OUTLINING HEALTHCARE UTLIZATION IN ORDER TO DEVELOP EVIDENCE BASED DATA COLLECTION TOOLS FOR PROSPECTIVE EVALUATION OF THE ECONOMIC BURDEN DUE TO INVASIVE MENINGOCOCCAL DISEASE (IMD) IN CANADA

by

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Submitted in partial fulfillment of the requirements for the
degree of Master of Applied Health Services Research

at

Dalhousie University
Halifax, Nova Scotia
March 2013

DALHOUSIE UNIVERSITY

SCHOOL OF HEALTH ADMINISTRATION

The undersigned hereby certify that they have read and recommend to the Faculty of Graduate Studies for acceptance a thesis entitled “OUTLINING HEALTHCARE UTLIZATION IN ORDER TO DEVELOP EVIDENCE BASED DATA COLLECTION TOOLS FOR PROSPECTIVE EVALUATION OF THE ECONOMIC BURDEN DUE TO INVASIVE MENINGOCOCCAL DISEASE (IMD) IN CANADA” by Sanela Gajic in partial fulfillment of the requirements for the degree of Master of Applied Health Services Research.

Dated: March 22nd, 2013

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DALHOUSIE UNIVERSITY

DATE: March 22nd, 2013

AUTHOR: Sanela Gajic

TITLE: Outlining Healthcare Utilization in Order to Develop Evidence Based Data Collection Tools for Prospective Evaluation of the Economic Burden Due to Invasive Meningococcal Disease (IMD) in Canada

DEPARTMENT OR SCHOOL: School of Health Administration

DEGREE: MAHSR CONVOCATION: May YEAR: 2013

Signature of Author

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ABSTRACT

Defining health and economic burden of Invasive Meningococcal Disease (IMD) in Canada is critical to inform Public Health Policy around immunization programs. A comprehensive literature review was conducted to assess available studies, a lack of comprehensive Canadian data to allow evaluation of total economic burden of IMD was identified in Canada. Thus, this dissertation proposes a prospective cost collection methodology tailored to Canadian data and healthcare utilization (HCU). All patient-related HCU is considered and outlined. HCU is then categorized as direct or indirect and relevant direct and indirect healthcare costs are detailed. Intangible costs are described and methodology for capturing these costs using validated quality of life instruments is proposed. As all published economic evaluations of this disease lack prospective collection of data, this study proposes the use of a patient diary to serve as a memory aid during patient cost-collection interviews.

LIST OF ABBREVIATIONS USED

CEA	Cost Effectiveness Analysis
COI	Cost of Illness
HCU	Healthcare Utilization
EQ-5D	EuroQoL, Standardized instrument for measuring health outcomes
IMD	Invasive Meningococcal Disease
NACI	National Advisory Committee on Immunization
MCV-C	Meningococcal C Conjugate Vaccine
MCV-4	Quadrivalent A, C, Y, W-135 Meningococcal Vaccine
MRF	Meningitis Research Foundation
SOS	Serious Outcomes Surveillance
QALY	Quality Adjusted Life Year
QoL	Quality of Life
SF-36	Health Survey for measuring health outcomes
PHAC	Public Health Agency of Canada

ACKNOWLEDGEMENTS

I would like to acknowledge and thank all of the wonderful professors that I met through this collaborative program at the Atlantic Regional Training Centre. I truly believe in fostering the Atlantic Canadian capacity in the area of applied health services research. I would like to extend appreciation to Dr. Sara Kirk for her guidance through the graduate program at Dalhousie University.

I would like to extent my sincerest gratitude to the Canadian Center for Vaccinology for an amazing opportunity during my residency term as well as its continuing support throughout my thesis. This research would not have been possible without the wonderful support of everyone at the Canadian Center for Vaccinology. A special thank you to the team that helped with the pilot study portion of this thesis work: Ardith Ambrose, Sarah De Coutere, Jessica Henneberry, and Wanda Allen.

I would like to thank Dr. Rick Audas for his academic support and for taking the time out of his busy schedule to thoroughly critique my thesis. I owe indescribable gratitude to my mentor and thesis supervisor, Dr. Shelly McNeil. Her patience, guidance, and tremendous support will be forever appreciated. Dr. Shelly McNeil made a lasting impression academically, professionally, and personally. Thank you so much for your countless hours of thoughtful revisions of this thesis.

Finally, I would like to thank my fiancé and best friend, Dragan Moraca, for his support and for always patiently listening.

CHAPTER 1: INTRODUCTION

Invasive meningococcal disease and prevention in Canada

Invasive meningococcal disease (IMD) is a notifiable disease in Canada (PHAC, 2006). Notifiable diseases differ from other infectious diseases, because they must be reported to the public health authorities, either on a national or an international level. IMD is caused by five serogroups of *Neisseria menigitidis*: A, B, C, Y, and W135. The overall incidence rate of IMD in Canada traditionally averages approximately 300 cases per year (slightly less than 2 per 100,000 cases) (PHAC, 2007). The latest preliminary reports by the Public Health Agency of Canada (PHAC) show that the incidence rate for period of 2005 – 2010 averages just under 200 cases per year (PHAC, 2012), perhaps owing to increased vaccine coverage. Although the incidence rates of this disease are not very high, IMD results in considerable morbidity and mortality in those affected. One in ten people infected with this disease die, and of the survivors one out of five is left with permanent life-long disabilities (MRFC, 2012). Patterns of IMD are unpredictable, seasonal, and vary according to population age, bacterial serogroups circulating, and geographical location across Canada (PHAC, 2007). IMD is frequently associated with devastating long term sequelae, both psychological and physical. Patients are often left with brain damage, behavioral issues, amputations of the extremities, vision, hearing and speech problems, and many other devastating long-lasting effects. The treatment of IMD often varies due to individual patient differences, such as patient health, age and the severity of sequelae.

Meningococcal disease is a severe invasive bacterial infection that has two typical presentations: meningococcemia and meningococcal meningitis, both of which are referred to as invasive meningococcal disease (IMD). *N. meningitidis* is exclusively a human infection. Humans get infected through close contact, as the bacteria are carried in the nose and throat. During periods of endemic infections, 5-10% of the population asymptomatically carries the bacteria (Welte et al., 2005). In Canada, bacterial serogroups B and C have been responsible for most cases, with serogroup C responsible for most outbreaks in schools and communities (NS Health Promotion and Protection, 2008).

Invasive meningococcal disease is a vaccine preventable disease; The Canadian National Advisory Committee on Immunization (NACI) recommends universal vaccination against meningococcal serogroup C. All Canadian Provinces and Territories now have publicly funded infant immunization programs against meningococcal serogroup C and some offer vaccines with broader serogroup coverage. Given the devastating impact of IMD, new vaccines, that prevent four bacterial serogroups A, C, Y and W-135 have been developed and approved in the Canadian market. Additionally, a conjugate meningococcal B vaccine is soon to be available in Canada. While the incidence rate of the non-serogroup C strains is relatively low, the epidemiology of these stains is unpredictable and varies geographically in Canada and world-wide. Public health decision-making regarding new vaccine products is hindered by the fact that cost-effectiveness of these new vaccines is unknown and assessment of cost effectiveness or, importantly, incremental cost effectiveness over the current universal serogroup C vaccination program, is not possible as the average patient cost of IMD in Canada is currently unknown. Thus, establishing valid methodology to gather Canadian costing data, as proposed in this thesis, is critical to inform decision-making around new and existing meningococcal immunization programs.

In Canada, the National Advisory Committee on Immunization (NACI) evaluates the latest vaccines and makes recommendations regarding the optimal use of new vaccines given available Canadian epidemiology. However, NACI does not evaluate budget impact or cost-effectiveness of vaccine programs, and therefore, does not make recommendations about which vaccines should be included in publically funded immunization programs. Implementation of NACI-recommended vaccines is the responsibility of the provinces and territories. It is therefore at the provincial and territorial level that decisions regarding which vaccines should be publicly funded must be made. Given this complex federal, provincial and territorial decision making structure, a National Immunization Strategy has been developed in hopes of harmonizing vaccine programs across Canada. Central to the National Immunization Strategy is the development of an analytic framework designed to "allow a comprehensive and systematic evaluation of all factors which should be considered before making decisions regarding the pertinence of new immunization programs" (Erickson, L.J., De Wals, P., Farand, L., 2005). This framework was developed with field experts across Canada; they were consulted through a questionnaire that resulted in 58 different criteria, grouped in 13 categories. The framework consists of the following categories to be considered when making decisions on immunization: burden of disease, vaccine characteristics, immunization strategy and program, cost-effectiveness of program, acceptability of vaccine program, feasibility of program, ability to evaluate programs, research questions, equity of the program, ethical considerations, legal considerations, conformity of program, and political considerations. The burden of disease component of the framework emphasizes the importance of the social and economic impact of the disease, taking into consideration direct and indirect costs, loss of productivity, health service utilization, costs to the health system, reduction of quality of life of affected individuals and other relevant criteria (Erickson, L.J., et al., 2005). Inconsistency in meningococcal vaccine recommendations across Provinces and Territories in Canada reflects, to some extent, variability in the epidemiology of the disease, but also reflects uncertainties about the relative cost effectiveness of available program options. As the epidemiology of the disease continues to evolve, with variability in the proportion of the disease caused by non-serogroup C isolates, Provincial/Territorial governments and other decision-makers need accurate Canadian costing data in order to make the best informed recommendations for meningococcal immunization programs in order to provide maximum protection to Canadians.

The Public Health Agency of Canada (PHAC) provides guidelines for 13 vaccine preventable diseases in Canada. NACI recommends that infants receive their first Meningococcal C vaccine before 12 months of age, and a booster dose between 12-24 months (PHAC, 2009). Research shows that effects of immunization against meningococcal disease may wane with time; hence a booster dose is recommended in adolescents, ideally at 12 years of age (De Wals et al., 2007; PHAC, 2009). The PHAC information website provides an overview of the latest provincial and territorial immunization strategies (Table 1).

Table 1. Immunization schedules for Meningococcal Vaccination across Canada as of December 2012 (PHAC, 2012).

Province or Territory	Schedule for routine Meningococcal-C conjugate, booster, and catch up	Men-C-ACYW
NACI recommendation	**Infancy (1-4 doses) AND Pre-teen (1 dose)**	**Pre-teen (1 dose)**
BC	2, 12 months, Grade 6	
AB	2, 4, 12 months	Grade 9 (1 dose)
SK	12 months	Grade 6
MB	12 mths; Grade 4 until 2017	
ON	12 mths	Grade 7
QC	12 mths; Catch-up < 18 yrs	
NB	12 mths	Grade 9
NS	12 mths; Grade 7	
PE	12 mths	Grade 9
NL	12 mths	Grade 4
NT	2, 12 mths; Catch-up <5 yrs, Grade 9	Post secondary students attending schools outside NT
YT	2, 12 mths; Catch-up Grade 6, post-secondary students not previously immunized	
NU	12 mths; Catch-up Grade 9 (14-16 yrs)	

Serious Outcomes Surveillance (SOS) and IMPACT Networks

The Serious Outcomes Surveillance (SOS) Network and the Canadian Immunization Monitoring Program ACTive (IMPACT) are both funded by PHAC, the Canadians Institutes of Health Research (CIHR), as well as industry partners in order to conduct active surveillance for vaccine preventable or soon to be vaccine preventable diseases. The SOS Network focuses on adult surveillance; similarly, IMPACT focuses on pediatric surveillance. Both networks conduct active surveillance for IMD in Canada, providing an opportunity to assess healthcare utilization and quality of life impact through prospective surveillance in Canada. This thesis is designed to directly inform data collection in these networks by providing evidence-based data collection instruments to allow comprehensive assessment of healthcare utilization and cost of IMD in Canada.

Overview of Costing Methodology

Although economic evaluation of healthcare programs is very important in Canadian decision making, there has not been an appropriate costing methodology developed to assess the total economic burden of IMD. Total economic burden of disease must consider direct costs, indirect costs, and intangible costs. While there have been attempts to cost various clinical syndromes associated with meningococcal disease (e.g. meningitis), all methodologies thus far have been based on either retrospective data collection or hypothetical case scenarios and none have used Canadian data. Both retrospective and scenario-based types of studies have major limitations in estimating the total economic burden of disease, in particular, the lack of consideration of indirect, as well as intangible costs of this disease.

A sound method for the economic evaluation of healthcare programs can be comprised of many different approaches. However, general principles for economic evaluation include systematic analysis of relevant alternatives, viewpoint or perspective (i.e. community or societal, individual patient specific, the government's overall budget, Ministry of Health budget, and many other), and measurement of cost versus benefit (Drummond, et al., 2007). Economic measurements are also categorized into cost-utility, cost-benefit, cost-analysis, and cost-effectiveness. The valuation for cost-effectiveness is measured with natural units, such as life-years gained. In order to calculate life years gained or lost, collection of data focusing on direct, indirect and intangible costs must be considered.

In order to determine the total economic burden of IMD, healthcare utilization associated with this disease must be outlined first. Because the clinical course and outcomes of IMD vary considerably among patients, costs to the patient, society and the healthcare system may vary widely and average case-cost estimates may not provide an accurate picture of the true costs. Case-costing is primarily an accounting method of collecting costs for programs and services within the hospital institution and related services provided by that hospital; therefore, the full scope of a societal perspective of what a particular disease actually costs is incomplete (Ministry of Health and Long-Term Care, 2010). Additionally, case costing methodology often fails to address long-term direct and indirect costs associated with sequelae and cannot account for intangible costs such as the impact of IMD on quality of life. Thus, quantifying the total economic burden of IMD in Canada requires development of a comprehensive data set detailing all potential IMD-associated healthcare utilizations over a lifetime. Once such a data set has been developed, direct and indirect costs associated with healthcare utilizations can be assigned. Additionally, standardized ways of measuring the intangible costs of IMD impact on Quality of Life can be established.

This thesis reviews potential strategies for establishing costing of IMD in Canada. Evidence based data collection tools are developed and pilot tested. A comprehensive guidance document outlining an appropriate cost collection methodology is proposed for the prospective surveillance of IMD by the Serious Outcomes Surveillance Network (SOS) and the participating

Immunization Monitoring Program ACTive (IMPACT) Network sites. This study also adds to the body of knowledge on IMD and the kind of costs that patients and caregivers encounter when they are faced with this disease.

CHAPTER 2: LITERATURE REVIEW

A comprehensive review of the literature was conducted and included all published Canadian and non-Canadian English-language publications examining burden of disease, costs, and quality of life impact of IMD. This chapter will identify, provide a review and critique the relevant literature.

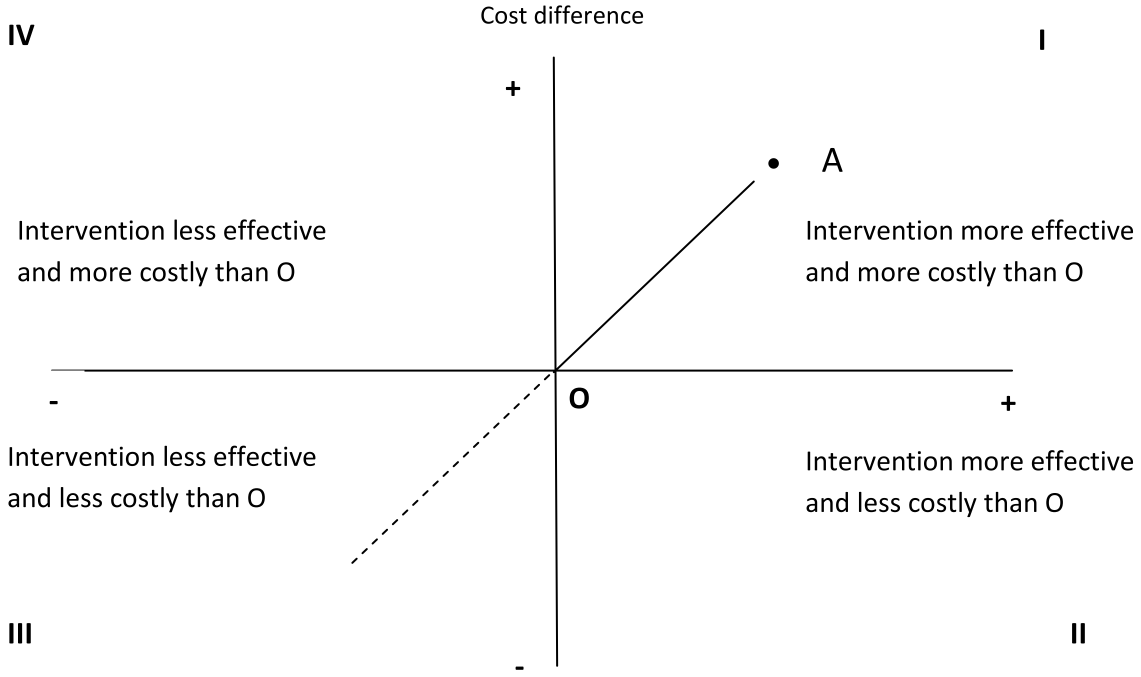
Several electronic databases: PubMed, BioCentral, Google Scholar, Cochrane Library, Medline, HealthSTAR were searched using combinations of search terms such as: ‘meningitis’, ‘invasive meningococcal disease’, ‘healthcare utilization’, ‘methodology’, ‘quality of life’, ‘cost of illness’, ‘Canada’, ‘cost-effectiveness’, and ‘cost-evaluation’. In addition to the electronic databases, Canadian government websites were also consulted for the latest guidance and recommendation documents.

The literature review includes books, Canadian Federal, Provincial and Territorial government guidance and recommendation documents, Canadian and international published literature, as well as a review of the references of any relevant publications. As the literature on evaluating the total economic burden of IMD is very limited, all relevant material was included and reviewed. Economic evaluations pertaining to healthcare recognize the importance of evaluating health issues with complete data. In addition to direct and indirect healthcare costs, complete data including societal aspects of a persons’ life, are also necessary to consider. Societal aspects focus on a broader inclusion of items, such as loss of work opportunity, including that of a caregiver/parent. In *Methods for the Economic Evaluation of Health Care Programmes*, Drummond et al. emphasize the importance and inclusion of a societal perspective in cost-effective economic analysis (Drummond et al., 2007). As this thesis's intention is to serve as a guidance document for the total economic burden of IMD, it is important to include the socioeconomic aspects of this disease.

Cost-Effectiveness

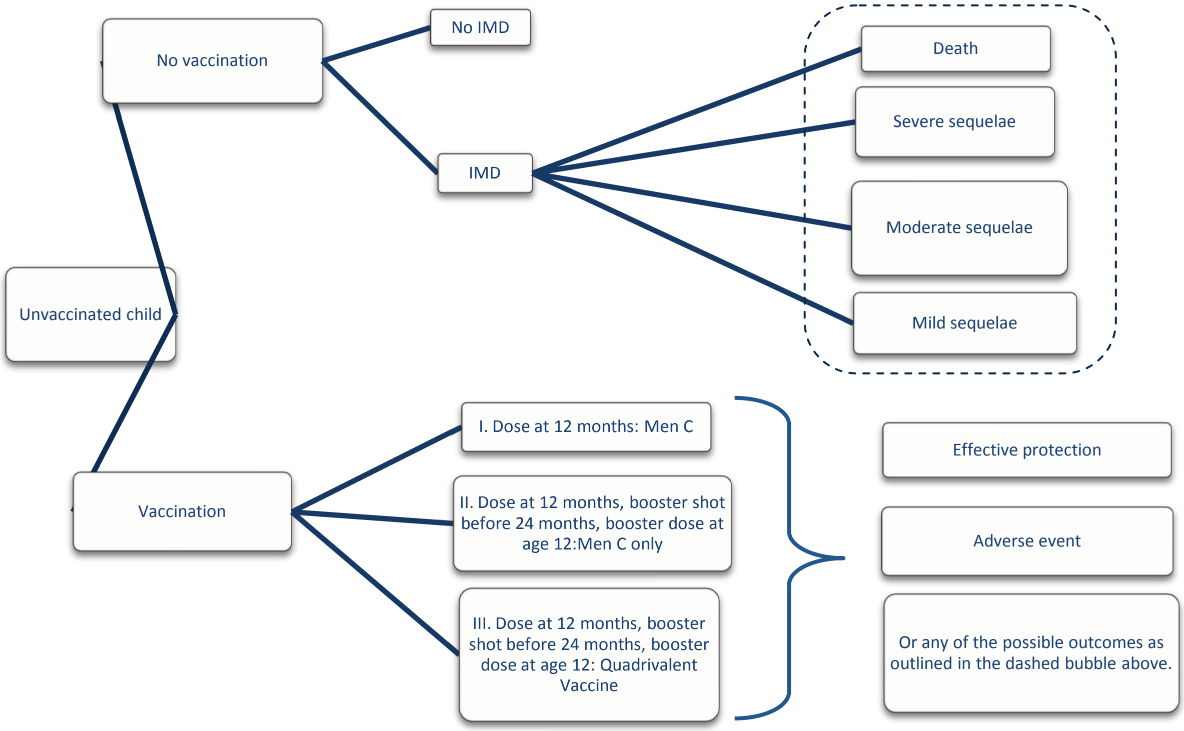
"Cost-effectiveness analysis is one form of full economic evaluation where both the costs and consequences of health programs or treatments are examined" (Drummond, et al. 2007, pg.102). Cost-effectiveness analysis uses measurements of monetary units. It is usually measured in natural units (such as life-years gained, disability-days saved, etc.), and a single effect of interest is identified, common to both alternatives, but achieved to different degrees (Drummond et al., 2007, pg.2). Our effect of interest would be vaccination against meningococcal disease; two alternatives would be keeping the present vaccination strategy or implementing a new one, and the degree of achievement would be the best vaccine option with highest protection against meningococcal disease. This concept is illustrated in the figure below in which 'O' represents the original or "old" intervention and 'A' represents the alternative or "new" intervention. If we are comparing the cost-effectiveness of old vaccine strategies versus new vaccine strategies, we would compare the two, where existing vaccine strategy = O and new vaccine strategy = A.

Figure 1. Cost-Effectiveness Plane: Methods for the Economic Evaluation of Health Care Programmes, by Drummond et al. 2007 (Third ed.).



A new intervention (or vaccine) would be viewed as desirable if evaluation revealed it to fall within quadrant I or II in the above plane. The slope of the line (between point O and A) is the cost-effectiveness ratio, typically expressed as cost per Quality Adjusted Life Year (QALY) gained. The cost effectiveness ratio which makes a new intervention acceptable may depend upon many factors such as budget impact, societal need or even political will. Traditionally, health interventions with a cost effectiveness ratio of less than $50 000 per QALY gained would be considered cost-effective and therefore would potentially be recommended or in some cases adopted (Drummond, 2007). However, this cost effectiveness threshold is outdated and felt to be somewhat arbitrary. A more recent approach sees economic evaluations in the field of cost effectiveness research adopting the WHO-CHOICE cost-effectiveness ratio (CER), which suggests a benchmark of less than three times the per capita gross domestic product (GDP) per "life year" (Hutubessy, R., et al., 2003). This benchmark also allows for varying "quality weights" as a metric for CER, such as QALY (quality-adjusted life year) or DALY (disability-adjusted life year) to name a few (Fisman, D.N., 2012). This benchmark is a more sensible *globally friendly* option, as it takes into consideration national population based levels of income as opposed to a certain amount of money attributed to a persons' life year gained or lost regardless of what economy they live in.

Figure 2. Decision-tree / data flow model for IMD.



Cost-effectiveness analysis can also be guided by a decision tree model, which allows comparison of clinically relevant immunization schedule to a base case of no vaccination program (Figure 2). This type of analysis also enables evaluation of costs of each vaccination strategy depending upon stratified assessment of outcomes: death; survival with severe sequelae; survival with moderate sequelae; survival with mild sequelae. The model cost inputs for such an analysis can be imputed from the literature or determined through prospective data collection as proposed in this thesis. Given the paucity of the data around the costs of IMD available in the literature, cost effectiveness models relying on such data will be imprecise and subject to the need for considerable sensitivity analysis. By conducting the prospective costing exercise proposed by this thesis, model inputs can be much more precise around the Canadian costs of IMD and results of such modeling much more compelling for Canadian decision-makers.

Vaccinating Adolescents Against Meningococcal Disease in Canada: A Cost-Effectiveness Analysis by De Wals et al., published in 2007, assesses the cost–effectiveness of a booster dose of meningococcal vaccine in adolescents using Canadian data. This publication is of particular interest as the authors simulated a method for assessing both the direct and indirect effects of vaccination. They also estimated cost-effectiveness of vaccination by assessing the three different vaccination strategies. The strategies of vaccination that the authors compare are: first, vaccination with meningococcal C conjugate vaccine at 12 months only; second, meningococcal C conjugate vaccine at 12 months with a booster dose at 12 years of age; and third, quadrivalent A, C, Y, W-135 meningococcal vaccine at 12 months with a booster dose at 12 years of age.

The authors discuss the economic parameters taken into consideration in order to estimate the cost-effectiveness of the booster option in the context of the two types of conjugate vaccines available to the Canadian market (meningococcal C conjugate vaccine and quadrivalent (A, C, Y, W-135) meningococcal vaccine). They considered short-term medical costs, where they included costs associated with hospitalization, costs associated with medical consultation before hospitalization, and chemoprophylaxis (prevention of secondary infection by public health). They also estimated short-term indirect costs that would cover sick leave for adults infected with meningitis. The authors provide references for assumptions; however the sources are around ten years old and most assumptions are based on non-Canadian data. Canadian data were not available to inform the model assumptions around short-term indirect costs or costs associated with sequelae. For the purposes of their study, the extent of the costs related to sequelae was sufficient, as they were only trying to show that inclusion of any sequelae makes a significant difference in overall costs, however evaluating the total economic burden of IMD is not discussed in any great detail. The study includes appropriate sensitivity analysis and provides a societal perspective. The societal perspective was based on Canadian statistics of age-specific mortality rates and distribution. However, vaccine efficacy is based on data from the U.K. and Spain due to absence of this information in Canada. Quality of life impact of IMD was not considered in the model.

The results of this study demonstrated a rate of IMD of 5.7 cases in the simulated one million study population at a cost over $735 000 in disease management post-infection in the “no vaccination” base case scenario. The model estimates a 28% reduction in cases (1.6 cases in the simulated study population) using meningococcal C conjugate vaccine at 12 months of age only with a total cost of $310 000 per one million simulated study population. Scenarios two and three, where booster doses are administered at age 12, are significantly more effective in disease reduction, 68% and 86% respectively. Although the third option of vaccination strategy proved to be more effective (86% vs. 68%) it is also more expensive for the government to fund. Based on this strategy, decision around supporting option two or three would have to be made.

This study by DeWals et al., identifies gaps in the Canadian data available to inform cost effectiveness modeling of immunization program options in Canada. Because insufficient Canadian data was available to inform the model, impacts of long-term sequelae were ignored, and significant direct, indirect, and intangible costs were also neglected. In this thesis, tools are developed to allow prospective data collection from patients and caregivers, which will fill these gaps.

Pediatric Infectious Disease Journal published *Long-term Sequelae of Childhood Bacterial Meningitis: An Underappreciated Problem*, by Chandran et al., in 2011. This article is written from the US perspective, and it describes and highlights some of the devastating issues that the survivors of bacterial meningitis have to face for the rest of their lives. It identifies a gap in literature by stating that: “[f]urther studies are needed to quantify the true societal and economic burden of long-term sequelae as well as fully understand the breadth of types of sequelae that survivors experience” (Chandran, A. et al., 2011). This thesis highlights the importance of economic burden that this disease has on survivors and their families. More importantly, this thesis focuses on developing tools that can be used to quantify the direct and indirect impact of IMD in both the patient (children and adults) and their caregiver, as well as propose established data collection instruments for use in assessment of quality of life impact on both the patient and their caregiver.

Chandran et al., effectively summarize the nature of the studies that have been done on this subject thus far. There are limited reports available on long-term sequelae for which survivors are followed for more than five years; in fact, studies examining long-term sequelae vary in their interpretations of what they consider “long term” to mean, and may only examine sequelae present immediately after survival of meningitis. Additionally, Chandran highlights the importance of the use of local, country or region-specific data to inform immunization recommendation by decision-makers. The use of data from regions/countries that are not demographically or economically similar is a significant limitation. While using studies from other countries can be informative, country specific data is critical for sound decision-making for a particular jurisdiction. Chandran et al. fail to address this important limitation in the article.

Although this thesis does not focus on estimating or suggesting the cost effectiveness of potential vaccination strategies, it aims to provide evidence-based tools for the comprehensive assessment of the cost of IMD in hospitalized patients. The tools developed as a result of this thesis will then be used by the Public Health Agency of Canada/Canadian Institutes of Health Research Influenza Research Network (PCIRN) Serious Outcomes Surveillance Network, to collect Canadian costing data, which can be used to inform cost-effectiveness analysis of potential meningococcal immunization program options in Canada, including the potential implementation of universal pediatric vaccination against *Neisseria meningitidis* type B.

Healthcare Utilization

Outlining healthcare utilization before proceeding to health economic analysis is critical (Schweikert et al., 2008, *"Development and first assessment of a questionnaire for health care utilization and costs for cardiac patients"*). As previously mentioned, incorporating a societal perspective is essential in order to develop an appropriate economic evaluation. A societal perspective includes cost components such as utilization of paid or unpaid home help, prescribed or non-prescribed medication, non-physician services or alternative care, various medical products, travel expenses to and from care facility, lost productivity time (such as labor costs for patients and/or their parents) and many other costs that may not be included in the direct (and most often hospital incurred) costs. Schweikert et al., report that of the total cost of illness incurred, indirect costs represent approximately 84%, while direct costs represent only 13%, the remaining 3% were non-medical costs. While the exact ratio of indirect to direct costs maybe disease specific, other studies also show that quantifying indirect healthcare utilization costs significantly increases the overall cost estimate of a disease (De Wals et al., 2011; Wright et al., 2010).

Only two published studies have attempted to fully define potential healthcare utilization associated with IMD. Karve et al. published a study on assessing health care utilization and costs among IMD (Karve et al., 2011, *Costs of Sequelae Associated with Invasive Meningococcal Disease: Findings from a US Managed Care Population*). The study compared two patients groups: IMD patients with no sequelae to IMD patients with sequelae. This study was retrospective in nature, the follow up period for assessing the associated costs was a 12-month period, and only third party payer (insurance claims) administrative data was collected. This study design showed that IMD patients with sequelae incurred costs three times higher than IMD patients with no sequelae, with mean costs of $96,826 and $32,414 respectively (Karve et al., 2011). This study method did not include any patient or other insurance co-payments, and no indirect costs were considered. Although the study poses many limitations, Karve et al. show that further health economic evaluations are critical for total economic assessment and a complete understanding of healthcare utilization around IMD. The dramatic increase in costs associated with sequelae does highlight the importance of longitudinal data collection and inclusion of long-term costs in economic evaluation to ensure a more accurate estimate of economic burden of disease. The authors validate this by comparing their results with a study by O'Brien et al., which only looked at hospitalization costs (O'Brien et al., 2006, *Managing meningococcal disease in the United States: hospital case characteristics and costs by age*). In an attempt to better define total healthcare utilization for IMD, the Meningitis Research Foundation (MRF) in the UK developed by Wright, Wordsworth, and Glennie and published in 2010 *Counting the Cost of Meningitis: A Severe Case of Meningococcal Septicaemia* and *Counting the Cost of Meningitis: A Severe Case of Meningococcal Meningitis*, use hypothetical two case-based scenarios designed to outline all healthcare encounters that an affected individual may experience (Wright, Wordsworth, & Glennie, 2010; *Counting the Cost of Meningitis: A Severe Case of Meningococcal Septicaemia* & *Counting the Cost of Meningitis: A Severe Case of Meningococcal Meningitis*). The authors achieved this detailed account of potential healthcare utilization by conducting face to face and telephone interviews with Meningitis Research Foundation (MRF) members. They also consulted with relevant healthcare and educational experts, social care professionals, Healthcare Resource Groups, health economists, and academics. After outlining all potential healthcare encounters, they assign costs to those via different perspectives: cost of disease to the survivor, to the families of the survivor, and to the healthcare system.

For both of these documents, the authors create a fictional individual and describe a scenario based on previous case studies, in order to guide the documents in estimating lifelong costs that are associated with IMD. Furthermore, they organize their cost collection into different costs: medical, and educational and social (Wright, Wordsworth, & Glennie, 2010). According to the hypothetical medical scenarios described, the authors elaborate on the different costs categories in great detail. Medical costs encompass the initial period of acute care hospitalization, the public health response and management, hospital and rehabilitation outpatient appointments, community therapies, prosthetic limb replacements and adjustments, cochlear implantation, pain management, epilepsy management, special medical equipment required, and any other relevant surgeries. Educational costs encompass employment of a learning assistant by individuals left with special education needs, special transport adjustment to and from school, and adaptations and equipment for school to adjust for special needs. Social care costs are outlined as direct costs to the state, indirect costs, and transfer payments.

Direct social costs include items such as government grants for adjustments that must be made to the family home in order to make it wheelchair accessible. The authors also include a special vehicle fund as a direct social cost, as often with a wheelchair a special vehicle is required for transportation of such a passenger. An indirect social cost is identified as lost earnings from a parent's job per year, and lost earnings from the survivor. The authors also include 'transfer payments' as indirect social costs. Transfer payments in this scenario include allowances for a caregiver to the survivor, child tax credits, disabled living allowances, housing benefits, and various tax credits supplied by various UK governments. The authors also take in account that individuals that are severely impacted by a disease might have a lower life expectancy than an average life expectancy, and therefore in the second document they predict their costs only up to age 55, this estimation is based upon expert opinion from pediatricians that were consulted.

While the hypothetical cost guidance documents developed by MRF identify legitimate healthcare utilizations that the impacted individuals are faced with, the types of costs that the authors outline in this document are very jurisdictional and most likely do not apply to Canada. In addition to the inapplicability of some of the costs outlined, the cost guidance documents proposed by MRF have several practical limitations; this makes their use as tools for conducting costing study, to define the total economic burden of IMD in Canada problematic. Although, the UK healthcare system is comparable to the Canadian system, the cost guidance documents that the MRF propose still lack the actual model of how to collect direct and social costs that the patient and their caregiver incur. Additionally, the MRF cost guidance documents fail to assess the emotional burden of this disease by looking at the quality of life (QoL) impact using standardized QoL questionnaires.

This thesis proposes a similar model for assessment of economic burden of IMD specific to Canada, with a focus on outlining direct and indirect healthcare costs, as well as defining the quality of life impact of IMD on patients and their family or caregiver. To achieve this, this thesis addresses the development and validation of data collection tools that allow collection of patient and caregiver incurred costs through comprehensive prospective identification of all healthcare utilization encountered following a diagnosis of invasive meningococcal disease.

Cost Collection Tools: Memory Aid

There are generally two approaches to collecting information from a target population: prospective and retrospective data collection. Retrospective collection of data requires collection of previously recorded information, whereas prospective collection of data requires collection of data into the future with set dates (i.e. from a certain date and to a certain date). Because retrospective data is data that already exists and was collected for other purposes, it is often limited, because not all information required is consistently available. Prospective data, on the other hand, is original data that is collected specifically for the study; it requires specific guidelines, standardized tools for collection of information, a pre-defined data collection period, and more resources. Both approaches have advantages and limitations. Because a comprehensive review of the literature concerning the economic burden of invasive meningococcal disease revealed a lack of complete information as previously discussed, this thesis proposes a collection of original data via a prospective methodology. The tool developed in this thesis, called a Patient or Caregiver Memory Aid, is a tool used by patients or caregivers, where healthcare utilization and its cost are tracked for a defined period of time (no longer than three months). The tool serves as an aid for the patient, to recall and record healthcare services that they used over the defined time period. Memory recollection alone causes significant underreporting of services previously used; this tool is designed in order to help eliminate the underreporting of those services used. Schweikert et al., discuss the impact underreporting, particularly around sick leave, where “indirect costs must be noted as this cost component is the dominant cost driver” (Schweikert et al., 2008). The same authors mention that multiple other studies (referenced in their article) found significant differences in underreporting of data that was collected via memory recall alone, versus prospective data collection, in particular around “comparison of hospitalization, sick leave, and physician visits” (Schweikert et al., 2008).

“The cost diary: a method to measure direct and indirect costs in cost-effectiveness research” an article by Goossens et al., published in 2000, recommends that studies which investigate cost-effectiveness of individual diseases ensure that their economic estimates include all relevant medical and non-medical costing data that are able to be collected. Goossens et al. offer evidence that a cost diary can be successfully used in cost-effectiveness studies of a societal perspective in nature if it is validated and tested for feasibility. Goossens et al. applied the cost diary to two patient populations: fibromyalgia and chronic low back pain patients. The study team decided that patients test the cost diary for either one week per month, two weeks per month, or for a full year. No significant differences were noted amongst the different time periods. Goossens et al. propose that self reporting questionnaires in form of a diary are important, because healthcare systems currently lack institutional records or tracking information quantifying the health services by patients and chronic disease and costs to the patient or institution for those services.

This publication focuses on three main themes: first, the development and content of the cost diary, second, the feasibility and data collection, and third, validity of the cost diary. In order to validate the collection of data through means of a costing diary, the authors use two randomized clinical trials, which included a sample of 72 and 133 patients over a two-year period. This article also only focuses on the methodological issues of a cost diary in general and not on the specific cost-effectiveness issues of health therapies that the sample patients used. This is of methodological relevance to this thesis, because healthcare utilization that the IMD study sample population are using are different than the ones that the sample population uses for the purposes of their health diary in the article.

Goossens et al. discuss the structure of the diary, including the time frame and duration of completion of the diary by patients. They also discuss the importance of pre-testing the diary before administration to the sample population. This stage is especially important, because it offers insight into clarity of the instructions for completing the diary, and provides opportunity to receive suggestions for improvement from the patient perspective. The importance of clear instructions for the diary is also mentioned in the discussion section of the article, thus amplifying the importance of clear instruction for filling out the diary. The authors do not discuss statistical sensitivity of the data collected from the diary. Goossens et al. provide compelling data about the utility of cost diaries in assessment of healthcare utilization cost and offer practical principles which should be adhered to in developing these tools. The article provides references that further support the use of a costing diary in collection of healthcare utilization costs incurred by the patient and their caregiver.

As published literature on healthcare utilization and associated cost for Invasive Meningococcal Disease (IMD) survivors is very limited and there are no published studies in evaluation of the total economic burden in regards to obtaining information via patient aids, a decision to expand the literature search to any acute disease was made in an attempt to find useful information pertaining to this thesis work. As previously mentioned, Schweikert et al. propose such research work in *Development and First Assessment of a Questionnaire for Health Care Utilization and Costs for Cardiac Patients*, published in BMC Health Services Research e-journal in 2008. Schweikert et al. identify the availability of valid and reliable measurements of health service utilization in health services research and health economic analysis as an important and under addressed gap. Although this is an internationally published article, it identifies another gap that the Canadian health care system also lacks: a single information source for comprehensive utilization and cost data of health services. Schweikert et al. provide useful information supporting methodology which uses a prospective questionnaire as a memory aid for patients and caregivers. This article is the most recent in proposing the methodology and includes the social care cost of a disease as well as the direct hospital cost, amongst many other costs involved in order to come to a total economic burden of a disease. The authors recognize the importance of adopting a societal approach in economic evaluations of a disease. Additionally, they recognize that in decentralized health care systems, such as in

Canada, effective cost information is collected via various sources in order to arrive at a complete economic evaluation.

The development strategy Schweikert et al. use to develop the questionnaires is of interest as they first develop a retrospective questionnaire to measure disease-related costs with 106 individuals and then compare the results from the retrospective questionnaires with the prospective questionnaires that they developed for the same patient population. The response rate of the prospective questionnaire is 88%, which is very acceptable for such a detailed collection of data from the patient population, demonstrating the feasibility of this means of data collection, even among patients experiencing a really severe illness. As expected, prospective data collection from the patient provided more detailed information than the questionnaire and correlated well with other methods of cost measurement. Some concerns about the use of a patient diary include the retention rate, the validity of the diary (e.g. are patient filling out the diary correctly and at the right times) and the reliability of the diary (e.g. how reliable is the information that the patients provide in the diaries). Schweikert et al. addressed all of these issues in their study and demonstrated that the use of such a diary is feasible and acceptable to patients and results in valid, reliable, comprehensive longitudinal healthcare utilization and costing data. While Schweikert et al. evaluated their data collection tools in a different target population; the use of such a health diary was demonstrated over a relatively long time period (up to a year at a time), which suggests that this methodology should be applicable to patients with IMD who are susceptible to long-term sequelae.

Summary of Literature

In summary, cost-effectiveness analysis is an important consideration for decision-makers around immunization program recommendations for prevention of IMD in Canada. Currently, comprehensive Canadian data is lacking, making assessment of relative cost effectiveness of different immunization program options impossible. Published methods for the economic evaluation of healthcare utilization are based on simulated models, highlighting the need for more precise Canadian data around IMD to inform health economic models. *Vaccinating Adolescents Against Meningococcal Disease in Canada: A Cost-Effectiveness Analysis* by De Wals et al. published in 2007, support the societal perspective chosen as the perspective for the methodology of this thesis work. Furthermore, the societal perspective is also supported by De Wals et al. 2011, Wright et al. 2010, as well as the work by Schweikart et al. 2008.

Healthcare services research around cost collection data emphasizes the importance of outlining healthcare utilization prior to execution of health economic analysis. Healthcare utilization can be collected to various degrees of specificity; economic analysis of a societal nature is broader and more encompassing than analysis of hospital incurred healthcare costs only. The UK Meningitis Research Foundation (MRF), authored by Wright et al., 2010, published documents describing hypothetical case scenarios that were informed by members of the MRF as well as a group of field experts, economists, and academics. The societal perspective relies on cost information provided by the patient as well as their caregiver. Literature around patient informed health costs regarding IMD were not found. A broader literature review showed that memory aids have previously been used in a patient population, that they prove very useful, are well accepted, and have a successful response rates of 88 percent (Schweikert et al., 2008).

Thus, collecting detailed costing and healthcare utilization data from survivors of IMD is challenging since many experience life-long health impacts and require extensive medical interventions and care beyond their hospital stay. Given the nature of IMD, retrospective collection of data is unreliable. Prospective data collection is clearly desirable, but can be problematic if patients are required to respond to periodic surveys of memory recall nature on all healthcare utilization; memory recall may be very incomplete, resulting in high underreporting. This thesis work proposes the use of a health costing diary, much like the one that Goossens et al. propose.

CHAPTER 3: RESEARCH METHODS

Purpose

As previously stated, the purpose of this thesis study is to provide information around healthcare utilization in an IMD population in order to provide critical evidence based Canadian informed data for evaluation of the total economic burden of the disease to better inform Public Health policy around immunization programs. Therefore, the main objectives of this chapter are to justify and describe the costing methodology chosen and to describe the process of outlining healthcare utilization associated with IMD. Further, this thesis aims to categorize the outlined healthcare utilization into direct and indirect healthcare costs, as well as discuss the intangible healthcare costs and lastly, to discuss the development process of the memory aid tools.

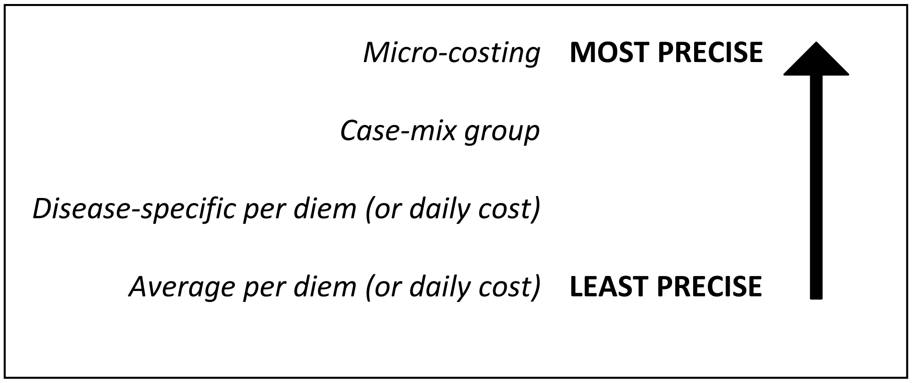
Choosing an Appropriate Costing Methodology: Societal Perspective

Health economics focuses around comparing options and choosing the best alternative for the scenario. Estimating costs in the context of healthcare economics entails the following steps: identifying costs (what that cost was for, e.g. type of medication), measuring costs (how many times was that cost used, e.g. how much medication was used over a set period of time), and valuing costs (what the actual dollar amount of that cost was) (Fisman, D.N., 2012). Further, after valuing costs, they can be compared with alternatives and an appropriate decision around uptake of choice can be made. In order to identify which costs to include in health economic evaluations, a decision around why that cost is included must be justified.

As mentioned in the literature review chapter, health economic evaluations must be undertaken from a certain perspective. Health economic evaluations can take a governmental perspective, a healthcare payer perspective, or a societal perspective. The cost-effectiveness ratio is affected by which perspective is taken. Welte et al. discuss this in detail in *The Role of Economic Evaluations in Vaccine Decision Making: Focus on Meningococcal Group C Conjugate Vaccine*, published in 2005. If one is interested in evaluating the total health economic burden of a disease, the most appropriate perspective is a societal one. A societal perspective not only includes hospital incurred costs, but also includes patient and caregiver incurred costs over a longer period of time. This is appropriate for IMD, because patients are often left with long term sequelae. Including patient and caregiver related costs provides insight into costs of an indirect nature and also allows for collection of intangible costs. It should also be noted that a societal perspective also considers costs over a longer period of time; hence this perspective is most appropriate for a longitudinal study, such as the one this thesis work supports.

There are various levels of precision when costing healthcare utilization (Figure 3). In health costing exercises, levels of precision are often only discussed around hospital attributed costs. Drummond et al., caution that prior to collection of costs, one must consider what degree of detail will be available at the time of cost attribution (Drummond et al., 2007). The least precise method of costing would be the '*Average per diem'* or daily cost, whereas the most precise level of costing would the '*Micro-costing'*. The level of precision used is of quantitative importance during the evaluation process (Drummond et al., 2007). The most accurate level of precision would clearly yield the best cost estimate results, however when data at a micro-level is not available, the next available level of precision should be chosen.

Figure 3. Levels of precision around hospital costing, adopted from Drummond et al., 2007.



Micro-costing is the most precise level of costing. Micro-costing is “an extreme approach” and would require detailed identification, counting, and pricing of every healthcare service (Polsky, D., & Glick, H., 2009, *Costing and Cost Analysis in Randomised Trials: Caveat Emptor*). The daily cost could be more practical to attribute, however important differences would be lost with this level of precision (Polsky, D., & Glick, H., 2009). During the process of outlining IMD related healthcare utilization it was evident that level of detail to be attained from varying participating hospital sites across Canada at this moment is still unknown. The diversity of resource use across Canadian hospitals may also not have the level of detail available that is needed for this precision. However, all foreseeable services used are included in hope that costs are able to be assigned. The healthcare utilization included will be described in the next section of this chapter. Due to this confounding factor, a case-mix level of precision is considered as the degree of precision for this methodology. Case-mix gives the cost for each category of case or hospital patient, it also takes into account the length of stay (Drummond et al., 2007). The Ontario Case Costing Initiative (OCCI) would be the only appropriate methodology that would fit this level of precision. OCCI also values “the cost of treating a patient over their entire episode of illness while in hospital and all services received after the patient has been discharged" (OCCI, 2010). However, OCCI methodology deals specifically with a hospital cost perspective, which in a case of total economic burden would lack the patient out-of-pocket, indirect costs, as well as the intangible costs.

Outlining Healthcare Utilization

The focus of this thesis is to outline all potential IMD-related healthcare utilization, and to develop and validate cost collection tools to allow prospective assessment of indirect costs. Identifying costs can only begin after appropriate healthcare utilization for a specific illness are outlined. IMD can leave infected individuals with varying degrees of sequelae, resulting in variability of health services use and intensity of use on per-case basis. In order to outline relevant healthcare utilization for this project the following steps were conducted: review of relevant published literature, a review of the Serious Outcomes Surveillance (SOS) Network data collection forms used for the IMD surveillance study already in place, and field experts consultations (members of the SOS Network). Healthcare utilization is outlined as events of occurrence. Events described here are similar to the flow model described in the second chapter (Figure 2. Decision-tree / data flow model for IMD).

In the case of IMD, sequence of events addressed in a health economic model would include the following healthcare utilization:

1. Routine vaccination against IMD under varying scenarios.
2. Secondary prevention in the case of an IMD outbreak response, considered from a public health perspective (Table 2).

3. Hospital/Acute care (in the worst case scenario, an individual could also face death, and associated costs should also be considered) (Table 3).
4. Post hospital discharge – short and long-term (or life-time) healthcare utilization for survivors, which will vary depending on severity of disease and sequelae (Table 4).

To address the complexity of assessment of the total economic burden, all of the events outlined are broken down and event specific costs are outlined. Routine vaccination against IMD under varying scenarios entails the following: cost of vaccine per dose + cost of equipment (syringes used, alcohol swabs) + cost of health professional time + cost of adverse effects. In cost effectiveness analysis, different vaccines can be compared as cost per dose may vary depending on the type of vaccine used (Meningococcal C Conjugate Vaccine (MCV-C) vs. Quadrivalent A, C, Y, W-135 Meningococcal Vaccine (MCV-4)). Literature shows that comparing different types of vaccines can result in price differences as high as three times the costs (De Wals et al., 2007). From a societal perspective, we are also interested in public health prevention of secondary cases in the event of an IMD outbreak in a community. Once all relevant activities are outlined, costs can be assigned to each item individually. Basic categories attributable to the outlined activities or services are: number (or measurement) of times that particular item was used (units, codes), “base value or range” of costs of that unit (costs may differ from one hospital institution to another), and the “source of information” for the cost in order to ensure validity, reliability, and to be able to track that information back to the original source. Outlining some secondary prevention items would therefore include the following items for consideration:

Table 2. Public Health Prevention of Secondary Cases - Costs associated with prevention of secondary cases.

Public Health Prevention of Secondary Cases	Measurement (units, codes)	Unit Cost	Base Value (and range)	Source of Information/Reference
Meningococcal Cases Identified				
Close Direct Contacts Given Prophylaxis				
Chemoprophylaxis				
Vaccination				
Administration				
People in Community Given Prophylaxis				
Chemoprophylaxis				
Vaccination				
Administration				
Health Staff Needed to Carry out Intervention				
Nurses				
Specialist				
Other Support Health Staff				
Materials Needed				
Syringes				
Medication				
Tray Fees				
Other Materials (i.e. swabs, bandages)				
Community Staff Needed to Carry out Intervention				
Fire				
Police				
Emergency				
Volunteers				
Public Relations				
Toll-free help phone lines				
Public Information/Advertising				
Staff Needed				
Total				

It is also important to note that the Public Health management of this disease may constitute of variable tiers of intervention such as: individual case management, secondary case management (where family members of an infected individual may be given prophylaxis), as well as public health management of an outbreak (in which case Table 2. is incomplete and would also include rental of a space for outbreak management, amongst other necessary supports).

Next, acute care costs are considered and outlined. These items were outlined through relevant literature, hospital patient charts, and data collection forms proposed for use in the IMD surveillance study conducted by the SOS Network.

Table 3. Costs Associated with Acute Care.

Acute care
GP Assessment
Ambulance Cost (if necessary)
Transferr
ER Assessment
Diagnostic Testing
x-Rays
CT-Scans
MRI
Ultrasounds
ECGs
Other (specify)________________
Lab Testing (orders)
Haematology
Coagulation (eg. INR)
Routine Urinalysis
Chemistry
Blood Gases
Blood Bank
Toxicology
Other (specify)________________
Lab Testing - cultures
Blood
CSF
Pleural Fluid
Urine
Throat Swabs
Sputum
Bronchial/Bal Specimen
NP Swab
Joint Fluid (specify)_________________
Perioneal Fluid (specify)_____________
Other (specify)________________
Medication
Antibiotics
Anti-virals
Other (specify)________________
Procedures
Intubation
IV Theraphy
PCR-ID bacteria,serotyping for strain
Surgical Intervention
OR Cost
Equipment
Surgical Staff
Surgeon
Nurses
Surgical Assistants
Ventilatory Care (Mechanic)
Oxygen Theraphy
Chest tube
Central/Arterial Line
Transfusions
Tracheotomy
Thoracentesis
Bronshoscopy
Catherization
Dialysis
Other (specify)________________
Hospital Bed Cost (*length of stay)
ICU Daily Care
Critical Care
Comprehensive Care
Health Professional Time
Nurse
Specialist
Care Team
Ward Daily Care
Consultations
Referring Hospital Costs
Re-admitted to acute care
Death Related Costs
Other
Total Acute Care Cost

The outlined services in Table 3 would potentially lead to a micro-costing approach; however the level of information collected is case dependant as individuals may require varying levels of treatment post infection. Hospital costing data may also vary from region to region and may not be available on micro-specific level; hence a case-mix approach would be preferable, as information at that level of precision could potentially be collected. Acute care costs also include costs incurred in the event of hospital re-admission, referring hospital costs, and in the worst case scenario, death related costs. All items outlined in Table 3 would also be assigned the following attributes (categories outlined in the columns): measurement or how often that one item is used (in codes or units), the value for that measurement, base value or range of cost of that particular item, and the source or reference for that item (as in Table 2).

Often, patients discharged from acute hospital care still face treatments by specialists and other care providers; some examples include: physiotherapy, occupational therapy, rehabilitation services, speech and language therapy, and many others. These visits, including associated educational costs and social care costs should all be included in the assessment of short-term costs collected post hospital discharge for a set period of time. Educational costs should refer to any costs that an individual would incur besides their regular cost of education; the same can be justified for social care costs. Anything over and beyond the normal cost of living should the disease not have happened to that individual, should be considered for inclusion. Short-term costs would also be inclusive of acute care and any hospital re-admissions that an individual would face prior to their discharge from hospital care. Thus, all items from the onset of the illness to a defined time point (disease specific) should be included in short-term estimate of the total economic burden of illness. All items outlined in Table 4 would again have the same categories of measurement, valuation, range, and source of reference (as discussed around Table 2).

Table 4. Short-term Associated Costs.

Medical Costs
Acute care (see Acute Care)
Public Health (see Secondary Prevention)
Hospital Outpatient Appointments
Paediatrician
Neurologist
Neurosurgeon
Orthopaedic Surgeon
Orthotist
Opthamologist
Community Medicine
Community Paediatrician/Family Doc
Community Physiotherapist
Hydrotherapy
Community Occupational Therapist
Health Home Visitor
Speech and Language Therapist
Cochlear Implantation
Full Assessment/Hearing Specialist
Bilateral Implantation
General Health Problems
Pain Medication Costs
Constipation
Double Incontinence
Other
Epilepsy Management
Epilepsy Medication Costs
Epilepsy Related Surgeries
Epilepsy Related Hospital Stay
Special Equipment Costs
Walkers
Benches
Standing Frames
Sleep Systems
Wheelchair + Maintenance
Orthotic Shoes
Communication Aid
Shunt Revision Surgery (if necessary)

Educational Costs
School
Special Needs Nursery
Special Needs School
Transport
Special Education Needs

Social Care Costs
Direct Social Costs
Disabled Facilities Grant Government Funded
Government's Specialized Vehicle Fund?
Social Care Assessment (home visits)
Home Care
Respite Care
Indirect Social Cost
Wage - Lost Opportunity From Parent's Job
CPP
Employement Insurance
Lost Tax Revenue From Parent's loss of income
Federal Tax
Provincial Tax
Loss of Income from the idividual over lifetime
Employement Insurance
Employement Insurance
Loss of Tax Revenue from the individual
Federal Tax
Provincial Tax
Child Tax Benefit
Disabled living allowance
Other Services
Family Resources Used
Additional Household Expenditures
Informal Caregiver
Total Cost

In order to allow for generalizability of the cost results generated, IMD cases should be stratified into three levels of severity: mild – cases with no sequelae, moderate – cases with short-term, self limited (< 1 year) sequelae, and severe – cases with long-term (≥ 1 year) sequelae. Any impacts reported beyond the first year post initial infection, are severe cases and should be followed for a minimum of three years in order to be able to gain an understanding of a more complete healthcare utilization picture. Collecting information from individuals for this long would also allow us to estimate the life-long impact of the disease. Long-term associated costs would entail the same kinds of items as outlined in Table 4 with the exception of the time frame. For example, an individual whose hearing has been severely impaired would continue with cochlear implantation device maintenance over their lifetime. Health economic evaluations that collect information for a certain set period of time, and based on that estimate costs over life-time, also include consideration for a method called discounting in order to account for economic impact of future inflation and increase in costs of living over time. Discounting is usually adjusted for differential timing, meaning that the rate chosen considers the present value of the identified items against future estimation of that same item value. As Drummond explains: “future dollar cost... ‘discounted’ to reflect the fact that dollars spent or saved in the future should not weigh as heavily in program decisions as dollars spent or saved today” (Drummond, et al., 2007).

Assigning Costs

Tables two, three, and four represent items that are of critical importance when collecting information around healthcare utilization. Outlining healthcare utilization is an imperative step in economic evaluations. Once all relevant potential healthcare utilization has been outlined, costs must be assigned. Before that can be done, potential means by which cost information can be obtained must be considered while outlining utilization. In order to better source costing information and assess the availability of data, costs can be categorized to: direct costs, indirect costs, and intangible costs.

Assigning Healthcare Utilization into Cost Categories

Direct costs are all disease associated costs in the health care sector (Drummond, et al., 2007). In the case of cost-assessment in IMD, direct costs would include cost of routine vaccination and cost of secondary prevention in the case of an outbreak response (Table 2) and acute care costs (Table 3) and required medical services, equipment and medication used to manage sequelae (Table 4). Information around direct costs can be gathered directly from the hospital providing the services, pharmacies and insurance providers. While some data is readily available, particularly for acute hospital costs, quantifying direct costs associated and long-term sequelae can be difficult. Patients with sequelae and their caregivers may require social care support (such as expensive rehabilitation equipment loaned by organizations like Red Cross). The cost of this is a direct cost to the healthcare system, and must be considered in health economic models, which take a societal perspective. Patients with sequelae may also be left with physical and behavioural issues, which impair their capacity to function normally, and may result in direct costs to the educational system, including special transport due to mobility issues, special equipment and the need for in-class support personnel. Sequelae may also result in life-long complex medical and functional problems such as epilepsy, disability due to amputations and hearing loss. Thus, direct costs and the direct impact of this disease would be grossly underestimated if only immediate acute hospital care is considered.

In health economic evaluations, indirect costs have been interchangeable with loss of productivity, loss of leisure time, missed work-opportunity (Drummond et al., 2007). Indirect costs “refer to the value of production lost due to illness-related absence, such as the number of days absent from work and days lost from housekeeping and other daily activities” (Goossens et al., 2000). Indirect costs are often ignored in decision-making processes, but it is imperative that total economic evaluations consider the indirect costs in order to portray a more accurate burden of the disease. Societal perspective focuses on a complete picture of costs involved around an illness, with an emphasis around patient and caregiver out-of-pocket healthcare costs not directly associated with acute care. Typically, indirect costs are those incurred by patients and their caregivers during and after their hospital stay. During the hospital stay, many patients face unexpected costs around transportation to the nearest hospital, missed opportunities at work or school, care for any dependants, and missed opportunities around their leisure activities. Frequently, as described in the review of the literature, these indirect costs are not considered in health economic evaluations. However, all are healthcare utilization that need to be addressed as indirect costs of this illness, if one is examining cost from a societal perspective. Following hospital discharge, patients and caregivers are faced with other items that are not considered as direct costs to the healthcare system. These include lost opportunity of work due to medical visits to various specialists, transportation to these visits, and childcare needs for dependants. These indirect costs can represent a significant proportion of the overall cost of IMD and must be considered when weighing the cost-benefits of one vaccine or vaccine schedule over another.

In addition to direct and indirect costs, total economic burden of IMD must also include intangible costs. Quality of life (QoL) can be measured with validated questionnaires. Intangible costs focus around the impact an illness has on the quality of life change to the patient and the caregiver. Typically, intangible costs, are costs that are quantified using a health utility index such as QALY. As mentioned in the second chapter, while clearly a potentially important contributor to overall cost of IMD, little regarding the impact of IMD on QoL is available from the literature. QoL questionnaires aim to provide a single utility index, which can then be used to measure the level of impact in terms of the quality adjusted life years (known as QALY's) in overall cost-effectiveness studies. Two QoL questionnaires were considered for use by the IMD patient population and their caregivers in order to provide collection tools for intangible costs in the IMD population. Based on review of the literature, both the SF-36 and EQ-5D are recommended for this population (Noyes, K., & Holloway, R.G., 2004, *Evidence from Cost-Effectiveness Research*).

The SF-36 is a generic health survey and is used for a wide variety of applications (Quality Metric, 2011). SF-36 is comprised of eight health domains, which yield a mental and physical health score. This survey is particularly used for adults and is therefore recommended for use with older IMD patients (≥ 16 years of age) and their caregivers. Due to the nature of the questions, more reading and comprehension is required making the SF-36 an inappropriate choice for younger patients.

The EQ-5D is a standardized instrument for use as a measure of QoL outcome (EuroQoL, 2009). Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. EQ-5D is designed for self-completion by respondents and offers multiple modes of administration. It is cognitively simple, and takes only a few minutes to complete. Instructions to respondents are included in the questionnaire. The EQ-5D can generate a utility value of the patient's current health state between 0, indicating a health state equivalent to death, to 1, which indicates a perfect health state. As previously mentioned, this utility value can then be used in QALY's gained or lost in cost-effectiveness studies. EQ-5D is short, and visually simple, it can be used for IMD patients as young as seven years as well as their primary caregivers.

Both of the above QoL questionnaires generate a health state preference value (or otherwise known as health utilities). This utility value (ranging from 0 to 1) can then be applied to the overall cost effectiveness analysis through measures of cost utility. Cost-utility analysis is identical to the cost-effectiveness analysis, apart from the outcomes (Drummond et al., 2007). Intangible, QoL health state value constitutes as one of the three (direct, indirect, and intangible) main outcomes of our total economic burden estimate of IMD. According to Drummond et al., cost-utility analysis should be used when quality of life is an important outcome (Drummond et al., 2007). This thesis work proposes that the intangible cost estimate solely relies on the quality of life impact and its generated health utility value, highlighting the need for this concept. After identifying the health utility value, a quality adjusted life year gained (QALY) can be calculated and incorporated into the overall cost-effectiveness analysis.

Development of the Memory Aid Tools

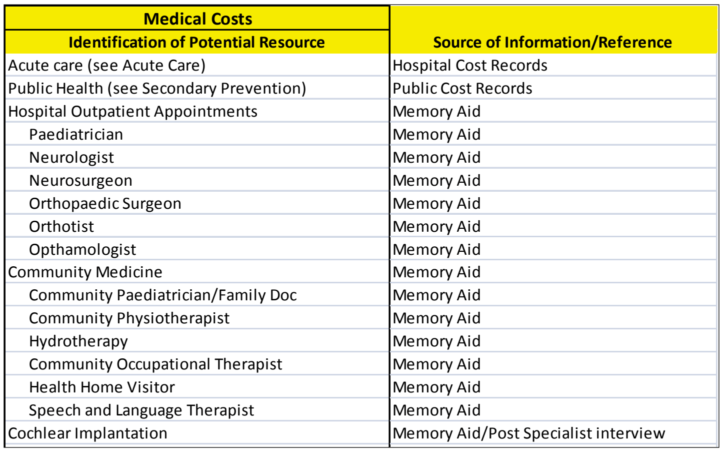
Health economic evaluations rarely focus on indirect healthcare utilization, since cost collection around it is often difficult and relies solely on patient recall. Studies show that this can be eliminated with a patient or caregiver cost collection memory aid. Literature review (Chapter 2) confirms the response rate of using such tools at about 80 – 90 percent, as well as high validity, and reliability of such tools in economic evaluations. Relying solely on patient recall results in high underreporting of healthcare services used and associated costs (Schweikert et al., 2008). The focus of this thesis work is around development of memory aid tools for use by patients and caregivers in order to capture relevant indirect costs. Similar in process to the one described around outlining of healthcare utilization, the development of patient and caregiver memory aid tools was sequential in nature.

During the hospital admission and stay patients and their caregivers are faced with various costs, which would not be captured during the process of outlining healthcare utilization around acute care costs, and some of these were outlined during the description of indirect healthcare costs. To allow capture of these indirect costs, a collection tool was developed to enable patients and caregivers to itemize out-of-pocket expenses during their hospital admission and stay (see Appendix A & B). Appendix A includes questions around how the patient arrived to the hospital and how they went home post discharge. Next, the questions focus on whether or not there was any missed opportunity for work or school, as well as leisure activities. Last, if the patient has dependants, whether or not they needed to arrange care for those dependants. During a patient's hospital admission, the patient's caregiver burden is also included in the healthcare costs as they not only experience great emotional turmoil, but the sudden onset of illness can have substantial economical impact as well. Appendix B focuses on gaining insight around the impact the patient's hospital admission has on the caregiver. Information around transportation costs to and from hospital for the duration of the patient's hospital stay are included. Meals are always provided for the patient in the hospital; however, caregivers are often there for long hours and sometimes for days during severe cases, therefore questions around incurred food costs are asked as well. Missed opportunities such as work time, student time, and leisure time are considered. Finally, if the caregiver has dependants that need care during this time, questions around care for any dependants are included as well. Both the patient and caregivers expenses during hospital stay (Appendix A and B) are provided with additional space should they feel that there are further details to include. The additional information provided by the patient or caregiver is collected, and a decision around whether or not that information should be included in the final economic evaluation is made by the research investigator.

Following hospital discharge the patient and the caregiver are left with the largest portion of indirect burden of this disease. To gain a better understanding of the services used and their associated costs, a memory aid in the form of a diary which can be used over several months at a time was developed. In cases where a patient is able to complete the diary themselves a Patient Confidential Memory Aid (Appendix C) should be used. In some cases, a patient will have moderate to severe sequelae and they will require assistance in completing the diary, in this scenario, a Caregiver Confidential Memory Aid (Appendix D) should be used. Both memory aids capture the same information; the memory aid tools only differ in instructions on how to complete the diaries. The Patient Memory Aid instructions speak directly to the patient, and the Caregiver Memory Aid speaks directly to the caregiver and instructs the caregiver to try and answer questions both as the patient and as their caregiver. The consistence in memory aid formats for both the patient and the caregiver would eliminate double counting of costs incurred by the family as a whole.

The memory aid (apart from the instructions, the Patient and the Caregiver Memory Aid are designed to collect the same information) is comprised of two parts. The first part of the memory aid collects information about each Health Professional visits following the initial hospital discharge (Part I in Appendix C). For this part of the memory aid, examples around what constitutes as a health professional are provided. Specific instructions around how to answer the questions as well as the corresponding answer boxes are also provided. The first part of the memory aid also collects information on hospital re-admissions for complications, if relevant due to this disease. The Patient and Caregiver Memory Aids will provide much of the information outlined in Table 4. For example;

Table 5. Medical costs with Source of Information/Reference.



Medical Costs	
Identification of Potential Resource	**Source of Information/Reference**
Acute care (see Acute Care)	Hospital Cost Records
Public Health (see Secondary Prevention)	Public Cost Records
Hospital Outpatient Appointments	Memory Aid
Paediatrician	Memory Aid
Neurologist	Memory Aid
Neurosurgeon	Memory Aid
Orthopaedic Surgeon	Memory Aid
Orthotist	Memory Aid
Opthamologist	Memory Aid
Community Medicine	Memory Aid
Community Paediatrician/Family Doc	Memory Aid
Community Physiotherapist	Memory Aid
Hydrotherapy	Memory Aid
Community Occupational Therapist	Memory Aid
Health Home Visitor	Memory Aid
Speech and Language Therapist	Memory Aid
Cochlear Implantation	Memory Aid/Post Specialist interview

Although, the above table represents only a small proportion of items to be referenced, we can see that most of the direct medical costs such as outpatient and specialist appointments would actually be sourced by the memory aid information provided by the patient and caregiver.

Due to the fact that a lot of information is asked, the focus while developing the tools was to create something that was visually simple. On the fourth page of the memory aid (see Appendix C, page 4 of 11) different categories were outlined in boxes of diverse colors, for example: possible treatments for IMD are in a red box, with the corresponding question on treatments received on the very adjacent page of the memory aid, therefore red box of examples correlates to the red row of questions. The same qualifies for the green box of diagnostic test examples with the adjacent green row question around diagnostic tests received.

The columns of this part of the memory aid aim to identify who incurred the cost for the particular service used. Generally, medically necessary services are covered by the provincial insurance. If not, most individuals have private insurance coverage, and in case where items are partially covered or not covered at all by private insurance, personal out-of-pocket cost is incurred either by the patient or the caregiver. Section two of the first part of the memory aid is on the next page of the memory aid, this section focuses on indirect costs related to the medical visit; i.e. missed work due to the medical visit by both the patient and caregiver, as well as transportation costs to and from the medical visit (Appendix C, page 6 of 11).

The second part of the memory aid follows the same format and style as described in the first part of the memory aid. However, the second part of the memory aid focuses on more indirect, long-term burden, such as community services used (blue box on page 7 of 11 Appendix C), over the counter medication and equipment used, household costs and chores. Items that would fall under this category of costs would be any respite care and home support workers used by the family, depending on the severity of the case, some families may use support by community help groups such as Red Cross (for example: bed loans for severely impacted patients). Some patients experience skin scarring for which ointments purchased over the counter is a viable, but health insurance non-covered, treatment option. Over the counter medication and equipment purchased would be patient out-of-pocket costs not necessarily captured in traditional patient memory recall interviews. The final two tables ask questions focused around education and social care costs and funding. A societal perspective includes all costs, no matter to whom they accrue, hence if families receive funding for special education or funding for special child tax or disability, the cost is accrued to the government. Often, the burden of IMD is so heavy, that at least one parent stops working in order to help out during the patient's illness, this would then be accounted for as wages lost by that parent.

Throughout the process of the memory aid development, consultation was sought from the research team, consisting of research assistants, nurses, statisticians, academics, and field experts. The tools were designed with great consideration that they were going to be used by patients and their families; therefore, the main focus of the memory aid tools is to be user friendly, clear, logical, and easy to use. The memory aids are also designed so that the research investigator can choose to collect the memory aids in paper form, or only collect the information via a telephone interview. Most individuals have someone taking care of them; hence caregivers' costs are included and in some cases, where the patient is so severely impacted, solely collected from the caregiver. All memory aid material is provided with research team contact information, in case of questions around how to complete the memory aid or uncertainties around what services and costs should be included (Appendix C & B, page 2 of the memory aids).

CHAPTER 4: PILOT STUDY AND RESULTS

Chapter three discusses the methodology for an appropriate collection of costs. Healthcare utilization are outlined and categorized as direct, indirect, and intangible costs. Use of memory aid tools is proposed. The development of the memory aid tools is described. In order to evaluate the tools developed, a pilot study was conducted to assess content validity, readability/flow, clarity, and ease of use of the proposed data collection instruments. This chapter describes content validity and details the methodology and results of the pilot study.

How to Evaluate the Tools: Content Validity

Content validity is the degree of content relevance of the items in a survey or questionnaire (Polit, D.F., & Beck, C.T., 2008). Content validity can be evaluated qualitatively, quantitatively, or both. This pilot study focuses on qualitative evaluation of the proposed data collection instruments in order to assess readability/flow, clarity, and ease of use. Pilot testing of the data collection tools also provided an opportunity to assess the feasibility of the proposed study design using the data collection tools to prospectively collect patient-reported health services utilization from IMD patients enrolled by active Canadian surveillance Networks.

In order to allow participants of the pilot study to provide input on the data collection instruments, modified instruments were developed, which included all elements of the proposed Memory Aids, but which also incorporated rating scales on which participants graded the question(s) on various factors (Appendix E-H). The content validity assessment consisted of two parts: (Part I) rating scales for each question assessing readability and clarity and (Part II) general open-ended questions seeking input on overall structure of the tool including flow, ease of use, clarity of questions and instructions and relevance. Participants were also given an opportunity to provide suggestions on how the tools could be improved.

The primary objectives of the pilot study are twofold:

First, to test the content validity of:

- The Patient and the Caregiver Hospital Admission and Stay Expenses Tool (See Appendix E and F, respectively)
- The Patient and the Caregiver Memory Aid (See Appendix G and H, respectively)

Second, to modify the data collection tools based on the feedback received from the participants of this pilot study.

Participants

Due to the low incidence rate of IMD, and in interest of time for the purposes of this thesis work, the pilot testing of the tools was conducted in a convenience sample of patients admitted to participating hospitals with more common diagnoses that are close to and/or comparable in the severity of impact. Conducting the pilot study with diseases other than IMD also allowed evaluation of the potential generalizability of the tools to patients with other diagnosis.

Participants were enrolled at two Nova Scotia hospitals: the IWK Health Centre, which is a pediatric acute care facility and the QEII Health Sciences Centre, an adult acute care facility. Both participating hospitals are active sites of the Serious Outcomes Surveillance Network and the Immunization Program Monitoring Program (IMPACT).

Participants were eligible to participate in the pilot if they met one or more of the following inclusion:

- Patients admitted to participating hospitals with diagnosis of:
    - Community acquired pneumonia (CAP)
    - Invasive pneumococcal disease (IPD)
    - Acute exacerbation of chronic obstructive pulmonary disease (COPD) or asthma in adults ≥ 16 years of age.
    - Asthma in children < 16 years of age.
- Willing and able to sign a written informed consent. If the patient is unable to sign the consent this may be signed by their authorized decision maker.

Patients were not eligible to participate in the pilot study if they met any of the following exclusion criteria:

- Inability of the patient or their authorized decision maker to complete interviews and questionnaires in English.

The target sample size for the pilot study was 10: 5 adults (≥ 16 years) and 5 children (< 16 years).

Recruitment

All patients presenting with CAP, IPD, asthma and acute exacerbation of COPD were approached for participation in the pilot study until a total of ten participants (5 adults and 5 children) were enrolled. Potential adult study participants were identified from a list of participating subjects in active studies being conducted by the Serious Outcomes Surveillance

(SOS) Network for CAP, IPD, and COPD. All potential participants were given preliminary information about the pilot study by the SOS Network Monitor with whom they already had a relationship and all had given permission to be approached by the student for discussion about potential involvement in the pilot study. If they agreed to participate, they were approached for consent. Pediatric patients were identified by screening daily admissions logs for eligible diagnoses. The patient's care team was approached and asked to confirm whether the patient was an appropriate potential participant in the pilot study. Permission was then sought by the care team to have the patient seen by the student for consideration of a study. Those children or their caregivers who gave permission were approached by the student for consent.

Study Procedures

During the first visit, written informed consent was sought from the participant or their legally authorized representative as appropriate (Appendix L-N). This procedure took approximately 20 minutes to complete. The study was explained and patients were given time to read the informed consent form. All questions asked by patients were answered to their satisfaction and participants signed written informed consent for participation in the pilot study. Participants were given a signed copy of the consent form and were notified that the second visit will occur just prior to their discharge from the hospital. During the second visit, the patient and their caregiver were instructed on how to complete the Memory Aids and content validity rating scales as well as the general comments section of the assessment tools. The patient and their caregivers were asked to complete the following tools:

- Patient Expenses during Hospital Admission and Stay – Appendix E

- Caregiver Expenses during Hospital Admission and Stay – Appendix F
- Patient Confidential Memory Aid – Appendix G
- Caregiver Confidential Memory Aid – Appendix H

Participants were instructed that they would need to spend no more than a few minutes each day to complete these tools. The second visit took approximately 30 minutes to complete. The last visit, visit three, took place 30 days after discharge from the hospital. Arrangements were made to contact them 30 days after discharge from hospital by telephone, to review their responses and to collect answers around content validity. The time required for this interview was expected to vary depending on the extent of data that the participant felt they had to report and was anticipated to take 30 minutes to one hour.

Ethical Considerations

Research ethics approval was sought and obtained from both participating hospitals, IWK Health Centre and QEII Health Sciences Centre - Capital District Health Authority (CDHA). Additional, Dalhousie University Research Ethics Board (REB) approval was not required. Only the study staff had access to the study files during the study. Representatives of the REB from IWK or the CDHA may have access to study records for audit purposes. Information that links a participants’ study file with their personal information is stored in locked file cabinets in locked offices accessible only by the study staff. At the end of the study, the files were stored in locked offices, which are only accessible by study staff. Long term storage is at the archiving facility, which is used for hospital medical records. Access to the study records after archival, is restricted to members of the study team only. If a participant requests access to their file, this can be facilitated by the study investigator.

Study participants are identified on the study documents only by a code, no medical or personal information is included in the study data collection forms. Study consent forms, that link participants with their study numbers are kept in locked filing cabinets in locked offices, and are only accessible to study staff as needed for the conduct of the study. Study records are maintained for at least seven years as per IWK and CDHA policies. Currently, the Canadian Center for Vaccinology keeps all records indefinitely and does not have a policy for destroying information after archiving.

Analysis

This is a qualitative, descriptive study. Participants were asked to rate the user-friendliness, clarity and ease of flow of each section or question of the Memory Aids on a 4-point Likert Scale where 1= strongly disagree and 4= strongly agree. Mean scores and ranges were calculated for all questions/sections. Open text fields were transcribed verbatim and general themes were derived.

Description of Tools

The memory aid consists of two parts with a set of instructions and examples of the kinds of things that the patient might encounter during their illness. The first part of the memory aid consists of a box presented on a single page. It asks ten general questions, which are answer dependant on whether more answers need to be provided. The questions are rated based on user-friendliness, clarity, and how easy they are to follow. The single page box also includes columns, which entail questions around how the healthcare utility or service was paid for. The second part of the memory aid consists of a table of examples of services that the patient might use, with five specific tables. The first two tables are supposed to generate a list produced by a patient on either community services used, or over the counter medications or equipment purchased, both tables have corresponding columns, which focus on gathering information on how those services, medication, or equipment were paid for. Should the patient not incur any of the above, they would simply check the box “none used” and not complete that table of questions. The following three tables have separated rows with a yes or a no answer; these again lead to corresponding columns, which focus on gathering information on how the healthcare utilization in question was paid for. Should additional information need to be shared and the question around that healthcare utilization was not asked, a separate page is provided for feedback. The memory aid’s content is the same for both the patient and the caregiver; however as previously described in chapter three, the instructions on how to complete this tool are slightly different.

“Patient Expenses during Hospital Admission and Stay” is comprised of five questions with variant response options that focus on gathering information on how much they cost. The “Caregiver Expenses during Hospital Admission and Stay” for the patient is comprised of five questions with variant response options or sub-questions, which focus on gathering information on how much they cost the caregiver specifically. Both of the tools, have additional space provided should there be other relevant costs no tasked in the five questions.

All questions for content validity are identified with a red brace with the content validity “question number” identified right next to it for easy identification. The questions are then rated in a table format by the study participant on a scale of one to four, with one being ‘strongly disagree’ to four being ‘strongly agree’. There are three categories used for this portion of content validity: user friendliness, clarity, and how easy to follow the questions were. Next, the overall survey design is asked to be rated. Survey design questions focus around, whether or not the participant thought the question items flowed in a logical order, whether the directions on how to complete the questionnaire were clear and easy to follow, as well as comments around items that lacked clarity, suggestions on any items that need to be re-worded, and general survey improvement ideas. Appendix G and H are the short in hospital expense and stay tools, they each contain five questions around user friendliness, clarity, and how easy to follow that question was, and five questions around survey design. Appendix I and J each contain two content validity surveys. First survey is based around each individual health professional visit (or Part I of the memory aid), this content validity survey contains ten questions around user friendliness, clarity, and how easy to follow that question was, as well as five questions on the overall survey design. The second survey is based around the second part of the memory aid which focuses on services used over a longer period of time. The content validity survey contains 14 questions around user friendliness, clarity, and how easy to follow that question was, as well as five questions on the overall survey design.

Results

Ten participants (n=10) were recruited and enrolled at both Capital Health and IWK hospitals. Two participants were lost to follow up, resulting in eight (n=8) participants who completed the pilot study. Adult participants (n=4) had a mean age of 50.25 (range 37 to 62); pediatric participants (n=4) had a mean age of 7.88 (range 18 months to 13 years); a total of 5 caregivers also participated. Participants admitting criteria included community acquired pneumonia (2 adult and 1 pediatric participants) and asthma (2 adult and 3 pediatric participants).

All ten consenting participants participated in the second visit, during which completion of the data collection tools and content rating scales were explained. Eight out of ten participants were able to be reached for the final phone interview at 30 days following discharge from hospital. One adult participant and one pediatric participant were not able to be reached for the final phone interview. Telephone review of the memory aid and content rating scales took an average of 20 minutes.

Memory aids and content rating scales were completed by caregivers for all (4 out of 4) pediatric participants. Two adult participants completed the study materials themselves, while one adult participant had a caregiver answer all questions for them, and one filled out the memory aid and content rating scales themselves, but had their significant other participate in the final phone interview as well (both the patient and the caregiver were involved in survey evaluation).

All individual survey questions around user friendliness, clarity, and ease of use were rated on a 4 point Likert scale where 1 equaled strongly disagree and 4 equaled strongly agree. Questions were rated as ‘agree’ or ‘strongly agree’, with majority of answers rated as ‘strongly agree’. Questions around survey design on whether ‘1) The question items flowed easily in a logical order' were answered as 'agree' and 'strongly agree' with majority of answers being 'agree'. Questions around '2) The directions on how to complete the questionnaire were clear and easy to follow' were again answered as 'agree' and 'strongly agree' with majority of answers being 'agree'. The next three questions of the content validity survey tool asked to provide comments on clarity and improvements. Below are the overall results of content validity.

Table 6. Overall Content Validity Results.

Patient Expenses during Hospital Admission and Stay		
		Overall Content Validity Results (mean)
Part I		3.86
Part II	Q1	Agree
	Q2	Agree
	Q3	No Comment
	Q4	No Comment
	Q5	Overall no improvement necessary

Caregiver Expenses during Hospital Admission and Stay		
		Overall Content Validity Results (mean)
Part I		3.97
Part II	Q1	Agree
	Q2	Agree
	Q3	No Comment
	Q4	No Comment
	Q5	Overall no improvement necessary

Memory Aid (both Patient and Caregiver results)		
		Overall Content Validity Results (mean)
Part I: Section I		3.91
Part I: Section II	Q1	Agree
	Q2	Agree
	Q3	No Comment
	Q4	No Comment
	Q5	Overall no improvement necessary
Part II: Section I		3.98
Part II: Section II	Q1	Agree
	Q2	Agree
	Q3	No Comment
	Q4	No Comment
	Q5	Overall no improvement necessary

One caregiver provided great feedback around usefulness of the memory aid. The caregiver has been dealing with caring for her son his whole life. Her description of the tools was that they would have been very useful from the very onset of the illness, the family expenses were enormous and the caregiver had to give up work almost immediately due to the work associated with taking care of her son. She found the design of the tools very interesting and said that the post medical visit questionnaire (Appendix H, Part I) was very useful. This caregiver also mentioned that she has been dealing with her son's illness for the duration of her son's life; therefore all impact was now a norm to her.

Another caregiver mentioned that due to the short span of the pilot testing the tools, she thought she was not as helpful as she could be over a longer duration of time. Another caregiver commented that not much impact happened so there was not a lot to report back, also that 30 days was perhaps too short for pilot testing, because her child has another episode and had to be hospitalized on day 30 of the pilot testing period. This same study participant, expressed concern that she: "[does] not know how feasible or punctual people would be about completing the tools, if they had a more severe illness." One participant did require more explanation on the difference between provincial and private insurance coverage of costs. Generally, the feedback and results were very positive. Below are some comments that were provided by the study participants during the final telephone interview:

> *"I don't work, so some of the questions did not apply to me."*
>
> *"I think the forms are designed pretty well."*
>
> *"The questions were excellent."*

“Wonderful design, wonderful questions, straight to the point. You knew what the question was and what it meant. I knew how to fill it out.”

“Overall, the questions are very easy to follow. The paper was very nice and easy to write on and keep track.”

“I really like the ideas for the category examples.”(For an example of what the participant meant: see Appendix C, page 4 of 11 of the Memory Aid)

“A lot of the questions did not relate because of the nature of patient’s illness.”The patient thought that their illness encounter was not severe enough; therefore a lot of the memory aid questions were left unanswered.

“The language was easy to follow, even though English is not my first language.”

“No issue with the flow of the tools, very well put together.”

Overall, the pilot study shows that the memory aid tools provide an acceptably successful response rate, consistent with the literature findings. The content validity of the tools developed for this project provides results that the tools are user friendly, clear, and easy to follow. The design of the tools was also shown to flow in a logical order, and little or no comments were provided on suggestions around improvement on how these tools could be improved, therefore no questions were re-worded or changed.

CHAPTER 5: DISCUSSION

IMD is a life-threatening vaccine preventable disease for which several preventative vaccines and immunization program options exist in Canada. Canadian Federal, Provincial and Territorial decision-makers rely on the availability of sound Canadian data on which to base decisions around optimal vaccine programs. Deciding amongst several vaccines and vaccine program options requires detailed Canadian data about relative costs and cost-effectiveness of available options. This thesis identifies important data gaps in the literature and aims to provide tools by which to address these gaps in Canada. The specific objectives of this thesis are as follows:

- To identify and outline all patient related healthcare utilization;
- To identify and outline all healthcare utilization as direct costs, indirect costs and intangible costs;
- To develop tools for cost collection, more specifically memory aids used by the patient population;
- To pilot test the tools developed for content validity.

Cost-effectiveness analysis requires careful quantification of health services utilization for IMD in Canada. This thesis provides a comprehensive, evidence-based framework for the collection of health services use in the Canadian context. Because assessment of various immunization and program options must consider a societal perspective, particular attention is paid to identifying not only direct costs, but also indirect, and intangible costs associated with IMD.

As much of the data required to populate cost-effectiveness models is not readily available in Canada, collection of healthcare utilization directly from affected patients is proposed using patient and caregiver memory aids. This methodology has proven effective for the assessment of healthcare utilization following other medical diagnoses and offers the advantage of allowing data collection over a long period of time without relying solely on patient recall. This is particularly important in a disease such as IMD, because many patients suffer long term sequelae, which results in associated health services utilization that can last many years.

Prospective surveillance for IMD in Canada is currently undertaken by two national hospital-based surveillance Networks: the adult Serious Outcomes Surveillance (SOS) Network and the pediatric Canadian Immunization Monitoring Program ACTive (IMPACT). Prospective identification of Canadians hospitalized with IMD provides an important opportunity to better define related health services utilization in Canada. This thesis project was designed to inform collection of comprehensive health services utilization data by the SOS and IMPACT Networks and to provide evidence-base data collection tools to allow prospective collection of direct, indirect and intangible costs directly from patients.

Study Strengths

This thesis identifies all relevant potential health services utilization related to IMD from several sources including the literature, case series and data collected in the SOS Network and IMPACT Networks, and experts in the field. Importantly, potential health services used are explored from the Canadian context since available descriptions of IMD-associated health services utilization in the literature were undertaken in other jurisdictions where healthcare delivery and social service options may be quite different than in Canada. The Memory Aids developed address potential health services use specific to Canada, thus making the content relevant to patients who will be completing them.

Because many patients with IMD suffer long term sequelae, which are often associated with long term health services use, the tools developed in this thesis have been designed to allow prospective data collection from patients over relatively short time frames to prevent reliance solely on patient recall yet allow long term data collection by providing new tools at regular intervals. This proposed methodology also has the advantage of ensuring periodic contact between patients and the research team, which should improve long term compliance in patients with sequelae followed over long periods of time.

Studies of health economic nature suffer a common methodological issue: there are too many methodological inconsistencies amongst studies conducted thus far. They all vary in the level of detail collected; therefore the level of interpretation also varies amongst the studies, making it almost impossible to compare research studies regarding health services and economic evaluations. A longitudinal study, such as the one proposed by this thesis, would provide some consistency in data for comparisons in future health economic evaluations, particularly cost-effectiveness.

Pilot testing of the tools developed in this thesis reveals them to be clear, user-friendly and easy to follow and suggests that compliance with completing the tools will be high. While the proposed Memory Aids are tailored to patients with IMD, pilot testing in other patient populations such as community acquired pneumonia and asthma suggests that the tools could readily be modified to reflect potential health services use following other diagnoses.

Finally, this thesis provides validated data collection instruments to assess impact of IMD on quality of life of both affected patients and their families/caregivers. This assessment of intangible costs associated with IMD has been a limitation of other studies exploring cost effectiveness of preventative strategies for IMD and will be an important contribution to the literature.

Study Limitations

While this thesis offers an important contribution by providing an evidence-based framework for the identification of IMD-associated health services utilization in the Canadian context, it was not designed to quantify the costs associated with this utilization. Canadian cost-effectiveness models will require not only quantification of health services use associated with IMD, made possible through use of the tools developed in this thesis by the SOS and IMPACT Networks, but also related costs. Once data regarding health services use has been prospectively collected, it will be necessary to assign costs to each health service used. In a decentralized healthcare system such as Canada, quantifying costs will require exploration of several sources of data. Assignment of costs to patient-informed health services utilization data collected is beyond the scope of this thesis.

Perceived limitations around collection of Quality of Life impacts should also consider variability of the Canadian population due to various social determinants. Collecting health utility information on QoL impact should consider aspects such as geographical location (i.e.

urban vs. rural area), access to prompt medical care, socio-economic aspects, health behavior as well as other relevant social determinants impacting QoL. Further exploration of literature review around QoL limitations would benefit in the proposed methodology in order to outline potential areas of concern.

The primary limitation of the pilot study was the need to conduct the pilot in a population different than the intended study population due to the rarity of IMD. While it would be optimal to pilot test the tools in the target population, conducting pilot testing in other hospitalized populations of similar age would be expected to provide reliable information about the clarity, ease of use and anticipated short term compliance with the tools. Conducting the pilot study in a different population offers the potential advantage of providing some insight into generalizability of the tools to patients with other diagnoses.

While the pilot study sample size is relatively small, testing in 5-10 people is fairly standard for assessment of content validity and would be expected to yield information on any significant problems with the tools. The pilot study was also limited in its ability to evaluate long-term use of the tools because the patient population studied in the pilot was less likely to experience long-term sequelae and evaluation was only conducted for the 30 days following hospital discharge. Thus, the pilot may not have identified potential issues with long-term memory aid completion compliance. Patients with IMD are likely to have much more intensive health services use than the patients in the pilot study and therefore, patients may find the tools more difficult to complete than patients in the pilot. This limitation will hopefully be mitigated by planned regular contacts between the study team and IMD patients during the long term follow-up. Although the response rate was relatively high at 80 percent, more than three phone calls (on average) were made in order to set the final telephone interview. Therefore it will be important to allocate sufficient resources within the prospective study in IMD patients to ensure regular contacts in order to enhance compliance.

Knowledge Translation

Themes around choosing the best healthcare options and practices are continually emerging in health policies and health economics research. Decisions around how the Canadian healthcare dollar is spent are important, and institutions involved around decision-making are increasingly interested in cost-effectiveness of immunization programs as new emerging immunization options are available. This thesis work provides a body of knowledge for health services research around IMD in Canada. As well, it also provides groundwork for future cost-effectiveness research.

This thesis work and the pilot study have been presented at several relevant peer reviewed local and national conferences in both oral and poster formats (see Appendix O-Knowledge Translation activities):

- Canadian Association for Health Services and Policy Research (CAHSPR); Montreal, PQ, May ,2012;
- Infectious Diseases (ID) Research Day/ Canadian Center for Vaccinology Annual Symposium, Dalhousie University; Halifax, NS, April, 2012;

- Public Health Agency of Canada (PHAC)/ Canadian Institutes of Health Research (CIHR) Influenza Research Network (PCIRN) Annual Meeting; Ottawa, ON, April, 2012
- Canadian Immunization Conference (CIC); Vancouver, BC, December, 2012;
- Canadian Center for Vaccinology (CCfV) Education Series; Halifax, NS, May, 2012.

These presentations afforded opportunity for discussion with field experts in Public Health, Epidemiology, Infectious Diseases and Vaccinology. Experts expressed a high degree of interest in this area of research and support for the importance of this work, and validated the literature review demonstrating significant data gaps in Canada around health services utilization associated with IMD. Pilot study methodology was discussed with experts at most of these events and feedback suggested that the proposed methodology was a feasible and acceptable means of evaluating the proposed data collection tools. Pilot study results were presented at the Canadian Immunization Conference held in Vancouver, December 2012.

Following completion of the pilot study, surveillance protocols of the Serious Outcomes Surveillance (SOS) Network and the Immunization Program Monitoring Program (IMPACT) were amended to include assessment of health services utilization using the data collection instruments developed in this thesis. A total of 8 SOS Network sites and 4 IMPACT sites now have REB approval and have begun prospective data collection. Site initiation and training has been completed and two patients with IMD have been enrolled. Both patients have completed the Memory Aids for the first 30 days post discharge and no issues with the tools have arisen. A total of 25 patients are anticipated to be enrolled in the coming 12 months.

Current Research Needs and Future Areas of Research

Ongoing data collection within the SOS and IMPACT Networks using the framework developed in this thesis will fill important gaps in our understanding of health services utilization associated with IMD in Canada. In parallel with this data collection, it will be critical to undertake an exercise to assign representative costs to identified health service use. Currently, most hospitals do not have a disease/diagnosis specific costing system. There are hospital costing systems (such as the OCCI) that are initiating a costing system on per case (infection/illness) basis. However, comprehensive costing will require use of multiple data sources and is an important part of the overall project being conducted by the SOS Network. By ensuring comprehensive collection of IMD-associated health services use and impact on quality of life, this thesis will enable the SOS Network to provide more accurate, standardized data inputs to ongoing health economic evaluation being conducted in Canada.

While the National Advisory Committee on Immunization (NACI) provides guidelines on optimal use of vaccines in Canada and the National Immunization Strategy of the Public Health Agency of Canada aims to standardize immunization programs across Canada, review of provincial and territorial immunization programs in Dec. 2012 reveals tremendous variability in meningococcal immunization programs across Canada. Cost effectiveness models populated by comprehensive Canadian data are urgently needed to inform decision making around optimal programs in hopes of achieving higher standardization of programs across Canada. Such models are currently being explored by the Canadian Immunization Committee, the manufacturers of meningococcal vaccines, and provinces and territories.

In conclusion, this thesis work discusses the importance of cost-effectiveness assessment in the evaluation of optimal preventative strategies for IMD. It outlines relevant direct, indirect and intangible healthcare costs and proposes the use of patient memory aids for collection of costs, allowing health economic assessment from a societal perspective. It provides data collection tools which have been pilot tested and found to be user-friendly, clear and readily understood. This thesis work has established a framework for prospective patient-reported data collection of health services utilization through the use of memory aids, which has now been operationalized within the prospective SOS and IMPACT surveillance Networks and will inform assessment of the economic burden of IMD in Canada and the relative cost-effectiveness of available vaccines and immunization program options.

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APPENDIX A: PATIENT EXPENSES DURING HOSPITAL ADMISSION AND STAY

Patient Expenses during Hospital Admission and Stay

Date Range of Hospital Stay: __________ – __________
(YEAR/MM/DD) (YEAR/MM/DD)

---

1. How did you get to and from the hospital?

☐ Car	→	Parking Total	$ _ _ _._ _
		Km (both ways)	km _ _ _._ _
		Time (both ways)	hr _ _ _._ _
☐ Taxi	→	Round Trip Fare	$ _ _ _._ _
☐ Ambulance	→	Personal Cost Incurred to you	$ _ _ _._ _
☐ Other _________		Please specify any Personal Cost to you	$ _ _ _._ _

---

2. Work and Missed Opportunity:

a. Were you employed during this hospital stay?	☐ Yes ☐ No
b. If yes, how many work days did you miss?	____________
i. Your age	____________
ii. Your approximate salary (in $ per hour)	____________
iii. Was your absence employer paid?	☐ Yes ☐ No

---

3. Student: Did you have to miss school time because of this hospital stay?	☐ **Yes** ☐ **No**
a. If yes, how many school days did you miss	____________

---

4. Did you have to miss any leisure activities (e.g. recreational activities you would normally attend)?	☐ **Yes** ☐ **No**
a. If yes, please specify how many hours	hr _ _ _._ _
b. Average cost of activity per hour (enter 0 if not a paid activity)	$ _ _ _._ _

---

5. Care for any dependants:	☐ **no dependants**
a. Did you have to arrange care for any dependants?	☐ Yes ☐ No
b. How many dependants was care arranged for?	____________
c. For how many hours did you get care?	hr _ _ _._ _
d. What was the cost per hour for this childcare?	$ _ _ _._ _

For other costs not mentioned above, please specify in the space below:

____

____

____

APPENDIX B: CAREGIVER EXPENSES DURING HOSPITAL ADMISSION AND STAY

Caregiver Expenses during Patient's Hospital Admission and Stay

Date Range of Hospital Stay: __________ to__________
(YEAR/MM/DD) (YEAR/MM/DD)

---

1. Transportation to stay with and/or visit the patient:

☐ Car	→	Parking Total	$ _ _ _._ _
		Km (both ways)	km _ _ _._ _
		Time (both ways)	hr _ _ _._ _
☐ Taxi	→	Round Trip Fare	$ _ _ _._ _
☐ Ambulance	→	Personal Cost Incurred to you	$ _ _ _._ _
☐ Other _________		Please specify any Personal Cost to you	$ _ _ _._ _

---

2. Did you pay for any of your meals during the hospital visit? ☐ **Yes** ☐ **No**

a. If yes, please specify number of meals purchased and average cost of each meal

1.	Breakfast	#____________	Avg. cost $	_ _ _._ _ per meal
2.	Lunch	#____________	Avg. cost $	_ _ _._ _ per meal
3.	Dinner	#____________	Avg. cost $	_ _ _._ _ per meal
4.	Snacks	#____________	Avg. cost $	_ _ _._ _ per meal

Other comments ____
____
____

---

3. Work and Missed Opportunity:

a.	Were you employed during this period?	☐ Yes ☐ No
b.	If yes, how many work days did you miss?	____________
i.	Your age	____________
ii.	Your approximate salary (in $ per hour)	____________
iii.	Did you take sick leave for the days missed?	☐ Yes ☐ No
iv.	Was this time employer paid?	☐ Yes ☐ No
v.	Did you have to take personal leave for the days missed?	☐ Yes ☐ No
vi.	Was this time employer paid?	☐ Yes ☐ No

4. Did you have to miss any leisure activities (e.g. recreational activities you would normally attend)? ☐ **Yes** ☐ **No**

a. If yes, please specify how many hours hr _ _ _._ _

b. Average cost of activity per hour (enter 0 if not a paid activity) $ _ _ _._ _

5. Care for any dependants: ☐ **no dependants**

a. Did you have to arrange care for any dependants? ☐ Yes ☐ No

b. How many dependants was care arranged for? ____________

c. For how many hours did you get care? hr _ _ _._ _

d. What was the cost per hour for this childcare? $ _ _ _._ _

For other costs not mentioned above, please specify in the space below:

Thank you for taking the time to complete this questionnaire!

APPENDIX C: PATIENT CONFIDENTIAL MEMORY AID

Patient Confidential Memory Aid

From ____________ To ____________
(YEAR/MM/DD) (YEAR/MM/DD)

Thank You for Making a Difference

Office use only

Study #:_________________

Date: ___________________

Dear Participant,

Thank you for taking the time to help us gather the information of your personal cost for health services that you will use because of this illness. Please fill this Memory Aid out as often as possible and include any relevant cost specific information that we did not ask for in the space provided at the end of the diary. If you have any further questions about how to fill this Memory Aid or about your participation in this study please contact the researcher below.

Name: ______________________________

Phone 1: ____________________________

OR

Name: ________________________________

Phone 1: ______________________________

PART 1 (Pages _ _ to _ _)

Please complete this part of the Memory Aid after every time you visit a health professional. We provided you with 10 sheets for 10 different medical visits, should you need more, please let us know and we will provide as many pages as you anticipate you will need.

Every **Health Professional** visit is dedicated a **single page** of this diary.

Health Professional could include but is not limited to any of the following:

Examples

- Family Doctor
- Pediatrician
- Neurologist
- Neurosurgeon
- Orthopedist

Examples

- Hearing Specialist
- Speech Specialist
- Nurse
- Nutritionist
- Social Worker

Examples

- Chiropractor
- Physiotherapist
- Naturopath
- Homeopath

This **section** should also include any of your **regularly** scheduled appointments and **hospital re-admissions** should you encounter any.

For each visit, procedure or treatment, test, medication or equipment:

- ✓ Check Yes: If it was covered by the Provincial Insurance and you did not have to pay or provide your Private Insurance information.
- ✓ Check No: If you are paying for the full cost proceed to answer questions about private insurance coverage and how much you paid. Continue to complete the table if you or your caregiver incurred direct cost and specify amount in $.
- ✓ Check Partial: If your provincial insurance covered part of the service, continue to complete the table to answer questions about private insurance coverage. Continue to complete the table if your private insurance did not cover the service or only covered it partially. Please specify the direct cost incurred to you or your caregiver in $.

Please refer to the table below for a list of items that could fall under different categories. Please note that the below are just some of the examples that could fall under those categories, there may be many other ones you encounter, please do not hesitate to list those.

TREATMENTS

- PHYSIOTHERAPHY
- HYDROTHERAPHY
- OCCUPATIONAL THERAPHY
- SPEECH AND LANGUAGE THERAPHY
- PROSTHETIC THERAPHY
- PSYCHIATRIC SESSIONS

DIAGNOSTIC TESTS

- HEARING TESTS
- SPEECH ASSESSMENT
- ULTRASOUND
- MRI
- BLOOD TEST
- PROSTHETIC TEST
- XRAYS

MEDICATION

- PAIN MEDICATION
- CONSTIPATION MEDICATION (LACTULOSE)
- EPILEPSY MEDICATION
- MEDICATED OINMENTS AND CREAMS
- BEHAVIOUR RELATED MEDICATION

MEDICAL EQUIPMENT

- CRUTCHES
- WALKERS
- ORTHOTIC SHOES
- DOUBLE INCONTINENCE EQUIPMENT
- THERAPHY BENCH FOR HOME USE
- STANDING FRAMES
- SPECIALIST TOYS
- WHEELCHAIR
- HEARING AID
- VISION AID (SPECIAL EYE GLASSES)
- HOSPITAL BEDS

HEALTH PROFESSIONAL VISIT

Were you ADMITTED to a hospital since your original hospitalization for your illness or since last study contact?	☐ YES	☐ NO	**Date:**
If YES, specify date and complete Section 2 on this page only. **If NO**, proceed with the questionaire below as well as Section 2.			**Hospital Name/Location:**

SECTION 1				
DATE of VISIT:	**COVERED BY PROVINCIAL INSURANCE**	**COVERED BY PRIVATE INSURANCE**	**PERSONAL COST**	
			TO YOU	**CAREGIVER**
HEALTH PRACTITIONER VISITED Specify: Related to your illness? ☐ YES ☐ I DON'T KNOW	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Did you receive any TREATMENT at this visit? If yes, please list all treatments received at that visit ________________________ ________________________ ________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Did you receive any DIAGNOSTIC TESTS at this visit? If yes, please list all tests received at that visit ________________________ ________________________ ________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Did you receive a MEDICATION PRESCRIPTION at this visit? If yes, please list all prescribed medication, inlcuding the name, dose and duration of prescription Name____________________ Dose____________________ Duration____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Name____________________ Dose____________________ Duration____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Did you receive a MEDICAL EQUIPMENT PRESCRIPTION at this visit? If yes, please list all prescribed medical equipment ________________________ ________________________ ________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _

Please turn the page over for SECTION 2

SECTION 2

Were you EMPLOYED at the time of this medical visit?	☐ YES ☐ NO	$_ _ _._ _	$_ _ _._ _
If yes, please specify your wage	$_ _ _._ _/hr		
Did you have to take sick time from your work for this visit?	☐ YES ☐ NO		
If yes, was that sick time employer paid?	☐ YES ☐ NO		
How many hours of sick time did you have to take?	# of hours _ _ _._ _		
Did you have to take personal time or vacation from your work for this visit?	☐ YES ☐ NO		
If yes, was that time employer paid?	☐ YES ☐ NO		

HOW DID YOU GET TO THIS MEDICAL VISIT?

☐ CAR	**COST** (fare or parking)	TRAVEL TIME (roundtrip)	$_ _ _._ _	$_ _ _._ _
☐ BUS	$_ _ _._ _	hr_ _ _._ _		
☐ TAXI		DISTANCE (roundtrip)		
☐ OTHER →	Specify____________	km _ _ _._ _		

DID ANYONE ACCOMPANY YOU TO THIS VISIT?

☐ YES →	If yes, did that person miss work because they accompanied you to this visit?	☐ YES ☐ NO
☐ NO	If yes, how many hours did they take off work and what is their wage?	# of hours _ _ _._ _
	Approximate age of the person accompanying you to this visit?	__________

PART 2

(PAGES _ _ TO _ _)

Please complete this section of the Memory Aid for the following time period:

DATE: from _______________ to _______________
(YEAR/MM/DD) (YEAR/MM/DD)

Please refer to the table below for a list of items that could fall under different categories. Please note that the below are just some of the examples that could fall under those categories, there may be many other ones you encounter, please do not hesitate to list those.

COMMUNITY SERVICES

- RESPITE CARE
- HOME SUPPORT WORKER
- COMMUNITY TRANSPORTATION
- NURSING CARE
- ANY SERVICES PROVIDED BY COMMUNITY HELP GROUPS (E.G. RED CROSS)

OVER THE COUNTER MEDICATION & EQUIPMENT

- PAIN RELIEF
- CREAMS AND OINMENTS
- BANDAGES
- WALKERS
- HOSPITAL BEDS
- SPECIAL SLEEP SYSTEMS

HOUSEHOLD COSTS & CHORES

- SPECIAL CUSTOM FURNITURE
- CHILD CARE
- SPECIAL DIET/NUTRITION REQUIREMENTS
- SPECIAL VEHICLE ADJUSTMENT

PLEASE LIST ALL **COMMUNITY SERVICES** USED OVER THIS PERIOD

☐ **none used**

	COVERED BY PROVINCIAL INSURANCE	COVERED BY PRIVATE INSURANCE	COVERED BY OTHER (e.g. Red Cross)	PERSONAL COST	
				TO YOU	CAREGIVER
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

PLEASE LIST ALL **OVER THE COUNTER MEDICATIONS or EQUIPMENT PURCHASED** OVER THIS PERIOD

☐ **none used**

	COVERED BY PROVINCIAL INSURANCE	COVERED BY PRIVATE INSURANCE	COVERED BY OTHER (e.g. Red Cross)	PERSONAL COST	
				TO YOU	CAREGIVER
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

HOUSEHOLD COSTS AND CHORES ☐ none used

If covered by provincial or private insurance, please list it under Community Services Used

Did you hire a Home Support Worker?	☐ YES → ☐ NO	Total # of hours hired: Wage paid:	hr ___:__ $___.__ / hr
Did you use any additional family resources? e.g. childcare, special house adaptation.	☐ YES → ☐ NO	If yes, please specify what and the cost ______________________________ ______________________________ ______________________________ ______________________________	

EDUCATIONAL COSTS

☐ none used

		COVERED BY PROVINCIAL INSURANCE	COVERED BY PRIVATE INSURANCE	COVERED BY OTHER	PERSONAL COST	
					TO YOU	FAMILY MEMBER
Special Needs Nursery	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
Special Needs School	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
Special Needs Transport	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

Government Disability Student Allowance	☐ YES → ☐ NO	Amount per month: $ ___.__ / month
Other Education Costs (i.e. school tutors, special equipment, note-taking services)	☐ YES → ☐ NO	______________________________ ______________________________ ______________________________

SOCIAL CARE COSTS/FUNDING Did you receive/encounter any of the following:		
Government Disability Funding	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year __________________
Special Child Tax Benefit	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year __________________
Special Social Care Assistance	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year ________________
Did you have to stop working because of this illness?	☐ YES → ☐ NO	Wage lost in $ per hour : $_ _ _._ _ / hr How long is your typical work day (e.g. 7.5 hrs)? ________________ How many days could you not work? ________________
Did any of your family members have to stop working to help you during your illness?	☐ YES → ☐ NO	**1st family member; their approximate age _____** Wage lost in $ per hour : $_ _ _._ _ / hr How long is their typical work day (e.g. 7.5 hrs)? ______________ How many days could they not work? ______________ **2nd family member; their approximate age _____** Wage lost in $ per hour : $_ _ _._ _ / hr How long is their typical work day (e.g. 7.5 hrs)? ______________ How many days could they not work? ______________
Other costs or social funding received associated with this illness during this time period? If yes, please specify what and how much it was.	☐ YES → ☐ NO	____________________ ____________________ ____________________ ____________________ ____________________

If there were any other costs that you incurred that were not mentioned in this Memory Aid please use the space below and:

- identify the health related service that you used
- number of times that service was used (# of times used)
- cost per each time that service was used ($ per service)
- specify if that service was covered by provincial or private insurance, covered by other provider, or if you or your caregiver personally incurred the cost of that service.

Thank you for taking the time in order to complete this Memory Aid as accurately and as often as possible.

APPENDIX D: CAREGIVER CONFIDENTIAL MEMORY AID

Caregiver

Confidential Memory Aid

From ___________ to ___________

(YEAR/MM/DD) (YEAR/MM/DD)

Thank You for Making a Difference

Office use only

Study #:___________________

Date: ____________________

Dear Participant,

Thank you for taking the time to help us gather the information of the personal cost for health services that you and ____________ will use because of this illness. Please fill this Memory Aid out as often as possible and include any relevant cost specific information that we did not ask for in the space provided at the end the diary. Please try and answer questions both as ____________ and as his/her caregiver. If you have any further questions about how to fill this Memory Aid or about your participation in this study please contact the researcher below.

Name: ____________________________

Phone 1: __________________________

OR

Name: ______________________________

Phone 1: ____________________________

PART 1 (Pages _ _ to _ _)

Please complete this part of the Memory Aid after every time you visit a health professional. We provided you with 10 sheets for 10 different medical visits, should you need more, please let us know and we will provide as many pages as you anticipate you will need.

Every **Health Professional** visit is dedicated a **single page** of this diary.

Health Professional could include but is not limited to any of the following:

Examples

- Family Doctor
- Pediatrician
- Neurologist
- Neurosurgeon
- Orthopedist

Examples

- Hearing Specialist
- Speech Specialist
- Nurse
- Nutritionist
- Social Worker

Examples

- Chiropractor
- Physiotherapist
- Naturopath
- Homeopath

This **section** should also include any of your **regularly** scheduled appointments and **hospital re-admissions** should you encounter any.

For each visit, procedure or treatment, test, medication or equipment:

✓ Check Yes: If it was covered by the Provincial Insurance and you did not have to pay or provide your Private Insurance information.

✓ Check No: If you are paying for the full cost proceed to answer questions about private insurance coverage and how much you paid. Continue to complete the table if you or your caregiver incurred direct cost and specify amount in $.

✓ Check Partial: If your provincial insurance covered part of the service, continue to complete the table to answer questions about private insurance coverage. Continue to complete the table if your private insurance did not cover the service or only covered it partially. Please specify the direct cost incurred to you or your caregiver in $.

Please refer to the table below for a list of items that could fall under different categories. Please note that the below are just some of the examples that could fall under those categories, there may be many other ones you encounter, please do not hesitate to list those.

TREATMENTS

- PHYSIOTHERAPHY
- HYDROTHERAPHY
- OCCUPATIONAL THERAPHY
- SPEECH AND LANGUAGE THERAPHY
- PROSTHETIC THERAPHY
- PSYCHIATRIC SESSIONS

DIAGNOSTIC TESTS

- HEARING TESTS
- SPEECH ASSESSMENT
- ULTRASOUND
- MRI
- BLOOD TEST
- PROSTHETIC TEST
- XRAYS

MEDICATION

- PAIN MEDICATION
- CONSTIPATION MEDICATION (LACTULOSE)
- EPILEPSY MEDICATION
- MEDICATED OINMENTS AND CREAMS
- BEHAVIOUR RELATED MEDICATION

MEDICAL EQUIPMENT

- CRUTCHES
- WALKERS
- ORTHOTIC SHOES
- DOUBLE INCONTINENCE EQUIPMENT
- THERAPHY BENCH FOR HOME USE
- STANDING FRAMES
- SPECIALIST TOYS
- WHEELCHAIR
- HEARING AID
- VISION AID (SPECIAL EYE GLASSES)
- HOSPITAL BEDS

HEALTH PROFESSIONAL VISIT

Were you ADMITTED to a hospital since your original hospitalization for your illness or since last study contact? **If YES**, specify date and complete Section 2 on this page only. **If NO**, proceed with the questionaire below as well as Section 2.	☐ YES	☐ NO	**Date:** **Hospital Name/Location:**

SECTION 1

DATE of VISIT:	**COVERED BY PROVINCIAL INSURANCE**	**COVERED BY PRIVATE INSURANCE**	**PERSONAL COST**	
			TO YOU	**CAREGIVER**
HEALTH PRACTITIONER VISITED Specify: Related to your illness? ☐ YES ☐ I DON'T KNOW	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Did you receive any TREATMENT at this visit? If yes, please list all treatments received at that visit	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Did you receive any DIAGNOSTIC TESTS at this visit? If yes, please list all tests received at that visit	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Did you receive a MEDICATION PRESCRIPTION at this visit? If yes, please list all prescribed medication, inlcuding the name, dose and duration of prescription Name____________________ Dose____________________ Duration____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Name____________________ Dose____________________ Duration____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
Did you receive a MEDICAL EQUIPMENT PRESCRIPTION at this visit? If yes, please list all prescribed medical equipment	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _

Please turn the page over for SECTION 2

SECTION 2

Were you EMPLOYED at the time of this medical visit?	☐ YES ☐ NO	$_ _ _._ _	$_ _ _._ _
If yes, please specify your wage	$_ _ _._ _/hr		
Did you have to take sick time from your work for this visit?	☐ YES ☐ NO		
If yes, was that sick time employer paid?	☐ YES ☐ NO		
How many hours of sick time did you have to take?	# of hours _ _ _._ _		
Did you have to take personal time or vacation from your work for this visit?	☐ YES ☐ NO		
If yes, was that time employer paid?	☐ YES ☐ NO		

HOW DID YOU GET TO THIS MEDICAL VISIT?

☐ CAR	**COST** (fare or parking)	TRAVEL TIME (roundtrip)	$_ _ _._ _	$_ _ _._ _
☐ BUS	$_ _ _._ _	hr_ _ _._ _		
☐ TAXI		DISTANCE (roundtrip)		
☐ OTHER →	Specify____________	km _ _ _._ _		

DID ANYONE ACCOMPANY YOU TO THIS VISIT?

☐ YES →	If yes, did that person miss work because they accompanied you to this visit?	☐ YES	☐ NO
☐ NO	If yes, how many hours did they take off work and what is their wage?	# of hours _ _ _._ _	
	Approximate age of the person accompanying you to this visit?	__________	

PART 2

(PAGES _ _ TO _ _)

Please complete this section of the Memory Aid for the following time period:

DATE: from ______________ to ______________
(YEAR/MM/DD) **(YEAR/MM/DD)**

Please refer to the table below for a list of items that could fall under different categories. Please note that the below are just some of the examples that could fall under those categories, there may be many other ones you encounter, please do not hesitate to list those.

COMMUNITY SERVICES

- RESPITE CARE
- HOME SUPPORT WORKER
- COMMUNITY TRANSPORTATION
- NURSING CARE
- ANY SERVICES PROVIDED BY COMMUNITY HELP GROUPS (E.G. RED CROSS)

OVER THE COUNTER MEDICATION & EQUIPMENT

- PAIN RELIEF
- CREAMS AND OINMENTS
- BANDAGES
- WALKERS
- HOSPITAL BEDS
- SPECIAL SLEEP SYSTEMS

HOUSEHOLD COSTS & CHORES

- SPECIAL CUSTOM FURNITURE
- CHILD CARE
- SPECIAL DIET/NUTRITION REQUIREMENTS
- SPECIAL VEHICLE ADJUSTMENT

PLEASE LIST ALL **COMMUNITY SERVICES** USED OVER THIS PERIOD

☐ **none used**

	COVERED BY PROVINCIAL INSURANCE	**COVERED BY PRIVATE INSURANCE**	**COVERED BY OTHER (e.g. Red Cross)**	**PERSONAL COST**	
				TO YOU	**CAREGIVER**
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

PLEASE LIST ALL **OVER THE COUNTER MEDICATIONS or EQUIPMENT PURCHASED** OVER THIS PERIOD

☐ **none used**

	COVERED BY PROVINCIAL INSURANCE	**COVERED BY PRIVATE INSURANCE**	**COVERED BY OTHER (e.g. Red Cross)**	**PERSONAL COST**	
				TO YOU	**CAREGIVER**
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

HOUSEHOLD COSTS AND CHORES

If covered by provincial or private insurance, please list it under Community Services Used

☐ **none used**

Did you hire a Home Support Worker?	☐ YES → ☐ NO	Total # of hours hired: Wage paid:	hr ___:__ $___.__ / hr
Did you use any additional family resources? e.g. childcare, special house adaptation.	☐ YES → ☐ NO	If yes, please specify what and the cost ____________________ ____________________ ____________________ ____________________	

EDUCATIONAL COSTS

☐ **none used**

		COVERED BY PROVINCIAL INSURANCE	**COVERED BY PRIVATE INSURANCE**	**COVERED BY OTHER**	**PERSONAL COST**	
					TO YOU	**FAMILY MEMBER**
Special Needs Nursery	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
Special Needs School	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
Special Needs Transport	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
Government Disability Student Allowance	☐ YES → ☐ NO	Amount per month: $ ___.__ / month				
Other Education Costs (i.e. school tutors, special equipment, note-taking services)	☐ YES → ☐ NO	____________________ ____________________ ____________________				

SOCIAL CARE COSTS/FUNDING Did you receive/encounter any of the following:		
Government Disability Funding	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year __________________
Special Child Tax Benefit	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year __________________
Special Social Care Assistance	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year ________________
Did you have to stop working because of this illness?	☐ YES → ☐ NO	Wage lost in $ per hour : $_ _ _._ _ / hr How long is your typical work day (e.g. 7.5 hrs)? ________________ How many days could you not work? ________________
Did any of your family members have to stop working to help you during your illness?	☐ YES → ☐ NO	**1st family member; their approximate age _____** Wage lost in $ per hour : $___.__ / hr How long is their typical work day (e.g. 7.5 hrs)? ______________ How many days could they not work? ______________ **2nd family member; their approximate age _____** Wage lost in $ per hour : $___.__ / hr How long is their typical work day (e.g. 7.5 hrs)? ______________ How many days could they not work? ______________
Other costs or social funding received associated with this illness during this time period? If yes, please specify what and how much it was.	☐ YES → ☐ NO	____ ____ ____ ____ ____

If there were any other costs that you incurred that were not mentioned in this Memory Aid please use the space below and:

- identify the health related service that you used
- number of times that service was used (# of times used)
- cost per each time that service was used ($ per service)
- specify if that service was covered by provincial or private insurance, covered by other provider, or if you or your caregiver personally incurred the cost of that service.

Thank you for taking the time in order to complete this Memory Aid as accurately and as often as possible.

APPENDIX E: CONTENT VALIDITY OF PATIENT EXPENSES DURING HOSPITAL ADMISSION AND STAY

Patient Expenses during Hospital Admission and Stay

Date Range of Hospital Stay: ___________ – ___________
(YEAR/MM/DD) (YEAR/MM/DD)

Question 1 of 5

1. How did you get to and from the hospital?

☐ Car	→	Parking Total	$ _ _ _._ _
		Km (both ways)	km _ _ _._ _
		Time (both ways)	hr _ _ _._ _
☐ Taxi	→	Round Trip Fare	$ _ _ _._ _
☐ Ambulance	→	Personal Cost Incurred to you	$ _ _ _._ _
☐ Other __________		Please specify any Personal Cost to you	$ _ _ _._ _

2 of 5

2. Work and Missed Opportunity:

a. Were you employed during this hospital stay? ☐ Yes ☐ No

b. If yes, how many work days did you miss? _____________

i. Your age _____________

ii. Your approximate salary (in $ per hour) _____________

iii. Was your absence employer paid? ☐ Yes ☐ No

3 of 5

3. Student: Did you have to miss school time because of this hospital stay? ☐ **Yes** ☐ **No**

a. If yes, how many school days did you miss _____________

4 of 5

4. Did you have to miss any leisure activities (e.g. recreational activities you would normally attend)? ☐ **Yes** ☐ **No**

a. If yes, please specify how many hours hr _ _ _._ _

b. Average cost of activity per hour (enter 0 if not a paid activity) $ _ _ _._ _

5 of 5

5. Care for any dependants: ☐ **no dependants**

a. Did you have to arrange care for any dependants? ☐ Yes ☐ No

b. How many dependants was care arranged for? _____________

c. For how many hours did you get care? hr _ _ _._ _

d. What was the cost per hour for this childcare? $ _ _ _._ _

For other costs not mentioned above, please specify in the space below:

____

____

____

PART I

Please rate the 5 questions of this survey tool using the following scale:

1	2	3	4
Strongly disagree	**Disagree**	**Agree**	**Strongly agree**

Question	User Friendly	Clear	Easy to Follow
1			
2			
3			
4			
5			

PART II: Survey Design:

Please answer the following questions about the questionnaire design

1) The question items flowed easily in a logical order.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree
2) The directions on how to complete the questionnaire were clear and easy to follow.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree

3) Please comment on any questions or answer choices you think lack clarity:

____
____
____
____
____

4) Please comment on any questions or answer choices you think should be re-worded:

____
____
____
____
____

5) Please provide any additional comments on how this questionnaire could be improved:

____
____
____
____
____
____
____
____
____
____

APPENDIX F: CONTENT VALIDITY OF CAREGIVER EXPENSES DURING HOSPITAL ADMISSION AND STAY

Caregiver Expenses during Hospital Admission and Stay

Date Range of Hospital Stay: __________ to__________
(YEAR/MM/DD) (YEAR/MM/DD)

---

1 of 5

1. Transportation to stay with and/or visit the patient:

☐ Car	→	Parking Total	$ _ _ _._ _
		Km (both ways)	km _ _ _._ _
		Time (both ways)	hr _ _ _._ _
☐ Taxi	→	Round Trip Fare	$ _ _ _._ _
☐ Ambulance	→	Personal Cost Incurred to you	$ _ _ _._ _
☐ Other _________		Please specify any Personal Cost to you	$ _ _ _._ _

---

2 of 5

2. Did you pay for any of your meals during the hospital visit? ☐ **Yes** ☐ **No**

b. If yes, please specify number of meals purchased and average cost of each meal

1. Breakfast	#____________	Avg. cost $	_ _ _._ _	per meal
2. Lunch	#____________	Avg. cost $	_ _ _._ _	per meal
3. Dinner	#____________	Avg. cost $	_ _ _._ _	per meal
4. Snacks	#____________	Avg. cost $	_ _ _._ _	per meal

Other comments ____
____
____

---

3 of 5

3. Work and Missed Opportunity:

a. Were you employed during this period?	☐ Yes ☐ No
b. If yes, how many work days did you miss?	____________
i. Your age	____________
ii. Your approximate salary (in $ per hour)	____________
iii. Did you take sick leave for the days missed?	☐ Yes ☐ No
iv. Was this time employer paid?	☐ Yes ☐ No
v. Did you have to take personal leave for the days missed?	☐ Yes ☐ No
vi. Was this time employer paid?	☐ Yes ☐ No

4 of 5

4. Did you have to miss any leisure activities (e.g. recreational activities you would normally attend)? ☐ **Yes** ☐ **No**

a. If yes, please specify how many hours hr _ _ _._ _

b. Average cost of activity per hour (enter 0 if not a paid activity) $ _ _ _._ _

Question 5 of 5

5. Care for any dependants: ☐ **no dependants**

a. Did you have to arrange care for any dependants? ☐ Yes ☐ No

b. How many dependants was care arranged for? ____________

c. For how many hours did you get care? hr _ _ _._ _

d. What was the cost per hour for this childcare? $ _ _ _._ _

For other costs not mentioned above, please specify in the space below:

____

____

____

____

____

____

____

____

____

____

____

____

Thank you for taking the time to complete this questionnaire!

PART I

Please rate the 5 questions of this survey tool using the following scale:

1	2	3	4
Strongly disagree	**Disagree**	**Agree**	**Strongly agree**

Question	User Friendly	Clear	Easy to Follow
1			
2			
3			
4			
5			

PART II: Survey Design:

Please answer the following questions about the questionnaire design

6) The question items flowed easily in a logical order.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree
7) The directions on how to complete the questionnaire were clear and easy to follow.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree

8) Please comment on any questions or answer choices you think lack clarity:

____
____
____
____
____

9) Please comment on any questions or answer choices you think should be re-worded:

____
____
____
____
____

10) Please provide any additional comments on how this questionnaire could be improved:

____
____
____
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____
____
____
____
____
____

APPENDIX G: CONTENT VALIDITY OF PATIENT CONFIDENTIAL MEMORY AID

Patient Confidential
Memory Aid

From ____________ To ____________

(YEAR/MM/DD) (YEAR/MM/DD)

Thank You for Making a Difference

Office use only

Study #:__________________

Date: ____________________

Dear Participant,

Thank you for taking the time to help us gather the information of your personal cost for health services that you will use because of this illness. Please fill this Memory Aid out as often as possible and include any relevant cost specific information that we did not ask for in the space provided at the end of the diary. If you have any further questions about how to fill this Memory Aid or about your participation in this study please contact the researcher below.

Name: ______________________________

Phone 1: ____________________________

OR

Name: ________________________________

Phone 1: ______________________________

PART 1 (Pages _ _ to _ _)

Please complete this part of the Memory Aid after every time you visit a health professional. We provided you with 10 sheets for 10 different medical visits, should you need more, please let us know and we will provide as many pages as you anticipate you will need.

Every **Health Professional** visit is dedicated a **single page** of this diary.

Health Professional could include but is not limited to any of the following:

Examples

- Family Doctor
- Pediatrician
- Neurologist
- Neurosurgeon
- Orthopedist

Examples

- Hearing Specialist
- Speech Specialist
- Nurse
- Nutritionist
- Social Worker

Examples

- Chiropractor
- Physiotherapist
- Naturopath
- Homeopath

This **section** should also include any of your **regularly** scheduled appointments and **hospital re-admissions** should you encounter any.

For each visit, procedure or treatment, test, medication or equipment:

✓ Check Yes: If it was covered by the Provincial Insurance and you did not have to pay or provide your Private Insurance information.

✓ Check No: If you are paying for the full cost proceed to answer questions about private insurance coverage and how much you paid. Continue to complete the table if you or your caregiver incurred direct cost and specify amount in $.

✓ Check Partial: If your provincial insurance covered part of the service, continue to complete the table to answer questions about private insurance coverage. Continue to complete the table if your private insurance did not cover the service or only covered it partially. Please specify the direct cost incurred to you or your caregiver in $.

Please refer to the table below for a list of items that could fall under different categories. Please note that the below are just some of the examples that could fall under those categories, there may be many other ones you encounter, please do not hesitate to list those.

TREATMENTS

- PHYSIOTHERAPHY
- HYDROTHERAPHY
- OCCUPATIONAL THERAPHY
- SPEECH AND LANGUAGE THERAPHY
- PROSTHETIC THERAPHY
- PSYCHIATRIC SESSIONS

DIAGNOSTIC TESTS

- HEARING TESTS
- SPEECH ASSESSMENT
- ULTRASOUND
- MRI
- BLOOD TEST
- PROSTHETIC TEST
- XRAYS

MEDICATION

- PAIN MEDICATION
- CONSTIPATION MEDICATION (LACTULOSE)
- EPILEPSY MEDICATION
- MEDICATED OINMENTS AND CREAMS
- BEHAVIOUR RELATED MEDICATION

MEDICAL EQUIPMENT

- CRUTCHES
- WALKERS
- ORTHOTIC SHOES
- DOUBLE INCONTINENCE EQUIPMENT
- THERAPHY BENCH FOR HOME USE
- STANDING FRAMES
- SPECIALIST TOYS
- WHEELCHAIR
- HEARING AID
- VISION AID (SPECIAL EYE GLASSES)
- HOSPITAL BEDS

HEALTH PROFESSIONAL VISIT

Question 1 of 10	**Were you ADMITTED to a hospital since your original hospitalization for your illness or since last study contact?** **If YES**, specify date and complete Section 2 on this page only. **If NO**, proceed with the questionaire below as well as Section 2.	☐ YES	☐ NO	**Date:** **Hospital Name/Location:**

	SECTION 1				
2 of 10	**DATE of VISIT:**	**COVERED BY PROVINCIAL INSURANCE**	**COVERED BY PRIVATE INSURANCE**	**PERSONAL COST**	
				TO YOU	**CAREGIVER**
3 of 10	**HEALTH PRACTITIONER VISITED** Specify: Related to your illness? ☐ YES ☐ I DON'T KNOW	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
4 of 10	**Did you receive any TREATMENT at this visit?** If yes, please list all treatments received at that visit	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
5 of 10	**Did you receive any DIAGNOSTIC TESTS at this visit?** If yes, please list all tests received at that visit	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
6 of 10	**Did you receive a MEDICATION PRESCRIPTION at this visit?** If yes, please list all prescribed medication, inlcuding the name, dose and duration of prescription Name______________________________ Dose______________________________ Duration___________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
	Name______________________________ Dose______________________________ Duration___________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
7 of 10	**Did you receive a MEDICAL EQUIPMENT PRESCRIPTION at this visit?** If yes, please list all prescribed medical equipment	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _

Please turn the page over for SECTION 2

SECTION 2

8 of 10

Were you EMPLOYED at the time of this medical visit?	☐ YES ☐ NO	$_ _ _._ _	$_ _ _._ _
If yes, please specify your wage	$_ _ _._ _/hr		
Did you have to take sick time from your work for this visit?	☐ YES ☐ NO		
If yes, was that sick time employer paid?	☐ YES ☐ NO		
How many hours of sick time did you have to take?	# of hours _ _ _._ _		
Did you have to take personal time or vacation from your work for this visit?	☐ YES ☐ NO		
If yes, was that time employer paid?	☐ YES ☐ NO		

9 of 10

HOW DID YOU GET TO THIS MEDICAL VISIT?

☐ CAR	**COST** (fare or parking)	TRAVEL TIME (roundtrip)	$_ _ _._ _	$_ _ _._ _
☐ BUS	$_ _ _._ _	hr_ _ _._ _		
☐ TAXI		DISTANCE (roundtrip)		
☐ OTHER →	Specify_____________	km _ _ _._ _		

10 of 10

DID ANYONE ACCOMPANY YOU TO THIS VISIT?

☐ YES →	If yes, did that person miss work because they accompanied you to this visit?	☐ YES ☐ NO
☐ NO	If yes, how many hours did they take off work and what is their wage?	# of hours _ _ _._ _
	Approximate age of the person accompanying you to this visit?	__________

PART I

Please rate the 10 questions of this survey tool using the following scale:

1	2	3	4
Strongly disagree	**Disagree**	**Agree**	**Strongly agree**

Question	User Friendly	Clear	Easy to Follow
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

PART II: Survey Design:

Please answer the following questions about the questionnaire design

1) The question items flowed easily in a logical order.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree
2) The directions on how to complete the questionnaire were clear and easy to follow.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree

3) Please comment on any questions or answer choices you think lack clarity:

____
____
____
____

4) Please comment on any questions or answer choices you think should be re-worded:

____
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5) Please provide any additional comments on how this questionnaire could be improved:

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PART 2

(PAGES _ _ TO _ _)

Please complete this section of the Memory Aid for the following time period:

DATE: from ______________ to ______________
(YEAR/MM/DD) (YEAR/MM/DD)

Please refer to the table below for a list of items that could fall under different categories. Please note that the below are just some of the examples that could fall under those categories, there may be many other ones you encounter, please do not hesitate to list those.

COMMUNITY SERVICES

- RESPITE CARE
- HOME SUPPORT WORKER
- COMMUNITY TRANSPORTATION
- NURSING CARE
- ANY SERVICES PROVIDED BY COMMUNITY HELP GROUPS (E.G. RED CROSS)

OVER THE COUNTER MEDICATION & EQUIPMENT

- PAIN RELIEF
- CREAMS AND OINMENTS
- BANDAGES
- WALKERS
- HOSPITAL BEDS
- SPECIAL SLEEP SYSTEMS

HOUSEHOLD COSTS & CHORES

- SPECIAL CUSTOM FURNITURE
- CHILD CARE
- SPECIAL DIET/NUTRITION REQUIREMENTS
- SPECIAL VEHICLE ADJUSTMENT

Question
1 of 14

PLEASE LIST ALL **COMMUNITY SERVICES**
USED OVER THIS PERIOD

☐ **none used**

	COVERED BY PROVINCIAL INSURANCE	**COVERED BY PRIVATE INSURANCE**	**COVERED BY OTHER (e.g. Red Cross)**	**PERSONAL COST**	
				TO YOU	**CAREGIVER**
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

Question
2 of 14

PLEASE LIST ALL **OVER THE COUNTER**
MEDICATIONS or EQUIPMENT PURCHASED
OVER THIS PERIOD

☐ **none used**

	COVERED BY PROVINCIAL INSURANCE	**COVERED BY PRIVATE INSURANCE**	**COVERED BY OTHER (e.g. Red Cross)**	**PERSONAL COST**	
				TO YOU	**CAREGIVER**
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

HOUSEHOLD COSTS AND CHORES

☐ none used

If covered by provincial or private insurance, please list it under Community Services Used

Question 3 of 14	Did you hire a Home Support Worker?	☐ YES → ☐ NO	Total # of hours hired: Wage paid:	hr ___:__ $___.__ / hr
	Did you use any additional family resources? e.g. childcare, special house adaptation.	☐ YES → ☐ NO	If yes, please specify what and the cost ____________________ ____________________ ____________________ ____________________	

EDUCATIONAL COSTS

☐ none used

			COVERED BY PROVINCIAL INSURANCE	COVERED BY PRIVATE INSURANCE	COVERED BY OTHER	PERSONAL COST TO YOU	PERSONAL COST FAMILY MEMBER
4 of 14	**Special Needs Nursery**	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
5 of 14	**Special Needs School**	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
6 of 14	**Special Needs Transport**	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
7 of 14	**Government Disability Student Allowance**	☐ YES → ☐ NO	Amount per month: $ ___.__ / month				
8 of 14	**Other Education Costs (i.e. school tutors, special equipment, note-taking services)**	☐ YES → ☐ NO	____________________ ____________________ ____________________				

	SOCIAL CARE COSTS/FUNDING Did you receive/encounter any of the following:		
9 of 14	**Government Disability Funding**	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year ________________
10 of 14	**Special Child Tax Benefit**	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year ________________
11 of 14	**Special Social Care Assistance**	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year ______________
12 of 14	**Did you have to stop working because of this illness?**	☐ YES → ☐ NO	Wage lost in $ per hour : $_ _ _._ _ / hr How long is your typical work day (e.g. 7.5 hrs)? ______________ How many days could you not work? ______________
13 of 14	**Did any of your family members have to stop working to help you during your illness?**	☐ YES → ☐ NO	**1st family member; their approximate age _____** Wage lost in $ per hour : $___.__ / hr How long is their typical work day (e.g. 7.5 hrs)? ____________ How many days could they not work? ____________
			2nd family member; their approximate age _____ Wage lost in $ per hour : $___.__ / hr How long is their typical work day (e.g. 7.5 hrs)? ____________ How many days could they not work? ____________
14 of 14	**Other costs or social funding received associated with this illness during this time period? If yes, please specify what and how much it was.**	☐ YES → ☐ NO	______________________________ ______________________________ ______________________________ ______________________________ ______________________________

PART I

Please rate the 14 questions of this survey tool using the following scale:

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

Question	User Friendly	Clear	Easy to Follow
1			
2			
3			
4			
5			
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7			
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9			
10			
11			
12			
13			
14			

PART II: Survey Design:

Please answer the following questions about the questionnaire design

1) The question items flowed easily in a logical order.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree
2) The directions on how to complete the questionnaire were clear and easy to follow.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree

3) Please comment on any questions or answer choices you think lack clarity:

____

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4) Please comment on any questions or answer choices you think should be re-worded:

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5) Please provide any additional comments on how this questionnaire could be improved:

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If there were any other costs that you incurred that were not mentioned in this Memory Aid please use the space below and:

- identify the health related service that you used
- number of times that service was used (# of times used)
- cost per each time that service was used ($ per service)
- specify if that service was covered by provincial or private insurance, covered by other provider, or if you or your caregiver personally incurred the cost of that service.

Thank you for taking the time in order to complete this Memory Aid as accurately and as often as possible.

APPENDIX H: CONTENT VALIDITY OF CAREGIVER CONFIDENTIAL MEMORY AID

Caregiver

Confidential Memory Aid

From ______________ to ______________

(YEAR/MM/DD) (YEAR/MM/DD)

Thank You for Making a Difference

Office use only

Study #:_________________

Date: ___________________

Dear Participant,

Thank you for taking the time to help us gather the information of the personal cost for health services that you and ____________ will use because of this illness. Please fill this Memory Aid out as often as possible and include any relevant cost specific information that we did not ask for in the space provided at the end the diary. Please try and answer questions both as ____________ and as his/her caregiver. If you have any further questions about how to fill this Memory Aid or about your participation in this study please contact the researcher below.

Name: ____________________________

Phone 1: __________________________

OR

Name: ______________________________

Phone 1: ____________________________

PART 1 (Pages _ _ to _ _)

Please complete this part of the Memory Aid after every time you visit a health professional. We provided you with 10 sheets for 10 different medical visits, should you need more, please let us know and we will provide as many pages as you anticipate you will need.

Every **Health Professional** visit is dedicated a **single page** of this diary.

Health Professional could include but is not limited to any of the following:

Examples

- Family Doctor
- Pediatrician
- Neurologist
- Neurosurgeon
- Orthopedist

Examples

- Hearing Specialist
- Speech Specialist
- Nurse
- Nutritionist
- Social Worker

Examples

- Chiropractor
- Physiotherapist
- Naturopath
- Homeopath

This **section** should also include any of your **regularly** scheduled appointments and **hospital re-admissions** should you encounter any.

For each visit, procedure or treatment, test, medication or equipment:

✓ Check Yes: If it was covered by the Provincial Insurance and you did not have to pay or provide your Private Insurance information.

✓ Check No: If you are paying for the full cost proceed to answer questions about private insurance coverage and how much you paid. Continue to complete the table if you or your caregiver incurred direct cost and specify amount in $.

✓ Check Partial: If your provincial insurance covered part of the service, continue to complete the table to answer questions about private insurance coverage. Continue to complete the table if your private insurance did not cover the service or only covered it partially. Please specify the direct cost incurred to you or your caregiver in $.

Please refer to the table below for a list of items that could fall under different categories. Please note that the below are just some of the examples that could fall under those categories, there may be many other ones you encounter, please do not hesitate to list those.

TREATMENTS

- PHYSIOTHERAPHY
- HYDROTHERAPHY
- OCCUPATIONAL THERAPHY
- SPEECH AND LANGUAGE THERAPHY
- PROSTHETIC THERAPHY
- PSYCHIATRIC SESSIONS

DIAGNOSTIC TESTS

- HEARING TESTS
- SPEECH ASSESSMENT
- ULTRASOUND
- MRI
- BLOOD TEST
- PROSTHETIC TEST
- XRAYS

MEDICATION

- PAIN MEDICATION
- CONSTIPATION MEDICATION (LACTULOSE)
- EPILEPSY MEDICATION
- MEDICATED OINMENTS AND CREAMS
- BEHAVIOUR RELATED MEDICATION

MEDICAL EQUIPMENT

- CRUTCHES
- WALKERS
- ORTHOTIC SHOES
- DOUBLE INCONTINENCE EQUIPMENT
- THERAPHY BENCH FOR HOME USE
- STANDING FRAMES
- SPECIALIST TOYS
- WHEELCHAIR
- HEARING AID
- VISION AID (SPECIAL EYE GLASSES)
- HOSPITAL BEDS

HEALTH PROFESSIONAL VISIT

Question 1 of 10	**Were you ADMITTED to a hospital since your original hospitalization for your illness or since last study contact?** **If YES**, specify date and complete Section 2 on this page only. **If NO**, proceed with the questionaire below as well as Section 2.	☐ YES	☐ NO	**Date:** **Hospital Name/Location:**

	SECTION 1				
2 of 10	**DATE of VISIT:**	**COVERED BY PROVINCIAL INSURANCE**	**COVERED BY PRIVATE INSURANCE**	**PERSONAL COST**	
				TO YOU	**CAREGIVER**
3 of 10	**HEALTH PRACTITIONER VISITED** Specify: Related to your illness? ☐ YES ☐ I DON'T KNOW	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
4 of 10	**Did you receive any TREATMENT at this visit?** If yes, please list all treatments received at that visit ____________________ ____________________ ____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
5 of 10	**Did you receive any DIAGNOSTIC TESTS at this visit?** If yes, please list all tests received at that visit ____________________ ____________________ ____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
6 of 10	**Did you receive a MEDICATION PRESCRIPTION at this visit?** If yes, please list all prescribed medication, inlcuding the name, dose and duration of prescription Name____________________ Dose____________________ Duration____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
	Name____________________ Dose____________________ Duration____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _
7 of 10	**Did you receive a MEDICAL EQUIPMENT PRESCRIPTION at this visit?** If yes, please list all prescribed medical equipment ____________________ ____________________ ____________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$_ _ _._ _	$_ _ _._ _

Please turn the page over for SECTION 2

SECTION 2

8 of 10

Were you EMPLOYED at the time of this medical visit?	☐ YES ☐ NO	$_ _ _._ _	$_ _ _._ _
If yes, please specify your wage	$_ _ _._ _/hr		
Did you have to take sick time from your work for this visit?	☐ YES ☐ NO		
If yes, was that sick time employer paid?	☐ YES ☐ NO		
How many hours of sick time did you have to take?	# of hours _ _ _._ _		
Did you have to take personal time or vacation from your work for this visit?	☐ YES ☐ NO		
If yes, was that time employer paid?	☐ YES ☐ NO		

9 of 10

HOW DID YOU GET TO THIS MEDICAL VISIT?

☐ CAR	**COST** (fare or parking)	TRAVEL TIME (roundtrip)	$_ _ _._ _	$_ _ _._ _
☐ BUS	$_ _ _._ _	hr_ _ _._ _		
☐ TAXI		DISTANCE (roundtrip)		
☐ OTHER →	Specify_____________	km _ _ _._ _		

10 of 10

DID ANYONE ACCOMPANY YOU TO THIS VISIT?

☐ YES →	If yes, did that person miss work because they accompanied you to this visit?	☐ YES ☐ NO
☐ NO	If yes, how many hours did they take off work and what is their wage?	# of hours _ _ _._ _
	Approximate age of the person accompanying you to this visit?	__________

PART I

Please rate the 10 questions of this survey tool using the following scale:

1	2	3	4
Strongly disagree	**Disagree**	**Agree**	**Strongly agree**

Question	User Friendly	Clear	Easy to Follow
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

PART II: Survey Design:

Please answer the following questions about the questionnaire design

6) The question items flowed easily in a logical order.
    - ☐ Strongly Disagree
    - ☐ Disagree
    - ☐ Agree
    - ☐ Strongly Agree
7) The directions on how to complete the questionnaire were clear and easy to follow.
    - ☐ Strongly Disagree
    - ☐ Disagree
    - ☐ Agree
    - ☐ Strongly Agree

8) Please comment on any questions or answer choices you think lack clarity:

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9) Please comment on any questions or answer choices you think should be re-worded:

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10) Please provide any additional comments on how this questionnaire could be improved:

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PART 2

(PAGES _ _ TO _ _)

Please complete this section of the Memory Aid for the following time period:

DATE: from _______________ to _______________
(YEAR/MM/DD) (YEAR/MM/DD)

Please refer to the table below for a list of items that could fall under different categories. Please note that the below are just some of the examples that could fall under those categories, there may be many other ones you encounter, please do not hesitate to list those.

COMMUNITY SERVICES

- RESPITE CARE
- HOME SUPPORT WORKER
- COMMUNITY TRANSPORTATION
- NURSING CARE
- ANY SERVICES PROVIDED BY COMMUNITY HELP GROUPS (E.G. RED CROSS)

OVER THE COUNTER MEDICATION & EQUIPMENT

- PAIN RELIEF
- CREAMS AND OINMENTS
- BANDAGES
- WALKERS
- HOSPITAL BEDS
- SPECIAL SLEEP SYSTEMS

HOUSEHOLD COSTS & CHORES

- SPECIAL CUSTOM FURNITURE
- CHILD CARE
- SPECIAL DIET/NUTRITION REQUIREMENTS
- SPECIAL VEHICLE ADJUSTMENT

Question 1 of 14

PLEASE LIST ALL **COMMUNITY SERVICES** USED OVER THIS PERIOD

☐ **none used**

	COVERED BY PROVINCIAL INSURANCE	**COVERED BY PRIVATE INSURANCE**	**COVERED BY OTHER (e.g. Red Cross)**	**PERSONAL COST**	
				TO YOU	**CAREGIVER**
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

Question 2 of 14

PLEASE LIST ALL **OVER THE COUNTER MEDICATIONS or EQUIPMENT PURCHASED** OVER THIS PERIOD

☐ **none used**

	COVERED BY PROVINCIAL INSURANCE	**COVERED BY PRIVATE INSURANCE**	**COVERED BY OTHER (e.g. Red Cross)**	**PERSONAL COST**	
				TO YOU	**CAREGIVER**
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
______________________________	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__

	HOUSEHOLD COSTS AND CHORES ***If covered by provincial or private insurance, please list it under Community Services Used***			☐ **none used**
Question 3 of 14	Did you hire a Home Support Worker?	☐ YES → ☐ NO	Total # of hours hired: Wage paid:	hr ___:__ $___.__ / hr
	Did you use any additional family resources? e.g. childcare, special house adaptation.	☐ YES → ☐ NO	If yes, please specify what and the cost ______________________ ______________________ ______________________ ______________________	

EDUCATIONAL COSTS

☐ **none used**

			COVERED BY PROVINCIAL INSURANCE	**COVERED BY PRIVATE INSURANCE**	**COVERED BY OTHER**	**PERSONAL COST**	
						TO YOU	**FAMILY MEMBER**
4 of 14	**Special Needs Nursery**	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
5 of 14	**Special Needs School**	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
6 of 14	**Special Needs Transport**	☐ YES → ☐ NO	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	☐ YES ☐ NO → ☐ PARTIAL →	$___.__	$___.__
7 of 14	**Government Disability Student Allowance**	☐ YES → ☐ NO	Amount per month: $ ___.__ / month				
8 of 14	**Other Education Costs (i.e. school tutors, special equipment, note-taking services)**	☐ YES → ☐ NO	______________________ ______________________ ______________________				

	SOCIAL CARE COSTS/FUNDING Did you receive/encounter any of the following:		
9 of 14	**Government Disability Funding**	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year __________________
10 of 14	**Special Child Tax Benefit**	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year __________________
11 of 14	**Special Social Care Assistance**	☐ YES → ☐ NO	Amount $_ _ _._ _ For what time period? e.g. week, month, year ________________
12 of 14	**Did you have to stop working because of this illness?**	☐ YES → ☐ NO	Wage lost in $ per hour : $_ _ _._ _ / hr How long is your typical work day (e.g. 7.5 hrs)? ________________ How many days could you not work? ________________
13 of 14	**Did any of your family members have to stop working to help you during your illness?**	☐ YES → ☐ NO	**1st family member; their approximate age _____** Wage lost in $ per hour : $_ _ _._ _ / hr How long is their typical work day (e.g. 7.5 hrs)? ______________ How many days could they not work? ______________ **2nd family member; their approximate age _____** Wage lost in $ per hour : $_ _ _._ _ / hr How long is their typical work day (e.g. 7.5 hrs)? ______________ How many days could they not work? ______________
14 of 14	**Other costs or social funding received associated with this illness during this time period? If yes, please specify what and how much it was.**	☐ YES → ☐ NO	______________________________ ______________________________ ______________________________ ______________________________ ______________________________

PART I

Please rate the 14 questions of this survey tool using the following scale:

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

Question	User Friendly	Clear	Easy to Follow
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			

PART II: Survey Design:

Please answer the following questions about the questionnaire design

6) The question items flowed easily in a logical order.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree
7) The directions on how to complete the questionnaire were clear and easy to follow.
   - ☐ Strongly Disagree
   - ☐ Disagree
   - ☐ Agree
   - ☐ Strongly Agree

8) Please comment on any questions or answer choices you think lack clarity:

____

____

____

____

9) Please comment on any questions or answer choices you think should be re-worded:

____

____

____

____

10) Please provide any additional comments on how this questionnaire could be improved:

____

____

____

____

____

____

____

____

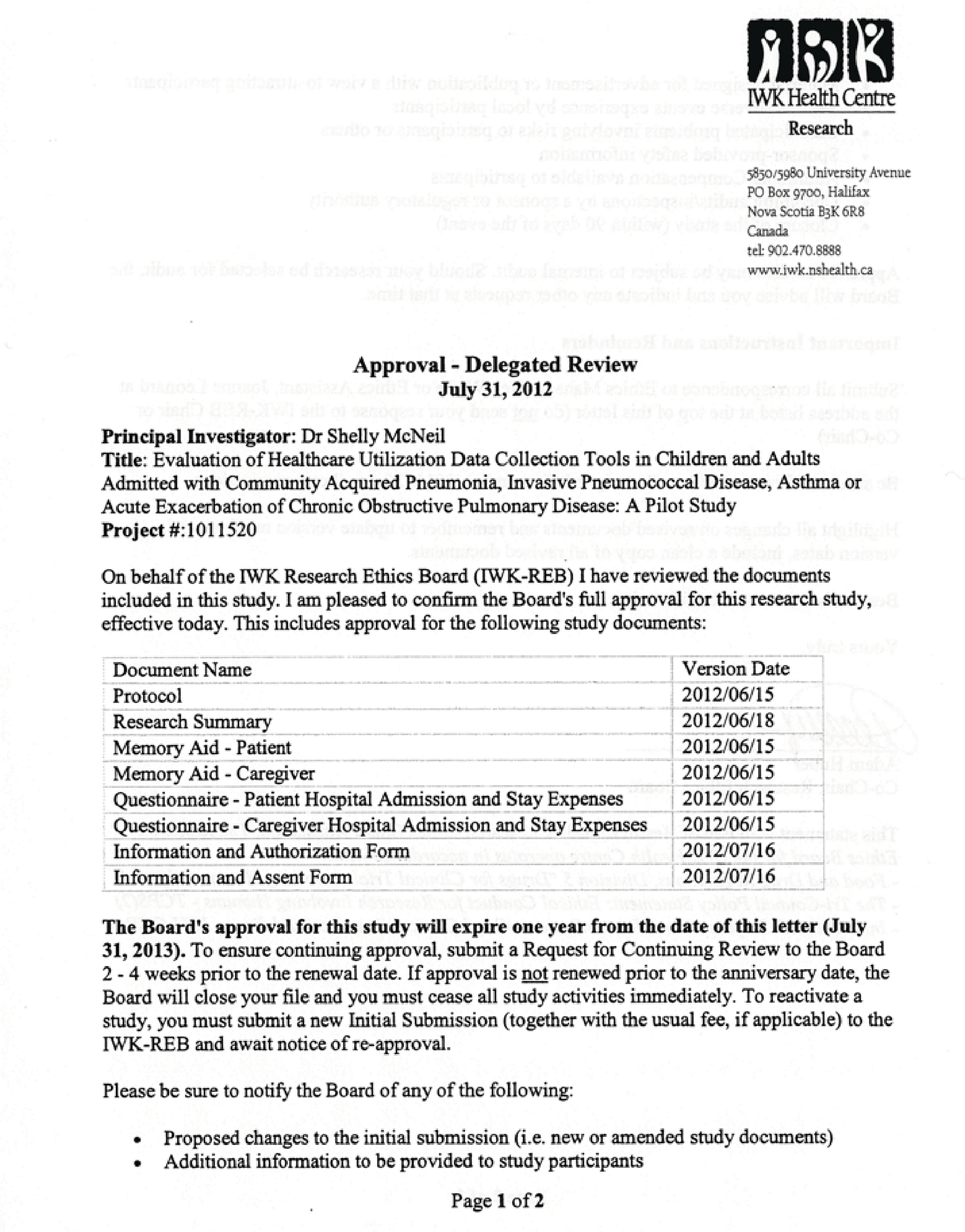
____

If there were any other costs that you incurred that were not mentioned in this Memory Aid please use the space below and:

- identify the health related service that you used
- number of times that service was used (# of times used)
- cost per each time that service was used ($ per service)
- specify if that service was covered by provincial or private insurance, covered by other provider, or if you or your caregiver personally incurred the cost of that service.

Thank you for taking the time in order to complete this Memory Aid as accurately and as often as possible.

APPENDIX I: IWK HOSPITAL REB LETTER OF APPROVAL – PILOT STUDY



IWK Health Centre
Research

5850/5980 University Avenue
PO Box 9700, Halifax
Nova Scotia B3K 6R8
Canada
tel: 902.470.8888
www.iwk.nshealth.ca

Approval - Delegated Review

July 31, 2012

Principal Investigator: Dr Shelly McNeil
Title: Evaluation of Healthcare Utilization Data Collection Tools in Children and Adults Admitted with Community Acquired Pneumonia, Invasive Pneumococcal Disease, Asthma or Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A Pilot Study
Project #:1011520

On behalf of the IWK Research Ethics Board (IWK-REB) I have reviewed the documents included in this study. I am pleased to confirm the Board's full approval for this research study, effective today. This includes approval for the following study documents:

Document Name	Version Date
Protocol	2012/06/15
Research Summary	2012/06/18
Memory Aid - Patient	2012/06/15
Memory Aid - Caregiver	2012/06/15
Questionnaire - Patient Hospital Admission and Stay Expenses	2012/06/15
Questionnaire - Caregiver Hospital Admission and Stay Expenses	2012/06/15
Information and Authorization Form	2012/07/16
Information and Assent Form	2012/07/16

The Board's approval for this study will expire one year from the date of this letter (July 31, 2013). To ensure continuing approval, submit a Request for Continuing Review to the Board 2 - 4 weeks prior to the renewal date. If approval is <u>not</u> renewed prior to the anniversary date, the Board will close your file and you must cease all study activities immediately. To reactivate a study, you must submit a new Initial Submission (together with the usual fee, if applicable) to the IWK-REB and await notice of re-approval.

Please be sure to notify the Board of any of the following:

- Proposed changes to the initial submission (i.e. new or amended study documents)
- Additional information to be provided to study participants

- Material designed for advertisement or publication with a view to attracting participants
- Serious adverse events experience by local participants
- Unanticipated problems involving risks to participants or others
- Sponsor-provided safety information
- Additional Compensation available to participants
- Upcoming audits/inspections by a sponsor or regulatory authority
- Closure of the study (within 90 days of the event)

Approved studies may be subject to internal audit. Should your research be selected for audit, the Board will advise you and indicate any other requests at that time.

Important Instructions and Reminders

Submit all correspondence to Ethics Manager Bev White or Ethics Assistant, Joanne Leonard at the address listed at the top of this letter (do not send your response to the IWK-REB Chair or Co-Chair)

Be sure to reference the Board's assigned file number, 1011520 on all communications.

Highlight all changes on revised documents and remember to update version numbers and version dates, include a clean copy of all revised documents.

Best wishes for a successful study.

Yours truly,

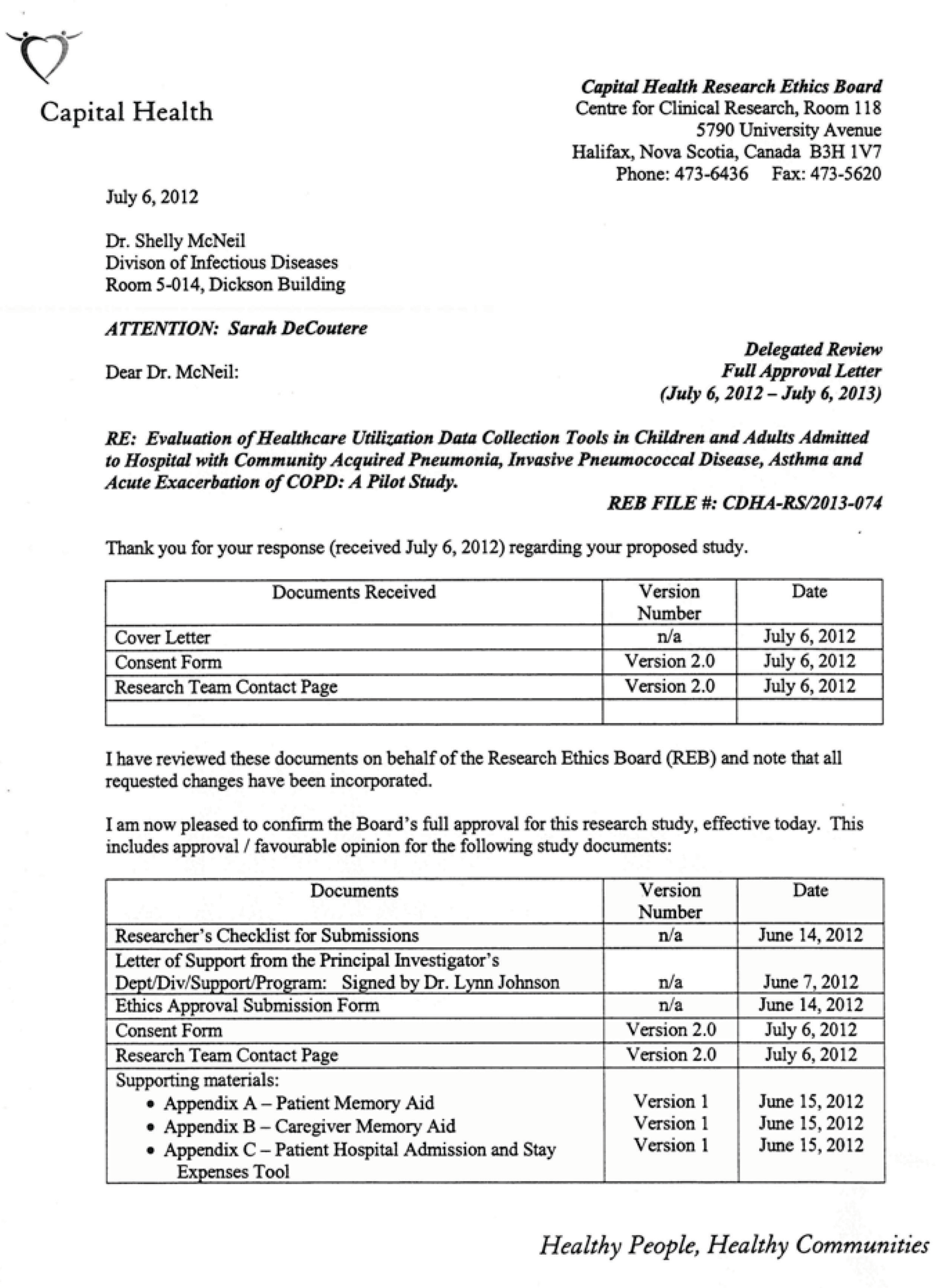
[redacted]

Co-Chair, Research Ethics Board

This statement is in lieu of Health Canada's Research Ethics Board Attestation: *The Research Ethics Board for the IWK Health Centre operates in accordance with:*
- Food and Drug Regulations, Division 5 "Drugs for Clinical Trials involving Human Subjects"
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS(2)
- International Conference on Harmonization - Good Clinical Practice Guidelines - ICH-GCP

Page **2** of **2**

APPENDIX J: CDHA HOSPITAL REB LETTER OF APPROVAL – PILOT STUDY



Capital Health

Capital Health Research Ethics Board
Centre for Clinical Research, Room 118
5790 University Avenue
Halifax, Nova Scotia, Canada B3H 1V7
Phone: 473-6436 Fax: 473-5620

July 6, 2012

Dr. Shelly McNeil
Divison of Infectious Diseases
Room 5-014, Dickson Building

ATTENTION: Sarah DeCoutere

Delegated Review
Full Approval Letter
(July 6, 2012 – July 6, 2013)

Dear Dr. McNeil:

RE: Evaluation of Healthcare Utilization Data Collection Tools in Children and Adults Admitted to Hospital with Community Acquired Pneumonia, Invasive Pneumococcal Disease, Asthma and Acute Exacerbation of COPD: A Pilot Study.

REB FILE #: CDHA-RS/2013-074

Thank you for your response (received July 6, 2012) regarding your proposed study.

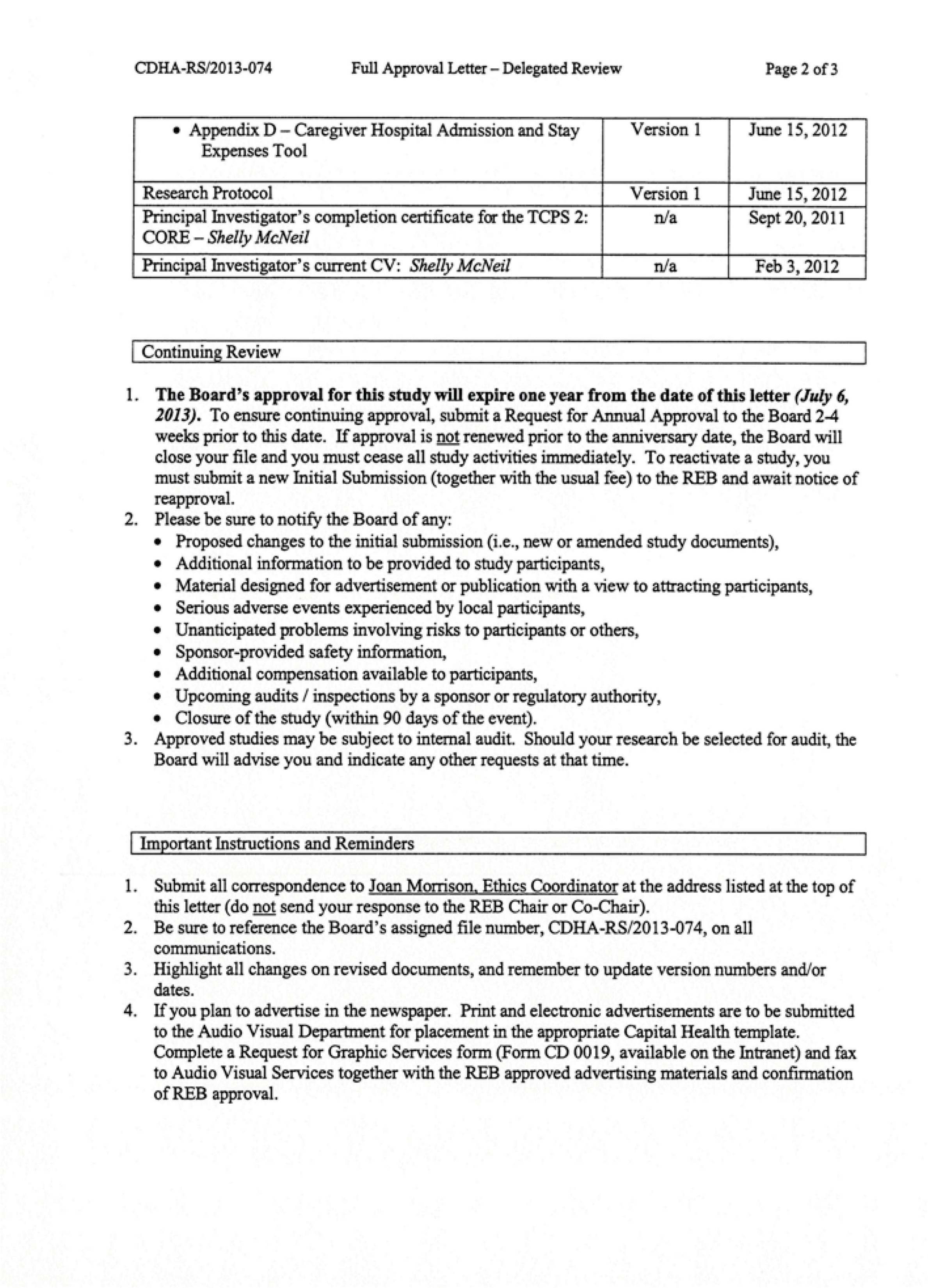
Documents Received	Version Number	Date
Cover Letter	n/a	July 6, 2012
Consent Form	Version 2.0	July 6, 2012
Research Team Contact Page	Version 2.0	July 6, 2012

I have reviewed these documents on behalf of the Research Ethics Board (REB) and note that all requested changes have been incorporated.

I am now pleased to confirm the Board's full approval for this research study, effective today. This includes approval / favourable opinion for the following study documents:

Documents	Version Number	Date
Researcher's Checklist for Submissions	n/a	June 14, 2012
Letter of Support from the Principal Investigator's Dept/Div/Support/Program: Signed by Dr. Lynn Johnson	n/a	June 7, 2012
Ethics Approval Submission Form	n/a	June 14, 2012
Consent Form	Version 2.0	July 6, 2012
Research Team Contact Page	Version 2.0	July 6, 2012
Supporting materials: • Appendix A – Patient Memory Aid • Appendix B – Caregiver Memory Aid • Appendix C – Patient Hospital Admission and Stay Expenses Tool	 Version 1 Version 1 Version 1	 June 15, 2012 June 15, 2012 June 15, 2012

Healthy People, Healthy Communities



• Appendix D – Caregiver Hospital Admission and Stay Expenses Tool	Version 1	June 15, 2012
Research Protocol	Version 1	June 15, 2012
Principal Investigator's completion certificate for the TCPS 2: CORE – *Shelly McNeil*	n/a	Sept 20, 2011
Principal Investigator's current CV: *Shelly McNeil*	n/a	Feb 3, 2012

Continuing Review

1. **The Board's approval for this study will expire one year from the date of this letter *(July 6, 2013).*** To ensure continuing approval, submit a Request for Annual Approval to the Board 2-4 weeks prior to this date. If approval is not renewed prior to the anniversary date, the Board will close your file and you must cease all study activities immediately. To reactivate a study, you must submit a new Initial Submission (together with the usual fee) to the REB and await notice of reapproval.
2. Please be sure to notify the Board of any:
   - Proposed changes to the initial submission (i.e., new or amended study documents),
   - Additional information to be provided to study participants,
   - Material designed for advertisement or publication with a view to attracting participants,
   - Serious adverse events experienced by local participants,
   - Unanticipated problems involving risks to participants or others,
   - Sponsor-provided safety information,
   - Additional compensation available to participants,
   - Upcoming audits / inspections by a sponsor or regulatory authority,
   - Closure of the study (within 90 days of the event).
3. Approved studies may be subject to internal audit. Should your research be selected for audit, the Board will advise you and indicate any other requests at that time.

Important Instructions and Reminders

1. Submit all correspondence to Joan Morrison, Ethics Coordinator at the address listed at the top of this letter (do not send your response to the REB Chair or Co-Chair).
2. Be sure to reference the Board's assigned file number, CDHA-RS/2013-074, on all communications.
3. Highlight all changes on revised documents, and remember to update version numbers and/or dates.
4. If you plan to advertise in the newspaper. Print and electronic advertisements are to be submitted to the Audio Visual Department for placement in the appropriate Capital Health template. Complete a Request for Graphic Services form (Form CD 0019, available on the Intranet) and fax to Audio Visual Services together with the REB approved advertising materials and confirmation of REB approval.

Best wishes for a successful study.

Yours very truly,

[redacted] BSc, MSN, MHSA
Co-Chair, Research Ethics Board

/jm

APPENDIX K: PILOT STUDY PROTOCOL

RESEARCH PROTOCOL

Evaluation of Healthcare Utilization Data Collection Tools in Children and Adults Admitted with Community Acquired Pneumonia, Invasive Pneumococcal Disease, Asthma or Acute Exacerbation of Chronic Obstructive Pulmonary Disease:

A Pilot Study

Shelly McNeil [1], Ardith Ambrose [2], Sanela Gajic [3]

[1] Principal Investigator, Division of Infectious Diseases, Queen Elizabeth II Health Sciences Centre and Canadian Center for Vaccinology, Halifax, NS

[2] Canadian Center for Vaccinology, IWK Health Centre, Halifax, NS

[3] Canadian Center for Vaccinology, IWK Health Centre, Dalhousie University, Halifax, NS

Version Date: June 15, 2012

Investigator Contact Information: Dr. Shelly McNeil

Email: shelly.mcneil@cdha.nshealth.ca

Phone: 473-8477

TABLE OF CONTENTS

*To avoid repetition this section was removed because appendices are already listed under separate list in this thesis (see Appendix list E-H)

Background, Rationale and Statement of Research Question

The Serious Outcomes Surveillance (SOS) Network of the Public Health Agency of Canada/CIHR Influenza Research Network (PCIRN) is a Network of adult care facilities comprising approximately 6000 tertiary care beds. Currently the SOS Network has sites in Vancouver, Winnipeg, Toronto, Ottawa, Hamilton, Quebec City, Sherbrooke, Montreal, Halifax and Saint John. The Network is designed to conduct active surveillance for vaccine preventable diseases in adults in order to better elucidate burden of disease and healthcare utilization and to evaluate the effectiveness of recommended vaccines in the prevention of serious outcomes. At present the SOS Network conducts active surveillance for influenza, community acquired pneumonia and invasive pneumococcal diseases. The Network is staffed with surveillance monitors in each site who conduct active and lab-based surveillance for influenza, community acquired pneumonia and invasive pneumococcal diseases.

Neisseria meningitidis represents another important vaccine preventable disease in adults for which insufficient epidemiologic data are available. As a result of the lack of available data, a set of tools are proposed for a prospective surveillance and data collection in order to provide an evidence based guidance document for future cost-effectiveness evaluations of immunization strategies available and soon to be available to the Canadian health market. The development of conjugate quadrivalent meningococcal vaccines against serogroups A, C, Y and W135, and vaccines under development against *Neisseria meningitidis* B offer tremendous potential to improve prevention of meningococcal diseases in Canadian adults and children. The decision to replace the monovalent meniningococcal C vaccines with quadrivalent vaccines and to implement publicly funded programs for meningococcal B vaccines will be informed by evaluation of the epidemiology of *N. meningitidis* in Canada and an assessment of the contribution of vaccine-preventable meningococcal serotypes to invasive meningococcal diseases (IMD) and healthcare utilization. Understanding both the acute and long term morbidity associated with meningococcal diseases, particularly meningitis, and the impact of individual serotypes will be important to predict the potential benefit of new vaccines. Establishment of baseline rates of hospitalized IMD and the serotype-specific rates of IMD will be critical to allow evaluation of the effectiveness of new vaccines as they are introduced in Canada and to evaluate the potential for serotypes replacement following vaccine introduction.

In order to allow evaluation of the effectiveness of new vaccines as they are introduced in Canada and to evaluate the potential for serotypes replacement following vaccine introduction, the total economic burden of invasive meningococcal disease must be determined and healthcare utilizations associated with this disease must be outlined first. Because the clinical course and outcomes of IMD vary considerably among patients, costs to the patient, society and the healthcare system may vary widely and average case-cost estimated may not provide an accurate picture of the true costs. Therefore the primary objective of the SOS Surveillance study is to assess the burden of disease by a comprehensive data collection on healthcare utilization and costs of invasive meningococcal disease.

Evidence based healthcare information is very important in the Canadian healthcare system. In order to determine cost effectiveness of the different vaccine options in regards to invasive meningococcal disease the total economic burden of this disease must be determined. Due to the decentralized healthcare system, there is no one database where all this information could be retrieved from, therefore tools in order to help patients report a lot of data have been developed. A literature review shows that for a prospective collection of data, memory aid tools have been validated and are reliable in obtaining information of healthcare utilization and costs [1].

Along with clinical surveillance of IMD a patient informed data collection plan is proposed for collection of information around healthcare utilization and related costs. Generally there are two approaches to collecting information from a target population, prospective and retrospective data collection. A retrospective collection of data requires collection of previously recorded information, whereas prospective collection of data requires collection of data into the future with set dates. Due to a comprehensive overview of literature concerning the economic burden of invasive meningococcal disease and the lack of complete information previously discussed, this SOS Surveillance study proposes a collection of original data via a prospective methodology. The tools in order to conduct the prospective surveillance have been developed, however it would not be feasible to conduct the study without pilot testing the tools first. Therefore, this pilot study proposes the testing of content validity and adjustment of the content before a mass implementation of these tools in the SOS Surveillance study.

Content validity is the determination of the content relevance of the items in a survey. Content validity of this survey will entail questions based around user-friendliness of the tools, readability, feasibility of the questions, and clarity. The Memory Aid and the Hospital Admission and Stay Expenses are either patient or caregiver specific, with specifically targeted questions around healthcare utilization and costs associated due to the patients' illness. Both the memory aid and the hospital stay expenses tool are meant to be left with the patient or the caregiver, the SOS surveillance study will not be collecting those tools and analyzing them, the tools are simply meant to aid the participant recollect specific information during their prescheduled interviews. The tools should be kept legible by the participants so that they can serve their purpose during the interviews. For the purposes of the pilot study, the participants will be asked to go through the tools with the study staff in order to test the content validity of the tools; the study participants will be given specific instructions on this process at the time of study enrollment.

Due to the low incidence rate of IMD, the pilot testing of the tools is proposed in patients admitted to hospital with more common diagnoses that are close to and/or comparable in the severity of impact of the disease. In future, the tools proposed for the SOS Surveillance study of IMD are meant to be used beyond just meningococcal disease. Therefore, conducting the pilot study with other diseases will also show relevance and comprehensiveness of the tools when used by patients with other diagnoses.

The primary objectives of this pilot study are twofold:

First, to test the content validity of

- The Patient and the Caregiver Memory Aid (See Appendix A and B, respectively)
- The Patient and the Caregiver Hospital Admission and Stay Expenses tool (See Appendix C and D, respectively)

Second, to modify the data collection tools based on the feedback received from the participants of this pilot study and disseminate the adjusted tools for use with the SOS Surveillance Network.

Subject Selection

A total of ten participants will be enrolled in this single centre study.

Inclusion criteria:

- All patients admitted to reporting hospitals (CDHA, IWK) with diagnosis of:
    - Community acquired pneumonia (CAP)
    - Invasive pneumococcal disease (IPD)
    - Acute exacerbation of chronic obstructive pulmonary disease (COPD) in adults ≥16 years of age.
    - Asthma in children <15 years of age.
- All patients that complete a written informed consent. If the patient is unable to sign the consent this may be signed by their authorized decision maker.

Exclusion criteria:

- Inability of the patient or their authorized decision maker to complete interviews and questionnaires in English.

Research Plan

Recruitment

All patients presenting with CAP, IPD, asthma and acute exacerbation of COPD will be approached for participation in this pilot study until a total of ten cases has been reached. The aim of this pilot study is to enroll five adult patients and five pediatric patients.

Potential adult study participants at CDHA will be identified from patients who are screened and enrolled in other active Serious Outcome Surveillance (SOS) Network studies for CAP, IPD, and COPD. These patients will have already established a relationship with the SOS Network Monitor. The Monitor will ask whether they are willing to speak with another team member regarding completing some questionnaires about how their illness has affected them financially. If they agree, they will be approached for consent.

Pediatric participants will be identified by screening daily admissions for eligible diagnoses. The patients' care team will be asked to confirm if they are appropriate for the study, and will ask the patient and caregiver/family if they can be approached by a research team member.

Study Procedures

Visit One:

Written informed consent will be obtained at this visit. This will take approximately 20 minutes to complete. All questions asked by patients will be answered to their satisfaction and they will be given a signed copy of the consent form. They will be notified visit two will occur just prior to discharge from the hospital.

Visit Two:

During this visit, the patient and his/her caregiver will be instructed on how to complete the survey tools. The patient and/or caregiver are asked to complete the following tools:

- Patient Memory Aid – Appendix A
- Caregiver Memory Aid – Appendix B
- Patient Hospital Admission and Stay Expenses tool – Appendix C
- Caregiver Hospital Admission and Stay Expenses tool – Appendix D

They will need to spend no more than a few minutes each day to complete these tools. Arrangements will be made to contact them 30 days after discharge from hospital to collect the information they have recorded. This may be by telephone or interview in person. Visit two will take approximately 30 minutes to complete.

Visit Three:

This visit will take place 30 days after discharge from hospital. Participants will be asked to report what they recorded on the study forms and to rate the ease and clarity of the questions asked and how easy the tools were to follow. The time of this visit will depend on the extent of data that the participant has to report, the anticipated amount of time this visit will take is between 30 min to an hour.

Patient Compensation

After the 30 day contact when the study data and assessments are collected from the patient, they will be offered a choice of a gift certificate, valued at $25 from a local business, in appreciation for their time commitment to the study. This will be mailed to them at the address they have provided. There are no costs related to participating in this study.

Data Analysis

This is a qualitative, descriptive study. There will be no statistical analysis. The sample size is one of convenience as five patients are often used with pilot testing of content validity.

The study aims to pilot test the content validity of the tools proposed; therefore, this study will directly inform the SOS Surveillance study on modifications that are required before mass implementation of the tools. The research team will address all recommended changes and adjust the tools by consensus.

Description of tools

Memory Aids:

The memory aid consists of two parts with a set of instructions and examples of the kinds of things that the patient might encounter during their illness. The first part of the memory aid consists of a box presented on a single page. It asks ten general questions which are answer dependant on whether more answers need to be provided. The questions are supposed to be user friendly, clear, and easy to follow. The single page box also includes columns which entail questions around how the healthcare utility or service was paid for.

The second part of the memory aid consists of a table of examples of services that the patient might use. The second part of the memory aid consists of five specific tables. The first two tables are supposed to generate a list produced by a patient on either community services used, or over the counter medications or equipment purchased, both first tables have corresponding columns which focus on gathering information on how those services/medication/equipment were paid for. Should the patient not incur any of the above, they would simply check the box “none used” and not complete that table of questions. The following three tables have separated rows with a yes/no answer, which again leads to corresponding columns which focus on gathering information on how the healthcare utilization in question was paid for.

Should additional information need to be shared and the question around that healthcare utilization was not asked, a separate page is provided for feedback. The memory aid's content is the same for both the patient and the caregiver; however the instructions provided on how to complete this tool are slightly different.

Expenses tools:

"Patient Expenses during Hospital Admission and Stay" is comprised of five questions with variant response options that focus on gathering information on how much they cost. The "Caregiver Expenses during Hospital Admission and Stay" for the patient is comprised of five questions with variant response options or sub-questions, which focus on gathering information on how much they cost the caregiver specifically. Both of the tools, have additional space provided should there be other relevant costs not asked in the five questions.

Confidentiality

Only study staff will have access to study files during the study. Representatives of the REB from CDHA or the IWK may have access to study records for audit purposes. Information that links a participants' study file with their personal information is stored in locked file cabinets in locked offices accessible only by study staff. Once the study ends, study files will be stored in locked cabinets in locked offices which are only accessible by study staff. Long term storage will be at the archiving facility used for hospital medical records. Access to the study records after archival will be restricted to members of the study team. If a participant requests accesses this could be facilitated by the local study investigator.

Participants are identified on the study documents only by a code, and no medical or personal information will be included in the study data collection forms. Study consent forms, that link participants with their study numbers will be kept in locked filing cabinets in locked offices, and will only be accessible to study staff as needed for conduct of the study. Study records will be maintained for at least 7 years as per CDHA and IWK policies. Currently, the Canadian Center for Vaccinology keeps all records indefinitely and does not have a policy for destroying information after archiving.

Harms and Benefits

There are no perceived harms for participating in this study. Alike, there are no perceived potential benefits for participating in this study; however the results of this pilot study will help inform the future studies involving the same tools on the user-friendliness and content validity of the tools.

The participants may find the questionnaires and interviews during the study upsetting or distressing. They may not like all of the questions that will be asked. They do not have to answer those questions they find distressing.

Disclosure of Any Financial Compensation

There are no financial compensations granted to the research team. This research study is not funded by any agency, study sponsors or a granting agency.

APPENDIX L: IWK INFORMATION AND ASSENT FORM

IWK Health Centre

Information and Assent Form
15June16 July 2012

Research Title: Understanding Healthcare Use and Cost.

Investigator: Dr. Shelly McNeil, Infectious Disease Doctor, QEII Health Centre

Why are you here today?

We want to tell you about a research study. A research study is a way to find out new information about something. This form tells you about the study. If there is anything you do not understand, please ask us or your parents. After we tell you about the study, we will ask you it you would like to be in this study. You do not need to be in this study if you do not want to. It is totally up to you.

Why are we doing the study?

You are being asked to take part in this research study because you have a certain type of illness. Admission to hospital for treatment of this illness is common in Canada. Information is often collected about the types of care patients need and how much money this costs the health care system for treatment of such illnesses. What is often not known is how much these illnesses cost patients and their parents/guardians. In this study we are asking you to help us collect this information and to tell us if the tools are easy to use.

What will happen to you in this study?

If you take part in this study, these things will happen:

- You and your parent/guardian will be asked some questions about regarding your general health and this illness.
- Before you go home you and your parent/guardian will be given a memory aide to record any costs related to this illness for the 30 days after you leave the hospital. This is to see how much this illness costs you and the caregivers who are affected by it.

- Study staff will contact you approximately 30 days after you are discharged to collect the information from your memory aide and to ask you how easy it was to use.

Can anything bad happen to you?

Taking part in this study means we will talk to you and your parent/guardian about your health. Taking part in the study will not hurt you in any way. There will be no extra tests of any kind needed for the study.

Can anything good happen to you?

This study will not help you get better quicker. We hope to find out information that may help other children in the future.

Do you have to be in the study?

No. You do not have to be in this study. Your parent/guardian has to say it's OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you wish you may also sign the form your parent signs agreeing that you want to take part. If you don't want to be in the study, just say no. No one will get mad at you. If you want to be in the study now and change your mind later, that's OK. You can stop at any time. Your doctor and the staff at the IWK will still take care of you in the same way whether or not you take part in the study.

Who will know that you were in the study?

Only people who are part of the study and people that make sure we are doing the study the right way may know that you were in the study. We will not give any information about who you are to anyone else without telling you and your parents or guardians. When we are finished with the study we will write a report about what was learned. This report will not include your name or that you were in the study.

Who can you talk to about the study?

You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to the study doctor, Dr Shelly McNeil. My name is __________________. My phone number is ___________ and Dr. McNeil's number is 470-8141. You can also call 470-8888 and ask for either Dr McNeil or me to be paged at any time. You will take home a copy of this form in case you want to ask questions later or in case you want to tell us that you do not want to be in the study any more.

APPENDIX M: IWK STUDY INFORMATION AND AUTHORIZATION FORM

Study Information and Authorization Form
16 July 2012

STUDY TITLE:	Evaluation of Healthcare Utilization Data Collection Tools in Children and Adults Admitted with Community Acquired Pneumonia, Invasive Pneumococcal Disease or Asthma: A Pilot Study
PRINCIPLE INVESTIGATOR:	Dr. Shelly McNeil, MD, Infectious Disease Specialist, QEII Health Sciences Centre
CO-INVESTIGATORS:	Sanela Gajic, Masters in Applied Health Services Research (candidate), Dalhousie University
SPONSOR:	Canadian Center for Vaccinology (CCfV)
FUNDING SPONSOR:	Unfunded

Introduction

We would like you and your child to participate in the research study named above at the IWK Health Centre. This form provides information about this study. Before you decide if you and your child want to take part, it is important that you understand the purpose of the study, how it may affect you and your child, the risks and benefits of taking part and what you and your child will be asked to do. A staff member of the research team will be available to answer any questions you have. Taking part in this study is you and your child's choice.

We refer to the process of giving you information about the study as "informed consent". This process starts with the first contact about the study and continues until the end of the study. You may decide today you want you and your child to take part in the study and change your mind later. You have the right to stop taking part at any time during the study. This will not affect the care you or your family members will receive from the IWK Health Centre in any way.

Why are the researchers doing the study?

Admission to hospitals for treatment of illness caused by an infection is not uncommon in Canada. Information is often collected about the types of care patients need and how much money this costs the health care system for treatment of such illnesses. What is often not considered is how much these illnesses cost patients and their caregivers. In this study we are asking you to help us collect this information and give us feedback on whether the tools we use to collect the information are easy to use.

The results will help us to improve and adjust the tools, which will then be implemented to assist with the national Serious Outcomes Surveillance (SOS) Network. This network is designed to look for vaccine preventable diseases in adults in order to better understand the burden of disease and healthcare utilization and to evaluate the effectiveness of recommended vaccines in the prevention of serious outcomes. At present the SOS Network conducts active surveillance for influenza, community acquired pneumonia and invasive pneumococcal diseases.

How will the researchers do the study?

Patients who are admitted to hospital due to certain types of illnesses such as the one your child has will be asked to take part in this study. We are conducting this study here at the IWK as well as the QEII Health Sciences Centre and the Dartmouth General Hospital. We plan to enroll 5 adult patients and 5 paediatric patients, for a total of 10 patients in this study. Information will be gathered about your child's illness, and general health. You will be given memory aides to use to collect information about costs to you related to your child's illness, while in the hospital and for 30 days after you go home.

What will you and your child be asked to do?

Visit One:

Written informed consent from the caregiver/family and, assent from the patient, if appropriate, will be obtained at this visit. This will take approximately 20 minutes to complete. All questions asked will be answered to your satisfaction and you will be given a signed copy of the assent and/or authorization form. If your hospital stay is short, the procedures at Visit Two will occur at Visit One.

Visit Two:

During this visit, you will be instructed on how to complete the survey tools. The patient will be asked to complete as much of the Patient Memory Aid as they can. The caregiver/family member will be asked to complete the Caregiver Memory Aid, if the patient cannot complete the Patient Memory Aid. Only one memory aid is to be completed. In addition, the Hospital Admission and Stay Expenses forms will be completed by both the patient, if they are able, and the caregiver/family member. These forms are listed below.

- Patient Memory Aid

- Caregiver Memory Aid
- Patient Hospital Admission and Stay Expenses tool
- Caregiver Hospital Admission and Stay Expenses tool

It will only take you a few minutes a day to complete these tools. Arrangements will be made to contact you 30 days after discharge from hospital to collect the information you have recorded. This may be by telephone or interview in person. Visit two will take approximately 30 minutes to complete.

Visit Three:

This visit will take place 30 days after discharge from hospital. You will be asked to report what you recorded on the study forms and to rate the user friendliness and clarity of the questions asked and how easy the tools were to follow. This visit will take between 30 minutes to an hour to complete. This will end your participation in the study.

What are the risks?

There are no risks for you and your child in taking part in this study. He/she is not being given any medication and no change in his/her treatment will result from participation.

You may find the interviews and questionnaires during the study upsetting or distressing. You may not like all of the questions that you will be asked. You do not have to answer those questions you find distressing.

What are the possible benefits?

Your child may not receive any benefit from participating in the study.

What alternatives do I have?

You and your child do not have to take part in this study. Not taking part in the study will not affect the care you or your family members will receive from the IWK Health Centre in any way.

Can I withdraw from the study?

Participating in the study is entirely voluntary. If you decide to enroll your child and later change your mind or your child changes his/her mind, you are free to withdraw your child at any time. If you decide to withdraw your child during the study, the data collected up until that time will not be removed. Withdrawing from the study will not affect the care you and your family will receive from your doctor or the IWK Health Centre in any way. Simply notify the study staff of your wishes.

Will the study cost me anything and, if so, how will I be reimbursed?

Taking part in this study will not result in any costs to you. You will receive the same care as you would receive if you were not in the study.

After completion of the questionnaire and the telephone call from study staff at day 30, you will be sent a gift card ($25) value from a local business or restaurant of your choice. This is in appreciation of the time you have taken to complete the study documents and provide us your feedback on them.

<u>Are there any conflicts of interest?</u>

No. The study doctors are not personally being paid to do the study.

<u>What about possible profit from commercialization of the study results?</u>

Neither you nor the investigators or study staff will receive any financial benefits from commercialization of the study results.

<u>How will I be informed of study results?</u>

General study results can be made available to you once the study is completed. The results will be mailed to you if you want to receive them.

<u>How will my and my child's confidentiality be protected?</u>

The research staff will keep all information that is learned about your child confidential, unless release is required by law. Any study information leaves this site will not include information that directly identifies your child. Instead, a code number is assigned to the study information. Study staff at this site will have access to your child's study and relevant medical records, which contain information that directly identifies you. In addition, your child's relevant records may be reviewed by representatives from CCfV, the Research Ethics Boards at Capital District Health or the IWK for audit purpose.

Anonymized data that does not contain information that could identify your child personally may be used publicly, such as for research and teaching purposes
If the results of the study are published in the medical literature, the publication will not contain any information which would identify your child. Study records will be stored in a locked area and will be kept 7 years, which meets or exceeds the requirements of the IWK Research Ethics Board, regulatory agencies in Canada.

<u>What are my research rights?</u>

Your signature on this form will show that you understand, to your satisfaction, the information about the research study. If your child becomes ill or injured as a result of participating in this study, necessary medical treatment will be available to you at no cost. However, you should be aware that no provision has been made to compensate you or your child for damage (e.g., lost time from work, disability or discomfort). By signing this form you are not waiving any of your rights, nor are you releasing the investigators, the sponsor or the institution from their legal and professional responsibilities.

Your child's participation in the study may be ended if, in the opinion of the study staff, it is not safe or reasonable for your child to continue. The sponsor also has the right to end this study at any time. If the study is changed in any way that could affect your decision to allow your child to continue to participate, you will be told about the changes and you may be asked to sign a new authorization form.

If you have any questions about this study or about research in general, you may contact the Research Office of the IWK Health Centre at 470-8520 Monday to Friday between 9 am to 5 pm.

What if I have study questions or problems?

If you have any questions, please call the study staff ______________________ at _______________ or the study doctor at 470-8141. You may also call the study coordinator, *(name and number to be inserted),* Monday to Friday between the hours of 9 am and 5 pm. **If you are calling after 5 pm or on the weekend/holiday, please call 476-8837 to reach the on-call study nurse.** The study doctor can be contacted at any time by calling the IWK at 470-8888 and asking for any of them to be paged.

Contact for future studies

You will be asked if you are willing to be contacted for future studies. If you do wish to be included, we will collect information needed to contact you in the future. This information would include name, address, phone number and date of birth, which we would store in a secure area. If you wish to be contacted, we will ask you to initial the signature page of this form to indicate this. We will not collect this information until the final study visit, when we will reconfirm you still wish to do this. If you indicate you agree today and change your mind later, it is not a problem and will not impact your care in any way.

Study ID: __________ **Study Initials:** _________

IWK Health Centre

Study Title: Evaluation of Healthcare Utilization Data Collection Tools in Children and Adults Admitted with Community Acquired Pneumonia, Invasive Pneumococcal Disease or Asthma: A Pilot Study

Parent/Guardian Authorization - I have read or had read to me the information and authorization form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand that I have the right to withdraw my child from the study at any time without affecting my family's care in any way. I will receive a copy of the Information and Authorization Form for future reference. I freely agree to allow my child to participate in this research study.

______________________________ ________________________________ **N/A**____
Name of Participant (Print) Signature of Participant

______________________________ __________________________________
Name of Parent/Guardian (Print) Signature of Parent/Guardian

Date: ____________________ Time:___________

I would like to receive study results. **(Please circle)** **YES / NO** **Initials**_________

I agree to be contacted and given information about future studies.
(Please circle) **YES / NO** **Initials**_________

STATEMENT BY PERSON PROVIDING INFORMATION ON THE STUDY

I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study.
Name (print):____________________________Position:__________________________

Signature: ________________________ Date: __________________ Time: ___________

STATEMENT BY PERSON OBTAINING AUTHORIZATION

I have explained the nature of the authorization process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time.
Name (print):______________________________ Position:________________________

Signature: ________________________ Date: __________________ Time: ___________

APPENDIX N: CDHA CONSENT TO TAKE PART IN A NON-CLINICAL TRIAL

Capital Health

CONSENT TO TAKE PART IN A NON-CLINICAL TRIAL

STUDY TITLE:	Evaluation of Healthcare Utilization Data Collection Tools in Children and Adults Admitted to Hospital with Community Acquired Pneumonia, Invasive Pneumococcal Disease, Asthma or Acute Exacerbation of COPD-A Pilot Study
PRINCIPAL OR QUALIFIED INVESTIGATOR:	**Dr. Shelly McNeil** QEII Health Sciences Centre Division of Infectious Diseases Room 5-014, Dickson Building 5820 University Ave, Halifax, Nova Scotia B3H 1V7 Telephone: (902) 473-8477
ASSOCIATE INVESTIGATORS:	Please see the attached Research Team Contact Page for a list of the associate investigators for this trial.
STUDY SPONSOR	Canadian Center for Vaccinology, Halifax

1. INTRODUCTION

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please read this carefully. Take as much time as you like. .Mark anything you don’t understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- Discuss the study with you
- Answer your questions
- Keep confidential any information which could identify you personally
- Be available during the study to deal with problems and answer questions

We do not know if taking part in this study will help you. You may feel better. On the other hand it might not help you at all. It might even make you feel worse. We cannot always predict these things. We will always give you the best possible care no matter what happens.

If you decide not to take part or if you leave the study early, your usual health care will not be affected.

2. WHY IS THIS STUDY BEING DONE?

Admission to hospitals for treatment of illness caused by an infection is not uncommon in Canada. Information is often collected about the types of care patients need and how much money this costs the health care system for treatment of such illnesses. What is often not considered is how much these illnesses cost patients and their caregivers. In this study we are asking you to help us collect this information on your illness and give us feedback on whether the tools we use to collect the information are user friendly, clear and easy to follow.

The results will help us to improve and adjust the tools, which will then be used to help with the national Serious Outcomes Surveillance (SOS) Network. This network is designed to look for vaccine preventable diseases in adults in order to better understand the burden of disease and healthcare utilization and to evaluate the effectiveness of recommended vaccines in the prevention of serious outcomes. The SOS Network conducts active surveillance for influenza, community acquired pneumonia and invasive pneumococcal diseases.

3. WHY AM I BEING ASKED TO JOIN THIS STUDY?

You are being asked to join this study because you have been admitted to hospital and have one of a variety of illnesses. Taking part in this study will not help you or change your course of treatment. You will be given the best possible care by the hospital staff no matter whether you take part in this study or not.

If you decide not to take part or if you leave the study early, your usual health care will not be affected.

4. HOW LONG WILL I BE IN THE TRIAL?

You will be in the study from the day you sign consent until about 30 days after discharge from hospital. Total time involved will be between 2-2 ½ hours over 3 visits. You participation will end after visit 3.

5. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study is being conducted in Halifax at the QEII Health Sciences Centre, the Dartmouth General Hospital, and the IWK Health Centre. We plan to enroll 5 adult patients and 5 pediatric patients for 10 patients in total. If someone enrolls in the study and changes their mind later we will enroll another person to take their spot.

6. HOW IS THE STUDY BEING DONE?

You will have already been approached and enrolled into the SOS Network by the study team member working on that project. This team member will ask you if you are willing to speak with another someone else regarding completing some questionnaires about how your illness has affected you financially. The study consists of an initial visit (Visit 1) to request your consent to take part in the study. This takes about 20 minutes. Before you are discharged from hospital the study staff will visit you a second time (Visit 2) to show you how to complete the questionnaires described above. You will be given a memory aide to take home to collect information about any costs to you related to your illness. If you are not able to complete the forms, a caregiver will be asked to do so. This form will take you only a few minutes each day to complete. This visit will last about 30 minutes. The final visit (Visit 3) will happen about 30 days after you are discharged from hospital to gather the information you entered on the forms. This can be in person or by telephone. You will be asked to rate the forms on how user friendly, clear and easy they were to follow. This will take between 30-60 minutes. Total time commitment to participate in this study will be about 2-2 ½ hours over the 3 visits.

7. WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

There are three visits you will be asked to complete in this study.

Visit One:

Written informed consent will be obtained at this visit. This will take approximately 20 minutes to complete. All questions you ask will be answered to your satisfaction and you will be given a signed copy of the consent form. We will let you know that visit two will occur just prior to discharge from the hospital.

Visit Two:

During this visit, you will be instructed on how to complete the survey tools. If you are unable to complete them, a caregiver will be asked to complete the following tools:

- Patient Memory Aid
- Caregiver Memory Aid
- Patient Hospital Admission and Stay Expenses tool
- Caregiver Hospital Admission and Stay Expenses tool

It will only take at most a few minutes each day to complete these tools. Arrangements will be made to contact you 30 days after discharge from hospital to collect the information you have recorded. This may be by telephone or interview in person. Visit two will take approximately 30 minutes to complete.

Visit Three:

This visit will take place 30 days after discharge from hospital. This can be done in person or by telephone. You will be asked to report what you recorded on the study forms and to rate the ease and clarity of the questions asked and how easy the tools were to follow. The time of this visit will depend on the extent of data that you have to report. This visit will take between 30 minutes to an hour to complete. This will end your participation in the study.

8. ARE THERE RISKS TO THE STUDY?

There are no risks for you in taking part in this study. You are not being given any medication and no change in your treatment will result from your participation.

You may find the questionnaires and interviews you receive during the study upsetting or distressing. You may not like all of the questions that you will be asked. You do not have to answer those questions you find too distressing.

9. WHAT HAPPENS AT THE END OF THE STUDY?

Your participation in the study will end approximately 30 days after you are discharged from hospital. Throughout the time you are in the study, you will continue to receive your usual care from your doctors as prior to the study.

10. WHAT ARE MY RESPONSIBILITIES?

As a trial participant you will be expected to answer the memory aid and questions as completely as you can. As noted previously you have the right to refuse to answer any questions you are not comfortable with.

11. CAN I BE TAKEN OUT OF THE STUDY WITHOUT MY CONSENT?

Yes. You may be taken out of the trial at any time, if in the opinion of the Principal Investigator it is not in your best interest to continue in the study.

12. WHAT ABOUT NEW INFORMATION?

It is possible (but unlikely) that new information may become available while you are in the study that might affect your health, welfare, or willingness to stay in the study. If this happens, you will be informed in a timely manner and asked if you wish to continue taking part in the study.

13. WILL IT COST ME ANYTHING?

<u>Compensation</u>

You will not be paid to be in the study. After completion of the questionnaire and the telephone call from study staff at day 30, you will be sent a gift card ($25) value from a local business or restaurant of your choice. This is in appreciation of the time you have taken to complete the study documents and provide us your feedback on them.

Research Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate as a subject. In no way does this waive your legal rights nor release the Principal Investigator, the research staff, the study sponsor or involved institutions from their legal and professional responsibilities.

14. WHAT ABOUT MY RIGHT TO PRIVACY?

Protecting your privacy is an important part of this study. A copy of this consent will be put in your health record.

When you sign this consent form you give us permission to:

- Collect information from you
- Collect information from your health record
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

Access to records

The study doctor and members of the research team will see health and study records that identify you by name.

Other people may need to look at the health and study records that identify you by name. These might include:

- the CDHA Research Ethics Board and Research Quality Associate
- the IWK Research Ethics Board

Use of records.

The research team will collect and use only the information they need to complete the study. This information will only be used for the purposes of this study.

This information will include:
Date of birth

Medical condition and length of hospitalization
Information from the study interviews and questionnaires

Your name and contact information will be kept secure by the research team in Halifax. It will not be shared with others without your permission. Your name will not appear in any report or article published as a result of this study.

Information collected for this study will kept as long as required by law. This could be 7 years or more.

If you decide to withdraw from the study, the information collected up to that time will continue to be used by the research team. It may not be removed.

After your part in this study ends, we may continue to review your health records.
We may want to follow your progress and to check that the information we collected is correct.

Information collected and used by the research team will be stored at The Canadian Center for Vaccinology located at the IWK Health Centre. The principal investigator is the person responsible for keeping it secure.

You may also be contacted personally by Research Auditors for quality assurance purposes.

Your access to records

You may ask the study doctor to see the information that has been collected about you.

15. WHAT IF I WANT TO QUIT THE STUDY?

If you choose to participate and later decide to change your mind, you can say no and stop the research at any time. If you wish to withdraw your consent please inform the Principal Investigator. All data collected up to the date you withdraw your consent will remain in the study records, to be included in any study related analysis. A decision to stop participating in the study will not affect your health care.

16. DECLARATION OF FINANCIAL INTEREST

This study is unfunded and the Principal Investigator has no financial interests in conducting this research study.

17. WHAT ABOUT QUESTIONS OR PROBLEMS?

For further information about the study call **Dr. Shelly McNeil.** Dr. McNeil is in charge of this study at this institution (she is the "Principal Investigator"). Dr. McNeil's work telephone number is (902) 473-8477. If you can't reach the Principal Investigator, please refer to the attached Research Team Contact Page for a full list of the people you can contact for further information about the study.

18. WHAT ARE MY RIGHTS?

After you have signed this consent form you will be given a copy.

If you have any questions about your rights as a research participant, contact the **Patient Representative** at **(902) 473-2133**.

In the next part you will be asked if you agree (consent) to join this study. If the answer is "yes", you will need to sign the form.

19. CONSENT FORM SIGNATURE PAGE

I have reviewed all of the information in this consent form related to the study called:
Evaluation of Healthcare Utilization Data Collection Tools in Children and Adults Admitted to Hospital with Community Acquired Pneumonia, Invasive Pneumococcal Disease, Asthma or Acute Exacerbation of COPD

I have been given the opportunity to discuss this study. All of my questions have been answered to my satisfaction.

I agree that my personal health and study information may be used as described in this consent form.

This signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time.

__________________________ __________________________ ________ ____/_____/____
Signature of Participant Name (Printed) Time Year Month Day*

__________________________ __________________________ ________ ____/_____/____
Signature of Authorized Decision Maker Name (Printed) Time Year Month Day*

__________________________ __________________________ ________ ____/_____/____
Witness to Participant's Signature Name (Printed) Time Year Month Day*

__________________________ __________________________ ________ ____/_____/____
Signature of Investigator Name (Printed) Time Year Month Day*

__________________________ __________________________ ________ ____/_____/____
Signature of Person Conducting Name (Printed) Time Year Month Day*

Consent Discussion

I WILL BE GIVEN A SIGNED COPY OF THIS CONSENT FORM.

*Note: Please fill in the dates personally **_Thank you for your time and patience_**

APPENDIX O: KNOWLEDGE TRANSLATION ACTIVITIES

Gajic, S., Ambrose, A., and McNeil, S. Outlining Healthcare Utilization for Invasive Meningococcal Disease to Quantify Economic Burden of Disease. In: Abstract Poster 10. PHAC/CIHR Influenza Research Network (PCIRN). Ottawa, Ontario. April 11-12, 2012.

Gajic, S., Ambrose, A., and McNeil, S. Outlining Healthcare Utilization for Invasive Meningococcal Disease to Quantify Economic Burden of Disease. In: Abstract Poster 19. ID Research Day & Canadian Center for Vaccinology Symposium. Halifax, Nova Scotia. April 23-24, 2012.

Gajic, S. Outlining Healthcare Utilization for Invasive Meningococcal Disease to Quantify Economic Burden of Disease. Oral presentation at: Canadian Center for Vaccinology. Friday Education Series on vaccine-related research. Halifax, Nova Scotia. May 11, 2012.

Gajic, S., Audas, R., and McNeil, S. Outlining Healthcare Utilization for Invasive Meningococcal Disease to Quantify Economic Burden of Disease. In: Abstract Poster 15. Canadian Association for Health Services and Policy Research (CAHSPR). Montreal, Quebec. May 29-31, 2012.

Gajic, S., Ambrose, A., Audas, R., McNeil, S., and the PCIRN Serious Outcomes Surveillance Network. Development of Evidence Based Healthcare Utilization Data Collection Tools for Prospective Evaluation of the Economic Burden Due to Invasive Meningococcal Disease (IMD) in Canada: A Public Health Agency of Canada/Canadian Institutes for Health Research Influenza Research Network (PCIRN) Study. In: Abstract Poster P-118. 10th Canadian Immunization Conference – Excellence in Immunization: Empowering, Engaging and Educating. Vancouver, Canada. December 3-5, 2012.