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Patient and Physician Characteristics as Predictors for Consent to Participate in an Electronic Medical Record Study

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RÉSUMÉ

Il y a une obligation générale d'obtenir le consentement d'un patient avant de pouvoir l'inscrire à un projet de recherche scientifique ou avant de communiquer de l'information personnelle relative à sa santé. Les motivations à donner un consentement dépendent à la fois du patient et du professionnel de la santé impliqués dans le processus.

Les caractéristiques de médecins et de patients ayant et n'ayant pas donné leur consentement à participer à un projet de recherche impliquant l'utilisation d'un dossier médical électronique pour gérer des prescriptions ont été analysées.

Les caractéristiques qui augmentent le taux de consentement comprennent le fait que le patient soit plus âgé, soit de sexe féminin et effectue plus de visites à la clinique médicale. Par contre, un nombre plus élevé de visites auprès de services d'urgence et un nombre plus élevé de visites à des pharmacies distinctes sont directement relié à un taux de consentement moins élevé.

Mots clés: système informatisé d'aide à la décision, prescription de médicament, dossier médical électronique, diffusion des innovations, consentement éclairé.

ABSTRACT

There is a general obligation to get a patient's consent to participate in a scientific research study or to communicate personal health information. Motives for giving consent may depend on both the patient and the health professional involved in the consent process.

Characteristics of physicians and of patients consenting and non-consenting to participate in an electronic medical record for prescription management research project were analyzed.

Characteristics that increased the chance of consenting included patients' older age, being female and more visits to the general practitioner. However, a higher number of visits to emergency rooms was directly correlated with a lower consent rate, as was an increased number a visited pharmacies.

Keywords: Computer-aided decision support, Prescription medication, Electronic medical record, Diffusion of innovation, Informed consent.

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CHAPTER 1 - INTRODUCTION

Background

Drug prescription management is the focus of extensive research regarding the suboptimal use of drugs and exploding costs. In order to address these issues, health care professionals are looking into ways to increase drug prescription performance. The introduction of computer technologies to manage drug prescriptions is seen as a favored way to increase the general drug prescription performance.

Medical drug consumption is growing in Canada due to various factors including a growing and aging population and the marketing of new promising drugs. In itself, prescription drug use represents the fastest-growing sector of health care spending. Recent figures estimate that, in 1999, total spending on prescribed drugs in Canada was of $10.3 billion, followed by a further increase to $11.4 billion in 2000 (10.3% and 10.6% annual increases) (Canadian Institute for Health Information, 2001).

Regarding the suboptimal utilization of prescription drugs, the related negative consequences include increases in the risk of adverse drug effects and negative effects on clinical benefits and cost-efficiencies. This suboptimal utilization has many negative implications and is very important as adverse drug effects are the 6th cause of mortality in the United-States (Lazarou & al, 1998; Hallas & al, 1990) and account for 2%-10% of hospital admissions (Colt & Shapiro, 1989; Ives & al, 1987;

Jha & al, 2001; Chan & al, 2001; Cooper, 1999; Raschetti & al, 1999; Stanton & al, 1994). Moreover, almost half of adverse drug effects, including dosing and administration errors, over and under-compliance, inadequate follow-up, and drug-disease, drug-allergy and drug-drug interactions, are preventable (Bates, Boyle & al, 1995; Bates, Cullen & al, 1995; Lesar, 2002; Halkin & al, 2001).

Incomplete information on current medication at the time of prescribing, errors in dose and drug selection, transcribing errors and unnecessarily costly prescribing are elements that contribute to suboptimal utilization of prescription drugs that could be addressed by information technology (Armstrong & Chrischilles, 2000; Bates & al, 2001; Nolan & al, 1999; Papshev & Peterson, 2001, Noffsinger & Chin, 2000; Rivkin, 1997; Monane & al, 1998). There is an obvious risk of having incomplete information as over 40% of elderly patients will use more than one pharmacy, 70% will have more than one physician prescribing medication, and as many as 5% will have more than six (Tamblyn & al, 1996). Furthermore, over one-third of elderly people will be prescribed a drug contraindicated by age, current disease, allergy, or another drug (Monane & al, 1998; Ostrum & al, 1995). Also, transcription errors are made in 10%-15% of prescriptions, of which 2% are serious, and increase with volume, poor writing, and level of pharmacist training (Bates, Cullen & al, 1995).

High costs related to medical drugs are also an incentive to promote a better management of drug prescription. Drug prescribing must also be better managed in order to be able to address the general rise in health care costs, and of drugs use in

particular. Health care data indicates that, for over 31 million existing Canadians, health expenditures, which includes spending by federal, provincial and local governments, workers compensation boards and the private sector, was of 95.1 billion of dollars in year 2000. This corresponds to 9.3% of gross domestic product. Of that amount, 30.2 billion was hospital costs, 12.8 billion for physicians, 11.2 billion to other professionals and 14.7 billion to prescription and non-prescription drugs. Global Canadian health expenditure climbed from 75.3 billion in 1996 to 95.1 billion in 2000, while the percentage this represents relative to the gross domestic product went from 9% to 9.3% (Canadian Institute for Health Information, 2000). On an individual basis, Canadians spent, in 2001, 4.7% of all personal expenditure on medical care and health services (Statistics Canada, 2003). According to the August 2000 report *Understanding Canada's Health Care Costs* by Canada's Provincial and Territorial Ministers of Health, the overall provincial and territorial operating health expenditures have gone up substantially over the past two decades, from about $11 billion in 1977/78 to almost $56 billion in 1999/2000. The report states that the cost increase is likely an underestimate, as it does not take into account cost accelerators such as emerging and new technologies, the increased incidence of chronic and new diseases, and the cost of renewal. This could bring the total of provincial and territorial health spending to over $100 billion within the next decade. Only for poor compliance results, it is estimated that the costs are of $3.5 billion per year in health care expenditures and that it represents 5.3% of hospital admissions (Sullivan & al, 1990). A review of the literature evaluating the direct costs of prescription drug related problems in Canada

reveal that hospitalization costs and loss of productivity account for as much as 7 to 9 billion dollars (Coambs & al, 1995).

The development of electronic medical records, or e-records, aims at resolving the problems of incomplete information on current medication at the time of prescribing, errors in dose and drug selection and transcribing errors and unnecessarily costly prescribing. Increasingly, the paper-based medical chart is being replaced by a computerized chart. Advantages of an e-record over a conventional paper record include the readily availability of patient information as they contact and re-contact players in the health care system, the permanent status of the patient's medical history and the fact that the patient does not need to be asked the purpose of his visit, in a different way, at every encounter. Furthermore, medical conditions that pose a serious health risk can be flagged by an adequate software algorithm in order to avoid medical errors. To date, there is evidence that computerized systems are effective in hospitals for reducing preventable adverse drug-related events (Bates & al, 1998; Hunt & al, 1998; Raschke & al, 1998, Bates, 2000), improving cost-effective decision-making in selection of drug therapy (Pestotnik & al, 1996; Hershey & al, 1986; Gehlbach & al, 1984; Rossy & Every, 1997; Evans & al, 1998) and possibly improving clinical decision-making for individual drug-dose calculation (Poller & al, 1993; Casner & al, 1993; Mungall & al, 1994; Walton, 1999; Fitzmaurice, 1998). Furthermore, an integrated physician-pharmacy-patient drug management system has the potential to: 1) reduce prescribing errors, 2) reduce transcription errors, 3) reduce utilization errors related

to the failure to communicate prescription stop and change orders, and 4) provide compliance monitoring tools.

Because of the complexity of the health system as a whole, and of drug prescription management in particular, and because of the high costs related to the implementation of necessary new technologies and managerial procedures, it is necessary to judicially evaluate ways to improve the system. Research can help evaluate new drug management paradigms through their implementation on a small scale, as pilot-projects. Such a project, the Medical Office for the Twenty First Century (MOXXI), was carried out in Montreal. The second phase of the Medical Office for the Twenty First Century initiative was carried out in Quebec in 1999-2000 to study how e-records could be used to manage information about prescription drugs. More precisely, the MOXXI-II project aimed at testing the potential benefits of electronic transmission of current drug profiles of patients, which would benefit both the patient, who would receive better services, and the physician, whose practice would be enhanced. The MOXXI-II project aimed at enhancing the quality of clinical care delivered by physicians by improving access to clinical data, including information about drugs prescribed by other physicians and laboratory results, and implementing a computer-generated patient alert system that would red-flag incompatible drug prescriptions. These goals are in line with the maximization of drug prescription and the will to curtail adverse drug affects caused by errors in prescriptions.

A crucial aspect of the MOXXI-II project was, as with many procedures involving patients, that patients were required to give consent to certain procedures. In this case, consent was required to authorize their physician to obtain their drug information from the *Régie de l'assurance-maladie du Québec* (RAMQ), the public government managed health insurance institution. This consent requirement had a double implication. Not only were the patients asked to give consent to the communication of personal health information, they were asked to do so in the context of a research project where a new technological means of intervention was tested. Asking for consent in such a research scenario raises issues of privacy and confidentiality of health information, which is often regarded as highly sensitive (Canadian Institute of Health Research, 2002), especially that there is health data linkages with different health professionals. Patients, health professionals and health care providers have expressed the need for controls on the collection, use and disclosure of personal health information.

At present times, general consent requirements regarding personal health information, including the use of secondary data for epidemiological and population health research, are not clearly defined in practice. Nevertheless, because consent to communicate personal medical information is, and will be, a requirement for certain aspects of medical practice and research and that refusal to give consent may be detrimental to clinical practice and medical research, it is necessary to understand the parameters of required consent. To further the understanding of consent scenarios, this thesis will see to establish characteristics of patients and physicians

as predictors of consent to the communication of personal health information in the context of the implementation of a new technology. Knowing what variables are related to a low and high consent rate will help health care professionals and researchers in their work by providing a clearer understanding of bias and consent approval.

It is important to understand the context within which patient consent is required to fully appreciate the scope and implications of this research. In order to accomplish this goal, a literature review of the theoretical foundations of consent requirements and health technology innovation will follow the description of the research's objectives.

The literature review will be followed by a presentations of the methodology of the study, followed by an exposé of the results, respectively through univariate and multivariate data analysis and a discussion of said results. A final chapter will summarize and conclude the research.

Objectives

The objective of the study is to identify patient and physician characteristics associated to their willingness to participate in studies where there is communication of their personal health information.

Sociodemographic and health related characteristics of patients will be analyzed in conjunction with sociodemographic and professional practice-related characteristics of physicians to establish if some characteristics, individually or in association with others, can help predict patient consent rate to participate in an electronic medical record study.

This study aims at bringing a valuable contribution to the study of patient consent to the communication of personal health information through the analysis of consent rate and physician bias.

CHAPTER 2 – LITERATURE REVIEW

The ethical and legal notions related to the concept of consent in health care will be the subjects of the first section. The second section will define what constitutes an electronic medical record, what advantages it can bring to the health care sector and what are the attitudes of health professionals who had to use one. This will be followed by a literature overview of patients' and health professionals' attitudes towards the mandatory consent. Finally, the conceptual framework of the research will be elaborated using the different variables recovered from the literature exploration.

Ethics, Law and Consent in Health Care

The sensitive nature of personal health data requires that the implementation and the use of an EMR take into account notions of privacy and confidentiality of health information, in both clinical and research environments. These notions of privacy and confidentiality are at the source of the patient consent requirement to communicate personal health data.

The following section will elaborate on the foundations of patient consent through an exposé of ethical principles and legal requirements. The practical aspects of patients' consent to participate in research will also be explored. Ethical and legal issues must be explored because they are the foundations of the notion of consent. Therefore, an understanding of what constitutes ethical and legal issues is necessary to establish the different characteristics associated with patient consent rate. Consent is seen, for the benefit of this research, as a dependent variable: it is given or it is not given.

Ethical issues

Medical ethicists point to two ethical rationales when discussing the necessity of protecting personal health information. The justification most commonly offered is a *consequentialist*, or utilitarian, one. The other justification relates to a *deontological* approach (Appelbaum, 2002).

The consequentialist, or utilitarian, approach supposes that patients must have the utmost confidence in the fact that their physician is going to keep any information they give them confidential in order for the diagnosis to be adequate and the treatment to be effective. Patients must trust the fact that their physician will not disclose personal information to third parties (Gillon, 1985). This trust is important so that the patient will not withhold information to their physicians or avoid going

for treatment. A Gallup survey conducted in 2000 for the American Institute for Health Freedom found that 78% of respondents felt that the confidentiality of their health information was very important (The Gallup Organization, 2000). In Canada, a 1999 survey conducted by the Angus Reid Group on behalf of the Canadian Medical Association showed that 65% of Canadians had concerns over privacy and confidentiality of personal information relating to health information such as the information about their physical and mental history and status contained in medical records. When analyzing if individuals acted in a particular way to protect their medical privacy, a study revealed that 15% of a national sample in California went out of their way to do so, including not seeking care or giving inaccurate or incomplete information (California Health Foundation, 1999). Furthermore, other research reveals that 25% of studied adolescents would abstain from care if they thought their parents would find out about their health inquiries (Cheng & al., 1993).

A second ethical argument, the deontological approach, has also been developed by advocates of medical privacy who felt that there was a dearth of data supporting consequentialist justifications. Proponents of the deontological approach argue that privacy is a good concept in itself and does not have to be viewed in relation to the positive consequences it can have on a patient's health (Shuman & al., 1986; Imwinkelried, 1998). The claim is that individual autonomy should be encouraged in society, and that privacy helps the advancement of this autonomy.

Professionals of the health care sector have incorporated ethical guidelines regarding privacy, confidentiality and related consent into their medical practice. The medical profession had adopted as a principle the notion that physicians have the duty to respect the patient's privacy and confidentiality unless they are relieved from this obligation by their patients offering consent to the disclosure of their medical information.

In Canada, the Canadian Medical Association (CMA) tackles the issue of ethics in two documents: The CMA Code of Ethics and the CMA Health Information Privacy Code. The Code of Ethics latest version dates from 1996 and is based on the fundamental ethical principles of medicine that are compassion, beneficence, non-maleficence, respect for persons and justice. The CMA code had a section on Confidentiality where section 22 states that a physician should "respect the patient's right to confidentiality except when this right conflicts with your responsibility to the law, or when the maintenance of confidentiality would result in a significant risk of substantial harm to others or to the patient if the patient is incompetent; in such cases, take all reasonable steps to inform the patient that confidentiality will be breached." Subsequent sections relate to confidentiality when a third party is involved and the provision of a medical record copy upon request. As for the CMA Health Information Privacy Code approved in 1998, it includes principles to deal with issues of protecting the privacy of patients, the confidentiality and security of their health information and the trust and integrity of the therapeutic relationship. It is based on the Canadian Standards Association's Model Code for the Protection of

Personal Information (CSA Code), of 1996, and describes the minimum requirements to protect the privacy of patients and the confidentiality and security of their health information. This code gives examples of what constitutes patients' fundamental rights and of basic duties meant to ensure that the privacy rights are adequately respected and protected. About consent, the CMA Health Information Privacy Code states that, except for very limited conditions concerning nonconsensual collection, use, disclosure or access permitted or required by legislation or regulation that meet the requirements of the Code, or ordered or decided by a court of law, consent is required for health information collection, use, disclosure or access for any purpose. It also states, at section 5.9 under the Consent Principle subdivision, that "Patient consent for secondary nonlegislated purposes shall be express, voluntary and fully informed." The code also gives provisions relating to individual access, security, accountability, transparency and openness, and collection, use, disclosure and access to health data.

As for the Code of Ethics specific for Quebec physicians, it has been written and approved by the Collège des médecins du Québec. This Code of Ethics of Physicians, which came into effect November 7th 2002 and has legal force, is viewed as being more stringent than the CMA code (Benady, 2002), including the obligation to use health-care resources wisely (section 11), to not go on strike (section 12), to own up to mistakes (section 54) and to ensure patient's right to accuracy of information (section 88). About privacy and confidentiality, the Code enacts at section 20, amongst other provisions, that "A physician, in order to

maintain professional secrecy, 1o must keep confidential the information obtained in the practice of his profession; (…) 3o must take reasonable means with respect to the persons with whom he works to maintain professional secrecy; (and) 5o may not divulge facts or confidences which have come to his personal attention, except when the patient or the law authorizes him to do so, or when there are compelling and just grounds related to the health or safety of the patient or of others;". Furthermore, section 21 lists items that must be listed in the patient's record by a physician who communicates information protected by professional secrecy, including "2o the identity of the person exposed to danger or of the group of persons exposed to danger; (…) 3o the identity of the person to whom the communication was made, specifying, according to the case, whether it was the person or persons exposed to danger, their representative or the persons likely to come to their assistance; (and) 5o the danger he had identified;". With respect to research and consent, a physician must ensure "that a voluntary and informed written consent, which is revocable at all times, is obtained from each subject before he begins his participation in the research project or when there is any significant change in the research protocol" (section 30.2). Furthermore, a "physician must, before undertaking his research on humans, obtain approval of the project by a research ethics committee that respects existing standards, notably in its composition and procedures" section 31).

Another important code of ethics for research in the medical field in Canada is the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,

where the three councils are the Natural Sciences and Engineering Research Council of Canada, the Social Sciences and Humanities Research Council of Canada and the Canadian Institute of Health Research. The practical aspects of this policy statement will be discussed further on as it has direct practical implications for research.

In the case where a physician would deliver a drug prescription to a patient and where this prescription would be sent electronically to a pharmacist, because of this pharmacists' implication, a section on confidentiality of the Quebec Code of Ethics of pharmacists would also have to be followed. It states, at article 3.06.01, that "A pharmacist must respect the secrecy of all confidential information acquired in the practice of his profession" and that "a pharmacist may be released from professional secrecy only upon the authorization of his patient or when so ordered by law."

Legal issues

In the province of Quebec, privacy concerns in health care must obey precise laws and regulations.

The concepts of privacy, confidentiality and security are distinct concepts that are nevertheless related. This is particularly the case when consent to electronic exchange of information is at the core of a system.

Privacy and confidentiality must not be confused. A person's name and address, for example, are elements relating to privacy but are not necessarily confidential. Otherwise, a document may be confidential without having any privacy inference, like a government memo. As for the concept of security, it relates to safety measures that concern the integrity of data and information exchange. Privacy and confidentiality concepts are essential to define because they are the cornerstone concepts of consent. In other words, you need to understand the notions of privacy and confidentiality in order to adequately comply with consent requirements.

Various laws and regulations regarding issues of privacy, confidentiality, security and consent must be taken into account in the province of Quebec context.

The Quebec *Charter of human rights and freedoms* states that, in article 5:

"Every person has a right to respect for his private life."

The *Civil Code of Quebec* states at article 35 that:

"Every person has a right to the respect of his reputation and privacy."

> "No one may invade the privacy of a person without the consent of the person or his heirs unless authorized by law."

Article 19 of the *Act respecting health services and social services* gives the basic requirements regarding consent:

> "The record of a user is confidential and no person may have access to it except with the consent of the user or the person qualified to give consent on his behalf, on the order of a court or a coroner in the exercise of his functions, or where this Act provides that an institution may be required to release information contained in the record."

Two other important Quebec laws have to be taken into account when dealing with aspects of privacy and confidentiality. The first of these laws is the *Act respecting Access to documents held by public bodies and the Protection of personal information* enacted on June 22, 1982, thereby creating the Commission d'accès à l'information du Québec (Access to Information Commission). The second of these laws is the *Act to establish a legal framework for information technology* enacted June 21, 2001, which establishes a legal framework for the exchange of electronic documents. This last law also gives requirements relating to the security of technologic documents.

In Quebec, the Commission d'accès à l'information (CAI) plays an important role regarding privacy and confidentiality issues and questions of consent in the health care sector in the province of Quebec. The CAI is responsible for administering the *Act respecting access to documents held by public bodies and the protection of personal information.* The Act applies to government departments and agencies, municipalities and agencies under municipal control, educational institutions and health and social service network institutions. The CAI is also responsible for the application of the *Act respecting the protection of personal information in the private sector.* All enterprises supplying goods and services must comply with this Act if they collect, store, use or communicate personal information. The CAI holds the role of an administrative tribunal (The Adjudication Function), it is responsible for overseeing compliance with the obligations imposed upon public bodies and private sector enterprises concerning the collection, storage, use and communication of personal information (The Supervisory and Control Function) and it facilitates the implementation of concrete measures designed to ensure compliance with both the spirit and the letter of the law (The Advisory Function) (Commission d'accès à l'information, Mandates and Functions).

Throughout its decisions and publication, the CAI has established that a given consent must be obvious, free, enlightened, and given for a specific reason and a specific length of time.

Given its essential and inevitable role regarding privacy and confidentiality issues in the province of Quebec, the CAI often intervenes in matters regarding health and information. Moreover, the CAI is often requested when carrying out research projects involving personal health data.

The commission seems to acknowledge the evolutionary nature of health care management, particularly regarding new technologies. It has recently studied matters relating to electronic exchange of data in the health care system. On this subject, the CAI recently recognized that "The networking of electronic clinical records challenges the rules governing the transfer of health information. The Commission, therefore, reiterates the importance of reviewing the Québec legal framework for access to and the protection of health data in light of the new dynamic for the exchange of clinical information, in the interest of the patient" (Commission d'accès à l'information. Étude sur l'inforoute de la santé au Québec: enjeux techniques, éthiques et légaux, p. 3, 2001; Commission d'accès à l'information, Study of the Health Information Highway in Québec: Technical, Ethical and Legal Issues, p. 3, 2001).

At the Canadian federal level, the *Personal Information Protection and Electronic Documents Act* (*PIPEDA*) sets out the ground rules for how organizations may collect, use or disclose personal information in the course of commercial activities. Although the PIPED Act was originally intended to regulate commercial use of electronic information, it is now the legal standard that will be used for health

researchers when they access personal information. However, personal information may be used for "research purposes" without knowledge or consent under certain circumstances "for purposes that a reasonable person would consider appropriate in the circumstances" (section 3). At present, Quebec is the only province with a personal data protection law in effect that applies to the provincially regulated private sector. In his *Report to Parliament Concerning Substantially Similar Provincial Legislation* (May 2002), on page 15, the Privacy Commissioner of Canada concluded that "Based on the foregoing analysis, I believe that Quebec's *Act Respecting the Protection of Personal Information in the Private Sector* legislation is substantially similar to the *PIPED Act* in terms of the extent to which it protects personal information."

Practical aspects

In the context of a scientific research project on the use of electronic medical records in a medical setting, these legal requirements and ethical guidelines are established in policies enacted by hospital Research Ethics Boards (REBs) or, if done in a university research setting, by an Institutional Review Boards (IRBs).

In the specific context of the MOXXI-II project, the research project had to obtain McGill University's IRB approval before undertaking their research.

McGill University follows the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, where the three councils are the Natural Sciences and Engineering Research Council of Canada, the Social Sciences and Humanities Research Council of Canada and the Canadian Institute of Health Research, and its IRB declares that its working procedures are consistent with the published guidelines of the Canadian Institute of Health Research. Furthermore, as a registered University IRB, the McGill IRB works in accordance with the published regulations of the US Department of Health and Human Services, and holds a Multiple Project Assurance Agreement approved by the Office for Human Research Protections (OHRP) that includes an Inter-Institutional Agreement between the University and its affiliated hospitals. Deliberations of the Committee must conform to applicable laws, including, where relevant, the Quebec Civil Code and the Quebec Act respecting health services and social services. The Minister of Health and Social Services has designated the McGill IRB to carry out the review, approval and follow-up for research to be conducted with children and cognitively impaired individuals as referred to in Article 21 of the Civil Code of the Province of Quebec (McGill University, IRB Mandate and Working Procedures).

Furthermore, because of the academic nature of the MOXXI project, it is also necessary for researchers to consult research ethic guidelines that concern these subjects, such as the ones given by the *McGill University Ethical and Legal Aspects of Research involving Human Subjects conducted in the Faculty of Medicine and Affiliated Hospitals* first written in 1993 and having been revised in 1994 and 1999.

Adopting the Electronic Medical Record

Like in every work sector of modern society, the health care sector is increasingly using information technologies to improve outcomes. This section will describe the various potential uses of information technologies in health care and how professionals and patients respond to these new technologies, then will be exposed a general theory describing characteristics of early adopters of technologies.

An important benefit of the use of information technologies in health care is that they enable linkages between clinical data and administrative data to improve quality of care and reduce the need to collect and re-collect the same information (Gostin & Hadley, 1998; Fitzmaurice & al., 2002). Other benefits brought by information technologies include the increasing use of email for correspondence between patients and physicians (Kane & Sands, 1998), the use of accessible internet and specialized web sites like PUBMED by the public and health professionals who can quickly find a wealth of information on health, including articles and research about medical conditions and treatments (Hayes & Lehmann, 1996) and the ability to act from a distance through the means of telemedicine (Lehoux & al., 1999; Mitka, 1998).

Automated technologies will most likely enable patients' electronic medical records to be recorded longitudinally from birth to death and be accessed through national health care information infrastructures (Gostin, 1997) while many benefits have been identified in relation to the systematic collection and use of electronic health data. More accurate data improves clinical care through faster and more accurate diagnoses (Hunt & al., 1998), increased checks on medical procedures (Bates & al., 1998) and prevention of adverse drug reactions (Raschke & al., 1998). Also, medical research and public health studies of morbidity and mortality across populations are facilitated by the increased access to information (Gostin & al., 1996; Flahault & al., 1998). On the technical side, new computer hardware and software facilitate network security and information protection through the requirement of personal codes for access to information, layers of access to information, firewalls and encryption programs, amongst others.

However, the use of information technologies in the health care sector has brought significant challenges to the sector. A major challenge concerns the issues of patient privacy and confidentiality of personal health information. These are important issues because individual health data is considered to be among the most sensitive type of personal information (Gostin, 1997). Privacy in a medical setting is defined as being information regarding a person's medical condition for which that person has interest in maintaining the control. Protecting personal health data is critical to the good workings of the medical profession because it enables trust in the patient-physician relationship. Not keeping personal health data in a secure fashion can lead

to unauthorized use and disclosure of this data (Beauchamp & Childress, 1994), which can lead to possible embarrassment and discrimination (Gostin & Hodge, 1998). The computerization of medical information into databases makes information more accessible and also easier to change, be copied, disclosed or deleted by more people than conventional paper records (National Research Council, 1998).

A particular field that is greatly transformed by computer technology is the one of patient medical record management. A literature review shows that there are different terminologies used to identify a patient record stored in electronic format, including Electronic patient record, Electronic medical record and Electronic medical record. The later will be used for this study. Furthermore, of the different definitions proposed by various health care organizations, the most thorough definition seems the one given by the Institute of Medicine (Dick & al., 1997) of the United states in 1997: "A *computer-based patient record* is an electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems, links to medical knowledge and other aids" (p. 55).

Patient medical records are increasingly digitalized and stored in governmental and other institutional electronic databases. Electronic medical records offer many potential advantages over paper-based records, including allowing providers to access information from a variety of locations and to share information more easily

with other potential users, allowing multiple users to have simultaneously access to information, allowing control of data access with logs to keep a history, and the possibility to present the information in different ways tailored to different clinical needs (Dick & al., 1997).

Characteristics of innovation adopters

Furthermore, it is essential to have a basic understanding of the theory of diffusion of innovations to fully appreciate the importance of identifying adopter characteristics when implementing a new technology or mode of intervention. Adopter characteristics can serve as a base to appreciate the characteristics of physicians adopting a new technology and mode of intervention like an EMR. Following is a brief overview of the general diffusion of innovations theory by Everett M. Rogers (1995), with an emphasis on innovativeness and characteristics of earlier adopters of innovations.

Everett M. Rogers defines an innovation as being "an idea, practice, or object that is perceived as new by an individual or other unit of adoption" (Rogers, 1995, p. 11). Example of "other" units of adoption would be, in the health care sector, a hospital, a group of professionals, a regional health board or patients.

Rogers (1995) has been studying for decades how individuals and systems adopt innovations and has published, in 1995, the fourth edition of a compendium on the subject titled "Diffusion of innovations" that is widely considered as the classic text in the field as the author has done a great effort to synthesize all the most valid findings and research on the subject. The origin of diffusion research dates, according to Rogers (1995), to a 1943 study by Ryan and Gross, two researchers from at Iowa State University in the field of rural sociology, who used interviews with adopters of an innovation to establish characteristics related to the adoption process.

In his book, the author elaborates a classification of adopters as he studies the adoption rate of innovations through time. Study data establishes that the rate of adoption of an innovation follows a normal bell-shaped curve showing the frequency, or number, of adopter through time. The rate of adoption can also be displayed as an S-shaped curve showing the cumulative rate of adoption through time. Theory establishes at between 10 and 20 percent the number of adopters needed so that an innovation will be viable and further individuals or systems adopt it. It is predicted that if an innovation cannot reach this acceptance zone, its diffusion will most likely fail.

Adopters are classified into categories of innovativeness, from individuals who are predisposed to being innovative and who will adopt an innovation early than to individuals who prefer the status quo or are very traditional and who will accept last

an innovation. The different adopters are categorized as innovators, early adopters, early majority, late majority and laggards.

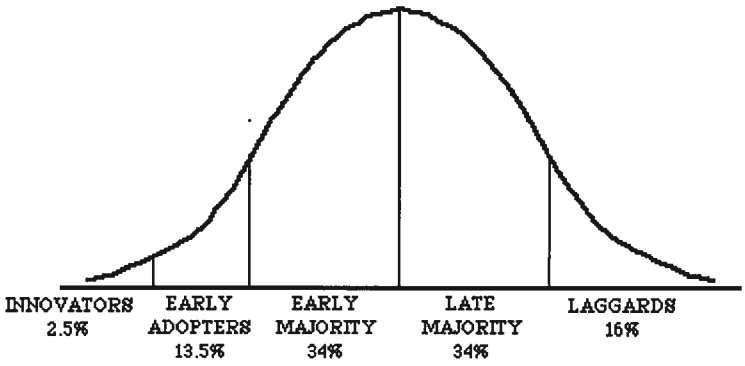

Figure 1. Bell shape curve showing the distribution of different categories of adopters with percentages.

The first group, innovators, represents the first 2.5% of adopters of an innovation. Rogers defines them as being venturesome to an almost obsessive point. They have a desire for the rash, the daring and the risky. Their interest in new ideas has them communicating more with like-minded individuals than with their peers and be disrespected by other members of a local system. The tendency to accept new innovations is often backed by their complex technical knowledge and financial resources. While being essential members of the community because they bring new ideas into their system, they must be prepared to accept set-backs when new ideas prove unsuccessful, as some inevitably do.

The next group representing 13.5% of adopters is composed of early adopters, who are more integrated to their local system than are innovators. They are respected by their peers and are viewed as role models by many other members of their social system regarding the adoption of innovations as they decrease uncertainty about a

new idea by adopting it. Early adopters are often sought by change agents as individuals who will embrace an innovation and speed its diffusion process. They must, in order to continue to earn the esteem of localites, make judicious innovation decisions.

Then comes the early majority, which represents 34% of adopters, bringing the total of adopters to 50% and the top of the bell curve. The early majority adopts an innovation before the average number in a system. They are individuals who much interact with their peers while seldom being opinion leaders in their system. The early majority, which makes up one-third of the members of a system, is an essential bridge between early adopters and the late majority as they secure the adoption of an innovation through the system's interpersonal networks. They have an intentional willingness to adopt an innovation, but are not going to lead this adoption.

The following group, the late majority, also is comprised of 34% of adopters, or one-third of the total. They adopt an innovation after the member of a system, either because of an economic necessity or because of pressure from peers. The late majority is skeptical and cautious of innovation and will only adopt one after most other members of their system have done so. The weight of system norms and the disappearance of uncertainties about a new idea are elements that prompt the late majority to adopt an innovation.

The final group is composed of laggards, which represent the last 16% of adopters and are considered to be almost isolated in their social system. They are viewed as traditional individuals having the past as a reference point and who mainly interact one with the other. Their suspicion of innovations and change agents makes them resistant to new ideas. This resistance is due in part to the fact that their resources are limited and they must be certain that a new idea will not fail before they adopt it.

This theoretical classification is based on empirical research and has a standardized percentage of respondents in each category. The frequency distribution is asymmetrical in that there are three adopter categories to the left of the mean and two to the right. This is explained by the fact that innovators and early adopters form clear and distinctive groups, which cannot be combined, and that laggards form a quite homogenous group and therefore cannot be devised in two categories.

It must be understood that these five adopter categories represent ideal types, which are not just an average of all observations about a category established to make comparisons possible, but are abstractions made from empirical investigations. Exceptions to the ideal types can be found in every category.

Furthermore, this classification is not exhaustive for it does not take into account incomplete adoption or non-adoption, as the author advances in his chapter defining The Method of Adopter Categorization, at page 263. Rogers states that this problem

is eliminated when a series of innovations are combined into a composite innovativeness scale.

The authors refers to a voluminous literature research about variables related to innovativeness and summarizes this diffusion research in a series of generalizations under three banners that are socioeconomic status, personality values and communication behavior. Earlier adopters are compared to later adopters.

The first observation on socioeconomic characteristics of adopters is that earlier adopters are not different from later adopters in age. Rogers (1995, pp. 269-272) found inconsistent evidence about the age relationship when studying 228 researches on the subject, with about half showing no relationship and a few concluding that early adopters are younger, and still a few stating the opposite. Other observations state that earlier adopters have more years of formal education than late adopters and that they are more likely to be literate, have higher social status than later adopters, status depending on such variables as income, level of living, possession of wealth and occupational prestige. Another observation describes earlier adopters as having a greater degree of upward social mobility than later adopters, maybe even using the adoption of innovations as means of climbing to higher levels of social status. A last observation on socioeconomic characteristics of adopters describes the earlier adopters as having larger social units (farms, schools, companies and so on) than later adopters.

Personality variables have not received as much consideration in research, in part due to difficulties of measuring personality dimensions in field interviews (Rogers, 1995, pp. 272-273). The first generalization about personality variables establishes that earlier adopters have greater empathy than later adopters, with empathy being the ability to project oneself into the role of another person. This enables the innovator to think counterfactually and better communicate with individuals who are in other systems. Another observation states that earlier adopters may be less dogmatic than later adopters, thus having their belief system more open to new ideas. However, evidence is not strong to support this generalization. Other observation makes the author state that early adopters have a greater ability to deal with abstraction, a greater rationality, a greater intelligence, a more favorable attitude toward change, are better able to cope with uncertainty and risk, a more favorable attitude toward science and are less fatalistic than later adopters, fatality being the perceived impression of not being in control of a situation. Finally, earlier adopters have higher aspirations (for formal education, occupations, and so on) than later adopters.

The first communication behavior generalization states that earlier adopters have more social participation than later adopters (Rogers, 1995, pp. 273-274). Others generalization state that earlier adopters are more highly interconnected through interpersonal networks in their social system and that they are more cosmopolite than later adopters in the sense that innovators' interpersonal networks are more likely to be outside of their system than inside. Others, still, state that earlier

adopters have more change agent contact, a greater exposure to mass media communications channels, greater exposure to interpersonal communication channels, seek information about innovations more actively and have greater knowledge of innovations than later adopters. Finally, earlier adopters have a higher degree of opinion leadership than later adopters.

Rogers' theory of diffusion of innovations has been used to study the diffusion of innovations in various fields. The author himself uses his work, with colleagues, to study subjects as the diffusion of patient oriented activities in Dutch community pharmacy (Pronk & al., 2002) and the adoption of work-sit AIDS programs (Backer & Rogers, 1998). He also applied his theory to the diffusion of the concept of Beyond War, a nonpartisan educational movement originating in the United States. The tenants of this concept are that war is obsolete, as is nationalism, and that the world is one interconnected, interdependent global system. Collaborating a chapter to the book Breakthrough: Emerging New Thinking, Soviet and Western Scholars Issue a Challenge to Build a World Beyond War, Rogers elaborates the framework for the Beyond War idea to be diffused throughout society.

The classic theory of diffusion of innovations had been used to study, amongst other subjects, the adoption of mobile internet services (Pederson, 2001), language and learning (Vanderslice, 2000), electronic commerce adoption by small and medium-sized enterprises (Kendall & al., 2001), management of new software engineering tools (Mathiassen & Sørensen, 1997), introduction of new ideas into

organizations (Manns & Rising, 2003) and solar oven use in Lesotho (Grundy & Grundy, 1994).

In the health care sector, Rogers's theory of innovations has been used to study the diffusion of innovations into psychiatric practice (Freedman, 2002), physician order entry in hospitals (Ash & al., 2001), the adoption of a Picture Archiving and Communication System (PACS) in a Quebec hospital (Trudel & Paré, 2002) and the relation between clinical team characteristics and the adoption of an online evidence information system (Goslin & al, 2003), as well as a general study, with recommendations, regarding the dissemination of innovations in health care (Berwick, 2003). A study describing the characteristics of woman who were early adopters of clinical BRCA1/2 testing is one of the only possible few studies that considers the patient's side in a scenario of new health technology adoption (Armstrong & al, 2003).

A more thorough analysis of the acceptance of electronic medical records would have to take into account other factors than adopter characteristics and could include different theoretical models such as the Knowledge Barriers Theory (Attewell, 1992; Tanriverdi & Iacono, 1999) and the Technology Acceptance Model (TAM) initially developed by Davis F.D in 1989.

Innovation characteristics and adoption context

Innovation characteristics and adoption context are interrelated as the behavior of the adopter is influenced at the same time by the innovation's characteristics and by the context within which the innovation is adopted.

The perceived characteristics of an innovation are going to influence technology adoption as an adopter will have a more positive attitude towards the innovation if there is a perception it will bring a relative advantage compared to not adopting it (Hebert & Benbasat, 1994). When considering an information technology system, the perception an adopter has of system characteristics will also favor adoption if the adopter sees positively the quality the system accuracy (Cork & al., 1998) and the screen design and layout (Sittig & al., 1999). Perceiving that confidentiality and privacy are secured also has a positive influence on adoption (Anderson & al., 1986, Gardner & Lundsgaarde, 1994).

Furthermore, the potential adopter's perception of the clinical impact the innovation will have has an effect on innovation adoption. Accordingly, there will be a greater rate of adoption if potential adopters perceive the innovation as improving efficient clinical workflow (Dansky & al., 1999, Gadd & Penrod, 2001), quality of care (Gardner & Lundsgaarde, 1994, Gadd & Penrod, 2001), workload (Gardner & Lundsgaarde, 1994) and patients' satisfaction with the quality of care (Gadd & Penrod, 2001).

Physicians and patients as adopters of the electronic medical record

Health professionals' attitude towards the utilization of information technology has been the focus of various studies. An assessment of physicians' attitude concerning the pilot implementations of an outpatient EMR in six practices of a large academic health system in Pittsburgh found that they were early adopters of the technology when it had value added for the effort required to use it. The ability of an EMR to facilitate efficient clinical workflows without negative effects on the valued relationship they had with their patients was crucial to the acceptance of the technology (Gadd & Penrod, 2001).

When studying the effects of an EMR on patient care and correspondent clinician attitudes in a large Health Maintenance Organization (HMO), researchers of the Kaiser Permanente Center for Health Research in Portland, Oregon, found that most clinicians felt that an outpatient EMR had improved the quality of patient care, including the quality of the patient-clinician interaction, the ability to coordinate the care of patients with other departments, the ability to detect errors, the timeliness of referrals, and the ability to act on test results in timely fashion (Marshall & Chin, 1998).

A cross-sectional mail survey of active members in the Indiana Academy of Family Physicians indicated that EMR users were more likely to practice in urban areas and that they were more incline to believe that the use of EMRs was beneficial to their

profession, improved the quality of medical records and reduced errors. The largest number of written comments regarded security and confidentiality issues and non-EMR users believed that there were more security problems involved with EMRs than with paper-based medical records (Murray & al., 2003). Another study, a survey of members of the American College of Physicians-American Society of Internal Medicine revealed that physicians younger than 50 years old who had full or part-time academic affiliation reported using computers more frequently for medical applications. Physicians expressed concerns about Internet security, confidentiality and accuracy. Computer use was not generalized and, while most respondent used computers and were connected to the Internet, few used them for clinical management. Respondents nevertheless said that they wanted to increase their knowledge of computer-based information-source for patient care, EMR systems and telemedicine (Lacher & al., 2000).

Reasons why physicians may resist the computerization of their practice include perceived low personal benefits, fear of loss of status, fear of revealing ignorance, fear of an imposed discipline, fear of wasted time, fear of unwanted accountability and fear of new demands (Lorenzi & al., 2001). A study about barriers regarding the use of EMRs at the Beth Israel Hospital, a Harvard teaching hospital, has concluded that clinician reluctance to type or perform data entry did not constitute a significant barrier, but concerns about privacy and security did (Rind & Safran, 1993).

A study done to evaluate 75 physicians' satisfaction regarding the use of an EMR, the Brigham and Woman's Integrated Computing system (BICS), showed that overall satisfaction was correlated with screen design and layout, and not with system response time (Sittig & al., 1999).

Fewer studies have looked at patients' attitude towards the use of EMRs (Bomba & de Silva, 2001). A 1985 study surveyed patients who had just consulted a doctor who was using the computer and others who had seen a doctor using more conventional procedures. No overall negative effects were recorded for patient reactions, and there was no difference between the control group and the study group with respect to patients' perception of the doctor's attentiveness and rapport, patients' satisfaction with the information received, their confidence in the treatment received and their expected compliance. There was, however, a relation with post-consultation stress and doctor computer use for patients unfavourable to the idea of doctors using computers (Brownbridge & al., 1985). A survey done in Australia of patients over a 13 day period of practice operation revealed that a large majority of respondents stated that the computer based patient record is an essential technology for health care in the future and that computers have the potential to improve the information management and efficiency at a medical practice, as well as the quality of care received. At the same time, patients felt that privacy and confidentiality issues were dominant concerns, as much with an EMR as with a conventional paper-based record (Bomba & de Silva, 2001).

A study assessing patients' satisfaction with their outpatient encounters in a clinic where and EMR system had been implemented found that patients did not indicate a sense of loss of rapport with their physician. They did, as did the physicians, have concerns about the privacy of the medical information contained in the EMR (Gadd & Penrod, 2000).

Patient and Physician Attitudes towards Consent

Consent in the health care sector is needed for different types of processes, including consent to communicate personal health information, consent to participate in research and consent to treatment. An understanding of patient and physician characteristics related to consent will help health professionals have a better understanding of decision-making processes and identify possible physician bias, with the goal of getting better patient participation in medical treatment and research. With this goal in mind, here is a literature review which unearths the variables related to patients, physicians and consent.

Relevant literature reveals that various patients and physicians characteristics related to consent requirements has been identified. For the purpose of this study, we will discuss characteristics specific to consent to share personal health information and consent to participate in research. We exclude consent for

treatment as it differs fundamentally from informed consent for research (Appelbaum & al., 1987; Taub & al., 1986).

Characteristics related to consent have been studied through both quantitative data, such as patients' socio economic status, and qualitative data, such as how the consent procedures are understood.

Quantitative data found in the literature concerns predominantly patients' characteristics in relation to consent, and few research exist regarding physician's or other health care professional's characteristics. It is the patients' social economic status that seems to be the most often studied characteristic in order to try to explain patterns of consent, with mix results depending on the research and the study subjects. Most studies found in the literature study only one aspect of patient's socio economic status, such as gender, age or education, but seldom take into account multiple characteristics.

Patient's sex and education are not definitive predictors of consent, and study results are not clear about their relationship to consent rate. For example, in the case of parents giving consent so that their children would participate in a randomized, double blind, placebo controlled trial of ibuprofen syrup to prevent recurrent febrile seizure, the sociodemographic status of the parents, mainly sex and education, did not influence consent rate (van Stuijvenberg & al., 1998). The study aimed at assessing the quality of the informed consent process in a pediatric setting.

Education will, however, directly influence consent rate in cardiovascular clinical trials in a study aimed at determining variables contributing to patient participation in randomized clinical trials while assessing the potential relationship of these variables to a valid consent process (DeLuca & al., 1995).

Studies taking into account qualitative data related to consent are more abundant and concern both patient and the physician characteristics. Amongst the research findings regarding patient characteristics, it has been shown that the perception the patients have of the usefulness of the procedure or diagnostic to which they are giving consent positively influences consent rate. Patients who perceive a benefit from the procedure or diagnostic they are to be undergoing are more likely to give a positive consent. It has been shown that elderly people who gave their consent to participate in clinical research had significantly positive feelings about being used as research subjects and were motivated, amongst other things, by the benefits others would gain by their participation in the research (Kaye & al., 1990). In the randomized controlled trial referred to earlier concerning children participating in a randomized, double blind, placebo controlled trial of ibuprofen syrup to prevent recurrent febrile seizure, contribution to clinical science and benefit to the child were the two main factors for parents granting approval (van Stuijvenberg & al., 1998).

Moreover, patients' perception of what constitutes informed consent itself and its usefulness also influences consent rate. Patients' trust in medical experiments and

in the integrity of physicians has an impact of their perception of information disclosure, which in turn has an impact on their willingness to give consent, as shown in an analysis of patient perceptions on informed consent based on 26 clinical trials (Verheggen & al., 1998). Perception and understanding of what constitutes consent may lack altogether as patients may not remember having signed a consent form, as shown in a study where a telephone survey was conducted among 314 former surgery patients to ascertain their opinion about informed consent (Guix Oliver & al, 1999) and another study asking patients having DNA stored their perception of consent (Moutel & al., 2001). Also, the elderly show significantly poorer comprehension of consent information than younger patients when asked to participate in research (Stanley & al., 1984).

Qualitative data relating to physicians and health professionals define how they can or may influence a patient's decision process and medical treatment. Studies show that physicians have an important role in influencing patients when comes time to decide for them whether to undergo a treatment or not. Physicians may also change to adapt their practice to consent requirements. As an example, when studying predictors of compliance in taking antidepressant medication, it has been shown that the amount of time a physician takes to explain the expected duration of treatment and possible side-effects to a patient is a key factor to compliance, and the physician's attitude towards the medication is also important (Demyttenaere, 2003). Another study shows that physicians may be unwilling to offer patients the opportunity to participate if they feel that the patient will be resistant to treatment

change or if the physician does not see themselves as the "responsible" physician for the drug management (Kroenke & Pinholt, 1990).

More specifically, some data has to do with physicians' approach towards the patient and their appreciation of the usefulness of asking for consent before undertaking a procedure or diagnostic. It has been studied that the interviewer's personality in a clinical trial is seen by participants to influence their consent dispositions in a clinical research setting (Kaye & al., 1990).

Moreover, the physician may see consent as an intrusion into the doctor-patient relationship (Taylor & Kelner, 1987). Some health researchers argue that the obligation to ask for patients' consent to use secondary data limits epidemiological and public health research (Gostin & Hadley, 1998; Hodge & al., 1999; Lawlor & Stone, 2001; Buckovich & al., 1999). It is believed that asking for obligatory consent can compromise many surveillance activities essential for individual and public health (Verity & Nicoll, 2002), institutionalize health inequalities and reduce access to services for vulnerable groups (Cassel & Young, 2002) and jeopardise the methodological integrity of research and audit (Al-Shahi & Warlow, 2000).

It can be resumed that people willing to participate in a new mean of healthcare deliverance are in fact adopting a new innovation. Early innovation adopters are shown to be more educated than the average, to have a higher living status, to

accept change and science and be able to deal with abstraction and to belong to interconnected social networks.

When a patient's consent to the transfer of personal health information is required in the course of the use of the innovation, it has been shown that the patient's gender is not related to consent rate while greater age is related poor comprehension of consent requirements and education may or may not constitute a defining factor depending of the study.

Also, consent rate is positively influenced when a patient perceives a benefit from granting consent. Furthermore, consent rate will be higher when a physician takes time to explain the necessity of the requirement and, on the other hand, a physician may be unwilling to spend time to have a patient participate in a study if he feels that the patient is reluctant to do so.

The field has not been much studied, maybe because studies regarding consent tend to focus on consent to undergo treatment and not consent to share personal health information. It would be quite valuable to have additional information regarding elements that influence consent to share personal health information, such as extra quantitative (i.e. income) and qualitative (i.e. motives) data on patients, as well and quantitative and qualitative data on physicians, which is strongly lacking. Studies and information regarding the context within which consent to share personal health

information are also scarce, so studies describing particular innovation characteristics in relation to consent issues.

It is in with the goal of improving consent understanding and bridging the exposed knowledge gaps that this study defines, using available variables, which physician characteristics, in combination with patient characteristics, serve as predictors for consent rates.

Elaboration of the Conceptual Framework

It was necessary to establish how physicians and patients reacted to the introduction of a new technology to understand technology adoption and to analyze patients' consent to share personal health information in the context of a structured research.

The link between innovation adoption and consent to participate in research

The first concept that has to be taken into account relates to the adoption of a new innovation. More precisely, in the present context, this concept concerns the adoption of a new mean of intervention in health care. Physicians' and patients' attitude towards adopting this new mode of intervention has to be explored.

Characteristics associated to new adopters of an innovation are grouped into three subclasses. The first of these classes, the socio-economic status, informs us that early adopters are neither younger nor older that other adopters. They tend to, however, have more years of formal education, be more literate, have a higher social status (income, level of living, possession of wealth and occupational prestige), have a greater degree of upward mobility, and belonging to a larger social unit. The second class refers to the "personality variables", and correspondent characteristics of early adopters identifies them as having greater empathy than later adopters, a greater ability to deal with abstraction, a greater rationality, a greater intelligence, a more favorable attitude toward change, are better able to cope with uncertainty and risk, a more favorable attitude toward science, being less fatalistic and having higher aspirations. The third class refers to the "communication behavior", and early adopters are viewed as having more social participation than later adopters, being more cosmopolite, having a greater exposure to information and knowledge of innovations, and having a greater degree of opinion leadership.

Other studies have shown early adopters of innovations in the medical field see an incentive to adopt if there was value added for the effort required to use the innovation. Physicians that were initial EMR users were more likely to practice in urban areas and were more inclined to believe that EMRs were beneficial to their profession, that it improved the quality of medical records and reduced errors than non-EMR users. Also, physicians younger than 50 years of age who had a full or

part-time academic affiliation were more likely to use computers for medical applications.

The second concept that has to be taken into account in the present study relates to patients' willingness to give consent to communicate their personal health information in the context of a health research.

Physicians and other health professionals often view the mandatory procedure as being an intrusion in the patient-physician relationship and fear that it is detrimental to individual and public health research and surveillance and that it may reduce access to services for vulnerable groups.

Patients, however, tend to be inclined to give consent if they perceive that a benefit will result and if they have a trust in the medical experiment and the integrity in the physicians involved. What is consent and why it is asked, however, is not always clear to patients. Furthermore, research does show that socioeconomic characteristics of patients did not have a clear effect on consent rate, with the exception that a higher education seems to correlate with a higher consent rate.

Both concepts have to be taken into account together. It would be possible to study the effects of adopting a new innovation without having to consider the consent factor, and it would be possible to study consent rates to communicate personal health information without the context of a new mean of intervention, but in the

scenario where both innovation adoption and consent play crucial roles, variables linked to both concepts have to be studied.

Hypothesis

Literature can be summarized into two main themes that concern both innovation adoption and consent to communicate personal health information. The first of these themes relates to the sociodemographic factors that are related to consent rates and the second theme relates to the attitudinal factors that are related to consent rates. However, variables obtained in the course of this study are best aimed at exploring the prior theme. In accordance with literature, the following hypothesis is suggested:

> Sociodemographic variables do not play a definite role when patients are asked for consent to communicate personal health information in the context of a health research, with the exception of education which is found to be directly correlated with a higher consent rate.

This hypothesis will be tested in real life with the data gathered through this study.

CHAPTER 3 - METHODOLOGY

A synthetic study model will be used for the study, consisting in investigating relationships between dependent and independent variables in a system of interdependency (Contandriopoulos & al., 1990). The study takes the form of a secondary analysis of existing data, which limits the study parameters to pre-existing variables. Available data will help us understand how consent rate is influenced in the context of giving consent to communicate personal information when adopting a new mode of health intervention. A regression statistical analysis will be used to validate the two working hypotheses.

The MOXXI-II Electronic Prescription System

The data used to establish what variables influence patient consent rates when asked to participate in an electronic medical record study was gathered while undergoing the MOXXI-II research project.

The goal of the MOXXI-II project was, as said before, to test the potential benefits of implementing an electronic prescription management system for general practitioners and their respective patients.

The rationale of this project was to enhance the quality of clinical care that could be delivered by primary care physicians by improving access to clinical data (drugs prescribed by all physicians, electronic lab result reporting), the uptake of new knowledge into practice by utilization of computer-generated patient level alerts and reminders for preventive care, optimal diabetes management and potential prescribing problems and, finally, to provide a mechanism to monitor the health of the general population for the public health unit by pilot testing a prototype for information collection through networked electronic medical records from primary care physicians.

Study Design

Within the context of the project, a dynamic electronic consent process was developed and implemented. This prototype was piloted in this project for potential application in the other parts of the health care system. The physician's practice population was defined using medical services claims and thus potentially eligible patients who could grant access were identified and verified. Physician authentication was verified through the professional personalized access key and PIN number. Legally, the RAMQ is not required to obtain patient consent prior to the release of prescription claims data, which means that the process was pre-tested in an environment that was not bound by the legal requirements for written consent (such as in hospitals). The process for eliciting prescription drug information through electronic consent worked in the following way. First, the practice

population was assembled by retrieving all patients who were seen by the physician in the past year, and all subsequent patients who were seen by the physician during the course of the study (dynamic update of potentially eligible patients). Second, all filled prescriptions for these patients were pushed to the MOXXI-II computer server located at the RAMQ. The electronic consent that interfaced with the RAMQ was developed by software consultants, and the law and ethics working group defined guidelines for electronic consent. To access prescription information, the physician needed to have his or her personalized access key inserted into his or her computer USB port and enter his or her PIN number. The patient signed the consent for access displayed on the screen while selecting one of several release periods (that visit only; 6 months; 12 months; or when the patient specified otherwise), which authorized the physician to obtain information for the specified time period. The "send" button initiated a FTP transmission of the consent signal to the RAMQ-MOXXI server, authorizing release of prescription and hospitalization information for the specified time period. For patients within a physician's practice that did not provide electronic consent, prescription and medical services information from administrative databases were available in a de-identified format. For the patients who had not provided consent, it is not known whether the patient was approached by the physician to obtain consent and declined or whether the patient was never approached.

In total, 50,657 patients were seen in the enrollment period. Among this pool of potentially admissible patients identified by the RAMQ, 1,846 were excluded

because they were seen only between June 1999 and November 1999, which was not part of the eligibility period, and another 83 patients were removed because they received only procedure services from the study physician. This left a pool of 48,728 patients of whom 181 had a temporary Medicare number or an invalid Medicare number, and a further 10,293 did not visit the study physician during the intervention period. As a result, 38,254 were considered eligible, and as of November 2000, 6,509 had consented. The analysis was based on the initial consenting 6,509 patients. Ultimately, 9,180 patients consented to participate of the 38,254, a participation rate of 24.0%.

Information retrieved from the patient demographic database included age (by 5 year group) and sex. The medical services database provided data on the medical visits including the type, location (e.g. inpatient, emergency department, private), diagnosis, treating and referring physician, and date of all services provided on a fee-for-service basis (95% of all services provided in Quebec). The hospitalization database provided records of all hospital discharges in Quebec including discharge diagnoses, type (i.e. emergency room), admission and discharge dates. The general practitioner demographics were provided by RAMQ and included sex, location of graduating medical school, year of graduation, and specialty.

List of variables

The dependent variable, *Patient consent indicator*, indicates if a patient seen during the study had provided consent.

Independent variables for patients are in the form of categorized variables.

Table I – Patients' variables description and source.

Variable	Description	Categories	Source
Sex Patient	Sex of the patient	Female; Male	RAMQ
Income	Revenu of the patient	<30000; 30000-37000; 37001-48000; >48000	RAMQ (via Census data)
Age	Age of the patient	<30; 31-47; 48-65; >65	RAMQ
Graduation	Population without a highschool diploma	Graduation; no graduation	RAMQ (via Census data)
Visits Med.	Number of medical visits	1-4; 5-10; 11-20; >20	RAMQ
Visits Hosp.	Number of hospital visits	>=1	RAMQ
Visits Emerg.	Number of emergency visits	>=1	RAMQ
Visits Int. Care	Number of intensive care visits	>=1	RAMQ
Visits GPS	Number of visits to general practitioners	1; 2-3; 4-7; >7	RAMQ
Visits Specialists	Number of visits to specialists	>=1	RAMQ
Consultation GPS	Number of consultation visits to general practitioners	>=1	RAMQ
Consultation Specialists	Number of consultation visits to specialists	>=1	RAMQ
Rx	Number of prescriptions by patient	>=1; 1-5; 6-17; 18-43; >43	RAMQ
Pharmacies	Number of pharmacies by patient	>=1; 1; 2; 3; >3	RAMQ
Unique Prescribing	Number of unique drug prescribing physician by patient	>=1; 1; 2; 3; >3	RAMQ

Independent variables for physicians are in the form of categorized variables.

Table II – Physicians' variables description and source.

Variable	Description	Categories	Source
Sex Physician	Sex of the physician	Female; Male	RAMQ
Grad Year	Year of graduation	1970-1979; 1980-1988; >=1989	RAMQ
Grad University	University of graduation	Université de Montréal; McGill; Sherbrooke; Other university in CCanada Foreign medical graduate	RAMQ
Patients by MD	Total number of patients by doctor	65-1214; 1215-1962; 1963-2840; >2840	RAMQ
Drugs prescribed	Number of different drugs prescribed	100-454; 455-542; 543-626; >626	RAMQ
Rx by MD	Number of total prescriptions written by the study doctor	926-5477; 5478-8484; 8485-12786; >12787	RAMQ

Statistical Analyses

Frequency distributions of general practitioner and patient characteristics were determined and the means, standard deviations (sd) and ranges were reported for continuous variables. The bivariate statistical analyses have been done using the chi-square test in accordance with the categorized nature of the data.

Stages of the analyses included an analysis of the distribution of the individual variables, an analysis of correlation between independent variables and the dependant variable, and between independent variables within themselves, and an analysis through multiple regression through multivariate logistic generalized

estimating equations (GEE), which were used to investigate whether patient or general practitioner characteristics increased the probability of consenting to participate. Patients were clustered within general practitioners with an exchangeable correlation structure. The unit of analysis was the patient with consent status (yes versus no) as the outcome of interest. Statistical analyses were conducted using SAS 8.02.

CHAPTER 4 – RESULTS

Patients and Consent Rates

Table III presents characteristics of consenting and non-consenting patients in the form of categorized descriptive statistics for the dependent variable. Correlation was analyzed with the chi-square test. More precisely, it shows the overall characteristics of the patients considered to be eligible for inclusion in the study, along with differences that existed between consenting and non-consenting patients. Overall, male patients were less likely to participate with 14.9% of male patients giving consent compared to 18.6% of female patients giving consent. The average income of people consenting to participate was close to $3,000 higher than those choosing not to participate. The average age of consenting patients was substantially older that non-consenting patients, with the age of consenting patients being 57.9 years and non-consenting patients being 45.16 years.

Table III - Patients' Demographic Characteristics

Patients N(%)	**Total N=38245**		**Consenting 6509 (17.02%)**		**Non-consenting 31736 (82.98%)**		**Test**
Sex	N	(%)	N	(%)	N	(%)	
• Female	21718	(56.8)	4049	(18.6)	17669	(81.4)	
• Male	16527	(43.2)	2460	(14.9)	14067	(85.1)	
Income	Means ± s.d. 41193.2± 21921.4		Means ± s.d. 43165.7 ± 25569.9		Means ± s.d. 40788.7 ± 21.072.9		
	N	(%)	N	(%)	N	(%)	<
• <$30 000	9877	25.8	1633	25.1	8244	26.0	0.0001
• $30000-37000	9692	25.3	1595	24.5	8097	25.5	
• $37001-48000	8816	23.1	1475	22.7	7341	23.1	
• > $48000	9363	24.5	1717	26.4	7646	24.1	
• Missing	497	1.3	89	1.4	408	1.3	
Age	Means ± s.d. 47.3± 22.2		Means ± s.d. 57.92 ± 17.29		Means ± s.d. 45.16 ± 22.47		
	N	(%)	N	(%)	N	(%)	<
• 0-30	9379	24.5	467	7.2	8912	28.1	0.0001
• 31-47	9731	25.4	1294	19.9	8437	26.6	
• 48-65	9841	25.7	2234	34.3	7607	24.0	
• > 65	9294	24.3	2514	38.6	6780	21.4	
Population without High School diploma	Means ± s.d. 34.89% ± 14.63		Means ± s.d. 33.07 %± 14.66		Means ± s.d. 35.26 ± 14.59		

Note: The bivariate statistical analyses have been done using the chi-square test in accordance with the categorized nature of the data.

In Table IV, showing categorized descriptive statistics for the dependent variable, it can be observed that, in average, consenting patients made 12 medical visits in the year prior to the start of the study, about one less that those made by non-consenting patients. Correlation was analyzed with the chi-square test. Overall, 9.0% of consenting patients were hospitalized in the baseline year in contrast to 9.5% of non-consenting. Also, non-consenting patients were also more likely to use the emergency room (29.1% made at least 1 visit in the baseline year in comparison to 23.0% of consenting patients). A disproportionately greater number of consenting patients made at least one visit to a specialist in the baseline year (75.2%) relative to

non-consenting patients (67.0%). In keeping with this observation, fewer patients were referred to specialists in the non-consenting pool of patients (15.9%) relative to consenting patients (17.7%).

Table IV - Patients' Medical Services Characteristics

Patients N(%)	**Total N=38245**		**Consenting 6509 (17.02%)**		**Non-consenting 31736 (82.98%)**		**Test**
Number of medical Visits	Means ± s.d 13.04 ± 21.60		Means ± s.d 12.34 ± 14.99		Means ± s.d 13.19 ± 22.72		
(%) N	(%)	N	(%)	N	(%)	N	<
1-4	31.1%	11891	24.7	1609	32.4	10282	0.0001
5-10	33.7%	12887	37.0	2406	33.0	10481	
11-20	20.3%	7760	23.4	1523	19.7	6237	
> 20	14.9%	5707	14.9	971	14.9	4736	
Number of Hospital visits							
% ≥1 visit (N)	9.4% (3598)		9.0%(584)		9.5%(3014)		< 0.0001
Means ± s.d.	22.37 ± 34.66		14.87 ± 22.06		23.82 ± 36.43		
Number of Emergency visits							
% ≥1 visit (N)	28.1% (10735)		23.0%(1498)		29.1%(9237)		< 0.0001
Means ± s.d	5.51 ± 12.24		4.68 ± 5.35		5.65 ± 13.00		
Number of intensive care visits							
% ≥1 visit (N)	0.6%(227)		0.5% (32)		0.6% (195)		< 0.0001
Means ± s.d	5.80 ± 8.16		3.06 ± 2.23		6.25 ± 8.67		

Table IV - Patients' Medical Services Characteristics (cont'd)

Number of visits to GPS	Means ± s.d 8.06 ± 12.79		Means ± s.d 7.46 ± 7.90		Means ± s.d 8.18 ± 13.57		
	(%)	N	(%)	N	(%)	N	< 0.0001
1	11.6%	4446	7.5%	490	12.5%	3956	
2-3	25.5%	9754	23.7%	1541	25.9%	8213	
4-7	31.6%	12071	36.01%	2344	30.7%	9729	
more than 7	31.3%	11974	32.8%	2134	31.0%	9840	
Visits to Specialist							
% ≥1 visit (N)	68.4% (26158)		75.2% (4895)		67.0% (21263)		< 0.0001
Means ± s.d.	7.62 ± 15.68		6.70 ± 10.74		7.83 ± 16.61		
Consultation visits to GP's							
% ≥1 visit (N)	38.6% (14754)		43.8% (2850)		37.5% (11904)		< 0.0001
Means ± s.d	1.93 ± 1.83		1.74 ± 1.24		1.98 ± 1.94		
Consultation visits to Specialists							
% ≥1 visit (N)	16.2% (6198)		17.7% (1152)		15.9% (5046)		< 0.0001
Means ± s.d	2.00 ± 2.11		1.72 ± 1.39		2.06 ± 2.23		

Note: The bivariate statistical analyses have been done using the chi-square test in accordance with the categorized nature of the data.

A higher proportion of consenting patients (57.0%) filled at least one prescription in comparison to 46.4% of non-consenting patients, reveals Table V that shows categorized descriptive statistics for the dependent variable. Correlation was analyzed with the chi-square test. Among those who filled a prescription, the average number of prescriptions filled by consenting patients was 39.06 prescriptions in the baseline year in comparison to 30.65 prescriptions by non-consenting patients. The average number of pharmacies attended was lower in the consenting group, an average of 1.62 pharmacies in the baseline in comparison to 1.83 pharmacies by the non-consenting patients. The number of unique drugs

prescribed for study patients by the enrolled physicians was 3.05 different drugs for consenting patients in comparison to 3.21 different drugs for non- consenting patients.

Table V - Patients' Pharmaceutical Services Characteristics

Patients N(%)	**Total N=38245**	**Consenting 6509 (17.02%)**	**Non-consenting 31736 (82.98%)**	**Test**
No.of Rx per patient				
	% (N)	% (N)	% (N)	< 0.0001
%Pt ≥1 Rx	48.2% (18434)	57.0% (3711)	46.4% (14723)	
• 1-5	26.3% (4845)	12.8% (474)	29.7% (4371)	
• 6-17	24.6% (4531)	20.4% (758)	25.6% (3773)	
• 18-43	24.6% (4543)	32.6% (1208)	22.7% (3335)	
• > 43	24.5% (4515)	34.2% (1271)	22.0% (3244)	
Mean ± s.d.	32.34 ± 49.36	39.06 ± 41.09	30.65 ± 51.10	
No. of pharmacy by patient				
	% (N)	% (N)	% (N)	< 0.0001
% ≥1 pharmacy	48.2% (18434)	57.0% (3711)	46.4% (14723)	
• 1 pharmacy	54.2% (9998)	60.2% (2235)	52.7% (7763)	
• 2	27.5% (5070)	26.3% (976)	27.8% (4094)	
• 3	10.8% (1985)	8.3% (307)	11.4% (1678)	
• > 3	7.5% (1381)	5.2% (193)	8.1% (1188)	
Mean ± s.d.	1.79 ± 1.22	1.62 ± 1.00	1.83 ± 1.26	
Number of unique drugs prescribing physicians by patient				
	% (N)	% (N)	% (N)	< 0.0001
% ≥1 unique drug dispensers by pt	48.2% (18434)	57.0% (3711)	46.4% (14723)	
• 1	24.8% (4577)	25.6% (949)	24.6% (3628)	
• 2	23.5% (4338)	23.7% (878)	23.5% (3460)	
• 3	18.4% (3394)	19.1% (707)	18.3% (2687)	
• > 3	33.2% (6125)	31.7% (1177)	33.6% (4948)	
Mean ± s.d.	3.18 ± 2.39	3.05 ± 2.17	3.21 ± 2.44	

Note: The bivariate statistical analyses have been done using the chi-square test in accordance with the categorized nature of the data.

Physician Characteristics

Table VI outlines the characteristics of the participating physicians as descriptive statistics of independent variables. Overall, 15% of participating physicians were female, all graduated after 1970 from medical school, and 45% of the physicians graduated from the University of Montreal. There was an imbalance in the distribution between the experimental and control groups, in part explained by the problem of having group practices of different sizes that had to be randomized as a unit to the experimental or control groups to avoid contamination.

Overall, in the year prior to the start of the intervention, the average number of patients seen in the prior year by study physicians was 2041, the average practice size being slightly lower for physicians randomized to the control group relative to the experimental group.

The average number of different drugs prescribed, as represented by different drug identification numbers, included in prescriptions written by the study physicians, was 552.5, and the average number of total prescriptions written by study physicians in the baseline year for their practice population was 9928.

Table VI - Study Physicians' Characteristics

Study physicians' characteristics	**Total Participating N=20**		**Control Group N=9**		**Experimental Group N=11**	
Sex	**N**	**(%)**	**N**	**(%)**	**N**	**(%)**
• Female	3	(15.0)	2	(22.2)	1	(9.1)
• Male	17	(85.0)	7	(77.8)	10	(90.9)
Year of Graduation	**N**	**(%)**	**N**	**(%)**	**N**	**(%)**
• 1970-1979	13	(65.0)	7	(77.8)	6	(54.6)
• 1980-1988	6	(30.0)	1	(11.1)	5	(45.5)
• Since 1989	1	(5.0)	1	(11.1)	0	(0)
University of graduation	**N**	**(%)**	**N**	**(%)**	**N**	**(%)**
• Montreal						
• McGill	9	(45.0)	2	(22.2)	7	(63.6)
• Sherbrooke	2	(10.0)	0	(0)	2	(18.2)
• Other university in Canada	1	(5.0)	1	(11.1)	0	(0)
• Foreign Medical Graduates	2	(10.0)	2	(22.2)	0	(0)
	6	(30.0)	4	(44.4)	2	(18.2)

Table VI - Study Physicians Characteristics (cont'd)

Practice characteristics	Total Participating N=20		Control Group N=9		Experimental Group N=11		T-test
Total patients by MD	**Means ± s.d. 2041.55 ± 997.50**		**Means ± s.d. 1769.56 ± 504.45**		**Means ± s.d. 2264.09 ± 1251.35**		**0.0167**
	N	(%)	N	(%)	N	(%)	
• 65-1214	5	(25.0)	1	(11.1)	4	(36.4)	
• 1215-1962	5	(25.0)	5	(55.6)	0	(0)	
• 1963-2840	5	(25.0)	3	(33.3)	2	(18.2)	
• > 2840	5	(25.0)	0	(0)	5	(45.5)	
No. of different drugs prescribed	**Means ± s.d. 552.5 ± 194.03**		**Means ± s.d. 540.11 ± 179.23**		**Means ± s.d. 562.64 ± 213.51**		**0.6328**
	N	(%)	N	(%)	N	(%)	
• 100-454	5	(25.0)	2	(22.2)	3	(27.3)	
• 455-542	5	(25.0)	3	(33.3)	2	(18.2)	
• 543-626	5	(25.0)	3	(33.3)	2	(18.2)	
• > 626	5	(25.0)	1	(11.1)	4	(36.4)	
No. of total Rx written by the study MD	**Means ± s.d. 9928.25 ± 6723.39**		**Means ± s.d. 8788.56 ± 6417.62**		**Means ± s.d. 10860.73 ± 7128.35**		**0.7811**
	N	(%)	N	(%)	N	(%)	
• 926-5477	5	(25.0)	2	(22.2)	3	(27.3)	
• 5478-8484	5	(25.0)	4	(44.4)	1	(9.1)	
• 8485-12786	5	(25.0)	2	(22.2)	3	(27.3)	
• > 12787	5	(25.0)	1	(11.1)	4	(36.4)	

Note: The bivariate statistical analyses have been done using the T-test in accordance with the quantitative nature of the data.

Multivariate Analysis

Patient variables integrated into the GEE regression included sex, age, income, the number of visits to consult the general practitioner participating in the study, the

number of emergency room visits and the number of different pharmacies that were visited. General practitioner variables included sex and the year of graduation, which was used as an indicator of years of experience in lieu of physician's age, since this variable was not available. Table VI presents the results for significant predictors from the GEE analyses.

Table VII – Multivariate GEE of predictors of consent adjusted for physician level clustering.

Predictors of Consent	GEE Estimate	Odds Ratio	95% CI
Patient-level characteristics			
Female	0.15	1.17	1.10-1.24
Age:			
<30 years	Reference		
31-47	1.06	2.90	2.60-3.24
48-65	1.76	5.79	5.21-6.43
>65 years	2.07	7.89	7.09-8.78
Income			
< $30,000	-0.04	0.96	0.88-1.04
$30,001-37,000	-0.09	0.91	0.84-0.99
$37,001-48,000	-0.07	0.93	0.86-1.01
≥$48,000	Reference		
Visits to study GP:			
< 3	Reference		
3-4	0.38	1.46	1.34-1.59
5	0.40	1.50	1.38-1.62
ER visits ≥ 1	-0.46	0.63	0.59-0.68
Pharmacies visited : 1	Reference		
2-3	-0.14	0.87	0.81-0.94
> 3	-0.30	0.74	0.63-0.88
Physician-level characteristics			
Female	1.38	3.96	3.63-4.32

Most variables affected significantly the probability that a patient would consent to participate in the research, with the exception of the general practitioners' year of graduation. To be a female general practitioner increased, on the physicians' side, the probability that a patient would offer consent.

Otherwise, patients more likely to give consent to participate in the research project tended to be older and were more likely to be female patients.

Patients who visited more often their study general practitioner also were more likely to give their consent to participate in the research.

However, a higher number of visits to emergency rooms was directly correlated with a lower consent rate, as was an increased number a visited pharmacies.

The strongest predictor of consent was, when looking at patient-level characteristics, related to older age, while the stronger predictor for a lower level of consent was related to a higher number of visits do different pharmacies.

It must be noted that it unsure why non-consenting patients refused to participate in the study, or even if they were asked to do so by the participating general practitioner. It would be valuable to study if non-consenting patients have been approached by the physician. However, if these patients have in effect refused to

give consent to participate in the research, it is to fear that they could also refuse to participate in this extra study.

CHAPTER 5 - DISCUSSION

Both physician and patient characteristics play a role in influencing consent rate. Many of these characteristics influence at different levels. Older female patients with higher income levels, for example, were more likely to consent. As for general practitioners, female physicians were more likely to enroll patients in the study, thus getting their consent to participate in the research project.

Discussing the Results

Some results of the analyses appear to be in line with observations seen in literature. Hence, when general practitioners tent to enroll more older patients than younger ones, this would support the hypothesis that that general practitioners enroll patients when there are value-added benefits (Gadd & Penrod, 2001; Marshall & Chin, 1998), which would be here that older patients have more complete prescription drug information due to continuous provincial public insurance. General practitioners do effectively seem to influence positively the use of a new medical technology when they feel it facilitates efficient clinical workflow and improves the quality of patient care. This emphasizes the role of opportunity for obtaining consent as well as the physicians' feeling that they are the primary physicians responsible for the care of the patient.

To consult a female general practitioner increased the probability that a patient would offer consent. More research would be needed to understand if, for example, this is due to the specific female physicians' personalities, or to patient's attitudes towards male and female health professionals.

In the study, patient income is related to a higher consent rate. This would concur with the theory saying that early adopters of an innovation tend to have a higher social status that late adopters (Rogers, 1995, pp. 269-272), where the social status depends on variables such as income, level of living, possession of wealth and occupational prestige. However, considering that income is but one of those variables, and that the concept of "social status" may differ from study to study, it is necessary to be careful when comparing such concepts.

More patient visits to the study general practitioner is directly related to higher consent rates. This would be interpreted by the fact that a greater number of appointments increases the confidence level that exists between the health professional and the patient, making him more likely to trust the physician and give consent to the research. It may also be explained by the fact that the physician has more time, over more patients visits, to explain the intricacies of the research and the implications related to granting consent, making the patient more knowledgeable of the benefits of the research.

The results show that more visits to different pharmacies are related to patients less likely to grant consent. It is uneasy to explain this phenomenon without extra data but possible explanations could be that the patient does not have a usual pharmacy to attend, nor a usual physician to see, and is therefore not interested in participating in a research where he would not foresee personal benefits. Another possible explanation would be that the patient is drug-shopping.

There are cases where results do not agree with literature findings, or for which no previous research has been done. While it was said that gender does not affect innovation adoption rate (van Stuijvenberg & al., 1998), the results show a direct relation between consent rate in the context of a medical administrative innovation and sex, whereby women were more inclined to give their consent to participate in the study.

Study Limitations

This study was based on a secondary analysis of existing data and, because of the intrinsic nature of such a study, it was not possible to expand the case analysis to all variables that were either found in the literature or was believed pertinent to observe.

A significant limitation relates to the impossibility to determine the nature of patients' non-consent, which could be a direct refusal to consent to communicate personal information to participate in the study when told about said study by the physician, or could result from the physician not asking a patient to participate in the study for whatever reason. It would be valuable to look into physicians' participation rates and patterns in further research and to inquire about reasons for not involving patients, if that situation does indeed occur. The high non-consent rate of almost 83% (Table III) tends to support the hypothesis that physicians did not ask all of their patients to participate in the study.

Another important limitation relates to the personality factor. In effect, apart from establishing that patients' consent rates vary strongly from one physician to another and inferring that the physician's personalities influence results, as suggests the literature, there are no available personality variables. To gather such variables would strongly confirm the personality-influence inference. In doing this, it would be interesting to also study the general practitioners' attitudes towards consent in order to verify if, in effect, their view towards asking for consent influences patients' consent rate.

It would be valuable to have data defining how a physician conveys information about consent issues. This could validate studies that show that the amount of time a general practitioner spends with a patient to explain the intricacies of a treatment or

a procedure is directly related to the level of acceptance to undergo the treatment or procedure.

Many observation related to innovation acceptance cannot be verified with the studied variables, including the level of living, possession of wealth, occupational prestige, upward social mobility and belonging to large social units, which are associated to early adopters.

In the literature, a higher level of education is associated with early adopters of innovations and higher incidences of consent rates, as well as higher understanding of the necessity to give consent. Such a variable was not used in the study. Understanding the necessity to provide consent is a factor of the patient's perception of what constitutes consent, and it's utility. Information on patients' perceptions towards the process, particularly regarding their trust in medical experiments and physicians, and their understanding of consent issues would have helped compare the study case to literature cases.

These limitations are important to expose and results must be construed while taking them into account. It is by combining and comparing these limitations to the previous elements of discussion that further subjects of study can be proposed.

Future Research

An overview of results and limitations brings to light that there is a need for more research involving qualitative data, including through interviews of patients and physicians. This will help assess their motivation, feeling and understanding of consent-related issues. More quantitative variables may also be studied, such as the level of education and occupation.

Other studies performed in other settings but with the same parameters would likewise be beneficial to the field of study as the present study would be validated.

Finally, it would be important to study how consent rate impacts on the primary objective of the study, being the introduction of an electronic medical record as a pharmaceutical tool maximize drug management.

CHAPTER 6 – CONCLUSION

There is an obvious need to maximize drug management through better administration of drugs and a reduction of adverse drug events and other negative effects. It is widely believed that information technologies can and will be used to achieve this goal.

However, the use of information technologies in health care has to follow certain rules. The crucial nature of personal health data has imposed the necessity to respect patients' privacy as they are given care and services. One such manifestation of the necessary respect of their privacy is the obligation to ask for their consent to use and communicate personal health data.

The whole process surrounding consent is only starting to be thoroughly investigated and variables relating to higher and lower consent rates, may they concern patients, physicians or other elements, have to be more adequately explored.

This study provides many descriptions of patient and physician characteristics that influence consent rate, and describes how they interact one with the other, or others. Hence, it is understood that elements of a patients' sociodemographic profile will incite them to give consent, with some elements having more influence than other. Also, physicians influence patients' willingness to consent, amongst other ways

through their seemingly bias consisting in enrolling patients they feel will most benefit from the research for which they have to give consent. Also, it is evident that general practitioners influence patients' motivation towards consent, but further studies have to be undertaken in this field.

The valuable contribution of the study is that it adds to the base of knowledge of factors and causes related to patients giving or not their consent to participate in research. It goes further as it investigates consent rates within a scenario of innovation and personal health information communication. The fact that physician characteristics were considered in relation with patient characteristics also brought new elements to understanding of consent issues.

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