

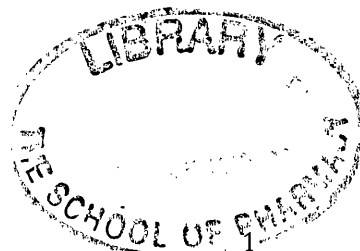
**PATIENTS' INFORMATION NEEDS AND
PERCEPTIONS OF MEDICINES AND ILLNESS:
A MULTI-METHOD APPROACH TO DEVELOP AND
VALIDATE MEASURES IN PORTUGAL**

Thesis submitted in accordance with the requirements of the University of London
for the degree of Doctor of Philosophy by

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I dedicate this thesis to two very special pharmacists:

To my mother, a living example of dedication to pharmacy practice, actively seeking the improvement of patients' well being and serving a community for over 50 years. I am proud to say my mother was my first real life teacher.

To Paula, who introduced me to research, taught me in a unique manner and made it become my life interest. Even more important than that, Paula taught me that tomorrow is always too late to say thank you to those we love.

Plagiarism Statement

This thesis describes research conducted in the School of Pharmacy, University of London between January 2003 and January 2006 under the supervision of Professor Ian Bates and Doctor Catherine Duggan. I certify that the research described is original and that any parts of the work that have been conducted by collaboration are clearly indicated. I also certify that I have written all the text herein and have clearly indicated by suitable citation any part of this dissertation that has already appeared in publications.

A handwritten signature in black ink, reading 'Filipa Alves da Costa'. The signature is written in a cursive, flowing style with some capital letters.

Filipa Alves da Costa
11/01/2006

Abstract

This thesis aimed to adapt a survey tool to measure patients' desires for information (EID), perceptions about medicines (PHM and PBM) and anxiety about illness (Ai and Ti) from the UK to Portugal and to explore how perceptions impact on medicines taking behaviours in different care settings.

The survey tool was adapted using a multi-method approach comprising translation and back-translation, rating of equivalence, and assessment of understanding in various stages of revision. The tool was tested in a patient sample recruited in different care settings in Portugal and the UK and responses were used to explore validity and reliability. Data was used to compare scores to the scales between patient samples and to investigate factors influencing adherence behaviours.

The survey tool was modified during validation, where the Ti scale was dropped for its validity and reliability. Four factors emerged in the course of factor analysis. One item was dropped in the PBM and PHM scales, which were weighed for comparison. Internal consistency of the Ai ($\alpha=0.756$) and PBM ($\alpha=0.695$) scales were good, while the EID ($\alpha=0.607$) and PHM ($\alpha=0.536$) were acceptable. All scales, except the EID, were consistent over time [$p(r)<0.001$; $p(t)>0.05$]. Portuguese, community recruited, female, higher educated and younger patients tended to desire more information. Patients prescribed more medicines tended to perceive medicines as more harmful. Anxiety tended to be higher in hospitalized patients, the elderly and lower educated and those prescribed more medicines. Patients feeling more anxious ($\rho=0.420$; $p=0.000$) and perceiving their health status as bad ($\rho=-0.213$ $p=0.000$) tended to perceive a greater harm from medicines.

Logistic modelling showed that patients aged ≥ 60 [Adj.OR=2.20 {1.38-3.53}] and patients scoring ≥ 17 on the EID scale [Adj.OR=2.57; {1.36-4.84}] were more likely to be compliant ($p<0.05$). These findings highlight the importance of tailoring information provision to patient's needs.

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PAPERS AND ABSTRACTS PRESENTED OR PUBLISHED RELATED TO THE STUDY

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Costa F., Duggan C., Bates I. Using a lay panel to validate a questionnaire exploring desires for information and perceptions about medicines and illness. Conference proceedings [Abstract CPS-P-076; 106 FIP, Cairo 2005]

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Abbreviations

ABC	Affective, Behaviour, Cognitive
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
ADP	Academic Department of Pharmacy
AI	Anxiety about Illness
Ai	Anxiety
ANF	Associação Nacional das Farmácias (National Association of Pharmacies)
ANOVA	Analysis of Variance
ATC	Anatomic Therapeutic and Chemical
BDI	Beck Depression Inventory
BMQ	Beliefs about Medicines Questionnaire
BMQ	Brief Medication Questionnaire
BTL	Barts & The London
CBT	Cognitive-Behavioural Therapy
CEFAR	Centro de Estudos de Farmacoepidemiologia (Centre for Pharmacoepidemiologic Research)
CHD	Coronary Heart Disease
CNS	Central Nervous System
COPD	Chronic Obstructive Pulmonary Disease
CMTS	Cognitive Medicines Taking Service
COOP/WONCA	Dartmouth COOP Function Charts/World Organisation of Family Doctors
CPD	Continuous Professional Development
C-SHIP	Cognitive-Social Health Information Processing
DoH	(English) Department of Health
D-T	Delighted Terrible Faces Scale
DOT	Directly Observed Treatment
<i>e.g.</i>	For example
EID	Extent of Information Desired
ELoC	External Locus of Control
EMs	Electronic Monitors
FFUC	Faculdade de Farmacia, Universidade de Coimbra (Faculty of Pharmacy, University of Coimbra)
FFUL	Faculdade de Farmacia, Universidade de Lisboa (Faculty of Pharmacy, University of Lisbon)
GP	General Practitioner
HBM	Health Belief Model
HCS	Health Care System
HCPs	Health Care professionals
HDL	High-Density Lipoproteins
GI	Gastro-Intestinal
GWBS	The (Psychological) General Well-Being Schedule
<i>i.e.</i>	<i>istum es</i> (this means)
IQOLA	International Quality of Life Assessment
IPQ	Illness Perceptions Questionnaire
ICU	Intensive Care Unit
IGIF	Institute for Computing and Financial Management oh Health
ILoC	Internal Locus of Control

Abbreviations (cont')

IMB	Information Motivation Behaviour
INN	International Non-Proprietary Name
LDL	Low-Density Lipoproteins
LoC	Locus of Control
MAPI	Marchés et Prospectives Internationaux
MARS	Medication Adherence Report Scale
MEMS	Medication Event Monitoring System
MMAS	Morisky Medication Adherence Scale
MUR	Medicines Use Review
NHP	Nottingham Health Profile
NHS	(English) National Health System
NPSA	National Patient Safety Agency
OTC	Over The Counter (Non-prescription medicines)
PBM	Perception about the Benefit of Medicines
PCA	Principal Components Analysis
PCTs	Primary Care Trusts
PDP	Personal Development Plan
PHM	Perception about the Harm of Medicines
PIL	Patient Information Leaflet
PPS	Portuguese Pharmaceutical Society
PSNC	Pharmacy Services Negotiating Committee
Pt	Patient
PUM	Perception about the Utility of Medicines
RCT	Randomised Controlled Trial
R-IPQ	Revised Illness Perceptions Questionnaire
RLH	Royal London Hospital
RPSGB	Royal Pharmaceutical Society of Great Britain
Rx	Prescribed
s.d.	Standard Deviation
s.e.	Standard Error
SE	Self-Efficacy
SF-36	Short-Form 36 Health Survey Questionnaire
SNS	Sistema Nacional de Saúde (Portuguese National Health System)
SPC	Summary of Product Characteristics
SRM	Self-Regulatory Model
Ti	Tolerance
TRA	Theory of Reasoned Action
TPB	Theory of Planed Behaviour
ULSOP	University of London, School of Pharmacy
UK	United Kingdom
<i>vs</i>	Versus
y.o.	years old

Glossary

Disease management	Framework to control the treatment of specific diseases; generally initiated by the physician and most often applied to expensive diseases. (van Mil, 1999)
Medicines management	Structured process designed to improve safe and effective medicines use, involving a partnership in prescribing and reviewing therapy, where the patient has an active and central role. (The Community Pharmacy Medicines Management Project, 2003)
Pharmaceutical Care	<i>"The responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patients' quality of life".</i> (Hepler&Strand, 1990)
Cognitive services	<i>"The act of pharmacists making use of their specialised knowledge in pharmacotherapy to provide a broad range of services, including provision of drug information, provision of non-prescription medicines, clinical interventions, medication management services, preventive care services for chronic patients and participation in prescribing decisions."</i> (Emerson, Whitehead, & Benrimoj 1998)
Clinical Governance	<i>"Framework through which National Health Services organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care flourish."</i> (Department of Health, 1998)
Evidence-based medicine	<i>"The conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual patients."</i> (Sackett, 1996)
Face validity	Verifies that all the items of the questionnaire appear in a clear and unambiguous way. (Streiner&Norman 2000).
Content validity	Verifies that all the items of the questionnaire are relevant and sufficient to measure the concept(s) of interest. (Streiner&Norman 2000)
Criterion validity	Considers if the scale is empirically associated with external criteria. (Streiner&Norman 2000)
Construct validity	Examines the inter-item relationships, and relationships between the items and hypothesised scales. (Fayers&Machin 2000)
Reliability	Determines if the concepts of interest are measured in a reproducible and consistent manner. (Streiner&Norman 2000)
Internal consistency	Ensures that all items in a scale contribute to measuring consistently the same property. (Smith 1997b)
Consistency over time	Evaluates if the measure produces the same results over time (when there are no reasons for change) (Streiner&Norman 2000)
Discriminatory power	Ability of the measure to achieve a good spread of scores, reflecting differences between patients or groups of patients with different characteristics. (Bradley 1994; Todd&Bradley 1994).
Responsive-ness	Ability of a measure to detect changes related to modifications in a patients' status. (Bowling 2002g; Todd&Bradley 1994).
Precision	Ability of a measure to detect small changes. (Bowling 2002g).
Sensitivity	Ability to accurately classify cases as positives. (Lilienfeld&Stolley 1994)
Specificity	Ability to accurately classify non-cases as negatives. (Lilienfeld&Stolley 1994)
Affections	Feelings (Manser & Turton 1987); Emotional reactions associated with experiences (Rothenberg & Chapman 1994)
Attitudes	Mental positions or feelings regarding something (Manser & Turton 1987)
Beliefs	Opinions; principles accepted as true (Manser & Turton 1987)
Behaviours	Ways of conduct (Manser & Turton 1987)
Perceptions	Observations; understandings (Manser & Turton 1987); Process by which information received by the senses is recognized, interpreted and analyzed to become meaningful (Rothenberg & Chapman 1994)
Cognitions	The mental faculty of knowing (including perceiving, thinking, recognizing and remembering) (Rothenberg & Chapman 1994) [or (including perception, judgement and intuition) (Manser & Turton 1987)]

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Preface

The purpose of the introductory chapter is to provide the reader with background information on the relevant issues around this thesis. The introductory chapter is divided into three main sections. The first section provides an overview on the evolution of medicine and healthcare. This section considers the wider concept of health care delivery in society to the perspective of the health care professional.

The two healthcare systems where the research takes place, the UK and Portugal are then reviewed and compared. Examining the wider concept of health care delivery, the reader will be guided through the causal attributions of illness, the discovery of medicines, their role in society, and the importance of patients' medicines taking-behaviours in maintaining health. The second section comprises a review of the theoretical models that have been proposed to explain or predict patient adherence to medicines taking.

The third section describes the importance of health care professional interaction with patients and the move from compliance to concordance. The research that has inspired this project and the development of the scales that will be used throughout this project conclude this chapter and provide background to the aims of the study.

The purpose of chapter II is to provide an overview of the project's aims and objectives. The research questions to be addressed throughout the thesis and the hypotheses to be tested are presented. A schematic diagram of the study structure is presented to clarify the sequence of methods to achieve the stated objectives.

The purpose of chapter III is to provide an overview of the different research methods used in health services research. These are described in overview and appraised for their suitability to address the research questions proposed. Chapter III is divided into three main sections. The first section deals with a general overview of research methods, section two provides an appraisal of methods for questionnaire development adaptation and validation (setting the scene for chapters IV and V respectively). Section three provides guidance to the procedures that need to be taken into account when collecting data from humans. These are the sampling methods,

piloting methods, data collection methods and ways of analysing different types of data. Section three provides an overview for methods used in chapters VI and VII

The purpose of chapter IV is to explore the approaches to adapting survey tools. Several methods have been proposed in literature forming the basis for the approach chosen here. This chapter is divided into four sections. Firstly, the literature around translation is appraised; the second section focuses on the processes of translation and back-translation; the third section, which explores ways of ensuring linguistic equivalence. The fourth and final sections explore different and complementary methods to assess understanding of the items comprised by the survey tool to its intended target audience. This section comprises the interviews with individual patients, group work with health care professionals and discussions with a lay panel.

Chapter V sets out the process of ensuring that the validity and reliability of the tool were not altered during the translation stages to effectively measure the concepts of interest. Chapter V is organised in three main sections. Firstly, the purpose of the pilot phase is described and provides context for the purpose, process and findings of the main experiment. The application of the survey tool in a large enough patient sample is described together with issues of validity and reliability.

Chapter VI describes the exploratory phase of the project, where the survey tool was used to measure chronic patients' desires for information and perceptions about medicines and illness. The purpose of the chapter was to test the scales to provide health care professionals with a greater insight into patients' medicines-related attitudes and behaviours. A comparison of the data between UK and Portugal and within Portugal is made.

Throughout the years several efforts have been made to understand patients' medicines taking behaviours, during this project several factors are explored, which potentially influence the way patients feel and act towards their medicines. Chapter VII investigates how these factors interrelate with perceptions of the utility of medicines and desires for information to better understand patients' medicines taking behaviours. Following the use of appropriate descriptive and inferential statistics, a model is proposed that seeks to explain patients' medicines taking behaviours and

the influence of information. This chapter finishes by presenting the main conclusions of this thesis drawing from the findings of each chapter to address the original aims and objectives.

CHAPTER I

INTRODUCTION

1.1 Perspective

The purpose of this chapter is to provide an overview of literature pertinent to this thesis. The introduction is divided into three main sections. The first section provides an overview of the evolution of medicine and healthcare and considers the wider concept of health care delivery in society from the perspective of the health care professional.

The two healthcare systems, the UK and Portugal are then reviewed and compared. The wider concept of health care delivery is examined; the causes of illness over time, the influence of the discovery of medicines and their role in society, and the importance of patients' medicines taking-behaviours in maintaining health. The second section reviews the theoretical models that have been proposed to explain or predict patient adherence to medicines taking.

The third section describes the importance of health care professional interactions with patients and the proposed move from compliance to concordance. The research behind this project together with the development of the scales used throughout this thesis are described at the end of this chapter and provide background to the aims of the study.

1.2 Literature review

Any literature reviews should be comprehensive and include all the pertinent and valid papers (Bowling 2002). Criteria for reviewing literature include: ensuring there is a clear statement of the problem, if it can be answered with empirical data, whether reviews included are comprehensive and up-to-date and if literature is critically and logically evaluated and finally if hypotheses are clear and related to the original research (Bowling 2002). In a PhD thesis, there are often multiple themes relevant to the research, so multiple searches may be appropriate. For the purpose of this thesis, several searches were undertaken in five databases: EMBASE (1980-2005), Medline (1966-2005), International Pharmaceutical Abstracts (1970-2005), BIOPsis Previews (1969-2005) and B-On Scielo (1924-2005). Definition of key words for each of the relevant searches initiated the process. As part of the strategy, the search was limited to papers in English, Spanish, French or Portuguese. Papers for which no abstract was available were excluded. The first selection of abstracts obtained after this procedure was appraised and those considered relevant entered into Reference

Manager Version 11 to check for duplications. For different searches specific criteria were defined. For example, searches for social cognition models included only papers describing the models themselves. Manual searches complemented these initial searches, identifying papers published by frequently mentioned authors. Additionally, keeping up-to-date with health news magazines, particularly pharmacy magazines, was considered important as this project covered a period of transition in regulation and functioning of pharmacy practice in both countries. Finally, because publishing in indexed databases is still not as common as desired in Portugal, manual searches and contacts with key people further informed sections related to health care focusing on the pharmacy profession.

1.3 Evolution of medicine and healthcare

The way health care provision has been evolving is a result of a combination of factors; firstly the evolution of diseases. In the past the main causes of death were predominantly infections, and fell into four major categories: air, water, food and vector borne diseases (Fitzpatrick 1991). Today in the developed world, the main causes of death are mostly degenerative diseases, often linked to lifestyle, such as cardiovascular diseases and cancer (Powles 1973). Other chronic illnesses like atherosclerosis, diabetes and osteoarthritis are also considered major problems of the developed world because of their costs to society and the individual (Fitzpatrick 1991). It has been argued that this shift is mostly attributed to sanitation and improvement of nutrition (McKeown 1979a). Others highlight the importance of public health interventions; widely appreciated among policy-makers (Szreter 1999;Szreter 2002;Szreter 2004). Little has been attributed to the evolution of medical care, in fact, the only drugs that have contributed were antibiotics (McKeown 1976). McKeown also recognised the role played by contraception in influencing mortality decline and life expectancy increase, but only as part of a triad encompassing environmental, behavioural and therapeutic measures that evolved in subsequent decades (McKeown 1979b).

The way that human understanding of disease has evolved has been explained by three models: the monocausal approach, where the disease is caused solely by an aetiological agent; the epidemiological triangle, an interaction between the agent, the

host and the environment; and the theory of general susceptibility, that considers socio-economical factors involved in the process of getting ill (Locker 1991).

1.3.1 Ancient medicine

In order to get a wider perspective of health and illness beliefs today, it is important to have some background understanding of how these were formed in different eras and various parts of the globe, especially because some of them still pervade or underpin beliefs held today.

The way health and illness are dealt with has changed throughout the centuries. In Traditional Chinese society there were 3 main religions, also described as philosophies of personhood (Shih 1996). Confucianism meant the rejection of spiritual explanations of phenomena, whereas Taoism encouraged the study of and observation of nature. Buddhism engendered a compassion for all living things. The pillars of health and disease were considered the Yin and Yang, paradoxical but the existence of both considered as vital. Whenever there was an imbalance, disease would appear. The Yin was considered dark, mysterious, feminine and evil; as such, when in excess it would cause chronic, cold and moist diseases. The Yang, considered as bright, active, masculine and beneficial when in excess was responsible for acute, feverish and dry diseases. Good health was then described as the result of harmony and balance between the five basic elements (earth, fire, water, metal and wood), where the Yin and Yang as circulating body energy would play a vital role. Drugs were then used as a means of maintaining the balance between these elements and energy flow (Borchardt 2003). Similarly, Yin and Yang were seen as two circulatory systems, where Yin would be responsible for the force of energy that gave the body life and Yang could appear in the six forms, also described as the environmental conditions (dry, wet, hot, cold, wind and flame) (Chan, Ho, & Chow 2001). External sources of harm, such as physical injury and overwork, were considered to have a role in the process, as well as the 7 emotions (joy, sorrow, anger, worry, panic, anxiety and fear). It was believed that health resulted from reconciliation with the Gods where good and evil were no longer in conflict (Angeletti & Frati 1989).

It is widely accepted that people respond to illness according to attributed causes, often rooted in cultural beliefs, which vary widely around the world. Still today

Christian and pagan rituals are held in many countries to deal with disease. In *e.g.* Sri Lanka sick people are confronted with dance rituals where 8 different masks are used, each corresponding to a demonic cause of illness, and their reaction dictates the correct diagnosis. Offerings are generally used to please the Gods or calm the spirits to reward patients with health. In Bangladesh, figures are used by the so called doctor-priest in situations where patients do not respond to herbal medicine (MacGregor 2003).

Theories of disease causation in the western society have also attributed disease to spiritual forces and punishment by God. Evidence of such can be found in the remains of skulls subjected to trepanning, the first surgical technique ever used, where a hole was made in the skull of sick people to allow the bad spirits to leave the body (The Wellcome Trust 2003). Theories of monocausal agents evolved to the well known web of causation, considering also sociological and psychological factors, leading later to theories of general susceptibility, where differential susceptibility to disease became the focus (Locker 1991). Western medicine can be seen as evolving into a more “ancient” type of medicine in the sense that health-care professionals are progressively more concerned with dealing with other aspects of patients’ health beyond the physical incapacity. These were previously believed to be the doctor’s single role and social relationships and psychological emotions were left to others like the social worker or even the pastoral counsellor (Chan, Ho, & Chow 2001).

1.3.2 The bio-medical model

To understand the way interpretations of health and illness evolved, an historic perspective of the most prominent models of illness prevention, cure and control is useful. During the 19th century, people believed that there was a complete separation between health and disease; a person would either be sick or healthy with no continuum. Causes of disease were mainly external factors such as viruses and bacteria. The sick individual was seen as a victim of the environment and the medical profession was the sole entity responsible for his treatment and full recovery (Ogden 1996a). In this same century, complying with such a model a poster could be seen on the wall of St. Bartholomew’s Hospital showing the eight rules that patients should follow (now on display in the Science Museum). One of these was that “*the*

patient must strictly obey the directions of physician and surgeon under whose care he or she may be placed' (The Wellcome Trust 2003). These rules follow the basic idea of compliance, where the patient is seen as a passive individual with no right to decide, whilst the doctor is the powerful one who dictates the best treatment. The understanding that the patient has the power to decide whether he intends to take his medicines or adopt a given behaviour was only highlighted when psychological factors were explored, through the development of the bio-psychosocial model.

1.3.3 The bio-psychosocial model

One century later, theories emerged of the influence of psycho sociological factors as possible causes of disease (Ogden 1996a). Psychological theories consider individuals, their beliefs and behaviours, whilst sociology focuses on the society, studying behaviours and views of groups. In the bio-psychosocial model both external and internal factors are considered. External factors, such as viruses, or social factors, such as housing, are seen as possible causes of disease. Internal factors involve mainly psychological factors. This model sees patients as partly accountable for their disease and also for their recovery, which may depend partly on behavioural factors.

1.3.4 Health system functioning in the UK (NHS) and Portugal (SNS)

In order to contribute to the improvement of health care delivery to patients it is essential to understand the functioning of the two healthcare systems involved in this thesis. This section of the introduction aims to provide a general overview of the evolution and current structure of the UK NHS and the Portuguese SNS.

1.3.4.1 The development and evolution of the NHS

The UK National Health Service (NHS) has been described as the best known system where care is available free of cost to every citizen, financing itself through a taxation system. It was established in 1948, when it was implemented with the purpose of providing free health care for everyone (Mays 1991). The general principle is similar to the SNS, where public financing is also obtained through taxation of contributors. Similarly, in both health care systems every citizen is entitled to have access to a GP, through whom referrals to specialist and hospital care can be

made. However, in the NHS, GP appointments are free of charge, whereas in the SNS there is a fee for service, similar to the way the NHS was organised in the 20th century. During the 20th centuries there was an emerging need to care for the poor and the sick, therefore several changes occurred. These started with the creation of the Friendly Societies Schemes, where GPs were paid per year per patient. Then, the National Health Insurance Schemes made access free of charge for those insured, resulting in care for working men. The creation of the “Poor law” (1834) made assistance free to the undeserving poor, *i.e.*, the sick and the old.

In the late 1930s, the idea that everyone should have right to care started to have growing support, culminating with the publication of the Beveridge Report (Beveridge Report 1942), which proposed that the welfare state should combat the 5 barriers to progress: want, disease, ignorance, squalor and idleness.

In 1974 there was a major reorganization of the NHS, which focused on coordination of local authority social services. Successive reviews were made in the 1980s and 1990s, with little incentive to work efficiently as funding was made on traditional geographical basis. The “internal market” proposed that the roles of purchasers of health care and providers should be separated, being argued that creating competition would improve efficiency (Mays 1991).

Professional accountability and more patient choice

With the publication of the 1989 White Paper “Working for Patients”, the concept of professional accountability was introduced, making clinical audit compulsory in hospitals and GP practices (Department of Health 1989). Additionally, one proposal aimed to introduce more patient choice of care provider. So, this may be seen as the turning point, where consumer freedom of choice was respected. With a revised GP contract issued in 1990, GPs became accountable for drug expenditure and were given a fixed budget for prescriptions issued (Mays 1991). This does not happen in the SNS and is actually one of the problems frequently brought up when discussing prescribing generic medicines.

Ensuring quality, information and safety for patients

Several key documents have been issued by the Department of Health that set out proposals reflecting on the Government's ideas to modernise the NHS. In 1997, the White Paper "The New NHS: Modern, Dependable" announced its aim to give people the best system of healthcare in the world by highlighting the importance of partnership and performance in running the NHS, setting quality standards and proposing ways to improve services' efficiency (Department of Health 1997b). This was further expanded in the paper "NHS: a First Class Service" (Department of Health 1997a). The following year the publication of "Information for Health", established information technology as a priority announcing an investment of £1 billion in modernising how NHS professionals collect, store and use information (Department of Health 1998). The challenge for the NHS set in 2001 in "The Expert Patient: A New Approach to Chronic Disease Management for the 21st Century" was to shift a patient's autonomy by working in partnership with patient organisations and other fundamental bodies to encourage and enable patients to have an active role in self-care (Department of Health (Expert Patient Taskforce) 2001). In 2001, the National Patient Safety Agency (NPSA) was launched with the purpose of ensuring quality care with maximum safety. Initiatives included documentation of errors, allowing the subsequent analysis of their cause and the development of strategies to prevent them in the future. Following from this initiative, in 2003, the Government issued a best practice guidance through the document "Building a safer NHS for patients: improving medication safety" stating as the major aim the ambitious reduction of errors by 40%; models of good practice to reduce risks of medication errors were proposed (Department of Health 2003c). In this same year, the Government began major reforms in the NHS, corresponding to the largest investment since its origins. In the White Paper "Building on the Best: Choice, Responsiveness and Equity in the NHS", information is central, NHS professionals need to provide the right information to patients, at the right time, suited to their personal needs and with the support they need to use it, all this with the ultimate aim of increasing patients' power and choice (Department of Health 2003b).

The pharmacist's role

One outstanding characteristic of the UK Government is its willingness to consult and then act, rather than issuing new ideas that come only from politicians' minds, who often are not patients themselves. The "Building on the Best: Choice, Responsiveness and Equity in the NHS" states that the NHS needs to above all "*listen to what patients and the public are telling us and then act*" (Department of Health 2003b).

In 2004, the Health Minister stated "*To date pharmacists have been a major untapped resource for health improvement*". This justifies the development of the Government's White Paper "Choosing Health" (Department of Health 2004) and the subsequent extension of pharmacists' roles "Choosing health through pharmacy: A programme for pharmaceutical public health 2005-2015" (Department of Health 2005). These documents focus on pharmacist's role across all NHS sectors, issuing good practice guidance and a strategy emphasising all areas of public health. One of the areas mentioned is the pharmacist's role in the provision of health-related information and advice, contributing to an improvement in the public's health literacy. These include the prevention, identification and reporting of medication errors contributing to the care of people with long-term conditions by ensuring effective medicines use, carrying out medication reviews and managing disease in cooperation with other healthcare professionals (Department of Health 2005).

1.3.4.2 The development and evolution of the SNS

One major difference between the NHS and the SNS is around the source of financing, which has implications for patients' adherence behaviour. Estimates from 1997 show that the public%/private% expenditure ratio in the UK was 96.9%/3.1%, compared to 57.5%/42.5% in Portugal (World Health Organisation 2000). Due to recent changes in the Portuguese health care system these are now even further apart. The Portuguese Health System is supported by a network of hospitals, local health centres and non-profit organisations, which depend on the Ministry of Health. The mission is to guarantee that all citizens have access to health care, based on the principle of a citizen's right to health. This principle was first set by the 1971 health reform and embodied in the constitution as early as 1976 (Simões 2004). The

Portuguese Constitution states that health care is to be delivered through a universal service that is comprehensive and free of charge service at the point of care. Health is funded by the State budget, which in turn depends on Social Security, fed by employers' and employees' taxes. Patients who may benefit include national citizens, foreign citizens coming from countries within the EU, foreign citizens living in Portugal in reciprocity conditions, and the stateless persons also living in Portugal.

Medicines' financing

Medicines are financed by both the patient and the Government, according to a reimbursement system in which the proportion is defined according to the therapeutic class (*e.g.* diabetic or glaucoma medicines are free for patients) and the patient's situation (patients earning less than the minimum salary as pension pay a lower percentage). On average, the SNS covers 70% of medicines' costs.

Primary care

Primary health care in the public sector is mostly delivered through publicly funded and managed health centres. Each of them covers an average of 28 000 people. In 1999, there was a total of 1 126 medical units and 390 health centres (Bentes et al. 2004). The main function of health centres is to provide ambulatory care on a regional level. The number of registered doctors at this time was nearly 7 thousand, clearly an insufficient number to provide quality services to the 27 million appointments held in 2001 (Ministério da Saúde 2004). These are the most up-to-date figures at the time of writing.

Secondary and tertiary care

Secondary and tertiary care is mainly provided in hospitals. One of the main problems that hospital services face in Portugal is the excessive use of emergency departments for non-urgent treatment (Bentes et al. 2004). Given the waiting lists for scheduled medical visits, many patients tend to routinely use the emergency department; over 6 million appointments were held in 1999 (Ministério da Saúde 2004). Health care provision depends on patients' socio-economic status, the fees varying between 2 and 7 €, according to the type and setting of care. Specific groups of patients, such as *e.g.* the elderly or children, may be released from paying these taxes. When a patient needs hospitalization, the associated costs are covered by the

Government, except when the patient benefits from any insurance or co-payment system, the latter leading to costs being divided between the SNS and other entities (*e.g.* militaries).

Patient satisfaction

A study carried out in 2002, showed that patients tended to more often visit health centres than hospitals, when compared to 1999 data. The health service least assessed during 2002 was private medical clinics (32%), and the most was the community pharmacy (85%). Patients were asked about their opinion on the quality of services provided in these settings and results show that the public ones, *i.e.*, hospitals and health centres were the ones generating higher proportion of dissatisfaction, when compared to private, *i.e.*, medical clinics, diagnostic centres and pharmacies. It must be pointed out that the most dissatisfactory were also the ones with higher frequency, exception made to the pharmacies. This study additionally showed that patients mostly complain about the waiting time in hospitals and health centres, as opposed to the high cost of appointments in the medical centres (Ordem dos Farmacêuticos 2002). An update of this study following from the most recent transitions in health care organization is imminent.

Most recent developments

At the end of 2002, the Government issued legislation initiating progressive change in the management model of all public hospitals into entrepreneurial schemes of different types, ranging from the standard public status to private for-profit organizations. About 40% of all SNS hospitals were selected to be transformed into state owned private enterprises at the beginning of 2003. In 2004 the first financial effectiveness evaluation was carried out and found a 5% increase in productivity. By the end of 2003, a network for continuity of care comprising public, social and private entities was approved, aiming at providing suitable care for citizens in need of them due to chronic or degenerative pain or physical or psychological dependence of others (Ministério da Saúde 2004).

Generic substitution

Major changes in medicines financing were implemented during 2003 in primary care, considered the most important in the last two decades. Prescribing by

International Non-proprietary Name (INN), reference prices and generic substitution was introduced. The first measure had an effect on price, which dropped to 50% of a similar brand drug (ANF 2004). The latest data indicated that the market share of generic medicines evolved from less than 1% to over 10% in value over a 3-year period. Data also showed that patients were penalized by the reference pricing system. This year, the savings from the State's perspective reached its peak, whilst from the patient's perspective there has been a rise in medicines expenditure (ANF 2005). The current law states that the choice between the brand drug and its equivalent generic depends exclusively on the doctor. It could be expected that patients would seek information on generics and request doctors to prescribe them, which does not seem to be happening, perhaps linked to a culture where the doctor is seen and likes to be seen as powerful and unquestionable and patients seem to have quite poor information. This is of particular interest in this thesis because it provides insight into how difficult it is to understand patients' needs and wants. A measure was put in place to benefit the patients economically without disregarding safety, but the current picture shows that patients are not engaging with generic substitution and are penalising themselves with regards to medicines costs, while being confident and happy complying with the doctors' insistence for the use of brand medicines. The generic substitution (or lack of it) may have implications on patients' adherence to prescribed medicines and leave a door open to research that contributes to a more tailored provision of information to patients. The outcome of this thesis will inform the reorganization of the system currently underway in Portugal.

Patient safety

In 2005, the piloting of the electronic medical prescription was initiated, resulting from a partnership established between the ANF and the Health Ministry, through IGIF (IGIF 2005). This was an important step for Portugal, as it is not available yet in many EU countries, including the UK, where it is planned for the end of 2005 (Thompson 2005). This initiative may have implications for reducing some of the types of medication errors happening across all care systems, with clear impact on patient safety. Recent changes in the SNS include the intention to distribute medicines that do not require medical prescription outside pharmacies, under the supervision of a pharmacist or a pharmacy technician (Ordem dos Farmacêuticos

2005), which led to the review of the pharmacist's professional legal status. However, it now seems that the supervision by a pharmacist may be remote as the most recent developments providing detail on how this measure is to be put in place advocates that a pharmacist will be responsible for five establishments, contrarily to what has previously been allowed in Portugal. In practice patients will not have a professional available to request information or receive counselling from, the PIL will be the most readily available information source. This is another area interesting for research on patient safety, which will certainly be closely monitored.

1.3.5 Community pharmacy in the UK and in Portugal

In the UK in 2000 there was a focus on the place of pharmacy in the NHS, setting out some specific challenges for community and hospital pharmacy. Some of the priorities were easier access to medicines, pharmaceutical advice and support for correct use of medicines. Arrangements for availability and reimbursement of generic medicines were announced. The need to enhance public confidence in the pharmacy profession was also recognised, being stated that should be sustained by ensuring pharmacists receive the appropriate education and training and keep up-to-date with progress. Repeat dispensing, prescribing pharmacists, electronic prescribing and medicines management services were introduced as objectives to be progressively implemented.

The UK pharmacy contract, 2005

The development of a national contract for community pharmacy was finally announced in 2004/2005, basing its principles in rewarding the delivery of high quality services (Department of Health 2000). Through this contract three levels of service provision to community patients are defined. Essential services comprise dispensing, disposal of unwanted medicines, promotion of healthy lifestyles, signposting (provision of information), support for self-care, support for people with disabilities (including impaired vision, manual ability and cognition), clinical governance (including CPD, auditing and assessment of patient satisfaction, use of standard procedures and reporting of ADRs). Advanced services constitute the second level and comprise medicines use review and prescription intervention services. Enhanced services comprise minor ailment services, smoking cessation,

supervised administration of prescribed medicines, needle and syringe exchange, anticoagulant monitoring, medicines assessment and compliance support, home care support, patient group directions and full medication review (Pharmaceutical Services Negotiating Committee 2004). Essential services are to be provided by every pharmacy in the country but for the provision of advanced services, both pharmacists and pharmacy premises need to be accredited; the existence of a private consultation area is one of the characteristics considered vital; the accreditation of pharmacists will be based on a competency assessment, ahead commented on (Anonymous 2004). In April 2005, it was revealed that only 33% of pharmacies had a private consultation area, which could seriously compromise the full implementation of advanced services as described in the contract; however, it is expected that these figures rapidly change by the end of the transition period to be reached in October 2005 (Anonymous 2005b). The Pharmaceutical Services Negotiating Committee expects that over a one-year transition period, all pharmacies in England and Wales will fulfil this requirement (Sharpe 2005). Enhanced services are not included in the national contract and will be commissioned by the local PCTs based on the assessment of the population's needs (Bellingham 2004a; Bellingham 2004b). Additionally, the PCTs may provide the necessary funding for pharmacy and/or pharmacist accreditation when commissioning such services (Patel 2005).

Background information on the Portuguese pharmacy law

Differences in the law between the UK and Portugal are worth mentioning to provide some context for the following section. The ownership law establishes that only qualified pharmacists can own, manage and supervise a single pharmacy; pharmacy chains are not allowed. Portuguese law has two main rules for the opening of new pharmacies that ensure accessibility to the population, based on demographic and geographical conditions. A pharmacy can only be opened by public tender if there is a minimum of 4 000 inhabitants in that area and if there is no other pharmacy within 500 metres (Ministério da Saúde 1965).

Development of services provided by Portuguese pharmacies

Pharmacies in Portugal have the exclusive right of preparation and dispensing of medicines and medical devices. The types of services that are routinely offered by community pharmacists include the provision of medicines or illness-related

information to patients and physiological parameters monitoring. The first comprises the writing or printing of labels to remind the patient how to take the drug and, when applicable, what to avoid. Community pharmacies have played an important role in providing nationwide intervention services within a framework of established protocols with the Health Ministry and other competent authorities. Some examples include the needle exchange programme, the methadone substitution programme and collection of unused medicines (Valormed). Another successful example was the diabetes protocol involving a multidisciplinary partnership with the aim of providing self-monitoring equipment at low cost. This was only possible through negotiations with all involved stakeholders who agreed to renounce all or part of their profit margins for the benefit of the patient (Museu de Farmácia 2005).

Medicines management/Pharmaceutical care/Disease management: different names for programmes with a shared goal

Since 1999, the National Association of Pharmacies (ANF) has developed a strategy, methods and tools for the implementation of pharmacy-based disease management programmes. Currently these are set for asthma and COPD, diabetes and hypertension. In the last year remuneration of the diabetes programme has been successfully negotiated with the government (Costa, Santos, & Silveira 2005). By April 2005, there were over 2 500 patients integrated in these programmes, followed-up in 328 pharmacies distributed nationwide (Martinho 2005). The health-gains shown by this service will inform the decision to also remunerate other pharmacist interventions. Additionally, the Dadér programme promoting patients' planned pharmacotherapeutic follow-up has started its implementation in some pharmacies in 2001 (Anonymous 2005a; Santos et al. 2004). Although they have different approaches, both programmes aim to promote pharmaceutical care as part of the pharmacist's role (Martinho 2005).

Ensuring the quality of pharmacy premises

To provide such services, the pharmacy premises do not need to be accredited or to have a private consultation area, although the latter is advised. This is different from the UK, where the existence of such an area is compulsory to obtain accreditation. The pharmacists providing such services need to attend specific training, as part of the current accreditation system implemented in Portugal but are insufficient alone;

this process will be detailed in section 1.3.6. The accreditation of premises is a voluntary process that was launched by the Pharmaceutical Society and the National Association of Pharmacies in 2000, based on the “Code of Good Pharmacy Practice” according to the ISO standards. There are currently 207 pharmacies accredited or going through the process (Departamento da Qualidade da Ordem dos Farmacêuticos 2005). Although, at present, there is no direct link between pharmacy accreditation and the provision of pharmaceutical care, the concept of cognitive services has been described as pharmacists making use of their specialised knowledge in pharmacotherapy to provide a broad range of services, including provision of drug information, provision of non-prescription medicines, clinical interventions, medication management services, preventive care services for chronic patients and participation in prescribing decisions (Emerson, Whitehead, & Benrimoj 1998). Barriers to the implementation were studied, suggesting the importance of the organisational aspects of community pharmacy which could be eased by the implementation of quality assurance guidelines (Roberts et al. 2003).

Focus on patient safety

Following the European focus on patient safety, one way to help community pharmacists in daily service provision without creating a useless overload of paperwork is to provide them with software on the patient level with inclusion of additional relevant information at any time, *e.g.* the detection of a potential interaction and the measure taken to prevent it. The development of Sifarma 2000 filled this gap and is currently installed in 189 pharmacies with an envisaged implementation of 500 per year until nationwide implementation in 2008 (Departamento de Apoio aos Associados 2005). Although Portuguese community pharmacies are currently equipped with over 10 000 computers supported by software with safety related information, the major difference is that this is totally patient-focused. Having records on the patient level will allow community pharmacists to detect and prevent errors even with different prescriptions issued by different doctors, with obvious gains for risk management and patient safety. Aside from this initiative, research is being developed to create preventable drug-related morbidity indicators for use in Portuguese community pharmacies, aimed at helping pharmacists intervene in collaboration with the patient and/or the physician to reduce the risk of drug misuse (Guerreiro, Cantrill, & Martins 2005). Hopefully, in

the near future these two initiatives will be linked to create a more comprehensive approach to risk management in the community.

1.3.6 Ensuring competence in pharmacy services delivery

For good service provision, accreditation of premises is essential, but even the best equipped healthcare setting will provide no added value to patients, unless the professionals working there are competent in their role. This section describes some of the initiatives that are being taken on board in the UK and in Portugal to ensure that pharmacists provide high quality services.

Increasingly a lack of harmonised standards for practice and development between and within different health care professions exists (Bates et al. 2004). Agenda for Change has been proposed to create guidelines for all allied health professionals that ensure equal quality of service with equal pay (Department of Health 2003a). The Knowledge and Skills Framework was created to clearly signpost the requirements needed for each level of practice while considering progression in the career path (Agenda for Change Project Team 2004). The development of competency frameworks to assess different levels of practice emerged in an effort to tackle these inequalities in an objective manner (Bates et al. 2004). Currently, a competency grid for junior pharmacists (McRobbie et al. 2001) and a general level competency framework (Antoniou et al. 2004) have been successfully developed. Additionally, an advanced level competency framework (Meadows et al. 2004) and a primary care and community pharmacists' competency framework (Mills et al. 2005) are being developed. The judgement of professional competence is made by the professionals who rate themselves in each of the domains (skills) considered relevant for the job, with minimum standards of quality corresponding to each of them. This method of evaluating competency is different from the traditional approach to CPD and seems to have the advantage of being practice-driven and dynamic.

CPD in the UK

Although CPD will become compulsory in the UK by the end of 2005, it has been argued that this will not ensure pharmacists' competence in their activities (Mills, Farmer, Bates, Davies, Webb, & McRobbie 2005). The process, as currently defined, consists of encouraging pharmacists to develop a personal development plan (PDP)

through which learning needs are identified using a reflective cycle that encompasses a phase of self-evaluation of how the acquired knowledge was implemented into practice (Centre for Pharmacy Postgraduate Education 2005; Royal Pharmaceutical Society of Great Britain 2005). Pharmacists' accreditation is compulsory for the provision of advanced services such as Medication Use Reviews (MUR) and universities are to be responsible for providing accreditation as designated by the RPSGB. However, it is widely recognised that a more thorough method to ensure the ability to practice is needed, so alternative models to (the passive) CPD, such as the use of competency frameworks, are likely to be taken on board (Patel 2005).

CPD in Portugal

In Portugal CPD became compulsory in 2004 (Aranda da Silva, Ramos, & Silva 2004). The Pharmaceutical Society created a process whereby certain activities and/or formative sessions are valued with accreditation points, imposing a minimum number that needs to be accumulated through a 5-year period to maintain the license to practice. The pitfalls are that it does not guarantee that the correct options are taken by pharmacists to ensure the quality of their practice, instead it assumes that healthcare professionals should be able to identify and actively seek to fulfil their learning needs. A good example of this is a grid created to attribute points, where successful completion of *e.g.* the pharmaceutical care programmes sessions attributes them 4 to 5 credits but then they are additionally rewarded with 0.5 to 2.5 credits depending on the number of patients followed (Martinho 2005). Nonetheless, similar to the UK, there is some concern on the extent to which passive CPD meets the requirements of enhanced practice competency (Aranda da Silva et al. 2005), suggesting that the process currently set up may need review. It must be acknowledged that in both countries, these requirements are fairly recent and hence the first months of implementation will provide useful information around what can be improved, which is then to be followed by revision to improve the initial formats by making it more practice-driven, *i.e.*, ensuring competent pharmacists deliver high quality services.

The following quote illustrates how the traditional model assumed university education was enough to guarantee graduates become good professionals:

“People who are conventionally clever get their jobs on their qualifications (the past), not on their desire to succeed (the future)”. (Arden 2003)

1.4 Medicines taking and the patient

Knowing how the health systems function is essential to identify initiatives to improve their quality. However, equally important is to understand the role of the different key players involved. Health professionals have been addressed in previous sections, but the final receptors of care are the patients, the focus. This section aims to provide an overview of the theories describing the ways patients interact with their illness and the actions they take to attempt recovery or control. This often involves taking medicines. Since the 1930s, researchers’ understanding of patients’ medicines taking behaviours has grown. Different theories have evolved over the years to determine the major determinants of behaviour. These were initially developed in a broader context and later adapted into medicine-taking behaviours.

1.4.1 Parsons’ theory of the sick role

The approach to the ideal patient behaviour from the biomedical perspective sees the patient as a passive recipient of expert-driven orders, forming the basis of the definition of compliance. Compliance has been defined as the extent to which a patient follows doctor’s indications (Sackett & Haynes 1976). From the most purist view, patients have a list of rules they should obey in order to be accepted as sick people. These comprise the duty to consult the doctor in case of illness or sickness and the duty to comply with what the doctor prescribes (Parsons 1951). This theory takes into account the assumption that human action is partly determined by normative standards. The “sick-role” was formulated around four major themes:

- 1) Sick people are exempt from their usual roles and obligations;
- 2) They are not responsible for their incapacity;
- 3) Sick people can only enter such a role if they want to get well and abandon such role;
- 4) They are obliged to seek technical qualified help and co-operate (word later replaced by “comply”) with prescribed therapy (Myers & Midence 1998).

As these models have evolved, patients have started to have an “active” voice and are entitled to choice. The development of social cognition models played an essential

role in highlighting the need to consider the individual's own beliefs, leading to the replacement of compliance by adherence, following which several authors have proposed definitions to distinguish between these two terms (Buchmann 1997; International Pharmaceutical Federation Statements on Professional Standards 2003; World Health Organisation 2003). Currently, the most commonly used term is concordance, implying that the patient is entitled to negotiate health-care decisions with providers on the basis of an equal partnership aiming to achieve a shared management plan (Royal Pharmaceutical Society of Great Britain 1997). The concepts behind this evolution really are the understanding of patients' views and concerns. However, the latter concept also involves a shift in the consultation process and in doctors' attitudes (section 1.5).

1.4.2 Social Cognition Models

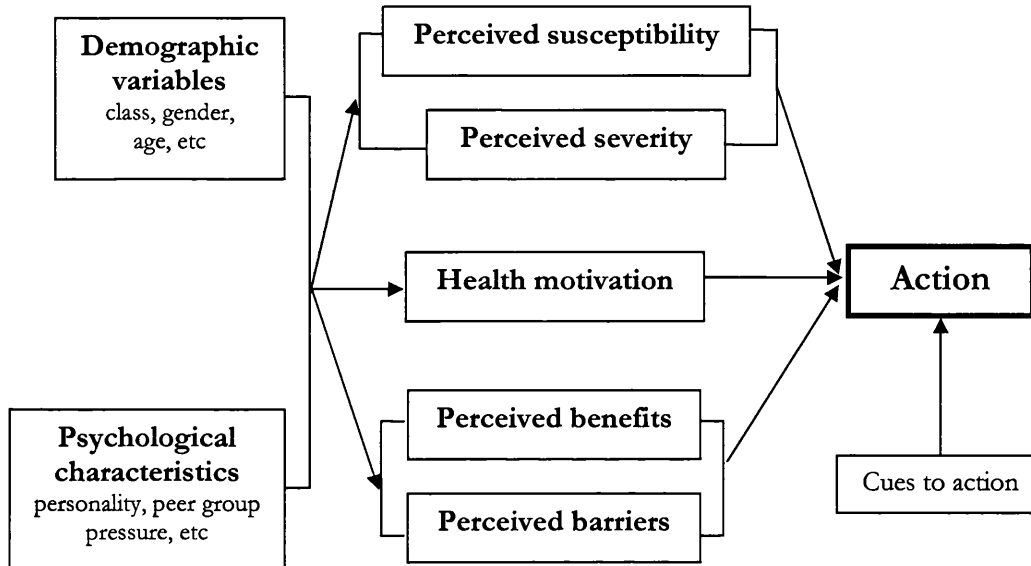
The classification of theoretical models developed to explain health behaviour is inconsistent across literature sources. This classification differs between social cognition models, stage models, self-regulatory model of illness and theoretical approaches and does not differentiate between cognition and social cognition models, as suggested by some (Ogden 1996c). It is beyond the scope of this thesis to describe all those developed (*e.g.* attribution theory, unrealistic optimism). The four major social cognition models that have been developed, regarded as shifting points in the understanding of patients' medicine-taking behaviour are described in this section.

1.4.2.1 The Health Belief Model (HBM)

This model was initially developed in the 1950s by Hochbaum, Kegels and Rosenstock to explain and predict preventive health-behaviour by focusing on the relationship between health behaviours and the utilization of health services (Ogden 1996c). The model comprises three main components:

- 1) Individual perceptions, focusing on the individual and attributed importance to health and disease, perceived severity and perceived susceptibility;
- 2) Modifying behaviours, demographic variables, perceived threats and cues to action;
- 3) Likelihood of action, the likelihood of executing the appropriate behaviour.

Figure 1.1 - The Health Belief Model (adapted from Rosenstock, 1974)



(James & Horne 2000)

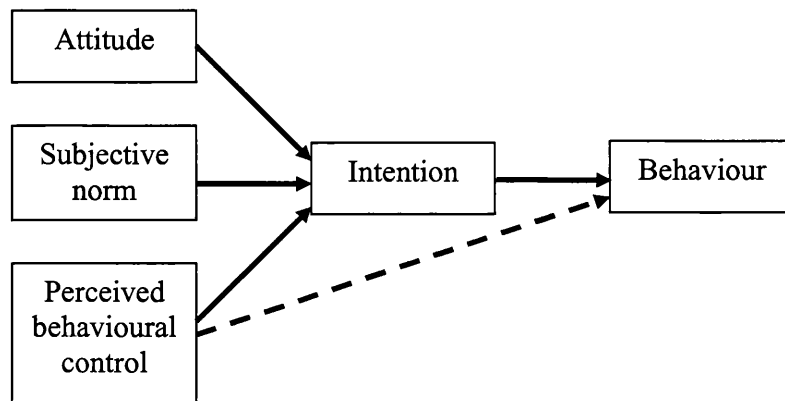
The combination of these factors generates action, making it theoretically possible to predict the way the individual use health resources. Some of the limitations include the focus on the weighing of barriers and benefits by patients, whilst failing to include beliefs or intention stages, it is better at modelling preventive health behaviour, when focus should be put on health maintenance given the high prevalence of chronic illnesses (Horne & Weinman 1998; Ogden 1996c). That it is too general may result in little practice and research applicability as behaviours may vary within the same individual according to different situations (Weinman 1987).

1.4.2.2 Theory of Reasoned Action and Theory of Planned Behaviour

It can be argued that the failure to acknowledge the role of intentions in dictating behaviour was an important concept missing in the Health Belief Model, which could be partly accountable for its inability to accurately predict behaviour in all situations. The development of the Theory of Reasoned Action and the Theory of Planned Behaviour inform the Health Belief Model adding that the main predictors of behaviour are intentions, comprising attitudes and subjective norms. The theory of reasoned action (TRA) was developed in 1967 and expanded in the 1970s (Ajzen

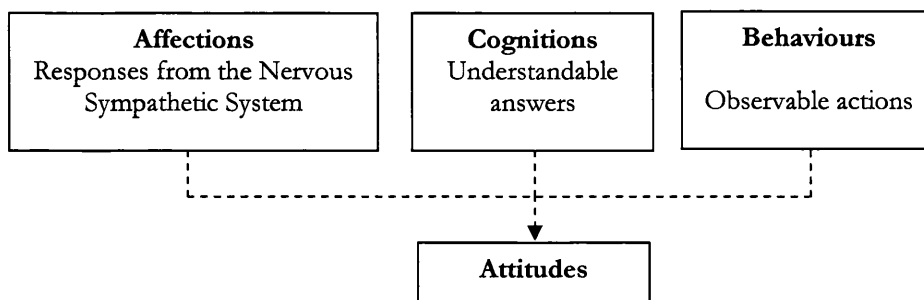
1991). In 1988, the theory of planned behaviour (TPB) was added to the initial model (Ogden 1996c).

Figure 1.2 – Representation of the Theory of Reasoned Action (Ajzen 1991)



By considering subjective norms this model encompasses the impact of societal influences on the individual behaviour. The concept of attitudes was introduced in 1960 by Hovland and Rosenberg, who stated that *“a person’s attitude towards an object is filtered by their affect, cognition and behaviour”* (Vala & Monteiro 1997).

Figure 1.3 – The three components of Attitudes (Vala & Monteiro 1997)



Both attitudes and subjective norms can be measured through scales and therefore have been vastly used in communication campaigns, namely against drugs and tobacco (Horne & Weinman 1998; Ogden 1996c). One of the criticisms is that it strongly predicts intention, but weakly predicts behaviour (Knapp et al. 2003). However, some authors have reported studies where this theory was successful in predicting adherence to chronic conditions (Miller, Wilcoff, & Hiatt 1992). Perceived behaviour control is the only component of the model that directly influences both

intention and behaviour, so another criticism of this theory could be that perceived control has relative importance for different individuals. Rotter's social learning theory focuses on beliefs about control, which was later developed into the locus of control theory (Rotter 1960;Wallston, Wallston, & DeVellis 1978).

1.4.2.3 Health Locus of Control

The first form of the Locus of Control theory was named Health Locus of Control (LoC), and applied the individuals' beliefs of control to their general health status. This theory puts forward individuals tend to attribute control over a situation to external or internal factors. Having an internal locus of control implies that events are a consequence of one's actions and are under one's control. An external locus of control refers to the belief that all events occur as a result of external factors, comprising fate or chance and powerful others; doctors, other people or God (Horne & Weinman 1998;Ogden 1996c). In response to the well accepted criticisms around its low ability to explain variance and the unidimensionality of the concept, multidimensional scales were developed, replacing the word "condition" by the specific disease under evaluation (Wallston, Wallston, & DeVellis 1978). However, it can be argued that the extent to which this solution solves the problem of low predictability is unclear and is more likely to be related to the fade link between perceived control and actual behaviour. Nonetheless, the LoC theory was subsequently used to predict adherence behaviours, but results are inconsistent (Schlenk & Hart 1984;Stanton 1987).

Beliefs that determine adherence behaviours have been described as efficacy beliefs and fall into two major categories, outcome efficacy and self-efficacy (Horne & Weinman 1998). Outcome efficacy relates to the extent to which the individuals think that taking a specific action will result in positive outcomes, whilst efficacy beliefs relate to the individuals' belief in their ability to perform such action (Horne & Weinman 1998). The latter is best described by Bandura's self-efficacy theory (Bandura 1977;Bandura, Adams, & Beyer 1977).

1.4.2.4 Self-efficacy

Efficacy beliefs describe what makes people feel motivated, well and personally fulfilled (Bandura 1977;Bandura, Adams, & Beyer 1977). Bandura argued that actions

can be better predicted by patients' beliefs in their own capabilities than their actual capabilities. If people do not believe in themselves and are not confident that their actions will have the outcome desired, it is unlikely that they perform any action. This explains why people with the same knowledge and skills behave differently in terms of productivity.

The adoption of self-efficacy theory to current managerial techniques is illustrated by the following quote:

‘Nearly all rich and powerful people are not notably talented, educated, charming or good looking. They become rich and powerful by wanting to be rich and powerful.’ (Arden 2003)

This theory has been widely used to predict adherence behaviours. One criticism is its lack of specificity to medicines-taking behaviour (Weinman 1987). Following such criticism, amendments to the initial general model created the currently existent specific self-efficacy scales (Baines, Joseph, & Jindal 2002). This model can be seen as a bridge between social cognition models and stage models, where the importance of past events is for the first time mentioned as a possible determinant of future events. Stage models are a natural evolution where past behaviours are then seen as stronger predictors to future behaviours than cognitions (Horne & Weinman 1998).

1.4.3 Stage Models

Stage models consider a dynamic balance between cognitions and behaviour, action is taken dependent on successive stages (Horne & Weinman 1998). Throughout these stages, cognitions have different influences. Several models of change have been proposed, the Prochaska's transtheoretical model is widespread in health research. This model describes how individuals change their behaviour based on the intentional decision to change it. The stages of change add the temporal dimension, where change occurs in five progressive stages, each having a temporal limit that determines action:

- 1) Pre-contemplation - not seriously considering changing behaviour in the next 6 months
- 2) Contemplation - considering changing behaviour in the next 6 months
- 3) Preparation - considering changing behaviour in the next month
- 4) Action - making behaviour changes

- 5) And maintenance - Maintaining these changes over time (varying according to the behaviour changed) (Prochaska 1991; Prochaska & Diclemente 1992; Prochaska & Velicer 1997)

Seeing behaviour as a process rather than as a single event has been acknowledged as a benefit of this model (Redding et al. 2003). It has been criticised for the lack of emphasis on the effect of motivation in maintaining behaviour (Horne & Weinman 1998) or external factors (Velicer et al. 1998). To overcome these limitations, a new model was developed that considers the dynamic balance between cognitions, motivations and behaviour, known as the self-regulatory model of illness (SRM) (Leventhal, Diefenbach, & Leventhal 1992).

1.4.4 Self-regulatory model of illness (SRM) and coping processes

Leventhal first categorised illness cognitions into identity, perceived cause, consequences, time line and cure or control. When introducing the SRM, he explained that they correspond to the way patients interpret the situation, which dictates the coping processes they develop. Additionally, the role of emotions is valued and influences the coping processes developed (Ogden 1996d). The interpretation of a situation is generated from the combination of the rational and the emotional, often described as IQ (intelligence quotient) and EI (emotional intelligence). There is a third factor, the appraisal of the results produced by the developed processes, but the strongest characteristics of the SRM is that these three phases occur in dynamic cycles to achieve balance, *i.e.*, health (Ogden 1996d). It is important to briefly describe some of the ways coping processes have been described.

Coping processes

Coping processes have been broadly categorised into “approach coping” and “avoidance coping” (Leventhal 1980). Some authors have gone into further detail by creating two types of processes for each category, “problem-focused coping” and “emotion-focused coping” for the first; and “behavioural disengagement coping” or “mental disengagement coping” for the second (Carver 1989). Beyond this categorisation, three different approaches to coping have been suggested: “coping with medical diagnosis” (Shontz 1975), “coping with a health crisis” (Moos and

Shaeffer 1984) and the theory of “cognitive adaptation” (Taylor 1983). The coping with medical diagnosis approach focuses on the existence of three phases occurring immediately after the patient is confronted with this new situation in his life: shock (characterised *e.g.* by indifference), encounter reactions (characterised by feelings of despair and such like), and retreat (characterised *e.g.* by denial); these are then followed by a gradual process of facing reality.

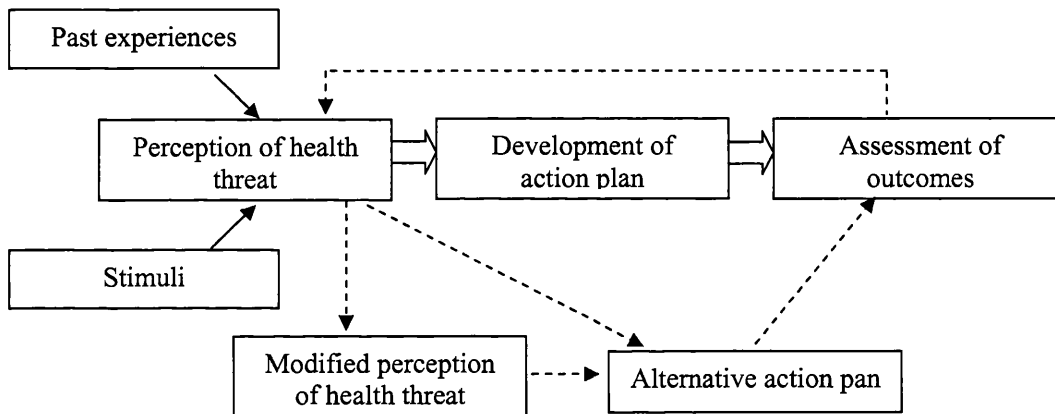
The coping with a health crisis focuses on factors that influence the coping strategy rather than the phase, which encompass the type of change and the nature of the crisis. The nature of the crisis is particularly interesting for this thesis as it mentions some of the potentially exacerbating factors include lack of clarity of the information received and the attribution of ambiguous meanings. Following this interpretative process, coping processes have been categorised into “appraisal-focused coping”, “problem-focused coping” (into which information seeking fits) and “emotion-focused coping”. The theory of “cognitive adaptation” suggests that people go through three phases when faced with a threatening situation, following which they develop illusions as part of the adaptation process; these illusions should not be seen as necessarily contradictory to reality but rather as a positive attitude. The three phases are:

- 1) The seeking of meaning, implying individuals have an intrinsic need to understand their situation;
- 2) The seeking of mastery, comprising information seeking, changes in medicines and control of side-effects; during this phase beliefs formed dictating the process chosen to achieve mastery are comparable to those described by the LoC theory, *i.e.*, individuals can influence the course of disease or it must be controlled by health care professionals;
- 3) The process of self-enhancement, which forms the basis of self-esteem reconstruction, achieved by downward (or upward) comparison with others (Ogden 1996d).

The SRM conceptualizes the patient as an active problem-solver, where the development of the problem solving action plan results from the interaction between the perception of health threat and the expected outcome. The way health threats are perceived is dependant on stimuli and past experiences; therefore the presence of

symptoms is particularly important to face these threats. This model poses problems when predicting adherence behaviours in asymptomatic diseases, such as hypertension; if blood pressure measurement is understood and taken into consideration may replace the feelings towards symptoms. The assessment of the outcomes of the action plan feeds back into patients' perceptions of the health threat, which may result either in an alternative representation of the threat or the development of an alternative action plan (Horne & Weinman 1998).

Figure 1.4 – Representation of the SRM of illness (Ogden 1996d)



Given the apparent advantages of such a theory, questionnaires have been developed to include the different dimensions, the Illness Perception Questionnaire (IPQ) (Weinman et al. 1996). The main drawback to this questionnaire in predicting adherence is that it focuses mainly on the illness and not so much on the medicine-taking behaviour. Illness obviously influences the action of medicine taking, as expressed in the SRM, but the perception of the health threat alone may be insufficient.

Many research studies have been undertaken using these models. However, international dissemination of Portuguese studies is still scarce, associated with a lack of national publications in international databases. A search carried out using the words Portugal and the different social cognition models (self-efficacy, theory of planned behaviour, locus of control) and stage models retrieved only two abstracts.

Most of these studies aimed to understand adherence-behaviours. Non-adherence has been subdivided into passive and active (Horne, Weinman, & Hankins 1999); the latter being dependant on two types of beliefs, medication and illness beliefs (Horne, Weinman, & Hankins 1999). Illness beliefs are assessed in the IPQ (Weinman, Petrie, Moss-Morris, & Horne 1996), whilst medication beliefs are assessed by the “Beliefs about Medicines Questionnaire” (BMQ) (Horne, Weinman, & Hankins 1999). The BMQ supports the theory that beliefs fall into four categories: specific value of medication for health; specific fears, which subdivide into belief of harm, as in long-term side-effects, or disruption of lifestyle; general fears; and general overuse (Horne, Weinman, & Hankins 1999).

1.4.6 Research on adherence behaviours

In order to have a complete overview of the research around adherence, awareness and understanding of the landmark models is essential. Some of these theories have been used as theoretical underpinnings for formulating research questions, while other researchers have approached patients’ medicines’ taking behaviours without pre-assumptions, a so-called atheoretical approach, some of which have resulted into categorizations of patients’ adherence, in terms of extent and cause. This section aims to provide a more complete understanding of all aspects of adherence.

Compliance, following doctors’ instructions, has been subdivided into null, partial and erratic (Cramer & Spilker 1991). The reasons associated are varied and have been explored through atheoretical study, related to demographics or as a product of health system functioning. When patients are prescribed medicines there are several possible paths to be taken.

The null compliers

Some patients do not get to use medicines prescribed, the so called the null compliers (Cramer & Spilker 1991), often a result of drugs being unavailable, perhaps most common in developing countries (Holland 2005). Other patients may have access to medicines but the geographical or economic conditions make them inaccessible in practice. Both these cases are also only possible in some health-care systems (HCS); *e.g.* in Portugal the majority of drugs are only partially reimbursed by the Government, which leads to the existence of a link between economic factors

and access to health-care. Within Portugal accessibility to pharmacies, in terms of distance to patients' homes, may also vary widely across regions. In the UK, patients may be exempt from any payment if they have a low socio-economic status; therefore economical factors are not as plausible. However, accessibility to pharmacies, particularly in rural settings, may also play a role in this context. A fourth group of patients may have access to drugs in all above mentioned cases but still do not get their prescribed therapy due to psychological factors (Horne, Weinman, & Hankins 1999; Weinman, Petrie, Moss-Morris, & Horne 1996).

The partial compliers

Partial compliers are those who have access to prescribed therapy who at times, and possibly for different reasons, only take it to a certain extent (generally expressed as a percentage) (Cramer & Spilker 1991). Some of the scenarios that have been described include forgetfulness, long-term referral of appointment, failure of physician to keep an appointment (Cramer & Spilker 1991), costs of therapy, improvement of clinical condition (Eca del Col·legi de Farmacèutics de Barcelona 2002), and considering "drugs are best avoided" (Benson & Britten 2002).

The erratic compliers

The erratic compliers are those patients who get their medicines but take them in an incorrect way (Cramer & Spilker 1991). Some of the factors associated with this behaviour include the complexity of medical regimens (World Health Organisation 2003), mental illness (Cramer & Spilker 1991) and inadequate healthcare professional-patient communication (Weinman 1987).

It is believed that poor compliance with therapy leads to undesirable effects in the quality of medical care, wastes financial resources and interferes with therapeutic effect, reducing the benefits of preventive care and treatment. It also may lead to unnecessary diagnostic and therapeutic procedures, generating additional costs (Giuffrida & Torgerson 1997). Therefore, any action taken to improve compliance to therapy should be encouraged.

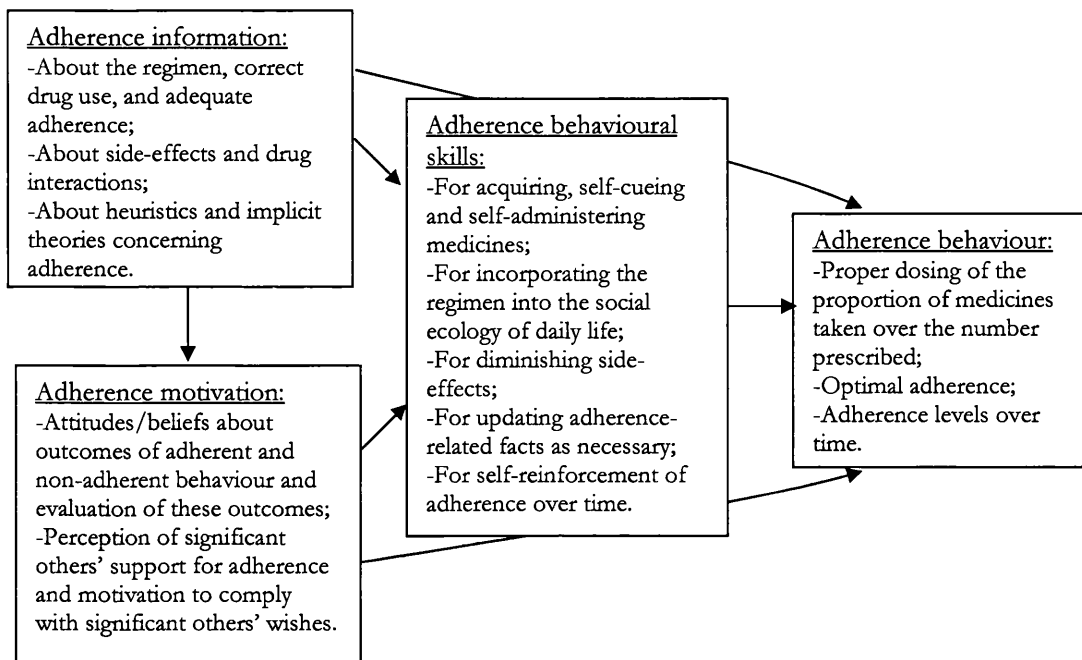
1.4.6 Interventions to improve adherence

Several studies using different approaches have reported successful pharmaceutical interventions to improve compliance to prescribed therapy (Friedman et al. 1996; Haynes et al. 1976; Logan et al. 1979). Not all have, however, managed to demonstrate an impact on clinical outcome (Baird et al. 1984; Gallefoss & Bakke 1999; Logan, Milne, Achber, Campbell, & Haynes 1979). Others have even failed to demonstrate any change in patients' compliance to therapy (Vivian 2002). There is vast literature around different approaches taken to increase compliance. These comprise the tailoring of dosing plans to individual patient routines (Norell 1981), categorisation of information by medical staff (Ley 1988b), and more recently the use of new technologies alerting patients either to refill their prescriptions or to take their medication (Costa et al. 2005; Gallefoss & Bakke 1999; Katon et al. 2001). The latter include the use of simple postcards or telephone calls, faxes, emails, beepers and even reminder cards specifically designed for this purpose.

All these interventions inform and stimulate strategies (World Health Organisation 2003). Others have explored reasons for non-compliance prior to designing an intervention, in an effort to tackle intentional compliance in a cost-effective manner (Barber et al. 2004).

In the 2003 WHO report, the Information Motivation Behaviour (IMB) model was proposed (World Health Organisation 2003). This model defends that both information and motivation are required to achieve adherence, or at least, to increase its likelihood. The developers of such model argue that information is a prerequisite for behavioural change. The following figure depicts the set of skills required for each of the dimensions.

Figure 1.5 – The IMB Model



However, the hypothesis that some patients may not desire such information is not acknowledged. Additionally, it is sometimes not clear if the skills proposed are for patients or for HCPs to acquire. A good example of the limitations of this model applies to the clinical applications where, for instance, changing a medical prescription to simplify the instituted regimen fits into the information dimension. Finally, there does not seem to be any added value in prediction of adherence as studies have only been able to explain 33% of variance. Nonetheless, some practitioners argue that its advantage lies in its easy application to daily practice (Amico, Toro Alonso, & Fisher 2005).

Affective Behaviour Cognitive (ABC) strategies aim to enhance self-efficacy and concordance and have been mostly used in nursing research. The basic principle is that no single intervention is effective by itself, so this model proposes an intervention focused simultaneously on affective, behavioural and cognitive strategies. It is also based on the previous assessment of patients' needs and then the development of the most appropriate strategy. For some patients, there is an emphasised need for one or another type of strategy (Schaffer & Yoon 2001). The following table provides some examples of interventions which fit into each of these three dimensions.

Table 1.1 – ABC strategies

Affective	Behaviour	Cognitive
Relationship stimulating debate on non-adherence	Simplification of regimen; use of forgiving drugs	Provision of education to patient and family/carers
Expression and listening of patients' concerns	Provision of reminder systems (e.g. telephone counselling, multi-dose aids, refills)	Provision of oral counselling
Ensuring social support and network involvement	Improvement of convenience of care (e.g. home care)	Provision of written instructions
Provision of motivation written information	Ensuring access to information	Use of video demonstrations
Provision of acceptable drug technology	Tailoring of therapy to social context	Use of computer-assisted education programmes
-----	Provision of access to role models and opportunity for mastery experience	-----
	Supporting of self-monitoring and ensuring of feedback	
	Setting of goals and plans	
	Facilitation of concordance contacts	

1.5 Moving from compliance to concordance

Following from the work developed in the 1970s and 1980s on compliance and adherence models, new approaches to medicines-taking emerged. The application of evidence-based medicine increased understanding that most research to improve compliance failed to effectively target the problem. Additionally, paternalistic patient care became increasingly viewed as inappropriate and was replaced by the establishment of a more equal partnership between providers and recipients of care. Consumer and patient associations started to have an active voice in developing healthcare. The importance of patient-doctor communication has been widely recognised (Knapp, Raynor, & Berry 2004; Mandy & Gard 2000; Weinman 1987). Patient empowerment became a priority in Government documents; pharmacists were to now focus on providing appropriate patient information (Royal Pharmaceutical Society of Great Britain 1997). Information provision plays a central role in concordance, both for patients and health care providers. The shift to concordance came from the development of the Concordance coordinating group set up by the RPSGB in 1998 and the subsequent establishment of a Task force on medicines partnership in 2001 (Royal Pharmaceutical Society of Great Britain 2002).

Concordance has been described as

“the clinical encounter with two sets of contrasted but equally cogent health beliefs – that of the patient and that of the doctor.” (Royal Pharmaceutical Society of Great Britain 1997)

Both parties convey their health beliefs (the doctor’s are professionally informed) to the other who enables this to happen.

“The intention is to assist the patient to make as informed a choice as possible about the diagnosis and treatment, about benefit and risk to take full part in a therapeutic alliance. Although reciprocal, this is an alliance in which the most important determinations are agreed to be those that are made by the patient.” (Royal Pharmaceutical Society of Great Britain 1997)

The concordance definition has been later simplified into

“an approach to prescribing and taking medicines, where an agreement is made taking into account the patients beliefs and wishes.” (Royal Pharmaceutical Society of Great Britain 2002)

Other authors have then built on the original definition stating that concordance refers to

“a consultation process between a patient and a health care professional, in which power is shared and the patients’ perspective is valued”

where “*primacy*” is given to patients’ views. (Weiss & Britten 2003)

It is important to highlight that concordance is not a replacement term for adherence, although it is sometimes wrongly used synonymously with compliance (Haynes et al. 2005). To clarify the differences and propose a way of preventing such mistakes the term “informed adherence” was introduced (Horne & Weinman 2004). There are key elements in the concordance model that depend not only on patients’ willingness to change behaviour but also, if not more, on the HCPs’ openness to changing attitudes. These encompass health professionals’ preparation for partnership, ensuring that patients are partners during the consultation process and

are supported in taking medicines (Herborg & Roberts 2005). Therefore the term “non-concordant” can only apply to the consultation process (Weiss & Britten 2003), and an individual can never be classified as “non-concordant” (Britten & Weiss 2004). Additionally, for patients to have the competence to take on such a role they need to have enough knowledge to participate in an equal partnership and need to be willing to be involved in such a model, which will not be a reality for all. This process is only possible to work if attention is paid to all the key factors, implying that both involved parties need to change their behaviour if willing to take on this partnership approach to care.

1.5.1 Communication between Health Care Professionals and Patients

When looking into compliance behaviours, Ley developed the cognitive hypothesis model of communication, which values a patient’s understanding of information and patient’s memory about received information as direct and indirect determinants of compliance, the latter via the interaction with patient’s satisfaction (Ley 1988a; Ogden 1996b). Studies using this model have concluded that patient satisfaction is a multidimensional concept resulting from a combination of affective and behavioural factors beyond the technical ability of the health care provider (Ogden 1996b). This simple component is enough to question the extent to which the model is in line with the traditional medical approach, where value was placed on the doctor’s expertise. Indeed, other studies have shown that patients express an enhanced need for a caring relationship, but care must ensure that satisfaction is not merely dictated by feelings of approachable professionals regardless of their technical capacity.

Communication styles have been divided into “directive consulting style” and “sharing consulting style” (Ogden 1996b). It has been suggested that the directive consulting style contributed to higher levels of satisfaction (Savage & Armstrong 1990), which contradicts the concordance approach. It should be considered that this study was undertaken 15 years ago; the patient’s willingness for involvement in decision making has been acknowledged as a prerequisite for concordance.

Parsons' Model of the sick role has been broadened to encompass a series of doctor’s duties applied by Stewart and Roter (1989) to describe 4 types of relationships

between doctors and patients based on the extent of control exerted by each party, as illustrated in the following figure:

Figure 1.6 – Types of doctor-patient relationships

Control		Patient	
		High	Low
Doctor	High	<p>Mutuality</p> <p>This type of relationship corresponds to the one advocated by the concordance approach to care.</p>	<p>Paternalistic</p> <p>This type of relationship has been exhaustively described corresponding to the most traditional type, long established, linked with the notion of a passive compliant patient</p>
	Low	<p>Consumerist</p> <p>The patient takes the active role.</p>	<p>Default</p> <p>Both parties have low control over the relationship but the patient is unaware of existing alternatives and is timid in the negotiating process.</p>

The author defends that these different relationship types may all be appropriate, depending on the conditions considered and on different illness stages (Morgan 1991).

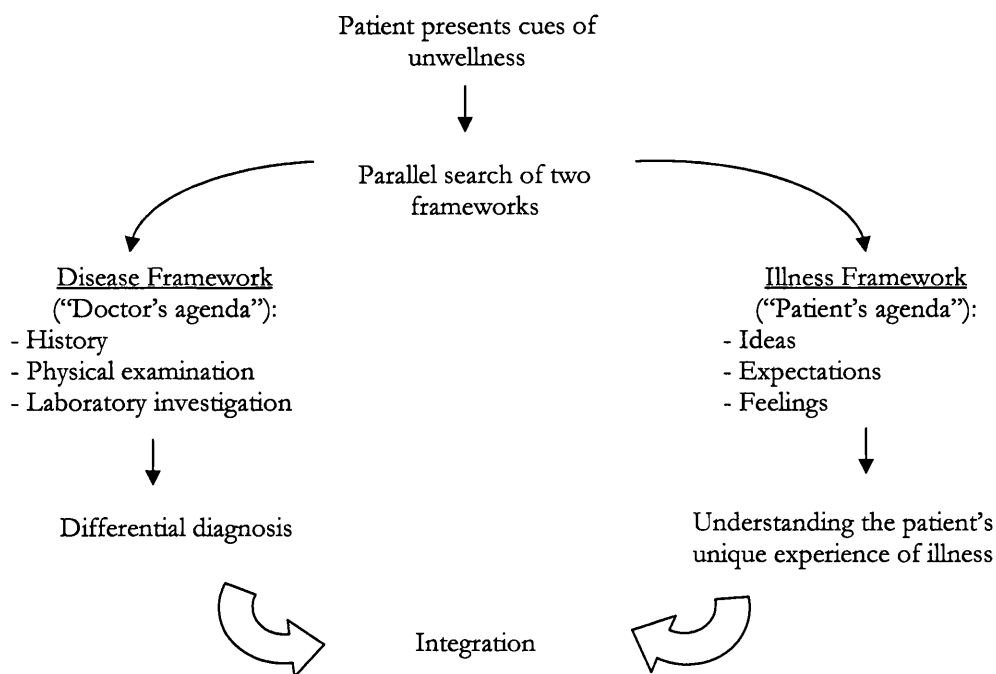
The perceived role of doctor has been described by Byrne and Long (1976) as the determinant for consultation styles; patient-centred or doctor-centred (Morgan 1991; Weinman 1987). The different styles can be linked to differences in the doctor's orientation and perception of the nature of the medical task. Doctors who adopt a patient-oriented approach frequently pay greater attention to the psycho-social aspects of illness in terms of its possible social origins and the patients' experience of anxiety, depression and other emotional problems. The proposed determinants of the nature of the relationship are:

- 1) Doctor's clinical practice style;
- 2) Structural constraints on the consultation;
- 3) Patients' ability to exercise control and participate in the consultation.

(Morgan 1991)

This active involvement is more likely to occur when patients possess considerable knowledge and familiarity with their condition, and doctors are often not aware of whether or not patients are satisfied with the consultation (Morgan 1991). These criticisms also apply to pharmacists and other health-care professionals; unless an effort is made by all involved parties to audit their services and enable expression of dissatisfaction.

Figure 1.7 – Patient-centred clinical interviewing (Levenstein et al, 1989)



(Morgan 1991)

Some of the factors to be tackled so as to move towards a patient-centred approach have been described by Weinman (1987) as:

1) Information: Apart from the time constraints, another objection is that some patients may not want to know very much about their condition and if the health care provider decides to routinely inform them, it may lead to additional stress and be counter-productive. However, Weinman argues that the best solution is to allow for areas of uncertainty to be mentioned, discussed and dealt during the consultation

process. By achieving this, it would be possible to determine whether patients want to be given information and ascertain the extent of detail that they want.

2) Communication gap: This term refers to the information passed to and from patient, which is not understood or is misunderstood, possibly leading to the attribution of different meanings to the same word. The use of jargon plays an essential role in such a context, equally used by the doctors and the patients. When used by doctors, patients say that they do not want to look stupid by admitting ignorance or that they do not want to cause trouble asking for explanations (Weinman 1987). Similarly, patients tend to use their own words which could be seen as jargon by HCPs, an example “my nerves” when referring to anxiety. This same term is typically a product of the modern world and a totally different meaning used to be attributed some decades ago “she has got the nerve” (Thompson 1939). Misunderstandings are not rare and may also result from importance attributed differently by people judging it. For example, a study has shown that patients’ interpretation of “family history” is totally different from the epidemiologists’ definitions (Hunt, Emslie, & Watt 2001).

Particular focus has been put on the impact and suitability of patient information leaflets (PILs) and on evaluation (Krass, Svarstad, & Bultman 2002; Vander Stichele 2004). A German study showed that as many as 98.5% of PILs contained repetitions, abbreviations and non-quantifiable statements and that nearly 10% contained contradictory information. Font size was smaller than recommended by the EU directive, in over 50% of PILs, indication of the maximum daily dosage, storage indications and what to do in cases of interactions or side-effects were omitted (Fuchs, Hippus, & Schaeffer 2003). Assessing patients' views confirmed problems with the leaflet, including a failure to understand key concepts about medicine interactions and contra-indications (Dickinson, Raynor, & Duman 2001). A Cochrane review showed that provision of written information, as well as verbal, increased patients' knowledge and satisfaction (Johnson, Sandford, & Tyndall 2003). In this context, the quality of printed information has been explored, suggesting that only trained dispensing staff provided satisfactory quality labelling (Boonstra et al. 2003). Some studies have suggested the use of pictograms for better understanding of information (Dowse & Ehlers 1998; Dowse & Ehlers 2003). All these studies have approached the same issue from a different angle but consensus seems to exist

around the importance and difficulty of conveying medicines and illness-related information to patients in a comprehensible manner.

Recognising the current pitfalls of the way information is conveyed to patients, regardless of setting, the Task Force on Medicines Partnership developed a project to revolutionise the way information is presented to patients, in terms of availability and user-friendliness. This includes information on disease, treatment options and specific information on the several medicines for the specified condition. This information should be available to patients at different stages, including prior to prescription, between prescription and dispensing and after acquisition. Additionally, availability of different channels is foreseen, including books, digital TV and information points (Task Force on Medicines Partnership 2005).

3) Poor recall: Recall is enhanced by providing advice before other information and emphasizing its importance; ensuring the information is comprehensible and organized into identifiable categories; providing specific rather than general advice.

4) Low empathy: A frequent complaint from patients is that many doctors just do not seem interested in their problems (Weinman 1987). Patients report that if a doctor is perceived as unsympathetic it will affect their behaviour, decrease the chance of visits or the likelihood of discussion of problems.

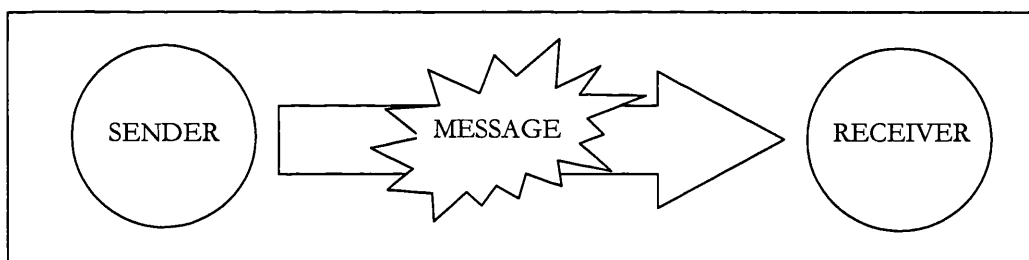
5) Passivity/activity: Whilst some patients prefer adopting a passive role and find it important that the doctor is in complete control, others value a more reciprocal relationship which allows them to describe problems in their own words and gives them the chance to bring additional issues for discussion not pursued by the doctor's agenda (Weinman 1987).

A systematic review (Cox et al. 2005) found patients considered it essential that doctors discussed possible side-effects of medicines. While many patients often adopted a passive role, it was acknowledged that doctors' attitudes during the consultation could act as either a barrier or a facilitator for patient involvement in the process. Different levels of involvement were desired by patients. Although doctors were generally regarded as the preferred source for information about medicines, one exception was OTCs. Additionally, prescription medicines were more often

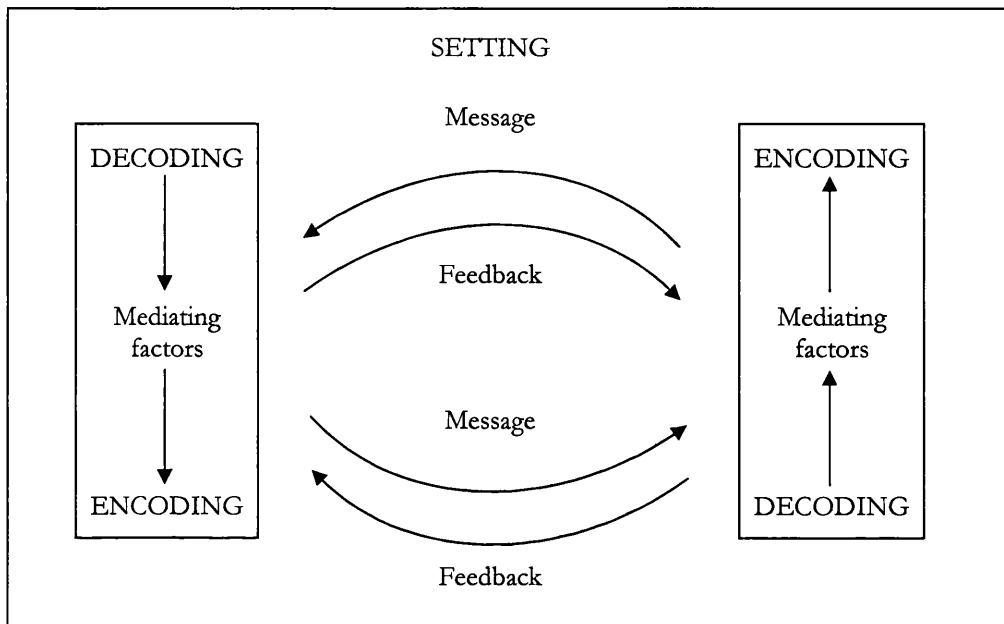
discussed with pharmacists than with assistants. However, communication styles of both doctors and pharmacists did not encourage patients to ask questions, the latter having the advantage of using more lay-friendly language. In general, it can be concluded that much of the communication remains asymmetric with the characteristics of the more paternalistic approach to care.

Evidence shows that better communication by the pharmacist can result in improved adherence to the advice given and the treatment regimen and therefore a better outcome. Additionally, if the information given makes sense to the patients they are more likely to follow the advice received (James & Horne 2000). The linear model of communication (Shannon & Weaver, 1949) highlights the importance of the message being understood by the target since the process is unidirectional, as displayed in figure 1.8.

Figure 1.8 – The linear model of communication *in* (Mandy & Gard 2000)



The later proposed skills model of communication (Hargie, 1994) considers such a process as bidirectional, and introduces the importance of feedback, whilst simultaneously considering other factors that potentially influence the process and which therefore need to be taken into account when aiming for an effective interaction. These comprise the setting (environment and social) and the mediating factors (*e.g.* motivation), as shown in figure 1.9 (Mandy & Gard 2000).

Figure 1.9 – The skills model of communication *in* (Mandy & Gard 2000)

Advice for the adoption of effective verbal and non-verbal communication styles that facilitate a closer relation has been suggested (Mandy & Gard 2000). However, it can be argued that many of these “rules” are not generalisable across cultures. Even within Europe cues to communication may be very differently interpreted. The hidden rules of “Englishness” describe “weather talk” as a means of initiating a conversation, while any other nationality would most likely perceive this as a purely meteorological comment (Fox 2005).

To achieve good communication between health professionals and patients, health professionals need strategies to cope with applying medical evidence to patients. Among these, slipping general reassurance from a test result and the certainty myth should be avoided (Griffiths, Green, & Tsouroufli 2005). The need for professionals to be trained in clinical communication is acknowledged, particularly regarding risk communication. Griffiths considers that the new challenge for health professionals is to be able to develop the skills necessary to admit uncertainty and negotiate provisional decisions (Griffiths, Green, & Tsouroufli 2005). Medical doctors' training is a potential barrier to patient empowerment and involvement in the decision-making process as doctors have been traditionally been encouraged to take full responsibility for patients' well-being (Russell & Smith 2003). This is also true for pharmacists; it has been suggested that pharmacy health promotion interventions to improve uptake of available screening and other health services need to focus on

effective communication, because simply presenting facts will not change behaviour (James & Horne 2000).

1.5.2 Provision of Information to patients

There is no single solution for the provision of information to patients. It has been widely acknowledged that some patients may benefit from a lot of information, whilst others will only be anxious with too much information (Duggan & Bates 2000). Weinman found a large proportion of patients complain they are not given enough information by those treating them and that additionally they seem more interested in what is wrong with them and in what will happen to them (Weinman 1987). Results from 15 surveys carried out by the Picker Institute over the past 7 years indicate that patients want more information about their treatment and want to be involved in the decision-making process. Patients are interested in potential side-effects of their medication (Kmietowicz 2005). The definition of population subgroups provides a general framework for healthcare providers to target their interventions, which needs additional individual tailoring only possible by means of in-depth patient contact.

Further research has been undertaken to develop ways to effectively measure patients' desires for information (Duggan 1998). The development of standardised scales to assess the correct amount of information for each individual patient can be of major importance to effectively target health care professionals' interventions (Duggan & Bates 2000).

1.5.3 Assessment of patients' desires for information: the development of the "Extent of Information Desired" (EID) scale

Research was undertaken to reduce discrepancies between primary and secondary care regarding prescribed medicines in the course of which in-depth interviews with domiciliary patients resulted in the development of a survey tool (Duggan et al. 1998; Duggan & Bates 2000). When subjected to factor analysis, five factors emerged describing patients "intrinsic desire for information" (IDI), initially called intrinsic desire for medicines knowledge, "perceived impact of illness" (PII), "perceived utility of medicines" (PUM), "anxiety about illness" (AI), initially called anxiety about illness and perceived consequences and "worry about changes" (WAC), initially called

confidence with changes to medicines (Duggan 1998;Duggan & Bates 2000). The first and last factors (IDI and WAC) were found to be associated with patient empowerment, where patients with a high desire for information and little worry about changes in their medicines felt more empowered when given additional information, and where patients with a low desire for information and worried about changes in their medicines felt uncomfortable and less able to deal with their therapy when given additional information (Duggan & Bates 2000).

Further validation work on the 12-item “Intrinsic Desire for Information” (IDI) scale resulted in a 5-item scale describing the “Extent of Information Desired” (EID) and a 3-item scale assessing an “inhibited desire for knowledge about illness/drugs”. In this study, socio-demographic characteristics influenced patients’ scores to these scales; a strong negative correlation between age and EID, implying that older patients desire less information (Astrom et al. 2000b). The EID was later refined into a reliable 6-item scale, while the second factor was dropped due to low reliability ($\alpha=0.5$). From this study onwards, all work performed referring to the EID scale addresses a 6-item scale, the one used also in the current project.

Associations between the EID scale and socio-demographic characteristics have been reported in all subsequent studies (Algernon 2001;Astrom et al. 2000a;Duggan et al. 2002). The consistent association between scores to the EID scale and age and significant associations with socio-economical classifications were found, implying that patients in higher professional classes tended to desire more information (Duggan, Bates, Sturman, Andersson, Astrom, & Carlsson 2002) and conversely the unemployed and retired tended to desire less information (Astrom, Carlsson, Bates, Webb, Duggan, Sanghani, & McRobbie 2000b;Duggan, Bates, Sturman, Andersson, Astrom, & Carlsson 2002). Patients’ leaving school at an earlier age were also found to desire less information (Duggan, Bates, Sturman, Andersson, Astrom, & Carlsson 2002).

The relationship between patients’ previous experiences with drugs and their current desires for information was explored in hospital patients and simultaneously for the occurrence of an ADR at admission (using the Naranjo algorithm). Results showed that patients experiencing ADRs (either before or at admission) were more prone to

an enhanced desire for information about drugs. An alternative hypothesis raised was that patients who intrinsically desired more information were more likely to identify ADRs. Nonetheless, the reverse was not verified, *i.e.*, not having experienced an ADR was not associated with a low desire for information (Laaksonen, Duggan, & Bates 2002). These findings are in line with suggestions that patients desiring more information refer to specific information, particularly about side-effects and interactions (Duggan, Bates, Sturman, Andersson, Astrom, & Carlsson 2002).

1.5.3.1 Using the “Perceived Utility of Medicines” (PUM) and the “Anxiety about Illness” (AI) scales

Despite the initial five factors having reliability over 0.8, most of subsequent work has focused on the use of the IDI scale. Nonetheless, during the validation of the initial survey tool, the high reliability of all five factors and the number of replicable items suggested additional refinement. Additionally, the strong associations between factors measuring illness-related concepts (perceived impact of illness and anxiety about illness) and medicines-related concepts (perceived utility of medicines and worry about changes) seem to indicate these could be combined in two main domains and further explored and validated (Duggan 1998).

The factor measuring the perceived utility of medicines (7-item scale) is negatively correlated with the number of prescribed drugs, suggesting that patients taking more drugs are more likely to view them as less useful (Duggan 1998). Additionally, these patients were also described as more anxious about their illness (measured through the 8-item AI scale), which could result from a perceived illness deterioration when prescribed with more drugs (Duggan 1998).

Considering that three of the most important dimensions for a better understanding of patients’ adherence are their perceptions about illness (included in SRM and explored through the IPQ), perceptions about medicines (explored also in the BMQ), and relationship developed with the healthcare provider (Horne, Weinman, & Hankins 1999; Weinman 1987; Weinman, Petrie, Moss-Morris, & Horne 1996), the EID, PUM and AI scales may be considered tools that partly explain such behaviours and are hence worth further exploration. The relationship established between patient and healthcare provider is not directly measured by any of these

scales. However, patients' information desires play an essential role in the communication context and may be useful for allowing a better understanding of patients' willingness for involvement in shared-decision making.

The scales used in this project are identified in figure 1.10 for easier understanding of subsequent chapters.

Fig. 1.10 – The 3 Scales used in this project

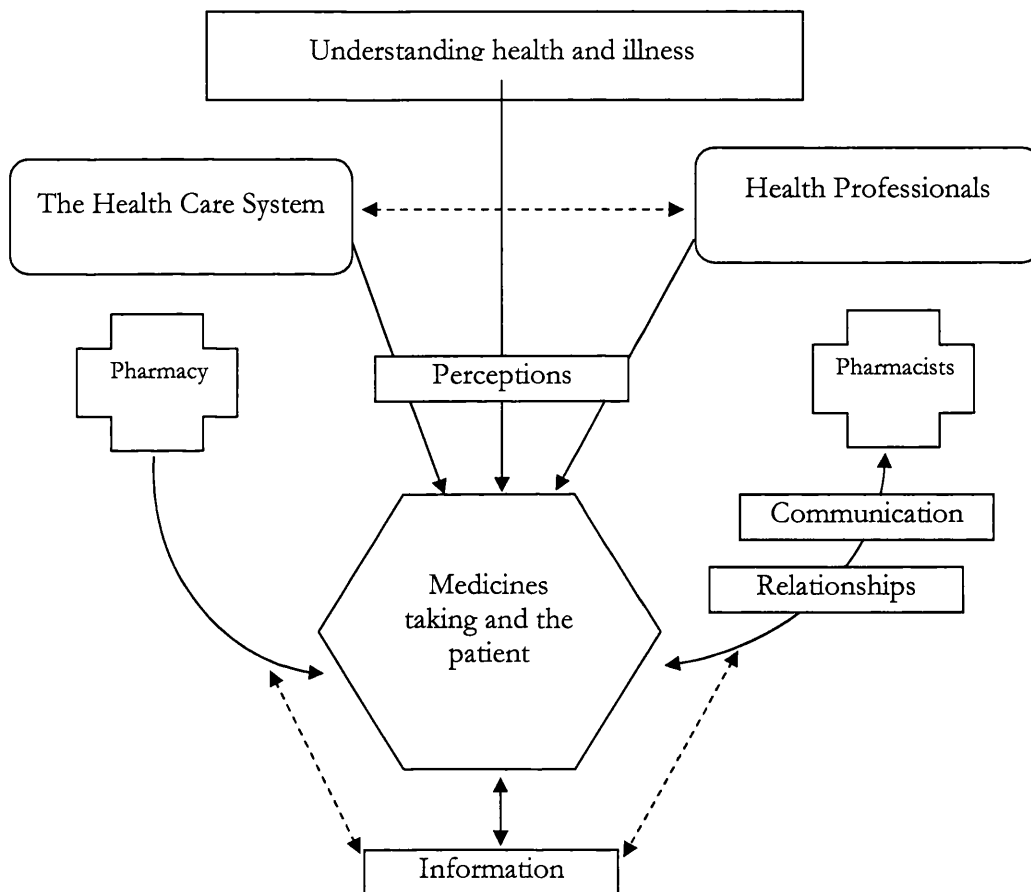
Extent of Information Desired (EID)	
S6	I need as much information about my medicines as possible
S7	Too much knowledge is a bad thing
S8	You can never know enough about these things
S9	I don't need any more knowledge
S10	I read about my medicines/illness as much as possible
S11	What you don't know doesn't hurt you

Perceived Utility of Medicines (PUM)			
Perceived Benefit of Medicines (PBM)		Perceived Harm of Medicines (PHM)	
T3	My medicines relieve my symptoms	I feel "trapped" by my medicines, I have to take them	T2
T5	I trust my medicines will make me better	It's hard to take my medicines, because taking them has altered my lifestyle	T4
T7	Without my medicines I would be so much worse	The side-effects are another form of disease	T6
T1	I find my medicines easy to take, I am used to them		T1

Anxiety about Illness (AI)			
Anxiety (Ai)		Tolerance (Ti)	
A1	I can't get used to this illness, I just get worried about it	I feel fine about my illness, you can't expect to always be well	A3
A6	I get really worried about it all, the worry makes me ill	I just want to blame someone for the way I feel	A4
A7	I feel anxious and concerned about the future	I would like to be completely better, but a bit better is good enough	A5
A9	I can't accept that there's something wrong, why me?		

Figure 1.11 summarises the various themes described in the introduction and how they link with each other in order to present visually the relevance of each section to inform this thesis.

Fig. 1.11 - Summary diagram of issues explored in the introduction



CHAPTER II

AIMS AND OBJECTIVES

2.1 Perspective

The purpose of this chapter is to provide an overview of the aims and objectives of the thesis. The research questions to be addressed throughout the thesis and the hypotheses to be tested are outlined. A schematic diagram of the study structure is presented to clarify the sequence of methods undertaken to achieve the stated objectives.

2.2 Aims and corresponding chapters where these will be met

Aims	Chapter
1. To adapt a survey tool to measure patients' information desires and perceptions about medicines and illness to Portugal	IV
2. To validate the adapted survey tool in Portugal	V
3. To compare patients' desires for information and perceptions about medicines and illness between Portugal and UK patients and within Portugal across primary and secondary care settings	VI
4. To develop a model that can describe patients' medicine taking behaviour and to recommend how such model can be useful in pharmacy practice	VII

2.3 Objectives

In order to achieve the main aims, the following objectives were operationalised.

1. To translate a scale to Portuguese (Portugal); to test its understanding and relevance in the target population and to ensure that the translated version is both linguistically equivalent to its original and culturally acceptable to the target country
2. To evaluate the translated tool's different forms of validity and compare it with the original tool's validity. To evaluate the translated tool's different forms of reliability and compare it with the original tool's reliability.
3. To compare patients' desires for information, patients' perceptions about medicines and patients' anxiety about illness between Portugal and UK patients; to undertake the same comparisons between Portuguese primary and secondary care.
4. To summarise the key findings from the thesis and discuss the implications for pharmacy practice.

2.4 Research questions

- 1 - Can different approaches to translation of a questionnaire enhance its equivalence to the original tool?
- 2 - Is the translated tool valid and reliable for use in a Portuguese patient sample?
- 3 - Are patients' desires for information, perceptions about medicines and illness the same in different countries?
- 4 - Are patients' desires for information, perceptions about medicines and illness the same across the health care interface?
- 5 - What are the determinants of patients' medicines taking behaviours?
- 6 - Can patients' perceptions be measured in the chosen setting? How useful and feasible is it?

2.5 Hypotheses

H0₁: Patients' desires and perceptions are the same in the UK and in Portugal

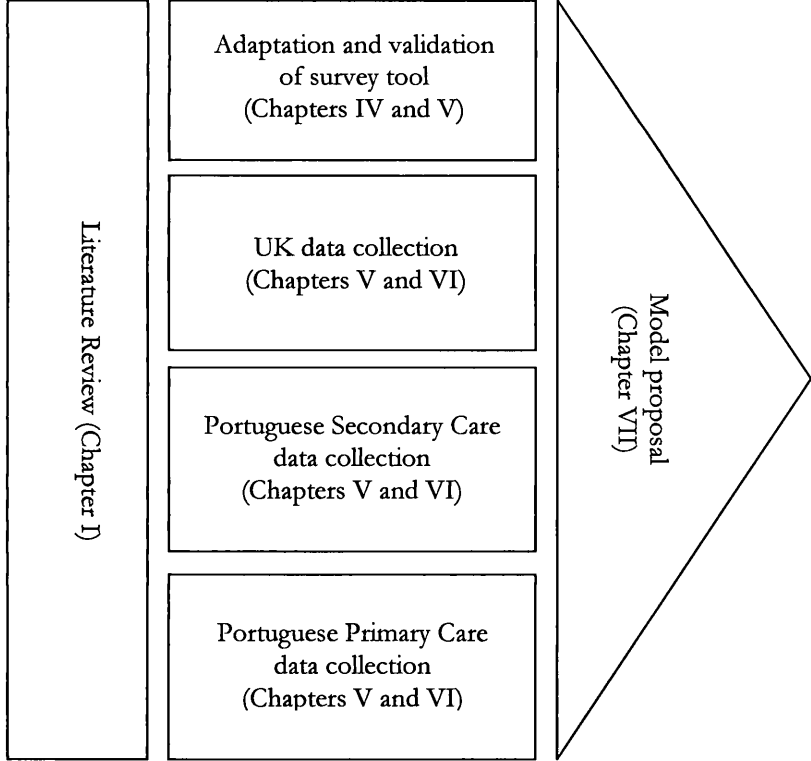
H0₂: Patients' desires and perceptions are the same in secondary care and in primary care

H0₃: Patients' desires and perceptions are the same independent of the demographic variables

H0₄: Patients' desires and perceptions are the same independent of the medical condition

H0₅: Patients' compliance may be predicted by the scales used and patients' characteristics

2.6 Study structure



CHAPTER III

MATERIALS AND METHODS

3.1 Perspective

The purpose of chapter III is to provide an overview of various research methods used in health services research. These are summarised and appraised in relation to the research questions posed in this thesis. Chapter III is divided in three main sections. Section one provides a general overview of research methods, sections two and three are dedicated to those pertinent to this thesis; methods for questionnaire adaptation and for questionnaire validation while section three reviews data management, issues around sampling, piloting, data collection and ways of analysing different types of data, focusing on the type of processes, data and analyses used in these studies.

3.2 General overview on different research methods

A general overview of the different research methods that may be used to inform practice is provided in this section. Medicine, as a closely related profession to pharmacy, was the first profession where the developments in practice had to be supported by research evidence. Since the early 1990s the concept of evidence-based medicine was introduced, advocating that every health care decision ought to be based on the best available evidence:

“Evidence-based medicine is the conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual patients”. (Sackett et al. 1996)

This concept was later adapted in pharmacy practice, where for example advice-giving needed to be based on available evidence to meet the clients’ needs (Smith 2000b). Nowadays, the importance of evidence to support practice is widely accepted, but it goes further than that. Evidence is essential to inform professional development and to improve health care delivery (Bond 2000).

In the UK in particular, this concept has been embraced by policy and health-care decision makers. In 1998, the Government produced the White Paper “The NHS Plan: A plan for investment, a plan for reform” defining clinical governance.

“Clinical governance is the framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence flourishes”. (Department of Health 1998b)

The difficulty often encountered is putting evidence into practice. Sometimes, research findings are not so applicable to everyday practice or are disseminated in a way that is not accessible to practitioners. Difficulties in judging the quality of published literature is an additional problem that practitioners may come across when trying to implement research findings into their routine practice.

To help with such judgements, the Cochrane Collaboration has defined levels of evidence and guidance on which study designs provide the soundest evidence. The study design providing the “strongest” evidence is the randomized controlled trial (RCT), often called the gold standard for studies such as clinical trials (Bowling 2002c). Evidence decreases in robustness (generalisability, etc) through the case control trials, controlled before and after studies, observational data and case studies (Bond 2000). Nonetheless, the value of combining different approaches to data, combining qualitative and quantitative techniques has also been acknowledged as a valuable way to inform one another and ensure that key issues are covered (Bond 2000). All these methods have their pros and cons and none should be disregarded before carefully evaluating the research question under investigation.

3.2.1 Different study designs

In this section the types of study are described by the Cochrane Collaboration. Additional study designs are briefly explained to provide a wider context for the possible approaches that can be taken in health services research.

3.2.1.1 Quantitative methods

Studies comprising the first three levels of evidence measure effects, and are often longitudinal in design, following the same patients over time. These types of studies are useful if one intends to evaluate causal relationships because the sequence of events is clear (Hennekens & Buring 1987c). One example of such a study is the evaluation of radiation exposure, where those exposed are compared with non-exposed for the appearance of the disease (or phenomenon of interest).

Randomised Controlled Trials (RCTs) are similar to cohort studies, the difference being that in RCTs the researcher controls the exposure whereas cohort studies are observational, *i.e.*, the researcher does not interfere with the exposure and simply evaluates its effects in terms of events, generally expressed as the attributable risk of the event from the exposure. RCTs are commonly used in clinical trials (Bowling 2002c). Patients are randomly allocated to either intervention or control group, which generally correspond to treatment or placebo, respectively. Patients are blinded to which group they belong, health care professionals are preferably also blinded (double blinded allocation) and sometimes even the researchers (triple blinded). Patients are followed prospectively to observe the impact of treatment on their illness (Hennekens & Buring 1987a). This type of study is not used as frequently as desirable in health care services research due to practical and ethical factors, since depending on what is known beforehand about the intervention, it may not be acceptable for pharmacists to provide a service believed to have an added value only to intervention patients.

Quasi-experimental studies are sometimes seen as a feasible version of RCTs, also described as a type of prospective cohort study, generally called intervention studies. The difference between cohort studies and quasi-experimental studies is identical to what has been described for the RCT, *i.e.*, it is the fact that in quasi-experimental studies the exposure is determined by the researcher, who can for instance decide which pharmacies will be providing the service and which will not. The exposure of interest can be for instance a new form of health care delivery, for which the impact will be assessed (Hennekens & Buring 1987d). These have also been described as community trials (Lilienfeld & Stolley 1994).

Cohort studies are often used to determine aetiology of disease assessment, for example to observe the incidence of infectious diseases. In a traditional cohort model patients are followed prospectively, included in the cohort based on the exposure of interest, for example having been to a party where contaminated food was served. When selected into this type of cohort they all have to be free of the event, which generally corresponds to the illness being studied. They are then followed up to observe the incidence of a given disease (Hennekens & Buring 1987b). The risk of

getting a disease is expressed as the risk attributable to the exposure [Attributable Risk (AR); Risk Ratio (RR) or Relative Risk (RR) *e.g.*] (Hennekens & Buring 1987a). This design is often used to assess rare events, in which case large samples are needed over several years, which is a major reason for the limited application of this design in health services research. Additionally, when measuring attitudes this type of study frequently leads to the Hawthorne effect, *i.e.*, study participants will be likely to change their behaviour because they are aware of being observed.

Another approach is to use historical cohorts, where patients are followed up retrospectively. Individuals are also included in the cohort based on their exposure to the risk factor, but in this case the disease has already occurred. These studies were used during the discoveries of various cancers and other diseases with long onsets, such as malformations occurring in children of women exposed to thalidomide (Bowling 2002c; Hennekens & Buring 1987b). Again this study is inappropriate for attitude measurement due to the likelihood of occurrence of recall bias, which could be greater when studying chronic patients whose average age facilitates this effect.

Case control studies may be seen as the opposite to cohort studies in terms of where the researcher starts from. In case-control studies, the focus is on the event, and those where the event is present (*e.g.* a given disease) are evaluated in terms of their past exposure. Similarly to cohort studies, results are expressed in terms of risk; however, in this case the risk is presented as Odds ratios (OR) (Hennekens & Buring 1987a).

Before and after studies comprise a longitudinal design where one single group of patients is followed throughout time. This type of study may be useful when a new intervention is being developed and tested. The analysis of the data compares baseline values with those at the end of follow-up, assuming that any changes are due to the impact of the service. The obvious limitation of this design is that there is no way to guarantee that changes could not be attributable to other factors external to the intervention itself (Smith 2002a). However, it provides useful insights for those designing the service, especially when few changes are introduced at once. This design may be followed by using a control group once implementation is achieved to demonstrate the value of such a service *e.g.* to decision-makers. This was the

approach taken in Portugal when implementing pharmaceutical care programmes in community pharmacies nationwide (Costa, Santos, & Silveira 2005; Santos et al. 2005). The priority was to implement the programmes, hence complex and research-led interventions were not considered appropriate. Analysis of the data obtained until now has been undertaken by before and after comparisons, which provide useful insight into the process but are not robust enough to provide evidence on added value of the pharmacist's interventions. At this point in time, a controlled study is being set up to provide feed-back to the Government for reimbursement purposes.

Cross-sectional studies are descriptive studies which capture reality at one moment in time. These studies cannot be used to evaluate the effect of an exposure because the time sequence is not clear so it is unknown to the researcher if the exposure or the effect occurred first. However, this study design is the most suitable for describing a situation and raising hypotheses, which can then be further investigated through longitudinal study. They are often used to measure the prevalence of a certain phenomenon (Bowling 2002d; Hennekens & Buring 1987c).

There are more complex designs, such as the case-crossover and the nested-case control designs. However, these are beyond the scope of this thesis as they are hardly applicable in health-services research.

3.2.1.2 Qualitative methods

When a new area is being investigated it may be particularly useful to combine these methods with a more interpretive approach to gain insight into possible reasons for patients' behaviours. For such a purpose, qualitative methodology is useful.

A characteristic of qualitative approaches is that no single methodology is seen as gold standard and in all methods; emphasis is put on processes and meanings. Qualitative methods have as such been described as a set of interpretative practices (Denzin & Lincoln 1994). In this section, a general approach to the use of qualitative data is described, highlighting the major steps in the process of data collection and analysis.

The nature of qualitative inquiry has two important implications on the sample chosen. Through this method the researcher aims to collect rich data and it is not important from how many participants this data comes from, the adequacy of data refers to how the content meets the aims of the research. The most common methods of sampling used are convenience, purposive, snowballing and theoretical sampling (described in section 3.4.1). It is widely accepted that 12 to 20 individual interviews and 8 to 12 participants in a focus group are enough to saturate data, *i.e.*, reach the point where no new themes emerge, although there is no consensus on these numbers. These are the two most commonly used data gathering techniques in health services research (Bowling 2002i).

Individual interviews can take the format of unstructured, semi-structured interviews and structured (also called interview surveys). Interview surveys are similar to self-completed questionnaires but occur in the presence of an interviewer (Smith 1998). Their advantages compared with self-administered questionnaires are that generally the response rate is higher and they allow the use of prompts or probes (Moore 2000). These are not necessarily qualitative and may provide generalisable descriptive data.

In semi-structured interviews, the interviewer records the patients' answers verbatim. Prompts can also be used but it is mostly spontaneous answers that are the focus of interest. When using in-depth interviews the interview guide may cover fewer issues in greater detail. The respondent is given enough time to think about their views and is encouraged to explain them. There is no fixed sequence on the issues to be debated but a background to the study and issues to be explored during the interview are presented at the beginning. Some authors purport that the sample size is dependent on the research questions being explored and emerges during the course of analysis when emergent themes are saturated (Bowling 2002i; Pope, Ziebland, & Mays 2000), whilst others have suggested from previous experience that such stage is usually achieved when 20 to 30 interviews have been conducted (Moore 2000) and others mentioning 30 to 50 but recognising the dependence on the research question (Pope & Mays 1997). It is uncommon to see studies where large samples are used for in-depth interviews, but especially when linking qualitative and quantitative data, such an approach may be useful, although time-consuming. This was the case in a 2-stage

study where 120 interviews were conducted (Mason 1994) and is the approach taken in the current project.

Unstructured interviews are often used when the research question addressed is new and needs more detailed insight into interviewees' views on the topic. It strongly depends on the experience of the interviewer to be flexible enough to conduct the interview as issues emerge but focused enough to stick to the topics central to the research (Samuels, Guerreiro, & Tully 2005).

Focus groups or group discussions have the advantage of allowing people to share and defend their views in light of others. The interviewer's role is to act as a moderator, encouraging debate and ensuring each person has the opportunity to speak. Generally only three to four topics are covered and prompts may also be used to clarify any issues debated. Focus groups have been described as informal group discussions ideally between 8 to 10 participants (Samuels, Guerreiro, & Tully 2005) or 6 to 8 people (Pope & Mays 1997).

It is important to distinguish between group discussions and focus groups and group interviews, where the latter should reflect issues relevant to the participants rather than following a pre-determined set of questions (Smith, Francis, & Rowley 2000). This approach has been used in studies looking at chronic patients' perspectives about long-term medication, providing useful insights into the views and concerns of different patient groups (Smith, Francis, & Rowley 2000). Patient groups are often used, which inevitably introduces a self-selection bias as patients belonging to such groups may have particular characteristics. They may therefore not be representative of all patients but that may not be a problem for the issue under investigation.

3.2.1.3 Consensus Methods

There are three main types of consensus methods: the Delphi process; the nominal group technique; and the consensus development (or expert) panel. In the Delphi technique, a survey is sent to a large number of participants, who are asked to answer a series of questions. Responses are compiled and resent for ranking until a "consensus" is reached. This method has the main advantage of allowing data collection from a large sample of experts in an inexpensive manner but it can be very

time consuming and consensus is difficult to reach (Bowling 2002a). In the consensus development panel, a group of experts in the field of interest gathers to debate the issue under exploration and the interviewer acts as a facilitator to achieve consensus. This method is used when knowledge or understanding about a new area needs to be gained. A small sample can be used, which may have practical advantages (Bowling 2002a), for example a nominal group technique uses a group of around 12 is gathered, having been previously informed of the issues to be discussed (Bowling 2002a). One possible approach to seek patients' views on the best wording for a questionnaire (as in this thesis) is to use vignettes, scenarios that are presented to participants asking them how they would react in such situations. This technique has wide application, having been used in surveys (Mason 1994) but is most often used in qualitative research.

3.3 Questionnaire Design, Adaptation and Validation

This section describes different approaches that can be taken to explore perceptions by means of a survey tool. A survey tool can be developed from the beginning, in which case, the processes most commonly used are detailed in section 3.3.1 or adapted from a previously existing tool, in which case the procedures to be taken into account are scrutinized in section 3.3.2. In either case, the validation of the survey tool is the process that ensures that the tool measures what was designed to measure, producing credible results. These issues are addressed in section 3.3.3.

3.3.1 Questionnaire Design

When designing a questionnaire, the researcher must focus on two aspects, what is to be measured and how it is to be measured. The first aspect relates to the content and questions to be included must focus on the theme to be investigated (Smith 1997b; Streiner & Norman 2000). These may come from literature or from experts in the area or from participants' ideas or a combination of both.

The second aspect of questionnaire design relates to the format, where different ways to assess participants' views must be considered. One option is to keep questions open, allowing respondents to share their views in their own words (Bowling 2002e). This possibly provides the researcher with a greater insight into the research theme but it may decrease the response rate and considerably increase the burden on

participants and researcher in terms of data management. For these reasons, open questions are generally used in early stages of questionnaire development or in combination with semi-structured questions, to allow respondents to clarify their previous responses.

Closed questions may appear in different formats. Single items are not often used in health services research because they provide very little information, except when the respondent is asked to rate their perceived health status, which can then be used to validate other measures or scales. Batteries are groups of single items and provide extra information. These, however, must be analysed independently and their scores cannot be summed. When their scores are to be summed, they are called scales (Bowling 2002e).

Scales

A commonly used scale is the Likert scale but there other scaling methods, such as the Thurstone or the Guttman method. The Thurstone method is based on ordering dichotomised response options, obtaining the final score by summing “yes” responses to provide an indication of the degree *e.g.* of disability. The Guttman method is based on the same principle but allows each item to have more than 2 response choices, although the final scoring is obtained the same way. The Nottingham Health Profile (NHP) and the Beck Depression Inventory (BDI) are widely used tools, the first having had its weights derived from the Thurstone method and the latter using a Guttman scale with 4 response choices (Bowling 1997). Likert scales appear in the form of statements where the respondents are asked to answer according a continuum of agreement. The most common are 5-point scales, used *e.g.* in the Diabetes Quality of Life measure (DQOL) (Jacobson & The Diabetes Control and Complications Trial Research Group 1994). Though 7-point scales are used, variants include the visual analogue scale (VAS) and the numerical forms, both anchored in their extremes by total agreement and disagreement (or equivalent) (Bowling 2002e). Some instruments use different scaling methods throughout the questionnaire. The General Well-Being Schedule (GWBS) is such an example, where one section uses a VAS anchored in the extremes “not concerned at all” (0) and “very concerned) (10) (Bowling 1997). Another variant of a 5-point scale used in the COOP/WONCA is the use of charts illustrating different degrees of *e.g.* physical

activity. Similarly, the Delighted-Terrible Faces (D-T) scale uses a 7-point quality of life scale illustrated with faces to enable cognitive evaluation (Bowling 1997).

3.3.2 Questionnaire Adaptation

When an existing survey tool is deemed suitable to meet the aims of the research it may be unproductive to develop a new one. In Portugal, as is the case in many non-English speaking countries, it is not so common to find a survey tool that meets the research aims that has been developed in Portuguese or adapted into Portuguese ensuring its validity and reliability. In these countries the cross-cultural validation of survey tools is therefore of major importance. Lately, the general issue of cross-cultural adaptation has been increasing even in English speaking countries, partly due to the enlargement of European Union. Multi-centred research projects have greater relevance in this context and therefore the development or adaptation of methods that allow further comparisons between countries involved is of major importance to EU policies and strategies.

Different authors have proposed different methods to ensure that the adapted tools are equivalent to the original and to enable accurate and comparable results, independently of the setting. Probably the most widely used translation model is the Brislin's model, where the process consists of two cycles of forward and back translation performed by independent bilinguals (Brislin 1986). The addition of a rewriting step by a monolingual between step 1 and 2 is suggested when the researcher performs step 1, which in most cases means that his knowledge of the target language is insufficient. Pre-testing of materials is always recommended, with a minimum of 10 respondents to verify understanding.

The most well established guidelines define a progressive process where the forward and back translation steps are followed by a committee review, pre-testing for equivalence and finally the re-examination of the weighting of scores. The proposed pre-testing methods are either a probe technique or bilingual lay people. The recommended methods for re-examination of weighting of scores are the Thurstone method, the Guttman method or factor analysis, the latter chosen in this project (Guillemin, Bombardier, & Beaton 1993). By undertaking factor analysis in a new pool of items following translation, the researcher may check if the domains

previously described are maintained and if the same items or if weighing techniques need to be used to allow future comparisons.

Standardized procedures in international research are necessary for increased sharing of information. The MAPI research institute, based in France, was created to do this with three main areas of expertise, one being linguistic validation. The model proposed by MAPI includes forward and back translation steps, followed by review by the questionnaire's author, cognitive debriefing and proofreading, and testing in a target population, this latter with the aim of evaluating maintenance of psychometric properties of the original tool (MAPI Research Institute 2005).

Another approach has evolved using this method as a framework, where the main differences are the inclusion of rating steps. Six translators are involved, where the role of the first two is to rate the difficulty of translation, translators 3 and 4 rate the quality of translation in terms of clarity and common language, and translators 5 and 6 are responsible for back translations, which are then rated in terms of equivalence with the original (Bullinger et al. 1998). A limitation of this approach is that there is little input from lay people and the ratings is with percentage rating scale. Using a minimum of 30 raters to compare the language and similarity of interpretation between original and back-translated version has been suggested as a means of checking for "correct back translations of incorrect translations" (Sperber 2004). A 7-point Likert rating scale has been proposed, which has the advantage of relating ratings with attributes.

Several adaptations to the initial methods have been suggested. An adaptation of Brislin's Translation Model involved two bilinguals in the translation step and another two in the back translation step, who should then meet for discussion and refine the translated tool. Two other bilinguals would be needed for the new back translation, followed by a second meeting. This iterative process is sustained until the team agrees on meaning in both languages. The final step is the validation and verification of the reliability of the back-translated version using a bilingual sample (Jones et al. 2001).

Taking into account the strengths and limitations of each method reviewed, a method was developed adapting both MAPI's model and incorporating Guillemin's guidelines. A rating model combining the process described by Bullinger and Sperber was adapted and used for the purposes of this thesis, further described in chapter IV.

3.3.3 Questionnaire Validation: issues of validity and reliability

When a questionnaire is developed, its validity and reliability need to be ensured. Validation is the process that determines if the questionnaire measures what it intends to measure (Smith 1997b). There are several forms of validity, which can be seen as steps to be followed to ensure the tool's validity.

Content validity checks to what extent the items are sensible and reflect the intended domain of interest (Streiner & Norman 2000). This is related to the comprehensive coverage of relevant issues to serve the adequacy of its content and contributes to the reason why content validity is problematic when measuring attitudes, which can be very complex (Openheim 1992). Items developed result from expert opinions, a review of published data, and patient interviews. Items subsequently considered redundant should be excluded; their relevance can be evaluated by an expert panel and/or by patients. The questionnaire used in this research resulted from patient interviews, the statements represent the way patients expressed themselves, thus were inherently valid.

Face validity involves checking all the items of the questionnaire appear in a clear and unambiguous way. It is intimately related to content validity and involves the critical revision of the instrument by experts and patients (Streiner & Norman 2000).

Criterion validity considers if the scale is empirically associated with external criteria, such as other established instruments (Streiner & Norman 2000). Because health services research is a fairly new research area instruments available to be used as gold standard are often scarce.

Construct validity examines the inter-item relationships, and relationships between the items and hypothesised scales. Among all types of validity, construct validity is the one most likely to be numerically examined by appraising these coefficients

which represent how much each item contributes to a factor and how much shared variance it has with other items (Fayers & Machin 2000). A cut-off of 0.4 for factor loadings has been suggested as high enough to characterise the factor (Todd & Bradley 1994). However, it has also been stated that construct validation is an ongoing process and that there is no single experiment able to attest the existence of a construct (Streiner & Norman 2000).

Reliability determines if a scale measures the concepts of interest in a reproducible and consistent manner (Streiner & Norman 2000). Consistency can be defined in terms of stability over time, equivalence obtained by two parallel forms and internal consistency; the methods used to estimate it vary accordingly. Multiple-item scales should be consistent in the sense that they should all measure the same property (Smith 1997b). The Cronbach's alpha is a statistical measure reflecting the correlation between all items part of the same measurement, often used to assess the internal consistency of the various dimensions of the questionnaire (Streiner & Norman 2000). Different authors have proposed distinct interpretations of this measure, with some defending a minimum of 0.85 and others a maximum of 0.7 (Smith 1997b; Streiner & Norman 2000). It should also be taken into account the number of items in the construct as this directly influences the interpretation of the alpha estimate (Todd & Bradley 1994). Other forms of reliability include the stability of the measurement over time, which is commonly evaluated by means of test retest using paired samples t-test (Streiner & Norman 2000). Factors associated with a low reliability include the use of ambiguous words, variation on the administration method, or even the measurements of concepts that may change respondents' attitudes just by asking them. Finally, reliability can also be expressed in terms of agreement between different observers, commonly measured through Cohen's kappa, a coefficient indicating the shared agreement while taking into account random error (Streiner & Norman 2000).

Generalisability, also known as external validity, evaluates to what extent the study results are applicable outside the sampling frame. The most important factors for generalisability are the sampling procedures, sample dimensions and response rates (Bowling 2002f).

Discriminatory power concerns the ability of the measurements to achieve a good spread of scores, which reflect differences between patients or groups of patients with different characteristics (Bradley 1994; Todd & Bradley 1994). This ability to correctly classify patients in either group has long been known as specificity and sensitivity, mostly used in medical research and practice when evaluating the ability of tests to accurately classify cases as positives (sensitivity) and non-cases as negatives (specificity), conversely minimising false positives and false negatives (Lilienfeld & Stolley 1994).

Responsiveness or sensitivity to change is related to the ability of a scale to detect changes when a patients' status changes, *e.g.* blood pressure getting controlled (Bowling 2002g; Todd & Bradley 1994). This measure can somehow be compared to precision, an attribute traditionally valued in epidemiologic research, which describes the ability to detect small changes (Bowling 2002g).

Discriminatory power can be evaluated through cross-sectional studies, but responsiveness needs to be evaluated longitudinally. One of the possible ways to evaluate discriminatory power is by exploring significant difference between groups of patients, which can be tested using independent-samples t-tests or ANOVA, according to the number of samples involved.

3.4 Data Collection and Analysis

The following section reviews different sampling methods and focuses on the methodological issues most relevant to the current research.

3.4.1 Sampling

Sampling is the procedure whereby a proportion of the population is selected to be studied. Ideally the sample should represent the population from which it was extracted, for which probability samples are needed. However, non-probability samples are often also used for several reasons, including feasibility, ethical constraints and the type of research question, *e.g.* purposive sampling may be the best way to ensure different perspectives are explored in qualitative research.

In probability samples each individual in the population has an equal chance of being selected (Smith 1997a). The most accurate of way of selecting a probability sample is by means of random number extraction. There are three other types of sampling often wrongly referred to as random samples; these are not strictly random as not every individual of the population has equal odds of being selected, but are so called because they are obtained by means of probability. These include stratified, cluster and systematic samples. In stratified and cluster sampling the population is divided into mutually exclusive groups (strata) or into clusters with shared characteristics and then randomly sampled (Smith 1997a). In a systematic sample *e.g.* every tenth participant is selected; it should be noted that this latter procedure is the least random as it uses a sequential selection method and often there is no guarantee that the order of *e.g.* entering a pharmacy has no influence on the studied phenomenon.

In non-probability samples, participants do not have equal chance of being included and therefore no claims of representativeness may be made. These include quota, purposive, snowball, theoretical and convenience sampling (Bowling 2002f). In quota sampling the researcher chooses a convenient setting for recruitment (*e.g.* shopping centre) with previous estimates of the proportions needed of each quota (male *vs* female *e.g.*) (Bowling 2002f; Smith 1997a). The selection, therefore, depends on specific attributes of individuals, including the likelihood of attending such a location and having the characteristic of interest. Purposive sampling is a judgemental type of sampling, where participants are deliberately chosen according to their knowledge about a particular issue for the very purpose of exploring their views (Bowling 2002f). Snowball sampling is a technique often used where people with particular characteristics are of interest to the research question, such as opinion leaders; through this technique the initially selected participants are asked to suggest new participants (Bowling 2002f). Theoretical samples are also common in qualitative research, which are generated during the course of data analysis by identifying attributes of interest worth further exploration (Bowling 2002f). Convenience samples comprise the most readily accessible participants (Smith 1997a). However, the convenience criteria is often omitted from reports, which is relevant as it may vary widely, *e.g.* geographical location or friends of the researcher, which may have different impact on the results presented.

3.4.2 Piloting

Before a study is undertaken, materials and methods should be tested to ensure that they are suitable, feasible and gather valid and reliable information for the purpose of the research (Smith 2002b). For example when questionnaires are used, prior testing allows the researcher to gain insights into the patients' views about the relevance of items and how they understand the wording. There is no standard regarding the number of patients that should be included although 12-20 in-depth interviews has been suggested as appropriate for the purpose of testing the questionnaire design (Bowling 2002e). Others have suggested previously sending a draft of the questionnaire to one or two experts in the field (Moore 2000). In order to pilot the chosen methods, to ensure the research's aims will be met and the setting, length of study, data collection tools, are appropriate, the same conditions as the real study needs to be used for the pilot (Moore 2000). Again, there is no consensus on the number of patients that should be included, but the use of 10% of the survey sample size is widely accepted.

3.4.3 Data Issues

These sections have provided an overview of different approaches that should be considered when designing a research study. The next sections deal with specific issues referring to the thesis.

3.4.3.1 Data manipulation

Surveys generally comprise several variables, which are coded and subsequently entered into SPSS version 13.0 for the purposes of analysis (Bryman & Cramer 2001). The different types of analysis undertaken are described under the appropriate section.

Qualitative data are often transcribed into QSR NUD*IST (revision 4.0) for coding (Richards & Richards 1990). Codes may be illustrated using extracts from patient interviews. Emergent themes from the interpretation of transcripts are analysed, interpreted and tabulated. This software is also suitable for interfacing qualitative and quantitative data through matrices.

3.4.3.2 Quality control

Following data entry, a quality control procedure ensures that data is error free and that coding was accurate. Data entry is first verified by printing frequency tables of all variables looking for improbable and impossible codes (Bowling 2002b). Then a sample is taken and both data coding and entry are checked. Data are compared between the original written questionnaires and data entered in the database. The number of acceptable errors was calculated using the quality level of 2.5% (Besterfield 1990). Whenever errors are detected, the type of error is examined; if systematic errors are detected the whole database is checked for the variables in question. Other types of error are quantified and then corrected.

3.4.4 Methods of analysis

This section provides a description of the important concepts associated with analysis relevant to the thesis.

3.4.4.1 Quantitative analysis

Data analysis comprised descriptive statistics to characterise the samples and inferential statistics to explore associations between variables, *e.g.* chi-square tests. Pearson's or Spearman's correlations were used to explore correlations between variables (for normal distributed and not normal distributed data, respectively) and T-tests to compare means between the same sample in two different time moments (paired-samples t-tests) and between two independent samples (independent-samples t-tests). Comparison of means between more than two samples was undertaken by means of analysis of variance (ANOVA) and when necessary post-hoc tests were used to further explore differences.

A substantial part of the work undertaken in this thesis focused on the cross-cultural adaptation of the survey tool, which involved factor analysis and reliability analysis techniques, which are further detailed in the following sections.

3.4.4.1.1 Factor analysis

Factor analysis is a technique used to determine empirically how many constructs or factors underlie a set of items and defines the meaning the latent variable (factor) that account for variation among a larger set of items. This technique is widely used, for

example in quality of life measures, to determine which group of single variables contributes to a particular dimension, such as physical impairment. It comprises correlation, extraction and rotation.

Firstly, a correlation matrix is presented, with all possible correlations for each individual variable. The most widely used extraction method is Principal Component Analysis (PCA), which involves several steps. The Kaiser-Meyer-Olkin (KMO) measures the sampling adequacy, while the Bartlett's test of sphericity indicates if factor analysis is an appropriate technique *e.g.* such technique cannot be used for dichotomous variables neither would it be appropriate to mix different scales in the same analysis, so these tests serve as an alert-type measure. The communalities table indicates how much each of the variables contributes to the total variance. To decide the minimum number of factors that explain the maximum variance, the researcher interprets the Total Variance Explained Table and the Scree Plot.

The choice of the rotational method relates to the assumed relationships between factors. If factors are assumed not to be correlated, orthogonal methods should be used (*e.g.* Varimax). If on the other hand, factors are assumed to be correlated, an oblique rotational method is the most appropriate (*e.g.* Direct Oblimin). The final rotated solution to be interpreted by the researcher appears in the form of a Structure Matrix. It is often easier to include only with loading values over 0.3 and to order the presentation. The final matrix is the component correlation matrix, which presents the coefficient values associated with the way factors are related between them (Bryman & Cramer 2001;Kline 1994).

3.4.4.1.2 Reliability analysis

Factor Analysis empirically extracts items related to the same factor. This is generally followed by reliability analysis to test the internal consistency, where the researcher checks if the items within the extracted factors all relate to the same construct.

The inter-item total correlation is a specific form of a Pearson test that indicates the strength of the relationship between a specific variable and the overall scale. The higher this coefficient, the stronger the relationship and should be interpreted along with Cronbach's alpha estimates. When interpreting the Cronbach's alpha estimate,

attention must be put on the alpha if item deleted for each variable, which is to be compared to the overall scale estimate. This means that if the alpha estimate correspondent to a specific variable is lower than the one associated to the overall scale, the scale's internal consistency would increase if this variable was deleted from the overall scale (Howitt & Cramer 2000).

Test-retest reliability is analysed by using parametric (paired samples t-test) or non-parametric (Wilcoxon signed ranks) tests to compare between the means (or medians, respectively) of the 2 paired samples. If the means or medians differ then it might be worth comparing the proportions to explore into further detail where differences occur. In such case the McNemar or the Wilcoxon-sign rank tests may be used, respectively. Cohen's Kappa is another method to test inter-rater agreement, a measure which also takes into account the error associated with chance (Howitt & Cramer 2000). This procedure is useful for assessing accuracy of coding where no standardised guidelines exist; *e.g.* the case of patients' stated occupation, further examined of where the discrepancies occurred led to using consensus techniques between coders to solve them.

3.4.4.1.3 Discriminatory power analysis

Discriminatory power looks at scores obtained by different subgroups of patients, *i.e.*, independent samples. If the comparison is between mean scale's scores between 2 samples, the independent samples T-test ought to be used, whilst if more samples are being considered the One-way ANOVA will be the most appropriate. In the latter, one will not know which subgroups are responsible for the differences detected unless ad-hoc tests are performed. These tests are used if data is normally distributed (and the sample is bigger than 30), otherwise the Mann-Whitney U and the Kruskal-Wallis tests should be chosen, respectively for 2 and k samples.

3.4.4.1.4 Regression analysis

Regression analysis is a predictive technique where the values of one or more independent variables can be used to estimate the value of the dependent variable. When there is one single independent variable regression is named simple, as opposed to multiple regression where several variables are used in the model (also called covariates) (Hair, Anderson, & Tatham 1987; Hosmer & Lemeshow

1989;Smith 2002c). Depending on the nature of the dependent variable, linear (continuous) or logistic (dichotomous) regression may be used (Hosmer & Lemeshow 1989). These techniques rely on the strength of relationships between variables indicated by the correlation coefficients (Cohen & Holliday 1996). The model obtained that best fits the data is the one where the higher amount of variance is explained. Being a predictive technique there is also room for error, which will be the minimum possible in the final model, but which results from the difference between the predicted value and the real value. These errors associated with prediction are called the residuals (Hair, Anderson, & Tatham 1987).

Logistic regression may be seen as an extension of linear regression, but for which some specific tests are more appropriate. Namely, the Wald test which estimates the significance of the partial logistic coefficients predicting if they should stay in the model, the Hosmer-Lemeshow statistic (C), is compared against the χ^2 test to infer the model's goodness of fit. The Pearson or Deviance residuals are used for model diagnosis to analyse its graphical representations (real against predicted) (Hosmer & Lemeshow 1989). The general equation that is used for logistic regression is:

$$g(x) = \beta_1 + \beta_2 x_1 + \beta_3 x_2 + \dots + \beta_p x_{p-1}$$

When interpreting the outputs, the $\hat{\beta}$ is the estimated value for the possible x coefficients and the Ψ is the multivariate equivalent to the odds ratio, which always refers to its comparison against the reference category. Logic functions are also a unique feature of logistic regression but are not used in this study.

Table 3.1 – Some applications of regression techniques in health research

Authors, year	Independent variable	Dependent variables	Summary/particularities	Setting
(Martins et al. 2002)	Self-medication	Demographic characteristics and use of health services	Large sample Repeated in different seasons	Portugal Community pharmacy Rural and urban locations
(Paulino et al. 2004)	Occurrence of drug-related problems (DRPs)	Patient demographics, therapy variables (e.g. number of drugs Rx; therapy changes)	Patients included if recently discharged from hospital	European collaboration Community pharmacy
(Cranor & Christensen 2003)	Illness status improvement	Involvement in diabetes-specific pharmaceutical care programmes	Aimed to assess effectiveness of programmes	US, Ashville Community pharmacy
(Ferreira 2002)	Prescribed hypertensive treatment	Patients medical and demographic data	Analysis performed by multidisciplinary team	Portugal Network of GPs
(Borja-Lopetegui et al. 2003)	Pharmacy workforce	Number and type of activities undertaken	Large sample	UK NHS hospital trusts
(Truett, Cornfield, & Kannel 1967)	Incidence of CHD	Physiological parameters (e.g. HDL, LDL, total cholesterol, triglycerides) Demographics (e.g. age, gender)	Accountable for the increasing popularity of logistic regression (Hosmer & Lemeshow 1989).	Framingham Cohort study

Most relevant to the current project are studies where regression techniques have been used to determine determinants of non-compliant behaviour, where variance explained by the models ranged from 19 to 67% (de Klerk et al. 2003; Horne & Weinman 1999; Schlenk & Hart 1984). In these studies, different socio-demographic variables and socio-cognition models were used as potential predictors of patients' medicines-taking behaviour. Many of them are difficult to compare, mostly because different definitions of compliance have been used and different methods for measuring it have also been employed. Nonetheless, it may be stated that regarding demography, gender is generally found to have no effect, but there are exceptions (Kiley, Lam, & Pollak 1993), whereas age is most often mentioned as influencing compliance. Regarding social-cognition models, coping patterns (de Klerk, van der, Landewe, van der, Urquhart, & van der 2003), health locus of control (Kiley, Lam, & Pollak 1993; Schlenk & Hart 1984) and self-efficacy (Baines, Joseph, & Jindal 2002)

have shown some success in predicting adherence behaviour. Surprisingly, from these studies the one where the lowest variance was explained used patient' beliefs about medicines as an important explanatory variable (Horne & Weinman 1999).

3.4.4.2 Qualitative analysis

Qualitative analyses include discourse analysis, content analysis and phenomenography (Miles & Huberman 1994). Content analysis is a systematic form of exploring what people say and what it means. Interview transcripts or field-notes form the raw data of qualitative analysis, which can be stored and analysed using computer-assisted programmes (Pope, Ziebland, & Mays 2000).

The procedure has mainly three stages: analysis, description and summary (Posner 1994); which have also been described as data reduction, data display and verification of conclusions (Miles & Huberman 1994). It has been argued that simultaneous analysis and data collection are almost inevitable because the researcher is immersed in both processes (Pope, Ziebland, & Mays 2000).

A unique characteristic of qualitative coding is that the categories or themes created do not necessarily need to be mutually exclusive (Bowling 2002h). These analytical categories may emerge inductively from the data or be deductively created from a pre-established coding frame (Pope & Mays 1997). Whichever approach is taken, the categorisation process is particularly important as subsequent interpretation depends on unbiased coding. One possible way of ensuring an accurate procedure is by having a second investigator checking the attributed codes (Bowling 2002i). Another way to improve the validity of qualitative analysis refers to the subsequent stage, where the researcher's interpretation of the data is presented. A key stage in explaining the findings is re-analysing the data (Pope & Mays 1997). It has been suggested that a sufficient amount of raw data is used to illustrate each piece presented, so that the reader has enough information to form his own impression of the presented theory (Mays & Pope 2000; Pope & Mays 1997). Additionally, one way to triangulate data is to obtain the same information by two or more different methods of data collection, such as interviews and structured questionnaires, a process that further contributes to increasing the credibility of the findings (Mays & Pope 2000).

3.5 Study Materials

Data were collected in several formats according to the study phase. The following diagram illustrates the study materials used in these different phases in summary, which are detailed further in the appropriate sections.

Table 3.2 – Summary of materials and variables used in each study phase

Study phase	Study materials	Variables
Translation and back-translation phase	Documentation form for each translator	Statements to be translated Scales to be translated
Rating phase	Rating sheet for each rater	Statements in 2 versions to be compared and rated
Health care professionals' group work	Background information Documentation form for each group Audio-tape recorder	List of statements for review
Lay panel	Interview guide Flipchart for presenting statements when seeking consensus Audio-tape recorder	Vignettes to be debated
Hospital recruitment	Invitation to participate in the study Informed consent form Interviewer administered questionnaire Refusal form	Demographic data Therapeutic data from chart Medical data from chart Scales (EID, PUM, AI) Open questions (1 per scale) Self-reported compliance
Community pharmacy recruitment	Invitation to participate in the study Informed consent form Self-administered questionnaire Refusal form	Demographic data Therapeutic data (in prescription, pharmacy software and patient-reported) Patient-reported diagnosis Scales (EID, PUM, AI) Self-reported compliance Section for pharmacist to record help provided and difficulties experienced by patients

3.5.1 Materials used for measuring compliance

Compliance has been defined as “*the extent to which the patient's behaviour coincides with the clinical prescription*” (Sackett & Haynes 1976). Others have defended that the concepts of errors in dosage or timing and simultaneous ingestion of interacting drugs should be included when defining non-compliance (Kent & Dalgleish 1986a). As described in chapter I, three types of non-compliance have been proposed, where one corresponds to patients taking medication in a deviant manner, another implies that the patient fails to take any medication, also termed as null compliance, and finally

the situation where the patient discontinues medication prematurely, also referred by others as persistence with therapy (Farmer 1999). Even though reasons for non-compliant behaviour are still poorly understood, strategies for increasing compliance do not cease to be developed. These strategies have been classified as enabling or stimulating (World Health Organisation 2003). Some examples are the use of new technologies alerting patients to refill their prescriptions or to take their medication (Costa et al. 2005c; Katon et al. 2001).

Direct methods

There are several possible methods for measuring compliance, each of them having its advantages and disadvantages. These can be divided in two main groups, direct and indirect methods (Farmer 1999). Direct methods include the detection and dosing of the drug, its metabolites or markers in blood or urine samples and directly observed therapy (DOT), the latter commonly used in tuberculosis treatment (Barker & Millard 2000). These are certainly the most accurate methods in the sense they guarantee the drug was ingested; however, they are often unfeasible outside clinical trials.

Indirect methods

Most of the methods commonly used in healthcare research fall into the indirect methods category (Farmer 1999). Electronic monitors (medication event monitoring systems – MEMS) are defended by many as the best possible option as they provide exact and comprehensive information on when the drug was removed from the bottle. However, they do not guarantee that the patient ingested the drug after its removal from the vial (Cramer 1991). The same criticism may be made to the pill-count method, through which there is additionally no information on timing compliance, but this latter method is often used due to high costs associated with MEMs. The use of pharmacy records provides readily accessible information with the advantage of the patient being unaware they are being monitored and as such behaving “normally”, something that does not occur in any of the previous methods mentioned, and provide reasons why they all need a washout period for better interpretation of results. The obvious disadvantage is that pharmacy records merely indicate that the patient acquired the drug but not what happens once the patient leaves the pharmacy. Prescribing records function similarly, but do not even provide

information about drug acquisition. Self-report is viewed with suspicion by many and strongly defended by others. Methods for self-report include the use of interviews, patient diaries and survey tools (Farmer 1999). Different survey tools have been developed with the aim of diminishing the likelihood of the social desirability bias or simply because the developers based their research on different theoretical underpinnings. Examples of these comprise the Morisky Medication Adherence Scale (MMAS) (Morisky, Green, & Levine 1986), commonly known as Morisky 4 from which a 9-item version is derived, the Medication Adherence Report Scale (MARS) (Horne & Hankins 2004), the Brief Medication Questionnaire (BMQ) (Svarstad et al. 1999), the Haynes single question (Haynes, McDonald, & Garg 2002) and the Stages of Change for Adherence Scale (Willey et al. 2000), among others.

In the current study, self-report by patients was the method chosen, mostly for the sake of simplifying the process as compliance was not the main outcome. The Haynes question was used as it has been reported to have good accuracy when correlated with alternative methods (Haynes et al. 1980).

3.5.2 Setting for data collection

Data collection was undertaken in distinct settings, at different levels. At the country level, data was collected in the UK and in Portugal. Within the UK, all data was collected at the Royal London Hospital, part of the Barts and the London NHS Trust. In Portugal data were collected in secondary care and primary care settings from different geographical regions. Additionally, data from previous UK studies was used to further explore the data; this was collected in different hospitals, in outpatients' clinics, in domiciliary visits to patients' homes and in community pharmacies. However, UK data from community pharmacy was not explored in this project since it was considered to have doubtful reliability.

3.5.2.1 UK Secondary care

Secondary care in England is organised into Trusts. Hospitals are managed by Acute Trusts, responsible for the hospitals' service and budget, which may be regional, national centres for specialised care and/or attached to universities for teaching purposes. Some of the most reputed Hospital Trusts in London are St Mary's, Barts and the London and Guy's and St Thomas'. Each of these may provide services from

different sites and for different types of care, the number of hospitals belonging to each Trust varies. The Barts and the London NHS Trust is one of the top teaching hospital trusts in the UK and serves essentially the City, East London and Bethnal Green through its three hospitals: St Bartholomew's Hospital, the Royal London Hospital and the London Chest Hospital. Data collection was undertaken at the Royal London Hospital, located in Whitechapel. The hospital has 1300 beds, 180 of which are destined for general medical patients. These are organised in 6 wards according to a medical speciality, each having approximately 30 beds with varying patient turnover. Cotton ward is specialised for cardiac patients; Currie ward is specialised for respiratory patients; Phyllis-friend ward is specialised for endocrine and dermatological patients; Croft ward is specialised for GI patients; and two other wards are specialised for care of the Elderly. The first four wards were used for patient recruitment. The hospital's location and the population it serves have implications on the study as it does not represent the rest of the UK. Whitechapel is a particularly deprived area with a large variety of ethnicity backgrounds and immigrants originating especially from countries undergoing war periods. Different diseases emerge from distinct cultures, language barriers and low socio-economic status; therefore, the provision of care and the conduction of research in such an environment are quite challenging and unique.

Pharmacy services in Barts & The London (BTL)-NHS Trust

Hospital pharmacy in the UK is strongly developed, especially in comparison with the Portuguese reality. The BLT-NHS Trust comprises eight specific pharmacy services: medicines information, clinical pharmacy services, community pharmacy services, technical services, dispensing and supply, interface work and the academic department of pharmacy (ADP). All of these are important in different aspects; the clinical pharmacy services are considered to one of be the most developed in Europe, where its strengths lie on developing specialist pharmacists whose work is based on the wards focusing on drug evaluation, ensuring the patients are adequately counselled about medicines' use previous to discharge, developing prescribing guidelines and working perfectly integrated with all the health-care team. The dispensing and supply, which is still the core pharmacist's activity in many Portuguese hospitals, is here technician-led and supported by robots to minimise pharmacist's workload, which can be used in more specialised services. The ADP

establishes the link between the pharmacy services at BLT and the department of practice and policy in ULSOP. The main aim of the ADP is to integrate research into practice and this is achieved by a two-way process, where clinical pharmacists are involved in teaching at the university, in a way that real life practice is valued, and in supervising pharmacy training at the hospital, both for undergraduates and for postgraduates. The pharmacy training may comprise clinical activities, research programmes or a combination of both. The implementation of research findings into practice is also part of the ADP aims in order to ensure an evidence-based practice.

3.5.2.2 Portuguese Secondary care

The Portuguese secondary care has a strong private component, with strong regional differences. Therefore, it was seen as important to distribute data collection throughout the country. Nonetheless, to make it feasible in the predefined timeframe, the three main cities were chosen; Lisbon, Coimbra and Porto. In Lisbon, three private hospitals were chosen, whereas two public teaching hospitals were used in Coimbra and Porto. The three private hospitals are quite small, two of them comprised 159 and 184 beds each (*Hospitais da CUF*) and the third being used in a similar model to a UK outpatients' clinic (*British Hospital*). Not all services were available for data collection in these hospitals and patient access to these hospitals is obviously conditioned by socio-economic factors. Conversely, the public hospitals selected were large teaching hospitals, comprising many more medical specialities. Access to these hospitals is free and available for every citizen. *Hospital da Universidade de Coimbra*, the oldest in Europe, is a 1208 bed-hospital with three general medicine wards, each of them comprising 33 beds. *Hospital de São João do Porto* is a 1300 bed hospital, having departments and services for all the medical and surgical specialities.

3.5.2.3 Portuguese Primary care

Relevant differences between community pharmacies in Portugal and UK include legislation about pharmacy ownership, which in Portugal is restricted to pharmacists, and regulation for new pharmacies installation, which have demographic and geographical conditionings (Ministério da Saúde 1965). The types of services available are quite different, with Portuguese pharmacists monitoring physiological parameters (such as blood pressure) as a strong component of their activity.

Community pharmacy is the most prominent area of practice in Portugal. By December 2004 there were 5 372 community pharmacists practising in 2 722 pharmacies, implying a ratio of 1.97 pharmacists/ pharmacy (Ordem dos Farmacêuticos 2005).

The National Association of Pharmacies (ANF) is an organisation, whose membership is voluntary for pharmacy owners. Within this organisation, CEFAR is the Centre for PharmacoEpidemiologic Research involved in the development and implementation of studies, which require pharmacists' involvement in data collection. Community pharmacists, in general, are very much aware of research studies and keen to be involved in them. The need to ensure pharmacists' permanent actualisation was felt and therefore the Portuguese Pharmaceutical Society (PPS) created a process of professional license revalidation, which was put into practice last January (2004). This process has as main aim to guarantee that "the pharmacist maintains up to date his technical and scientific skills to constantly improve his activity in a way that allows him to develop his professional duties towards society (Aranda da Silva, Ramos, & Silva 2004). Currently, participating in pharmacoepidemiology or pharmacy practice research studies is accredited by the PPS which shows the relevance of evidence-based pharmacy. This was seen as a unique opportunity to effectively collect a large data set over a wide location. To allow for future comparisons between the health care interface only pharmacies located in the formerly mentioned geographical areas were included.

Primary care in the UK is not described because it is beyond the scope of this thesis, as no data collection was undertaken there.

3.5.3 The interviewers

In secondary care phase three pre-registration pharmacists assisted with patient interviews. All of them undertook a period of observation, where they shadowed the main investigator during interview, followed by a period of accompanied interviews, where they undertook the interviews but were monitored by the main investigator, and finally independent interviews. In primary care, the questionnaires were self-administered; pharmacists were instructed to administer the tools in cases where the patients could not read, either because they had not been to school or because they

had poor eyesight. Also pharmacists were asked to monitor patients while they were answering should any questions be raised. In such cases, these questions were noted together with the type of help or explanation. To ensure consistency in the pharmacists' responses of questionnaires, a training session was held for participating pharmacists. Here an overview on interviewing techniques was presented and the questionnaire was carefully examined, providing practical examples on what to do and what not to do.

3.5.4 Ethics Approval

Data used in this project that had been previously obtained in the UK had ethical approval (Duggan 1998). For this project, a renewal of such approval was sought, as appropriate (reference: EC 93/161, protocol in appendix 8) and a new ethics application was started in Portugal. Ethics committees there function at the hospital level rather than at the regional level, hence one approval per hospital was obtained (references: letter 05/03/2003; letter 23/05/2003 and protocols in appendix 8).

Guidelines also differ among hospitals; for some a request per service was needed. In such cases, a written authorisation was obtained from the Head of Service prior to submission (references: letter 18/02/2004 and protocols in appendix 8). Within the Portuguese primary care there is no formal procedure or body responsible for research where ethical approval can be sought. As such, no request was submitted. Nevertheless, the same procedures ensuring data protection and patients' informed decision to participate were followed.

CHAPTER IV

ADAPTATION OF A SURVEY TOOL

4.1 Perspective

The purpose of this chapter was to explore the various approaches taken when adapting survey tools. Several methods have been proposed in the literature that informed the chosen approach. This chapter is divided into four sections. Firstly, the literature around translation is appraised; the second section focuses on the processes of translation and back-translation; the third section explores the ways to ensure linguistic equivalence. The fourth and final sections explore the different complementary methods to assess the understanding of the items used in the survey tool by its intended target audience, the results from the interviews with individual patients, group work with health care professionals and lay panel discussions.

4.2 Aims and objectives

Aims

This phase aimed to adapt a survey tool to measure information desires and perceptions about medicines and illness of patients.

Objectives

- 4.2.1 To evaluate the published literature on the translation of survey tools.
- 4.2.2 To translate a scale originally developed in English (UK) to Portuguese (Portugal).
- 4.2.3 To ensure linguistic equivalence of the translated survey tool.
- 4.2.4 To explore the understanding of the translated tool in Portuguese and to refine the necessary items.

4.3 Methods overview

A combination of methods was used to achieve the objectives set, which are depicted in figure 4.1, where the phase of the study is related to the purpose and the methods undertaken. Taking this sequential approach allowed each stage to inform the next, which enhanced credibility.

Figure 4.1 Schematic representations of adaptation stages

Adaptation phases	Methods	Purpose
Literature search	Database and manual searches Critical appraisal of the literature	To create guidelines on the best process for the characteristics of this project
Translation	Translation by 2 independent Portuguese native speakers fluent in English (HCPs) Agreed translation (GD) Back Translation by two independent English native speakers fluent in Portuguese Agreed back translation (GD) Review by research team	To develop a Portuguese survey tool semantically equivalent to its original English version
Refinement of items I	Health care professionals group work	To explore the conceptual equivalence of the translated survey tool by seeking the perceptions of health care professionals
Rating of versions	Independent assessment of the translation difficulty by two bilingual raters Independent assessment of the quality of the translation by two bilingual raters Independent assessment of the equivalence between the original and back translation by two English native monolinguals	To control for different types of equivalence between the Portuguese and English survey tool
Refinement of items II	Individual patient interviews Lay panel debate	To explore the understanding of the translated tool in a Portuguese target audience and to explore cultural suitability by seeking the perceptions of patients to enhance content equivalence

GD=Group discussion; HCPs=Health Care Professionals

4.3.1 Literature search

References were identified from four databases (Embase, Medline, IPA and Biopsis Previews) to evaluate the literature on translation of survey tools. The keywords used were “cross-cultural adaptation”, “survey tool/questionnaire”, “translation” and “reliability/validity”. Limits were imposed on papers not written in English, French, Spanish or Portuguese, as they could not be understood by the main researcher. Manual searches were performed for authors frequently mentioned or references cited in the primary papers. References were considered relevant when the abstract

referred to the process used, rather than simply reporting on validity and reliability results. Those considered relevant were then critically appraised for the pros and cons of each approach, seeking to create an innovative method that would combine the strengths and minimise the pitfalls of those previously tested.

4.3.2 Translation and Back-translation methods

The basic principles of Brislin's translation model were used in the initial steps (Brislin 1986). This author was one of the first to describe a model that comprised cycles of translation and back translation by bilinguals to pick apart the concepts. This model was later adapted to produce valuable guidelines (Guillemin, Bombardier, & Beaton 1993), which have been widely used in cross-cultural research (El Meidany, El Gaafary, & Ahmed 2003; Litlere et al. 2003; Padua et al. 2002; Pouchot et al. 1996).

Although the one-way translation is the most commonly used method (Hilton & Skrutkowski 2002), the translation and back translation was considered a better approach as it does not uniquely depend on the skill of one translator and hence contributes to an increased validity and reliability of the translated version (Bontempo 1993). Brislin also recommended that all resulting materials should be pre-tested by the intended target audience to guarantee that monolinguals would also consider the wording suitable (Brislin 1970). This latter aspect is explored further in the last section of this chapter.

The intermediate steps between the translation and the back translation and the review by the research team include group discussions. These were held between the two independent translators for each phase and the main researcher, to reach a consensus on the best understood wording (Jones et al. 2001).

The last step of the translation phase was where the research team reviewed the back-translated version against the original to ensure that meaning was not lost in the course of translation (semantic equivalence).

The documentation sheets used during the translation process are included in appendix 1 (MAPI Research Institute 2005).

4.3.3 Refinement of items I – Input from Health Care Professionals

The first phase of refining items with input from health care professionals aimed to explore the conceptual meaning of the statements, to contribute to conceptual equivalence (MAPI Research Institute 2005). Taking a qualitative approach allowed possible reasons for potential non-equivalence to be explored.

Consultation with bilingual experts has been recommended as a possible way to explore the area to be covered by the survey tool (Small et al. 1999). It has also been recommended that proficient interviewers need not only linguistic expertise but also a deep understanding of the cultures considered (Small, Yelland, & Lumley 1999). In this context, experts are no different from interviewers and rarely can one have equivalent understanding of two cultures. For these reasons, two separate groups were convened, where experts were chosen using different criteria.

The role of the first group was to explore the concepts behind each statement and produce detailed descriptions. Experts were therefore chosen for being native English speakers and having conducted research into patients' perceptions of medicines and illness.

The role of the second group was to suggest items that reflected such concepts, based on the descriptions produced by the first group. They examined the original items and their initial translations and took into account possible barriers that could be encountered in the Portuguese culture. These experts were chosen on the basis of their bilingual ability, their understanding of the Portuguese culture, typical beliefs and understandings achieved by conducting previous research exploring patients' views and attitudes towards the health care system.

4.3.4 Rating methods

The rating phase sought to control the different types of equivalence between the Portuguese and English survey tools to increase the reliability of methods and achieve a semantically equivalent tool in Portuguese (Hilton & Skrutkowski 2002). The complete procedure is explained in figure 4.2





Rating steps have been included in large-scale multi-centred projects to ensure equivalence of both wording and meaning, whilst taking account of the clarity of the language used (Bullinger et al. 1998). Furthermore, rating steps are considered a further way to ensure that good back translators do not make sense out of a poor forward translation (Bontempo 1993). The scales used in this project to rate the relevant types of equivalence result from a combination of others previously proposed (Bullinger et al. 1998; Sperber 2004; Wagner et al. 1998).

In the IQOLA team approach, a rating scale ranging from 0 to 100 was adopted, having no pre-defined cut-off for acceptable items (Bullinger et al. 1998). In the Sperber approach, a scale from 1 to 7 was proposed, where 1 was the best agreement and 7 the worst agreement. Revision of the translation was suggested whenever any mean score was above 3 or between 2.5 and 3 for the equivalence of meaning score (Sperber 2004). A 7-point rating scale with a pre-defined cut-off was considered more accurate and was adopted in this study. Conversely, the use of a scale where the greatest number corresponded to the highest agreement was seen as more straightforward. Therefore, the resulting scale used had 7 points, as suggested by Sperber (Sperber 2004), but numbers ascended for agreement, as suggested by Bullinger (Bullinger et al. 1998). Additionally, as later concluded and further explained (see section 4.4.2), the mode was used as a cut-off rather than a predefined value.

The raters of difficulty were the forward bilingual translators, as suggested by Bullinger et al (Bullinger et al. 1998). However, in the IQOLA project, all groups of raters had been previously involved in the project, whilst in this project independent bilingual raters were blinded to the previous research to avoid potential biases. Additionally, raters C were also blinded to the previous research and were chosen as native-English speakers.

Ratings of quality and equivalence can be seen as outcome indicators and hence more relevant to the aim of such a study. Rating the quality of translation is particularly important, because it directly refers to the version of the questionnaire to be field tested in the target population. Equivalence ratings may be seen as a control measure, since they are used to compare English versions.

Figure 4.2 – Procedure used to rate different versions of the survey tool

Versions compared	Raters	Raters' characteristics	Type of rating
Forward translation A (Portuguese)			
Comparison 	Raters A1 & A2 (HCPs)	Bilinguals (translators)	Rate the difficulty of translation on a 7-point scale from 1 (very easy) to 7 (very difficult)
Forward translation B (Portuguese)			
Agreed forward translation (Portuguese) 			
Comparison 	Raters B1 & B2 (HCPs)	Independent bilinguals	Rate the quality of the final translation in terms of clarity on a 7-point scale from 1 (very poor quality) to 7 (very good quality)
Original scale (English)			
Comparison 	Raters C1 & C2 (HCPs)	Independent monolinguals (English)	Rate the equivalence in terms of common use of language and same interpretation on a 7-point scale from 1 (totally different words; totally different meaning) to 7 (very similar words; very similar meaning)
Agreed back translation (English)			

4.3.5 Refinement of items II – Patient input

This approach had the major drawback of receiving little input from lay people (Mkoka et al. 2003). Given the difficulty of recruiting a bilingual patient sample, this sequence was considered the most thorough. Even if bilingual patients were to be used they would very likely use different words from other lay people, as bilinguals tend to be highly educated people, who do not represent the national reality (Brislin 1986).

The following subsections focus on the second phase of refining of the items by seeking views from patients, first individually and then in group.

4.3.5.1 Pre-testing for equivalence - individual patient interviews

Pre-testing in the target population aimed to ensure the questionnaire was suitable for its intended audience (Guillemin, Bombardier, & Beaton 1993). It further explored the relevance of each item for the target culture, ultimately contributing to content equivalence (Hilton & Skrutkowski 2002).

The Portuguese agreed version was pre-tested in a sample of hospitalised patients in Portugal to evaluate whether the content and wording was understandable. Face-to-face interviews were conducted with patients where they were initially asked to respond and then to comment on each item. They were asked what they understood the question to mean, if any item was considered difficult or confusing and, where appropriate, suggest alternative wording. This approach has also been taken in the IQOLA project, where a modified version of the EORTC debriefing questionnaire was used (Bullinger et al. 1998). However, in the current study it was not considered relevant at this stage to evaluate if any item were considered upsetting, an issue explored later. Eligible patients were present for hospital admission on the specified day and agreed to participate once informed about the aims of the study.

4.3.5.2 Enhancing equivalence - Lay patient panel

The development of a patient panel aimed to further enhance content equivalence. The advantage of having a group of people interacting is that those who may feel inhibited in individual interviews with a stranger tend to contribute more as debate is stimulated. Additionally, groups may be used to reach consensus, which was the ultimate aim of this phase.

A purposive sample of patients with chronic conditions covering a wide range of educational levels and ages was recruited through a rural community pharmacy. Inclusion criteria included patients who were prescribed with daily chronic medication and who were responsible for their medication taking.

Patients were identified from their pharmacy medication records to ensure they fulfilled the inclusion criteria and were invited to participate by a phone call (made 2 weeks previously). The pharmacist explained that the purpose of the meeting was to talk about their experiences with their illness and medicine taking, in order to help

modify a questionnaire that was being adapted from English to Portuguese to address these issues. They were told that the meeting would last between 1 and 2 hours.

When the patients said they would be willing to participate and were available for the suggested date and hour, they were sent a formal invitation letter by post, together with more information about the project. Those agreeing to participate in the panel discussion met at the local town hall. As an ice-breaker, some refreshments were provided with time for informal conversation for about 15 minutes. The community pharmacist was present at the meeting for two main reasons, to introduce the researcher to participants, making them feel more at ease, and to enhance the credibility of the findings.

The purpose of the meeting and the procedure was explained; scenarios of medicine taking were to be reviewed and the patients would be asked to comment on how they would react or feel towards them, using their own words freely. An interview guide was used to conduct the meeting. Structured prompts were used when needed to stimulate debate or to put participants back on track when they started to wander to other themes not immediately relevant to the present study.

Statements that best described the concepts in each scenario emerged, alternative statements for each item discussed were written on a flipchart and patients were asked to choose the one they felt best reflected their feelings. A consensus was sought using this Nominal group technique. Field notes and audio-taping were used for clarification following transcribing. Data are presented as quotes to explore patients' "translation" of the underlying concepts.

4.4 Results

This section is organised in four sections, reflecting the previous stages. The literature review fed into the entire chapter and justified the approaches taken. The four sections include translation and back-translation; rating; refinement of items by health care professionals; and refinement of items by patients, from the individual interviews and lay panel.

4.4.1 Translation and Back-translation results

This section describes the results of the translation and back-translation phase, prior to developing an objective rating scheme. The measures reflect mostly the group discussions held to reach an agreed version, where translators debated the process with the principal investigator. There were no major difficulties encountered during the translation process. Both translations were quite similar, so reaching agreement was not difficult. The complete procedure is illustrated in figures 4.4 and 4.5, where raw data was transcribed to provide detailed information of the different translations; whenever the translation in Portuguese is a literal translation it is presented between brackets for better understanding. Figure 4.3 is previously presented where each item comprising the 3 scales used are described.

Fig. 4.3 – The 3 Scales used in this project

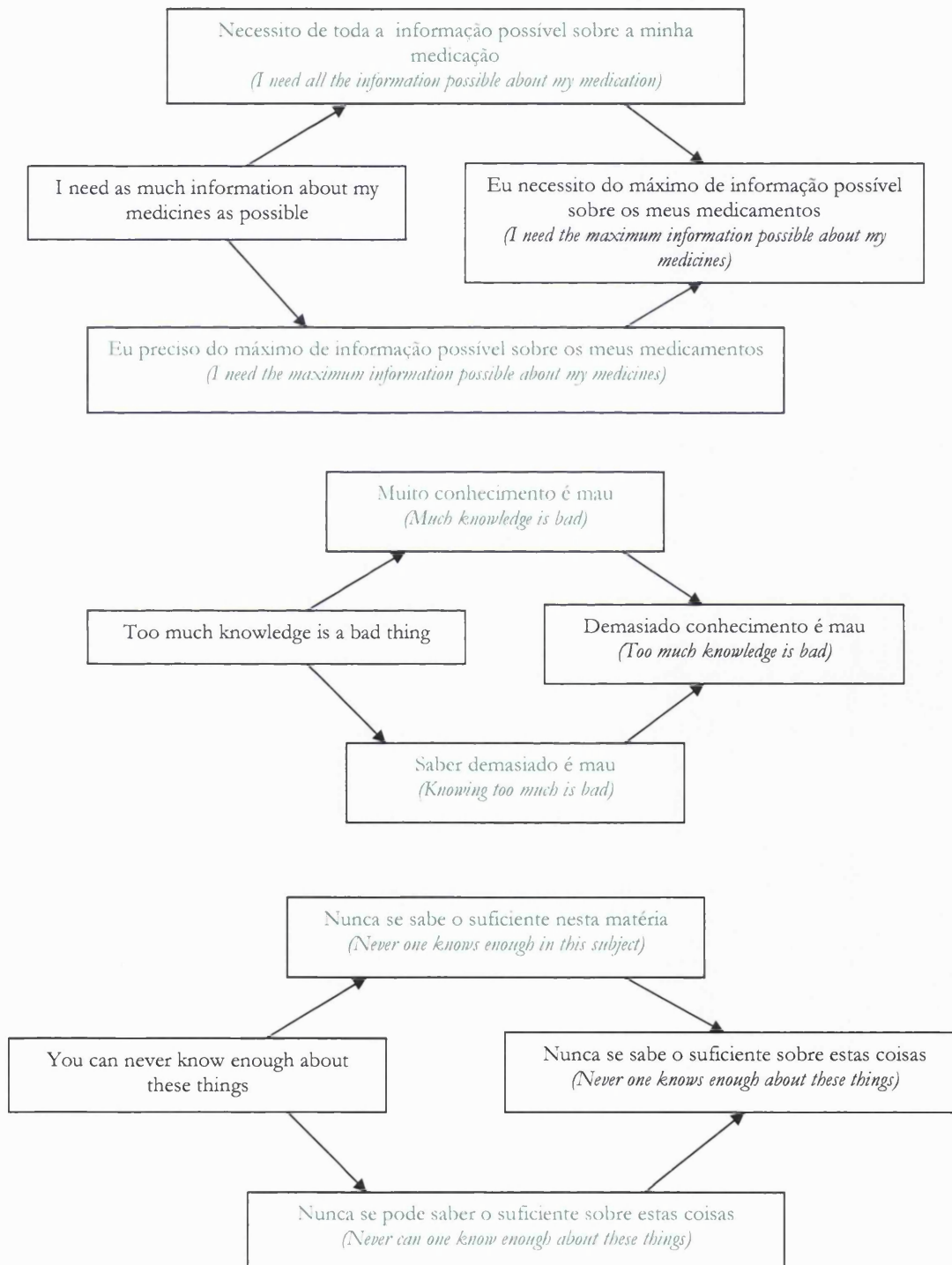
Extent of Information Desired (EID)	
S6	I need as much information about my medicines as possible
S7	Too much knowledge is a bad thing
S8	You can never know enough about these things
S9	I don't need any more knowledge
S10	I read about my medicines/illness as much as possible
S11	What you don't know doesn't hurt you

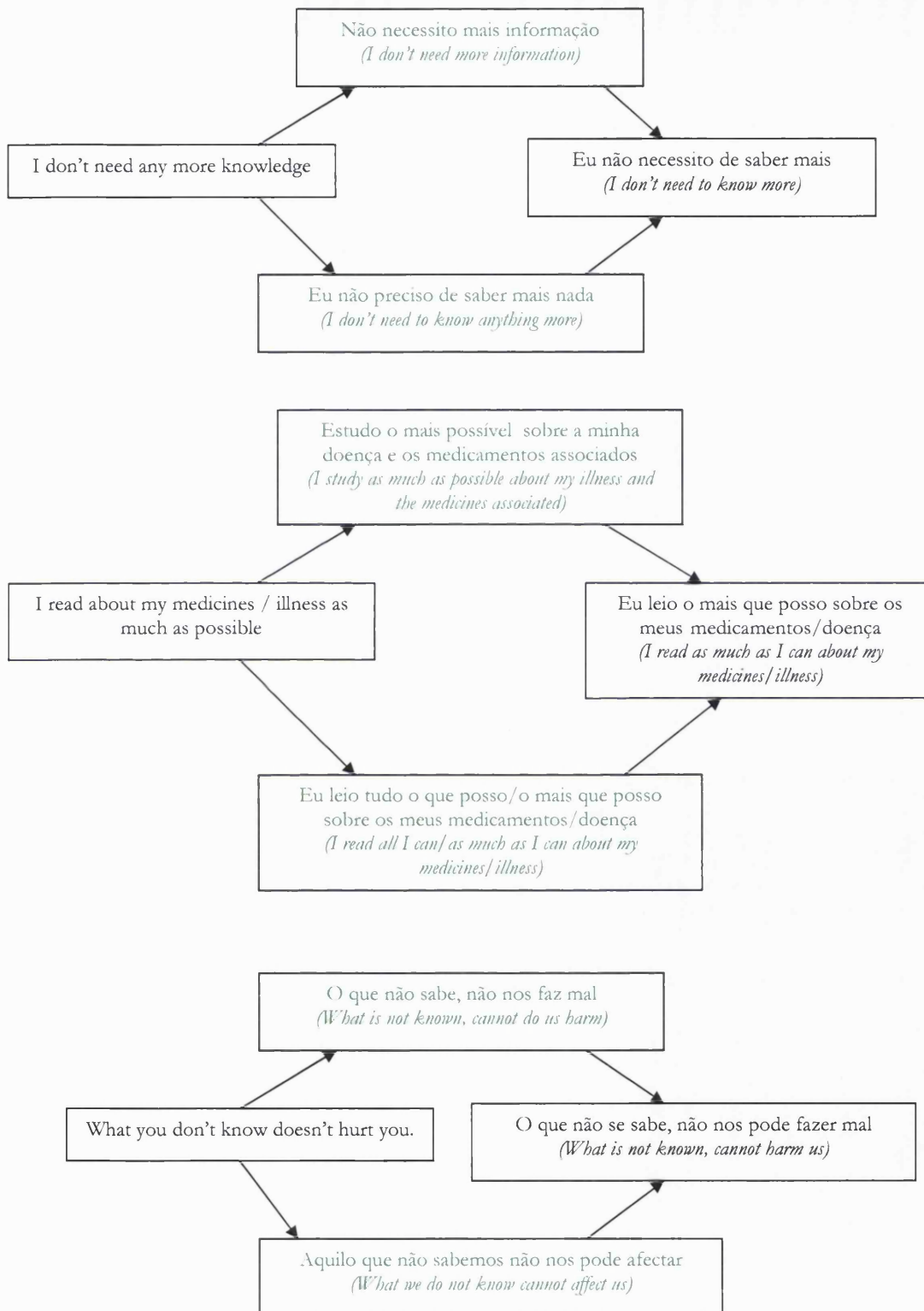
Perceived Utility of Medicines (PUM)			
Perceived Benefit of Medicines (PBM)		Perceived Harm of Medicines (PHM)	
T3	My medicines relieve my symptoms	I feel "trapped" by my medicines, I have to take them	T2
T5	I trust my medicines will make me better	It's hard to take my medicines, because taking them has altered my lifestyle	T4
T7	Without my medicines I would be so much worse	The side-effects are another form of disease	T6
T1	I find my medicines easy to take, I am used to them		T1

Anxiety about Illness (AI)			
Anxiety (Ai)		Tolerance (Ti)	
A1	I can't get used to this illness, I just get worried about it	I feel fine about my illness, you can't expect to always be well	A3
A6	I get really worried about it all, the worry makes me ill	I just want to blame someone for the way I feel	A4
A7	I feel anxious and concerned about the future	I would like to be completely better, but a bit better is good enough	A5
A9	I can't accept that there's something wrong, why me?		

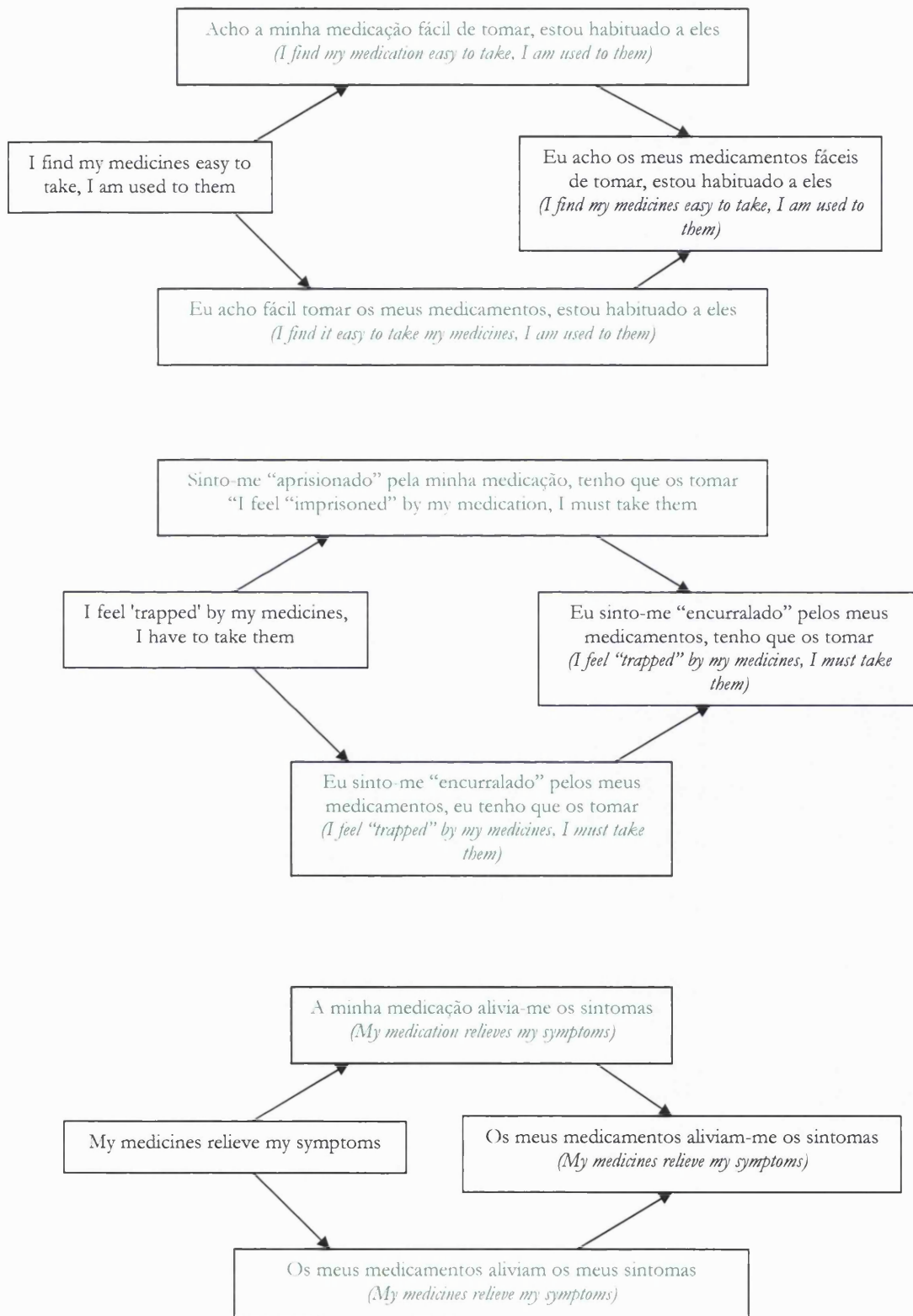
Figure 4.4 – Forward translation of all items (original and agreed translation in black; two independent forward translations in green)

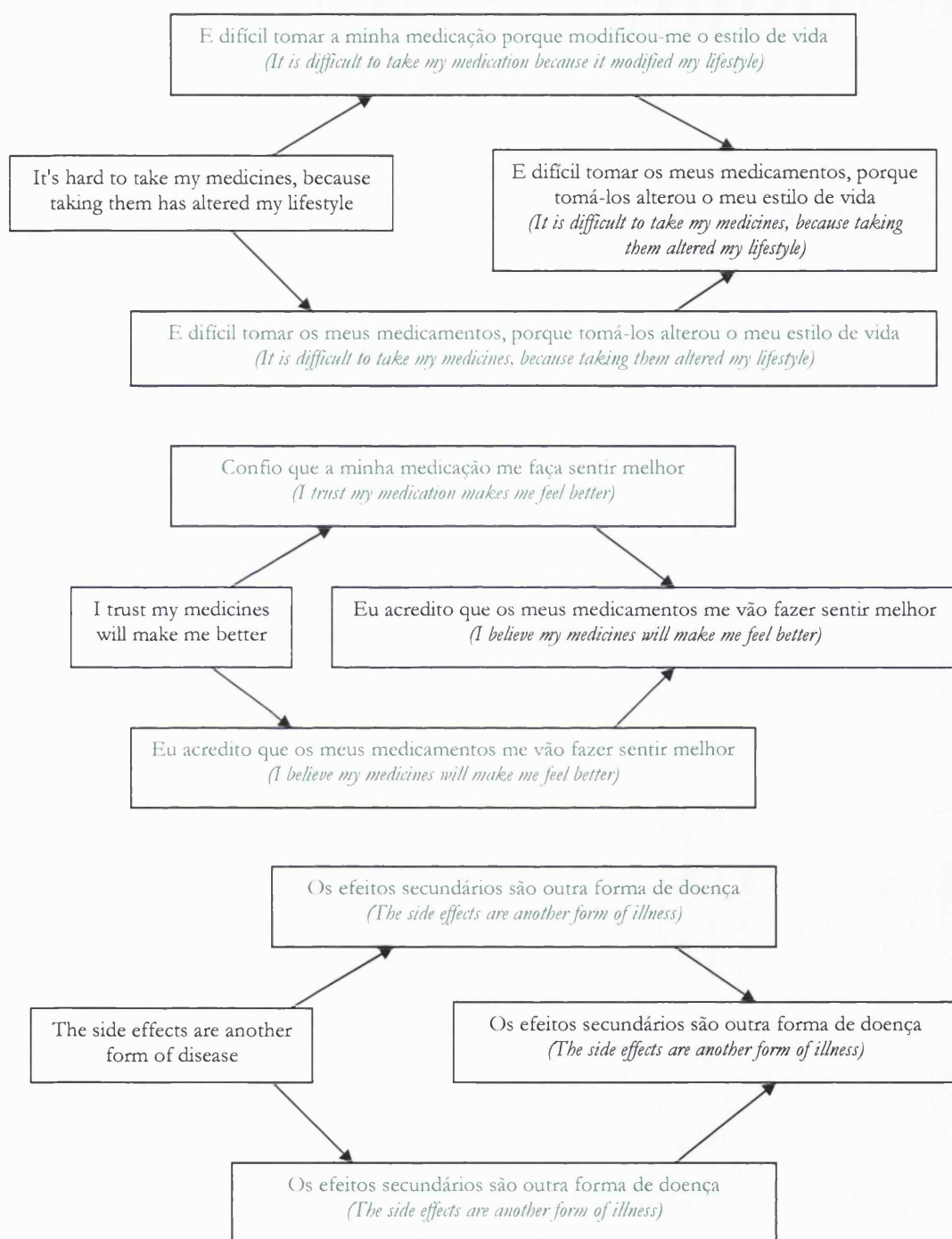
EID Scale (6 items)

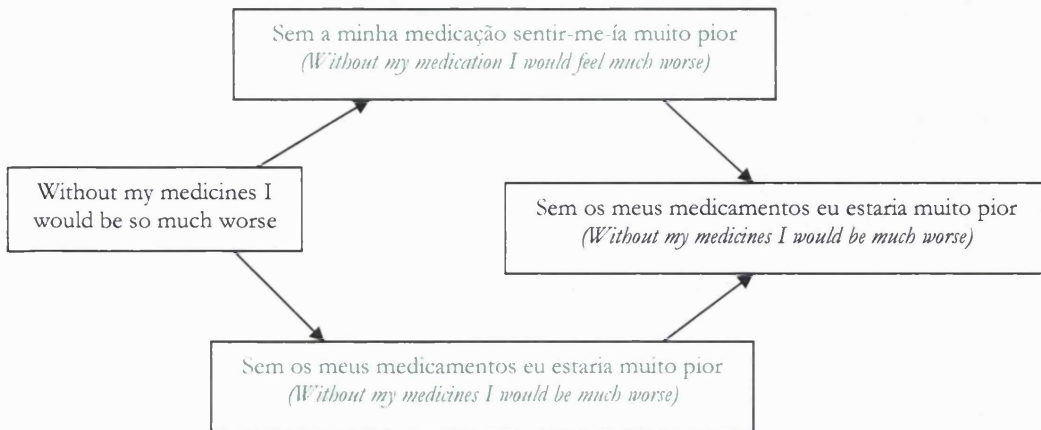




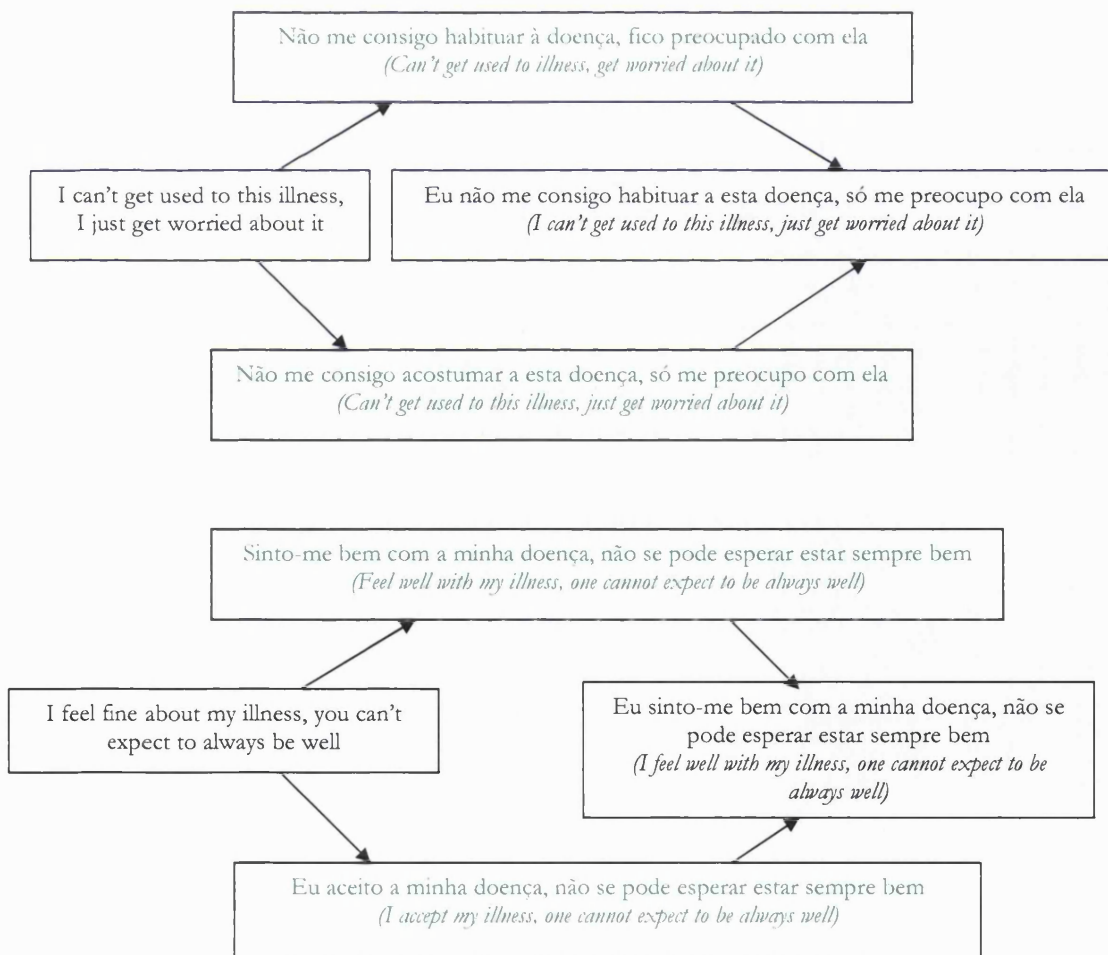
PUM Scale (7 items)

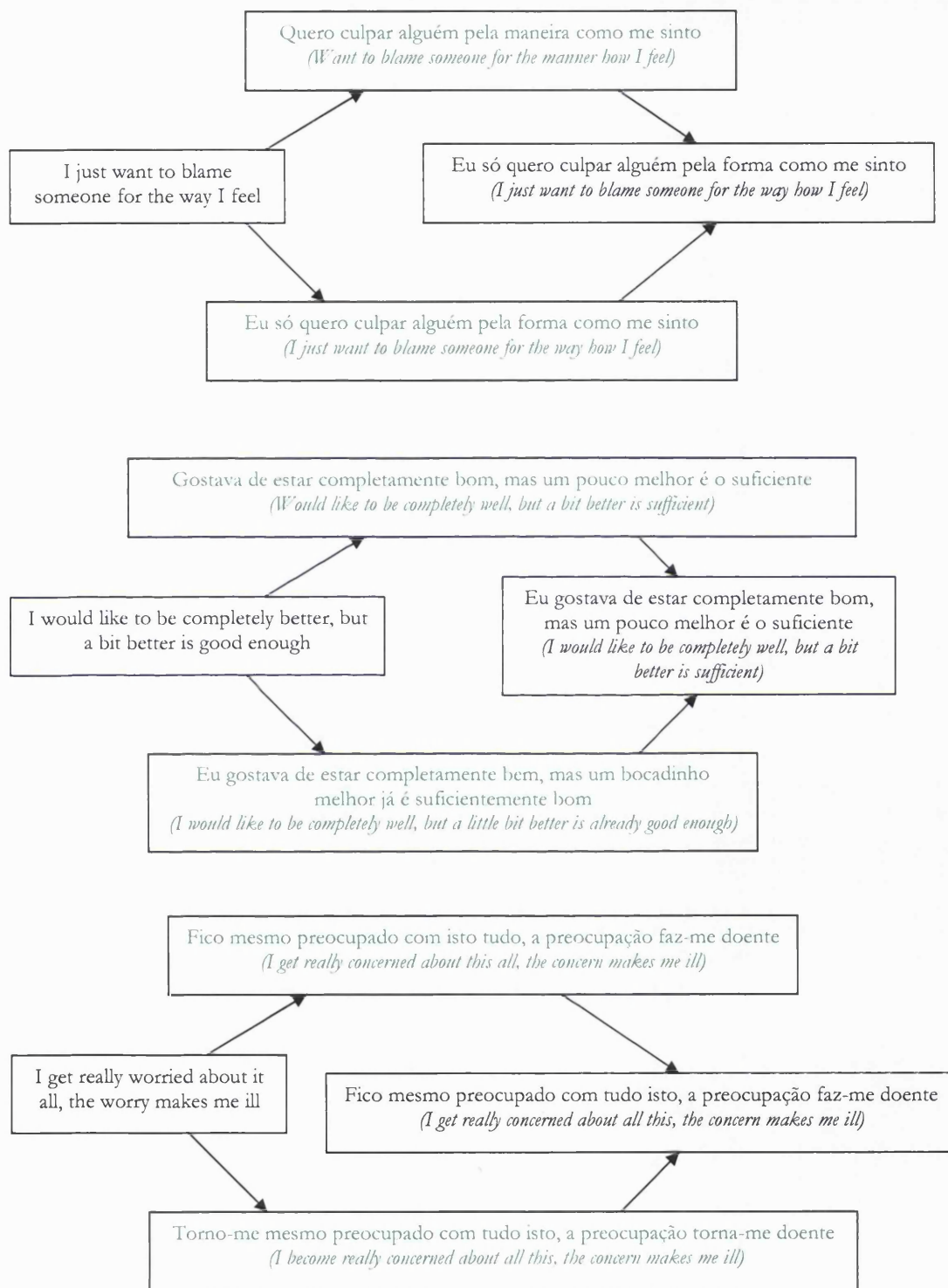






AI Scale (7 items)





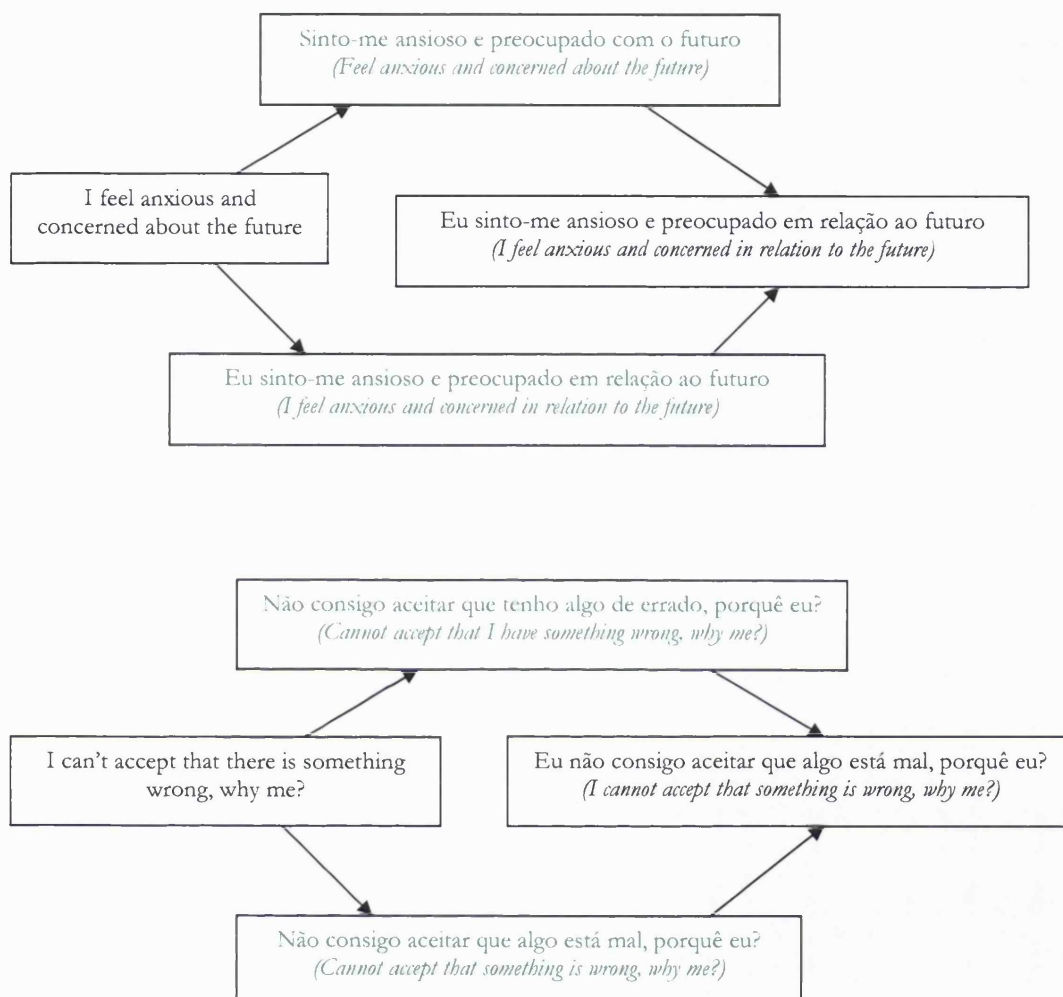
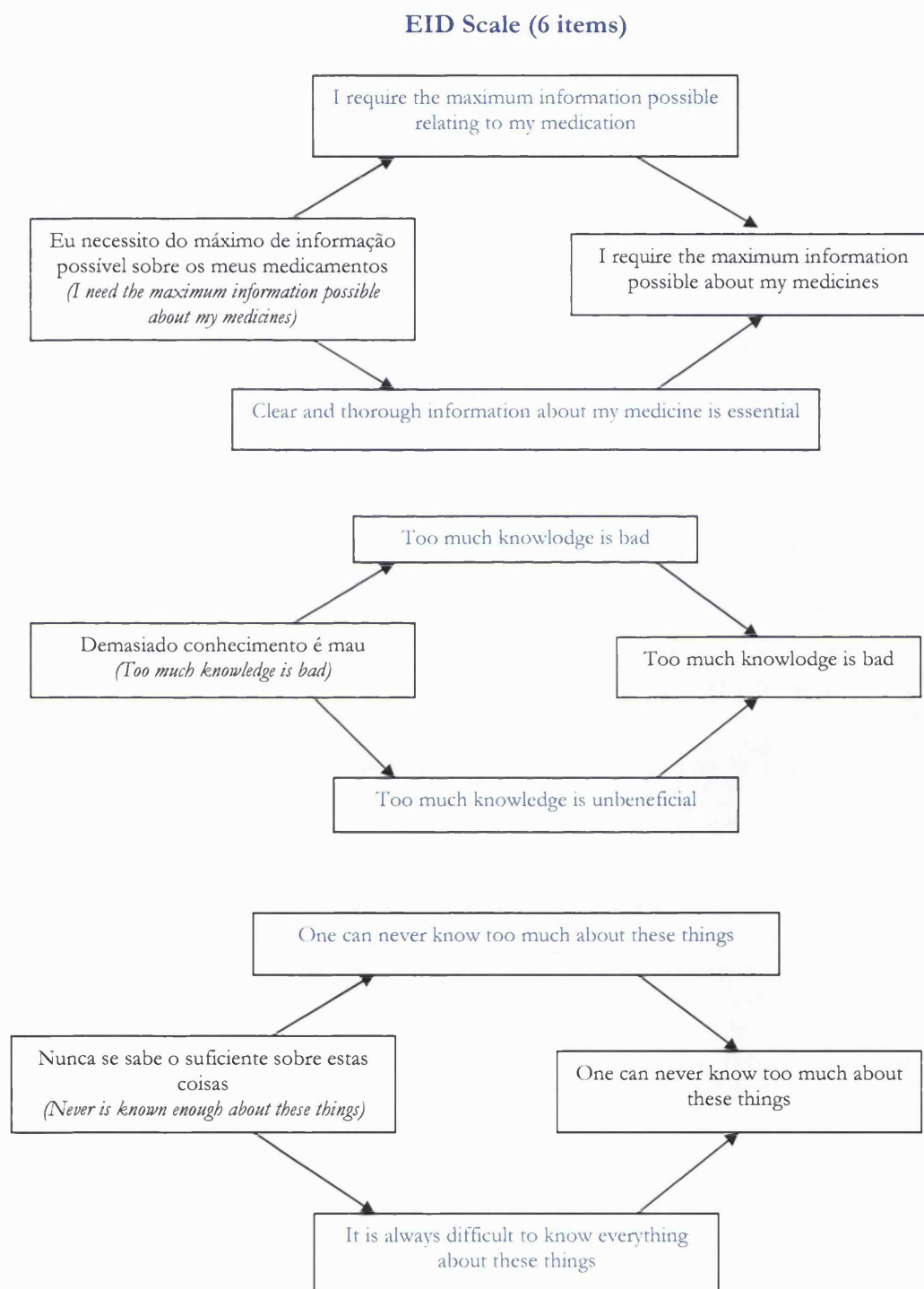
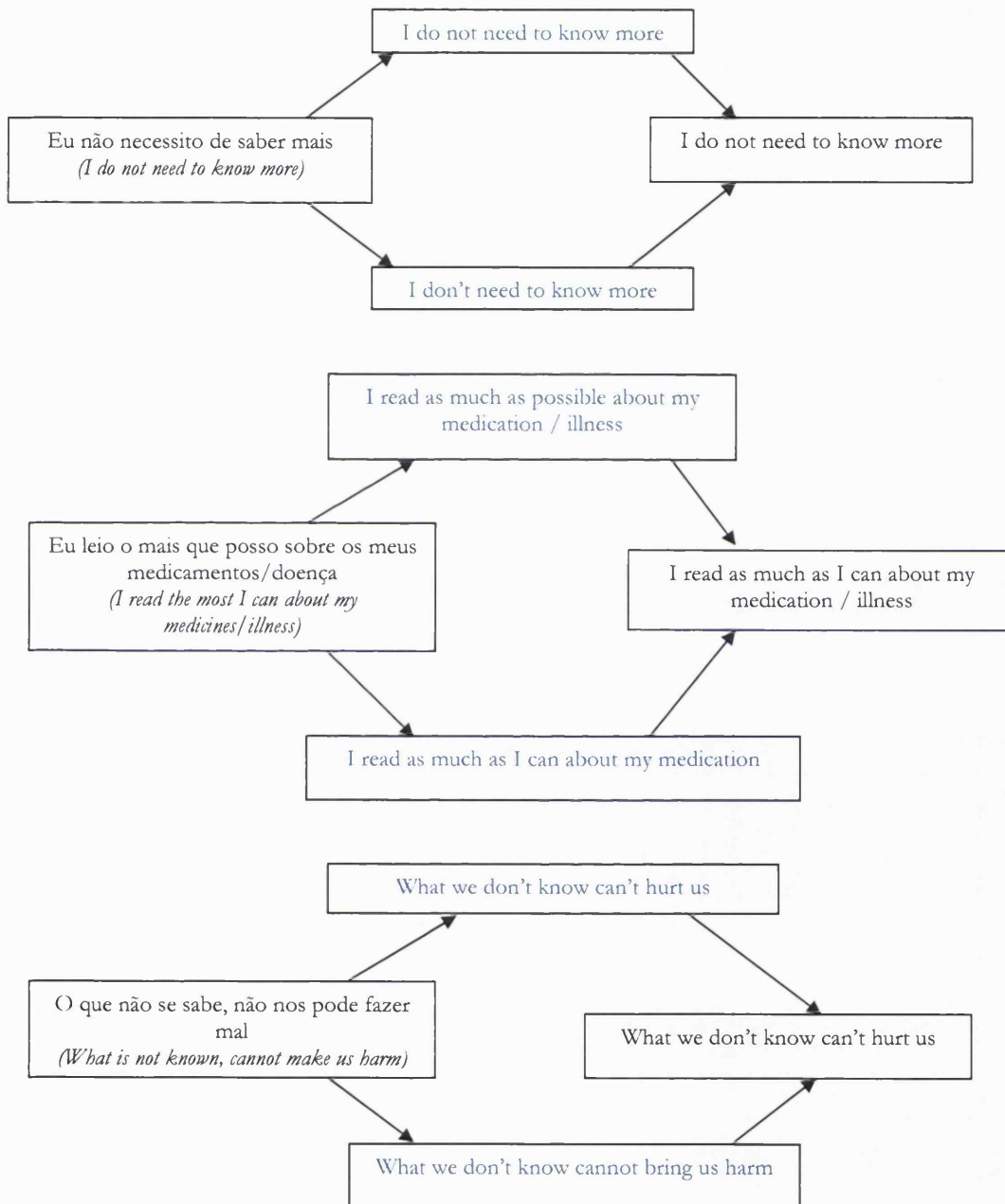
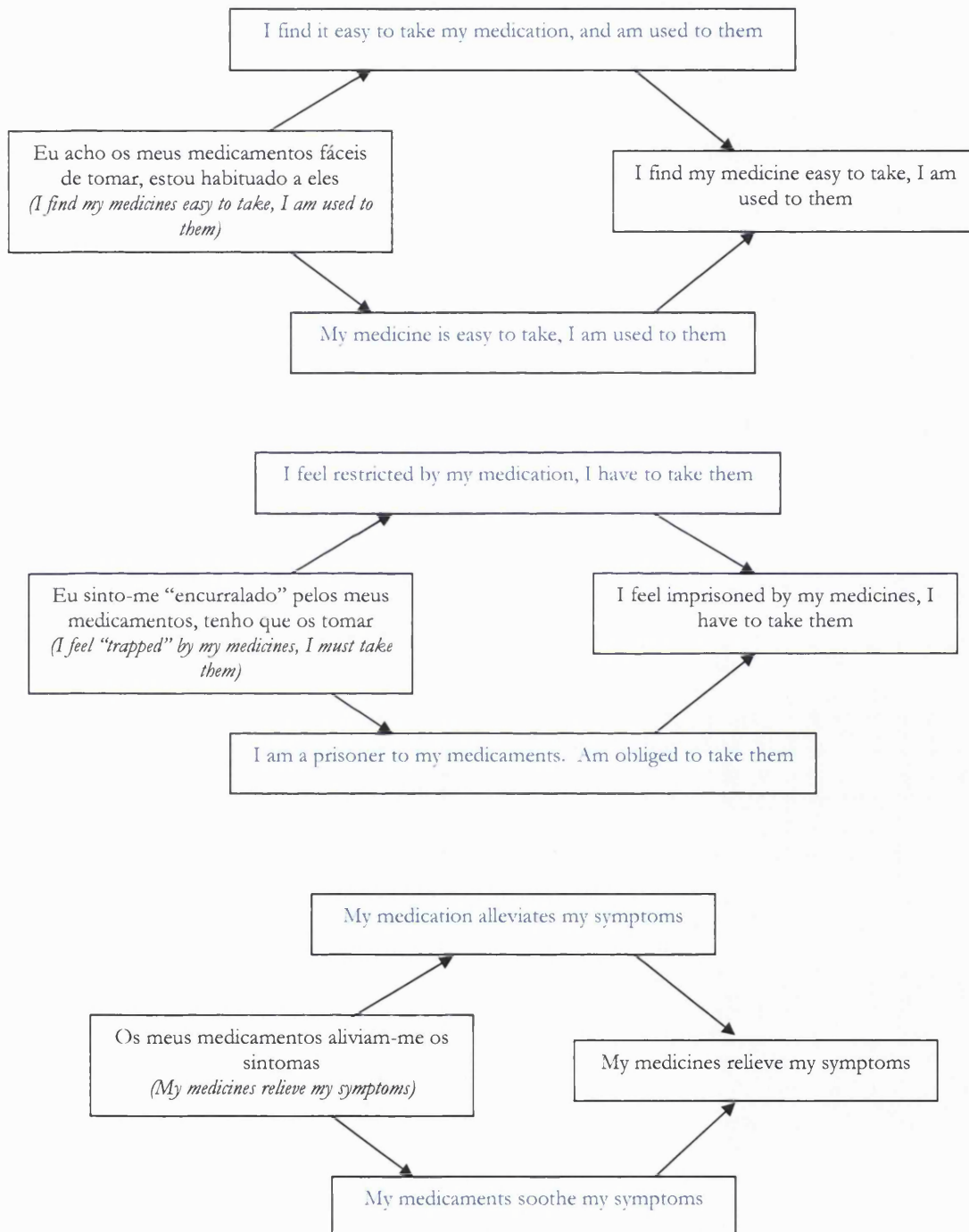


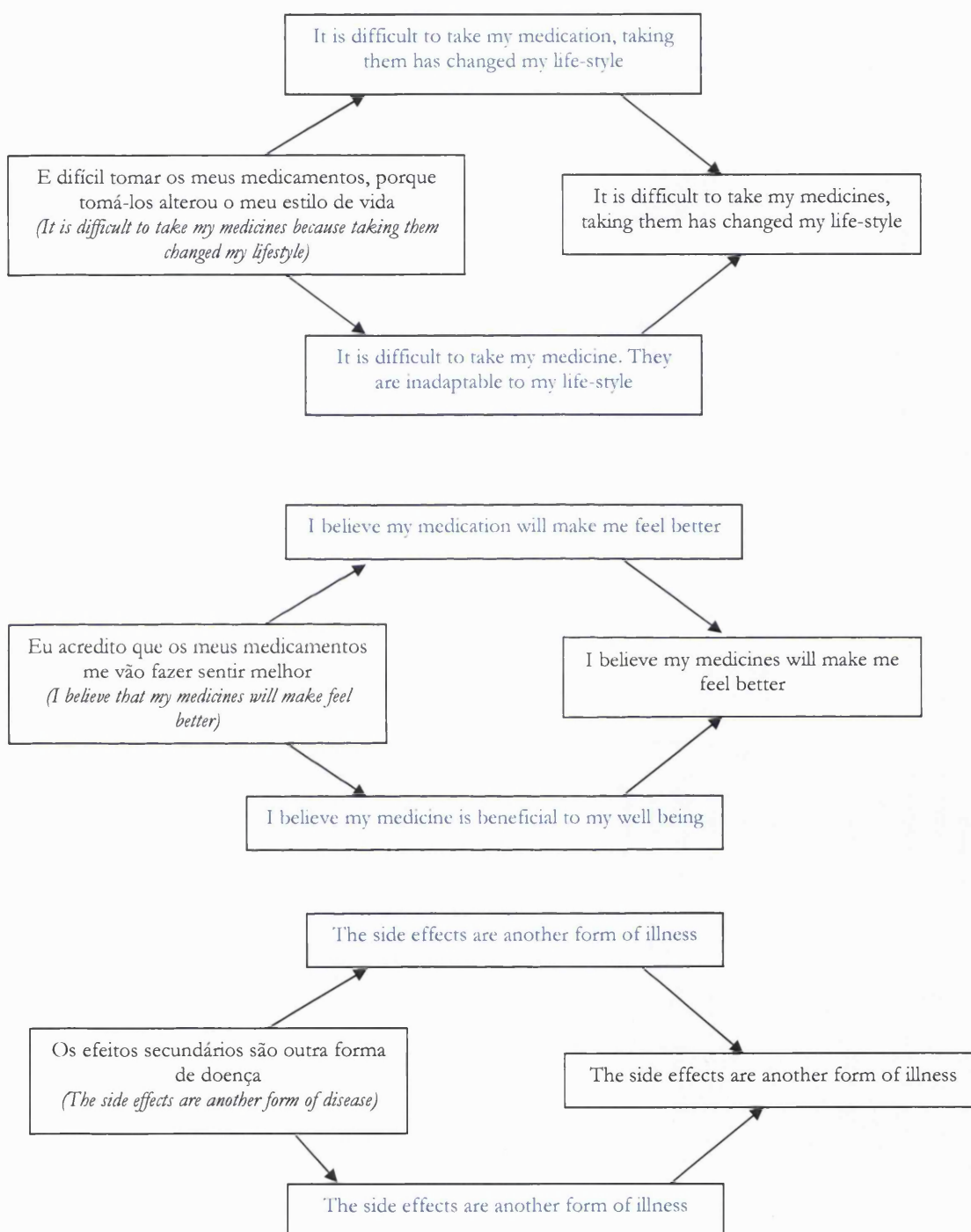
Figure 4.5 – Back translation of all items (agreed Portuguese version and agreed back translation in black; two independent forward translations in blue)

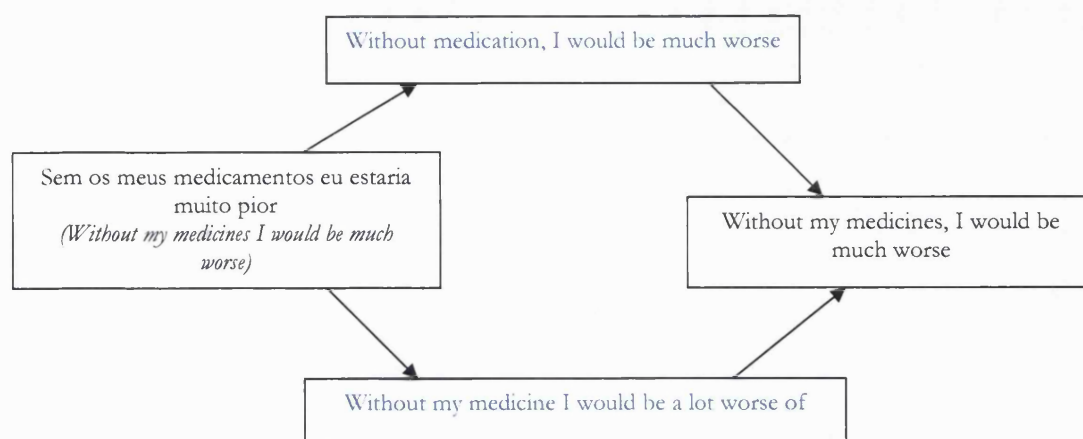




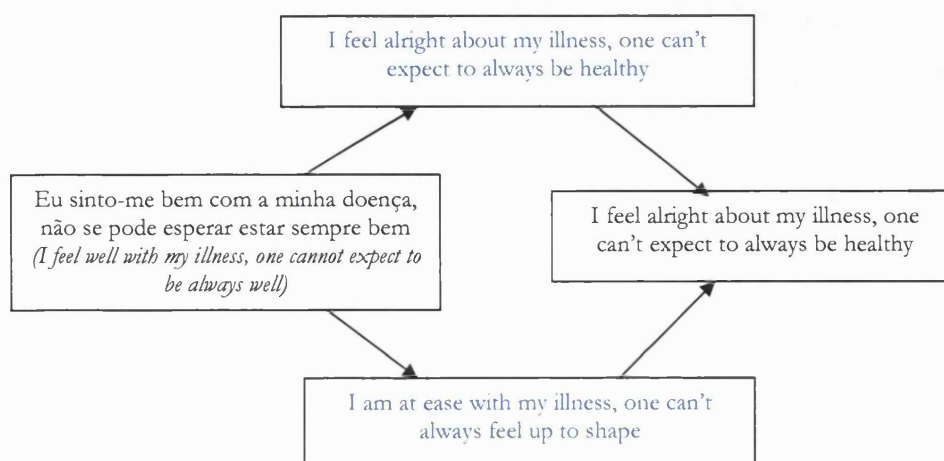
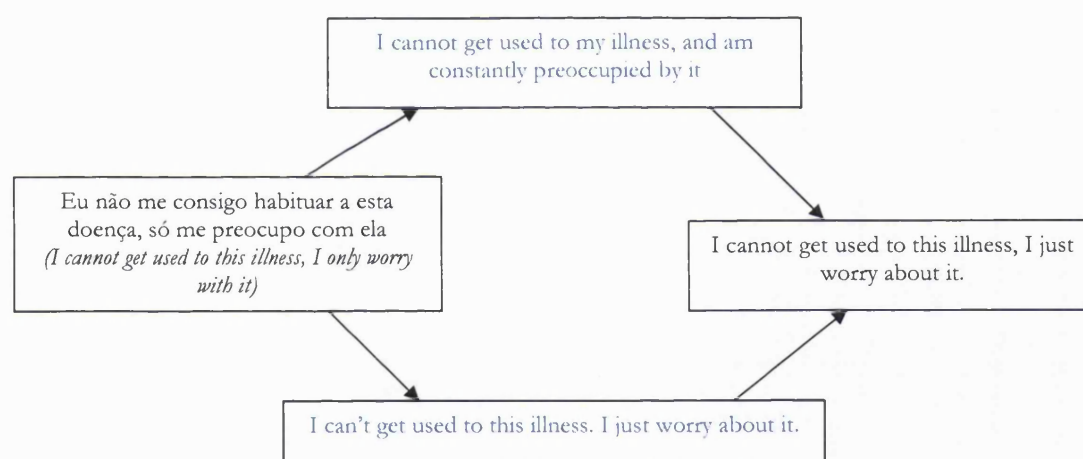
PUM Scale (7 items)

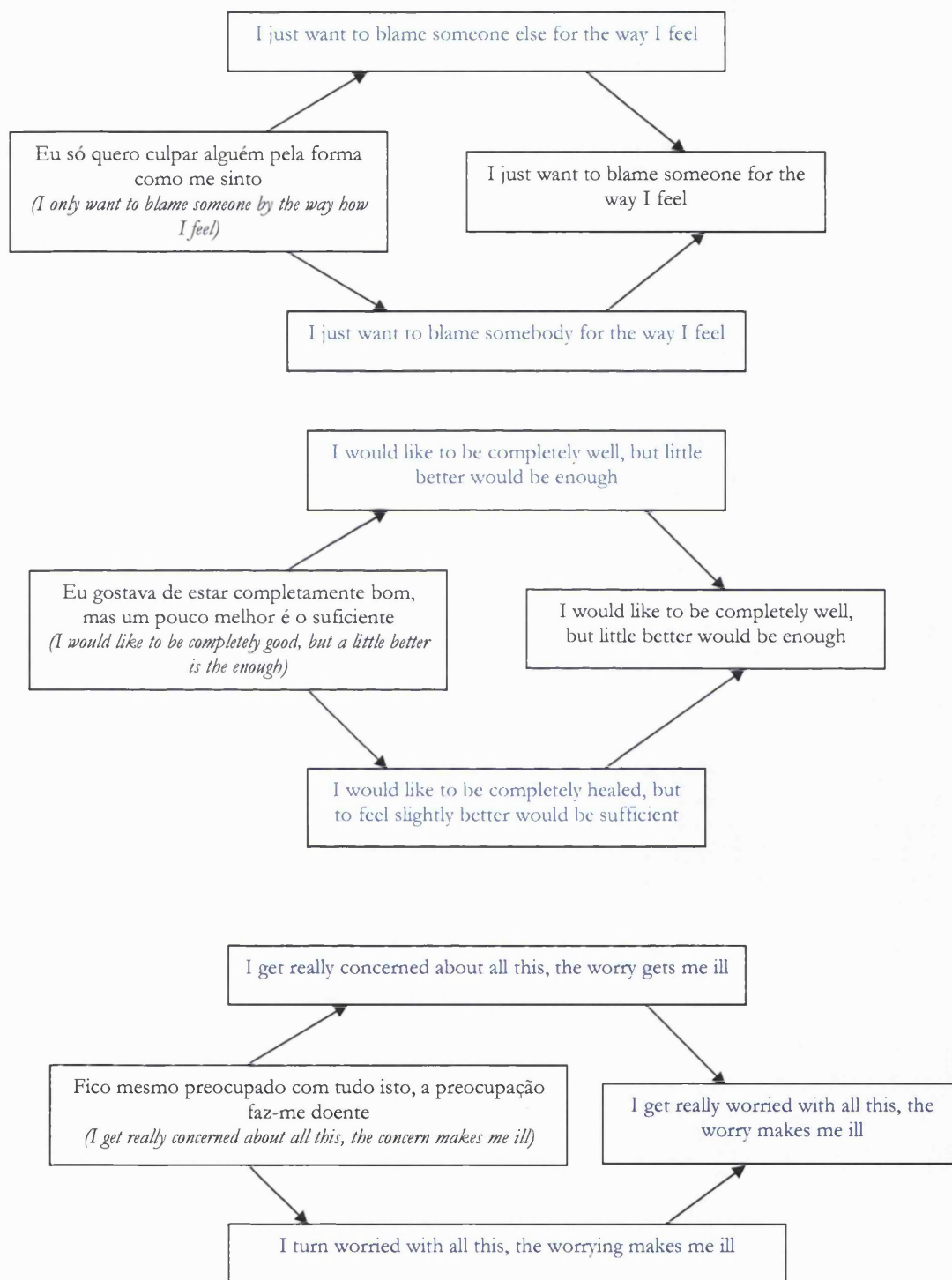


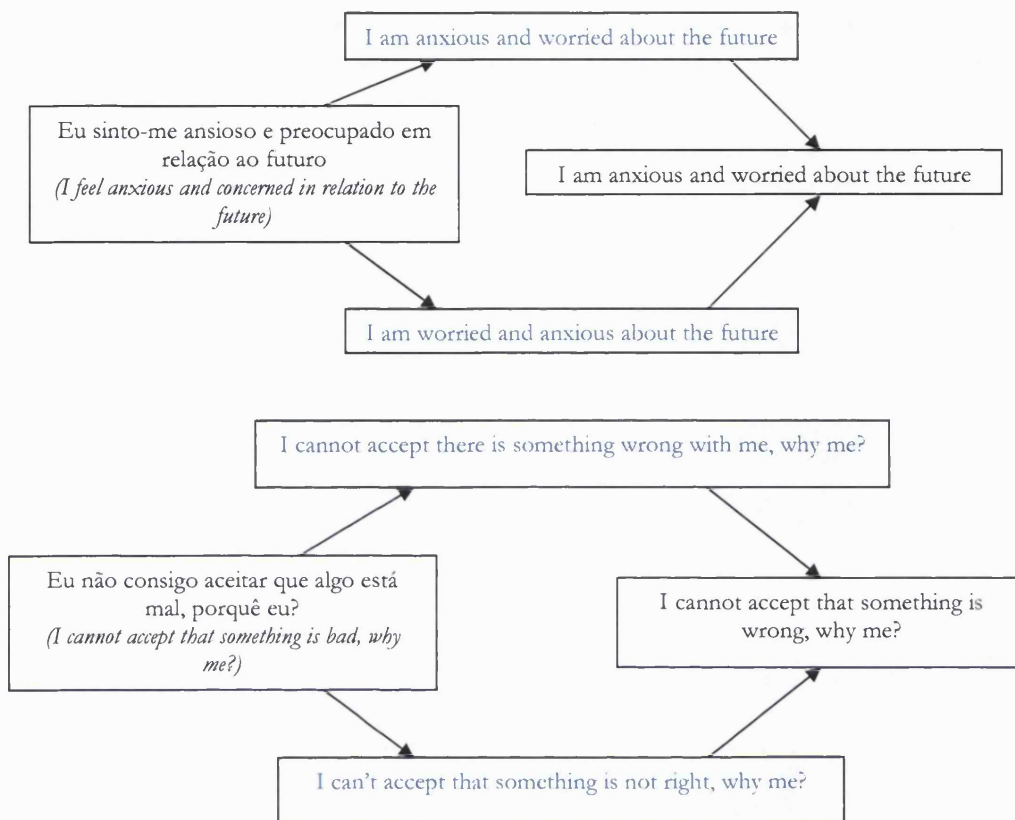




AI Scale (7 items)







4.4.2 Rating results

Different measures were used, where the first (rating of difficulty), was considered a process indicator, but with no proven implication on the outcomes. Comments made by translators provided insight into the possible implications of the difficulty when rating the quality of translation, which would influence further steps of the process.

Table 4.1 – Rating results (rating of difficulty, quality and equivalence)

Scale Item number – statement		Difficulty (mean of 2 raters)	Quality (mean of 2 raters)	Equivalence (mean of 2 raters)	
				Language	Meaning
		1 – extremely difficult 7 – not at all difficult	1 – not at all clear 7 – extremely clear	1 – not at all similar 7 – extremely similar	1 – not at all comparable 7 – extremely comparable
EID	S6 - <i>I need as much information about my medicines as possible</i>	4.5	4.5	6	7
	S7 - <i>Too much knowledge is a bad thing</i>	5.5	6.5	6.5	6.5
	S8 - <i>You can never know enough about these things</i>	6.5	7	6	6.5
	S9 - <i>I don't need any more knowledge</i>	6	7	6	6
	S10 - <i>I read about my medicines/illness as much as possible</i>	5.5	7	7	7
	S11 - <i>What you don't know doesn't hurt you</i>	6	7	6.5	6.5
PUM	T1 - <i>I find my medicines easy to take, I am used to them</i>	6	7	6.5	6.5
	T3 - <i>My medicines relieve my symptoms</i>	6.5	7	7	7
	T5 - <i>I trust my medicines will make me better</i>	6.5	6	6.5	5.5
	T7 - <i>Without my medicines I would be so much worse</i>	6.5	7	6	6.5
	T2 - <i>I feel 'trapped' by my medicines, I have to take them</i>	4.5	6	6	6.5
	T4 - <i>It's hard to take my medicines, because taking them has altered my lifestyle</i>	5.5	7	6	6.5
	T6 - <i>The side effects are another form of disease</i>	6	6.5	7	6.5
AI	A1 - <i>I can't get used to this illness, I just get worried about it</i>	5	5	5	5.5
	A3 - <i>I feel fine about my illness, you can't expect to always be well</i>	5.5	6	6.5	5.5
	A4 - <i>I just want to blame someone for the way I feel</i>	6	7	6.5	6.5
	A5 - <i>I would like to be completely better, but a bit better is good enough</i>	5.5	6	6.5	6.5
	A6 - <i>I get really worried about it all, the worry makes me ill</i>	5.5	6.5	6.0	6.0
	A7 - <i>I feel anxious and concerned about the future</i>	6.5	7	7	7
	A9 - <i>I can't accept that there is something wrong, why me?</i>	6	7	6.5	7
Mode		6	7	6.5	6.5

Only two items (10.0%) received difficulty ratings of 5 or lower. Raters assessing the difficulty of language both commented that achieving linguistic equivalence was difficult in the items rated as low, as there having used a literal translation would result in long statements that sounded strange and/or which would not mean the same.

“Nem sempre é fácil traduzir à letra, porque o significado em Inglês posto da mesma maneira em Português muitas vezes não significa a mesma coisa (It is not always easy to translate literally because the meaning in English put the same way in Portuguese often does not mean the same”

(Translator 1)

These same two items (10.0%) received mean quality scores of 5 or lower (*“I need as much information about my medicines as possible”* and *“I can't get used to this illness, I just get worried about it”*). However, only the second item resulted in a back-translation rated 5 or lower in language equivalence (5.0%), implying more attention needed to be put on the revision of this item's wording.

Using the cut-off as suggested by Sperber, items that needed revision would be those lower than 5 for language equivalence and lower than 4.5 for equivalence of meaning (Sperber 2004). This meant that no items needed revision, as depicted in table 4.1.

However, Sperber suggested 30 raters (Sperber 2004), compared to the 2 raters suggested by Bullinger et al (Bullinger et al. 1998), it was more appropriate to use the mode as the cut-off point [standard deviation (sd) =1] to make the method more rigorous.

This implied that items S6 (*I need as much information about my medicines as possible*), T2 (*I feel 'trapped' by my medicines, I have to take them*) and A1 (*I can't get used to this illness, I just get worried about it*) required revision.

4.4.3 Refinement of items I – Health Care Professionals input

Items identified as problematic, in the course of analysis of patients' answers to the scales, were refined by health care professionals, to explore the concepts underlying each item and to ensure this was reflected in the translated version. Concepts were debated as defined by the English health care professionals, and then alternative statements were suggested by the Portuguese health care professionals (table 4.2).

Table 4.2 - Potential problems debated by health care professionals

Original item and initial translation	S7 - Too much knowledge is a bad thing. <i>Demasiado conhecimento é mau</i>
English group debate	<p>Debate focused on the broad concept being captured by this statement. “Too much knowledge about what? Is it not too broad?”</p> <p>The negativity implied in having knowledge of medicines was seen as associated to the doctor-patient relationship, comprising the traditional paternalistic approach, independently of being initiated by the doctor’s attitude or by patients’ beliefs about his role and his ability. “Older people to “slap down” younger people don’t question the system...not our place “leave to people who know more...” Leave it to experts. It is not your place to know. Paternalistic concept implied.” Safety associated with not knowing was also an issue raised and the current trend to always provide standard information despite patients’ wants. “It is associating knowledge with negativity. It represents people who are fearful or scared of what they’ll be told. You can be told too much. Set your own limits. Autonomy issue: people can ask questions and say no. Fear of knowing too much, particularly the negative aspects. In the contemporary world we [HCPs] have to tell everything.”</p> <p>Additionally, assumptions about how these feelings towards this statement could evolve throughout time were made. “It implies there might be a shift in patient autonomy in the course of illness career.”</p>
Portuguese group debate and reviewed translation	<p>It was considered that direct translation loses meaning and that a colloquial expression would possibly be more easily understood. The statement proposed was <i>Saber demais não é bom</i></p>
Original item and initial translation	T 2 - I feel trapped by my medicines, I have to take them. <i>Sinto-me ‘encurralado’ pelos meus medicamentos, tenho de os tomar</i>
English group debate	<p>Issues of control over medicines and lack of alternatives patients has when faced with an illness were debated. “No alternative. Lack of control, lack of choice; no choice, no control. As if there was a bit missing “...I have to take them!” shows that there is no alternative for the patients.” How medicines impact a patients’ life were explored. “Explains by having to take. Affects my live negatively. There is no representation of adverse effects but there is nothing positive.”</p>
Portuguese group debate and reviewed translation	<p>The main problem was considered to be the fact that it was a double meaning statement, resulting in controversial feelings responding as patients could agree with one part and disagree with the other. The statement proposed was: <i>Sinto-me prisioneiro dos meus medicamentos porque tenho de os tomar</i></p>
Original item and initial translation	T4 - It’s hard to take my medicines because taking them has altered my lifestyle. <i>É difícil tomar os meus medicamentos, porque tomá-los alterou o meu estilo de vida.</i>
English group debate	<p>Part of the debate was around how this statement differed from the former. It was agreed that here it was implied that patients had a choice. “Living with medicines. How does it differ?...Reluctance to take but still choosing to take. Usually they won’t take them because of the effect on lifestyle...here it’s the opposite. Negative consequence of taking medicines but not enough to stop. Not as hard or negative or strong as in the former statement.” Additionally the concept of taking medicines was defined as all the environment surrounding the act of swallowing pills. “Not just taking, being on medicines; take may be associated to the practicality issue. Something like “to be on medicines has...” or “living my life with medicines ...” would possibly be more adequate than to take, because it doesn’t imply the practicality issues so much as when using the verb to take”.</p>
Portuguese group debate and reviewed translation	<p>The statement was considered to have two meanings creating controversial feelings. Additionally the word “<i>estilo de vida</i>” could be unclear for some patients. The replacement item suggested was: <i>Ter de tomar medicamentos altera o meu dia-a-dia</i></p>

Table 4.2 (cont') - Potential problems debated by health care professionals

Original item and initial translation	T 6-The side effects are another form of disease <i>Os efeitos secundários são outra forma de doença</i>
English group debate	Two main issues arose debating this statement. The first was the difficulty of patients to distinguish effects of medicines from effects of the disease and how patient leaflets impacted on their perceptions. "Influence of patient information leaflets; how they impact and worry patients. They certainly do in mentally ill patients. Is it a worry or an experience?" "It is as if the condition was being substituting with side-effects. It is hard to label side-effects as something separate; is it a consequence of the medicine or of the illness?" The second issue debated was on the difficulty of finding a term to describe side-effects which would be understood by lay people but still be pharmacologically accurate. "All medicines have "counter-effects"... The word counter-effects is not pharmacologically true. Unwanted effects of medicines. Iatrogenic disease. Nothing is free Maybe if more background is given..."
Portuguese group debate and reviewed translation	Side-effects were confirmed to be a difficult word. Secondly, their occurrence seems to be associated with misuse among those who have never experienced them. The new item suggested was "bad effects": <i>Alguns dos efeitos dos medicamentos são quase tão maus como ter outra doença</i>
Original item and initial translation	T 1 - I find my medicines easy to take, I'm used to them. <i>Eu acho os meus medicamentos fáceis de tomar, estou habituado a eles</i>
English group debate	Debate focused on the use of the verb to take, where it should be clear that it implied the sphere surrounding patients' experience with medicines taking, rather than the simple process of swallowing a pill. "To take. Not just taking, <i>i.e.</i> , swallowing a tablet, it's the whole experience, the impact it has on life. Adjusted to them. I am adjusted to taking meds, living with them...may have made a few adjustments; not a problem – no need to compromise. In control now."
Portuguese group debate and reviewed translation	The way the item reads now seems to be associated with the practicality, <i>i.e.</i> , "yes, they are just pills, I have them with water". Additionally, there also seemed to have the double statement problem. The replacement item suggested was developed by changing the focus of the action: <i>Porque tenho de tomar medicamentos habituei-me a eles</i>
Original item and initial translation	A 3- I feel fine about my illness, you can't expect to always be well. <i>Eu sinto-me bem com a minha doença, não se pode esperar que estejamos sempre bem</i>
English group debate	This item was defined as trying to reflect one of the stages of illness, where the patient no longer has a problem with it and accepts it. "Acceptance of illness, compromise, realistic. Gone through all processes of denial and anger. Adapted now. Made a rational decision about it."
Portuguese group debate and reviewed translation	The phrasing gives a double meaning, leading to controversial feelings. One hypothesis suggested was the replacement of the comma with the word "because" or "therefore" in a way that one part of the statement would be clarifying the other: <i>Nem sempre se pode estar bem, por isso aceito a doença</i>

Table 4.2 (cont') - Potential problems debated by health care professionals

Original item and initial translation	A 4 - I just want to blame someone for the way I feel. <i>Eu só quero culpar alguém pela forma como me sinto</i>
English group debate	The concept implied in this statement was mainly seen as associated with external locus of control and with the coping strategies developed by patients to adapt to illness. "Anger, no compromise, no acceptance; external locus of control, someone else is responsible. Coping strategies. Take away responsibility, change the emphasis. Denial, guilt, blame parents <i>e.g.</i> , anger, depression." The group agreed that focus of the statement could be changed as long as care was taken not to change the concept of anger to resignation.
Portuguese group debate and reviewed translation	It was agreed that blame was something that cannot be phrased this way in a catholic country, <i>i.e.</i> , guilty religious feelings. Alternatives discussed comprised changing the focus of blame, as suggested by group 1: "I (really) wish I could blame..." or "I'd like to blame..." or "I blame myself for the way I feel" or "I'm not responsible for..." or "I'm not to blame..." or "It's not my fault..." or "I want to take the burden out of myself" or "I take total responsibility for...". The final statement suggested was: <i>Se há alguém culpado pela minha doença sou eu</i>
Original item and initial translation	A 5 - I would like to be completely better but a bit better is good enough. <i>Eu gostava de estar completamente bom, mas um pouco melhor é o suficiente</i>
English group debate	This statement was defined as associated with the acceptance stage in the course of illness, becoming realistic that there was no cure and being happy with some relief. "Acceptance of limitations, compromise. A dream would be to be completely better but this is not achievable and the patient has realised that; therefore he wants to be a bit better. Satisfied with what they've got, <i>i.e.</i> , not going to be completely better. Equilibrium again."
Portuguese group debate and reviewed translation	The first part of the statement was seen as too obvious, everyone would like to be completely better. Hence, this part was disregarded with no implication on the meaning and the statement read as: <i>Se estivesse um bocadinho melhor já seria bom</i>

4.4.4 Refinement of items II – Patient input

The survey tool was further refined by seeking patients' perceptions through interviews and a lay panel. This section describes the results of these two phases in this sequence.

4.4.4.1 Pre-test for equivalence results – individual patient interviews

Individual patient interviews aimed to explore the understanding of the translated tool in a Portuguese patient population, and to explore the relevance of the items by seeking patients' perceptions.

Table 4.3 – Demographic characteristics of pre-test patients

Demographic characteristics		n=6
Gender	Male	5
	Female	1
Age	Mean (sd)	44.5 (20.23)
	min-max	{23-73}
Educational level	Primary school	1
	Preparatory school	1
	High school	1
	University	3

The three patients with university education had no problems using the Likert scale, whilst those who had either lower education or were older seemed to have more difficulty and tended to either agree or disagree, sometimes answering yes or no. Only in some cases were “strongly agree” and “strongly disagree” used. Alternative forms of strong agreement were often used, *e.g.* “no doubt” or “absolutely”.

There were some difficulties with some of the terms used, one patient did not understand the phrase “*side-effects*” whilst another felt that some statements were not appropriate for acute situations; such as “*I feel ‘trapped’ by my medicines, I have to take them*”. A third patient considered the statement “*I feel fine about my illness, you can’t expect to always be well*” ambiguous; but did not expand nor suggested alternatives.

There were three possible actions; the 5-point Likert scale could be changed into a 3-point scale, which would potentially compromise the scale’s reliability and sensitivity. The phrase “side effects” could be changed to a simpler form, but as only one patient expressed difficulty and the phrase is used in all patient information leaflets, it was decided it be kept for further testing. Finally, adapting the scales to acute disease states was a third possible option, but as the main focus of this study was to explore perceptions in patients with chronic conditions and in long term medicines users, so it was kept.

4.4.4.2 Enhancing equivalence results- Lay patient panel

This phase aimed to refine the wording of items in the translated tool and to explore their cultural suitability in a Portuguese population by seeking perceptions of patients. Data were transcribed and are presented quotes under each item reviewed. As in table 4.4, the sample comprises 6 patients, 4 females and 2 males, with ages

between 30 and 78, including patients with no qualifications and up to high school education, from various chronic conditions.

Table 4.4 – Demographic and medical characteristics of panel patients

Patient number	Participant	Gender	Age	Educational level	Diagnoses
1	DT	F	78	No education (illiterate)	Type II Diabetes
2	PCB	M	59	Primary school	Type II Diabetes Hypertension Angina pectoris
3	MSD	M	66	High school	Hypertension
4	MLC	F	67	Primary school	Type II Diabetes Hypertension Glaucoma Angina pectoris
5	MAPC	F	76	No education (literate)	Hypertension
6	MMP	F	30	High school	Hypertension

The first item reviewed was *“The side-effects are another form of disease”*. Patients’ comments are included in table 4.5.

Table 4.5 – Side-effects scenario

<i>The side-effects are another form of disease</i>	
Quote	Patient characteristics
<i>I take my medicines all right, nothing ever happens to me.</i>	Pt.4, F, 67, primary school, diabetes & hypertension
<i>If that would happen to me, I would stop taking my meds and call my doctor</i>	Pt.5, F, 76, no education (literate), hypertension
<i>That has happened to me, I spoke to the specialist and he changed my medication because it was causing a rise in the diabetes</i>	Pt.2, M, 59, primary school, diabetic
<i>I don't have any problem, Thank God.</i>	Pt.1, F, no education (illiterate), diabetes
<i>The side-effects may become another disease in the sense that they may aggravate your symptoms</i>	Pt.3, M, 66, high school hypertension
<i>The simplest way to think about it is the good and bad, they either cause you good or harm.</i>	Pt.6, F, 30 high school, hypertension

It can be seen by these quotes that ‘side-effects’ is not a phrase generally used by these patients. Furthermore, there seems to be an association between the expression of any opinion and having had previous experience of a side-effect. Patients also seem to believe that experience of side-effects is down to God; perhaps a suggestion of external locus of control, which is further explored.

Table 4.6 Words and phrases used to refer to side-effects

Side-effects	Efeitos secundários
To do bad	Fazer mal
To harm	Prejudicar
It alters the system	Altera o sistema
It would do bad to another disease	Provocava mal a outra doença
To aggravate others	Agravar outras

The second scenario related to the item *“It’s hard to take my medicines because taking them has altered my lifestyle”*, detailed in table 4.6 and grouped into 4 major attitudes.

Patients described the routines they create to make their lives compatible with medicines taking as a sign of adaptation. Some of these patients referred to perception of benefit of their medicines, eventually as an explanation for their created routines. Resignation was felt by those patients who are not happy with having to take medicines but realise it is something they must do. Passive acceptance was another feeling, where patients seem to see medicines taking as a natural thing because it was decided so by God. The “good patient” was the one who will always do what the doctor says, considering that it is not his place to ask questions (Leydon et al. 2000), even if this leads to potential non-compliance.

Table 4.7 – The lifestyle scenario

<i>It's hard to take my medicines because taking them has altered my lifestyle</i>		
Quote	Theme	Patient characteristics
<i>I have God on my side</i>	Acceptance	Pt.1, F, no education (illiterate), diabetes
<i>That effort we have to make to take our medicines at the right time. It causes profound sadness.</i>	Resignation	Pt.5, F, 76, no education (literate), hypertension
<i>It is to have to follow a schedule. When it passes [i.e. we forget] it instantly alters the system</i>	Adaptation	Pt.2, M, 59, primary school, diabetes & hypertension
<i>Any patient already knows that in the morning he must take his medicines, it is our own routine/habit.</i>	Adaptation	Pt. 3, M, 66, high school, hypertension
<i>It is the way it must be. We must take them, it is an obligation.</i>	Acceptance	Pt. 4, F, 67, primary school, diabetes & hypertension
<i>Sometimes we don't ask the assistant doctor because we are embarrassed; they say breakfast and we are afraid to ask if it is before or after breakfast</i>	The good patient	Pt.3, M, 66, high school, hypertension
<i>It is a way so that I do not forget</i>	Adaptation	Pt.2, M, 59, primary school, diabetes & hypertension
<i>Maybe there are problems that occur more in active people; if you are home you can wait more than 15 minutes</i>	Adaptation	Pt. 4, F, 67, primary school, diabetes & hypertension
<i>I always take them when I see they don't harm me</i>	The good patient	Pt.3, M, 66, high school, hypertension
<i>It is a dependence, physical, but many times it is psychological</i>	Resignation	Pt.6, F, 30, high school, hypertension
<i>You must always take the little box with you. I cannot live without them, I really must take them!</i>	Adaptation	Pt. 4, F, 67, primary school, diabetes & hypertension
<i>It is a developed habit; it must be till the end.</i>	Acceptance	Pt.5, F, 76, no education (literate), hypertension

The main theme to emerge on perceptions of medicines taking was the influence of religion. Religion seems to have a great impact on the way these patients face situations, some tend to accept whatever God decides. Some just simply accept it and find it normal to get it into their routine, whilst others may feel sad but ultimately also create their own schemes to become a part of their life. Of course, this is a small sample but is worthy of further exploration

The third item discussed was *"I feel trapped by my medicines. I have to take them"*, which gave rise to the concepts of obligation or dependence. Feeling imprisoned and trapped (*prisoneiro e encurralado*) were both judged to be "violent words", whereas "obliged" (*obrigação*) was seen as a more positive and realistic term.

"Não, prisão é muito violento! É mais como uma obrigação" (Pt. 3, M, 66, high school, hypertension).

The fourth item was *"I find my medicines easy to take, I am used to them"*. Different words that could be used in Portuguese to express the concept of "being used to" (*habituated vs acostumado*) were debated. Regional expressions were discussed but it was commonly agreed that the latter term would be more accurate and less likely to be linked to the concept of dependence. The resulting item was only slightly different, since the Portuguese verb to describe "getting used to" is synonymous with the verb.

"Some tablets you take them and then you get used to them; there is times when I run out of them and you feel the effects when you stop like the ones for depression I haven't taken for 4 days since I came and I feel tearful." (Pt.155, M, 61 y.o., no qualifications, blood disorder unclear cause)

The fifth scenario related to the item *"I just want to blame someone for the way I feel"* and generated a very interesting debate. Essentially two concepts emerged in the course of these debates. Again, cause was considered external, and reflected by an external locus of Control (ELoC), whether attributed to luck, God or family from whom they inherited the disease. However, when referring to negative feelings, such as blame or anger, these were more associated with an Internal Locus of Control (ILoC).

Table 4.8 –The blame scenario

<i>I just want to blame someone for the way I feel</i>		
Quote	Theme	Patient characteristics
I did not feel revolt (revolta), I accepted it. I was a bad luck I had and I accept it. I didn't know I had them [diabetes] so it was harder to accept because I didn't know. It came as a surprise because I am very careful with what I eat.	Acceptance ELoC-fate/luck Initial chock-surprise	Pt.4, F, 67, primary school, diabetes & hypertension
Our Lord had given us that [when found out that had diabetes], I thanked. We cannot blame God, we must ask Him for health. I accepted because I had to.	ELoC-God Acceptance	Pt.1, F, no education (illiterate), diabetes
I cannot explain. If I didn't have them [diabetes] it would be much better, because it's an annoying condition, one of the most annoying here is. But it's like this, it must be... There are people for whom it is harder to accept. I have diabetes because they are hereditary.	ELoC-ancestors Acceptance- charity for others	Pt.2, M, 59, primary school, diabetes & hypertension
I felt a great sadness, a deep one. When I went to Lisbon, I was going to the infinite, I was going not to return; the surgeries are all difficult. I don't know if I was going with hate, if I was angry (zangado)...was altered (alterado). They operated me, I woke up...today I feel well, conditioned..."	Initial chock-sadness	Pt.3, M, 66, high school, hypertension
Those things are really with us, the hate is not to anybody... when I say hate (ódio) I mean anger. When they discovered I had [the disease]...I cried, I got a very big disappointment (desilusão), I was a bit choked (chocada), it is hard to get used to it, our life changes from day to night. Sometimes we feel like eating a little something. To think that there is no cure...	ILoC Initial chock-disappointment Adjustment of life to illness Despair	Pt.5, F, 76, no education (literate), hypertension
I felt a great revolt. I got irritated. It is the anger, it had to happen to me, why me? In those diseases where we think we are going to die it must be even worse, we must keep thinking why me?	Initial chock-rejection	Pt.6, F, 30, high school, hypertension
Prompt: When that happened didn't you feel like blaming someone?		
Not to blame! Who are we to blame? I think we cannot blame anyone		Pt.4, F, 67, primary school, diabetes & hypertension
If we are going to blame God it is a sin .		Pt.1, F, 76, no education (illiterate), diabetes
It depends on the disease. If it is cirrhosis or something like that, the person can blame himself.		Pt.2, M, 59, primary school, diabetes & hypertension
To blame ourselves, I don't think it is appropriate either		Pt.3, M, 66, high school, hypertension
When they come [the diseases], we must accept it; and to blame God even less, we must ask for help.		Pt.1, F, 76, no education (illiterate), diabetes
Sometimes we even say things we don't want to. I think we can get angry...with our grandchildren and all		Pt.5, F, 76, no education (literate), hypertension
Anger is a sin (revolta). To hate someone is even a bigger sin (odiar)		Pt.1, F, 76, no education (illiterate), diabetes
To be altered is also a sin . It is the same thing!		Pt.6, F, 30, high school, hypertension
Upset and irritated (chateada e irritada)		

The second concept related to the different phases that a patient goes through when diagnosed with an illness. Some quotes clearly referred to the initial feelings, often negative, such as sadness, disappointment, surprise and rejection. Two other evident phases were the acceptance of illness and the adjustment of the patient's life to his

illness. Finally, feelings of despair also emerged when referring to future and prognosis of illness.

The blame scenario was most difficult to discuss and reach agreement. Strong religious beliefs certainly influenced; perhaps where one of the participants thought that all of the suggested words for feelings were sinful (*alterada*, *zangada*, *chateada*, *irritada*, *culpar*). The term chosen (revolt; *revolta*) was the one considered to be less punishable in catholic terms, *i.e.*, it was still a sin but somehow allowed to humans in desperate situations. However, this raises issues related to compliance behaviours; perhaps patients who expressed views about religion tend to adapt more passive behaviour and simply comply with what “powerful others” dictate (Schlenk & Hart 1984), or if on the other hand what they say is not consistent with what they do. In the latter case, only through more robust methods of compliance measurement could this issue be further explored, *e.g.* by means of using electronic monitors (EMs) (Bond & Hussar 1991).

The sixth scenario was about medicines information, to explore three items of the EID scale *“You can never know enough about these things”*; *“I read about my medicines and illness as much as possible”*; *“I need as much information about my medicines as possible”*. The quotes from this debate are summarised in table 4.9.

Table 4.9 – Quotes referring to information

<p>"You can never know enough about these things" "I read about my medicines and illness as much as possible" "I need as much information about my medicines as possible"</p>		
Quote	Theme	Patient characteristics
<i>If the doctor says to take it is because it's good.</i>	The good patient	Pt.5, F, 76, no education
<i>I would like to know... what the medicines for. I don't know anything, if it will do me good or harm. I ask the pharmacist and it is the same thing.</i>	Specific information Recognition of doctor's and pharmacist's expertise	(literate), hypertension
<i>Sometimes there are words [in the patient leaflets] that I do not understand but I get the general idea.</i>	Readability of PILs	Pt.2, M, 59, primary school, diabetes & hypertension
<i>What we want to know is about those we take.</i>	Specific information	
<i>I ask to know what the medicine is for, for this and for that. I ask for explanation. I prefer to listen</i>	Enquiring for specific information	Pt.4, F, 67, primary school, diabetes & hypertension
<i>When there is interest we can read the leaflet [package insert]. I always read...well, not this time</i>	Specific information	Pt. 3, M, 66, high school, hypertension
<i>I have difficulties in reading but I go to the pharmacy to ask for an explanation</i>	Enquiring for specific information	Pt.5, F, 76, no education (literate), hypertension
<i>We arrive to the point that we don't know if we are doing well or wrong</i>	Shortfalls of not having enough information	Pt. 3, M, 66, high school, hypertension
<i>Those I take I always try to inform myself about them</i>	Specific information	Pt.6, F, 30, high school, hypertension
<i>To have knowledge is enough (é quanto basta). The maximum is too much</i>	We are not the experts	Pt. 3, M, 66, high school, hypertension
<i>For me it is difficult to read because I have glaucoma, so the statement [S10- I read] makes sense but not to me. There are people who cannot read, but I can; only there are letters I can't reach because of the glaucoma.</i>	Readability of PILs	Pt.4, F, 67, primary school, diabetes & hypertension
<i>Knowledge, is not very simple, for people that cannot read.</i>	We are not the experts	Pt. 3, M, 66, high school, hypertension
<i>I look for the maximum information about my medicines</i>	Eager learner	Pt.6, F, 30, high school, hypertension
<i>You never know everything (nunca se sabe tudo)...</i>	We are not the experts	Pt. 3, M, 66, high school, hypertension
<i>We, the patients, never understand well</i>	Eager learner	Pt.6, F, 30, high school, hypertension
<i>It is always worth to know more about medicines (vale sempre a pena saber mais sobre os medicamentos)</i>		
<i>I need to have knowledge about my medicines...</i>	Specific information	Pt.4, F, 67, primary school, diabetes & hypertension
<i>There comes a time when we know the aim of what is of interest to us</i>		
<i>I need to understand what the medicine is for</i>	Specific information	Pt.5, F, 76, no education (literate), hypertension
<i>I like to know all about the medicines I take (gosto de saber tudo)</i>	Specific information	Pt.6, F, 30, high school, hypertension
<i>When you don't feel the security of the doctor it is complicated, if the doctor says take that, it is the same, then we take it [referring to generics]</i>	The good patient	Pt.5, F, 76, no education (literate), hypertension
<i>The doctors are a very important source of information. This pharmacist I have is not like the majority there are...she explains everything</i>	Recognition of doctor's and pharmacist's expertise	Pt. 3, M, 66, high school, hypertension
<i>I am mostly afraid is of the doctor's reaction [referring to generics]</i>	The good patient	Pt.2, M, 59, primary school, diabetes & hypertension

During debate, issues related to literacy were raised. The participants considered that using the term "look for" instead of "reading" should address illiteracy issues, with

acknowledgement that these patients are not the experts. However, knowledge was acknowledged as a means to make informed decisions about generic medicines. Patients recognised that a lack of information was a reason for not being able to decide on less costly treatment options. Doctor patient communication difficulties were apparent during the debate around sources of medicines-related information (Bissell, May, & Noyce 2004), the fear of asking doctors implied the pharmacist was a more approachable health-care professional (Smith 1992).

Different attitudes towards information were evident in the debate; basic knowledge was sufficient for some patients; fear about knowing too much was expressed by other patients; whilst for others (the “eager learners”) the more knowledge the better. Not all patients want the same extent of information or at the same phase of their disease (Baker 1995). This could imply that the “blunters” may become the “monitors” at a later stage of their disease, and vice-versa; it is important to recognise behaviours can change over time, an issue further developed in the discussion.

Specific individualised knowledge was most often wanted, where patients wanted to know about their case, their medicines, not necessarily about medicines in general, the latter was left for health care professionals. The need to know about the actual use of medicines is equivalent to the so called specific knowledge in this study (Britten 1994).

There were difficulties associated with patient information leaflets, referring to difficult words used, which has been extensively researched elsewhere (Fuchs, Hippus, & Schaeffer 2003; Raynor & Knapp 2000; Vander Stichele 2004).

Following these debates, consensus about replacement items was sought by a nominal group technique. Seven items were modified with the panel’s agreement (table 4.10).

Table 4.10 – Revised items

Item	Portuguese statement	English literal translation
S6	<i>Gosto de saber tudo sobre os medicamentos que tomo</i>	I like to know everything about the medicines I take
S8	<i>Vale sempre a pena saber mais sobre medicamentos</i>	It is always worth knowing more about medicines
S10	<i>Eu procuro o máximo de informação que posso sobre os meus medicamentos ou doença</i>	I look for the maximum possible information about my medicines
T1	<i>Porque tenho de tomar medicamentos acostumei-me a eles</i>	Because I have to take medicines I got used to them
T2	<i>Sinto obrigação em tomar os meus medicamentos</i>	I feel obliged to take my medication
T6	<i>Há medicamentos que fazem bem a uma coisa e mal a outra</i>	There are medicines that do well to one thing and bad to the other
A4	<i>Sinto-me revoltado com isto que me aconteceu</i>	I feel revolt about what happened to me

4.5 Summary of findings

The main findings of this phase were that the different stages of the process were useful for enhancing the equivalence of the translated survey tool. While for some statements, equivalence was readily achieved following translation and back-translation (anxiety and PBM scale items), for other statements refinement produced modifications in items, either through health care professionals input (PHM and tolerance scale items) or through patients' input (EID scale items). For some items, equivalence was particularly difficult to achieve, having gone through all these stages (side-effects item within the PHM scale and the blame item within the tolerance scale).

4.6 Discussion

The sample selected to adapt the survey tool comprises various sub-samples, which are here discussed separately. The “ideal” translator, in general would be a health care professional or a patient, as appropriate, who was simultaneously a professional translator. This scenario is hardly conceivable as health care professionals and translators are distinct occupations, implying a person with two combined jobs would be required. Being “patient” results from the individual's health status, therefore in theory one could find a professional translator with a chronic illness. However, it may be assumed that the occupation would be superimposed on the health status, resulting in literal translations, which would not necessarily reflect the way patients express themselves. Another point to be emphasised is that in Portugal it may be relatively common for native speakers to speak and write in English as it is

part of formal education, but fluency is mostly encountered in higher educated individuals, who do not reflect the average citizen. Contrarily, it is quite rare to find an English native speaker fluent in Portuguese; perhaps because Portuguese is a difficult language to learn, because Portugal only recently opened its borders to immigration, and/or because English natives can easily live in Portugal without the need to learn the language in great depth. All these reasons justified the selection of the translators. While the forward translators were both health care professionals fluent in English with part of their lives spent in English speaking countries, the back translators were individuals with health-unrelated occupations whose fluency can be questioned, despite having been living in Portugal for several years. The shortcomings of this approach were nonetheless overcome by including additional steps where the wording was reviewed, including other health care professionals, researchers and patients.

The choice of raters was underpinned by objective criteria, where those judging the difficulty of the translation inevitably had to be the same producing the forward translation. The raters evaluating the quality of the translation in comparison with the original survey tool were bilinguals, assuming that Portuguese native speakers living in English speaking countries for periods longer than 6 months and maintaining regular use of English could be considered as such. Finally, the choice of raters assessing the equivalence of the back translation and the original survey tool focused on having native English speakers as both versions being compared were in English. Additionally, these raters were health care professionals and researchers with experience in using survey tools, which valued their input.

The development of a health care professionals' group discussion aimed to review the wording ensuring the concepts were not lost during translation. To achieve this it was considered that two separate groups were needed and would result in an added-value as it may be assumed that even when a person is bilingual, living in the country is essential to maintain or acquire the cultural values and even to have a deep understanding of the words and phrases various meanings. Using this reasoning the English group defined the concepts represented by the original statements and the Portuguese (bilingual) group suggested statements in Portuguese that would better

address these concepts, minimising the risk of misinterpretation, sometimes resulting from more literal translations.

Including patients in the revision of the translated survey tool was essential to ensure its adequacy for the target population. Initially individual interviews were undertaken to evaluate if each individual correctly interpreted the statements without suggestions from others. However, these patients were recruited in an urban setting where the educational level tends to be higher than the population average; perhaps for this reason, no major difficulties were encountered during this phase. However, when administering the survey tool to a larger patient sample during the pilot phase, analysis of responses suggested some statements were not appropriate and/or clear for some patient groups, namely the elderly and the less educated, more often found in rural settings.

This justified the development of a lay panel recruited in a rural setting. Additionally, previous patient recruitment was undertaken in hospital wards and hospitalised patients may not be representative of the rural population, who can spend most of their lives without visiting a hospital getting medical attention from a local health centre and getting their prescriptions and closer follow-up from the local community pharmacy. This justified the inclusion of a community pharmacist for patient recruitment in an area where there is only 1 health centre and the nearest hospital is 40 km away. This approach allowed exploring issues not deeply addressed in previous stages, such as regional variations and the impact of religion on patients' coping processes developed.

As reported in the results, one of the back-translations prior to the agreed version was found to be considerably different from its original and was therefore disregarded. An example was the item *"I need as much information as possible about my medicines"*, which was back translated as *"Clear and thorough information about my medicine is essential"*. A possible explanation for these difficulties was the use of unprofessional bilinguals. Additionally, one back translator had lived in Brazil for many years, where people speak Portuguese but the interpretation of some words is different, which could contribute to the variance. Nonetheless, the other back-translation was very similar to its original, reflecting a good forward translation process.

The inclusion of a rating step, whilst useful for exploring potential problematic items, revealed little sensitivity. This may result from few raters being used, which could be a limitation of the approach. Nonetheless, all forms of equivalence highlighted difficulties in translating one specific item “*I need as much information about my medicines as possible*”. The results exhibited where only 10.0% of the items received low mean difficulty ratings, are consistent (13.9%) with results shown in previous studies using identical methodology (Bullinger et al. 1998). Comparing this study results with those reported in the IQOLA project, one can see that the proportion of items rated lower for language and meaning equivalence is considerably lower in this study (5% compared to 14% for language and 0% compared to 28% for meaning), which indicates that the translation procedure was thorough, or, on the contrary, that using only two raters is insufficient and may compromise sensitivity using the approach chosen by these authors (Bullinger et al. 1998).

One important rule used in the IQOLA project was to instruct translators that the reading level should be compatible with that of a 14-year old (Bullinger et al. 1998). However, this is only appropriate if a perspective where no language is central and the translation process is decentred, *i.e.*, *etic*, is possible to take (Berry 1969; Brislin 1970).

Feedback from health-care professionals together with individual interviews with hospitalised patients and the development of a patient panel all contributed to refining the wording of some items following these translation procedures. Health care professionals’ input was particularly useful to highlight double-barrelled statements and seek adequate alternative wording. Examples of such statements include most of those separated by a comma in the English version, where the translated Portuguese version needed revision to transform it into one single statement.

Statements with double meaning may be useful in some cases to acquire a special meaning are known to create additional problems in the translation process (Todd & Bradley 1994). A better approach would have been to develop items from in-depth interviews with chronic patients. However, this would have had considerable time implications for the purpose of this research, and would not have fit the objective of assessing the translation process.

Patient input was most useful for unravelling jargon commonly used by health care professionals, not necessarily understood by lay people, including the term “side-effects”. Additionally, seeking perceptions from patients highlighted the difficulties associated with negatively worded items, such as *“You can never know enough about these things”*.

The use of negatively worded statements is a common technique to minimize acquiescence response (Winkler, Kanouse, & Ware, Jr. 1982) or the halo effect (Todd & Bradley 1994). Being aware this technique poses additional problems with understanding, particularly among the less educated population, one may question its suitability for use in some strata of the Portuguese population. Nonetheless, national socio-demographic data reveal a trend towards progressive institutionalised education (Instituto Nacional de Estatística 2003), which led to the investment in the forthcoming population who could potentially benefit from the use of this questionnaire in pharmacy practice.

Using a group of patients rather than individual interviews was particularly useful to stimulate debate and explore controversial issues, such as the impact of religion on the way people express themselves. This could potentially cause discomfort if explored in one-to-one interviews. One item that exemplifies this question is *“I just want to blame someone for the way I feel”*. Emotionally evocative terms have been described as particularly difficult to translate (Sperber 2004) and this study attests it.

Some of the concepts debated indicated that some interpretations of illness and medicines and coping processes developed were related to patients having an external or internal locus of control. A study on haemodialysis patients showed that patients with an internal locus of control adapt better to disabilities (Poll & De-Nour 1980). However, religious coping (one form of ELoC) has been suggested to divide into active and passive, where the latter would be associated with worse adjustment (Braido-Lanza, Vasquez, & Echeverria 2004). It is almost as if the active religious coping was equivalent to having an internal locus of control, making the patient accept his illness and create his self-efficacy mechanisms to adjust to it (Braido-Lanza, Vasquez, & Echeverria 2004).

Other authors have described these phases classifying them into alternatively worded categories, such as anger, suddenness and previous experience of the illness (Lewis 1998) or as acceptance, denial, avoidance and disavowal (Buetow, Goodyear-Smith, & Coster 2001). One of the developed mechanisms is the belief that the disease must be accepted and the patient will have to live with it, exactly as stated in this panel discussion, adapting in the course of the disease's different stages (Grimaldi 2003). It must be noted that not all patients go necessarily through all these stages or evolve in the same order or at the same pace.

The development of coping processes to deal with a health threat was briefly summarised in the introduction. However, coping styles have not been addressed elsewhere and these are different mostly in regards to their stability. It has been suggested that individuals possess different coping styles to face health threats which most often fit into one of two categories: "monitors" or "blunters" (Miller 1987; Miller 1995).

"Monitors" are described as active information seekers, who prefer quite detailed information, while placing high importance on negative aspects. These are often so valued that the risk for developing a disease is overestimated and generates increased anxiety, often linked with loss of hope in recovery and in treatment's effectiveness (Lerman et al. 1993; Schwartz et al. 1995). Nonetheless, when anxiety does not reach such peaks, monitors tend to be more prone to adhere to preventive and curative recommendations given the high value they place on health threats (Miller et al. 2001).

"Blunters" and "repressors" are described as reacting to health threats by what could be compared with avoidance-coping. However, the repressive style seems to develop as a result of past experiences (*e.g.* childhood) that made them create defensive mechanisms to act indifferent to stressful situations and maintain a high self-image and social acceptability (Myers, Brewin, & Winter 1999; Perini et al. 1994), blunting theory developed in a later context where not so much value is put on the past but rather on their natural lower concern with health threats that are further minimised by distracting themselves with other aspects of their lives (Miller et al. 2001). Blunters

prefer being given the minimum information possible about their illness and medicines (Miller, Shoda, & Hurley 1996) and have also been reported to be less likely to adhere to health-related recommendations given the low importance they attribute to it (Miller et al. 2001).

While the use of a consensus technique to reach a conclusion at the end of the session can be criticised (Bond 2000), such a technique was useful for generating new items to be subsequently further tested in a larger sample.

Individual interviews, on the other hand, were useful to reveal that some statements may be of particular sensitive nature, especially in the anxiety scale. As such, if such scale is pursued in future developments, these statements should be kept at the end of the questionnaire to minimise poor-response (Edwards et al. 2003).

Individual patients highlighted the difficulties of using multi-item response scales, where patients often disregarded some points of the scale as potential options. Some may question the usefulness of using multi-item scales as opposed to a dichotomously responded question. However, it is general knowledge that this technique is used to minimize the social desirability bias. Again, this problem is more common among the less educated which further justified the approach taken.

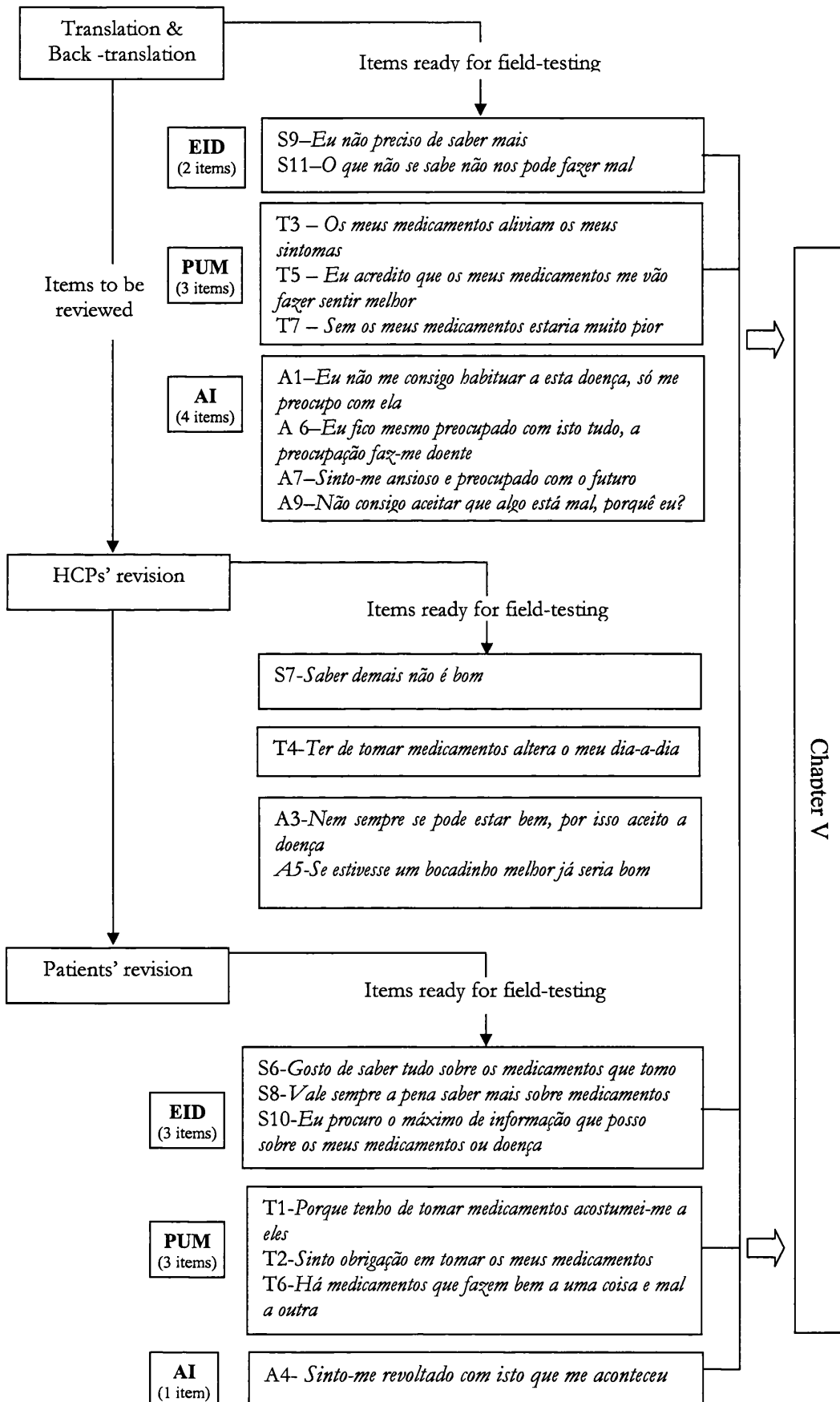
Ongoing research is addressing the applicability of the PUM scale in 3 groups of immigrant populations in Northeast London (Rennie, Engova, & Bates 2004). The approach taken differs substantially since both the population and the settings are different (Costa, Bates, & Duggan 2004). Preliminary findings indicate that three items had the same difficulties as those here reported. The verb *“to take”* when translated into Turkish was associated with the practicalities, *i.e.*, swallowing pills, rather than with the process; the verb *“used to”* in Bengali had to be replaced by an alternative colloquial expression (item T1). Both of these issues were encountered in this study. Being *‘trapped’* did not translated well into Turkish and was considered double-barrelled when translated into Bengali (item T2). These two problems were also reported in this study (table 4.2 and section 4.4.4.2). The word *“side-effects”* was hard to understand in Bengali and Urdu, as in Portuguese. Additionally, the use of *“form of disease”* in this same statement was reported as too technical in Turkish and

hence refined into “like” (item T6), similar to the solution proposed here (Rennie 2005). The consistency of the findings adds to the credibility of the approaches.

There are always issues with cross-cultural validation to be carefully addressed, such as differences in literacy and religious beliefs, which need to be taken into account. Projects that take such issues into consideration are of great value, and is undoubtedly one of the strengths of this study.

Each stage of the process is summarized in figure 4.6. The resulting Portuguese survey tool achieved through this sequential approach was tested in a patient sample to ensure the scales’ validity and reliability was not lost in the process of adaptation; in chapter V.

Figure 4.6 Summary of findings from Chapter IV feeding into chapter V



4.7 Conclusions

The aim of the phase described in chapter IV was to adapt a survey tool to measure information desires and perceptions about medicines and illness of patients. To achieve this aim the objectives set were to evaluate the published literature on the translation of survey tools, to translate the original English survey tool to Portuguese, to ensure its linguistic equivalence, and to explore its understanding in Portuguese and to further refine the wording of statements, as appropriate.

The main findings were that a straightforward translation of the survey tool is insufficient to ensure equivalence and understanding among the target population. While some of the scales were relatively easy to translate and needed little refinement (*e.g.* PBM), others benefited from successive modifications, where health care professionals' input was particularly useful to explore issues around the use of words with different meanings or hardly understood by lay people (*e.g.* PHM) and patients' input emphasised the inadequacy of some expressions for a different culture with distinct beliefs (*e.g.* AI) and with distinct educational background (*e.g.* EID).

The obtained Portuguese survey tool at this stage, apparently suitable for the target population, needs to be explored for issues around validity and reliability. These are always essential to verify and cannot be taken for granted, otherwise one may risk using a tool that does not measure what it is intended to measure and/or that does not measure the concepts of interest in a consistent manner. Additional care in this process is needed when the tool is substantially modified, as it was the case for some of the statements comprised in different scales. These issues will be explored in chapter V.

CHAPTER V

VALIDATION OF A SURVEY TOOL

5.1 Perspective

This chapter describes the processes to ensure the validity and reliability of the survey tool following translation. Chapter V is organised in three main sections. Firstly, the pilot phase provides context for the main experiment; the application of the survey tool in a large patient sample.

The survey tool used in this study measured three main concepts, the validated scales “Extent of Information Desired” (EID), the “Perceived Utility of Medicines” (PUM), and the “Anxiety about Illness” (AI) (Astrom et al. 2000b; Duggan & Bates 2000; Duggan et al. 2002).

5.2 Aims and objectives

Aims

This phase aimed to validate a survey tool to measure patients’ information desires and perceptions about medicines and illness

Objectives

- 5.2.1 To explore the translated tool’s validity in Portuguese patients
- 5.2.2 To explore the translated tool’s reliability in Portuguese patients
- 5.2.3 To explore the translated tool’s credibility in Portuguese patients
- 5.2.4 To explore the perceptions of Portuguese patients about medicines and illness

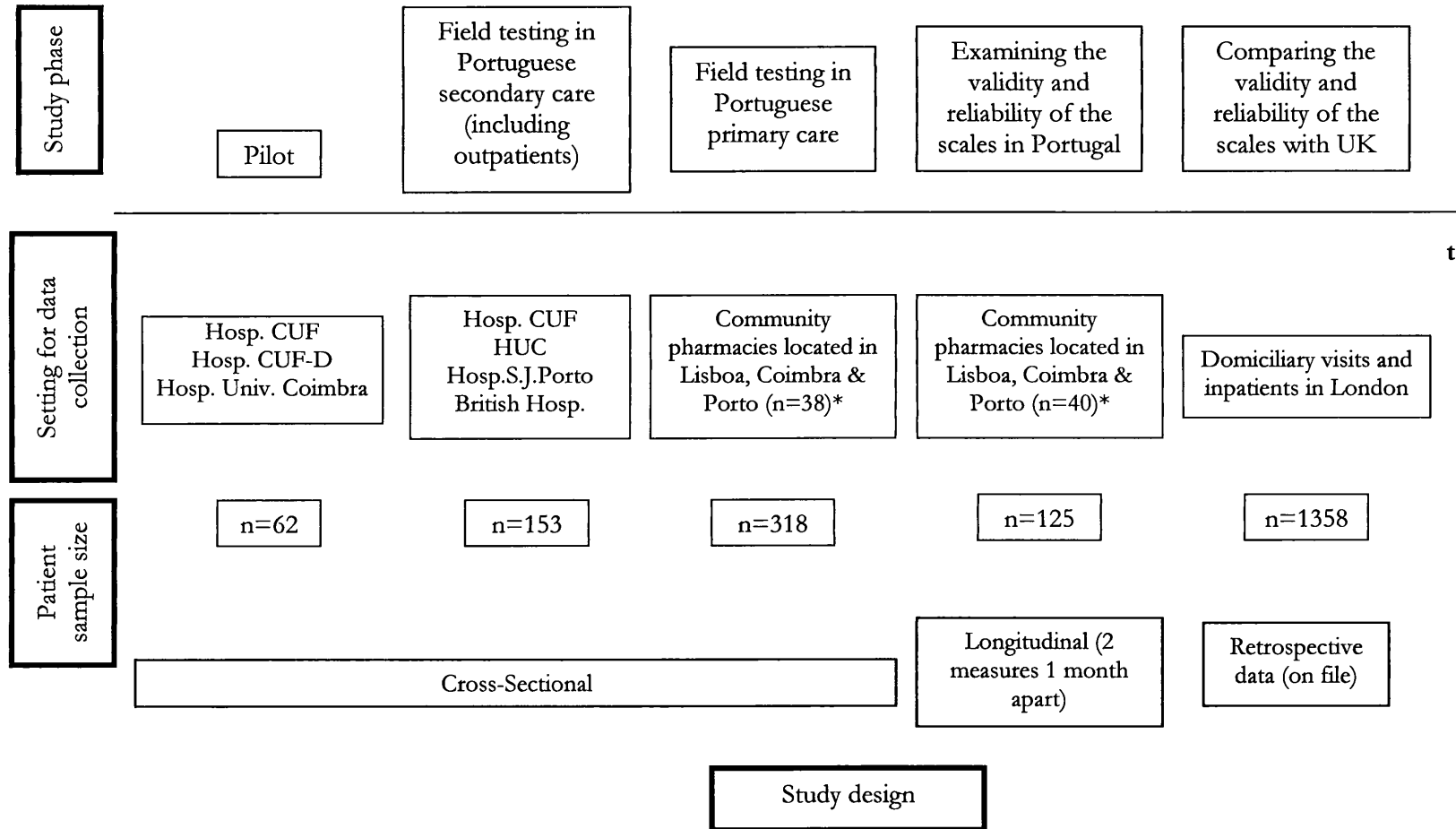
5.3 Methods

This section describes the study design, the patient sample, the patient recruitment procedures and data management.

5.3.1 Study design

An initial exploratory study was undertaken using a cross-sectional design to evaluate the translated tool’s validity and internal consistency. A longitudinal study was subsequently undertaken to explore the tool’s consistency over time (also called temporal stability) through a test-retest design. Figure 5.1 illustrates the different study designs and settings used for data collection in chapter V.

Figure 5.1 – Diagram of study designs and settings used in this chapter



*Some of these pharmacies participated in both phases

5.3.2 Sample

Sample size considerations for cross-cultural validation studies have been widely discussed; it is generally accepted that the number of patients to include in field-testing is either related to the number of items in the questionnaire or to the number of factors that should be extracted (DeVellis 2003a). Previous studies by the research team resulted in a reduced version of the 50-items survey tool, from which 5 factors emerged: EID, Perceived Harm of Medicines (PHM), Perceived Benefit of Medicines (PBM), Tolerance and Anxiety (both within AI), implying that 100 study recruits were necessary for validation. However, the highest estimate is 10 times the number of items in the questionnaire, *i.e.*, 250 patients. For purposes of test-retest reliability analysis, a sample of 200 patients was considered necessary to detect differences between mean scores to the scales, for a 95% confidence interval (5% error and an 80% power) (Machin et al. 1987). As these phases were undertaken sequentially; in some analyses a total of 450 patients are presented in the analysis.

5.3.3 Piloting

The pilot phase aimed to ensure that the materials and methods chosen were appropriate for the main study. Chapter IV demonstrated the equivalence of the survey tool with the original. In this chapter, the maintenance of the tool's validity and reliability was tested. A set of documentation forms were developed as required by the local ethics and research committees, which comprised an information sheet with details of the study, an informed consent form and a refusal form; all of which needed to be piloted to ensure their suitability. Additionally, the research was set to take place in different hospitals and community pharmacies using different data collection methods, which also needed piloting to ensure that health care professionals involved in the process were cooperative in data collection and to evaluate the possible difficulties with patient recruitment.

5.3.4 Field-testing in Portuguese primary and secondary care

The health care professionals' group work, the individual patient interviews and lay panel explored and established face and content validity of the survey tool, as described in chapter IV. The next step involved testing the translated questionnaire

in an independent medical patient sample, large enough to explore validity and reliability (Guillemin, Bombardier, & Beaton 1993).

The inclusion criteria included adult patients who were prescribed with medication, who understood written and/or spoken Portuguese and who agreed to participate in the study once informed. Patients were invited to participate and were then provided with additional information about the research by means of a written invitation (appendix 2). Prior to the interview, patients read and signed and informed consent form (appendix 3). Patients in the ambulatory care setting also read this form.

Participants recruited in the hospital setting were interviewed at their bedside using a standardised questionnaire, comprising three main sections: demographic data, diagnoses and prescribed medicines; the survey tool's items, which were statements to be answered using a 5-point Likert scale, ranging from strongly agree to strongly disagree; and a set of open questions to address the concepts explored through the scales, *i.e.*, extent of information desired, perception of the utility of medicines and anxiety about illness, additionally exploring their adherence prior to hospital admission and its potential determinants (appendix 4). In the community pharmacy setting, questionnaires were self-administered but comprised a similar content (appendix 5). During this phase, an additional section was used by the pharmacists recruiting the patients to document whenever the patient needed help when responding to the survey tool, to say why and where such help was provided.

Patients who were unwilling to participate were asked to answer some questions (appendix 6). These "refusal forms" sought to explore different characteristics of non-respondents.

Pharmacists were given a questionnaire to evaluate their participation in the study, including any implications for normal pharmacy working, and ease of recruiting patients (appendix 7).

5.3.5 Analysis of data - Quantitative

Quality control was performed prior to data analysis. The database contained a total of 617 cases; hence 80 randomly selected individuals were verified (11.5%). From these, the maximum number of errors would be 5 and 2 were detected (table 5.1), after cleaning for systematic errors. Subsequently, those patients where most of the items comprised by the scales were left unanswered were removed from the database ($n=21$), hence a final sample of 596 patients was used in this phase of the project.

Table 5.1 – Data cleaning process

Sample size	Sample to be checked	Errors allowed	Errors detected	Conclusion
617	80	5	2	Ok (after correcting the 2 errors)

Data were analysed using descriptive statistics to characterise the sample and responses to the scales. The Kolmogorov-Smirnov Test was used to explore the distribution of scores to scales before deciding on the use of parametric or non-parametric tests. Construct validity was explored in factor analysis, using Principal Components Analysis (PCA) with Oblimin rotation. The emerging subscales were subsequently compared with retrospective UK data. Criterion validity was explored by correlating scores to the anxiety scale and patients' responses to the SF-36 general question included in the questionnaire (DeVellis 2003b). The tool's discriminatory power, *i.e.*, the ability to distinguish scores between groups of patients, was assessed using ANOVA or independent samples t-test, as appropriate. Internal consistency was analysed using Cronbach's coefficient alpha (α) and inter-item correlations (r) and again compared with the UK retrospective data. Test-retest reliability was explored in a sub-sample of patients who responded to the questionnaire at two time points one month apart; data were treated as paired samples, using a T-test to compare their mean scores.

5.3.6 Analysis of data - Qualitative

Criterion validity was further assessed by comparing qualitative data (responses to semi-structured questions) with scores. Patients were asked questions at the end of the survey to explore any perceptions. These quotes were then coded for meaning, allowing themes to emerge and were compared with scores and demographics.

Matrices were used to display the interfaced data and compare similarities and differences. An iterative process was used, through which the codes were refined, and credibility was ensured by an independent researcher checking the codes, to verify the meaning and to agree the themes.

5.4 Results

5.4.1 Pilot study

A sample of 62 patients was recruited for the pilot phase (table 5.2). These were recruited in 3 hospitals: *CUF* (n=13; 21.0%), *CUF-Descobertas* (n=25; 40.3%) and *HUC* (n=24; 38.7%).

Table 5.2 – Pilot sample characteristics

Characteristic	Variables	n
Gender (n=62)	Male	38
	Female	24
Educational level (n=62)	No education (illiterate)	4
	No education (literate)	3
	Primary school	20
	Preparatory school	6
	Secondary school	6
	High school	9
	University (including post-graduate)	11
Presenting condition (n=61; missing=1)	Cardiovascular System	4
	Endocrine System	1
	Respiratory System	7
	Renal or liver impairment	5
	Osteoarticular problems	31
	Immune System	1
	Tumours	1
	Genitourinary tract	1
	Blood disorders	4
	Other (includes intoxication and unspecific symptoms)	6
Characteristic	Mean; median; sd	
Age (n=61; missing=1)	51.1; 51.0; 18.7	
Rx medicines (n=62)	4.1; 4.0; 3.2	

Note: n differs between variables because of missing data

The pilot study highlighted difficulties in recruitment associated with some of the study sites. It was not feasible to recruit patients from two of the hospital sites as access was restricted to wards where chronic medication was not frequently

prescribed. This is evident in table 5.2 where one can see that half the patients recruited had “ostheoarticular problems” as presenting condition, *i.e.*, many of these were healthy individuals who had *e.g.* broken a leg. This fact was also reflected in patients’ reports about their perceived health status, where an important reported feeling proportion “good” (n=25; 40.3%). Patients’ responses to the questionnaires, the numbers of prescribed medicines and their diagnoses confirmed the unsuitability of recruitment at these two sites; the use of the PUM was particularly inappropriate for acute diagnoses. Therefore, inclusion criteria were reviewed to explicitly include “patients taking daily medication/with chronic diagnosis confirmed”.

5.4.2 Field testing in primary and secondary care

The main experiment tested the survey tool on a medical patient sample. Data was collected from patients recruited at different study sites. The results of this section are organised in three sub-sections. Firstly, the sample is characterised (including description of non-respondents) together with distribution of scores. The second and third sub-sections present data from tests for validity and reliability, respectively.

5.4.2.1 The patient sample (responses to scales)

After data cleaning (explained in section 5.3.5), a total of 596 cases were kept for analysis. Table 5.3 summarises the demographic, medical and therapeutic characteristics of the sample.

Table 5.3 – Portuguese sample characteristics

Characteristic	Variables	n	%
Gender (n=596)	Male	249	42
	Female	347	58
Educational level (n=575; 21 missing)	No education (illiterate)	36	6
	No education (literate)	50	9
	Primary school	248	43
	Preparatory school	25	4
	Secondary school	95	17
	High school	51	9
	University (including post-graduate)	70	12
Existing condition (n=596)	Cardiovascular System (<i>e.g.</i> hypertension, angina pectoris)	190	32
	Endocrine System (<i>e.g.</i> diabetes, thyroid disorders)	148	25
	Respiratory System (<i>e.g.</i> asthma, COPD)	65	11
	CNS (<i>e.g.</i> depression, Alzheimer)	67	11
	GI System (<i>e.g.</i> peptic ulcer, gastritis)	33	6
	Immune System (<i>e.g.</i> lupus; rheumatoid arthritis)	24	4
	Tumours (<i>e.g.</i> lung cancer, stomach cancer)	11	2
	Other (includes disorders from the Musculoskeletal System, Renal or Hepatic System, Sensorial organs, Blood disorders, Transplants, Genital disorders, Intoxication and unspecific symptoms)	58	10
Characteristic	Mean; median; sd		
Age (n=595; 1 missing)	59.0; 62.0; 15.1		
Rx medicines (n=589; 7 missing)	4.4; 4.0; 2.8		

Note: n differs between variables because of missing data

The study participants were recruited through general medicine wards in 4 different hospitals (n=103), 2 outpatient clinics (n=50) and 38 community pharmacies (n=443). Recruitment sites were located in three main geographical regions (Lisbon, Coimbra and Porto). In the secondary care sample, patients with acute diagnosis were excluded (n=30).

The sample was evenly distributed in terms of gender. The mean age may be considered as expected given the study focuses on chronically ill patients. The educational level found in the sample shows a high proportion of people without education, which is not surprising, but an extremely high proportion of individuals with primary school education (4 years of formal education). The sample comprised a majority of cardiovascular and endocrine patients (57%), which include patients with some of the most prevalent diseases, like hypertension and diabetes.

A total of 25 patients refused to participate in the study. Their characteristics are presented in table 5.4 and reasons given for non-participation are presented in table

5.5. As the number of non-respondents was very low (4%) no statistical tests were performed to quantify these differences. Nonetheless, table 5.4 shows that there were some characteristics differently distributed between these two groups. To be mentioned are the lower proportion of non-respondents among outpatients, the higher proportion of endocrine patients and the higher proportion of literate patients with no qualifications, all in comparison with the proportion for these groups among the respondents.

Table 5.4 – Non-respondents characteristics compared with respondents

Characteristic	Variables	Non-Respondents (%)	Respondents (%)
Setting	Inpatients	24%	17%
	Outpatients	4%	8%
	Community Pharmacy	72%	74%
Gender	Male	36%	42%
	Female	64%	58%
Educational level	No education (illiterate)	8%	6%
	No education (literate)	23%	9%
	Primary school	31%	43%
	Preparatory school	8%	4%
	Secondary school	15%	17%
	High school	8%	9%
	University	8%	12%
Existing condition	Cardiovascular System	39%	32%
	Endocrine System	44%	25%
	Respiratory System	9%	11%
	CNS	--	11%
	GI System	--	6%
	Immune System	--	4%
	Tumours	--	2%
	Other	9%	10%
Characteristic			
	Non-Respondents	Respondents	
	(Mean; median; sd)	(Mean; median; sd)	
Age	62.7; 65.0; 14.5	59.0; 62.0; 15.1	
Rx medicines	5.1; 4.0; 3.6	4.4; 4.0; 2.8	

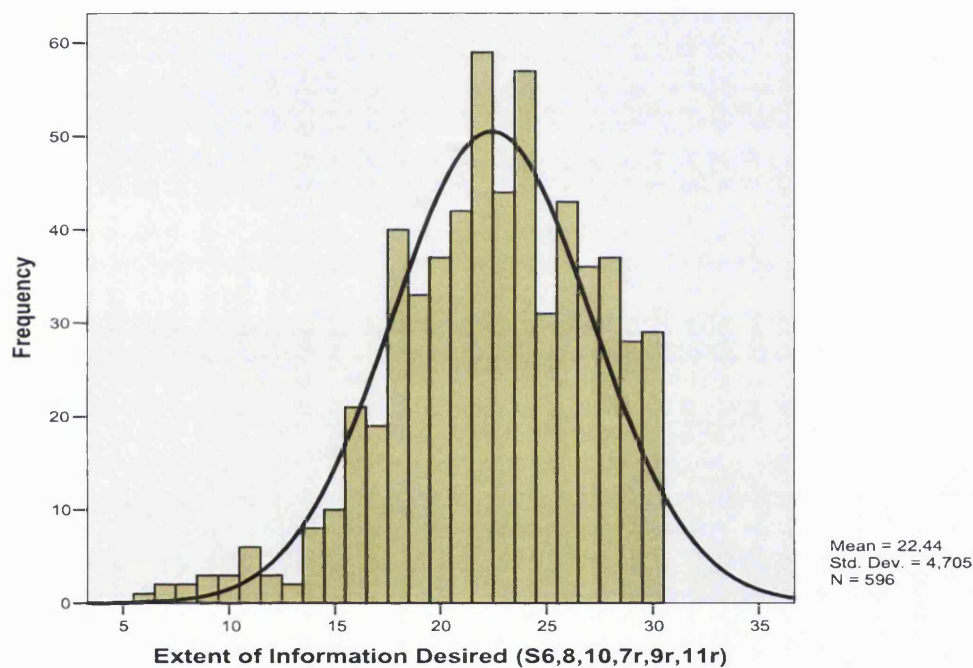
Table 5.5 – Reasons given for not participating in the study

Reason	n
Not having time	13
Being in pain	3
Not wanting to sign an informed consent form	2
Not wanting to provide personal information	2
Not liking questionnaires	2
Other	3

Although the settings were quite similar, potential recruitment problems may occur because there were a lower proportion of non-respondents in community pharmacy than in the hospital setting.

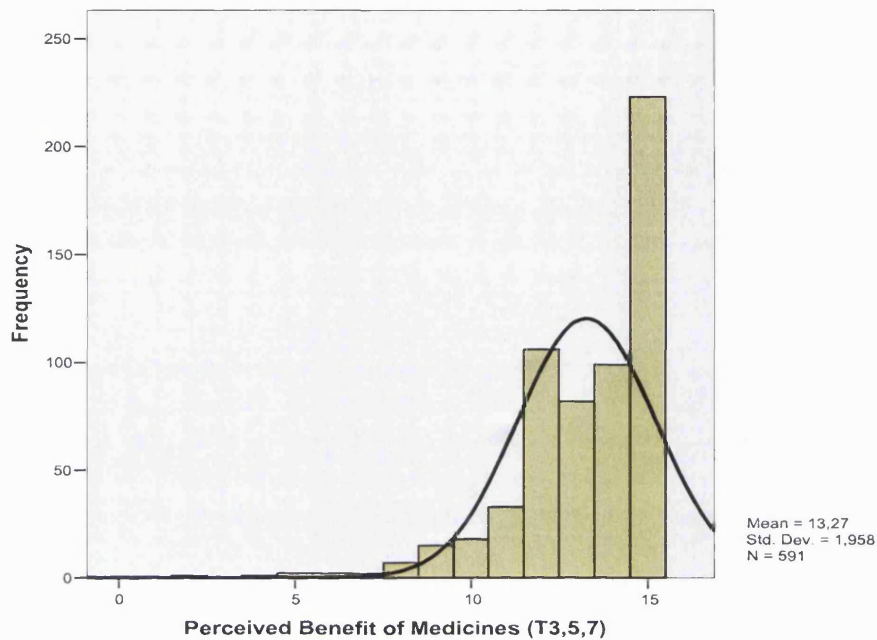
The following figures (5.2-5.5) display the distributions of scores to the 4 scales in the study sample.

Figure 5.2 – Histogram of scores to the EID scale



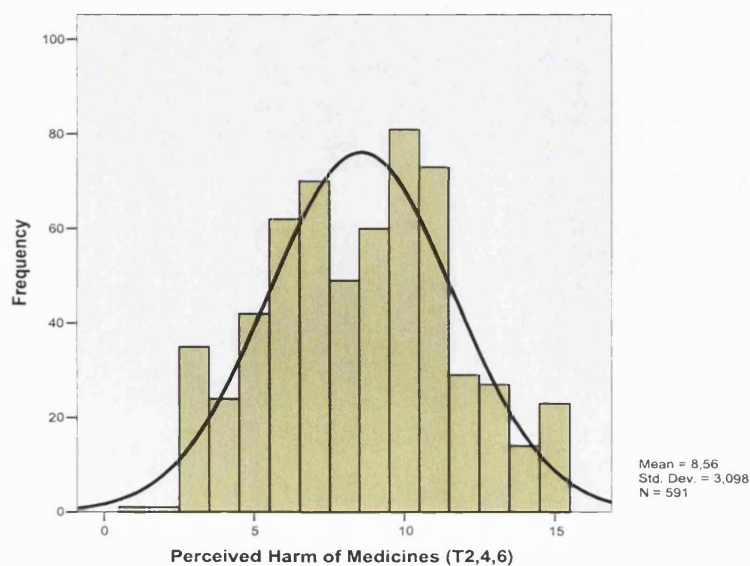
There was a wide distribution of scores to the EID scale. The skewness to the right and the mean score of 22.4 indicates that the majority of patients have a high desire for information, (as suggested in many previous studies). Nonetheless, a percentage of the sample scored below the mean, indicating there are patients who would rather be less informed about their medicines and/or illness.

Figure 5.3 – Histogram of scores to the PBM scale



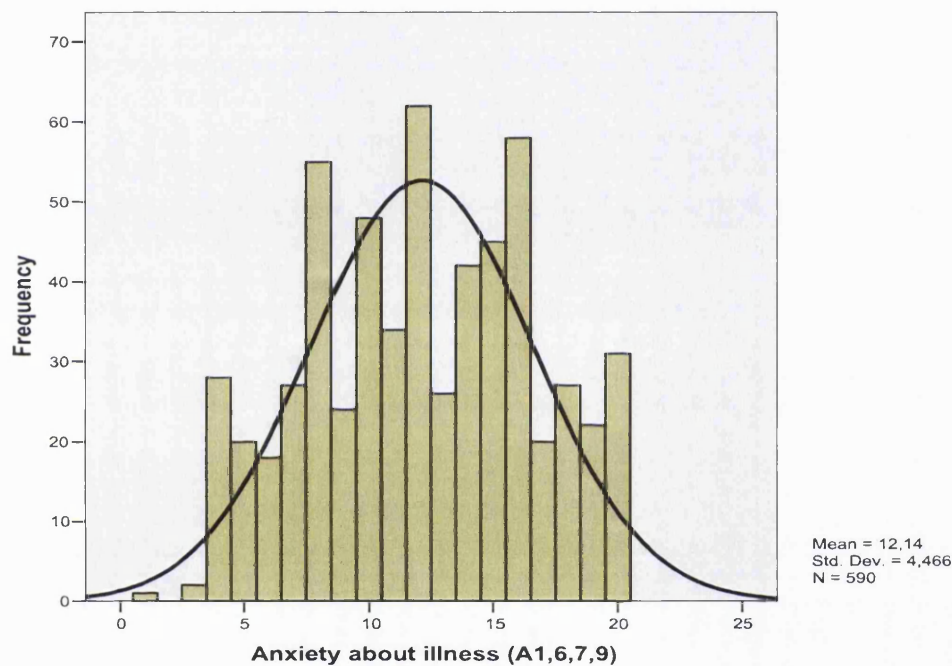
The distribution of scores to the PBM scale is clearly skewed to the right (mean score= 13.3), indicating that most of the sample perceive their medicines as beneficial. It is worth emphasising the peak observed for the score 15, which corresponds to patients who expressed total agreement with all items comprised by the PBM scale.

Figure 5.4 – Histogram of scores to the PHM scale



Scores to the PHM scale (assumed to be the reverse of the former scale), are well distributed with a mean score (8.6) very near the mid point of the scale (9.0). this could imply that patients perceive harm in their medicines to different extents and is worthy of further study.

Figure 5.5 – Histogram of scores to the Ai scale



Scores to the Anxiety scale are well distributed, the mean score (12.1) is near its mid point (12.0). This could indicate that anxiety levels differ across this sample, worth further exploring.

These figures provide a visual representation of data distribution, allowing assumptions on its normality guiding the option for using parametric tests in further analyses, except when analysing the PBM scale for which non-parametric statistics were chosen.

5.4.2.2 Examining the validity of the scales

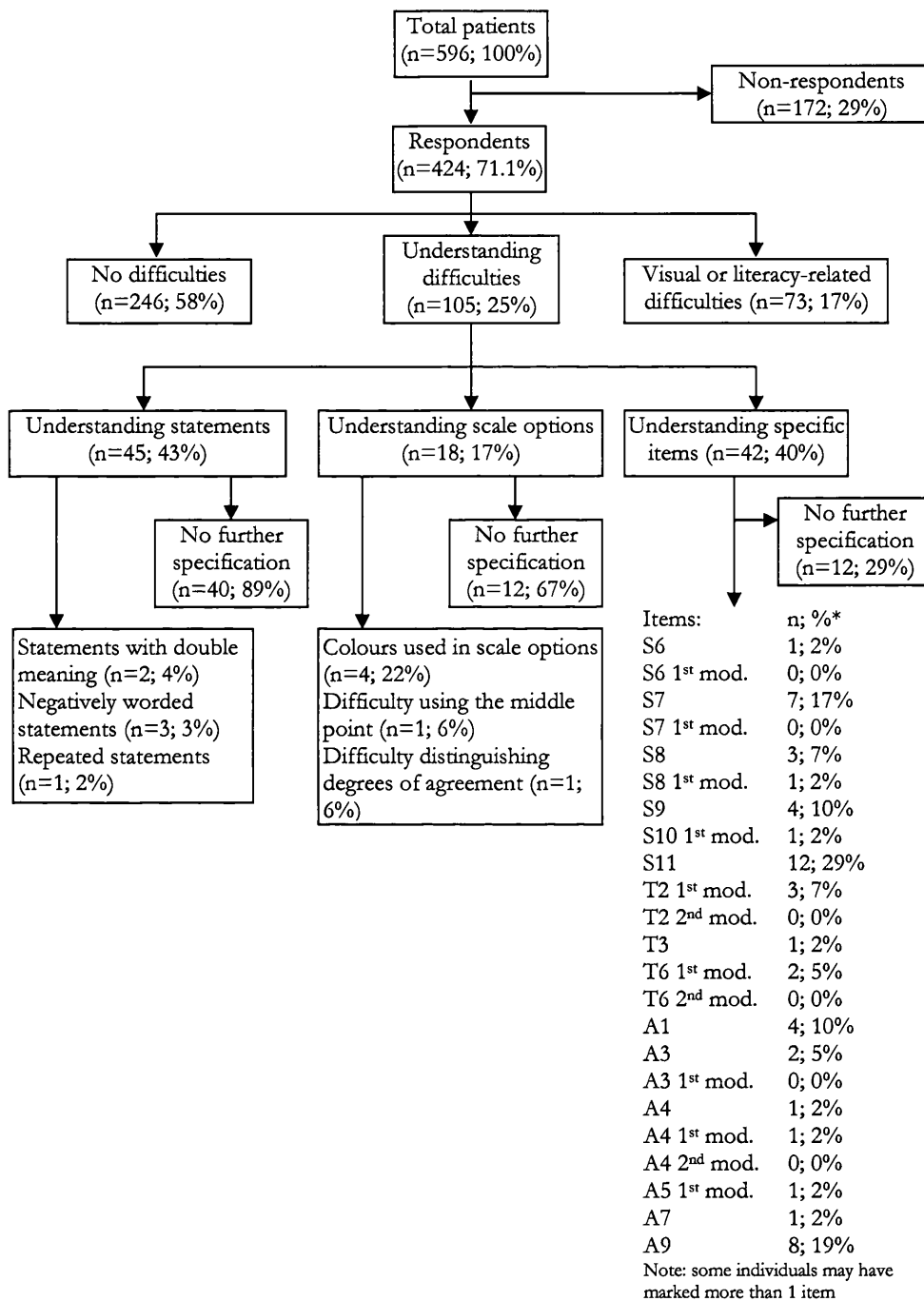
The purpose of this section is to explore the validity of the tool.

Face and content validity were mainly explored in the course of chapter IV by seeking perceptions from patients and health care professionals to ensure the understanding and the relevance of survey items. Nonetheless an additional way of exploring the relevance and/or clarity of the items was by analysing the percentage of patients answering “unsure”.

One statement used to illustrate this was item T6 - *“The side-effects are another form of disease”*, where 25.4% of patients answered “unsure”. After the first modification, *“Some of medicines’ effects are nearly as bad as having another disease”*, 19.4% were unsure. Following the second revision *“Some medicines are good for one thing and bad for another”*, 13.2% were unsure. This implied the modified item was clearer for patients.

Another measure of how the patients understood the questionnaire were the difficulties reported, detailed in figure 5.6

Figure 5.6 – Patient-reported difficulties answering the questionnaire



Almost a quarter of patients had difficulties with understanding (25%) and 73 patients (17%) had visual or literacy-related difficulties. Whilst this value is high, it should be noticed that some of the items listed were modified, leading to less difficulties. The potential problems remaining in the last version of the survey tool refer to the items S11 and A9, which were not further modified in this study. It

should be considered that the validation of a survey tool is an ongoing process so subsequent modifications are possible once implemented in practice.

Colours were used in self-administered questionnaires to improve the layout. Following patients' comments in the figure, this option may be reconsidered prior to implementation in pharmacists' daily practice. The criticism made about negatively worded statements was repeated for the adherence question (n=2) and should be taken into account when assessing patients' adherence in daily practice.

Despite being valid, some questions were too personal for some respondents, especially the Anxiety scale and elicited emotional responses. A pharmacist reported that he found the situation very uncomfortable and that he would not be very happy using this scale in practice as it made his patients often tearful or feel anguish.

Criterion validity refers to the way through which items from one survey relate to another that measures the same concepts. The term "gold standard" is sometimes used to refer to such tools, which is dependant on the criteria to be compared. Throughout the thesis, the term "the best available" will be used to refer to those instruments in the literature. In the course of this study, criterion validity of the survey tool was explored in three ways. Data from open questions, (patients' quotes) were used to explore how they illustrated their attitudes to the concepts (table 5.6). Secondly, these data were interfaced with patients' scores to the scales, to explore how patients giving high or low scores to a given scale describe their attitudes to the concept being measured (table 5.7 to 5.9). These approaches consider patients' expressions of their views and experiences as the best available comparison. Thirdly, scores to the Anxiety scale were correlated with another pre-established tool, the SF-36 (general health item).

Major themes emerged from the data, including information desires or perception about medicines, previous experiences or beliefs, such as perceptions of health care professionals and coping mechanisms (table 5.6). Relevant patients' quotes illustrating these themes using more detailed coding are presented to demonstrate the credibility of the interpretations, together with reference to relevant published work. Full discussion of the findings is made in section 5.5.

Table 5.6 – Major themes emerging from the interviews

Information desires	Wanting information	Patients wanting information, two degrees of complexity were found. Patients who want to be informed about specific issues of their medicines (“minimum is enough” patients) and patients who want to know as much as possible and see that as their right (“eager learner” patients).
	Not wanting information	Two groups of patients were classified within this attitude code. Those that do not want to know because they get anxious when informed about side-effects for example and because they find information confusing (“afraid to know” patients), and those that are happy not having information because they think that is the doctor’s role and it is not their place to know (“happy ignorant” patients).
	Already have information but still ant some more	In this group patients seem to have two types of attitude. They all assume they already know everything, either because they have been on medicines for long or because they have excellent communication with their doctor. This raised awareness causes patients to either state they still want to know or that they do not need any more (“knows it all” patients).
Perceptions of medicines	Unnatural	Medicines are described as best avoided, often by patients on 5 or more drugs.
	Dislike	Medicines are referred to as unpleasant, mostly due to past experiences of side-effects.
	Impact on life	The impact of medicines in patients’ life was mainly described in economic terms (“medicines are very expensive”) and in terms of the implications of taking them. The latter include details of impact on social and sexual life.
	Benefits	Medicines’ benefit seems to be perceived differently according to the therapeutic class or to patients’ perception of risk of an adverse outcome, such as stroke.
Perceptions of HCPs	Perception of doctors’ info-related attitudes	Doctors were criticised for keeping information from patients and for using jargon when communicating.
	Perception of doctors’ behaviours	Doctors seen as unquestionable experts, whose decisions are to be rigorously followed. On the other hand, they were criticised for having a superior attitude and sometimes even little respect for patients.
	Doctors’ characteristics	Older doctors perceived as more professional but less humanitarian and more distant.
	Faith in God	Acceptance of disease was often explained by God’s decision, which was to be taken as the right thing. Men were referred to as impotent when faced with God’s decisions. Fate was somehow seen as unreligious, hence not believed in general.
Coping mechanisms	Trust in doctor	The doctor was also mentioned as a “powerful other”, not able to dictate the onset of disease but as the one who would be entirely responsible for its cure, which made patients feel safe.
	Charity for others	This theme appeared mostly in two scenarios, when explaining why doctors did not dedicate more time to them and when expressing the way they tolerated their disease as it was not that bad.
	Need to be cared	Criticisms made to the lack of humanity in hospitals were in line with the expression of a desire to be treated kindly, sometimes mentioned as more important than the technical aspects of care provided.

Information about medicines

When asked about their preferences in receiving information responses varied. *“Do you like to receive information about your medicines or illness?”*

Several criticisms were made about patient information leaflets (PILs), most of it referring to the non-specific information contained in PILs, the type of language and the font size. These patients tended to be quite young and well educated, indicating it is not a literacy-related problem.

Q1 - *“Side-effects are foreseen by the doctor, but he should alert the patient because if it was so, people would have to read the PILs, because that doesn’t say anything anyway and the letters are too small.”* (Pt 49, male, 60 y.o., secondary school, school teacher, liver impairment, 5 meds Rx)

Q2 - *“I don’t want to read, I want to listen I don’t want to read papers with funny language”* (Pt 23, male, 26 y.o., university, engineer, respiratory condition, 3 meds Rx)

Q3 - *“I think that information about medicines is good but must be directed to the target. If it is for lay people it must be so that people understand. In PILs sometimes they use words that are not understandable and I must use the dictionary... I don’t need to know the chemical formulas.”* (Pt 27, male, 51 y.o., university, engineer, cardiovascular condition, 2 meds Rx)

Q4 - *“I read only by curiosity but you can’t understand a word of those technical terms and I assume they were well prescribed.”* (Pt 49, male, 60 y.o., secondary school, school teacher, liver impairment, 5 meds Rx)

Some thought the PIL was a security net, only to be read when problems arose.

Q5 - *“I am not a maniac to read all the papers. Usually I trust the doctors if they treat me well. I only read the PIL if there is any problem.”* (Pt 53, female, 59 y.o., university, school teacher, cardiovascular condition, 4 meds Rx)

Trust in doctor’s expertise was mentioned as a reason for not having to read all medicines-related information. However, there was a possibility that something bad might happen when taking medicines hence the reading of PILs was considered

useful for clarification. Other patients referred to PILs as being very useful for obtaining information sometimes kept from the patients by doctors.

Q6 – *“I used to read [leaflet], but every time I read the contra-indications everything would appear to me. Now only my husband does it”.*

(Pt 43, female, 63 y.o., primary school, domestic, respiratory condition, 5 meds Rx)

Q7 – *“When it [knowledge] is too much it may have a negative effect because the person may retract from taking them since all have side-effects. I try to read it all [leaflet] because I am afraid of the side-effects of some medicines ... sometimes I don't take because it is an anti-inflammatory and I have a bad impression of anti-inflammatories; without having any knowledge but it is a suggestion I have because according to what they say [people in general] they attack your kidneys.”*

(Pt 116, male, 82 y.o., secondary school, manager, genital disorder, 4 meds Rx)

Q8 – *“You shouldn't take anything without reading. It has happened that I was prescribed a drug that if I hadn't read, it would have killed me. I had to burn them straight away. That man was not my physician any longer!”*

(Pt 48, male, 65 y.o., primary school, mason, respiratory condition, 3 meds Rx)

These statements show how sometimes patients cannot handle too much information, especially if it is negative. This could eventually lead to null (Q8) or partial (Q7) intentional non-compliance, where the physician may not even get to know what happens (Q8) or such information led to a change in attitude (Q6).

On the other hand, for some patients, not having information was clearly a cause of distress.

Q9 – *“I will feel well when the doctor tells me what it is. Until then it's a big anxiety (starts crying).”*

(Pt 43, female, 63 y.o., primary school, domestic, respiratory condition, 5 meds Rx)

Nonetheless, this increase in anxiety caused by uncertainty was most often associated with illness-related information rather than medicines-related information.

Selective reading of the leaflet was commonly mentioned.

Q10 - *"I read them when I have to take something, mostly to see the adverse effects"*

(Pt 20, male, 63 y.o., high school, engineer, cardiovascular condition, 1 med Rx)

Q11- *"I am a bit against medicines so I am always very careful with what I take. I don't take a medicine just like that. It's just a last resource. Those I take daily make me feel dependent. It is because of those things (side-effects) that I am always careful to read the leaflets, I go and seek for the pros and cons. It's a precaution I have"*

(Pt 120, male, 61 y.o., primary school, labourer, cardiovascular condition, 3 meds Rx)

These quotes support criticisms made by patients when they want specific information, relevant to their case and not somebody else's, with special emphasis put on information about the side-effects.

Perceptions of harm of medicines

When asked *what they felt about their medicines*, four codes emerged: unnatural, dislike, impact on life and benefits (table 5.6). The first three were different ways of expressing the negative side of medicines, whilst the fourth theme refers to the positive effects of medicines. These two major themes can be compared with concepts represented by the PHM and PBM scales.

Many patients, who scored high in the PHM scale, *i.e.*, perceived their medicines mostly as harmful, expressed their views on medicines and their effects as being unnatural (Q12) and unpleasant when having to take too many (Q13)

Q12 – *"I don't like because the organism [the body] was not made to be always taking [medicines]"*. (Pt 132, male, 69 y.o., secondary school, banker, cardiovascular condition, 6 meds Rx)

Q13 – *"Nobody has any pleasure in taking drugs!... To take 10 drugs a day for months you start thinking "Won't they ever find one single drug?!"*

(Pt 58, male, 81 y.o., high school, manager, cardiovascular condition, 3 meds Rx)

Patients expressing these views had in common the fact they were both taking many medicines, which may lead to think that there is some link with being tired or

saturated of taking medicines. Additionally, they both had cardiovascular disease, commonly asymptomatic, possibly influencing the fact that the perception of harm outweighs the perception of benefit.

Patients gave clear reasons for their dislike of medicines and focused on descriptions of experienced side-effects (Q14) mostly, but also on administration related fears (Q15).

Q14 – *“That problem of medicines causes lots of discussion between us because I couldn’t... (You know)...any more. And also medication turns me into a plump! I always had faith in my doctors...”* (Pt 90, male, 63 y.o., illiterate, gutter cleaner, cardiovascular condition, 5 meds Rx)

Q15 – *“These I have to take now are to be injected and I am always afraid of sticking the needle”... “To me, Thank God, nothing has happened yet!”* (Pt 133, female, 49 y.o., primary school, domestic, tumour, 5 meds Rx)

These patients describing experienced side-effects had two things in common, their low literacy and an expressed faith in a “powerful other”, either the doctor or God. The connection between the latter and compliance behaviours has been extensively studied, but results presented are controversial (Kiley, Lam, & Pollak 1993; Raiz et al. 1999; Schlenk & Hart 1984). Nonetheless, it seems that this faith in others has an influence on the pros and cons that ultimately lead to the decision to take medicines or not.

The third way in which patients expressed their views on the negative side of medicines was by referring to the way they interfered with their daily life (Q16 and 17), including mentions of the high costs of medicines (Q18).

Q16 – *“... They haven’t told me but I understand that when I have to eat and have a drink or two I don’t take medicines.”* (Pt 90, male, 63 y.o., illiterate, gutter cleaner, cardiovascular condition, 5 meds Rx)

Q17 – *“Sometimes I have to go out and I don’t take them because I need time; it is about 2 hours always urinating”.*

(Pt 85, male, 76 y.o., primary school, billing agent, cardiovascular condition, 11 meds Rx)

Q18 – *“Medicines are very expensive and I don’t earn enough; they ought to be cheaper.”*

(Pt 80, female, 51 y.o., primary school, labourer, respiratory condition, 3 meds Rx)

Intentional partial compliance is clear in these descriptions of patients’ lives, where it seemed perfectly reasonable for patients to adapt the doctors’ recommendations on how to take medicines to fit their daily life. These three patients had low literacy, and their quotes seem to imply these decisions had not been discussed with their doctors, possibly due to the type of relationship established.

Perception of benefit of medicines

Perceptions of the benefits of medicines were associated with perception of illness risk. Some conditions were described as more serious, hence the medicines used to treat them were vital (e.g. epilepsy, stroke).

Q19 – *“Without them [medicines] I would have died by now, having epilepsy, we without medicines “ouch”! I have the duty to take them until the end of life, or else bum!”*

(Pt 127, male, 43 y.o., primary school, merchant, CNS condition, 6 meds Rx)

Q20 – *“Blood pressure is good. Without them I certainly would have died, with high blood pressure I would have got a stroke, before I always used to have it at 19.”*

(Pt 151, female, 61 y.o., primary school, merchant, cardiovascular condition, 5 meds Rx)

Q21 – *“Maybe I wouldn’t be alive any more [without drugs]. At least for the pressure, angina and diabetes; I have had it at 580 and now I have controlled them [blood sugar levels].”*

(Pt 82, female, 63 y.o., primary school, labourer, endocrine condition, 10 meds Rx)

Q22 – *“Warfarin as I had an operation and I have the valve I have to take... Warfarin I always take because that one is complicated not to take... These are important but warfarin is the one that really is [important], if I don’t take it I risk... [dying]”*

(Pt 118, male, 60 y.o., primary school, industrialist, cardiovascular condition, 5 meds Rx)

Patients prescribed several medicines often referred to some therapeutic classes as being more important than others, or as having a stronger effect.

Q23 – *“When I come to have exams I change the hours of meals so that I adapt medication hours ... sometimes I take them all together, those at breakfast together with the lunch ones. Not all, only those I need more, the one that is do dilate arteries [diltiazem], the alprazolam I don’t take it any more in the morning, and then the half one for the arteries, despite speeding my heart, but I have to take it, and the one for the heart also [DIS].”*

(Pt 142, female, 66 y.o., primary school, labourer, cardiovascular condition, 8 meds Rx)

Q24 – *“They relief, especially the anti-depressant...and the one against stress, I see that if I don’t take them I am not well.”*

(Pt 91, female, 31 y.o., secondary school, auxiliary, liver impairment, 6 meds Rx)

Q25 – *“God save me, don’t even talk about it [being without drugs], when time of their action finishes I get into lots of pain and I take another one, after 1 hour it starts relieving.”*

(Pt 71, male, 71 y.o., primary school, entrepreneur, cardiovascular condition, 8 meds Rx)

These quotes indicate how either those conditions perceived as serious or drugs whose effects are more notorious may lead to different compliance patterns within the same patients. In these quotes, the emphasis was often placed on drugs acting on the CNS and on the cardiovascular system.

While discussing the effectiveness of some drugs some patients mentioned not needing other drugs, making choices between those that had been prescribed. This case shows how one patient’s conscious decision to choose between drugs together with impaired eye sight could lead to dangerous situations.

Q26 – *“The doctor said that those were for the stomach so I understood I was feeling well and I didn’t take them. I am taking so much rubbish; why should I take more? These [diltiazem] are the ones I was one week without taking [he thinks these are for the stomach; chooses drugs by touch; nearly blind]. These [cozaar] are for pressure and I always took them.”*

(Pt 93, female, 74 y.o., illiterate, domestic, cardiovascular condition, 4 meds Rx)

Patients' opinions of healthcare professionals

Patients were not specifically asked for their opinions about health care professionals (HCPs). However, this issue often arose while they expressed views on information or on how they dealt with the disease. Three major codes were attributed to perceptions expressed by patients, their views on doctors' attitudes towards sharing of information, their views on doctors' behaviours and their perceptions of how doctors' characteristics influenced one or both. Patients were often critical of doctors' ways of communicating with them.

Q27 - *"Doctors use many technical terms that we do not understand, but I need to know."*

(Pt 27, male, 51 y.o., university, engineer, cardiovascular condition, 2 meds Rx)

Q28- *"I used to be so healthy! I used to work a lot in the land, in the fields and now for the past years I started having this anaemia, from menopause or something. I got some blood samples but the doctor didn't tell me what I had. It was in the lab they told me I was very bad... Then they had a lot of young doctors, they must be in their training period with their teacher, and they told me my liver was sick. I'm really scared because I have been hospitalised here before. I am scared of needing to get blood. They would say there that it was a medullar plasia or whatever that is, but here they give it a different name I don't know. I don't understand. When we get old everything appears to us. I must get used to what God gives us. Sometimes I feel like crying."*

(Pt 63, female, 68 y.o., primary school, domestic, cardiovascular condition, 4 meds Rx)

Comments about withholding information from patients were made and had a negative impact on patient's anxiety.

Q29 - *"I really want to know and I feel is it up to me for them to provide me with information and I think that is what creates more anxiety. I look at the present and I am taking 10 sedatives a day but I don't know what that will cause me in 10 years time. Information should be provided in a more direct way, without going round. I want to have things explained, the prognosis, what I can do to avoid the worst and maximise the best. When we are sick, sometimes we are anxious to get answers that could have already been given, but are not to prevent false alarms, but that can be even worse. An educated patient is his best doctor."*

(Pt 23, male, 26 y.o., university, engineer, respiratory condition, 3 meds Rx)

These quotes indicate there might be a need for improved doctor-patient communication, which was described either as poor in quantity (Q29) or in quality (Q27). Patients' perception of doctors seemed to influence their relationship, namely in terms of information sharing. Being a "good patient" was being informed but not too much, so as not to supersede the doctor's power.

Q30 - *"Doctors are very tough; they consider themselves as a separate class because everyone depends on them."*

(Pt 3, male, 38 y.o., high school, occupation not stated, cardiovascular condition, 6 meds Rx)

Q31 - *"Doctors think they are a little above. I cannot accept that they don't follow schedules. There is a lack of respect for the users."*

(Pt 20, male, 63 y.o., high school, engineer, cardiovascular condition, 1 med Rx)

Q32 - *"It is good to have knowledge but to know too much is to overcome the ability of the doctor. That will not be very convenient."*

(Pt 26, male, 39 y.o., secondary school, musculoskeletal)

Doctors were described as individuals on a different level from the common people (Q30 and 31), which had implications on the way patients felt they should act towards them (Q32). Some patients went to the extent of trying to identify shared characteristics in HCPs that determined behaviour to help them better understand. Doctors' and nurses' demographics were perceived to influence their behaviours (Q33). Conversely, patients' characteristics also influenced HCPs' attitudes, where feelings of some discrimination were implied (Q34).

Q33 - *"In the wards when the nurses are older they start getting tougher, they don't get so involved, they become less human because it is a very tough occupation...The younger nurses listen to my opinions, the elder ones don't even give me a chance. It is as if they are very human in the beginning and not so professional and then as professionalism increases the humanity decreases. In doctors I also notice the same. When they are at 10 years before retirement they have such a status...The doctors when they get older they become more distant. "*

(Pt 27, male, 51 y.o., university, engineer, cardiovascular condition, 2 meds Rx)

Q34 - *“People are also treated differently if they are unemployed or engineers or even gipsies or white. You can see staff is more careful if they notice that the person has a higher social-economic status. You can tell differences in their behaviour when they see you have or haven’t got an academic degree and that can be scandalous!”*

(Pt 27, male, 51 y.o., university, engineer, cardiovascular condition, 2 meds Rx)

Feelings towards disease/Coping mechanisms

When asked about their feelings towards disease, patients' discourse often focused on the coping mechanisms they had developed. These same mechanisms were clear when referring to medicines. For this reason coping mechanisms were coded in the same way, independently of whether the patient was referring to the disease itself or to the medicines taken to treat it. These mechanisms were classified in four major groups: faith in God, trust in Doctor, charity for others and need to be cared. Faith in God and the belief that He would keep patients from medicines' negative effects was clear in some quotes.

Q35 – *“These I have to take now are to be injected and I am always afraid of sticking the needle”... “To me, Thank God, nothing has happened yet!”*

(Pt 133, female, 49 y.o., primary school, domestic, tumour, 5 meds Rx)

Feelings of acceptance and tolerance towards the disease seemed to often be associated with religious beliefs and patients tended to refer to God, explaining that whatever He decided had to be accepted.

Q36 – *“We put ourselves in the hands of God (starts crying). May He give us health... We must accept everything, the bad, the worries and all things. I don't feel that bad either, thank God. We must put our heart aside and accept all that comes. Everything is necessary for the life experience, because if I had immediately come to the doctor aggravating this much would have been avoided, but I thought it would pass...and it will pass, if God wants it. Our lives are in the hands of who gave it to us, that is our Lord in heaven. Only He can take care of us. I accept, thank God. There are people who cry for the life they have. We mustn't cry, we should put ourselves in the hands of God.”*

(Pt 111, female, 72 y.o., primary school, domestic, cardiovascular condition, 4 meds Rx)

Q37 – *“I believe there is no destiny; my religion has taught me that. I believe in the future, but not that made by men, made by God...yes, what can I do? The human being can do very little. I must accept it, the unforeseen happens to anyone.”*

(Pt 126, female, 54 y.o., primary school, agriculturalist, cardiovascular condition, 2 meds Rx)

Q38 – *“We must suffer, because God has also suffered!”*

(Pt 75, female, 67 y.o., illiterate, labourer, cardiovascular condition, 4 meds Rx)

God was often mentioned in patients' comments, which could perhaps be expected in a Catholic country. These references were however more frequent in patients with low literacy levels, and seemed to be linked with feelings of tolerance, either towards the disease or towards the medicines. Some degree of fatalism was expressed e.g.: Q38 indicated that everything could be accepted as humans are expected to suffer according to the Catholic religion.

References to patients' trust in the doctor were quite frequent as a means of explaining why they kept taking medicines despite all their negative effects.

Q39 – *“That problem of medicines causes lots of discussion between us because I couldn't... (You know)...any more. And also medication turns me into a plump! I always had faith in my doctors... They haven't told me but I understand that when I have to eat and have a drink or two I don't take medicines.”*

(Pt 90, male, 63 y.o., illiterate, gutter cleaner, cardiovascular condition, 5 meds Rx)

Q40 – *“I believe that when they [Drs] prescribe them, it is with the best of intentions...they also make mistakes”.*

(Pt 126, female, 54 y.o., primary school, agriculturalist, cardiovascular condition, 2 meds Rx)

Q41 – *“I have been taking so many drugs and I don't see myself away from here...I trust my doctor and I think that is fundamental”. “I don't even care any more but if it has to be, it has to be!”*

(Pt 43, female, 63 y.o., primary school, domestic, respiratory condition, 5 meds Rx)

When discussing their feelings about the disease, a common theme was patients' trust in doctors' expertise, which meant they did not get worried.

Q42 – *“To get worried? No, if they are specialists they should know!”*

(Pt 63, female, 68 y.o., primary school, domestic, cardiovascular condition, 4 meds Rx)

Similarly to a faith in God, trust in doctors' expertise was most common in patients with lower literacy levels. Trust in the doctors was often mentioned as a reason for accepting whatever decisions they made. Even in patients who apparently had no

reasons to continue taking their medicines, the respect or trust for doctors' decisions determined their ultimate compliant behaviour.

Some of the patients who accepted or tolerated their condition mentioned some degree of charity for other patients, which could be interpreted as a conscious or unconscious mechanism to better cope with a negative situation. This has been previously referred as “downward comparison” (Ogden 1996d) or “charity for others” (Leydon et al. 2000).

Q43 – *“This appears to us and there is nothing we can do and there is always other people who are worse than us. I seek the [patient] association because those that haven't suffered this do not know what it is and those who have the disease understand.”*

(Pt 78, female, 57 y.o., primary school, auxiliary, cardiovascular condition, 10 meds Rx)

In some cases, this charity for others was also related to religion and God's will.

Q44 – *“It is all in the hands of God, He is the one who knows what He does. There are worse things happening to others, a lot, a lot worse and it is God who knows, we must accept it. Health depends on God and must accept it.”*

(Pt 93, female, 74 y.o., illiterate, domestic, cardiovascular condition, 4 meds Rx)

Tolerance seemed to be associated with religion and was the same feeling as Faith in God. This might explain why, despite all efforts in adapting the tolerance scale to Portugal, this concept had to be dropped. As beliefs are very different, a new process would be required to develop a tolerance scale, perhaps starting with in-depth interviews as in the original survey tool.

Despite all the understanding around accepting the disease, tolerating medicines and such like, there was also the expression of both a need to be cared for and a wish for not having to be responsible. These can also be related to one of the approaches to another coping mechanism described as the “search for mastery” (Ogden 1996d).

Q13 - *“What should I know?! I wish they [doctors] took care of me!” “...support, people to talk to me. Apart from that I would only want health.”*

(Pt 62, female, 70 y.o., primary school, domestic, cardiovascular condition, 5 meds Rx)

This emerging theme also illustrates Parson’s theory of the sick role, where the patient is expected to be in need of care and search for it, previously described as one of the factors involved in the acceptance of disease process (Krupp 1976;Morgan 1991).

Interfacing the qualitative data (quotes) and quantitative data (scores) was undertaken to explore the relation between coded interview data and scores to scales. Tables 5.7 to 5.9 displays high and low scores to the scales (EID, PUM and AI) interfaced with codes emerging from the data (information-related attitudes, perception about medicines codes, and feelings towards illness codes, respectively).

Table 5.7 – Scores to the EID scale and attitudes to information

	High scorers to EID –desiring much information	Low scorers to EID–desiring little information
Knows everything needed	<p>Patients mention their relationship with the doctor as a partnership and refer to good information sharing: “<i>The more you know the better. I think it is good that people read but I don't do that anymore. The first time I took [drugs] I had to go to the doctor because it wasn't working and we had to change them</i>” (Pt73, M, 46y.o., prim sch, imm syst)</p>	<p>Patients have been taking medicines for many years, having lots of experience, therefore not needing information: “<i>I have already taken so many medicines that I already have a lot of information. I have much experience.</i>” (Pt 103, M, 54y.o., no qualif, cardiov)</p>
Minimum information is enough	<p>Patients generally refer reading the PIL in a selective manner. Not all information included is needed or understood. Patients often ask doctors for doubts or when problems occur: “<i>..but I don't want to know 100%...I always want to know what it is for, what are the reactions it may have, such as drowsiness, the indications and contra-indications. There are words very complex but when I go to the doctor I try to clarify the doubt.</i>” (Pt 91, F, 31y.o., sec sch, liver impairm)</p>	<p>Many admit not reading PILs, some saying they know they should and others saying they'd rather listen. Understanding or eye sight problems are commonly referred. Doctors are described as trustworthy and as a source of information. However, obtaining too much information is described as wanting to overcome the doctor. Selective reading is also mentioned: “<i>It is good to have the knowledge but to know too much is to overcome the ability of the doctor...Maybe I should read. When I am prescribed any drug I try to obtain some information by reading the PIL and if I have any doubt I ask the pharmacist.</i>” (Pt 26, M, 39y.o., sec sch, osteoarthl)</p>
Happily ignorant	<p>This case scored high on the EID, implying to desire much information, and yet clearly stated to never have read. It could be the case that the patient wants to be informed by other means of communication: “<i>I never have read</i>” (Pt 3, M, 38y.o., high sch, cardiov)</p>	<p>Many patients state never reading the PIL, some adding that the doctor is the one who should know and that they take all they're given. Recognition of their incapacity to understand medical information is common among these patients: “<i>When the doctor prescribes I think he knows what he is doing so me reading...I don't understand any of that. I only take what the doctor tells me to and I am not there to discuss because I don't understand anything about medicines. I don't read anything</i>” (Pt 134, F, 39y.o., prep sch, imm syst)</p>
Eager learner	<p>Having the knowledge is considered to be a right of these patients, who classify themselves in thirst of knowledge. Most refer reading the whole leaflet, wanting to be informed to make their own judgements. Patients want to feel empowered to alert doctors about side-effects, need for monitoring and best managing their illness. There is a recognition that doctors also fail and aren't always informed as medicine is in constant evolution: “<i>The doctor discussed the case with me every day. The fact that I knew was a great relieve...For me it is fundamental to be aware of all the risks that I might take so that I can decide.</i>” (Pt 40, M, 35y.o., univ, respir)</p>	<p>Patients that never take anything without reading the PIL first. These patients seem to want the information for different purposes as there is no mention of weighing risks and discussing them with doctor: “<i>Before I take I read it all rigorously. The doctor may explain but before I take I like to read it all. When it is those with foreign names I ask the doctor or nurse.</i>” (Pt 97, M, 45y.o., cardiov)</p>
Afraid to know	<p>Although being afraid to know, this patient needs to ensure there is a carer who detains the necessary information in case it is needed: “<i>I used to read but all would appear so I stopped, now it is my husband who reads</i>” (Pt 43, F, 63y.o., prim sch, resp)</p>	<p>Information is considered confusing and making patients more anxious: “<i>Doctors say medicines should act but in me they don't. I am always afraid. I always have doubts. I am very nervous and I get paranoid so I prefer not to know things</i>”. (Pt 133, F, 49y.o., prep sch, tumour)</p>

Table 5.8 – Scores to the PUM scale and perceptions about medicines

	High Scorers to PBM – medicines perceived as mostly beneficial	High scorers to PHM – medicines perceived as mostly harmful
Long-term dependence	Patients scoring high in the PBM tended to give signs of dependence but not acknowledging them as such, and on the contrary, referring to them as a sign of the medicine being effective: “While I don’t take them I won’t fall asleep” (Pt 52, F, 79y.o., no qualific, CNS).	The totally different style of speech in patients perceiving dependence from medicines as a bad thing is represented in this quote: “I do feel (trapped) because I can’t go a day without them; some tablets you take them and then you get used to them; there is times when I run out of them and you feel the effects when you stop like the ones for depression I haven’t taken for 4 days since I came and I feel tearful. I can’t go out for a social drink for example so I’ve stopped that.” (Pt 155, M, 61y.o., sec sch, endocr)
Side-effects (SE)	Patients’ beliefs about SE indicate there might be misconceptions about causes of SE, which help patients to tolerate SE or not identifying them as such: “SE only happen if you take them (meds) a lot” (Pt.8, M, 26y.o., prim sch, respir). Others identify SE but feel they must bare them because drugs are essential and/or SE are foreseen by drs: “I had a surgery done to my prostate 5 years ago and I take Casodex but it made my feelings a lot like... because I cannot go the beach now and walk without a t-shirt because I got this (points to the chest), I don’t know what it is but it is acceptable. I don’t think SE are disease because I was warned about them and he (dr) doesn’t know if I take them or not and if I wanted to I would throw them away.” (Pt.100, M, 67y.o., prim sch, prostate neopl)	Some therapeutic classes are often referred when mentioning experiences of SE: “It happened with cortisone, I lost my figure” (Pt.28, F, 27 y.o., univ, respir) Others refer to SE when they interfere with daily life: “It does interfere, because sometimes I have to go out and I will not take it (diuretic) because I need time; it’s about 2 hours always urinating. There were days when e.g. there is one that makes me urinate a lot and when I go to the doctor I don’t take not to ruin my day, so I take it the next day. This is the only that affects me in such way that obliges me to urinate all the time. The others don’t have such a quick effect.” (Pt 85, M, 76y.o., prim sch, cardiov)
Administration-related fears	The administration form of medicines was often associated with the burden caused in daily life: “Depending on how they (meds) are, but these were good to take; if it is only pills; if it is syrup it is bad, but having to be...” (Pt. 93, F, 74y.o., no qualific, cardiov)	Another association made with the administration form was fear, perhaps due to experiences of SE or simply because of discomfort: “They are easy to take, only this one now that I have to inject makes always afraid of sticking the needle. (Shakes head negatively for several times when hearing the word “relief”). I don’t believe in anything, I have been taking them (meds) for so many years and I don’t improve anything... Some time ago, when I started the injections, I noticed this little red rash in my legs and I called the dr all day to find out what it was.” (Pt 133, F, 49y.o., prim sch, imm syst)
Money issues	Some patients referred to the costs of medicines as a problem, while acknowledging them as essential. “Diabetes and cholesterol do not hurt, so I don’t feel bad, but I have the illness here. What I think is that medicines are extremely expensive. I cannot stop taking them because it immediately goes up (cholesterol).” (Pt 136, F, 71y.o., sec sch, endocr)	Others concluded their remarks about perceived harm of medicines, justifying not taking with the implied costs: “I take 1 drug for asthma, ... and he (dr) also gave me small pumps, 1 green and 1 orange, but I don’t get along with that, it makes me sleepy, I can’t work and I’m always shaking. I stopped taking, the Dr said it was for all my life but I don’t want to. For example I take some for asthma and they’ll hurt my kidneys. Medicines are very expensive and I don’t earn enough for that; they should be cheaper.” (Pt. 80, F, 51y.o., prim sch, respir)
Effectiveness of medicines	Effectiveness of medicines is mostly referred to when patients perceive the symptoms to improve: “I had a disease 13 years ago and I got a huge nervous system. While I don’t take them (tranquil) I will not fall asleep” (Pt.52, F, 79y.o., no qualific, CNS). or when they perceive them as essential for their life: “The ones for BP I have to take them every day”. (Pt 38, F, 59 y.o., high sch, cardiov), even if they don’t feel any effect: “they do not (relief), because I only take for diabetes, BP and warfarin. Only after I measure diabetes... (I will know)” (Pt 87, M, 69y.o. prim sch, endocr)	Patients may not perceive any benefit nor harm; others do not perceive benefit but perceive harm. These tended to comment on lack of improvement, whilst acknowledging their need, but in a sense of dependence: “Some relief, others don’t. Do you really want me to be honest? At this point I have a medium question mark. I have been taking so many drugs and I don’t see myself away from here...I feel dependent, as if it was a drug I couldn’t live without...I don’t even care anymore if it’s hard or not, if it has to be has to be” (Pt 43, F, 63y.o., prim sch, respire)

Table 5.9 – Scores to the AI scale and feelings about illness

	High Scorers to AI – High anxiety about illness	Low scorers to AI – Little anxiety about illness
Prognosis & duration of illness	Realising that the illness had no cure was sometimes associated with high anxiety, despite some stating that having it for long led to not worrying: “I don’t worry. I’ve been ill since birth. Arthritis is incurable, they can only relieve the pain basically and diabetes won’t get any better and the damage to the heart won’t get any better, there’s nothing they can do about that.” (Pt.161, F, 56y.o., high sch, cardiov)	However, feeling that the illness was a “prison”, perhaps associated with thinking nothing could be done, resulted in decreased anxiety: “I feel trapped by the illness, not by the medicines” (Pt. 148, M, 52y.o., univ, liver imp). Not having symptoms was helpful to decrease anxiety while also recognising there was no cure: “I don’t worry at all, it doesn’t bother me, there are no symptoms, I only remember when I have an appointment. I know I am ill and that is serious but I feel fine. I must live with it (illness) because I know there is no cure.” (Pt.140, F, 72y.o., sec sch, liver imp). Having the illness for long, in general, led to decreased anxiety: “I don’t worry a thing, I am used to it, for 7 years now; it is not worth one worrying about it (illness).” (Pt.134, F, 39y.o., no qualific, imm syst)
Responsibility	Feeling that the illness was not his fault, or anyone else’s, led to anxiety, even when patients tried to use mechanisms such as “charity for others”. Having an internal locus of control perhaps increased anxiety as some patients realised that despite any efforts, the situation was unlikely to be resolved: “I don’t blame anyone. Besides I think there are people who are worst. It is obvious that it (worry) affects us but not to the point of getting ill. There is some concern. I don’t believe in destiny, I feel well and wait patiently. In this case I got quite scared when I saw there was bone metastasis, it was a life sentence. At a certain point I also thought “if it must be”. There is never certainty that the situation got into control. I think we can go around where situations lead us, I don’t believe in predestined things. Because there are people that nothing happens to them and it had to be me!? But there are also many a lot worse. Let’s say it’s about 50%. And mostly because I’ve been through so much.” (Pt.129, M, 57y.o., sec ch, GI)	Anxiety caused by feeling responsibility for delaying treatment was overcome by “optimistic unrealism”: “Everything is needed for the life experience, because if I had come immediately to the Doctor aggravation this much would be avoided, but I thought it would pass ...and it will pass, if God allows it.” (Pt. 111, F, 72y.o., no qualif, cardiov). Feeling responsible for the illness whilst acknowledging the power to control it decreased anxiety (internal locus of control): “I used to (worry) but not any more, they explained the cause of it. I’m ill now; 20 years ago I used to smoke and cough; I should have stopped and I didn’t so the cough got worse but apart from that I could go on with my life; If I got worse they’d put on a machine to keep me alive and I don’t want that. No, it’s all down to me. I don’t worry now. ‘Cos it’s all down to me from the beginning. There was a time I didn’t have any oxygen so I’d get panic attacks and I’d go to the window to try and get some air.” (Pt.173, M, 76 y.o., no qualific, tumour)
Information/awareness	Lack of unawareness was mostly linked to worrying when the illness came unexpected, as a surprise, and also when there was no information on what to expect from this new situation: “I find it hard to believe because it was with a chicken bone, I came here for a biopsy, then I was hospitalized, then I went home; now I am having a surgery but this is bad; I was in ICU for 12 days. One cannot feel well.” (Pt.104, M, 71y.o., no qualific, tumour). Actively seeking for information was a means for some to decrease their anxiety and worry persisted until an answer was provided: “Sometimes I get worried about it but you’ve got a medical book at home and you always check it. I will never be well. I’ve had 14 operations but I’ll never get better. I’m used to because I’ve had it for nearly all my life.” (Pt.184, F, 54y.o., no qualific, respir)	Awareness of the illness, its specificity and details was referred as necessary not to worry, as opposed to uncertainty, which led to worrying until clarification was obtained: “Right now I have some concern, it is not an obsession but I worry about the SE, the possible surgery... before I wasn’t (worried), until I had the collapses I kept on smoking and living my life. It is a very specific disease, considered congenital...but one ends up getting used to living with a chronic illness without thinking about it every day. My worry is not the illness, it is fundamentally knowing what is going on, it is having the knowledge.” (Pt114, M, 54y.o., univ, cardiov). “Worry does not makes us ill; I like to know what I have wrong; I am worried for not having the results; once I have them, well...” (Pt.151, F, 61y.o., no qaulific, cardiov). “Yes, I am worried until I get the surgery done.” (Pt.98, M, 60y.o., no qualific, cardiov)

Table 5.9 (cont') – Scores to the AI scale and feelings about illness

Feelings	Being worried about the impact of illness in daily life increased anxiety in patients who saw themselves as inheritably nervous (type A patients): <i>"One is always thinking about life, I am worried about work. Pulling it too much (the thoughts) it is also harmful because it dilates my nerves."</i> (Pt.90, M, 63y.o., no qualific, cardiov)	Avoidance coping was a way patients tried not think about the illness to spare themselves from depression, one of the feelings linked with anxiety: <i>"If you worry about it you're just going to depress yourself. You just can't do anything about it; if you worry you'll be all over the place."</i> (Pt.162, M, 61y.o., no qualific, endocr).
External factors	Hospital was mentioned as an external factor enabling high anxiety: <i>"I believe (I am ill) because I'm hospitalized; I can't be well."</i> (Pt.120, M, 61y.o., no qualific, cardiov). <i>"Now I only want to worry about this (illness), nothing else. I come here to get treated; nobody has any pleasure in being in a house like this (hospital); I am 57 and I want to continue with my life; let's see if all goes well..."</i> (Pt.153, M, 57y.o., no qualific, endocr)	Tranquilizers were conversely an external factor leading to decreased anxiety: <i>"If I am worried I might not feel well, but because I take Xanax...I don't (worry) anymore, the future is decided."</i> (Pt.142, F, 66y.o., no qualif, cardiov). Actually, medicines in general, and doctors, were seen as the ones in charge of controlling illness (external locus of control), resulting in decreased anxiety: <i>"It (illness) is company, one lives well with it. The control depends on the doctor and on the efficacy of pills"</i> (Pt. 115, M, 54y.o., univ,cardiov)
Acceptance/ Resignation	Difficulty in accepting illness and being highly anxious about it was associated with being caught by surprise, leading to shock: <i>"I can't accept it; it came as such a shock it all happened in just 2 days. I had 3 strokes but before that I was strong like a man, I looked after 7 children and 3 grandchildren; and I never complained; then when he died (husband) that finished me. That's right isn't it? Sometimes I feel like crying but most of the times I think that's God's will and I can't do nothing about it; it came as a big shock to me I tell you. There isn't no good to blame no one is there? I don't know the cause of it; it's just bad luck isn't it?"</i> (Pt.159, F, 67y.o., sec sch, tumour)	Some patients showed little anxiety resulting from resigning to illness and accepting it (Type B patients): <i>"Because it doesn't really worry me anymore; there's no point; I know I'm not going to get rid of it, it's as simple as that. I was always well till 10 years ago. I don't feel fine, I feel resigned to it. I don't think there's any point in worrying about it."</i> (Pt.167, M, 63y.o., high sch, cardiov). The acceptance was often achieved by having something to hold on to (external locus of control), such as a religious motivation: <i>"We must suffer, because God has also suffered."</i> (Pt. 75, F, 67y.o., no qualific, cardiov). Charity for others was also a feature present among "holding on to something": <i>"Look, we place ourselves in the hands of God [starts crying]. May He give us health; but I am not very thoughtful about the disease because that's when we find ourselves worse. My husband is also ill and he cannot come here... We must accept everything, the bad and the good, the worry and all things. It would be good (to be a little better) but I don't feel that bad, thank God. I don't think that much about those things (worries), only in being a little better so that I can go away (from hospital). We must open our heart and accept all that comes. Our lives in the hands of the One who gave it to us, Our Lord in heaven. Only He may care for us. There are people who cry for the life they have. We must not cry and put ourselves in the hands of The Lord."</i> (Pt. 111, F, 72y.o., no qualific, cardiov)

Criterion validity was lastly explored comparing scores to the AI scale and an external measure of perceived health status, using the SF-36. Spearman's rho was used as scores were not normally distributed, and a negative and statistically significant correlation was found ($\rho = -0.318$; $p = 0.000$), indicating that patients who perceived their health status as worse (scoring lower on the SF-36) were more

anxious (scoring higher on the AI scale). This result indicates that the AI scale is externally valid in comparison with a well-established measure (good criterion validity).

Construct validity

This section details the construct validity of the translated survey tool and subsequent comparison with the original survey tool. As described earlier in chapter III, principal components analysis (PCA) using Direct Oblimin rotation was used and resulted in six factors (figure 5.7 and tables 5.10-5.11).

Figure 5.7. - Scree plot

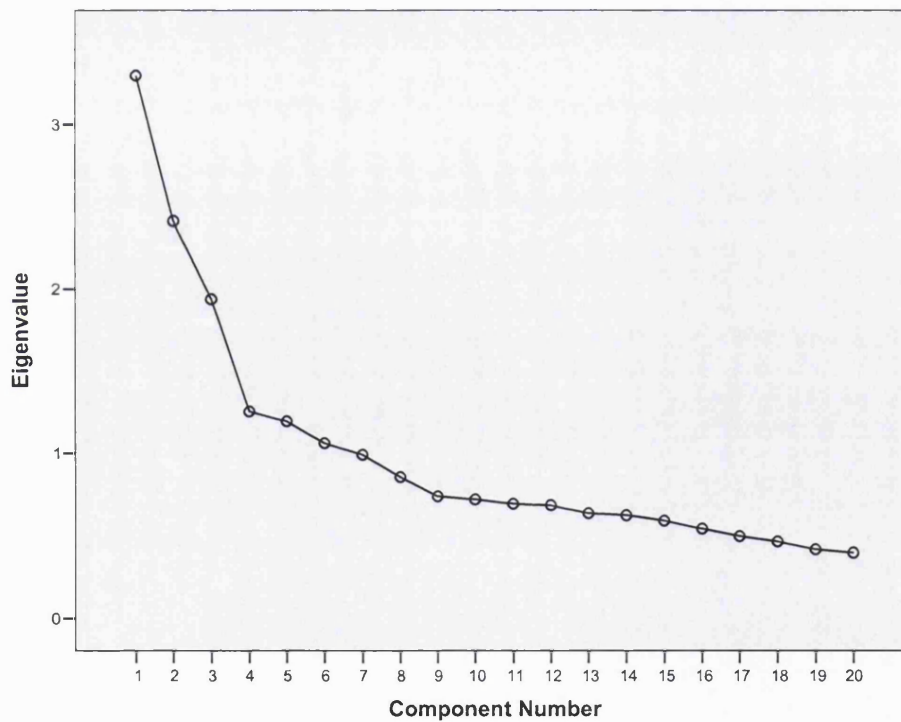


Table 5.10 – Extraction table with the Total variance explained

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings(a)
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	
1	3.298	16.492	16.492	3.298	16.492	16.492	2.790
2	2.411	12.056	28.548	2.411	12.056	28.548	2.266
3	1.939	9.695	38.243	1.939	9.695	38.243	1.946
4	1.254	6.270	44.513	1.254	6.270	44.513	2.044
5	1.193	5.965	50.478	1.193	5.965	50.478	1.628
6	1.061	5.305	55.783	1.061	5.305	55.783	1.638
7	.990	4.951	60.734				
8	.856	4.280	65.015				
9	.739	3.693	68.708				
10	.720	3.598	72.306				
11	.693	3.464	75.770				
12	.684	3.421	79.192				
13	.636	3.181	82.373				
14	.624	3.120	85.493				
15	.591	2.955	88.448				
16	.540	2.701	91.149				
17	.495	2.475	93.624				
18	.463	2.316	95.941				
19	.416	2.079	98.020				
20	.396	1.980	100.000				

Extraction Method: Principal Component Analysis. (a): When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

This additional factor emerged (F6), when compared to the original tool and corresponds to those items that did not “work” in a Portuguese sample, despite modifications in translation. This factor comprised the items A4 (*I just want to blame someone for the way I feel*) and T1 (*I find my medicines easy to take, I am used to them*).

Table 5.11 - Structure Matrix of the constructs emerging from the translated tool

	Ai	PBM	EID	Ti	PHM	F6
I get really worried about it all, the worry makes me ill	0.814					
I can't get used to this illness, I just get worried about it	0.783					
I feel anxious and concerned about the future	0.745					
I can't accept that there is something wrong, why me?	0.635					
I trust my medicines will make me better		0.794				
My medicines relieve my symptoms		0.792				
Without my medicines I would be so much worse		0.634				
I find my medicines easy to take, I am used to them				-0.512		0.450
The side effects are another form of disease					0.753	
I feel 'trapped' by my medicines, I have to take them					0.730	
It's hard to take my medicines, because taking them has altered my lifestyle					0.443	
I don't need any more knowledge			0.759			
What you don't know doesn't hurt you			0.665			
Too much knowledge is a bad thing			0.659			
You can never know enough about these things			-0.430			
I need as much information about my medicines as possible			-0.408			
I read about my medicines / illness as much as possible			-0.339			
I just want to blame someone for the way I feel						0.751
I feel fine about my illness, you can't expect to always be well				-0.759		
I would like to be completely better, but a bit better is good enough				-0.637		

This table shows that most items fell into the expected domains, for the Ai and EID scales. The Ti scale, a subscale of the “Anxiety about Illness” scale originally had weak internal consistency ($\alpha=0.470$) and contained only 3 items. One of these items did not load into this factor and was then dropped, leaving this scale with only two items, insufficient to form a scale. As such, the Ti scale was dropped and considered unsuitable for the Portuguese population.

The items of the PUM scale loaded well into the expected sub-factors. The exception was the item T1, which loaded into factor 6 and into the tolerance scale, implying a weak performance in this sample. For such reason, this item was dropped. Both the PHM and PBM subscales comprised only 3 items, rather than 4.

Following these analyses on the scales' validity, the version used in Portugal was modified by removing the tolerance scale and by removing one item of the PUM scale, comprising a total of 16 items, as illustrated in figure 5.8.

Fig. 5.8 – The 3 Scales following validation

Extent of Information Desired (EID)			
S6	I need as much information about my medicines as possible		
S7	Too much knowledge is a bad thing		
S8	You can never know enough about these things		
S9	I don't need any more knowledge		
S10	I read about my medicines/illness as much as possible		
S11	What you don't know doesn't hurt you		

Perceived Utility of Medicines (PUM)			
Perceived Benefit of Medicines (PBM)		Perceived Harm of Medicines (PHM)	
T3	My medicines relieve my symptoms	I feel "trapped" by my medicines, I have to take them	T2
T5	I trust my medicines will make me better	It's hard to take my medicines, because taking them has altered my lifestyle	T4
T7	Without my medicines I would be so much worse	The side-effects are another form of disease	T6

Anxiety about Illness (AI)	
Anxiety (Ai)	
A1	I can't get used to this illness, I just get worried about it
A6	I get really worried about it all, the worry makes me ill
A7	I feel anxious and concerned about the future
A9	I can't accept that there's something wrong, why me?

5.4.2.3 Examining the reliability of the scales

In order to explore the reliability of scores to the scales, two types of analysis were performed. Internal consistency of the constructs identified through factor analysis verified that the items within each domain were correlated with each other and contributed to the concept. Additionally the consistency over time was evaluated by means of test-retest.

Internal consistency

Table 5.12 displays the Cronbach's alpha values and the inter-item correlations range for each scale and item in the Portuguese sample. Table 5.13 displays the summary of the Portuguese data compared with retrospective UK data.

Table 5.12 - Internal consistency of the 4 subscales in the Portuguese sample

	Mean if item deleted	Variance if item deleted	r	Multiple r ²	α if item deleted
EID (Standardized $\alpha=0.612$)					
I need as much information about my medicines as possible	18.3	16.525	0.355	0.198	0.563
You can never know enough about these things	18.3	17.334	0.276	0.130	0.588
I read about my medicines / illness as much as possible	18.9	15.317	0.303	0.158	0.579
Too much knowledge is a bad thing (recoded)	19.1	14.660	0.340	0.178	0.564
I don't need any more knowledge (recoded)	18.9	13.651	0.439	0.216	0.517
What you don't know doesn't hurt you (recoded)	19.2	14.554	0.351	0.173	0.559
PBM (Standardized $\alpha=0.693$)					
My medicines relieve my symptoms	8.9	1.732	0.573	0.337	0.518
I trust my medicines will make me better	8.8	1.863	0.539	0.308	0.566
Without my medicines I would be so much worse	8.6	2.329	0.432	0.188	0.696
PHM (Standardized $\alpha=0.534$)					
I feel 'trapped' by my medicines, I have to take them	5.4	4.564	0.395	0.157	0.353
It's hard to take my medicines, because taking them has altered my lifestyle	6.4	5.586	0.313	0.101	0.488
The side-effects are another form of disease	5.6	5.241	0.339	0.121	0.449
Ai (Standardized $\alpha=0.755$)					
I can't get used to this illness, I just get worried about it	9.1	11.732	0.549	0.306	0.700
I get really worried about it all, the worry makes me ill	9.2	11.031	0.629	0.400	0.654
I feel anxious and concerned about the future	8.7	11.958	0.550	0.319	0.700
I can't accept that there is something wrong, why me?	9.6	12.711	0.483	0.237	0.734

Table 5.13 - Internal consistency of the 4 subscales in both samples

Scale	Portugal (n=596)	UK (n=1756)	Portugal	UK
	α	A	R min-max	r min-max
EID	0.607	0.784	0.28-0.44	0.42-0.53
PBM	0.695	0.784	0.43-0.57	0.29-0.41
PHM	0.536	0.746	0.31-0.40	0.23-0.40
Ai	0.756	0.740	0.48-0.63	0.47-0.67

Items comprised by the EID and the PHM scales were substantially modified during the adaptation process (chapter IV). These modifications led to a successive increase in these scales' internal consistency, with the final estimates reaching acceptable reliability. Nonetheless, these could be further improved by means of additional modifications. Both the Ai and the PBM scales revealed good internal consistency estimates (Smith 1997b). In all the scales, the removal of any item would result in a decrease of its overall internal consistency.

Consistency over time

In order to explore the consistency of the scales over time, a sub-sample of community pharmacy patients (n=125) responded to the questionnaire twice, one month apart. All the scales, except the EID were temporally stable, since their mean scores did not differ between baseline and after one month.

Table 5.14 – Paired samples t-test results for the 4 subscales

	Correlation		Differences in means	
	coefficient (r)	p-value	t-test value	p-value
EID	0.573	<0.001	2.092	0.039
PBM	0.350	<0.001	1.506	0.135
PHM	0.553	<0.001	0.682	0.496
Ai	0.765	<0.001	1.490	0.139

The correlation between the PBM, PHM, and Ai scores (at baseline and after one month) was high and statistically significant, indicating the concepts are being measured consistently. Furthermore, their mean scores were not significantly different, confirming these scales are consistent over time. Scores to the EID scale were strongly correlated between the two time points, but mean scores were significantly higher at baseline (25.9) than after one month (24.2). Albeit this

difference was significant when considering α set at 5%, it was not significant setting α at 1%. It must be considered that the p-value shown is 0.04 and the correlations for this scale are stronger than those found for the PHM and PBM scales, leading to assume it could be due to chance. Nonetheless, the hypothesis that asking about information is factual contrarily to perceptions cannot be disregarded.

Discriminatory power

A survey tool intended to measure patients' information desires should be able to distinguish between different characteristics that may influence desires, including gender, educational level, the setting where the patient was recruited, the number of prescribed drugs and the main diagnosis. The same approach was followed for the other two scales measuring patients' perceptions about medicines and illness.

The discriminatory power was evaluated by comparing scores to scales in different sub-samples, using the appropriate statistical tests to assess the significance of such differences (t-test or One-Way ANOVA, the latter followed by Post-Hoc Tests - Bonferroni).

The scores to the four suitable scales were explored between inpatients, outpatients and community pharmacy patients (table 5.15). Significant differences of mean scores to scales were detected for the EID scale between groups recruited in the three settings ($F=9.891$; $p=0.000$) and the Ai scale ($F=4.916$; $p=0.008$), implying patients recruited in different study sites had different degrees of desires for information and anxiety about their illness. Differences were also shown for the two PUM subscales, near significance in the PHM scale ($F=2.921$; $p=0.055$) and not significant in the PBM scale ($F=1.807$; $p=0.165$).

Table 5.15 – Mean scores to scales by recruitment setting

Scale	(I) Setting where data was collected**	(J) Setting where data was collected	Mean difference (I-J)	t-test value***	Sig.
EID	Inpatients	Community pharmacy	-2.3*	-4.5	0.000
		Outpatients	-1.8	-2.2	0.082
	Community pharmacy	Inpatients	2.3*	-4.5	0.000
		Outpatients	0.5	0.7	1.000
	Outpatients	Inpatients	1.8	-2.2	0.082
		Community pharmacy	-0.5	0.7	1.000
PBM	Inpatients	Community pharmacy	-0.3	-1.3	0.578
		Outpatients	-0.6	-2.1	0.190
	Community pharmacy	Inpatients	0.3	-1.3	0.578
		Outpatients	-0.3	1.3	0.702
	Outpatients	Inpatients	0.6	-2.1	0.190
		Community pharmacy	0.3	1.3	0.702
PHM	Inpatients	Community pharmacy	-0.1	0.3	1.000
		Outpatients	1.0	-2.1	0.171
	Community pharmacy	Inpatients	0.1	0.3	1.000
		Outpatients	1.1*	-2.7	0.048
	Outpatients	Inpatients	-1.0	-2.1	0.171
		Community pharmacy	-1.1*	-2.7	0.048
Ai	Inpatients	Community pharmacy	1.1	2.3	0.061
		Outpatients	2.3*	2.9	0.008
	Community pharmacy	Inpatients	-1.1	2.3	0.061
		Outpatients	1.2	1.7	0.237
	Outpatients	Inpatients	-2.3*	2.9	0.008
		Community pharmacy	-1.2	1.7	0.237

* Statistically significant difference

**Each row is compared against the other two

***Calculated separately

Community pharmacy patients scored significantly higher than inpatients to the EID scale, implying they desire more information about their medicines and illness, likely to be associated with them being in control of the situation rather than being cared for in hospital.

Inpatients were found more anxious about their illness than those patients recruited in other study sites, which could be related to their condition being worse at the moment of interview or even to the hospital environment itself.

Community pharmacy patients perceived their medicines as more harmful than inpatients and outpatients, these differences being significant only for extreme

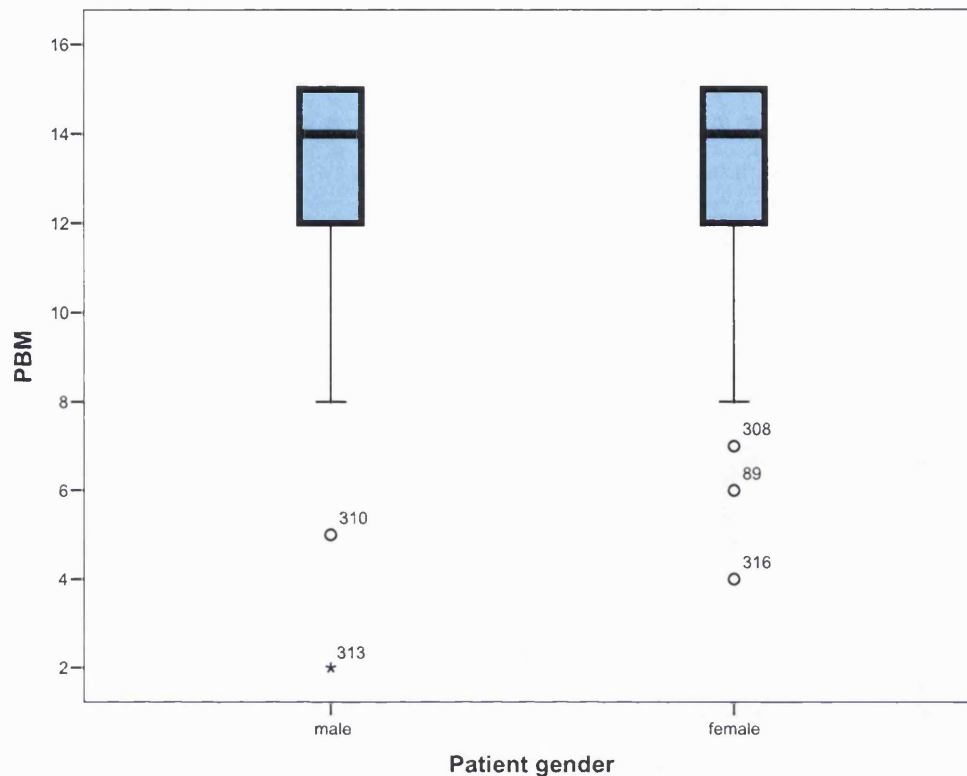
groups. It is possible that community patients have more control over their medication and simultaneously have a higher desire for information so are particularly interested in negative information, such as side-effects and contra-indications. If this desire is unmet, their “suspicion” about medicines increases.

Trends found in the mean PBM scores, despite not significant are worth a comment. Inpatients clearly perceived their medicines to be less beneficial, which is possibly linked to their hospital admission. Outpatients scored the highest in the PBM scale, but careful interpretation is required because this patient sample was mainly composed of endocrine patients; so diagnosis may be a confounding factor.

To ensure that the setting had no influence on further analyses around the scales’ discriminatory power, it was considered sensible to restrict analysis to community pharmacy patients (the larger sample with a good spread of diagnoses).

Females scored higher than males to the EID, Ai and PBM scales. However, this difference was only significant for the PBM scale ($t=-2.174$; $p=0.031$), depicted in figure 5.9. The only scale where males scored higher was the PHM scale (also not significant), which confirms the previous difference reported for the PBM, *i.e.*, women perceive their medicines to be more beneficial than men.

Figure 5.9 – Box plots of scores to the PBM scale by gender



Age was negatively correlated with scores to the EID scale ($r=-0.24$; $p<0.001$) and positively correlated with scores to the Ai scale ($r=0.16$; $p=0.001$), both correlations weak but statistically significant. Categorizing age into two broad groups allowed further exploring of the scales' discriminatory power.

Mean scores to the EID and the Ai scales were significantly different by age group (figures 5.10 and 5.11, respectively). Younger patients expressed a higher desire for information ($t=4.19$; $p=0.000$) and lower anxiety about their illness ($t=-2.00$; $p=0.047$). These findings perhaps result from older patients' upbringing, where traditional beliefs have always been that doctors know better, adopting a more passive attitude towards information, or perhaps from having had the disease for longer where no additional information is seen as beneficial. These patients are also more likely to have a worse health status, which may result in increased anxiety. Similar mean scores were obtained for both the PBM and PHM scales, regardless of patient's age.

Figure 5.10 – Error bars of mean scores to the EID scale by age group

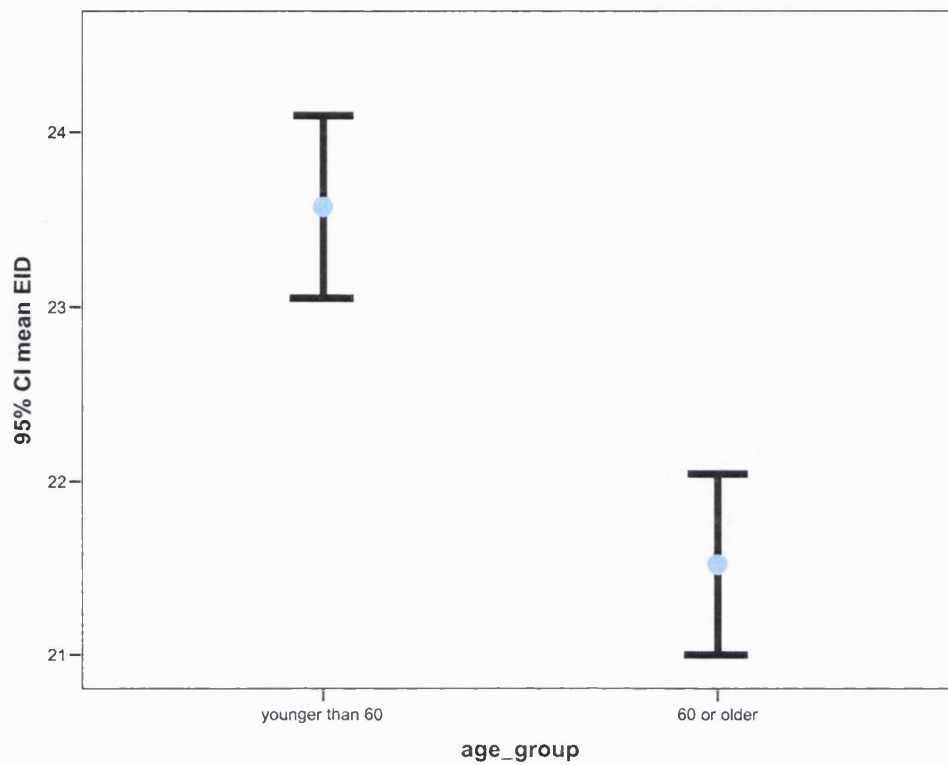
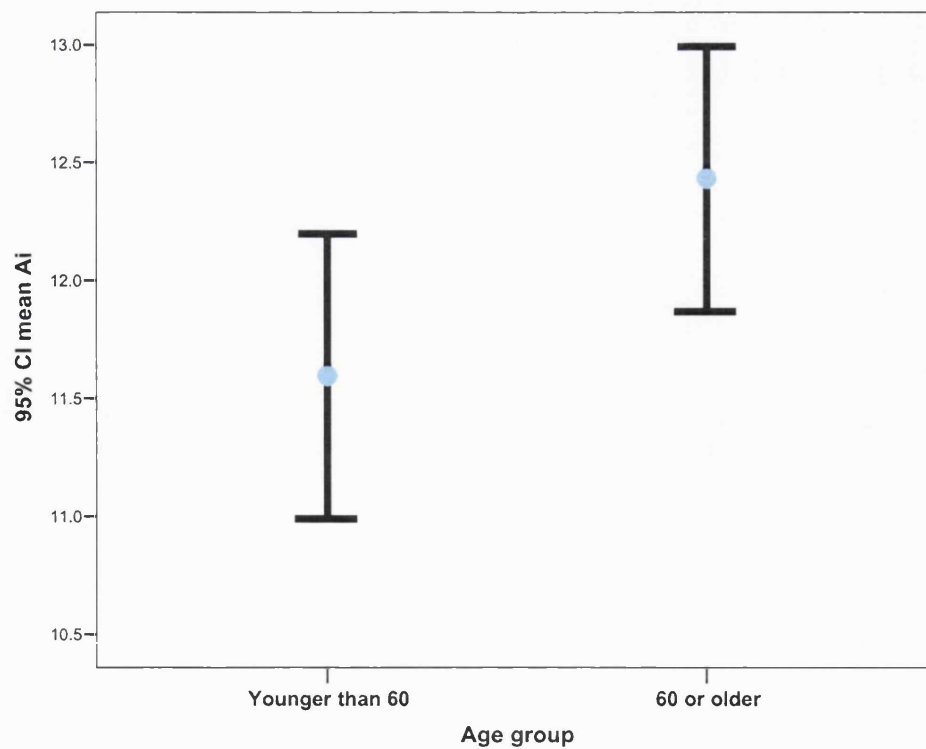


Figure 5.11 – Error bars of mean scores to the Ai scale by age group



Mean scores to the EID, PHM and the Ai scales varied according to the patients' educational level. A relatively linear trend was observed (taking into account that some groups had few cases confusing the visual effect and invalidating post-hoc tests), where the lowest educational level was associated with the lowest desire for information, the highest perception of harm and the highest anxiety: The desire for information increased, the perception of harm and anxiety decreased as years of formal education increased. Statistical significance was only demonstrated for the lowest level compared with all others (EID: $F=3.92$; $p<0.001$); (PHM: $F=2.10$; $p=0.011$); (Ai: $F=5.18$; $p<0.001$), but these trends are clearly shown in figures 5.12 to 5.14. The PBM scale scores by educational level were slightly above significance (PBM: $F=1.74$; $p=0.055$) but the trend was not linear as the illiterate patients scored the lowest, and except for those the lowest educated had the highest scores, *i.e.*, perceiving medicines as mostly harmful. This further implies that medicines information should be provided in different ways for different patients.

Figure 5.12 – Error bars of mean scores to the EID scale by educational level

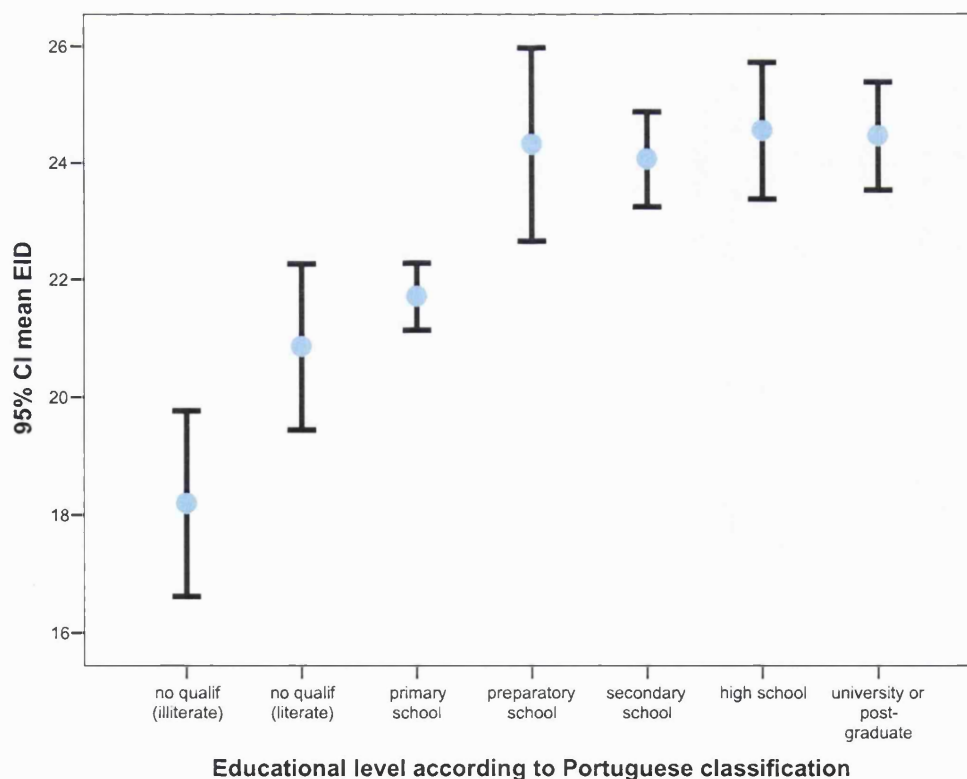


Figure 5.13 – Error bars of mean scores to the PHM scale by educational level

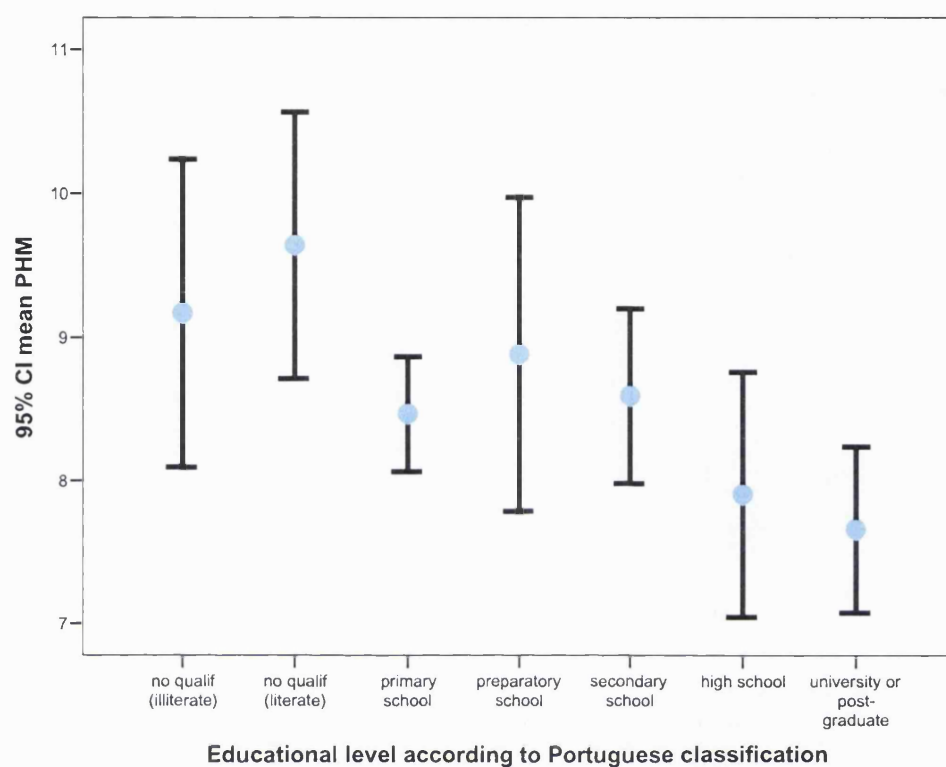
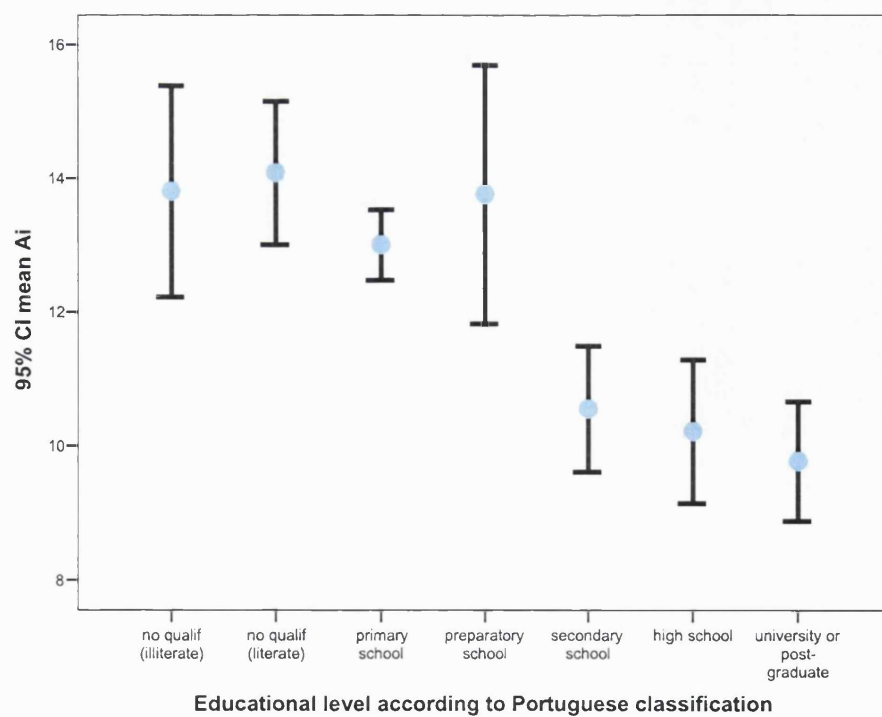
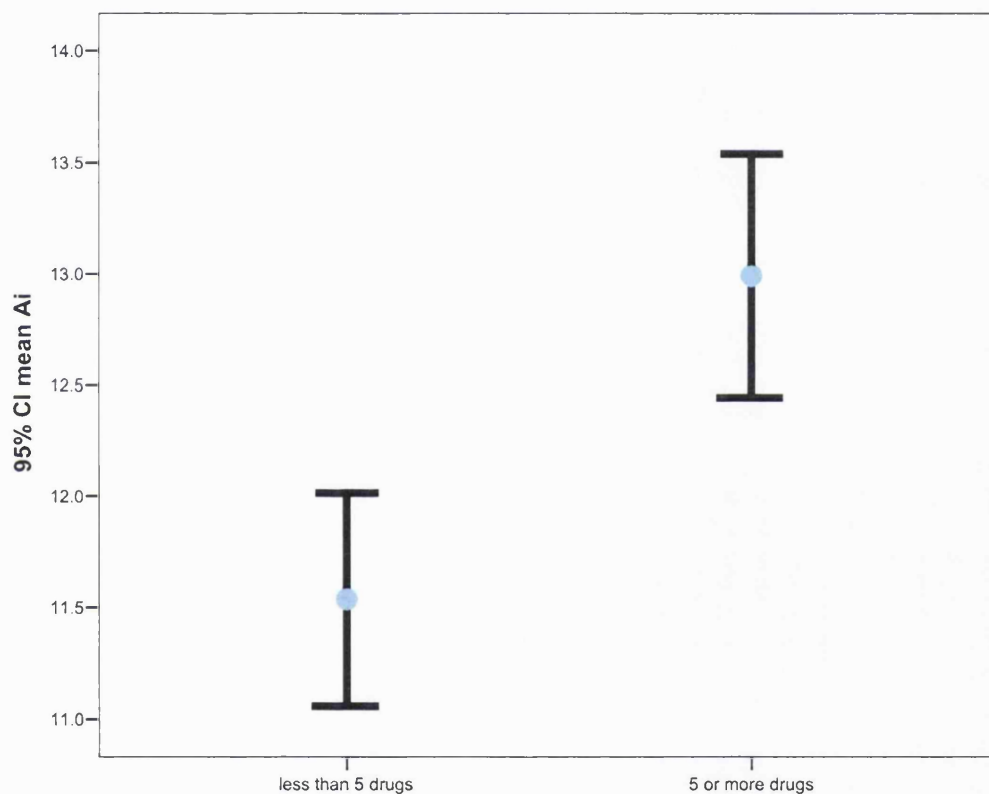


Figure 5.14 – Error bars of mean scores to the Ai scale by educational level



Patients prescribed 5 or more drugs scored significantly higher on the Anxiety scale ($t=-3.22$; $p=0.001$). These patients also scored lower in the EID scale, although none of the differences were significant. It may be assumed that when patients are prescribed more drugs, they interpret this as a signal of deterioration in their condition, hence increasing their anxiety. This difference is depicted in figure 5.15.

Figure 5.15 – Error bars of mean scores to the Ai scale by number of prescribed drugs



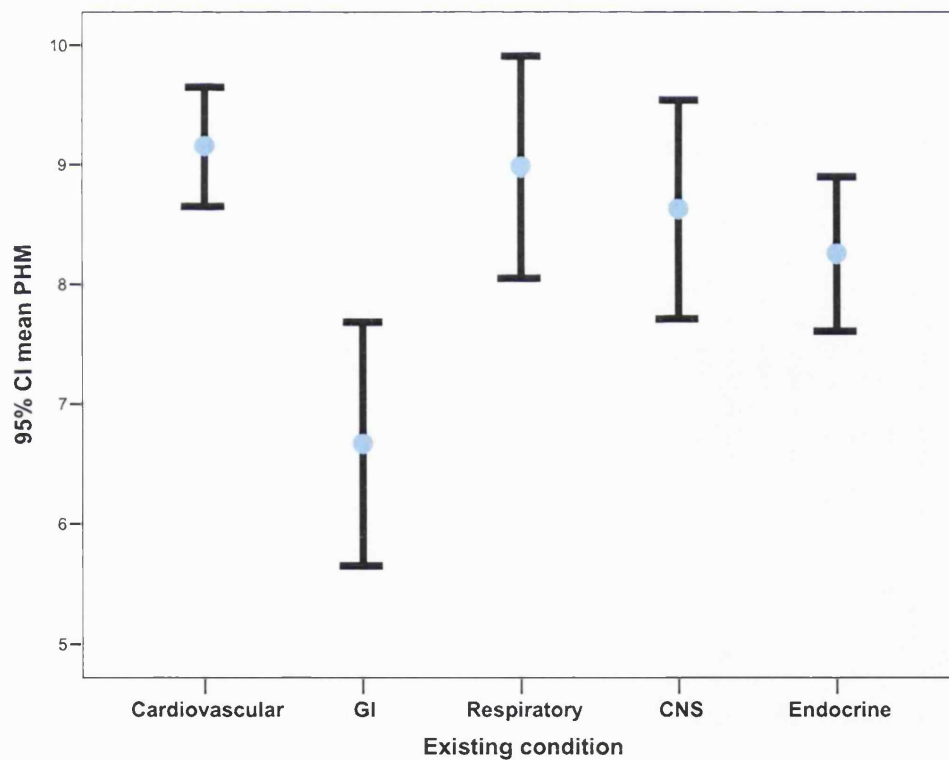
Discriminatory analysis was performed for the five more represented diagnoses (cardiovascular, endocrine, GI, CNS and respiratory), while there were no clear trends observed, it is worth reporting that the diagnoses scoring higher in the EID scale were the GI patients, followed by respiratory, CNS, cardiovascular and finally the endocrine patients.

The highest scores to the Ai scale was CNS, then cardiovascular, endocrine, respiratory and GI. Patients perceiving medicines as most beneficial were patients with respiratory diagnosis, followed by CNS, endocrine, GI and ultimately

cardiovascular patients who perceived less benefit from medicines. These were also those patients perceiving medicines as most harmful, followed by respiratory, CNS, endocrine and with a significantly lower score appeared the GI patients ($F=4.06$; $p=0.003$).

This overall effect for the PBM resulted from the difference between GI patients and the two highest scoring diagnoses, cardiovascular ($p=0.002$) and respiratory ($p=0.022$) and can be observed in figure 5.16. It can be noticed that the GI patients were often the extreme group, those with the highest desire for information, the least anxious and who perceived medicines to be less harmful.

Figure 5.16 – Error bars of mean scores to the PHM scale by diagnostic group



CNS patients reported the highest anxiety. Cardiovascular patients were those perceiving their medicines as less beneficial and also as more harmful. Endocrine patients expressed the lowest desire for information.

5.4.2.4 Pharmacists' evaluation of the study

From the 38 participating pharmacies, 25 answered the questionnaire (66%). In some of these pharmacies, there were 2 or 3 participating pharmacists, who responded individually, resulting in a total of 32 questionnaires. Table 5.16 summarises their impressions of the study.

Table 5.16 – Pharmacists' evaluation of the study

Question		n
Did your participation in the study affect normal service delivery? (missing=1)	Yes	21
	No	10
Did you find it easy to approach patients to participate?	Yes	25
	No	7
Did you find it easy to approach patients to participate in hours of greater movement? (missing=3; N/A=7)	Yes	10
	No	12
How did you select the patients? (missing=3)	The first 15 meeting the inclusion criteria	11
	According to my availability	5
	According to patients' availability/disposition	2
	By prescriptions presented	5
	By the prescriptions I filled in	1
	The first patient every hour	1
	The first patient in less busy hours	1
	Patients I knew what illness they had	1
	Patients with the illness from different social strata	1
Do you think it would be possible to recruit e.g. the patient number 3, 10...?	Yes	7
	No	25
Comments	Questionnaire is too long	10
	Statements are hard to interpret	14
	Wording is difficult (e.g. side-effects)	2
	Statements are viewed as questions	2
	Use of colours in rating scale makes it confusing	3
	Rating scale is difficult (yes/no better)	1
	Particularly difficult for low literacy patients	4
	Most respondents were retired	1
	Needed pharmacist's help as majority of patients are illiterate	2
	Refusal forms are too complex/long	3
	Many did not want to participate (refusals not filled in)	2
	Those refusing to participate also refused answering refusal form	1
	Having an interviewer would help (e.g. pre-reg student)	1
	People were suspicious about it	1
	Patients get annoyed/tired due to length	2
	Thinking about illness makes patients sad	1
	Recruitment period should be at least 4 months	1
	February is a bad month for recruiting patients	1
	Repeated statements	1
	Negative statements	1
	Double-barrelled statements	1
	"This was the most complex questionnaire we have had"	1
	"All patients and pharmacists were satisfied with participation"	1

N/A=not applicable

This table shows that the decision to participate in a research study affects normal service delivery (68%). This was the opinion of those participating, but it may explain why many studies have low response rates. Nonetheless, in this study, the majority of participants (78%) considered recruitment easy, despite more difficult in rush hours (46%). Pharmacists were instructed on the recruitment procedure but only 38% stated to have followed it, albeit another 24% answering in an open enough manner that could mean the same (*i.e.* by their prescriptions, randomly). It is worth noticing that 28% admitted to have recruited the patients in a biased way (*i.e.* when pharmacists were available, when patients were available, selecting those they already knew had the condition), and another 13% stated to have adopted their own criteria (*i.e.* picking from different strata, the first per hour).

Reasons given for not thinking random selection was possible varied, including *e.g.* implying the cooperation of all team, being particularly difficult at rush hour to control the order, considering it only possible in pharmacies where patients get a ticket with their number, interfering with normal service delivery, not practical, it would make recruitment more difficult (*i.e.* ensure the third would meet the inclusion criteria and/or losing others that met but were not included in those numbers), among others.

The comments made freely, in their majority reflect what was presented in figure 5.6, where pharmacist referred to patients' difficulty in understanding the statements or in viewing them as statements rather than questions (28%), the scale (2%), the colours used for the scale (5%), the use of double-barrelled questions (2%), negative statements (2%), repeated statements (2%) and specific words (3%). However, some comments added new information, namely about the length of the questionnaire (17%) and the format and acceptance of refusal forms (10%); additionally, specifying the added difficulty in low literacy patients was important (10%). Others were useful to consider when planning future studies, namely regarding the recruitment period (duration and month; 3%), and the use of interviewers (2%).

5.5 Summary of findings

In summary, the translated survey tool was found to be both valid and reliable after being tested in a patient sample of 596 patients with a wide representation of

demographic and medical characteristics. The sample reflected the general characteristics of the Portuguese population quite well, despite not having been randomly selected.

The original five scales described in previous research behaved differently in the Portuguese population following their translation. One of these scales, the tolerance scale, was dropped during the course of validation work as it was deemed to be unsuitable for use in this patient sample as demonstrated by construct validity. Additionally, the two subscales composing the PUM scale were transformed by dropping one item common to both, as it did not load into any of the expected factors and when deleted both these scales' internal consistency increased. Despite this modification, these scales are further explored in the following chapters, providing the adequate weighting procedure is taken into account when any comparisons with the UK sample are made. Both the EID and the Ai scales were left unaltered and were found to have good construct validity.

✓ The EID scale showed to have an acceptable internal consistency ($\alpha=0.607$) and consistency over time ($p>0.10$; $p<0.01$). Its face and content validity were judged as acceptable with room for improvement. Criterion validity was considered good when interfacing scores to the scales with themes emerging from open-ended questions about information. The EID scale was able to discriminate between settings, age group and educational levels ($p<0.05$).

✓ The PBM scale showed to have a good internal consistency ($\alpha=0.695$) and being consistent over time ($p>0.05$; $p<0.01$). Construct validity results led to dropping one of the items, whilst not compromising its reliability. Criterion validity was judged as good when matching scores to the scales and emerging themes. Its face and content validity were judged as good. This scale showed to discriminate between different genders and diagnoses ($p<0.05$). The distribution of scores to the PBM scale showed small spread, indicating a possibility for little added-value in its use.

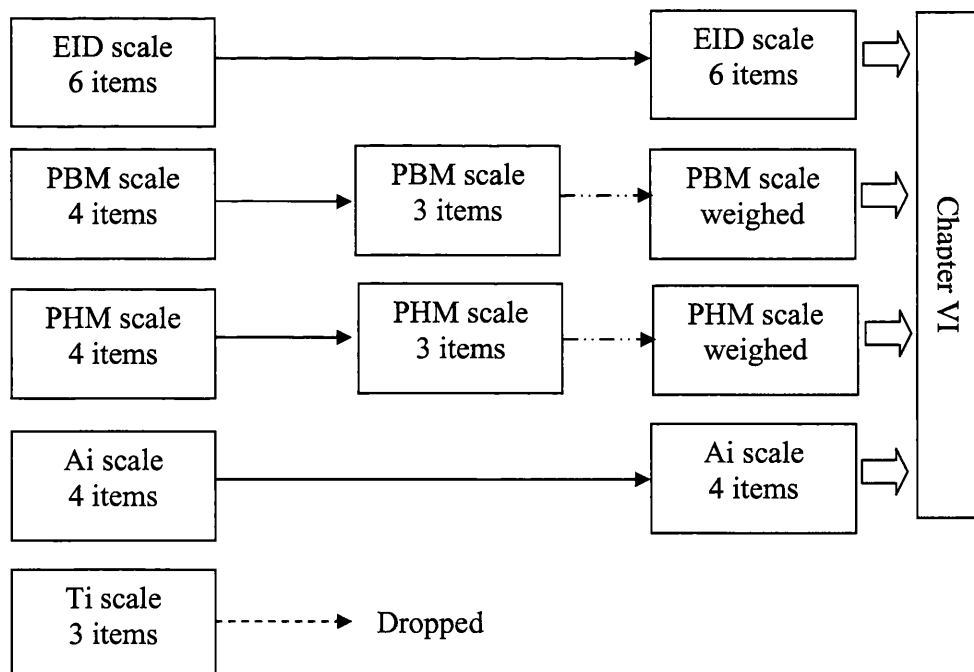
✓ The PHM scale was the one with the lowest internal consistency ($\alpha=0.536$), considered fair, but being consistent over time ($p>0.05$; $p<0.01$). Construct validity results led to dropping one of the items, whilst not compromising its reliability.

Criterion validity was considered acceptable as not all themes emerged in qualitative analysis were represented in this scale. Its face and content validity were judged as low, although improving throughout modifications of wording. This scale showed to discriminate only between educational levels ($p < 0.05$), although on the border of distinguishing between settings ($p = 0.055$).

✓ The Ai scale was the one with the highest internal consistency ($\alpha = 0.756$), considered good, and also showing consistency over time ($p > 0.05$; $p < 0.01$). Its face and content validity were judged as good. This was also the only scale quantitatively explored for criterion validity, showing good results when compared with the SF-36 ($p < 0.05$) (DeVellis 2003b). Additionally it showed to discriminate between settings, age group, educational levels and number of prescribed drugs ($p < 0.05$).

✓ The Ti scale was dropped due to its face, content and construct validity and hence considered unsuitable for use in a Portuguese sample.

Figure 5.17 – Summary of findings from Chapter V feeding into chapter VI



5.6 Discussion

Discussing sample characteristics

The characteristics of the sample were compared to national data, where illiterate people represent 8% of the population (compared to 7% in the study sample) and people with university education account for 11% (compared to 12% in this sample). Study recruits with primary school education accounted for 47% of the sample, compared to 35% in the national population. Nonetheless, it may be concluded that the sample educational level represents the Portuguese population fairly well (Instituto Nacional de Estatística 2003).

Looking at the pharmaceutical market expenditure, cardiovascular drugs represent the highest percentage of sales (28%), which seemed to be consistent with the high proportion of cardiovascular patients in the study sample. The high proportion of endocrine patients could be compared with sales data on alimentary tract drugs nationally. However, for many such conditions, hormones are also used and additionally, many of the drugs classified within the alimentary tract are used for other illnesses, such as GI conditions; direct comparison of pharmaceutical expenditure and endocrine diagnosis can be misleading. Prescription data for respiratory conditions was considerably lower (5%) than the sample of patients classified as “respiratory”. Notwithstanding, it is general knowledge that this is a condition particularly under treated and many of these patients use a high proportion of anti-infective drugs (11%). Nervous system drugs, on the contrary, represent higher consumption data than the percentage in this sample classified as “CNS”. In this case, once again it should be remembered that drugs included in this ATC category are used for example as pain-killers and hence direct comparison is not valid (Organisation for Economic Co-operation and Development 2004).

Discussing non-response

The lower proportion of non-respondents in the hospital setting may be unexpected, as hospitalized patients may be assumed to be more available to participate. It is possible that the data collection method used had an effect, since experience shows that pharmacists tend to invite patients they know, hence minimising the probability of refusal. The major differences between responders and non-responders are the diagnoses, where the non-respondents group has more endocrine patients (and some

other diagnoses missing). This fact may have two possible explanations; one is that these patients have had their illness for longer, and do not believe anything will benefit them and hence do not see the point of responding to any questionnaire about their medicines and illness; or that some pharmacists have made more use of refusal forms than others. Since pharmacies were clustered by diagnostic groups, pharmacists more aware of the importance of refusal forms could have been those instructed to recruit endocrine patients.

Discussing the internal consistency

Internal consistency of the EID was not as high as expected from previous UK studies (Algernon 2001; Astrom et al. 2000b; Duggan & Bates 2000; Duggan et al. 2002). A Cronbach's alpha value of 0.7 has been suggested as "good" (DeVellis 2003b) and the fact that the value reported for the EID in the Portuguese sample roughly passes 0.6 is an issue of concern. However, this scale has been further tested in another study including 112 hypertensive patients recruited from Lisbon pharmacies, where the value obtained was 0.683 (Costa et al. 2005a). This increase may be related to distinct characteristics of the samples, the later study was conducted in a particularly developed area, where educational levels are generally higher. This may imply that this scale's performance may improve as the Portuguese population's literacy increases. This trend is supported by successive legislation reviewing the minimum compulsory education, where it is stated that "those born before the 1st January 1967 must have primary school education" (4 years), "those born after the 1st January 1967 must have preparatory school education" (6 years), and that "those attending the first year of school in 1987/88 or later must have secondary school education" (9 years) (Ministério da Educação 1979; Ministério da Educação 1986; Ministério da Educação 1993; Ministério da Educação 2002a; Ministério da Educação 2002b; Ministério da Educação 2005). This year, the prime minister has already announced his intentions to further extend the minimum education to high school (12 years) (Ricardo Jorge Costa 2005).

Discussing consistency over time

Internal consistency is only one of the possible ways of evaluating a survey tool's reliability and consistency over time results here exhibited revealed stability for all scales. Potential explanations for only detecting consistency over time for the EID

scale using a 1% α -level include chance; the possibility that the concept measured changes just by asking the patients; and also a possible unconscious intervention made by the pharmacists, resulting from raising their awareness of patients' need for information while administering the questionnaire. Alternatively, information needs may be easily changed dependent on situations, time, severity of symptoms, whereas anxiety and perceptions of medicines may be less so.

Discussing validity

This section discusses alternative ways of measuring validity and relates the relevant findings with published literature.

Different ways have been suggested to evaluate face and content validity. Some authors have described them as subjective measurements (Streiner & Norman 2000). The different analyses performed revealed problems with face and content validity of the EID, PHM and Ti scales. The latter was dropped; the others may need additional work when being tested in practice. The PHM scale needed additional care with refining words (chapter IV) and was explored in chapter V by analysing the proportion of patients using the mid point of the scale. The use of five-point scales has been associated with a tendency to use the mid point (Cassileth et al. 1980). However, the use of scales with an odd number of points is particularly useful in initial validation stages to provide insights into potential problems. Most patients reported difficulties of understanding with the EID scale, implying it would benefit from further modifications in this population.

Additional problems were encountered with the Anxiety scale as it led to anguish in some patients, which could potentially compromise its use in pharmacy practice. Nonetheless, it may be worth exploring its applicability in medical settings, where scales such as the Beck's Depression Inventory (BDI) have been employed (Coelho et al. 1989; Coelho et al. 1999; Coelho et al. 2000).

Criterion validity

Criterion validity is a property often not reported when validating scales, generally because of lack of comparative tools. Criterion validity was explored in three different ways, using qualitative data, interfacing qualitative and quantitative data and

external measures to correlate with some of the scores to scales. The emerging themes from patients' free responses elaborated on the concepts of the three scales, the EID, PHM and PBM scales (Liekweg et al. 2005).

Criterion validity: information desires

Patients expressed different attitudes towards information, ranging from being happy knowing little to aiming to find out as much as possible about their medicines and illness. These codes were consistent with the different degrees of information measured by the EID scale, implying good criterion validity.

Criterion validity: beliefs and perceptions about medicines

Patients' experiences with medicines were more focused on the negative aspects of medicines, as explored by the PHM scale. However, whilst some of the emergent codes were consistent with items comprised by this scale, such as the side-effects and the impact on daily life activities, other items comprised by the scale such as the feeling of entrapment did not emerge, which may explain the difficulties encountered in the course of adapting this item. Additionally, new codes emerged which were not completely covered by the PHM scale, such as the economic impact of medicines' taking in daily life, a fact that might be related to the different functioning and financing in particular of the two health care systems involved. These findings indicate room for improvement in the PHM criterion validity. Conversely, patients' comments about the benefits of medicines focused on the perceived relief and on their need to be cured or at least protected from an adverse outcome, the same concepts being measured by the items comprised by the PBM scale, indicating good criterion validity. The perception of benefit was associated with compliant behaviour (compliance will be further addressed in chapter VII), regardless of a high knowledge about potential side-effects. This has been studied in the Portuguese student population looking at CNS drugs consumption, which found a high prevalence of continuous psychoactive drug consumption in people considering themselves as well-informed about these drugs' side-effects (Cabrita et al. 2004).

Criterion validity: perceptions of illness

The additional themes emerged when exploring patients' perceptions about illness indicate there might be a close link between patients' views of illness and

experiences, with the health care system in general, and with health care professionals in particular. This study showed that communication between patients and doctors are not ideal and may influence patients' representations of illness and medicines, ultimately influencing their adopted behaviours.

Issues of communication between patients and health-care professionals have been debated over many years. A multi-centred study analysing physicians' style of disclosing a cancer diagnosis and its impact on patients' reactions, depending on the country the word "cancer" was replaced by a "less scary" term, often the more-straightforward term was preferred in Nordic countries (Holland et al. 1987). However, in all countries physicians agreed that revealing the diagnosis to patients, emotional distress was transitory and ultimately led to a positive effect on patients' coping processes, compliance behaviour and communication in subsequent consultations (Holland et al. 1987). Depending on the context of the words used, the relationship established between patients and health care providers is essential for achieving optimal outcomes for the patients. Such studies indicate possible reasons for difficulties associated with adapting words such as "*side-effects*" other than understanding or statements where disclosure of diagnosis and understanding illness may greatly impact (*e.g. "I just want to blame someone for the way I feel"*).

The influence of religious beliefs and societal influences on the way doctors are perceived in the studied sample indicated that there might be peculiarities in the Portuguese culture contributing to difficulties in transferring the tolerance scale. Some of the findings reported for patients' views about their illness and doctor have been previously described, namely charity for other patients, faith in doctor's expertise and not requesting or searching information allied to the concept of being a good patient as described in the paternalistic approach of care (Leydon et al. 2000). The last two are intimately related. It is acknowledged that patients who are more in favour of a paternalistic approach to care, like to be passive recipients and do not demand for additional information, apart from knowing how to take their medicines, *i.e.*, how many times a day (Anonymous 1999). Additionally, these patients are also likely to become more anxious if provided with more information (Duggan 1998). This seems common behaviour in Portugal, mostly among elderly less educated patients, as shown in extracts from patient interviews. This trend is likely to change,

but it will take some years for patients to become active in information-seeking and in shared-decision consultations.

Charity for other patients has also been described as a “downward coping mechanism”, helping patients to face their situation in a positive way as opposed to the “search for mastery mechanism”, which seems to be more typical of those patients entrusting their life and all decisions in doctors (Ogden 1996d). The findings refer to an additional recipient of faith, God, most likely linked to the religious culture embedded in the Portuguese population. In other countries, religion has been described as a major source for coping (Strickland et al. 2001). This may be seen as part of an emotion-focused coping process, during which people develop their own illusions or beliefs to better adapt to a new situation (Ogden 1996d). What people choose to believe in may change across cultures, saying that belief in God is an illusion would be cause for severe reprehension in a Catholic country, whilst for others would be seen as a logical scientific explanation. Independently of where the truth is, people often need something to hold on to when faced with a confronting situation and these factors need to be considered when transferring scales to different cultures.

Discussing the use of external measures for evaluating criterion validity

Some studies based in Portugal have reported the use of the Beck’s Depression Inventory (BDI) to explore the psychological factors involved in cardiovascular disease in general and hypertension in particular, acknowledging that the risk factors known through the biomedical model do not fully explain clinical outcomes of treatment (Coelho et al. 1989; Coelho et al. 1999; Coelho et al. 2000). Although an ideal choice for validating the Anxiety scale would be the Beck’s Anxiety Inventory, the former could be considered good enough. This would have undisputed advantages, but also an additional burden for respondents which could potentially have an impact on the response rate, so was disregarded in this study.

No external measures were correlated with the EID or the PUM scales. There is no best tool available that could have been used for the EID scale, leaving patients’ own words as the only possible option. Interfacing qualitative and quantitative data supplied an additional confirmation of the scales’ criterion validity as most of the

patients who scored high on the EID scale, for example, had made quotes representing an extended desire for information. The BMQ questionnaire could have been used as the best available comparison for the PUM scale (Horne, Weinman, & Hankins 1999). However, this questionnaire is not validated to Portuguese and its validation would constitute by itself another research project.

Relating scores to scales with characteristics: information desires

Results pointed to a lower desire for information among inpatients, who were male, aged 60 or over, less educated patients, and prescribed 5 or more drugs, with an endocrine condition. Similar findings have been reported; studies exploring advice-giving in community pharmacies have suggested that consumers in general use the pharmacy primarily to obtain information about the effectiveness of medicines acquired (Hassell et al. 1998). Hence, it is not strange that inpatients express a lower desire for information. Additionally, while in hospital patients are cared for, needing to know very little, a situation that changes at discharge.

Evidence of differences in desire for information by gender is scarce and controversial. One large UK study on cancer patients reported that women were more interested in knowing the specific name of the illness and what were all the possible treatments, despite having found no overall differences in extent of information desired (Jenkins, Fallowfield, & Saul 2001).

A study evaluating the amount of information chemotherapy patients felt they should be given reported that information requirements tended to be greater in people under 60 years (Barnett et al. 2004). Cassileth (1980) reported that younger cancer patients were more prone to becoming well-informed and participating in clinical decisions, whereas older patients tended to favour the non-participatory patient role (Cassileth et al. 1980), which was backed up by a study comparing characteristics of individuals seeking information through different sources found that the internet was mostly used by younger people to ask medicines-related questions, when compared to the telephone (Bouvy et al. 2002). Actually, this is not surprising as the internet has been reported as the main source of information among adolescents (Gray et al. 2005).

Educational level was also shown to influence the extent of information desired. Other researchers have suggested health literacy as an important factor in determining the use of written drug information (Koo, Krass, & Aslani 2003). A Dutch study showed that patients on insulin were prescribed more drugs when compared to other chronic conditions (Rahimtoola et al. 1997), which may indicate an association between these two variables independently of the effect on the EID scale. Previous studies from our research group found that older patients (Astrom et al. 2000b) and those leaving school at an earlier age (Duggan et al. 2002) desired less information about their medicines.

Relating scores to scales with characteristics: perception of medicines

Patients perceiving their medicines as more harmful were found to be those recruited in the community pharmacy setting, male, with a lower educational level, prescribed with 5 or more drugs and cardiovascular patients. The fact that community pharmacy patients perceived medicines as more harmful may be linked to greater autonomy, implying that if side-effects or interactions occur, patients will have to deal with them rather than a nurse around will take care of the problem in hospital.

All the results must be carefully interpreted as they may be interrelated, as it is often the case of age and educational level. A study looking at gender differences in treatment of hypertension showed that when patients are prescribed only one drug, the therapeutic class differs by gender (Lunet & Barros 2002). This implies that perceived benefit or harm from drugs may be related to the specific class used more than diagnosis or gender. In this case, the two classes were ACE-inhibitors and diuretics, both with side-effects that may be considered burdensome to different extents by different patients. A study on self-medication among the Portuguese urban population concluded that a high educational level was an important predictor of self-medication (Martins et al. 2002), from which it can be inferred that patients with higher educational levels perceive medicines as less harmful.

Previous research from our group suggested that the perceived utility of medicines was negatively associated with the number of prescribed drugs (Duggan 1998), as found in this study. Additionally, a community pharmacy-based study reported patients-perceived problems as one of the main causes for poor outcomes in

antihypertensive therapy, the most common being adverse drug effects (Enlund et al. 2001). Assessing hypertensive patients' views on desire for information, Lisper found that information about possible side-effects and long-term effects of therapy in the organism were the only points regarded as important or interesting (Lisper et al. 1997), which seems to confirm this group of patients' worry about harm caused by medicines.

Conversely, those perceiving medicines to be the most beneficial were outpatients, female, respiratory patients and prescribed 5 or more drugs. It could be expected that outpatients perceived their medicines as beneficial; otherwise they would be in hospital. The fact that respiratory patients have been found to perceive medicines as more beneficial may be related to the fact that this condition is not well managed with bronchodilators (Rabe et al. 2000). The apparent relationship between perception of medicines and the characteristics of the illness in terms of symptoms' perception is later further discussed. A study on Portuguese patients with asthma assessing their unmet health-related needs revealed a high need for medicines-related information, particularly on understanding how medicines work, followed by long and short-term undesirable effects (Costa 2002). This indicates that respiratory patients are also conscious of negative effects of their medication. The fact that 70% of asthmatics have been reported to stop their medication when it makes them "feel bad" (Anonymous 2001) leads to think that respiratory patients while perceiving the negative effects of their medicines, still acknowledge their need, resulting in a perception of benefit that outweighs the harm. A study looking at psychotic patients' medicines-taking behaviour reported that compliance significantly improved when patients trusted their medicines and did not subscribe to drug's negative beliefs (Bordenave-Gabriel et al. 2003).

Relating scores to scales with characteristics: anxiety about illness

The more anxious patients tended to be those in hospital, female, aged 60 or older, with a lower educational level, prescribed 5 or more drugs and with a CNS condition. Hospitalized patients could be more anxious as the hospital environment itself as been described as a cause of distress (Kent & Dalgleish 1986b). Additionally, these patients may have a worse health-status at the time when the interview was undertaken, hence feel anxious. A community-based study on cardiovascular patients

reported higher mean depression scores in women and in individuals with lower educational level (Coelho et al. 2000). Despite depression not being equivalent to anxiety, they are often intimately linked, hence supporting this study's findings. Patients prescribed with more drugs were also found in previous work to be more anxious about their illness; a perception of deterioration when prescribed with more drugs (Duggan 1998).

It is well-known that the elderly are those most often prescribed more drugs, hence these variables are likely to be related (Qazi 2005). Probably age does not increase anxiety, but the fact that the health status is deteriorating and more drugs are being prescribed. Also, lowest educational levels were most common in the elderly in this sample, implying another association between variables likely to influence the reported findings. A recently published study on management of epilepsy-related information revealed that most patients report needing more time to discuss the causes of their illness with the physician to be able to reduce stigma and fear (Prinjha et al. 2005). Until this need is met these patients will be particularly anxious about their illness. Fabbri also reported increased anxiety as a common feature in patients attending neurology clinics for the first time, CNS patients (Fabbri et al. 2001). This study's findings are extended to cardiology patients, who also commonly have CNS acting drugs prescribed. The difficulties in finding clear trends for all tested scales by medical diagnosis might be partly explained by coping strategies, including information seeking, which tend to be minimally explained by medical diagnosis (Felton, Revenson, & Hinrichsen 1984). Nonetheless, to further interpret the scores to the scales by diagnosis, each was analyzed taking into account patients interviews and physiology and pharmacotherapy knowledge about the illness and drugs.

Patients with a CNS condition are inherently prone to anxiety as that is one of the issues of their conditions. Medicines used are extremely powerful and individuals using them are more susceptible to become dependent than those treated with other classes of drugs.

“They (medicines) relief, especially the anti-depressant... (Trapped) especially by the anti-depressant and the tranquilizer, I notice that if I don't take them I don't feel well. It always interferes (with

life) a little because it (medicines) starts to create dependence.” (Pt.91, F, 31 y.o. secondary school, alcoholism, high scorer to the Ai scale)

“Yes, yes (they relief), really a lot. (Without them) I would have “kicked the boot” (i.e. died); having epilepsy, if we don’t have medicines, auch! I have the duty to take them until the end of life, otherwise “boom”! (Pt127, M, 43 y.o., no qualifications, epilepsy, high scorer to the Ai scale)

“I do feel (trapped) because I can’t go a day without them; some tablets you take them and then you get used to them; there is times when I run out of them and you feel the effects when you stop like the ones for depression I haven’t taken for 4 days since I came and I feel tearful. I can’t go out for a social drink for example so I’ve stopped that... my life in the last 5 years has dramatically changed and don’t take it badly but all these medicines have ruined my sex life. I feel very upset about it and I want to be well.” (Pt.155, M, 61 y.o., no qualifications, blood disorder cause unclear, high scorer to the Ai scale)

Having this into account it is not withstanding that these patients were found to score the highest on the anxiety scale and also quite high on the PBM scale. Simultaneously, it is natural that patients are aware of these drugs’ side-effects and this recognition was likely to influence the relatively high score also in the PHM scale. Nonetheless, while weighing the advantages and disadvantages of taking centrally acting drugs it is not surprising that the benefits perceived outweigh the harms.

Respiratory patients are recognized for their exacerbated use of relieving drugs in detriment of preventive therapy (Rabe et al. 2000). This fact may have implications on results found in mean scores to the PBM and the PHM scale. It is possible that patients’ reports about benefit had in mind relieving drugs, such as β -agonists, while PHM reports could be more associated with preventive therapy, such as corticosteroids, widely reported as disliked by patients. These assumptions are supported by the following quotes:

“They started me on steroid inhalers and I had my gums bleeding so I stopped it.”

(Pt 160, F, 74 y.o., no qualifications, hypertension and COPD)

“Only the cortisone I used to take 1 and I changed it to ½ because I was getting a bit swollen.”

(Pt 142, F, 66 y.o., no qualifications, hypertension and asthma)

“For me the important ones are those for bronchitis, 10 days a month and it is the most secure thing I’ve had in my life, and the puffers are also there and that’s it.”

(Pt 79, F, 59 y.o., no qualifications, osteoporosis and bronchitis)

“Some of them you can get addicted to. Like this one (salbutamol) I always carry it in my pocket and if I loose one I get into panic; I can’t live without it. I’m just used to it; it’s like having a cup of coffee in the morning. Not really (side effects) the ones I take...the salbutamol can make you a bit shaky sometimes if you take too much.”

(Pt 168, M, 56 y.o., no qualifications, asthma)

Cardiovascular patients perceived medicines as most harmful and the least beneficial, which perhaps is related to the asymptomatic characteristics of these conditions (Medical Encyclopedia 2005), leading to patients not experiencing any benefit from drugs. The high scoring in the PHM scale can perhaps result from side-effects of some of the therapeutic groups used to treat these conditions, as shown in these quotes:

“It does interfere, because sometimes I have to go out and I will not take it (diuretic) because I need time; it’s about 2 hours always urinating. There were days when e.g. there is one that makes me urinate a lot and when I go to the doctor I don’t take not to ruin my day, so I take it the next day. This is the only that affects me in such way that obliges me to urinate all the time. The others don’t have such a quick effect.”

(Pt 85, M, 76 y.o., primary school, hypertension, high scorer to the PHM scale)

“And that pill to put under the tongue it ruining my heart...Norvasc I never forget (opens eyes widely); even once I was going out of the house and I remembered I hadn’t taken it so I went back. That one to put under the tongue I also forgot now and then because I didn’t like it, it felt like a plastic bomb, I didn’t like it all.”

(Pt 95, M, 74 y.o., no qualifications, hypertension and angina pectoris, high scorer to the PHM scale)

Endocrine patients were the middle scoring group for the PBM, PHM and Ai scales. It would have been interesting to differentiate between insulin-treated and non-insulin treated patients but the sub samples' size and some incompleteness in the information collected about therapy made this analysis impossible. Nonetheless, it can be hypothesized that these patients having a long-term condition are not likely to be very anxious about it, while still recognizing it as a burdensome condition.

"It stops you socializing, going out without taking a bag full of medication with you.... They (medicines) keep me alive, put it that way....I don't worry. I've been ill since birth...Diabetes won't get any better and there's nothing they can do about that."

(Pt 161, F, 56 y.o., high school, diabetes, arthritis, heart problems)

Regarding diabetes therapy, while not seeing themselves improve due to the characteristics of the illness do not perceive their medicines as particularly beneficial (or relieving), whilst being aware they are essential for sustaining an acceptable quality of life.

"I am used (to medicines). They don't (relief) because I only take for diabetes, for tension and varfine, so only when I measure diabetes...(I will know). For diabetes I must diet and can't eat but I have medicines to help. I must take them because the doctor orders. I take medicines with me in a little box I have especially for that, but sometimes I also forget and then I don't take, but it's very rare...For example, I was worried with Risidon but the doctor explained it was a bigger than before, it was the 850 and now the 1000; he even said it was one of those new drugs that exist now, what's their name?"

(Pt 87, M, 69 y.o., no qualifications, diabetes, hypertension, blood disorder)

Analysing these quotes, it may be assumed that the benefits and the harms of these medicines had similar weightings.

The mean EID scores are likely to be confounded with the length of medical diagnosis, where except for the respiratory patients who are in general particularly well informed and closely monitored by specialist doctors in Portugal (Costa 2002), the endocrine and cardiovascular patients had a longer history of the disease

(mean=12 years; median=10), hence not feeling such a strong desire for additional information.

Discussing the difficulties and limitations

Some of the limitations of this study include not having used an external measure for each scale to explore criterion validity, limiting quantitative analysis of this type of validity to the Anxiety scale. The “limited” length of hospital stay resulted in the impossibility of having repeated the questionnaire also in hospital patients to explore consistency over time, which would have the advantage of ensuring the same interviewer, minimising probabilities of interviewer-related bias.

Selection bias in community pharmacy was admitted by participating pharmacists while considering it essential to be able to combine participating in a research study while affecting minimally the normal service delivery. The inability to guarantee response of refusal forms limited the usefulness of the analysis undertaken to explore comparability of respondent and non-respondents, but this was a limitation impossible to overcome as people cannot be forced to answer.

Interviewing patients in Portuguese and transcribing quotes and reporting findings in English was a major difficulty of this study as it was necessary to ensure that the ideas were not “lost in translation”, either by simplifying them or adding words to make it understood, which was only possible by external reviewing of coding and checking of meaning.

5.6 Conclusions

The main conclusions of this chapter are that the translated tool was valid and reliable in Portuguese patients, exception made to the Tolerance scale which was dropped. Some of the scales may benefit from further refinement to improve their validity, such as the PHM scale. The successive modifications needed to increase the tool’s validity and reliability confirm that scales are not directly transferable from one country to another and demonstrate the importance of ensuring these processes are undertaken to measure the concepts of interest in a credible manner.

Portuguese patients' perceptions about medicines and illness was characterised while evaluating criterion validity, the most prominent features observed being a high desire for information, particularly in young higher educated females prescribed few drugs. Higher anxiety was frequent in older lower educated females prescribed several drugs. Highest perception of harm was most common in lower educated males prescribed several drugs, while highest benefit was perceived by females, but also prescribed several drugs. These findings provide general indications on information desires and perceptions about medicines and illness vary widely according to different characteristics. This issue will be further explored in chapter VI, comparing between the UK and Portugal and between care settings within Portugal.

CHAPTER VI

COMPARING AND CONTRASTING PATIENTS' INFORMATION DESIRES AND PERCEPTIONS OF MEDICINES AND ILLNESS

6.1. Perspective

This chapter describes the exploratory phase of the study, measuring patients’ desires for information and perceptions about medicines and illness. In this chapter, patients’ perceptions are compared between the UK and Portugal, within Portugal between the different care settings. The findings aim to provide health care professionals with a greater insight into patients’ medicines-related attitudes and behaviours using these validated scales. Each section of the chapter VI focuses on comparisons between the countries, followed by comparisons within Portugal.

6.2 Aims and objectives

Aims

1. To compare patients’ desires for information and perceptions about medicines and illness between Portugal and UK patients.
2. To compare patients’ desires for information and perceptions about medicines and illness within the Portuguese health care setting

Objectives

- 1.1. To compare patients’ desires for information between Portugal and UK patients
- 1.2. To compare patients’ perceptions about medicines between Portugal and UK patients
- 1.3. To compare patients’ anxiety about illness between Portugal and UK patients
- 1.4. To compare patients’ desires for information between Portuguese primary care and secondary care
- 1.5. To compare patients’ perceptions about medicines between Portuguese primary care and secondary care
- 1.6. To compare patients’ anxiety about illness between Portuguese primary care and secondary care

6.3 Methods

This section describes the design of the exploratory phase, how patients were recruited and how data was collected and analysed. Firstly, data collected in the hospital setting in similar conditions in both countries, called the secondary care study, data previously collected from UK inpatients is used in this section to compare with data from Portugal. Secondly, the exploratory phase undertaken in

Portugal is described together with recruitment of pharmacists and patients and data collection methods and analysis. This section is referred to as the Portuguese study.

6.3.1 Study design

The study design of the secondary care study was cross-sectional, where patients were surveyed at one point in time to evaluate their desires for information and perceptions about medicines and illness. Ethics approval was obtained as described in section 3.5.4. Data recruitment in the primary care study was undertaken in two stages; for validation purposes explored in chapter V, while this cross-sectional data is used for comparison purposes in this chapter.

6.3.2 Patient recruitment and inclusion criteria

As stated above the secondary care study was undertaken at the same time as the validation phase; data from patients were used in both phases. The same recruitment procedure, patients’ inclusion criteria and written tools were used, as described in chapter V. The settings within each country were chosen using convenience sampling; patients were recruited from general medical wards at the Royal London Hospital in London in the UK. In Portugal, four general hospitals were used for patient recruitment: Hospital da CUF, Hospital da Universidade de Coimbra, Hospital de São João and the British Hospital. Access to the wards varied between hospitals, as described in the section 5.4.1, hence patients were recruited from different types of wards. In both countries, methods for data collection were identical; every eligible patient was invited to participate. Inclusion criterion was defined as adult patients taking chronic medication. Only patients unable to communicate were excluded; reasons included mental or physical incapacities, language barriers and disease states such as coma.

For the Portuguese primary care study, patients were also recruited from community pharmacies (see section 6.3.3). Each pharmacy involved was asked to recruit 15 patients (independent of the number of pharmacists involved) over a period of 2 months in the cross-sectional phase and 10 patients in the longitudinal phase. Experience of previous studies carried out nationwide had shown that random recruitment of patients was incompatible with normal service delivery, hence systematic sampling was adopted. Pharmacists were asked to recruit the first patients

that came into the pharmacy after the start date, who complied with the inclusion criteria. Patients who had no control over their medicines (*i.e.* nursing homes and paediatrics) were excluded from recruitment; otherwise inclusion was the same as the secondary care arm of the study. Pharmacies were clustered according to different target diagnoses, *i.e.*, a group of pharmacies recruited only cardiovascular patients, whilst others recruited respiratory patients etc. to ensure patients with major conditions were included. Patients were identified when they obtained their medicines from the pharmacy through the corresponding ATC classification, through pharmacy records or when entering the pharmacy for *e.g.* blood pressure testing.

6.3.3 Recruitment of pharmacists

A sample of community pharmacies associated with the National Association of Pharmacies (ANF) were invited to participate ($n=40$). These were chosen by convenience sampling, *i.e.*, pharmacies located within the same 3 regions used for secondary care data collection, who had previously participated in pharmacoepidemiology studies or other initiatives from the ANF and had been *e.g.* involved in pharmacy-based disease management programmes and/or CPD sessions. Pharmacists were invited by means of a written invitation letter, followed by a telephone call to confirm their willingness and availability to participate in a session introducing them to the project. All the pharmacists attended this session, where background information about the UK work was provided, up to date developments in the project in Portugal and preliminary results. Emphasis was placed on patient recruitment procedures, inclusion criteria, questionnaires’ administration techniques, the help to be provided to patients experiencing difficulties, and tools that should be used in such cases to document this.

6.3.4 Data collection methods and tools

In the secondary care, every eligible patient within each ward was approached at their bedside and invited to participate and offered written invitation. Patients agreeing to participate gave written consent prior to the interview. The interview schedule comprised an initial section with demographic and medical information, followed by the 23 statements ranked on a 5-point Likert scale. A general question from the SF-36 was included to assess patients’ perceptions about their health status together with

five open questions, designed to explore perceptions of the scales, self-reported adherence and feelings about the health-care system. Patients refusing to participate in the study were asked the reason why which was collected with their demographic and medical data to explore differences between respondents and non-respondents.

A modified version of the questionnaire was subsequently developed for collecting data in the community pharmacy. Community pharmacists did not have enough training in interviews and National studies suggested that using a self-administered tool would have less impact on normal service delivery. The cases when pharmacists administered the survey tool themselves included recruiting illiterate patients or patients with visual problems. The modifications to allow self-administration were the clarification of introductory remarks and a visual illustration of the Likert scale. A section was included at the end of the questionnaire for pharmacists to document the help given to the patient in responding to the questionnaire, the reasons, and the items where the patient had problems.

6.3.5 Data analysis

Descriptive statistics were used to characterise both patient samples involved in the secondary care study and the samples recruited in the hospital and in the community pharmacy Portuguese settings. Demography and medical characteristics are presented followed by the patients’ responses to the scales. Subsequent associations and comparisons of scores to scales by country and by health care settings respectively and by different demographic or medical characteristics were undertaken using chi-square tests, t-tests for independent samples and ANOVA, as appropriate. The statistical significant level for all analyses was set at 0.05.

6.4 Results

Results are presented in three main sections, each of them focusing on the comparison between countries, *i.e.* the secondary care study (where UK data on file was used after excluding community pharmacy patients), and then on the comparison between primary and secondary care in Portugal. The latter includes an additional section where the participation rate of pharmacies is reported. Socio-demographic characteristics, medical and therapeutic data are presented together

with major findings from the scores to scales. Adherence data is explored in the subsequent chapter.

6.4.1 Patients' characteristics

Socio-demographic data were collected in both countries to explore similarities of the samples and thus enable further comparisons. The classification systems used are discrepant for some characteristics, such as educational level, so some data were recoded and/or computed to allow direct comparisons.

Table 6.1 Patients' characteristics in UK and Portugal samples

Variable		UK	Portugal	p
		n (%)	n (%)	
Gender	Male	662 (49%)	60 (58%)	0.063
	Female	696 (51%)	43 (42%)	
Ethnicity	White	1021 (75%)	102 (99%)	0.004
	Black-African	55 (4%)	1 (1%)	
	Black-Caribbean	74 (6%)	-	
	Black-other	16 (1%)	-	
	Bangladeshi	44 (4%)	-	
	Indian or Pakistani	28 (2%)	-	
	Other	25 (2%)	-	
Educational level	No qualifications*	433 (69%)	73 (71%)	0.197
	Secondary school (A-levels)	131 (21%)	14 (14%)	
	High school (O-levels)	23 (4%)	5 (5%)	
	University degree	42 (7%)	11 (11%)	
Existing condition	Cardiovascular	367 (28%)	36 (35%)	0.179
	GI	84 (6%)	5 (5%)	
	Respiratory	209 (15%)	11 (11%)	
	Endocrine	325 (25%)	21 (20%)	
	Tumours	89 (7%)	6 (6%)	
	Other	243 (19%)	24 (23%)	
Perceived health status	Poor	32 (33%)	34 (34%)	0.683
	Fair	33 (34%)	35 (35%)	
	Good	19 (20%)	25 (25%)	
	Very good	8 (8%)	4 (4%)	
	Excellent	4 (4%)	3 (3%)	
Age	Mean; sd	58.85; 17.30	60.92; 15.20	0.190
	Median; mode; {min-max}	61; 65; {16-100}	63; 72; {19-92}	
No Rx meds	Mean; sd	6.68; 4.06	5.79; 3.15	0.008
	Median; mode; {min-max}	6; 6; {1-27}	5; 6; {1-19}	

*No qualifications include patients with less the minimum compulsory education at the time of interviewing [Portugal: patients with no qualifications (either literate or illiterate), with primary and with preparatory school are included; UK: those never attending or leaving school prior to completion of A-levels]

Table 6.1 shows the differences between the two samples recruited in terms of ethnicity and number of prescribed medicines. Whilst some characteristics such as ethnicity could be expected to differ, the difference in number of medicines prescribed may reflect the different health care systems medical practices involved and may also reflect different recruitment procedures as the UK sample was recruited from different study sites at different occasions. If this was so, other variables may also be distributed differently; therefore the possibility of bias was disregarded.

According to OECD data, the perceived health status of the Portuguese and English population is different (Organisation for Economic Co-operation and Development 2004), but was not found in this study. This is likely to result from OECD’s data referring to the UK, whilst this study is based in London, a city with specific characteristics, and this recruitment site is known for housing many immigrants from various ethnicities, as reflected in this table and previously detailed in section 3.5.2.1.

In the Portuguese primary care study, 40 pharmacies were invited to participate (in total, *i.e.*, in the cross-sectional and longitudinal phase, where some only participated in one or the other whilst others participated in both phases), 35 of which agreed and attended the compulsory introductory session (participation rate=88%). During the course of the study, four (11%) dropped out for different reasons (staff getting ill, pregnant or on holiday; one mentioned “forgetting about the study”). During subsequent developments, a panel of pharmacies was added (n=9), 8 of whom completed the study, while an extra pharmacy was recruited by one of the participating pharmacists (total n=40; a full list is provided in the acknowledgements). A total of 443 patients were recruited by the participating community pharmacists. The following table (table 6.2) summarises the most relevant characteristics of the patients recruited within Portugal, including the hospital inpatients (compared with the UK sample), the patients recruited in these 38 pharmacies and additionally 50 patients recruited in the outpatients’ clinic of the two large teaching hospitals.

Table 6.2 Patients' characteristics in different Portuguese recruitment sites

Variable	Community pharmacy	Outpatients	Inpatients	p
	n (%)	n (%)	n (%)	
Gender				
Male	162 (37%)	27 (54%)	60 (58%)	0.000
Female	281 (63%)	23 (46%)	43 (42%)	
Educational level				
No qualifications*	259 (61%)	32 (64%)	73 (71%)	0.346
Secondary school	71 (17%)	10 (20%)	14 (14%)	
High school	44 (10%)	2 (4%)	5 (5%)	
University degree	53 (12%)	6 (12%)	11 (11%)	
Age				
Mean; Sd	58.6; 15.3	59.0; 12.5	60.9; 15.2	0.354
Median; mode; {min-max}	62; 70; {15-87}	60; 67; {29-82}	63; 72; {19-92}	
Existing condition				
Cardiovascular	143 (32%)	11 (22%)	36 (35%)	0.000
Endocrine	99 (22%)	28 (56%)	21 (20%)	
Respiratory	53 (12%)	1 (2%)	11 (11%)	
CNS	60 (14%)	1 (2%)	6 (6%)	
GI	27 (6%)	1 (2%)	5 (5%)	
Immune System	15 (3%)	1 (2%)	8 (8%)	
Tumours	5 (1%)	0 (0%)	6 (6%)	
Other	41 (9%)	7 (14%)	10 (10%)	
Number of prescribed medicines				
Mean; Sd	4.1; 12.6	4.6; 2.2	5.8; 3.2	0.000
Median; mode; {min-max}	3; 2; {1-17}	4; 4; {1-10}	5; 6; {1-19}	
Duration of illness (years)				
Mean; Sd	14.2; 12.6	10.3; 8.2	10.7; 10.2	0.081
Median; mode; {min-max}	10; 10; {0.1-73}	9; 10; {1-30}	9; 10; {0-39}	
Perceived health status				
Poor	78 (27%)	16 (34%)	34 (34%)	0.110
Fair	150 (52%)	19 (40%)	35 (35%)	
Good	50 (18%)	10 (21%)	25 (25%)	
Very good	6 (2%)	1 (2%)	4 (4%)	
Excellent	2 (1%)	1 (2%)	3 (3%)	

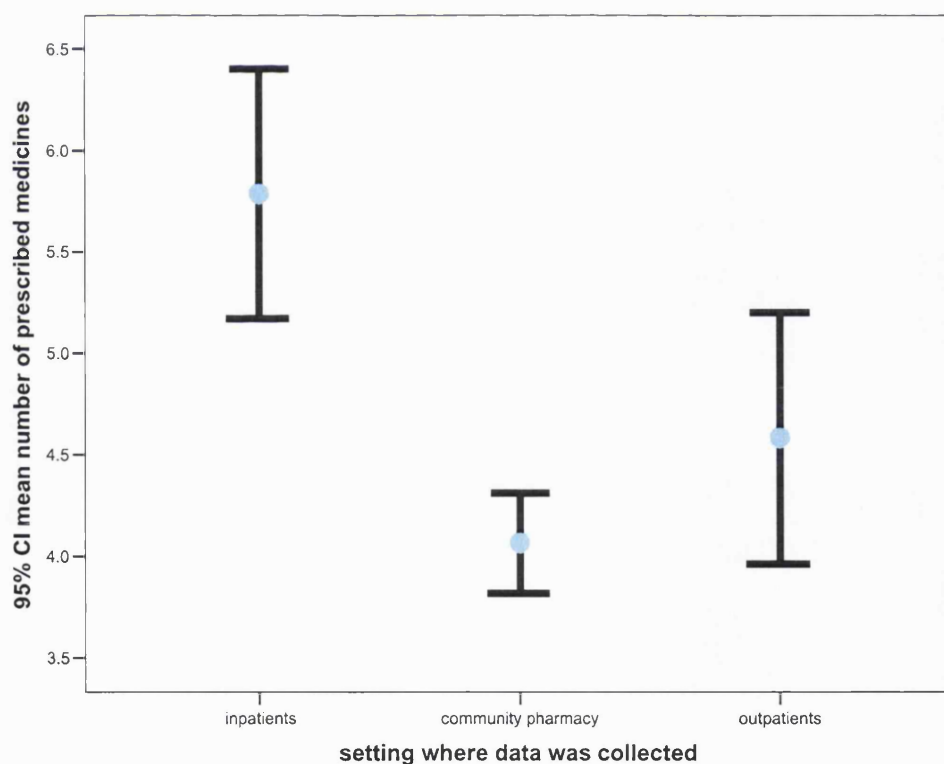
*No qualifications include patients with less the minimum compulsory education at the time of interviewing [patients with no qualifications (either literate or illiterate), with primary and with preparatory school are included]

This table shows that most characteristics are similar independent of the recruitment site. Exceptions include gender, diagnosis and number of prescribed medicines. The distribution of gender was unequal across recruitment settings, with a higher proportion of females in the community pharmacy compared to the other study sites. This may be because there still seems to be a tendency for females to come to the pharmacy more often, even when acquiring medicines for male relatives. This fact cannot explain the difference as it was compulsory that the drugs were prescribed for the patient answering the questionnaire; however, it could be possible that male

patients tend to acquire their medicines more often at night or weekend shifts, a time when the study was not being undertaken.

Inpatients were prescribed statistically significant more medicines than outpatients ($t=2.44$; $p=0.016$) and than community pharmacy patients ($t=5.76$; $p=0.000$). This might be a true reflection of medical practice resulting from a worse disease status at time of hospitalization, even with possible hospital acquired complications, but it could also be a result of the way the data was collected. For inpatients, prescribed drugs were systematically collected from the patients' medical charts whereas for both outpatients and community pharmacy patients data was collected by means of patient self-report whenever records were unavailable, increasing the odds of incompleteness.

Figure 6.1 – Error bars of mean number of prescribed medicines by setting



Diagnoses were unevenly distributed by setting. Assuming this difference could be mostly due to the patients recruited in the outpatients' clinic (mostly endocrine), diagnosis was compared only between inpatients and community pharmacy patients, still an uneven distribution of diagnosis was found ($\chi^2=17.76$; $p=0.013$). This fact

may be a result of the gender distributions between settings, since some conditions have different prevalence in males and females. This may also have an influence on the differences found for the number of prescribed medicines, since some conditions are inevitably treated with more medicines than others.

6.4.2 Non-respondents characteristics

From all the patients approached (n=695), 34 (4.9%) refused to participate in the study. There was a higher proportion of non-participants in the UK (n=9; 8.2%) than in Portugal (n=25; 4.3%). When exploring Portuguese non-respondents by setting, there was a higher proportion of non-respondents in the hospital setting (n=6; 5.5%), followed by the community pharmacy (n=18; 4.2%) and only 1 patient (2.0%) refused to participate in the outpatients' clinic. The latter findings imply it is likely the recruitment setting influences response rate than the country. One may expect to have a higher participation rate in the hospital, where patients are approached at their bedside, and are a "captive audience", the low proportion of non-responders in the community pharmacy may be related to under-reporting of refusals by community pharmacists or to a selection bias, inviting *e.g.* only regulars to the pharmacy.

Non-respondents' characteristics are analysed overall, since the total number of non-respondents was low. Table 6.3 shows that there were no differences in the non-respondents, implying that bias was unlikely.

Table 6.3 – Characteristics of respondents and non-respondents compared

Variable	Respondents	Non-respondents	p
Gender (male/female) %	44%/56%	41%/59%	0.718
Age (mean; sd)	59.3; 15.1	61.7; 18.3	0.423
Educational level			
No qualifications	65%	73%	0.910
Secondary school	16%	13%	
High school	8%	7%	
University	11%	7%	
Diagnosis (only where there were enough non-respondents for comparison)			
Cardiovascular; Endocrine	58%; 42%	54%; 46%	0.697
No Rx meds (mean; sd)	5.3; 3.7	6.0; 3.8	0.317

6.4.3 Patients' information desires

The purpose of comparing scores to scales in the two samples was to explore differences in patients' perceptions of their medicines and illnesses that could eventually result in behaviours differing between the health care setting in which they are treated. This hypothesis was tested for the four scales, the EID, PHM, PBM and Ai. This section explores the scores to the EID in the two countries and then within Portugal in the three health care settings.

Exploring the EID scores

The mean scores obtained for the EID by the Portuguese (n=560) and the UK samples (n=1860) were compared, showing that Portuguese patients have a higher desire for information than UK patients (figure 6.2), the differences between mean scores from the 2 samples were statistically significant ($t=14.29$; $p<0.001$).

Figure 6.2 – Error bars of mean scores to the EID scale by country

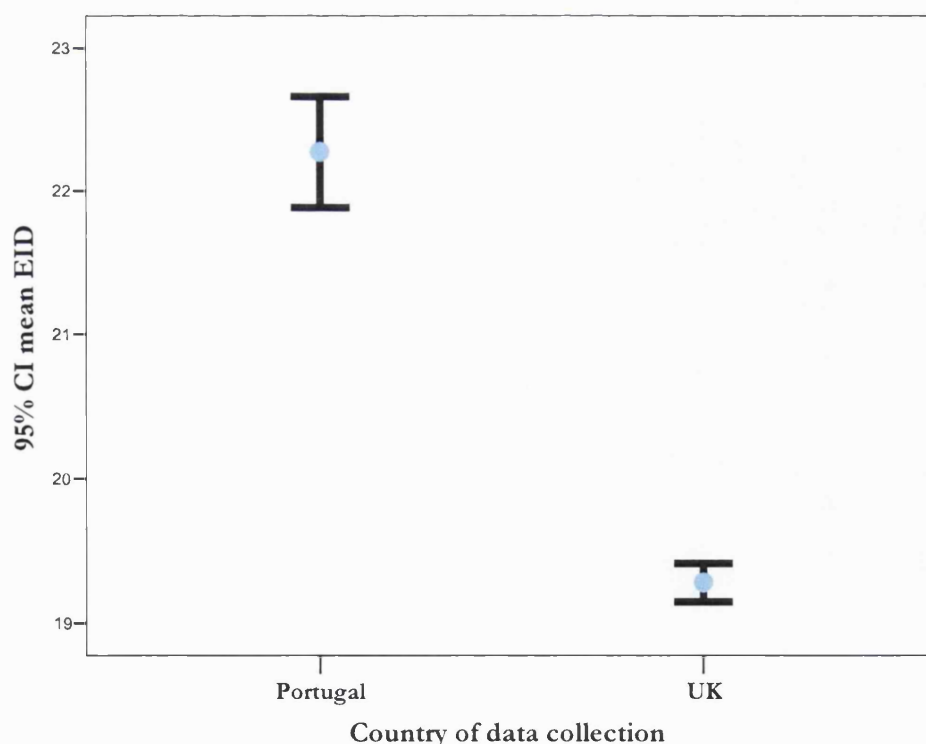


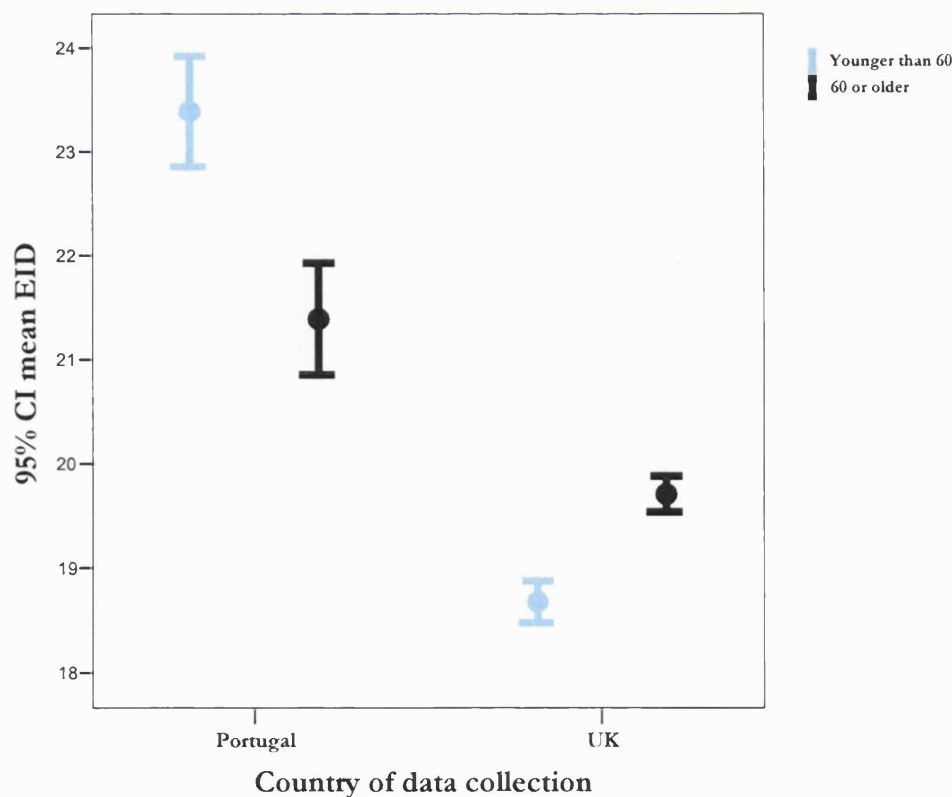
Figure 6.3 shows differences in scores to the EID scale by age group. Comparing scores to the EID scale by demographic characteristics between the two countries; in Portugal patients desiring more information tended to be female ($t=-2.01$; $p=0.045$), the younger ($t=5.12$; $p<0.001$), and the higher educated ($t=-7.06$; $p<0.001$). In the

UK gender had no influence on information desires ($t=-0.23$; $p=0.819$), the lower educated and the older tended to desire more information, while this difference was only significant for age ($t=-7.66$; $p<0.001$). The age categories created are very broad and to support that such grouping does not influence the findings, the correlations between age and scores to EID for each country are firstly presented in table 6.4, showing a negative correlation between these two variables for Portugal and a positive correlation for the UK.

Table 6.4 – Correlations between age and scores to EID for both countries

EID*age	Country	
	UK	Portugal
Spearman's rho	0.219	-0.237
p	<0.001	<0.001

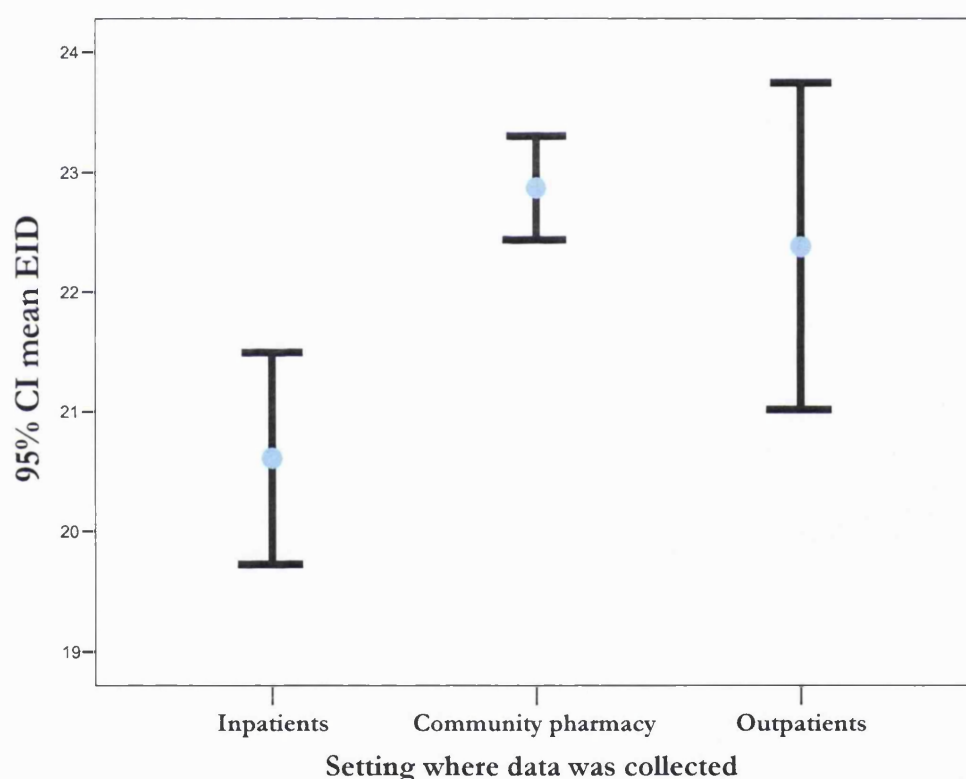
Figure 6.3 – Error bars of mean scores to the EID scale by age group clustered by country



In Portugal, the diagnostic groups who scored the highest on the EID scale were GI, followed by respiratory, tumours, endocrine and cardiovascular diagnoses. However,

none of these differences was significant ($F=1.02$; $p=0.404$) and some of these groups were quite small and had a broad dispersion of scores (*e.g.* patients with tumours). In the UK, cardiovascular patients scored higher than any other, followed by GI, respiratory, endocrine and tumours. These differences were significant overall ($F=7.10$; $p<0.001$), however, the cardiovascular group was accountable for this overall difference, scoring significantly different than both tumour ($t=3.31$; $p=0.001$) and endocrine patients ($t=5.02$; $p<0.001$).

Figure 6.4 – Error bars of mean scores to the EID scale by Portuguese setting



Within Portugal mean scores to the EID scale were compared between the three recruitment settings. Hospitalized patients tend have less control on the medicines they are taking because they are being cared for, which could have a potential influence on desires for information about medicines at the stage in care, so such hypothesis was investigated. Mean scores to the EID scale were significantly different across settings ($F=9.89$; $p<0.001$), but this overall difference resulted from community patients scoring higher in this scale than hospital patients ($t=4.46$; $p<0.001$). Outpatients' mean scores to the EID scale were very similar to community patients (mean difference=0.46; $p=1.000$) and not higher than inpatients' mean

scores (mean difference=1.77; $p=0.082$). This group also had a large spread of scores resulting from a small sample size (fig. 6.4).

This confirms that patients recruited outside the hospital setting are more “in charge” of their medication and therefore need the appropriate information to use it the best possible way.

Analysis was restricted to inpatients and community pharmacy patients to explore characteristics and influences on EID scores. Females scored slightly higher in both settings, not statistically significant. Age was negatively but weakly correlated with scores to the EID in hospital ($r=-0.30$; $p=0.002$) and in the community ($r=-0.24$; $p<0.001$), implying that younger patients tended to desire more information, that desire decreased with age. Conversely, a positive but weak correlation was found between scores to the EID scale and educational level (taking this as ordinal) both in hospital ($r=0.22$ $p=0.025$) and community ($r=0.25$; $p<0.001$), implying that the desire for more information increased with educational level. These two findings are likely to be related as the younger population tend to be the higher educated (table 6.5).

Table 6.5 – Partial correlations between age and educational level for scores to EID

Control variable (mean EID \pm sd)	22.6 \pm 4.7
Educational level*age	
Spearman’s r	-0.466
p	<0.001

This is associated with the mandatory requirements for additional education which changed in Portugal in 1979, 1986 and 1993 (Ministério da Educação 1979; Ministério da Educação 1986; Ministério da Educação 1993). The change in the educational level of the population has implications for pharmacy practice as patients become progressively more able to be involved in decision-making. These findings reveal that currently, regardless of the setting, in general more information should be provided to the younger and higher educated as these seem to be those more willing and/or capable to be empowered. This may change as the young population of today will be the elderly of tomorrow, still having high educational levels.

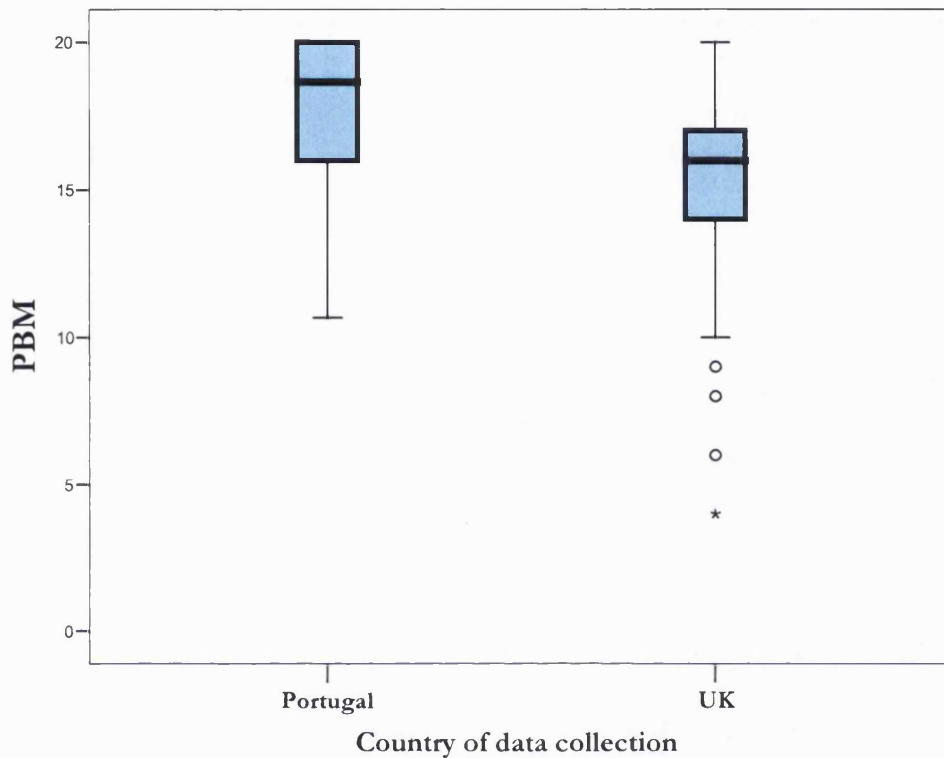
The number of drugs patients were prescribed correlated negatively with their scores to the EID scale, only significant for inpatients though (Inpatients: $r=-0.20$; $p=0.048$; Community: $r=-0.07$; $p=0.124$). Similarly, patients’ mean scores to the EID scale did not differ across different diagnoses in both recruitment settings (Community: $F=1.78$; $p=0.090$; Inpatients: $F=0.37$; $p=0.918$). It can be emphasised that despite the differences being small and some diagnoses being small samples, if these findings are disregarded, the similarities found for both settings were that the endocrine patients tended to score lower in the EID scale, implying a low desire for information, whereas GI patients tended to score higher showing a high desire for information, which indicate that in the Portuguese sample demographic characteristics seem to be better predictors of scores to the EID scale than medical characteristics.

6.4.4 Patients’ perceptions about medicines

The hypothesis that patients hold different perceptions of their medicines was explored by comparing scores to scales from the UK and Portugal samples. As mentioned in chapter V, the PBM and PHM scales in Portugal were modified by dropping one of their items. To compare between countries, scores to these scales were weighed to take this into account ($PUM_w = PUM * 4/3$).

There were significant differences in mean PBM scores between countries ($n_{port}=556$; $n_{UK}=1238$; $t=13.89$; $p<0.001$), indicating that Portuguese patients tended to perceive their medicines as more beneficial, as displayed in figure 6.5. Similarly, the Portuguese sample tended to score higher in the PHM scale, indicating a higher perception of harm, although this difference was not significant ($t=1.50$; $p=0.133$). These findings indicate that Portuguese patients felt medicines as more beneficial while acknowledging their harm, in comparison with UK patients.

Figure 6.5 – Box plots of scores to the PBM scale by country

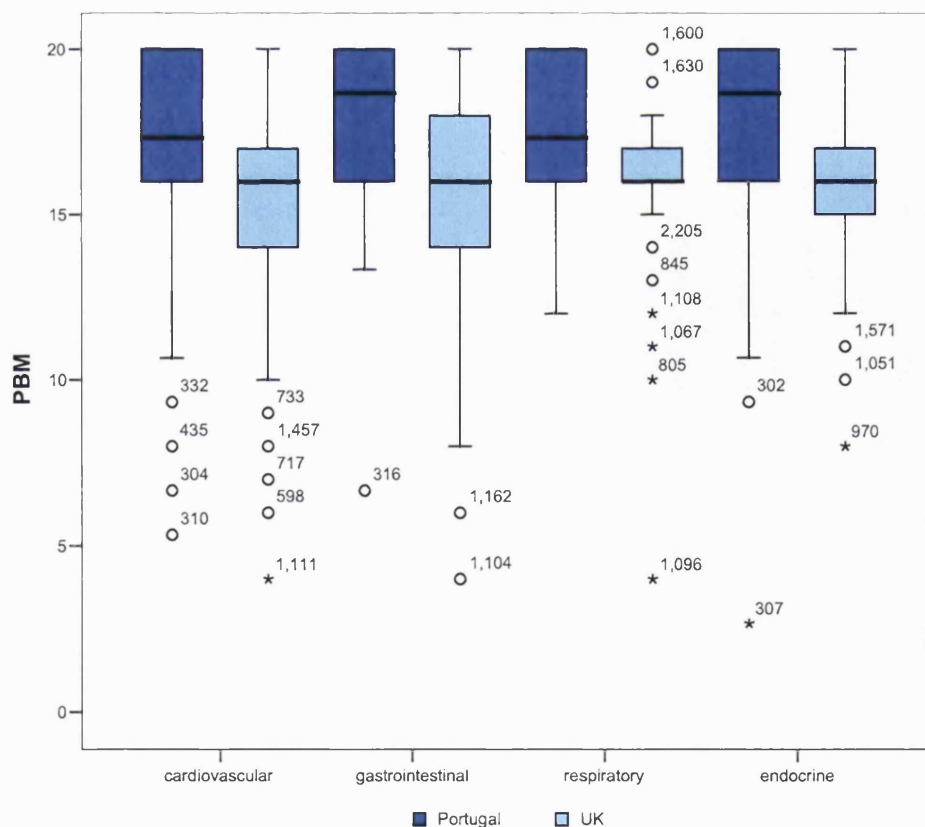


In Portugal, male patients scored lower to the PBM scale and higher to the PHM scale, whilst in the UK the opposite was found, *i.e.*, male scores higher to the PBM scale and lower to the PHM scale. However, these differences were not significant, so gender did not affect scores to either of these scales in both countries. Additionally, patients' age did not affect scores to either the PBM ($\rho < 0.06$; $p > 0.05$) or PHM ($r < 0.06$; $p > 0.05$) scales in either country.

There were no significant correlations detected between the number of prescribed medicines and patients' scores to the PHM scale in either of the countries. However, the number of prescribed medicines was positively correlated with scores to the PBM scale in both countries; implying that patients taking more medicines perceive them as more beneficial. However, it must be emphasised that these correlations were quite weak and whilst significant in the UK ($\rho = 0.06$; $p = 0.046$), they were not significant in Portugal ($\rho = 0.08$; $p = 0.055$). There were no differences in mean scores to the PBM scale between different diagnoses in Portugal ($F = 1.31$; $p = 0.241$) but there were for the UK sample when considering all possible diagnoses ($F = 2.28$;

$p=0.026$) and when restricting analysis to the four most frequent diagnoses ($F=3.94$; $p=0.008$). In this latter analysis it is worth mentioning that the respiratory patients scored significantly higher than cardiovascular ($t=3.18$; $p=0.002$) and GI patients ($t=3.09$; $p=0.002$), and endocrine patients were the second highest scoring group but not statistically different from any other diagnosis. In Portugal, the GI patients were the highest scoring group, followed by the endocrine, respiratory and then cardiovascular. The mean scores to this scale in both countries for these four diagnoses are displayed in figure 6.6. It should be noticed that the small sample size of the GI group in Portugal results in a large spread of scores, findings should be carefully interpreted (discussed in section 6.5).

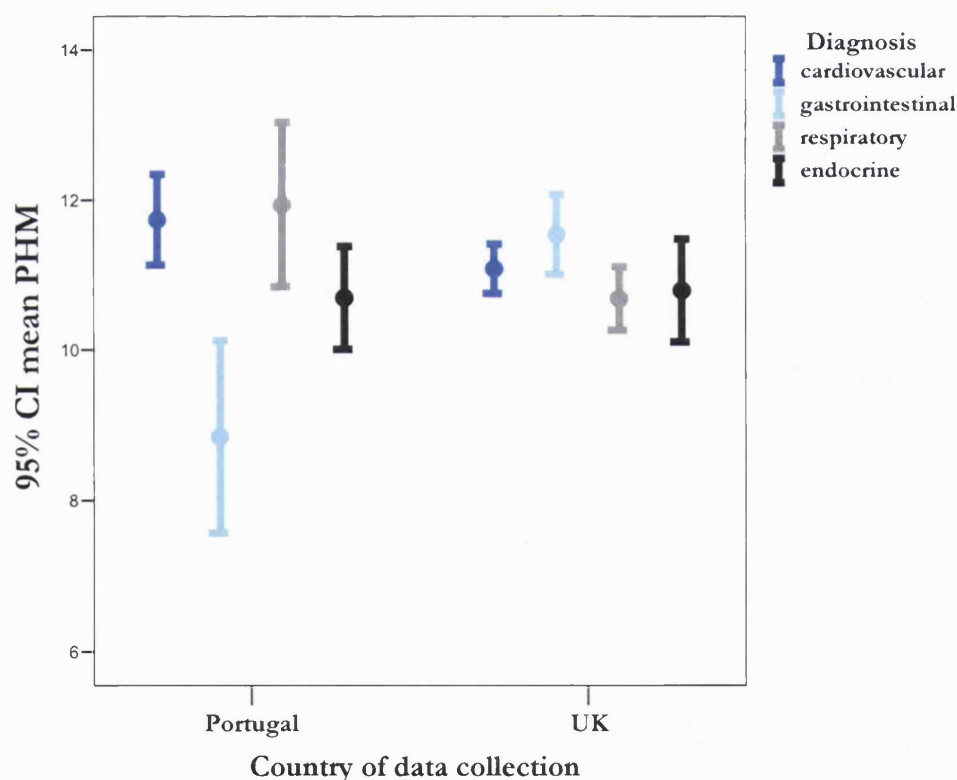
Figure 6.6 – Box plots of scores to the PBM scale by the most frequent diagnoses clustered by country



Conversely, mean scores to the PHM scale varied significantly between diagnoses in Portugal ($F=5.76$; $p=0.001$) but not in the UK ($F=1.99$; $p=1.113$). In Portugal, respiratory patients were those perceiving their medicines to cause most harm,

followed by cardiovascular, endocrine and GI patients. The GI patients were accountable for the overall difference, as their mean score was significantly different from respiratory patients ($t=3.42$; $p=0.001$) and cardiovascular patients ($t=3.70$; $p<0.001$). In the UK, GI patients scored higher in this scale, followed by cardiovascular patients, endocrine and respiratory. It is interesting to notice that while middle scoring diagnoses (cardiovascular and endocrine) maintain their rankings in both countries the extremes invert their positions (*i.e.*, GI and respiratory), as depicted in figure 6.7.

Figure 6.7 – Error bars of mean scores to the PHM scale by country clustered by the most frequent diagnoses



Similar to the approach taken when comparing countries, it was hypothesised that patients' perceptions about medicines might differ according to the setting where they were recruited. Theoretically, hospitalised patients, having a worse health status, might question their medicines' efficacy and hence perceive their medicines as less beneficial when compared to those patients recruited in the community. No pre-assumptions were made for the perception of harm, because, on the other hand

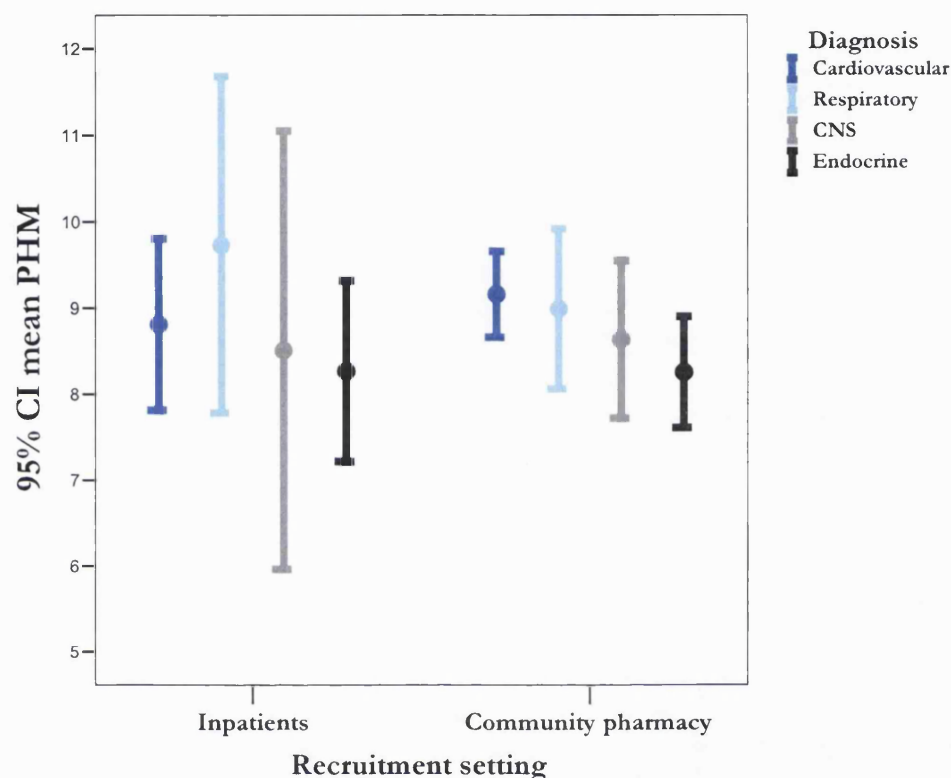
inpatients could have had their hospital admission caused by side-effects or interactions and in such case should perceive them as more harmful; on the other hand, inpatients are more closely monitored and could feel more protected from medicines’ negative effects, perceiving them as less harmful.

There were no significant differences of mean scores to the PBM scale between the three Portuguese recruitment settings ($F=1.81$; $p=0.165$). Despite none of these groups scoring significantly differently from each other, the outpatients scored higher, followed by community patients and then inpatients, confirming the hypothesis. Similarly, there were no significant differences of mean scores to the PHM scale in these three settings ($F=2.92$; $p=0.055$), where the community pharmacy patients scored higher, followed by inpatients, the outpatients were those perceiving their medicines to be more harmful. The difference between extreme groups (outpatients and community pharmacy patients) was significant ($t=2.3$; $p=0.023$), therefore the subsequent exploring of demographic and medical characteristics considered these three groups.

Male patients scored higher than females on the PBM scale in the hospital setting, none of these differences were significant. Conversely, in the community pharmacy setting, mean scores of females to the PBM scale were statistically significantly higher ($t=-2.17$; $p=0.031$). Exactly the opposite was found for mean scores to the PHM scale by gender, where females scored higher in both the inpatient and the outpatient samples and scored lower in the community pharmacy setting. Again, none of the differences was statistically significant. There were no significant correlations between patients’ age and their scores to the PBM or the PHM scale in any of the three settings. There were only statistically significant correlation found between patients’ educational level and PHM scores ($r=-0.25$; $p<0.001$) and between patients’ educational level and PBM scores ($\rho=-0.13$; $p=0.006$) for the community pharmacy. It must be emphasised that these correlations are weak, but indicate that the least educated patients perceive highest benefit and harm from drugs. In the other settings, these correlations were also weak but positive, implying the most educated perceive highest benefit and harm from drugs.

A positive correlation was found between the number of prescribed drugs and patients' scores to the PHM scale for inpatients ($r=0.23$; $p=0.03$), indicating the more drugs the patients are prescribed the more harmful they perceive them to be. This was not the case in the other recruitment settings, where correlations were not significant. No significant correlations were either detected between the number of prescribed drugs and PBM scores in any of the settings. There were no significant differences in mean scores to either the PBM or the PHM scale by different diagnoses in any of the three settings considered. For this analysis the outpatients' clinic was disregarded the few cases were not diagnosed as endocrine or cardiovascular. Regardless of significance, it could be observed that mean scores of the different diagnostic groups to the PBM scale varied in their order between the hospital and the community pharmacy setting. A more orderly display of mean scores by diagnosis was visible for the PHM scale between these two settings (figure 6.8), where endocrine patients always scored lower, followed by CNS patients. These two groups hence perceived their medicines as less harmful. Cardiovascular patients tended to be those perceiving the highest harm in the community pharmacy setting, whereas the GI patients perceived the highest harm in the hospital setting. However, it can also be seen in this figure that in the hospital setting, there were large confidence intervals especially for GI and CNS patients resulting from the small sample size of these diagnostic groups.

Figure 6.8 – Error bars of mean scores to the PHM scale by the four most frequent diagnoses clustered by setting



From this overall analysis, it can be concluded that scores to the PUM scales were most influenced by medical characteristics than by demographics of patients, mostly noticeable in the comparison between countries, in contrast to what was seen for the EID. This implies that perhaps medical characteristics can better predict patients' perceptions of medicines, or that perceptions may be influenced by diagnosis whereas information desires may be a construct more associated with personality traits or demographics.

6.4.5 Patients' anxiety about illness

This section explores how patients recruited from the two countries and in different health care settings felt about their illness. The scores to the Ai scale were compared between Portugal and the UK and within Portugal between different recruitment sites, similar to the approach taken when analysing the other scales.

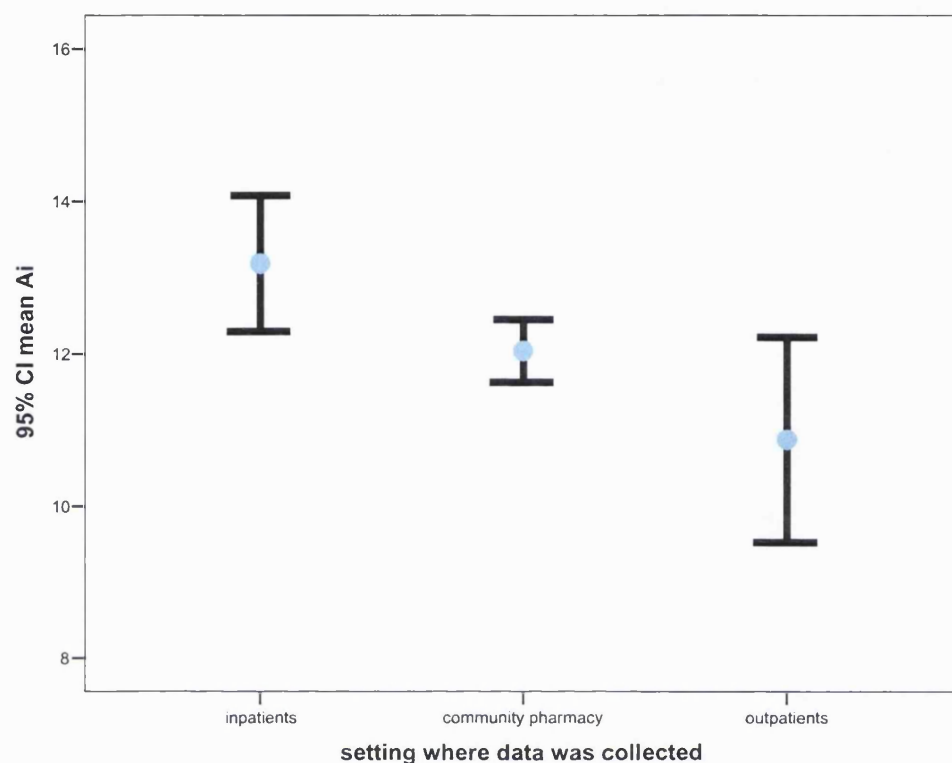
There were no statistically significant differences between mean scores to the Ai scale by country of data collection ($n_{\text{Port}}=555$; $n_{\text{UK}}=1148$), but UK patients scored slightly higher, implying a tendency to be more anxious about their illness ($t=0.42$; $p=0.676$). The scores to the Ai scale were higher in female patients in both countries, while the difference was not statistically significant ($t_{\text{Port}}=-0.17$ and $t_{\text{UK}}=-1.08$; $p>0.05$), which indicates that females tended to be more anxious about their illness. Correlations between age and scores to the Ai scale were weak and not significant for both countries. There was a negative correlation between scores to the Ai scale and the patient's educational level in both countries (while only significant for Portugal: $r=-0.20$; $p<0.001$), implying that the patients with less education tended to be more anxious about their illness, a finding that backed up work presented in chapter V.

The number of prescribed medicines was positively correlated with the scores to the Ai scale in Portugal ($r=0.12$; $p=0.007$) and negatively correlated in the UK ($r=-0.03$; $p=0.250$), only the first statistically significant. There were no statistically significant differences between mean scores to the Ai scale by medical diagnosis in both countries. However, it is worth mentioning that in the UK, the most anxious patient group was endocrine patients, followed by the cardiovascular patients, GI patients and respiratory patients. In Portugal, respiratory patients tended to be the most anxious, followed by cardiovascular, endocrine and GI patients.

When exploring differences to scores to the Ai scale between Portuguese recruitment settings, the hospitalized patients may be more anxious about their condition at the time of interview, especially when this occurred shortly after admission.

As hypothesised, the data showed there were significant differences in patients' anxieties between the three settings ($F=4.08$; $p=0.018$); inpatients were the most anxious, followed by community pharmacy patients and the outpatients were the least anxious, as displayed in figure 6.9. The inpatients scored higher on the Ai scale compared to community pharmacy patients' ($t=2.34$; $p=0.019$) and outpatients' scores ($t=2.91$; $p=0.004$), while the difference between these two last settings was not significant. Such findings may be linked to the perception of a more serious illness condition when hospitalised, naturally leading to anxiety. Alternatively, it may be the hospital environment makes patients feel more anxious.

Figure 6.9 – Error bars of mean scores to the Ai scale by recruitment setting



Females scored higher on the Ai scale both in the hospital and the community pharmacy settings, while this was not found for outpatients. None of these differences were significant. There was a weak but significant correlation between scores to the Ai scale and patients' age in the community pharmacy sample ($r=0.16$; $p=0.001$), implying older patients tended to be more anxious; this correlation, despite weak and not significant, was negative in the other two recruitment sites. Scores to the Ai scale were negatively correlated with patients' educational levels in all study sites, although only significant for the community pharmacy sample ($r=-0.38$; $p<0.001$); which implies less educated patients tended to feel more anxious about their illness. These findings may be related to patients' perceptions towards health care professionals and to patients' religious beliefs, where the less educated may adopt a more passive attitude which may increase their anxiety because they do not feel they can complain and believe they should accept whatever doctors and/or God dictate.

There were positive significant correlations between scores to the Ai scale and the number of prescribed drugs for community pharmacy patients ($r=0.13$; $p=0.008$) and

for inpatients ($r=0.21$; $p=0.039$); that the more drugs the patient is prescribed the more anxious they get (or vice versa). There were no differences found for mean scores to the Ai between the main medical diagnoses in either of the settings. However, whereas in the hospital the more anxious patients were the respiratory, followed by CNS, endocrine and cardiovascular, in the community pharmacy the most anxious were the CNS patients, followed by the cardiovascular, then endocrine and the respiratory patients were the least anxious group.

This difference in scores to the Ai scale from respiratory patients by setting is similar to what was observed by country; this patient group tended to be the most anxious in Portugal and in the hospital setting and were conversely the least anxious in the UK and in the community pharmacy setting. Possible explanations for this finding could be that respiratory conditions are typically associated with anxiety, which may decrease as a result of feeling more in control over their illness, either by patients' self-monitoring or by high quality care. Based on the reality in the two countries and in the different care settings, it may be that the lowest anxiety seen for UK patients is related to the fact that most of these patients were recruited in a secondary care setting where the quality of care is comprehensive for these patients compared to the hospital care in Portugal. Among other factors, the presence of a multidisciplinary team on the RLH wards, comprising medics, nurses, pharmacists and respiratory therapists is an important feature but absent from Portuguese hospitals. The lowest anxiety in community pharmacy patients in Portugal may result from the closer contact between patients and pharmacists, where many are even involved in providing enhanced services such as peak-flow monitoring, teaching and monitoring of the appropriate inhaling techniques, among other services such as counselling on the use of medicines. These enhanced services probably lead to patients feeling more accomplished and supported and hence less anxious.

6.5 Summary of findings

This chapter explored the influences of the care settings and country on patients' desires for information and perceptions about medicines and illness. The main findings can be summarised for each of the scales as follows:

Extent of Information Desired (EID)

- Patients' desires for medicines and illness-related information vary across health care settings.
- Portuguese patients tended to have higher desires for medicines and illness-related information than UK patients;
- Portuguese patients recruited from the community pharmacy tended to desire more information than those recruited in hospital;
- Scores to the EID scale were mainly influenced by patients' demographic characteristics. In particular, in Portugal for both the hospital and community settings female, higher educated and younger patients tended to score higher in the EID scale, implying these groups have higher desires for information.

Perception of Utility of Medicines (PUM)

- Patients' perceptions about medicines varied between countries. Portuguese patients tended to perceive their medicines as more harmful and more beneficial than UK patients;
- Scores to these scales varied between medical diagnoses, specifically for the PBM scale in the UK sample and for the PHM scale in the Portuguese sample;
- Scores to both these scales were similar across the different Portuguese recruitment settings, indicating the setting did not influence patients' perceptions about medicines;
- Portuguese patients recruited from the community pharmacy with lower educational levels tended to score higher for both the PHM and the PBM scales; perceiving their medicines to be beneficial but acknowledging some harm;
- Patients prescribed more medicines tended to perceive medicines as more harmful.

Anxiety about illness (Ai)

- Patients' anxiety about illness did not differ between Portugal and the UK;
- Hospitalized patients in Portugal tended to feel more anxious about their illness than community patients (pharmacy and outpatients).
- Lower educated patients and those prescribed more medicines tended to feel more anxious about their illness in both countries, and in both the community pharmacy and the hospital settings in Portugal;

- Older patients recruited in the community pharmacy tended to score higher on the Ai scale, indicating higher anxiety; perhaps viewing medicines as an indication of failing health;

Table 6.6 – Summary of main characteristics associated perceptions

	EID (high)	PBM (high)	PHM (high)	Ai (high)
Country	Portugal ($t=14.29$; $p<0.001$)	Portugal ($t=13.89$; $p<0.001$)	Portugal ($t=1.50$; $p=0.133$)	UK ($t=0.42$; $p=0.676$)
Setting	Community ($F=9.89$; $p<0.001$)	---	---	Hospital ($F=4.08$; $p=0.018$)
Gender	Female ($t=2.01$; $p=0.045$)	---	---	Female ($t=0.76$; $p=0.449$)
Age	Young ($r=-0.25$; $p<0.001$)	---	---	Old ($r=0.16$; $p=0.001$)
Literacy	High ($r=0.25$; $p<0.001$)	Low ($\rho=-0.13$; $p=0.006$)	Low ($r=-0.25$; $p<0.001$)	Low ($r=-0.20$; $p<0.001$)
No. meds	---	High ($\rho=0.08$; $p=0.055$)	High ($r=0.23$; $p=0.023$)	High ($r=0.12$; $p=0.007$)

6.6. Discussion

Patient samples

During this chapter several samples were used to enable the comparisons presented. The UK sample comprised patients recruited specifically for this study but some of the analyses presented also used data on file from patients recruited in previous studies. This implies an immediate limitation related to the comparability of results collected in different time periods. However, this approach was taken because all the UK samples were recruited using a cross-sectional design, hence there was no reason to assume that patients might differ. What is most likely to differ is the type of care they receive as treatments are constantly progressing aside with the shift in practitioners' practice, motivated by policies advocating a patient-centred approach to care.

The Portuguese samples, on the other hand, were recruited specifically for this study; therefore the potential limitation mentioned does not apply to these patients. The inclusion of patients recruited in hospital wards, hospital outpatients' clinics and community pharmacies, albeit providing strength of the study for representing various "types" of patients may be questioned in terms of comparability of the recruitment methods and the sample sizes achieved in each of these three settings. In fact, patients recruited in hospital (wards and outpatients' clinics) were all selected by the main researcher who conducted the interview using a structured questionnaire.

On the other hand, patients recruited in community pharmacies were recruited by the participating pharmacists, who received training on the selection procedures but which does not ensure standardisation *per se*. Furthermore, in the majority of these patients, the questionnaire was self-administered, which limits the comparability of results.

Such procedures, having its flaws, enabled recruiting a larger sample of patients in the community, an advantage that contributes to the external validity of the study. Recruitment in hospitals was not equal, as access to wards was varied according to local policies. This includes patients recruited in outpatients’ clinics, where *e.g.* in one hospital the clinic was specialised in cardiovascular conditions whereas in another it was specialised in endocrine conditions. All these situations contributed to the final sample size reported in these three settings (n=103; n=50; n=443), all of which were large enough to enable overall comparisons, but in some cases limited further exploring of differences *e.g.* by diagnoses.

This fact is more evident when comparing the overall UK sample (n=1860) with the Portuguese sample (n=596). The settings used for patient recruitment were also not identical between countries, where the UK sample was recruited in hospitals and through domiciliary visits, while the Portuguese sample was recruited in hospitals and in community pharmacies. Nonetheless, the focus of the study was the Portuguese population, where the UK patients were mostly used as baseline data contributing to interpretations of the findings in Portuguese. Additionally, it should be highlighted that the UK sample does not represent British citizens only, whereas the Portuguese sample comprises a minority of emigrants (1%).

Desire for information

The greater desire for information expressed by the Portuguese sample may result from the way the health care system is structured and its implications on health care professionals’ attitudes towards provision of information. The UK health policies have for long now been focusing on patient education, involvement and empowerment (Elliot, Barber, & Noyce 2003), leading to patients being generally better informed about their medicines and illness. In Portugal, this is still not a current practice, and a considerable proportion of patients are unaware of what their

medication is exactly and sometimes what their illnesses are. Some of the comments made by pharmacists support this, when stating that “*patients could often not answer themselves what medical conditions they had*” and also by reporting on the medication profile e.g. “*drug for blood pressure*”.

The association between gender and the extent of information desired seems to verify results from other authors, where women are frequently described as the information-seekers or those requiring more specific information (Jenkins, Fallowfield, & Saul 2001). Some studies have failed to show a difference in desire for information by gender, likely to be associated with a skewed sample (as acknowledged by the authors) but also potentially related to a failure to identify gender as a confounding factor for the association between desire for information and a female-exclusive diagnosis (Liekweg et al. 2005). Others have described lower desire for information in males to be associated with a pressure to “be brave”, which stopped them from asking questions (Leydon et al. 2000). This study used in-depth interviews with cancer patients to explore reasons for not wanting information. By focusing on a particular diagnosis, these findings may not be directly transferable to this study. Nonetheless, the features described are consistent with lay knowledge about different behavioural characteristics between genders, hence quite plausible. The increased anxiety observed among females may result from an unmet need for information because females also scored higher to the EID scale, implying higher desire for information overall (Fallowfield & Hall 1994).

The finding that younger patients desired more information is consistent with previous studies, where the extent to which patients wished to be involved in decision making was explored by relating their desire for information and their preferences for a passive or active role in the consultation process (Cassileth et al. 1980; Jenkins, Fallowfield, & Saul 2001). Both these studies were restricted to cancer patients but the use of a questionnaire to assess patients’ needs to information is similar to the method employed in this study. Additionally, the latter study used a larger heterogeneous sample, providing increased confidence in results presented. In Leydon’s study on cancer patients’ reasons for not seeking information, reported a higher desire for information among younger and more educated patients, which despite being conducted on a restricted sample with a specific diagnosis, is consistent with these findings (Leydon et al. 2000). It has been suggested that patients with less

education share the view that medical knowledge is difficult to understand, which could explain their lower desire for information (Leydon et al. 2000). These two variables are often interrelated as there is a tendency for younger people to take more advanced and formal education, as opposed to the education available for the elderly. A study looking at older patients’ and GPs’ views on involvement in consultations highlighted patients’ respect for doctors as a strong barrier, additionally hindered by GPs’ lack of time for consultations (Wetzels et al. 2004). This was a qualitative multi-centred study where codes in the Portuguese data included patients’ acceptance of doctors’ authority, GPs’ negative attitudes towards patient involvement and GPs’ routine behaviour in their daily practice. This implies that these findings may be telling part of the story as health care professionals’ views were not sought but could play a very active role in this process. Another explanation for older patients wanting less information is that they have been diagnosed for longer ($\rho=0.34$; $p<0.001$), so may need less information. This is not backed up by findings about their anxiety, but anxiety may increase for other factors such as health status.

The need for health care professionals to tailor information to patients’ educational and cultural backgrounds has been acknowledged in a review of literature around information, education and communication needs of patients published over 18 years, which recommended how health care professionals should act to achieve effective information sharing are provided (Harris 1998). This study recommended focus on providing the right amount of information to the individual patient rather than flooding patients and their carers with standardised and often incomprehensible information; a finding backed up by this thesis (chapter V).

Various studies have focused on different medical groups identifying that information needs vary. A study on asthmatic patients found that nearly 90% of the patients wanted to receive more information about their illness and medicines (Costa 2002). Another study exploring epileptic patients’ needs for information suggested these were unmet; most patients wanted much more information than they currently received, particularly about treatment options and causes of illness (Prinjha et al. 2005). Exploring cancer patients’ preferences for information Jenkins (2001) found that 87% of patients wanted to receive all possible information, regardless of being good or bad, adding that the few who did not want information tended to be older

and preferred the traditional consultation models where details are left for the doctor, in whom they entirely trust (Jenkins, Fallowfield, & Saul 2001). Although these studies have used different methodologies, were undertaken in different countries and in different years, their findings suggest that patients with different diagnoses may desire information to different extents and that their interest for particular details may vary. In this study, it was found that the extent of information desired varied between diagnoses, although it was not possible to disclose specific features for all conditions included. The more prominent characteristics were the lowest desire for information expressed by endocrine patients and the highest desire for information was from GI patients. Nonetheless, it indicates that in daily practice, information provision may need to be tailored according to the patients’ illnesses and may therefore need to be assessed rather than assuming all patients will benefit from the provision of standardised leaflets. This was also identified during the patients’ interviews (chapter V).

The desire for information may be seen as an indirect measure for patients’ willingness for involvement in the decision-making process. It has been identified that people may vary in the extent to which they want to be involved and acknowledged the need for health professionals to be aware of these differences (NHS Centre for Reviews and Dissemination 2000). This supports the assumption that such a measure is useful for practitioners when targeting their services. The use of a 6-item scale cannot be considered a purely research-led measure; transferring it to daily practice would not be hard to achieve, particularly if incorporated into the software used where the patient’s details are recorded during their initial assessment and subsequent monitoring. At that stage, considering some of the comments made by participating pharmacists will be particularly useful, namely *“patients view statements as questions”*, and *“scales are too complex”*, so there might be a need for further simplification for this measure to become fit to practice.

Role of the pharmacist

The role of the pharmacist as information provider has been explored in different studies. Using the pseudo-customer methodology in the US, it was shown that the quality and completeness of information provided by pharmacists varied according to their age; younger pharmacists were more likely to present more information, focus

on risk information and assess the customers’ understanding (Svarstad, Bultman, & Mount 2004). A review of literature published over a 15 year-period concluded that the quality of advice given varied widely and concluded that the pharmacists needed to better understand to whom, when and how information should be provided (Tully, Hassell, & Noyce 1997). The authors suggested a greater connection with consumer associations to achieve such goal. The relevance given to different aspects of information was found to differ between pharmacists and the public, where the first seem to focus on safety and the latter on effectiveness (Hassell et al. 1998). Additionally, a general lack of unawareness from the public about the pharmacists’ role and a failure to acknowledge them as a health advisor was found. Assessing patients’ views on amount, type and source of health information, it has been shown that patients preferences vary *e.g.* on the perceived risk of illness and perceived benefit from taking medicines. However, a clear finding was that health care professionals are the preferred source of information (Dickinson & Raynor 2003). This study also shows that often health professionals are not aware of patients’ desires for information or are available to provide it, suggesting that if an effort is not made to change current practice to meet patients’ demands, they will undoubtedly seek information from other sources. Pharmacists should take this opportunity to be integral to the healthcare team by offering high quality and accessible services for which there is apparent demand and little offer, except from inadequate resources, such as the media.

The concept of “available information” may be essential to some patients whilst others are more interested in information related to the disease. There have been reports of patients experiencing a dearth of information when trying to help cancer patients to work in partnership with health professionals. A key for success was that health professionals started supporting patients in finding, understanding and applying the relevant information for their individual needs (Smith 2000a). Others have reported a minority of patients reading the information they are provided with package inserts (Raynor & Knapp 2000), which indicates that the simple inclusion of a standardised leaflet in medicines packages is not an effective measure to convey information to many patients. Additionally, patients’ failures to understand important concepts contained in the PIL, such as contra-indications and interactions, has been acknowledged (Dickinson, Raynor, & Duman 2001), reinforcing that the current PIL

is not a suitable tool for effective information transfer for many patients, except maybe when mediated by a healthcare professional. Others have found that most patients read leaflets, although some patients reported that reading increases their anxiety (Koo, Krass, & Aslani 2002). This study also suggested that this is linked to trust in the health care professional whilst increased use is linked with illness severity. This finding gives additional credibility to studies that have found that older and less educated patients desire less information, often relying on faith in their doctor’s expertise, as described in the previous chapter. Additionally, these studies indicate that patients vary in the extent of information they desire but vary mostly on the format and type of information they desire. The type of information most sought by patients has been divided into four major categories: the way to take the medicines, the indication, the potential side-effects, and the potential contra-indications (Raynor et al. 2004). It is likely that there is more to it if one also considers disease-specific information.

Perceptions of benefit and harm

Portuguese patients were those perceiving highest benefit and highest harm from medicines, when compared to UK patients. Perceptions of benefit may be related to the undisputed confidence and trust placed in doctor’s decisions. The greater perception of harm may be related to the information that patients in each country are provided with; Portuguese patients had a greater desire for information overall. The importance of side-effects and the communication of risk to patients has been issue of great concern. Following the issuing of a EU guideline proposing the use of qualitative descriptors in PILs to provide an estimate of the incidence of medicines side-effects, some studies have explored the effect on patients’ perceptions of risk compared to the traditional quantitative descriptors and found that the adoption of this measure resulted in overestimation of risk (Berry, Knapp, & Raynor 2002), reflected in patient’s subsequent intentions to take their medicines (Berry et al. 2004). The author argues that patients do need information to participate in decisions about their own health, particularly on the risks associated with medicines. However, this information needs to be presented in an accurate and comprehensible manner, negative outcomes may result otherwise (Berry et al. 2003). Knapp (2004) added that patients want and need information on risks and benefits of medicines, which needs to be understandable for them to become partners in medicine taking (Knapp,

Raynor, & Berry 2004). This evidence implies that changing current practice to systematically provide patients with this type of information without firstly assessing the right way to convey it would not necessary lead to improved medicines-taking behaviours and could actually result in the opposite.

Patients scoring higher on the both the PBM and the PHM scales tended to be less literate. Patients with lower literacy levels have been reported as having more difficulty in interpreting pictograms (Dowse & Ehlers 2003), which suggests that the perceptions of medicines may be related to the information that patients have, or the interpretation. There are also reports of less literate patients being less prone to self-medicate (Martins et al. 2002), which may be related to a greater fear from harmful effects of medicines or to a lower confidence in taking decisions about their own health. This latter assumption was confirmed in a study looking at the participatory role of patients, where the less literate were found to prefer less involvement in the consultation and decision-making processes (Kaplan et al. 1995). Increased trust in doctor’s decisions may also be linked to the greater perception of benefit expressed by less educated patients. The value placed on the exchange of information about a patient’s personal medical condition between different health professionals has been shown to be linked with low literacy and interpreted as a need for additional reassurance in a study exploring asthmatic patients’ health-related needs (Costa, Duggan, & van Mil 2004). This could partly explain the mixed feelings about medicines found in this study. Patients prescribed more medicines tended to perceive greater harm but also greater benefit from medicines, which may indicate that when prescribed more medicines patients see it as a sign of deterioration of their condition, but perceive medicines as effective treatments. In fact, previous studies have found that patients’ perceptions of medicines benefit are closely linked to the perception of illness severity (Dickinson & Raynor 2003). On the other hand, taking more medicines leads to a greater likelihood of experiencing side-effects and drug-drug interactions. These issues could go part way to explaining the increased perception of harm. A variation in beliefs about medicines between asthma, renal, cardiac and oncology patients has been reported (Horne & Weinman 1999), but did not identify any clear patterns except that cardiac patients were more likely and asthma patients were less likely to adhere to medication. Adherence to medication is further explored in chapter VII but the results here indicate cardiac and respiratory patients were

those perceiving the highest harm and also the highest benefit from medicines. Although the sample size of the renal and oncology group was small, an inability to identify a clear link between perceptions of medicines and medical diagnosis is not a failure but rather an issue that is difficult to pin down.

The findings imply that UK patients are more anxious about their illness, which may be related to the recruitment site, since hospitalized patients tended to feel more anxious, and the UK sample comprised a large proportion of study recruits from the hospital setting. The greater anxiety of hospital patients may be potentially associated with their health status at the time of the interview, which is likely to be worse when compared to patients in the community. Again, it may also be linked to the environment itself, which has been reported as a potential booster of anxiety (Kent & Dalglish 1986b). Alternative explanations relate to available information, as some of patients’ comments during interviews indicated that in hospital they are not given any indication of the medicines they are taking nor they have access to the information package insert as they do when purchasing medicines from a pharmacy.

Dissatisfaction with information received has been suggested to increase anxiety in cancer patients (Fallowfield & Hall 1994). Satisfaction with information does not necessarily imply that patients were provided with as much information as possible, but rather that they were provided with information that met their needs and that it was presented in a comprehensible manner at the right moment and conveyed in the context of a “friendly” relationship established between patient and health professional. The communication style of the physician when providing information to patients may also be different in hospital and in the ambulatory setting, which has also been reported to have an effect on patients’ anxiety (Takayama, Yamazaki, & Katsumata 2001). This study was carried out in a Japanese oncology centre and suggested that when the physician’s communication style was neutral or hostile, *i.e.*, inappropriate, patients left the consultation with increased anxiety levels. Cancer patients may be more likely to be highly sensitive when compared with other less threatening conditions; nonetheless, the main critiques presented may be transferable to any other consultation process, where patients do not like to feel that the physician is not really interested in their problems. Higher anxiety tended to be reported by older patients, who were female, with lower educational levels and

prescribed a greater number of medicines. Although different stages of coping strategies have been described as evolving with the illness (Buetow, Goodyear-Smith, & Coster 2001), it may be hypothesised that the greater anxiety reported by women may be related to their age, when they are hospitalized at a later age possibly with a worse health status, and at a phase where their coping stages have passed, reducing their hope for recovery. Patients with a lower education seemed to have greater confidence in their doctor’s expertise, but simultaneously needed additional reassurance. Hence, when information is not provided anxiety may increase. Lower education levels were often related to older age in this sample, indicating that several demographic factors may be linked.

Limitations and strengths of the study

The main limitation of this study was the incompleteness of data in patients’ medical records, which sometimes did not document the main diagnosis, but rather the reason for hospital admission. Additionally, when the main diagnosis was documented, there was not always a date when first diagnosed. The definition used in this study for main diagnosis was the chronic condition with greater negative impact on patients’ life. This was assessed by asking the patients which disease concerned them the most and which they had for longer. This was combined with information on record, when available, and the medicines prescribed. When no information apart from the prescribed medicines was available, diagnosis was inferred by assessing the medicines, also taking into account the administration route, such as insulin injections or inhalers. When the length of medical diagnosis was not documented, this was assessed by asking the patient, which gives room for recall bias, and was sometimes reported as a range of years. When this was the case, the average was used as the best approximation. For all these reasons, the length of medical diagnosis was not fully explored during data analysis. Information on prescribed medicines was obtained by patient files in the hospital and by prescriptions presented at the pharmacy; hence the completeness of data may not be assured. In the community pharmacy setting, it is generally acknowledged that patients do not necessarily present all prescriptions at the same time, therefore the pharmacist asked the patient to bring all the other medicines he was taking at another time, to increase the quality of data. This was not always possible and patient report was sometimes used, in which case there is also some room for incompleteness of data. In all the formerly

mentioned cases, it is acknowledged that information on use of non-prescription medicines and on herbal medicines was often missing, which may have implications on patients’ perceptions about medicines and could not therefore be explored. It would have been interesting to investigate if patients using medicines indicated by the doctor only (even if some are non-prescription) had different perceptions and/or desires for information than those who self-medicated, and among the latter those using non-prescription medicines only (available only at the pharmacy at the time this study was conducted), those using non-prescription medicines and herbal medicines, and those using only herbal medicines.

Information on the occupation of participants was collected but not on their salaries, therefore creating difficulties in classifying them in the most appropriate SEC category. During the pilot study, two coders classified patient-reported occupations using the seven levels of the NC-SEC, which resulted in low agreement and confirmed previous studies reporting the low reliability of this classification (Andersson, Bates, & Duggan 2001). These data were therefore dropped from subsequent analysis, but would make further study more complete.

The non-random selection of participants may have influenced the findings presented, but feasibility issues were considered when designing the exploratory study. Collecting data from non-participants minimised this limitation; non-respondents could be assumed to have a different profile from study recruits, which could be a potential bias. However, analysis of refusal forms indicated this was not the case, strength of the study. Nonetheless, whilst in hospital data was collected by the main researcher, in the community pharmacy data was collected by participating pharmacists, so under-reporting of refusals could have occurred. Albeit not quantified, this fact was reported by pharmacists where one of the comments made was that *“patients who did not want to participate did not want to answer the refusal forms either”*.

A major strength of this study is the exploration of an important topic both in Portugal and the UK, which provided added value to previous research undertaken only in the UK. Recruiting patients from different study sites, while leading to methodological difficulties, provided a greater insight into the extent to which the health care setting influences patients’ information desires and perceptions about

medicines and illness. Involving various diagnoses restricted data analysis in some instances where few cases were included, but added considerably to what had already been studied in one particular group of patients. Having a large sample was another of the study strengths, and recruiting patients from different geographical locations in Portugal added to the study’s external validity.

6.7 Conclusions

The main conclusions of this chapter are that patients’ desires for information vary between Portugal and UK, where Portuguese patients were found to have greater information desires, particularly those recruited in the community setting. This finding was interpreted as resulting mainly from the policies guiding health care professionals’ interventions, where in Portugal the shift towards focusing on patient education and empowerment should move faster to meet these unmet needs, with special emphasis on practitioners working at the community level where patients are responsible for their treatment needing information to support their decisions.

Patients’ perceptions of medicines also varied between Portugal and the UK, albeit not linked to the setting within Portugal. The Portuguese sample perceived greater benefit from their medicines while stronger acknowledging their harm. This finding may impact on patients’ behaviour towards medicines; focus needs to be put on determining the reasons and consequences for such finding, *e.g.* exploring readiness of Portuguese patients for empowerment.

Patients’ anxieties about illness varied between Portugal and the UK, where UK patients and hospital patients within Portugal were the most anxious. These findings lead to conclude that the hospital environment has a strong influence on patients’ feelings, and strategies should concentrate on transforming the hospital into a friendlier atmosphere, which is perhaps improved simply by changing practitioners’ attitudes in disclosing health-related information.

CHAPTER VII

RELATING PERCEPTIONS, INFORMATION DESIRES AND MEDICINES TAKING BEHAVIOURS

7.1. Perspective

Over recent years, much research has been undertaken to understand and predict patients' medicines taking behaviours, often with little success. During this study several factors have been explored which potentially influence the ways patients feel and act towards their medicines. This chapter investigates how these factors interrelate and explore which can be used to better understand patients' medicines taking behaviours. Chapter VII is organised in four main sections: the first explores relationships between the scores to the scales previously addressed regardless of recruitment site (within Portugal) or patients' characteristics, to best understand how information desires, perceptions of medicines and anxiety about illness may relate with each other. The second section presents bivariate analysis of independent variables and self-reported compliance behaviour while the third section presents multivariate analysis considering compliance behaviour as the dependent variable. In the fourth section, results presented in previous sections are appraised with literature from the different chapters of this thesis to propose a model that partly explains patients' medicines taking behaviours and additionally draws on considerations about its potential applicability and usefulness for pharmacy practice development in Portugal.

7.2. Aims and objectives

Aims

1. To explore how the three concepts of information desires, perceptions of medicines and anxieties interrelate
2. To describe medicines taking reported behaviour in the study samples
3. To develop a model that can predict patients' medicine taking behaviours
4. To conceptualize how such model can be useful in pharmacy practice

Objectives

- 1.1. To explore relationships between the EID, PHM, PBM and Ai scales
- 1.2. To explore bivariate relationships between compliance behaviour and samples' characteristics, including recruitment sites and patients' demographic and medical variables

- 1.3. To explore multivariate relationships between the various independent variables and compliance behaviour, *i.e.*, the dependent variable
- 1.4. To propose a model to explain medicines-taking behaviour taking all previous findings and literature appraised into account
- 1.5. To suggest ways to apply the model to community pharmacy practice

7.3. Methods

Data collected during the different study phases were analysed using various methods.

7.3.1 Exploring relationships between scores to the EID, PHM, PBM and Ai scales

In previous chapters, scores to the scales were analysed to explore the distribution of scores, the scales' validity and reliability, and how they related to the samples' characteristics. In this section, relationships between the different scales are explored using parametric tests to explore how the concepts addressed by each scale interrelate.

7.3.2 Exploring bivariate relationships between compliance and samples' characteristics

Patients' compliance was measured by means of self-report, simply asking the patient if on the previous week there was any occasion that he had missed a dose. Patients' answers were dichotomous, *i.e.*, yes or no, and were further quantified wherever possible. However, the latter information was often missing (*e.g.* patient did not remember) or imprecise (*e.g.* patient would provide qualitative descriptors, such as "a few" or "often"). For these reasons, this information was considered of low validity and hence not further explored.

Self-reports at the community pharmacy referred to medicines taking in the previous week, whereas the hospital patients' reports referred to the week prior to their hospital admission. Findings require careful interpretation since a differential time scale may impact on a patient's memory and introduce recall bias. Additionally, the fact that questionnaires were self-administered in community pharmacy and

administered by an interviewer in hospital may also impact on the findings. Another issue worth considering is that, the interviewer was unknown to the patients in hospital, whereas in the community patients were answering upon request of their community pharmacist, potentially a social desirability bias.

Bivariate analysis presented in this section compared the proportion of compliant and of non-compliant patients with a given characteristic of interest using chi-squared test, whenever the data were categorical; independent samples t-tests were used to compare means between two groups. In both cases, the significance level of $p < 0.05$ was considered.

7.3.3 Exploring multivariate relationships between compliance and potential predicting variables

Logistic regression is the appropriate multivariate technique to predict the values that may be assumed by the dependent variable, when it is dichotomous, given the values of a number of independent variables.

7.4 Results

7.4.1 Relationships between scores to the scales

The following table shows how the concepts underlying the scales related with one another, by presenting the correlations between their scores and respective significance.

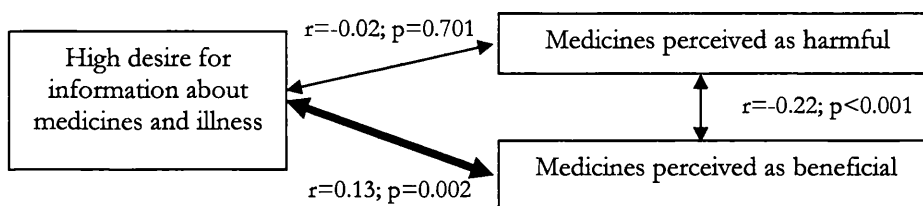
Table 7.1 – Correlations between scores to the scales

R; p	EID	PBM	PHM	Ai	SF-36
EID	$r=1.00$				
PBM	$r=0.13$; $p=0.002$	$r=1.00$			
PHM	$r=-0.02$; $p=0.701$	$r=-0.22$; $p<0.001$	$r=1.00$		
Ai	$r=-0.14$; $p<0.001$	$r=0.07$; $p=0.008$	$r=0.38$; $p<0.001$	$r=1.00$	
SF-36	$r=0.07$; $p=0.166$	$r=-0.06$; $p=0.184$	$r=-0.22$; $p<0.001$	$r=-0.32$; $p<0.001$	$r=1.00$

The positive correlations shown between the scores to the EID scale and the scores to the PBM scale imply that patients' high desire for information is associated with a greater perceived benefit from medicines. Conversely, there was a negative

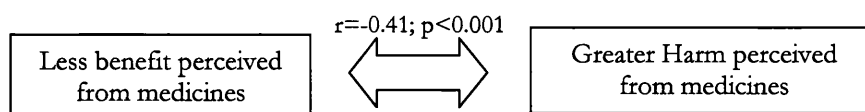
correlation between the scores to the EID scale and the scores to the PHM scale, suggesting that patients perceiving medicines as more harmful tend to desire little information; however, this correlation was not statistically significant. It may be that information and perceptions about medicines are directly linked, but it must be emphasised though that even the statistically significant correlation was quite weak.

Figure 7.1 – Correlations between scores to the EID scale and PUM subscales



The PHM and PBM scales were weakly correlated, although statistically significant, which was unexpected (figure 7.1). However, exploring this correlation in the overall sample, the findings are very different, showing a strong negative correlation with statistical significance ($r=-0.41$; $p<0.001$), indicate that patients perceiving medicines as more harmful tend to perceive them as less beneficial and vice versa (figure 7.2). This may result from the PHM scale having been frequently modified, where perhaps the scores to the first versions diluted the true effect.

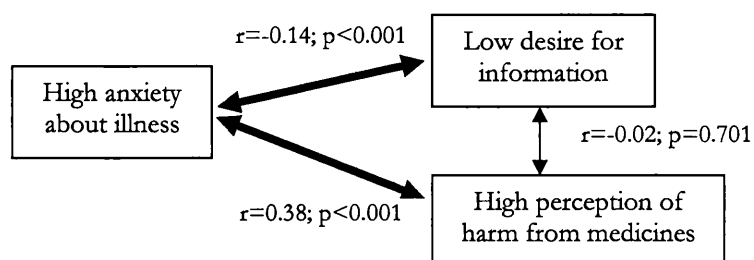
Figure 7.2 – Correlations between scores to the PHM and PBM scales



The correlation between the scores to the EID scale and the scores to the Ai scale indicate that patients with higher anxiety tend to desire less information (or vice versa), perhaps their anxiety levels make them feel incapable of coping with any additional information provided, or maybe they do not desire much information because they already have it and being negative led to higher anxiety.

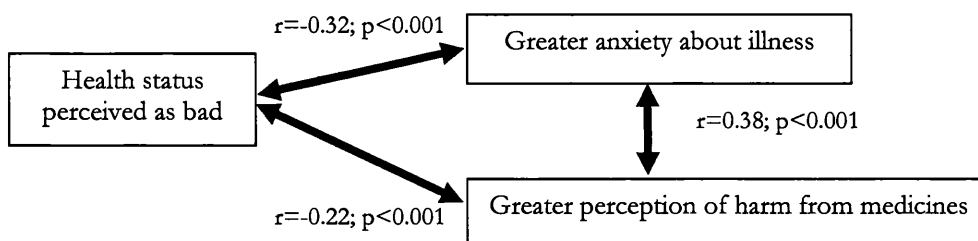
The correlations between the scores to the Ai scale and scores to the PHM scale imply that greater anxiety is closely linked with greater perception of harm from medicines, which may be expected, and may contribute to explain the previous relationship found between information desires and anxiety.

Figure 7.3 – Correlations between scores to the Ai and the EID and PHM scales



Negative correlations between the perceived health status measure and both the scores to the Ai and the PHM scales imply that patients who perceived their health status to be better tended to feel less anxious and tend to perceive less harm from medicines. Scores to the health status measure were not found to be significantly correlated with either the scores to the EID or the PBM scale.

Figure 7.4 – Correlations between perceived health status and scores to the Ai and PHM scales



In general, only the correlations between the scores to the Ai scale and the scores to both the PHM scale and the health-status measure were quite strong (in bold in table 7.1 and figure 7.4), indicating this strong link between anxiety and perception of harm and also between anxiety and the way the patient perceives his medical condition.

7.4.2 Bivariate relationships between compliance and patients' characteristics

Patients' behaviours towards medicines have been reported to relate to patients' socio-demographic, medical and therapeutic characteristics (Asplund, Danielson, & Ohman 1984; Bittar 1995; Bordenave-Gabriel et al. Calop 2003; Lacro et al. 2002; Ren et al. 2002). In this section, results from bivariate statistical analyses relating compliance and the several variables characterising the patient samples are presented in table 7.2.

Table 7.2 – Characteristics of the sample and their compliance behaviour

Variable	Compliant (n)	Non-compliant (n)	Prevalence (%)*	Test-value; p
Country				
UK	62	19	77%	(χ ² =2.08; p=0.149)
Portugal	424	86	83%	
Recruitment site				
Community pharmacy	342	59	85%	(χ ² =7.96; p=0.019) [#]
Outpatients' clinic	38	12	76%	
Hospital inpatient	106	34	76%	
Gender				
Male	207	44	83%	(χ ² =0.02; p=0.897)
Female	279	61	82%	
Education				
No qualifications	310	63	83%	(χ ² =0.71; p=0.400)
Any qualifications	163	40	80%	
Perceived health status				
Poor or fair	250	47	84%	(χ ² =0.60; p=0.439)
Good or better	71	17	81%	
Diagnosis (most frequent groups)				
Endocrine	124	20	86%	(χ ² =3.45; p=0.327)
Cardiovascular	157	29	84%	
CNS	49	12	80%	
Respiratory	57	17	77%	
Variable	Compliant (mean±sd)	Non-compliant (mean±sd)	Test-value; p	
Age (years)	60.15±14.50	54.96±16.20	(t=-3.24; p=0.001) [#]	
Number of Rx meds	5.26±3.73	4.76±3.06	(t=-1.27; p=0.206)	
Length of diagnosis (years)	13.44±11.88	11.22±11.60	(t=-1.44; p=0.152)	
EID	22.32±4.70	21.65±5.01	(t=-1.32; p=0.189)	
PHM	11.24±4.03	11.47±4.18	(t=0.52; p=0.600)	
PBM	17.57±2.56	17.47±2.84	(t=-0.37; p=0.710)	
Ai	12.21±4.46	12.09±4.81	(t=-0.25; p=0.803)	

*Number of individuals with a given characteristic of compliance divided by the total number of individuals with that characteristic; [#] Significant difference at the α 0.5 level

There were only two variables for which compliance behaviour significantly differed, *i.e.*, age and recruitment site. Further analysis on these two variables by compliance behaviour revealed that patients aged 60 or older were nearly twice more likely to be compliant than those who were younger (OR=1.97; 95%C.I.=1.25-3.10). Similarly, community patients were almost twice as likely (OR=1.86; 95%C.I.=1.16-3.00) more to report compliant behaviour than inpatients. The lack of significance in compliance behaviour between diagnostic groups may be related to some under-reporting of non-compliance, as values are much lower than those described in literature for chronic conditions (World Health Organisation 2003).

Nonetheless, the findings relating to compliance in respiratory and cardiovascular patients are in line with previous studies (Horne & Weinman 1999).

7.4.3 Multivariate relationships between compliance and patients' characteristics

All independent variables that seemed appropriate for inclusion, either by previous bivariate analysis or by literature reports, were initially included in the model using the Enter method. There were 10 variables entered in the models (gender, age, educational level, number of medicines, length of medical diagnosis, perceived health status and scores to the EID, PHM, PBM and Ai scale), depicted in table 7.3. Only two were found to significantly predict patients' compliance behaviour (dependent variable where non-compliance assumed the value 0 and compliant the value 1), depicted in table 7.4.

Table 7.3 – Variables included in the initial model

Step 1	B	s.e.	Wald	Df	p	Exp(B)	95% C.I. for Exp (B)	
							Lower	Upper
Gender	-0.172	0.430	0.257	1	0.612	0.842	0.432	1.639
Age	0.022	0.013	2.964	1	0.085	1.022	0.997	1.072
Qualifications	0.362	0.410	0.782	1	0.377	1.437	0.644	3.206
Duration	0.032	0.019	2.794	1	0.095	1.033	0.994	1.072
SF36 (2 cat)	-0.242	0.390	0.385	1	0.535	0.785	0.365	1.687
No meds	0.008	0.055	0.022	1	0.883	1.008	0.906	1.122
EID	0.014	0.038	0.136	1	0.713	1.014	0.941	1.093
Ai	0.059	0.046	1.622	1	0.203	1.060	0.969	1.160
PBM	-0.072	0.071	1.011	1	0.315	0.931	0.809	1.070
PHM	-0.046	0.046	0.973	1	0.324	0.955	0.873	1.046
Constant	0.919	2.161	0.181	1	0.671	2.507		

B=estimated coefficients for the possible x values; s.e.=Standard error; Wald= test statistics for significance of OR (obtained comparing the estimate of the slope against the estimate of the s.e.); p= statistical significance value associated with the test; df= degrees of freedom; Exp (B) = multivariate equivalent to the odds ratio, which is presented in comparison with the reference category

Table 7.4 – Variables included in the final model

Step 1	B	s.e.	Wald	df	P	Exp(B)	95% C.I. for Exp (B)	
							Lower	Upper
EID	0.053	0.027	3.893	1	0.048	1.055	1.000	1.112
Age	0.029	0.008	12.046	1	0.001	1.029	1.013	1.046
Constant	-1.279	0.870	2.163	1	0.141	0.278		

Table 7.4 indicates that older patients with higher scores to the EID scale (*i.e.*, desiring more information) were more likely to comply with prescribed medication.

The interaction between the variables entered in the model were checked by entering an additional variable, corresponding to the product of the independent variables (in this case EID*age) and observing the effects on the model, the results in table 7.5 indicate that this variable should not be included in the model because the correlation is not significant ($p=0.570$). Furthermore, when entered in the model, the two independent variables lose their significance ($p_{\text{EID}}=0.969$ and $p_{\text{age}}=0.830$); the inclusion of the interaction variable does not provide any added-value for the interpretation of the model.

Table 7.5 – Alternative model considering an interaction variable (EID*age)

Stepwise method (step1)	B	s.e.	Wald	df	p	Exp(B)	95% C.I. Exp (B)	
							Lower	Upper
Age	0.007	0.035	0.046	1	0.830	1.008	0.941	1.079
EID	0.004	0.092	0.001	1	0.969	1.004	0.837	1.203
EID by age	0.001	0.002	0.323	1	0.570	1.001	0.998	1.004
Constant	-0.025	2.196	0.000	1	0.991	0.975		

The Hosmer and Lemeshow test is an indication of the quality of the adjusted model. The result found ($\chi^2=15.237$; $p=0.055$) shows that the adjusted model is on the borderline of being “good”, “good” would be to have a $p<0.05$. One way of evaluating the “goodness of fit” of the model is by using the χ^2 associated with the difference between the -2LogLikelihood of the final model and of a reduced model. The value obtained ($\chi^2=12.987$; $p=0.002$) confirms the final model, where 2 independent variables were included, more information about the effect being studied is provided, *i.e.*, compliance behaviour, than the reduced model.

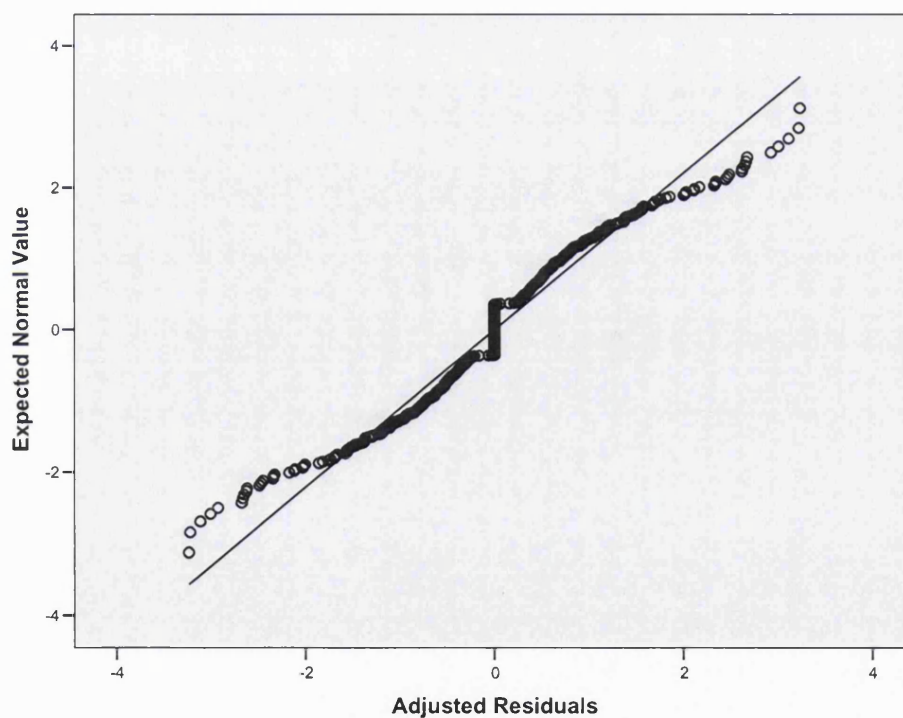
The goodness of fit of the Pearson and Deviance residuals for the proposed model were explored and found the model fitted the data well, as displayed in table 7.6.

Table 7.6- Goodness-of-Fit of Model residuals

Residuals	χ^2	df	p
Pearson	362.40	374	0.657
Deviance	350.51	374	0.803

Transforming the independent variables into dummy variables by categorising them by their distribution quartiles, allows their linearity in the logic function to be observed. This table represents the categories created, where the mean point was used as the x-point with the corresponding Exp (B) as the y-point. The graphic representation indicated that both variables were linear (figure 7.5); hence there is no need for categorization as they can treat as continuous to be put in the model.

Figure 7.5 - Normal Q-Q Plot of Adjusted Residuals



Overall, the multivariate analysis indicated that compliance behaviour can be predicted by patients' age and their scores to the EID scale, as summarised in tables 7.7 and 7.8.

Table 7.7 – Variables predicting compliance and their effects

Independent predictor variable	Actual data		Inputed data	
	β (p)	OR (95% CI)	β (p)	95% CI
Age	0.02 (0.001)	1.022 (1.01-1.04)	1.03 (0.001)	1.01-1.04
EID	0.03 (0.189)	1.030 (0.99-1.08)	1.06 (0.048)	1.01-1.11
Constant	0.27(0.507)/0.89(0.073)	NA	0.30 (0.141)	NA

Table 7.7 indicates that for each year the patient gets older his odds of being compliant increase 1.03 times and for each additional point in the score to the EID scale his odds for being compliant increase 1.06 times. It must be emphasised that these effects are very weak, as shown by the corresponding confidence intervals, but are still interesting and warrant further study.

Table 7.8 –Independent variables categories predicting compliance

Independent variable		Crude OR (95%C.I.)	p	Adjusted OR (95%C.I.)	P
Age group	< 60 y.o.	Reference	0.004	Reference	0.001
	≥ 60 y.o.	1.97 (1.25-3.10)		2.20 (1.38-3.53)	
	Constant	3.481	NA	1.461	NA
High/ Low scorers to the EID	< 17	Reference	0.010	Reference	0.004
	≥ 17	2.20 (1.21-4.02)		2.57 (1.36-4.84)	
	Constant	2.444	NA	1.461	NA

Table 7.8 indicates that older patients are 1.97 times more likely to be compliant and that higher scorers to the EID scale are 2.20 times more likely to be compliant. When a patient is older and desires much information, the adjusted odds ratios increase to 2.20 and 2.57, respectively.

Compliance behaviour (possible values are 0 or 1) = $0.278 + 1.092 \cdot \text{age} + 1.055 \cdot \text{EID score}$

OR Compliance = $1.46 + 2.20 \cdot \text{age group} + 2.57 \cdot \text{High/low scoring to EID}$

7.5 Main findings and discussion

This chapter further explored the relationships between three types of variables, those characterising the sample (demographic and medical characteristics), those characterising the sample's perceptions towards medicines and illness (responses to standardised scales used) and those characterising how the sample acted towards medicines (self-reported compliance). The way Donabedian described structure,

process and outcomes, can extrapolate this model by introducing the concept of Pharmaceutical care (figure 7.6) to categorise the types of variables explored in this thesis. The demographic and medical characteristics of patients can be seen as the structure, most of which are inherited characteristics, albeit some can change. The scales measured the way patients feel, which could be seen as proxies to a process; it could be hypothesised that patients perceiving medicines as harmful will use medicines differently to those perceiving medicines as beneficial. However, perceptions cannot be observed, so they are also in this sense similar to care delivery, *i.e.*, what pharmacists do, which changes through observation (except for cases of covert studies). This would then result in an observable action, taking medicines as prescribed or not, *i.e.*, measured by self-reported compliance, which was here considered as the outcome.

Figure 7.6 – Donabedian's care model (1976)

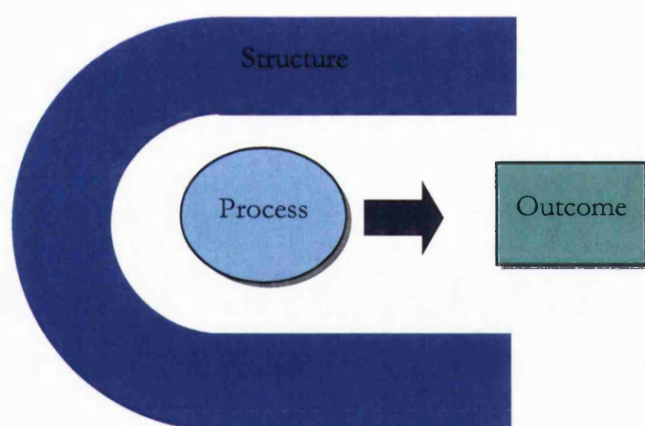


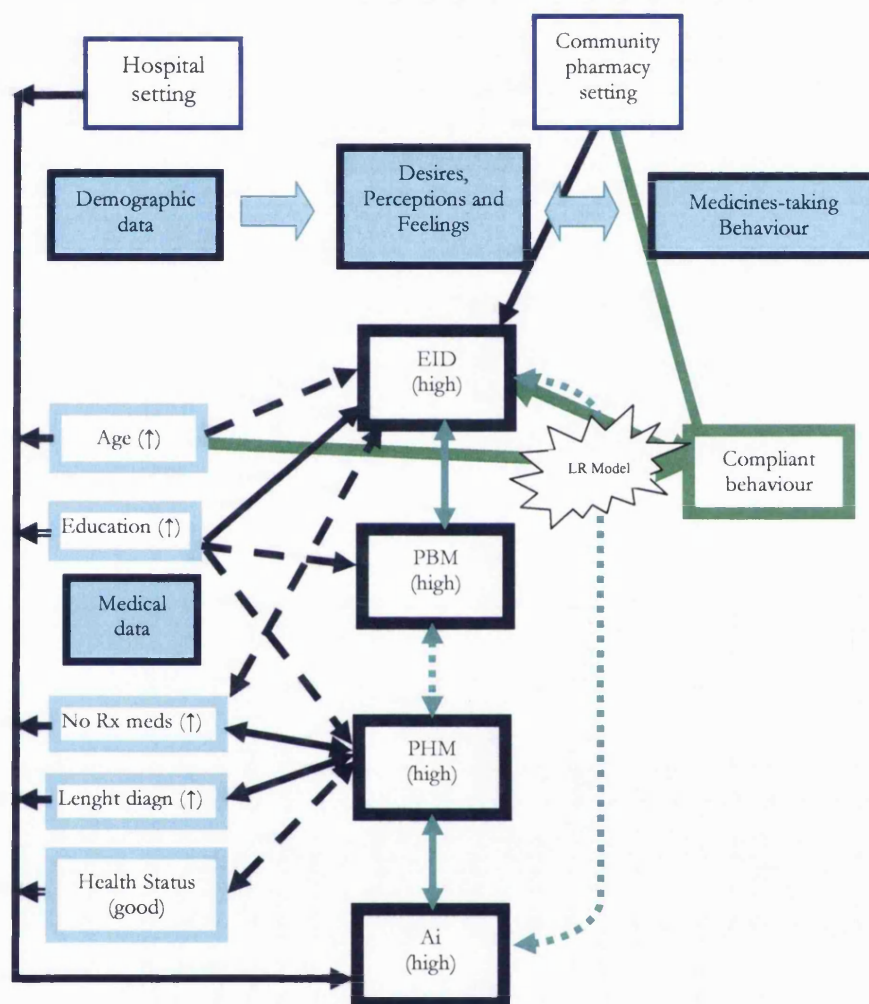
Table 7.9 summarises the relationships between structure indicators (sample characteristics) and process indicators (scores to scales), and within the different scales, whereas figure 7.7 depicts these same correlations, without quantifying them, additionally showing the links with the outcome measure.

**Table 7.9 – Correlations between scores to the scales and sample
characteristics**

Scale	Demographics	Medical characteristics	Other scales
EID	Education (+correlation) Age (-correlation)	No Rx meds (-correlation)	PBM (+correlation) Ai (-correlation)
PHM	Education (-correlation)	Health status (-correlation) No Rx meds & Duration of illness (+correlation)	PBM (-correlation) Ai (+correlation)
PBM	Education (-correlation)	-----	PHM (-correlation) EID (+correlation)
Ai	Age (+correlation) Education (-correlation)	Health status (-correlation) No Rx meds & Duration of illness (+correlation)	PHM (+correlation) EID (-correlation)

This table shows that scores to the EID scale correlate with the patients' demographic characteristics and with medical data; additionally the EID scale positively correlates with the PBM scale and negatively correlates with the Ai scale. Scores to the PHM and PBM scales only correlated with patients' educational level but the PHM scale was also related to medical characteristics. Furthermore they were negatively correlated with each other, whereas only the PHM correlated with the Ai scale and only the PBM scale correlated with the EID scale. Finally, scores to the Ai scale correlated with the sample's characteristics, including demographics and especially medical data.

Figure 7.7 – Links between sample characteristics, scores to the scales and compliance



The dashed lines represent negative correlations, *i.e.*, when patients score high in one dimension they tend to score low on the other. Conversely, the bold lines indicate positive correlations.

Moving backwards from the “outcome” on figure 7.7, it is possible to postulate that the patients who tend to be more compliant are the elderly. This association also emerged during bivariate analysis, where those aged 60 or older were nearly twice more likely to comply with therapy prescribed. The extent of information desired was not significantly different between compliant and non-compliant patients, although the compliant tended to score higher. However, when categorised into high

and low scorers to the EID scale, patients desiring more information were also twice more likely to comply with prescribed therapy. Another project exploring determinants of compliance in hypertensive patients using the EID scale, the self-efficacy scale and the stages of change scale, showed that only the scores to the EID scale explained different reported compliance behaviours; where compliers scored significantly higher, *i.e.*, desired more information ($t=-2.35$; $p=0.021$). Additionally, when categorising patients into high and low scorers to the EID scale, high scorers (>21) were 3.4 times more likely to be compliant than low scorers {95% C.I. = 1.26-9.24; ($p=0.013$)}. The large confidence intervals may be due to the reduced sample size ($n=107$) (Costa et al. 2005b).

Research on psychotic patients has shown that treatments with different therapeutic classes was linked to some patients having greater odds of experiencing side-effects and also of receiving less information from their care provider, impacting on their compliance which was found to be poorer compared to patients taking other therapeutic classes. This study suggests there might be a link between experiences with medicines and/or information received about them and the patient's compliance, confirming these findings (Hogman & Sandamans 2000).

During this thesis, the scores to the PHM scale strongly and positively correlated with scores to the Ai scale, implying that higher anxiety is linked with greater perception of harm associated with medicines. Additionally, perceptions of a low health status were associated with increased anxiety, increased perception of harm from medicines, and higher number of medicines prescribed. A high number of prescribed medicines was also associated with increased anxiety, but also with a high perception of benefit from medicines and a longer duration of illness, which may imply patients got “used” to their medicines as their condition stabilized. On the other hand, the PBM scale was found to positively correlate with the EID scale, whereas the Ai scale negatively correlated with the EID scale, implying that those perceiving medicines as beneficial and those less anxious, tended to desire a great deal of information. Furthermore, only the EID scale directly influenced medicines-taking behaviours, which may be due to the dependent measure being compliance behaviour and behaviour is not necessarily directly linked with perceptions or intentions. These findings are consistent with those from another project using the

PUM scale and R-IPQ questionnaire exploring how medicines and illness perceptions condition medicines-taking behaviours. These were measured through self-reported medication consumption and attendance to a TB clinic, where it was found that the scores to the PUM scale were associated with emotional representations of illness and fatalism, but that there was no direct relation between medicines' perceptions and adherence behaviours (Rennie et al. 2005).

There seem to be two important components influencing patients' cognitions: perception of illness and perception of medicines. These, in turn may generate different needs for information which, depending if they are met, may ultimately influence patients medicines-taking behaviours. However, the links are not straightforward and other factors may influence behaviours. Figure 7.8 represents a hypothetical example to better demonstrate how these components could interact.

Figure 7.8 – Hypothetical example on how domains assessed may interact

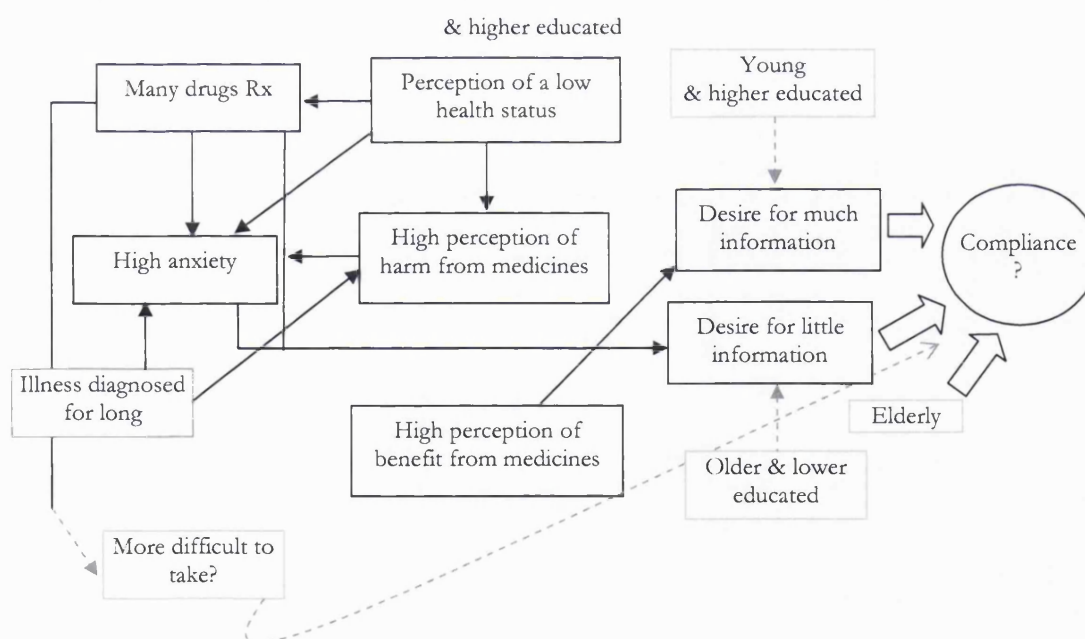


Figure 7.8 visually represents the findings and the literature around how medicines-taking behaviours may be influenced. Compliance is a multidimensional concept; some patients may be taking medicines for different conditions, some of which they consider more important than others. Therefore patients, may be compliant for a specific therapeutic class while non-compliant for another, additionally, intentional and unintentional compliance may coexist in the same individual.

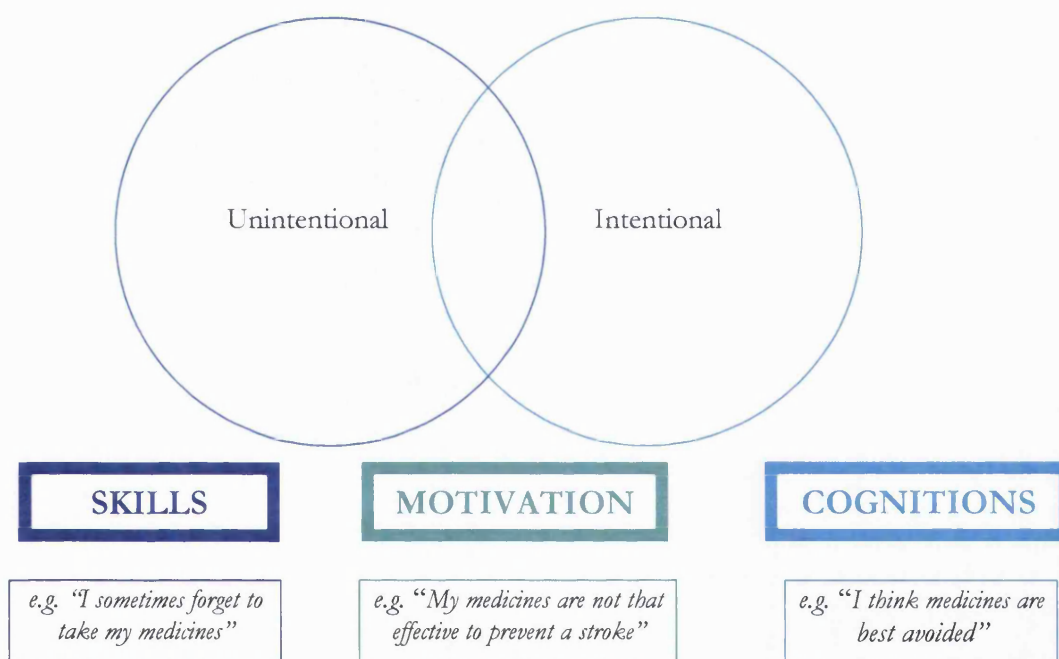
Taking the example in figure 7.8, where a patient perceives his health as quite poor and is being prescribed various medicines. Having had the disease for long, he perceives his medicines as more harmful, perhaps due to previous experience of side-effects or simply by the disruption of lifestyle, but also as less useful because he cannot see himself improving despite taking them as directed. Considering these facts together potential reasons for intentional non-compliance may be easily imagined. Additionally, having a complex medication regimen is known to make medicines-taking more difficult (Baird et al. 1984; Claxton, Cramer, & Pierce 2001), so at times he may be unintentionally non-compliant.

The elderly were shown to be more likely to be compliant with instituted therapy, which may mean they intend to take their medicines as prescribed because they recognise the doctor's expertise, because they feel more anxious about being ill and therefore see medicines as a solution, etc. It is also known that mental state decreases as age increases, which may imply that sometimes even when wanting to take their medicines, forgetfulness is likely to occur. An old patient may therefore be intentionally compliant but unintentionally non-compliant. This apparent contradiction may also explain why the elderly were found to be more likely to comply as were those with a greater desire for information, but also older patients and those less educated tended to desire less information. Elderly patients may be quite happy knowing little and taking their medicines as prescribed but if they desire more information than they are given, that may result in intentional non-compliance, as could the converse situation where they are provided with more information than they can handle. Therefore, the main conclusion is that intentional compliance may be influenced by providing the right amount of information to meet the individual patient's needs, where unintentional non-compliance would need intervention strategies including the use of *e.g.* reminders.

Relating findings to other literature, causes for non-compliance as intentional and unintentional, has been widely accepted as useful and has been used in various studies (Barber et al. 2004; Horne 1997; McGavock, Britten, & Weinman 1996). However, a third category between these two is proposed, as depicted in figure 7.9, where some of the behaviours adopted fit both groups. The example given describes

a cognition that medicines have little effectiveness (several others could be given, *e.g.*, “the illness is not that important” or “the risk is not that high”...), the patients do not take the conscious decision of not taking their medicines, but may be more likely to forget them, as the importance attributed is low.

Figure 7.9 – A third category between intentional and unintentional non-compliance



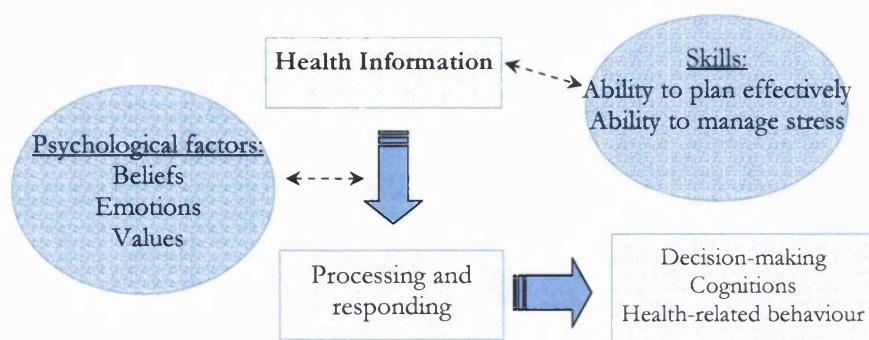
It should be acknowledged that the difficulty is not in creating additional categories to those previously described but to determine the minimum number where most cases will fit. An example is the complexity of the therapeutic regimen, which has been mentioned in literature as a barrier to adherence (Eisen et al. 1990; Schroeder, Fahey, & Ebrahim 2004). Where would this case fit? If patients are prescribed many medicines, they may not be capable of remembering the right time to take them (skills-related); they might consider the disruption in their lifestyle does not outweigh the benefits (motivation) and may adapt the regimen; or they might feel well with those already prescribed and feel that those that have been added will not improve their health, but will increase the odds of experiencing side-effects (cognition).

The provision of health-related information to patients can be a driver for the best use of medicines. To attest this, the lack of insight into the illness has been suggested as one of the factors leading to non-compliance (Gray, Wykes, & Gournay 2002; Lacro et al. 2002; Nosé, Barbui, & Tansella 2003) and insufficient information about the benefit risk ratio of medicines and illness (Oehl, Hummer, & Fleischhacker 2000), which is likely to happen unless a successful therapeutic alliance is established between the patient and health professional. A poor relationship between patients and doctors has also been suggested as a major factor leading to non-compliance (Lacro et al. 2002; Oehl, Hummer, & Fleischhacker 2000). Health-information, when adequately provided, may impact on patient's skills, motivations and cognitions, however, depending on the method, the detail and stage of illness when presented, it may result in adverse results. It has been shown that patients have different needs for information and cope differently with information, particularly with regards to risk (Barnett et al. 2004; Berry, Knapp, & Raynor 2002; Sanz, Gomez-Lopez, & Martinez-Quintas 2001). The findings here presented also suggest that patients desiring less information may be more anxious and as anxiety levels may change over the illness progression, so will patient's willingness to receive and/or actively seek for information.

Existing models of psychology and therapies

The cognitive-social health information processing (C-SHIP) model is a framework that has been applied to explore patients reactions when faced with a threatening situation, and coping styles' impact on adherence to recommendations (Miller, Shoda, & Hurley 1996). This framework may be useful to explain some findings presented in this thesis linking information with medicines-taking behaviours and hence further detailed in this section (figure 7.9). Using the C-SHIP framework, Miller suggested that monitors have greater odds of adhering to health-related recommendations than blunterners, which confirms the findings presented.

Figure 7.10 - The C-SHIP framework (Miller, Fang, Diefenbach, & Bales 2001)



The role of “emotions” in influencing actions should be emphasised. In this thesis there was a negative correlation between patients’ anxiety levels and the extent of information desired, confirming that the way people process information results from the interaction between their inherited or acquired need for information (skills) and their emotions at present to be able to process it. “Monitors”, who tend to adhere more, report higher anxiety levels; but when anxiety is too high they adhere less (Miller et al. 2001), as if they were no longer able to cope with additional information, confirming the results here found. As in most theories, people cannot be clustered into groups, *e.g.* information-seekers and information-avoiders, or monitors and blunters. When several factors interact to produce a response, there is room for developing an “it depends situation”. Miller later acknowledged this suggesting high and low monitors aside from high and low blunters (Miller et al. 2001). In this thesis dividing patients into high and low scorers to the EID scale, the best cut-off point was “manipulated” to explore data differently from other studies using the same scale. The existence of “high information-seekers” and “low information seekers” aside from “high information avoiders” and “low information-avoiders” is similar to Miller’s work (Miller et al. 2001).

Although there was no direct link found between anxiety and compliance, it can be assumed that if anxiety is negatively correlated with the extent of information desired, and if patients’ attitudes towards information partly predict compliance to treatment, anxiety indirectly conditions compliance, confirming theories that emphasize the role of emotions in modulating information processing and actions taken to face health-threats. Miller’s work developed around the C-SHIP framework

is one of many that have been restricted to specific situations, such as cancer and mental illnesses (Miller et al. 2001).

To illustrate how people may perceive the role of information differently the following quotes are presented:

*“That must be wonderful, I don’t
understand it all”* Molière

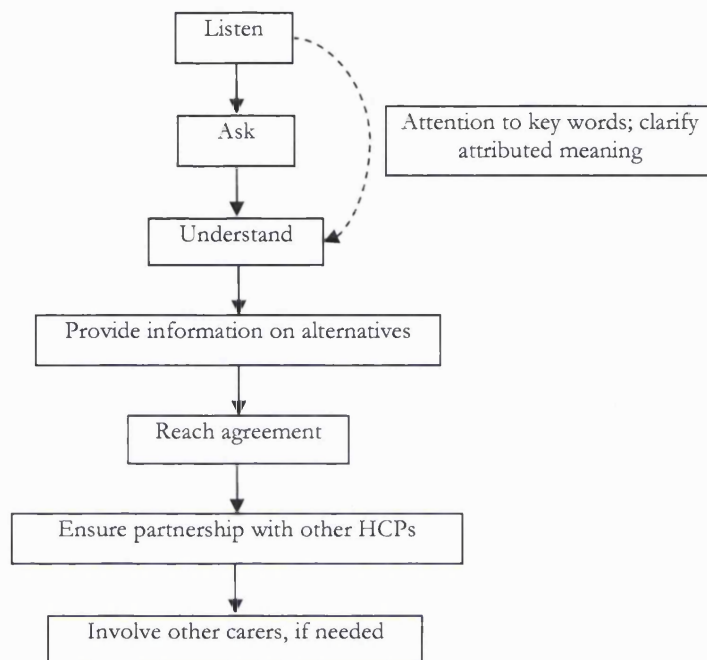
*“Information is only useful when it
can be understood”* Muriel Cooper

These quotes illustrate that while some are only keen on receiving information suited for their learning capabilities, others think that all information provided is satisfactory, i.e., *“if the doctor told me that/if it is written in the PIL it must be important”*, even when they do not understand it. In this latter scenario, they may ask for clarification, they may pretend to understand, or may think they understand while differently interpreted, possibly leading to biased cognitions that may influence their behaviour. However, it is the health professional’s role to ensure that messages are effectively transmitted and received.

Conveying information

Conveying information plays a vital role for effective communication and their adequacy depends on the purpose of the message and its intended recipient. While it is essential to effectively communicate with patients, specific skills are also needed to maximise communication between health care professionals. Preliminary findings suggest that letters are inappropriate for pharmacists to communicate with doctors about patients’ therapy-related issues, despite still being widely used (Paulino, Costa, & Benrimoj 2005). It may be argued that these difficulties are a direct product of the healthcare system itself, which poses additional problems by attempting to solve them (Eppel et al. 1999). Effective communication between all parties involved in the concordance model is essential.

Figure 7.11 – A proposed schematic approach to the concordance model



In this model, partnership between healthcare professionals is acknowledged as essential for achieving concordance. Research on barriers and facilitators for successful dissemination of pharmaceutical care programmes is being developed in Portugal to promote enhanced collaboration between pharmacists and doctors (Paulino, Costa, & Benrimoj 2004a; Paulino, Costa, & Benrimoj 2004b; Paulino, Costa, & Benrimoj 2005).

7.6 Developing a model to improve service delivery to chronic patients

In light of the findings presented and the theories reviewed, this section proposes adapting psychological therapies established in other areas to develop strategies to influence medicines-taking.

There is vast clinical literature around the use of psychological or behavioural therapies in the treatment of mental disorders. Behavioural therapies may be defined as “a form of psychotherapy which seeks to improve the way a person feels by changing what they do.” Conversely, Cognitive Behavioural Therapy (CBT) emphasises the important place of people thinking about the way they feel and act, involving identifying how

negative thoughts may affect behaviour, followed by the development of strategies to challenge those thoughts (The Royal College of Psychiatrists 2005). This implies that behavioural changes occur as a result of the modification of cognitions.

The “vicious circle” describes how people act in an unhelpful manner when confronted with stressful situations, such as being confronted with an unexpected diagnosis faced by avoidance coping. CBT aims to break this circle encouraging the development of skills to confront situations positively (different from unrealistic optimism). There is a pre-assumption that the identification of core beliefs must precede modification (Dryburgh 2005). The concept is similar to that proposed in the C-SHIP framework, the difference lying on the application; the first focusing on mental disorders and the latter on cancer.

An RCT showed that cognitive therapy and behavioural stress management were similarly effective in anxiety management (Mayou & Farmer 2003). These authors proposed a model focusing on the interactive nature of unexplained symptoms, where beliefs, personality and perceptions directly influence cognitive interpretations, which dictate behavioural change.

Psycho-education is a technique that emphasises the importance of contributing to a patient’s enhanced awareness of the nature of their illness while highlighting the relevance of adhering to treatment (Vieta 2005). A review of interventions to improve adherence compared the effectiveness of educational, affective and behavioural approaches, each *per se* and combined. Eight out of twelve combined interventions successfully improved adherence (Dolder et al. 2003). Others have found that only half of those using educational and psychotherapeutic approaches to adherence enhancement showed added value compared to standard care (Nosé & Barbui 2003).

Researching the care provided to cancer patients with special emphasis on patients’ expectations and their experiences, Price and Leaver highlighted the importance of effective communication. They gained an understanding of patients’ views to build on an egalitarian relationship and then provided information to patients with an enhanced impact on their coping processes. They thus proposed a model for planning consultations and patient-centred interventions. Again, cognitions are

central to the model demonstrating how they dictate behaviour, in the forms of personal behaviour and social behaviour, maybe implying they are not equal. Also, as in the previous model, perceptions, emotions and beliefs dictate behaviour (Price & Leaver 2003).

Traditionally, CBT considers that past experiences are of minor importance and excludes those with illness and medicines, which may be seen as vital in the context of medicines-taking. However, as any theory, sooner or later other researchers suggest modifications to take their own views into account. Based on cognitive-behavioural techniques and on motivational interviewing, Kemp introduced “Compliance therapy” (Kemp, David, & Hayward 1996), which confronted the notion that CBT was an alternative to pharmacological treatment, or even incompatible.

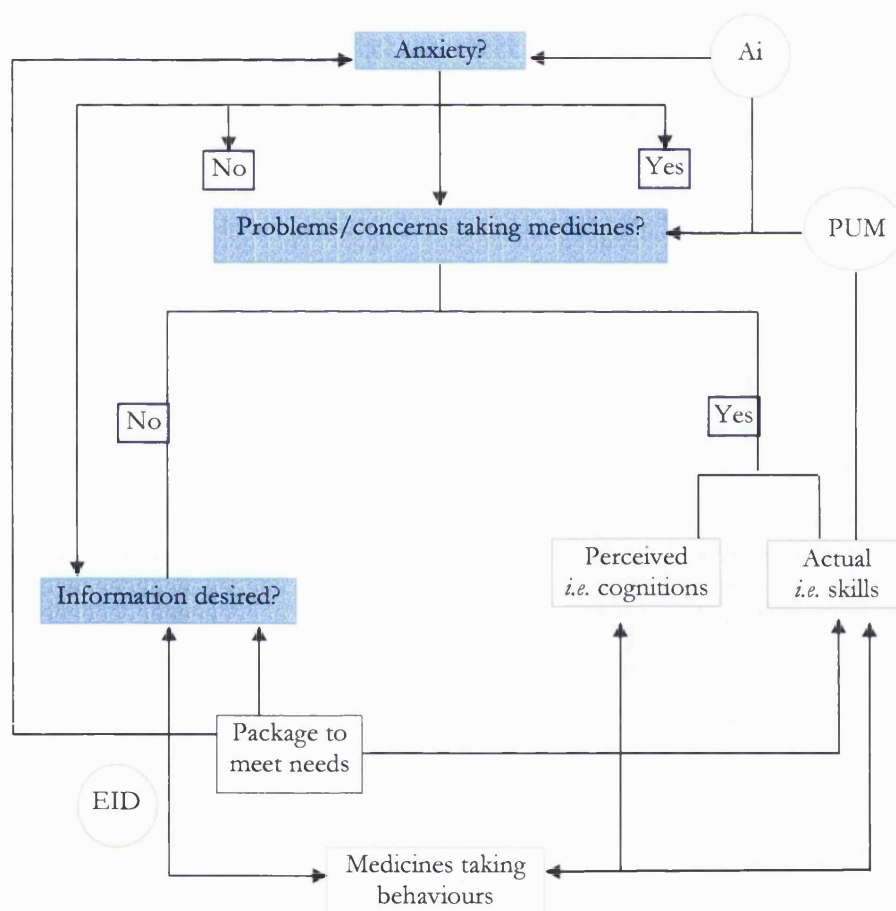
Kemp suggested that compliance therapy involved a first phase where the focus was put on patients’ perceptions and concerns, allowing room for patients’ to talk about previous experiences of symptoms and of taking medicines, where professionals gain insight into potential difficulties in adhering to therapy and motivate memories of good experiences. The second phase further explores negative sides of taking medicines, allowing professional to clarify misconceptions or provide information on the hazards of medicines in context with their benefits. The third phase ensures the patient acknowledges the importance of behaviour maintenance (Kemp et al. 1998). The main criticism of this theory is its failure in acknowledging the role of information; hence it may not have the same results for information-seekers and information-avoiders.

Following the studies comprising this thesis, “cognitive-medicines taking” (CMT) is proposed as a model to target information to patients to address their past medicines-taking experiences, their current perceptions of medicines, their emotional representations of illness, their inherited or acquired skills to deal with medicines and their motivation to change behaviour with the ultimate aim of modifying a negative (or maintaining a positive) cognition of medicines with positive impact on medicines-taking behaviours.

Developing Cognitive Medicines-Taking Services (CMTS) for pharmacy

Figure 7.12 illustrates a simple model developed from the concepts measured in this thesis, as context for developing a pharmacy targeted service through which cognitive medicines-taking can be maximized.

Figure 7.12 – Cognitive medicines-taking model



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graph TD
    Q1[Are patients concerned about illness?] -->|Yes| Q2[Do patients have problems or concerns taking their medicines?]
    Q1 -->|No| Q2
    Q2 -->|No| Q3[Do patients want to know more about their illness and/or medicines?]
    Q2 -->|Yes| PUM((PUM))
    PUM --> Skills[Skills]
    PUM --> Cognitions[Cognitions]
    Skills --> Ex1[E.g. cannot remember right hour to take medicines]
    Cognitions --> Ex2[E.g. had negative past experiences taking medicines]
    Q3 -->|How much do they want?| Q4[How much can they handle?]
    Q3 -->|How much can they handle?| Q5[How much do they need?]
    Q4 --> Q6[Provide tailored information]
    Q5 --> Q7[Provide aid e.g. reminders]
    Q6 --> Q8[Ensure understanding e.g. feedback]
    Q8 --> Q6
    Q7 --> Q9[Work together on remembering positive experiences]
    Q9 --> Q10[Provide evidence on benefit/risk ratio; Emphasise benefits]
    Q10 --> Q9
    Q10 -.->|*| Q11[Evaluate situation and change therapy if appropriate engaging with health care team]
    Q11 -.-> Q7
  
```

The flowchart illustrates a process for patient education and support. It begins with the question "Are patients concerned about illness?". If "Yes", it leads to "Do patients have problems or concerns taking their medicines?". If "No", it also leads to "Do patients have problems or concerns taking their medicines?". From "Do patients have problems or concerns taking their medicines?", if "No", it leads to "Do patients want to know more about their illness and/or medicines?". If "Yes", it leads to "PUM". "PUM" branches into "Skills" and "Cognitions". "Skills" leads to "E.g. cannot remember right hour to take medicines". "Cognitions" leads to "E.g. had negative past experiences taking medicines". From "Do patients want to know more about their illness and/or medicines?", it branches into "How much do they want?" and "How much can they handle?". "How much do they want?" leads to "How much can they handle?". "How much can they handle?" leads to "How much do they need?". "How much do they need?" leads to "Provide tailored information". "How much do they want?" leads to "Ensure understanding (e.g. feedback)". "Ensure understanding (e.g. feedback)" leads to "Provide tailored information". "Provide tailored information" leads to "Provide aid (e.g. reminders)". "Provide aid (e.g. reminders)" leads to "Work together on remembering positive experiences". "Work together on remembering positive experiences" leads to "Provide evidence on benefit/risk ratio; Emphasise benefits". "Provide evidence on benefit/risk ratio; Emphasise benefits" leads to "Evaluate situation and change therapy if appropriate engaging with health care team". "Evaluate situation and change therapy if appropriate engaging with health care team" leads to "Provide aid (e.g. reminders)".

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pharmaceutical service. In this example, while valuing the patients' views and experiences with medicines that condition their cognitions and therefore dictate behaviour, the medicine might in fact not be appropriate for their specific situation (e.g. leading to a DRP), so the therapy needs to be changed working in a multidisciplinary team.

Education in practice

It must be emphasised that professionals need to be trained to develop their own skills to adopt such techniques. Currently, in Portugal the pharmacists' pre-graduation curriculum includes topics such as communication skills, but does not include for example psychology. Obviously, a balance needs to be reached and one cannot be expected to learn about everything during the pre-graduation period, indeed practice-based post-graduate development might also have a role to play in acquiring these new competencies needed to provide enhanced services to patients.

7.7 Discussion of the overall thesis

The findings from each chapter were discussed separately, the purpose of this section is to draw together those discussions, emphasizing the strengths and limitations of the study design and elaborating on the applicability of findings to pharmacy practice in Portugal in particular.

Strengths of the study

Major strengths of this thesis include the development of a multi-method approach to the cross-cultural adaptation of survey tool, including the advantages of previous described approaches and guidelines, whilst minimising the flaws. The inclusion of views from health care professionals and patients further enhanced the reasons why some items performed poorly while providing guidance on ways to modify them.

The thorough validation procedure provided useful and exhaustive detail about the translated tool's validity and reliability. The tool was tested on a large patient sample recruited from two different countries, covering a wide range of medical conditions. Furthermore, in Portugal three different health care settings were explored with a wide geographical distribution. Literature from other disciplines outside the typical

pharmaceutical frame provided additional ideas on ways to improve service delivery, while taking into account the realities of pharmacy practice.

Limitations of the study: sample

There were also limitations associated with the sample, which although large and with good geographical coverage was not fully representative of the Portuguese population. Furthermore, while several medical conditions were explored, some were not large enough to fully explore the data; an example was the few cancer patients included in the Portuguese sample. However, this is mainly a result of the health-care organisation; most of these patients would be recruited in tertiary care, which was beyond the scope of the thesis, and forms the basis for further research (see section 7.9).

Recruitment procedures in the community pharmacy setting could have resulted in selection bias leading to a less representative sample because, although pharmacists were instructed to recruit the first patients meeting the inclusion criteria, previous experience indicates that this is often not compatible with pharmacy functioning and that some pharmacists tend to choose their regular patients.

Limitations of the study: study design

The study design for the validation and comparison was cross-sectional, which is known to have several limitations. The most relevant limitation of this design for this thesis is the inability to explore the survey tool's responsiveness to change. It would be interesting to explore the effects of information provision over time on scores to the EID scale; and the impact of experiencing adverse effects of medicines on scores to the PHM scale. Both of these are suggested as future research (section 7.9).

Another limitation of a cross-sectional design is the inability to know the direction of the effects, a phenomenon commonly known as protopathic bias. This has led to careful interpretation of the findings as one cannot be certain *e.g.* if it is patients' anxiety about their illness that determines the extent of information desired or vice-versa.

Limitations of the study: measurement of compliance

Measurement of compliance was reviewed in section 3.5.1 and appraised for advantages and disadvantages. While there is no ideal method the best available option is a combination. For practical and economic reasons, only patients self-report was used here as dichotomous responses. This led to limited associations between patient variables and compliance as an outcome, and limited comparisons between hospital and community patients. Although patients were asked to quantify non-compliance, poor quality of data led to both disregarding data and the awareness that self-reports are prone to recall bias, most likely to occur in the elderly who more often reported compliance. Patients with greater odds of forgetting to take their medicines may also have greater odds of forgetting to report forgetfulness; implying unintentional compliance may be underestimated. Comparing hospital and community reported compliance rose the awareness of different time scales, *i.e.* hospital patients referred to the week prior to admission while community patients referred to the previous week, thus reducing comparisons.

Limitations of the study: translating findings

During this study, data was collected in the UK and in Portugal. The main researcher is Portuguese, hence conducted the UK interviews in a second language. Conversely, interviews in Portugal were conducted in the interviewer and interviewees' mother tongue, but reporting of the findings in this thesis was done in English. All these factors have been acknowledged to have a potential impact on the validity of the research and its report (Birbili 2005). Different situations have been described, where in this study the researcher was also the translator. In such cases the most important factors to consider are: the autobiography, the knowledge of the culture and the people under study, and the fluency in the language used to write the thesis (Vulliamy, Lewin, & Stephens 1990). The autobiography reflects the knowledge of English acquired in years of formal education and the skills developed in writing and presenting in English through the professional evolution. The knowledge of the culture is pre-assumed as the study focused on the researcher's own culture. Lastly, the fluency of English to write the thesis was improved during the course of the study by living in the country, reading also non-pharmacy related literature in English and regularly writing reports on the project's evolution, all of which in combination

contributed to a final acceptable writing level. The number of recommendations provided is countless, being worth mentioning the difficulties in using quotes from Portuguese patients and reporting them in English. There are two options to take, go for the literal translation (which perhaps in some cases is harder to result in correct English) or go for a free translation, where focus is put on the meaning rather than on the words (which perhaps reads better but is prone not to make justice of exactly what patients had said and it may lose any emotional connotations attached) (Honig 1997). The option taken in this thesis was to use literal translations, which were followed by an explanation of their meaning between brackets, whenever the meaning was unclear *e.g.* colloquialisms.

Evidence-based practice

The key to putting research into practice is to consider the applicability of findings in the health care setting. As described in chapter I (section 1.3.4.2 and 1.3.5), the primary care setting in Portugal is particularly developed and especially well organised and supported. As such, initiatives targeted at community pharmacists' interventions are likely to be well accepted in Portugal. Considering the potential impact on the improvement of health care delivery by targeting information at medicines-related behaviours, it should be emphasised that community pharmacies are geographically well spread, and are the most accessible place for patients to seek counselling. Ambulatory patients need to have more control over their medication and are not closely monitored by health professionals as in hospitals or nursing homes. Additionally, it is in the community that most problems with compliance are likely to occur.

Applicability in Portugal

The findings from this thesis provided community pharmacists in Portugal with a tool ready for implementation, to provide useful information to practitioners involved in direct patient care. In general, questionnaires are regarded as research-focused and generate an additional burden for pharmacists with no immediate visible benefits. However, every situation needs to be put into context and, at the present time, Portugal is experiencing rapid and important changes in the services provided in community pharmacies. Several initiatives have been implemented over the past

years, which are now seeing benefit. Two relevant developments are worth emphasising, in addition to the review in section 1.3.5.

Applicability in Portugal: Patient-focused software

The development of the patient-focused software Sifarma 2000 enables pharmacists to easily document relevant information for each individual patient (Departamento de Apoio aos Associados 2005). It would be possible to include the survey in this software, with clear practical implications. However, not every individual visiting a pharmacy may be classified as a patient; some even like to be called “pharmacy-users” (or customers). Still, there is an important part of the population with chronic conditions or at high risk for developing them for whom a specific programme would be useful.

Applicability in Portugal: Pharmaceutical care programmes

Currently pharmaceutical care programmes are either targeted at any patient presenting a potential drug-related problem or at specific patient groups for whom their condition is not under the best possible control. Examples include cardiac patients, diabetics and patients with asthma or COPD. These programmes may be extended in the near future to other conditions, such as HIV, cancer and GI disorders. The patients enrolled in such programmes are followed-up in the pharmacy and the pharmacist responsible for them establishes the necessary links with the health care team to provide comprehensive care. Some of the services are in an early implementation phase; the development of strategies to improve compliance for patients having problems. These interventions are based on the most common pre-assumption that most cases will benefit from reminder aids, which may tackle unintentional non-compliers but will certainly provide no benefit for intentional non-compliers. These interventions are quite costly and if they are not beneficial, they will impact through increased taxes to cover for non cost-effective health care. For these patients in particular, a tool that is easy to use and gives guidance to pharmacists about the correct amount of information for the individual, which additionally impacts on compliance, will benefit pharmacy practice.

7.8 Conclusions

1. The survey tool used in this thesis was adapted to Portuguese (for Portugal). However, the successive steps needed to refine the wording highlighted the difficulty of simply transferring measurement scales from one country to another. Additional difficulties in the adaptation process were found for the tolerance scale, particularly the item where “blame” was mentioned; religious beliefs held in Portugal had an important impact. The scale measuring perception of harm of medicines was also subjected to successive word changes. All items needed clarification, as a result of the lower literacy level of the Portuguese population; educational and health literacy. These scales were not primarily developed with the purpose of subsequent adaption for other countries; hence it is also possible that the use of words with a single (or most common) meaning in English resulted in ambiguous translations, and different interpretations.
2. The validation of the translated survey tool confirmed the unsuitability of the tolerance scale in the Portuguese sample, which was dropped. The items loaded across different domains, highlighting low construct validity and internal consistency. One item from the PUM scale was also dropped as it did not contribute to the internal consistency. The internal consistency of the PHM scale was considered acceptable, while the PBM was found to be valid and reliable. The Anxiety and EID scales were successfully validated, although future refinements may improve internal consistency once implemented, in comparison to the original English version.
3. Portuguese patients revealed a greater desire for medicines and illness-related information and also a greater perception of medicines’ utility than UK patients. Conversely, UK patients tended to feel more anxious about their illness than Portuguese Patients. The null hypothesis that patients’ desires and perceptions are the same between different countries is therefore rejected. Within Portugal, patients recruited in the community pharmacy tended to desire information to a greater extent than hospital patients, while the latter tended to feel more anxious about their illness; there were no overall differences between settings, which indicate that the hypothesis information desires are the same across health care

settings is also rejected together with the null hypothesis feelings towards illness are the same across settings. However, the hypothesis that medicines perceptions are the same across health care settings cannot be immediately disregarded.

4. Females were found to score high on the EID and Ai scales, implying they desire more information but tended to feel more anxious about their illness than male patients (although neither was statistically significant). Younger patients tended to desire more information, while older patients tended to feel more anxious about their illness. Patients with lower educational levels tended to simultaneously perceive a greater harm and benefit from their medicines, and also feel more anxious, while desiring information to a lesser extent than the higher educated. These results indicate that the null hypothesis that information desires and medicines and illness perceptions are independent of demographic characteristics is rejected. It should be emphasised that only educational level was found to influence patients' scores to the PUM scale.
5. Patients with endocrine diagnoses tended to desire less information than patients with other medical conditions. Cardiovascular patients tended to perceive medicines as less beneficial, while respiratory patients tended to perceive them as more harmful. Patients with a CNS disorder tended to feel more anxious about their illness than others. In general these findings indicate that the hypothesis that information desires and medicines and illness perceptions are the same independent of medical diagnosis is rejected.
6. Patients aged 60 or older and those scoring 17 or higher on the EID scale were twice as likely to report compliance behaviour (Adjusted OR = 2.20 and 2.57, respectively). The null hypothesis that compliance can be partly predicted by patients' demographic characteristics and their scores to the scales (age and scores to EID scale) cannot be rejected.
7. The CMTS model suggests one possible way to target information provision to patients, while taking into account emotional representation of illness and working on their medicines-related cognitions. The evidence suggests that information seekers are more likely to comply with prescribed therapy provides

an insight for pharmacists to work with the individuals. This model may appear too complex when first presented to pharmacists, and unlikely to succeed without the necessary training (section 7.6). Easier implementation by using software systems has been recommended (section 7.7). There is however some concern on the acceptability of the Ai scale in pharmacy practice (as reported by some pharmacists) but the extent to which pharmacists are engaged in patient-centred care initiatives may influence their willingness and ability to use it.

7.9 Future research

During the discussion of the overall thesis (section 7.7), some areas worth further investigation arose. Three possible projects that could follow from the findings are suggested.

Project 1 - It has been shown that the scores to the EID scale are associated with patients' self-reported compliance. The direction of the effect could not be evaluated, as previously acknowledged. A longitudinal study to evaluate the impact of meeting patients' information desires on their compliance by testing the impact of different information packages on medicines-taking. Measurement of compliance should be undertaken using two methods in combination, for example self-report and EMs. A long follow-up period (minimum of 6 months) to allow for the wash-out period is advisable. Depending on available resources, considering compliance as an intermediate indicator and further evaluate its impact on illness control may be an option.

Project 2 – Undertake the last phase of this thesis in an oncology centre, considering different types of cancer and severity, to evaluate information desires. Baseline data would be fed into oncologists to act accordingly. A follow-up study could be undertaken to evaluate the impact of doctor's attitudinal change, to provide evidence on the impact of doctor's approaches to patient-centred care on patient's satisfaction.

Project 3 – Exploring the impact of past experiences of medicines adverse events (ADEs) on patients' scores to the PHM scale and evaluate impact on cognitive-medicines taking.

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APPENDICES:

- 1 – Translation sheets
 - 2 – Invitation to participate in a research project
 - 3 – Informed consent form
 - 4 – Interviewer administered questionnaire
 - 5 – Self-administered questionnaire
 - 6 – Refusal form
 - 7 – Pharmacists' questionnaire
 - 8 – Protocols submitted to Ethical Committees
- Abstracts presented in congresses related to the PhD project

TRANSLATION SHEETS

Please fill in the following grid for translating all 23 statements. These are subdivided into 3 scales (one per page), each with a distinct title. For that purpose, you can either **handwrite** directly on the questionnaires or use the **electronic automatic correction function**.

Country: Portugal

Language: Portuguese

Reviewer name:

Scale 1	ORIGINAL - ENGLISH	TRANSLATION - PORTUGUESE
Title of scale	Extent of Information Desired	
Statements	I need as much information about my medicines as possible	
	Too much knowledge is a bad thing	
	You can never know enough about these things	
	I don't need any more knowledge.	
	I read about my medicines / illness as much as possible.	
	What you don't know doesn't hurt you.	

Scale 2	ORIGINAL - ENGLISH	TRANSLATION - PORTUGUESE
Title of scale	Perceived utility of medicines	
Statements	I find my medicines easy to take, I am used to them	
	I feel 'trapped' by my medicines, I have to take them	
	My medicines relieve my symptoms	
	It's hard to take my medicines, because taking them has altered my lifestyle	
	I trust my medicines will make me better	
	The side effects are another form of disease	
	Without my medicines I would be so much worse	
	I would feel worried if I noticed a change in my medicines, because it could be a mistake	

Scale 3	ORIGINAL - ENGLISH	TRANSLATION - PORTUGUESE
Title of scale	Anxiety about Illness	
Statements	I can't get used to this illness, I just get worried about it	
	I can't believe I am ill, I have always been well	
	I feel fine about my illness, you can't expect to always be well	
	I just want to blame someone for the way I feel	
	I would like to be completely better, but a bit better is good enough	
	I feel anxious and concerned about the future	
	I feel fine about the future, it's all in the hands of fate	
	I can't accept that there is something wrong, why me?	

	ORIGINAL – ENGLISH	TRANSLATION - PORTUGUESE
Response choices	I totally agree	
	I partially agree	
	I don't agree or disagree	
	I partially disagree	
	I totally disagree	
Additional comments		



INVITATION TO PARTICIPATE IN A RESEARCH PROJECT



Measuring medicine information needs of patients: evidence based approaches

Academic Department of Pharmacy, Barts and the London NHS Trust
Saint Bartholomew's Hospital, West Smithfield, London EC1A 7BE

We invite you to take part in a research study, which we think may be important. The following information tells you about it. It is important that you understand what is in this leaflet. It says what will happen if you take part and what the risks might be. Try to make sure you know what will happen to you if you decide to take part. Whether or not you do take part is entirely your choice. Please ask any questions you want to about the research and we will try our best to answer them.

What is this study about?

We are exploring patients' perceptions of information regarding their drugs and disease through a questionnaire. We have developed the questionnaire during previous studies on General and Emergency Medicine patients at Barts and the London NHS Trust Hospitals. By increasing our understanding of patients' perspectives we can provide them more appropriate care so they will feel more satisfied. Since you are a General and Emergency Medicine patient, we would like to invite you to participate.

What would participation in the study involve?

The whole study will take place over 18 months. Although we will consider you as a participant over this period, your actual participation will be on one occasion. On *one* occasion we would like you to participate in an interview. This will be carried out by one researcher from the research team and will take place at your bedside if you are an in-patient or whilst you're waiting at the outpatient clinic. It will take approximately twenty minutes. During the interview we will ask you some questions about your prescribed drugs and how you feel about them.

Why are we doing this study?

Our findings will be used to inform future improvements in the type of care we provide to patients. If we are able to find out what patients want in terms of care, namely the extent of information about their prescribed drugs and what in particular troubles them about their illness, we can develop different types of interventions based on those needs.

Confidentiality

All the information that we will collect from you will be treated as *strictly confidential* and will not be revealed to anyone. Your responses will be anonymised. You will not be identified in any report or publication on the project. No one else other than the research team will have access to the information collected during the study. We would be grateful if you are willing to help us with this study. However, it is entirely *your choice* whether or not you decide to take part. If you decide not to participate, or drop out at *any* time during the study, this will *not* affect your ordinary medical care in any way.

Would you like more information?

If you would like more information or if you get worried at any time during the study or if there is an emergency, you can contact the main investigator, details below.

Name: Dr Catherine Duggan, Director; **Address:** Academic Department of Pharmacy, Saint Bartholomew's Hospital London EC1A 7BE **Telephone number:** 020 7601 7555



CONVITE PARA PARTICIPAR NUM PROJECTO DE INVESTIGAÇÃO



*Avaliação das necessidades de informação dos doentes sobre
medicamentos: análise baseada na evidência*

Centro de Estudos de Farmacoepidemiologia (CEFAR)

School of Pharmacy, University of London (SOP)

Convidamo-lo a participar num estudo de investigação, o qual pensamos ser importante. Este folheto dá-lhe mais informação. É importante que o leia e entenda em que consta a sua participação. A decisão de participar ou não é inteiramente sua. Coloque, por favor, qualquer questão que deseje sobre o estudo e faremos o melhor para a responder.

Sobre que é o estudo?

Pretendemos, através de um inquérito, analisar as percepções dos doentes sobre a informação relacionada com os medicamentos e a doença. O questionário que vai ser usado resultou das opiniões de outros indivíduos com diversas patologias internados noutros hospitais. Aumentando o nosso conhecimento sobre as perspectivas dos doentes, podemos fornecer cuidados de saúde mais apropriados para que se sintam mais satisfeitos. Visto ser utente de um serviço de saúde, gostaríamos de o convidar a participar.

O que é que a sua participação envolve?

O estudo demorará cerca de 18 meses. Apesar de ser considerado um participante ao longo deste período, a sua verdadeira participação será em apenas uma ocasião. Nessa ocasião, gostaríamos que participasse numa entrevista. Esta será conduzida por um membro da equipa de investigação e terá lugar junto à sua cama. Demorará cerca de 10 a 15 minutos. Durante a entrevista, ser-lhe-ão feitas algumas perguntas sobre a sua doença e os medicamentos e a forma como os encara.

Vire a página por favor

Porque é que estamos a fazer este estudo?

Os nossos resultados serão usados para aumentar a informação que existe por forma a melhorar os cuidados de saúde prestados aos doentes. Se conseguirmos saber o que os doentes querem em termos de cuidados de saúde, nomeadamente o grau de informação sobre os medicamentos e aquilo que os preocupa sobre a doença, podemos desenvolver diferentes tipos de intervenções baseadas nas necessidades identificadas.

Confidencialidade

Toda a informação recolhida será tratada como sendo **estritamente confidencial** e não será revelada a ninguém. As suas respostas serão tornadas anónimas. Não será identificado em nenhum relatório ou publicação do estudo. Ninguém, para além da equipa de investigação, terá acesso à informação recolhida durante o estudo. Agradecemos-lhe se estiver disposto a ajudar-nos neste estudo. No entanto, a decisão de participar ou não é inteiramente sua. Caso decida não participar, ou desistir a qualquer momento, isso **não afectará** de forma alguma os cuidados médicos que recebe.

Gostaria de ter mais informação?

Se deseja ter mais informação, poderá contactar o investigador principal. Os seus detalhes são os seguintes:

Nome: Dr.ª Filipa Alves da Costa

Morada: Centro de Estudos de Farmacoepidemiologia. R. Marechal Saldanha, 1
1249 069 Lisboa

Telefone: 213400671



WRITTEN CONSENT FORM



Measuring medicine information needs of patients: evidence based approaches

REC Number:

Name of Patient/Volunteer (Block Capitals):

Address (Postcode):

- The study organisers have invited me to take part in this research. ☐
- I understand what is in the leaflet about the research. I have a copy of the leaflet to keep. ☐
- I have had the chance to talk and ask questions about the study. ☐
- I know what my part will be in the study and I know how long it will take. ☐
- I know how the study may affect me. I have been told if there are possible risks. ☐
- I understand that I should not **actively** take part in more than 1 research study at a time. ☐
- I know that the local East London and The City Health Authority Research Ethics Committee has seen and agreed to this study. ☐
- I understand that personal information is strictly confidential: I know the only people who may see information about my part in the study are the research team or an official representative of the organisation which funded the research. ☐
- I freely consent to be a subject in the study. No one has put pressure on me. ☐
- I know that I can stop taking part in the study at any time. ☐
- I know if I do not take part I will still be able to have my normal treatment. ☐

I know that if there are any problems, I can contact:

Dr Catherine Duggan
Tel. No. 020 7601 7555

Patient's/Volunteer's Signature:

Witness's Name

Witness's Signature:

Date

As the Investigator responsible for this research or a designated deputy, I confirm that I have explained to the patient/volunteer named above the nature and purpose of the research to be undertaken.

Investigator's Name:

Investigator's Signature: Date:.....



DECLARAÇÃO DE CONSENTIMENTO INFORMADO



Avaliação das necessidades de informação dos doentes sobre medicamentos: análise baseada na evidência

Código doente

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Declaro ter sido informado pela Dr.^a Filipa Alves da Costa que o Centro de Estudos de Farmacoepidemiologia da Associação Nacional das Farmácias (CEFAR) e a School of Pharmacy da Universidade de Londres estão a realizar um estudo sobre “DESEJOS DE INFORMAÇÃO DOS DOENTES SOBRE MEDICAMENTOS”.

Concordo em participar no estudo, tendo sido informado que, para tal, devo fazer o seguinte:

- Participar numa entrevista em que se falará da forma como encaro o meu estado de saúde, a necessidade de tomar medicamentos e ainda a informação que gostaria de obter sobre os medicamentos que tomo.

Compreendo que a minha participação é inteiramente voluntária e que, se assim o entender, posso recusar responder a qualquer pergunta ou em qualquer momento posso recusar a minha participação no estudo, sem que isso prejudique os serviços e seguimento que habitualmente recebo neste hospital.

Compreendo que a informação recolhida sobre mim será tratada de forma confidencial e não serei pessoalmente identificado.

Nome (primeiro e último) _____

(Assinatura do doente)

(Assinatura do investigador)



3. Sex: Male ☐ Female ☐

4. Age: _____ y.O. (at time of interview)

6. Ethnicity: _____

8. Age when left school: _____

9. Profession: _____ (state if retired)

10. Main diagnosis: _____ 11. Diagnosed: _____ (year)

12. Reason for hospital admission (presenting complaint): _____

12.1. Admitted on the _____ 12.2 in _____ ward _____

13. Co-Morbidities (past medical history); state when diagnosed, if available:

13.1. _____; 13.2. _____

13.3. _____; 14. Prescribed therapy:

Name, dosage, and route of administration

BNF code

- if insulin mention the brand between brackets; if administered only as required add "PRN"

[illegible]

15. In general, would you say your health is:

1

7

7

7

Excellent

Very good

Good

Fair

Poor

16- You will be read some statements, which have been said by other people in other hospitals. They all refer to their illness and medication. Please state to what extent you think these are applicable to you. You can answer to each statement by saying "I strongly agree", "I agree", "I'm uncertain", "I disagree" or "I strongly disagree".

SA	A	U	D	SD
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In relation to the medicines you are taking: (EID)

I need as much information about my medicines as possible					
Too much knowledge is a bad thing					
You can never know enough about these things					
I don't need any more knowledge					
I read about my medicines / illness as much as possible					
What you don't know doesn't hurt you					

(PUM)

I find my medicines easy to take, I am used to them					
My medicines relieve my symptoms					
I trust my medicines will make me better					
Without my medicines I would be so much worse					
I feel 'trapped' by my medicines, I have to take them					
It's hard to take my medicines, because taking them has altered my lifestyle					
The side effects are another form of disease					

In relation to the your illness: (AI)

I can't get used to this illness, I just get worried about it					
I can't believe I am ill, I have always been well					
I feel fine about my illness, you can't expect to always be well					
I just want to blame someone for the way I feel					
I would like to be completely better, but a bit better is good enough					
I get really worried about it all, the worry makes me ill					
I feel anxious and concerned about the future					
I feel fine about the future, it's all in the hands of fate					
I can't accept that there is something wrong, why me?					

17. When you take medicines, do you like to have information about them? (What type?

How/by whom do you like to receive it?)

18. What do you feel about your medicines? (beneficial/harmful/a prison...?)

19. In the past week have you ever not taken your medicines? (if yes, how many times and why? If no, would there be something that would make you not take them?)

20. How do you live with your illness? (accept/fight it/depends on you/others...) [if the patient has several illnesses ask him which concerns/bothers him most]

21. Is there something that you think could be improved in the health-care? (Whether in the hospital or the community; if the patient says he's satisfied ask him what are the most important things for him to be satisfied, i.e., what does he value)

16- Ser-lhe-ão lidas algumas afirmações que se referem à sua doença e medicação. Diga por favor até que ponto acha que são aplicáveis ao seu caso. Pode responder dizendo “Concordo totalmente”, “Concordo”, “Não sei”, “Discordo” ou “Discordo totalmente”.

C T	C	N	D	D T
--------	---	---	---	--------

Em relação aos seus medicamentos: (GID)

Eu necessito do máximo de informação possível sobre os meus medicamentos					
Demasiado conhecimento é mau					
Nunca se sabe o suficiente sobre estas coisas					
Eu não necessito de saber mais					
Eu leio o mais que posso sobre os meus medicamentos/doença					
O que não se sabe, não nos pode fazer mal					

(PUM)

Eu acho os meus medicamento fáceis de tomar, estou habituado a eles					
Os meus medicamentos aliviam-me os sintomas					
Eu acredito que os meus medicamentos me vão fazer sentir melhor					
Sem os meus medicamentos eu estaria muito pior					
Sinto-me 'encurralado' pelos meus medicamentos, tenho que os tomar					
É difícil tomar os meus medicamentos, porque tomá-los alterou o meu estilo de vida					
Os efeitos secundários são outra forma de doença					

Em relação à sua doença: (AD)

Eu não me consigo habituar a esta doença, só me preocupo com ela					
Eu sinto-me bem com a minha doença, não podes esperar estar sempre bem					
Eu só quero culpar alguém pela forma como me sinto					
Eu gostava de estar completamente bom, mas um pouco melhor é o suficiente					
Eu fico mesmo preocupado com tudo isto, a preocupação faz-me doente					
Eu sinto-me ansioso e preocupado em relação ao futuro					
Eu não consigo aceitar que algo está mal, porquê eu?					

17. Quando toma medicamentos gosta de ter informação sobre eles? (que tipo; procura-o por si mesmo ou gosta que lhe seja dada? dada por quem? Se falar no folheto informativo averiguar se o lê todo ou só parte e se tem alguma dificuldade na leitura?

18. O que sente em relação aos seus medicamentos (acha-os benéficos/prejudiciais/uma prisão...)?

19. Na última semana alguma vez deixou de tomar os seus medicamentos?

☐ Não

☐ Sim



Quantas vezes e porquê?

20. Como vive com a sua doença? (depende de si, do médico, do destino; aceita-a/combate-a?)

21. Quais seriam os cuidados de saúde que idealmente gostaria de receber?



QUESTIONÁRIO PARA AUTO-PREENCHIMENTO

PARTE A – A SER PREENCHIDO PELO DOENTE:

5. Qual é o seu Sexo? ☐ Masculino ☐ Feminino

6. Qual a sua Idade actual? _____ anos

7. Qual a sua Nacionalidade? _____

8. Qual a sua Etnia? (exemplo: branco/ negro-Africano/ negro-Caraibas/...) _____

9. Que estudos tem? (exemplo: quarta classe/ 9º ano/12º ano/...) _____

10. Qual a sua profissão? (se de momento não trabalha, diga qual a profissão que exerceu durante mais tempo) _____

10.a. Actualmente está: ☐ Activo (a exercer) ☐ Desempregado ☐ Reformado

11. Qual a doença crónica que tem há mais tempo? _____

11.a. Diagnosticada há: _____ meses/anos (risque o

que não interessa)

12. Que outras doenças crónicas sabe ter?

12.1. _____

12.2. _____

12.3. _____

13. Qual de todas as doenças que tem, aquela que mais a/o preocupa? _____

14. Em geral, como julga ser a sua saúde?

☐☐☐☐☐

Excelente

Muito boa

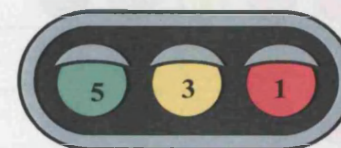
Boa

Razoavel

Fraca

15- As seguintes afirmações foram feitas por outras pessoas referindo-se à sua doença e medicação. Diga por favor, para cada uma delas, se “Concorda totalmente”, “Concorda”, “Não sabe”, “Discorda” ou “Discorda totalmente” em relação ao seu caso particular. Numa escala numérica, as respostas poderão variar entre 1 e 5, sendo 1 o máximo de desacordo e o 5 o total acordo. Tente responder sózinho, mas caso tenha alguma dúvida poderá esclarecê-la com o seu farmacêutico. O seguinte semáforo, representa as possíveis respostas que pode dar:

- o **verde** corresponde ao “**concordo totalmente**”
- o **amarelo limão** (não ilustrado) será o grau intermédio, ou seja, “**concordo**”
- o **amarelo** corresponde ao “**não sei**”
- o **laranja** (não ilustrado) será o grau intermédio, ou seja, “**discordo**”
- o **vermelho** corresponde ao “**discordo totalmente**”



Assinale assim uma cruz em cima do círculo correspondente à sua opinião

Em relação aos seus medicamentos:

15.1. Eu necessito de tanta informação quanto possível sobre os meus medicamentos	5	4	3	2	1
15.2. Saber demais não é bom	5	4	3	2	1
15.3. Nunca se sabe o suficiente sobre estas coisas.	5	4	3	2	1
15.4. Eu não necessito de saber mais	5	4	3	2	1
15.5. Eu leio o mais que posso sobre os meus medicamentos ou doença	5	4	3	2	1
15.6. O que não se sabe, não nos pode fazer mal	5	4	3	2	1

15.7. Demasiado conhecimento é mau	5	4	3	2	1
15.8. Porque tenho de tomar medicamentos, habituei-me a eles	5	4	3	2	1
15.9. É difícil tomar os meus medicamentos, porque tomá-los alterou o meu estilo de vida	5	4	3	2	1
15.10. Os meus medicamentos aliviam-me os sintomas	5	4	3	2	1
15.11. Sinto-me “encurralado” pelos meus medicamentos, tenho de os tomar	5	4	3	2	1
15.12. Eu acredito que os meus medicamentos me vão fazer sentir melhor	5	4	3	2	1
15.13. Os efeitos secundários são outra forma de doença	5	4	3	2	1
15.14. Sem os meus medicamentos eu estaria muito pior	5	4	3	2	1
15.15. Sinto-me prisioneiro dos meus medicamentos porque tenho de os tomar	5	4	3	2	1
15.16. Ter de tomar os medicamentos altera o meu dia-a-dia	5	4	3	2	1
15.17. Alguns dos efeitos dos medicamentos são quase tão maus como ter outra doença	5	4	3	2	1
15.18. Eu acho os meus medicamentos fáceis de tomar, estou habituado a eles	5	4	3	2	1

16. Já alguma vez deixou de tomar os seus medicamentos?

☐ Sim

☐ Não

Se respondeu sim, qual a razão?

Se respondeu não,

qual a razão? (Se não souber, escreva "não sei")

Muito obrigado pela sua colaboração!

Em relação à sua doença:

15.19. Eu não me consigo habituar a esta doença, só me preocupo com ela	5	4	3	2	1
15.20. Nem sempre se pode estar bem, por isso aceito a doença	5	4	3	2	1
15.21. Eu não acredito que esteja doente, tenho estado sempre bem	5	4	3	2	1
15.22. Eu sinto-me bem com a minha doença, não se pode esperar que estejamos sempre bem	5	4	3	2	1
15.23. Se há alguém culpado pela minha doença sou eu	5	4	3	2	1
15.24. Eu sinto-me ansioso e preocupado em relação ao futuro	5	4	3	2	1
15.25. Se estivesse um bocadinho melhor já seria bom	5	4	3	2	1
15.26. Eu fico mesmo preocupado com tudo isto, a preocupação faz-me doente	5	4	3	2	1
15.27. Eu só quero culpar alguém pela forma como me sinto	5	4	3	2	1
15.28. Eu gostava de estar completamente bom, mas um pouco melhor é o suficiente	5	4	3	2	1
15.29. Eu sinto-me bem em relação ao futuro, está tudo nas mãos do destino	5	4	3	2	1
15.30. Eu não consigo aceitar que algo está mal, porquê eu?	5	4	3	2	1

16. Na última semana alguma vez deixou de tomar os seus medicamentos?

☐ Sim

☐ Não

Se respondeu sim, quantas vezes e porquê? _____ Se respondeu não, consegue imaginar alguma situação que o levaria a não tomar os seus medicamentos? Se sim, qual?

Muito obrigado pela sua colaboração!



QUESTIONARIO PARA AUTO-PREENCHIMENTO



PARTE B - A SER PREENCHIDO PELO FARMACÊUTICO:

1. Código da Farmácia (ANF): ☐☐☐☐☐

2. Código do doente (nº sequencial): _____

3. Data: _____

4. **Terapêutica prescrita:** Nome do medicamento, incluindo dose, via de administração e posologia

I) _____
II) _____
III) _____
IV) _____
V) _____
VI) _____
VII) _____
VIII) _____
IX) _____
X) _____
XI) _____
XII) _____
XIII) _____
XIV) _____
XV) _____

I) _____
II) _____
III) _____
IV) _____
V) _____
VI) _____
VII) _____
VIII) _____
IX) _____
X) _____
XI) _____
XII) _____
XIII) _____
XIV) _____
XV) _____

Documente ainda as dificuldades que sentiu por parte dos doentes:

Este doente sentiu alguma dificuldade no preenchimento do questionário? _____ Ajudou-o em algum momento? _____

Se respondeu sim, diga por favor que tipo de ajuda (especifique se foi nalguma quetão em particular) prestou e porque razão



4. Age: _____ years old (current)

6. Ethnicity: _____

8. Profession: _____

10. Main diagnostic: _____ 11. Diagnosed: _____ months ago

12.1. Admitted on the

13.2. _____

13.3. _____

14. Prescribed therapy:

Active substance (DCI)

BNF code

ATC code

[illegible]

15. Why don't you want to participate?



Formulário destinado ao farmacêutico



Documente por favor a sua opinião sobre a exequibilidade no recrutamento dos doentes:

Participar neste estudo interferiu com a sua actividade na farmácia?

Achou fácil abordar os doentes convidando-os a participar? _____

Caso tenha respondido que sim → mesmo nas horas de mais movimento? _____

Como seleccionou os doentes? _____

Julga que seria possível recrutar apenas por exemplo, o terceiro, o décimo e o décimo nono doente a entrar na farmácia? _____ Porquê? _____

Outros comentários: _____

Para o efeito, anexa toda a documentação relativa ao dossier dessa Comissão respeitante a projectos de investigação.

Com os melhores cumprimentos,

Porto, 23 de Maio de 2003

O INVESTIGADOR PRINCIPAL

Exmo. Senhor

**Ilmo. Presidente da Comissão de Ética do
Hospital de S. João**

Assunto: Pedido de apreciação e parecer

Nome do Investigador Principal: Filipa Alves da Costa

Título do projecto de investigação: Medição dos desejos de informação dos doentes: avaliação baseada na evidência.

Pretendendo realizar no Serviço de Higiene e Epidemiologia do Hospital de S. João o projecto de investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador Principal, a sua apreciação e a elaboração do respectivo parecer.

Para o efeito, anexo toda a documentação referida no dossier dessa Comissão respeitante a projectos de investigação.

Com os melhores cumprimentos.

Porto, 23 de Maio de 2003

O INVESTIGADOR PRINCIPAL

Ex.mos Senhores,

Venho por este meio solicitar a Vossa autorização para a realização de um trabalho de investigação nos Hospitais da Universidade de Coimbra, especificamente no internamento do serviço de Medicina II.

Este trabalho insere-se no âmbito de um projecto de Doutoramento em farmácia, o qual é sediado na “University of London, School of Pharmacy”, contanto com a colaboração de duas entidades portuguesas, a Faculdade de Farmácia da Universidade de Coimbra, na pessoa da Exma. Sra. Prof. Doutora Margarida Caramona, e o Centro de Estudos de Farmacoepidemiologia da Associação Nacional das farmácias (CEFAR), na pessoa da Exma. Sra.Dra. Ana Paula Martins.

Este projecto pressupõe que parte da recolha de informação seja realizada em doentes crónicos recrutados a nível hospitalar, justificação esta para o presente pedido.

Na expectativa de poder contar com a Vossa melhor colaboração, subscrevo-me com os mais cordiais cumprimentos,

Lisboa, 16 de Fevereiro de 2004

Filipa Alves da Costa

HOSPITAIS DA UNIVERSIDADE DE COIMBRA
COMISSÃO DE ÉTICA PARA A SAÚDE
PROJECTO DE INVESTIGAÇÃO

1. IDENTIFICAÇÃO DO PROJECTO

- a) Nome do Investigador principal: Filipa da Palma Carlos Alves da Costa
- b) Título do Projecto: Medição dos desejos de informação dos doentes: avaliação baseada na evidência
- c) Serviço hospitalar / Instituto ou Laboratório onde o projecto será executado
Consulta externa de Endocrinologia
- d) Existem outros centros, nacionais ou não, onde a mesma investigação será feita?

Sim ☒

Não ☐

Em caso afirmativo indique-os: Hospital de S. João, Hospital CUF Descobertas e Royal London Hospital

- e) Descreva sucintamente os objectivos da investigação:

- 1) Adaptar linguística e culturalmente três escalas desenvolvidas no Reino Unido: Grau de Informação Desejado (sobre medicamentos), Percepção da Utilidade dos Medicamentos e Ansiedade associada à Doença.
- 2) Esta adaptação é um pré-requisito para a posterior comparação cultural, o qual será o segundo objectivo: comparar os comportamentos dos doentes relacionados com a terapêutica prescrita entre estes dois países.

- f) A Investigação proposta envolve:

- a) Exames complementares – indique o tipo, frequência a natureza da amostra. Especifique se estes exames são feitos especialmente para esta investigação ou se serão executados no âmbito dos cuidados médicos habituais a prestar aos doentes:

Não envolve exames complementares

- g) Questionários

- A quem são feitos? A todos os doentes medicados cronicamente, independentemente da patologia que concordem em participar; serão excluídos os doentes que não sejam responsáveis pela sua medicação, como sejam as crianças ou os incapacitados; Serão igualmente excluídos os doentes cuja capacidade de comunicação esteja comprometida, nomeadamente por alterações mentais.
- Como será mantida a confidencialidade? Nos questionários serão apenas recolhidos dados sócio-demográficos, dados sobre o diagnóstico e a terapêutica como variáveis caracterizadoras do doente. A cada doente será atribuído um número de código sequencial, o qual não está associado ao processo do mesmo.

(Nota: Junte 1 exemplar do questionário que será utilizado)

2. ENSAIOS CLÍNICOS DE NOVOS FÁRMACOS

a) Tipo de Ensaio:

Fase III ☐ Fase IV ☐ Marketing ☐

b) Tipo de Fármaco:

- Nome(s) Genérico(s) _____
- Grupo farmacológico ou terapêutico _____
- Aprovação noutros países _____
- Aprovação pelo INFARMED
 - Fármaco: Aprovado ☐ Não Aprovado ☐
 - Forma Medicamentosa: Aprovada ☐ Não Aprovada ☐
 - Indicação terapêutica contemplada na investigação:

Aprovada

Não Aprovada

☐

☐
 - Posologia contemplada na investigação:

Aprovada

Não Aprovada

☐

☐
 - Via de administração contemplada na investigação:

Aprovada

Não Aprovada

☐

☐
- Tipo de Ensaio
 - Comparação com placebo ☐
 - Comparação com fármaco padrão ☐
 - Ensaio com dupla ocultação randomizado ☐
 - Ensaio aberto ☐
 - Outro tipo (especifique) _____

(Nota: 1 – No caso de medicamentos já aprovados oficialmente junte a bula oficial do produto comercializado.

2 - No caso de medicamentos ainda não aprovados, junte documento do fabricante, certificando a segurança do produto no qual conste a posologia e vias de administração recomendadas, bem como as indicações terapêuticas.)

3. JUSTIFICAÇÃO CIENTÍFICA DA INVESTIGAÇÃO - descreva sucintamente os fundamentos científicos da investigação. Indique, em particular, se a investigação já foi feita anteriormente com seres humanos, se o problema foi devidamente estudado a nível experimental de modo a otimizar os aspectos analíticos e técnicos e a avaliar os possíveis efeitos adversos.

Esta investigação foi conduzida de forma semelhante no Reino Unido aquando do desenvolvimento da primeira versão do questionário. Envolveu até ao momento cerca de 700 doentes crónicos com patologias diversas, em regime de internamento ou de consulta externa. Visto ser um estudo exploratório, em que se avalia essencialmente a opinião das pessoas sobre a temática de interesse à equipa de investigação, não trouxe nem se prevê possível vir a trazer, qualquer dano ou incómodo aos doentes participantes. Os primeiros resultados da investigação foram considerados pelo NHS (Sistema de Saúde Inglês) como potencialmente úteis para redireccionar a intervenção dos vários profissionais de saúde que lidam directa ou indirectamente com eles ao nível da terapêutica.

4. DOENTES ABRANGIDOS NA INVESTIGAÇÃO

. Número: 50

. As mulheres grávidas são excluídas? Sim ☐ Não ☒

desde que fossem antes da gravidez doentes crónicas medicadas.

. Indique como se processará o recrutamento dos doentes

Será feito em dias específicos, acordados com a Chefe de Serviço, de forma exaustiva. Todos os doentes, que nesses dias forem à consulta, serão abordados e, caso cumpram com os critérios de inclusão, serão convidados a participar. A entrevista decorrerá preferencialmente enquanto o doente espera pela consulta médica, caso este tenha acedido em participar.

5. CONTROLES

. Número: 0

. Indique como serão escolhidos _____

6. DESCRIÇÃO RESUMIDA DO PLANO DA INVESTIGAÇÃO

7. ENUMERAÇÃO DOS PROCEDIMENTOS, EXAMES OU SUBSTÂNCIAS QUE IRÃO SER ADMINISTRADAS AOS DOENTES (dietas especiais, medicamentos, radioisótopos, etc.): Nenhum

8. RISCO/BENEFÍCIO

a) Que riscos ou incómodos podem ser causados aos doentes pelo estudo? Nenhum

b) Que benefícios imediatos poderão advir para os doentes pela sua anuência em participar no estudo? Nenhum

c) Considera que os meios utilizados no estudo podem violar a privacidade do doente?

Sim ☐ Não ☒

Em caso afirmativo, indique que medidas serão tomadas para assegurar a confidencialidade.

d) Os doentes que não aceitarem participar no estudo ficarão, por esse facto, prejudicados em termos de assistência médica, relativamente aos participantes?

Sim ☐ Não ☒

9. CONSENTIMENTO

a) A expressão do consentimento informado terá forma escrita, conforme a Lei.

Junta-se cópia do seu texto, a ser assinado pelo doente ou pelo seu representante legal.

b) Descreva resumidamente o conteúdo da informação a transmitir.

A informação a transmitir está subdividida nas seguintes secções: “Sobre que é o estudo?”, “O que é que a sua participação envolve?”, “Porque é que estamos a fazer o estudo?”, “Confidencialidade”, “Gostaria de ter mais informações”. Ao longo destas secções é explicado ao doente para que serve o estudo, *i.e.*, o que se pretende avaliar, é-lhe explicado que a sua participação corresponde a responder numa única ocasião a uma série de perguntas com a duração de cerca de 20 minutos, é-lhe assegurada a confidencialidade dos dados e que a sua participação é voluntária, o que implica que no caso de recusa não tem qualquer influência sobre os cuidados de saúde recebidos. Por fim, é-lhe facultado o contacto do investigador principal para esclarecimento ou obtenção de mais informação.

c) A investigação ou estudo envolve:

- | | | |
|----------------------|------------------------------|---|
| . Menores de 14 anos | Sim <input type="checkbox"/> | Não <input checked="" type="checkbox"/> |
| . Inimputáveis | Sim <input type="checkbox"/> | Não <input checked="" type="checkbox"/> |

Em caso afirmativo que medidas estão previstas para respeitar os seus direitos e obter o seu consentimento esclarecido ou dos seus representantes legais?

10. RELATIVAMENTE AO ESTUDO

a) Data prevista do início ___/03/2004
Data prevista da conclusão ___/12/2004

b) Pagamento aos doentes:

- | | | |
|---|------------------------------|---|
| . Pelas deslocações | Sim <input type="checkbox"/> | Não <input checked="" type="checkbox"/> |
| . Pelas faltas ao Serviço | Sim <input type="checkbox"/> | Não <input checked="" type="checkbox"/> |
| . Por danos resultantes da sua participação no estudo | Sim <input type="checkbox"/> | Não <input checked="" type="checkbox"/> |

Em caso afirmativo especifique a identidade que assume a responsabilidade das indemnizações:

Outros pagamentos (especifique):

c) Do estudo que espécie de benefícios, financeiros ou outros resultarão para o investigador e/ou instituição? Especifique em caso afirmativo.

Obtenção de grau de Doutor em Farmácia

d) Os dados obtidos constituirão propriedade exclusiva da companhia farmacêutica ou outra entidade?

Sim ☒ Não ☐ Que entidade? School of Pharmacy, University of London. Laboratório de Farmacologia Da Faculdade de Farmácia da Universidade de Coimbra. Centro de Estudos de Farmacoepidemiologia (CEFAR, ANF)

11. TERMO DE RESPONSABILIDADE

Data do pedido de aprovação 19/02/2004

Eu abaixo assinado, Filipa da Palma Carlos Alves da Costa,

na qualidade de investigador principal, declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsínquia II e da Organização Mundial de Saúde, no que se refere à experimentação que envolva seres humanos.

12. (Reservado à C.E.S.)

PARECER EMITIDO NA REUNLÃO DE ____/____/200__

A COMISSÃO

gai/mr

Validation of the "Extent of Information Desired" (EID) into Portuguese, a pilot study

Costa F(a), Duggan C (b), Bates I (c)

(a) CEFAR - ANF, Portugal, (b) ADP, Barts and the London NHS Trust, UK, (c) School of Pharmacy,
University of London, UK

Patients' desires vary widely and the way health care professionals adapt their service provision is thought to impact on drug-related behaviours. The need to assess patients' information needs in a standardized way lead to the development of this scale. The use of such scale in a different setting can be of much use. However huge discrepancies between these 2 countries lead to a challenging procedure to guarantee its validity.

We are undertaking a cross sectional study to explore the applicability of the scale in a Portuguese hospital setting. General medicine hospitals in the 3 main cities are being used for data collection. Patients are approached once deemed suitable for inclusion and are interviewed at the bedside.

Data includes responses to the questionnaire items and patient demographics. Data is being analysed using SPSS Version 11.0. Psychometric properties are evaluated using Cronbach alpha (α) and Corrected item-total correlation (r).

A pilot study was undertaken in spring 2003, where 62 patients were included. The sample comprised a majority of men ($n=38$; 61.30%). Age was normally distributed, ranging from 18 to 92 years old ($\bar{x}=51$; $SD=18.68$) and the most frequent level of education was primary school ($n=20$; 32.30%). However, there were still 6.50% of patients who were illiterate in the sample. Most patients were employees in routine occupations ($n=13$; 22.80%). Median number of prescribed drugs was 4. Scores to EID were found to be normally distributed in the patient samples from both countries. Cronbach's α in the Portuguese sample was 0.54 (compared to 0.73 in UK) and r ranged from 0.14 – 0.50 (0.42-0.53 in UK). The mean scores to the EID scale 21.20, ranging from 10 to 30 ($SD=3.35$) and patient age was shown to be correlated with EID score ($r=-0.41$; $p=0.01$), as in the UK sample.

The findings highlight some difficulties with the direct transferability of the scale. Although Portuguese literacy problems have reduced in the past years, there is still a high proportion of illiterates in the more elderly population. The next stage of the study includes conducting in-depth interviews with illiterate patients to improve our understanding of their information desires. These findings will be presented in more detail at the conference.

An evidence-based approach to the cross-cultural transfer of measurement scales

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Background: Medicines taking behaviours of patients are increasingly a focus for the attention of pharmacists. Several factors contribute to the adoption of different behaviours, including perceptions about medicines and illness and the provision of information are some examples. There is no single method for information provision; some patients may benefit from information, whilst others will be anxious about too much information¹. The development of strategies to identify patients' desires and perceptions will influence the ways care is tailored to meet their needs. Research has been undertaken to develop ways to effectively measure the "extent of information desired"(EID), the "perceived utility of medicines" (PUM) and the "anxiety about illness" (AI)². The adaptation of standardised scales for use in other countries is increasingly important when developing interventions to improve patient care.

Aim: This study aimed to adapt and validate a set of measurement scales for use in a cross-cultural comparative study.

Methods: Validated translation and back-translation procedures were used³. The agreed back-translated version was administered to a sample of patients recruited in general medicine wards during the pre-testing phase. Six translators rated the difficulty of the translation process; clarity of translated version; and equivalence in wording and meaning of this version, compared with original⁴. Group work in two independent samples of health care professionals (UK and Portugal) allowed further understanding of why certain items required refinement. The standardised scales were administered to an independent patient sample recruited in 4 general medical hospitals in Portugal.

Results: The pilot was undertaken in 62 patients, followed by a main experiment (a total of 171 patients). The rating process highlighted two items that required revision. Factor analysis confirmed the previously described factors (Cronbach's α EID=0.606)¹. Some items were identified as potentially problematic (eg: mention of "side-effects" or "blaming others" for being ill). Group work explored and clarified these cultural differences, to interpret fieldwork problems and suggest alternatives. Whilst some of the modified items tested showed no difference, others undoubtedly contributed to an increased reliability, for example Cronbach's α using the original items contained in the "Tolerance" subscale of AI=0.081, increasing to 0.665 using the modified items. Quotes describe the possible reasons for modification: "blame seems to be something that they can't do; may be associated with religion, i.e., guilty religious feelings".

Discussion: An independent sample recruited through community pharmacy will further strengthen the method and subsequent findings. The direct translation of health services research type tools is problematic and the use of a more rigorous method is needed to ensure validity. Through this research, it is intended to demonstrate that the combination of several approaches contributes to achieve a valid and reliable tool allowing future comparisons between countries.

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- 2) Duggan C. (1998). *An Evidence Based Approach to Developing Pharmaceutical Service Provision Across the Primary: Secondary Care Interface*. (PhD Thesis). London: School of Pharmacy, University of London
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METHODS TRIANGULATION BROADENS RESEARCHERS' INSIGHTS: A CROSS CULTURAL EXAMPLE

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Better understanding of medicines and information related behaviours can lead to targeted interventions to improve patients' outcomes. This study aims to measure and compare information desires, perceptions of medicines and anxieties towards illness between two countries. Method: A cross-sectional study was conducted in UK and Portugal secondary care settings. Extent of information desired (EID), anxiety towards illness (AI) and perceived utility of medicines (PUM) were measured using Likert statements and open questions. Data were entered into SPSS v12 and NUD*IST v4 for analysis. Merging data allowed further understanding what influences patients' preferences as indicated by their scale scores. Results: Data from 118 Portuguese patients were analysed and compared with UK data. EID scores correlated with educational level ($\chi^2=14.5; p=0.04$). The reliability was $\alpha=0.58$ (EID), 0.55(PUM) and 0.68(AI). The range of inter-item correlations allowed exploring scale performance. Qualitative data validated the poor performance of some translated items and highlighted difficulties with understanding. Findings were used to develop replacement items. Bivariate analysis showed that 1 item referring to reading about medication was answered differently by illiterate patients ($\chi^2=8.6; p=0.04$). Combined results suggest differences in educational level and cultural upbringing, with implications for the research process. The methods described are being used to measure medicine and illness information needs in different cultures. Our results indicate that direct translation of existing scales to different cultural settings is problematic and that a research skill mix is necessary.

Patients in Portugal have greater desires for information than patients in the UK

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Introduction

A scale to measure the Extent of Information Desired (EID) has been developed, helping health care providers' to become more aware of patients' needs (1). It can be argued that the delivery of an inadequate amount of information to patients can negatively influence their drug-related behaviour (2). The adaptation of this scale to a different cultural environment is of major importance; the process adopted comprised the translation and back translation method, as described elsewhere (3). We believe that the way health care is provided to patients in different countries can potentially influence the way patients behave towards their medication.

Methods

A cross-sectional study was undertaken in Portugal to explore patients' expressed desires for information about their medication. This data was compared against UK data on record from previous studies (1, 2), using the same standardised interview method. Data were collected from general medical hospitals located in metropolitan areas of both countries. Patients were approached at their bedside and interviewed after consenting on their participation. Data collected included socio-demographical information, prescribed therapy, diagnosis and patients' responses to the EID scale. Analysis comprised comparison of mean EID scores between countries, comparison of diagnostic groups within each country, and verification of relationships by means of post hoc tests (Bonferroni). Sample groups were tested for unequal variance before conducting comparative statistics.

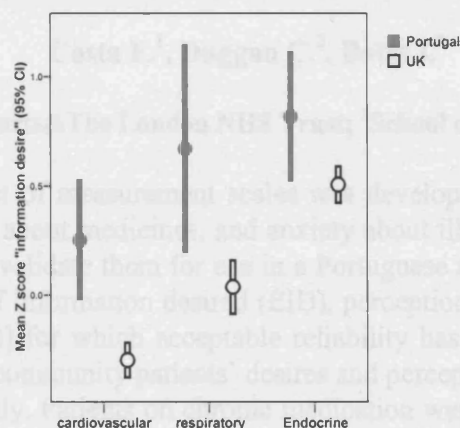
Results

A sample of 108 Portuguese patients was recruited and compared against 1756 UK patients on record. The majority of patients were male in both countries (61.6% in UK and 63.0% in Portugal); mean age was 61.6 in the UK (range 17 to 92) and 63.0 in Portugal (range 19 to 93). All patients in Portugal described their ethnic background as white, compared to 81.5% in the UK. The mean EID in the overall Portuguese sample was found to be significantly different from the UK ($t=5.228$; $p<0.001$). The same was verified, when analyzing mean EID scores in the main diagnostic subgroups: cardiovascular ($t=3.728$; $p<0.001$), endocrine ($t=2.067$; $p=0.039$), and respiratory ($t=2.16$; $p=0.032$). Analysis in both countries separately shows the same trends; where endocrine patients seem to desire more information about their medicines than respiratory, which in turn desire more information than cardiovascular patients. This difference was verified for both countries (Portugal: $F_{2,82}=4.08$; $p=0.02$. UK: $F_{2,1112}=82.342$; $p<0.001$). However, in the UK sample this difference was significant for all 3 subgroups ($p<0.001$), whilst in Portugal only the extreme subgroups, i.e., cardiovascular and endocrine, showed a significant difference ($p=0.021$); this effect could be attributed to the relatively smaller patient sample size, evident in figure 1.

Discussion

Results indicate a greater desire for information among Portuguese patients when compared with the UK. Preliminary analysis from face-to-face interviews suggests that this might be due to distinct care patterns; health care providers in the Portuguese secondary care tend not to inform patients so much about their prescribed medication. To our knowledge there is no published study comparing the type of care in these countries, so further research is needed to support this hypothesis.

Figure 1 – Mean EID Z-scores in three diagnostic groups in UK and in Portugal ($\pm 95\%$ CI)



- The Extent of Information Desired (EID) is a useful tool to measure patients' desires for information
- Patients desires for information in Portugal are greater than in the UK
- The way health care is provided may impact on patients' desires for information
- Diagnostic groups membership influences patients' desires for information

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ARE PATIENT PERCEPTIONS OF MEDICINES AND ILLNESS DIFFERENT BETWEEN HOSPITAL AND COMMUNITY?

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Background and aims: A set of measurement scales was developed to assess patients' desires for information, their perceptions about medicines, and anxiety about illness (1). These are being used in a project aiming to adapt and validate them for use in a Portuguese setting (2). This paper focuses on three of these scales [extent of information desired (EID), perception of benefits of medicines (PBM) and anxiety about illness (Ai)] for which acceptable reliability has been achieved. The scales were used to compare hospital and community patients' desires and perceptions.

Design: A cross-sectional study. Patients on chronic medication were recruited in three geographical areas, in hospital wards and in community pharmacies. Patients responded to a questionnaire, comprising these scales, rated on a 5-point Likert. The scales' mean scores were compared between the two samples.

Results: A sample of 462 patients was recruited, 342 in community and 120 in hospital. Inpatients were found to have statistically significant higher anxiety levels when compared to community patients ($t=3.098$; $p=0.002$). In contrast, community patients' scores indicated that they perceived their medicines as more beneficial and that they had a greater desire for information about their medicines and illness. However, only the latter difference was statistically significant ($t=3.531$; $p=0.001$). These findings seem robust as inpatients are more likely to have a more severe condition or at a worst stage, and therefore tend to be more anxious about it. PBM trend implies that inpatients might assume their medicines are less effective, perhaps contributing to their hospital admission. Regarding the EID, it is natural that patients in the community have greater information desires as they need to be in charge of their medicine taking. Furthermore, they have the power to decide whether they intend to take them, and might desire to make informed decisions.

Conclusions: The results indicate that these scales are sensitive in detecting differences between hospital and community patients. Future work will further explore these issues in the tolerance and perceived harm of medicines scales.

References:

- (1) Duggan, C. Bates, I. Development and evaluation of a survey tool to explore patients' perceptions of their prescribed drugs and their need for drug information. *Int J Pharm Pract* 2000;8:42-52.
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Lost in translation (1): Ensuring accuracy and representation in multicultural research in a EU setting

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Introduction

The need to align policy and research has been widely recognised and organisations such as the WHO periodically issue reports stating the priority areas that should be focused on. Among these, we can read the catalysing of change through technical and policy support, in ways to stimulate cooperation and action and help to build sustainable multinational policy (1). With the enlargement of the EU the need to ensure that valid methods exist to enable future comparison between countries has increased. One of the core issues is the demand for evidence on effective interventions in the different health care systems. There is vast literature around patients' medicine taking behaviour and many scales have been developed to help health care professionals understand why patients perceive their medicines in a different way. However, there is still, for many Non-English speaking countries, a demand for measurement tools validated in their own language. The perceived utility of medicines (PUM) developed in the UK, is used in this project as an example of possible approaches to cross-cultural validation within the EU allowing for subsequent comparisons (2). This scale comprises two sub-scales, described as the Perceived Harm of Medicines (PHM) and the Perceived Benefit of Medicines (PBM).

Objectives

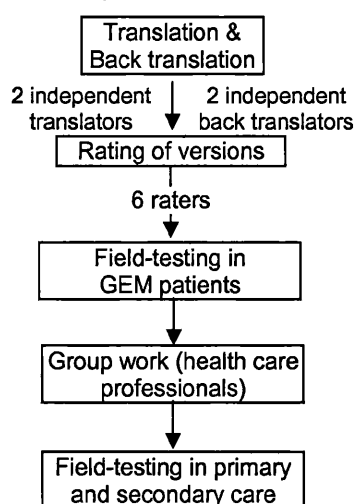
To design an approach for the adaptation and validation of a measurement tool to evaluate the perceptions of Portuguese patients (with chronic illnesses) about their medicines.

Method

A flexible approach was undertaken, where the results produced dictated the method used. A seven-stage process described the method used and, to date, 5 have been achieved (figure 1). The first stage was based on published translation and back-translation procedures (3). An adapted rating scheme ensured linguistic and conceptual equivalence (4, 5). The third stage comprised field-testing of the translated version in a sample of general medical patients. Two groups of health care professionals (one in each country) evaluated difficulties encountered, suggesting alternative wordings for some items. The new version (5th stage) was then administered to an independent patient sample, recruited through primary and secondary care. Both field-testing stages described were undertaken cross-sectionally, allowing the evaluation of the scales' internal consistency (through Cronbach's alpha and inter-item correlation) and subsequent comparison against the original.

The next stages of the project envisage the development of a lay bilingual panel to suggest a possible third version of this scale (stage 6). Finally, a longitudinal study will allow evaluating temporal stability and responsiveness (stage 7).

Figure 1: Schematic representation of project stages



Results

Two items were identified in the rating process as being linguistically different, but considered conceptually equivalent; therefore, no changes were made. A sample of 108 Portuguese patients was recruited during first field-testing. Analysis of their responses highlighted potential problems with some items, both through internal reliability analysis and patients quotes from open-ended questions. Four items were identified as needing major revision, one being used in both PHM and PBM; the remaining three belonged to PHM. These items being presented to the health care professionals' groups, a modified version resulted. Some of the changes included the use of alternative ways to describe "side effects", which many Portuguese patients are unfamiliar with. The use of expressions such as "feeling trapped" was another issue, being replaced by "imprisoned". The two other modified items included verbs apparently easily understood, such as "I am used to" or "to take medicines". Nonetheless these were understood differently. The need to use longer statements in Portuguese to express the same concept was also seen as a possible reason in the latter, these being modified to shorter and simpler statements by changing the focus.

This was then tested in a sample of 344 patients. The sample comprised mainly females (63.1%), with a mean age of 57.31 (sd=15.43) and the majority having a maximum of 4 years of formal education (51.5%). The major diagnostic groups recruited were endocrine (28.4%), cardiovascular (26.9%), respiratory (12.5%) and CNS (12.5%). The most frequent number of medicines prescribed was 4. Table 1 shows the internal consistency of both scales in the two countries involved, specifying the effect of the modified items as compared to the original (in Portuguese).

Table 1: Internal consistency of PHM and PBM in the UK and in Portugal

	UK sample	Portugal sample	
		version 1	version 2
n*	1258	462	344
Cronbach's α PHM	0.746	0.357	0.512
Cronbach's α PBM	0.784	0.696	0.708

*All the patients answering version 2, are included in those answering version 1 (total=462)

Discussion

The process used demonstrates that direct transferability of measurement scales results in invalid tools. The combining of several approaches in a sequential manner allows the difficulties encountered to be identified and indicate alternatives to resolve them. The PBM scale seems to present no relevant problems when adapted to Portuguese. However, the PHM scale clearly involves statements which are hard to adapt. The persistent low Cronbach's alpha estimate of PHM in the modified version is associated with one particular statement. Field notes indicate that it could be that the current translation of "I got used to" is linked to a concept of dependence. The next stage will further inform this assumption and, if confirmed, a new translation will be adopted.

References

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Do hospitalized patients perceive their medicines and illness differently from community patients?

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Background and aims: Seeing the patient as the driver to improve practice is now recognized. Hence, patient-focused research is central to health-care interventions. A set of measurement scales developed in the UK to assess patients' desires for information, their perceptions about medicines, and anxiety about illness (1) are being adapted for use in Portugal (2). We describe the use of three of these scales [extent of information desired (EID), perceived benefit of medicines (PBM) and anxiety about illness (Ai)] in comparing Portuguese hospital and community patients' desires and perceptions, following from comparable research at the BTL.

Methods: Using a cross-sectional design, patients on chronic medication were recruited in hospital wards and in community pharmacies. Patients responded to the three scales, rated on a 5-point Likert and their mean scores were compared between the two samples.

Results: A sample of 462 patients was recruited. Inpatients had higher anxiety levels than community patients ($t=3.098$; $p=0.002$). In contrast, community patients perceived their medicines as more beneficial and that they had a greater desire for information about their medicines and illness (only the latter significant; $t=3.531$; $p=0.001$).

Discussion: These findings seem robust as inpatients are more likely to have a more severe condition or at a worst stage, leading to higher anxiety. The PBM trend implies that inpatients might perceive medicines as less effective, which may have contributed to their hospital admission. The EID scores suggest that community patients might wish to make informed decisions about adherence to prescribed medicines.

References:

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- (2) Costa F., Duggan C., Bates I. Validation of the "extent of information desired" (EID) into Portuguese, a pilot study. *PWS* 2004;26(2):A27

Keywords (please provide three):

1. patients' desires for information
2. perceptions about medicines
3. health care interface

USING A LAY PANEL TO VALIDATE A QUESTIONNAIRE EXPLORING DESIRES FOR INFORMATION AND PERCEPTIONS ABOUT MEDICINES AND ILLNESS

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Aims: To ensure that the language used in a questionnaire measuring patients' desires and perceptions about medicines and illness is understood by the target audience, items are relevant, and culturally suitable. **Methods:** A purposive sample of chronic patients was recruited through a rural community pharmacy. Informed patients agreeing to participate in the panel met to comment on scenarios of medicine-taking, each corresponding to an item needing refinement. A consensus was sought through a Nominal group technique. Notes and audio-taping were used for clarification. **Results:** Seven patients participated where 6 scenarios were discussed. The first focused on side-effects, referred to as "they either cause you good or harm". Three of the scenarios described situations where medicines-taking could negatively impact on the patient's life; a passive perception was shared: intentional non-compliance was seen as inappropriate and doctors' decisions as undisputed. Discussing information seeking, generics were in focus and the pharmacist was referred as the one to ask as "the doctor might not like it". In the debate around feelings when diagnosed with a chronic disease, there was a struggle between what is felt and what God allows; several words were classified as "sinful", including blame, hate, etc; with different degrees of severity. Consensus was reached around the least punishable expression. **Conclusion:** Using a lay panel provided useful insights into patients' interpretations of medical jargon and cultural barriers that may be encountered in the adaptation process.