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m-HEALTHCARE APPROACHES FOR IMPROVING OUTPATIENT ADHERENCE IN SELF-MANAGEMENT OF CHRONIC DISEASES

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ABSTRACT

Using mobile information technology applications to improve outpatient adherence to prescribed treatment and behavioural changes may be a novel approach for more effective self-management of some chronic diseases and conditions. Non-adherence is a major barrier undermining all healing efforts within disease management programs resulting in the waste of important human and social resources. This indicates that an innovative attempt could be helpful in combating non-adherence through the latest mobile healthcare technologies, combined with a carefully planned approach that encourages self-management of chronic diseases or conditions. This paper analyzes the factors affecting patient adherence and formulates concrete interventions through which mobile and wireless solutions may address these determinants for some chronic illnesses that may be cared for in outpatient conditions. Six types of interventions are analyzed by mirroring expected benefits and possible challenges associated with their implementation: monitoring, reminding, consulting, informing, supporting, and educating. The work outlines some of the business aspects of using a mobile healthcare philosophy in this area and concludes with several principle questions that will stimulate further research into collaboration between patients and the healthcare system, using mobile solutions in an endeavour to improve adherence.

KEYWORDS

mobile healthcare (m-Healthcare), patient adherence

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1. INTRODUCTION

Contemporary human society is displaying unprecedented changes such as an increasing tendency towards mobility and an active lifestyle, as well as an expanding diffusion and impact of new information technology. Within this context, today's patients, including the so-called "baby boomers", are more knowledgeable, computer-literate, and better informed than ever and this has the potential of bringing fundamental changes in healthcare (Ball and Lillis 2001; Grimson and Grimson 2002; PricewaterhouseCoopers 1999). Modern patients are now requiring healthcare systems to offer them the same level of advanced technology support and efficiency as sectors such as manufacturing, banking, etc. (Forkner-Dunn 2003; Grover et al. 2002) and this puts a serious strain on the healthcare sector in trying to cope with these new demands. Overall, various forces in the contemporary world are tending to change the traditional healthcare model and contribute to the emergence of the "impatient patient" (Forkner-Dunn 2003; PricewaterhouseCoopers 1999) who asks for high quality, immediate, and personalized medical care. Relevant influences include:

- individuals are better educated in any field today, including health matters;
- people have easy access to huge volumes of recent information through the Internet;
- consumers are becoming more unsatisfied and impatient with the inefficiency and high costs of healthcare;
- patients feel generally more isolated and helpless in a world that is cultivating individualism (e.g. Internet surfing and telecommuting that reduces opportunities for socializing).

Another challenge for the healthcare sector comes from a distinctive feature of today's society: the world is greying. In 1999 the ratio between working people and non-working pensioners in the developed world (North America, Japan, Europe, Australia, and New Zealand) was 3 to 1 but by 2030 it will fall to 1.5 to 1 (PricewaterhouseCoopers 1999). By 2013 "the proportion of Canada's population aged 20 to 44 will decline by nearly 12% while the proportion of the population aged 45 to 64 will increase by nearly 20%" (Ward 2003). Accordingly, more people will be in an age category with additional medical problems while fewer gainfully employed people will be available to contribute to the social funds required to support the healthcare system.

The above problems are further exacerbated by the increasing limitation of healthcare resources, leading to a shortage of hospital beds and healthcare personnel (Siau et al. 2002). This causes, among others, the physicians to spend less and less time with patients while waiting lists are growing, thus amplifying patient feelings that they are being abandoned by the system (PricewaterhouseCoopers 1999).

Contemporary society is thus witnessing an overall and acute contradiction between increasing demands of patients for improved quality of care and the vitality of healthcare resources to support that (Cowling et al. 1999; Forkner-Dunn 2003). This may, generally speaking, set the "Finance and Health ministries … on a collision course in many countries", potentially leading to major alterations of healthcare management, with advances in information technology having a central role in this changing picture (Grimson and Grimson 2002).

A supplementary element that aggravates the above already complicated portrait of today's healthcare is the growing incidence of chronic conditions and diseases. This combined category represented 54% of the burden of all illnesses worldwide in 2001 and will exceed 65% in 2020 (WHO 2003). In absolute figures the burden of chronic conditions is expected to increase from approximately 600,000 *DALYs* to over 900,000 *DALYs* worldwide in the period 1990-2030. *DALYs* signifies *Disability Adjusted Life Years* and is the standard single measure that allows comparisons across many different disease conditions by totalling the lost years of healthy life regardless of whether the loss is caused by premature death or by disability (NIMH 2004).

Chronic conditions and diseases are infectious (e.g. HIV-AIDS or tuberculosis) or non-communicable (e.g. diabetes, hypertension, or asthma) maladies having several distinct features in terms of:

- duration (permanent, or necessitate a long period of care);
- consequences (caused by non-reversible pathological deterioration leaving remnant disability); and,
- treatment (necessitate multidisciplinary management and special conditions and training for patient rehabilitation) (Cheah 2001; WHO 2003).

As the terms "disease", "illness", and "condition" are used with comparable meanings in the specialty literature to describe maladies in the above category, this work will make no distinction between the three expressions.

Because of their medical, social, and financial consequences, chronic conditions are a serious concern for contemporary healthcare. For instance, about 10% of people aged over 75 years suffer from congestive heart failure and it is estimated that this percentage will more than double by the year 2030 (Celler et al. 2001). Asthma and depression are estimated to account for $5.1 billion and $12.4 billion, respectively, in annual direct medical costs in the U.S. alone. The above figures are further magnified by the indirect costs generated by the loss of work time and decreased worker productivity (Weingarten et al. 2002).

Confronted with the above-described problems, the healthcare system is under great pressure to find alternative ways of treatment. Changes are necessary since recent studies show that less than half of the patients with asthma, depression, and diabetes are receiving beneficial treatment (Rundall et al. 2002). Disease management of some chronic illnesses, in outpatient conditions, could be a possible approach in addressing a number of problems in today's healthcare world, to help deal with the fundamental changes occurring in the more general picture of modern healthcare. Keeping patients out of hospitals while at the same time providing them the best treatment conditions possible should be a win-win situation for both individuals and society.

Self-management is a major component of disease management that resonates with the modern concept of "self-care by allowing patients to manage their own health conveniently and proficiently" (Forkner-Dunn 2003). Although it seems to be an appealing approach, self-management of chronic conditions outside of the hospital environment is seriously hindered by limited patient adherence to treatment which statistics generally show to be no more than 50% on average (Bayliss et al. 2001; Dezii 2000; WHO 2003). Non-adherence may also be considered "a veritable epidemic" with serious medical, social, and financial consequences that account for almost 6 percent of hospital admissions (near 2 million a year) in the U.S. alone (Lowes 1998).

The problems in the healthcare system that we have described above on one hand, coupled with the recent tremendous advances in mobile information and communications on the other hand, can lead to a new approach in providing services for patients in ambulatory treatment for chronic conditions. These problems can be alleviated by improving patient adherence to disease self-management programs through the use of mobile and wireless information technology. The success of disease management programs from a social point of view depends heavily on early detection of people at risk for developing chronic diseases (Cheah 2001). Home telemedicine-based approaches may provide unique opportunities for the success of disease management by allowing the timely delivery of care, immediately after the illness is diagnosed. For patients identified as having the highest risks this can avoid much of the cost of acute care that would normally follow in classical treatment patterns (Schlachta 1998).

This paper discusses the value proposition of mobile and wireless solutions for improving treatment and behavioural adherence of patients with certain chronic conditions, cared for outside of a hospital environment. Section 2 presents an overview of disease management and self-management paradigms together with their importance for today's outpatient healthcare approach. Section 3 explores in detail the concepts and forms of patient adherence and shows adherence's pivotal role for all healthcare initiatives. Section 4 depicts and systematizes the main categories of factors affecting adherence. Section 5 justifies the necessity of m-Healthcare approaches for improving adherence, and proposes six concrete

interventions: monitoring, reminding, consulting, informing, supporting, and educating. Section 6 discusses challenges and concerns that may obstruct mobile and wireless initiatives for improving adherence, and Section 7 synthesizes possible barriers from the existing healthcare system that inhibit the implementation of such initiatives. Finally, after a brief business case discussing the benefits and costs of the use of m-Healthcare solutions for adherence, conclusions and some key questions to be addressed in future research are presented in section 9.

2. DISEASE MANAGEMENT AND SELF-MANAGEMENT OF CHRONIC ILLNESSES

Disease management is a relatively new paradigm, developed as an answer to relapses of chronic illnesses. Disease management represents a coupled effort to improve the quality together with the efficiency of care for patients with chronic illnesses (Weingarten et al. 2002).

The Disease Management Association of America defines disease management as "a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant" (Landis et al. 2003a). Other definitions show that disease management of chronic conditions is "a multidisciplinary approach to care for chronic diseases that coordinates comprehensive care along the disease continuum across healthcare delivery systems" or "a population-based approach to health care that identifies patients at risk, intervenes with specific programmes of care, and measures outcomes" (Weingarten et al. 2002). The multifaceted aspects of this newer approach in healthcare are captured in the definition stating that disease management is "a knowledge-based process intended to improve continuously the value of health care delivery from the perspectives of those who receive, purchase, provide, supply, and evaluate it" (Couch 1997, p. 4).

The disease management philosophy also tries to standardize the care and treatment for high cost chronically ill patients in order to achieve a simultaneous impact that both improves health-related outcomes and relieves the healthcare system from some of its burden (Moran 1999; Schlachta 1998). Thus, disease management would answer the divergent conditions of today's world: better care for patients with less effort from the healthcare system.

Disease management is becoming increasingly attractive in the healthcare world as various studies have demonstrated that this type of program is effective in improving the *Quality of Life (QOL)* for people with certain chronic conditions. A study done in the U.S. monitored the *QOL* for patients with diabetes enrolled in a nurse-mediated disease management program. *QOL* was assessed based on *SF-8*, an 8-item validated survey used to estimate patient quality of life in terms of mental health (*Mental Component Summary Score – MCS*) and physical health (*Physical Component Summary Score – PCS*). The study was done for a representative sample of 693 patients that were in the program for at least 90 days. The average age of the patients was 67 years, with an age span between 22 and 94. The average time in the disease management program was a little over one year. Results showed that 20% of the patients had a significant improvement in *MCS* and another 59% remained at the previous level. In terms of *PCS*, 30% of the patients showed a clinically significant improvement whereas for another 51% the level remained stable. The above results led the researchers to the conclusion that disease management improves the quality of life for diabetics (Cocosila et al. 2004, Landis et al. 2003b).

A similar study targeted 18,262 patients living with chronic conditions and enrolled for at least 180 days in a disease management program. At the end of the 6-month period of taking part in one of four studies (chronic obstructive pulmonary disease, coronary artery disease, diabetes, or chronic heart failure) patients were assessed for changes in their mental and physical quality of life. The outcomes revealed that 84% of the patients had a clinically significant increase in their mental health score or remained clinically stable, and 86% of the patients showed a significant improvement in their physical score or at least remained clinically stable. These findings indicate that disease management programs can ameliorate *QOL* for some patients with chronic conditions, and that the improvement in physical condition is higher than that in mental health (Cocosila et al. 2004; Walker et al. 2002).

Similarly, other U.S. research has proven that disease management is effective in managing some chronic illnesses such as hypertension (15% improvement), chronic heart failure (40% reduction in mortality), asthma, depression, epilepsy, and AIDS (Celler et al. 2001).

Beyond its clear advantages in terms of health outcomes, disease management also implies a fundamental change of vision regarding the way medical treatment is delivered to patients with chronic conditions. Thus disease management's premise is that of a "change from the acute perspective of healthcare delivery to a proactive, preventive perspective" (Schlachta 1998). Disease management programs aim at keeping patients out of hospitals and emergency rooms by preventing their health state from becoming acute, with a twofold positive outcome: containing illnesses within acceptable limits, and saving the efforts of the healthcare system and society by avoiding or minimizing the services of the increasingly expensive and deficient acute healthcare delivery (Glasgow 2001).

Modern acceptance of disease management of chronic conditions is therefore associated with treating patients in ambulatory conditions, outside the hospital environment. Furthermore, a substantial body of evidence has shown that it is not possible to treat effectively this category of patients during visits to a physician's office. This is mostly because of the limited duration of a consultation; there is not enough time to educate and support the patient as well as to evaluate the patient's behavioural and life style modifications during a regular visit with the primary care physician (Celler et al. 2001). In addition, as patient education and support are expected to be continuous processes, they cannot be appropriately managed through a succession of short period episodes. Therefore there is a definite need for a steady disease management approach.

Shifting health delivery practices towards long-term home care would not mean neglecting the patients. The reasons behind this transfer would be "the better possibilities for managing chronic care, controlling health delivery costs, increasing quality of life and quality of health services and the distinct possibility of predicting and thus avoiding serious complications" (Maglaveras et al. 2002).

Taking into account the above picture, the management of diseases encompasses not only the necessary direct therapy but also support mechanisms for the patient and caregivers:

- health outcomes longitudinal measurement, evaluation, and management;
- lifestyle and medication management;
- communication and collaboration between patient and the healthcare system (home care, physician, and health plan);
- patient access to health self-management education regarding primary prevention, behaviour modification programs, adherence, and monitoring; and,
- sustaining mechanisms from the social support organizations for patients and their family members (Celler et al. 2001; Cocosila et al. 2004; Hudson and Cohen 2003).

The whole concept of long-term disease management in ambulatory conditions relies heavily on the patient's involvement and proactive attitude. Patient self-management, a hands-on attitude, and collaboration with health professionals are critical to the success of any patient-centred healthcare solution, including disease management (Landis et al. 2003a). The principle of self-management is to delegate, to the patient, responsibility for the management of his/her chronic illness at home so as to improve or at least maintain a certain health condition (Lorig et al. 1999; Lorig and Holman 2000; MDNetGuide 2004). The patient would thus be able to live a life as normal and active as possible while carrying out specific actions such as:

- taking medication (e.g. prescribed pills),
- performing self-tests (e.g. blood pressure, blood glucose),
- monitoring indicator levels (e.g. weight),
- following a certain diet (e.g. watching for food sugar),
- pursuing physical activity (e.g. practicing daily physical exercise), and
- maintaining a healthy life-style (e.g. avoiding smoking or alcohol consumption) in general.

Beneficial outcomes of having patients perform self-management programs would be twofold, for both patients and society. Patients, besides improving (or, at least, preventing the deterioration of) their health state, would also progressively develop a responsive and participative attitude, self-confidence, optimism, improved education and mobility (Rohm and Rohm 2002; WHO 2003). For society, the visible gain would be an enhanced overall efficiency of the healthcare system since patient activities would save financial and human resources. However, there would also be a more profound significance due to proactive and optimistic patient attitudes. Thus patients would live a life as normal and active as possible without serious negative effects on their work, school, family, or social existence.

Various research has shown that self-management may lead to positive outcomes for some chronic non-communicable conditions with high incidence and significant treatment costs such as chronic heart failure, depression, asthma, diabetes, or hypertension (Celler et al. 2003; Chin 2002; Wolf et al. 2002). Within the concept of 'preventing is better than curing', self-management may lead to desirable positive outcomes for both the patient and the healthcare system by starting intervention immediately after health problem diagnosis and before acute events can occur (Schlachta 1998).

A study done in Finland on 115 outpatients with mildly to moderately severe asthma had the objective of comparing the efficacy of self-management with the traditional acute-care treatment for this disease. The 12-month randomized trial demonstrated an almost doubling of the quality of life score (16.6 versus 8.4) simultaneously with the following reductions in the self-management group compared to the traditionally treated group: 50% of the average number of unscheduled visits to care facilities, 44 to 60% of the specific drug use, and 42% of the absenteeism. The conclusion of the trial was that "self management reduces incidents caused by asthma and improves quality of life" (Lahdensuo et al. 1996).

A wealth of studies has examined diabetes patient self-management and adherence to prescribed plans for treatment and care (Kuo et al. 2003; Lutfey and Wishner 1999; Sulway et al. 1980; Wing et al. 1985). These works concluded that self-monitoring of blood glucose is a key factor in the diabetics' efforts to stabilizing glycaemia levels and, thus, to at least maintaining the current health state, reducing the incidence of complications, and improving the quality of life (AHRQ 2000).

Despite such obvious advantages, a disease self-management approach cannot be a panacea. Success of self-management within disease management programs depends on many factors such as the patient, specific illness, treatment, healthcare system, socio-economic environment, and culture (MDNetGuide 2004; Nurse Week 2004). Obviously there could be no positive outcome of any patient-centred long-term disease management program without the patient accepting and following that specific program. Therefore one of the critical factors conditioning the success of any self-management intervention is patient adherence to the prescribed disease treatment and to a healthier attitude and lifestyle in general (CPC 2002; Lutfey and Wishner 1999; MDNetGuide 2004).

3. PATIENT TREATMENT ADHERENCE

Patient adherence is becoming more and more widespread in the medical language as being commonly associated with a long-term therapy for a chronic illness. The focus on adherence is occurring within the more general context of a "revolution is under way in health care" since "after decades of patriarchal provision of services, governments are now accepting that patients should have a say in what is provided" (Richards 1999).

3.1. WHAT IS ADHERENCE?

First attempts to define adherence have related it to medication only (MSH 2004). Thus adherence was understood as "the extent to which the patient follows medical instructions" (WHO 2003). However, this definition had some drawbacks:

- "medical": is insufficient in describing the whole range of interventions used to treat chronic diseases;

- "instructions": implies the patient to be only a passive, consenting recipient of expert treatment advice.

The modern perception of adherence is broader in that adherence to any regimen also reflects a behaviour (Bayliss et al. 2001; Mallion and Schmitt 2001). From a more general perspective there are two types of therapeutic behaviours:

- medical-related (e.g. seeking medical attention and advice, filling prescriptions, taking medication as prescribed, obtaining immunizations, attending follow-up appointments); and,
- individual-related (e.g. following personal hygiene rules, smoking or not, following dietary habits or various levels of physical activity) (Mallion and Schmitt 2001; WHO 2003).

Modern acceptance of patient adherence also means breaking down "the wall between patients and professionals" (Richards 1999). Healthcare professionals are now acknowledging that patients have always had views and priorities that the healthcare system could not perceive. Consequently a patient's treatment adherence should not be perceived today as anything other than a shared medical decision based on collaboration and communication between patient and provider (Holman and Lorig 2000; Osborne 2002, p.3). The collaboration view is based on:

- informing and explaining to the patient the medical problem,
- sharing of views, perceptions and beliefs,
- exploring alternative therapeutic means,
- negotiating a regimen,
- discussing adherence,
- making a clinical decision, and
- setting a follow-up plan (Coulter et al. 1999; Forkner-Dunn 2003; Richards 1999).

Consequently, a more encompassing definition of adherence is: "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (WHO 2003).

In describing the above aspects of patient adherence some recent studies use the term "*concordance*" (Banning 2004; Ferner 2003). A significantly larger number of works use the term "*compliance*" (Cohen 1979). Although compliance is still a very popular term, modern studies consider it inappropriate today for several reasons:

- it is linked to the traditionally unequal model of healthcare that assumes the physician is superior to the patient (who is seen only as a passive recipient of health care);
- it suggests that a dependent person has to carry out the advice, suggestions, or orders given by a professionally dominant person; and,
- the negative variant – *non-compliance* - is misleading since it bears the significance of an unwillingness to follow a medical treatment and may even be considered a symptom of the disease, or a disease itself (Nurse Week 2004).

Recent research has been categorical in showing that patients want decisions about their medical condition to be shared between physicians and themselves, and any modern treatment must display two key features for effective clinical practice:

- involving patients as active partners in their own care, with health professionals; and,
- fostering good communication between patients and healthcare professionals (Nurse Week 2004).

Consequently, modern health practitioners should learn how to talk *with* (not *to*) patients (Lowes 1998; MDNetGuide 2004). Using "*adherence*" is more appropriate than "*compliance*" because the former term

suggests that the patient's agreement to the recommendations, and active involvement in the treatment are essential conditions. However, there is still a debate in the literature about the time succession of events:

- should the patient's agreement be *prior* to making a clinical decision on the prescribed treatment by the health professional and the patient? or,
- should the decision be made mainly by the physician, who must have the ability to inform and convince the patient about the best treatment? (Ende et al. 1989; WHO 2003).

Treatment adherence also resonates with another modern concept, "*patient centred medicine*" that means "treating patients as partners, involving them in planning their health care and encouraging them to take responsibility for their own health" pioneered by family physicians at the University of Western Ontario, in the 1970s (Lowes 1998).

3.2. WHY IS ADHERENCE IMPORTANT?

Research has been unanimous in showing that adherence is an essential component for any self-management program of a chronic disease. For instance, a wealth of studies has examined the implications of adherence for outpatient diabetic care (Biermann et al. 2002; Burge 2002; Diehl et al. 1985; Kuo et al. 2003; Lutfey and Wishner 1999; Paes et al. 1997; Ruggiero et al. 1990; Sulway et al. 1980; Wing et al. 1985). All these researchers have demonstrated that an increased compliance achieved through the self-monitoring of blood glucose rewarded patient efforts in stabilizing blood sugar levels and improving their general state of health.

From a more general perspective, non-adherence is harmful to the care of all chronic illnesses from multiple points of view:

- ***Patients.*** Non-adherence may lead to medical complications and to the triggering of other diseases, with increased risks of morbidity and mortality. Duration of treatment (at least during the onset phase) would be very likely extended for non-adherent patients and this may generate hospitalization and absenteeism. As an intangible consequence, psychosocial complications of diseases and lower quality of life may follow (Dezii 2000; Pfizer 1996; WHO 2003). Also, not to be neglected is the effect induced on healthcare personnel since non-adherence may mislead physicians, hide certain psychological aspects, and cause needless changes in therapy with ricochet effects on the patients themselves (Dezii 2000; Weiner 2004).
- ***Healthcare professionals.*** From a concrete perspective, non-adherence obviously wastes professional resources by unnecessary diagnostic tests, appointments, and follow-ups. From a more sensitive viewpoint, the lack of adherence has been shown to violate professional beliefs, norms, and expectations about professional relationships with patients. Non-adherence challenges professional skills in maintaining correct therapeutic relationships with patients. It may also challenge their ability to conceal discouragement and, sometimes, even anger when patients systematically ignore advice (Nurse Week 2004; Weiner 2004).
- ***Healthcare systems and society.*** Poor adherence can have dramatic consequences in the waste of human effort and other resources on patients who do not need them when these resources are diverted from patients who most need extra services (DCMR 2003; Dezii 2000; Nurse Week 2004). For instance, failure to take medication correctly (although, as shown above, this is only one aspect of non-adherence) has been estimated to cost the U.S. economy $100 billion per year (Nurse Week 2004). Transcending immediate monetary consequences, lack of adherence is the primary cause of sub-optimal clinical benefits, causing psychosocial complications from disease, and waste of health care resources in general (WHO 2003). Good adherence based on well-informed and involved patients is also likely to increase patient satisfaction (and hence reduce the risk of litigation) and would thus work towards everyone's advantage (Richards 1998).

3.3. CAN ADHERENCE BE MEASURED?

Research has shown the continuing importance and interest in measuring adherence. Because of the challenges of aggregating into only one quantifiable results as well as attitudes and beliefs, a variety of measurement strategies have been used and there is no standard accepted procedure (Dezii 2000; Lowes 1998; Mallion and Schmitt 2001; Nurse Week 2004; WHO 2003). Four strategic approaches towards measuring adherence have been reported so far, all of them showing advantages but also drawbacks (Meichenbaum and Turk 1987; WHO 2003):

1. Subjective (clinical) strategies
These are comprised of two methods:

- Ask providers and patients for their ratings of adherence behaviour. Practical experience has proven that providers tend to have a positive attitude and overestimate patient adherence of patients in following their recommendations. Also, patients who attempt but fail to follow advice tend to report higher adherence whereas patients who do not follow advice tend to report their non-adherence correctly.
- Use standardized patient-administered questionnaires. This approach tries to predict adherence by linking it to stable "personality" traits although there is no scientific proof that such a relationship exists, and the result is usually an overestimation of adherence.

2. Objective strategies
Quantitative measurements (e.g. pill counts, date when prescriptions are dispensed or renewed) may seem more realistic than subjective strategies. However, there are also problems with this approach:

- Pill counting inaccuracies are common since they are done at certain time intervals (e.g. weekly) and may result in overestimation of adherence.
- Pill dispensers do not indicate actual medication timing (except the *medication event monitoring system - MEMS* - which is still an expensive device).
- Using pharmacy databases is difficult (because of the mismatch of systems) and gives incomplete information (obtaining the medicine does not ensure its use as long as even opening the pill dispenser does not guarantee the patient is taking the pill).

An additional problem with this strategy is the use of thresholds ("good" and "bad") whereas adherence is best viewed as a continuum.

3. Biochemical (pharmacological) measurement strategies
These strategies include using non-toxic biological markers added to regular medication. Marker concentration in blood or urine can then provide information about the patient's dosage. Several problems with this approach hamper its accuracy. The most important include individual factors including diet, absorption, and rate of elimination, which seriously affect measurement interpretation. Generally, this method has been found to under-estimate adherence, compared to other measures, and it has a higher sensitivity and specificity.

4. Clinical outcomes assessment strategies
These strategies are based on the assumption that there is a close causality between adherence to treatment and the desired result. However, adherence is only one of the factors influencing treatment outcome and there is no proven straightforward relationship between the assumed "cause" and "effect" (Meichenbaum and Turk 1987, p. 38).

Taking into account all of the above, one can formulate some conclusions regarding the measurement of adherence:

- all measurement strategies capture only narrow medication-taking aspects whereas adherence involves more complexities than just taking medication;
- the pattern of medication timing is lacking or, at best, lagging (as in *MEMS*); and,
- no single measurement strategy has been deemed optimal (Nurse Week 2004; WHO 2003).

Therefore current *state of-the-art* adherence assessment requires a combination approach, consisting of feasible self-reporting strategies and reasonable objective measures (WHO 2003).

4. FACTORS AFFECTING ADHERENCE

Researchers have described several forms of non-adherence, depending on the involvement of the patient's willingness in this process. There are three forms of non-adherence enumerated below in ascending order of intentionality (MDNetGuide 2004):

- *Unwitting*. This is fully non-intentional and indicates the situation when the patient would like to adhere to the treatment but does not understand the medical advice he or she is given.
- *Erratic*. The patient comprehends the therapy and wants to follow it but has difficulties in complying with the procedure because of various external factors such as forgetfulness, financial problems, family difficulty, complicated regimen, or medication side effects. This form includes a certain amount of intentionality since adherence in this case is ranked after other issues in the patient's personal hierarchy.
- *Generated by health beliefs*. Because of the patient's perceptions of the illness or the treatment, the patient (or the patient's family) does not believe a therapy is needed as prescribed or that it is needed at all. Consequently, the medication pattern is altered or discontinued. This is the "traditional" type since it is fully intentional, and in nursing "*non-compliance*" is defined as "unwillingness to practice prescribed health-related behaviours" (Nurse Week 2004).

Non-adherence generated by unwillingness is closely associated with a common belief in the healthcare world that "patients are solely responsible for taking their treatment" (AMA 2004; WHO 2003). Non-adherent patients are regarded as interfering with (and in some instances, even sabotaging) the normal process and practice of healthcare. Patients persisting in making choices that produce poor health care outcomes are seen as behaving in a deviant and irrational manner (Nurse Week 2004). These misleading concepts come from a narrow view that shows a misunderstanding of how other factors affect a patient's behaviour and adherence to treatment (WHO 2003). Adherence is in fact a multidimensional phenomenon determined by the interplay of several sets of factors, of which patient-related factors are just one determinant. Because of the complexity of the topic there is a debate in the literature over the categories of factors affecting adherence. One reasonable approach is to consider a primary division into (Figure 1):

- patient related-factors: all of the factors under patient control that contribute to the experience with a treatment, and,
- external influences: all of the factors outside a patient's control that have the potential to impact adherence (CPC 2002).

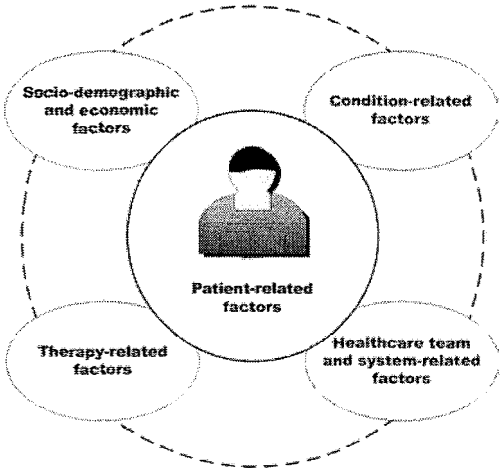

Figure 1. Categories of factors affecting a patient's adherence

4.1. PATIENT-RELATED FACTORS

Patient-related factors spring from psychological/behavioural/attitudinal/lifestyle issues associated with the patient and are usually related to concrete concerns about medication (based on side-effects, symptoms, and experiences) as well as to more abstract worries about the long-term effects and dependence on medication (WHO 2003).

Some patient-related factors that are more or less under patient control and reportedly decrease adherence are:

- forgetfulness or misunderstanding of treatment instructions;
- stress and anxieties about medication and its effects;
- state of motivation/apathy/hopelessness;
- lack of knowledge and skill in managing the disease treatment;
- unperceived need for treatment;
- unperceived disease progress/efficacy of treatment;
- unperceived health risk associated with the disease;
- negative beliefs regarding the treatment;
- negative expectations of treatment outcomes;
- misunderstanding/non acceptance of the disease or diagnosis;
- unacceptance of monitoring;
- frustration with healthcare provider work style/waiting too much for consultations;
- unperceived need for follow-up consultations or counselling sessions;
- fear of complexity or of dependence on the drug regimen; and,
- anxiety over the possible social stigmatization associated with the disease (CPC 2002; Dezii 2000; Mallion and Schmitt 2001; Weiner 2004; WHO 2003).

Studies have been unanimous in agreeing on the importance of this category of factors and on their interactions with factors in other categories. For instance, little can be done through various types of interventions for a patient who does not perceive the need for treatment.

4.2. EXTERNAL INFLUENCES

External influences arise from elements beyond patient control. External influences could be further divided into four subcategories: socio-demographic and economic, condition-related, therapy-related, and healthcare team and system-related.

(a) Socio-demographic and economic factors

Socio-demographic factors refer to elements that are partially characteristic of the patient but not under his/her control such as: race, gender, marital status, age, educational level, and health status. According to some studies, these factors have a relatively small influence on adherence (WHO 2003). Other researchers published more detailed opinions stating that, although there is no indication of a strong correlation of adherence with age and sex (CPC 2002; Mallion and Schmitt 2001):

- elderly patients have an objective tendency for poor compliance because of cognitive and functional (kinetic and dynamic) impairments;
- senior patients have less desire to make decisions and to be informed about their treatment;
- adolescents are less adherent than younger children or adults because of an age-induced tendency of rebellion against the regimen's control over their lives, as well as of peer-related issues; and,
- some children who need to take responsibility for their own treatment because their parents are single and/or away from home working, may also display poor adherence (Ende et al. 1989; WHO 2003).

Many other factors belong to the socio-economic category:

- socio-economic status/income/high cost of medication;
- job/unemployment;
- education/literacy;
- living/environmental conditions;
- family conditions/harmony; and,
- culture (including race-generated) beliefs about illness and treatment.

There are divergent opinions in the literature about the influence of socio-economic factors on adherence (CPC 2002; Mallion and Schmitt 2001; Nurse Week 2004; WHO 2003). For instance, research has not shown that patients who are uneducated or are from lower social and economic groups are less adherent (CPC 2002; Nurse Week 2004) as it would be tempting to assume. Most frequently, socio-economic status influences adherence only in combination with other factors.

(b) Condition-related factors

Condition-related factors refer to specifics of the illness, symptoms, and treatment, and are closely connected with the illness stage of the patient. Some determinants of adherence in this category are:

- severity/absence of the symptoms;
- awareness/acceptance/knowledge about the disease state;
- knowledge about the implications of non-adherence/benefits of therapy;
- nature and severity of the possible disability (physical, psychological, social and/or vocational);
- stage and rate of progression of the disease; and,
- the availability and commonality of effective treatments (CPC 2002; MSH 2004; Nurse Week 2004; WHO 2003).

The above factors can influence the patient's adherence directly but they may also serve as mediators by modifying the patient's risk perception and beliefs about following the prescribed treatment. The

impact of the above factors may also be moderated by other factors such as usual co-morbidities (e.g. depression in diabetes) and drug and alcohol abuse (WHO 2003).

Trying to infer logical connections between condition-related factors and adherence may be erroneous. For instance, studies have shown that patients with less severe health problems were more eager to make decisions on their treatment and follow the prescribed regimen, compared to patients with more advanced illnesses (Ende et al. 1989; Nurse Week 2004). Even more puzzling, other studies have found that ill people who have no or few symptoms (e.g. most hypertensive patients) had difficulty in accepting treatment or life style changes necessary to prevent the onset of possible problems (e.g. cardiac events) (Lowes 1998; Mallion and Schmitt 2001).

(c) Therapy-related factors

Researchers have reported that the characteristics of therapies associated with certain diseases may not have a larger influence on adherence than other factor categories, but they may their magnitude. Common elements in this category are:

- form and complexity of the medical regimen;
- product and packaging of the medicine;
- duration/frequent changes/previous failures of the treatment;
- outcomes of the treatment (not noticeable, delayed onset, prophylactic use);
- the immediacy of beneficial effects;
- significant adverse reactions/side effects; and,
- the availability of medical support to help deal with therapy problems (AMA 2004; CPC 2002; Dezii 2000; Mallion and Schmitt 2001; Weiner 2004; WHO 2003).

Logical analysis of how the above factors influence adherence may lead to unrealistic conclusions. For instance, adverse effects have been shown to arise if a patient fails to take a drug as instructed (Dezii 2000). However, the patient may think that adverse effects are caused by the medication itself and drop it altogether, with dire consequences for adherence and the entire treatment.

(d) Healthcare team and system-related factors

Studies and trials have been categorical in demonstrating that organizational variables and, especially, good patient-provider relationships and communication, as well as the faith of the patient in his/her physicians, nurses, and pharmacists are essential for the acceptance and adherence to prescribed treatments (Kaplan et al. 1989; Nurse Week 2004; Mallion and Schmitt 2001; MSH 2004). Particularly important is the "*first encounter*" when the healthcare professional must spend sufficient time with the patient so as to gain his/her confidence and be sure the patient fully understands the medical problem and the necessary treatment (Dezii 2000). However, many other factors have a negative effect:

- inappropriate knowledge and beliefs of healthcare professionals in managing chronic diseases;
- brief consultations preceded by a long waiting time;
- unsuitable communication and interpersonal style of the physician;
- inappropriate counselling, prescribing, or support tools;
- lack of incentives and feedback on performance for healthcare professionals;
- lack of tools for continuity of care provided by healthcare workers;
- inadequate or non-existent reimbursement for treatment by health insurance plans;
- inappropriate medication distribution systems;
- incapacity of the system to medically educate patients and provide follow-up;
- inability of the system to encourage community support and self-management of diseases;
- undeveloped social attitudes on adherence and on effective interventions for improving it;
- social negative beliefs and habits regarding chronic diseases and drugs;

- inappropriate government regulation about certain specific diseases; and,
- insufficient news information, and more or less informed opinions available in the media and on the Web about diseases and adherence to treatment (CPC 2002; Dezii 2000; Richards 1998; WHO 2003).

Some studies have directed attention to unexpected effects of changes in the health care delivery system that may place the physician-patient relationship at risk (Kaplan et al. 1989). For instance a patient may wait too long before receiving a consultation by a very skilled but busy and overworked physician. Paradoxically, such a patient, especially if he/she has the impression of not being treated with sufficient compassion, may "retaliate" through non-adherence (Dezii 2000). In such situations the whole illness may be overshadowed by the patient's feelings.

5. IMPROVING OUTPATIENT SELF-MANAGEMENT ADHERENCE BY MOBILE HEALTHCARE

The use of self-management to deal with some non-infectious chronic illnesses in ambulatory conditions is certainly a tempting approach for the patient, the healthcare system, and society. However, the practical implementation of this vision is at risk due to issues arising from intrinsic problems of the stakeholders involved in this process (patients and the healthcare system) as well as inappropriate links between them.

Since every patient is unique, he/she may respond differently to a particular chronic disease and treatment. Therefore patients in a self-management program must undertake different healing strategies that include learning about the condition, managing symptoms and treatment, and deciding when medical or professional help is needed. While the value of these plans may be clear, practicing one or more of them can be quite challenging, due to a patient, medical, and social environment factors and peculiarities on one hand, as well as to the difficulties of communication between the patient and the healthcare system on the other hand. In the absence of appropriate tools for improving the patient's adherence to prescribed treatment plans, all of the above challenges may seriously hamper the success of self-management and disease management programs. Therefore it is reasonable to determine if the much-desired improvement in the self-management of some chronic diseases could be achieved by the use of modern tools of information technology.

5.1. WHY LOOK FOR MOBILE HEALTHCARE SOLUTIONS?

Despite its undeniable advantages, existing approaches of outpatient self-management pose several challenges, *most of them gravitating around non-adherence*, that information technology may be able to address:

- non-existent or outdated information on whether the patient is taking medication as prescribed, and/or executing lifestyle changes;
- no permanent link between patient and healthcare system for support and counselling,
- no possibility of support from the patient's community/peers;
- no support for informing and educating the patient on the disease and its treatment;
- no support for acknowledging the patient's progress or stagnation with the treatment;
- untimely sharing of information on the disease and treatment changes between the patient and healthcare system;
- no rapid-reaction system to help the patient make decisions so as to reinforce adherence, while coping with unforeseen challenges of today's dynamic environment; and,
- inability to call for emergency support when necessary.

Furthermore, researchers have demonstrated that the traditional "current methods of improving adherence for chronic health problems are mostly complex and not very effective" (Haynes et al. 2004).

Today, information technology is opening the road to dramatically improved patient adherence through outcomes from disease and self-management programs by enabling them with new tools (encompassed, in a more general context, under the terms of e-Healthcare and m-Healthcare) (Bergeron and Bailin 1999; Coursaris 2003; Hoise 1999) "that support a more coordinated and proactive approach to managing chronic illness" (First Consulting Group 2004). Mobile solutions may help overcome the above barriers to self-management and adherence because of their features:

- ***Access.*** Mobile services travel with the patient, allowing him or her to reach or be reached by the healthcare system anytime and anyplace, if necessary for fast intervention and support or counselling. In contrast to fixed phones or the wired Internet that reach fixed locations, mobile devices are always with the person.
- ***Quality.*** Mobile applications provide patients more timely information and superior communication capabilities. This allows them to be better educated, active, and responsible, thus improving their self-management efficacy. Patients can maintain an always-on private link with the healthcare system that increases their confidence and positive attitude. Conversely, healthcare has a refined tool providing information on the patient's treatment attitude and state of health.
- ***Value.*** Mobile solutions allow patients the highest independence possible. Patients are able to live their lives as normal as possible for their condition and disease, while they are going to work or school, by maintaining a permanent connection with the healthcare system. This would presumably diminish the incidence of unexpected health situations and co-morbidities associated with chronic diseases, thus saving direct costs for the healthcare system by helping patients improve their adherence. Social costs can also diminish since patients live less disturbed lives (Cocosila et al. 2004; Hatzakis et al. 2003).

Besides the above-mentioned reasons, using mobile solutions in healthcare would benefit from the effect of the tremendous amount of innovation in mobile information and communications currently generated by other sectors such as voice communications, data transfer, gaming, banking, etc.

5.2. POSSIBLE BENEFITS OF MOBILE HEALTHCARE SOLUTIONS FROM INCREASED ADHERENCE

Researchers have demonstrated that a patient's ability to adhere to prescribed treatments is frequently compromised by several factors (Gerber 1986). Consequently, focusing on uni-dimensional interventions (primarily patient-related) has limited effectiveness either through outcome or time duration, due to interaction with other factors (WHO 2003). Therefore mobile information technology solutions may help only if targeting one or more essential adherence factors while being embedded in systematic multi-dimensional interventions. Giving patients medicine and instructions on how to take it does not mean they will follow instructions appropriately and beneficially (Schlachta 1998) and solutions for improving patient compliance must also be provided.

However, it is important for mobile solutions to be used only when they can add value (Davies and Henderson 2003) to remote health management. Using pervasive mobile solutions (as in any other technology solution, in fact) is virtually useless for patients not willing to adhere to a treatment. Possible interventions through mobile solutions to improve adherence and effectiveness of disease management should therefore target the unwitting and erratic forms of non-adherence. This would be similar to the possibilities offered by telemedicine and Web-based services (Hudson and Cohen 2003) but with increased flexibility in: monitoring, reminding, consulting, informing, supporting, and educating.

(a) Monitoring

"Successful patient monitoring is reliant on efficiently extracting the relevant information from a patient without excessive intrusiveness to both patient and health care professional" (Mazzi and Kidd 2002). Monitoring consists of longitudinally tracking parameters by either or both the patient and the healthcare system thus achieving tighter control and management of the disease (Magrabi et al. 2001). Parameters should have a high degree of personalization based upon agreement between healthcare professionals and the patient.

Monitoring consists of the patient doing certain tests (e.g. blood glucose for diabetes or tension for hypertension) and recording the results. The classical way for documenting test outcomes is to use pen and paper but a more modern technique that diminishes errors and reduces burden on the patient is to use mobile devices such as Personal Digital Assistants (PDAs).

In order to be efficient, monitoring has to follow a rigorous time schedule. Mobile solutions can provide this critical feature by going everywhere with the patient and being ready anytime for recording and statistics generation or transmission. Moreover, for increased efficiency of the whole disease management process, monitored results that exceed individualized preset ranges should be sent automatically to a central monitoring system for a healthcare professional's immediate attention. Mobile solutions empowered by wireless capabilities offer the anytime and anywhere capability necessary to this feature.

Monitoring should not end with recording test results or sending them to healthcare personnel. A monitoring system should be able to give patients' immediate feedback on test results and their evolution. Real-time feedback is crucial for changing behaviour and improving adherence, for the success of self-management of chronic diseases (DMN 2002; Mazzi and Kidd 2002). Feedback may come from either the mobile device or from the central system, depending on the situation, and would recommend to the patient a course of action (Cocosila et al. 2004). Mobile solutions would allow patients to receive timely feedback in almost any situation.

Through the activities we have indicated, monitoring would likely have positive effects for adherence by diminishing patient forgetfulness and reducing stress. In addition, there should be less deviation of discontinuity from specified treatment regimens, or treatment failure, thus allowing prompt detection of side effects and of state of health. Also, appropriate monitoring would improve motivation, knowledge, and skills in managing the disease symptoms and treatment. For instance, it has been shown that compliance and monitoring resulted in a decrease in hospitalization for cardiovascular diagnoses by one third (Shah et al. 1998), and to reduce medical interventions caused by morbidity by half for asthma patients (Steel et al. 2002).

(b) Reminding

Reminding consists of sending patients notifications concerning to taking a medication, performing a self-test, following a diet, or exercising, thus improving preventive practices (Shea et al. 1996). Other proactive outreach could remind patients to start or stop a medication, refill a prescription, a doctor appointment, or a homecare visit. In a more advanced approach, patients would acknowledge having complied with the notification (e.g. taking a pill once a day). This approach would track medication patterns and give patients the ability to receive feedback for their actions, with positive outcomes for adherence, similar to those for monitoring. Feedback would encourage patients who comply with the treatment, acknowledge their progress, and discourage noncompliant attitudes.

Mobile solutions would successfully fulfill such tasks since they would always accompany the patient. A variety of possibilities allowing such features are already a reality in cell phone technology: written messages (such as SMS), audible signals, or even vibrations. Reminding would be done in a personalized way, thus helping the patient follow the treatment plan previously agreed upon.

Proactive outreach to patients would presumably have positive implications for adherence by decreasing forgetfulness and treatment stress, fears and anxieties, by diminishing side effects and treatment discontinuities or alterations, as well as by discouraging the use of aggravating factors (e.g.

alcohol or smoking). Moreover, personalized and non-intruding reminders would improve self-confidence, motivation, and attendance at follow-up consultations.

(c) Consulting

Concepts such as disease self-management and patient-centred medicine rely heavily on including the patient as an integral part of the treatment process. Patients communicating to the healthcare system conditions such as pain, feelings, symptoms, anxieties, and concerns about the results of self-administered physiological tests (e.g. blood glucose or blood pressure) has been shown to have a positive effect on the healing process (Mazzi and Kidd 2002). Surveys have revealed, for instance, that physicians consistently reported that email communication with patients helped to enhance chronic-disease management through improved continuity and flexibility of care (Patt et al. 2003).

Patient demands for continuous contact with their physicians as well as for receiving real-time information are driving the introduction of new technologies for disease management (Mazzi and Kidd 2002). Mobile solutions would offer support for such consulting processes, having time and location independence as key advantages, compared to other channels such as landline telephone or email. Communication could be initiated by either the patients or the healthcare system when urgent matters related to patient health and disease treatment required it. There are three possible patterns: synchronous, asynchronous, and mediated. Synchronous communication allows phone-type direct conversations and is the preferred channel by the party initiating the dialogue because of cognitive psychological effects based on the performance of human memory (Parker and Coiera, 2000); people need to communicate fast before issues are altered by forgetting (Coeira, 2000). Asynchronous communication through email or text messaging is preferred by the party being called (especially if this is the healthcare system) because it is less disruptive. Mediated communication would involve patients carrying out a synchronous or asynchronous basic dialogue with an automated central system empowered by intelligent agent technology and able to handle more standard tasks such as information search and triage (Mazzi and Kidd 2002; Revere and Dunbar 2001).

Some forms of asynchronous text communication may be difficult for older or less technically proficient patients and, accordingly, conversion of text messages to voice or voice to text may be necessary. The necessary technology is already present in some cell phones (Nokia 2003) and such applications have already been conceptualized in the medical environment (Bludau 2003; Rebentisch 2002). Significant value can be brought to the patient-healthcare professional relationship by the newer camera cell phones, adding a completely new dimension to the consultation (BBC 2003; Wallace and Gibson 2004).

Instant consulting between the patient and the healthcare system (physician, nurse, pharmacist, or even an automated system) may be valuable for supplementary consultation support, initiated by the patient/healthcare system when necessary. This would help combat one lack of the current home and ambulatory care management model: access to physicians may be difficult when needed (Celler et al. 2001). Consequently, this could have a significant role in improving patient adherence by diminishing stress, anxiety, misunderstanding, or misperceptions of medical or treatment terms, and consequences of missing knowledge or skills. Also, online consulting might diminish side effects, treatment discontinuities or alterations, as well as the incidence of aggravating factors such as depression or alcohol abuse. Instant support from the healthcare system could help to improve patient knowledge about the disease and increase self-confidence and motivation. This could be especially effective if an alarm could be directed to a support call centre as an extreme level of instant consultation (Magrabi et al. 2001).

(d) Supporting

Studies of factors conditioning patient adherence have reported consistently that social support, attitudes, and rewards to be factors that significantly improve patient health outcomes and behaviours (Meichenbaum and Turk 1987, p. 212; WHO 2003). Patients can find large amounts of medical information on the Web today (much of which is opinion rather than fact). However, patients still need

human support and counselling in a society where individual loneliness is becoming more of a problem (PricewaterhouseCoopers 1999). Within socio-demographic factors that affect adherence, an important element for outpatients is social support, feedback, and information exchanges with peers in similar situations or with other members of the community. It is also vital for fostering positive beliefs and optimistic attitudes to understand that their illnesses are not unique and that other persons have had similar experiences and anxieties but successfully overcame them. These social links make patients feel less isolated, and they receive valuable support when lifestyle changes are necessary but difficult (Celler et al. 2001).

Web support groups have also proven benefits for adherence due to exchange of information but also due to the emotional support and encouragement they provide. For instance, studies showed that patients who participated in an online diabetes education and support group had better health outcomes than patients attending only regular medical control meetings (McKay et al. 2001). Other research has shown that diabetes chat rooms on the Internet improved medical readings, positive attitudes, and the capacity for self-management in general (Mazzi and Kidd 2002).

Mobile information technology offers an ideal tool for social support by facilitating convenient and continuous (*anytime and anywhere*) communications and exchange of information with peers or within communities. Built-in capabilities of today's cell phones such as text messaging or voice conferencing, or newer features such as multimedia messaging service incorporating images and being linked with the wired Internet make mobile solutions an ideal tool for social support. Mobile technology also allows a high degree of customization, thus adapting the type of support to the patient. For instance, messages sent to young people could be of the SMS type because of the popularity of this channel of communication within that age category whereas senior people would likely be more comfortable with regular phone conversation.

(e) Informing

There is evidence that patients want more information about their disease and condition than they usually get from their doctors. Physicians, in turn, overestimate how much information they supply (Richards 1998). The modern patient is more technically savvy and, especially with the advent of the Internet and specific search tools, compact and readily available information is at hand.

Mobile solutions would not be able to offer much information because of the input/output data entry and retrieval limitations of specific devices. However, they would be able to notify of interesting and useful news from other media (TV and radio broadcasts, newspapers, Internet). Mobile solutions would also have the advantage of being able to convey timed alerts tailored to the patient (e.g. a specific article in today's newspaper). Besides the above “push” approach, mobile solutions could also facilitate a "pull" model that relies on the patient seeking and retrieving specific information. For maximum convenience, due to device input/output limitations, mobile solutions could provide a basic search feature to prompt for access to archives of useful news and articles available on the Internet.

Informing interventions would help patients to stay updated with helpful knowledge about their disease and its treatment and could help to improve adherence by fighting anxiety, misunderstanding, negative beliefs, and lack of knowledge and skills.

(f) Educating

Adherence factors and disease self-management studies have clearly demonstrated that constant education and self-education are an important success factor for treating and improving patient conditions. Education is a more complex process that covers a long time span and implies *involvement and action besides information.* Mobile solutions are not expected to bring significant benefits in terms of patient education. However, improved patient education could be achieved as a result of applying with perseverance and high personalization the other interventions: monitoring, reminding, consulting supporting, and informing.

6. MOBILE INFORMATION TECHNOLOGY AND OUTPATIENT ADHERENCE

This section explores the requirements, possibilities, and challenges associated with utilizing mobile information technology interventions to improve outpatient treatment adherence. Relevant issues discussed are the necessity of mobile or wireless solutions, as well as implementing solutions for specific interventions to target patient adherence as presented in the preceding section.

6.1. INFORMATION TECHNOLOGY ATTEMPTS TO ADDRESS DISEASE MANAGEMENT AND ADHERENCE

Advances in wireless and Internet technology have already made possible the development of new healthcare services, two of the most popular being remote monitoring and the management of patients under treatment at home. Trials of distance monitoring of blood glucose or blood pressure with the help of a computer showed improved outcomes and efficiency together with a more active participation of patients on their own behalf (Balas and Iakovidis 1999). Extrapolating from the success of preliminary results with the *Telephone-Linked Care* technology, Friedman et al. (1997) suggest that "the market demand for technology-based delivery systems used by patients in their homes will be strong". Husemann (2004) sees a future in the emerging field of information-based medicine, for solutions like monitoring vital measurements on-the-go or for pill dispensers reminding patients to take the appropriate medicine.

Electronic monitoring is constantly expanding in application, and innovative approaches are becoming increasingly available for a variety of diseases. In particular, analysts foresee wireless medical devices helping chronically ill outpatients with asthma or diabetes (Duan 2003; Hoise 1999) and distance monitoring of diabetic patients has already been shown to ameliorate clinical outcomes (Weingarten et al. 2002).

Wexler (2001) reports on a development by *IMetrikus Company* that allows diabetics to test their health parameters and upload the results through the Web. The future will bring a Web-free solution using a direct connection between the glucose monitor and a cell phone, without patient intervention. Furthermore, a healthcare alert triggering feature would reportedly be incorporated.

Medtronic CareLink™ Network has been promoting a remote monitoring service that is totally Web-based, for patients with implanted cardiac devices. With this service, patients can send timely information to their clinic from a regular phone (Medtronic 2004).

WellMed Inc. has developed a wireless application supporting patient information (e.g. health or insurance information) and communication (e.g. physician contact) activities (Conlin 2000). *SmartMeds.com* and *AT&T Wireless* have jointly developed a wireless solution for reminding patients to take prescribed medication and allowing patients to provide feedback about complying with the reminders (Conlin 2000; Wirelessnewsfactor 2000).

IBM researchers pioneered an information technology solution to track and send vital health signs remotely. The device includes a pillbox and a wristwatch-like blood pressure monitor able to communicate via a Bluetooth short-range radio connection with a mobile phone which, in turn, sends the data to healthcare personnel. Only authorized personnel are able to view patient data. This technology is thought able to reduce the number of checkups, the length of hospitalization periods, and patient health risk (Husemann 2004).

In recent years a significant effort has been made in Europe towards employing the Internet or wireless remote monitoring for health support. Maglaveras et al. (2002) advocate the "necessity for restructuring the medical knowledge for education delivery to the patient" exemplifying this through the novel idea of a contact centre enabled by wireless technology and meant to manage the home care of some patients remotely.

Patients using *ProWelness,* a Web-based information system for remotely managing chronic diseases (e.g. diabetes), are able to record specific disease management activities daily by fixed or mobile cell phone. The philosophy behind the system is that the two key elements essential for success in

managing a chronic disease are "careful self-care and good communication with the care team" (ProWellness 2004).

Following the implementation of a three-year project financed by the *British Engineering and Physical Sciences Research Council* with £160,000, doctors in the U.K. have monitored the health condition of some patients remotely by analyzing medical data gathered by a device communicating with a normal cell phone (Van Impe 2001).

Bludau (2003) describes a platform for patient home monitoring by physicians at a hospital. This solution uses medical Bluetooth-enabled modular sensors and cell phone technology to transmit data such as blood pressure, pulse rate, or temperature.

Arbonaut, (Finland), and *Virtual Medical World Solutions*, (U.K.), have been trying to set a platform for real-time remote monitoring based on an investment of EUR 1.7 million from the *European Commission for Telecare* project. The solution targets patients with a "stable medical condition that allows a near normal life but may suddenly deteriorate and put life at risk" (Poropudas 2001).

The above examples illustrate early attempts to use information technology for gathering and delivering real time medical information in order to improve the quality of care for patients. As both fixed and mobile solutions have been developed, an issue to be discussed is the justification for the use of mobile approaches to best address adherence of outpatients in self-management programs.

6.2. HOW CAN ADHERENCE BE ADDRESSSED BY MOBILE OR WIRELESS SOLUTIONS?

Mobility in the context of communication and information "should not be understood simply as a new distribution channel, a mobile Internet, or a substitute for PCs" (Yuan and Zhang 2003). A mobile information technology is justified only by the particular location of the user needing an information or communication service, or by the utility or urgency of that service (Mennecke and Strader 2003). All three elements justify the use of mobile solutions to improve outpatient adherence in self-management programs for chronic illnesses:

- ***Location.*** Patients, as all people, have inherent mobility when changing spatial positions for work, school, shopping, walking, or various other activities. Given the diversity of their potential physical location, it is important for them to have self-confidence and feel that they are in constant contact with nurses or doctors as well as with social support groups.
- ***Utility.*** For the success of disease management it is essential for patients to be monitored continuously so that their medical condition remains within safe (i.e. acceptable) limits. Also the patients should be constantly reminded to comply with the prescribed treatment plan, e.g. take pills, start or stop a medication or a diet, visit a doctor for periodical consultations, etc.
- ***Urgency.*** In most cases, time is not a critical factor for patients with chronic illnesses. However, in extreme cases when health equilibrium is broken, some patients may need fast intervention. This capability would enhance the patients' perceived level of safety and security, and promote a generally optimistic attitude.

Additional reasons for providing mobile solutions for patient care outside the hospital environment can be found in the collection and analysis of patient data. By utilizing electronic devices for this purpose, there is significant potential for improving the quality of care for these patients, through increased convenience and accuracy. Furthermore, a device with an inherent communication feature would enable prompt interventions when abnormal data require it.

The reasons above, combined with the analysis in the previous section may be used to justify mobile solutions for improving outpatient treatment adherence. However, a further question is whether mobile solutions should also be 100% wireless. That is, mobility does not automatically imply wireless access. Wireless is only one technology (e.g. cell phones) that enables mobility by the use of specific wide area networks.

For most of the previously identified interventions to improve adherence, wireless technology is best suited for enabling the required features. Wireless connection between the patient and the healthcare system can be very effective since it: fosters patient self-confidence and perceived safety; provides a virtually permanent connection with nurses and doctors as well as with social support groups; gives access to timely and useful information; alerts the healthcare system when indicators exceed normal limits, and provides access to fast intervention in emergency situations. However, improving patient connections with the healthcare sector must be selective and gradual, based on segmentation and prioritization of patient conditions, so as to not overload the system when patient situations do not require intervention by health professionals (Cocosila et al. 2004). Thus, the system would improve efficiency in managing mostly uncommon conditions.

It is arguable whether wireless connection is really necessary. With the goal of improving patient quality of care, while offering savings in healthcare resources, *some other features* such as constant monitoring or reminding patients to take prescribed medication or to adhere to diets set by experts, or to perform self-tests at the required times *can be fulfilled by a mobile but not wireless application.* Wireless networks and "always on" connectivity need only be used for remotely contacting healthcare personnel in out-of-range situations, as well as for alerts and emergency functions. For normal situations the application could use just the built-in capabilities of the mobile device. However, this would prevent the medical healthcare system from having real-time information on the patient's health and medication state, and the loss of ability to provide useful feedback and encouragement, very effective in improving patient adherence.

A more complete analysis involving business aspects is necessary in order to find the best compromise between functionality and cost effectiveness for patients and the healthcare system. Irrespective if performed by a central system or by a mobile device with enhanced capabilities, monitoring and reminding should be automated as much as possible in order to offer additional savings and increased reliability to the healthcare system in general.

Thus, it appears that a combination of wireless (i.e. network enabled) and mobile (i.e. carried by person) solution would be best for improving outpatient adherence to chronic disease treatment. Depending on how the functionality is shared between a central system and the mobile device carried by the patient, the tool could have various capabilities. An over-riding feature is that the device should be kept as simple, robust, and reliable as possible in order to be accepted by large categories of users (Bludau 2003).

6.3. ISSUES AND CHALLENGES ASSOCIATED WITH MOBILE AND WIRELESS SOLUTIONS TO IMPROVE ADHERENCE

Improving patient adherence through mobile and wireless solutions seems to be a good approach. However it raises a series of issues and challenges that arise from adherence itself as well as from the peculiarities of the technology. This section discusses adherence-related problems in principal, since technology-related issues referring to human-mobile device interaction have already been studied extensively (Chan et al. 2002, Hassanein and Head 2003, Tarasewich 2003, Tudiver 2003). For reasons of rigor, the issues and challenges are listed in order of the specific interventions to improve adherence, as described in Section 5.2.

(a) Monitoring

Various monitoring devices that link to the Internet and help patients to manage their medical conditions at home have been already developed. Diabetics, for instance, can test their blood sugar with an e-device that sends the results automatically to a health care professional (Forkner-Dunn 2003). Adaptation of such testing devices to mobile information technology would not be difficult. However, one problem, besides

health outcomes and cost effectiveness, would be the long-term acceptance by patients (Forkner-Dunn 2003).

Research has yet to determine which approach would work best for patients: highly automated devices performing the monitoring, storing the results, and alerting the healthcare system when necessary, or a combination of less automation and more human action with the same purpose. The former approach would be more convenient for people with busy schedules but would risk transforming patients into low intelligence machines. Furthermore there is a risk of too many false alarms (Mazzi and Kidd 2002). The latter approach would involve a more proactive attitude by the patient, but having to think about it more frequently would tend to be more disruptive.

A subsequent issue is how often and what coverage would be necessary for the monitoring. A danger is to try to collect "too much data too often, "heavily perturbing the patient's life (Mazzi and Kidd 2002). A related question is where to store the results of the monitoring: on the device or on a central system. The former approach would be more convenient and less costly whereas the latter would give the healthcare system immediate access to the patient's health parameters.

Because intelligent feedback is an essential feature for success in monitoring and adherence improvement, another issue is how much automation and how much personalization (from the healthcare professionals involved) should the feedback contain in order to be most effective? A subsequent problem is what steps should be taken if the patient does not comply with the agreed monitoring program (e.g. send reminders, notify the nurse, contact the patient, etc.).

(b) Reminding

The main issues associated with reminding are very similar to those of monitoring. For instance, reminding a patient to take a medicine could make the patient open an "intelligent" pill dispenser. This would record the time when the medicine was supposedly taken. The opposite approach would have the pill dispenser send a wireless signal to a central system to confirm that the medicine container was opened. A variant that involves the patient more would require a button to be pushed on the wireless device to signal the central system that the medication was taken. The last approach, although the most intrusive for the patient, would have the highest involvement and responsibility, thus being more likely to improve adherence. Furthermore, it would open the door for highly beneficial feedback from the healthcare system.

(c) Consulting

The main danger for compromising a consulting intervention is the possible overflow of the system by patient-initiated synchronous communication. Patients trying to call doctors/nurses unjustifiably much may result in rejection of the system by healthcare professionals (Forkner-Dunn 2003). As in email communications between physicians and patients, some issues must be addressed before mobile consulting becomes viable: identifying clinical situations where such communication would be effective, incorporating the process into the office flow, and, most of all, providing reimbursement for the healthcare professionals that offer the consultation (Patt et al. 2003). The problems mentioned above may be attenuated if the patient population is segmented and prioritized, but this is a sensitive problem that must be addressed periodically. At the same time, patients should be involved in decision to alert the healthcare system as this leads to more conscious, active, and self-educating patients (Mazzi and Kidd 2002).

Another problem with consulting is how to match various communication needs: voice is usually preferred by the caller whereas text is usually preferred by the called person. Also, there may be some age predilections as discussed in Section 4 above. A technical problem that influences speed and accuracy of communication when text/voice or voice/text conversion is necessary is whether to perform the translation at the device or system level.

Assuring privacy during online consultation can also be an issue. For instance, other people may hear a conversation between a physician and a patient if either is in a public place, and this would infringe standard healthcare requirements.

Finally, there is the matter of liability: who would be responsible if the patient did not understand correctly the doctor's advice due to technology or environmental drawbacks (e.g. too much signal noise, temporary loss of connectivity, or high background noise).

(d) Supporting

As discussed above, support from peers and social groups is an excellent vehicle for improving adherence. However, this should be questioned, because there is a limit to how much trust should be placed in advice from untrained individuals and, further, who would bear the liability for wrong advice? As an example from the Internet experience, anonymity favours freedom of expression but may also serve as a cover for malicious advice.

A possible solution to this issue would be for the healthcare system to provide a moderator of conversations within social groups. For instance, a diabetologist serving as a moderator in an Internet diabetes chat room for adolescents was proven to have a positive effect on their glucose levels and self-management attitudes (Mazzi and Kidd 2002). However, this would certainly lead to problems about reimbursement, privacy, and liability.

Another possible consequence of support arises from patients who seek extensive remote consultations with their physicians in an attempt to clarify issues developed in peer dialogues. This may easily overwhelm physicians with unnecessary conversations.

(e) Informing

Mobile solutions would likely not extract information from certain verified databases but would only point to news that might be of interest for patients. A question that arises is the selection and assessment of the quality and utility of such news. A related problem occurs if the news might appear to the patient as being endorsed by the healthcare system.

There is also a risk for the healthcare system of being flooded by communication demands from patients wanting to clarify or know more about what they learned from the news. An associated risk: doctors or nurses could be put in an embarrassing position if some of the news did not match their medical knowledge and recommendations (Forkner-Dunn 2003). A reality the medical system must face is that today's people are becoming better informed on health issues and want greater involvement in the decision making process (Richards 1998).

(f) Educating

Education would imply a combination of the other interventions, and there is a danger of mismatch and non-concordance between them. Ideally, education would take place under an integrated and overall view but this would require more patient and healthcare professional dialogue through other media (ex. leaflets, phone, email) and face-to-face meetings.

In conclusion, mobile solution interventions to improve patient adherence would generate, in addition to the presumed benefits, certain challenges and concerns. Table 1 mirrors the two sides of the problem. Some concerns may be individual while others are common and may require rethinking the way some home care services are provided.

Table 1. Benefits and concerns due to actions to improve adherence by mobile and wireless solutions

Action	Type of Intervention	Possible Benefits	Concerns
Monitoring	Patient-related	Diminishing patient forgetfulness and	Long-term acceptance by patients;

	Condition-related Therapy-related	treatment stress; Diminishing treatment alteration, discontinuities, and failure; Allowing prompt detection of side effects and of health state alteration; Improving motivation, knowledge, and skills in managing disease symptoms and treatment.	Which is better: highly automated devices or a combination of less automation and more human action; Risk of too many false alarms; Collect "too much data too often"; Where to store the monitoring results; How much automation and how much personalization should feedback contain; What steps to undertake if a patient does not comply with monitoring.
Reminding	Patient-related Condition-related Therapy-related	Decreasing forgetfulness and treatment stress; Lowering fears and anxieties; Diminishing the side effects and treatment discontinuities or alteration; Discouraging the use of aggravating factors; Increasing attendance at follow-up consultations; Boosting self-confidence and motivation.	Similar to monitoring.
Consulting	Patient-related Condition-related Therapy-related Healthcare team and system-related	Diminishing stress, anxieties; Avoiding misunderstandings or misperceptions of medical or treatment terms; Lowering consequences of the lack of knowledge or skills; Diminishing side effects and treatment discontinuities or alteration; Minimizing use or incidence of aggravating factors; Improving patient knowledge about the disease; Improving self-confidence and motivation.	Overflow of the system by patient-initiated synchronous communication; Identifying clinical situations where such communication would be effective; Incorporating the process into office flow; Providing reimbursement for healthcare professionals; Patient segmentation and prioritizing; How to match various communication needs: voice/text; Privacy of consulting; Liability for treatment advice.
Supporting	Patient-related Social and economic interventions	Fostering patient positive beliefs and optimistic attitudes; Overcoming anxieties and concerns; Improving capacity for self-management;	How much trust should be placed in non-medical people's advice; Who bears the liability for wrong advice; Possibility of malicious advice;

		Making patients feel less isolated; Providing patients emotional support and encouragement for lifestyle changes.	Difficult to use a moderator; Numerous attempts of patients to clarify with physicians issues developed in peer dialogues.
Informing	Patient-related	Keeping patients updated with valuable knowledge; Fighting anxieties, misunderstanding, negative beliefs; Fighting lack of knowledge and skills.	Who would select and assess the quality and utility of the news; Would news be endorsed by the healthcare system; Excessive communication demands from patients wanting to clarify issues or know more; Doctors or nurses possibly put in embarrassing situations.
Educating	Patient-related Social and economic interventions	Consequence of applying with perseverance and high personalization the other interventions.	Danger of mismatches and non-concordances between interventions; Difficult to obtain an integrated view; Require more patient and healthcare professional dialogue through other media and face-to-face meetings.

7. HUMAN BARRIERS TO IMPLEMENTING m-HEALTHCARE SOLUTIONS

Despite the foreseeable benefits, attempting to address disease self-management and patient adherence issues through mobile information technology is expected to encounter system obstacles and human obstructions.

On the system side, it would be important for such services to be based on an open platform in order to be able to interface with various other devices and systems (Mazzi and Kidd 2002) already in place in the healthcare environment. This is a major problem that must be addressed early in the design process of the system since, in contrast to the Internet, mobile services are based on various proprietary standards and solutions (Yuan and Zhang 2003).

Another important issue is the changes such an approach may require for home care infrastructure. Empowering outpatients with mobile healthcare technology with a view to improving their adherence and efficiency of disease management programs would necessitate some alteration of existing home care systems. Thus, call centres would need to be created or, where they already exist, they must be enabled with capabilities for wireless communication and patient data storage and processing. This may generate resistance towards adopting such a project. Specialized personnel for maintaining the information technology infrastructure as well as healthcare personnel (e.g. nurses) participating in communication and data exchange with patients and/or the responsible physicians would be necessary. Therefore a transition of some personnel and workload from the existing home care services would be needed, in addition to re-training programs. However, from the viewpoint of the general healthcare system, the approach should lead to global savings in the work force and to lighter and more productive work for home care personnel. Part of boring, low-level duties (e.g. routine patient field data collection) would be assumed by responsible patients and the latest information technology.

Besides the above infrastructure obstacles, but by far more important, are the expected people barriers because human factors are the leading element of any system. Research has mentioned some important obstructions to the altering of existing healthcare processes among which the most significant are

overwork, especially for doctors, and the shortage of staff and financial resources. Consequently, there is a resistance to change, because it is not possible to launch any new initiative that requires even more work in existing and already difficult conditions (Rundall et al. 2002). Moreover, human barriers are expected to arise from all of the actors in the existing healthcare model: patients, home care nurses and other practitioners, and physicians.

Patients

The main resistance from patients could come from discomfort with newer solutions or implementations. The problem may be more significant for some social categories such as seniors, minorities, and lower-income patients that may develop a higher resistance to adopting new technology because of lower levels of experience and familiarity (Moyer et al. 1999).

One of the most important features for general acceptance would be simplicity (Gillespie 2000; Mazzi and Kidd 2002). Bludau (2003) insists that devices used in remote healthcare delivery must be kept simple and robust in order to have high approval among patients. Related issues are reliability and connectivity. A successful solution must provide service anywhere and anytime. However, mobile solutions may be hindered by temporary loss of connectivity or unexpected mobile phone battery discharge or failure. This would undermine patient receptiveness and cause further resistance.

There are other sensitive issues that may occur in long-term use of some devices by patients. Research on a telephone-linked home showed that "technology can serve as a projective device for peoples' values and psychological issues" and "people also form relationships with technologies" (Kaplan et al. 2003). Therefore, more profound psychosocial investigations of non-apparent consequences of using information technology tools may be necessary.

A major concern for any information technology solution is the security and privacy of data (Mazzi and Kidd 2002). Data communicated through mobile solutions may be critical and of a private nature, so data exchange, data storage, and patient-provider communication may need to have more than the normal security level of cell phone conversations (e.g. through the use of encryption at a suitable level). Otherwise, anxiety about the perceived security level may create a reluctance among patients and healthcare providers to use the service. Security and privacy concerns are addressed by the recent *HIPAA* (*Health Insurance Portability and Accountability Act*) legislation by the U.S. government and by the somewhat similar *PIPEDA* (*Personal Information Protection and Electronic Document Act*) legislation in Canada. The mobile system must support security and privacy to at least the level of these regulations in the relevant jurisdiction.

Home care personnel

Although information technology would simplify and reduce the workload of home healthcare professionals, their work patterns would change, and this could lead to unexpected barriers. Thus, home care nurses might allocate less time to informal face-to-face discussions with outpatients or to sharing their impressions with other nurses after outpatient visits (Karsten et al. 2002). This may raise change barriers because a part of the social side of their work would be replaced by a more technical one. Clearly, training in handling new technologies and different procedures would be required of these workers.

Physicians

The greatest resistance to change is expected to come from physicians since even the new approaches to disease management are not particularly popular among physicians (Cheah 2001). However, physicians are not against the technology but rather against the way it is applied in practice (Shactman 2000).

The most important issue is that physicians will fear being excluded from their current roles as major players by the health insurance and disease management companies (major promoters of the disease management paradigm) and become "an appendage to a program that will save the health plan money" (Chin 2002). Physicians are concerned that a third party may thus interfere with relationships between them and their patients, making doctors to "not be treated as equal partners with the health plan and the disease management company" since "nurses handling the monitoring for insurers could unintentionally circumvent the treatment plan" (Chin 2002).

Equally important is the liability problem. Disease management companies do not interfere in the treatment programs set by the physicians. They only perform outpatient remote monitoring and reminding and may alert the physicians when necessary for possible treatment modifications. Therefore it is still the physician who bears the liability in all conditions (Chin 2002).

The financial problem is similarly salient for physicians because health care companies do not pay doctors for services related to home-care monitoring. Consequently, the only real gain for physicians from an outpatient disease management program is the ability to provide better patient care (Chin 2002).

A wide-open channel of communication with patients is a serious source of concern for physicians and nurses since this may lead to an increase in an already heavy workload. This is the main reason, besides privacy and security, why communicating by email with patients has not been successful among physicians to date. Recent surveys show that only about 13% of doctors exchange emails with patients (Harris Interactive 2001), and numerous problems with physicians adopting this technique still exist (e.g. time spent at the computer, medical and legal risks, and ability of patients to use email correctly themselves) (Bauchner et al. 2002; Houston et al.2003). It is therefore expected that mobile consultations with patients would face obstacles of the same nature.

Physicians would also presumably have to spend much time answering patient questions about issues the patients discovered while searching the Internet or in discussions with peers. The immense quantity of low-quality information present on the Internet has the potential of harming patients (Mazzi and Kidd 2002) but may also alter the patient-provider relationship (Shactman 2000).

Clearly there are numerous barriers to adopting mobile solutions within the existing healthcare system, in order to improve outpatient adherence to disease management programs. The most important and numerous are human aspects, and particularly problems that physicians might see with these approaches. "Reimbursement, mobility, and physician issues are key links that must be connected to improve the value chain of remote patient monitoring" remarked DMN (2002) and many studies in the field agree with this remark.

However, all the actors of the existing healthcare system must understand that the picture continues to change, and "widespread implementation of home telecare will require fundamental changes in the healthcare system" (Celler et al. 1999). In this novel situation, doctors would have the opportunity to "take a leading role in re-engineering health care" (Cheah 2001).

8. BUSINESS CASE FOR MOBILE SOLUTIONS TO IMPROVE ADHERENCE

Researchers have been unanimous in stressing the major financial implications of adherence, especially in the negative direction, for existing healthcare services. Various statistics clearly indicate dire monetary consequences of non-compliance:

- "125,000 people die each year" in the U.S. because of medication non-compliance (Walker 2001);
- non-compliance costs the healthcare system and businesses over $100 billion per year in the U.S. alone (Walker 2001);
- "10% of all hospitalizations and 14.5% of emergency room visits are attributable to prescription drug-related problems" (Walker 2001);
- "more than $113 million worth of prescription drugs in Canada have been wasted due to non-compliance or a change in drug or dosage" (German 2000);

- "50% of all prescriptions filled are taken incorrectly" and 44,000 people die in the U.S. each year due to drug-related illness (Perreault 2002);
- in 1918 there where 1,000 drugs on the market, whereas in 1998 there were 24,000. This has lead to a rocketing number of "33,000 drug interactions, 6,500 contraindications for different diseases and 3,500 contraindications for allergies" (Perreault 2002);
- "annual hospitalization cost of medication noncompliance" is "US$0.735 billion in Ontario, Canada" and "US$13.35 billion in the U.S." (Cleemput et al. 2002);
- hospitalization costs of noncompliance represent 0.8% all health-care costs in Ontario whereas for the U.S. the same measure represents 1.7% (Cleemput et al. 2002).

Non-adherence is a key cause of chronic illness recurrence, and the financial aspects for this category of diseases are equally gloomy:

- the care of the 90 million Americans with chronic conditions consumes more than 75% of the $1,000 billion annual medical costs in the U.S. (Chin 2002);
- chronic non-infectious diseases with high social costs in the U.S. are: cardiovascular disease that affects 60 million people and costs $300 billion, diabetes that affects 16 million and costs $98 billion, and asthma that affects 15 million and costs $13 billion per year (Chin 2002);
- chronic disease management accounts for about 60% of medical care costs in the U.S. (Mazzi and Kidd 2002);
- healthcare costs in Canada increased to about 10% of the nation's gross domestic product (GDP) due to, among others, the high incidence of chronic illnesses (Coambs 2002).

8.1. COSTS OF NON-ADHERENCE

Beyond the above figures, a more refined analysis reveals that non-adherence involves two types of costs: intrinsic and disease-mediated.

(a) Intrinsic costs of non-adherence refer to the actual costs of non-complying to a medication, non-attending a consultation, or missing an appointment, etc. These costs are generally visible but it is difficult to generalize their magnitude and significance. For instance, in some cases involving expensive medications, the "unprovided treatment offsets the cost of increased morbidity" and the implications of real adherence cost should be analyzed with care (Cleemput and Kesteloot 2002). For instance, a survey of 57,687 diabetic patients showed that increased pharmaceutical adherence led to a reduction in medical care services (e.g. emergency department visits and hospitalizations) but not to overall lower costs because the medication charges offset the medical savings (Hepke et al. 2004).

It is, nonetheless, clear that some actions for improving intrinsic adherence would be beneficial. For instance, a recent attempt has been made to reduce the cost of missed appointments with U.K. doctors that amounts to an estimated £400 million per year in England alone. The initiative used SMS messages on mobile phones to remind patients of their appointments (Dyer 2003). In a separate scheme reported in the same study, a department of *Homerton Hospital* in Hackney, East London, said that it reduced missed appointments by about 8% with a similar automated SMS service. Each message cost 5 pence and was "more than offset by the savings in reduced missed appointments" (Dyer 2003).

(b) Disease-mediated costs of non-adherence are the costs of diagnosing and treatment for illnesses and morbidities triggered and/or aggravated as a result of poor medication and behavioural adherence (Cleemput and Kesteloot 2002; German 2000). These costs are very significant and represent an important part of the price that society is paying for the inappropriate management of chronic diseases.

Since chronic illnesses involve a disproportionate share of general health costs (Chin 2002), there are strong initiatives, especially from health insurance companies, to promote adherence in an attempt to lower health care costs through various methods (of which home monitoring is the most popular).

8.2. SAVINGS GENERATED BY ADHERENCE

Improving the management of chronic diseases in outpatient conditions would bring both direct and indirect savings. The economic impact (both types of savings) of enhanced disease management due to better adherence would be about "$8 billion annually in Canada, and $80 billion in the U.S." (Iskedjian, 2002).

(a) Direct savings includes the decrease in cost due to direct medical treatment through hospitalization, primary care, and home care. Better adherence would mean reductions in wasted time, medical resources, and medication, as well as a decrease in the number of additional physician visits and unnecessary hospital admissions.

Based on 15 studies on hospital admissions with a total of 6,144 patients, Iskedjian (2002) estimated the total healthcare expenses generated by non-adherence to prescribed medication to be about $1.7 billion annually in Canada, of which approximately $1 billion is hospital-related costs.

Diabetes is one chronic illness that is often used to demonstrate cost, because this is one of the biggest cost generators in healthcare (Chin 2002). It costs approximately $9 billion per year in Canada and $98 billion per year in the U.S. (Edwards 2002, Health Canada 2003) and the picture will be even gloomier due to the expected increase of the global population aged over 65 in the next 25 years, and of the increased incidence of this illness among elderly people.

A study done in several developed countries in Europe and entitled "*CODE-2 (Cost of Diabetes in Europe – type 2)*" and referenced by the *World Health Organization* revealed that only 28% of diabetic patients achieved good glycaemic control thanks to following all the steps involved in the self-management of this disease: taking the prescribed medicine, self-monitoring of blood glucose, undertaking dietary restrictions, and performing regular foot care and ophthalmic examinations (WHO 2003). The consequence of poor adherence to the accepted standards of care usually leads to medical complications, generating both direct and indirect costs. The study found that the direct cost of non-adherence reflected in the medical care of complications due to poor control of this disease was 3-4 times higher than in cases of good control. Most direct costs (about 30-65% of the total for the disease) was incurred from hospitalizations necessary to treat long-term complications such as heart malady. All the above figures further complicate the already gloomy socio-economic statistics in the countries surveyed. This report showed that the overall cost of treating patients with type 2 diabetes is on average over 1.5 times higher than per capita health care expenditures and the cost multiplies by a factor of 2 to 3.5 once patients develop *preventable* micro- or macro-vascular complications (WHO 2003).

(b) Indirect savings would come from a reduction in social costs related to the illness (e.g. absenteeism, early retirement, or premature death). "In 1998, prescription non-compliance cost between $7 and $9 billion in Canada" and "one-half of those costs were linked to the workplace" (Coambs 2002).

According to some studies, the potential reduction in this area is even larger than direct savings since the $98 billion (in U.S. funds) diabetes is costing the U.S. are divided as follows: $44 billion directly due to medical treatment and $54 billion from indirect costs due to disability and social problems (Mazzi and Kidd 2002). Similarly, the *CODE-2* study found that the indirect cost of diabetes in Europe was about as large as the direct costs (WHO 2003).

Important savings could be achieved by reducing absenteeism at work by following compliance-enhancing actions: "$290 per hypertensive employee, $631 per employee with heart disease, $1710 per depressed employee and $1458 per diabetic employee, expressed in dollar values for 2000, from the point of view of the employer" (Cleemput et al. 2002). Improving adherence would have the potential of diminishing productivity losses (e.g. lost salaries or work time) generated by adherence-induced illnesses that were estimated to total $465 million annually as well as the personal costs that amount to $517 million annually in Canada alone (Iskedjian 2002).

8.3. COST OF ADHERENCE INITIATIVES

It is clear that improving self-management of some chronic conditions through adherence would have significant beneficial consequences for patients, the healthcare system, and society. However, a complete analysis should also consider the costs of deploying such initiatives.

The objective of this paper is to consider the cost of improving adherence through mobile application initiatives alone. As the field is very new, little reliable information is available in this area and most of it deals with remote monitoring interventions. Some market analysts are optimistic about the figures: "It costs $5 to $10 per day to equip a patient with a remote-monitoring system while an emergency-room visit costs an average of $900" (Edwards 2002) and the device used for the remote monitoring of diabetes "will cost about as much as a single trip to the local emergency room" (Duan 2003). Although researchers are unanimous in stressing the importance of this type of project for health insurance companies because of the potential savings, some analysts suggest that patients would be willing to support some or part of the mobile devices' costs: "People who have diseases such as asthma and diabetes are more motivated than the rest of the population and more likely to pay for these devices" (Duan 2003). Operating costs of such initiatives have the potential to be very low (Dyer 2003) especially if the solutions could be fully automated and based on a careful patient condition segmentation and prioritization (Cocosila et al. 2004).

In the future more in-depth research must examine carefully all the business aspects involved in adherence-improving initiatives through mobile services, by mirroring the benefits and costs of addressing adherence itself, as well as the related diseases. Telemedicine can prove its cost-effectiveness only if it provides at least the same level of monitoring for the patients at home while costing less than regular home care visits (Field and Grigsby 2002). More generally, future research should demonstrate the viability of cost-effective prevention programs able to replace "large, last-minute healthcare expenses (such as surgery) with cheaper early interventions (such as prevention)" (Coambs 2002). A more complete analysis must also reveal the critical number of users for which the anticipated savings in terms of medical and societal costs would offset the necessary investments and operating expenses required by the new infrastructure.

9. CONCLUSIONS

Today's global changes in the delivery of health services and shrinking healthcare budgets have contributed to the need for patients to become more skilful in managing their own treatments. Adherence to the medical treatment and necessary behavioural changes is a requisite success factor within the emerging paradigm of disease management and self-management of chronic illnesses in outpatient conditions. Various studies have shown that real-world adherence of around 50% (Coambs 2002) and even lower for "more behaviourally demanding regimens" (Haynes et al. 2002) causes poor health outcomes and increased medical costs from long-term therapies. Because of this, adherence is a major source of concern in the medical world and in society in general.

Improving adherence may be achieved by a comprehensive approach, involving simultaneous actions in several directions. Mobile and wireless information technology solutions may bring benefits in this multidisciplinary fight for better adherence. However, some questions still persist:

- Which adherence factors could be significantly improved by exclusively mobile solutions?
- What type of mobile information technology interventions would really help patients and what type may instead just disturb them, in an effort to improve adherence?
- How much may mobile solutions intrude in the patient's life in an effort to help?
- What combination of patient action and mobile solution action would work best?
- How much automation and how much human healthcare effort should be behind the services provided by effective mobile solutions?

Pursuing an improvement in patient adherence by mobile and wireless information technology solutions may be worthwhile since no substantial body of research has been developed in the area so far. This is especially important, because

> "Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments" (WHO 2003).

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