only high quality observational studies.

### Communicating Prognostic Information

Another issue facing clinicians is how to communicate risk and prognosis information to patients. Medical professionals already have a difficult time discussing risk with patients as the medical lexicon and layperson's vocabulary usually differ significantly. In addition, treatment choices for patients are largely based on emotion rather than statistics. (Gigerenzer, 2003) Numbers and statistical testing can even mislead doctors with years of clinical experience as the following example displays:

*“Doctors with an average of 14 years of professional experience were asked to imagine using the Haemoccult test to screen for colorectal cancer. The prevalence of cancer was 0.3%, the sensitivity of the test was 50% and the false positive rate was 3%. The Doctors were asked: What is the probability that someone who tests positive actually has colorectal cancer? The correct answer is about 5%. However, the doctor’s answers ranged from 1% to 99%, with about half of them estimating the probability as 50% (the sensitivity or 47% (sensitivity minus false positive rate).” (Gigerenzer, 2003)*

One major reason for this potential for misinterpretation of numbers is that relative risk tends to exaggerate the perception of the effect of an intervention. For instance, a doctor may tell a patient that their chances of dying from a disease are reduced by 25% if they take a certain treatment. These numbers are “relative” as they provide a probability relative to another population. Therefore, the doctor is telling the patient that 25% more of a population that did not take the treatment died when compared to the group that did take the treatment. On the other hand, two absolute risk statements related to the previous relative risk example would be that 3 in 100 people who took the treatment died and 4 in 100 people who did not take the treatment died. These statements refer to absolute risk as each statement is independent of the other. The statement that 4 in 100 people who did not take the treatment died can be made with or without comparing it to the number of people who died taking the treatment. Both of the absolute and the relative risk statements provide correct and similar information. However, looking at the three statements does show that the relative statements can be misleading. The 25% reduction compared to the difference of 1/100 between the two groups makes the former statement seem much more convincing.

### Retrieving Prognostic Information Ready For Clinical Use

In summary, doctors are faced with the following challenges:

* The rate of publication far exceeds the amount of time a doctor has available to read.
* The baseline risk information provided by RCTs (or systematic reviews of RCTs) is at high risk of selection bias
* Tools such as systematic reviews of prognostic studies are not entirely effective at compiling and synthesizing information due to bias and heterogeneity of source studies and are difficult to keep up to date
* Estimates of risks are often given in relative rather than absolute measures which can be misleading
* Relevant and useful studies are often scattered across several journals rather than in one paper or place

When these issues are seen together, it becomes apparent that a tool which offers clinicians a concise display of absolute risk information in an intuitive way that is accessible and constantly updated would be of great use to clinicians in their work of thinking about prognostic information. As of 2015, development of a tool named BRiskeT which has been designed to meet these needs is underway. McMaster University’s PLUS database has been chosen to supply primary research articles to BRiskeT. To extract information from these articles, an eForm-based extractor interface has been developed, building on a paper-based extraction system that had been used to test the feasibility of BRiskeT in 2012. The goal of this thesis is to investigate whether this newly developed online method of extraction and entry allowed for quicker extraction and whether the eForm-based model would allow for greater efficiency of baseline risk data extraction when compared to the paper based method.

# Methods

### Overview of BRiskeT

McMaster University through HIRU has begun to develop a tool named BRiskeT. Its goal is to provide baseline risk information that can be used when prognostic information is needed by clinicians, families and patients. The BRiskeT database will contain the extracted data from important prognostic research articles. The database will utilize information from high quality observational studies which have passed through the PLUS database’s inclusion criteria. Studies which have met PLUS criteria (See Appendix 1) are fed into an online interface named MacPrognosis. Information pertaining to baseline risk for any outcome is extracted manually along with the condition, sub condition and outcome name as well as a text excerpt which describes the baseline risk statement within the study by a user of the MacPrognosis system. This extraction process involves searching the journal articles for information to populate predefined fields reflecting baseline risk. These pieces of data are then placed into a database, which can subsequently be searched for on the basis of conditions and outcomes as well as indexing terms through a user-friendly interface. Information pertaining to risk that meets the user’s search criteria is then displayed in a tabular format, where one row in the table represents baseline risk data for one outcome from one study.

### Scope of Current Study

Work toward the realization of the BRiskeT database is ongoing. The feasibility of a database for baseline risk information has been tested (Jacob, 2012). During this feasibility-testing phase a paper-based extraction system was developed and employed which utilized a printed form to prompt extractors to look for certain data within an article. These data were manually transcribed from the forms to an Excel spreadsheet that could then be searched. This extraction and entry process was laborious and prone to transcription errors.

The formal question for this thesis was whether this newly developed online method of extraction and entry allowed for quicker extraction and whether the eForm-based model would allow for greater efficiency of baseline risk data extraction. In this current study, the new eForm-based extractor interface (named MacPrognosis) was tested for data entry into BRiskeT and compared against the paper-based process, used during feasibility testing.

### Development of First iteration of Extractor interface

In this study, a new extractor interface was developed with the help of McMaster University’s HIRU. The extractor interface was to serve as the layer that sat between the PLUS database which enforces inclusion and exclusion criteria for articles to be included and the BRiskeT database which will house the baseline risk information. This interface built on the logic that had been developed in the feasibility testing (the details of the development of this extraction process can be seen in Appendix 2).

#### First Iteration Feature List

The first step in developing the new extractor interface was to build a list of features to be included. In this way, the development process followed the agile model, with potential users of the software developing feature lists that drove development forward, and thereby allowing mutual feedback between users and developers (Johannessen, 2010).

The first feature requested was the need for online hosting. This feature was necessary to centralize access to the extractor interface. The full release of the BRiskeT database would require baseline risk information from a random sample of articles to be extracted by more than one extractor. By conducting the extraction in duplicate, the accuracy of the each extractor’s work could be evaluated by comparing the extractors’ results for the same article. This would mean that two extractors would have to be able to access the same database. It was determined that the most scalable solution to this issue would be to host the extractor interface online.

Next, it was determined that it would be helpful for certain data to be pulled directly from the PLUS database. Articles within the PLUS database are tagged with a variety of information including disciplines, indexing terms and information about populations contained within the article. In the paper-based model, this information was extracted by hand, which is laborious and prone to error. The HiRU technical team was able to help define which fields could be pulled directly from the PLUS database. These fields have been noted in Table 1.

The next feature that was deemed necessary was to allow for a single step input of information. Previously, it had been necessary to re-enter information from a paper-based extraction form into an Excel spreadsheet which acted as a database. This process was prone to transcription error. To reduce this error, we dictated that the process of entering information should only be done once.

Another useful feature that we thought would save a large amount of time was direct access to the PDF version of articles through the extractor interface. Previously, each article that had been selected for inclusion in the BRiskeT database had to be searched in PubMed. After this the articles had to be saved as a PDF in folders organized by discipline. This process was very time consuming. To change this, we requested that the extractor interface display a link directly to the full PDF.

Lastly, although the idea was thought of in BRiskeT’s infancy, HiRU provided tools to allow for SNOMED disease code indexing within BRiskeT. SNOMED is a codified set of clinical terminology that allows for a standard code to apply to medical terms (Allones, 2014). Previously, all conditions and sub-conditions were described using their names. These names are often interchangeable with other terms, which makes indexing difficult and inconsistent. To translate these condition names into SNOMED codes, it was necessary to look up each disease name for an associated SNOMED number. To speed up this process, we incorporated HiRU’s SNOMED tool, which allows the user to search disease names and provides related diseases and their associated SNOMED numbers.

#### Modifications to the database schema

Following the development of a feature list, the database schema that had been developed for the feasibility testing was remodelled to allow for inclusion of the necessary fields. The database schema represents the organization of information within a database. In the first iteration of the extraction process, the focus was largely on incorporating the appropriate number of fields. The correct number of fields would allow any person to easily interpret the information presented. We began planning for the most appropriate fields with the schema that had been previously created for the feasibility study:

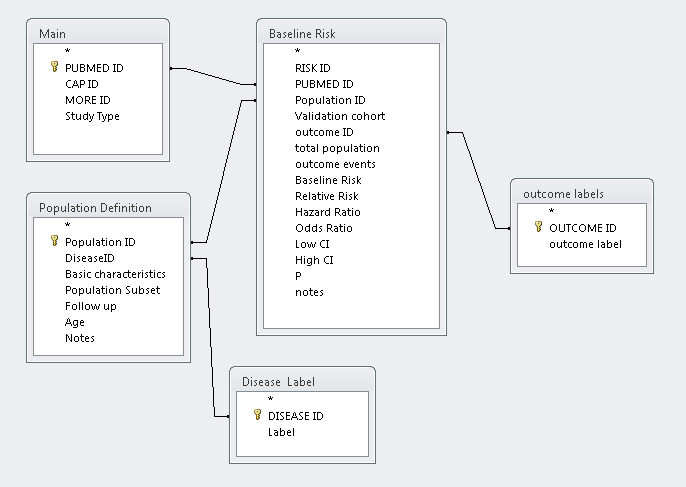


Figure 1: feasibility testing database schema

We clarified the definitions of all fields and specified whether each field was a text, numeric or alphanumeric field. The details of these fields are presented in Appendix 3. Figure 3 reflects the changes made to the structure of the tables and the fields found therein in the first round of development:

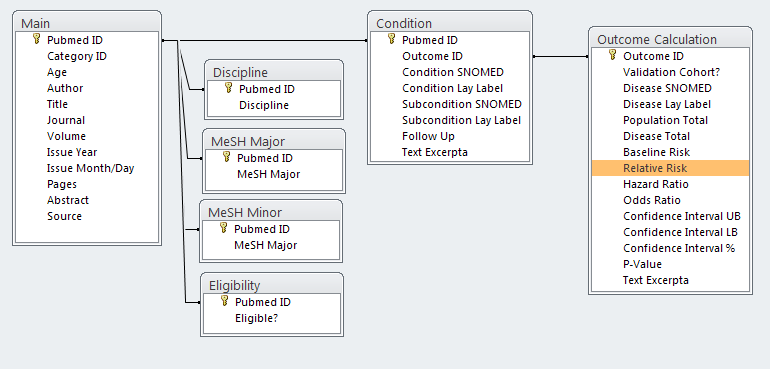


Figure 2: First iteration of eform based database schema

The Tables in the Schema represent the general structure of the database. The Main table contains bibliographic as well as indexing-related information for articles from the PLUS system. The Eligibility table determines if articles can be included into the database. The Discipline table relates medical disciplines to Pubmed ID (a number from the PubMed database which is a unique accession number) allowing the database to be searchable by Discipline. The MeSH tables are dependent on MeSH terms, which are pulled from PubMed. MeSH terms are Medical Subject terms which relate to the US National Library of Medicine’s indexing system (National Library of Medicine, 2014). The MeSH terms (which are used as indexing search terms within BRiskeT) are related to the PubMed ID of the article, which allows the database to be searchable by MeSH terms. The Conditionstablegives characteristics of the population being studied in the article. Finally, the Outcome Calculation table contains the information related to risk based on what data are found in the articles. Table 1 defines each field found within the tables. In addition, Table 1 also defines where the data are inputted from, whether it is from the PLUS database, or from a data extractor (the users of MacPrognosis.)

TABLE 1: Field description for first iteration database schema for eForm-based model

|  |  |  |  |
| --- | --- | --- | --- |
| Field Name | Inputted From | Description | Field Type |
| PUBMED ID | PLUS | Based on Identifiers from the PubMed website (<http://www.ncbi.nlm.nih.gov/pubmed>). This is a secondary identifier for an article that is providing data that are accepted into the database. This is a unique identifier. | Numeric |
| Category ID | PLUS | An ID that refers to the type of article, whether prognosis or Clinical Prediction Guideline (CPG). For the pilot, we used only prognosis articles. Expanded functionality will also include CPG. (categorized by either 4 or 7 which denote prognosis or CPG articles respectively) for categorization purposes within the database. | Numeric |
| Age of Subjects | PLUS | Age of subjects in the population as recorded during the Critical Appraisal Process. | Text |
| Author/title | PLUS | All of the included authors names and title of the individual journal articles. | Text |
| Journal | PLUS | The name of the journal that the article was taken from. | Text |
| Volume | PLUS | The volume of the journal that the article was taken from. | Numeric |
| Issue year | PLUS | The year the article was published in paper. | Numeric |
| Month Day | PLUS | The month and day the article was published for the paper format of the paper. | Alphanumeric |
| Pages | PLUS | The pages that the article in the journal | Numeric |
| Abstract | PLUS | A copy of the abstract of the article, used to summarize what the article is about and the results attained. | Alphanumeric |
| Source | PLUS | Citation, including journal name, volume and page number that can be used to look up an article. | Alphanumeric |
| Eligible? | Manually searched for and input by Human Extractor | In (default) and out option for each paper to determine if paper is eligible according to whether the extractor is able to extract baseline risk information for at least one outcome. | Checkbox |
| Discipline | PLUS | The field to which the article pertains. Individual entries for each discipline can be multiple entries per article. | Text |
| MeSH (Medical Subject Headings) Major terms | PLUS | Indexing terms for the article. The major terms are those that reflect the major concentration of the article. These are search terms that are used to find the article on a database. | Alphanumeric |
| MeSH (Medical Subject Headings) Minor terms | PLUS | Indexing terms for the article for those issues in the article that are lesser importance. These are search terms that are used to find the article on a database. MeSH Major and Minor terms are used for the same purpose in the BRiskeT database but reflect the content and its relative importance. | Alphanumeric |
| Outcome ID | Manually searched for and input by Human Extractor | A unique indexing number given to an outcome in the study for database organization purposes. Studies may have multiple outcomes. | Numeric |
| Condition Lay Label | Manually searched for and input by Human Extractor | Pre-existing conditions for the population involved as described by disease or condition name. | Text |
| Condition SNOMED | Manually searched for and input by Human Extractor | Pre-existing conditions coded in SNOMED. This is a numeric field. May be added for prognosis purposes in addition to the tagging done by PLUS indexers. | Alphanumeric |
| Sub condition SNOMED | Manually searched for and input by Human Extractor | Cohort descriptor terms. May be multiple descriptors. | Alphanumeric |
| Sub condition Lay Label | Manually searched for and input by Human Extractor | Cohort as described by disease or condition name. Maybe multiple terms. | Text |
| Follow up (months) | PLUS | The length of time the cohort was followed. Data are converted into months. | Numeric |
| Age of subpopulation | PLUS | The categories for the population subsets, e.g., adults. We will stay with CAP categories to start. If no subpopulation age is available, the null value should be the same as the Age of population field in MAIN table of the database. | Text |
| Text Excerpta Population | Manually searched for and input by Human Extractor | Excerpt from the article pertaining to population characteristics. | Text |
| Disease Lay Label | Manually searched for and input by Human Extractor | Disease condition as described by disease name | Text |
| Disease SNOMED | Manually searched for and input by Human Extractor | Disease coded in SNOMED. | Alphanumeric |
| Disease Total | Manually searched for and input by Human Extractor | The total number in the population who have the disease in question (e.g., diabetes) | Numeric |
| Population Total | Manually searched for and input by Human Extractor | The total number of individuals studied in the article. | Numeric |
| Baseline Risk | Manually searched for and input by Human Extractor | If given in the study, it is directly inputted or calculated from the outcome total/population total OR outcome total/ person years of follow up. If risk given as hazard ratio or odds ratio, then stays as null value | Numeric |
| Relative Risk | Manually searched for and input by Human Extractor | If risk is given in a relative manner, it is inputted here. Otherwise stays as null value. | Numeric |
| Hazard Ratio | Manually searched for and input by Human Extractor | If risk is given as a hazard ratio, it is inputted here. Otherwise stays as null value. | Numeric |
| Odds Ratio | Manually searched for and input by Human Extractor | If risk is given as an odds ratio, it is inputted here. Otherwise stays as null value. | Numeric |
| Lower Bound Confidence Interval | Manually searched for and input by Human Extractor | The lower bound confidence interval (e.g. 90%, 95%, 99%) that gives an estimate of the accuracy of a risk value. Only inputted if given in study, otherwise stays as null value | Numeric |
| Upper Bound Confidence Interval | Manually searched for and input by Human Extractor | The upper bound confidence interval, which gives an estimate of the accuracy of a risk value. Only inputted if given in study, otherwise stays as null value. | Numeric |
| Confidence Interval | Manually searched for and input by Human Extractor | The percentage confidence interval, usually 95%. Only inputted if given in study, otherwise stays as null value. | Numeric |
| P-value | Manually searched for and input by Human Extractor | The p-value given in the study for each outcome | Numeric |
| Text Excerpt Risk | Manually searched for and input by Human Extractor | Excerpt from the article pertaining to risk calculation. | Alphanumeric |

#### First Iteration Coding And Testing

The first iteration of the extractor interface was developed by the HiRU technical team and tested using a small subset of articles (the inclusion criteria for this subset are listed in Appendix 2). The first modules to be developed were the User Credentials and Login Module, the Home page and the Extractor Interface. Once these modules were developed, the system underwent user testing by extractors who, through a series of extractions, determined further features which could be added that would add greater functionality and efficiency to MacPrognosis.

### Second Iteration Development

#### Feature List Generation For Second Iteration

The first feature that was deemed necessary was the ability to edit article related information. This was thought to be a useful feature because in case any errors were made during extraction, they could potentially be caught and edited afterward using this feature.

Next, the ability to view information that had been inputted was listed as another useful feature. An extractor would often likely want to re-verify his or her recently inputted data. In these cases, the “View articles” page would allow the user to see all of the inputted data.

In certain articles, instead of having a population total from which baseline risk could be calculated, the total number of person years of follow up is given. In these cases it was necessary to input person years of follow up as a replacement for the population total.

While inputting data for a large number of articles, it seemed likely that an extractor might forget to put in certain information. To remedy this situation, the addition of basic data logic to assist the extractor was necessary. For example, this logic would display a prompt in red if the article had been flagged not of interest but did not have a reason for being ineligible. Also, if prevalence data were entered, it was necessary to input both outcome total and the population total value before the article could be submitted. The extractor interface would also prompt the user if he or she were missing any data for a particular field prior to submitting data for an article.

To speed up the extraction process, another feature that was requested was the ability for the conditions field to be prepopulated with data from the PLUS database. The PLUS database contains information about which conditions are addressed within an article. It was suggested that these data should pre-populate the condition column so that the extractor simply had to confirm or delete the presence of the condition, thereby saving time.

Another feature that was proposed to increase the speed of the extraction process was to add buttons that allowed for the deletion of prepopulated data or carrying over correct data from the condition to the sub condition column. When the prepopulated condition column information was not deemed to be of interest, a simple click of the proposed delete button would remove the information from the selected cell. In addition to the delete button, the copy button within the condition column would allow for the copying of a condition to the sub-condition column when no sub-condition was present in a study.

Lastly, the addition of a reason for ineligibility field was thought to be useful because the reasons could later be queried for further analysis.

#### Field Definition Refinement

In addition to adding new features to the extractor interface, certain field names were changed to eliminate confusion. What had previously been named Disease was changed to Outcome within the Outcome calculation table, along with the change from Disease Lay Label to Outcome Lay Label. The reason for this change was that in certain articles, the outcome of interest was not a disease (for example mortality). Also, the Outcome ID field was changed to Risk ID, which more accurately encapsulated the idea of the table. In addition to these changes, the Person Years field was added to the Outcome Calculation table as certain articles reported person years of follow up rather than a population total. The field Reason for Ineligibility was also added due to allow for the categorization of ineligible papers. Lastly, Confidence Interval Percentage was omitted as it was almost always 95%, and if it were not, the discrepancy would be mentioned in the text excerpt associated with each Risk ID. The omission of this field also helped the entire online extraction form to fit onto one screen without having to scroll to fill in more information. This small change made a very large impact in the efficiency of the extraction process.

#### Modification Of Database Schema

The new schema, with the changes defined by the iterative, agile development process is in Figure 3:

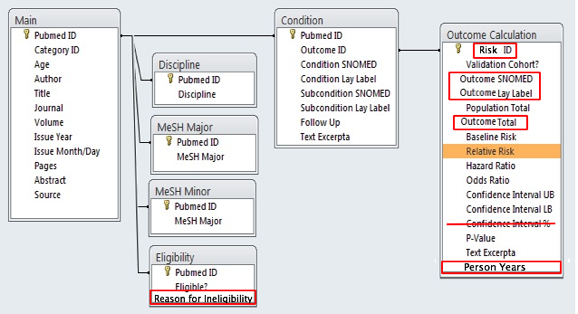


Figure 3: Final iteration of database schema for eForm-based model with annotated changes

With the schema now complete, the extractor interface was finalized with the necessary changes outlined above.

### Using MacPrognosis

The iterative development process produced a system we called MacPrognosis, which is an eForm-based baseline risk extraction interface. Following the completion of its development, MacPrognosis was moved onto McMaster’s HiRU server, which allowed for access both locally or remotely. To gain access to the site, the user is given credentials to log onto the website from the system administrator.

Once credentials have been verified, an extractor is taken to the home page which normally lists the first ten articles which are waiting to be extracted.

Once an article has been chosen, the extractor is taken to the MacPrognosis extraction page. The major functionality associated with the extraction page is detailed in Figure 4:

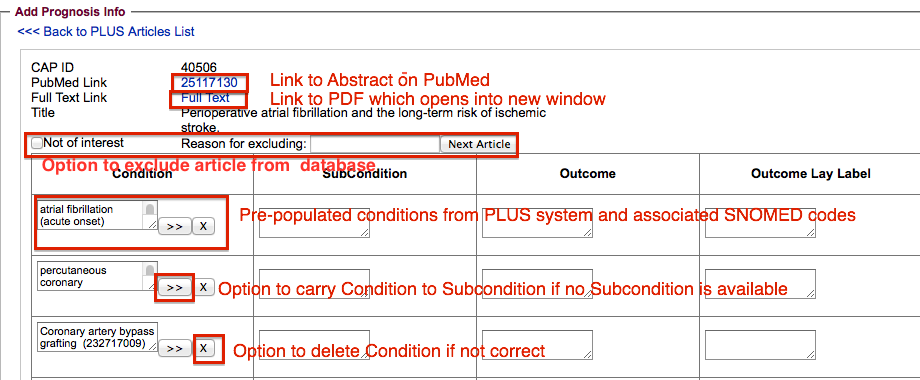


Figure 4: Annotated Screenshot of the MacPrognosis interface detailing major functions of the page

Included on the extraction page is a version of HiRU’s SNOMED Tool. This allows for a keyword search based on disease name, which subsequently looks for similar disease names within the SNOMED repository.

Figure 5: Macprognosis snomed tool

Once a disease name has been searched by a user of MacPrognosis, a branched view of closely associated conditions appears and the user simply clicks the correct term. Figure 6 displays what is shown on the screen after selecting a disease.

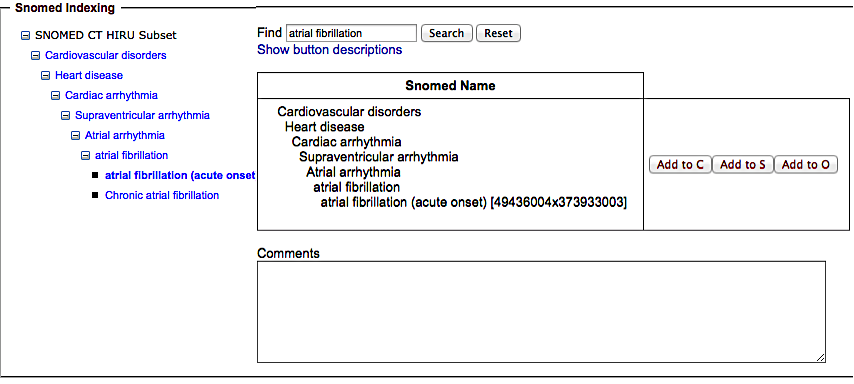


Figure 6: macprognosis search results for snomed tool

After this, the user selects whether this term will be added to the condition (C), sub condition (S) or outcome (O) column (utilizing the Add to C, Add to S and Add to O buttons respectively) and it is then added into the next available row within the column.

Once the baseline risk information has been inputted for the article the extractor clicks Submit, which brings him or her back to the home page. If desired, the information inputted can be modified in the edit article page. This page lists all of the article names from which information has been extracted or articles which have been flagged as “Not of Interest.”

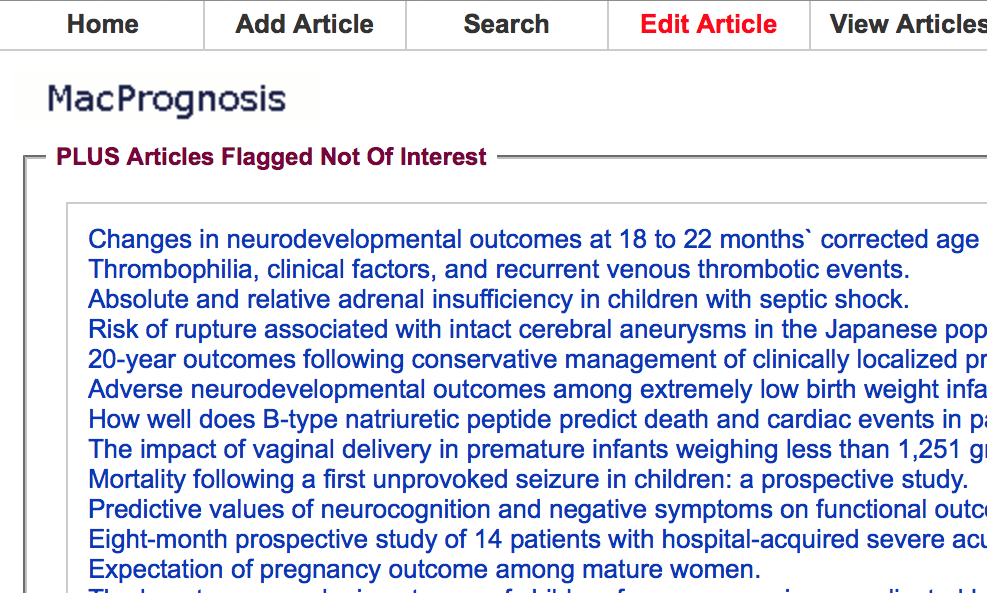


Figure 7: edit article page

Clicking the article title within the Edit Article tab brings the user back to the extraction interface page which, in turn, allows the user to edit the information that has been inputted.

MacPrognosis also allows the user to look at a line-by-line list of all baseline risk information that has previously been inputted. This view represents the complete data set, which can also be queried by the system administrator based on specific criteria relating to predefined fields. For a sample extraction using the new MacPrognosis system please See Appendix 4.

### Testing of Extractor Interface

#### Article Selection

After the extractor interface was finalized, a test set of articles was gathered from the PLUS database. To be included in the test set, the articles had to meet PLUS inclusion criteria (see Appendix 1.) This meant that included articles must come from a list of pre-approved journals, and meet strict criteria relating to the quality and clinical relevance of the article.

These articles could be RCTs, systematic reviews and meta-analyses of RCTs, observational studies (whether prospective or retrospective) and systematic reviews and meta-analyses of these observational Studies.

Clinical prediction guides and case studies were specifically excluded from this study. Clinical prediction guides are guidelines that recommend the best course of treatment. Clinical prediction guides were found to require a completely different database and extraction process when compared to other article types, and therefore were omitted.

Articles that have passed through the Critical Appraisal Process for PLUS inclusion are rated on a scale from 1-7 for their clinical relevance and newsworthiness. To be included in this study, articles must have had a rating of greater than 6 in both clinical relevance and newsworthiness. There were 656 articles (categorized and listed in Works Cited section) which met the inclusion criteria as mentioned above.

#### Outcome Measures

This study involved the development and modification of an extraction process for the BRiskeT tool. To refine the extraction process, this study focused on process outcomes. The outcome measures for the study were the amount of time spent per article to extract information, and the proportion of articles from which baseline risk data were successfully extracted. The time spent per article was measured as the amount of time required to find, copy and enter baseline risk information into the extractor interface. The amount of time was manually measured by marking the time when an article was opened to the time when the “Next Article” button was clicked on MacPrognosis. The articles chosen for timing were chosen at random by the data extractor. These times were placed in a table to be compared against times required to extract baseline risk data from the feasibility study which was done in 2012. Five studies from the 2012 study were chosen at random to be re-extracted to compare against the results from the current study. Due to the fact that these articles had not been read for over two years, the extractor had no familiarity with the baseline risk data. Re-extracting these articles also ensured that a similar timing method could be employed reliably for both study periods.

The extraction proportion percentage was calculated as the number of papers from which baseline risk data were successfully extracted divided by the total number of papers for which data extraction was attempted. Each article either had its baseline risk information inputted into the database or was deemed “Not of interest” with an associated reason for ineligibility. To determine the proportion of articles from which data were successfully extracted, the database was queried at the end of the test to compare those with baseline risk information and those deemed “not of interest”. This proportion was then compared against results from the feasibility study. The pre-established threshold for success was an extraction proportion of greater than 50%.

# Results

As has been mentioned above, the two main outcomes of interest were the amount of time required to extract information from an article and the proportion of articles from which data could be successfully extracted. The results of the 2012 study utilizing the paper based extracted process are contrasted against the current study which utilized the eForm-based MacPrognosis interface in terms of these outcomes.

### Results of Feasibility Study – Successful Extraction Proportion

In 2012, a feasibility study was undertaken to pilot the BRiskeT concept. Mockups of the potential front-end system, along with an extraction process were tested. Thirty-eight articles were chosen from the PLUS database and baseline risk data was attempted to be extracted from them. Eighteen out of thirty-eight articles were successfully extracted for the feasibility study. What was not considered at the outset of the study was that papers which display results on a continuous variable scale were not able to be extracted as the form that had been generated was designed for dichotomous outcomes. For example, in the feasibility study it was not possible to extract information from Pain-related articles. This was because results from pain based articles are given on a continuous scale. The outcomes are typically pain rated on a discipline-specific scale, which are not easily translated to the dichotomous form that had been developed. Discounting these articles, 18 out of 34 articles were successfully extracted, which was above our predetermined 50% threshold. These results were used as a benchmark with which to test MacPrognosis.

### Results of the Current Study - Successful Extraction Proportion

In total 656 articles comprised the current study set. Of these, 295 were successfully added to the BRiskeT database and 361 articles were unable to have had their data extracted. Please note that articles with two reasons of ineligibility have been categorized twice.

**TABLE 2: ARTICLES FLAGGED NOT OF INTEREST**

|  |  |  |
| --- | --- | --- |
| Reason why deemed not of Interest | Number of Articles | Description |
| Articles discarded by mistake | 3 | These articles were simply categorized incorrectly by the extractor and should be inputted into BRiskeT database. |
| PDF Not Available | 44 | These articles did not have the PDF version of the article, as a result, they were flagged as not of interest. |
| More than 10 outcomes reported | 50 | MacPrognosis was built with the option to include up to 10 rows of baseline risk information for one article. The 50 articles that were classified as “not enough rows” had more than 10 lines of baseline risk information. The next iteration of the extractor interface must be able to add rows as needed for articles that require more data space. |
| No absolute data | 66 | These articles only contained information regarding relative risk. This may have taken the form of relative risk/odds ratio or hazard ratio without the requisite population total for back calculation of other necessary numbers. |
| Systematic review and meta-analysis | 58 | Systematic reviews almost always provided more than 10 rows of baseline risk information |
| Not suitable for extraction | 130 | These articles may have been wrongly categorized or did not include baseline risk information |
| Imaging | 31 | Imaging, as pain-based articles had proven in the feasibility study, were not suitable for data extraction. This was due to the fact that the information provided was largely communicated in imaging scans (e.g., magnetic resonance imaging scans, X-ray computed tomography scans). It was not possible to convey these risks in a way that fit into the form that had been developed. |

Once again, a success rate of 50% was the goal for this study. Although this mark was not quite reached (295/656 = 45%) a portion of the articles deemed not of interest could easily be extracted with minimal changes to the interface, these included (From Table 6):

Articles discarded by mistake: 3 articles

PDF not available: 44 articles

More than 10 outcomes reported: 50 articles

Meta-analysis or systematic review: 58 articles

Together, these articles which can be extracted with minimal changes to the interface add up to 155 articles. Hypothetically, once these changes are made and these articles have their baseline risk data extracted, a total of up to 450 articles from which baseline risk data have been extracted would populate the BRiskeT database (295 + 155 = 450). Once these articles have been extracted, the proportion of articles from which data has been extracted would become 68% (450/ 656).

### Time required to extract data from one article – Paper Based Process

The next outcome of interest for this study was the amount of time required, on average, to extract data from one article. In 2012, after building a test set of articles, extraction was attempted using a paper-based system. The extraction process was timed for a random sample of these for analysis. It was the initial intention of the current study to compare and contrast the times from the 2012 study with the current study’s results using MacPrognosis to determine if time could potentially be saved. Unfortunately, the timing process differed significantly between the 2012 study and the current study. The feasibility study was timed solely on the basis of filling in the paper-based form, while the current study was timed from the moment that the paper was selected until the time the data was submitted to the database. To ensure similar methods for timing, a random sample of articles were extracted utilizing similar methods to those used for the timing of the extraction process utilizing MacPrognosis. The time required to extract baseline risk information from an article using the paper-based process, from selection to submission, are shown below in Table 3:

Table 3: Time required to extract baseline information utilizing paper- based extraction process

| Article | Time required |
| --- | --- |
| Article 1 | 15 minutes |
| Article 2 | 24 minutes |
| Article 3 | 19 minutes |
| Article 4 | 11 minutes |
| Article 5 | 9 minutes |
| Average Time Required | 15.8 minutes |

### Time required to extract data from one article – eForm-based Process

To compare the amount of time required to extract baseline risk information between the paper-based and eForm-based process, 10 papers from the test set of 656 articles were chosen at random for timing of the extraction process. The time required to extract baseline risk information from an article using MacPrognosis, from selection to submission to the database, are shown below:

Table 4: Time to extract articles using macprognosis

| Article No. | Time to Extract |
| --- | --- |
| Article 1 | 9 minutes |
| Article 2 | 6 minutes |
| Article 3 | 4 minutes |
| Article 4 | 11 minutes |
| Article 5 | 13 minutes |
| Article 6 | 21 minutes |
| Article 7 | 4 minutes |
| Article 8 | 8 minutes |
| Article 9 | 10 minutes |
| Article 10 | 5 minutes |
| AVERAGE TIME | 9.1 Minutes / article |

According to Tables 3 and 4, utilizing the MacPrognosis system reduced the average time required to extract data from an article when compared to the paper-based method in the small sample set of articles which were timed.

### Article data sorted by Medical discipline in the Current Study

The 2012 feasibility study for BRiskeT found that entire disciplines were not suited for the paper-based extraction process that had been developed. For example, it was found that Pain-related articles were not suitable for the extraction process. This is because the extraction process was largely dependent on outcomes being dichotomous to fit into the extraction forms that had been developed. Pain-based articles’ outcomes were usually classified on a continuous, Pain discipline-specific scale that would make it difficult to fit into the extraction process. After discovering that baseline risk data for entire disciplines may not be able to be extracted, another criteria for success was developed: for BRiskeT to be successful, it was necessary that it be as inclusive as possible to all disciplines.

The test set of the feasibility study had been chosen at random from 5 selected disciplines. Rather than select the test set for the current study on the basis of selected disciplines, the criteria for inclusion into the current study was simply to be rated by PLUS rating for clinical relevance and newsworthiness as either a 6/7 or a 7/7. This allowed for the inclusion of many more disciplines when compared to the 2012 study. The criteria for success in this area of BRiskeT was to be as inclusive as possible. In this case, only one discipline (imaging) was found to be not suitable for extraction. Table 5 and Figure 8 are indicative of the inclusiveness of the new extraction process utilizing MacPrognosis.

Table 5: Number of lines of baseline risk extracted per medical discipline

|  |  |
| --- | --- |
| **Discipline** | **Lines of Baseline Risk Data Extracted** |
| Pediatrics (General) | 107 |
| Internal Medicine | 86 |
| General Practice /Family Practice | 79 |
| Pediatric Neonatology | 69 |
| General Internal Medicine-Primary Care | 68 |
| Cardiology | 67 |
| Neurology | 43 |
| Rheumatology | 42 |
| Obstetrics | 41 |
| Infectious Disease | 34 |
| Endocrinology | 28 |
| Nephrology | 28 |
| Pediatric Hospital Medicine | 28 |
| Respirology/Pulmonology | 26 |
| Hospital Doctor/Hospitalists | 24 |
| Hematology/Thrombosis | 20 |
| GP/FP/Obstetrics | 19 |
| Emergency Medicine | 16 |
| Gastroenterology | 15 |
| Oncology - General | 15 |
| Allergy and Immunology | 13 |
| Surgery - Cardiac | 13 |
| Intensivist/Critical Care | 12 |
| Genetics | 10 |
| Public Health | 10 |
| Surgery – Orthopaedics | 7 |
| Special Interest - Obesity -- Physician | 7 |
| Geriatrics | 6 |
| Gynecology | 6 |
| Psychiatry | 6 |
| Oncology - Gastrointestinal | 5 |
| Oncology – Gynecology | 5 |
| Oncology – Hematology | 5 |
| Physical Medicine and Rehabilitation | 4 |
| Surgery - Ophthalmology | 4 |
| Oncology - Genitourinary | 4 |
| Surgery – General | 3 |
| Surgery – Neurosurgery | 3 |
| Surgery – Urology | 3 |
| Surgery - Ear Nose Throat | 3 |
| General Practice/Family Practice/Mental Health | 2 |
| Tropical and Travel Medicine | 2 |
| Surgery - Head and Neck | 2 |
| Surgery – Oncology | 2 |
| Surgery – Vascular | 2 |
| Pediatric Emergency Medicine | 2 |
| Surgery - Gastrointestinal | 1 |
| Surgery – Plastic | 1 |
| Surgery – Thoracic | 1 |
| Oncology – Breast | 1 |
| Oncology – Lung | 1 |
| Oncology – Pediatric | 1 |
| Imaging | 0 |

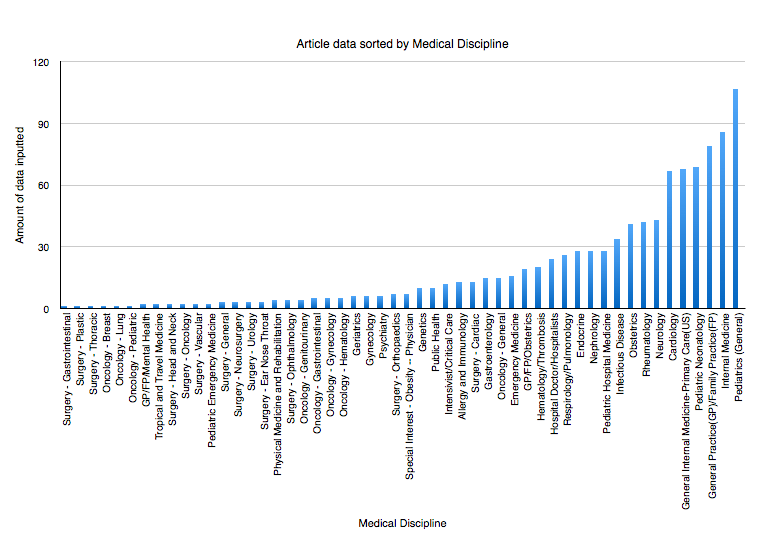


Figure 8: article data as represented by Baseline Risk Lines sorted by medical discipline

# Discussion

There was a reduction in the average extraction time spent per article between the paper-based and eForm-based extraction processes for BRiskeT in the small sample of articles that were timed. According to Table 3 and Table 4, the average time spent per article dropped from 15.8 minutes in the feasibility study to 9.1 minutes in the current study. To improve time management and further timing analysis, a timer could be added for the extraction page.

It could be derived that the experience garnered through the feasibility test may have exaggerated the effect of implementing MacPrognosis due to the fact that the original feasibility test was done prior to this study and thereby MacPrognosis built on the experience gained from the original feasibility test. To avoid this issue, instead of using the timed results taken directly from the feasibility study, extraction was redone for five articles picked at random from the 2012 study. These five articles had last been read in 2012, and there was no familiarity with the risk data found therein after two years. In this way, an unbiased extraction time could be compared and contrasted between the two studies.

The proportion of articles that could be extracted stayed relatively similar between the two iterations of the extractor interface. As shown in the results section, 45% of the articles were successfully extracted utilizing the paper-based process. However, with a few minor alterations up to 68% of the articles in the current study could be successfully extracted using MacPrognosis in a hypothetical third trial of extraction. For example, from the outset of the study, systematic reviews were expected to yield a large quantity of high quality baseline risk information. However, during the first trial extractions on systematic reviews, it was found that more than ten lines of baseline risk information could be extracted from each systematic review. Rather than fill in the first ten lines of baseline risk information using MacPrognosis, a decision was made to categorize these articles utilizing the “Not of Interest” feature so that they could be returned to when a new feature allowing the input of more than ten lines of baseline risk information was added. If the first ten lines of baseline risk information had been filled out, it would be difficult to find the articles to add to them as they would simply be categorized as an article from which baseline risk was extracted. This would place it in the same category as the other 295 articles, rather than categorized as a systematic review from which baseline risk could be extracted.

The eForm-based model was tested utilizing articles from more disciplines than the articles from the 2012 feasibility study. Whereas the articles for the feasibility study were drawn from five disciplines, the current study successfully extracted baseline risk data from over fifty disciplines as shown in Table 5. It is of the utmost importance that BRiskeT includes as many disciplines as possible to develop a database that can be useful to as many users as possible. The new, eForm-based model has shown that it is able to encompass the vast majority of disciplines it has encountered. Pain and Imaging are the noticeable exceptions in being able to extract data successfully thus far; largely due to the fact results are rarely reported dichotomously.

The development of MacPrognosis brought about several improvements to the extraction process. In addition to speeding up the extraction process, it also established a database, which was automatically populated from the extractor interface. All of the fields previously required for a baseline risk data line were manually extracted and first placed onto paper forms and subsequently placed onto Excel sheets with the paper-based process. Now using MacPrognosis, a large proportion of the fields have data that are pulled directly from the PLUS database, including bibliographic information, as well as data regarding the population and the amount of follow up. This reduces the number of fields that the extractor must manually fill out (see Table 1), saving time and reducing the number of possible errors. Once the data have been filled in, the extractor simply needs to submit the data to the database directly rather than transpose information from the paper-based extraction forms to the Excel spreadsheet as was done in the feasibility study. Lastly, once submitted, the data now populate into a query-able database, which can be searched on fields such as Outcome or Condition as well as indexing terms like MeSH Minor and MeSH Major terms.

In spite of its several accomplishments, MacPrognosis does have its limitations. As mentioned in Table 2, several small changes such as the expansion of the number of allowable rows per article could lead to a larger proportion of articles with extracted information.

There are other limitations that apply to the study in general. For instance, the estimates of time per article were simply conducted by starting and stopping a stopwatch between the start and end of extracting information from an article and was done only for a small percentage of articles:

**FEASIBILITY:** 5 articles timed / 38 articles = 13%

**CURRENT STUDY:** 10 articles / 656 articles = 2%

This timing process could easily be integrated into MacPrognosis by incorporating a timer for articles to develop better estimates of time required per article. This could allow for better forecasting of time required to clear backlogs and amount of funds potentially required to hire extractors.

In addition to this, agreement between extractors was checked for only a few articles. In total, four articles were checked for agreement and agreement was only verbally discussed between two duplicate extractors. To better estimate agreement between extractors, a feature could be developed for MacPrognosis that would compare the results of extractions between the same articles. MacPrognosis is already equipped with the ability to allow for duplicate extractions utilizing two sets of different user credentials.

Moving forward, several features must be modified or created in the system. MacPrognosis should be modified with the changes listed above to allow for a more efficient extraction process. Lastly, development should begin on the front end of BRiskeT. Key features to be added include

1. A New User Generation Feature: when a new user wants to be able to access the BRiskeT database they will be able to choose their user credentials
2. A more user friendly Search Feature
   * + Search based on Outcome
     + Search based on Conditions and Sub Conditions
     + Search based on PubMed ID
     + Search based on population (among other options)
3. The ability to download data found through the search functionality in a variety of formats (Excel, Word etc.)

These essential front-end features will allow for primary user testing and successive iterations with refinements as required.

# Conclusion

This thesis was conducted in order to determine if the use of an eForm-based extractor interface would allow for quicker and more efficient extraction of baseline risk information from scientific journal articles. In general, the use of the eForm-based extractor interface has shown the potential for an improvement in the speed and efficiency of the extraction process when compared to the previously used paper-based system. The improvements in the speed and the potential efficiency of data extraction are indicative of the effect that applying relatively simple technology to a manual process can yield.

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# Appendix 1

### PLUS System Logic and Inclusion Criteria

BRiskeT uses the existing McMaster PLUS database developed by the HiRU as a primary filter. By doing so, BRiskeT only populates itself with the most relevant, and methodologically rigorously tested journal articles. The PLUS system’s logic is described below (HiRU, 2011):

1. The first step of the PLUS system is to select the journals from which papers will be drawn. These journals are chosen based on the Science Citation Index Impact Factors, and suggestions from various individuals. Content of these journals is monitored for at least 6 months and if it meets the inclusion criteria (See appendix 1), the journal is selected as another candidate from which to extract articles from. At present there are just over 120 journals that have been accepted (see Appendix 2)
2. Next, trained readers read the articles from the selected journals and apply the inclusion criteria to the papers. Any papers that do not meet the inclusion criteria (see Appendix 2) are filtered out.
3. The selected papers are then entered into the Critical Appraisal Process (CAP) system and PnbMed ID is applied to prevent the redundancy of duplicates. In this system, the paper is categorized based on Article Type, Purpose Categories, patient population, and clinical discipline.
4. After having passed through the CAP system, the papers are checked by clinical experts. In this step, the experts check the data added by the research associates as well as the indexing added by the CAP system.
5. The verified articles then pass onto the McMaster Online Rating of Evidence (MORE) system wherein the system pulls up further information on the articles, including abstracts as well as major and minor MeSH headings to further index the papers.
6. Next, the MORE system forwards these articles to their Raters, who are either Doctors with an MD or equivalent, nurses or rehabilitation specialists. These raters rate the papers on two 7 point scales: one based on relevance and the other on newsworthiness. Each paper is rated by at least three people from each discipline and then finally transferred into the PLUS system.
7. The papers that are extracted from the PLUS system for use in the database must be:
   * 1. Original studies, review articles or Individual Patient Data (IPD) (no case reports, general and miscellaneous articles, or secondary publications)
     2. Of interest to the health care to humans (ie. no studies looking at methodology, or medical profession)
8. For prognosis,
   * 1. Must include patients with a disease at the beginning of the study, and have been followed up with over a period of time
     2. The inception cohort must be at a similar stage in the disease when the study is done to allow for the ability to compare results, as well as follow-up information from >80% of beginning population

As is shown above, the inclusion criteria to the PLUS database is sufficiently stringent to act as the primary filter for BRiskeT.

# Appendix 2

### Development of Feasibility Data Extraction Process

#### Preliminary Check of PLUS and selection of test set

In order to test the feasibility of BRiskeT, a preliminary study was conducted to determine if enough high quality data could be extracted from journal articles taken from the PLUS database starting in 2011. In order to do this, Dr. Alfonso Iorio searched the papers available through McMaster University’s PLUS database. An analysis was then conducted which yielded information regarding year of publication as well as discipline (among other descriptors) that were subsequently used to choose a relevant subset of papers for the feasibility study. In total there were 1270 papers found between the years 2005 to 2011.The number of articles that were accepted into the PLUS database varied from year to year as shown below in Table 1:

|  |  |
| --- | --- |
| Year | Prognosis |
| 2005 | 129 |
| 2006 | 185 |
| 2007 | 227 |
| 2008 | 213 |
| 2009 | 254 |
| 2010 | 209 |
| 2011 | 52 |
| Mean/yr | 189 |

APPENDIX 2 TABLE 1: Number of prognosis studies per year from 2005-2011 (courtesy of Dr alfonso iorio)

Each discipline had a varied amount of papers associated with it. For example, Neurology was one of the more popular disciplines that was found with 260 papers attributed to the discipline between 2005 and 2011, while Gynecology was significantly less prevalent within the database (only 27 papers written regarding the discipline were included in the PLUS system). Please see Table 2 below for a full list of the disciplines related to PLUS articles between 2005 and 2011.

|  |  |
| --- | --- |
| Discipline | Prognosis |
| Pediatrics (General) | 357 |
| Internal Medicine and its subspecialties | 344 |
| General Practice (GP)/Family Practice(FP)(all) | 308 |
| Neurology | 260 |
| Cardiology | 222 |
| Pediatric Neonatology | 191 |
| Obstetrics | 155 |
| Rheumatology | 148 |
| Endocrine | 104 |
| Nephrology | 102 |
| Infectious Disease | 92 |
| Respirology/Pulmonology | 92 |
| Oncology – General | 89 |
| Gastroenterology | 80 |
| Pediatric Intensive Care | 79 |
| Pediatric Hospital Medicine | 76 |
| Hematology/Thrombosis | 72 |
| Psychiatry | 60 |
| Emergency Medicine | 57 |
| Geriatrics | 57 |
| Intensivist/Critical Care | 54 |
| Allergy and Immunology | 50 |
| Surgery – Orthopaedics | 48 |
| Physical Medicine and Rehabilitation | 39 |
| Genetics | 31 |
| Public Health | 28 |
| Gynecology | 27 |
| Oncology – Breast | 24 |

APPENDIX 2 TABLE 2: Number of articles per discipline in the plus database as of 2011 (courtesy of dr alfonso iorio)

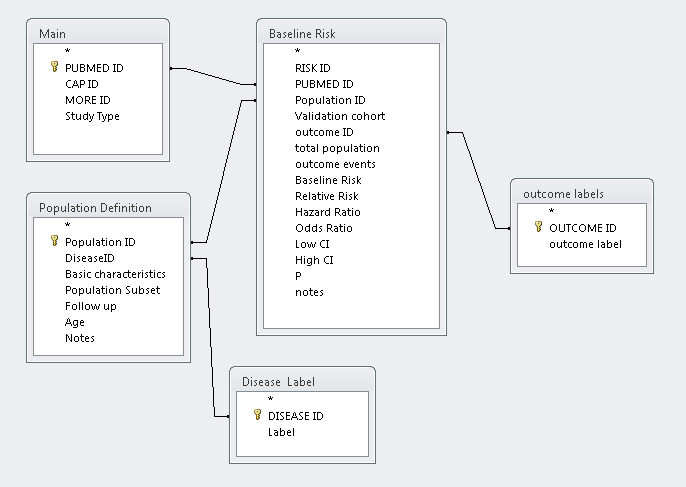
It was decided to choose random disciplines to make sure that any schema that was developed was adaptable enough. The following disciplines were selected to form the subset of papers:

* Cardiology (11)
* Internal Medicine (17)
* Obstetrics (4)
* Pain (4)
* Surgery- Ear, Nose, Throat (2)

The goal of the primary feasibility study was to determine whether high quality data could be extracted from papers that populated the PLUS database. The criteria for success was the extraction of useful data from greater or equal to 50% of the total study set. Secondly, it was important to understand whether the schema that was to be developed was adaptable to capture a sufficient amount of data from a wide variety of disciplines.

#### Database Schema

The next step was to develop a database schema that was adaptable enough to accurately represent the data available from a wide variety of papers and medical disciplines. The data structure that was decided upon for the feasibility study was as follows:



APPENDIX 2 FIGURE 1: PRELIMINARY DATABASE SCHEMA AS SHOWN ON MICROSOFT ACCESS

In essence the database was structured in a way to allow for the repeated use of a defined population, disease and outcome (represented by indexing numbers) while also assigning each piece of baseline risk information an ID. Structuring the database this way allowed for a solution, which would allow for searching based on a particular population, disease, or outcome as well as to be able to search based on a single journal article or even a particular baseline risk data line.

#### Data Extraction Process and Rules

Once a structure for the database was agreed upon for the feasibility study, the data extraction process was defined. First, all of the articles in the test set were found on PubMed and their full PDF’s were downloaded to a file. Next, each article in the test set of articles was carefully read and the pertinent data was extracted. In order to reduce the risk of extractor bias, a random selection of the articles were periodically extracted in duplicate and compared to determine whether similar results were obtained. In order to guide extraction, a paper-based form was generated and filled out for each article. The form is shown in the sample extraction below and again in the appendix. Once these forms were filled out for all of the articles in the primary feasibility set, the data was then transferred to an Excel spreadsheet.

The most important information to extract is categorized as follows:

* Study ID’s for sourcing purposes
  + CAPID, MOREID, PUBMED ID
* Disease Reference
  + SNOMED, Common disease name
* Population Characteristics
  + Severity, surgical procedures, comorbidity, age, gender if indicated, population number
* Outcomes
  + Number and/or proportion of events in total population/subpopulation

The following rules were set in advance of the first article being extracted:

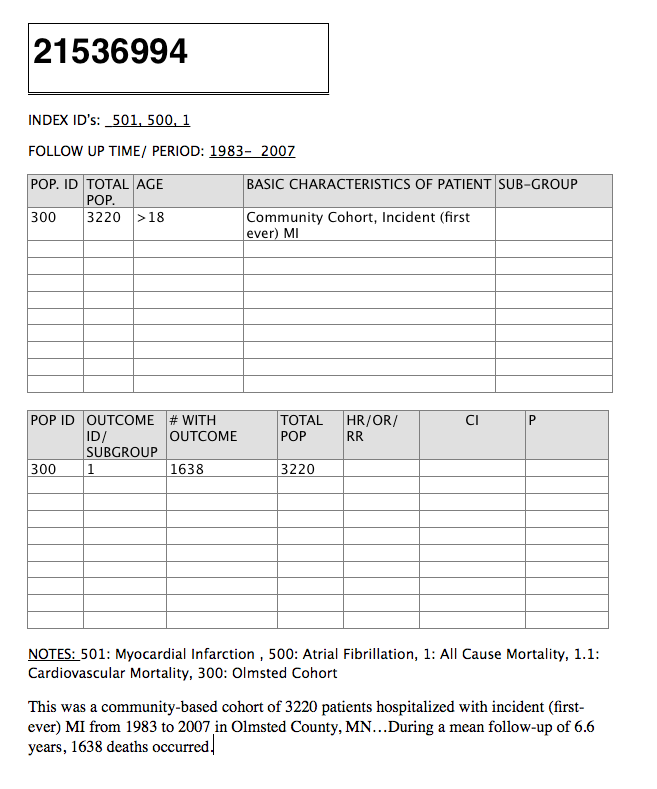
* Loss to follow up is not to exceed 20%
* When more than one population is reported:
  + Extract data for one relevant subpopulation described, sample size and event number
  + Provide relative measures of Risk (RR, OR, HR) only population total value is available for back-calculation
  + When extracting from meta-analyses
  + Extract pooled estimates only when Absolute measures of Risk reduction are given and heterogeneity is low (0-30%)
  + IF heterogeneity is high (>30%) information will be extracted from source papers if they pass the PLUS refinery

#### Sample extraction using Paper-based process

38 studies comprised the article set for the feasibility study. In order to understand the process of paper-based extraction, a step-by-step extraction is provided below for a piece of baseline risk information. The article chosen for this purpose was: Atrial Fibrillation and death after Myocardial Infarction.

1. Search for article on PUBMED
2. Pull article PDF
3. Fill in PUBMED ID for referencing in large box
4. Read Abstract to become familiar with article context
5. Begin gathering information about which conditions and outcomes are involved in the article
6. Begin gathering information regarding the population of interest
7. Read Methods to gather full understanding of population of interest
8. Search POP ID index for similar cohort
   * If no similar entry is found, create new entry for current cohort based on conditions and age
9. Enter details regarding population on extraction sheet:
   * POP ID (based on previous reference to indexing sheet) and make a note at the bottom regarding pop ID number
   * Population Total
   * Age of Cohort (mean or range)
   * Basic Characteristics: Key factors distinguishing the cohort (pre-existing conditions, cohort location and type, etc.
   * Sub-Group within the cohort
10. Read Results to understand baseline risk information pertaining to article
11. Search Indexing sheet for Outcomes to see if a new entry needs to be made
    * If no similar outcomes can be found to match, make entry to index
12. Enter pertinent outcome along with population ID into second table
    * Make note at bottom of sheet labeling the index number entered for later reference
13. Enter outcome Total and population total into table
14. Enter Relative risk information (RR/OR/HR) if necessary
15. Make note at bottom of sheet of text excerpt that represents baseline risk information
16. Search for information regarding follow up and enter near top of sheet
17. Enter all index numbers from the sheet into INDEX IDs near top of sheet

Below is an example of a manual extraction sheet that was filled out:



APPENDIX 2 FIGURE 2: An example of an extraction form filled out for an article comprising the feasibility set

# Appendix 3

### Field Descriptions for Feasibility Study

#### Table Definitions

The tables in the first iteration of the database Schema are described below:

* **Main: t**his table contains all bibliographic for the article in question.
* **Population Definition:** This table is categorized based on a population ID. This ID describes a unique population with characteristics based on pre-existing condition, basic characteristics, population, etc. This table also contains a notes field, which allows for a text excerpt describing the population from the article.
* **Baseline Risk:** This table contains all information based on baseline risk. This includes an identifier for the risk line (RISK ID) as well as a link back to the article identifier (PUBMED ID.) A series of other fields combine to give a definition of each piece of risk information. It is also accompanied by a notes field similar to the population definition table to allow for an excerpt describing the baseline risk from the article.
* **Disease Label:** This table simply allows for a unique key to align with each disease name to allow for users of the full system to be able to search for a disease and link back to the population definition. The disease label table is linked to the population definition table via the disease id.
* **Outcome Labels:** This table allows for a unique key to be associated with each outcome to allow users of the full system to be able to search for an outcome and link back to the risk table. The outcome label table is linked to the baseline risk table via the outcome ID field.

#### Field Definitions

The fields for the first iteration of the database Schema are described below:

* **Pubmed ID:** Based on Identifiers from the Pubmed website (<http://www.ncbi.nlm.nih.gov/pubmed>) This is a primary identifier for data that is accepted into the database. This is a unique identifier placed in a numeric field.
* **CAP ID:** based on identifiers from McMasters Critical Appraisal Process. This is a unique identifier placed in a numeric field.
* **MORE ID:** another identifier based on the PLUS appraisal process. This is a numeric field.
* **Study Type**: An ID that refers to the Type of article, whether prognosis or CPG. For the pilot, we will only be dealing with Prognosis articles, but expanded functionality will also include Clinical Practice Guidelines. These are numeric fields (categorized by either 4 or 7 which denote prognosis or CPG articles respectively).
* **Population ID:** A unique identifier for each population that accurately describes the population related to it. This is a numeric field.
* **Disease ID**: A unique identifier for each pre existing condition related to populations. This is a numeric field.
* **Basic Characteristics**: Characteristics that define the population in question. This may be information based on the type of cohort that is being described, further information on pre-existing conditions or how data was collected (national registry, etc.) This is a text field.
* **Population Subset:** If the cohort is subdivided (control vs. treatment cohort) this field is to make the distinction clear. This is a text field.
* **Follow-up:** Information on the follow-up period for subjects of the study This may be in the form of a period, range or mean. This is an alphanumeric field.
* **Age:** Manually inputted age as found in the article (can be a range or mean) this is an alphanumeric field.
* **Notes:** A text excerpt that describes the population of interest. This is an alphanumeric field
* **Risk ID**: This is a unique ID that describes each line of baseline risk information, This is a numeric field.
* **Validation cohort:** This is a yes/no field
* **Outcome ID**: This is a unique ID that describes each Outcome.
* **Total Population:** The total number of individuals studied in the article. This is a numeric field.
* **Outcome Events**: The total number in the population who have the disease in question (e.g.. Diabetes, etc.) This is a numeric field.

# Appendix 4

### Sample Extraction using MacPrognosis

For the purposes of the current study, over 600 studies comprised the article set. In order to understand the differences between extracting information on MacPrognosis rather than Paper Based.

The article chosen for this purpose was: [Perioperative atrial fibrillation and the long-term risk of ischemic stroke.](javascript:WebForm_DoPostBackWithOptions(new%20WebForm_PostBackOptions(%22ctl00$ContentPlaceHolder$ctl00%22,%20%22%22,%20false,%20%22%22,%20%22AddArticle.aspx?capid=LpziMvj2p43cTjhMXk4NTw%3d%3d%22,%20false,%20true))) Below is a step-by-step walkthrough of the steps taken to extract information from the article:

1. Log into MacPrognosis
2. Select the Article by title on the home Page
3. Click the link for Full Text
4. Select File from Downloads
5. Read Introductory Paragraph to get a sense of the Background information of the article and begin to look for information about the population involved, Condition Sub condition and Outcome
   * This particular article is about Perioperative Atrial fibrillation and subsequent Ischemic Stroke risk
   * The study is a retrospective short study
   * Data was taken from non-federal California Acute Care Hospitals between 2007 and 2011
   * Study utilized validated diagnosis codes to identify strokes in the preoperative period
   * Condition: Perioperative Atrial Fibrillation
   * Outcome: Ischemic Stroke
   * Sub condition: Hospitalized for surgery
6. Screen paper’s results section for details about inception cohort Population Total (or if not available Person Years of follow up), Outcome Total
   * Total Cohort: 1 729 360
   * Total Population who met inclusion Criteria: 24 711 had new onset preoperative atrial fibrillation
   * Outcome Total: 13 952

The information above encapsulates the main baseline risk information pertaining to the objective of the article, however it is useful to peruse the article for more information pertaining to risk

7) After finding information pertaining to risk, a text excerpt that accurately sums up the risk statement must be included, for this particular piece of information the following includes information regarding the risk statement, inclusion criteria and follow up:

*We included 1 729 360 eligible patients with a mean follow-up time of 2.1 years (SD, 1.3 years). Among these patients, perioperative AF was documented in 24 711 cases (1.43%; 95% CI, 1.41%-1.45%…After discharge from the index hospitalization for surgery, 13 952 patients (crude rate, 0.81%; 95% CI, 0.79%-0.82%) went on to experience an ischemic stroke.*

Given the preceding information, the following would be entered into the MacPrognosis interface:

**Condition:** Perioperative AF

**Sub condition:** Hospitalized for Surgery

**Outcome:** Ischemic Stroke

**Outcome Lay Label:** N/A

**Outcome Total:** 13952

**Population Total:** 24711

**Person Years:** N/A

**RR/ HR/ OR:** N/A

**LB/ UP CI:** N/A

**Text Excerpt Risk:** We included 1 729 360 eligible patients with a mean follow-up time of 2.1 years (SD, 1.3 years). Among these patients, perioperative AF was documented in 24 711 cases (1.43%; 95% CI, 1.41%-1.45%…After discharge from the index hospitalization for surgery, 13 952 patients (crude rate, 0.81%; 95% CI, 0.79%-0.82%) went on to experience an ischemic stroke.

The last thing to do is to ensure that whatever can pass through the SNOMED tool, does. The extraction interface had already pre-populated the following possible information into the Condition column:

Atrial fibrillation (acute onset) (49436004x373933003)

Percutaneous coronary intervention (415070008)

Coronary artery bypass grafting (232717009)

Prognosis (170967006)

Adult (133936004)

Postoperative care (133899007)

Elderly person (105436006)

Non-drug therapy/prevention (1006)

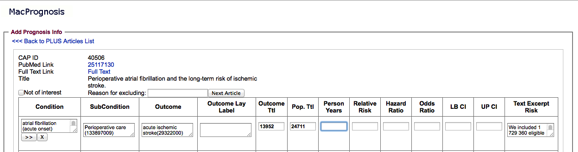
Of the information provided above, only “atrial fibrillation (acute onset) (49436004x373933003)” is appropriate. Due to this, all other rows will be deleted by clicking the (x) button. In order to accurately convey the fact that this time period and sub condition pertains to the preoperative period, I used the SNOMED search tool and searched for the term “perioperative” the following branch was provided for me:



APPENDIX 4 FIGURE 1: SNOMED TOOL PERIOPERATIVE BRANCH

Of the options shown in the figure above, preoperative care appeared to be the best descriptor of the cohort. This was selected and added to the sub condition box. Although condition always describes the main inclusion criteria for the inception cohort, the sub condition field has evolved to become more of a population descriptor rather than strictly describing another condition. Lastly, “Ischemic stroke” was searched in the SNOMED tool and once the appropriate term was selected from the branch, it was added to the Outcome Column.

In the end the full baseline risk row looks as follows after the data has been extracted:

APPENDIX 4 FIGURE 2: Extractor interface following input of one line of data

And once the data has been inputted, it is represented in the view articles page as follows:

APPENDIX 4 FIGURE 3: View articles page following input of one line of data

## 