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DETERMINING THE BIAS IN WAITING TIMES REPORTED BY THE ONTARIO JOINT REPLACEMENT REGISTRY

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DETERMINING THE BIAS IN WAITING TIMES REPORTED BY THE ONTARIO JOINT REPLACEMENT REGISTRY

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ABSTRACT

Ontario Ministry of Health and Long-Term Care (MOHLTC) established the Ontario Joint Replacement Registry (OJRR) in April 2000 to provide information needed to assess waiting times for Total Joint Replacement (TJR) surgery on an ongoing basis. Therefore a major concern of the OJRR is the quality of its waiting time data. The primary objective of this study was to determine the quality of the OJRR waiting time data by measuring the bias in these two waiting time periods: referral to surgery and decision to surgery. The mean difference method was used to estimate bias in its waiting times reported as a continuous variable and the McNemar test was used to estimate bias in its waiting times reported as a dichotomous variable. In continuous form, bias in OJRR waiting times was estimated as a relatively small point estimate (i.e. 0.13 and 0.66 weeks for decision and referral to surgery, respectively); but with considerable variability associated with these values (i.e. +/- half a year). As a binary variable, indicating if surgery was received within a waiting time threshold, no bias was found. Our results suggested that better definitions for waiting time date fields, especially for decision date and referral date fields, may be in order.

Keywords: Waiting Time, Total Joint Replacement Surgery, Registry, Bias, Data Quality

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TJR	Total Hip and Knee Joint Replacement
OJRR	Ontario Joint Replacement Registry
RFC	Regional Field Coordinator

Chapter One

Introduction

1.1 The Problem

Arthritis and related conditions are among the most prevalent chronic conditions in Canada, and have a major impact on individuals and on society (Badley and DesMeules, 2003). Of all procedures relevant to arthritis management, total hip and knee joint replacement (TJR) surgery has perhaps commanded the most attention at public and policy levels. These procedures have been shown to have a valuable place in the management of end-stage arthritis, and a number of studies have shown them to be cost effective (Perruccio et al., 2004; Bunker et al., 1994; Hawker et al., 1998; Chang et al., 1996). However, the timely delivery of TJR surgeries is a growing concern in Canada.

The most recent Health Services Access Survey results have pointed out that Canadians see referral to surgery waiting times as the greatest barrier to accessing specialized health care services. One in ten Canadians waiting for specialized care reported that they had to cope with pain while waiting (The Daily from Statistics Canada, 2006). Consistent with this, there is some evidence that functional health status deteriorates in patients who wait more than 6 months for TJR surgery (Mahon et al., 2002; Ostendorf et al., 2004; Kili et al., 2003). Mahon et al. (2002) conducted a prospective study to test whether a longer wait was associated with poorer postoperative health-related quality of life. Outcome measures, including the Western Ontario McMaster University (WOMAC) Osteoarthritis Index and the 6-minute walk test, were assessed at baseline and every 3-6 months thereafter until at least 3 months after the surgery (i.e.

some subjects were followed longer than others). The results showed that patients who undergo the procedure within 6 months after referral for surgery have greater disability at the time of the referral, and realize greater gains in health-related quality of life (as measured by the WOMAC) and mobility (as measured by the 6-minute walk test) after surgery, than patients waiting more than 6 months (Mahon et al., 2002). Ostendorf et al. (2004) conducted a prospective study to determine the effect of waiting times for total hip arthroplasty in terms of loss in quality-adjusted life years and additional burden perceived. Outcome measures, including the Oxford Hip Score, the WOMAC Osteoarthritis Index, the SF-36, and the EuroQol health status instrument, were assessed when the patient was placed on the waiting list, and 3 and 12 months after surgery. The disease-specific scores showed a significant deterioration during the waiting time. Moreover, a considerable loss of quality-adjusted life years occurred simply by postponing surgery (Ostendorf et al. 2004). Kili et al. (2003) conducted a prospective study to investigate the change in the Harris Hip Score in patients waiting for a total hip replacement. The Harris Hip Score was taken both at the time of the listing for surgery and at the pre-operative assessment two weeks prior to surgery. The results showed that the Harris Hip Score decreased prior to surgery. The authors concluded that waiting time should be as short as possible to reduce unnecessary suffering (Kili et al. 2003). While the most common impacts of waiting have been reported to be worry and stress (The Daily from Statistics Canada, 2006), some have shown that very long referral to surgery wait times (greater than 12 months) result in worse post-operative outcomes after TJR surgery (Ostendorf et al., 2004).

Currently, there is variability across Ontario in referral to surgery and decision to surgery waiting times for TJR surgery (Access to Health Services in Ontario: ICES Atlas). The Ontario government has committed funding to improve access to TJR surgery in the province, recommending that all Ontarians should have equitable access to TJR surgery, regardless of geographical location (Access to Services/Waiting Times, MOHLTC 2005). To begin to achieve this goal, the Ontario Ministry of Health and Long-Term Care (MOHLTC) established the Ontario Joint Replacement Registry (OJRR) in April 2000 to provide information needed to assess wait times for TJR surgery on an ongoing basis. Therefore, a major concern of the OJRR is the quality of its wait time data.

To measure waiting times, the OJRR adopted waiting time definitions from a waiting time pathway developed by the Western Canada Wait List (WCWL) project (The OJRR 2003 Report). The pathway identifies specific waiting time periods using the date of occurrence from four key events that take place along the clinical pathway for TJR surgery. These events and their corresponding dates are (1) the date that the referral for consultation is received by the orthopaedic surgeon (referral date), (2) the date of the first consultation with the orthopaedic surgeon (first consult date), (3) the date that the patient and the surgeon decide to proceed with TJR surgery (decision date), and (4) the surgery date. Two waiting time periods calculated using these dates are of interest in this thesis. Referral to surgery waiting time is the time between referral date and surgery date. Decision to surgery waiting time is the time between decision date and surgery date. This is the waiting time that most people think of as the wait for surgery since the queue for operating room availability commences at the decision for surgery. The primary objective of this thesis was to determine the quality of the OJRR waiting time data by measuring the bias in these two waiting time periods: referral to surgery and decision to surgery.

Chapter Two
Review of Literature

2.1 Arthritis Epidemiology

Arthritis is one of the most prevalent chronic health conditions in Canada and a leading cause of morbidity, disability and health care utilization. It poses a major economic and health burden in our society (Badley, 1995; Badley and Wang, 1998; Badley et al., 1998).

According to the 2000 Canadian Community Health Survey (CCHS), arthritis affects nearly 4 million Canadians aged 15 years and older, including over 1.6 million Ontarians. With the aging of the "baby boomer" population, by 2026 the number of Canadians with arthritis is expected to increase to more than 6 million aged 15 years and older, including 2.8 million Ontarians (Badley and Glazier, 2004). Arthritis was reported more frequently by women, older people, and people with lower levels of education and lower incomes (Arthritis in Canada: An Ongoing Challenge, 2003).

Costs for arthritis have been estimated by Coyte (1998) to be $ 4.4 billion CDN (1998 dollars). The economic burden of arthritis conditions in Canada accounted for 10.3% of the total economic burden of all illnesses (Arthritis in Canada: An Ongoing Challenge, 2003).

Osteoarthritis is one of the most common forms of arthritis, commonly affecting the hip and knee joints. Osteoarthritis may progress to the point where surgery is necessary. Severely damaged joints can be removed surgically and replaced with artificial ones. Joint replacement is major surgery and it is most often performed to replace arthritic hip and knee joints (Arthritis in Canada: An Ongoing Challenge, 2003).

2.2 Total Hip and Knee Joint Replacement Surgery

2.2.1 Indication for Surgery

Patients with severe symptomatic osteoarthritis of the hip or knee joint who experience significant pain and pain-related disability, loss of function and joint deformity may be considered for surgical intervention. Total hip replacement (THR) and total knee replacement (TKR) surgeries are the most common type of total joint replacement (TJR) surgery, an orthopaedic procedure where the diseased or damaged joint is removed and replaced with an artificial joint or prosthesis. The general aim of the surgery is to decrease pain and stiffness and enable the new joint to move like a normal, healthy joint.

2.2.2 Primary and Revision TJR

When a joint is replaced for the first time it is referred to as a primary total joint replacement or arthroplasty. Despite good outcomes after a primary joint replacement, the prosthesis can loosen and fail with time, often due to weakening of adjacent bone (a process called osteolysis). When this occurs, revision arthroplasty surgery is required. This entails removal of the old failed prosthesis and insertion of a new one. There are several parts to a joint prosthesis. Often only a single part or component of the prosthesis needs to be replaced. Revision arthroplasty is more costly than primary joint replacement surgery due to a longer operating time, the use of special instruments, increased complication rates, longer lengths of hospital stay, and longer rehabilitation (Lavernia et al., 1999; Iorio et al., 1999). Nevertheless revision surgery has been shown to be effective in improving function and quality of life (Porabeck and Murray, 1997).

2.2.3 Patient Outcomes

Primary TJR surgery appears to result in greater health improvement than revision arthroplasty. As a group THR patients have better outcomes than TKR patients (Ethgen et al., 2004). Many long-term follow-up studies have reported clinical success rates for primary TJR surgery that were greater than 90% in terms of patient satisfaction, pain reduction, functional improvement, and the absence of further surgery (Bourne et al., 2004; Soderman et al., 2000; Chang et al., 1996; Hawker et al., 1998; Dleppe et al., 1999). Furthermore, compared to other surgical and medical interventions, TJR surgery has been shown to be a highly effective intervention when one assesses its ability to impact on patients' health-related quality of life (Rorabeck et al., 1994).

2.2.4 Epidemiology

2.2.4.1 Canada

There were 68,746 total hip and total knee replacements performed in Canada among Canadian residents in 2005–2006. For both types of joint replacements, more of these surgeries were performed on women than men. With respect to age at the time of surgery, the majority of surgical cases (57% for hip, 63% for knee respectively) were done on patients from 65 - 84 years of age. From fiscal 2005 to fiscal 2006, 88% of THR surgeries were primary procedures and 12% were revisions. Primary total knee replacements accounted for 95% of all TKRs and revision surgeries accounted for the remaining 5%. Increases in hip and knee replacement surgeries between 2003–2004 and 2005–2006 were mainly driven by primary procedures which increased by 52% and 78% for THRs and TKRs, respectively. In contrast, revisions increased by only 37% and 58%, for THRS and TKRs, respectively. (CJRR Annual Report, 2007).

2.2.4.2 Ontario

In Ontario, the age-standardized rates for total hip and knee replacement surgery were higher for women than for men, regardless of the surgical joint. Over a ten year time period, while the volume of TJR surgery has increased steadily, the growth in TKR surgery has been greater than that for THR surgery. Between 1994/95 and 2004/05, the annual number of total hip replacements grew by over 50 per cent, while the annual number of total knee replacements grew by over 100 per cent. Age- and sex-adjusted total hip and knee replacement surgeries increased nearly 20 per cent over the last three years (2002/2003-2004/2005) (Access to Health Services in Ontario: ICES, 2006). The demand for total hip and knee replacement surgeries is expected to increase with the aging of the population and an associated increase in the number of people with arthritis (CJRR Annual Report, 2006; Access to Health Services in Ontario: ICES, 2006).

2.3 Joint Replacement Registries

One major societal response to the growth in the demand for hip and knee replacement surgery has been the development of hip and knee joint replacement registries. Internationally, a number of countries have established joint replacement registries. These registries capture information about recipients of hip and knee joint replacement surgery with longitudinal follow-up to monitor revision rates and outcomes at both regional and national levels.

2.3.1 International Joint Replacement Registries

2.3.1.1 Sweden

The Swedish National Knee Arthroplasty Registry is the oldest national arthroplasty registry in the world. In 1975, at the annual meeting of the Swedish Orthopedic Association in Uppsala, about 20 surgeons decided to start a voluntary multi-center registration of knee arthroplasty cases. This initial effort has grown to the point where all Swedish surgical units that routinely perform knee arthroplasty operations now participate in the registry. Robertsson et al. (1999) published a validation study regarding the accuracy of revision arthroplasty information provided by the Swedish knee arthroplasty registry between 1975 and 1995. They found that one fifth of all revision surgeries that were performed over this 20-year period had not been reported. Sweden has used administrative data to determine case ascertainment. The Swedish Patient Administrative System was used to identify unreported revisions, resulting in an estimated coverage of 94% of all revisions (Robertsson et al., 1999). In 2004, 9,170 primary arthroplasties were reported to the registry. This was a 10% increase over the previous year. In the same time frame, the number of revisions increased by 3% to 603.

The Swedish National Hip Arthroplasty Registry has been collecting and analyzing data about all primary total hip replacements and revisions of hip implants performed in Sweden since 1979. During the period 1979-2004, information from 242,393 primary hip arthroplasties and 22,840 revision arthroplasties has been collected (Swedish National Hip Arthroplasty Registry 2004 Annual Report). In 2000, a validation study was published, comparing the Swedish National Hip Arthroplasty Register, the National Discharge Register, and the National Death Register. Nationally, no significant differences were found between the registers with respect to frequency of primary operations, gender and age. In large urban centers, there were differences regarding the procedure incidence of revisions between the Swedish National Hip Arthroplasty Register and the National Discharge Register. Nationally, there also were differences between the registers regarding how many patients that were missing in one or the other register. Of the patients missing in one or the other register, 5% were lost because of a wrongly reported diagnosis or operation. Another reason for differences in the Swedish Hip Arthroplasty Register and the Discharge register was different definitions for revision (Soderman et al., 2000). While these two registries made efforts to evaluate their data quality, neither reported waiting time data in their annual reports and consequently no reports on waiting time data quality have been identified.

2.3.1.2 Norway

The Norwegian Arthroplasty Register (NAR) was started in 1987. Initially, only THR patients were registered, but in 1994 knee, elbow, ankle, toe, finger, shoulder and wrist joint replacements were also added to the data collection protocol. From 1987 to

2004 information from 106,700 hip replacement surgeries, 21,500 knee replacement surgeries and more than 6,600 prostheses in other joints has been submitted to the register. The NAR published a data validation study in 2005. In this study even though the NAR collected data from more than one local hospital, the validation was performed on one site only. The study compared the number of hip replacements reported to the Register with data recorded at a local hospital site. Of 5,134 operations performed at a local hospital, 0.4% had not been reported to the NAR. Arthursson et al. (2005) also reported the surgery date had been recorded incorrectly in 56 cases (1.1%), including 29 with the incorrect day, 17 with a wrongly recorded month, and 10 with the incorrect year. After investigation of these errors, typing errors and illegible writing were the two main causes of incorrect registration (Arthursson et al., 2005). Reports on other waiting time data quality except surgery date have not been identified in the register annual reports (The Norwegian Arthroplasty Register Website).

2.3.1.3 Australia

In June 1998, the Australian Orthopaedic Association received government funding to establish a national joint replacement registry. The registry captures data on demographic and diagnostic characteristics of patients undergoing joint replacement surgery. The main aim of this registry is to provide accurate information on the use of different types of prostheses in primary and revision joint replacement surgery and the evaluation of the effectiveness of different types of surgical techniques and prostheses. The total number of TJR surgeries recorded by all state governments for the financial year 2003-2004 (1/7/2003-30/6/2004) was 29,899 and 29,165, for TKR and THR, respectively (Australian National Joint Replacement Registry 2005 Annual Report). The Registry validates data collected from individual hospitals by comparing them against administrative data provided by state and territory health departments. This validation process revealed that 90% of the surgical records were an exact match, with an additional 3% matching partially on the patient identifier, the procedure code for primary/revision surgery, the admission date and the discharge date. No waiting time data have been presented in this registry's annual reports and no reports of waiting time data quality were identified (Australian National Joint Replacement Registry 2005 Annual Report).

2.3.1.4 New Zealand

The New Zealand National Joint Register has been capturing data regarding joint replacements for hip, knee, shoulder, elbow and ankle surgery since January 2000. In this registry, all registered patients are sent a questionnaire to measure the outcome of their surgery approximately six months following surgery. The total number of hip and knee replacement cases registered to March, 31, 2004 was 29,492 and 17,390, respectively (New Zealand National Joint Register Annual Report 2004). Neither waiting time data nor waiting time data quality has been found in the register's annual reports.

2.3.1.5 United Kingdom

The National Joint Registry (NJR) in the United Kingdom has collected information on hip and knee replacement surgery since April 2003. The NJR seeks to provide evidence of long-term effectiveness of TKR/THR surgery. The NJR also monitors individual hospital performance. Patients are sent a questionnaire at 3 months and 12 months post-operatively to measure surgical outcome. The total number of knee and hip replacements recorded for fiscal year 2003-2004 was 44,898 and 48,987, respectively (UK National Joint Replacement Registry 2005 Annual Report). In February 2005, the NJR performed an internal audit of its data submission procedures, but results have yet to be reported. Furthermore, the NJR has not reported on waiting time data nor have they reported results of waiting time data quality analyses (UK National Joint Replacement Registry 2005 Annual Report).

2.3.2 Canadian Joint Replacement Registry

The Canada Joint Replacement Registry (CJRR) captures information on hip and knee joint replacements performed in Canada and follows joint replacement patients over time to monitor their revision rates and outcomes. The purpose of the CJRR is to collect and analyze summary data on hip and knee replacement procedures performed in Canada, and support evidence-based decision making to improve the quality of care for joint replacement recipients. Participation in the CJRR is voluntary and has been steadily increasing since orthopaedic surgeons began submitting operative data in May 2001. As of April 2006, 70% of orthopaedic surgeons who perform total hip and total knee replacement surgery in Canada were participating in the registry (CJRR 2006 report). In April 2005, the registry began collecting additional data to facilitate the calculation of waiting times for primary joint replacement. To do this, the following new data elements were added to the data collection protocol: referral date, first consult date and decision date for surgery. By December 2005, these dates were available for 1,078 knee replacement and 837 hip replacement patients (Waiting for Health Care in Canada, CIHI

2006). CJRR has published data quality documents for a single fiscal year 2003-2004. This document contains information on coverage issues, data limitations, and comparability. As of June 2004, 67% of orthopaedic surgeons performing hip and knee replacement surgery in Canada were participating in the registry. There is no other known national source to compare or validate the exact rate of surgeon under-coverage in Canada. It is therefore difficult to accurately ascertain the total number of hip and knee replacement procedures performed in Canada and the total number of hip and knee replacement procedures performed by the surgeons participating in CJRR. Data are collected either by paper, via two distinct hip and knee replacement data collection forms, or via electronic files. Data submission is voluntary on behalf of the providers. All the paper forms for fiscal 2003-2004 were verified for completeness and data entry verification was performed on approximately 80% of the data entered for fiscal 2003. During fiscal 2003-2004, other than the national Hospital Morbidity Database (HMDB), there are no other known national external sources of published information on hip and knee replacements performed in Canada that can be used to validate information in CJRR. However, the CJRR has not reported on waiting time data quality (Data Quality Documentation, 2005).

2.3.3 Ontario Joint Replacement Registry

The Ministry of Health and Long Term Care funded the Ontario Joint Replacement Registry (OJRR) in 2000 to providing information about access to and the quality of total hip and knee replacements for people of Ontario. The OJRR's vision is to provide data that will result in a reduction of revision rates and improve access to joint replacement surgery in Ontario. The OJRR is the means by which the CJRR obtains TJR data for the Province of Ontario.

In its 2004 Annual Report, the OJRR reported on patient characteristics as a function of waiting time. The report discussed how waiting time periods may be viewed differently by patients, surgeons and hospital administrators. For example, patients' and surgeons' views of a 'waiting time' may include the total waiting time from referral to surgery. From this perspective, OJRR data for referral to surgery waiting time indicate that 48% of patients had their surgery within six months of referral while 22% of patients had to wait more than one year from referral to surgery. Alternatively, a hospital administrator's view may only include the wait from decision to surgery because the decision for surgery usually starts the wait for operating room availability and it is the hospital that allocates operating room time. OJRR data for decision to surgery waiting time showed that 69% percent of patients waited six months or less and only 6% waited more than one year. Since both waiting time periods give different messages about and insight into access to TJR surgery, any evaluation of waiting time data quality should consider both waiting time periods (OJRR 2004 Annual Report). There was no report of waiting time data quality in the OJRR Annual Report (2004). This is because the initial stages of the analysis were taking place which formed the primary objective of this thesis: to determine the quality of the OJRR waiting time data by measuring bias in referral to surgery and decision to surgery waiting times. This evaluation of the waiting time data is the first 'reported' evaluation of waiting time data quality among THR/TKR registries.

2.4 Waiting Time

Many Canadians waiting for specialized care, such as orthopaedic assessment and hip or knee replacement surgery, report that they have to cope with the pain, anxiety and stress of waiting for health care (The Daily from Statistics Canada, Accessed March 2006). In one recent national survey (conducted in 2003, published in June, 2004), while each respondent may have had a different definition of an acceptable waiting time, almost one third of respondents reported that their waiting time for medical care was unacceptable. In this section of the literature review, the effects of waiting for TJR surgery are summarized as well as the methods of reporting waiting time.

2.4.1 Effects of Waiting for TJR Surgery

There is limited evidence indicating that a deterioration in functional health status occurs in patients waiting more than six months for joint replacement surgery. Three studies reported statistically or clinically relevant deterioration in health-related quality of life (HRQL) while patients waited for surgery (Mahon et al., 2002, Ostendorf et al., 2004, Kili et al., 2003).

There is even less evidence indicating that very long waits result in poorer post-operative outcomes after joint replacement surgery. Hajat et al. reported that patients who waited more than 6 months and more than 12 months from referral to consultation had worse Oxford Hip Scores compared to patients who waited less than three months. Those patients who waited 12-18 months from consultation to surgery had worse Oxford Hip Scores compared to patients who waited less than 6 months (Hajat et al., 2002).

2.4.2 How Waiting Times Are Reported

Since a potential barrier to reporting waiting times is the lack of standardized definitions, the OJRR used waiting time definitions developed by the Western Canada Wait List (WCWL) project (OJRR 2003 Report). These waiting time periods used the date of occurrence from four time points along the clinical pathway from referral to surgery until the surgery date. The key dates are (1) the referral date to the orthopaedic surgeon, (2) the first consult date with the orthopaedic surgeon, (3) the decision date for surgery by the patient and the surgeon, and (4) the surgery date. The waiting for TJR surgery can be divided into three distinct time periods as illustrated in Appendix I.

Referral to first consult is the time between the receipt of a referral by an orthopaedic surgeon and the date of the first patient assessment by the orthopaedic surgeon. This waiting time period is unique because (1) the patient is queuing for the orthopaedic surgeon's time as opposed to operating room time, and (2) the patient's clinical status has not yet been evaluated by the surgeon.

First consult date to decision date reflects the time between the first visit with the orthopaedic surgeon and the date that both patient and surgeon decide to proceed with TJR surgery. The majority of patients often make their decision to proceed with surgery at their first consult so this waiting time is usually equal to zero (OJRR Annual Report, 2004). Decision date to surgery date is the time that a patient waits for an available operating room after both the surgeon and the patient have agreed to proceed with surgery. This waiting time period is important because hospital factors can impact on the wait due to the availability of beds, surgical facilities and staff. This in turn can be affected by budgetary restraints.

There are different ways of reporting waiting times. Some have reported average waiting times (Waiting for Health Care in Canada, CIHI, OJRR 2004 Report), while others have published median waiting times because the distributions are typically skewed in a manner that is similar to length of stay. (Waiting for Health Care in Canada, CIHI, OJRR 2004 Report). Based on data entered between April and December 2005, the CJRR reported the median waiting time for decision to surgery was about four and a half months for THR and seven months for TKR (Wait for Health care in Canada, CIHI). ICES reported that in 2003/04, median waiting times for TJR in Ontario were 5-6 months for hip replacement and 7-8 months for knee replacement (Access to Health Services in Ontario, ICES 2006). The OJRR has indicated that older patients (75 years or more) had shorter 'median' waiting times than younger people, with those in the 85+ category having their TJR surgery the fastest. (OJRR 2004 Report).

Alternatively, the proportion of patients who received surgery within a given waiting time threshold (e.g. three months, six months) can be calculated (Access to Health Services in Ontario, ICES 2006). The OJRR indicated that 48 percent of patients had their surgery within six months and 22% percent of patients had to wait more than one year from referral to surgery. Sixty-nine per cent of patients waited six months or less from decision to surgery and six per cent waited more than one year from decision to surgery (OJRR 2004 report). This reporting method is relevant to the development of benchmarks for the maximum acceptable wait time (MAWT) for total hip and knee replacement surgery, highlighting the contribution that joint replacement registries can make to health policy.

In Canada, the Canadian Orthopaedic Association National Standards Committee produced benchmarks for orthopaedic waiting times using the best available data from Canada, the United States and other international sources (Rumble and Kreder, 2005). The committee recommended that no patient referred to an orthopaedic surgeon should be asked to wait longer than 3 months under any circumstance. Furthermore, no patient should be asked to wait longer than 6 months after both the patient and the surgeon have made the decision to operate (Noseworthy et al., 2005). In Saskatchewan, the Western Canada Waiting List (WCWL) Project recently introduced a priority scoring system (WCWL Project; Hadorn, 2003, Conner-Spady et al., 2004) for the Saskatchewan Surgical Care Network (a province-wide surgical registry established in part to monitor provincial waiting time). Target time frames are linked to six priority levels. A 'priority 3' level has a target waiting time of 90% of patients within 3 months. The target time frame for all patients is within 18 months (Saskatchewan Surgical Care Network).

Reporting waiting times as means or medians as opposed to the proportion of surgical cases performed within a waiting time threshold is relevant to this thesis because the two reporting methods use different scales of measurement and there is a relationship between the level of measurement and the appropriateness of various statistical procedures. Scales of measurement are commonly broken down into four types: nominal, ordinal, interval and ratio. Mean and median waiting times are measured on the ratio scale, while the proportion of patients receiving surgery within a benchmark time period uses the nominal scale (Koval, 2004). Nominal scales with only two values are called dichotomous scales. Waiting times defined as the proportion of patients that were performed within a waiting time threshold could be treated as a dichotomous variable because one either did or did not receive the TJR surgery within the specified waiting time threshold. The next section identifies the appropriate statistics for evaluating bias in waiting time data, in consideration of the scale of measurement.

2.5 Evaluation of Data Quality in Surveillance Systems

Population-based registries need extensive, high-quality data for evaluating disease burden and medical resources planning. Data quality reflects the completeness and validity of the data recorded in a public health surveillance system. A full assessment of the completeness and validity of the system's data might require a validity study (Guideline for Evaluating Surveillance Systems, CDC, 1998).

2.5.1 Validity and Reliability

Validity refers to the closeness with which a measurement approaches the true value. Lack of validity is referred to as "bias" or "systematic error." Most biases (systematic error) related to surveillance data can be classified into three basic categories: programming errors (such as data entry modules or extraction software), unclear definitions for data items (such as the lack of a clear definition for data fields and insufficient guidelines and training for data collection), and violation of the data collection protocol (Szklo and Nieto, 2000). Moreover, Sobolev et al. (2000) have shown that retrospectively collecting waiting time data may cause bias since any patient removed from the list before receiving the medical service would not be included to measure waiting time in a retrospective study. This type of bias is not a problem for the OJRR where waiting time data are captured prospectively.

Reliability refers to the extent to which multiple measurements agree. Reliability studies assess the extent to which results agree when obtained by different approaches, that is, different observers, study instruments, or procedures (Szklo and Nieto, 2000).

2.5.2 Indices of Validity

In this section, some of the most frequently used indices of validity are briefly described. Sensitivity and specificity are the two traditional indices of validity when the definitions of exposure and outcome variables are categorical. The study exposure or outcome categorization is contrasted with that of a more accurate method (the "gold standard," which is assumed to represent the "true" value and thus to be free of error). Sensitivity and specificity are also frequently used in the evaluation of diagnostic and screening tools.

In real life, a true "gold standard" may not be available, thus sometimes making it difficult to distinguish between validity and reliability measures. When a "gold standard" is not clearly identified, reliability estimates are often referred to as "validity" results.

Therefore, Kappa is occasionally used for the assessment of validity when the definitions of exposure and outcome variables are categorical (Szklo and Nieto, 2000).

The indices most frequently used to evaluate the validity of a given continuous measurement are the 95% limits of agreement approach by Bland and Altman (1986). They recommended the 95% limits of agreement be expressed as a mean difference between two measurement methods, plus or minus 1.96 standard deviations. This would tell how much the measurement by two methods were likely to differ for most individuals. One could then say that 95% of the differences in measurement by two methods will be laid between these limits. The limits of agreement approach is fundamentally very simple and direct. It provides statistics that are easy to interpret in a meaningful way (Altman and Bland, 2003).

When waiting times have been defined as the proportion of patients whose sugeries were performed within a waiting time threshold (i.e. a dichotomous variable); then McNemar's chi-squared test is the appropriate statistic to evaluate the validity of waiting time. This is because McNemar's test pertains to proportions from matched samples and the two methods of measuring wait times are matched because they both independently measure the waiting time for the same surgical event. Thus, the McNemar's test examines the null hypothesis that the waiting time proportions estimated from the two matched samples (i.e. methods) are the same (Bland, 2000).

In recent publications different statistical methods have been chosen to evaluate data quality for patient registries. The European liver transplant registry performed validation audits by comparing the data contained in the database with data contained in the hospital record. Cohen's kappa value was used to assess the agreement between the two data sources for each condition. And sensitivity and specificity of each condition were calculated by designating the patient chart review data as the gold standard (Karam et al., 2003). Some registries calculated the percent of errors to determine data quality (Hakansson et al. 2001, Surawicz et al. 2000, Arthursson et al. 2005, Laustsen et al. 2004, Hlaing et al. 2006, Olsson et al. 2006, Stevens et al. 2008). In others, data quality studies were performed by using both kappa, sensitivity and specificity statistic methods (Surawicz et al., 2000, Wang et al., 2001).

2.6 Summary of Literature Review

The literature review has established that waiting time for total joint replacement surgery is an acknowledged issue in terms of access to care. Furthermore, given the number of total joint replacement registries in the world, and the concern about the negative effects of waiting time, very few registries report waiting time for surgery. Reporting waiting times as a continuous variable as opposed to the proportion of surgical cases performed within a waiting time threshold is relevant to this thesis because the two reporting methods use different scales of measurement and a relationship exists between the level of measurement and the most appropriate statistical procedure. Finally, the review of validity and reliability highlight the importance of choosing the statistic that is best suited to the study question. For example, the most appropriate statistical analysis for determining waiting time data quality is using the mean difference method when waiting time is treated as continuous variable and the McNemar test when waiting time is treated as a dichotomous variable.

2.7 Thesis Objectives

The primary purpose of this study was to determine the bias in two waiting time periods: referral to surgery and decision to surgery, derived from the relevant dates collected by the Ontario Joint Replacement Registry (OJRR). In doing so, four waiting time date fields in the OJRR database were of interest: referral date, first consult date, decision date and surgery date.

The specific objectives of the study were:

1. To determine the bias in the OJRR waiting time date fields by
   a. describing the frequency of error in these date fields, and
   b. estimating the mean difference and 95% limits of agreement between the wait times derived from the OJRR database and those calculated with the corresponding dates in the patients' medical record.
2. To investigate the possible reasons for any difference in waiting times derived from the OJRR database and the patients' medical record.

A secondary objective was to compare the inference about waiting time bias obtained from the 95% limits of agreement approach with that of the McNemar chi-squared approach for dichotomous measures.

Chapter Three
Methods

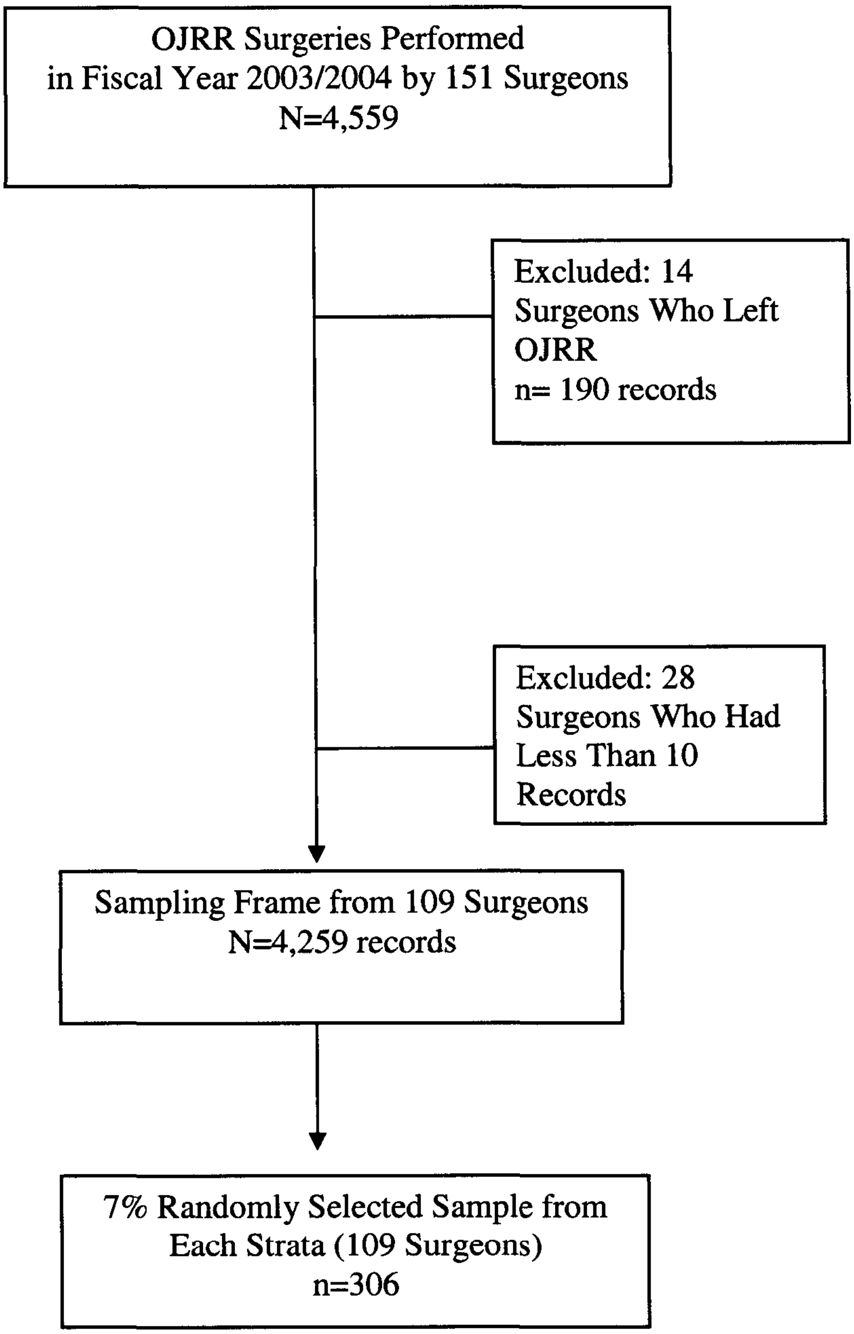
The project was approved by The Research Ethics Board for Health Sciences Research Involving Human Subjects at the University of Western Ontario (see Appendix II) as well as the OJRR Research Subcommittee.

3.1 Study Population and Sampling Strategy

The study population of interest was composed of all THR and TKR surgical events (n = 4,559) that (i) took place in Ontario during fiscal year 2003/2004, and (ii) had been submitted to the OJRR and therefore were included in the analytic cohort used to generate waiting time reports for the OJRR Annual Report, 2004.

Derivation of the sampling frame for this study is shown in Figure 1. The sampling frame (n=4,259) was derived from the study population of interest by removing surgical events that did not qualify for sampling (n=300) (Figure 1). Ineligibility for sampling was defined in two categories: access to the medical record (n=190) and practical issues when drawing the sample (n=110). More specifically, there was no ability to access the medical records of one surgeon who was deceased, five who had retired, four who were no longer participating with the OJRR and three who had moved outside of Ontario. For another surgeon who practiced in a remote location in Northern Ontario, it was cost prohibitive and geographically impractical to travel to the site to audit medical records for a single case. The practical issue that evolved when drawing the sample arose from using a stratified sampling method.

Figure 1. Derivation of Sample Frame:



Each orthopaedic surgeon in the sampling frame was considered a stratum. Since some surgeons had contributed small volumes to the study population (i.e. less than 10 surgical events in a fiscal year), the sampling procedure would identify less than one case from these surgeons. Sampling one case would inflate the contribution of that surgeon's data to the waiting time comparisons that were to be made. A decision was made to accept any bias related to omission of these 28 surgeons compared to the bias of over-representing them in the sample. Of the 151 surgeons who were in the analytic cohort, 109 or 72% were actually in the sampling frame. A 7% random sample proportionate to the number of surgical events submitted by a surgeon, was drawn from the surgical cases of each surgeon in the sampling frame. In total, 306 subjects were drawn from the sampling frame. Justification of sample size follows.

3.2 Sample Size Justification

Estimation of the bias in OJRR waiting times was determined by calculating the mean difference between the waiting time derived from the medical record and the waiting time calculated using the OJRR database. A sample size was selected to give a narrow 95% confidence interval ± 1 week about that mean difference using the following formula from Woolson and Clarke, 2002:

$$95\% \text{ confidence interval} = \bar{d} \pm 1.96\sqrt{\frac{\sigma^2}{n}} \qquad (1)$$

Where,

$\bar{d}$ = Mean difference between waiting times derived from the OJRR database and the medical records

σ = Standard deviation of the difference between OJRR waiting times and medical records waiting times

n= Number of surgical events in the sample

$$\text{Solving for n from equation (1), n} = \frac{\sigma^2(2*1.96)^2}{(Upper - Lower)^2} \qquad (2)$$

Where,

Upper-Lower = 2 weeks (i.e. a confidence interval of plus 1 week and minus 1 week)
and
σ = 8 weeks from OJRR internal pilot study for Referral to Surgery, thus, n = 246
and
σ = 6 weeks from OJRR internal pilot study for Decision to Surgery, thus, n = 139

Therefore, n = 246 was chosen as a sufficient sample size to achieve the confidence interval specified above. Then the sample size was adjusted for missing and invalid records using results from an internal OJRR pilot study (DeGroot et al. 2005). This assumed that missing and invalid records were random events and not related to the study end-point (i.e. surgery date). Thus, $n_{adjusted}$ = 246 / 0.83 = 297. So, 297 surgical events were required for this study. Drawing the sample yielded an additional 9 surgical events (n = 306) because of rounding the required proportion of cases to be sampled within a stratum.

3.3 Data Source and Data Elements of Interest

Two sources of data were used in this study. One was the OJRR database, the other was the patients' medical records.

As mentioned, the waiting time date fields of interest were referral date (date that the surgeon received the referral for an orthopaedic consultation), first consult date (date of the patients' first consultation with the orthopaedic surgeon), decision date (date that the patient and the surgeon decided to proceed with surgery) and surgery date (date of the joint replacement surgery). Two waiting times were calculated from each of the two data sources. Referral to surgery waiting time was obtained by determining the number of weeks between the referral date and the surgery date. Decision to surgery waiting time was calculated as the number of weeks between the decision date and the surgery date.

3.4 Data Collection Methods

3.4.1 Data Collection from the Medical Record

At the time of enrolment with the OJRR, all participating surgeons signed a participation agreement that made provisions for OJRR staff to access patient's medical records to conduct random record audits for data validation purposes.

OJRR Regional Field Coordinators (RFCs) participated in planning and training sessions for the data collection protocol. The training sessions involved reviewing the rules for obtaining the four date fields from the medical record. The rules were developed from pilot work and revised after that field experience. Details of these rules can be found in Appendix III.

In January 2005, a letter from the OJRR advised surgeons of the project (letter details in Appendix IV). Data collection took place over a three month period commencing in February 2005. All data from the medical records were collected by nine OJRR RFCs. To identify the correct surgical case in the medical record, RFCs were provided with the following information from the OJRR database: surgeon's name, patient's first and last name, patient's gender (male/female), joint of surgery (hip/knee), side of surgery (left/right/bilateral), type of surgery (primary or revision), and surgery date. The RFCs were blinded to the OJRR values for referral date, first consult date and decision date for each surgical event.

RFCs reviewed the patient's medical record that was maintained in the surgeon's office or in the hospital Medical Records departments to collect the following data: referral date, date of first consult, decision date, date of surgery and an indication if the initial surgery date had been delayed (ie. re-scheduled). Data were also collected to ensure that dates retrieved from the medical record were (i) not interpreted incorrectly because of ambiguous date formats and (ii) correctly assigned to the action/event associated with the date (i.e. referral, decision and surgery). For example, for each date abstracted from the medical record, RFCs also collected the following information: an indication if the date format was known (yes or no) (eg. can one tell from looking at the date, which component is the day, which component is the month and which component is the year?) and the format of the date field, if known (eg. day/month/year or month/day/year, etc). To ensure that the correct date was associated with the action/event of interest, the source of the date information was recorded (e.g. written referral for referral date, clinic note for decision date, operating room note for surgery date). In addition, for decision date, RFCs also recorded if an explicit statement of the context of the decision date was found (eg. 'decided to proceed with surgery' or 'will put on waiting list for surgery').

An open text field was provided to allow additional comments regarding data collection for a given surgical event (eg. ' two referral dates are present, second date is <datevalue>' or 'discrepancy in demographic or surgical information was found, the medical record value is <value> for <variableName>', etc.).

Data were recorded using secure laptop computers and custom software developed for this study by OJRR staff. The custom software was developed from pilot work and revised after that field experience. Software details can be found in Appendix VII. Data collected from the patient's medical record were transferred from RFC laptops to the secure network at London Health Sciences Centre.

3.4.2 Data Extraction from the OJRR Database

Data from the OJRR database were extracted by OJRR staff from the secure server that housed surgical records after data cleaning. The following data fields were included for each one of the sampled surgical events: referral date, first consult date, decision date, surgery date, surgery type (primary/revision), surgical joint (hip/knee), hospital teaching status (teaching/nonteaching), surgery date delayed (yes/no), ASA Physical Status score (normal-healthy/mild systemic disease/severe systemic disease/life threatening), gender (male/female), region (MOHLTC planning region), primary diagnosis (osteoarthritis/all others) and Charnley category (AB/C). Details of these data fields are summarized in Appendix V. A detailed description of data capture procedures for the OJRR can be found in Appendix VI.

3.5 Confidentiality

The OJRR has been prescribed as a registry within Bill 31 and maintains confidentiality of participants' records and its data holdings by the following methods:

(1) a secure database with limited, controlled access rights.

(2) the OJRR physical office space is a controlled-access environment.

(3) all OJRR computers and software are password protected

(4) all OJRR personnel sign a statement of confidentiality.

As a graduate student working on this project Lili Liu signed a statement of confidentiality and was categorized as a 'third party researcher'. As such, she did not have access to personal identifying information. All file manipulation and data analyses conducted by Lili Liu were done with de-identified data. OJRR staff with 'read' access to record-level data performed all necessary de-identification of files.

3.6 Data Management

3.6.1 Data Entry and Verification

Data that were recorded and sent by RFCs using the OJRR secure custom software were imported into a Microsoft Access 2000 database by OJRR staff and then stored on the secure network at London Health Sciences Centre. For analysis an OJRR staff also imported all data into Excel before de-identifying all records in the file. Lili Liu performed date formatting for the following four date fields: referral date, first consult date, decision date and surgery date. Using the SAS date9 format, the form ddmmmyyyy, was used to perform statistical analysis for date variables.

Three components to a date field were defined. These components were the day value, the month value and the year value that, when combined together to represent a given day within a calendar year thus comprising the complete calendar date. The relevance of the date components to the calculation of waiting times lies in the fact that SAS statistical software uses all three date components to generate what is referred to as an internal date value. This internal value is the number of days between the date of interest and January 1, 1960. For dates after this date, the internal value is a positive integer.

Once all dates had been changed into the SAS date9 format, a portion (1.75%, n=54) were randomly selected using SAS for verification of data entry accuracy. The accuracy of data entry for the four date fields of interest was verified for values inputted by Lili Liu and and an independent third party (i.e. M.Sc. student in the Department of Epidemiology and Biostatistics). No data entry errors were identified in referral date, first consult date, decision date and surgery date.

3.6.2 Data Analysis

3.6.2.1 Calculation of Waiting Time

Waiting times were calculated using the SAS internal value. To express waiting time as a positive value, referral to surgery waiting time was equal to surgery date minus referral date. Decision to surgery waiting time was equal to surgery date minus decision date.

3.6.2.2 Comparison of the Sample with the Study Population

To determine the comparability of the two groups, characteristics of the surgical events in the study population and in the sample were compared with the Chi-square test for categorical variables (Woolson and Clarke, 2002) and the two sample *t* test for continuous variables (Woolson and Clarke, 2002). Since stratified sampling methods were used to select the sample, a one-way ANOVA *F*-test and visual inspection of the data were performed to test whether the mean of the waiting times differed among the 109 surgeon strata and to determine if it was reasonable to pool the data from each surgeon .

3.6.2.3 Description of Waiting Time Errors

Using the medical record values as the gold standard, the frequency of error in the OJRR waiting time date fields (referral date, first consult date, decision date and surgery date) was calculated.

3.6.2.4 Determination of Bias in Waiting Times

Bias was determined by calculating the mean difference between the waiting time derived from the medical record and the waiting time calculated using the OJRR database. Calculation of the difference between the two waiting times was performed so that positive differences reflected OJRR over-estimates of waiting time and negative differences expressed OJRR under-estimates of waiting time. Following Bland and Altman (1986) the 95% limits of agreement were determined by calculating the mean difference between the two measurements plus or minus 1.96 standard deviations of this difference.

The 95% limits of agreement depend on two assumptions about the data (Bland and Altman, 2003). First, the mean and standard deviation of the differences are constant throughout the range of measurements. Second, the differences are from an approximately normal distribution. To check the first assumption, the differences were plotted against the average of the waiting time captured from the medical record and the OJRR database. A histogram of the differences was created to check the second assumption. When the first assumption was violated, the logarithm of the waiting time difference was calculated following Bland and Altman (1986). Since the antilog of the difference between two values on a log scale is a dimensionless ratio, the limits of agreement were then expressed in the form of proportions (Bland and Altman, 1986).

3.6.2.5 Investigation of Reasons for Bias in Waiting Times

Several hypotheses were tested, to investigate three possible reasons for any difference in waiting times derived from the OJRR database and the patients' medical record. These are listed below with brief rationale.

Reason #1: A delay in surgery may affect the accurate recording of the true surgery date.

Rationale:

One common reason for delaying the initial date for surgery is a situation often described as the 'snowbird' phenomenon. This occurs when a senior citizen who plans to travel south for the winter is provided with a surgery date that conflicts with his/her travel plans. Often, the patient declines the date, preferring to wait until after he/she returns to Canada. In this case, the surgeon's secretary would have to change the initial recording of the surgery date. If this was not done, there would be an error in the recording of the surgery date. This could potentially underestimate both referral to surgery and decision to surgery wait times.

To determine if a delay in surgery was related to the accurate recording of the true surgery date, the following hypotheses were tested.

Hypothesis #1a: There is an association between the presence of a surgery date error and the presence of a delayed surgery date.

For both data sources, the association between these two categorical variables was tested using the chi-square test (Woolson and Clarke, 2002). The Fisher's exact test was used when at least one cell count in the 2 by 2 table was less than five (Woodward, 2005). Odds ratios and 95% confidence intervals were calculated to test the hypothesized association (Woolson and Clarke, 2002). If the interval failed to include the null value (i.e. 1), then it was concluded that there was an association between the two variables. Because this association could be related to how well a surgery delay was captured in the medical chart and in the OJRR database, the Kappa statistic was used to determine the agreement between the medical chart and the OJRR for documentation of a 'delayed surgery'(Szklo and Nieto, 2000).

Reason #2: A delayed decision to proceed with surgery may affect the accurate recording of the true decision date.

Rationale:

Among OJRR surgeries performed in fiscal 2003/2004, for 80% of the surgical events, the decision date for surgery was made on the first consult date (i.e. these surgical events had the same decision date and consult date) (OJRR 2004 Annual Report). This may increase the chances that the correct decision date was captured because the capture of the decision date would take place at the point in time on the clinical pathway where this event usually occurs. Alternatively, the surgeon may advise surgery on that first consult date, but the patient prefers to make the decision after returning home from this first visit with the surgeon, wishing to think about it or confer with a spouse, family members or friends. In this scenario, patients may phone the secretary at some point in time after the first consult date to indicate they are ready to proceed with surgery. In this event, it is possible that the surgeon's decision about the appropriateness of surgery may be recorded on the 1st consult date and the patient's decision date may or may not be recorded, increasing the chances of an error in the recording of the true decision date because the patient agrees to proceed with surgery after the first visit with the surgeon. This could potentially overestimate decision to surgery wait times.

To determine if a delayed decision to proceed with surgery may affect the accurate recording of the true decision date, the following hypotheses were tested.

Hypothesis #2a: There is an association between the presence of a decision date error and the presence of a delayed decision date by the patient.

For both data sources, the association between these two categorical variables was tested using the chi-square test (Woolson and Clarke, 2002). Once again the Fisher's exact test was used when at least one cell count in the 2 by 2 table was less than five (Woodward, 2005). Odds ratios and 95% confidence intervals were calculated to test the hypothesized association (Woolson and Clarke, 2002). Because this association could be related to how well identical decision and first consult dates were captured in the medical chart and in the OJRR database, the Kappa statistic was used to determine the agreement between the medical chart and the OJRR for the presence of identical first consult and decision dates (Szklo and Nieto, 2000).

Reason #3: Use of a Fax machine date to obtain the referral date from a referral that was faxed to a surgeon may affect the accurate recording of the true referral date.

Rationale: If referral date is recorded from the FAX machine, an additional source of bias at data entry arises from the variability in date formats on FAX machines, plus the possibility that the Fax machine date had not been correctly set up in the surgeon's office. This could potentially overestimate or underestimate referral to surgery wait times. To determine if the use of a fax date as a proxy for referral date may affect the accurate recording of the true referral date, the following hypotheses were tested.

Hypothesis #3: There is an association between the presence of a referral date error and the use of a Fax machine date from the faxed referral to the surgeon.

As noted before, for both data sources, an association between these two categorical variables was tested using the chi-square test (Woolson and Clarke, 2002). Again the Fisher's exact test was used when at least one cell count in the 2 by 2 table was less than five (Woodward, 2005). Odds ratios and 95% confidence intervals were calculated to test the hypothesized association (Woolson and Clarke, 2002). For all hypothesis testing significance was set at the 0.05 level.

3.6.2.6 Determination of Bias using Waiting Time Thresholds (secondary objective)

For the secondary objective, to compare the inference about waiting time bias obtained from the 95% limits of agreement approach, the McNemar's chi-squared test (Bland and Altman, 2003) was performed to determine whether there were significant differences between the OJRR database and patient medical records when waiting times were defined as the proportion of cases that were performed within a waiting time threshold or cut-off. Two waiting time thresholds were used. For decision to surgery waiting time, the thresholds were six and nine months. For referral to surgery waiting time, the thresholds were 9 and 12 months. The distribution of date component errors across the four cells of the 2 by 2 table was examined descriptively.

All statistical analyses were performed with SAS, version 8.0 (SAS Institute, Cary, NC).

Chapter Four
Results

4.1 Sample Characteristics

Derivation of the analytic sample for this study is shown in Figure 2. After sampling, 15 surgical cases (5%) were excluded from the analysis because the record review indicated these cases were patient re-assessments, not new referrals to the orthopaedic surgeon. In this instance, the referral date represents the time of referral for the previous total joint replacement. Therefore a referral to surgery waiting time could not be calculated for the upcoming index surgery. Another 22 cases (7%) were excluded because of missing date fields in the medical record. Among these cases 13 had no referral date, three had no first consult date, four had a missing decision date, one had no referral date, no first consult date and no decision date, and one had no referral date and no decision date. No cases had a missing surgery date. Of the 306 cases sampled, 269 cases were retained for the analysis.

Sample characteristics are shown in Table 1. The mean age of the sample was 68 (SD = 11) years. Consistent with the elective nature of most THR and TKR surgery, a majority of cases were primary surgeries (94%) and 61% had an ASA Physical Status Score equal to normal/healthy or mild disease. Consistent with the OJRR participation rates across the province, more cases (71%) were performed in non-teaching hospitals. The median decision to surgery waiting time for the sample was 17 weeks. The median referral to surgery waiting time was 33 weeks. Table 1 also shows the comparison between the analytic sample (n = 269) and the study population (n = 4,559). There were no differences between the sample and the study population (all P values > .20).

Figure 2. **Derivation of Sample:**

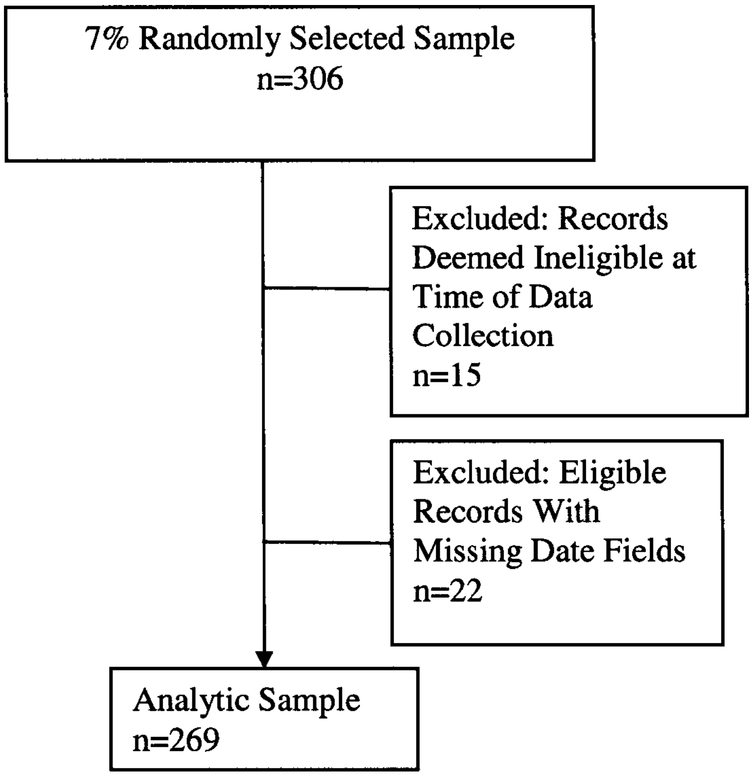


Table 1. Characteristics of surgical events in study population and analytic sample.

Variables	Study Population (n=4559) Frequency	Percent	Analytic Samples (n=269) Frequency	Percent
MOHLTC[a] Planning Regions				
A (North)	200	4	8	3
B (Central West)	465	10	22	8
C (Toronto)	940	21	54	20
D (Central South)	455	10	26	10
E (Central East)	719	16	47	17
F (South West)	1242	27	78	29
G (East)	538	12	34	13
Surgery type				
Primary	4320	95	252	94
Revision	239	5	17	6
Surgical joint				
Hip	2244	49	151	56
Knee	2315	51	118	44
Hospital Teaching Status				
NonTeaching Hospital	3297	72	190	71
Teaching Hospital	1262	28	79	29
Primary Diagnosis				
Degenerative Osteoarthritis	3982	87	228	85
All Others	577	13	41	15
Surgery Date Delayed				
Delayed	453	10	34	13
No Delay	4106	90	235	87
Gender				
Female	2739	60	162	60
Male	1820	40	107	40
ASA[b] Physical Status Score				
Normal/Healthy	277	6	13	5
Mild Disease	2526	55	151	56
Severe Disease	1653	36	100	37
Life Threatening	103	2	5	2
Charnley Category[c]				
AB	4523	99	266	99
C	36	1	3	1

* All p values comparing proportions across study population and analytic samples are greater than .20.

[a] Ontario Ministry of Health and Long Term Care

[b] American Society of Anesthesiologists

[c] Charnley category C is a patient who in the opinion of the surgeon would have abnormal gait even if the hip and knee joints were normal.

4.2 Bias in Waiting Time Date Fields

Since stratified sampling methods were used to select the sample, a one way ANOVA *F*-test was performed to determine whether the mean of the waiting times differed among the 109 surgeon strata. No significant differences were detected among strata ($p > .05$). Visual inspection of box and whisker plots for both waiting times was also performed to establish the similarity of waiting times across the surgeon strata. Therefore all cases in each strata were combined for the analysis of waiting time bias (n=269). Table 2 summarizes the waiting times for the two data sources: the medical record and the OJRR.

4.2.1 Frequency of Error in Date Fields

Using the medical record as the gold standard, among all surgical cases in the sample, the referral date had the highest frequency of date field errors (38%, n=102) followed by the decision date (20%, n=53). First consult date was in error 14% of the time (n=39), with surgery date errors found in only 10% of cases (n=28). Thirty-eight percent of cases (n=102) had no errors in all four date fields.

4.2.2 Mean Difference between OJRR and Medical Record

The mean difference (SD) between the waiting time derived from the medical record and the waiting time calculated using the OJRR database was 0.13 (11.32) weeks for decision to surgery waiting time and 0.66 (9.64) weeks for referral to surgery waiting time (Table 3). Using the 95% limits of agreement approach by Bland and Altman (2003), 95% of the time a decision to surgery waiting time calculated by the OJRR database could vary from 22 weeks 'shorter than' to 22 weeks 'longer than' the waiting time calculated with date fields from the medical record. For referral to surgery waiting time, the OJRR database could yield a value that varies from 18 weeks 'shorter than' to 20 weeks 'longer than' the waiting time calculated from the medical record. In other words, the OJRR waiting times for decision to surgery and for referral to surgery could overestimate or underestimate the true waiting time for surgery by as much as 4½ to 5½ months, assuming the medical record is the gold standard.

Figures 3 through 8 show the results from checking the assumptions about the data when using the 95% limits of agreement. Figure 3 shows for decision to surgery waiting time, a scatter plot of the difference between the two waiting time data sources plotted on the y-axis against the average of the two waiting times obtained from the two data sources plotted on the x-axis. While 97% (261/269) of the data points are contained within the 95% limits of agreement, the figure shows that the variation in the differences are not constant throughout the range of measured waiting times. There is less variability in the difference between data sources when waiting times are shorter and more variability when waiting times are longer. This violates the assumption that the differences are constant throughout the range of measurements that were made. Figure 4 shows the log-transformed data of Figure 3. This scatter plot shows that the logarithms of differences are constant throughout the range of the logarithm of the waiting time. The mean difference is -0.019 on the log scale and the limits of agreement are -1.08 and 1.04. If one takes the antilogs of these limits the values are 0.34 and 2.83, respectively. However, the antilog of the difference between two values on a log scale is a dimensionless ratio. The limits in this form indicate that for about 95% of cases, the OJRR waiting time will be between 0.34 and 2.83 times the medical record waiting time. Therefore, the OJRR waiting time may differ from the medical record waiting time by 66% below to 183% above the medical record value. i.e. 95% of the time the OJRR waiting time could differ from the medical record by 2/3rd's lower than the medical record waiting to almost 2x (1.83x) larger than the medical record .

Figure 5 shows a histogram of the difference in decision to surgery waiting time between the medical record and the OJRR database. As assumed by the limits of agreement approach, it shows a symmetrical, approximately normal distribution of differences in waiting time.

Figure 6 shows, for referral to surgery waiting time, a scatter plot of the difference between the two waiting time data sources plotted against the average of the two waiting times obtained from the two data sources. This figure shows that 96% (258/269) of the data points are contained within the 95% limits of agreement. Once again, there is some tendency for longer wait times to be associated with larger differences. The log-transformed data was used to resolve this difficulty. This scatter plot in Figure 7 shows that the logarithms of differences are constant throughout the range of the logarithm waiting time. The mean difference is 0.024 on the log scale and the limits of agreement are -0.48 and -0.53. If we take the antilogs of these limits we get 0.62 and 1.69. The limits tell us that for about 95% of cases, the OJRR waiting time will be between 0.62 and 1.69 times the medical record waiting time. Therefore, the OJRR waiting time may differ from the medical record waiting time by 38% below to 69% above. i.e. 95% of the time the OJRR waiting could be approximately half the medical record waiting time value to 69% larger.

Figure 8 shows a histogram of the difference in referral to surgery waiting time between the medical record and the OJRR database. It shows a symmetrical, approximately normal distribution of differences in waiting time.

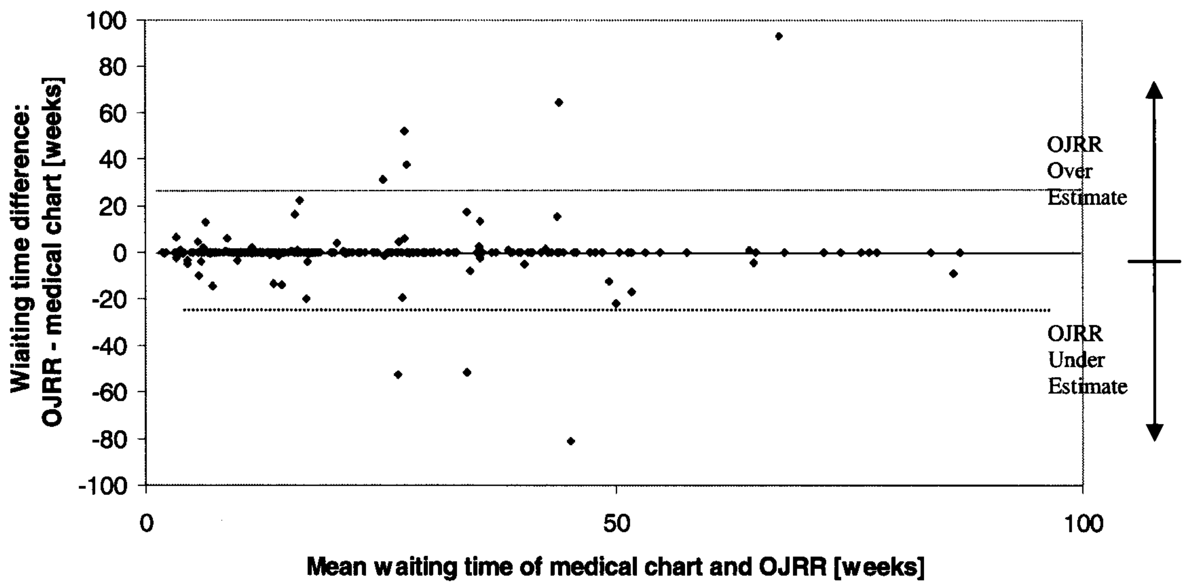
Table 2. Summary of waiting times for the two data sources: the Ontario Joint Replacement Registry and the medical record (n= 269)

Waiting Times	Mean (Weeks)	SD	Median (Weeks)	25th Percentile (Weeks)	75th Percentile (Weeks)
OJRR Decision to Surgery	22.73	18.32	16.86	9.86	29.71
Medical Record Decision to Surgery	22.85	18.75	16.57	9.57	30.57
OJRR Referral to Surgery	38.66	25.52	32.57	18.43	51.29
Medical Record Referral to Surgery	39.32	25.51	33.29	19.29	51.43

Table 3. 95% limits of agreement for the mean difference between the waiting time derived from the medical record and the waiting time from the Ontario Joint Replacement Registry (n= 269)

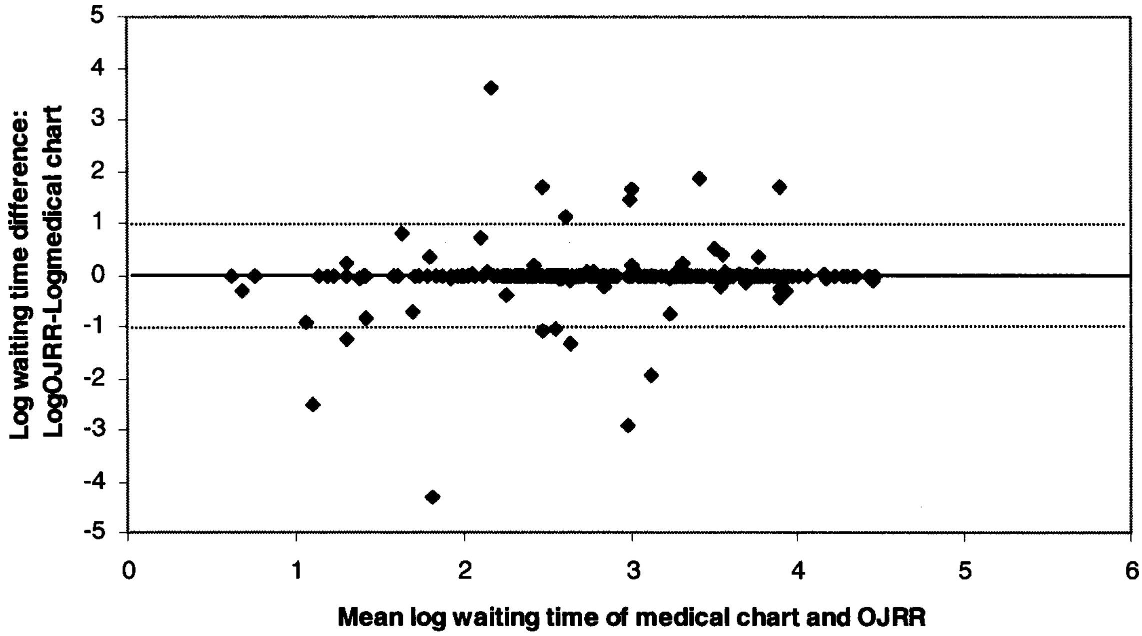
Waiting Time Period	Mean Difference (weeks)	SD	95% limits of agreement: Mean Difference ± 1.96 SD
Decision to surgery	0.13	11.32	(-22, 22)
Referral to surgery	0.66	9.64	(-18, 20)

Figure 3. Difference versus mean scatterplot for decision to surgery waiting time from medical record and Ontario Joint Replacement Registry (OJRR) (n= 269)



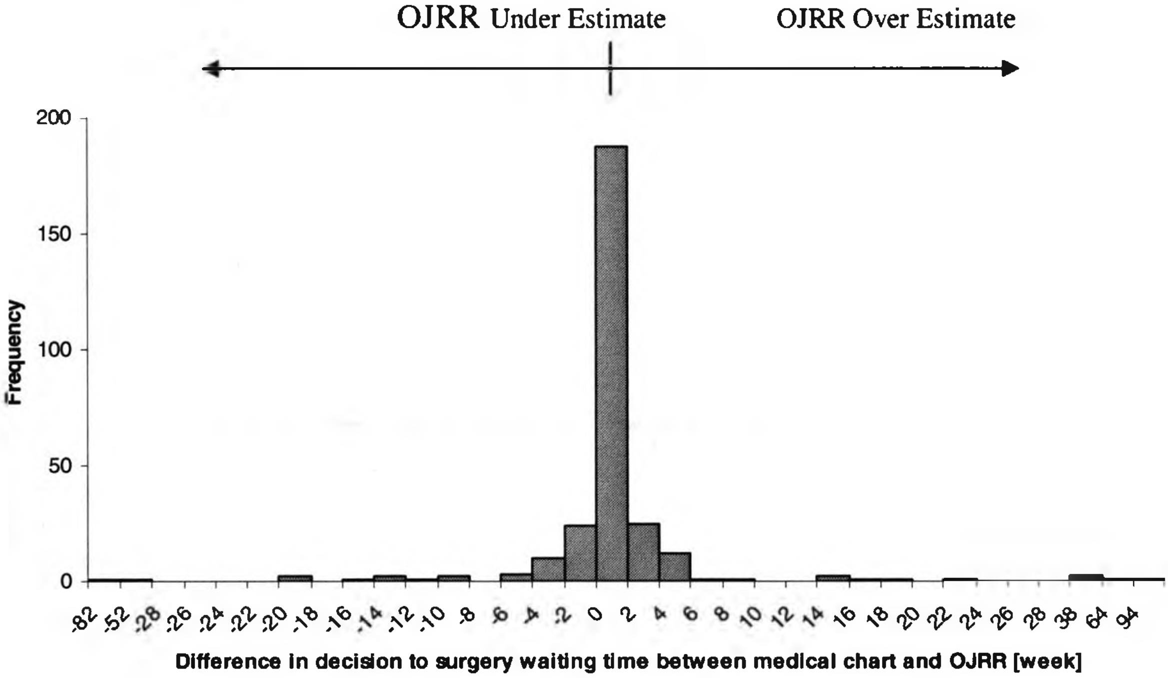
Note: horizontal dotted lines indicate the 95% limits of agreement (mean ± 1.96 SD) for decision to surgery waiting time

Figure 4. Difference in log waiting time versus mean log waiting time scatterplot for decision to surgery waiting time from medical record and Ontario Joint Replacement Registry (OJRR) (n= 269)



Note: horizontal dotted lines indicate the 95% limits of agreement (mean ± 1.96 SD) for log decision to surgery waiting time

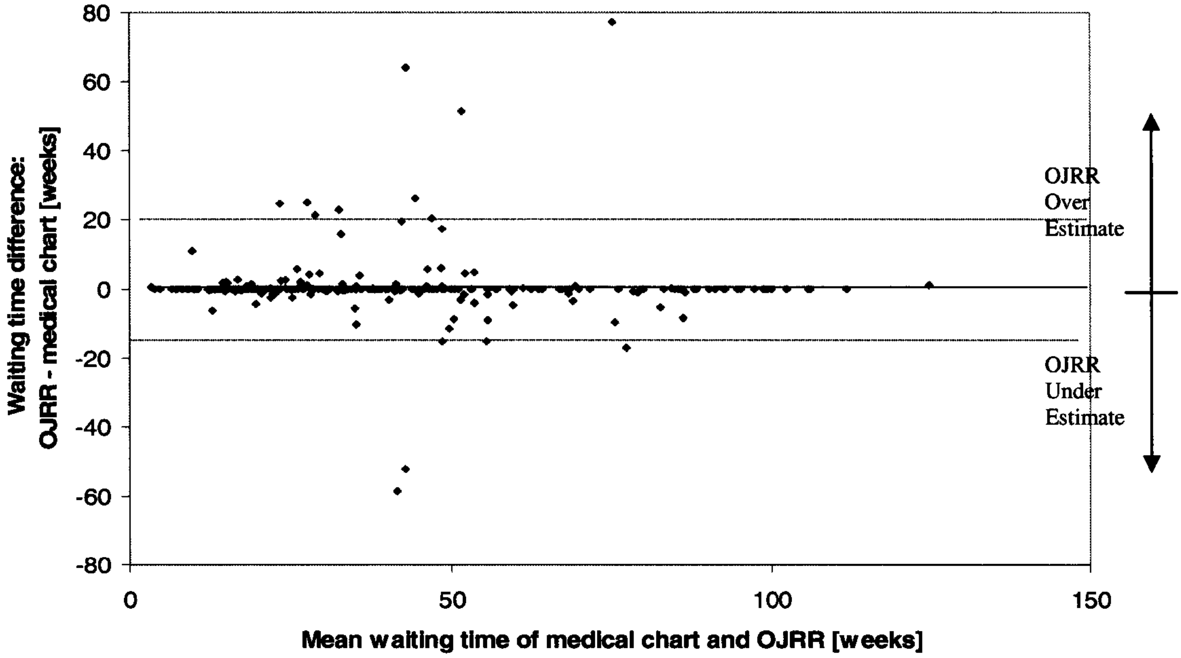
Figure 5. Histogram of difference in decision to surgery waiting time from medical record and Ontario Joint Replacement Registry (OJRR) (n= 269)



x-axis title: Difference in decision to surgery waiting time: OJRR-medical record [weeks]

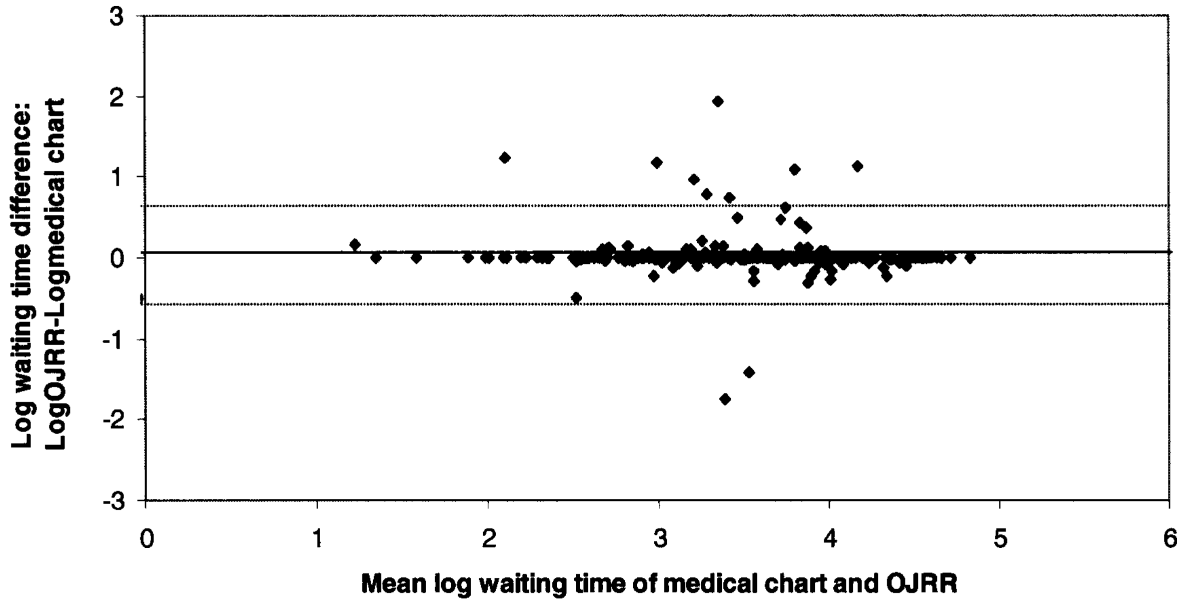
y-axis label: Number of surgical cases

Figure 6. Difference versus mean scatterplot for referral to surgery waiting time from medical record and Ontario Joint Replacement Registry (OJRR) (n= 269)



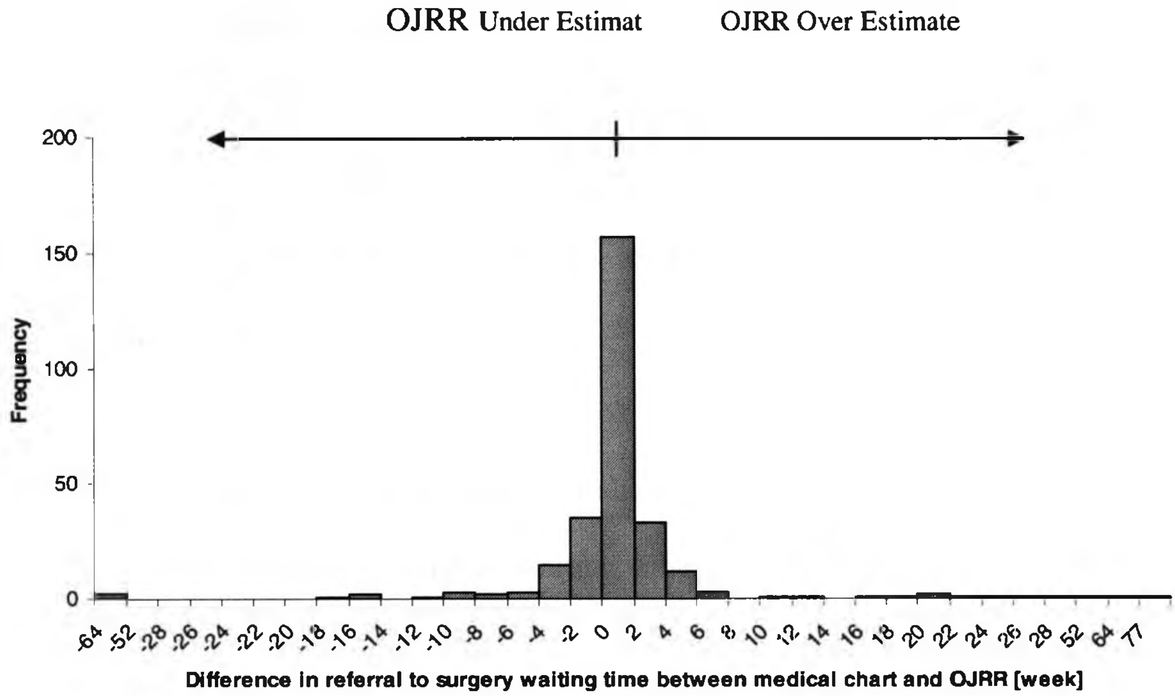
Note: horizontal dotted lines indicate the 95% limits of agreement (mean ± 1.96 SD) for referral to surgery waiting time

Figure 7. Difference in log waiting time versus mean log waiting time scatterplot for referral to surgery waiting time from medical record and Ontario Joint Replacement Registry (OJRR) (n= 269)



Note: horizontal dotted lines indicate the 95% limits of agreement (mean ± 1.96 SD) for log decision to surgery waiting time

Figure 8. **Histogram of difference in referral to surgery waiting time from medical record and Ontario Joint Replacement Registry (OJRR) (n= 269)**



x-axis title: Difference in referral to surgery waiting time: OJRR-medical record [weeks]

y-axis label: Number of surgical cases

4.3 Errors in the Date Fields and their Component Parts

4.3.1 Decision to Surgery Waiting Time

4.3.1.1 The Distribution of Entry Errors

After comparing waiting times from both data sources, decision to surgery waiting times were the same in 73% (n=197) of cases. For the remaining 72 cases, Table 4 shows the individual contribution of the decision date field and the surgery date field to waiting time error. The majority of decision to surgery waiting time error (75%) came from the decision date field.

The frequency of error among the individual components of the two date fields used to calculate decision to surgery waiting time is shown in Table 5. For both date fields, errors in the 'day' component were most frequent and errors in the 'year' field were the least frequent.

Figure 9 shows the histogram from Figure 5 (the difference in decision to surgery waiting time between the medical record and the OJRR database) compared with a table of the distribution of error in the day, month and year components grouped by differences in waiting time shown in Figure 5. Eighty-eight percent of year errors contribute to large differences in waiting time (over 28 weeks). Month and day errors contributed primarily to differences less than 24 weeks (88 and 89 percent respectively) with small differences composed of relatively more day errors.

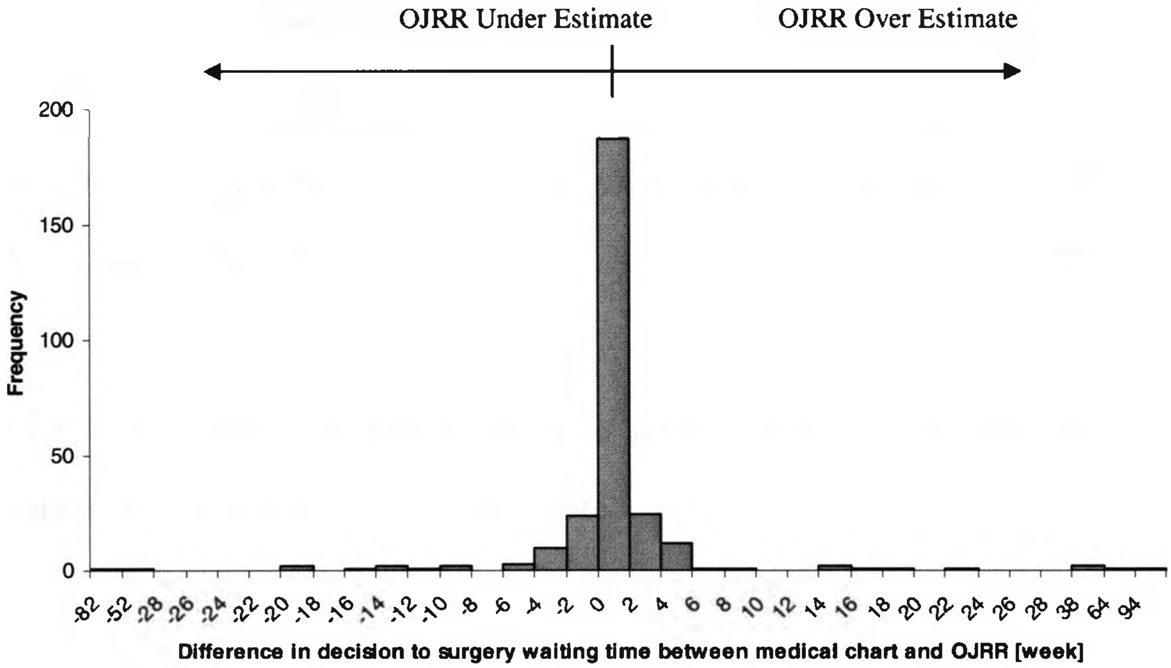
Table 4. Decision to surgery waiting time: frequency of error by date field used to calculate waiting time among cases with waiting time errors (n=72)

Date Error	Frequency	Percent
Decision date error only	44	63
Surgery date error only	19	25
Both decision date and surgery date error	9	12
Total	72	100

Table 5. Decision to surgery waiting time: frequency of date component errors among cases with waiting time errors (n=72)

	Frequency of error	
Date component	**Decision Date**	**Surgery Date**
day	52	23
month	31	9
year	6	2

Figure 9. **Difference in decision to surgery waiting time from medical record and Ontario Joint Replacement Registry (OJRR) compared to frequency of date component errors in grouped waiting time differences (n=269)**



Date Component	Grouped difference in decision to surgery waiting time [weeks]					
	[-28, -82]	[-8, -20]	[-6, 0]	[0, 10]	[12, 24]	[38, 94]
Day	2 (3%)*	10 (13%)	31 (41%)	20 (27%)	6 (8%)	6 (8%)
Month	1 (2%)	11 (27%)	10 (25%)	7 (18%)	7 (18%)	4 (10%)
Year	3 (38%)	0	0	0	1 (12%)	4 (50%)

*** row raw (%) frequency**

4.3.1.2 Reason #1: A delay in surgery may affect the accurate recording of the true surgery date.

There was poor agreement regarding the documentation of delay of surgery in the OJRR database and the medical record (kappa = 0.23). There was no relationship between the presence of a surgical delay and the presence of a surgery date error in both the medical record (OR = 1.38 (0.38, 5.02), p = 0.23) and the OJRR database (OR = 0.88 (0.23, 3.34), p = 0.26) (Details in Appendix VIII: Table A-1, TableA-2 and Table A-3).

4.3.1.3 Reason #2: A delayed decision to proceed with surgery may affect the accurate recording of the true decision date.

There was poor agreement regarding concurrent decision date and first consult date in the OJRR database and the medical record (Kappa = 0.04). There was no significant relationship between the presence of a decision date error and whether or not the decision date was equal to first consult date in both the medical record (OR = 0.37 (0.12, 1.18), p = 0.09) and the OJRR database (OR = 0.48 (0.12, 1.87), p = 0.15)) (Details in Appendix VIII: Table A-4, Table A-5 and Table A-6).

4.3.1.4 Summary

Error in decision to surgery waiting times arose from a minority of the sample (27%). Decision date was in error more often than surgery date. The day and month components of these two date fields contained the most errors. The large difference cases are comprised of more year errors and the small differences are composed of relatively more day errors. Ninety-five percent of the time a decision to surgery waiting time calculated by the OJRR database could vary from 22 weeks 'shorter than' to 22 weeks 'longer than' the waiting time calculated by the medical record. There was no relationship between the presence of a surgical delay and the presence of a surgery date error in both the medical record and the OJRR database. There was no significant relationship between the presence of a decision date error and whether or not the decision date was equal to first consult date in both the medical record and the OJRR database.

4.3.2 Referral to Surgery Waiting Time

4.3.2.1 The Distribution of Entry Errors

After comparing waiting time from both data sources, referral to surgery waiting times were the same in only 58% (n=157) of cases. For the remaining 112 cases, Table 6 shows the individual contribution of the referral date field and the surgery date field to waiting time error. The majority of referral to surgery waiting time error (89%) came from the referral date fields.

The frequency of error among the individual components of the two date fields used to calculate referral to surgery waiting time is shown in Table 7. For both date fields, errors in the 'day' component were most frequent and errors in the 'year' field were the least frequent.

Figure 10 shows the histogram from Figure 8 (the difference in referral to surgery waiting time between the medical record and the OJRR database) compared with a table of the distribution of error in the day, month and year components grouped by differences in waiting time shown in Figure 8. Seventy percent of year errors contribute to large differences in waiting time (over 24 weeks). Month and day errors contributed primarily to differences less than 24 weeks (89 and 92 percent respectively) with small differences composed of relatively more day errors.

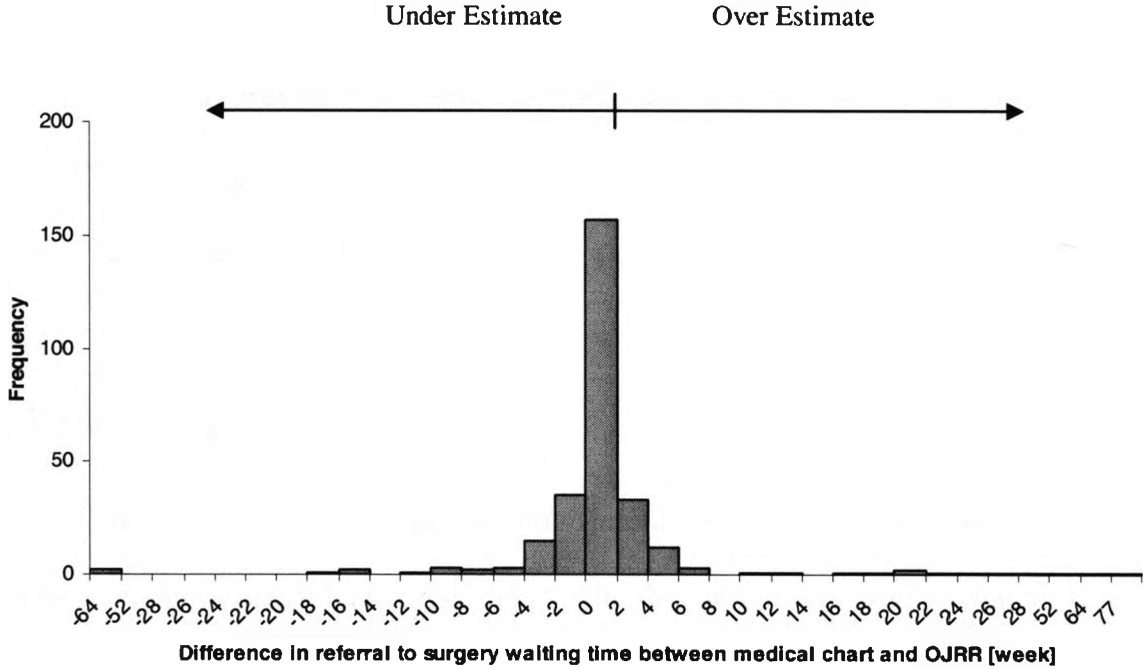
Table 6. **Referral to surgery waiting time: frequency of error by date field used to calculate waiting time among cases with waiting time errors (n=112)**

Date Error	Frequency	Percent
Referral date error only	84	74
Surgery date error only	10	11
Both referral date and surgery date error	18	15
Total	112	100

Table 7. **Referral to surgery waiting time: frequency of date component errors among cases with waiting time errors (n=112)**

	Frequency of error	
Date component	**Referral Date**	**Surgery Date**
Day	97	24
Month	46	10
Year	8	2

Figure 10. Difference in referral to surgery waiting time from medical record and Ontario Joint Replacement Registry (OJRR) compared to frequency of date component errors in grouped waiting time differences (n=269)



Date Component	Grouped difference in referral to surgery waiting time [weeks]					
	[-52, -64]	[-10, -18]	[-10, 0]	[0, 8]	[10, 24]	[24, 77]
Day	3 (2%)*	10 (8%)	42 (35%)	50 (42%)	9 (7%)	7 (6%)
Month	1 (2%)	8 (14%)	17 (30%)	15 (27%)	10 (18%)	5 (9%)
Year	3 (30%)	2 (20%)	0	0	1 (10%)	4 (40%)

*** row raw (%) frequency**

4.3.2.2 Reason #3: Use of a Fax machine date to obtain the referral date from a referral that was faxed to a surgeon may affect the accurate recording of the true referral date.

There was a significant relationship between the presence of a referral date error and whether a referral date was the same as a FAX date (OR = 4.17 (1.1, 15.9), $p = 0.03$). When referral date was recorded from the FAX date, the likelihood of a referral date error was 4.17 times greater than when the referral date did not come from the Fax date (Details in Appendix VIII: Table A-10).

4.3.2.3 Summary

Error in referral to surgery waiting time arose from 42% of cases. Referral date was in error more often than surgery date. The day and month components of these two date fields contained the most errors. The large difference cases are comprised of more year errors and the small differences are composed of relatively more day errors. Ninety-five percent of the time a referral to surgery waiting time calculated by the OJRR database could vary from 18 weeks 'shorter than' to 20 weeks 'longer than' the waiting time calculated by the medical record. After excluding cases with year error, ninety-five percent of the time a referral to surgery waiting time calculated by the OJRR database could vary from 8 weeks 'shorter than' to 8 weeks 'longer than' the waiting time calculated by the medical record. There was a significant relationship between the presence of a referral date error and whether a referral date was the same as a FAX date.

4.4 Comparisons between OJRR Database and Medical Records using Possible Waiting Time Threshold or Cut-Off

4.4.1 Decision to Surgery Waiting Time

When decision to surgery waiting time was described with a binary variable (i.e. <= 6 months vs. >6 months), there was no significant difference between the OJRR database and the medical record (McNemar 's Chi-square = 0.27, p = 0.60). Using medical record data, the proportion (95% CI) of people who waited <= 6 months for their surgery was 0.66 (0.60, 0.72). Using OJRR data, this value was 0.67 (0.61, 0.73). Similar results were found when a threshold of 9 months was used to create the dichotomous waiting time variable (McNemar 's Chi-square = 1.23, p = 0.26) Using medical record data, the proportion (95% CI) of people who waited <= 9 months for their surgery was 0.81 (0.79, 0.83). Using OJRR data, this value was 0.83 (0.81, 0.85). (Details in Appendix VIII: Table A-11 and Table A-13).

When the distribution of the date component errors within the four cells of the 2 by 2 table was investigated, seventy-six percent of the date component errors were located within the concordant cells. In the medical record 3% of the short waiters were incorrectly categorized as long waiters by the OJRR and 10% of the long waiters were incorrectly classified as short waiters by the OJRR. Details are given in Appendix VIII (Table A-12).

4.4.2 Referral to Surgery Waiting Time

Similarly, there was no significant difference in referral to surgery waiting time between the OJRR database and the medical record when referral to surgery waiting time, regardless of the threshold waiting time was used to split the 2-level variable. For the split at 9 months (i.e. <=9 months vs. >9 months) McNemar 's Chi-square was 2.77, p = 0.10. Using medical record data, the proportion (95% CI) of people who waited <= 9 months for their surgery was 0.58 (0.55, 0.61). Using OJRR data, this value was 0.61 (0.58, 0.64). For the 12-month split (i.e. <=12 months vs. > 12 months) the McNemar 's Chi-square was 0.06, p = 0.80. Using medical record data, the proportion (95% CI) of people who waited <= 12 months for their surgery was 0.76 (0.73, 0.79). Using OJRR data, this value was 0.75 (0.72, 0.78). (Details in Appendix VIII: Table A-14 and Table A-15).

When the distribution of the date component errors within the four cells of the 2 by 2 table was investigated, seventy-five percent of the date component errors were located within the concordant cells. In the medical record 5% of the short waiters were incorrectly categorized as long waiters by the OJRR, and 12% of the long waiters were incorrectly classified as short waiters by the OJRR. (Details in Appendix VIII: Table A-16).

4.4.3 Summary

There was no significant difference between the OJRR database and the medical record when decision to surgery waiting time was described with a binary variable (i.e. <= 6 months vs. >6 months, <= 9 months vs. >9 months,). Similarly, there was no significant difference in referral to surgery waiting time between the OJRR database and the medical record when referral to surgery waiting time, regardless of the threshold waiting time used to split the 2-level variable. However, the majority of date component errors fell in the concordant cells (i.e. the pairs in which both OJRR waiting time and record waiting time were the same when waiting time was described with a binary variable).

Chapter Five

Discussion

5.1 Summary of Findings

This study used a random sample of surgical cases submitted to the Ontario Joint Replacement Registry to estimate bias in its waiting times reported as a continuous variable (e.g. mean or median) and as a dichotomous waiting time threshold (e.g. proportion of patients who waited over 6 months for surgery). In continuous form, bias in OJRR waiting times was estimated as a relatively small point estimate (i.e. 0.13 and 0.66 weeks for decision and referral to surgery, respectively); but with considerable variability associated with these values (i.e. +/- half a year). As a binary variable, indicating if surgery was received within a waiting time threshold, no bias was found. These opposing conclusions are relevant to policy makers because benchmark waiting time thresholds are currently being developed in Ontario and Canada while average and median waiting times continue to be reported.

5.2 Implication of Findings

5.2.1 Testing the assumptions of the statistical method

In continuous form, bias in OJRR waiting time was initially estimated as approximately +/- half a year. Bias was determined by the mean difference between the waiting time derived from the medical record and the OJRR database. This method depends on two assumptions (Bland and Altman, 2003). In this study, the first assumption tested was that the mean and standard deviation of the waiting time differences are constant throughout the range of measured waiting times. This was checked by creating a scatter plot of the difference between the two waiting time data sources plotted against the average of the two waiting times obtained from these two sources. These scatter plots (Figure 3: decision to surgery and Figure 6: referral to surgery) showed that the variance in the difference in the waiting times obtained from the two sources increased as the average waiting time got larger, violating the assumption of constant variation throughout all possible waiting times. Therefore, following Bland and Altman (2003), the scatter plots were repeated using the logarithm of the waiting time measurements. This led to limits of agreement in the form of proportions rather than in the original units (Bland and Altman, 2003). The log transformed limits of agreement estimated bias in the OJRR waiting times that was between one-third and almost three times the medical record waiting times for decision to surgery, and between two-thirds and 1.7 times the medical record waiting times for referral to surgery.

The following example illustrates the effect of using limits of agreement while ignoring the violation of the assumption of constant means and standard deviations. If for example, a reported waiting time estimate was 24 weeks for decision to surgery, the 95% limits of agreement obtained while ignoring this assumption would suggest this estimate could be as short as a two week wait (i.e. 24 minus the lower limit of agreement or 22) or as long as a 46 week wait (i.e. 24 plus the upper limit of agreement or 22). In contrast, using the antilogs for the upper and lower limits of agreement (0.34 and 2.83, respectively), given the violation of the constancy assumption, the estimated waiting time of 24 weeks could actually vary from 8 weeks (i.e. 0.34 times 24) to 68 weeks (i.e. 2.83

times 24). This example highlights the importance of checking the assumptions of statistical tests because in this case, the improper method for estimating bias underestimates the potential bias in the dataset. This underestimate is particularly problematic for the upper estimate of bias since the antilog method adds 22 weeks to the upper limit of agreement.

When testing the second assumption that differences in waiting time between the two data sources are from a normal distribution, histograms of these values (Figure 5 and Figure 8) showed how these differences were distributed in terms of positive or negative differences. In practical terms these differences are either 'over' or 'under' estimates of the true waiting time. Overestimated waiting times might be more acceptable to patients than underestimated waiting times, because it is more likely that a patient would not mind if the estimated waiting time was wrong, provided the surgery was received earlier than advised.

5.2.2 Reasons for waiting time data discrepancies

When attempting to explain possible reasons for waiting time data discrepancies, several hypotheses were tested. The possibility that a delayed surgery date might affect the accuracy of the recorded surgery date could not be proven. This is because there was poor agreement between the medical record and the OJRR regarding the presence of a surgical delay. Consistent with this finding, there was also no relationship between the presence of a surgical delay and the presence of a surgery date discrepancy in either data source. These findings might be the result of insufficient power to find the hypothesized relationships. Regardless of this, a more clear definition of surgery delay may need to be established.

In the OJRR data, a relationship between the presence of a decision date discrepancy and the fact that the decision date was not the same as the first consult date could not be found. However in the medical record, while the odds ratio was not significant (OR = 0.37, p = .09); consistent with the low p-value, the 95% confidence interval (0.12, 1.18) was asymmetric around the odds ratio null value. In this analysis, the interpretation of an odds ratio less than one, is that the presence of a decision date discrepancy was less likely when the decision date was equal to the first consult date (i.e. there was less discrepancy when patients and surgeons agreed to proceed with surgery on the date of the first consult with the surgeon). Alternatively this means that a decision date discrepancy could be more likely when the decision date is not the same as the first consult date. While these findings are not conclusive because they did not reach the critical p-value, the confidence intervals do support further inquiry into the concept of a delayed decision date as a possible source of bias in decision to surgery waiting times. These non-conclusive findings might be the result of insufficient power to find the hypothesized relationship.

Finally, there was a significant relationship between the presence of a referral date discrepancy and whether a referral date was the same as a FAX date. When referral date was recorded from the FAX date, the likelihood of a referral date discrepancy was about

4 times greater than when the referral date did not come from the FAX date. This finding indicates that future initiatives should not use the FAX date as a proxy for the referral date to the surgeon.

5.2.3 Discrepancy in Dates and date components

A discrepancy rate found in a given study sample, during a given time period generally provides information about the overall quality of data during that period: the lower the value, the higher the probability that the quality of the data is being maintained. Higher rates identify areas where improvement in data capture is required (Hlaing et al. 2006). In the OJRR data, the referral date had the highest frequency of discrepancies, followed by decision date; with the surgery date having the lowest frequency of discrepancies. This hierarchy of date discrepancies was also found by Olsson et al (2006). They evaluated the Swedish Heart Surgery Register for patients with surgery on the proximal thoracic aorta. Medical records from a random sample of 300 patients in the Swedish Heart Surgery Register were reviewed with register data items systematically re-reported. The re-reported validation data were entered into a database and compared to the originally reported data contained in the registry. Frequency of reporting for individual variables was evaluated. They reported the correct date of acceptance for surgery (i.e. decision date) was found in 75-85% of records, with the date of surgery found to be correct in over 95% of cases. Both of these studies showed that the surgery date had the lowest frequency of discrepancies, which may have been due to the fact that traditionally health care systems have paid more attention to the capture of the surgery date field compared to the other three date fields.

Although discrepancies in decision to surgery waiting times were detected for a minority of the sample (27%), the high frequency of day and month discrepancies combined with a small number of year discrepancies to produce OJRR estimates that could underestimate true waiting time by one-third and overestimate true waiting time by almost a factor of three. The same pattern was found with referral to surgery waiting times. These findings are consistent with the data validation study done by Arthursson et al. (2005). They compared the number of hip replacements reported to the Norwegian Arthroplasty Register with data recorded at the local hospital. They found that the surgery date had been recorded incorrectly in 56 cases (1.1%), including 29 with the incorrect day, 17 with the incorrect month, and 10 with the incorrect year. The day and month components of surgery date contained the most discrepancies among those cases with surgery date discrepancies. These observations were in keeping with our findings. After investigation of the surgery date discrepancies, Arthursson et al. found that typing discrepancy and illegible hand writing were two main causes of incorrect registration for surgery date.

As mentioned previously, most biases (systematic error) related to surveillance data can be classified into three basic categories: programming errors, unclear definitions for data items, and violation of the data collection protocol (Szklo and Nieto, 2000). For example, some referral dates were recorded earlier by the OJRR than those found in the medical chart. In this situation, it may be that a referral had been previously arranged between the surgeon's office and the referring physician by telephone, and a paper referral was faxed or mailed at a later date. This subtle change in the definition of referral to the surgeon would result in an overestimate of referral to surgery waiting time by the OJRR.

5.2.4 Bias in binary waiting times

No bias was found when waiting time was defined as a binary variable that indicated if surgery was received within a waiting time threshold. There are three possible reasons for this. First, seventy-five percent of all date component discrepancies fell into the concordant cells of the McNemar's 2x2 table, illustrating a well-known epidemiologic and biostatistical measurement principle that information is lost when continuous variables are collapsed into categorical variables (Altman and Royston, 2007). Second, only the discordant cells contribute to the McNemar chi-square test statistic (Bland 2003). In this study, only 25% of the date discrepancies fell into these two discordant cells. The rest of the date discrepancies (ie 75%) were not captured by the McNemar chi-square test. These two factors led to a somewhat different conclusion about bias than the results of the mean difference score calculations. Third, sample size calculations were based on the mean difference, not the proportions used in the McNemar test. Therefore, it is possible that this study did not have a large enough sample size to test for a significant difference in proportions between the two data sources.

The mean difference scores were small (i.e. less than 1 week) suggesting minimal bias in the OJRR waiting times. However, the 95% limits of agreement associated with these differences reflected a level of precision in the estimates that is not optimal given the possibility that the estimates could underestimate true waiting time by one-third and overestimate true waiting time by almost a factor of three. These wide confidence limits suggest caution when making favorable conclusions about the accuracy of OJRR waiting times reported as a mean or median value. Conversely, the waiting times from the medical record and the OJRR are no different when reported as the proportion of persons who received surgery within a waiting time threshold. For policy makers and others who measure access to care with a benchmarking approach, this is the more appropriate statistical test to determine bias in waiting times because matched values for each observation exist in the two comparison datasets, the waiting time variable form (scale) is dichotomous, and the resultant loss of discrepancy information from collapsing a continuous waiting time variable is acceptable because it is the dichotomous waiting time variable that is of primary interest to the end-user of the study findings.

5.3 Limitations of the Study

The results of this study must be considered in the context of the following limitations. First, while the process of validating data using medical charts is a universally employed method for data quality review (Goldberg et al., 1980, Iezzoni et al., 1997), it assumes that surgeons and secretaries accurately document waiting time date fields to track waiting times. The OJRR prospectively collected information from the surgeon's office except for referral date, which was retrospectively collected from the medical chart. So it may be that the prospectively collected OJRR data were a better 'gold standard' than the retrospectively audited mecial chart data. Moreover, some variables may be poorly documented in the surgeon's medical chart. For example, OJRR field staff generally believed that the presence of a delayed surgery date was poorly documented in the surgeon's medical chart. Therefore, further investigation into the use of the medical record as the 'gold standard' for the true waiting time may be necessary. Second, by design, this data quality initiative was limited to OJRR data that were available during the roll-out phase of the registry, so the results may not be generalizable to joint replacement registries in full operation. Third, the histogram of differences in waiting time between the two data sources, while symmetrical, were not perfectly normally distributed. Therefore, using a nonparametric approach to the construction of confidence intervals for the limits of agreement should be explored, as this may generate a more narrow 95% limit of agreement.

5.4 Recommendations Based on the Study Findings

Despite these limitations, this is the first study to examine the validity of waiting time data reported by a registry database. The results were somewhat concerning in that only 38% of cases had no discrepancies in all four date fields. The 95% limits of agreement for two waiting times were wider than we expected; bias was estimated between one-third and almost three times the true waiting time. However, when waiting time was treated as a binary variable, indicating if surgery was received within a waiting time threshold, no bias was found.

There is a need for defined strategies to ensure valid waiting time data. We believe that clear guidelines for coding and proper instructions for participating surgeons could make the registries easier to use and more complete (Laustsen et al. 2004). Our analyses also suggested the need for a better protocol with more precise definitions to collect waiting time date fields, especially for decision date and referral date fields. Additional recommendations for accurate reporting of data should include routine education for all coders. Furthermore, since no standardized methodology for auditing waiting time variables for a registry was available, this methodology may be used as a model for quality control.

5.5 Future Research

Robertsson et al. (1999) found better reporting of knee arthroplasty revisions from university hospitals than from smaller units. On the other hand, Puolakka et al. (2001) observed large variations to the Finish Arthroplasty Register (65-99%) related to different types of hospitals, where a small regional hospital had the most complete reporting. Thus, it would be interesting to investigate if the biases in waiting time variables are related to the different type of hospitals, which would offer more in-depth information to improve data quality. Moreover, it would be interesting to determine the bias for the different MOHLTC regions, which would give more useful information to improving data quality. However these subgroups would need to be over-sampled to allow for adequate sample size to detect the bias and relevant associations.

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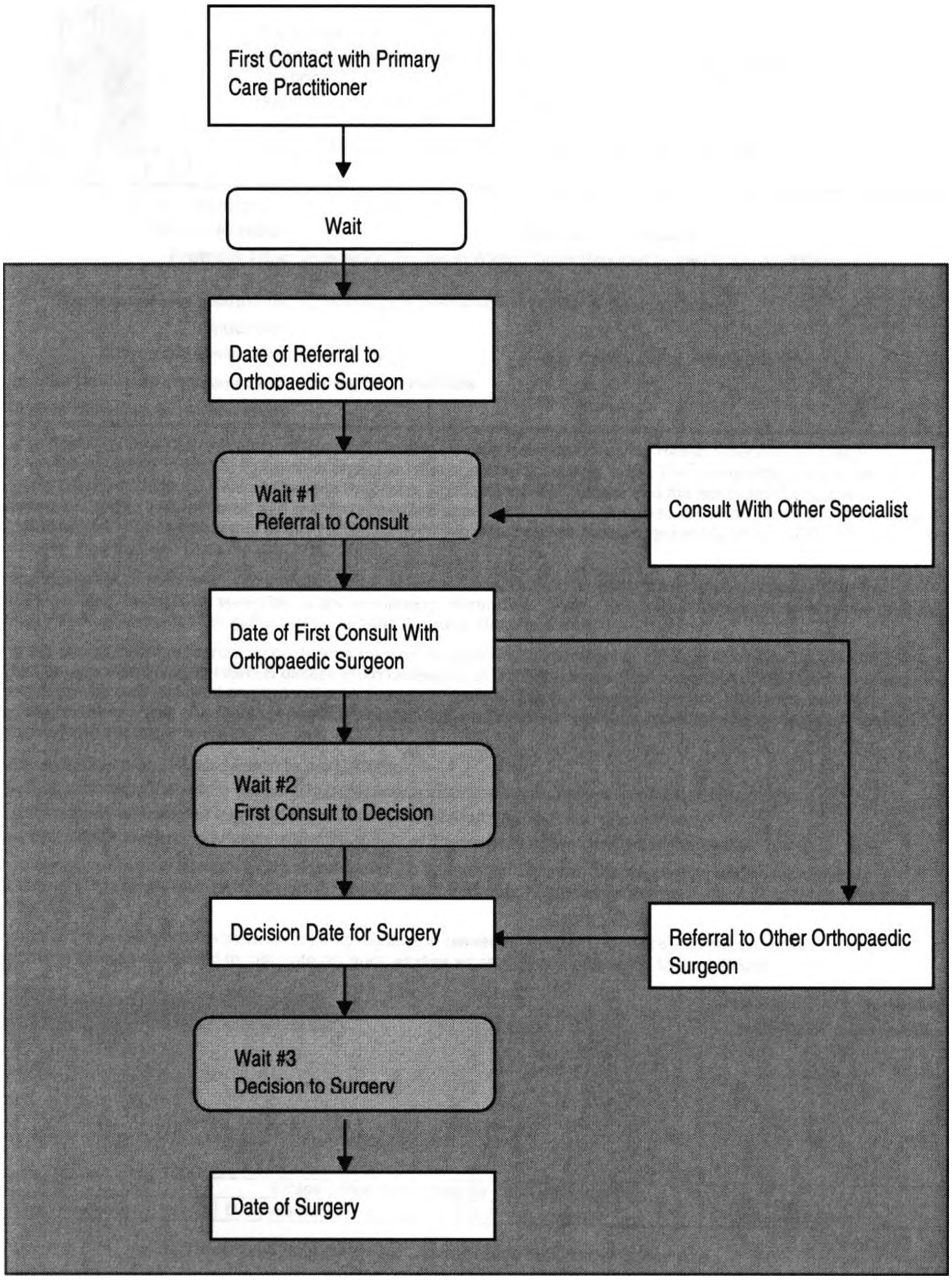
Appendix I: Waiting Time Flow Record



Appendix II: Ethics Approved Letter from University of Western Ontario

Office of Research Ethics

The University of Western Ontario
Room 00045 Dental Sciences Building, London, ON, Canada N6A 5C1
Telephone: (519) 661-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. B. Chesworth
Review Number: 11189E **Revision Number:** 1
Protocol Title: Determining the Bias in Waiting Times Reported by the Ontario Joint Replacement Registry
Department and Institution: Epidemiology & Biostatistics, University of Western Ontario
Sponsor:
Ethics Approval Date: May 03, 2005 **Expiry Date:** May 31, 2005
Documents Reviewed and Approved: Revised Study End Date
Documents Received for Information:

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted expedited approval to the above named research study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

This approval shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request Form.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:

a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;

b) all adverse and unexpected experiences or events that are both serious and unexpected;

c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

Chair of HSREB: Dr. Paul Harding
Deputy Chair: Susan Hoddinott

Ethics Officer to Contact for Further Information			
☒ Karen Kueneman	☐ Janice Sutherland	☐ Susan Underhill	☐ Jennifer McEwen

This is an official document. Please retain the original in your files. Faxed: Y/N Date: MAY 04 2005

Appendix III: An official letter from OJRR was sent to each surgeon to notify them the data audit project was beginning

March 03, 2005

«Title» «FirstName» «LastName»
«Address1» «Address2»
«City» «Province» «PostalCode»

Dear Dr. «LastName»,

The OJRR is conducting a quality assurance project to estimate the accuracy of the waiting times reported by the OJRR in the 2004 Annual Report. To complete this project Mary Derks, your Regional Field Coordinator, will require access to your office records to look at four date fields - referral date, first consult date, decision date and surgery date. For this purpose, a 7% random sample will be selected from all of your newly referred patients that are in the OJRR database, who received surgery in fiscal year 2003/04.

We expect that the record review to collect data regarding the date fields mentioned above will commence on Monday March 14, 2005 and will end by April 30.

Please note that information collected regarding the date fields of interest, are completely confidential and only summary reports will be released. Individual surgeon's data will NOT be identified. Also please note that all patients being reviewed have consented to participate in the OJRR.

If you have any questions, please don't hesitate to contact Bert Chesworth at [redacted]. We thank you in advance for your support of this important project.

Sincerely,

[redacted] [redacted]

Dr. R. B. Bourne, FRCSC,
Medical Director
Ontario Joint Replacement Registry

Bert M. Chesworth, Ph.D.,
Director of Data Operations and Research
Ontario Joint Replacement Registry

Appendix IV RFC's Training Sessions Materials

Determining Bias in OJRR Waiting Times
Data Collections Procedures

Study Objective:

- Primary objective - to determine the bias in waiting times reported for FY 03 / 04 in the OJRR 2004 Annual Report.

Overview of Methods:

Sample:

- Study population - all new referral surgical events in FY 03 /04 contained in waiting time reports for OJRR 2004 Annual Report.
- Exclusions:
  - o Exclude surgeons who left OJRR (retired, moved or deceased).
  - o Exclude surgeons who have provided less than 10 records in waiting time reports for OJRR 2004 Annual Report.
- Random sample is drawn from every surgeon.

Data Collection Procedure:

- Data collection occurs using Microsoft Access.
- In Access a list of cases by surgeon is provided to each RFC.
- For each case, the patient name, gender, dob, joint, surgery type and the date of surgery will be provided to help RFCs identify the correct patient and the correct surgical event in the surgeon's office file.
- Data are collected for surgery date, referral date, 1st consult date and decision date.
- 4 important aspects to data collection in addition to accurate recording:
  - o Recording of date exactly as typed / written in office file.
  - o Identifying if date format is 'known' or 'unknown'.
  - o Recording date format if known (eg. *y/m/d*, *d/m/y* etc.)
  - o Identification of 'implicit' or 'explicit' date format:
    - Implicit
      - can tell date format because year is 4 digits and/or month is text (eg. Nov.) and/or day is more than 12.
    - Explicit
      - Secretary knows correct format.

Comments on Data Collection Processing:

- Surgery Dates form
  - Look in OR notes first. 2nd choice use clinical progress note. If other data source is used, please indicate in the open text box.

- Referral Dates form
  - Identify whether this surgery event is new referral. If this event is not a new referral, you can skip into next case.
  - For referral date, look for a Fax date first. Alternate sources are provided on data collection, or use open text box.
  - If more than one referral date is found, record a form for each date following questions in the form. If a fourth referral date is found, record information in the Additional Comments open text area.

- 1st Consult Dates form
  - Identify if there was an explicit statement indicating that this is a 1st consult. If no, explain your judgment in the open text box.
  - Look for 1st consult date in clinic/dictated note. If other data source is used, please indicate in the open text box.

- Decision Dates form
  - Identify if there was an explicit statement regarding the surgeon's decision to proceed with surgery. If no explicit statement, record the wording exactly as shown in the patient record.
  - Identify if there was an explicit statement regarding the patient's decision to proceed with surgery. If no explicit statement, record the wording exactly as shown in the patient record.
  - For decision date source, look first in the clinic/dictated note. 2nd choice use indication of a patient calling back to the office. 3rd choice use the date on the OJRR consent form or WOMAC form. If date source is not from the above sources, please indicate in the open text box.
  - If more than one decision date is found, record a form for each date following questions in the form. If a third decision date is found, record information in the Additional Comments open text area.

Appendix V Details of data fields

Variables	OJRR Data Capture
Referral date	Captured prospectively when referral received by secretary in surgeon's office
First consult date	Captured prospectively when 1st consult with surgeon takes place
Decision date	Captured prospectively when the patient and the surgeon decide to proceed with surgery
Surgery date	Captured prospectively when surgery takes place
Surgery type	Surgeon enters in OR on day of surgery
Surgical joint	Surgeon enters in OR on day of surgery
Hospital teaching status	Default settings in electronic data capture
Surgery date delayed	Entered by secretary at clinic visit
ASA physical status score	Entered by surgeon in OR – provided by anaesthesiologist
Gender	Entered by secretary at clinic visit
Region	Default settings in electronic data capture
Primary diagnosis	Surgeon enters in OR on day of surgery
Charnley category	Surgeon enters in OR on day of surgery

Appendix VI Ontario Joint Replacement (OJRR) data capture procedures

The OJRR recruited patients at the time the decision to proceed with surgery was made by both the surgeon and the patient. Most of the time, this took place during the first consultation with the surgeon in his or her orthopaedic clinic. In this situation, after the patient consented to participate in the OJRR, and following the surgeon's orthpaedic clinic, the patient's name and demographic information (as shown in Section 1 of the data collection form - see page 92 for the hip form and page 95 for the knee form) along with the decision date to proceed with surgery, the first consult date (in this case the same as the decision date) were provided to the surgeon's secretary who then entered this information into the custom-built OJRR electronic data collection software.

When the surgeon recommended surgery and patients were unable to make that decision at the time of the clinic visit, they were told to advise the secretary by telephone of their decision to proceed with surgery at a later date in the near future. In this situation, after the patient consented to participate in the OJRR, and after the telephone call, the information previously noted was entered into the OJRR electronic data collection software following the telephone call.

In both of these situations, the secretary would also capture the referral date with the OJRR software. The referral date was captured from office files, patient schedulers and medical charts available to the secretary. In the event that a typed or written referral date was not available; if a referral received by the surgeon's office had a FAX date-stamp, this was used as a proxy for the referral date.

The secretary entered the surgery date into the OJRR electronic data collection software, either once a date was secured for time in the operating room or on the day of surgery. In the event that (i) a patient declined a surgery date because s/he was planning to be out of the country (e.g. a patient-related factor such as the 'snowbird phenomenon'), (ii) a surgery date was cancelled because of patient medical problems (e.g. a medical problem contraindicated having surgery on the planned surgery date), or (iii) a surgery date was cancelled because of limited hospital resources (e.g. a hospital-related issue such as no available bed, being bumped from the operating room because of emergency procedures taking priority over elective surgery), secretaries would flag the 'Surgery Date Delayed' variable as 'Delayed'. When the revised surgery date was available and the surgery was conducted, this new surgery date was entered into the OJRR electronic data collection software by the secretary.

At the time of or shortly after surgery, the surgeon or his or her surgical staff or field staff from the OJRR entered the data fields pertaining to the consultation details (section 2 of hip and knee form), the medical/surgical history (section 3 of hip and knee form), surgical details (section 4) and implant details (section 5) in data collection form (see page 93 and 94 for the hip form and page 96 and 97 for the knee form). Hospital teaching status and planning region were pre-programmed into the OJRR electronic data collection software.

OJRR
ONTARIO JOINT REPLACEMENT REGISTRY

H
Hip Replacement - Data Form

Section 1

PATIENT INFORMATION

Has Patient Consent Been Obtained? ☐ Yes ☐ No

Last Name

First Name

Middle Initial

Street Number and Street Name

Apartment Number (if applicable)

City

Province

Postal Code ☐☐☐ - ☐☐☐

1 9
Y Y Y Y M M D D
Birth Date

☐ Male ☐ Female
Gender

Health Card Number

Hospital Chart Number

Hospital Institution Number

Section 2

CONSULTATION DETAILS

2 0
Y Y Y Y M M D D
Referral Date (if new)

Referral Status
☐ New ☐ Re-Assessment

Referral Source: ☐ Specialist – Ortho
☐ Specialist – Other
☐ GP

2 0
Y Y Y Y M M D D
Date of First Consultation (if new referral)

Consult Delayed by Patient?
☐ Yes ☐ No

2 0
Y Y Y Y M M D D
Decision Date for Surgery

2 0
Y Y Y Y M M D D
Admission Date

Surgery Date Delayed
☐ Yes ☐ No

2 0
Y Y Y Y M M D D
Surgery Date

Reason: ☐ Medical (Patient Medical Status
☐ Patient (Non-medical, Personal)
☐ Hospital (Insufficient Resources)

Y Y Y Y M M
Date of Last Implant (if revision)

Surgeon Last Name

Surgeon First Name

OJRR
ONTARIO JOINT REPLACEMENT REGISTRY

H
Hip Replacement - Data Form

Patient Last Name

Anaesthetic	Check (✓) ALL that apply: ☐General ☐ Spinal ☐ Epidural ☐ Peripheral Nerve Block ☐Local Infiltration
OR Environment	Check (✓) ONE only: ☐ Standard ☐ Laminar Air Flow ☐ Body Exhaust ☐ Laminar Air Flow & Body Exhaust ☐ Ultraviolet
Antibiotic	Will Antibiotics Be Administered Prophylactically? ☐ Yes ☐ No if yes, duration? ☐ ≤ 24 hrs. ☐ > 24 hrs.
DVT Prevention	Will DVT prophylaxis be given in hospital? ☐ Yes ☐ No If yes, check (✓) ALL that apply: ☐ Warfarin ☐ LMW Heparin ☐ ASA ☐ SC Heparin ☐ Foot Pump ☐ Pneumatic Stockings ☐ Blinded Clinical Trial ☐Other
Patient Comorbidity	ASA Physical Status Classification System: (obtain from anaesthesiologist) – Check (✓) ONE only: P1 ☐ - normal healthy P2 ☐ - mild systemic disease P3 ☐ - severe systemic disease P4 ☐ - severe systemic disease that is a constant threat to life Height: ☐☐☐ cm or ☐ feet ☐☐ inches Weight – circle one: ☐☐☐ kg or pounds
	☐ Right ☐ Left ☐ Bilateral
Pre-op Joint Status (for Charnley)	Contralateral Hip - Check (✓) ONE only: ☐Symptomatic ☐Replaced ☐Symptomatic and Replaced ☐Not Yet Assessed ☐No Joint Complaints Left Knee - Check (✓) ONE only: ☐Symptomatic ☐Replaced ☐Symptomatic and Replaced ☐No Joint Complaints ☐Not Yet Assessed Right Knee - Check (✓) ONE only: ☐Symptomatic ☐Replaced ☐Symptomatic and Replaced ☐No Joint Complaints ☐Not Yet Assessed Would walking be LIMITED if hips AND knees were normal? ☐ Yes ☐ No
Primary Dx	Check (✓) MOST RESPONSIBLE diagnosis for involved hip (Check ONE only): ☐ Degenerative OA ☐ Inflammatory Arthritis ☐ Post-Traumatic OA ☐ Osteonecrosis ☐ Childhood Hip Problem ☐ Old Hip Fracture ☐ Acute Hip Fracture ☐Tumour ☐ Infection ☐ Other
Secondary Dx ☐ None or ➔	Check (✓) ALL that apply to involved hip: ☐ Degenerative OA ☐ Inflammatory Arthritis ☐ Post-Traumatic OA ☐ Osteonecrosis ☐ Childhood Hip Problem ☐ Old Hip Fracture ☐ Acute Hip Fracture ☐Tumour ☐ Infection ☐ Other
Type of Replacement	Check (✓) ONE only: ☐ Primary ☐ R1 ☐ R2 ☐ R3 ☐ >R3 IF REVISION FOR INFECTION, ALSO CHECK (✓) ONE: Re-Implantation: ☐ 1-stage or ☐ 2-stage First Stage of Revision Spacer Details Check (✓) ONE only: ☐ None ☐ Spacer (Non-Antibiotic) Inserted ☐ Antibiotic Spacer Inserted ☐ Antibiotic (Temporary) Arthroplasty Inserted Second Stage of Revision: Did You Do Stage 1? ☐ Yes ☐ No If No, indicate the Removal Date of Original Prosthesis: 2 0 ☐☐☐☐☐☐ Y Y Y Y M M D D
Reason(s) for Revision	Check (✓) ALL that apply to involved hip: ☐ Aseptic Loosening ☐ Poly Wear ☐ Osteolysis ☐ Instability ☐ Malposition ☐ Implant Fracture ☐ Bone Fracture ☐ Infection ☐ Reattach Trochanter ☐ Other
Previous Operations ☐ None or ➔	Check (✓) ALL that apply to involved hip: ☐ Primary THA ☐ Hemiarthroplasty ☐ Resection Arthroplasty ☐ Revision ☐ Fracture Fixation ☐ Pelvic Osteotomy ☐ Femoral Osteotomy ☐ Arthrodesis ☐ Surface Replacement ☐ Other
Surgical Approach	Check (✓) ONE only: ☐ Smith/Peterson ☐ Anterolateral ☐ Direct Lateral ☐ Posterolateral ☐ MIS – Anterior ☐ MIS – Posterior ☐ MIS – 2 Incision
Special Techniques ☐ None or ➔	Check (✓) ONE only: ☐ Extended Trochanteric ☐ Trans-Trochanteric ☐ Slide Trochanteric Computer Assisted? ☐ Yes ☐ No

Section 3

Section 4

OJRR
ONTARIO JOINT REPLACEMENT REGISTRY

H
Hip Replacement - Data Form

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
Patient Last Name

Acetabular Component Replaced? ☐ Yes → ☐ No ↓	Bipolar: ☐ Yes ☐ No Modular ☐ Yes ☐ No→ Cemented (all-poly cup) ☐ Or One Piece ☐ If Cementless (shell) **Check (✓) ALL that apply:** ☐ Porous In-Growth Screws: ☐ Yes ☐ No ☐ H.A. Coated Screws: ☐ Yes ☐ No Outside Cup Diameter ☐☐ mm BONE GRAFTING? ☐ None **or Check (✓) ALL that apply:** ☐ Structural ☐ Onlay ☐ Morsellized ☐ Autograft ☐ Allograft ☐ Bone Substitute	Manufacturer See Legend Below Acetabular Component ☐☐	Affix sticker(s) or catalogue and lot number beside specific component. **Do not include screws** Sticker(s) for Acetabular Component
Acetabular Insert/Liner Replaced? ☐ Yes → ☐ No ↓	Material: ☐ Polyethylene Standard ☐ Polyethylene Cross-Linked ☐ Ceramic Alumina ☐ Ceramic Zirconia ☐ Metal ☐ Other Lateralized Liner: ☐ Yes ☐ No Constrained or Capture Cup: ☐ Yes ☐ No	Insert/Liner ☐☐ Capture Cup ☐☐	Sticker(s) for Acetabular Insert/Liner Sticker(s) for Acetabular Capture Cup
Acetabular Ring/Mesh: Replaced? ☐ Yes → ☐ No ↓	Antiprotrusio Ring: ☐ Yes ☐ No Wire Mesh: ☐ Yes ☐ No	Ring ☐☐	Sticker(s) for Acetabular Ring
Main Femoral Stem Replaced? ☐ Yes → ☐ No ↓	Cemented: ☐ Yes ☐ No Cementless **Check (✓) ALL that apply:** ☐ Porous In-Growth ☐ H.A. Coated ☐ Grit Blasted Calcar Replacement ☐ Yes ☐ No Multipiece Stem ☐ Yes ☐ No Increased (Lateralized) Offset Stem ☐ Yes ☐ No BONE GRAFTING? ☐ None **or Check (✓) ALL that apply:** ☐ Structural ☐ Onlay ☐ Morsellized ☐ Impaction using Morsellized ☐ Autograft ☐ Allograft ☐ Bone Substitute	Main Fem Stem ☐☐	Sticker(s) for Main Femoral Stem
Proximal Femoral Stem Replaced? ☐ Yes → ☐ No ↓		Proximal Fem Stem ☐☐	Sticker(s) for Proximal Femoral Stem
Femoral Head Replaced? ☐ Yes → ☐ No ↓	Surface Replaced ☐ Yes ☐ No Modular head: ☐ Yes ☐ No Size (mm): ☐ 22 ☐ 26 ☐ 28 ☐ 32 ☐ >32 ☐ Other Material: ☐ Cobalt Chrome ☐ Ceramic Zirconia ☐ Ceramic Alumina ☐ Oxinium ☐ Other	Fem Head ☐☐	Sticker(s) for Femoral Head
Cement Details ☐ N/A or →	**For each item Check (✓) ONE only:** Cement Name: ☐ Simplex ☐ CMW ☐ Versabond ☐ Osteobond ☐ Palacos ☐ Zimmer ☐ Other Antibiotic Type: ☐ None ☐ Erythromycin ☐ Tobramycin ☐ Vancomycin ☐ Gentamycin ☐ Other Mixing Method: ☐ Vacuum-Mixed ☐ Centrifuge ☐ Manually Mixed **Antibiotics Added by Surgeon:** ☐ None ☐ Erythromycin ☐ Tobramycin ☐ Vancomycin ☐ Gentamycin ☐ Other **Antibiotic Mixing Method:** ☐ Vacuum-Mixed ☐ Centrifuge ☐ Manually Mixed		

Section 5

LEGEND OF MANUFACTURER CODES:	**01** Biomet **02** Ceraver **03** J&J/DePuy	**04** Smith & Nephew Richards **06** Stryker/Osteonics/Howmedica **06** Sulzer/Centerpulse	**07** Wright Medical **08** Zimmer **99** Other, Please Specify________

OJRR
ONTARIO JOINT REPLACEMENT REGISTRY

K
Knee Replacement - Data Form

PATIENT INFORMATION

Has Patient Consent Been Obtained? ☐ Yes ☐ No

Last Name

First Name

Middle Initial

Street Number and Street Name

Apartment Number (if applicable)

City

Province

Postal Code

1 9 Y Y Y Y M M D D
Birth Date

☐ Male ☐ Female
Gender

Health Card Number

Hospital Chart Number

Hospital Institution Number

Section 1

CONSULTATION DETAILS

2 0 Y Y Y Y M M D D
Referral Date (if new)

Referral Status

☐ New ☐ Re-Assessment

Referral Source:
☐ Specialist – Ortho
☐ Specialist – Other
☐ GP

Consult Delayed by Patient?

☐ Yes ☐ No

2 0 Y Y Y Y M M D D
Date of First Consultation (if new referral)

2 0 Y Y Y Y M M D D
Decision Date for Surgery

Section 2

Surgery Date Delayed

☐ Yes ☐ No

Reason:
☐ Medical (Patient Medical Status
☐ Patient (Non-medical, Personal)
☐ Hospital (Insufficient Resources)

2 0 Y Y Y Y M M D D
Admission Date

2 0 Y Y Y Y M M D D
Surgery Date

Y Y Y Y M M
Date of Last Implant (if revision)

Surgeon Last Name

Surgeon First Name

OJRR
ONTARIO JOINT REPLACEMENT REGISTRY

K
Knee Replacement - Data Form

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
Patient Last Name

Anaesthetic	**Check (✓) ALL that apply:** ☐General ☐ Spinal ☐ Epidural ☐ Peripheral Nerve Block ☐Local Infiltration
OR Environment	**Check (✓) ONE only:** ☐ Standard ☐ Laminar Air Flow ☐ Body Exhaust ☐ Laminar Air Flow & Body Exhaust ☐ Ultraviolet
Antibiotic	Will Antibiotics Be Administered Prophylactically? ☐ Yes ☐ No if yes, duration? ☐ ≤ 24 hrs. ☐ > 24 hrs.
DVT Prevention	Will DVT prophylaxis be given in hospital? ☐ Yes ☐ No **If yes, check (✓) ALL that apply:** ☐ Warfarin ☐ LMW Heparin ☐ ASA ☐ SC Heparin ☐ Foot Pump ☐ Pneumatic Stockings ☐ Blinded Clinical Trial ☐ Other
Patient Comorbidity	**ASA Physical Status Classification System: (obtain from anaesthesiologist) – Check (✓) ONE only:** P1 ☐ - normal healthy P2 ☐ - mild systemic disease P3 ☐ - severe systemic disease P4 ☐ - severe systemic disease that is a constant threat to life **Height**: ☐☐☐ cm **or** ☐ feet ☐☐ inches **Weight – circle one**: ☐☐☐ kg **or** pounds
	☐ Right ☐ Left ☐ Bilateral
Pre-op Joint Status (for Charnley)	**Contralateral Knee - Check (✓) ONE only:** ☐**Symptomatic** ☐**Replaced** ☐**Symptomatic and Replaced** ☐**Not Yet Assessed** ☐**No Joint Complaints** **Left Hip - Check (✓) ONE only:** ☐**Symptomatic** ☐**Replaced** ☐**Symptomatic and Replaced** ☐**No Joint Complaints** ☐**Not Yet Assessed** **Right Hip - Check (✓) ONE only:** ☐**Symptomatic** ☐**Replaced** ☐**Symptomatic and Replaced** ☐**No Joint Complaints** ☐**Not Yet Assessed** **Would walking be LIMITED if hips AND knees were normal?** ☐ Yes ☐ No **Involved Knee Joint Deformit y – For each deformity Check (✓) ONE only:** Varus Deformity: ☐ None ☐ <15° ☐ ≥ 15° Valgus Deformity: ☐ None ☐ <15° ☐ ≥ 15° Flexion Contracture: ☐ None ☐ <15° ☐ ≥ 15° **Involved Knee Pre-op Flexion Range of Motion - Check (✓) ONE only:** ☐ < 90° **or** ☐ ≥ 90°
Primary Dx	**Check (✓) MOST RESPONSIBLE diagnosis for involved knee (Check ONE only):** ☐ Degenerative OA ☐ Inflammatory Arthritis ☐ Post-Traumatic OA ☐ Osteonecrosis ☐ Infection ☐ Tumour ☐ Acute Fracture ☐ Other
Secondary Dx ☐ None or ➔ ↓	**Check (✓) ALL that apply to involved knee:** ☐ Degenerative OA ☐ Inflammatory Arthritis ☐ Post-Traumatic OA ☐ Osteonecrosis ☐ Infection ☐ Tumour ☐ Acute Fracture ☐ Other
Type of Replacement	**Check (✓) ONE only:** ☐ Primary ☐ R1 ☐ R2 ☐ R3 ☐ >R3 IF REVISION FOR INFECTION, ALSO CHECK (✓) ONE: Re-Implantation: ☐ 1-stage **or** ☐ 2-stage **First Stage of Revision** **Spacer Details Check (✓) ONE only:** ☐ None ☐ Spacer (Non-Antibiotic) Inserted ☐ Antibiotic Spacer Inserted ☐ Antibiotic (Temporary) Arthroplasty Inserted **Second Stage of Revision:** Did You Do Stage 1? ☐ Yes ☐ No If No, indicate the Removal Date of Original Prosthesis: 2 0 ☐☐☐☐☐☐ Y Y Y Y M M D D
Reason(s) for Revision	**Check (✓) ALL that apply to involved knee:** ☐ Unresurfaced Patella ☐ Replace Tibial Polyliner ☐ Aseptic Loosening ☐ Poly Wear ☐ Osteolysis ☐ Instability ☐ Malposition ☐ Patellar Maltracking ☐ Implant Fracture ☐ Bone Fracture ☐ Failed Patellar Component ☐ Arthrofibrosis ☐ Infection ☐ Other
Previous Operations ☐ None or ➔ ↓	**Check (✓) ALL that apply to involved knee:** ☐ Primary TKA ☐ Unicondylar Arthroplasty ☐ 2-Stage Resection Arthroplasty ☐ Revision ☐ Unispacer ☐ Tibial Osteotomy ☐ Femoral Osteotomy ☐ Fracture Fixation ☐ Arthrodesis ☐ Patellectomy ☐ Open Menisectomy ☐ Arthroscopic Menisectomy ☐ Arthroscopic Debridement ☐ Ligament Repair ☐ Other
Surgical Approach	**Check (✓) ONE only:** ☐ Medial – Standard ☐ Lateral – Standard ☐ Intravastus ☐ Subvastus ☐ Other ☐ Medial – Minimally Invasive ☐ Lateral – Minimally Invasive
Special Steps ☐ None or ➔ ↓	**Check (✓) ALL that apply to involved knee:** ☐ Lateral Patellar Retinacular Release ☐ Medial Release for Varus Knee ☐ Lateral Release for Valgus Knee ☐ Rectus Snip ☐ Quadriceps Turndown ☐ Tibial Tubercle Osteotomy ☐ Medial Epicondyle Osteotomy **Computer Assisted?** ☐ Yes ☐ No

Section 3

Section 4

OJRR
ONTARIO JOINT REPLACEMENT REGISTRY

K
Knee Replacement - Data Form

Patient Last Name

Unicompartmental Prosthesis? ☐ No ☐ Yes If Yes, ☐ Medial? or ☐ Lateral? or ☐ Patello-Femoral?

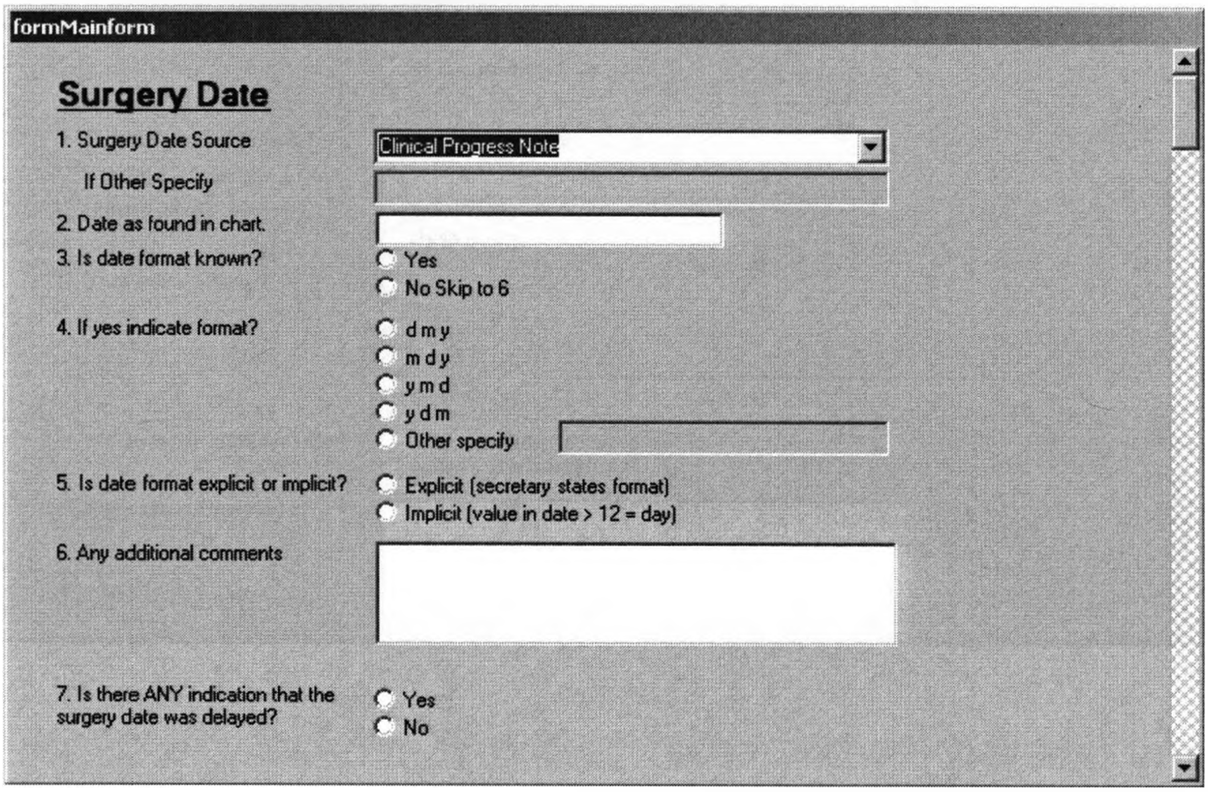
Femoral Component Replaced? ☐ Yes → ☐ No ↓	Cemented: ☐ Yes ☐ No **If Cementless Check (✓) ALL that apply:** ☐ Porous In-Growth ☐ H.A. Coated ☐ Press-Fit	Manufacturer See Legend Below	Affix sticker(s) or catalogue and lot number beside specific component. **Do not include screws.**
	Femoral Stem: ☐ Yes ☐ No **If Yes, Check (✓) ALL that apply:** Fixed ☐ Yes ☐ No Standard Modular ☐ Yes ☐ No Offset Modular ☐ Yes ☐ No Cemented ☐ Yes ☐ No	Femoral Component	Sticker(s) for Femoral Component.
	BONE GRAFTING? ☐ **None or Check (✓) ALL that apply:** ☐ Structural ☐ Onlay ☐ Morsellized ☐ Autograft ☐ Allograft ☐ Bone Substitute METAL AUGMENTS? ☐ **None or Check (✓) ALL that apply:** ☐ Distal ☐ Posterior ☐ Anterior	Modular Stem Only	Sticker(s) for Modular Femoral Stem Only.
Tibial Component Replaced? ☐ Yes → ☐ No ↓	Type: ☐ All Poly or ☐ Metal-backed Tibial Component Thickness: ___ mm Mobile Bearing: ☐ Yes ☐ No Cemented: ☐ Yes ☐ No	All Poly Component or Poly Insert	Sticker(s) for All Poly Component or Poly Insert
	If Cementless Check (✓) ALL that apply: ☐ Porous In-Growth Screws: ☐ Yes ☐ No ☐ H.A. Coated Screws: ☐ Yes ☐ No PCL Retaining? or PCL Sacrificing? ☐ Standard ☐ Post & Cam ☐ Medial Pivot ☐ Deep Dished ☐ Constrained ☐ Medial Pivot ☐ Hinged	Tibial Base Plate	Sticker(s) for Tibial Base Plate.
	Tibial Stem: ☐ Yes ☐ No (Used Standard Peg) **If Yes – Check (✓) ALL that apply:** Fixed Long ☐ Yes ☐ No Standard Modular ☐ Yes ☐ No Offset Modular ☐ Yes ☐ No Cemented ☐ Yes ☐ No BONE GRAFTING? ☐ **None or Check (✓) ALL that apply:** ☐ Structural ☐ Onlay ☐ Morsellized ☐ Autograft ☐ Allograft ☐ Bone Substitute METAL AUGMENTS? ☐ **None or Check (✓) ALL that apply:** ☐ Medial ☐ Lateral ☐ Full	Modular Stem Only	Sticker(s) for Modular Tibial Stem only.
Patella Replaced? Replaced? ☐ Yes → ☐ No ↓	If resurfaced: ☐ Cemented or ☐ Porous In-Growth Resurfaced Method: ☐ Inset or ☐ Onlay	Patella	Sticker(s) for Patella.
Cement Details ☐ N/A or →	**For each item Check (✓) ONE only:** Cement Name: ☐ Simplex ☐ CMW ☐ Versabond ☐ Osteobond ☐ Palacos ☐ Zimmer ☐ Other Antibiotic Type: ☐ None ☐ Erythromycin ☐ Tobramycin ☐ Vancomycin ☐ Gentamycin ☐ Other Mixing Method: ☐ Vacuum-Mixed ☐ Centrifuge ☐ Manually Mixed **Antibiotics Added by Surgeon:** ☐ None ☐ Erythromycin ☐ Tobramycin ☐ Vancomycin ☐ Gentamycin ☐ Other **Antibiotic Mixing Method:** ☐ Vacuum-Mixed ☐ Centrifuge ☐ Manually Mixed		

Section 5

LEGEND OF MANUFACTURER CODES:

01 Biomet	**04** Smith & Nephew Richards	**07** Wright Medical
02 Ceraver	**05** Stryker/Osteonics/Howmedica	**08** Zimmer
03 J&J/DePuy	**06** Sulzer/Centerpulse	**99** Other, Please Specify________

Appendix VII The details of the custom software used by RFCs to collect data from medical record


formMainform

Surgery Date

1. Surgery Date Source — Clinical Progress Note

If Other Specify

2. Date as found in chart.

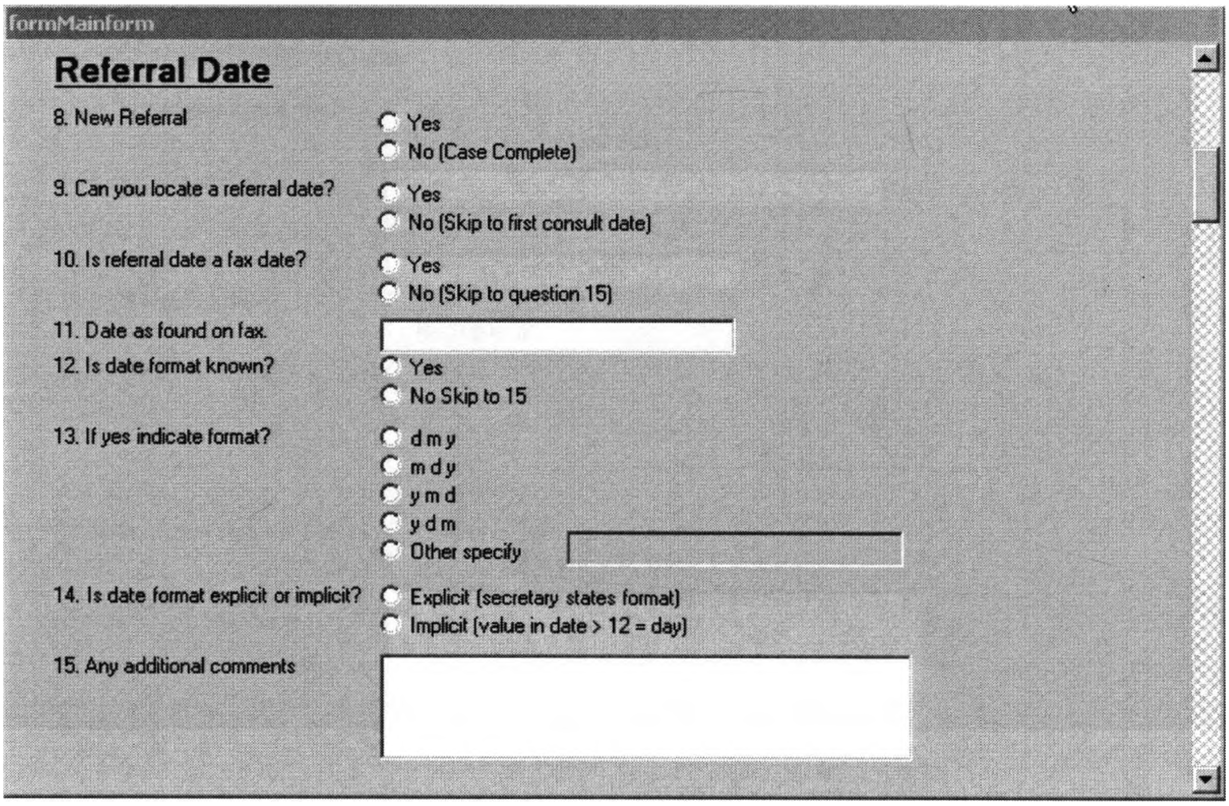
3. Is date format known?
   - Yes
   - No Skip to 6

4. If yes indicate format?
   - d m y
   - m d y
   - y m d
   - y d m
   - Other specify

5. Is date format explicit or implicit?
   - Explicit (secretary states format)
   - Implicit (value in date > 12 = day)

6. Any additional comments

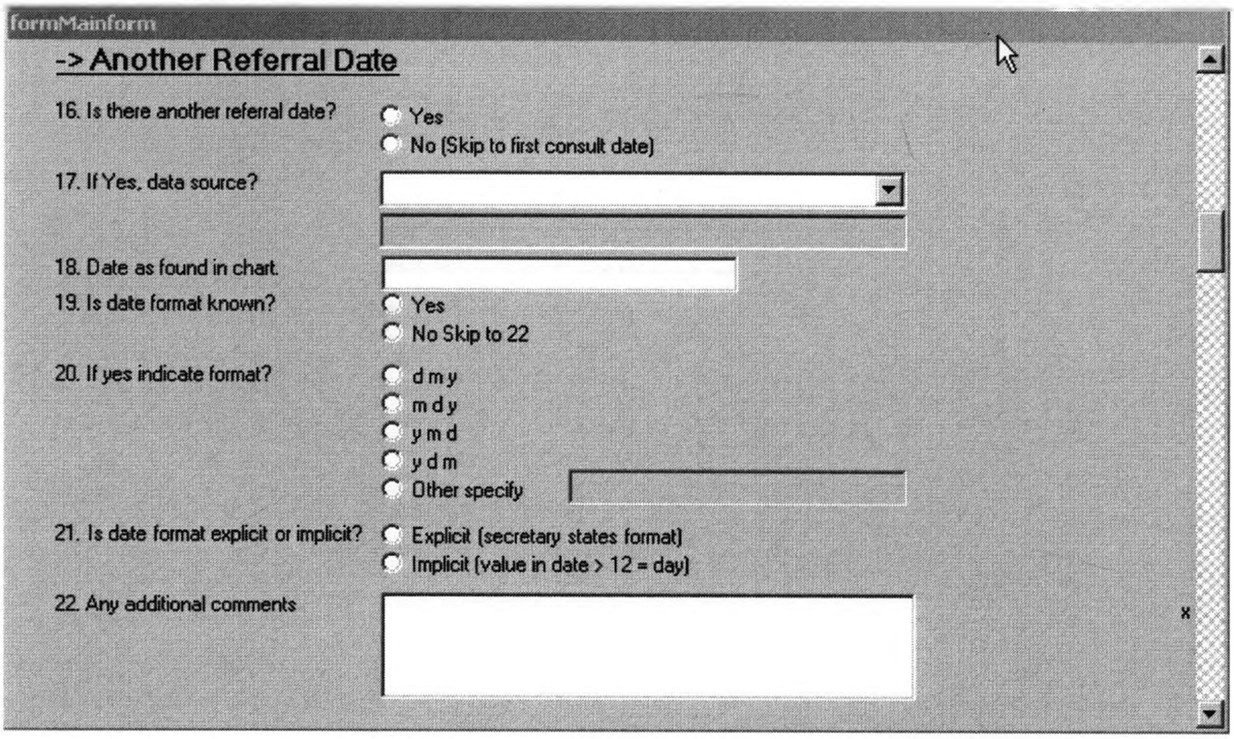
7. Is there ANY indication that the surgery date was delayed?
   - Yes
   - No



formMainform

Referral Date

8. New Referral
   - Yes
   - No (Case Complete)
9. Can you locate a referral date?
   - Yes
   - No (Skip to first consult date)
10. Is referral date a fax date?
   - Yes
   - No (Skip to question 15)
11. Date as found on fax.
12. Is date format known?
   - Yes
   - No Skip to 15
13. If yes indicate format?
   - d m y
   - m d y
   - y m d
   - y d m
   - Other specify
14. Is date format explicit or implicit?
   - Explicit (secretary states format)
   - Implicit (value in date > 12 = day)
15. Any additional comments



formMainform

-> Another Referral Date

16. Is there another referral date?
- ○ Yes
- ○ No (Skip to first consult date)

17. If Yes, data source?

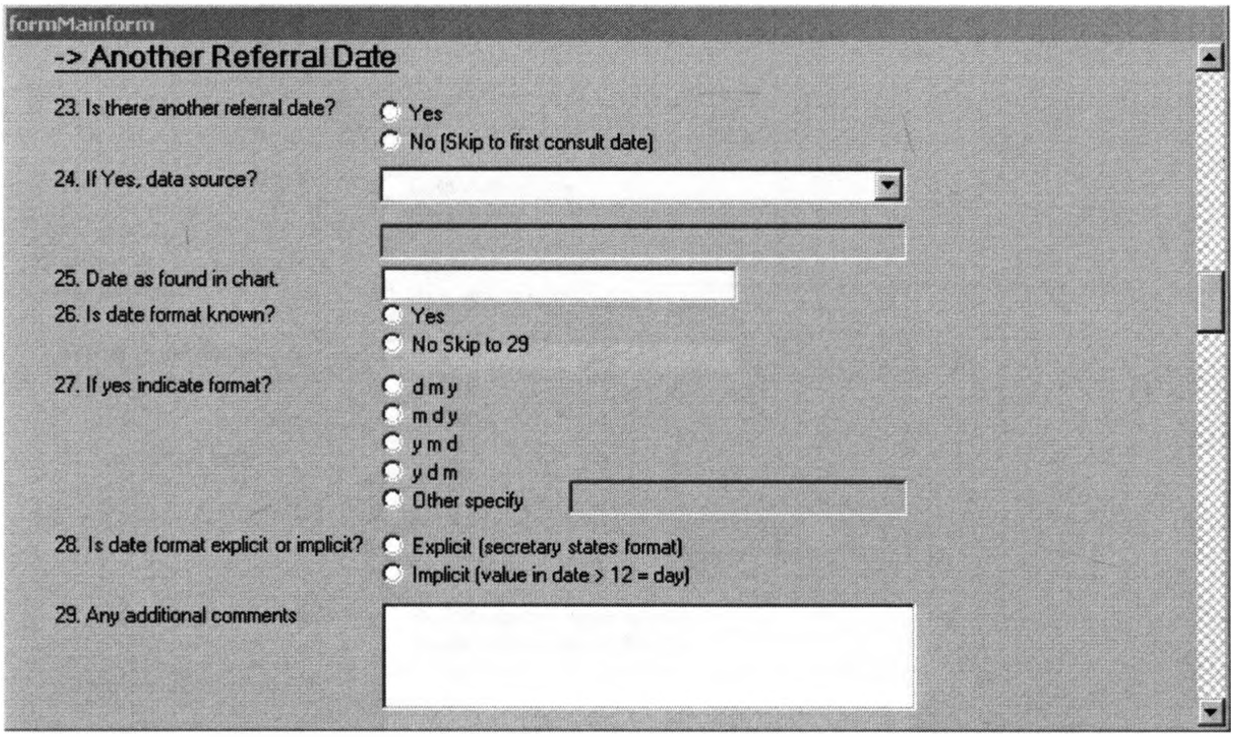
18. Date as found in chart.

19. Is date format known?
- ○ Yes
- ○ No Skip to 22

20. If yes indicate format?
- ○ d m y
- ○ m d y
- ○ y m d
- ○ y d m
- ○ Other specify

21. Is date format explicit or implicit?
- ○ Explicit (secretary states format)
- ○ Implicit (value in date > 12 = day)

22. Any additional comments



formMainform

-> Another Referral Date

23. Is there another referral date?
- Yes
- No (Skip to first consult date)

24. If Yes, data source?

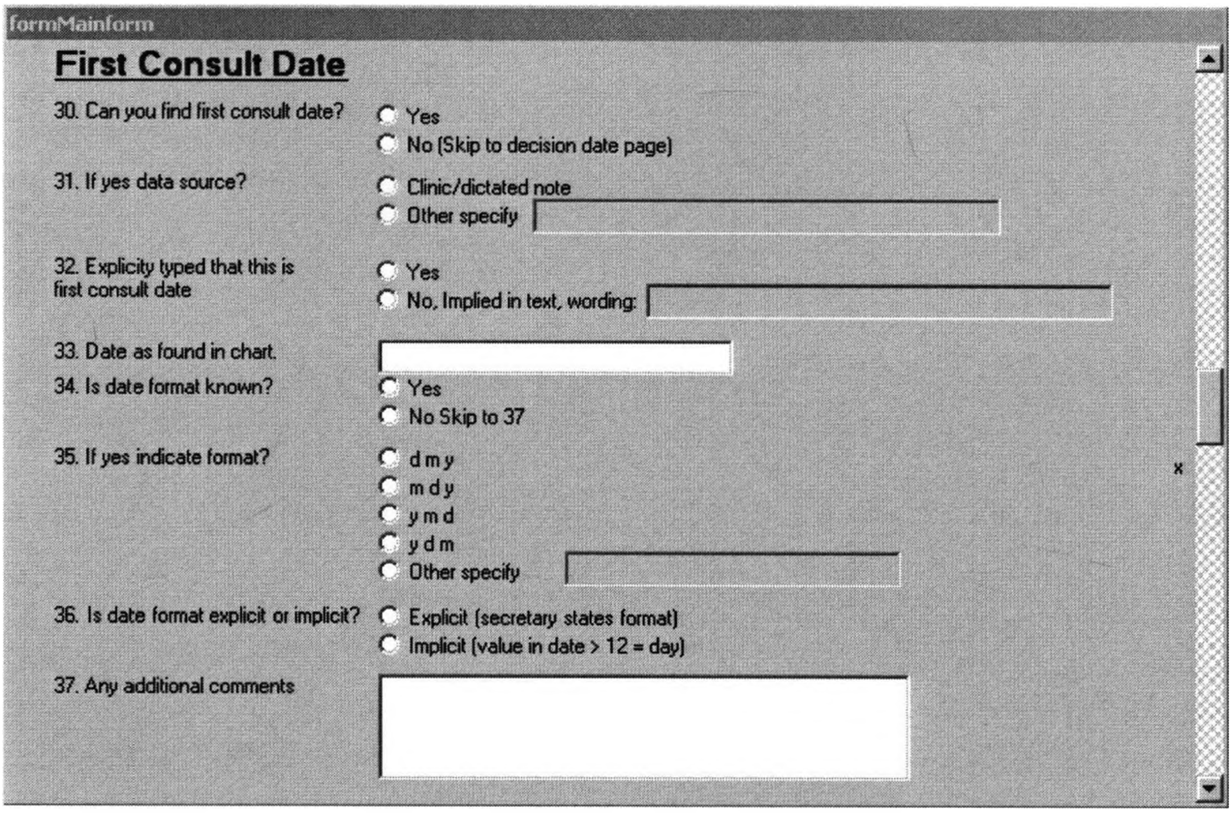
25. Date as found in chart.

26. Is date format known?
- Yes
- No Skip to 29

27. If yes indicate format?
- d m y
- m d y
- y m d
- y d m
- Other specify

28. Is date format explicit or implicit?
- Explicit (secretary states format)
- Implicit (value in date > 12 = day)

29. Any additional comments



formMainform

First Consult Date

30. Can you find first consult date?
- Yes
- No (Skip to decision date page)

31. If yes data source?
- Clinic/dictated note
- Other specify

32. Explicity typed that this is first consult date
- Yes
- No, Implied in text, wording:

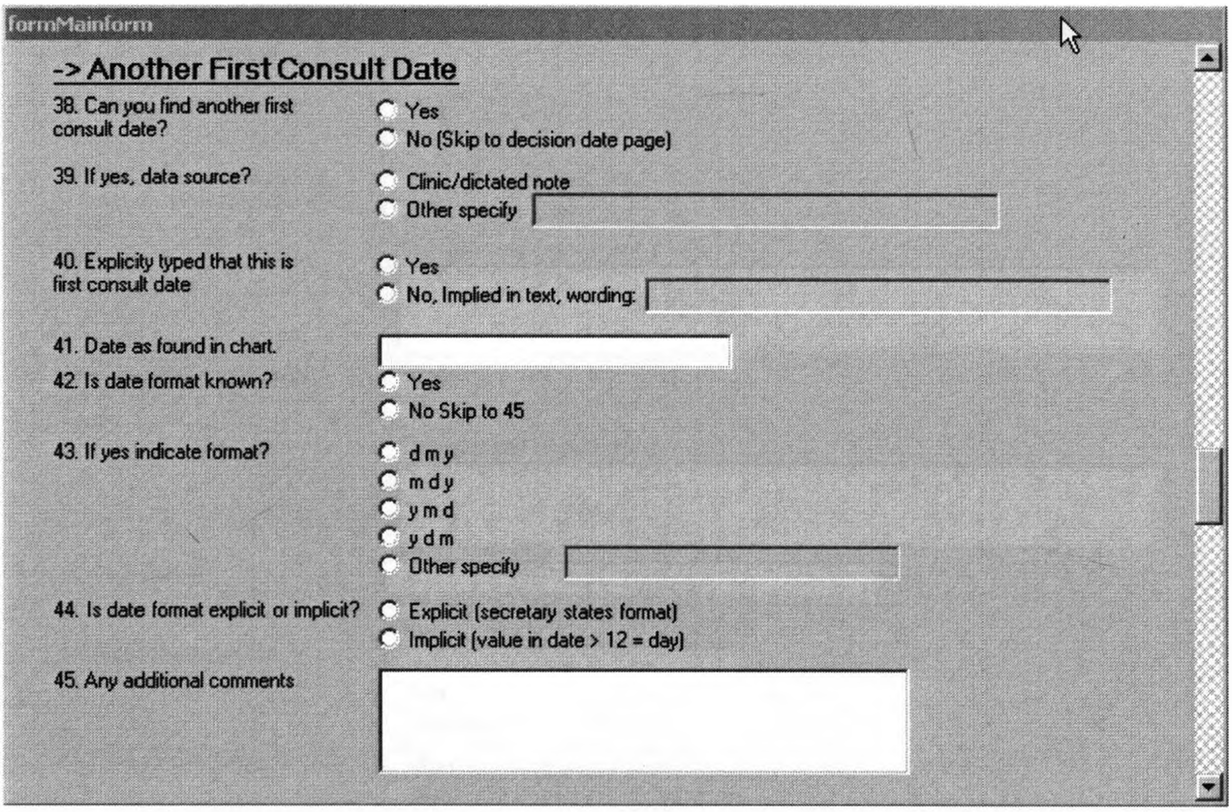
33. Date as found in chart.

34. Is date format known?
- Yes
- No Skip to 37

35. If yes indicate format?
- d m y
- m d y
- y m d
- y d m
- Other specify

36. Is date format explicit or implicit?
- Explicit (secretary states format)
- Implicit (value in date > 12 = day)

37. Any additional comments



formMainform

-> Another First Consult Date

38. Can you find another first consult date?
- Yes
- No (Skip to decision date page)

39. If yes, data source?
- Clinic/dictated note
- Other specify

40. Explicity typed that this is first consult date
- Yes
- No, Implied in text, wording:

41. Date as found in chart.

42. Is date format known?
- Yes
- No Skip to 45

43. If yes indicate format?
- d m y
- m d y
- y m d
- y d m
- Other specify

44. Is date format explicit or implicit?
- Explicit (secretary states format)
- Implicit (value in date > 12 = day)

45. Any additional comments

formMainform

Decision Date

46. Can you find a decision date?
   - ( ) Yes
   - ( ) No (Case Complete)

47. Explicit statement regarding surgeon decision to proceed with surgery
   - ( ) Yes
   - ( ) No

   Comments and record wording:

48. Explicit statement regarding patient decision to proceed with surgery
   - ( ) Yes
   - ( ) No

   Comments and record wording:

49. Data source?

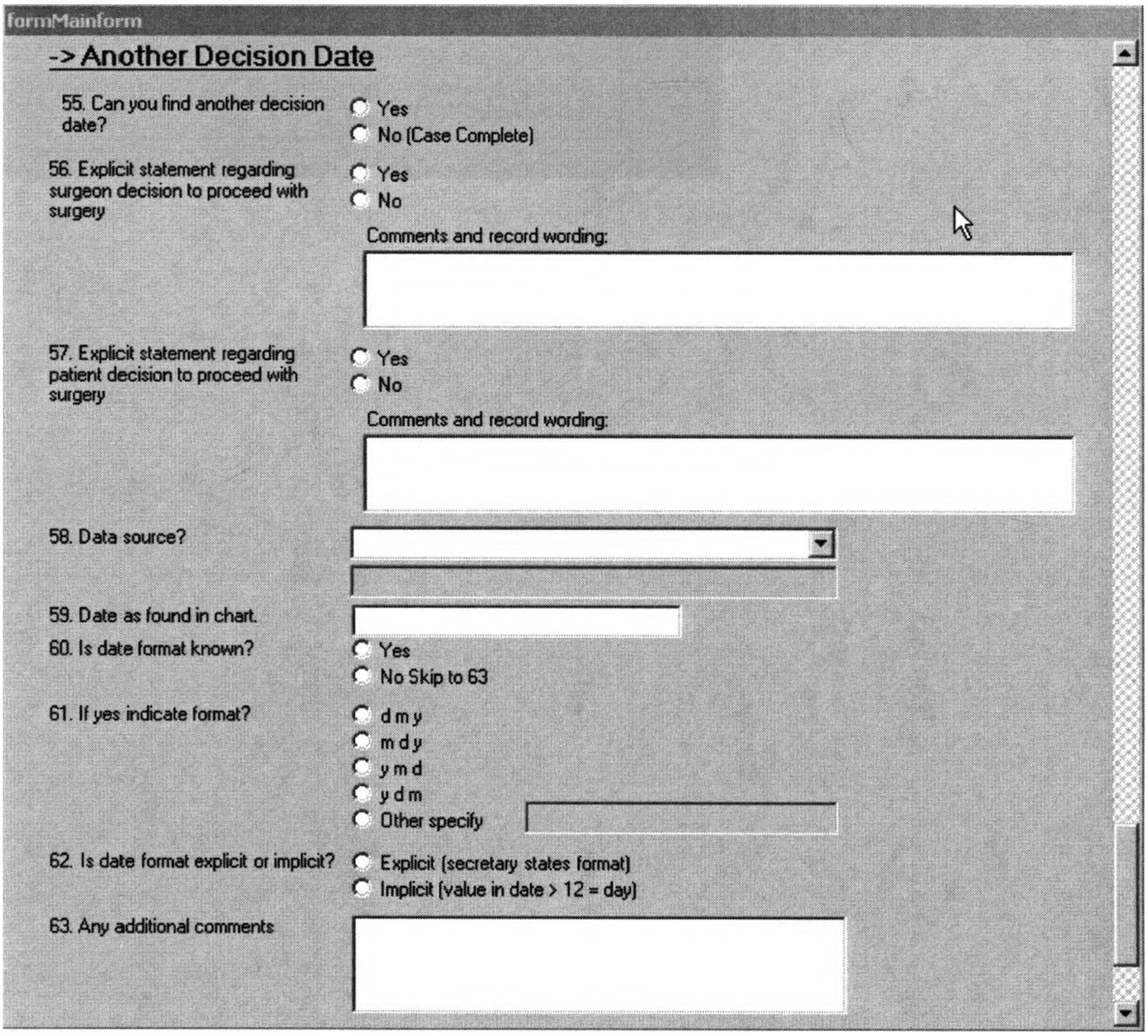
50. Date as found in chart.

51. Is date format known?
   - ( ) Yes
   - ( ) No Skip to 54

52. If yes indicate format?
   - ( ) d m y
   - ( ) m d y
   - ( ) y m d
   - ( ) y d m
   - ( ) Other specify

53. Is date format explicit or implicit?
   - ( ) Explicit (secretary states format)
   - ( ) Implicit (value in date > 12 = day)

54. Any additional comments



formMainform

-> Another Decision Date

55. Can you find another decision date?
- Yes
- No (Case Complete)

56. Explicit statement regarding surgeon decision to proceed with surgery
- Yes
- No

Comments and record wording:

57. Explicit statement regarding patient decision to proceed with surgery
- Yes
- No

Comments and record wording:

58. Data source?

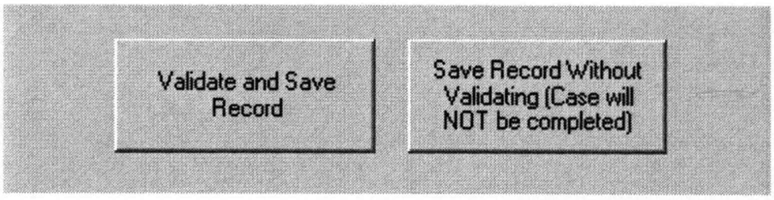
59. Date as found in chart.

60. Is date format known?
- Yes
- No Skip to 63

61. If yes indicate format?
- d m y
- m d y
- y m d
- y d m
- Other specify

62. Is date format explicit or implicit?
- Explicit (secretary states format)
- Implicit (value in date > 12 = day)

63. Any additional comments


Validate and Save
Record
Save Record Without
Validating (Case will
NOT be completed)

Appendix VIII Tables of Some Study Outcomes

Table A-1 The association between surgery date entry errors and OJRR surgery delay (n=72)

OJRR Surgery Delay	SurgeryDate Error	
	Yes	No
Yes	4	7
No	24	37

Fisher's exact test, p=0.2596
OR=0.88 (0.23, 3.34)

Table A-2 The association between surgery date entry errors and medical record surgery delay (n=72)

Record Surgery Delay	SurgeryDate Error	
	Yes	No
Yes	5	6
No	23	38

Fisher's exact test, p=0.2295
OR=1.38 (0.38, 5.02)

Table A-3Agreement in OJRR Surgery Delay and Record Surgery Delay (n=72)

OJRR Surgery Delay	Record Surgery Delay	
	Yes	No
Yes	4	7
No	7	54

Kappa=0.23 (Poor agreement between the OJRR and the medical record)

Table A-4 The relationship between decision date errors and whether or not the record decision date was equal to first consult date (n=72)

Record SameConsultDecision Date	DecisionDate Error	
	Yes	No
Yes	27	14
No	26	5

Fisher's exact test, p=0.09
OR=0.37 (0.12, 1.18)

Table A-5 The relationship between decision date errors and whether or not the OJRR decision date was equal to first consult date (n=72)

OJRR SameConsultDecision Date	DecisionDate Error	
	Yes	No
Yes	38	16
No	15	3

Fish's exact test: p=0.15
OR=0.48 (0.12, 1.87)

Table A-6 Agreement in consult date equal to decision date between OJRR database and medical record (n=72)

OJRR Same Consult and Decision Date	Record Same Consult and Decision Date	
	Yes	No
Yes	32	22
No	9	9

Kappa=0.04

Table A-7 The association between surgery date entry errors and OJRR surgery delay (n=112)

OJRR Surgery Delay	SurgeryDate Error	
	Yes	No
Yes	12	4
No	72	24

Fisher's exact test, p=0.2431
OR=1.00 (0.29, 3.39)

Table A-8 The association between surgery date entry errors and medical record surgery delay (n=112)

Record Surgery Delay	SurgeryDate Error	
	Yes	No
Yes	7	5
No	77	23

Fisher's exact test, p=0.1008
OR=0.42 (0.12, 1.44)

Table A-9 Agreement in OJRR surgery delay and record surgery delay (n=112)

OJRR Surgery Delay	Record Surgery Delay	
	Yes	No
Yes	5	11
No	7	89

Kappa=0.30 (Poor agreement between the OJRR and the medical record)

Table A-10 The relationship between referral date errors and whether or not the referral date were the Fax date (n=112)

Fax Referral Date in Record	Referral Date Error	
	Yes	No
Yes	75	4
No	27	6

Fish's exact test: p=0.03
OR=4.17 (1.1,15.9)

Tables A-11 Comparison between OJRR database and medical record using decision to surgery waiting time threshold or cut off at 6 months (n=269)

OJRR Decision to Surgery Wait Time	Record Decision to Surgery Wait Time		
	<=6 months	**>6month**	**Total**
<=6 months	171	9	180
>6 months	6	83	89
Total	177	92	269

$X^2 = 0.27$, $p = 0.60$

Table A-12 Decision to surgery waiting time: frequency of date component errors

	Record Decision to Surgery Waiting Time	
OJRR Decision to Surgery Waiting Time	**<= 6 months (Frequency of Errors)**	**> 6 months (Frequency of Errors)**
<= 6 months (Frequency of Errors)	Day Error 47 Month Error 17 ***(cell a)*** Year Error 1	Day Error 7 Month Error 7 ***(cell b)*** Year Error 6
> 6 months (Frequency of Errors)	Day Error 4 Month Error 4 ***(cell c)*** Year Error 1	Day Error 17 Month Error 12 ***(cell d)*** Year Error 0

Total frequency of date component errors in the decision to surgery waiting time: 75 (Day Error) + 40 (Month Error) + 8 (Year Error) =123

Total frequency of date component errors in cell a and cell d: 64 (Day Error) + 29 (Month Error) + 1 (Year Error) = 94

The percentage of data component errors in cell a and cell d: 94/123 = 76%

Tables A-13 Comparison between OJRR database and medical record using decision to surgery waiting time threshold or cut off at 9 months (n=269)

OJRR Decision to Surgery Waiting Time	Record Decision to Surgery Waiting Time		
	<=9 months	**>9 month**	**Total**
<=9 months	214	9	223
9 months	4	42	46
Total	218	51	269

$X^2 = 1.23$, $p = 0.26$

Tables A-14 Comparison between OJRR database and medical record using referral to surgery waiting time threshold or cut off at 9 months (n=269)

OJRR Referral to Surgery Waiting Time	Record Referral to Surgery Waiting Time		
	<=9 months	**>9 month**	**Total**
<=9 months	154	10	164
>9 months	3	102	105
Total	157	112	269

$X^2 = 2.77$, $p = 0.10$

Tables A-15 Comparison between OJRR database and medical record using referral to surgery waiting time threshold or cut off at 12 months (n=269)

OJRR Referral to Surgery Waiting Time	Record Referral to Surgery Waiting Time		
	<=12 months	**>12 month**	**Total**
<=12 months	194	8	202
>12months	10	57	67
Total	204	65	269

$X^2 = 0.06$, $p = 0.80$

Table A-16 Referral to surgery waiting time: frequency of date component errors

	Record Referral to Surgery Waiting Time	
OJRR Referral to Surgery Waiting Time	<= 12 months (Frequency of Errors)	> 12 months (Frequency of Errors)
<= 12 months (Frequency of Errors)	Day Error 80 Month Error 28 ***(cell a)*** Year Error 3	Day Error 12 Month Error 11 ***(cell b)*** Year Error 4
> 12 months (Frequency of Errors)	Day Error 8 Month Error 8 ***(cell c)*** Year Error 3	Day Error 21 Month Error 9 ***(cell d)*** Year Error 0

Total frequency of date component errors in the referral to surgery waiting time: 121 (Day Error) + 56 (Month Error) + 10 (Year Error) =187

Total frequency of date component errors in cell a and cell d: 101 (Day Error) + 37 (Month Error) + 3 (Year Error) = 141

The percentage of data component errors in cell a and cell d: 141/187 = 75%

Table A-17. 95% limits of agreement for the mean difference between the waiting time derived from the medical record and the waiting time from the Ontario Joint Replacement Registry (n= 254)

Waiting Time Period	Mean Difference (weeks)	SD	95% limits of agreement: Mean Difference ± 1.96 SD
Decision to surgery	-0.08	4.01	(-7, 6)
Referral to surgery	-0.18	3.34	(-8, 8)