

**DEVELOPING A MODEL OF PATIENT VALUES IN MEDICAL
DECISION MAKING: A QUALITATIVE INQUIRY INTO
INSULIN INITIATION IN TYPE 2 DIABETES**

LEE YEW KONG

**THESIS SUBMITTED IN FULFILLMENT OF THE
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PREFACE

UNIVERSITI MALAYA

Original literary work declaration

Name of Candidate: **LEE YEW KONG**

(IC No: **820430-14-6469**)

Registration/Matric No: **MHA 100021**

Name of Degree: **Doctor of Philosophy**

Title of Project Paper/Research Report/Dissertation/Thesis (“this Work”): **Developing a Model of Patient Values in Medical Decision Making: A Qualitative Inquiry into Insulin Initiation in Type 2 Diabetes**

Field of Study: **Shared Decision Making**

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Abstract

Developing a model of patient values in medical decision making: A qualitative inquiry into insulin initiation in type 2 diabetes

Background: Shared decision making (SDM) is a medical decision making model where at least two parties (for example, patient and doctor) share information and values in order to build consensus on the preferred treatment to implement. Patient values are the most mentioned element in definitions of SDM. However, there is no agreed definition of patient values in both SDM and the larger field of medical decision making. Therefore, this study aimed to develop a model of patient values using insulin initiation in type 2 diabetes as an exemplar.

Methods: The study design was a qualitative study based on an interpretive descriptive approach. Data was collected from both healthcare professionals (HCPs) and patients. The conceptual frameworks used were the Ottawa Decision Support Framework and Schwartz's theory of values. Purposive sampling was used to recruit HCPs involved in insulin initiation and patients who were deciding about insulin. Participants were recruited from the three main healthcare settings in Malaysia (public health clinics, public university-based primary care clinics, and private clinics). An interview topic guide was developed based on the conceptual frameworks and expert opinion. In-depth interviews and focus group discussions were conducted between January 2011 and June 2012. Interviews were stopped when data saturation was achieved. The interviews were transcribed verbatim and managed with Nvivo9 software. Data was analysed using thematic analysis and Strauss' method of coding. A process of open, selective and axial coding was used to develop the model of patient values.

Results: Forty-one HCPs were interviewed (30-66 years old; females, n=31). The sample was diverse in terms of professional background (general practitioners, medical

officers, family medicine specialists, government policy makers, diabetes nurse educators, endocrinologists and pharmacists), healthcare settings (public, private) and ethnicity (Malays, Chinese, Indians, other ethnicities). Twenty-one patients were interviewed (28-67 years old; males, n=12) from diverse healthcare settings and ethnic backgrounds.

Based on HCP interviews, barriers and facilitators to insulin initiation included patient barriers (e.g. injection-related barriers, insulin-related barriers, social factors, emotional barriers), HCP barriers (e.g. lack of HCP motivation and confidence, lack of training, conflicting advice between HCPs), and system-related barriers. These factors provided the psychosocial and cultural context in which patient values were explored.

Based on patient interviews, the types of patient values during insulin initiation were identified. Three categories of values emerged: (1) positive and negative insulin-specific beliefs, (2) personal life goals (e.g. health, career, finance) and philosophies (e.g. avoiding suffering, fatalism, not being a burden), and (3) socio-cultural values (e.g. religious teachings, cultural practices) and family background. A model of patient values was then developed based on the three categories.

Conclusions: When supporting patients in decision making, HCPs need to address more than just treatment-specific beliefs. A deeper understanding of patients' life priorities and socio-cultural background are essential, as these also influence decisions about treatments. The proposed model of patient values helps to clarify the definition of patient values in SDM and can be used to systematically explore patient values during consultations.

Abstrak

Membangunkan satu model nilai-nilai pesakit untuk membuat keputusan perubatan: Siasatan kualitatif ke dalam keputusan memulakan insulin dalam diabetes jenis 2

Latarbelakang: *Shared Decision Making* (SDM) adalah model membuat keputusan perubatan di mana sekurang-kurangnya dua pihak (pesakit dan doktor) berkongsi maklumat dan nilai-nilai dalam usaha untuk membina konsensus mengenai rawatan pilihan. Nilai-nilai pesakit adalah elemen yang paling disebut dalam takrif SDM. Walau bagaimanapun, tidak ada definisi yang jelas mengenai nilai-nilai pesakit dalam SDM dan bidang "*medical decision making*". Oleh itu, kajian ini bertujuan untuk membangunkan satu model nilai-nilai pesakit menggunakan permulaan insulin dalam diabetes jenis 2 sebagai contoh.

Kaedah kajian: Kajian ini menggunakan siasatan induktif bersifat kualitatif berdasarkan kaedah "*interpretive descriptive*". Data dikumpulkan dari kedua-dua professional penjagaan kesihatan (PPK) dan pesakit. Rangka kerja konsep yang digunakan adalah *Ottawa Decision Support Framework* (PPK) dan *Schwartz et al's Theory of Human Values* (pesakit). Persampelan bertujuan telah digunakan untuk memilih PK yang terlibat dalam permulaan insulin dan pesakit yang membuat keputusan mengenai insulin. Data dikumpulkan melalui temu bual secara mendalam dan perbincangan kumpulan fokus di antara Januari 2011 hingga Jun 2012. Data dianalisis menggunakan analisis tema (PPK) dan kaedah pengekodan Strauss (pesakit).

Keputusan: 41 PPK ditemubual (usia 30-66 tahun; perempuan, n = 31). Sampel adalah berbeza dari segi latar belakang profesional (doktor am/ pegawai perubatan, pakar perubatan keluarga, pembuat polisi kerajaan, jururawat pendidik diabetes, ahli endokrinologi dan ahli farmasi), sektor kesihatan (awam, swasta) dan kumpulan etnik

(Melayu, Cina, India, etnik lain). 21 orang pesakit telah ditemubual (usia 28-67 tahun; lelaki, n = 12) dari pelbagai latar belakang etnik dan sektor kesihatan (hospital universiti berasaskan klinik penjagaan utama, n = 7; klinik kesihatan awam, n = 8; klinik swasta, n = 6). 10 orang pesakit berminat untuk memulakan insulin, 8 tidak berminat, seorang belum membuat keputusan, dan 2 orang pesakit telah ditemubual selepas memulakan insulin.

Pelbagai halangan dan fasilitator untuk permulaan insulin telah dikenal pasti. Halangan terdiri daripada halangan pesakit (contohnya halangan yang berkaitan dengan suntikan, halangan yang berkaitan dengan insulin, faktor-faktor sosial, halangan emosi peribadi), halangan PK (contohnya kekurangan motivasi HCP dan keyakinan, kekurangan latihan, nasihat bercanggah antara PK), dan halangan berkaitan dengan sistem .

Seterusnya, nilai-nilai pesakit semasa permulaan insulin telah dikaji. Pesakit mengenal pasti pelbagai kepercayaan tentang insulin yang positif atau negatif. Pesakit menyatakan bagaimana matlamat kehidupan peribadi (seperti kesihatan, kerjaya, kewangan) dan falsafah (contohnya mengelak penderitaan, fatalisme, tidak membebankan orang lain) mempengaruhi keputusan mereka. Akhir sekali, pesakit menggambarkan bagaimana nilai-nilai sosio-budaya (contohnya ajaran-ajaran agama, amalan budaya) dan latar belakang keluarga berkaitan dengan keputusan mereka tentang insulin. Akhirnya, model nilai-nilai pesakit telah dibangunkan berdasarkan tiga kategori nilai-nilai pesakit.

Kesimpulan: Apabila menyokong pesakit dalam membuat keputusan, doktor perlu menerokai lebih daripada sekadar kepercayaan tentang rawatan. Pemahaman yang lebih mendalam tentang matlamat hidup pesakit dan latar belakang sosio budaya adalah penting kerana ini juga mempengaruhi keputusan mengenai rawatan. Model nilai-nilai pesakit yang dicadangkan membantu menjelaskan definisi nilai-nilai pesakit dalam

SDM dan boleh digunakan oleh PK untuk meneroka secara sistematik nilai-nilai pesakit dalam perundingan.

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List of symbols and abbreviations

<u>Abbreviation</u>	<u>Full Text</u>
CJ/ NCJ	Chirk Jenn (Ng)
DMIT	Decision Making in Insulin Therapy (Project)
EBM	Evidence Based Medicine
EM	Ee Ming (Khoo)
GP	General practitioner
HCP	Healthcare Professional
IDI	In-depth Interview
IPDAS	International Patient Decision Aids Standards
KL	Khatijah Lim Abdullah
NGO	Non-governmental organization
NSP-NCD	National Strategic Plan for Non-Communicable Diseases
ODSF	Ottawa Decision Support Framework

PANDAs	Patients ANd Decision Aids
PDA	Patient Decision Aid
PIS	Participant Information Sheet
PY/ LPY	Ping Yein Lee
SA	Syahidatul Akmal Azmi
SDM	Shared decision making
SMBG	Self Monitoring of Blood Glucose
UKPDS	United Kingdom Prospective Diabetes Study
UMMC-MEC	University Malaya Medical Center-Medical Ethics Committee
WY/ LWY	Wah Yun (Low)
YK/ LYK	Yew Kong (Lee)
y.o.	years old

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List of publications and manuscripts

List includes all publications produced in the period of study (Oct 2010- Sept 2013). Asterisk under ‘Status’ () indicates publications included in this thesis.*

<u>Title</u>	<u>Status</u>
Lee, Y.K., Lee, P.Y. & Ng, C.J. (2012). A qualitative study on healthcare professionals' perceived barriers to insulin initiation in a multi-ethnic population. <i>BMC Family Practice</i> , 13, 28 (ISI-Cited Publication)	Published*

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Lee YK , Lee PY, Ng CJ. (2013). Tactics in counselling patients to start insulin. <i>Diabet Med</i> , 30, 373–374 (ISI-Cited Publication)	Published*
Lee, Y. K. , C. J. Ng, <i>et al.</i> (2013). "What are the barriers faced by patients using insulin? A qualitative study of Malaysian health care professionals' views." <i>Pt Pref Adherence</i> , 2013(7), 103-109. (ISI-Cited Publication)	Published
Ng CJ, Lee YK , Lee PY, Abdullah KL. (2013). Health innovations in patient decision support: Bridging the gaps and challenges. <i>Australas Med J</i> , 6(2), 95-9. (Pubmed-Cited Publication)	Published
CJ Ng, PY Lee, YK Lee , BH Chew, JP Engkasan, ZI Irmi, NS Hanafi, SF Tong. An overview of patient involvement in healthcare decision-making: A situational analysis of the Malaysian context. <i>BMC Health Serv Res</i> , 13(1), 408.(ISI-Cited Publication)	Published*
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CJ Ng, PSM Lai, YK Lee , SA Azmi. Barriers and Facilitators to Starting Insulin in Patients with Type 2 Diabetes: A Systematic Review. <i>To be submitted.</i>	Manuscript*
YK Lee , WY Low, CJ Ng. Factors influencing decision-making role preferences: A qualitative study of Malaysian patients with type 2 diabetes during insulin initiation. <i>To be submitted.</i>	Manuscript*

List of awards and travel scholarships

Awards

- **Universiti Malaya Three Minute Thesis (UM3MT) 2013 Competition Faculty Level 1st Prize:**
YK Lee. Developing a model of patient values in medical decision making: A qualitative inquiry into insulin initiation in type 2 diabetes, University of Malaya Three Minute Thesis Faculty Level Competition, 19 July 2013, Faculty of Medicine.
- **Universiti Malaya Three Minute Thesis (UM3MT) 2013 Competition University Level 1st Prize:**
YK Lee. Developing a model of patient values in medical decision making: A qualitative inquiry into insulin initiation in type 2 diabetes, University of Malaya Three Minute Thesis University Level Competition, 23 August 2013, Faculty of Medicine.
- **Asia Pacific Primary Care Research Conference (APPCRC) 2012 Rajakumar Award- Best Overall Paper:**
PY Lee, YK Lee, CJ Ng. Negotiating with patients about insulin initiation, 4th Asia Pacific Primary Care Research Conference 2012, 1-2 Dec 2012, National University of Singapore, Singapore.
- **Diabetes Asia 2012 Best Oral Presentation Award:**
CJ Ng, PY Lee, YK Lee. What happens during insulin counselling? A consultation blackbox. “Diabetes Asia 2012” Conference & Workshop, 17-21 Oct 2012, Hotel Istana, Kuala Lumpur.
- **APPCRC 2012 Best Poster Merit Award:**
YK Lee, PY Lee, CJ Ng. Involving family during insulin initiation: Views from the Malaysian healthcare professionals, 4th Asia Pacific Primary Care Research Conference 2012, 1-2 Dec 2012, National University of Singapore.
- **APPCRC 2011 2nd Prize Poster Award:**
YK Lee, PY Lee, Syahidatul Azmi, CJ Ng. Insulin myths: Healthcare professionals views of patients perceptions towards insulin therapy, 3rd Asia Pacific Primary Care Research Conference 2011, 03 Dec 2011 to 04 Dec 2011, Asia Pacific Primary Care Research Network, Kuala Lumpur.

Travel scholarships

- **Society of Medical Decision Making 2012 International Travel Scholarship Award:**
34th Annual Meeting of the Society of Medical Decision Making, 17-20 October 2012, Hyatt Regency Phoenix, Arizona.
- **Association of Commonwealth Universities Commonwealth Residential School 2013 Reserve Candidate Selection Shortlist:**
Commonwealth Residential School: The World in 2113, 8-12 August 2013, Cumberland Lodge, Windsor Great Park, United Kingdom

List of presentations

List includes all conference presentations in the period of study (Oct 2010- Sept 2013).

Workshop/ Symposium/ Oral

- **YK Lee**, WY Low, CJ Ng. Culture & SDM: How Patient's Values Influence Preference Mapping During Insulin Initiation, in Symposium "Culture & SDM", 7th International Shared Decision Making Conference "Pacientes-@ The Centre of Healthcare", 14-16 June 2013, International Shared Decision Making Conference, Lima.
- CJ Ng, **YK Lee**. Culture & SDM: Developing a patient decision aid for a multi-ethnic setting- Lessons for the Malaysian Insulin Patient Decision Aid, 7th International Shared Decision Making Conference "Pacientes-@ The Centre of Healthcare", 14-16 June 2013, International Shared Decision Making Conference, Lima.
- CJ Ng, **YK Lee**, PY Lee, Khatijah LA, EM Khoo, WY Low, Azah AS, WS Chen, Azmi SA. Development of a patient decision aid for patients with diabetes: A systematic approach, 7th International Shared Decision Making Conference "Pacientes-@ The Centre of Healthcare", 14-16 June 2013, International Shared Decision Making Conference, Lima.
- **YK Lee**, WY Low, CJ Ng. Decision-making role preferences in patients with type 2 diabetes during insulin initiation, 7th International Shared Decision Making Conference "Pacientes-@ The Centre of Healthcare", 14-16 June 2013, International Shared Decision Making Conference, Lima.
- CJ Ng, PY Lee, **YK Lee**, N Mathers. Helping Your Patients to Make an Informed Decision: A Shared Decision Making Approach, 19th WONCA Asia Pacific Regional Conference- Clinical Excellence in Family Medicine: Evidence-based Approach in Primary Care, 25 May 2012 to 25 May 2012, World Association of Family Doctors (WONCA), Jeju.
- PY Lee, **YK Lee**, CJ Ng. Negotiating with patients about insulin initiation, 4th Asia Pacific Primary Care Research Conference 2012, 1-2 Dec 2012, National University of Singapore, Singapore. (Rajakumar Award- Best Overall Paper)

- CJ Ng, PY Lee, **YK Lee**. What happens during insulin counselling? A consultation blackbox. “Diabetes Asia 2012” Conference & Workshop, 17-21 Oct 2012, Hotel Istana, Kuala Lumpur. (Best Oral Presentation Award)

Posters

- PY Lee, **YK Lee**, EM Khoo, WY Low, Khatijah LA, WS Chen, Azah AS, Azmi SA, CJ Ng. Expert Panel Feedback: An Important Step in the Development of Patient Decision Aids. 7th International Shared Decision Making Conference “Pacientes-@ The Centre of Healthcare”, 14-16 June 2013, International Shared Decision Making Conference, Lima.
- Khatijah LA, **YK Lee**, PY Lee, EM Khoo, WY Low, WS Chen, Azah AS, Azmi SA, CJ Ng. Development and Evaluation of a Shared Decision Making Training Workshop for Health Care Professionals in Primary Care in Malaysia. 7th International Shared Decision Making Conference “Pacientes-@ The Centre of Healthcare”, 14-16 June 2013, International Shared Decision Making Conference, Lima.
- **YK Lee**, CJ Ng, WY Low. Patient Values in EBM: A Case of Insulin Initiation in Type 2 Diabetes, 19th WONCA Asia Pacific Regional Conference- Clinical Excellence in Family Medicine: Evidence-based Approach in Primary Care, 25 May 2012 to 25 May 2012, World Organization of Family Doctors (WONCA), Jeju.
- **YK Lee**, PY Lee, CJ Ng. Involving family during insulin initiation: Views from the Malaysian healthcare professionals, 4th Asia Pacific Primary Care Research Conference 2012, 1-2 Dec 2012, National University of Singapore. (Best Poster Merit Award)
- **YK Lee**, PY Lee, Syahidatul Azmi, CJ Ng. Insulin myths: Healthcare professionals views of patients perceptions towards insulin therapy, 3rd Asia Pacific Primary Care Research Conference 2011, 03 Dec 2011 to 04 Dec 2011, Asia Pacific Primary Care Research Network, Kuala Lumpur (2nd Prize Poster Award)
- PY Lee, **YK Lee**, Syahidatul Azmi, CJ Ng. What are the tools and gadgets that healthcare professionals use to facilitate insulin initiation in patients with type 2 diabetes?, 3rd Asia Pacific Primary Care Research Conference 2011, 03-04 Dec 2011, Asia Pacific Primary Care Research Network, Kuala Lumpur.
- **YK Lee**, PY Lee, Syahidatul Azmi, CJ Ng. What are the strategies used by healthcare professionals to improve the practice of insulin initiation?, National Diabetes Conference 2011, 8 -9 Jul 2011, Persatuan Diabetes Malaysia, Kuala Lumpur.
- PY Lee, **YK Lee**, Syahidatul Azmi, CJ Ng. Why are patients hesitant to start insulin? Healthcare Professionals Views, National Diabetes Conference 2011, 8 -9 Jul 2011, Persatuan Diabetes Malaysia, Kuala Lumpur.
- **YK Lee**, PY Lee, CJ Ng. Sharing a decision vs Shared Decision Making: What's the difference? 6th International Shared Decision Making Conference. "Bridging the gap between research and practice: patient pull or clinician push?" 19-22 Jun 2011, Maastricht University, Maastricht.
- CJ Ng, PY Lee, **YK Lee**. Whose choice? Patient, Healthcare Professional or

Family? – Views of Malaysian Healthcare Providers, 6th International Shared Decision Making Conference. "Bridging the gap between research and practice: patient pull or clinician push?" 19-22 Jun 2011, Maastricht University, Maastricht.

- PY Lee, CJ Ng, **YK Lee**. Improving service delivery of insulin initiation: Views of Health Care Professionals, "Diabetes Asia 2012" Conference & Workshop, 17-21 Oct 2012, Hotel Istana, Kuala Lumpur.

Chapter 1

Introduction

Chapter 1: Introduction

The focus of this thesis is on exploring the role of patient values in shared decision making (SDM), using insulin initiation in patients with type 2 diabetes as an exemplar. The papers compiled in this thesis were published from data collected as part of the Decision Making in Insulin Therapy (DMIT) Project (see Appendix A for an overview of the project's aims, methods and research team). This 3-year project aimed to develop a patient decision aid (PDA) for use during insulin initiation and was conducted in Malaysia, an ethnically diverse country located in South East Asia. Some data from this thesis was used to inform the values elicitation section of the PDA and also the accompanying Trainer's Guide.

This chapter introduces the concept of SDM, which forms the overarching paradigm in which patient values are investigated. SDM is a component of medical decision making, whereby medical decision making includes the various types of decisions that are made in the various disciplines (e.g. health economics, decision psychology, and health policy and systems research) and levels (individual consultations, local practice settings and policies, and global health). SDM is a model of medical decision making which is multi-disciplinary (e.g. decision psychology, medical ethics, evidence-based practice) and is practiced at the level of individual patient-doctor consultations.

Next, reasons are given for the focus on the concept of patient values within SDM and why insulin initiation serves as a good exemplar in which to explore patient values.

Lastly, Malaysia's unique multi-cultural society and dual-sector healthcare system is described for the benefit of readers who are unfamiliar with Malaysia. As an introduction to SDM in Malaysia, a situational analysis on the current state of patient involvement in SDM is included after this chapter (refer to Chapter 2).

1.1 Introduction to shared decision making

Bensing (2000) wrote that the two main paradigms of modern medicine can be identified as “patient-centred medicine” and “evidence-based medicine (EBM)”.

Despite EBM appearing later in medical literature in 1992, as compared to the 1970's for patient-centeredness, the total number of papers discussing EBM is almost three times as much as the number of papers discussing “patient-centred medicine” (Bensing, 2000).

EBM appeals strongly to healthcare professionals (HCPs) because this approach enables them to combine both individual expertise with best external evidence and the output is the best health decision option for their patients (Bensing, 2000). However, EBM is criticised as being too disease-centered owing to a *biomedical* approach and its reliance on randomised controlled trials (RCTs) as the gold standard for decision making (Bensing, 2000). On the other hand, patient-centered medicine uses a *biopsychosocial* model that focused on the needs and preferences of the patient, but was criticised for not having any theory or evidence to guide understanding of what these needs and preferences might be (Bensing, 2000). Efforts to address these criticisms include incorporation of patient values as a component of EBM alongside best evidence and clinical experience (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000).

SDM is a medical practice model which aims to incorporate *both* evidence and patient values in medical decisions. The term ‘shared decision making’ is used fluidly and the model is still being refined. A systematic review of 161 articles which contained a conceptual definition of shared decision making, identified six key sources, whereby these six articles were cited by more than 5% of the other papers (Makoul & Clayman, 2006).

The review showed that over three decades, SDM grew from a conceptual model into a model with standards and concrete practices. Makoul *et al* (2006) developed an integrative model of SDM based on the six key sources (Table 1.2). Their framework lists the essential elements (which must be present for SDM to occur), ideal elements (which may enhance SDM, but are not necessary) and the general qualities of SDM (relatively general characteristics describing SDM). More recent developments in SDM include closer international collaborations such as establishing international standards for patient decision aids (PDAs) (International Patient Decision Aids Collaboration, 2006, 2012) and developing simplified SDM practice models and tools (Elwyn *et al.*, 2012).

Table 1.1: The development of the SDM model (1982-2003)

Year	Authors	Source document	Main points	Key development
1982	14 member presidential committee	United States (1982). President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. <i>U S Code Annot U S Title 42 Sect. 300v as added 1978.</i>	<ul style="list-style-type: none"> • Focus of the report was on informed consent in the patient-doctor relationship • First time the term shared decision making mentioned • Defined SDM as the ethical relationship between doctor and patient • The commission called for more research on formalizing shared decision making 	First time SDM was mentioned
1997	Charles, Gafni, <i>et al.</i>	Charles, Gafni, <i>et al.</i> (1997). Shared Decision-Making in the Medical Encounter: What Does it Mean? (Or it Takes at Least Two to Tango). <i>Soc. Sci. Med.</i> 44(5), 681-692.	<ul style="list-style-type: none"> • Defined SDM as a medical practice model by comparing it against paternalism, the informed model and doctor-as-agent. • Defined shared decision making as involving four criteria: • At least two participants- doctor and patient must be involved • Both parties (doctors and patients) take steps to participate in the process of treatment decision-making • Information sharing is a prerequisite to SDM • That an agreement is reached on the treatment to be implemented 	Identified four key criteria for defining SDM

Table 1.1, continued

1999	Charles, Gafni, <i>et al.</i>	Charles, Gafni, <i>et al.</i> (1999). Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. <i>Soc Sci Med</i> 49(5), 651-661.	<ul style="list-style-type: none"> • Emphasized the process of SDM • Identified three stages in the consultation • Information exchange (flow, direction, type of information, amount) • Deliberation (Both physician and patient, including significant others, are involved in making the decision) • Deciding on treatment to implement (Both physician and patient make the decision) 	Identified the processes involved in SDM
1999	Towle and Godolphin	Towle, & Godolphin. (1999). Framework for teaching and learning informed shared decision making. <i>BMJ</i> 319(7212), 766-771.	<ul style="list-style-type: none"> • Defined the skills needed for practice of SDM • Listed eight doctor competencies and seven patient competencies needed for informed shared decision making. 	Identified the HCP and patient skills (competences) needed for SDM
1999	Coulter <i>et al</i>	Coulter, Entwistle, <i>et al.</i> (1999). "Sharing decisions with patients: is the information good enough?" <i>BMJ</i> 318(7179), 318-322.	<ul style="list-style-type: none"> • Emphasized the need to bridge conceptual and actual practice of SDM • Advocated patient decision aids as a tool for practical implementation of SDM 	Emphasize the need to develop practical ways to implement SDM
2003	Elwyn <i>et al</i>	Elwyn, Edwards, <i>et al.</i> (2003). Shared decision making: developing the OPTION scale for measuring patient involvement. <i>Qual & safety in healthcare</i> 12(2), 93-99.	<ul style="list-style-type: none"> • Created the 12-item OPTION scale for measuring SDM 	Develop a measure for SDM

Table 1.2 An integrated model of SDM

Essential elements	Ideal elements	General qualities
<ol style="list-style-type: none"> 1. Define/explain problem 2. Present options 3. Discuss pros/cons (benefits/risks/costs) 4. Patient values/preferences 5. Discuss patient ability/self-efficacy 6. Doctor knowledge/recommendations 7. Check/clarify understanding 8. Make or explicitly defer decision 9. Arrange follow-up 	<ol style="list-style-type: none"> 1. Unbiased information 2. Define roles (desire for involvement) 3. Present evidence 4. Mutual agreement 	<ol style="list-style-type: none"> 1. Deliberation/negotiation 2. Flexibility/individualized approach 3. Information exchange 4. Involves at least two people 5. Middle ground 6. Mutual respect 7. Partnership 8. Patient education 9. Patient participation 10. Process/stages

Source: Makoul & Clayman, 2006

1.2 Patient values in shared decision making

Makoul & Clayman noted in their review that the most commonly mentioned element in SDM was “patient values/ preferences” (Makoul & Clayman, 2006). In the President’s Commission, patient values were mentioned numerous times, often clustered with “goals”, “attitudes” and/or “preferences” (United States, 1982). The term ‘patient values’ in the President’s Commission was used to explain the two principles of informed consent, which are subjective patient well-being and patient self-determination. In subjective patient well-being, patient’s values were the subjective criteria on which the patient would choose the best health option according to their perspective. In patient self-determination, the patient should be allowed to choose their preferred medical option after weighing the risks and benefits according to their values. This early example indicates the centrality of values in determining patient participation in healthcare decisions. However, no specific examples or definitions were provided on what values were.

Charles *et al.* discussed patient values as a necessary step in SDM which went beyond just eliciting patient preferences i.e. stating which option was preferred (Charles, Gafni, & Whelan, 1997). Instead, sharing the decision process with patients meant “eliciting patient preferences so that treatment options discussed are compatible with the patient's lifestyle and values” (Charles, Gafni, & Whelan, 1997). However, again, no specific definition or example was given on what was meant by patient values.

In 1999, the list of characteristics that patients would bring to the consultation was further expanded as “beliefs, values, fears, illness experiences and, increasingly, information about various treatment options” (Charles, Gafni, & Whelan, 1999).

Charles *et al.* stated that values and beliefs functioned as the filter for the amount of information received and how this information was interpreted (pg 655, Charles, Gafni, & Whelan, 1999).

Towle and Godolphin acknowledged that one of the competencies needed by doctors to practice SDM was to “...help patients to reflect on and assess the impact of alternative decisions with regard to his or her values and lifestyle” (pg 767, Towle & Godolphin, 1999). This use of the term values was similar to Charles *et al.* in saying that decisions should be compatible with a patient's values (Charles, *et al.*, 1997). However, no definition or example of patient values was given.

Coulter *et al.* did not mention patient values in their checklist of patient information material for SDM. However, they acknowledged that “Patients whose doctors are ignorant of their values and preferences may receive treatment that is inappropriate to their needs” (Coulter, Entwistle, & Gilbert, 1999).

For Elwyn *et al.*, their OPTION checklist did not include mention of patient values (Elwyn *et al.*, 2003). However, the checklist included these other patient perspectives: expectations, concerns and understanding of information.

Thus, even though patient values were the most commonly mentioned element of SDM, a search of the main sources for defining SDM reveals that there is no clear definition of the term, much less a consensus or a discussion on what values are. Specific discussion on patient values in SDM is located in literature on value clarification exercises, which are considered a necessary component of PDAs by the International Patient Decision Aids Collaboration (IPDAS) (International Patient Decision Aids Collaboration, 2012).

The 2012 update to the value clarification section in the IPDAS documents points out that most research on value clarification has not focused on patient values per se, but more on the use of value clarification methods (Fagerlin *et al.*, 2012). These methods include considering pros and cons, utility assessment, prioritization and rating scales. Researchers have recognised that values clarification (insight into what a patient considers important) is different from preference elicitation (asking the patient to state their preference) and that some gaps exist in understanding values clarification (Llewellyn-Thomas & Crump, 2013).

These gaps include a lack of research on implicit value clarification, a weak theory base and poor understanding of how patients themselves naturally evaluate healthcare options (Fagerlin *et al.*, 2012). In the 2012 update of the IPDAS chapter “Clarifying and Expressing Values”, the following points are noted in the authors’ definition of values clarification (Fagerlin, *et al.*, 2012):

- 1) Although values clarification can be understood to be implicit (the patient considers what is important to them) or explicit (the patient uses a structured method such as a rating scale to determine the importance of each option), the explicit clarification methods are better understood as more research evidence is available.
- 2) No definition of patient values is given in the chapter and only one theory (Fuzzy Trace Theory) from a theory base of seven theories mentions the need to help patients retrieve relevant values.
- 3) Implicit values clarification based on intuitive patient decision processes is little understood although evidence indicates that such intuitive processes may be just as accurate as explicit value clarification in integrating and reflecting a large amount of information.

1.3 Research gaps in patient values

From the section above, there are two areas in which gaps in research exist for patient values in SDM. Firstly, there is no clear definition of patient values in the literature.

Although commonly mentioned as being an essential part of SDM, none of the sources above provided a clear definition of the characteristics and scope of patient values.

Charles *et al* have pointed out that current definitions of SDM are subject to many underlying, unclear assumptions (Charles, Gafni, Whelan, & O'Brien, 2005). A clear definition of patient values is one of these assumptions.

Secondly, little is understood about how values intuitively influence patient decisions.

In order to capture real-life examples of how values work, data should be based on patients' actual decisions, rather than hypothetical scenarios. This data should be analysed in light of the larger cultural context and the practice background within which

decisions are made. The former is important as values differ from culture to culture and there is a need to explore cultural values in order to adapt SDM to the local cultural context (Charles, Gafni, Whelan, & O'Brien, 2006).

1.4 Patient values in insulin initiation

A good decision is defined as one that is “informed, consistent with personal values, and acted on and in which participants express satisfaction with decision making” (O'Connor, *et al.*, 1999). Decisions that depend on patient values cannot be judged on the basis of clinical outcomes alone, as good decisions can sometimes result in bad clinical outcomes due to the range of variables and odds that affect outcomes (O'Connor, Mulley, & Wennberg, 2003). This thesis uses insulin initiation in type 2 diabetes as an exemplar of patient values in medical decision making. Insulin initiation is a preference-sensitive medical decision which is influenced by patient (as well as HCP) values. A preference-sensitive medical decision is defined as a medical choice in which there is no single best option due to insufficient evidence about outcomes or a need to trade off known benefits and harms (Stacey, *et.al*, 2011).

In terms of health outcomes, insulin is the best option to lower risk of developing diabetes complications. However, patients may consider the risks of side effects and other negative outcomes of insulin such as socio-cultural stigma to outweigh the benefits from a quality of life perspective and may choose to delay insulin initiation. Also, tension may exist between HCP and patient values; the HCP may prioritise health outcomes, whilst patients may consider quality of life to be more important. This makes insulin initiation a preference-sensitive decision.

A preference-sensitive choice is influenced by a wider set of background factors (besides medical risks and benefits). In order to investigate patient values in insulin initiation, it was important to understand the process of insulin initiation in the Malaysian context. Data was collected on the range of factors influencing insulin initiation. This data framed the decisional context in which values in patient decision making were to be investigated. An understanding of the background of insulin initiation (e.g. barriers, available options, and healthcare system) was incorporated into patient interview topic guides (as prompts), thereby helping to inform the investigation of patient values.

1.5 Research question and research objectives

1.5.1 Research question

My research question can be stated as:

What are patient values in medical decision making, using insulin initiation in type 2 diabetes as an exemplar?

1.5.2 Research objectives

There were three research objectives in this study which aimed to answer the research question stated above. An inductive approach was used whereby insulin-specific beliefs were explored before a general model of patient values was developed.

1) To identify factors influencing insulin initiation in Malaysia.

Insulin initiation is a complex decision influenced by a variety of beliefs. In order to understand the medical context and healthcare system in which patients values are to be investigated, the first objective of the study was to identify the

range of factors which influence insulin initiation, which include patient, HCP and system factors. Data was collected from patient, HCP and policy maker perspectives on the barriers and facilitators to insulin initiation. A systematic review of barriers and facilitators was conducted on the medical literature. This overview provided an understanding of the medical, cultural and health system contexts in which patient values were investigated.

2) To explore patient values amongst type 2 diabetes patients in Malaysia who are making a decision about starting insulin

This objective focused on identifying values which influenced patients' decisions about insulin. The implicit and intuitive influence of values on patient decisions using insulin initiation as an exemplar was explored.

3) To develop a model of patient values in SDM

Lastly, using the examples and themes of values derived from patient decisions about insulin, a model of patient values for use in SDM was developed.

1.6 Research background: Malaysia

The following section describes the socio-cultural environment and health system of Malaysia. The research is conducted and analysed in light of the environment described here.

1.6.1 Malaysia's sociocultural and socioeconomic context

Malaysia is a culturally and linguistically diverse country located in Southeast Asia (Figure 1.1). The country comprises 13 states and 3 federal territories, distributed between a peninsular and the island of Borneo. In June 2012, its population totalled 29.3

million (Department of Statistics Malaysia, 2012). Malaysia's population consists of three main ethnic groups (Malays, Chinese and Indians) and numerous other smaller ethnicities (refer to Figure 1.2). The main ethnic group are the 'Bumiputeras' (indigenous people) consisting of Malays and other Bumiputeras, who total 62% of the total population. There are a sizable number of non-citizen residents in the country (8%), who are mostly lower-wage foreign workers.



Figure 1.1: Map of Malaysia
Source: Central Intelligence Agency

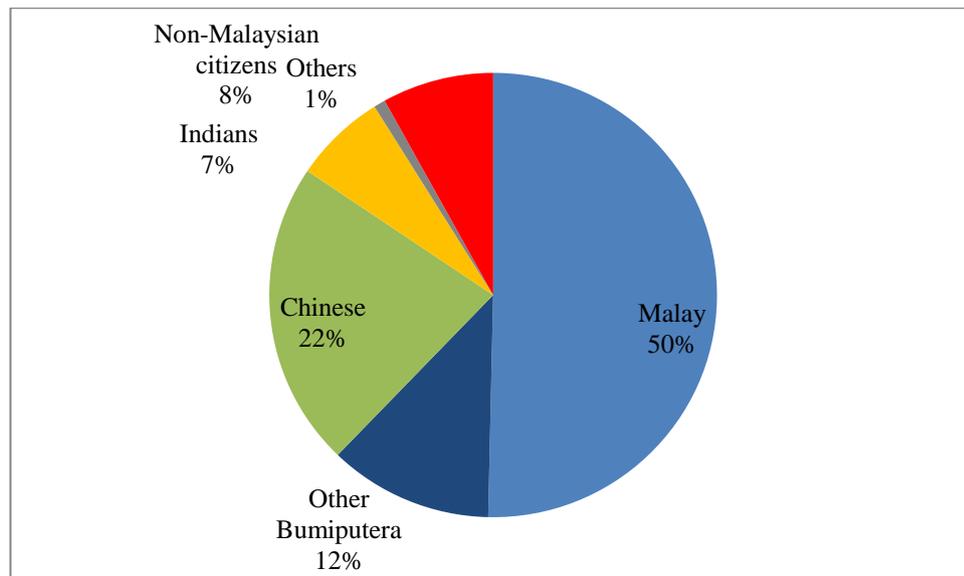


Figure 1.2: Population of Malaysia
Source: Department of Statistics Malaysia, 2012

Islam is the most commonly professed religion (61.3%). However, significant populations of Buddhists (19.8%), Christians (9.2%) and Hindus (6.3%) exist (Department of Statistics Malaysia, 2010). The official, and most widely spoken, language is Malay, but English, Chinese (Mandarin) and Indian (Tamil) are also spoken. A variety of Chinese, Indian and indigenous dialects are found in various communities in Malaysia. This melting pot of cultures influences healthcare practices in the country in various ways. For example, HCPs must navigate issues such as language and communication barriers, dissonant religious beliefs, common use of complementary and traditional medicine and cultural beliefs about health. Swami *et al* (2009), sampling 371 women and 350 men using the Health and Illness Scale to explore lay perceptions of determinants of health status, concluded that although Malaysians have a general belief structure similar to the West, significant differences in health beliefs were found between religious groups.

Economically, the World Bank (2012) classifies Malaysia as an upper-middle income country as it has a 2011 per capita income of USD 8420. The mean monthly household income of Malaysia was RM 4029 (USD 1243) in 2009 (Department of Statistics Malaysia, 2009). Income distribution is unequal between states, with the administrative and economic centres of Wilayah Persekutuan (W.P.) Putrajaya, W.P. Kuala Lumpur and Selangor having roughly triple (RM 5488- 6747/ USD 1693-2081) the mean monthly household income of the lowest three states (RM 1713-1966/ USD 528-606) (Department of Statistics Malaysia, 2009). The poverty rate in Malaysia has declined from 8.5% in 1999 to 3.8% in 2009 (Department of Statistics Malaysia, 2009).

1.6.2 Malaysia's dual-sector healthcare system

Malaysia has a dual-sector healthcare system comprising government-subsidised universal public healthcare facilities and fee-for-service private healthcare clinics and hospitals. Free or nominal-fee healthcare is provided in primary care through a network of health clinics ('Klinik Kesihatan') throughout the country. These clinics would refer patients with more severe conditions to tertiary hospitals located in the major towns or cities. Majority of the population is treated in public facilities as costs are lower and the government maintains a network of health clinics especially in states and areas where the density of both public and private primary care clinics in Malaysia is less than the national average of 2.09 clinics per 10000 persons (Clinical Research Centre, 2011). In 2009, there were 806 public health clinics and 5104 private primary care clinics in the country (Clinical Research Centre, 2011). The national doctor to population ratio in Malaysia was 1: 791 in 2011 (Health Informatics Centre Planning and Development Division, 2012).

In primary care, the private sector comprises mostly solo general practice clinics (Ramli & Taher, 2008) while public primary care consists of government health clinics and university-based primary care clinics. There are about five times more private primary care clinics compared to the public sector in Malaysia (Clinical Research Centre, 2011). Primary care practice is expected to play a gatekeeper role for secondary care referrals (Clinical Research Centre, 2011).

Beginning with the 1990s, the number of private hospitals began to rise in the urban centres as affluent patients could afford the higher fees charged at these hospitals and they would be able to avoid the long waiting lists associated with specialist treatment in public hospitals. The decade since the millennium has seen the growth of large healthcare conglomerates which own and operate more than one hospital. Chee (2008) has reported that between 1980 and 2003, the number of private hospital beds increased nine times and he foresees that the dual trends of increasing private beds and government-backed medical tourism initiatives will lead to a segmented healthcare industry where the well-heeled local and foreign private clientele will be treated privately. One result of this demand is an exodus of specialists from the public to the private. Estimates are that 60% of specialists in the country operate in private facilities (Prime Minister's Department, 1993).

Addressing long-term finance and access issues is important in light of Malaysia's increasing lifestyle-related disease prevalence. Between 1996 and 2006, Malaysia reported a 43% increase in hypertension, 88% increase in diabetes and a 250% increase in obesity (Ministry of Health, 2010a). Malaysia has the highest prevalence rate of type 2 diabetes (11.7%) in the Western Pacific region and this figure is projected to rise to 13.3% by 2030 (International Diabetes Federation, 2011). As such, healthcare policies

target increasing quality, capacity and coverage of the healthcare system and shifting the focus from disease treatment towards wellness and disease prevention (Ministry of Health, 2010a). The prevention and treatment of type 2 diabetes and cardiovascular disease are the two main thrusts of the integrated National Strategic Plan for Non-Communicable Disease (NSP-NCD) Medium Term Strategic Plan 2010-2014 (Ministry of Health, 2010b).

1.6.3 Policies related to type 2 diabetes and insulin in Malaysia

Policies related to diabetes are divided into strategic plans and clinical practice guidelines. Diabetes was the first non-communicable disease in Malaysia to be targeted with a disease-specific plan in the 1980s when the National Diabetes Programme was launched following the results of the first National Health and Morbidity Survey in 1986 (Ministry of Health, 2010b). This was replaced in 2010 with the National Strategic Plan for Non-Communicable Disease (NSP-NCD) as the Ministry of Health acknowledged that traditional single-disease strategies are inadequate to target and control non-communicable diseases. Based on the WHO Western Pacific Regional Action Plan for Non-Communicable Diseases (WHO Western Pacific Regional Office, 2008), the NSP-NCD lists seven strategies to prevent and treat cardiovascular disease and diabetes: prevention and promotion; clinical management; increasing patient compliance; action with Non-governmental Organizations (NGOs), professional bodies and other stakeholders; monitoring, research and surveillance; capacity building; and policy and regulatory interventions (Ministry of Health, 2010b). Diabetes-specific activities are included under each of the seven strategies and are summarised under Table 1.3 (Ministry of Health, 2010b).

Table 1.3: Activities targeting diabetes under the seven NSP-NCD strategies

Strategy	Activities
Prevention and promotion	No diabetes-specific activities
Clinical management	<ol style="list-style-type: none">1. Equip all health facilities with minimum clinical equipment and tools for assessment and management of diabetes2. Create a system of supervision to ensure practice is in-line with Clinical Practice Guidelines and Standard Operating Procedures3. Reinforce importance of screening for diabetes-related complications4. Strengthen and expand rehabilitation services of diabetes-related complications
Increasing patient compliance	<ol style="list-style-type: none">1. Ensure all health facilities have an NCD Resource Centre staffed by appropriately trained diabetes educators or suitably trained healthcare personnel2. Make available subsidised glucostrips for Self-Monitoring of Blood Glucose (SMBG)
Action with NGOs, professional bodies and other stakeholders	No diabetes-specific activities
Monitoring, research and surveillance	<ol style="list-style-type: none">1. Implement a system to monitor degree of control and quality of management of diabetes patients2. Nation-wide implementation of National Diabetes Registry3. Encourage research in diabetes in aspects of:<ol style="list-style-type: none">a. Health economics of population based interventionsb. Novel approaches for behavioural modificationsc. Novel approaches for clinical management
Capacity building	No diabetes-specific activities
Policy and regulatory interventions	No diabetes-specific activities

Source: Ministry of Health, 2010b

Insulin can only be prescribed by doctors in Malaysia and can be initiated at either primary or secondary care settings. Nurse educators play an important role in the public sector as doctors would refer patients to the nurses for education and instruction after

prescribing insulin. On the other hand, private doctors often seek help from diabetes educators, who are sponsored by pharmaceutical companies or non-governmental organizations (Lee, Lee, & Ng, 2012).

The Malaysian clinical practice guideline (CPG) for type 2 diabetes was last updated in 2009 and insulin therapy was stated as part of the treatment algorithm (Ministry of Health, 2009). However, there was no mention of how insulin initiation could be implemented in the local healthcare setting. Recognising this gap, a practical guide for insulin therapy was developed in 2010 and a section was dedicated specifically to addressing patients' barriers to insulin initiation (Ministry of Health, 2010c). However, the recommendations are based on Western data and experts' opinions.

1.7 Conclusion

Patient values are a crucial, yet understudied component of SDM, with a lack of research based on actual patient decisions. This study seeks to explore the patient values which influence insulin initiation are. This information will help to how these values work to influence the patient decision and clarify the range of values which should be elicited during values clarification. Insulin initiation is a good exemplar for investigating patient values as it is a preference-sensitive trade-off between the risks and benefits of insulin and other treatment options. In Malaysia, understanding why patients are reluctant to initiate insulin will help to address the lack of timely insulin initiation in patients with type 2 diabetes in a complex, multicultural, dual-sector healthcare setting.

Chapter 2.0: An overview of patient involvement in healthcare decision making: a situational analysis of the Malaysian context

The following paper presents an overview on the state of patient involvement in healthcare decision making in Malaysia. Using situational analysis, including a review of a local Malaysian journal database, the section introduces readers to the current state of SDM in Malaysia. The chapter reports how little emphasis or support was available for advocating that patients should be involved in their medical decisions.

This chapter contributes to the thesis by describing the current state of SDM in Malaysia whereby there is a clear lack of support for patient involvement in research, practice, policy and advocacy. Given this gap, there exists a potential to develop SDM as strategy to implement patient-centred care in Malaysia. Developing easily understood indigenous models (such as the proposed patient values model) for training of SDM skills and concepts will complement existing projects which produce SDM tools (such as the DMIT insulin choice PDA).

**Chapter 2.0: An overview of patient involvement in healthcare
decision-making: A situational analysis of the Malaysian context**

*Chirk Jenn Ng, Ping Yein Lee, Yew Kong Lee, Boon How Chew, Julia P Engkasan,
Zarina Ismail Irm, Nik Sherina Hanafi, Seng Fah Tong*

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Author contributions:

NCJ led the study, compiled and wrote the final manuscript. JPE, PYL, BHC, and SFT collected data on the medical syllabus and training. PYL reviewed official Web sites of government, non-governmental organisations and private healthcare facilities for public information on SDM. YKL conducted the literature review on SDM and patient involvement in Malaysia. ZII reviewed legislation related to SDM and patient involvement. NSH reviewed policies related to SDM and patient involvement. BHC conducted e-mail correspondence with national patient bodies to enquire about patient involvement and support.

YKL compiled reviewer comments and author corrections and oversaw revisions to the submission.

Abstract

Background

Involving patients in decision-making is an important part of patient-centred care. Research has found a discrepancy between patients' desire to be involved and their actual involvement in healthcare decision-making. In Asia, there is a dearth of research in decision-making. Using Malaysia as an exemplar, this study aims to review the current research evidence, practices, policies, and laws with respect to patient engagement in shared decision-making in Asia.

Methods

In this study, we conducted a comprehensive literature review to collect information on healthcare decision-making in Malaysia. We also consulted medical education researchers, key opinion leaders, governmental organisations, and patient support groups to assess the extent to which patient involvement was incorporated into the medical curriculum, healthcare policies, and legislation.

Results

There are very few studies on patient involvement in decision-making in Malaysia. Existing studies showed that doctors were aware of informed consent, but few practised shared decision-making (SDM). There was limited teaching of SDM in undergraduate and postgraduate curricula and a lack of accurate and accessible health information for patients. In addition, peer support groups and 'expert patient' programmes were also lacking. Professional medical bodies endorsed patient involvement in decision-making, but there was no definitive implementation plan.

Conclusion

In Malaysia, there is a lack of patient involvement in decision-making. More research and training are necessary to bridge this gap. The authors call for health authorities to develop a strategy to explore effective ways to implement SDM in Malaysia.

Background

Involving patients in decision-making is a good clinical practice and, in some countries, it is imperative for routine patient care (Coulter, Edwards, Elwyn, & Thomson, 2011; General Medical Council, 2009; Secretary of State for Health, 2010; Shared decision-making demonstration project). This forms part of patient-centred care and is increasingly considered to be the gold standard of medical care by the public, clinicians, and policy makers (Secretary of State for Health, 2010). There is growing evidence, suggesting that involving patients in decision-making helps improve their knowledge and healthcare experience and reduce health service utilisation and cost (Coulter & Jenkinson, 2005). The evidence also suggests that patients may modify their health behaviour and status after being involved in decision-making (Coulter & Jenkinson, 2005).

Focus on decision making has led to the development of the shared decision-making (SDM) model, whereby patient and doctor share information and values, and the patient plays an active role in healthcare decisions (Charles, Gafni, & Whelan, 1997; Makoul & Clayman, 2006). However the concept of SDM is interpreted differently in various social and cultural contexts. For example, a recent review found wide SDM practice and policy variations across 13 countries in the Middle East, Europe, and North and South America (Harter, Elwyn, & van der Weijden, 2011). Thus, implementing shared decision making remains challenging, even in countries where shared decision making is officially endorsed by government, such as the UK and USA (Barry, 2012; Coulter, *et al.*, 2011; Frosch *et al.*, 2011). Practising SDM is seen to be even more challenging in countries that have scarce healthcare resources and an overburdened healthcare system, which are common in Asia. Despite these challenges, there is a growing interest in SDM

globally in terms of “scope (as a component of patient-centred care) and spread (as a component of healthcare everywhere for everyone)” (International Shared Decision Making Conference 2013, 2013).

In Asia, there is limited knowledge of how the SDM concept has been, or could be, integrated into existing practice. At a micro level, little is known about the decision-making role preference of patients and physicians. At a macro level, it is uncertain whether the Western model of SDM is transferable to societies where healthcare decisions of individuals are strongly influenced by their families and communities (Ruhnke *et al.*, 2000). Asia is not a homogenous continent; for instance, healthcare decisions of Chinese, Japanese, and Vietnamese people are influenced by diverse concepts of harmony and filial piety, which originate from different religious or moral codes (McLaughlin & Braun, 1998). In 2005, Charles argued that SDM should not be practised without considering the cultural context, of a clinical consultation (Charles, Gafni, Whelan, & O'Brien, 2006). Studies with ethnic minorities in the West have identified the challenges in practising SDM, particularly in communities where the concept of SDM is foreign or non-existent (Katz *et al.*, 2011; Peek *et al.*, 2009; Searight & Gafford, 2005).

There is one assumption that people in the East prefer a more clinician-centred healthcare system, though there is a lack of evidence. A recent survey in Japan shows that patients want to be more involved in healthcare decision-making (Alden, Merz, & Akashi, 2011). Although there are still significant differences between Western and Asian cultures, globalisation and advancement of telecommunication have blurred distinctions significantly over the past two decades. Moreover, the overall improvement

in literacy rates and health awareness mean that public health expectations are rising in Asia (Benbassat, Pilpel, & Tidhar, 1998; Hirono Ishikawa & Eiji Yano, 2008).

Therefore, it is prudent and timely to review the current research evidence, practices, policies, and laws with respect to SDM in Asia. This article uses Malaysia, a multi-cultural Asian society, to exemplify the existing and emerging issues of SDM in the areas of education, clinical practices, and healthcare policies in Asia.

Malaysia has a population of 28.3 million and comprises three main ethnic groups: Malays (67.4%), Chinese (24.6%), Indians (7.3%), and others (0.7%) (Population and Housing Census of Malaysia, 2010). Malaysia is classified by the United Nations as an upper-middle income nation and has a dual sector (public and private) healthcare system. People pay a nominal fee for public health services, which are often overburdened and have long waiting times. On the other hand, the private health sector charges a fee for services and people can choose the hospital, clinic, and healthcare professionals. A multi-cultural society and a dual-sector health system in Malaysia provide an opportunity to study Asian patients' involvement in decision-making, using the SDM concept to analyse the structures that form decision-making practice and policy.

Methods

The authors met in July 2011 and came to consensus on five key areas, which reflect the condition of patient involvement in the Malaysian healthcare system. The five categories reviewed were (1) clinical training and education, (2) research, (3) patient information and support, (4) laws and regulations, (5) and health policies.

Study design

This study comprised of an environmental scan followed by group consensus methods. In the environmental scan, four sources were used to determine the status of patient involvement in Malaysia. The research group then met to discuss the findings and formulate strategies for increasing SDM in Malaysia.

Sources of data

As the study covers a wide range of objectives, a range of data sources were used to determine the status of patient involvement in decision making in Malaysia. These sources include (1) academicians from main public universities in Malaysia; (2) databases searched for literature review; (3) patient support groups and review of governmental and non-governmental web sites on health information for patients; and (4) Malaysian laws and health policies.

Identification of eligible material

The study aimed to include any data or information on the following key areas: SDM training and education; research and clinical practice of SDM; patient information and support; legislations and policies on or related to SDM.

Data extraction

The following methods were used to collect data from the four sources: (1) an online survey with academicians from main public universities in Malaysia; (2) a comprehensive literature review of patient involvement in decision making; (3) an online survey of patient support groups and review of governmental and non-

governmental web sites on health information for patients; and (4) a document review of Malaysian laws and health policies.

1. The online survey on clinical training and education in SDM

We wrote emails to 15 academicians in eight most established public (n=6) and private medical schools (n=2) to seek information on training and education. The participants were selected based on their active involvement in undergraduate and postgraduate teaching in their institutions. The participants were asked to provide information on whether the patient involvement and SDM were included in the medical curriculum and, if so, to what extent they were being implemented in practice. Descriptive data using simple frequency count was used to capture the extent to which SDM was incorporated into the medical curriculum.

2. A comprehensive literature review on research and practice of SDM

We searched PubMed, CINAHL, and MyJurnal (a database of Malaysian publications) to identify SDM-related publications up to March 2013. Our search strategies were as follows:

- PubMed: “(patient-centred care OR decision-making OR shared decision-making OR patient participation) AND (Malaysia)” and “patient preference [MeSH] AND Malaysia” (n = 162)
- CINAHL: “(patient-centred care OR shared decision-making OR decision-making OR patient participation) AND (Malaysia)” (n = 105)
- MyJurnal “patient” (n = 995).

Both qualitative and quantitative studies were included in the review. Published articles which met the following criteria were considered for inclusion: qualitative or quantitative studies which collected original data; performed in a healthcare setting; published in English; and those that reported how patients were involved in medical decision-making. Studies that reported patient beliefs and levels of knowledge were excluded. Only studies published as full text articles were included in the review. Review articles were also excluded as they did not report any original data. Duplicates and non-relevant references were removed. One of the researchers identified the relevant articles which were reviewed, extracted and synthesised.

3. Online survey of patient support group and review of official websites for patient health information

We sought information regarding patient involvement in decision-making from four established patient support groups for: diabetes, systemic lupus erythematosus, drug users, and HIV infection. These groups were chosen as they were the few most established support groups in Malaysia. We gathered information from these groups by conducting an informal e-mail survey, enquiring about existing programmes for patient decision support from both healthcare professionals and peers. For patient information and support, we systematically searched the official web sites of the Ministry of Health (Ministry of Health), main public and private medical centres, and healthcare-related non-government organisations. The amount and quality of patient information were appraised according to: the scope of health topics covered by the website; language available (English, Malay, Mandarin, Tamil); user-friendliness (readability); and patient involvement in the development of the health depository.

4. Document review of the laws and policies on SDM

For standards and policies, we reviewed legislations and policies enacted by the Malaysian Medical Council, which is the official body for medical policy, legislation, and regulation in Malaysia. The relevant sections which described patient involvement were extracted and described in the results.

Data analysis

Simple descriptive analysis was use to describe the data collected from the various sources.

Group consensus methods

The group corresponded via email to discuss and compile the findings of the environmental scan. Based on the findings, a strategy to increase awareness and implement SDM in Malaysia was formulated (Table 2.1).

Table 2.1: Proposed strategy to increase awareness and implement SDM in Malaysia

Proposed strategy	Description
1 Education	<ul style="list-style-type: none"> • Incorporating teaching of SDM into undergraduate curriculum <ul style="list-style-type: none"> ○ General communication and consultation skills ○ Risk communication ○ Evidence-based medicine • Incorporating a more structured SDM teaching into postgraduate curriculum <ul style="list-style-type: none"> ○ Communication and consultation skills ○ Emphasis on specific areas requiring informed consent such as surgeries, chemotherapy, screening ○ Assessment of trainees competency in SDM • Incorporating SDM training into continuing professional development, including workshops on SDM and how to use patient decision aids
2 Clinical practice	<ul style="list-style-type: none"> • Incorporating SDM in clinical practice guidelines • Advocate the use of patient decision aids or other decision support tools in patient care • Patient involvement in decision making as a quality indicator • Payment/reimbursement for practices which implement SDM or use decision aids
3 Research	<ul style="list-style-type: none"> • Baseline research on patient involvement in decision making at the national level • Exploratory studies on the factors influencing decision making in a multi-cultural and multi-lingual context • Developing and evaluating decision support interventions to help patients make informed decisions • Develop and evaluate interventions to incorporate SDM in routine care
4 Policy and law	<ul style="list-style-type: none"> • Malaysian Medical Council should consider developing a national healthcare policy on SDM • The Ministry of Health should improve on the existing patient health information system to make the content more accurate, user-friendly and accessible to the public • Public health campaigns should target at empowering people to be more involved in their health care and making decisions about their health care

Results

SDM training and education

Teaching SDM was not explicitly stated as an objective in most undergraduate and postgraduate curricula in Malaysia. Only one medical school mentioned SDM in their primary care curriculum. However, how SDM is being taught was not clearly defined and evaluated. The process of SDM, such as sharing information, offering treatment choices, exploring patient preferences, involvement of family in decision-making, and sharing the decision, was taught as part of other components of the training programme. For example, risk communication is taught under evidence-based medicine; information sharing and exploring patients' ideas, concerns, and expectations form part of the communication and consultation skill training; and respecting patients' autonomy and providing them adequate and accurate information to make an informed decision are taught in medical ethics and informed consent. Feedback from the respective postgraduate coordinators of the discipline of Family Medicine highlighted a lack of structured SDM teaching. Most commented that SDM is being taught as part of the communication and consultation skill training. Overall, structured teaching of SDM in Malaysia is non-existent and, at best, fragmented.

Research and clinical practice of SDM

We identified 1262 articles, of which 20 focused on SDM or patient involvement in decision-making (Chan & Ahmad, 2012; Che Ngah, 2005; Crabtree, 2005; Eng, Yaakup, Shah, Jaffar, & Omar, 2012; Loh, Packer, Yip, & Passmore, 2009; Loh, Yip, Packer, & Quek, 2010; Martinez *et al.*, 2005; Mazlina & Julia, 2011; Nugent, 2003; Partridge *et al.*, 2005; Siew, 2005; Talib, 2005; S.F Tong & Chen, 2007; S. F. Tong,

Low, Ismail, Trevena, & Willcock, 2011; Yen, 2006a, 2006b; Yousuf, Fauzi, How, Akter, & Shah, 2009; Yousuf, Fauzi, How, Rasool, & Rehana, 2007; Zainudin, Anisah, Rahim, & Shariff, 2012; Zalilah, Mazanah, & Ahmad Zamri, 2008). Studies focused on the areas of informed consent, patient autonomy, decisional role, and the information needs of patients with diabetes, children, the elderly and patients living with cancer. Research on SDM in Malaysia remains scarce. Data suggest that there is a lack of information available for patients to make an informed choice and patients and their parents are not actively involved in decision-making. Overall, despite patient's desire for quality information (Eng, *et al.*, 2012; Yen, 2006a, 2006b) patients were not given enough information to make an informed choice (Lei, Har, & Abdullah, 2011; Yousuf, *et al.*, 2009; Zalilah, *et al.*, 2008). Although healthcare professionals, mainly doctors, were aware of the importance of taking informed consent, some would choose not to practise it if diagnosis was unfavourable or if truth was deemed harmful (Che Ngah, 2005; Yousuf, *et al.*, 2007).

Levels of patient-centeredness varied amongst medical specialities (Chan & Ahmad, 2012). Among the Malaysian paediatric population, the practice of SDM was even less. Only 20% of the decisions on resuscitation of pre-term babies were made by the parents. 72% and 8% of the decisions were made by the physician and ethics committee, respectively (Martinez, *et al.*, 2005). Similarly, Mazlina and Julia found that most (58%) of the rehabilitation physicians would practise medical paternalism and over-ride a patient's earlier directive to withdraw life-sustaining treatment (Mazlina & Julia, 2011). Efforts to encourage patient participation include engaging healthcare practitioners in self-management programs (Loh, Yip, Packer, & Quek, 2010) and training on patient-centeredness (Nugent, 2003).

Patient information and support

Patient education is an important step towards empowering patient involvement in decision-making. Accessibility to accurate, relevant, and readable health information increases health literacy and engages patients in the discussion of choosing the best option for their health. Low health literacy rate may be an important contributing factor to the lack of patient involvement in decision-making in Malaysia (Loh, Packer, Yip, & Passmore, 2009).

The Ministry of Health is the main provider of patient health education resources in Malaysia. It recognises the importance of disseminating “accurate, appropriate, and relevant information in a timely, equitable, and innovative manner” and “empowerment of individuals and communities to enable them to take action on the determinants of health” (Health Education Division, 2012). The Ministry has established a health education Web site for the public (Ministry of Health). However, the development process of these educational materials is not clear and only limited health topics are covered (obesity, physical activity, smoking, diabetes, heart disease, and mental health). The Web site provides an interactive risk calculator and helps users discuss their results further with doctors. However, SDM is mentioned neither implicitly nor explicitly. Moreover, the usability, the usefulness, and the comprehensiveness of the health information of this Web site have not been evaluated. We are also not sure of the extent to which consumers were involved in the development process. Currently, the Web site is available only in two languages, that is, English and Malay; however, it is not available in Chinese and Tamil, which are spoken by up to one-third of the population. Besides the Ministry of Health Web site, other patient information resources are

scattered and are mainly produced by private medical centres or voluntary and patient support groups.

Currently, there are no structured peer support or 'expert patient' programmes in Malaysia. Most programmes involve patients as volunteers or counsellors, providing emotional support rather than peer education. However, some patient support groups and organisations, such as the National Diabetes Institute, Malaysia, are pursuing links with international peer support organisations, such as Peers for Progress (American Academy of Family Physicians), to empower patients to care for themselves and their peers. The recent clinical practice guideline for breast cancer involved breast cancer survivors in the development process (Ministry of Health, 2010d).

Legislations and policies on SDM

The Malaysian legislation follows the British common law and the main conflict in SDM involves the concept of consent to care (Putri, 2010). According to the law, patients must have sufficient information regarding the specific condition he or she is suffering from and the nature and purpose of care being recommended before giving the consent. It is the patient's right to know and the doctor's responsibility to warn the patient about the risks (that would make a significant difference in the patient's life if they materialise) when undergoing or refusing any proposed care (Cusack). In Malaysia, informed consent is often not practised (Che Ngah, 2005) and this is often because of a lack of doctor-patient communication (Putri, 2010).

The Malaysian Medical Council published a guideline on duties of a doctor in 2001, which outlined the moral and professional obligations expected of a medical practitioner in Malaysia (Malaysian Medical Council, 2001). The guideline states that the

relationship between a doctor and a patient should be “collaborative” and they should be in a “partnership”. It reaffirms the importance of the doctor–patient relationship, which “paves the way for frank discussion in which a patient’s needs and preferences and a doctor’s clinical expertise are shared to select the best treatment option”. The doctor is also required to “give relevant options when discussing treatment, and the limitations and possible complications”. These recommendations concur with the principle of SDM, where information is exchanged and decisions are made based on a shared understanding and agreement between the two parties.

Discussion

This study identified the gap in the research, practice, policies and laws related to SDM in Malaysia. The findings from the limited research studies on SDM revealed a low health literacy rate among patients, which may be attributed to, or compounded by, inadequate health information. Medical practitioners still play a paternalistic role in making healthcare decisions for patients and they do not involve patients in decision-making. It is also noted that these studies involved patients of extreme ages (children and elderly) as well as those with life-limiting illnesses. There is a lack of data on how adult patients are involved in making diagnostic or treatment decisions in various clinical settings. Most studies looked at SDM from the perspective of healthcare professionals. None of the studies looked at how patients prefer to be involved in decision-making. In a cross-sectional study involving patients from 11 European countries, there was a significant difference between what decisional roles patients wanted to have and how they were involved in decision-making in the actual clinical encounter (Coulter & Jenkinson, 2005). Therefore, future studies should look at patients’ preferred roles and their healthcare experiences in decision-making. This will

provide a definitive answer to the question of how Asian patients prefer to be involved in healthcare decision-making.

There was an increasing interest in the development, evaluation, and implementation of SDM in clinical practice and undergraduate and postgraduate curricula. However, efforts were fragmented and not ideal. Teaching and learning of SDM are essential in cultivating a patient-centred approach to healthcare and should be an integral part of the medical curriculum across all disciplines.

In addition, the practice of SDM is complicated by the cultural and language diversity in Malaysia. Doctors not only have to understand patients' personal and cultural values, but also have to communicate in a language that may not be their mother tongue. Risk communication, negotiation, and achieving agreement require high-level communication skills and demand high language proficiency. Moreover, the public-private dual system results in practice variations. Both factors make the implementation of SDM a challenging task. Future research should focus on effective ways to improve cross-cultural communication and consultations across the two sectors. Interventions to improve SDM, such as patient decision aids, may play a role in reducing practice variations.

Health literacy remains low in Malaysia, which could contribute to the lack of patient involvement in decision-making (Loh, Packer, Yip, & Passmore, 2009). Studies have found that improving health literacy empowers patients to play a more active role in managing their health (Hirono Ishikawa & Eiji Yano, 2008; Koo, Krass, & Aslani, 2006). Patients who know about their health problems and respective treatments are more likely to be involved in making healthcare decisions (Griffin SJ *et al.*, 2004; Kim *et al.*, 2001; Wetzels, Harmsen, Van Weel C, Grol, & Wensing, 2007). The quality of

local health information is generally poor and this is compounded by the lack of translation into common languages. This poses a significant barrier to increasing health awareness and improving health literacy. Government organisations, non-government organisations such as patient and professional bodies, and academic institutions should work together to improve the quality of, and access to, patient information.

Although SDM practice is endorsed by the Malaysian Medical Council, its implementation remains challenging. This requires the council to work closely with the stakeholders, namely the Ministry of Health, professional bodies, patient support agencies and researchers, to develop a strategy to increase the awareness and the implementation of SDM in Malaysia. SDM should be incorporated in the policies to drive changes within the healthcare system. An example is the Washington State Legislation that approved the use of decision aids and SDM when provided with treatment choices (Washington State legislation). Currently, there is no health policy in Malaysia that specifically addresses the issues related to SDM. National clinical practice guidelines suggest only the involvement of patients in making medically informed decisions. The council should consider the experiences of countries that have existing healthcare policies on SDM, such as the International Patient Decision Aid Standards Collaboration (International Patient Decision Aid Standards Collaboration), the Health Foundation (Cobble, 2009) and the Foundation for Informed Medical Decision Making (Foundation for Informed Medical Decision Making).

There are limitations in this study. Firstly, limited data sources have been used in this study, which comprise mostly secondary data such as literature and Web pages. We did not consider grey literature such as reports and dissertations for this study. Secondly, our results on SDM training and education are based on a convenience sample, which

comprised lecturers in the primary care medicine departments only and not in other disciplines.

Conclusion

In summary, there appears to be little training or research on SDM in Malaysia. More research needs to be done in this area, including baseline information on the preferred and actual decision-making roles. The authors have provided a set of recommendations on how SDM can be effectively implemented in Malaysia.

Conflict of interest

The authors declare that they have no conflict of interests.

Acknowledgement

NCJ led the study, compiled and wrote the final manuscript. JPE, PYL, BHC, and SFT collected data on the medical syllabus and training. PYL reviewed official Web sites of government, non-governmental organisations and private healthcare facilities for public information on SDM. YKL conducted the literature review on SDM and patient involvement in Malaysia. ZII reviewed legislation related to SDM and patient involvement. NSH reviewed policies related to SDM and patient involvement. BHC conducted e-mail correspondence with national patient bodies to enquire about patient involvement and support.

Chapter 3: Literature review

The aim of this chapter is to provide a review of the literature based on the three objectives identified in Chapter 1.5.2. The first section of the review is focused on the barriers and facilitators to insulin initiation in type 2 diabetes (Chapter 3.1). This section provides an overview of the range of negative and positive beliefs about insulin. Besides patient beliefs, a range of barriers from the HCPs and the healthcare system are identified.

The second section is a systematic review of patient values in medical decision making. The scope of the review on definitions of patient values was broadened to medical decision making in general because no clear definition existed in SDM. This systematic review of patient values in medical decision making (which includes SDM) is reported in Chapter 3.2.

Following this, a review of two value-specific theories from the social sciences is presented. These theories describe the characteristics and functions of human values. These theories have previously been applied to healthcare research, but not specifically to shared decision making. This section discusses the key definitions of values, the function of values and how these values can be applied to patient values research in SDM (Chapter 3.3). One of these theories is later used to develop the patient interview topic guide (Chapter 4).

Chapter 3.1: Barriers and facilitators to starting insulin in patients with type 2 diabetes: A systematic review

Chirk Jenn Ng, Pauline Lai Siew Mei, Yew Kong Lee, Syahidatul Akmal

To be submitted

Author contributions:

CJN led the study. SA conducted the database search. CJN, PLSM, YKL, and SA reviewed all papers, extracted data and performed quality analysis on all reviewed papers. YKL designed the study results tables.

Abstract

Background

Despite the proven benefits and efficacy of insulin, up to 27% of patients are reluctant to initiate insulin therapy. In order to overcome these barriers, it is important to identify the factors influencing insulin initiation both from the perspectives of patients and healthcare professionals.

Objectives

To identify the barriers and facilitators to starting insulin in patients with type 2 diabetes

Methods

We conducted a systematic search using PubMed (1966-2011) for all original articles in English using Medical Subject Headings (MESH) terms: “type 2 diabetes”, “insulin”, and free texts: “barrier” or “facilitate”. Both qualitative and quantitative studies were included. Two pairs of reviewers independently selected, assessed and extracted the data. Study quality was assessed using Qualsyst.

Results

A total of 7104 references were identified: 18 full text articles were selected and assessed for eligibility. Finally, 15 papers (8 qualitative and 7 quantitative) were included in the review. Good inter-rater reliability was observed for the Qualsyst score. Three main themes identified were: patient-related, healthcare professional and system factors. The main patient-related barriers were fear of pain, fear of injection, difficulty in making dose adjustments and delivery of injection. Insulin was perceived to have “negative health outcomes”, was “ineffective” and may worsen quality of life. There

were also concerns about the side effects of insulin (hypoglycaemia/weight gain). Healthcare professionals' barriers were: lack of knowledge and skills, poor doctor patient relationship and poor communication. System barriers included lack of dedicated diabetes services and educational resources.

Conclusion

This systematic review identified major barriers in insulin initiation despite the availability of newer insulin which are safer and easier to use. Healthcare professionals should explore and address these barriers when supporting patients in making decisions about starting insulin. Suitable interventions will need to be developed to overcome these barriers.

Introduction

Background

Clinicians face challenges when advising patients with type 2 diabetes to start insulin, particularly in patients who have poor glycaemic control despite maximal oral glucose-lowering drugs. Up to 27% of patients are reluctant to start insulin when advised to do so (Larkin *et al.*, 2008; Peyrot *et al.*, 2005; Polonsky, 2007; UK Prospective Diabetes Study (UKPDS) Group, 1998). This is despite clear evidence that good glycaemic control reduces micro-vascular, and to a lesser degree, macro-vascular complications (Korytkowski, 2002).

There are many reasons why patients are hesitant to start insulin. This resistance to insulin initiation has been termed “Psychological Insulin Resistance” (Nam *et al.*, 2010; Polonsky, 2007; Polonsky & Jackson, 2004). Patients concerns can be categorised as coping-oriented and knowledge-based barriers (Larkin, *et al.*, 2008). Coping-oriented barriers include negative feelings and phobias like depression, anxiety and embarrassment, feelings of failure, lack of confidence and needle phobia. Knowledge-based barriers include myths or misperceptions about insulin including addiction concerns, doubting the effectiveness of insulin, fear of hypoglycaemia and inadequate knowledge of glycaemic targets (Larkin, *et al.*, 2008).

However, recent evidence shows that tight glycaemic control, particularly for those on insulin, has been associated with increased mortality (e.g. ADVANCE, Veteran trials) (Skyler *et al.*, 2009). This has resulted in the revised approach towards titrating glucose-lowering drugs by considering not just patient clinical profiles but their psychosocial

background. Clinicians need to consider the barriers and facilitators to insulin initiation when counselling patients who are making decisions.

Therefore, this systematic review aimed to identify the barriers and facilitators to insulin initiation in patients with type 2 diabetes. This review is important because it will document the range of factors that may influence patients' decision to start insulin. Effective intervention can be developed to support patients and clinicians in insulin initiation only if we have a better understanding of these barriers and facilitators.

Methods

The selection and reviewing process of this systematic review is shown in Figure 3.1.1. A comprehensive search was conducted using PubMed (1966-2011) for all studies of barriers and facilitators of initiating insulin in patients with type 2 diabetes. We used Medical Subject Headings (MeSH) "type 2 diabetes" and "insulin" as well as text word searches such as "barrier" (or similar terms like "obstacle" or "hurdle" or "limit" or "problem" or "difficult" or "hindrance") and "facilitate" (or similar terms "aid" or "assist" or "support" or "encourage" or "promote" or "motivate").

Identification

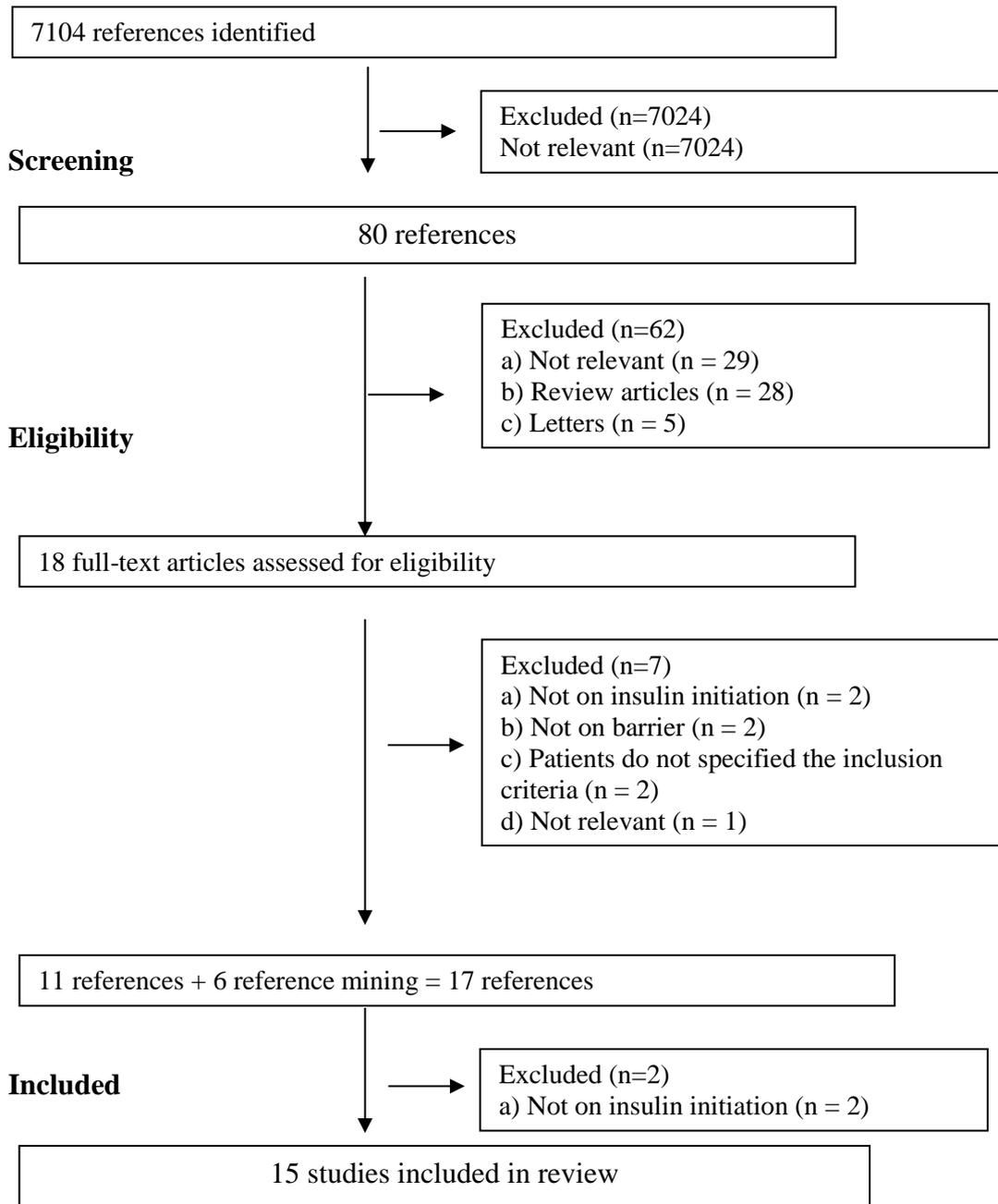


Figure 3.1.1 Flow chart of studies included in the systematic review

Table 3.1.1: QualSyst scoring criteria for assessing study quality

Checklist for assessing the quality of quantitative studies					
Criteria		Yes (2)	Partial (1)	No (0)	N/A
1	Question / objective sufficiently described?				
2	Study design evident and appropriate?				
3	Method of subject/comparison group selection or source of information/input variables described and appropriate?				
4	Subject (and comparison group, if applicable) characteristics sufficiently described?				
5	If interventional and random allocation was possible, was it described?				
6	If interventional and blinding of investigators was possible, was it reported?				
7	If interventional and blinding of subjects was possible, was it reported?				
8	Outcome and (if applicable) exposure measure(s) well defined and robust to measurement / misclassification bias? means of assessment reported?				
9	Sample size appropriate?				
10	Analytic methods described/justified and appropriate?				
11	Some estimate of variance is reported for the main results?				
12	Controlled for confounding?				
13	Results reported in sufficient detail?				
14	Conclusions supported by the results?				
Checklist for assessing the quality of qualitative studies					
	Criteria	Yes (2)	Partial (1)	No (0)	
1	Question / objective sufficiently described?				
2	Study design evident and appropriate?				

Table 3.1.1, Continued

3	Context for the study clear?				
4	Connection to a theoretical framework / wider body of knowledge?				
5	Sampling strategy described, relevant and justified?				
6	Data collection methods clearly described and systematic?				
7	Data analysis clearly described and systematic?				
8	Use of verification procedure(s) to establish credibility?				
9	Conclusions supported by the results?				
10	Reflexivity of the account?				

Source: Kmet, Lee, & Cook, 2004

Inclusion and exclusion criteria

Published articles which met the following criteria were considered for inclusion:

qualitative or quantitative studies; original articles; conducted in a healthcare setting; published in English; focused on patients initiating insulin in type 2 diabetes; and barriers and/or facilitators. Only full text articles were included in the review.

Duplicates were identified and excluded.

Data extraction and synthesis

Four reviewers worked independently in pairs to assess and extract data from each included study. The study quality was assessed using the QualSyst scoring system which is a validated tool incorporating both quantitative and qualitative research appraisal (Table 3.1.1) (Kmet, Lee, & Cook, 2004). Scores ranged from 0 to 1 where a higher score indicates higher quality. Intra-class correlation coefficients (ICC) were calculated to determine inter-rater agreement for both quantitative and qualitative papers. Any discrepancy was resolved through discussion. Data from included studies

were analysed for themes and managed using NVivo version 9 from QSR International (Nvivo9, 2010).

Table 3.1.2 Barriers and facilitators to insulin overview

QUALITATIVE STUDIES (Patients, Doctors and Nurses)

Reference	Level of evidence (QualSyst Score, range 0 to 1)	Setting, country	Method	Participants	Sample size (response rate)	Theoretical framework	Analysis	Main findings
(Hunt, Valenzuela, & Pugh, 1997)	0.83	Public clinics (n=2) at San Antonio and Laredo, Texas, USA	In-depth interviews. Convenience sampling from patients waiting to see internal medicine doctors or participants in a diabetes patient education trial	Patients. Mexican American, low income, type 2 diabetes \geq 1 year.	44 (NA)	Not specified	Concept analysis	Barriers: Negative perceptions of insulin, emotional barriers, lack of knowledge, socio-demographic factors, negative attitudes, needle phobia, side effects of insulin, barriers in administering, inconvenience, stigma and discrimination Facilitators: Improved quality of life, benefits of insulin

Table 3.1.2, continued

(Phillips, 2007a)	0.78	Not specified	In-depth interview. Purposive sampling of men and women who had been converted to insulin between 2 to 4 years who had a broad range of experience with diabetes and insulin therapy.	Patients. Converted to insulin \geq 1 year.	8 (NA)	Phenomonological approach (Hunt, <i>et al.</i> , 1997)h	Content analysis	Barriers: Not involving patients in decision making, HCPs' lack of knowledge and skills, emotional barriers, lack of knowledge or misconception, interference with work and social activities Facilitators: providing patient education, improved health, benefits of insulin, peer support
(Brown <i>et al.</i> , 2002)	0.73	Primary care practices, Canada	Focus group discussions. Convenience sampling from a simultaneous quantitative study on management	Primary care doctors.	30 (33.3%)	Not specified	Constant comparison analysis	Barriers: : HCPs lack knowledge and skills. Facilitators: Initiating insulin in primary care (vs secondary care)

Table 3.1.2, continued

			of type 2 diabetes.					
(Goderis <i>et al.</i> , 2009)	0.88	GP practices, Belgium	In-depth interviews. Purposive sampling. Participants randomly selected from a stratified sample according to clinical performance scores before and after an 18 month quality improvement program (QIP). The strata were weak baseline and modest improvement; weak baseline and substantial improvement;	General practitioners. Participated in an 18 month QIP.	20 (90.9%)	Implementati on model	Thematic analysis	Barriers: Patients lack knowledge or have misconceptions about side effects, patients negative attitudes, fear of needles and pain Facilitators: HCPs provide patient education, patient education as part of the system

Table 3.1.2, continued

			strong baseline and modest improvement; and strong baseline and substantial improvement.					
(Haque, Emerson, Dennison, Navsa, & Levitt, 2005)	0.78	Community health centres (primary health service centres), South Africa	Focus group discussions (n=5), in-depth interviews (n=10). Purposive sampling was based on work experience years: <1 year, 1-3 years, 4-10 years, >10 years	Medical officers. Practicing in the Cape Town metropolitan region. Sampling based on number of work experience years.	46 (54.1%)	Grounded theory	Grounded theory methodology	Barriers: Communication barriers, HCPs negative attitudes, patients negative perceptions of insulin, patients lack of knowledge/misconception about side effects, socio-demographic factors, needle phobia, side effects of insulin, interference with social and work activities, lack of educational resources
(Greaves <i>et al.</i> , 2003)	0.83	Primary care practices, UK	In-depth interviews. Purposive	Practice nurses. Holding	25 (53.2%)	Not specified	Content analysis	Facilitators: Initiating insulin in primary care (vs secondary care)

Table 3.1.2, continued

			sampling based on nurses' relevant expertise and experience.	responsibilities for diabetes care.				
(Phillips, 2007b)	0.85	Primary and secondary care practices, UK.	In-depth interview. Purposive sampling was used to identify nurses who had experience in converting patients to insulin therapy.	Nurses. Full-time diabetes nurses employed in the study area.	4 (80%)	Not specified	Thematic framework	<p>Barriers: Not involving patients in decision making, patients negative perceptions of insulin, patients emotional barriers, patients poor physical health, patients negative attitudes, needle phobia, side effects of insulin, barriers in administering, hassle of home glucose monitoring, inconvenience, stigma and discrimination, lack of system diabetes services.</p> <p>Facilitators: Setting glycaemic targets for patients, involving patients in decision making, improved health,</p>

Table 3.1.2, continued

								benefits of insulin, initiate insulin early, giving dummy injections, showing hands on demonstrations, peer support, give enough time to patient, follow up patients
(Sigurdardottir, 1999)	0.85	Hospital and community clinics, UK	In-depth interview. Purposive sampling whereby a diabetes care coordinator helped to identify six diabetes nurse specialists who were employed as a part of a multidisciplinary team offering diabetic care.	Diabetes nurse specialists. Possess at least diploma in diabetes care, been in their post for about 2 years.	6 (100%)	Heideggerian hermeneutic phenomenology	Colaizzi's modification of phenomenological inquiry	Barriers: HCPs lack knowledge and skills, lack of social support

QUANTITATIVE STUDIES (Patients, Doctors and Nurses)

Reference	Level of evidence (QualSyst Score, range 0 to 1)	Healthcare setting, country	Method	Participants	Sample size (response rate)	Instrument	Main findings (Top 5 barriers and facilitators by percentage)
(Ahmed <i>et al.</i> , 2010)	0.78	Aga Khan University Hospital, Karachi, Pakistan	Cross-sectional prospective interviewer-assisted survey. Consecutive sampling on patients with Type 2 diabetes presenting to endocrinology out-patient clinic over a six week period	Patients with type 2 diabetes. ≥ 18 years old. 2 groups: current insulin users (n=210), insulin naive patients (n=107)	317 (89.5%)	Not specified	Barriers: <ul style="list-style-type: none"> - Insulin is a last resort (72.9%) - Transport of insulin difficult (60.5%) - Not possible to stop insulin once started (56.6%) - Insulin injection is uncomfortable (55.1%) - Perceived to be painful (54.8%)
(Karter <i>et al.</i> , 2010)	0.80	Managed-care settings of Kaiser Permanente Northern California	Cross-sectional prospective telephone and postal questionnaires. Block random sampling identified	Patients. Poorly controlled, insulin naive and insulin eligible T2DM	169 (44.4%)	Not specified	Barriers (for the non-adherent group): <ul style="list-style-type: none"> - Risks and benefits not well explained (39%) - Belief that insulin causes renal failure (32%)

Table 3.1.2, continued

		(Kaiser) and Horizon Blue Cross Blue Shield of New Jersey, Northern California and New Jersey, USA	using pharmacy records from two groups: respondents prescribed, but never initiating, insulin (n=69) with those dispensed insulin (n=100).	patients.			-difficulty giving insulin due to poor eyesight, shakiness or arthritis (30%) - Cost of insulin (27%) - Patient planned to change health behaviours instead of starting insulin (25%)
(M. E. Larkin <i>et al.</i> , 2008)	0.84	Massachusetts General Hospital Diabetes Center, Massachusetts, USA	Cross-sectional, prospective self- completed questionnaire. Purposive sampling was used to recruit adult, insulin-naive patients with type 2 diabetes at an outpatient diabetes center in a university affiliated teaching hospital.	Patients. ≥ 25 years old, insulin naive.	100 (NA)	A Survey for People who do not take Insulin (SPI) The Insulin Treatment Appraisal Scale (ITAS)	Barriers:- Perception that the disease is worse (85%) - Perception that life would be less flexible (82%) - Fear of hypoglycaemia (76%) - Perception that family and friends will be more concerned (76%) Facilitators: - Maintain good control (97%) - Prevents complication (91%) - Improves health (91%)

Table 3.1.2, continued

							- Improves energy (85%)
(Nakar <i>et al.</i> , 2007)	0.80	Central District of the Clalit Health Services (district health service), Israel	<p>Patients: Case-control prospective telephone interview. Random sampling from central register of patients of chronic disease in a health maintenance organization (HMO).</p> <p>Doctors: Written questionnaire. Sampling population was family doctors working in the district, who actively treat patients and participate in CME</p>	<p>Patients. Study group consisted of T2DM patients who are insulin naive on maximum OHAs. Control group consisted of T2DM patients who had begun insulin 3-6 months previously.</p> <p>Family doctors. Actively treat patients and participate in CME</p>	Patient study group: 92 (70%), patient control group: 101 (79%), doctor group: 157 (87%)	Not specified	<p>Barriers (patients):</p> <ul style="list-style-type: none"> - Believe the illness is not very serious (46.7%) - Fear of addiction (39%) - Believe that insulin makes one fat (12%) - Fear of hypoglycaemia (12%) - Fear of pain (12%) <p>Barriers (doctors)</p> <ul style="list-style-type: none"> - Believe patient will not comply with treatment (92.3%) - Patients' fear of hypoglycaemia (79.7%) - Patients cannot cope with pain (53.9%) - Patients are too old (47.4%) - Have no experience with

Table 3.1.2, continued

			studies within various frameworks. Sampling frame not specified.	activities.			insulin (27.4%)
(Oliveria <i>et al.</i> , 2007)	0.83	Henry Ford Health System (Mixed-model health maintenance system), Detroit, USA	Cross-sectional, prospective telephone interview. Purposive sampling of patients who met the inclusion criteria in computerized laboratory results database of the health maintenance system.	Patients. Two groups: 'Discontinuers' (patients who discontinued insulin use for at least 120 days in previous year) and 'non-initiators' (patients who did not initiate insulin despite HbA1c \geq 9%)	Discontinuers: 73 (80%), Non-initiators: 129 (82%)	Not specified	<p>Barriers (non-initiators):</p> <ul style="list-style-type: none"> - Using other methods to control diabetes (27.7%) - Injection-related issues (7%) - Doctor advised them against using insulin (7%) <p>Barriers (Discontinuers):</p> <ul style="list-style-type: none"> - Doctor advised not to take (47.1%) - Using other methods to control diabetes (17.7%) - Believe that diabetes is within control/ normal (11.8%) - Painful injections (11.8%) -Hard to maintain blood glucose when off schedule (8.8%)

Table 3.1.2, continued

(Polonsky, <i>et al.</i> , 2005)	0.83	1- day diabetes conferences, San Diego, California; Raleigh, North Carolina; Portland, Oregon; Minneapolis, Minnesota; Philadelphia, Pennsylvania; and Honolulu and Hilo, Hawaii, USA	Cross-sectional prospective self-completion questionnaire. Convenience sampling by including questionnaire in the participants' conference syllabus for return at end of conference.	Patients. Participants at 1-day diabetes conferences.	1267 (33.1%)	A Survey for People who do not take Insulin (SPI)	Barriers: - Not confident to handle demands of insulin therapy (58.1%) - Feel that insulin would restrict them (56.1%) - Feelings of personal failure (55.0%) - Permanence of insulin (53.1%) - Fear of pain (50.8%)
(Hayes, Fitzgerald, & Jacober, 2008)	0.93	Primary care practice, USA	Cross-sectional prospective email questionnaire. Convenience sampling from doctor panel of a market research firm with >3 years clinical practice	Primary care doctors. Certified in Family Practice, General Practice or Internal	505 (19.8%)	Self-designed questionnaire	Barrier: - Insulin can only be administered by injection (93%) - Patients fearful of insulin therapy (80%) - Training on insulin is too complicated for patients (58%)

Table 3.1.2, continued

experience, who treat > 10 pts with T2DM/week.	Medicine	<ul style="list-style-type: none">- Follow up for patients on insulin too resource intensive for staff (53%)- Patients view insulin initiation as a personal failure (53%) <p>Facilitator:</p> <ul style="list-style-type: none">- Patient education (93%)- Benefits outweigh the risks (88%)- Patients feel better once accustomed (76%)- Patients will avoid diabetic complications (75%)- Demands of insulin therapy less than expected (63%)
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Results

A total of 15 articles were included in this review (Figure 3.1.1).

Study characteristics

Majority of the studies extracted were conducted in North America (Hayes, Fitzgerald, & Jacober, 2008; Hunt, Valenzuela, & Pugh, 1997; Karter *et al.*, 2010; Larkin, *et al.*, 2008; Oliveria *et al.*, 2007; Polonsky *et al.*, 2005) and Europe (Goderis *et al.*, 2009; Greaves *et al.*, 2003; Nakar, Yitzhaki, Rosenberg, & Vinker, 2007; Phillips, 2007b; Sigurdardottir, 1999), with a few from Asia (Ahmed *et al.*, 2010), Canada (Brown *et al.*, 2002) and Africa (Haque, Emerson, Dennison, Navsa, & Levitt, 2005) whilst one was not specified (Phillips, 2007a). Four studies were conducted in hospitals (Ahmed, *et al.*, 2010; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Oliveria, *et al.*, 2007), seven in clinics (Brown, *et al.*, 2002; Goderis, *et al.*, 2009; Greaves, *et al.*, 2003; Haque, *et al.*, 2005; Hayes, *et al.*, 2008; Hunt, *et al.*, 1997; Nakar, *et al.*, 2007) whilst two studies were conducted in both hospital and clinic (Phillips, 2007b; Sigurdardottir, 1999), and another study recruited respondents from a conference (Polonsky, *et al.*, 2005) whilst one was not specified (Phillips, 2007a). Studies were mainly conducted in patients (Ahmed, *et al.*, 2010; Hunt, *et al.*, 1997; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Oliveria, *et al.*, 2007; Phillips, 2007a; Polonsky, *et al.*, 2005), doctors (Brown, *et al.*, 2002; Goderis, *et al.*, 2009; Haque, *et al.*, 2005; Hayes, *et al.*, 2008) and nurses (Greaves, *et al.*, 2003; Phillips, 2007b; Sigurdardottir, 1999) whilst one study was conducted in both patients and doctors (Nakar, *et al.*, 2007). Fourteen studies identified barriers to insulin initiation (Ahmed, *et al.*, 2010; Brown, *et al.*, 2002; Goderis, *et al.*, 2009; Haque, *et al.*, 2005; Hayes, *et al.*, 2008; Hunt, *et al.*, 1997; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007; Phillips, 2007a, 2007b;

Polonsky, *et al.*, 2005; Sigurdardottir, 1999) whilst only seven studies identified facilitators to insulin initiation (Goderis, *et al.*, 2009; Greaves, *et al.*, 2003; Hayes, *et al.*, 2008; Hunt, *et al.*, 1997; Larkin, *et al.*, 2008; Phillips, 2007a, 2007b) (Table 3.1.2).

Quality assessment of included studies

A total of 8 qualitative studies (Brown, *et al.*, 2002; Goderis, *et al.*, 2009; Greaves, *et al.*, 2003; Haque, *et al.*, 2005; Hunt, *et al.*, 1997; Phillips, 2007a, 2007b; Sigurdardottir, 1999) and 7 quantitative studies (Ahmed, *et al.*, 2010; Hayes, *et al.*, 2008; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007; Polonsky, *et al.*, 2005) were identified in this review. Overall, most of the studies were of good quality and we included all 15 studies in the analysis. Final QualSyst score (maximum 1.0) ranged from 0.70 to 0.95 for quantitative studies and 0.65 to 0.95 for the qualitative studies. Intra-class correlation was 0.805 suggesting high inter-rater agreement (Shrout & Fleiss, 1979).

Quantitative studies

Six cross-sectional (Ahmed, *et al.*, 2010; Hayes, *et al.*, 2008; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Oliveria, *et al.*, 2007; Polonsky, *et al.*, 2005) and one case control study (Nakar, *et al.*, 2007) were included in this review. Response rates ranged from 19.8% to 89.5%. Sample size ranged from 100 to 1,267 patient participants varied from study to study; from insulin users, (Ahmed, *et al.*, 2010; Karter, *et al.*, 2010; Nakar, *et al.*, 2007; Polonsky, *et al.*, 2005) insulin naïve patients, (Ahmed, *et al.*, 2010; Larkin, *et al.*, 2008; Nakar, *et al.*, 2007; Polonsky, *et al.*, 2005) discontinuers (Oliveria, *et al.*, 2007) to non-initiators of insulin (Karter, *et al.*, 2010; Oliveria, *et al.*, 2007) (Table 3.1.2).

Table 3.1.3 Structured instruments for assessing the barriers and facilitators in insulin initiation in diabetes

References	Questionnaires/ instruments	Area assessed	No. of items	Reliability and validity	Participa nts	Methods	Findings
Larkin <i>et al.</i> , 2008	A Survey for People who do not take Insulin (SPI)	Perceptions of patients on insulin therapy	9-item questionnair e	Internal reliability (Cronbach's $\alpha = 0.834$)	Patients with type 2 diabetes not on insulin	Cross-sectional, prospective self- completed questionnaire.	Barriers: - Perception that the disease is worse (85%) - Perception that life would be less flexible (82%) - Fear of hypoglycaemia (76%) - Perception that family and friends will be more concerned (76%)
	The Insulin Treatment Appraisal Scale	Willingness of patients to begin insulin therapy	Response: 6- point Likert scale (1 = strongly disagree, 6 = strongly agree) Total score: 9 to 54			Purposive sampling was used to recruit adult, insulin- naive patients with type 2 diabetes at an outpatient diabetes center in a university affiliated teaching hospital.	Facilitators: - Maintain good control (97%) - Prevents complication (91%)
		Reasons why patients were reluctant to start	20-item scale Response: 5-	Internal reliability (Cronbach's	Insulin naïve and insulin		

Table 3.1.3, continued

	(ITAS)	insulin, including risk of side effects, complications or changes in lifestyle	point Likert scale (1 = strongly disagree, 5 = strongly agree)	$\alpha = 0.884$)	treated patients		- Improves health (91%) - Improves energy (85%)
		Patient's perceptions and current appraisal of insulin therapy	Total score: 0 to 80				
Karter <i>et al.</i> , 2010	Not specified	Not specified	Not specified	Not specified	Patients. Poorly controlled, insulin naive and insulin eligible T2DM patients.	Cross-sectional prospective telephone and postal questionnaires. Block random sampling identified using pharmacy records from two groups: respondents prescribed, but never initiating	Barriers (for the non-adherent group): - Risks and benefits not well explained (39%) - Belief that insulin causes renal failure (32%) -difficulty giving insulin due to poor eyesight, shakiness or arthritis (30%)

Table 3.1.3, continued

						insulin (n=69) with those dispensed insulin (n=100).	- Cost of insulin (27%) - Patient planned to change health behaviours instead of starting insulin (25%)
Oliveria <i>et al.</i> , 2007.	Self-designed questionnaire	Possible reasons for insulin discontinuation or non-initiation.	Not specified	Not specified	Patients. Two groups: 'Discontinuers' (patients who discontinued insulin use for at least 120 days in previous year) and 'non-initiators' (patients who did	Cross-sectional, prospective telephone interview. Purposive sampling of patients who met the inclusion criteria in computerized laboratory results database of the health maintenance system.	Barriers (non-initiators): - Using other methods to control diabetes (27.7%) - Injection-related issues (7%) - Doctor advised them against using insulin (7%) Barriers (Discontinuers): - Doctor advised not to take (47.1%) - Using other methods to control

Table 3.1.3, continued

					not initiate insulin despite HbA1c \geq 9%)		diabetes (17.7%) - Believe that diabetes is within control/ normal (11.8%) - Painful injections (11.8%) -Hard to maintain blood glucose when off schedule (8.8%)
Hayes <i>et al.</i> , 2008.	Self-designed questionnaire called 'I believe...'	Patient's perceptions and current appraisal of insulin therapy	30-item beginning with 'I believe...' Response: 5-point Likert-type scale (1 = strongly disagree, 5 = strongly agree)	Not specified	Primary care physicians . Certified in Family Practice, General Practice or Internal Medicine	Cross-sectional prospective email questionnaire. Convenience sampling from physician panel of a market research firm with >3 years clinical practice experience, who treat > 10 pts with T2DM/week.	Barrier: - Insulin can only be administered by injection (93%) - Patients fearful of insulin therapy (80%) - Training on insulin is too complicated for patients (58%) - Follow up for patients on insulin too resource

Table 3.1.3, continued

intensive for staff
(53%)

- Patients view
insulin initiation
as a personal
failure (53%)

Facilitator:

- Patient education
(93%)

- Benefits
outweigh the risks
(88%)

- Patients feel
better once
accustomed (76%)

- Patients will
avoid diabetic
complications
(75%)

- Demands of
insulin therapy
less than expected
(63%)

Table 3.1.3, continued

Polonsky <i>et al.</i> , 2005.	A Survey for People who do not take Insulin (SPI)	Perceptions of patients on insulin therapy	9-item questionnaire	Internal reliability (Cronbach's $\alpha = 0.834$)	Patients. Participants at 1-day diabetes conference	Cross-sectional prospective self-completion questionnaire. Convenience sampling by including questionnaire in the participants' conference syllabus for return at end of conference.	Barriers: - Not confident to handle demands of insulin therapy (58.1%) - Feel that insulin would restrict them (56.1%) - Feelings of personal failure (55.0%) - Permanence of insulin (53.1%) - Fear of pain (50.8%)
		Willingness of patients to begin insulin therapy	Response: 6-point Likert scale (1 = strongly disagree, 6 = strongly agree)				
		Reasons why patients were reluctant to start insulin, including risk of side effects, complications or changes in lifestyle	Total score: 9 to 54				
Nakar <i>et al.</i> , 2007.	Self-designed questionnaire	Patients' barriers to insulin therapy	Not specified	Not specified	Patients. Study group consisted of T2DM patients who are insulin	Patients: Case-control prospective telephone interview. Random sampling from central register of	Barriers (patients): - Believe the illness is not very serious (46.7%) - Fear of addiction (39%) - Believe that insulin makes one

Table 3.1.3, continued

naive on maximum OHAs. Control group consisted of T2DM patients who had begun insulin 3-6 months previously .	patients of chronic disease in a health maintenance organization (HMO).	fat (12%) - Fear of hypoglycaemia (12%) - Fear of pain (12%)
Family physicians . Actively treat patients and participate in CME activities.	Doctors: Written questionnaire. Sampling population was family physicians working in the district, who actively treat patients and participate in CME studies within various frameworks. Sampling frame not specified.	Barriers (doctors) - Believe patient will not comply with treatment (92.3%) - Patients' fear of hypoglycaemia (79.7%) - Patients cannot cope with pain (53.9%) - Patients are too old (47.4%) - Have no experience with insulin (27.4%)

Table 3.1.3, continued

Ahmed <i>et al.</i> , 2010.	Self-designed questionnaire	Insulin naive patients - perceptions and possible difficulties related to insulin use. Current insulin users – experiences and difficulties in using insulin.	Not specified	Not specified	Patients with type 2 diabetes. > 18 years old. 2 groups: current insulin users (n=210), insulin naive patients (n=107)	Cross-sectional prospective interviewer- assisted survey. Consecutive sampling on patients with Type 2 diabetes presenting to endocrinology out-patient clinic over a six week period	Barriers: - Insulin is a last resort (72.9%) - Transport of insulin difficult (60.5%) - Not possible to stop insulin once started (56.6%) - Insulin injection is uncomfortable (55.1%) - Perceived to be painful (54.8%)
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Qualitative studies

Six studies used in-depth interviews (Goderis, *et al.*, 2009; Greaves, *et al.*, 2003; Hunt, *et al.*, 1997; Phillips, 2007a, 2007b; Sigurdardottir, 1999), one used focus group discussion (Brown, *et al.*, 2002) whilst one study used both in-depth interview and focus group discussion (Haque, *et al.*, 2005). Sample size ranged from 4 to 46. Only four studies (Goderis, *et al.*, 2009; Haque, *et al.*, 2005; Phillips, 2007a; Sigurdardottir, 1999) stated their theoretical framework: phenomenology (Phillips, 2007a), implementation model (Goderis, *et al.*, 2009), grounded theory (Haque, *et al.*, 2005), and Heideggerian hermeneutic phenomenology (Sigurdardottir, 1999). Sampling method used were mainly convenient (Brown, *et al.*, 2002; Hunt, *et al.*, 1997) and purposive (Goderis, *et al.*, 2009; Greaves, *et al.*, 2003; Haque, *et al.*, 2005; Phillips, 2007a, 2007b; Sigurdardottir, 1999). Types of analyses used were: concept (Hunt, *et al.*, 1997), content (Greaves, *et al.*, 2003; Phillips, 2007a), constant comparison (Brown, *et al.*, 2002), thematic (Goderis, *et al.*, 2009; Phillips, 2007b), grounded theory (Haque, *et al.*, 2005), and Colaizzi's modification of phenomenological inquiry (Sigurdardottir, 1999) (Table 3.1.2).

Research instruments used in surveys

Only two (Larkin, *et al.*, 2008; Polonsky, *et al.*, 2005) out of seven quantitative studies used validated instruments to identify the barriers and facilitators in initiating insulin in patients with type 2 diabetes. "A survey for people who do not take insulin" (SPI) was used in two studies (Larkin, *et al.*, 2008; Polonsky, *et al.*, 2005) whilst the "Insulin Treatment Appraisal Scale" (ITAS) was used in one study (Larkin, *et al.*, 2008). Both instruments used a Likert scale to assess the barriers and facilitators. Five studies did not provide any information on whether the instrument they used was validated

(Ahmed, *et al.*, 2010; Hayes, *et al.*, 2008; Karter, *et al.*, 2010; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007). Four out of 5 studies used self-designed questionnaire (Ahmed, *et al.*, 2010; Hayes, *et al.*, 2008; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007) and one did not specify the instrument used (Karter, *et al.*, 2010). Areas assessed were: patient's perception of insulin; difficulties, barriers and willingness to start insulin; reasons for hesitance to start, discontinuation and non-initiation (Table 3.1.3).

Barriers and facilitators to insulin initiation

Barriers and facilitators can be divided into three categories: patient-related, healthcare professional and system factors. The most commonly reported barriers were insulin-related barriers while patient's belief that insulin improved their health was the most frequently cited facilitator to start insulin. More barriers than facilitators were reported (Table 3.1.4).

Patient-related factors

Injection-related barriers were the most commonly reported barriers. Nine papers identified the fear of injections as a barrier (Ahmed, *et al.*, 2010; Goderis, *et al.*, 2009; Haque, *et al.*, 2005; Hayes, *et al.*, 2008; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007; Phillips, 2007b) of which five (Ahmed, *et al.*, 2010; Haque, *et al.*, 2005; Karter, *et al.*, 2010; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007) differentiated between the fear of pain from injections from the fear of injections themselves. Insulin administration was perceived to be difficult and complicated (Ahmed, *et al.*, 2010; Hayes, *et al.*, 2008; Hunt, *et al.*, 1997; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Oliveria, *et al.*, 2007; Phillips, 2007b) Patients found it hard to adjust insulin dosages (Karter, *et al.*, 2010) and some thought that insulin was given

intravenously (Phillips, 2007b) Home monitoring of blood glucose was seen as an additional burden (Karter, *et al.*, 2010) and one study reported that monitoring of blood glucose was more painful than insulin injections (Phillips, 2007b).

Insulin-related side effects, namely hypoglycaemia (Hunt, *et al.*, 1997; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Nakar, *et al.*, 2007; Phillips, 2007b; Polonsky, *et al.*, 2005) and weight gain (Haque, *et al.*, 2005; Larkin, *et al.*, 2008; Nakar, *et al.*, 2007; Phillips, 2007b) were cited as barriers in eight studies. Patients were concerned about hypoglycaemia (Karter, *et al.*, 2010) even if they had not experienced any previous insulin-related side effects (Phillips, 2007a). Concerns about weight gain were especially prevalent in patients who were already overweight (Phillips, 2007b). Seven papers (Ahmed, *et al.*, 2010; Haque, *et al.*, 2005; Hunt, *et al.*, 1997; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Phillips, 2007a; Polonsky, *et al.*, 2005) reported patient misperceptions associating insulin with blindness, renal failure and amputations (Ahmed, *et al.*, 2010; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Polonsky, *et al.*, 2005).

Nine studies reported negative perceptions which prevented patients from starting insulin therapy. Patients perceived insulin to be ineffective (Ahmed, *et al.*, 2010; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007), unnecessary (Karter, *et al.*, 2010), caused health deterioration (Larkin, *et al.*, 2008) and worsened quality of life (Ahmed, *et al.*, 2010). The permanency of insulin was highlighted as a barrier by three studies (Ahmed, *et al.*, 2010; Larkin, *et al.*, 2008; Polonsky, *et al.*, 2005) with one study reporting that 53.1% of patients who were unwilling to take insulin felt that not being able to stop insulin therapy was a barrier (Polonsky, *et al.*, 2005). The belief that tolerance to insulin would develop (Ahmed, *et al.*, 2010) and patients would become addicted to insulin (Nakar, *et al.*, 2007) were also reported.

Table 3.1.4 Taxonomy of barriers and facilitators of insulin initiation in type 2 diabetes

Barriers	Number of studies in which this factor was identified as a barrier (Reference)	Facilitators	Number of studies in which this factor was identified as a facilitator (Reference)
Healthcare professional factors			
▪ Lack of knowledge and skills	5 (Brown, <i>et al.</i> , 2002; Karter, <i>et al.</i> , 2010; Oliveria, <i>et al.</i> , 2007; Phillips, 2007a; Sigurdardottir, 1999)	▪ Providing patient education/health information	2 (Goderis, <i>et al.</i> , 2009; Phillips, 2007a)
▪ Lack of doctor-patient relationship	4 (Karter, <i>et al.</i> , 2010; Larkin, <i>et al.</i> , 2008; Nakar, <i>et al.</i> , 2007; Oliveria, <i>et al.</i> , 2007)	▪ Effective communication	2 (Hayes, <i>et al.</i> , 2008; Nakar, <i>et al.</i> , 2007)
▪ Communication barriers	2 (Haque, <i>et al.</i> , 2005; Karter, <i>et al.</i> , 2010)	▪ Setting glycaemic target with patients	1 (Phillips, 2007b)
▪ Not involving patients in decision making	2 (Phillips, 2007a, 2007b)	▪ Involving patients in decision making	1 (Phillips, 2007b)
▪ Negative attitudes	1 (Haque, <i>et al.</i> , 2005)		
Patient factors			

Table 3.1.4, continued

<ul style="list-style-type: none"> ▪ Negative perception of insulin 	<p>9 (Ahmed, <i>et al.</i>, 2010; Haque, <i>et al.</i>, 2005; Hunt, <i>et al.</i>, 1997; Karter, <i>et al.</i>, 2010; Larkin, <i>et al.</i>, 2008; Nakar, <i>et al.</i>, 2007; Oliveria, <i>et al.</i>, 2007; Phillips, 2007b; Polonsky, <i>et al.</i>, 2005)</p>	<ul style="list-style-type: none"> ▪ Improved health (Feeling better with insulin and better QoL) 	<p>6 (Ahmed, <i>et al.</i>, 2010; Hayes, <i>et al.</i>, 2008; Hunt, <i>et al.</i>, 1997; Larkin, <i>et al.</i>, 2008; Phillips, 2007a, 2007b)</p>
<ul style="list-style-type: none"> ▪ Emotional barrier 	<p>9 (Ahmed, <i>et al.</i>, 2010; Hayes, <i>et al.</i>, 2008; Hunt, <i>et al.</i>, 1997; Karter, <i>et al.</i>, 2010; Larkin, <i>et al.</i>, 2008; Oliveria, <i>et al.</i>, 2007; Phillips, 2007a, 2007b; Polonsky, <i>et al.</i>, 2005)</p>	<ul style="list-style-type: none"> ▪ Poor physical health (feeling unwell) 	<p>1 (Phillips, 2007b)</p>
<ul style="list-style-type: none"> ▪ Lack of knowledge/Misconception about insulin side effects 	<p>8 (Ahmed, <i>et al.</i>, 2010; Goderis, <i>et al.</i>, 2009; Haque, <i>et al.</i>, 2005; Hunt, <i>et al.</i>, 1997; Karter, <i>et al.</i>, 2010; Larkin, <i>et al.</i>, 2008; Oliveria, <i>et al.</i>, 2007; Phillips, 2007a; Polonsky, <i>et al.</i>, 2005)</p>	<ul style="list-style-type: none"> ▪ No choice 	<p>1 (Nakar, <i>et al.</i>, 2007)</p>
<ul style="list-style-type: none"> ▪ Socio-demographic factor 	<p>5 (Ahmed, <i>et al.</i>, 2010; Haque, <i>et al.</i>, 2005; Hunt, <i>et al.</i>, 1997; Karter, <i>et al.</i>, 2010;</p>		

Table 3.1.4, continued

	Oliveria, <i>et al.</i> , 2007)		
▪ Negative attitudes	5 (Goderis, <i>et al.</i> , 2009; Hunt, <i>et al.</i> , 1997; Karter, <i>et al.</i> , 2010; Oliveria, <i>et al.</i> , 2007; Phillips, 2007b)		
▪ Lack of self-efficacy/skills	2 (Larkin, <i>et al.</i> , 2008; Polonsky, <i>et al.</i> , 2005)		
Insulin related factors			
▪ Fear of needle and pain	11 (Ahmed, <i>et al.</i> , 2010; Goderis, <i>et al.</i> , 2009; Haque, <i>et al.</i> , 2005; Hayes, <i>et al.</i> , 2008; Hunt, <i>et al.</i> , 1997; Karter, <i>et al.</i> , 2010; Larkin, <i>et al.</i> , 2008; Nakar, <i>et al.</i> , 2007; Oliveria, <i>et al.</i> , 2007; Phillips, 2007b; Polonsky, <i>et al.</i> , 2005)	▪ Benefits of insulin (improve sugar control, more effective than oral medications, prolong life, reduce complications)	6 (Ahmed, <i>et al.</i> , 2010; Hayes, <i>et al.</i> , 2008; Hunt, <i>et al.</i> , 1997; Larkin, <i>et al.</i> , 2008; Phillips, 2007a, 2007b)
▪ Side effects of insulin	7 (Haque, <i>et al.</i> , 2005; Hunt, <i>et al.</i> , 1997; Karter, <i>et al.</i> , 2010; Larkin, <i>et al.</i> , 2008; Nakar, <i>et al.</i> , 2007; Phillips,	▪ Timing of insulin initiation – initiate early	1 (Phillips, 2007b)

Table 3.1.4, continued

	2007b; Polonsky, <i>et al.</i> , 2005)		
▪ Barriers in administering	7 (Ahmed, <i>et al.</i> , 2010; Hayes, <i>et al.</i> , 2008; Hunt, <i>et al.</i> , 1997; Karter, <i>et al.</i> , 2010; Larkin, <i>et al.</i> , 2008; Oliveria, <i>et al.</i> , 2007; Phillips, 2007b)	▪ Able to self-adjust	1 (Ahmed, <i>et al.</i> , 2010)
▪ Hassle of home glucose monitoring	3 (Karter, <i>et al.</i> , 2010; Nakar, <i>et al.</i> , 2007; Phillips, 2007b)	▪ Dummy injections	1 (Phillips, 2007b)
		▪ Hands-on demonstration	1 (Phillips, 2007b)
Social factors			
▪ Inconvenience	7 (Ahmed, <i>et al.</i> , 2010; Hunt, <i>et al.</i> , 1997; Karter, <i>et al.</i> , 2010; Larkin, <i>et al.</i> , 2008; Oliveria, <i>et al.</i> , 2007; Phillips, 2007b; Polonsky, <i>et al.</i> , 2005)	▪ Peer support	2 (Phillips, 2007a, 2007b)
▪ Interference with social and work activities	6 (Ahmed, <i>et al.</i> , 2010; Haque, <i>et al.</i> , 2005; Karter, <i>et al.</i> , 2010; Larkin, <i>et al.</i> , 2008; Oliveria, <i>et al.</i> , 2007;	▪ Partner support	1 (Phillips, 2007a)

Table 3.1.4, continued

	Phillips, 2007a)		
▪ Stigma and discrimination	5 (Hunt, <i>et al.</i> , 1997; Larkin, <i>et al.</i> , 2008; Oliveria, <i>et al.</i> , 2007; Phillips, 2007a, 2007b)		
▪ Lack of social support	1 (Sigurdardottir, 1999)		
System factors			
▪ Lack of diabetes services	1 (Phillips, 2007b)	▪ Patient education	1 (Goderis, <i>et al.</i> , 2009)
▪ Lack of education resource	1 (Haque, <i>et al.</i> , 2005)	▪ Giving enough time	1 (Phillips, 2007b)
		▪ Follow up	1 (Phillips, 2007b)
		○ with telephone calls	
		○ giving telephone contact to patients	
		○ regular follow up	
		▪ Initiating insulin in primary care (vs secondary care)	1 (Greaves, <i>et al.</i> , 2003)
		▪ Referral to specialists	1 (Nakar, <i>et al.</i> , 2007)

For patient facilitators, the benefit derived from insulin was the most important factor and these include: more effective glycaemic control, improved chances of survival and reduced risk of complications (Ahmed, *et al.*, 2010; Greaves, *et al.*, 2003; Hayes, *et al.*, 2008; Hunt, *et al.*, 1997; Larkin, *et al.*, 2008; Phillips, 2007a, 2007b). Demonstrating the insulin injection technique using ‘dummy injections’ would also improve patient’s confidence to initiate insulin (Hunt, *et al.*, 1997; Phillips, 2007b). Other facilitators include early initiation of insulin (Hunt, *et al.*, 1997; Phillips, 2007b) and the flexibility of self-adjustment (Ahmed, *et al.*, 2010; Hunt, *et al.*, 1997).

Sociodemographic barriers to insulin initiation included being elderly (Haque, *et al.*, 2005; Karter, *et al.*, 2010), unable to afford the cost of insulin (Hunt, *et al.*, 1997; Karter, *et al.*, 2010; Oliveria, *et al.*, 2007) and religious obligations (Ahmed, *et al.*, 2010). Elderly patients were hesitant to initiate insulin if they had poor vision, unsteady hands or arthritis, and if they had little, or no social support (Haque, *et al.*, 2005; Karter, *et al.*, 2010). Patients would preferred to use other treatment options (Haque, *et al.*, 2005; Hunt, *et al.*, 1997; Oliveria, *et al.*, 2007) and had ‘more faith’ in complementary and alternative medicines (Haque, *et al.*, 2005).

One study noted that diabetes as a whole was a very frustrating illness (Phillips, 2007a) and there were many psychological barriers to insulin initiation (Brown, *et al.*, 2002). Six studies reported that patients felt that starting insulin meant that their diabetes had reached an advanced phase of illness (Ahmed, *et al.*, 2010; Hunt, *et al.*, 1997; Larkin, *et al.*, 2008; Phillips, 2007a, 2007b; W. H. Polonsky, *et al.*, 2005). Some patients thought that they had developed a different form of diabetes (Phillips, 2007a). Patients’ emotional barriers included the feeling of personal failure or punishment (Hayes, *et al.*, 2008; Hunt, *et al.*,

1997; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Phillips, 2007a; Polonsky, *et al.*, 2005) and feeling a lack of fairness (Larkin, *et al.*, 2008; Polonsky, *et al.*, 2005) when asked to start insulin. Other patient barriers included anxiety (Phillips, 2007b), depression (Ahmed, *et al.*, 2010; Oliveria, *et al.*, 2007), low self-efficacy (Larkin, *et al.*, 2008; Polonsky, *et al.*, 2005), forgetfulness (Oliveria, *et al.*, 2007) and being too busy to take insulin (Oliveria, *et al.*, 2007; Phillips, 2007b).

Lack of patient education was reported as a barrier (Goderis, *et al.*, 2009; Haque, *et al.*, 2005). Poor knowledge and misperceptions were not only barriers to insulin initiation but also to adherence. One study found that among patients starting insulin, there were significantly more non-adherent patients reporting poor health literacy compared to those who adhered to insulin (Karter, *et al.*, 2010).

The facilitators highlighted in the studies included patients desire to feel better symptomatically and have better quality of life (Ahmed, *et al.*, 2010; Greaves, *et al.*, 2003; Hayes, *et al.*, 2008; Hunt, *et al.*, 1997; Larkin, *et al.*, 2008; Phillips, 2007a, 2007b), to improve their poor physical health (Hunt, *et al.*, 1997; Phillips, 2007b) and having no choice (Hunt, *et al.*, 1997; Nakar, *et al.*, 2007).

Insulin treatment was viewed as inconvenient not only to patients themselves (Hunt, *et al.*, 1997; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Oliveria, *et al.*, 2007; Phillips, 2007b; Polonsky, *et al.*, 2005) but also with significant others. Physical inconveniences associated with insulin include problems with transport (Ahmed, *et al.*, 2010) and insulin cases (Oliveria, *et al.*, 2007; Phillips, 2007b). Insulin was viewed as affecting social ties (Ahmed, *et al.*, 2010; Haque, *et al.*, 2005; Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Phillips, 2007a), family relationships (Larkin, *et al.*, 2008) and work (Ahmed, *et al.*, 2010; Karter, *et al.*,

2010; Oliveria, *et al.*, 2007). Support from others was important to patients starting insulin and one study noted that a lack of social support could be a barrier to insulin initiation (Sigurdardottir, 1999).

For the facilitators, peer (Phillips, 2007a, 2007b) and partner (Hunt, *et al.*, 1997; Phillips, 2007a) support are considered as important factors that influence their uptake of insulin therapy.

Healthcare professional factors

Healthcare professionals' lack of knowledge and skills were the most commonly cited barrier for insulin initiation in patients (Brown, *et al.*, 2002; Karter, *et al.*, 2010; Oliveria, *et al.*, 2007; Phillips, 2007a; Sigurdardottir, 1999). Some patients found difficulty in starting insulin due to poor communication with their healthcare professionals (Haque, *et al.*, 2005; Karter, *et al.*, 2010) and a lack of good doctor-patient relationships (Karter, *et al.*, 2010; Larkin, *et al.*, 2008; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007). Other barriers include healthcare professionals' negative attitudes towards insulin (Haque, *et al.*, 2005; Karter, *et al.*, 2010) and not engaging patients in decision making (Phillips, 2007a, 2007b).

The review found that effective communication (Hayes, *et al.*, 2008; Nakar, *et al.*, 2007) and adequate patient education (Goderis, *et al.*, 2009; Phillips, 2007a) were two factors that facilitate insulin initiation. Patients were more likely to initiate insulin if healthcare professionals set glycaemic targets (Hunt, *et al.*, 1997; Phillips, 2007b) and involve them in decision making (Hunt, *et al.*, 1997; Phillips, 2007b).

System factors

Two studies reported on barriers found in the healthcare system. Phillips (Phillips, 2007b) reported that a lack of diabetes service in the community was a barrier and Haque *et al* (2005) found that there was a lack of educational resources available for patients in their preferred language in South Africa.

A number of facilitators were identified as important: patient education (Goderis, *et al.*, 2009; Hunt, *et al.*, 1997), having sufficient time for counseling (Hunt, *et al.*, 1997; Phillips, 2007b), regular follow up via clinic visits or telephone calls (Hunt, *et al.*, 1997; Phillips, 2007b) initiating insulin in primary care (vs secondary care) (Greaves, *et al.*, 2003), and referral to specialists (Hunt, *et al.*, 1997; Nakar, *et al.*, 2007).

Discussion

This systematic review documented the range of barriers and facilitators patients face during insulin initiation. By including both quantitative and qualitative studies, this systematic review managed to identify a range of factors (insulin-related, patient, healthcare professional, social and system factors) that the healthcare professionals should consider when advising patients with type 2 diabetes.

The quality of the papers were good and most achieved the QualSyst assessment scores of more than 0.7. However, the inter-rater reliability was below average (ICC less than 0.6) (Shrout & Fleiss, 1979). However, the two teams discussed and arrived at a consensus on the quality of the papers. For qualitative studies, three out of eight studies did not specify the qualitative approach (Brown, *et al.*, 2002; Greaves, *et al.*, 2003; Phillips, 2007b) but the analysis methods were stated in all studies and were appropriate. In two studies, the setting

where the studies were conducted were not mentioned. For quantitative studies, the response rates of most of the surveys were good (above 70%) except for three studies. The doctor survey, which was conducted via email by a research marketing company, achieved only 19.8% response rate (Hayes, *et al.*, 2008) while the two patient surveys recorded response rates of 33.1% (Polonsky, *et al.*, 2005) and 44.4% (Karter, *et al.*, 2010). The former was conducted with patients attending a diabetes conference while the latter used telephone to survey those who did not fill in the prescription after it was prescribed by the doctors. Interviewer-administered questionnaire survey achieved a better response rate compared to those administered via emails, telephones or at conferences.

The key barriers to insulin initiation in patient with type 2 diabetes appear to be related to insulin treatment and patient factors. Fear of pain and needles, concern about the side effects of insulin and the complexity of delivering the insulin remain major hurdles in insulin initiation. This is despite marked improvement in the delivery process (Brunton, 2008) and development of newer insulin with better safety profile (Rosenstock *et al.*, 2008). Patients perceived starting insulin as an indication of advanced diabetes which may lead to complications such as blindness, amputation and renal failure. This misconceptions cause delay in patient's decision to start insulin. Patients also 'blamed' themselves for failing to control their diabetes and some perceived insulin therapy as a punishment. These negative emotions could be avoided by explaining to the patients that the need for insulin therapy is part of the disease progression, (UK Prospective Diabetes Study (UKPDS) Group, 1998) particularly at the early stage of the illness rather than at the point of decision making (Lee, Lee, & Ng, 2013) Another key barrier concerns the healthcare professionals' ability to guide patients in making decisions about starting insulin. Those who lack knowledge and

have poor communication skills might face difficulty counselling patients on insulin treatment.

On the other hand, the main facilitators focus on the clinical benefits of insulin in reducing symptoms and complications as well as improving survival and quality of life. Providing patients with accurate health information and education can help to make a more informed decision about starting insulin therapy. In addition, system factors such providing adequate time for consultation and regular follow up may allow patients and healthcare professionals to discuss their concerns and expectations. Decision support tools such as a patient decision aid might be helpful to overcome this barrier (Mathers *et al.*, 2012).

This systematic review included studies which surveyed or interviewed patients who were at different stages of decision making as well as those who were already using insulin. The barriers and facilitators faced by insulin-naïve patients might be different from those who have already started insulin. There might be recall bias for insulin users and patients who have already started on the insulin might rationalise their decision by playing down the harms (Ahmed, *et al.*, 2010; Hunt, *et al.*, 1997; Karter, *et al.*, 2010; Nakar, *et al.*, 2007; Oliveria, *et al.*, 2007; Phillips, 2007a; Polonsky, *et al.*, 2005). Nevertheless, this systematic review aimed to identify the range of factors that influence insulin initiation and not to quantify the frequency of these factors. Patients and healthcare professionals have different views on which barriers and facilitators are more relevant to the patients. While healthcare professionals emphasise on patients' concerns about side effects of insulin and injections, patients were also worried about the lack of social support and emotional impact.

Therefore, there is a need for the healthcare professionals to ask patients for their concerns and address them accordingly as their concerns are often different from those assumed by

the healthcare professionals (Brown, *et al.*, 2002; Goderis, *et al.*, 2009; Greaves, *et al.*, 2003; Haque, *et al.*, 2005; Hayes, *et al.*, 2008; Nakar, *et al.*, 2007; Phillips, 2007b; Sigurdardottir, 1999).

There are limitations in this systematic review. Firstly, this review only searched PubMed database and included only English articles. Future systematic review may consider expanding to include other databases such as CINAHL and PsycInfo as well as other languages.

Conclusion

This systematic review has identified the key factors that influence insulin initiation in patients with type 2 diabetes: insulin-related, patient, healthcare professional, social and system factors. When counselling patients who are considering insulin, it is important to explore the barriers faced by patients and address them accordingly. This will ensure that patients will make an informed decision about their diabetes treatment.

Chapter 3.2: Definitions and concepts of patient values in medical decision making: A systematic review

Yew Kong Lee, Chirk Jenn Ng, Wah Yun Low.

Submitted

Author contributions

YKL led the study, conducted the database searches and prepared the final manuscript. CJN and YKL reviewed all papers. WYL contributed to the final manuscript.

Abstract

Background: Patient values are the main component of patient participation in medical decision making. However, there is no consensus on what patient values are and how they should be incorporated in medical decision making.

Purpose: This systematic review aimed to identify definitions of patient values within the context of medical decision making and synthesize these definitions into an integrated model of patient's values.

Data sources: Database searches were conducted in April 2011 in Pubmed, CINAHL and PsycINFO on the terms patient values and decision making.

Study selection: Out of a total of 614 articles retrieved, 43 had a definition of patient values and were included for review. Slightly over half of these articles linked their concept of patient values to a theory or conceptual framework.

Data extraction: Key phrases which mentioned patient values were extracted by trained reviewers.

Data synthesis: A thematic analysis of the definitions was performed.

Results: The review did not find a common definition for patient values. However three major themes were identified. Firstly, values can be divided into two categories: healthcare and decision-making preference. Secondly, there are two dimensions in the structure of values: relative priority and longitudinal stability. Thirdly, values function by filtering information and determining which goals are most important to patients. These themes are synthesized into an integrated model of patient values. By including the dimension of

longitudinal stability into patient values, this model is especially useful for long-term care situations such as chronic disease management and primary care practice.

Limitations: Non-English language studies on values have been excluded. These studies may be important to inform culture-specific categories of patient's values.

Conclusions: Researchers and practitioners should clarify their use of the term patient values in research and practice. A clear definition which embraces a range of concepts will help practitioners understand and examine the patient perspective.

Keywords: Patient values; decision making; conceptual framework

Introduction

Patients are increasingly being involved in medical decision making. This follows a shift in healthcare models from a paternalistic model (Charles, Gafni, & Whelan, 1997) to one where the patient's perspective is seen as integral to the healthcare process (Sullivan, 2003). Collaborative, patient-centred decision-making is viewed as a key process indicator of the quality of healthcare (Spring, 2008).

Patient values are a central component of patient participation. For example, in evidence-based medicine, patient values are considered alongside best research evidence and clinical expertise (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000). In the shared decision-making model, the concept of "patient's values or preferences" was the most mentioned concept (Makoul & Clayman, 2006). In research to support patients in decision making, good decisions are defined as those that achieve patient value-decision concordance (Elwyn, Frosch, Volandes, Edwards, & Montori, 2010; International Patient Decision Aids Collaboration, 2006; O'Connor, Tugwell, & Wells, 1998; Stacey et al., 2011). Patient values are described as being 'crucial' (Ikomi & Kunde, 2002), 'essential' (Makoul & Clayman, 2006) and a 'guide to medical decision making' (Miller & Bolla, 1998).

Acknowledging that patient values are to be incorporated into healthcare decisions is only useful if there is a clear definition of what patient values are. Therefore, this review aimed to systematically review how the term 'patient values' is used within the context of medical decision-making and to synthesize a model what patient values are.

Methods

Search strategy

A three-staged search and data extraction strategy was developed based on the review aims. Stage 1 and Stage 2 involved database searching and reference mining to extract relevant full-text articles. Stage 3 involved the extraction of data from these articles using a standardised data extraction form.

Stage 1 (Database search)

Database searches were conducted in April 2011 on Pubmed, CINAHL and PsycINFO, which are the three main databases for patient-related literature. The closest Pubmed MeSH term to patient values was “patient preference” (defined as “Individual's expression of desirability or value of one course of action, outcome, or selection in contrast to others.”) (National Center for Biotechnology Information). However, the search with the term “patient preference” identified studies describing quantitative decision preferences between two or more healthcare options; there was no mention of the concept of patient’s values. Furthermore, this MeSH was only created recently in 2010. Therefore, a free text search was performed using the Pubmed Advanced Search Builder indexing function to help identify similar and related terms. The search results were then combined with the MeSH term “Decision Making”. The search yielded a total of 138 articles.

We also searched the CINAHL database using free-text terms “patient values”, “patient attitudes” and “patient beliefs” and they were combined with the major heading “Decision Making, Patient”. The search was further combined with “"Definition" OR "Literature Review" OR "concept analysis"” to more accurately capture articles discussing the concept

of patient values. Lastly, the PsycINFO database was searched using the free-text terms (“Value*” OR “Attitude*” OR “Preference*”), “Decision Making” and “Patients”.

Two independent reviewers (NCJ, LYK) reviewed all titles and abstracts based on a set inclusion criteria (Table 3.2.1). A more inclusive stance was adopted at this stage and articles which we were uncertain about were included for full-text review in stage 2. The results between the reviewers were compared and discrepancies resolved by discussion until a consensus was reached.

Table 3.2.1: Inclusion criteria for articles

- 1) Only articles within the context of Medical Decision Making within the context of patient and healthcare professional consultation.
- 2) The authors state a clear definition of patient values OR the authors give a description of how they elicit or clarify patient values. In the latter, the values clarification method will then be analysed to provide a definition of patient values. The definition will also be inferred if patient values are explicitly mentioned in the article title as this signifies that the concept is a focal point of the article.
- 3) Only articles published as full text will be included. Articles published only in abstract format will not be reviewed.
- 4) Only English articles will be reviewed.
- 5) The search period will cover articles from 1966 – 4 April 2011.

Stage 2 (Stage 1 full text review and snowballed references)

Full text articles from Stage 1 were reviewed by a trained reviewer (LYK). Only articles that explicitly discussed the concept of patient's values were included for further review.

Articles that met the inclusion criteria were included for Stage 3.

References from Stage 2 articles were reviewed and 'footnote chasing' (Wilson, 1992) was conducted whereby the list of references from Stage 2 articles was searched for more articles and the article list was expanded by adding articles that met the inclusion criteria until saturation was reached.

Stage 3 data extraction

Two researchers (NCJ, LYK) developed the data extraction form and the form was pilot tested and further refined. Full text articles from Stage 2 were reviewed by LYK. As the purpose of the review was a qualitative synthesis of the patient's values concept, articles were not assessed for strength of quantitative research evidence.

Data analysis

The data was analysed in two ways; theoretically and thematically. Firstly, a theoretical or conceptual analysis was performed to identify the theory or conceptual framework used to discuss patient values. Secondly, a thematic analysis of the definitions was performed. Key phrases which mentioned patient values were extracted and these were used to develop themes for the patient values concept, which were further grouped into larger categories.

Results

The final number of articles reviewed was 613, of which 43 mentioned the patient values concept (Figure 3.2.1). Stage 1 database searching identified 30 articles and a further 13 were included through Stage 2 reference-searching.

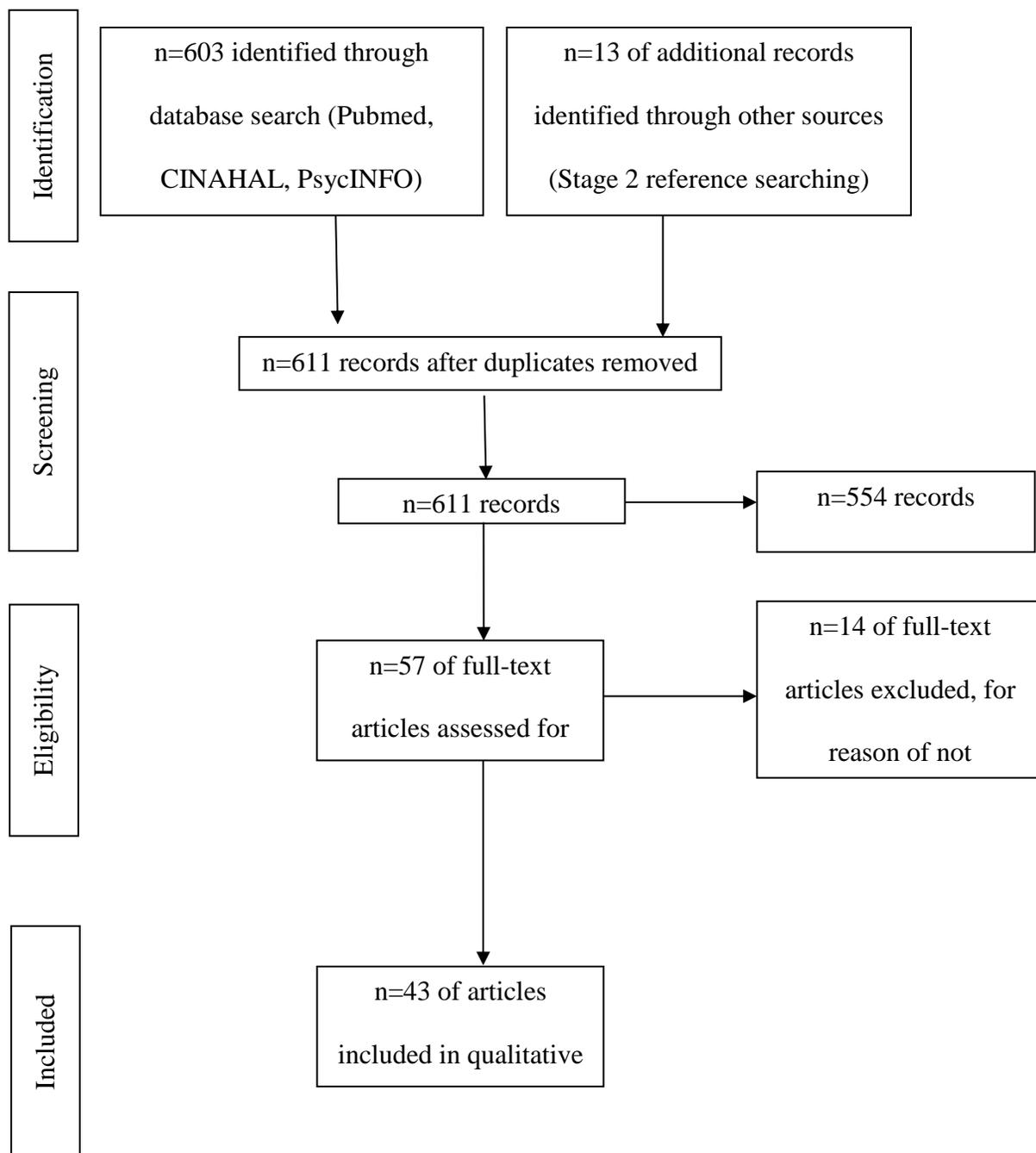


Figure 3.2.1: PRISMA search flowchart for definition of patient values (Liberati et al., 2009).

In Stage 1, a total of 606 articles were retrieved from the three databases of which three articles were duplicated and discarded (Table 3.2.2). Out of 603 articles, 49 articles were included for full-text review in Stage 2 based on the titles and abstracts. Two full text articles could not be retrieved and attempts to contact the authors were not successful, therefore these articles were excluded from Stage 2. In Stage 2, a total of 30 articles were included for data extraction in Stage 3 after the full text review. A further 13 articles were included after searching the references of these 30 articles.

Table 3.2.2: Stage 1 literature search strategy

Database	Search terms	Articles
Pubmed	("Patient value*" OR "patient attitude*" OR "patient belief*" OR "patient preference*") AND "Decision Making" [Mesh]	138
CINAHL	("Patient value*" OR "patient attitude*" OR "patient belief*" OR "patient preference*") AND (MM "Decision Making, Patient+") AND ("Definition" OR "Literature Review" OR "concept analysis")	212
PsycINFO	("Value*" OR "Attitude*" OR "Preference*") AND "Decision Making" AND "Patients"	256
TOTAL (Note: 3 articles discarded)		603

Included articles which mentioned patient values are summarised in Table 3.3.3. The articles consisted of literature reviews (n=3), essays (n=18), original research reports (n=18), book chapters (n=2), and one letter. Patient values were discussed in the following contexts: gerontological or end-of-life conditions or advanced directives (n=19); other medical conditions (urology, various cancers, transfusion medicine, breech deliveries, mammographic screening, prenatal testing, psoriasis, hormone replacement therapy) (n=12); medical decision making frameworks (shared decision making, evidence based medicine, informed consent, biopsychosocial models) and ethics (n=12).

The theory base for patient values

A total of 27 articles referred to a theory or conceptual framework when discussing patient values. The most common frameworks used were shared decision making (n=10), evidence based medicine (n=5), and expected utility theory (n=4) (Table 3.2.4).

Table 3.2.3 Articles included for review on patient values

No.	Reference	Year	Manuscript type	Decisional Context	Theory base	Description of patient values
1.	Baron J. Biases in the quantitative measurement of values for public decisions. Psychol Bull. 1997;122(1):72-88. (Baron, 1997)	1997	Discussion	The role of patient values in policy making	Baron's Norm-endorsement Utilitarianism	<i>"The idea of values is that we have some sort of ultimate standards by which we evaluate states of affairs (Baron, 1996). We define our good in terms of these standards."</i> pg 74
2.	Black K, Emmet C. Nurses' advance care planning communication: an investigation. Geriatr Nurs. 2006 Jul-Aug;27(4):222-7; quiz 8. (Black & Emmet, 2006)	2006	Research article	Advanced Directives, end of life	None	Under the Advance Directive Communication Practices Mean Subscale and Item Scores, the item "Elicitation of patient values" contained five items (pg 225): 1. Impact on self-care 2. Values of resuming prior lifestyle 3. Concerns regarding dependence on others 4. Issues regarding nursing home placement 4. Costs of treatment
3.	Black K. Advance directive communications practices:social worker's contributions to the interdisciplinary health care team.	2005	Research article	Advanced Directives, end of life	None	The advanced directive phase of "Elicitation of patients values" is defined as <i>"Encouraged consideration about impact of treatment decisions on future ability for self-care, importance to</i>

Table 3.2.3, continued

	Soc Work Health Care. 2005;40(3):39-55. (Black, 2005)					<i>patient of resuming previous lifestyle, likelihood of dependence on others for future care, patient concerns about post-acute rehabilitation and potential nursing home placement, financial concerns about treatment" pg 45</i>
4.	Brock DW. The ideal of shared decision making between physicians and patients. Kennedy Inst Ethics J. 1991 Mar;1(1):28-47. (Brock, 1991)	1991	Discussion	Ethics in 'shared treatment decision making'	Shared Decision Making/ Informed Shared Decision making/ Shared Model	<i>"The patient's role in this division of labor is to provide the values- <u>his or her own conception of the good</u>- with which to evaluate these alternatives, and to select the one that is best for himself of herself" pg 28</i>
5.	Canfield SE, Dahm P. Evidence-based urology in practice: incorporating patient values in evidence-based clinical decision making. BJU Int. 2010 Jan;105(1):4-5. (Canfield & Dahm, 2010)	2009	Discussion	Urology	None	Values and preferences are defined as patients' goals, predispositions and beliefs. The phrase patient values is explicitly stated in the title. The definition of values is quoted as " <i>patient's individual circumstances, values and preferences , which are defined as 'the collection of goals, expectations, predispositions, and beliefs that individuals have for certain decisions and their potential outcomes' (Montori et al, 2008)"</i> pg 4.
6.	Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter:	1999	Discussion	General medical	Shared Decision Making/ Informed Shared	Values function as filters in processing medical information. " <i>Patients interpret information on average treatment outcomes in order to make</i>

Table 3.2.3, continued

	revisiting the shared treatment decision-making model. Soc Sci Med. 1999 Sep;49(5):651-61. (Charles, Gafni, & Whelan, 1999)			practice	Decision making/ Shared Model	<i>them personally meaningful within the decision-making context they face (Adelsard and Sachs, 1996; Turney, 1996; Charles et al., 1998). In so doing, their own values and beliefs act as filters in processing what information is allowed in and how it is understood (Williams and Calnan, 1996)." pg 655</i>
7.	Coppola KM, Ditto PH, Danks JH, Smucker WD. Accuracy of primary care and hospital-based physicians' predictions of elderly outpatients' treatment preferences with and without advance directives. Arch Intern Med. 42001 Feb 12;161(3):431-40. (Coppola, Ditto, Danks, & Smucker, 2001)	2001	Research article	Advanced Directives, end of life	None	Values are the preference for health outcomes along different life-sustaining options and their requisite risks and benefits " <i>In the patient version of the LSPQ, patients imagined themselves in each medical scenario and indicated their preference for receiving each of the 4 medical treatments</i> " <i>Advance Directives Values Assessment and Communication Enhancement (ADVANCE) project, pg432</i>
8.	Coverdale J, McCullough LB, Molinari V, Workman R. Ethically justified clinical strategies for promoting geriatric assent. Int J Geriatr Psychiatry. 2006 Feb;21(2):151-7. (Coverdale, McCullough,	2006	Discussion	Geriatric Assent	Coverdale et al's framework for patient participation	Values are what is important to patients and what their goals are. " <i>Promoting geriatric assent in this context means that as part of the overall work-up and assessment of the patient's decision-making capacities the psychiatrist should elicit from the patient his or her values and preferences. One way to accomplish this is simply</i>

Table 3.2.3, continued

	Molinari, & Workman, 2006)					<p><i>to ask patients what is important to them under the current circumstances (McCullough et al., 1993). One could also ask the patient what his or her goals are." pg 153</i></p> <p>Long-standing & Stable vs. Current and at-odds <i>"Sometimes patients with significant cognitive impairments may express values and preferences at odds with their long-standing values. Some have proposed treating such values as authoritative, when the patient's current quality of life seems satisfactory to him or her (Dresser, 1994, 1995). A full discussion of the philosophical problems with such a view is beyond the scope of this paper. However, we suggest that it is not at all clear that current values should have controlling authority over prior expression of values, because they are expressed by an individual whose self has been significantly diminished by memory loss, thus unhinging the patient from his or her past." pg 153</i></p>
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Table 3.2.3, continued

9.	DeSanto-Madeya S, Nilsson M, Loggers ET, Paulk E, Stieglitz H, Kupersztoch YM, et al. Associations between United States acculturation and the end-of-life experience of caregivers of patients with advanced cancer. <i>Journal of Palliative Medicine</i> . 2009 Dec;12(12):1143-9. (DeSanto-Madeya et al., 2009)	2009	Research article	End of Life	None	Values are a part of culture. "Culture, which refers to the beliefs, values, and lifeways of people of diverse races and ethnicities, shapes how individuals view health, illness, and death" page 1143
10.	Doukas, D. J., & McCullough, L. B. (1991). The values history. The evaluation of the patient's values and advance directives. <i>J Fam Pract</i> , 32(2), 145-153.	1991	Discussion	End of life, living will, advanced directives	None	Values as relevant to terminal care are of personal importance to patients. The "The Values Section" in the Values History questionnaire is described as: "The first choice in the Values Section of the Values History is basic: the question of length of life vs quality of life. Next, the patient is asked to identify which values relevant to terminal care (eg, based on dignity, comfort, or personal philosophy) are important. These values-based statements have been found in pilot testing with patients to be those that express commonly held values in patient health care decision making. Obviously these values may be supplemented to reflect the values of an individual patient. Alternatively, the patient may

Table 3.2.3, continued

						<i>add other value-based statements to the list. The list provided is a useful starting point."</i>
11.	Doukas DJ, Antonucci T, Gorenflo DW. A multigenerational study on the correlation of values and advance directives. <i>Ethics & Behavior</i> . 1992;2(1):51-9. (Doukas, Antonucci, & Gorenflo, 1992)	1992	Research article	End of Life	None	Same definition as Doukas 1991. This paper reports a multigenerational survey using the Values History (n=105).
12.	Feldman-Stewart D, Brennenstuhl S, Brundage MD, Roques T. An explicit values clarification task: Development and validation. <i>Patient Education and Counseling</i> . 2006 Nov;63(3):350-6. (Deb Feldman-Stewart, Sarah Brennenstuhl, Michael D. Brundage, & Tom Roques, 2006)	2006	Research article	Prostate cancer	Svenson's Differentiation and Consolidation (DiffCon) Theory of Decision Making	Values are qualities that patients consider desirable. "Values" refers to qualities that the individual considers desirable or not, and in these situations they often relate to quantity or quality of life" pg 350
13.	Epstein, R. M. and E. Peters (2009). "Beyond information: exploring patients' preferences." <i>JAMA</i> 302(2): 195-197. (Epstein	2009	Discussion	General medical practice	Shared Decision Making/ Informed Shared Decision	Values are beliefs underlying preferences. <i>The values underlying preferences (eg, a meaningful life) also may change as patients get sicker.</i> pg

Table 3.2.3, continued

	& Peters, 2009)				making/ Shared Model and Patient- Centred Care/ Person-Centred Practice	196
14.	Guyatt GH, Straus SE, McAlister FA, Haynes RB, Sinclair J, Deveraux PJ, et al. Moving from evidence to action: incorporating patient values. In: G G, D R, editors. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice: The Evidence-Based Medicine Working Group. Chicago: JAMA & Archives Journals AMA Press; 2002. p. 567-82. (Guyatt et al., 2002)	2002	Book chapter	EBM practice	Evidence Based Medicine/ Evidence Based Practice	Values are how patients feel about the health states/ options. The phrase patient values is explicitly stated in the title. No explicit definition of patient values. There are two fundamental strategies to incorporating patient values: 1. Communicating the risks and benefits to the patient so that they can incorporate their own values and preferences, 2. Ask patients to place a relative value on the key outcomes associated with management options. (p 571). On pg 575 there is a description of a 'health thermometer method' for eliciting patient values which is used to elicit how do patients feel about the health states in (p. 575)
15.	Heddle NM. Evidence-based decision making in transfusion medicine. Vox Sang. 2006 Oct;91(3):214-20. (Heddle, 2006)	2006	Discussion	Transfusion medicine	Evidence Based Medicine/ Evidence Based Practice	Values are related to patient choices of different treatment options. Under the section " <i>Patient preferences and values</i> " the following is described " <i>When the term evidence-based medicine was first coined in the early 1990s, it</i>

Table 3.2.3, continued

						<p><i>was realized that patient's preferences were an important part of the process; however, as the concept of evidence-based medicine evolved, it became recognized that the patient's values should also be taken into account". There is no explicit description of patient values. A case scenario involving a couple who was allowed to choose the 'no treatment' option after a receiving Rh-positive blood for anemia even though the pregnant patient was Rh-negative was used to illustrate "that the decision in this scenario incorporate the patient's own preferences and values". pg 217</i></p>
16.	Ikomi A, Kunde D. Managing term breech deliveries. Patient values are crucial for good medical decision making. BMJ. 2002 Jan 5;324(7328):50; author reply -1. (Ikomi & Kunde, 2002)	2002	Letter	Breech deliveries	Evidence Based Medicine/ Evidence Based Practice	<p>Values are the individual importance placed on different birth options. The term patient values is explicitly stated in the title. However, the only description of values is as follows: "<i>Individual women place different value on birth processes and outcomes</i>" pg 50</p>

Table 3.2.3, continued

17.	Karel MJ, Powell J, Cantor MD. Using a Values Discussion Guide to facilitate communication in advance care planning. <i>Patient Educ Couns.</i> 2004 Oct;55(1):22-31. (Karel, Powell, & Cantor, 2004)	2004	Research article	End of life, advanced care planning	None	<p><i>Values are: what is most important; what is meaningful of good; religious or personal beliefs; treatment decision making; feelings; surrogate decision making preference; financial concerns; family concerns; instruction compliance preference.</i> From the revised Values Discussion Guide, pg 30:</p> <ol style="list-style-type: none"> <i>1. First, think about what is most important to you in your life. What makes life meaningful or good for you now?</i> <i>2. Now, think about what is important to you in relation to your health. What, if any, religious or personal beliefs do you have about sickness, health care decision-making, or dying?</i> <i>3. (a) Have you or other people you know faced difficult medical treatment decisions during times of serious illness? (b) How did you feel about those situations and any choices that were made?</i> <i>4. Some people feel a time might come when their life would no longer be worth living. Can you imagine any circumstances in which life would be so unbearable for you that you would not want medical treatments used to keep you alive?</i> <i>5. If your spokesperson ever had to make a medical decision on your behalf, are there certain</i>
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Table 3.2.3, continued

						<p><i>people you would want your spokesperson to talk to for advice or support (family members, friends, health care providers, clergy, other)?</i></p> <p><i>6. Is there anyone you specifically would NOT want involved in helping to make health care decisions on your behalf?</i></p> <p><i>7. How closely would you want your spokesperson to follow your instructions about care decisions, versus do what they think is best for you at the time decisions are made?</i></p> <p><i>8. Should financial or other family concerns enter into decisions about your medical care? Please explain.</i></p> <p><i>9. Are there other things you would like your spokesperson to know about you, if he or she were ever in a position to make medical treatment decisions on your behalf?</i></p>
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Table 3.2.3, continued

18.	Karel MJ. The assessment of values in medical decision making. <i>J Aging Stud.</i> 2000;14:403-22. (Karel, 2000)	2000	Discussion	Aging Studies	None	<p><i>“A further challenge for the development of a health care values assessment tool is to determine what we mean by “values.” How broadly or specifically should this construct be conceived to be useful for the above-stated goals? <u>Values most broadly conceived may be defined as “(a) concepts or beliefs, (b) about desirable end states or behaviors, (c) that transcend specific situations, (d) guide selection or evaluation of behavior and events, and (e) are ordered by relative importance”.</u> A number of models exist regarding definition of core values. For example, Rokeach (1973:7) distinguished between instrumental and terminal values, respectively referring to “beliefs concerning desirable modes of conduct or desirable end-states of existence.” Examples of instrumental values include ambitious, honest, and independent; examples of terminal values include equality, happiness, and wisdom. It is unclear whether the range of values identified by researchers in this field, developed empirically through studies with generally healthy people, apply in situations of illness and disability. One hypothesis is that</i></p>
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Table 3.2.3, continued

						<p><i>the range of values guiding decision making and behavior becomes restricted in ill health or terminal illness. Health care values might be more narrowly conceived as beliefs pertinent to health care choices such as meanings of pain and suffering, importance of choice and control, comfort with risk taking, and importance of interpersonal connection" pg 412-413.</i></p>
19.	<p>Kennedy ADM. On what basis should the effectiveness of decision aids be judged? Health Expect. 2003;6:255-68. (Kennedy, 2003)</p>	2003	Review	Effectiveness of Decision Aids	None	<p>Values are patients values about potential health outcomes and available options <i>"The Decisional Conflict Scale measures subject's perceptions of the extent to which they are uncertain about which option to choose, the factors contributing to this uncertainty and the effectiveness of their decision. Of the 16 items that make up the scale just one, on the decision effectiveness subscale, addresses whether the choice reflected the patient's values, and this particular subscale exhibits low discriminant abilities."</i> pg 265 (Item 14 "My decision shows what is important to me")</p> <p><i>"...then the effectiveness of decision aids should</i></p>

Table 3.2.3, continued

						<i>be judged by the extent to which patients undergo treatments that are consistent with their values for the potential outcomes of the available options."</i> pg 265
20.	Keyser PK. After Cruzan: the "values base" to advance directives. Orthop Nurs. 1992 Sep-Oct;11(5):37-40. (Keyser, 1992)	1992	Discussion	Advanced Directives, end of life	None	<i>"<u>Values are the lived sources of meaning for a person, and they actively constitute a person's history when put into words</u>"</i> pg 39
21.	Kirk TW, Luck GR. Dying tax free: the modern advance directive and patients' financial values. J Pain Symptom Manage. 2010 Mar;39(3):605-9. (Kirk & Luck, 2010)	2010	Research article	Advanced Directives, end of life	None	<i>"This raises the larger question of whether health care providers should- or, even can,-evaluate which kinds of patient values are appropriate to use in medical decision making. The literature is replete with evidence that cultural and religious values are accorded great respect in medical decision making especially at the end of life. Why would these kinds of patient values be considered valid and appropriate reasons for extending life-sustaining treatment but financial values (which could also be construed as values about the family) considered inappropriate?"</i> pg 608

Table 3.2.3, continued

22.	Llewellyn-Thomas H, Sutherland HJ, Tibshirani R, Ciampi A, Till JE, Boyd NF. The measurement of patients' values in medicine. <i>Med Decis Making</i> . 1982 Winter;2(4):449-62. (H. Llewellyn-Thomas et al., 1982)	1982	Research article	healthcare decision making	Expected Utility/ Utility Theory	Patient values are stated in the title and defined in the text as preference for a health state (according to standard gamble theory).
23.	Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. <i>Patient Educ Couns</i> . 2006 Mar;60(3):301-12. (Makoul & Clayman, 2006)	2006	Review	Shared Decision Making	Shared Decision Making/ Informed Shared Decision making/ Shared Model, and, Lewin's transactional theory of communication	<i>"Physicians and patients should discuss the pros and cons of options raised, particularly because they may have different perspectives on the relative importance of benefits, risks, and costs, including convenience and opportunity cost. These perspectives become evident through <u>explication of patient values and preferences – including ideas, concerns, and outcome expectations – as well as physician knowledge and recommendations in the context of the decision at hand.</u>" pg 305</i>
24.	Martin VC, Roberto KA. Assessing the stability of values and health care preferences of older adults: a long-term comparison. <i>J Gerontol Nurs</i> . 2006;32(11):23-33. (Martin &	2006	Research article	Stability of values in gerontological decision making	Etzioni's Normative-Affective model of decision making	Values are religious/ spiritual values <i>"Among the values and beliefs found to be specifically influential in the decision-making process of older adults are religion and spirituality."</i> pg 24 Values are used to evaluate medical treatment

Table 3.2.3, continued

	Roberto, 2006)					<p>options. <i>"Collectively, these values serve as the foundation from which older adults formulate opinions about accepting or rejecting medical treatment options." pg 25</i></p> <p>Values are consistent beliefs and can be prioritized. <i>"In perhaps the most notable values study across time and health states, Rokeach and Ball-Rokeach (1989) surveyed 1,409 participants for a period of 13 years. The participants, ranging in age from 11 to 90 years, were asked to rank a group of 18 values at four different points in time. The researchers described the results as incredibly stable, with the top six and the bottom six values receiving identical priority rankings across the 13 years." pg 25</i></p>
25.	McAlister FA, Straus SE, Guyatt GH, Haynes RB. Users' guides to the medical literature: XX. Integrating research evidence with the care of the individual patient. Evidence-Based Medicine Working Group. JAMA. 2000 Jun 7;283(21):2829-	2000	Discussion	General	Concept	<p>Under the section "Patients Values and Preferences:</p> <p>Values are patient's preferences for participation at various stages of DM " <i>..the initial step in this process is to determine the extent to which your patient wants to be involved in decision making"</i></p>

Table 3.2.3, continued

	36. (McAlister, Straus, Guyatt, & Haynes, 2000)					Values are patient's preference for likelihood of being helped or harmed (healthcare options)"The first step in this method is the exploration of patient values about receiving the treatment (vs not receiving it) and the severity of adverse events that might be caused by the treatment (vs the severity of the target event that we hope to avoid with the treatment" - under Patients Values and Preferences.
26.	McCormack B. A conceptual framework for person-centred practice with older people. <i>Int J Nurs Pract.</i> 2003 Jun;9(3):202-9. (McCormack, 2003)	2003	Discussion	Gerontological nursing care	Shared Decision Making/ Informed Shared Decision making/ Shared Model	Values are what patient's value about their life and how they make sense (meaning) of what is happening. "It is important to develop a clear picture of what patients value about their life and how they make sense of what is happening." pg 205
27.	Meropol NJ, Egleston BL, Buzaglo JS, Benson AB, 3rd, Cegala DJ, Diefenbach MA, et al. Cancer patient preferences for quality and length of life. <i>Cancer.</i> 2008 Dec 15;113(12):3459-66.	2008	Research article	Cancer	C-SHIP (Cognitive-Social Health Information Processing)	Values are the importance of QOL and LOL life in cancer treatments. "Since distress can impact a patient's ability to process critical prognostic and treatment-related information relevant to treatment choice, examination of its relationship to an individual's values (e.g.

Table 3.2.3, continued

	(Meropol et al., 2008)					<p><i>importance of quality of life and length of life) and communication preferences is essential."pg 2</i></p> <p>Values are influenced by emotions "<i>Given a potential relationship between affect and values, an association between patient distress and QOL vs. LOL preferences was investigated." pg 5</i></p>
28.	<p>Michaels C, McEwen MM, McArthur DB. Saying "no" to professional recommendations: client values, beliefs, and evidence-based practice. J Am Acad Nurse Pract. 2008;20(12):585-9. (Michaels, McEwen, & McArthur, 2008)</p>	2008	Discussion	Declining HCP recommendations	Health Belief Model	<p>Values are how patients define their own bodies, identities and experiences. These definitions influence a patient to agree or disagree with HCPs' recommendations."<i>Because values and beliefs tend to be deeply held, clients themselves may not readily be aware. But, by simply listening to a client's health stories, values and beliefs can be identified. As stated by Holloway and Freshwater (2007), "In our society, health professionals are seen as members of an elite culture. Their clients do often believe in and follow the dominant discourse of health professionals. . In storytelling, however, participants in narrative inquiry have the power to define their own bodies, identities and experience, rather than having their reality</i></p>

Table 3.2.3, continued

						<i>shaped by others'' (p. 9). The core belief and values that underlie health-related values and beliefs will be evident in their stories."pg 588</i>
29.	Miller DL, Bolla LR. Patient values: the guide to medical decision making. Clin Geriatr Med. 1998 Nov;14(4):813-29. (Miller & Bolla, 1998)	1998	Discussion	Advanced Directives, end of life	None	The term 'patient values' is stated in the title and the article describes how patient values are to be incorporated in end-of-life situations.
30.	Montori V, Deveraux PJ, Straus SE, al e. Decision making and the patient. In: Guyatt G, Rennie D, Meade MO, DJ C, editors. Users' Guides to the Medical Literature: a Manual for Evidence-Based Clinical Practice. 2 ed. New York: American Medical Association; 2008. p. 643-61. (Montori, Deveraux, Straus, & al, 2008)	2008	Book chapter	EBM practice	Evidence Based Medicine/ Evidence Based Practice	<i>"We use values and preferences as an overarching term that includes patients' perspectives, beliefs, expectations and goals for health and life. We also use this phrase, more precisely, to mean the processes that individuals use in considering the potential benefits, harms, costs, and inconveniences of the management options in relation to one another." Pg 644</i>
31.	Myers RE. Decision Counseling in Cancer Prevention and Control. Health Psychol. 2005; 24	2005	Research article	Cancer prevention and control	Shared Decision Making/ Informed Shared Decision	Types of values (under the Preventive Health Model) are: Cognitive, Affective and Cultural. <i>"For study participants, the distribution of prostate cancer screening representations was as</i>

Table 3.2.3, continued

	(4):S71-S7. (Myers, 2005)				making/ Shared Model, and, Informed Decision Making/ Informed model/ Informed Choice, and, Preventive health model	<p><i>follows: cognitive-pro (43.5%), affective-pro (23.5%), cognitive-con (17.5%), affective-con (15.5%). The following statements are examples of cognitive-pro decision factors articulated by the men: "Testing would show if I am likely to have a health problem" and "Screening is just part of how I take care of my health." pg S74</i></p> <p><i>"In a PHM-based decision-counseling session, healthcare providers may be able to help patients clarify their preferred course of action and facilitate movement toward selection of a behavioral alternative that is consistent with expressed personal values and compatible with good medical care" pg S76</i></p>
32.	O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, et al. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. Patient Educ Couns. 1998 Mar;33(3):267-79. (O'Connor, et	1998	Research article	HRT after menopause	Shared Decision Making/ Informed Shared Decision making/ Shared Model	<p><i>"Decision aids may also clarify personal values by either implicitly or explicitly asking individuals to consider the personal importance they place on each benefit and risk and to identify the tradeoffs they will need to make in choosing one alternative...Another potential mechanism..lies in the detailed descriptions of benefits and risks depicting their impact on physical, emotional and social function."pg 269</i></p>

Table 3.2.3, continued

	al., 1998)					
33.	Pellissier JM, Venta ER. Introducing patient values into the decision making process for breast cancer screening. <i>Women Health</i> . 1996;24(4):47-67. (Pellissier & Venta, 1996)	1996	Review	Mammographic screening	Shared Decision Making/ Informed Shared Decision making/ Shared Model, and, Expected Utility/ Utility Theory	<p>Values are patients feelings about their current larger personal and societal context, their disease and their feelings about disease in general. Values include how patients perceive physicians approval or feelings about themselves <i>"Similarly, patient values regarding her current situation (personally, family-wise, and community-wise), her feelings about the disease (its prognosis and outcomes), and her feelings about the disease process in general will also affect the conversation. Furthermore, the perceived physician values by the patient and the perceived patient values by the physician have an impact. They suggest questions like, "Will the physician approve of my decision?," or "How does the physician feel about me personally?" pg 53</i></p> <p>Values are patient's perceptions of how society will react and judge their decision. <i>"Societal values, as perceived by the physician and the</i></p>

Table 3.2.3, continued

						<p><i>patient, reflect attitudes about the resource-allocation priority of the disease, the current political climate and community perceptions. These values constrain the range of treatment options that the physician considers. A patient's treatment choice will involve their perception of how society will react to and judge their decision." pg 53</i></p> <p>Values are equated with utility when eliciting patient values is discussed. <i>"Values or utilities are assigned to different aspects (attributes) of the problem via an assessment procedure, then these results are used to calculate an expected utility for the decision action." pg 60</i></p>
34.	Potter BK, O'Reilly N, Etchegary H, Howley H, Graham ID, Walker M, et al. Exploring informed choice in the context of prenatal testing: findings from a qualitative study. <i>Health Expect.</i> 2008;11(4):355-65. (Potter et al., 2008)	2008	Research article	Prenatal testing for Down's Syndrome	Informed Decision Making/ Informed model/ Informed Choice	<p>Values are expressions of moral views or statements reflecting beliefs about how life should be lived. <i>"Acceptability of pregnancy termination and the role of fate. Values were reflected in two major themes: acceptability of pregnancy termination and the role of fate. Many women directly associated testing decisions with potential decisions about abortion." pg 358</i></p> <p>Values are also expressed as patient's</p>

Table 3.2.3, continued

					<p>underlying moral ideals.<i>"Some women explicitly associated values with religious beliefs. This was particularly evident in discussions about the morality of pregnancy termination but was not exclusively associated with declining testing" pg 359</i></p> <p>Values as defined are contrasted with literature which is seen as equating values with preferences and the Multidimensional Measure of Informed Choice (MMIC) which is seen as equating values with attitudes.<i>"We defined values as expressions of moral views or statements reflecting beliefs about how life should be lived. This definition differs from the concept of values in the decision support literature,16 which reflects preferences for outcomes rather than underlying ideals. It also differs from the MMIC, where values were operationalized as a woman s attitude toward taking a prenatal screening test,based on Rokeach. Differences in the definition and application of the construct of values both across and within disciplines are well-documented, emphasizing the need to be clear about how they are measured in a par</i></p>
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Table 3.2.3, continued

						<i>ticular study. Although the term values is not consistently used in the way we defined it, other studies support the importance of moral views or attitudes toward pregnancy termination and other values-type notions as contributors to women s decision making about prenatal screening. Thus, it may be that in the context of prenatal testing, the definition of values that emerged from our data is particularly relevant. Values often dominated discussions about prenatal testing decisions among women who were morally opposed to pregnancy termination." pg 361</i>
35.	Stiggelbout, A. M. and J. C. de Haes (2001). "Patient preference for cancer therapy: an overview of measurement approaches." J Clin Oncol 19(1): 220-230. (Stiggelbout & de Haes, 2001)	2001	Discussion	Cancer	Expected Utility/ Utility Theory	Values can be elicited through utility assessment methods. <i>Nevertheless, utility elicitation is sometimes used in the clinical encounter in order to help patients clarify for themselves the values that are at stake in the decision problem.pg 225</i>

Table 3.2.3, continued

36.	Sullivan M. The new subjective medicine: taking the patient's point of view on health care and health. Soc Sci Med. 2003 Apr;56(7):1595-604. (Sullivan, 2003)	2003	Discussion	Bioethics: Reasons for including patient perspectives	Clinical epidemiology (“Clinimetrics”)	Value is a verb for how much patient's value their health state. A distinction is made between objective and subjective values towards health related QOL measures. <i>"For reasons like this, Gill and Feinstein (1994) have criticized many measures claiming to be HRQoL measures for being inadequately sensitive to patient values. ‘Quality of life can be suitably measured only by determining the opinions of patients and by supplementing (or replacing) the instruments developed by ‘experts’.’ They argue that expert derived categories and weightings in questionnaires cannot accurately reflect the patient’s point of view. Elements of health status that are not valued are not distinguished from those that are valued. And most important, ‘the value of the subjective experience of living’ cannot be discerned from expert-designed questionnaires.” pg 1600</i>
37.	Tan J, Stacey D, Fung K, Barankin B, Bissonnette R, Gulliver W, et al. Treatment decision needs of psoriasis patients: cross-sectional survey. J Cutan Med Surg. 2010 Sep-	2010	Research article	Psoriasis	Shared Decision Making/ Informed Shared Decision making/ Shared Model, and,	Values are defined as important factors for treatment decisions. E.g.: - information on risks & benefits - being clear on what is important - information about options - skill or ability to make treatment decisions

Table 3.2.3, continued

	Oct;14(5):233-9. (Tan et al., 2010)				Ottawa Decision Support Framework (ODSF)	- having access to the HCP
38.	Tulsky JA, Fischer GS, Rose MR, Arnold RM. Opening the black box: how do physicians communicate about advance directives? Ann Intern Med. 1998 Sep 15;129(6):441-9. (Tulsky, Fischer, Rose, & Arnold, 1998)	1998	Research article	Advanced Directives, end of life	None	<i>"Patients' personal values, goals for care, and reasons for treatment preferences were discussed in 71% of cases and were explicitly elicited by 34% of physicians. For example: Physician: Right now, even though you do not have a terminal condition, you feel that you would not want to be resuscitated? Patient: Yes. Physician: Why do you feel that way? ' Patient: I've been feeling that I don't have that much to live for." pg 445</i>
39.	Ubel PA, Loewenstein G. The role of decision analysis in informed consent: choosing between intuition and systematicity. Soc Sci Med. 1997 Mar;44(5):647-56. (Ubel & Loewenstein, 1997)	1997	Discussion	Using Decision analysis to practice informed consent	Expected Utility/ Utility Theory	<i>"How do patients express their values in a way that decision analysis can use? <u>The most common method for measuring patients' values (or "utilities") is the standard gamble.</u>" pg 648</i>

Table 3.2.3, continued

40.	van Kleffens T, van Leeuwen E. Physicians' evaluations of patients' decisions to refuse oncological treatment. <i>Journal of Medical Ethics: Journal of the Institute of Medical Ethics</i> . 2005 Mar;31(3):131-6.(van Kleffens & van Leeuwen, 2005)	2005	Research article	Cancer treatment	None	<i>"...keeping her breast may reflect personal values such as identity, dignity, and/or integrity" pg134</i>
41.	Vranceanu AM, Cooper C, Ring D. Integrating patient values into evidence-based practice: effective communication for shared decision-making. <i>Hand Clin</i> . 2009 Feb;25(1):83-96, vii. (Vranceanu, Cooper, & Ring, 2009)	2009	Discussion	Decision making models in Medical Decision making	Shared Decision Making/ Informed Shared Decision making/ Shared Model, and, Evidence Based Medicine/ Evidence Based Practice, and, Patient- Centred Care/ Person-Centred Practice, and, Biopsychosocial illness model	Patient values are stated in the title. In the article, values are elicited on a small or large scale according to which model is being used. E.g. Biomedical illness model: focus on the values of the disease "Cure my pain" while in the biopsychosocial illness model: larger value context of the patient's life "How confident am I to have a child with this illness?" Eliciting patient's values includes information on: - sources of distress - social issues - behavioural issues - goals - resources - distinguishing HCP and patient's values

Table 3.2.3, continued

42.	White, D. B., Braddock, C. H., 3rd, Berekyei, S., & Curtis, J. R. (2007). Toward shared decision making at the end of life in intensive care units: opportunities for improvement. <i>Arch Intern Med</i> , 167(5), 461-467. doi: 167/5/461 [pii] (White, Braddock, Berekyei, & Curtis, 2007)	2007	Research article	Advanced Directives, end of life	Shared Decision Making/ Informed Shared Decision making/ Shared Model	"Values and preferences" are one of the 10 items evaluated in the study on advanced directives. The item "What do you know about patient's medical preferences and values?" was coded in about 80% of transcripts.
43.	White DB, Malvar G, Karr J, Lo B, Curtis JR. Expanding the paradigm of the physician's role in surrogate decision-making: an empirically derived framework. <i>Crit Care Med</i> . 2010 Mar;38(3):743-50. (White, Malvar, Karr, Lo, & Curtis, 2010)	2010	Research article	Advanced Directives, end of life	None	Values are patient preference for or against life support. <i>"Most simply, these physicians made efforts to bring the patient's values and preferences to the fore by asking questions such as, "has she ever talked about whether she would accept being on a breathing machine longterm?" and "if she could sit up in bed, what would she say about this decision?" Some physicians also made explicit the value-sensitive nature of the decisions." pg 746</i>

* Author-extracted definitions of values are in bold, or if explicitly stated in the text, are underlined.

Table 3.2.4: Theoretical context for the concept of patient values

Theory/ Decision making framework	References	Theoretical context for patient's values
Shared Decision Making/ Informed Shared Decision making/ Shared Model	(Brock, 1991; Charles, et al., 1999; Epstein & Peters, 2009; McAlister, et al., 2000; Myers, 2005; O'Connor, et al., 1998; Pellissier & Venta, 1996; Tan, et al., 2010; Vranceanu, et al., 2009; White, et al., 2007)	"Patient's values/ preferences" is the most common element of the SDM concept (Makoul & Clayman, 2006); a doctor brings information whilst the patient brings values to the physician-patient encounter (Brock, 1991); values (both physician's and patient's) pervade the SDM process (Charles, Gafni, Whelan, & O'Brien, 2005).
Evidence Based Medicine/ Evidence Based Practice	(Guyatt, et al., 2002; Heddle, 2006; Ikomi & Kunde, 2002; Montori, et al., 2008; Vranceanu, et al., 2009)	EBM is defined as "the integration of best research evidence with clinical expertise and patients' values" (Sackett, et al., 2000).
Expected Utility/ Utility Theory	(H. Llewellyn-Thomas, et al., 1982; Pellissier & Venta, 1996; Stiggelbout & de Haes, 2001; Ubel & Loewenstein, 1997)	In utility theory, patient's values are synonymous with utility functions of different health states. A utility is the "subjective value of an outcome, or what the outcome is actually worth to an individual"(Reed, 2000).
Informed Decision Making/ Informed model/ Informed Choice	(Charles, et al., 1999; Myers, 2005; Potter, et al., 2008)	An informed choice is defined as "one that is based on relevant knowledge, consistent with the decision maker's values and behaviourally implemented" (O'Connor & O'Brien-Pallas, 1989)
Patient- Centred Care/ Person-	(Epstein & Peters, 2009; McCormack,	Patient- Centred Practice requires healthcare professionals to focus on

Table 3.2.4, continued

Centred Practice	2003; Vranceanu, et al., 2009)	the patient's personal and authentic values (McCormack, 2003) as part of making the patient the centre of the care process.
Biopsychosocial illness model	(Vranceanu, et al., 2009)	The biopsychosocial illness model looks at how illness affects the patient's life as a whole. Values are elicited on a larger scale in the biopsychosocial model when compared to the biomedical model of viewing illness (Vranceanu, et al., 2009).
Health Belief Model	(Michaels, et al., 2008)	The health belief model incorporates 1) individual perspectives, 2) modifying factors and 3) likelihood of action in order to understand patients' perspectives on the threat or susceptibility of a disease. Patient's values comprise part of the factors that determine individual perspectives that lead to beliefs about disease susceptibility.
Preventive health model	(Myers, 2005)	The preventive health model focuses on external and internal factors that predict health behaviour. Part of the internal self-system includes cognitive, affective and social evaluation. These are the main evaluative considerations when making a decision between alternative choices and the author specifically explores cognitive and affective considerations as part of patient values. Social factors are excluded, but no reason is given (Myers, 2005).
Ottawa Decision Support Framework (ODSF)	(Tan, et al., 2010)	The ODSF is a framework for meeting decisional needs by providing decisional support. It lists values as part of the Decisional Needs category (O'Connor, 2006).

Table 3.2.4, continued

Coverdale et al's framework for patient participation	(Coverdale, et al., 2006)	Coverdale et al (1996, 1997) framework outlines the steps for patient participation in the decision-making process. The concept "Evaluative understanding" is used to define decision making that is done together with values and beliefs.
Etzioni's Normative-Affective model of decision making	(Martin & Roberto, 2006)	<p>Etzioni's normative-affective model states that people are more affected by values and emotions when making decisions than by rational cognitive factors. Thus values are given prominence under this model as strong influencing factors in decision making.</p> <p>Emotion (Affect) and values are distinguished as such: "...values differ from sheer affective involvements in that they contain a justification and define a wider claim (e.g. others to whom the same right applies), while sheer affective states contain no such statements. (Love for mankind is a value; love for a particular person is an emotion.)" (Etzioni, 1988)</p>
Baron's Norm-endorsement Utilitarianism	(Baron, 1997)	Baron's norm-endorsement utilitarianism (Baron, 1996) argues that following normative moral principles will lead to utilitarianism (the greater good). These normative moral principles are described as our values which are ultimate evaluative standards which we use to evaluate states of affairs (e.g. the health states and options for a patient.)
Lewin's transactional theory of communication	(Makoul & Clayman, 2006)	Lewin's transactional theory of communication was used in the integrative definition of SDM as all elements of SDM (including

Table 3.2.4, continued

		patient’s values) happened through the exchange and interpretation of messages and influence between physician and patient (Makoul & Clayman, 2006).
Clinical epidemiology (“Clinimetrics”)	(Sullivan, 2003)	Clinimetrics attempts to incorporate subjective measures of health instead of just using morbidity and mortality alone for healthcare measurements. It is important to accurately represent patient’s values, especially in Health-related Quality Of Life measurements (2003).
C-SHIP (Cognitive-Social Health Information Processing)	(Meropol, et al., 2008)	The C-SHIP model is a comprehensive framework of cognitive and affective components in health information processing. Patient’s values are mentioned under affective components.
Svenson's Differentiation and Consolidation (DiffCon) Theory of Decision Making	(Deb Feldman-Stewart, et al., 2006)	The goal of decision making is to choose the best option pre-decision (differentiation) and reducing post-decision regret (consolidation). Values discovery is part of the differentiation phase and helps patients to determine which attributes are most important to them.

Definitions of patient values

There were no commonly-referenced sources in the definitions of patient values. Only one article had a definition of patient values specific to health: "*Health care values might be more narrowly conceived as beliefs pertinent to health care choices such as meanings of pain and suffering, importance of choice and control, comfort with risk taking, and importance of interpersonal connection*" (Karel, 2000).

Four articles had a sentence stating the authors' definition of values. Feldman-Stewart et al defined values as "*qualities that the individual considers desirable or not, and in these situations they often relate to quantity or quality of life*"(D. Feldman-Stewart, S. Brennenstuhl, M. D. Brundage, & T. Roques, 2006). Montori et al defined values and preferences together as "*We use values and preferences as an overarching term that includes patients' perspectives, beliefs, expectations and goals for health and life.*"(Montori, et al., 2008). Potter et al defined values as "*expressions of moral views or statements reflecting beliefs about how life should be lived.*"(Potter, et al., 2008). The last article provided the following definition: "*The idea of values is that we have some sort of ultimate standards by which we evaluate states of affairs*" (Baron, 1997). One other article stated that patient values were "*his or her own conception of the good*" (Brock, 1991).

Two articles had definitions of values taken from the social sciences (Karel, 2000; Keyser, 1992). One article (Keyser, 1992) referenced a sociological definition of values ("*Values are the lived sources of meaning for a person, and they actively constitute a person's history when put into words*") (Gibson, 1990) while the other article (Karel, 2000) referred to psychological value theories ("*Values most broadly conceived may be defined as (a) concepts or beliefs, (b) about desirable end states or behaviors, (c) that transcend specific situations, (d) guide selection or evaluation*

of behavior and events, and (e) are ordered by relative importance”(Rokeach, 1973; S. H. Schwartz & Bilsky, 1987).

In three articles, patient’s values were deliberately distinguished from preferences and attitudes. Values were considered to be underlying, moral ideals and thus more abstract than preferences (which are concrete choices between two or more available treatment options) (Epstein & Peters, 2009; Heddle, 2006; Potter, et al., 2008) and attitudes (which are context-dependent beliefs framed by the healthcare decision) (Potter, et al., 2008).

Besides the articles above, the rest of the articles did not state a specific definition of patient values but gave examples of values (e.g. importance of quality of life and length of life) (Meropol, et al., 2008) or identified the process or strategies for incorporating patient values (e.g. utility measurement exercises) (Stiggelbout & de Haes, 2001). By combining an analysis of the definitions with the concepts in the other articles, we categorised the concept of patient values into three main themes.

Main themes in patient values

Three themes of patient values were derived from analysis of the definitions, examples, and processes found in the articles. These are: 1) types of values (healthcare and decisional), 2) structure of values and 3) function of values.

Types of patient values

Patient values could be divided into two main categories: healthcare-related values and decision-making values.

Healthcare-related values

The first category of patient values was related to patient values in the context of evaluating healthcare-related risks and benefits (Black, 2005; Black & Emmet, 2006; Canfield & Dahm, 2010; Coppola, et al., 2001; Doukas, et al., 1992; Ikomi & Kunde, 2002; Karel, 2000; Kennedy, 2003; Llewellyn-Thomas, et al., 1982; Makoul & Clayman, 2006; McAlister, et al., 2000; McCormack, 2003; Meropol, et al., 2008; Miller & Bolla, 1998; Montori, et al., 2008; Ruland & Bakken, 2001; Stiggelbout & de Haes, 2001; Sullivan, 2003; Tan, et al., 2010; Ubel & Loewenstein, 1997; Vranceanu, et al., 2009). For example when choosing cancer treatments, patients' decisions are affected by their value preferences in terms of quality and/or length of life (Meropol, et al., 2008).

Types of healthcare values

Articles identified specific types of values or gave examples of patient values. Seven types of patient values were identified: personal, affective, cognitive, financial, religious, socio-cultural and ethical/moral values. Personal values describe an individual's priorities and sense of meaning (Epstein & Peters, 2009; Deb Feldman-Stewart, et al., 2006; Karel, 2000; Karel, et al., 2004; Keyser, 1992; McCormack, 2003; Michaels, et al., 2008; O'Connor, et al., 1998; van Kleffens & van Leeuwen, 2005). Affective values are how patients feel about the decision (e.g. feeling miserable or unmotivated to live if they had a terminal condition) (Guyatt, et al., 2002; Myers, 2005; Pellissier & Venta, 1996; Tulsky, et al., 1998) while cognitive values are how patients appraise healthcare information such as risks and benefits (Myers, 2005). Financial values included not only patient treatment costs but also the financial implications of health outcomes on others, such as inheritance tax on heirs after death (Black, 2005;

DeSanto-Madeya, et al., 2009; Karel, et al., 2004; Kirk & Luck, 2010). Religious values are religious beliefs relating to religious issues such as death and the afterlife as well as religious rituals and practices (Bosek, 2008). Socio-cultural values are values that are determined by a patient's demographic and socio-economic background such as ethnicity, family values, and social support availability (Karel, et al., 2004; Myers, 2005; Pellissier & Venta, 1996). Ethical or moral values are patient's conceptions of right and wrong, or what outcomes are considered good or ideal (Brock, 1991; Karel, 2000; Potter, et al., 2008). Patients are more aware of their moral values when faced with a moral dilemma such as deciding on whether or not to have an abortion (Potter, et al., 2008).

Decision-making values

The second category of patient values are values related to patient preferences for participation in decision-making (Heddle, 2006; McAlister, et al., 2000). Another type of decision making values were patient's values concerning surrogate decision making in allowing others to make decisions on their behalf (Karel, et al., 2004; White, et al., 2010). These were most often discussed in the context of advanced directives when a patient's decision making ability was diminished by loss of function or absent if the patient slipped into a coma.

Structure of patient values

Patient values were organized along two dimensions: relative priority and longitudinal stability. Firstly, patient values are ordered by relative importance whereby some values are prioritised over others (Karel, 2000). Two articles indicated that patients possessed a core set of values (Karel, 2000; Martin & Roberto, 2006). These core values are

context-independent ideals such as happiness or wisdom that are desired by a patient regardless of whether or not they are facing a healthcare decision.

Values were prioritised or ranked in relation to each other. For example, religious or spiritual values were seen as being more important than other values in gerontological patients who were confronted with their own mortality and drew a continuing sense of purpose from their religious beliefs (Martin & Roberto, 2006). However it was acknowledged that decision making is incredibly complex and experiments to elicit rank-ordered values have found that patients themselves find it difficult to rank which values are most important (Karel, 2000).

Secondly, although values are relatively stable over time (Martin & Roberto, 2006), it was possible that a patient's values could change over time. Possible reasons for this change include a worsening health (Coverdale, et al., 2006), or improved knowledge of their disease (Epstein & Peters, 2009).

Description of how values function

Some papers described the function of values in the decision making process. Firstly, values are motivational in the sense that they direct patients towards making a decision because values determine which goals or end states are most important or desirable to a person (Canfield & Dahm, 2010; Coverdale, et al., 2006; Karel, 2000; Montori, et al., 2008). For example a patient considering a urological procedure would weigh the relative importance of urinary, sexual and bowel function on their overall well-being and this would motivate their decision (Canfield & Dahm, 2010). Secondly, patient's values act as an informational filter and determine how information is processed for decision making (Charles, et al., 1999).

A model of patient's values

We developed an integrated model of patient's values based on themes identified from the systematic review (Figure 2). Patient values from two categories (healthcare-related and decision-making related) are arranged in a hierarchy of values, whereby some values are considered to be more important than others. Although values are ranked according to relative priority, this hierarchy of values may change over time. Changes to value priorities are due to influencing factors such as changing health states or patient knowledge.

We would like to propose a definition of patient values in medical decision making as “healthcare priorities that may change over time depending on patient health state and knowledge, and the patient's decision making role preferences”.

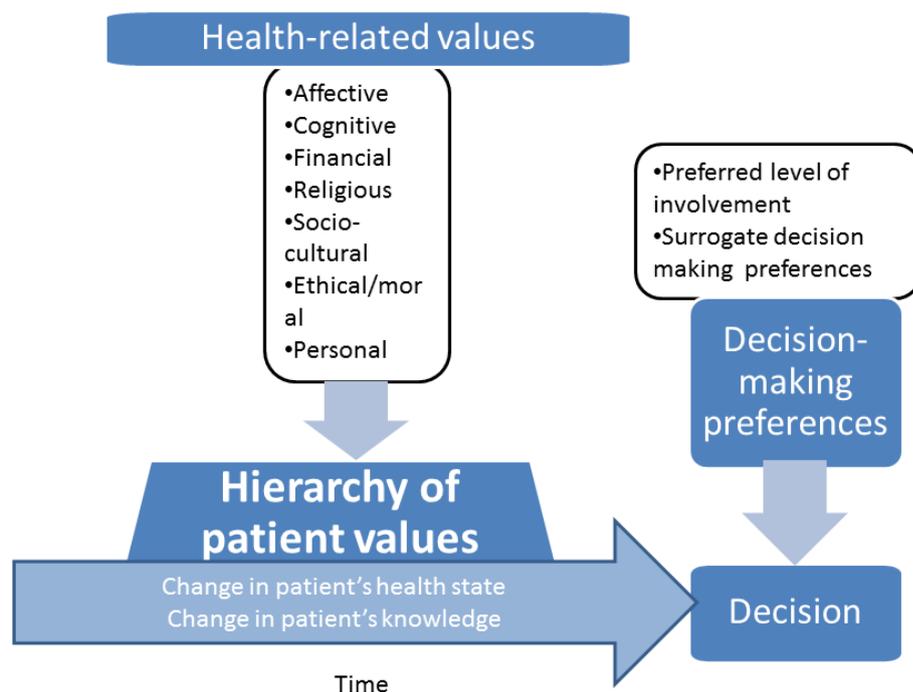


Figure 3.2.2: A model of patient values in medical decision making

Discussion

This review summarises the main themes for the patient values concept from the literature. All authors recognised that it was important to incorporate patient values and values were an integral part of conceptual or theoretical frameworks (Table 3.2.4).

However, few authors actually clarified what they meant by the term.

This plurality of definition stems from two possible reasons. The first is epistemological as the term ‘patient values’ itself is intrinsically broad in definition and open to various interpretations. Therefore, authors found it useful to use the term values as label for a variety of constructs. For example, the term was used to refer to health utilities (a measurable outcome) as well as moral conceptions of what is good (a philosophical concept). This polysemy is not confined to medicine; in the social sciences, the values construct is oft-debated and various measures for human values have been developed (Rohan, 2000). Given the usefulness of the term in health disciplines, models and decisions, it would be overly restrictive to suggest that a particular definition should be considered right while another wrong. Rather, authors should clarify their concept of patient values when using the term and not assume that their readers share their concept of values.

The second possible reason for multiple meanings stems from the growth of the patient-centred paradigm (Bensing, 2000). From the results, the use of the term ‘patient values’ is most often used within evidence-based medicine and shared-decision making models (Table 3.2.4). Both of these models are supportive of patient-centred care and the term patient values is used to express the idea that patients should also participate in consultations. As these models are discussed and refined by the research community, the concept of patient values remains dynamic (thus leading to broad definitions) as

researchers discuss how best to involve patients in medical decision making.

Researchers should keep in mind that in order to remain true to patient-centred philosophy, definitions of values should not come from researchers only but also from patients themselves. For example, one study defined patient values based on qualitative interview data from patients with type 2 diabetes who were making a decision about insulin therapy and the values that affected their choice (Lee, Low, & Ng, 2013).

The results summarise the various categories of values and highlight that these categories are structured according to two dimensions: relative priority and longitudinal stability (Figure 3.2.2). The concept of relative priority is supported by research on similar concepts such as life goals (Schwartz, Hazen, Leifer, & Heckerling, 2008). Studies have found that patients are more willing to trade life years or health to achieve family goals compared to other types of goals such as wealth, job, education, health/fitness, travel, and personal fulfilment (Schwartz, et al., 2008). Indeed, most research on patient values has focused on the use of value clarification methods (e.g. considering pros and cons of each treatment option, utility assessment, prioritization and rating scales) in order to make explicit patients preferred options (Fagerlin et al., 2012). However, some researchers consider these methods to be preference elicitations (asking a patient to identify which option is preferred) and argue that value clarification (helping a patient understanding why an option is preferred) is also needed in consultations (Llewellyn-Thomas & Crump, 2013). Broader categories of values such as life goals should also be discussed with patients in consultations.

The second dimension of longitudinal stability should be considered in light of current perspectives on the stability of values over time. Traditional values theory views values as being stable and relatively static over time (Rokeach, 1973). On the other hand,

research on constructed preferences believes that preferences are constructed only when a decision is posed and cannot be elicited outside of a specific decisional context (Payne & Bettman, 1999). We suggest that it is necessary to revisit a patient's values as both values and preferences may change over time in response to disease progression or paradigm shifts.

There are a few limitations to this study. The list of value categories is not an exhaustive list of all types of values. As this review only included English-language articles, studies on values published in other languages have been excluded. These studies may be important to inform culture-specific categories of patient's values.

Future research can focus on identifying trigger events which may influence value priority and longitudinal research on why and how value priorities change (Makoul & Clayman, 2006). While it is recognised that values are relatively stable (Martin & Roberto, 2006), values may change due to deteriorating health states (Coverdale, et al., 2006) and interactions with significant others such as family or doctors (Karel, 2000). By knowing when priorities are likely to change, healthcare professionals will revisit a decision in a timely manner. This is especially relevant in the context of chronic conditions and primary care where, often, decisions need to be made over a more prolonged period.

In conclusion, clear definitions of patient values are important for research as well as practice. Clarifying patient values in consultations is especially crucial as disagreement between patients/families and a healthcare provider over treatment decisions is considered to be the highest ranked ethical challenge facing the public in health care (Breslin, MacRae, Bell, & Singer, 2005). Figure 2 summarises the various categories

and dimensions of values; it serves as an educational tool and quick reference guide in training healthcare professionals to understand and examine the patient perspective.

Chapter 3.3 The values construct in social science

The review of patient values (Chapter 3.2) showed there is no agreed definition of what values are in medical decision making. In medicine, the term “values” is broadly used to describe a variety of constructs. Value-specific research, which defines and measures values in a valid and reliable manner, is well-established in the social sciences (Braithwaite & Scott, 1991; Rohan, 2000). In social science, value theories are focused explicitly on the subject of human values, as compared to medical decision making in which values are only a component of the overall theory. Value-specific theories try to define values, differentiate values from beliefs and attitudes, and measure which values are most preferred in society.

The two most prominent value theorists in social psychology are Milton Rokeach and Shalom Schwartz. The two theories share similarities as the latter’s theory builds on the former. In the following section, the basic tenets of their theories are described and the relation of these value constructs to the idea of patient values are discussed. The section ends with a review of healthcare literature on studies that have used the two value theories in order to provide an idea of how these theories might be applied to researching healthcare decision making values.

3.3.1 Definitions of values

Both Rokeach and Schwartz defined values as personally and socially preferable goals. Rokeach formally defined values as “*an enduring belief that a specific **mode of conduct** or **end-state of existence** is **personally** or **socially preferable** to an opposite of converse mode of conduct or end-state of existence*” (pg 30, Rokeach, 1973). Schwartz emphasized the motivational aspect of values and identified values according to

motivational needs arising from biological, social and survival or welfare concerns (Schwartz, 1992).

Rokeach also discussed the differences between values, beliefs and attitudes. For Rokeach, values are closely related to the concepts of beliefs and attitudes. A belief is defined as *“any simple proposition, conscious or unconscious, inferred from what a person says or does, capable of being preceded by the phrase “I believe that...”*

(Rokeach, 1968). Thus a person may possess hundreds or even thousands of beliefs.

Values are a kind of belief which are more personally and socially prominent than others. He defined attitudes as a cluster of beliefs around a single subject- *“a relatively enduring organization of beliefs around an object or situation predisposing one to respond in some preferential manner”* (pg 112, Rokeach, 1968). Attitudes are what predispose a human to acting preferentially in relation to an object or situation.

Values possess the following five criteria (Schwartz & Bilsky, 1987):

- 1) **Values are beliefs.** They are beliefs tied inextricably to emotion, not objective, cold ideas.
- 2) **Values are a motivational construct.** They refer to the desirable goals people strive to attain.
- 3) **Values transcend specific actions and situations.** They are abstract goals. The abstract nature of values distinguishes them from concepts like norms and attitudes, which usually refer to specific actions, objects, or situations.
- 4) **Values guide the selection or evaluation of actions, policies, people, and events.** That is, values serve as standards or criteria.
- 5) **Values are ordered by importance relative to one another.**

3.3.2 Structure of values

Rokeach believed in a central-peripheral system of beliefs. A person's beliefs are ordered according to how connected beliefs are to one another. Core or central beliefs were more connected to other beliefs compared to more peripheral beliefs. Within this structure of beliefs, values could be considered to be more core beliefs as they were enduring and universal, and therefore more connected to a variety of beliefs.

Rokeach divided values into two types; goals (terminal values) and modes of conduct (instrumental values). Examples of goals included such things as a "comfortable life (a prosperous life)" and "self-respect (self-esteem)," while mode of conduct values included being "broad-minded (open-minded)," "forgiving (willing to pardon others)," and "helpful (working for the welfare of others)". In order to measure which values were most important to people, Rokeach developed the Rokeach Values Survey (RVS) (Rokeach, 1973). Respondents were instructed to rank order 18 terminal and 18 instrumental values in the order which was most important to them personally. The list of values was drawn from a variety of sources based on intuition about what constituted a reasonably comprehensive sample of possible human values.

Rokeach's theory was criticized for lacking a formal structure i.e. the list of 36 values was an unrelated list of words and no indication is given on how prioritizing one value affects another (Rohan, 2000). In contrast to Rokeach's list of 36 values, Schwartz's theory only had 10 basic universal values (Table 3.3.1). For Schwartz, a structure of values was developed based on the hypothesis that these 10 values could be arranged according to how congruent or conflicting their motivations were to each other. In order to develop this model, Schwartz collected data from 20 countries on importance ratings of different values. Data was then analysed using the intercorrelation matrix of Pearson

correlations between the importance ratings of the values with the Guttman-Lingoes Smallest Space Analysis (Schwartz, 1992).

Table 3.3.1: Ten universal values in Schwartz’s theory of values

Universal value	Description
1. Self-Direction	Independent thought and action; choosing, creating, exploring.
2. Stimulation	Excitement, novelty, and challenge in life.
3. Hedonism	Pleasure and sensuous gratification for oneself.
4. Achievement	Personal success through demonstrating competence according to social standards.
5. Power	Social status and prestige, control or dominance over people and resources.
6. Security	Safety, harmony, and stability of society, of relationships, and of self.
7. Conformity	Restraint of actions, inclinations, and impulses likely to upset or harm others and violate social expectations or norms.
8. Tradition	Respect, commitment, and acceptance of the customs and ideas that traditional culture or religion provide the self.
9. Benevolence	Preserving and enhancing the welfare of those with whom one is in frequent personal contact (the ‘in-group’).
10. Universalism	Understanding, appreciation, tolerance, and protection for the welfare of all people and for nature.

Source: Schwartz, 2006

According to Schwartz, values were divided along two main dimensions: *openness to change- conservation* (following their own intellectual and emotional interests in unpredictable and uncertain directions vs. preserving the status quo and the certainty it provides) and *self-enhancement-self-transcendence* (looking after the consequences of own and others' actions for the self vs the social context) (Schwartz, 1992 p. 43). A circular structure of a values system was constructed, based on how the different values were more congruent (closer together in the circle) or more in conflict with each other

(Schwartz, 1992, 2006) (Figure 3.3.1). For example, the value of security (social order) is opposite the value of stimulation (exciting life).

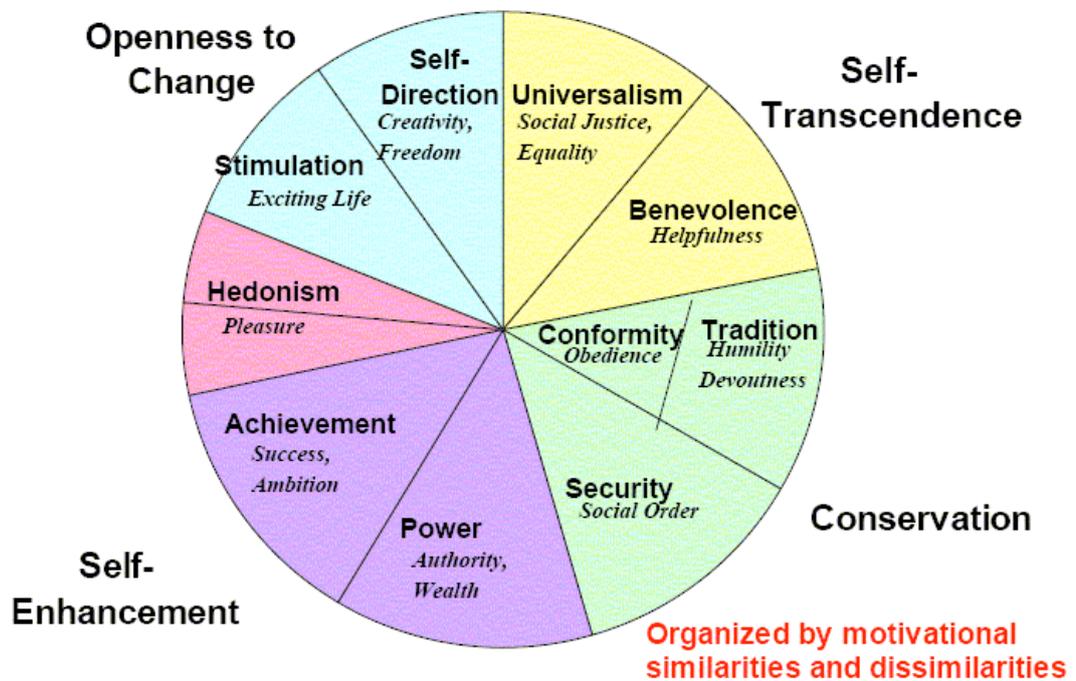


Figure 3.3.1 Theoretical model of relations among ten motivational types of values

Source: Schwartz, 2006

One criticism of both lists of values is that the lists can be seen to be incomplete (Braithwaite & Scott, 1991). Indeed, it is hard to imagine that given the diversity of cultures and complexity of individual differences that an exhaustive list of values is possible. Pragmatically, some studies modify the lists to include values that are relevant to the research context, such as including health as a terminal value (Kristiansen, 1985).

3.3.3 Application of value theories to the patient values concept

The value theories described above can be applied to the concept of patient values in three ways. Firstly, they help to formally define what values are. Values are core beliefs which are personally or socially preferable, are enduring, and limited in number. The

latter is to say that a patient would not have a large number of values influencing their choice, but only a small number which are personally important.

Secondly, the theories explain how patient values are related to attitudes. Attitudes are beliefs about a certain topic. For example, misconceptions (wrong beliefs) about insulin can lead to a negative attitude about insulin. However, it would be wrong to call this attitude a value as values are more enduring; once the misconceptions are addressed, the attitudes may change, but the values are the same. Research on patient values should go beyond measurements of attitude and beliefs, which are condition-specific.

Thirdly, the value theories help to inform how values influence patient choice. Based on the five criteria of values listed by Schwartz and Bilsky (Chapter 3.3.1), values would influence patients' choices in five ways: 1) values would influence patients' emotional beliefs about their health options, 2) values would motivate patients to want to achieve a desired health state, 3) values would be more abstract than just norms or attitudes about specific health options, but instead would be beliefs that are applied to all areas of life, 4) values would serve as an evaluative lens through which information about medical options are interpreted, and 5) value hierarchies would be different in each individual patient and what one patient wants may be entirely different from another patient facing the same medical condition.

3.3.4 Healthcare studies which have used the value theories of Rokeach and Schwartz

Antecedents are available for the use of both value theories in healthcare research. A literature search for health-related studies that have used either Rokeach's or Schwartz's value instrument was conducted in Pubmed in December 2011 using the search terms

("values" AND ("rokeach's theory"[All Fields] OR "rokeach's value theory"[All Fields]) for Rokeach's theory of values and ("Shalom SH" [author]) for Schwartz's theory of values. The search was further expanded using the 'Related Citations' function in Pubmed. Overall, the search revealed that most research focused on the measuring of concrete value differences between countries, cultures and gender. Application of the theories of values to the healthcare context was limited to a few studies, which are reported below. Two types of studies have been conducted on values and health. The first category comprises studies that investigate the effect of adverse health events on personal values, while the second category of studies investigated how interventions to change personal values promote health behaviour. The studies are reported using these two categories. In addition to these two categories, some studies investigated if 'health' in itself was a type of value.

3.3.4 (a) The effect of adverse health events on patient's values

Patient's values were changed due to major adverse health events. Some studies investigated self-reported within-subject changes in patient's values. In a study using the Rokeach Value Survey as the study instrument, 50 cancer patients were asked to evaluate their current values and retrospective values before being diagnosed with cancer (Greszta & Sieminska, 2011). Out of 36 values measured, 16 values were significantly more important, 11 were decreased in importance and nine were unchanged. For patients with cancer, value clusters which had to do with 'setting things right' became more important: religious morality, personal orientation (e.g. friendships), self-constriction (e.g. being obedient and honest), family security and delayed gratification (e.g. wisdom and harmony). Values that had to do with self-ambition and achievements became less significant in light of cancer diagnosis: immediate

gratification, self-expansion and competence (e.g. a sense of accomplishment). Patient's values were changed because the diagnosis of cancer was a significantly emotional event and the author's suggested that the mechanism of change was to shift priorities towards those values which could still be achieved despite being ill (such as spiritual or moral values) and to move away from values whose goals were compromised by the limitations of illness (e.g. self-ambition).

However, another study on 67 patients undergoing coronary artery bypass graft surgery using the Rokeach Values Survey found that measurements of values taken one day before surgery and 6 months after surgery did not show any significant change between the top three (honest, loving, responsible) and bottom three values (logical, obedient, imaginative) of patients (Flanagan, 1998).

One other study used the Portrait Values Questionnaire based on Schwartz's Theory of Values to measure the values of 64 palliative care patients with advanced cancer or amyotrophic lateral sclerosis (Fegg, Wasner, Neudert, & Borasio, 2005). The most important personal values were benevolence, self-direction, and universalism, whereas power, achievement, and stimulation were the least important. Compared to data from healthy adults, palliative care patients scored higher in benevolence and lower in self-enhancement values. It was reported that self-transcendence values were higher than self-enhancement values in all patients and this was attributed to the coping process involved.

It can be summarised that adverse health events would change patient's values, whereby patients would re-prioritise their values in light of the illness being faced. Patients would shift towards values which were aimed at 'setting things right' (Greszta & Sieminska, 2011) and self-transcendence (Fegg, *et al.*, 2005) as patients would want to

set their relationships in order rather than to focus their actions on themselves, more so in palliative patients.

3.3.4 (b) Interventions aimed at patient's values

Some studies were on healthcare interventions aimed at using values to promote health behaviour. A technique called value self-confrontation (VSC) was developed by Rokeach (1973) in which target participants' values were measured using the Rokeach Value Survey and they were asked to compare their value priorities against value priorities from positive and negative reference groups. Behaviour change is effected when: 1) a person becomes aware of their previously unnoticed value priorities, 2) they notice the discrepancy between their values and perceived morally or socially competent groups (the positive set) and similarities with the negative set, and lastly 3) the person consciously adjusts their value priorities to resemble the positive set, which leads to behaviour change. VSC was found to be successful for encouraging more weight loss over 2 months in overweight adults in a study comparing VSC (n=30), group discussion (n=24) and a non-treatment control group (n=30) (Schwartz & Inbar-Saban, 1988). Only personally important values are used for VSC as values that were not important would have little impact on behaviour. In this study, only two values were chosen, which were 'wisdom' and 'happiness'. These were obtained from a preliminary study on obese patients who were successful or unsuccessful at losing weight.

3.3.5 Conclusion

Rokeach and Schwartz describe universal, context-independent values in their research. In SDM values are elicited in reference to the healthcare options (for example, by asking the patient to weigh the risks and benefits of differing options). Thus, the use of

the term ‘values’ in SDM is more similar to the Rokeach’s ‘attitudes’ which are beliefs surrounding a specific object and/or situation. In the case of SDM, the object would be the healthcare decision being made and the context would be a doctor-patient healthcare setting.

One implication of this is that the current scope of values clarification in SDM may be too narrow and not really address core patient values. According to Rokeach, attitudes are less enduring than values, because attitudes change with the reference objects. By eliciting attitudes or beliefs instead of values in a values clarification exercise, HCPs may not really address core concerns of the patient. Research on patient values needs to explore in depth the range of values which influence patient decision making so that important values are not excluded from the consultation. The methodology for establishing this range of values is detailed in the next chapter.

Chapter 4: Methodology

The previous chapter reviewed the literature and identified the research gaps in the three research objectives from Chapter 1.5.2. This chapter describes the study design, conceptual framework and methods used to investigate these research objectives. Although the methods are also described as part of the research articles in Chapter 5 (Results), this chapter provides the reader with a more coherent view of the overall study design and the differences and similarities between the HCP and patient methods. It was important to capture patients and HCP perspectives (rather than patients alone) as the HCP perspectives informed the healthcare context in which patient values were investigated.

4.1 Qualitative approach

While quantitative research undergirds objective biomedical advances (for example, development of easier and cheaper insulin regimes), subjective factors such as patient adherence and decisional preferences are best explored qualitatively from patient perspectives (The PLoS Medicine Editors, 2007). The results of qualitative research are complementary to quantitative research as qualitative themes can inform HCPs on patient preferences, thus informing the patient values component of evidence-based practice (Pope & Mays, 1995; Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000).

A qualitative approach was chosen for this study based on three reasons. Firstly, a qualitative approach was suited to the exploratory nature of the research. Apart from statistical data on the percentage of insulin users in Malaysia, there is little research available which explains why the use of insulin remains underutilized despite poor

control in patients with type 2 diabetes. Although there are existing instruments to measure prevalence of barriers to insulin initiation, Malaysia's unique socio-cultural and dual healthcare-sector settings mean that there may be beliefs and barriers in the country which are not found elsewhere and therefore not included in these questionnaires.

Secondly, qualitative methods enabled investigation of the process of how patient values influenced choice during insulin initiation. Whereas quantitative research can only measure the relationship between inputs and outputs, qualitative research enables exploration of the process of interaction between input and output (Silverman, 2006), which in this study are the interpretative role that values play. In this study, individual in-depth interviews (IDIs) with patients were used to understand how different values affected the patient's decision. IDIs allow the researcher to be interactive and sensitive to the language and concepts used by the interviewee, and to maintain a flexible agenda (Britten, 1995). The IDI aims to go beyond simplistic descriptions of the phenomena, to explore what participants say in more detail, and to uncover new areas or results that were unknown at the start of the study (Britten, 1995). The use of IDIs in this study is consistent with recommendations that qualitative interviews are particularly suitable for exploring six areas: behaviour or experience; opinion or belief; feelings; knowledge; sensory; and background or demographic (Patton, 1987; Britten, 1995). Patient values are related to all six areas.

Thirdly, qualitative analysis enabled the development of a structured model of patient values from unstructured interview data. As shown in Chapter 3.2, there is no clear definition of patient values in medical decision making. Research on patient values lacks a theoretical framework, and uncertainty exists on how broad or specific a useful

definition of values should be (Karel, 2000). Combining a general theory of values with an SDM-specific framework in the topic guide enabled the study to explore both general and specific values during interviews with patients. Then, using thematic analysis, the researchers moved from specific nodes to a general model of patient values.

In terms of specific qualitative methodology, an interpretive descriptive approach was employed in the study (Thorne, 2008). By the term interpretive, this approach is philosophically grounded in the hermeneutic and constructivist schools, whereby the researcher interprets what is said by the participants (St. George, 2010). On the other hand, the interpretation also occurs from the participant perspective as values are used to interpret the suggestion to start insulin and participants share what the decision means to them viewed through the lens of values. The interpretive stance in this study is also elaborated in Chapter 5.1 Methods.

The term descriptive refers to the act of writing about the subject being investigated, which is an important part of the process of making sense of qualitative research.

Holstein and Gubrium (2005) define description as “Description- This is the act of giving an account of that which we perceive”. Thorne (2008) sees the role of description as a way to understand the complex social contexts in which research is conducted in order to be able to apply the results of the research into similar situations.

Pragmatically, interpretive description is motivated by a desire to see that qualitative results are valuable for clinical practice. Interpretive description goes beyond merely exploring ‘how’ or ‘why’ questions to a ‘so what’ approach whereby the researcher is interested in applying this research to actual clinical situations. Indeed, in this study the goal developing a patient values model based on actual clinical decisions is intended to

help HCPs understand what types of values influence patient decision-making behaviour.

The version of grounded theory described by Strauss ('Straussian') was employed in the study. In general, the choice of grounded theory was to achieve the research objective of generating a model of patient values based on patient perspectives whereby grounded theory has as its goal the inductive development of theory or concepts that emerge from the data (Strauss & Corbin, 1990). The use of Strauss and Corbin's method of coding for patient data and how the model was developed is described in Chapter 4.8.2 as well as Chapter 5.5.

In this study pre-research literature review was conducted based on two reasons. The first reason was to establish the use of a qualitative approach as the most appropriate methodology for exploring patient values (Cutcliffe, 2000). The systematic review of patient values (Chapter 3.2) showed that in a thorough review of the literature, no model of patient values existed in SDM, nor was there consensus on what patient values are. Little is known about the topic of patient values; a grounded theory approach with its emphasis on starting with a broad approach to the phenomenon before inductive theory development is useful in an under-researched field as the researcher remains open to the various possible directions in which the theory can develop. Indeed, in this study, the literature search for definitions of values were not limited to the medical field but definitions of values from social science were also included.

The second reason was to identify a theoretical construct to serve as the conceptual framework from which to explore patient values during interviews. Cutcliffe (2000) has pointed out that prior reading may be needed in order for the researcher to clarify concepts and build an emergent theory on these. Given that the term values is

intrinsically broad in definition, there was a need to identify at least the key attributes of what values are. Heath (2004) has pointed out that using existing concepts to frame the area of inquiry contradicts the grounded theory approach of the theory emerging from the data if a theory is simultaneously emergent (from the data) and built on concepts selected from literature. Other researchers however have attempted to develop grounded theory after conducting concept analysis on the literature (Jezewski, 1995). In this study, the use of Schwartz's theory of human values (Schwartz, 2006) as the theoretical construct was justified for two reasons. Firstly, the value attributes described in the theory were broad enough to encompass the range of patient values. Secondly, Schwartz's theory served only as a guide to developing a comprehensive topic guide for interviews and was not used to code or organize the data. It was not used simultaneously with the interview data for coding (for example, by using the attributes as a preset coding framework) and the model of patient values was developed from the Straussian coding framework of open, axial and selective coding.

4.2 Study design

The following section reports the study design in more detail, consisting of the conceptual framework, sampling and recruitment, data collection, and lastly data analysis. If needed, the details are divided into HCP and patient sections to describe the respective methods used.

4.3 Conceptual framework: The Ottawa Decision Support Framework, Schwartz's Theory of Values

This study was based on the SDM model, which aims to help clinicians and patients practice EBM by making a decision together based on the integration of clinician's knowledge and patient values (Makoul and Clayman, 2006; Barratt, 2008). Drawing on the Ottawa Decision Support Framework (ODSF), which is a framework to support SDM in practice, a HCP interview topic guide was developed (O'Connor, Tugwell *et al.*, 1998; O'Connor, Drake *et al.*, 1999; O'Connor, 2006). The ODSF identifies the range of decisional needs that need to be addressed during a healthcare decision (refer to Figure 4.1). These needs are decisional uncertainty, knowledge and expectations, values, support and resources, decision attributes (type, timing, stage of leaning) and personal/ clinical characteristics. Thus, the framework includes both treatment-specific needs (e.g. knowledge and expectations) to more system-level needs such as support and resources. This framework was selected as it provides a comprehensive overview of the range of factors which influence a preference-sensitive decision.

For the patient interview topic guides, the five criteria of values found in Schwartz's theory of human values were used to explore the concept of values with patients (Schwartz, 2006). These key attributes are (1) values are concepts or beliefs, (2) values

pertain to desirable end states or behaviours, (3) values transcend specific situations, (4) values guide selection or evaluation of behaviour and events, and (5) values are ordered by relative importance (Schwartz and Bilsky, 1987). Schwartz's theory of values relates to more general human values and was chosen in order to explore patient values in as much depth and breadth as possible, rather than limiting the scope of values to a narrow range of health-related values.

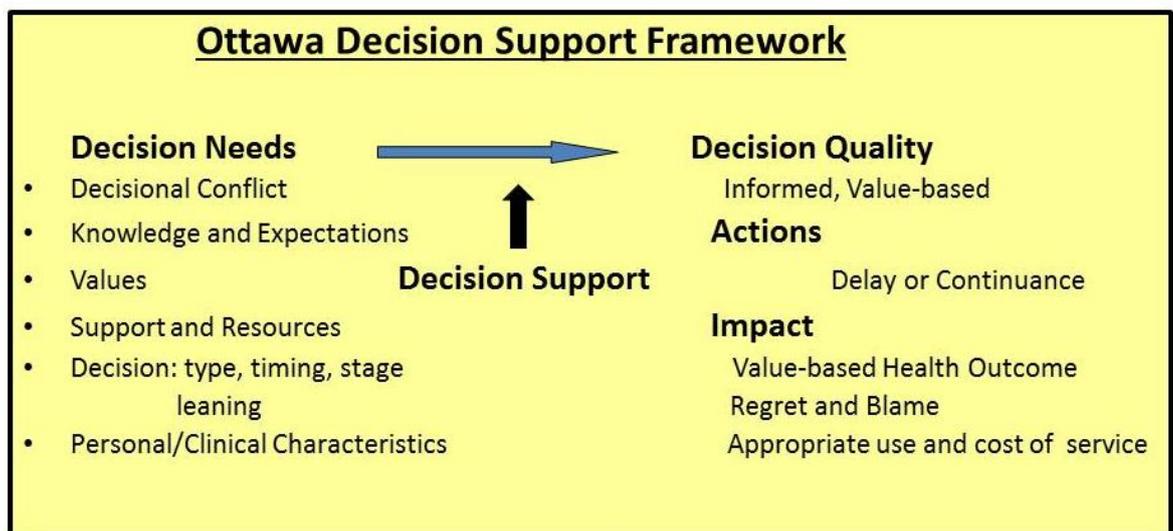


Figure 4.1 The Ottawa Decision Support Framework

Source: O'Connor, Tugwell et al. 1998

4.4 Study setting

The study setting is diverse in terms of healthcare setting (public and private). Diversity in the setting was based on the principle of maximum variation sampling. Patton (1990) explains that the strategy of maximum variation sampling is to capture and describe the central themes or principal outcomes that cut across a great deal of participant or program variation. The logic of maximum variation sampling is that any common

themes or patterns which emerge from a heterogeneous sample can be considered core experiences or beliefs shared across groups (Patton, 1990). The procedure for maximizing a sample is by identifying diverse characteristics or criteria for constructing the sample. In the case of this study setting, the healthcare setting was one of the sample characteristics used. Other criteria for both HCP and patients are described under purposeful sampling in Chapter 4.5.2.

Healthcare professionals

The study was conducted amongst HCPs who provided diabetes care in the three healthcare settings in Malaysia: the government health clinics; government university-based primary care clinic and hospital; and private general practice (GP) clinics and hospitals. Key government policy makers who were involved in shaping the national diabetes strategic plans were also interviewed. A spectrum of practice experience was represented. The HCPs came from three different states (Wilayah Persekutuan Kuala Lumpur, Selangor and Negeri Sembilan) and from both urban and semi-rural locations.

Investigating the views of HCPs was part of the dialogical approach in Straussian grounded theory, which acknowledges that theory construction is a dialogical process between the various stakeholders. This constructivist approach is a shift away from the more positivist philosophy of the original Glaser and Strauss model; Strauss and Corbin developed an approach to grounded theory that was post-positivist, constructivist and relativist (Cooney, 2010). Anells (1997) noted that Strauss and Corbin acknowledged that researcher and researched create the theory together, therefore, macro-social factors influence action and that reality cannot be fully known but are linked to time and place. In this study, the influence of macro-social factors was informed by an understanding of the HCP and system factors in which patients made their decision to initiate insulin. For

example, patients in public and private settings would have different experiences in terms of cost, consultation time and clinic setting. Such factors would in turn influence the decision making process.

Patients

Patient settings were similar to the HCPs. Patients were recruited from the three healthcare settings in Malaysia, came from the three states stated above and lastly, were from both urban and semi-rural locations. For a more detailed description on diabetes, insulin, and the healthcare system in Malaysia, refer to Chapter 1.6.3.

4.5 Sampling and recruitment

4.5.1 Inclusion Criteria

Healthcare professionals

The inclusion criteria were HCPs who were involved in insulin initiation in both primary and secondary care, as well as policy makers who were involved in insulin-related policies in Malaysia. The range of participants included endocrinologists, family medicine specialists, government policy makers, general practitioners, government medical officers and diabetes nurse educators.

Patients

The inclusion criteria were patients with type 2 diabetes who were making or had made a decision about insulin initiation within the past one year. The initial criterion only included patients who were currently making a decision about insulin i.e. had recently been asked to start insulin by their doctor, and were deciding on accepting or rejecting

the doctor's advice. However, this inclusion criterion was later expanded to include those who had made a decision about insulin within the past one year.

There were two reasons for this; firstly, wide variation was found in the time frame for insulin decision making. This was because as part of a chronic treatment regime, insulin is not often confined to an acute, time-critical decision frame. Patients are known to delay insulin initiation despite poor HbA1c control (Calvert, McManus *et al.*, 2007) and many patients initiate and then discontinue insulin due to concerns with injections, medication interaction, side-effects and doctor's advice to discontinue insulin (Oliveria, Menditto *et al.*, 2007). Secondly, patients with gestational diabetes or emergency insulin requirements had little time to make a decision about insulin as their conditions were acute. Such patients could only be interviewed retrospectively after they had initiated and used insulin.

One limitation of including patients who had already started insulin is that patients who initially held negative beliefs about insulin may have rationalised the decision and justified their choice to start insulin as a correct one. As such, there is a possibility that patients interviewed post-initiation may have 'changed' their values. Another limitation is that patient memory of their decision making process at the time of initiation may be diminished after time. This may lead to a less than accurate recollection of their concerns and values as occurred during the initiation of insulin. However, as the methodological frame is a descriptive qualitative analysis, these limitations do not influence the study findings. Future methodological strategies to explore these issues includes the use of longitudinal case studies to investigate how decisions may be justified or changed over time and critical discourse analysis to explore if the patient justifies their views in the course of the interview.

4.5.2 Sampling and recruitment

Healthcare professionals

Purposive sampling was used whereby stakeholders who were involved in insulin initiation in both primary and secondary care were identified and HCPs from each stakeholder group were invited to participate in the study. HCPs were sent an invitation email or letter explaining that the purpose of the study was to interview HCPs about their experience with insulin initiation in order to develop a PDA.

These stakeholders included both primary and secondary care HCPs: endocrinologists, family medicine specialists, government policy makers, general practitioners, government medical officers and diabetes nurse educators. As explained in the section above, maximum variation sampling involved the identification of diverse criteria for constructing the sample. Including a range of primary and secondary care HCPs covered the spectrum of HCPs who were involved in insulin initiation in Malaysia. Patton (1990) notes that data obtained from maximum variation sampling is useful because it will yield both high-quality descriptions of unique individual experiences as well as important shared patterns that cut across cases and are significant because they derive out of diversity. Indeed the HCP results reported in Chapter 5 are a combination of larger thematic categories illustrated by unique individual quotes.

For government policy makers, key informants from both the clinical as well as policymaking arms in the Malaysian Ministry of Health were identified. Some HCPs also played a role in formulating insulin-related policies and guidelines and were interviewed on both practice and policy aspects.

Patients

Purposive sampling was used in order to achieve maximal variation based on three factors: healthcare setting, patients' decision about insulin, and ethnicity of patients. The rationale for choosing these three factors was to ensure that a range of views was captured from the main socio-cultural and decision making dimensions. Purposive sampling involved the deliberate choice of sample participants to achieve a representative sample of views from the broad socio-demographic spectrum in the population (Pope & Mays, 1995). In this study, patients were recruited from both public and private settings as well as from both rural and urban settings. HCPs were asked to identify and recruit patients who were both open to insulin as well as adverse to it. Patients who had prior experience with insulin use but had now stopped using it if they had initiated insulin within the past one year were also included. Constant communication with key clinicians to update them on the required sample was maintained.

HCPs from the various healthcare settings were asked to help identify and recruit suitable patients. This was done by explaining the study to the clinicians and distributing brochures detailing the inclusion criteria for our study and our contact information. Clinicians recruited patients whom they knew had recently been advised to start insulin while nurses assisted by referring patients whom they knew had recently been counselled to start insulin. Interviews were conducted soon after insulin had been introduced in order to capture patients' initial experience and values in regards to insulin initiation.

4.6 Research instrument

4.6.1 Topic guide

Healthcare professionals

The HCP interview topic guide (Appendix B) was developed based on the conceptual framework (ODSF), literature review and expert opinion. The first draft of the topic guide was informed by the Patients AND Decision Aids (PANDAs) study, which involved one of the study supervisors (Academic Unit of Primary Medical Care School of Medicine and Biomedical Sciences University of Sheffield).

The ODSF identifies the various types of decisional needs that need to be addressed when a decision needs to be made. These needs are: decisional conflict; knowledge and expectations; values; support and resources; decision (type, timing, stage, leaning); and personal/clinical characteristics (O'Connor, Tugwell *et al.*, 1998). These needs in turn require decision support from the HCP or other resources. The topic guide explored these needs as relating to insulin initiation and the support provided by the HCP to patients.

Literature review and expert opinion from the DMIT research team provided examples which were included as prompts for the questions. For instance, examples of barriers commonly encountered in insulin initiation were listed so that these could be explored with participants.

The topic guide was iteratively modified based on modification and consolidation of the items, and participant background (for example, policy makers were asked additional questions about insulin-related health policies).

The final version of the HCP topic guide consisted of 16 questions divided into four parts (Appendix B). The first part was a general introduction about HCPs' experiences in starting insulin (e.g. number of diabetic patients treated, decisions faced by patients with diabetes). Part two focused on patients' decision making needs during insulin initiation (barriers, feelings, concerns, informational needs, influence of significant others). Part three consisted of questions related to how HCP's supported the patients who were making decisions (discussing options; explaining risks and benefits; role of HCP in decision making; exploring patient values, ideas, concerns and expectations; coaching and motivation; help or resources needed to overcome barriers faced with patients). The last part consisted of HCP's views on four different types of methods for decision support (one-to-one counselling, discussion groups, information materials, PDAs).

For policy makers, an additional three questions about health policies related to insulin were added (policies related to insulin in Malaysia, roles of various categories of HCPs, barriers to shaping policies).

The same guide was used for HCP focus group discussions (FGDs). A separate topic guide was not necessary as the FGDs aimed to cover the same topics.

Patients

The patient interview topic guide was developed based on the conceptual frameworks (ODSF and Schwartz's Theory of Human Values), literature review, expert opinion and emerging themes from the HCP interviews. The outline of the patient topic guide was based on the HCP topic guide (introduction, insulin decision-making, decision support, views on methods of support). The patient topic guide was modified to explore the area

of patient values in more depth, as well as to incorporate emerging themes which emerged from patient interviews (Appendix C). Questions were modified to explore the attributes of values described in Schwartz's Theory of Human Values. A description of how the various questions explored these value attributes is described in Chapter 5.5. The literature review and expert opinion (from the DMIT research team) was used to provide examples barriers to insulin initiation which served as prompts during the interviews. Some barriers emerged from the HCP interviews (for example, the use of complementary and alternative medication).

The final patient topic guide consisted of 16 questions divided into six parts. The first part was a general introduction to the patient's history of diabetes management. The second part was focused on the decision to initiate insulin (time when advised, HCP who advised, stage of readiness to start). The third part related to the patient decision making process (knowledge and beliefs about insulin; sources of knowledge and beliefs, barriers to starting insulin, informational needs, how the patient chooses between options, what support is needed to help make the decision). The fourth part explored the patient values (priorities) at this current point of decision making (types of life priorities influence of priorities on insulin initiation).

The fifth part concerned patients decision making roles (significant others who were involved in the decision, preferred decisional role). The last part consisted of patient's views on four different types of methods for decision support (one-to-one counselling, discussion groups, information materials). Both participant information sheet and topic guide were translated into Malay and Chinese by researchers or translators who were fluent in these languages.

4.7 Data collection

4.7.1 Semi-structured in-depth interviews and focus group discussions

Healthcare professionals

Both IDIs and FGDs were conducted with HCPs. For the FGDs, participants were selected and grouped based on their practice background and location to ensure homogeneity and to capitalise on their shared experiences (Kitzinger, 1995). IDIs were used for key opinion leaders, such as government policy makers, and also for those who were unable to commit to a focus group session due to their busy schedule. The use of IDIs, FGDs and field notes provided the basis for the triangulation of the data. Although all interviews were conducted in English, some participants used Malay-language words and phrases during the interviews.

Patients

Semi-structured IDIs were conducted with patients in their preferred language (English, Malay or Chinese). Interviews lasted 30-45 minutes per interview. Researchers arranged to interview patients at a time and location of their convenience, including their homes or workplaces if patients were unable to travel due to work commitments or infirmities. Participants were reimbursed for their time and travel.

4.7.2 Recording and Field Notes

Digital voice recorders were used to record each interview or FGD session. Before and during each interview, the researcher took care to build rapport with the participants through the use of ice-breaker questions and giving verbal and non-verbal cues to indicate active listening during the interview.

After the interview, initial impressions and thoughts about the patients and HCPs were recorded in a research diary. Any insights that were gleaned from post-interview conversation were also included as field notes. These notes were later sifted and transferred as memos in Nvivo9 for easy access when coding and analysing the interview transcripts

4.8 Data management, analysis and saturation

4.8.1 Data management

Data analysis was facilitated by the use of Nvivo9- a qualitative research software (Nvivo9, 2010) - to manage transcripts, themes and quotes, while keeping in mind the context of the quotes within the individual interviews. Interviews were transcribed verbatim and checked for accuracy. English and Malay interviews were transcribed verbatim while Chinese interviews were translated into English for analysis. Malay interviews were not translated as all researchers were familiar with the language. These transcripts were transferred into Nvivo9 for analysis and coding.

4.8.2 Data analysis

A thematic analysis was used for data analysis, based on Strauss and Corbin's method of open, axial and selective coding (Strauss and Corbin, 1990). The choice of the Straussian instead of the Glaserian version of analysis was based on the more structured approach to coding employed by Strauss. Strauss prescribed clearer guidelines for data analysis (Strauss & Corbin, 1990) (for example, describing the steps of open, axial and selective codes) whereas Glaser believed that a more open, less structured approach was important for the theory to emerge without being prematurely forced to do so (Glaser,

1992). The Straussian approach was chosen as the more explicit and systematic guides on analysis were found to be helpful, rather than restrictive.

The researchers coded two interviews line by line to develop an initial list of codes (open coding). A process of constant comparison was employed whereby subsequent interviews were coded using this list and new themes which emerged from new interviews were added to the list upon consultation with the research team (Glaser, 1965).

The open codes were organised and re-organised into broader categories based on thematic similarities between open codes (axial coding) as researchers collaborated on interpreting the data in monthly face-to-face discussion meetings. Throughout the coding process, codes were checked by researchers to ensure consistency of coding and consensus on axial and selective codes.

Finally, selective coding was used to generate central or core categories from the axial codes. For the HCP data, the core categories that emerged described the main categories of factors influencing insulin initiation. These were patient, HCP and system factors. For the patient data, based on the goal of developing a model of patient values, selective coding was conducted to generate central or core categories based on connecting and consolidating axial codes which were related to patient values. Three core categories emerged, which were treatment-specific values; life priorities and philosophies; and socio-cultural and personal values. For example, 'denial', 'feeling punished' and 'social stigma' were open codes from interview transcripts. These were consolidated into the axial code 'negative emotions about insulin'. This axial code was connected together with other axial codes ('positive emotions about insulin', 'positive factual beliefs about insulin', 'negative factual beliefs about insulin') to form the central category of

‘treatment-specific values’ based on the common characteristic that all these axial categories described insulin-specific beliefs.

4.8.3 Data Saturation

Data collection was stopped when data saturation was reached. Evidence of data saturation was obtained when no new axial or selective codes emerged from the data, showing that the core categories had already been captured (Strauss and Corbin, 1990; Bowen, 2008). A secondary saturation criterion was based on the saturation of open codes, evidenced by repeated coding within the same codes. For example, in Appendix E (Section E.1.2), items such as “Severity of disease” (believing that insulin use meant diabetes was severe) and “Pain” (fear of pain from injections) were repeatedly coded in 10 and 7 participants respectively. Bowen (2008) supports the use of axial codes as the primary criteria for saturation by explaining that the saturation of data should be based on the lack of emerging themes, signifying that core concepts for the theory have been captured.

The coding frameworks are included as Appendix D (HCP) and Appendix E (patient).

4.9 Rigour in research

Rigour is required in both quantitative and qualitative studies. When describing rigour in quantitative research, validity (how accurately the study measures the target construct) and reliability (how repeatable are the study results) measures are examined. In qualitative research, rigour is defined as ‘The striving for excellence in research through the use of discipline, scrupulous adherence to detail and strict accuracy’ (Burns & Grove, 1997, p793). Three criteria are considered when describing the rigour of a

qualitative study: credibility, transferability and auditability (Lincoln & Guba, 1985; Twycross & Shields, 2005). These criteria are described in the context of this study.

Credibility is the degree of confidence a researcher inspires in the reader (Lincoln & Guba, 1985) and can be achieved through the use of prolonged data collection, verification or member-checking, and theoretical verification (Twycross & Shields, 2005). In this study, the data was collected over a prolonged period; eight months for HCPs (October 2010- May 2011) and over one year for patients (Jan 2011- Feb 2012). Member checking was not performed as it was logistically difficult to reconvene participants from various states. Theoretical verification (comparison with previous studies) is discussed in Chapter 6.2 where similarities between the patient values model and the biopsychosocial model are noted.

Transferability in qualitative research is how much similarity readers can see in the results which may relate to other settings (Twycross & Shields, 2005). From the researcher perspective, transferability is related to the concept of generalizability, in that generalizability is how probable the findings from a smaller, more focused condition or setting can be said to be similar to findings in larger or different settings. Transferability of the study results are discussed in Chapter 6.4. In brief, the patient values model is probably transferable to other healthcare conditions as it was developed from Straussian analysis and it contains general categories of values which can be applied to other medical decisions besides insulin initiation. Furthermore, the participants were sampled from a variety of backgrounds and practice settings, thus aiding the generalizability of the results to other settings. Also, the researcher needs to provide a lot of detail about the setting and the events which take place. In this thesis, the reader is provided with

details on the Malaysian healthcare setting (Chapter 1), and the actual participant quotes used to develop the codes (Chapter 5).

For auditability, the researcher needs to ‘provide a sufficiently clear and full account of the research process so that the reader can judge the dependability of the qualitative study’ (Twycross & Shields, 2005). Qualitative research is often exploratory and involves various degrees of subjective interpretation. The interpretive process needs to be sufficiently detailed to let the reader judge if they can depend on the methods that the researcher has used to analyse the data and arrive at conclusions. In this study, dependability means that readers can judge if the descriptive interpretive method accurately captures the themes of the participant quotes. The research process involved in this study has been described at length in both Chapter 4 (Methods) as well as the methods sections for each of the research manuscripts.

4.10 Research ethics

This study received ethics approval from the Medical Research and Ethics Committee, Ministry of Health, Malaysia, Reference Number: NMRR 10-1233-7299, and the Medical Ethics Committee, University of Malaya Medical Centre (MEC-UMMC), Reference Number: 841.6 (Appendix F). Minor changes to the consent form for a cleaner layout and language translations were submitted as amendments to the MEC-UMMC and were approved by the ethics committee.

4.9.1 Participant information sheet, consent form and demographic data form

Before conducting an IDI or FGD, researchers gave participants a copy of the Participant Information Sheet (PIS) (refer to Appendix G for the HCP PIS and Appendix H for the patient PIS). The patient PIS was available in English, Malay and

Chinese. This document explained the purpose of the study, the procedures involved, the benefits of the study, the possible drawbacks, the participant's right to withdraw at any time, and a list of contact persons for the study. After the participants had read the PIS, they were given an opportunity to ask questions about the study.

If participants agreed to participate, they were asked to give their consent using a consent form (Appendix I). All participants gave written consent to participate in the research and for their interviews to be audio-recorded. In cases where the participant was illiterate, the information sheet was read out to the patient and patients indicated their consent by initialling the consent form. However, most illiterate participants were accompanied by a literate family member who was able to read and explain the information sheet to them.

Participants also completed a brief demographic data form (Appendix J for HCPs, Appendix K for patients). Participants were assured that personal data would be kept confidential and that their identities would be anonymised.

4.11 Research funding

Funding for the research was provided by the DMIT 3-year research grant under the Health and Translational Medicine Cluster, University Malaya Research Grant (Reference Number UMRG 236/10HTM).

4.12 Reflexivity

Researchers themselves are the instrument through which data is analysed and interpreted (Watt 2007). Purely objective interpretation is impossible in qualitative research, as each researcher differs in terms of their personality, background and values. Instead of striving for objectivity and removal of bias, qualitative research incorporates

the practice of reflexivity to make clear the personal framework through which data is interpreted (Watt, 2007). By making clear their personal background, the researcher enables readers to understand why the data is interpreted in a certain way, and more importantly, to evaluate if the interpretations are within an acceptable and logical framework, i.e. the researcher does not make the data say what it does not say. This process of personal reflection on how the researcher interacts with the data is known as reflexivity.

There are three factors which influenced the way I approached the research process. These are: being a psychology graduate; prior work on heuristics decision making; and lastly learning how to use qualitative research for the first time. Because of my background as a psychology major, my interviews and analysis tended to focus more on personal traits and values. I did read to gain basic knowledge on diabetes drugs and health measures, but my interviews did not focus much on the medical, but more on the psychological. In contrast, I observed during interview sit-ins that medically-trained researchers would often explore the details of the treatment regimens when interviewing patients in much more detail.

Secondly, my undergraduate dissertation was on the topic of heuristics, which are cognitive time-saving short cuts employed for quick decision making. Studying heuristics made me realize that decision making was often non-rational and I was interested to explore the intuitive side of patient decision making where values were used as criteria to evaluate the decision to initiate insulin. The main theory related to intuitive decision making in medical decision making is Reyna's Fuzzy Trace Theory, which suggests that patients make decisions based on a 'gist' interpretation of the information. Values are said to play a role in evaluating the gist representations of

information, together with principles and knowledge (Reyna, 2008). However, the theory was not useful as no definition of values was provided. Coming from a social science background, I expanded my search for value theories into the broader social science field, especially psychology.

Thirdly, I had never worked with qualitative research methodologies before this study as qualitative research was not taught in undergraduate curricula. Thus, I endured a steep learning curve when I chose a qualitative research approach, beginning with a simple understanding of qualitative research which progressed into a more complex understanding of the approaches and philosophies underlying the qualitative approach. For example, I initially used a simple thematic analysis for analysing the HCP data (see Methods in Chapter 5.1), which was initially labelled as grounded theory. A reviewer pointed out that the method described was more accurately labelled as thematic analysis. Subsequently, especially for the patient data, a more systematic approach to data analysis and theory generation based on Straussian grounded theory was utilised.

4.13 Language considerations

Issues related to multilingual qualitative research were given consideration. These issues are separate from the need for accurate translation of the participant information sheet and topic guide, which were standard practice in this study. Baumgartner (2012) states that there are two language issues to be considered in multilingual qualitative research: 1) which language should be used as the inquiry language for each of the interviews? and, 2) which language should be used in the data analysis and at which stage of the research is this most appropriate to transition from the inquiry language to the target language of research?

For the first issue, it is important to conduct interviews in a language that was most comfortable for the participant to enable them to express themselves comfortably. It also allows for emotional and cultural language nuances to be captured in the interviews (Baumgartner, 2012). Most HCP interviews were conducted in English as most professionals in Malaysia are fluent English speakers. Only one HCP interview was conducted in Malay. For the patients, given that most Malaysians are multilingual, the researcher (YK) was able to conduct most of the interviews with patients in either English or Malay (n=19). Three interviews were conducted in Mandarin by two other researchers (CJ, PY) as YK is not fluent in the language. Very often interviews involved a mix of multiple languages or phrases as is common in everyday conversation.

For the second issue, Baumgartner highlights that consideration must be given to the type of coding used whereby some researchers code the interviews in the source language in order to retain the original phrases used in coding. In this study, the coding framework was developed in English via a process of constant comparison. As the analysis was a descriptive thematic analysis, interviews in Malay were not translated as fluency with both languages meant that the researcher could easily understand the meaning of the participant and identify the appropriate English code. Mandarin interviews were translated into English by a trained translator and independently checked by a reviewer. The translation of Mandarin interviews was necessary as YK was not fluent in the language. Although emotional nuances and cultural phrases may have been lost, this does not adversely affect the descriptive thematic analysis of the translated transcript as the content and subject matter were clear in the translation.

4.14 Conclusion

In summary, a qualitative study design was chosen to explore the topic of patient values in medical decision making. Using the Ottawa Decision Support Framework and Schwartz's Theory of values as conceptual frameworks, topic guides were developed for use in IDIs and FGDs. The study was conducted amongst HCPs and patients from the various healthcare settings in which insulin is initiated in Malaysia. Purposive sampling was used to identify participants and recruitment was stopped when saturation was reached. The interviews were transcribed verbatim and managed using qualitative data analysis software. Thematic analysis was conducted based on Strauss' technique of open, axial and selective coding. The results of the analysis are reported in Chapter 5.

Chapter 5: Results

Chapter 5 reports the results of the study in the format of research publications. The study sought to answer three research objectives outlined in Chapter 1.5.2. These were (1) to identify factors influencing insulin initiation in Malaysia, (2) to explore patient values among type 2 diabetes patients in Malaysia who are making a decision about starting insulin, and (3) to develop a model of patient values in SDM. The results were reported as four original research articles and one research letter.

The first three articles relate to the first research objective. These first three articles (Chapters 5.1, 5.2 & 5.3) were published from the HCP data and describe the context in which patient values are explored, which is insulin initiation. The articles illustrate how insulin initiation is a complex decision involving many factors. The first article entitled “*A qualitative study on healthcare professionals’ perceived barriers to insulin initiation in a multi-ethnic population*” (Chapter 5.1) reports on the range of patient, HCP and system barriers to insulin initiation from a HCP perspective. The second article is “*How can insulin initiation delivery in a dual-sector health system be optimized? A qualitative study on healthcare professionals’ views*” (Chapter 5.2) and reports on how a dual-sector healthcare system poses problems for insulin initiation for HCPs and patients who lack access to resources. The third article is a research letter entitled “*Tactics in counseling patients to start insulin*” (Chapter 5.3) and describes the persuasive strategies that HCPs use to convince patients to start insulin.

The fourth and fifth articles (Chapter 5.4 & 5.5) are related to the second research objective, which is to explore patient values in insulin initiation. These articles report the analysis of data collected from patients. The systematic review of patient values in medical decision making (Chapter 3.2) showed that patient values could be divided into

two main categories: decision making preferences and healthcare values. Patient decision making preferences are reported in the fourth article which is entitled “*Factors influencing decision-making role preferences: A qualitative study of Malaysian patients with type 2 diabetes during insulin initiation*” (Chapter 5.4). Patient healthcare values are reported in the fifth article “*Exploring patient values in medical decision making: a qualitative study*” (Chapter 5.5). Three categories of healthcare values are reported: insulin-specific values; life priorities and philosophies; and socio-cultural and personal background.

The third research objective of developing a model of patient values is reported in Chapter 5.5. This conceptual model of patient values was developed from the three categories of values which emerged from the patient interviews. Explanation of the rationale underlying the arrangement of the categories in the patient values model is provided in the discussion section of Chapter 5.5.

While each chapter in the Results is reported with its own objectives, findings and conclusions, each chapter contributed to the final objective of developing the model of patient values. This is because it was important to understand context when developing the patient values model. Especially for the first category or ‘layer’ of the values model, which are context-dependent beliefs and feelings, awareness of the context helps to inform why patients expressed certain beliefs or feelings about insulin. For example, one context is interactional, whereby values are influenced by the doctor-patient relationship. Understanding that doctors often practice paternalistic styles (Chapter 5.3) helps to inform why some patients feel punished or threatened when asked to start insulin (Chapter 5.5). Another context is resource availability, whereby an understanding of the cost factors involved in insulin initiation in the dual-sector health

system (Chapter 5.2), for example a lack of subsidies for self-monitoring of blood glucose helps to inform why patients express concern about the cost of insulin treatment (Chapter 5.5).

Chapters 5.1, 5.2 and 5.3 were based on the same HCP data. The differences in number of participants between Chapters 5.1 and 5.2 (n=38); and Chapter 5.3 (n=41) are due to the former being written up earlier during the ongoing process of data collection. The extra three participants did not change the saturation of the data codes, but added to the richness of the participant data through new quotes.

Chapters 5.4 and 5.5 were based on the same patient data. As above, the differences in number of participants (Chapter 5.4, n=22; and Chapter 5.5, n=21) are due to the differences in time of manuscript preparation.

Chapter 5.1: A qualitative study on healthcare professionals' perceived barriers to insulin initiation in a multi-ethnic population

Yew Kong Lee, Ping Yein Lee, Chirk Jenn Ng

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Author contributions:

YKL, PYL and CJN were involved in developing the interview topic guides used for data collection, facilitating the data collection interviews and focus groups, and analysing the data for reporting. All authors read and approved the final transcript.

Abstract

Background

Nationwide surveys have shown that the prevalence of diabetes rates in Malaysia have almost doubled in the past ten years; yet diabetes control remains poor and insulin therapy is underutilized. This study aimed to explore healthcare professionals' views on barriers to starting insulin therapy in people with type 2 diabetes.

Methods

Healthcare professionals consisting of general practitioners (n=11), family medicine specialists (n=10), medical officers (n=8), government policy makers (n=4), diabetes educators (n=3) and endocrinologists (n=2) were interviewed. A semi-structured topic guide was used to guide the interviews by trained facilitators. The interviews were transcribed verbatim and analysed using a thematic analysis approach.

Results

Insulin initiation was found to be affected by patient, healthcare professional and system factors. Patients' barriers include culture-specific barriers such as the religious purity of insulin, preferred use of complementary medication and perceived lethality of insulin therapy. Healthcare professionals' barriers include negative attitudes towards insulin therapy and the 'legacy effect' of old insulin guidelines; whilst system barriers highlight the lack of resources, language and communication challenges.

Conclusions

Tackling the issue of insulin initiation should not only happen during clinical consultations. It requires health education to emphasise the progressive nature of

diabetes and the eventuality of insulin therapy at early stage of the illness. Healthcare professionals should be trained how to initiate insulin and communicate effectively with patients from various cultural and religious backgrounds.

Background

The incidence of diabetes is increasing globally (IDF, 2009; Tunstall-Pedoe, 2006) particularly in the Asia Pacific region (Cheng, 2010). Currently, Malaysia has the highest prevalence rate of diabetes (11.6%) in the Western Pacific region (Letchuman *et al.*, 2010) and it is the 10th highest in the world (IDF, 2009). This alarming rise in the prevalence of diabetes has been attributed to increasing affluence, rapid urbanization, and a diet rich in carbohydrates (Letchuman, *et al.*, 2010). In addition, Malaysia having an upper-middle-income economy, high treatment costs of diabetes and its associated complications have imposed a substantial healthcare burden to her already stretched health system (The World Bank, 2012). As such, in 2010, the Ministry of Health of Malaysia has included diabetes as a priority area in the National Strategic Planning for Non-Communicable Diseases (Ministry of Health, 2010b).

Malaysia has a dual-sector healthcare system comprising government-subsidised public healthcare facilities and more expensive, private healthcare clinics and hospitals (Chee, 2008). Patients are free to choose where they receive treatment, but patients prefer to seek treatment in government facilities as treatment costs are lower there compared to private clinics. Out-of-pocket expenditure was 40.5% of total healthcare expenditure in 2009 (The World Bank, 2009). In primary care, the private sector comprises mostly solo general practice clinics (Ramli & Taher, 2008) whilst public primary care consists of government health clinics and university-based primary care clinics. There are about five times more private primary care clinics compared to the public sector in Malaysia (Clinical Research Centre, 2011). Primary care practice is expected to play a gatekeeper role for secondary care referrals (Clinical Research Centre, 2011).

The quality of diabetes care in private primary care clinics is doctor-dependent as clinics are mostly solo practices employing nursing aides with little formal training (Clinical Research Centre, 2011; Ramli & Taher, 2008). In the public sector, the quality of care also varies, often better in the urban health clinics and university-based primary care clinics due to the presence of family medicine specialists and multidisciplinary diabetes teams (Ramli & Taher, 2008). Clinics in the public sector provide more comprehensive diabetes services but have a high patient load compared to private clinics (Clinical Research Centre, 2011).

The majority of patients with diabetes are managed in the government facilities; the rest are treated by private general practitioners or take complementary and alternative medications (Letchuman, *et al.*, 2010). Despite the established risk of microvascular complications associated with hyperglycaemia (UKPDS Group, 1998), diabetes control remains poor in the Malaysian primary care setting. Eighty percent (80%) of the patients in the private (Mafauzy, 2005), and 69.1% in the public setting, failed to achieve an HbA1c level of less than 7.0% (Ismail *et al.*, 2011). One main reason for poor control is the lack of timely treatment intensification such as initiation of insulin therapy (Donnan, Steinke, Newton, & Morris, 2002). In a community based national health survey, only 7.2% of Malaysian patients with type 2 diabetes used insulin, either alone or as combination therapy (Letchuman, *et al.*, 2010), compared to 36% in the United States (Centers for Disease Control and Prevention).

The Malaysian clinical practice guideline (CPG) for type 2 diabetes was last updated in 2009 and insulin therapy was stated as part of the treatment algorithm (Ministry of Health, 2009). However, there was no mention of how insulin initiation could be implemented in the local healthcare setting. Recognising this gap, a practical guide for

insulin therapy was developed in 2010 and a section was dedicated specifically to addressing patients' barriers to insulin initiation (Ministry of Health, 2010c). However, the recommendations are based on Western data and experts' opinions. There is little research on what barriers the multi-ethnic Malaysian patients with type 2 diabetes face when deciding to initiate insulin. Studies from other countries have described various barriers to insulin initiation such as needle phobia, low self-efficacy and feelings of personal failure (Larkin *et al.*, 2008; Polonsky, Fisher, Guzman, Villa-Caballero, & Edelman, 2005). It is reported that up to a third of patients are unwilling to start insulin therapy when advised to do so (Larkin, *et al.*, 2008; Polonsky, *et al.*, 2005).

Insulin can only be prescribed by doctors in Malaysia and can be initiated at either primary or secondary care settings. Nurse educators play an important role in the public sector as doctors would refer patients to the nurses for education and instruction after prescribing insulin. On the other hand, private doctors often seek help from diabetes educators, who are sponsored by pharmaceutical companies or non-governmental organizations.

Malaysia's multi-cultural society consists of three main ethnic races (Malays, Chinese and Indians) and many other smaller ethnic groups (Swami *et al.*, 2009), which may influence how both healthcare professionals and patients view insulin therapy. This study, therefore, aimed to identify barriers to insulin initiation from the healthcare professionals' perspective. It is only through understanding the barriers to insulin initiation that healthcare professionals can address patients' concerns and help them make decisions about starting insulin. This study was part of a larger three-year complex intervention study which aimed to develop a local patient decision aid for insulin initiation.

Methods

Design

Qualitative, semi-structured interviews and focus groups were used to identify and explore barriers to insulin initiation as viewed by healthcare professionals. A qualitative methodology was used as it allowed us to explore and probe the beliefs, experiences and views of the healthcare professionals concerning insulin initiation as encountered in their respective local practices (Pope & Mays, 1995).

For the focus group discussions, we selected and grouped the participants based on their practice background and location to ensure homogeneity and to capitalise on their shared experiences (Kitzinger, 1995). The focus groups consisted of two groups of private primary care doctors (n=4, n=7), public family medicine specialists (n=8) and public medical officers in a university hospital primary care clinic (n=8). In depth interviews were used for key opinion leaders, such as government policy makers, and also for those who were unable to commit to a focus group session due to their busy schedule. The use of in-depth interviews, focus group discussions and field notes provided the basis for the triangulation of the data. Although all interviews were conducted in English, some participants used Malay-language words and phrases during the interviews as Malay is the national language.

Setting

The study was conducted amongst healthcare professionals who provided diabetes care in the three healthcare settings in Malaysia: the government health clinics; government university-based primary care clinic and hospital; and private general practice (GP) clinics and hospitals. Key government policy makers who were involved in shaping the

national diabetes strategic plans were also interviewed. A spectrum of practice experience was represented. The healthcare professionals came from three different states and from both urban and semi-rural locations.

Participants, recruitment, sampling

Purposive sampling was used whereby we identified stakeholders who were involved in insulin initiation in both primary and secondary care and contacted healthcare professionals from each stakeholder group. They included: endocrinologists, family medicine specialists, government policy makers, general practitioners, government medical officers and diabetes nurse educators. A pattern of snowball sampling developed as the participants named individuals and organizations who were involved in diabetes care particularly healthcare professionals who initiated insulin therapy.

Sample size was determined by data saturation whereby interviews were stopped when no new themes emerged from the interviews.

Data collection

An interview topic guide was developed based on literature review, clinical knowledge and research experience (Table 5.1.1). The same guide was used for both individual and focus group discussions. Participants consented to be audio-recorded and interviews were carried out by either one of two researchers who were trained to conduct qualitative interviews and facilitate focus groups. Care was taken to avoid potential participant response bias by avoiding, whenever possible, having participants interviewed by close acquaintances, lecturers or colleagues. An assistant took detailed notes and observed non-verbal cues during the interviews and these observations acted as field notes. Between October 2010 and May 2011, we conducted ten 30-40 minute

individual interviews and four one hour-long focus groups. We stopped data collection when data saturation was reached for both interviews and focus groups. The interviews and focus groups were audio-recorded and transcribed verbatim. The transcripts were checked for accuracy and used as data for analysis.

Table 5.1.1 Barriers to insulin initiation interview/focus group topic guide

- Is starting insulin a difficult decision for your patients?
- How do they feel when making this decision?
- What are the things that patients consider before they decide whether or not to start insulin?
 - Information
 - Values
 - Influence from others
- What barriers do you face when advising them to start insulin?
- What kind of help do you need to overcome these barriers?
- What barriers do you face when shaping policies on insulin treatment? (additional question for policy makers)

Data analysis

A hermeneutic-phenomenological approach was employed when analysing the data, which was viewed as being both descriptive and interpretive (Van der Zalm & Bergum, 2000). The interpretive focus of hermeneutics occurred from the ‘outside’, whereby two of the researchers’ backgrounds as clinicians influenced how they not only interpreted the data but also how their interactions with the participants during interviews were

influential in constructing the text. The hermeneutic perspective was also acknowledged on the 'inside', from the perspective of the participants, whereby data was viewed as consisting of how participants interpreted barriers to insulin initiation, both from their perspective as healthcare providers, and also on behalf of their patients (Cohen, Kahn, & Steeves, 2000). The researchers familiarised themselves with the data by reading and re-reading the transcripts. Three researchers coded two transcripts (interviews with a primary care physician and a government policy maker) independently and created a list of nodes (themes). Subsequently, the researchers used this framework to code (label) the two other transcripts individually. The coding was then compared for inter-rater consistency and any coding discrepancies were resolved by discussion until consensus was reached on the list of nodes and the coding descriptions. The finalised list of nodes and coded transcripts were imported into Nvivo9 software which formed the basis for future coding.

The remaining transcripts were distributed among the three researchers (YK, PY, CJ) and coded individually. Any new nodes emerging during coding were added to the list upon consultation with the other researchers. The list of nodes was regrouped into larger categories as a pattern of themes emerged from the data.

Two of the researchers (CJ, PY) are family medicine specialists and the third is a postgraduate psychologist (YK) and thus data analysis was from both clinical and non-clinical perspectives. The researchers constantly reflected and debated on the potential biases which they might carry with them due to their backgrounds to improve credibility of the analysis.

Ethics approval

This study received ethics approval from the Medical Research and Ethics Committee, Ministry of Health, Malaysia.

Results

A total of 38 healthcare professionals participated in the study. Besides individual interviews, two focus group discussions were conducted with general practitioners in private practice (n= 7; n=4), one focus group with family medicine specialists from public health clinics (n=9), and another focus group (n=8) with medical officers from a public hospital-based primary care clinic. Participants' demographic data are shown in Table 5.1.2.

Three main categories of barriers emerged from the analysis and are reported below: patient barriers, healthcare professional barriers and system barriers (Table 5.1.3).

Quotations are verbatim whereby colloquialisms and Malay-language words (with translations), if any, are not re-worded in order to give perspective on Malaysia's multi-lingual setting.

Table 5.1.2 Demographic profile of participants

Characteristics	Number (n= 38)	%	Mean \pm SD (Range)
Age			47.0 \pm 9.9 years (30-66 years)
Sex			
Female	29	76.3	
Male	9	23.7	
Ethnicity			
Malays	13	34.2	
Chinese	12	31.6	
Indians	10	26.3	
Others	3	7.9	
Professional background			
General practitioner	11	36.7	
Family medicine specialist	10	33.3	
Medical officer	8	21.1	
Government policy maker	4	13.3	
Diabetes nurse educators	3	10.0	
Endocrinologists	2	6.7	
Healthcare sector			
Public	24	63.2	
Private	14	36.8	

Table 5.1.3 Barriers to insulin initiation faced by Malaysian healthcare professionals

<p>Patient barriers</p> <ul style="list-style-type: none">• Fear of side effects and pain• Misconceptions about insulin<ul style="list-style-type: none">○ Insulin is lethal○ Insulin is a punishment○ Insulin is a stigma○ Insulin is a medication for old people○ Insulin causes sexual dysfunction○ Insulin is unlawful for Muslims• Inconvenience in starting insulin• Seeking alternative treatment• Lack of knowledge and self-efficacy• Negative influence from family members
<p>Healthcare professional barriers</p> <ul style="list-style-type: none">• Negative attitudes towards insulin• Lack of motivation and confidence• Training-related barriers• Conflicting advice from the healthcare professionals
<p>System barriers</p> <ul style="list-style-type: none">• Lack of continuity of care• Lack of manpower• Lack of resources• Language barriers

Patient barriers

The participants highlighted a range of barriers faced by patients when starting insulin. The list includes fears associated with insulin; patients' perceptions of insulin; lack of knowledge and self-efficacy.

Fear of side effects and pain

The healthcare professionals found that patients' fear of side effects, such as hypoglycaemia and weight gain, were common barriers faced by patients.

“(Patients are) afraid of hypo. Because they have seen people with hypo, it’s so bad. They lost consciousness and they talk nonsense and all that.”

Family medicine specialist, public health centre

“The youngsters especially...they are very worried about weight gain.”

Medical officer, public university primary care clinic

Other emotional factors that influenced patients' decision on starting insulin included patients' fear of needles and pain.

“All of us are brought up (to believe that) injection is pain. So a lot of them have a (pause) idea that it is associated with pain”

Diabetes nurse educator, public university hospital

“The moment we say injection, for them, injection is the long needle...the big needle. So that’s the idea...”

Medical officer, public university primary care clinic

Misconceptions about insulin

- Insulin is lethal

The healthcare professionals cited that patients’ perceived insulin as a drug with ‘lethal’ complications. Patients believed that they would die soon after initiating insulin because they observed that the disease deteriorated in other patients soon after insulin initiation. As a result, they perceive that insulin is the cause of severe diabetic complications.

“It’s..it’s a...especially among the elderly patients, they’ll be told that when they reach the stage where they need insulin, err...that’s one foot in the grave already”

Endocrinologist, private hospital

“...so they (patients) feel that the moment they put insulin, after a few years is kidney damage, then dialysis. So they have that fear, every time they’ll ask us, “Doctor if I use insulin, will my kidneys get damaged?””

General practitioner, private practice

- Insulin is a punishment

Some patients perceived insulin as a ‘punishment’ to them. The healthcare professionals believed that this could be due to doctors framing insulin as a penalty for failing to

control their disease. A doctor quoted a patient as saying “...one doctor very garang (*‘fierce’*), you know, scolded me because my sugar is like this. And said if it’s not okay, I’ll start you on insulin. So for (me) it’s a punishment”.

- Insulin is a stigma

According to the healthcare professionals, using insulin might be perceived by some patients as a stigma as they associated needles with drug abuse. One endocrinologist observed that,

“I’ve no idea why they think they will be addicted to insulin...I don’t know what it is about insulin perhaps it’s the fact there’s a needle and I don’t know whether they think it’s dadah (drugs) or what, but very often like, ‘Oh does it mean sampai mati saya kena ambil (I have to take insulin until I die) or umm... does it mean I can’t come off it, imply that I addicted...dependent on it...’”.

Patients also worried about having to inject insulin during social functions where they would be surrounded by other people.

“How to inject in front of public, like I go for dinner, I’m going to attend a dinner with everybody on the round table. So when can I inject myself...am I going to inject myself in public...or where can I go myself injection?”

Medical officer, public university primary care clinic

- Insulin is a medication for old people

Younger patients viewed diabetes as an ‘old people’s disease’ and considered insulin as only needed for the elderly.

“They (young people) got a stigma... Because you see, insulin, and diabetes, is old peoples’ disease.”

General practitioner, private practice

- Insulin causes sexual dysfunction

Insulin was also associated with men’s sexual dysfunction.

“They think by taking this tablet (diabetes medication), it makes them, you know... ED (erectile dysfunction), so no injection, any medicine, or any injection”

General practitioner, private practice

- Insulin is unlawful for Muslims

Muslim patients were concerned over the origin of insulin as many still believed that it was a porcine derivative, which is unlawful under Islamic religious law.

“I think they were thinking that the insulin is from, what do you call this, non-halal (‘lawful’)...ah...products”

Family medicine specialist, public health centre

Inconvenience in starting insulin

Patients also perceived insulin therapy as inconvenient and interfering with their lifestyle.

“Yeah, I think some of them said inconvenience because they said uh especially those already retired, they actually want to go into you know, different-different places, different child each month, or go to the relatives’ house and all that. So,

yeah to bring, they thought that they actually have to keep that in the fridge all the time. So, it's actually inconvenient for them. Also for injection lah. I mean, if they're actually go out, injections probably a problems for them."

Family medicine specialist, public health centre

Seeking alternative treatment

Complementary and traditional medications for diabetes were also preferred for diabetes control.

"And when you tell them, your diabetes has come to a stage where you need, er, injections, they will say they have uh...these herbs and so on. They want to try out herbs first."

General practitioner, private practice

Lack of knowledge and self-efficacy

Patients with diabetes often considered starting insulin therapy as a complex task and this caused patients to delay insulin therapy. Patients felt overwhelmed by the instructions and were not confident to handle injections.

"...let's talk about older people, for the older people, they always know insulin is more complicated rather than just following medicine. So they always say that I cannot handle it, so I don't want it."

Diabetes nurse educator, private practice

Patients' lack of self-efficacy stemmed from worries about following the insulin regimen in novel situations such as during festive meals, which are a common occurrence in Malaysian culture.

“...there is a lack of self-efficacy...Now self-efficacy is mainly can you handle in a s-situation, in a situation that you are in. And is not just what you can do, can you handle it? Even if you know how to give yourself injection, if you have to go for some s-social function. What do you do? What do you do?”

Diabetes nurse educator, private practice

Being elderly, relying on others for care, suffering from visual impairment and having irregular mealtimes also caused patients to hesitate over starting insulin.

“For my patient, like elderly, we have resistant to start insulin because cannot read the pen- too small and then blur.... So, because cannot see, cannot read...they got the eye problem”

Family medicine specialist, public health centre

The healthcare professionals felt that some patients lacked knowledge and were reluctant to start insulin, especially those who had a short history of diabetes. Some were not aware of the natural progression of diabetes and the need for insulin eventually.

“In fact probably they're already diabetes for many years but just diagnosed for two years. So they thought, you know, it's...it's just too early. It's just too early for them to actually go for insulin.”

Family medicine specialist, public health centre

Negative influence from family members

Another barrier noticed by the health care professional is some patients with diabetes were facing negative influence and poor support from family members especially from their spouse to initiate insulin.

“(Patient) agreed to have insulin...Next day he came back and said “My wife doesn't want me to...start insulin”...My personal feeling is that he's completely under her thumbs, and she has decided “My husband doesn't need insulin”.

Endocrinologist, private hospital

Healthcare professional barriers

Healthcare professional barriers to initiating insulin therapy comprised psychological barriers such as negative attitudes towards insulin therapy, lack of motivation and confidence. Unfamiliarity with starting insulin therapy was also highlighted.

Negative attitudes towards insulin

Some healthcare professionals felt that it was unlikely for patients to change their negative attitudes towards insulin and to modify their lifestyle to suit the insulin regimen. These healthcare professionals were unwilling to take time to teach patients about insulin therapy, and viewed insulin as a hassle.

“I also discuss (insulin) with, um...the FMS (Family medicine specialists) or in Terengganu and the physicians...and a matter of factly it's...it's as if they just accept the fact (that patients won't start insulin). “It's difficult here! The patient

doesn't want to do, what can we do...Patient don't want insulin, so what can we do?"

Government policy maker

Lack of motivation and confidence

Some doctors were not motivated to start patients on insulin themselves as they could refer patients to an endocrinologist or a diabetic nurse. Furthermore, some doctors still subscribed to the old school of thought that insulin could only be initiated in a hospital setting and not in clinics.

"I don't push... I don't push, because I let the specialists handle it. Yeah, I refer them to the specialists..."

General practitioner, private practice

Besides motivation, some doctors lacked confidence in starting a patient on insulin. Reasons included feeling uncomfortable with needles and unfamiliarity with the various insulin regimens and devices. Some healthcare professionals blamed the patients for their reluctance to accept insulin. Even those who were successful at initiating insulin viewed the counselling process as a battle to be won and one requiring considerable mental preparation.

"...we ourselves have got such a mental block. I mean, as doctors it's very easy to preach, but when it comes to needles I think we doctors also freak out. So when we had to inject it was like, 'Oh dear...must I do it?'"

General practitioner, private practice

Training-related barriers

Training-related barriers include: organizational policies that do not support staff who want further training and the quality of the training programme.

“...even though they (sponsors) write there black and white for the (diabetes) educator from the clinic to go (for training)... we are not at liberty to improve ourselves”

Diabetes nurse educator, public university hospital

“...the training in the Ministry (of Health) is very much didactic, not so much practical.”

Government diabetes policy maker

Conflicting advice from the healthcare professionals

Conflicting information given by healthcare professionals, peers and media tended to delay patients' decision in starting insulin.

“...the GP told him... “No, why you so silly start on injection for? I give you medicine. Forget it, throw it all away.” So he went back to oral medicine....and he came back 6 months later with renal failure.”

General practitioner, private practice

Doctors in the private sector felt that the decision to start insulin or not was out of their control as patients could “shop with another doctor who will tell them that they don't need (insulin)” (Diabetes nurse educator, private practice).

System barriers

System barriers to insulin initiation could be divided into four main areas: lack of continuity of care, manpower, resources and language barriers.

Lack of continuity of care

The lack of continuity of care in primary care made insulin initiation and management challenging. Therefore, patients were often unable to maintain the follow-up which is crucial to address individual patient's concerns about insulin. The lack of continuity of care is particularly problematic in the public sector due to high turnover of doctors.

Patients are often not being given a choice on who they would like to consult as they are unable to book to see the same practitioner at each visit.

“So, I’ve learned that it’s important to...to...to know your patient well but the only problem with MOH (Ministry Of Health) is that you can’t see the same doctor..... so this fact about not having the same doctor, patients don’t like it. They don’t like it.”

Endocrinologist, public hospital

Lack of manpower

The lack of manpower was apparent especially in the government hospitals and clinics. Despite recognising the important role of a nurse educator in insulin counselling, only a small number of diabetes nurse educators and dieticians were trained in the government sector and, when present, they had to handle heavy patient loads. Although privately-sponsored diabetes nurse educators were available to help educate patients on starting insulin in private clinics, there were very few of them.

Lack of resources

While insulin is subsidized in the public clinics and hospitals, there is no financial assistance for glucometers and test strips. This hampers insulin initiation.

“The other thing is that I think, uhh...most of our patient do not have home blood sugar monitoring. This is actually very difficult in starting insulin. To actually titrate insulin, especially for BIDS (bedtime insulin daytime sulphonylurea) regime, it’s very difficult.”

Family medicine specialist, public health centre

Education materials about insulin were not easily available and most insulin-prescribing doctors preferred to sketch out information on blank paper. There was also a lack of dedicated diabetes education rooms and facilities. Counselling patients about insulin initiation was seen as time consuming especially in government clinics with heavy patient load.

“...the workload...500, 600 patient a day and per doctor we are seeing umm, 70 to 100. Not a good day, one MC (medical leave), one taking leave, 100 a day. So I was you know, practicing there, I have to be a regular MO (Medical Officer), so I can find it is difficult to counsel patient in this kind of situation. Time is definitely you know really un-under constraint”

Family medicine specialist, public health centre

Language barriers

Language issues made it difficult for healthcare professionals to communicate with patients. Some patients from rural and agricultural estates can only speak their native

language. This poses a big communication barrier if the healthcare professional and the patient are from different ethnic and linguistic backgrounds.

“...the big, important issue is language barrier...we actually do not have enough...uh...Indian staff.”

Family medicine specialist, public health centre

Discussion

This study highlights the wide range of barriers to insulin initiation in Malaysia and provides an overview as to why the use of insulin remains low. What is remarkable is the similarity of the barriers encountered in a multicultural, Asian country to barriers reported in studies conducted in the West. A Pubmed search of qualitative studies which focus on barriers to insulin initiation identified eight studies from North American (J. B. Brown *et al.*, 2002; Hunt, Valenzuela, & Pugh, 1997), UK (Greaves *et al.*, 2003; Phillips, 2007a, 2007b; Sigurdardottir, 1999), European (Goderis *et al.*, 2009) and South African (Haque, Emerson, Dennison, Navsa, & Levitt, 2005) settings. Thematic consistency is apparent between these studies and our study, suggesting that these barriers are widely held ideas that the results of this study are generalizable.

Studies on psychological insulin resistance amongst multi-ethnic populations have found that ethnicity is an important determining factor. Studies in the west have found that Hispanic and ethnic minorities are less willing to start insulin therapy (Nam, Chesla, Stotts, Kroon, & Janson, 2010; Polonsky, *et al.*, 2005). Reasons for this resistance include perceived lack of access to care and language barriers between healthcare provider and patient (A. F. Brown *et al.*, 2003; Caballero, 2006). Malaysian society consists of three main racial groups, each with distinct cultural practices and

close-knit community structures. The healthcare professionals cited patients' misconceptions of insulin as a major barrier. Our study identified three misperceptions that arise out of this multicultural setting: religious barriers, use of complementary medicines and lethal connotations about insulin.

The majority of Malaysia's population are Muslim, in which the origin of food and products must comply to strict religious standards in order to be considered lawful ('halal'). Healthcare professionals need to reassure Muslim patients that modern, synthetic insulin is not derived from a porcine source (Qureshi, 2002), which is strictly forbidden except under emergency situations (Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia, 1983). Another concern for Muslim patients is the use of insulin during Ramadan, where the Muslims would be on a full-day fast from food and drink (Salti *et al.*, 2004). Healthcare professionals (including non-Muslims) must be able to advise Muslim patients on appropriate insulin regimes during the fasting month of Ramadan (Benaji *et al.*, 2006).

Patients' preference to try out complementary therapies before insulin usage is often overlooked by the healthcare professionals in Malaysia. In a local study, the use of complementary therapies was prevalent among people with type 2 diabetes mellitus (Hasan, Ahmed, Bukhari, & Loon, 2009). Half of Malaysian patients with chronic diseases do not report their use of complementary therapy to their doctors or pharmacists (Hasan, *et al.*, 2009). This is of concern as the use of traditional herbs has been identified elsewhere as a barrier to insulin therapy whereby patients were perceived to have more faith in herbs than in insulin (Haque, *et al.*, 2005). Increasing healthcare professional awareness on complementary and traditional therapies will help to reduce healthcare professionals' anxiety in advising patients on the use of such

therapies (Corbin Winslow & Shapiro, 2002). Healthcare professionals need to play a more active role in asking their patients about their use of complementary therapies when initiating insulin (Busse, Heaton, Wu, Wilson, & Mills, 2005).

Patients often associate insulin usage with co-morbidities. Although it has been reported elsewhere that patients associate insulin with disease severity (Hunt, *et al.*, 1997; Peyrot *et al.*, 2005), this misconception appeared to be more serious among the Malaysian patients who consider insulin to be lethal. Healthcare professionals should, therefore, address this misconception by counselling patients about the natural progression of diabetes at early stage of the illness. It should be emphasised to patients that early initiation of insulin helps to reduce morbidity and mortality. The myth about the association between insulin and advanced disease and deaths should be dispelled by providing accurate and timely information to the patients.

In this study, most system barriers are similar to those found elsewhere, including short consultation times, rapid staff turnover and lack of continuity of care (Haque, *et al.*, 2005). However, further matrix analysis of the data identified two issues which were only identified in healthcare professionals from the public healthcare system in Malaysia. Firstly, the lack of continuity of care is particularly problematic in the public healthcare setting due to fast turnover of doctors and patients not being given a choice on who they would like to consult. Continuity of family physician care in patients with diabetes is associated with better quality of life (Hanninen, Takala, & Keinanen-Kiukaanniemi, 2001), and lower mortality and hospitalization in elderly patients (Worrall & Knight, 2011). According to Prochaska's transtheoretical model (James O. Prochaska, 2008), insulin initiation requires patients to move from stages of precontemplation, contemplation and finally to action, with patients often cycling back

and forth between these stages (J. O. Prochaska, DiClemente, & Norcross, 1992).

Continuity of care would play an important role as healthcare professionals assess the stage of patient's readiness to initiate insulin and customize a follow-up plan to help patients initiate and optimize the use of insulin (Singer, 2007).

The language barrier was especially pressing in rural and semi-rural locations of the public healthcare system. Patients with limited language proficiency have problems with healthcare access, comprehension, adherence and receive lower quality of care overall (Jacobs, Chen, Karliner, Agger-Gupta, & Mutha, 2006). As a self-administered injection, insulin requires an understanding of injection techniques and self-titration. Thus, difficulty in communication during patient education still poses a substantial barrier to insulin initiation in Malaysia. Strategies to overcome language barriers in practice include employing a diverse healthcare workforce and using translation services when necessary (Campos, 2007). Preparing healthcare professionals to serve in diverse communities can be done by offering medical language courses in medical schools to help familiarise students with medical terminologies they will encounter in different communities (Groman & Ginsburg, 2004).

Both public and private healthcare professionals stated that the lack of resources was an important barrier to insulin initiation. Diabetes nurse educators are an important, but lacking resource for insulin initiation, with less than 600 diabetes nurse educators in the country serving a diabetes population of approximately 1.6 million (Tan, Magarey, Chee, Lee, & Tan, 2011). The cost and lack of availability of self-monitoring of blood glucose (SMBG) contribute to patients' reluctance to start insulin. Although the cost of insulin is subsidized in Malaysia, glucometers and test-strips are not. There is evidence to suggest that the frequency of SMBG is inversely related to out-of-pocket expenses

(Nyomba, Berard, & Murphy, 2002, 2004) and countries with the highest relative strip-cost have the lowest use of self-monitoring (SMBG International Working Group, 2008). Thus, one place to start is to look into providing patients with financial assistance to acquire glucometers and test-strips for SMBG as they are essential for monitoring the response to and side effects of insulin therapy.

Patients perceive that their diabetes is advanced once they are advised to start insulin therapy (Polonsky, *et al.*, 2005). This perception may stem from the healthcare professionals' belief that insulin could only be started once the patients reach maximum numbers and doses of oral glucose-lowering drugs. Previous Malaysian CPGs recommended that insulin should only be considered in patients with poor glycaemic control after lifestyle modifications and maximum oral glucose-lowering therapy (Ministry of Health, 2004). In the latest CPG released in 2009, the recommendation has been changed and healthcare professionals are now advised to start insulin early, especially for patients who have poor glycaemic control at diagnosis. More research is needed on the prevalence of the 'legacy effect' of past guidelines and changes made from previous guidelines should be highlighted during the training and dissemination of new guidelines (Home, Mant, Diaz, & Turner, 2008).

The strength of this study lies in the fact that the sample encompassed all healthcare sectors and stakeholders who were involved in insulin initiation. We were thus able to gain an in-depth understanding of the barriers to insulin initiation from a wide range of perspectives. Analysis of barriers according to participant ethnicity did not reveal significant differences in terms of themes mentioned as healthcare professionals treat patients from various ethnicities and encounter a range of barriers in patients. However,

participant responses highlighted the nature of culture-specific barriers as the examples provided were often specific to one culture, such as the names of traditional herbs.

There are a few limitations in this study. Only participants from three states (Kuala Lumpur, Selangor and Seremban) in Malaysia were included in this study. The culture of patients in other states, in particular the East coast of the peninsula and East Malaysia, might be different and hence the patients might face different barriers when starting insulin. This limits transferability. Future studies should include participants from other states of Malaysia. As sample size was determined by thematic saturation, the sample population was too small to be analysed according to healthcare professions. Lastly, only healthcare professionals' perspectives were included for this study. However, this study forms part of a larger study and we are embarking on a study exploring patients' views and perceived barriers to starting insulin. More research is necessary to explore the patients' perspectives of insulin therapy. This will help substantiate the findings from this study and identify the needs of patients when starting insulin.

Conclusions

Tackling the issue of insulin initiation should not happen only at the point of decision during clinical consultations. A more comprehensive healthcare education programme should be designed and implemented. Patients should be informed early on about the natural progression of diabetes and the need for insulin therapy 10-15 years after the diagnosis. At the macro level, understanding the barriers to insulin initiation helps government policy makers develop effective public educational programmes; design and implement training curriculum of healthcare professionals; and plan the resources necessary to manage this disease. At the micro level, the awareness of the barriers to

insulin initiation helps the healthcare professionals to explore and address patients concerns and help them to make an informed decision about insulin initiation.

Competing interests

None.

Authors' contributions

YKL, PYL and CJN were involved in developing the interview topic guides used for data collection, facilitating the data collection interviews and focus groups, and analysing the data for reporting. All authors read and approved the final transcript.

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Chapter 5.2: How can insulin initiation delivery in a dual-sector health system be optimised? A qualitative study on healthcare professionals' views

Ping Yein Lee, Yew Kong Lee, Chirk Jenn Ng

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Author contributions

PYL wrote the first draft of the paper and led the critical review and revision of the paper. PYL, YKL and CJN were involved in the study design, development of the interview topic guides used for data collection, facilitation of the data collection interviews and focus groups, analysis of the data for reporting, interpretation of the data, and review of the paper. All authors have read and approved the final manuscript.

Abstract

Background: The prevalence of type 2 diabetes is increasing at an alarming rate in developing countries. However, glycaemia control remains suboptimal and insulin use is low. One important barrier is the lack of an efficient and effective insulin initiation delivery approach. This study aimed to document the strategies used and proposed by healthcare professionals to improve insulin initiation in the Malaysian dual-sector (public–private) health system.

Methods: In depth interviews and focus group discussions were conducted in Klang Valley and Seremban, Malaysia in 2010–11. Healthcare professionals consisting of general practitioners (n=11), medical officers (n=8), diabetes educators (n=3), government policy makers (n=4), family medicine specialists (n=10) and endocrinologists (n=2) were interviewed. We used a topic guide to facilitate the interviews, which were audio recorded, transcribed verbatim and analysed using a thematic approach.

Results: Three main themes emerged from the interviews. Firstly, there was a lack of collaboration between the private and public sectors in diabetes care. The general practitioners in the private sector proposed an integrated system for them to refer patients to the public health services for insulin initiation programmes. There could be shared care between the two sectors and this would reduce the disproportionately heavy workload at the public sector. Secondly, besides the support from the government health authority, the healthcare professionals wanted greater involvement of non-government organisations, media and pharmaceutical industry in facilitating insulin initiation in both the public and private sectors. The support included: training of healthcare professionals; developing and disseminating patient education materials; service

provision by diabetes education teams; organising programmes for patients' peer group sessions; increasing awareness and demystifying insulin via public campaigns; and subsidising glucose monitoring equipment. Finally, the healthcare professionals proposed the establishment of multidisciplinary teams as a strategy to increase the rate of insulin initiation. Having team members from different ethnic backgrounds would help to overcome language and cultural differences when communicating with patients.

Conclusion: The challenges faced by a dual-sector health system in delivering insulin initiation may be addressed by greater collaborations between the private and public sectors and governmental and non-government organisations, and among different healthcare professionals.

Keywords: Insulin initiation, dual-sector health system, Malaysia, diabetes, private sector.

Background

The United Kingdom Prospective Diabetes Study (UKPDS) has found that intensification of glycaemic control prevents and delays diabetes-related complications (UK Prospective Diabetes Study (UKPDS) Group, 1998). This often requires oral glucose-lowering drugs in addition to lifestyle modification. However, because of progressive insulin depletion, the majority of patients with type 2 diabetes will require insulin to achieve optimal glycaemic control 5–10 years after diagnosis (DeWitt & Hirsch, 2003; UK Prospective Diabetes Study (UKPDS) Group, 1998). Internationally, most studies found only about 26–34% of patients with type 2 diabetes achieved optimal glycaemic control (Fox, Gerber Pharmd, Bolinder, Chen, & Kumar, 2006; Kosachunhanun *et al.*, 2006; Liebl, Mata, & Eschwege, 2002; McFarlane *et al.*, 2002). This could be related to low employment of an insulin regimen (Eliasson, Cederholm, Nilsson, & Gudbjornsdottir, 2005; Koro, Bowlin, Bourgeois, & Fedder, 2004; Kosachunhanun, *et al.*, 2006).

In Malaysia, the prevalence of type 2 diabetes ranks seventh in the world (International Diabetes Federation, 2009a) and is the highest in the Western Pacific region (International Diabetes Federation, 2009b). A recent study found that 81.9% of Malaysian adults with diabetes seen at the primary care setting did not achieve the recommended glycaemic goal of less than 6.5% haemoglobin A1c (Ismail *et al.*, 2011). One important reason for poor glycaemic control is the delay in initiating and intensifying insulin therapy (Donnan, Steinke, Newton, & Morris, 2002). In Malaysia, studies have reported very low usage of insulin among patients with type 2 diabetes (Ismail, *et al.*, 2011; Letchuman *et al.*, 2010).

Many factors contribute to the delay in insulin initiation in clinical practice: patient factors, such as psychological insulin resistance; clinician factors, such as lack of training and confidence; and system factors. Common system barriers include: short consultation times, rapid staff turnover and lack of continuity of care (Haque, Emerson, Dennison, Navsa, & Levitt, 2005), and these barriers vary across different health systems. Malaysia has a dual-sector healthcare system comprising public (government subsidised) and private (fee for service) sectors. Almost three-quarters of patients with diabetes are managed in the public sector, which often has a high patient load and turnover of doctors (Letchuman, *et al.*, 2010). Furthermore, patients in the public sector are often not given a choice of which doctor they would prefer to consult. Therefore, to improve optimisation of glycaemic control and update of insulin, effective and efficient strategies are needed, particularly those targeting the healthcare delivery system. This study aimed to explore the views of Malaysian healthcare professionals (HCPs) on the strategies that would facilitate insulin initiation among patients with type 2 diabetes.

Methods

Design

We conducted semi-structured interviews and focus group discussions with HCPs to explore the strategies they used or proposed to improve service delivery in order to facilitate insulin initiation. A qualitative methodology allowed us to explore views on healthcare delivery systems related to the practise of insulin initiation in local practice situations (Pope & Mays, 1995). This also enabled us to have a more holistic view of service delivery and strategies for its improvement (Bogdan & Taylor, 1975; Patton, 1980).

HCPs participating in the focus group discussion were grouped according to their practice background and location. This was to ensure homogeneity and to capitalise on shared experiences among the HCPs (Kitzinger, 1995). For logistic reasons, we conducted individual in-depth interviews with key opinion leaders, such as government policy makers. The use of in-depth interviews, focus group discussions and field notes served to triangulate of the data.

Setting

In Malaysia, insulin therapy is initiated by HCPs from government hospitals and health clinics; university-based hospitals and primary care clinics; and private hospitals and general practice clinics. In this study, we recruited the HCPs from three states (Wilayah Federal Territory, Negeri Sembilan and Selangor) and from both urban and semi-rural locations. Two key policy makers from the Ministry of Health who were involved in developing and implementing the national diabetes strategic plan were also interviewed.

Participants, recruitment and sampling

We used purposive sampling to identify the stakeholders who were involved in insulin initiation. They comprised family medicine specialists, general practitioners (GPs), government medical officers and diabetes nurse educators, endocrinologists and government policy makers. We used the ‘snowballing’ technique to recruit participants by asking stakeholders to identify individuals and organisations who were involved in insulin initiation. We interviewed and analysed in an iterative manner until no new themes emerged. The recruitment was stopped when researchers discussed and reached consensus that the analysis had reached thematic saturation.

Data collection

An interview topic guide was developed based on literature review and expert opinion. The questions in the topic guide were based on the conceptual framework where health care professionals, patients and the health care delivery system are factors that may influence the initiation of insulin (Haque, *et al.*, 2005). We interviewed the HCPs using open-ended questions and used prompts only if important issues did not emerge spontaneously during the interview. The HCPs were informed that the interview focused on patients with type 2 diabetes who are indicated to start insulin. The HCPs were asked about the barriers, facilitators and their experience of insulin initiation and this has been reported elsewhere (Lee, Lee, & Ng, 2012). They were also asked to suggest strategies they used or would recommend to optimise insulin initiation. Three trained researchers conducted the individual interviews and focus groups using the topic guide.

We sought written consent from all the participants for audio-recording and the interviews. An assistant took field notes on non-verbal cues and interview dynamics. Between October, 2010, and May, 2011, we conducted individual interviews and focus groups, lasting about 30 and 60 minutes, respectively. We reached data saturation after ten individual interviews and four focus groups. All the interviews were audio recorded, transcribed verbatim and the transcripts were used as data for analysis.

Data analysis

A thematic analysis approach was used. The researchers familiarised themselves with the data by reading and re-reading the transcripts. Three researchers coded two transcripts (interviews with a primary-care physician and a government policy maker) independently and a list of free nodes (themes) was created. The free nodes were

merged to form larger categories. This framework, consisting of categories and themes, was used subsequently to code (label) another two transcripts by the researchers independently. The coding was then compared for inter-rater consistency and any discrepancies were resolved by discussion. Consensus was reached on the final list of nodes and their descriptions. This final list of revised nodes was imported into Nvivo9 software and served as the framework for coding the rest of the transcripts. New themes that were identified were added to the list upon consultation with the research team.

Two of the researchers (CJN and PYL) are family medicine specialists and the third is a postgraduate psychologist (YKL). The researchers were conscious of their personal and professional views on insulin initiation. The team underwent constant reflection and open discussion throughout the interviews and analysis to reduce possible biases. This study was part of a larger 3-year study that aimed to develop a patient decision aid for people with type 2 diabetes who are considering insulin therapy.

Ethics approval

This study received ethics approval from the University of Malaya Medical Centre Medical Ethics Committee and the Medical Research and Ethics Committee of the Ministry of Health, Malaysia.

Results

Characteristics of the participants

A total of 38 HCPs participated in the study: 11 general practitioners, ten family medicine specialists, eight medical officers, four government policy makers, three diabetes educators and two endocrinologists. Of the 38 HCPs, 24 were from the government sector and 14 from the private sector. Their mean age was 47 years (range

30–66 years). There were 29 women and nine men; and 13 Malays, 12 Indians, 10 Chinese and three other races.

Three main strategies to improve insulin initiation emerged from the data: (1) collaboration between the public and private sector; (2) greater involvement of pharmaceutical industry, media and non-government organisations (NGOs); and (3) establishment of multidisciplinary teams.

Collaboration between the public and private sector

Doctors from the private sector lacked resources to initiate insulin. Therefore, HCPs suggested that the government medication subsidies be made available to patients on diabetes follow-up at private facilities. The public sector, on the other hand, faced the problem of a heavy workload and limited consultation time. Shared care between the public and the private sectors would help to overcome the barrier of limited consultation time in the public sector.

“The Government should set aside a fund, where... it’s not that only poor people should do this thing, I think it should be sort of like... we GPs have no backup. (Government should set aside a fund to be used by private sector GPs for people treated by GPs; currently these GPs have no backup) They should let us, maybe with the patient’s IC (identity card), prove ourselves that our patients are diabetic, and we should at least be able to get the needles and some basic things from the Ministry.” (GP, private practice)

“... like my patients I see from the hospitals, they are going to the Klinik Kesihatans (Government Health clinics). All their HbA1c is about 9, 9.5... I don’t blame the doctors, because how much time do they have in contact with

the patients? So there should be a sharing treatment on diabetics with private clinics where they should be able to see these doctors and the Government should subsidize their treatment or something, ok in 6 months' time you go back here, get your thing, but other times go and visit your nearest clinic, GP clinic, where they can spend more time with you.” (GP, private practice)

In the private sector, most general practitioners did not have supporting staff such as diabetic educators and dieticians to provide patient education. One option was to enrol their patients for diabetes education in the government health clinics.

“I mean the Government has a lot of budget for many mega-projects, ... and I think there should be some kind of subsidy (patient education) program when GPs can participate. ... It shouldn't just be limited to the hospital. The participation should be open to the GPs.” (GP, private practice)

Greater involvement of pharmaceutical industry, media and non-government organisations

Pharmaceutical industry

Pharmaceutical companies could play an important role in continuing medical education by organising training and workshops on insulin initiation for HCPs.

“So, that is actually with the help of some educational grant, there's been a lot of help from the pharma industry.....they have also given a grant to run the workshops ...” (Endocrinologist, government hospital)

Pharmaceutical representatives may act as a resource person to support the doctors in starting their patients on insulin. Unlike medical colleagues, the pharmaceutical representatives spent time with the GPs and guided them through the insulin initiation process step-by-step.

“The pharma companies, they have been very good, so the guy will come with every literature to me, he will train me up, and then I will say, oh, so many units, what if the patient goes into hypo (hypoglycaemia), and then they will have to convince me, doctor, they are not going to go into hypo. We believe in that because we are going to start with a very low dose, these drugs are very different from the old insulin. So they are holding my hand, and they have guided me to use insulin.....so I have learnt my insulin not through any endocrinologist, not through any doctor, but these guys... they walk the talk, walk the talk with me.” (GP, private practice)

In the government sector, pharmaceutical companies were involved in providing patient educational and decision support material, which healthcare providers used when helping a patient to make decisions about initiating insulin. Most of the patient health education materials on insulin were developed and provided by the pharmaceutical companies.

“Decision maps like those provided by Pharmaceutical Company A, that kind of thing. Some clinics have started doing that, erm... it is something which we supported, but I’m not sure how many clinics are motivated enough to move, to want to organise. ...I see it as a good tool. I see it as a different approach to health education.” (Government policy maker)

“That's not the 'in' thing in Malaysia. Pharma. A lot people are not comfortable. For me, as long as it's not biased. You know. This one (guide book) for example, this is supported... printing supported by Pharmaceutical Company B...(I) have to source for the fund. The ministry don't want to pay. I think, that it's a bit ridiculous. I asked Pharmaceutical Company B, I asked around, I asked Pharmaceutical Company C, Company C don't want.” (Government policy maker)

“So, that is actually with the help of some educational grant, there's been a lot of help from the pharma industry, so even to develop this guide, it is actually with the help of pharma...” (Endocrinologist, government hospital)

The pharmaceutical industry also helped to supply insulin pens to patients free of charge. In addition, in the private sector, where there was a lack of resources, some pharmaceutical companies employed diabetes educators to assist the doctors in educating patients about insulin therapy.

“For me I would talk to the company and tell them, you make sure if you want me to use your insulin, you had better supply enough pens for me.” (Family Medicine Specialist, Government health clinic)

“You can get them (pharmaceutical companies)...you can just give them a call, and you have a certain patient you think has to be on insulin, and that patient refuses to take the insulin in spite you have informed him, and you find resistance. And you can get these people, these people who market you this insulin, they will do the marketing for you. They will go to the house; they'll talk

to the patient. I had one patient who had a problem, but after about 5 months the patient finally accepted to take insulin. (GP, private practice)

Media

Some HCPs felt that the media played an important role in educating the public about diabetes and the benefits of insulin.

“I feel the media should play a part. An important role. Like, you know, a TV channel... Just every day, two, three times say, 5 minutes, what is diabetes, how important it is, how insulin is important... Because every day we all see the TV, in Tamil, or Malay, or Chinese, or English... if they put every day 5 minutes of time out, three times a day, I think people will think, you know, these are the psychological feelings, every day goes to the mind and they come to think of it.”
(GP, private practice)

Non-government organisations

NGOs could be involved in organisation of conferences for training of HCPs in education and counselling of patients with diabetes.

“...health counselling or health education delivery. Erm... Prof Prochaska’s, transtheoretical model, he came to Malaysia last year. So, there was a diabetes conference, erm... held by the erm, the Diabetes Education arm of, educators arm, of Persatuan Diabetes Malaysia (Malaysia Diabetes Association)”
(Government policy maker)

When facing time constraints and lack of expertise, some doctors from the private sector felt that NGOs could help by providing a dietetic service and by engaging diabetes educators to counsel patients about insulin therapy.

“...behind (my clinic) there’s diabetic centre of Malaysia... The diabetes centre is just behind. So if they actually need some further explanation, just go round the corner ...that’s for my area. And then there’s also the nutrition specialist, they have full diet (full dietary advice) and everything they will...can be referred. So in our locality, quite easy.” (GP, private practice)

Other important roles of NGOs included organising peer support group sessions, health screening and road shows; and subsidising glucometers, strips and needles for patients with diabetes.

“We have two big NGOs for diabetes, which is um...the PDM, Malaysian Diabetes Association and then NADI, the National Diabetes Institute. So in terms of patient support, um...you know I mean...PDM is good in the sense that it gives patients the facilities to get uh...you know...I mean, at cost price all the equipment, test strips, meters and...and they have very good network, branches all over the country. So, they’re actually helping patients. ...they are developing patient support material and then they go for road shows for screening, public screening, the usual thing.” (Endocrinologist, government hospital)

Multidisciplinary team

The HCPs suggested that setting up multidisciplinary teams, consisting of doctors, assistant medical officers, diabetic educators, nurses, pharmacists and dieticians, would greatly facilitate insulin initiation. However, information provision should be consistent

to avoid giving contradictory advice. The involvement of other healthcare team members could overcome the time constraints of doctors to counsel patients.

“...ermm, forming a multidisciplinary team. Although probably not a complete team like they have in the hospital, but at least you should have a nurse, a medical officer, a specialist will not be available in our clinic. And then the pharmacist actually can be involved in the team so that everybody should be having a role and then of course you have to make sure that these people understand each other’s roles and are giving similar information.” (Family Medicine Specialist, government health clinic)

“Uh, in the way there’s short of time, the patient lack of counselling, so I have to get somebody, the counselling nurse, to do the counselling. So those are uncontrolled they will send to the nurse, the nurse will try to talk to the patient and talk about diet, exercise, all those stuff. And then uh they will go back and take their medicine and go. So, with the counselling nurse on and then subsequently the pharmacists, uh, it can improve a bit. I think for the doctor it’s very difficult for the MOs (medical officers) to do the talking. They have no time to talk, basically.” (Family Medicine Specialist, government health clinic)

To overcome the problem of short consultation time and fast turnover of doctors in the government clinics, policy makers advocated the empowerment of paramedical staff to counsel patients with diabetes who needed insulin. The proposed strategies included a reference guide and training programmes targeted at the allied health workers.

“Policy level, I feel, although the paramedics can’t prescribe, I feel that they actually can play a big role in influencing patient’s decision, whether they want it or not, how empowered are they to... to... self-titrate, or to monitor. Erm, at the primary care level, because they are the constant figure in that particular clinic, the doctors come and go. So, I’m keen actually, for this, for example, for the insulin to come out with the quick reference to teach the paramedics as well. These are the things that can be done.” (Government policy maker)

The HCPs emphasised the importance of teamwork in helping patients to control their diabetes and to advise them on insulin initiation.

“Hmm... so that’s why our arrangement there... before the doctor sometimes sees us first, then we educate them...ha... so we explain to them what they should do, should increase which medicine, why sugar levels are high, why sugar levels are low, what...hmm... things like that... so teamwork is always better.” (Diabetic educator, government university hospital)

“It should be...there must be a diabetic educator, dietician. It should be a combined work, not only a doctor who does this. There must be team play. A team work to do this.” (GP, private practice)

Some doctors noted that having team members from different ethnic backgrounds helped to overcome the language barriers they face during consultations.

“...that uh language, I feel, is a very important barrier you have to overcome. But anyhow with the help of my MOH (Medical officer of Health) I manage to get, uh, lots of Indian staff to be in the clinic. Even I got the sister who’s Indian,

I got the attendant who is Indian. So, basically it when we improve the communication, the patient can accept it (the treatment) better.” (Family Medicine Specialist, government health clinic)

Discussion

The finding from the study highlighted three main strategies to improve insulin initiation in a dual-sector health system: (1) collaboration between the public and private sector; (2) greater involvement of pharmaceutical industry, media and non-government organisations (NGOs); and (3) establishment of multidisciplinary teams.

The participants highlighted the uneven distribution of resources for the management of chronic diseases such as diabetes within the dual-sector healthcare system. The government health clinics are facing a shortage of doctors (Family Health Development Division, 2009; Planning and Development Division Ministry of Health, 2010; National Institute of Health, 2010), and the rising incidence of type 2 diabetes will aggravate the situation as the majority of patients with diabetes are managed in the public health sector. On the other hand, most of the private GPs in Malaysia run solo practices and they lack resources and support to initiate insulin. The lack of integration and collaboration of the dual-sector health system is a major barrier for insulin initiation in patients with diabetes. However, this dual-sector healthcare system may provide a good opportunity to improve the care of diabetes by utilising the strength of each sector to integrate diabetic care. Studies by the World Health Organisation and others have found that an integrated health system can be effective in improving quality of care (Bazzoli *et al.*, 1997; WHO, 2008). Recently, a new national healthcare financing mechanism has been proposed to integrate the public and private healthcare systems under the 9th Malaysia Plan 2006–2010, and this includes the primary care services (Economic

Planning Unit, 2006; Safurah, 2011; WHO, 2010). This would help to reduce the existing discrepancy in the distribution of resources and manpower between the public and private sectors for diabetes care, as emphasised by the HCPs in this study.

In this study, the HCPs also highlighted the role of the pharmaceutical industry in providing HCP training and diabetes educators to counsel patients. In recent years, pharmaceutical companies have faced criticism (Angell, 2004; Carre, 2001; Moynihan & Cassells, 2005) and there are rising concerns about their influence on the HCPs' prescribing decisions (Chren, 1999; Wazana, 2000). Restricting contacts between the pharmaceutical industry and HCPs could limit open dialogue, hamper innovation and create a gap in educational support for HCPs, at least in developing countries like Malaysia (Shipp & Mallarkey, 2009). Moreover, collaboration may result in mutual benefit for all parties, including health professionals, the pharmaceutical industry and patients (White, 2008). In the care of diabetes and insulin initiation, the collaboration between HCPs and the pharmaceutical industry in educational programmes and counselling for patients will eventually benefit all parties. However, some regulations are needed to prevent undue influence from the pharmaceutical companies. Some countries have put in place processes, such as the review and management of research, industry codes of conduct, community responses and guidelines by practitioner associations, to protect the interests of individual patients and community interests (Bickestaffel *et al.*; Komesaroff, Carney, La Brooy, Tattersall, & Greenberg, 2006; Komesaroff, 2007; Komesaroff *et al.*, 2004). This may also help to foster research and the development of new products, maintain public confidence in pharmaceuticals and medicine, and facilitate ethical decision making among various stakeholders (Green, 2008; Haines & Olver, 2008; Komesaroff, 2007). The Malaysian Government and local

professional bodies in the country may need to develop more comprehensive regulations in relation to the involvement of pharmaceutical companies in supporting health promotion programmes.

Non-profit, non-government health organisations play an important role in providing counselling services and support in terms of health education, peer group programmes and financial assistance to patients with diabetes who need insulin initiation. Danika *et al.* reported that non-profit organisation-sponsored programmes promoting awareness about a disease or health condition are more effective than those sponsored by a pharmaceutical company (Danika, Jones., & Iverson., 2011). Some consumer groups have stressed the importance of active collaborations between health consumer organisations and the pharmaceutical industry (Consumers Health Forum of Australia & Medicines Australia, 2008).

The multidisciplinary team approach to diabetes care, such as insulin initiation, is considered an essential step towards improvement of patient care (Del Prato *et al.*, 2005; Kahn & Anderson, 2009). Besides improving the efficiency of the diabetes service by reducing the doctor's consultation time, a multidisciplinary team has been shown to improve glycaemic control, lower the risk of diabetes complications, decrease health care costs and improve patients' quality of life (Codispoti, Douglas, McCallister, & Zuniga, 2004; Gagliardino & Etchegoyen, 2001). As highlighted by the HCPs in this study, a multidisciplinary team from different ethnic backgrounds is crucial to overcome the problem of language and cultural barriers, particularly in a multi-ethnic country like Malaysia. In a review by Caballero, increased cultural awareness and use of diabetes educators speaking the same language as the patients improved acceptance of insulin therapy in patients with type 2 diabetes (Caballero, 2006). Currently, in Malaysia, the

diabetes care teams are located mainly in the government health care clinics or university primary care clinics in urban areas. In the rural settings, many patients with diabetes are managed by medical assistants, whose role is mainly to prescribe, provide basic health education and identify complications. In view of the benefits of a multidisciplinary team approach, Malaysia's healthcare system should empower the allied health workers, such as the medical assistants, by continuously training and enhancing their knowledge and skills on diabetes care, including insulin initiation. This will reduce the healthcare burden and cost without compromising patient care.

The strength of this study lies in the fact that the sample encompassed all healthcare sectors and stakeholders who were involved in insulin initiation. We were thus able to gather data from all levels of HCPs involved in diabetes care. . This study also allows comparison of views from the private and government HCPs in a dual-sector health system, which may be applicable to other developing countries with a similar health system.

The limitation of this study was that only HCPs' perspectives were included and patients' views were not captured. The researchers are planning to conduct interviews with patients with type 2 diabetes who are considering insulin as part of a larger study. Besides that, as the study was conducted in urban and semi-rural areas, therefore the findings cannot be generalisable to rural settings. Finally, two of the researchers are primary care physicians (PYL and CJN) and this may influence the interpretation of the data. These potential biases are reduced by constant reflection by the two researchers about their roles and by involving an independent non-clinician (YKL) in the analysis process.

Future research should look into how pharmaceutical industry may be involved in educating the HCPs in the use of insulin especially in resource-limited countries. Secondly, the policy makers should develop strategies to facilitate collaborations between public and private health sectors especially in terms of how resources can be shared more effectively.

Conclusions

The importance of integration and collaboration between the public and private sectors, multidisciplinary teamwork and active involvement of NGOs was considered as crucial to improve service delivery for insulin initiation and diabetes care in Malaysia. The involvement of pharmaceutical industry and NGOs may be important in the resource-limited private sector. However, some regulations need to put in place to prevent undue influence from the pharmaceutical industries on physicians' clinical decisions. Therefore, a proposed integration of the public and private healthcare systems may help to make diabetes care, including insulin initiation delivery, more effective and efficient.

List of abbreviations

GP: general practitioner; HCP: healthcare professional; NGO: non-government organisation; UKPDS: United Kingdom Prospective Diabetes Study.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

PYL wrote the first draft of the paper and led the critical review and revision of the paper. PYL, YKL and CJN were involved in the study design, development of the

interview topic guides used for data collection, facilitation of the data collection interviews and focus groups, analysis of the data for reporting, interpretation of the data, and review of the paper. All authors have read and approved the final manuscript.

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Chapter 5.3: Tactics in counselling patients to start insulin

Y.K. Lee, P.Y. Lee and C.J. Ng

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Author contributions:

YKL, PYL and CJN were involved in developing the interview topic guides used for data collection, facilitating the data collection interviews and focus groups, and analysing the data for reporting. All authors read and approved the final transcript.

Research Letter

51% of patients with type 2 diabetes in Malaysia are reluctant to take insulin (Nur Azmiah Z, Zulkarnain AK, & A, 2011). Patient education plays an important role in facilitating insulin initiation. In Malaysia, patient education material on insulin is lacking and patient education delivery relies on individual healthcare professionals (HCPs). Our study aimed to explore HCPs' views on the content and delivery of patient education on insulin initiation. This study was part of a larger three-year study aimed at developing a decision support tool for insulin therapy.

Purposive sampling was used to identify the range of HCPs involved in insulin initiation. Between October 2010 and May 2011, fourteen individual interviews (30-40 minute) and four one-hour-long focus group discussions were conducted (n=41) (Table 5.3.1). Sample size was determined by data saturation whereby data collection was stopped when no new themes emerged. Interviews were audio-recorded and transcribed verbatim.

We employed a qualitative thematic approach to data analysis by coding the transcripts according to themes found in the data. Ethics approval was obtained from the Medical Research and Ethics Committee, Malaysian Ministry of Health.

Our analysis showed that patient education content included three issues: the progressive nature of diabetes and eventual need for insulin; short- and long-term benefits of insulin for diabetes control; and the risk of diabetes complications associated with uncontrolled hyperglycaemia. When discussing insulin, HCPs concentrated on addressing insulin-related misperceptions and addressing injection-related issues.

Table 5.3.1 Demographic profile of participants

Characteristics	Number (n= 41)	%	Mean \pm SD (Range)
Age			46.6 \pm 9.8 years (30-66 years)
Sex			
Female	31	75.6	
Male	10	24.4	
Ethnicity			
Malays	15	36.6	
Chinese	10	24.4	
Indians	13	31.7	
Others	3	7.3	
Professional background			
General practitioner/ Medical Officer	20	48.8	
Family medicine specialist	10	24.4	
Government policy maker	5	12.2	
Diabetes nurse educators	3	7.3	
Endocrinologists	2	4.9	
Pharmacist	1	2.4	
Healthcare sector			
Public	26	63.4	
Private	15	36.6	

HCPs described four approaches to educate patients on insulin initiation: simplifying the insulin initiation process; downplaying side effects; giving worst case scenarios; and using analogies to describe the need for insulin. Although some HCPs realised that

downplaying the side-effects and risks could be misleading, they would only explain the risks once the patient agreed to start insulin. Most, however, felt that it was important to educate the patient about hypoglycaemia.

“You cannot tell them the bad points. Bad points will only be, tell them if you have hypoglycaemia, be prepared to watch out for yourselves. That’s all...everything else is benefits.”

General practitioner, private practice

As a result of a lack of patient education material, HCPs used a variety of gadgets and handwritten information to counsel patients during insulin initiation, including: demonstrating to patients how to use an insulin pen; using HbA1c records as evidence of poor diabetes control; and using aids such as models of the pancreas to help explain the pathophysiology of diabetes. HCPs also provide written patient-specific information as they felt that verbal information alone was not enough for patient education.

This study found that insulin counselling approaches used by HCPs often involve providing comprehensive information on benefits (rather than the risks) of insulin and ensuring patient understanding with the intention of persuading patients to start insulin. One concern is that, although a persuasive communication style may help to convert patients to insulin therapy, it may negatively affect future adherence to treatment. Non-adherent patients frequently feel that their HCP had not properly explained the risks and benefits of insulin to them (Karter *et al.*, 2010).

In conclusion, Malaysian HCPs counselled patients who are considering insulin treatment; however, the information provided was biased towards the benefits of insulin. Therefore, patient education would benefit from a more structured and balanced

approach. This may involve training HCPs to support patients in decision making (Legare *et al.*, 2012). In view of recent evidence that intensive glycaemic control with insulin may cause harm (Skyler *et al.*, 2009), it is prudent that HCPs discuss the risks and benefits of insulin treatment with patients and help them make an informed decision.

Declaration of competing interests

Nothing to declare.

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¹ Department of Primary Care Medicine, Faculty of Medicine, University of Malaya,
50603 Kuala Lumpur, Malaysia.

² Department of Family Medicine, Faculty of Medicine and Health Sciences, Universiti
Putra Malaysia, 43400 UPM Serdang, Malaysia.

Chapter 5.4: Factors influencing decision-making role preferences: A qualitative study of Malaysian patients with type 2 diabetes during insulin initiation

Yew Kong Lee, Wah Yun Low, Ping Yein Lee, Chirk Jenn Ng.

Submitted

Author contributions:

YKL, WYL and CJN were involved in developing the interview topic guides used for data collection and analysis of the data. YKL conducted 17 out of the 22 interviews.

YKL led the preparation and critical review of the manuscript.

Abstract

Objectives

This study aimed to explore patients' views on their decision-making (DM) role preference and factors influencing this during insulin initiation.

Methods

We conducted individual in-depth interviews with people with type 2 diabetes who were making decisions about insulin treatment. Participants were selected purposively to achieve maximum variation. A semi-structured topic guide was used to guide the interviews which were audio-recorded and analysed using a thematic approach. We interviewed 22 participants between January 2011 and March 2012. The age range of participants was 28-67 years old. Our sample comprised 9 women and 13 men.

Results

The majority of patients preferred an active role in decision making (n=10). Six patients preferred a passive role where the doctor should make the decision. Lastly, only one patient expressed a preference for a collaborative role (patient prefers to share the decision with the doctor). In five participants, we were unable to determine their decision making preference. The following themes emerged as factors influencing patient's DM role preference: trust in HCPs, responsibility for diabetes care, level of knowledge and awareness, involvement of family and personal characteristics.

Conclusion

Patient DM role preferences are influenced by views of the doctor-patient relationship, societal roles amongst family and peers, and their knowledge of the disease. Most

patients in Malaysia have a pre-existing DM role preference. However, few patients in Malaysia view the doctor-patient relationship as a collaborative partnership and more research needs to be done on encouraging shared decision making in Malaysian healthcare practice.

Introduction

Encouraging patient participation in the clinical decision making encounter is advocated in healthcare policies (Institute of Medicine, 2012), research initiatives (Selby, Beal, & Frank, 2012) and medical practice models (Charles, Gafni, & Whelan, 1997; Elwyn *et al.*, 2012). One aspect of patient involvement is decision making (DM) role preference. A patient's DM role preference can be defined as "the degree of control an individual wants to assume when decisions are being made about medical treatment." (Degner, Sloan, *et al.*, 1997b). Patients desire different levels of participation; this may range from desiring an active role (patient prefers to have full control of the decision), collaborative/ shared role (patient and doctor share control of the decision) to a passive role (patient prefers doctors to make the decision)(Caress, Luker, Woodcock, & Beaver, 2002; Degner, Sloan, *et al.*, 1997b; Heesen, Kasper, Segal, Kopke, & Muhlhauser, 2004; Kraetschmer, Sharpe, Urowitz, & Deber, 2004).

Studies have shown that a discord often exists between patients' DM role preferences and actual roles in decision making. In a review of 22 studies, Tariman *et al* reported that across all cancer types, patients wanted more participation than what actually occurred (Tariman, Berry, Cochrane, Doorenbos, & Schepp, 2010). Some socio-demographic groups experience more discord than others; in another review, less women than men (60% vs 66%, $P = .001$) and less Canadian patients than US patients (54% vs 84%, $P < .001$) reported concordance between their preferred versus actual roles (Singh *et al.*, 2010). Accurate elicitation of DM role preference is important in order to address preference-specific barriers to patient participation (Caress, *et al.*, 2002). Strategies for elicitation include the use of vignettes and card sorts. Such

strategies however are limited by a short consultation and poor relationship between patient and doctor (Caress, *et al.*, 2002).

A variety of factors have been significantly associated with patients' DM role preference, including: type of disease (Beaver, Bogg, & Luker, 1999), information-seeking preference (Loeffert *et al.*, 2010), trust in doctor (Kraetschmer, *et al.*, 2004; Loeffert, *et al.*, 2010), doctors' participatory decision-making style (Loeffert, *et al.*, 2010), educational level (Levinson, Kao, Kuby, & Thisted, 2005; Loeffert, *et al.*, 2010), age (Loeffert, *et al.*, 2010), gender (Levinson, *et al.*, 2005), level of health (Levinson, *et al.*, 2005) and race (Levinson, *et al.*, 2005). However, little research has been conducted on exploring the motivation behind patients' DM role preference. One qualitative study of adult asthma patients (n=32) revealed how patients desire for participation was different from their desire for control. The study concluded that although most patients wished to contribute or feel involved in decision making, this would not necessarily mean they wanted to control it (Caress, *et al.*, 2002).

Decision-making may also involve significant others, especially family members. Despite this, instruments used to assess DM role preference usually only focus on the patient-doctor dyad (Degner, Sloan, *et al.*, 1997b). For example, the widely-used Control Preferences Scale was developed from grounded theory that initially included a family-controlled decision making preference (Degner & Russell, 1988). However subsequent versions of the scale only included options related to the patient-doctor dyad (Degner *et al.*, 1997a; Degner, Sloan, *et al.*, 1997b; Frank-Stromborg & Olsen, 2004).

The study of patient's DM role preference during insulin initiation in type 2 diabetes in Malaysia is useful in two ways. Firstly, exploring DM role preferences may elicit some barriers to patient participation which may hinder informed decision making about

insulin. Study had shown that patients with diabetes who feel that their autonomy has been supported are more satisfied and have a better mental health-related quality of life (Y. Y. Lee & Lin, 2010). Hence, understanding the patients' DM role preferences may improve the approaches in discussion of insulin initiation. This is important as insulin uptake in Malaysia remains poor (Letchuman *et al.*, 2010) despite a high prevalence of poor glycemic control (Mafauzy, 2005). The Malaysian clinical practice guideline also recommends insulin initiation in patients with type 2 diabetes mellitus who are poorly controlled despite taking optimal oral glucose-lowering drugs (Ministry of Health, 2009).

Secondly, the study would shed light on discrepancies between preferred and actual DM role preference in Malaysia where medical paternalism (Mazlina & Julia, 2011; Zalilah, Mazanah, & Ahmad Zamri, 2008) and a lack of patient information (Yousuf, Fauzi, How, Akter, & Shah, 2009) are common. Malaysia has a dual-sector healthcare system comprising public government-subsidized healthcare and private fee-for-service sectors. One previous study has noted that a consumerist DM role preference mentality is common even in UK's exclusively public-funded health system, signifying a consumerist shift away from paternalism in healthcare (Caress, *et al.*, 2002). This study would help to assess if patients from both private and public sectors in an Asian country like Malaysia, desire to be involved within the context of chronic disease treatment decisions.

Studies on patient preferences for participation in clinical decision making are mostly population-based survey data. Little research has been conducted on exploring patients' DM role preference regarding significant others. This study aimed to explore patients'

views on their decision-making role preference and factors influencing this during insulin initiation.

This study is part of a larger 3-year study that aims to produce a patient decision aid for use in a local primary care setting with patients with type 2 diabetes who are making a decision about insulin initiation.

Methods

Methodological approach

As few studies have been reported on the rationale for patient's DM role preferences, and in view of the exploratory nature of the research question, a qualitative study design was chosen. We decided on using semi-structured in-depth individual interviews as this would allow us to explore in depth each patient's preferences within their experience of insulin initiation.

Conceptual framework

We used the shared decision making model as our conceptual framework, which aims to help clinicians and patients collaborate on making a decision together based on the integration of clinician's knowledge and patient preferences (Barratt, 2008; Makoul & Clayman, 2006). Drawing on the Ottawa Decision Support Framework (O'Connor, 2006), we developed an interview topic guide exploring patients' DM role preferences and barriers and facilitators to making a shared and informed decision.

Setting

This study was conducted in Malaysia, a multi-cultural country comprising three main ethnicities (Malay, Chinese and Indian) and numerous other smaller ethnic groups.

Malay is the official and most common language, but each ethnicity usually also speaks their mother tongue. The country has a dual healthcare system: public (government subsidized hospitals and health centres serving majority of the population) and private (fee-for-service hospitals and clinics) sectors. Patients are free to choose where they receive treatment.

Sampling

Patients with type 2 diabetes who were making or had made a decision about insulin within the past 1 year were included in this study. Healthcare professionals from the various healthcare settings helped to recruit participants for our study. We did this by explaining the study to the clinicians and distributing brochures detailing the inclusion criteria for our study and our contact information. As much as possible, we tried to conduct the interviews soon after doctors had advised patients to start insulin in order to capture patients' initial experience and values in regards to insulin initiation.

Purposive sampling was used in order to achieve maximal variation based on three factors: healthcare setting, patients' decision about insulin, and ethnicity of patients. To achieve a broad socio-demographic range, we recruited patients from both public and private settings as well as from both rural and urban settings. We sought patients who were both open to insulin as well as averse to it. We also included patients who had prior experience with insulin use but had now stopped using it if they had initiated insulin within the past one year.

Data collection

An interview topic guide was developed based on literature review, conceptual framework and expert opinion (Table 5.4.1). The topic guide was pilot-tested and

iteratively modified based on themes that emerged during both pilot and subsequent interviews. Both participant information sheet and topic guide were translated into Malay and Chinese by researchers who were fluent in these languages.

Table 5.4.1 Interview topic guide

Introduction

1. Have you been asked to start insulin?
2. What has been going through your mind since you were advised to start insulin?

Actual decision making role

3. Who else is involved in making this decision? What are their roles?
 - a. doctors,
 - b. family and
 - c. friends

Preferred decision making role

4. Who do you think should make the decision about you starting insulin?
 - a. Yourself
 - b. Doctors
 - c. Family
 - d. Others

Semi-structured in-depth interviews were conducted with patients in their preferred language (English, Malay or Chinese). Interviews were conducted by three researchers trained in qualitative research methods (YK, CJ, and PY) and each lasted 30-45 minutes. Researchers arranged to interview patients at a time and location of their convenience, including their homes or workplaces if patients were unable to travel due to work commitments or infirmities. Participants were reimbursed for their time and travel.

All participants gave written consent to participate in the research and for their interviews to be audio-recorded. In cases where the participant was illiterate, the information sheet was read out to the patient and patients indicated their consent by

initialling the consent form. However, most illiterate participants were accompanied by a literate family member who was able to explain the information sheet to them.

Patients were told that the data would be confidential and anonymous.

We chose to explore DM role preference verbally with the question “Who should make the decision about insulin?” with prompts for self, doctor and family. In cases where the family accompanied the patient for the interview (n=2) we observed and recorded interactions between the family and patient in the field notes and sought information from the family regarding the family’s participation in the decision making process.

Data analysis

Interview transcribing was the first step in analysis. English and Malay interviews were transcribed verbatim whilst Chinese interviews were translated into English for analysis. Malay interviews were not translated as all researchers have good command of the language. Thematic analysis was used to analyse the data where by connected themes were coded into larger nodes. Three researchers (YK, WY, and CJ) coded two interviews line by line to develop an initial list of nodes. A process of constant comparison was employed whereby subsequent interviews were coded using this list and new themes which emerged from new interviews were added to the list upon consultation with the research team.

Nodes were collated into broader categories based on thematic similarities between nodes in monthly face-to-face discussion meetings. Finally selective coding was conducted to generate central or core categories based on connecting and consolidating axial codes. All codes were checked by two researchers (YK, CJ) to ensure consistency of coding and consensus on the list of nodes.

After thematic analysis, a framework analysis was applied to the categories of data to categorize patients according to their expressed DM role preference based on patients' responses to the DM role preference prompt in the interview.

Data collection was stopped when thematic data saturation was reached. Evidence of data saturation was obtained when no new free nodes emerged from the data, showing that the core categories had already been captured. A secondary saturation criterion was based on the saturation of free nodes, as there was evidence of repeated coding within the same codes.

Data analysis was facilitated by the use of Nvivo9 software (Nvivo9, 2010) to manage transcripts, themes and quotes, whilst keeping in mind the context of the quotes within the individual interviews.

Ethics

Ethics approval was obtained from the Medical Research and Ethics Committee, Ministry of Health, Malaysia and the Medical Ethics Committee, University of Malaya Medical Centre.

Results

Sampling characteristics

A total of 22 patients were interviewed between January 2011 and February 2012.

These patients came from 5 different healthcare locations (1 public hospital based primary care clinic, 3 public health centres, 1 private clinic). Patient demographic information can be found in Table 5.4.2. Although most patients were from an urban setting, even within the urban sample patients were very diverse as they came from

different socio-economic levels. Although patients were informed that they would be participating in an individual interview, four patients were accompanied by family members. In such instances, care was taken to avoid having the family members dominate the discussion by consciously focusing questions on the patient.

The majority of patients preferred an active role in decision making (n=10). Six patients preferred a passive role where the doctor should make the decision. Lastly, only one patient expressed a preference for a collaborative role (patient prefers to share the decision with the doctor). In five participants, we were unable to determine their decision making preference. They were unable to respond to the question when asked about their DM role preference despite repeated prompts and most (n=4) had minimal formal education (primary school or no formal education).

The following themes emerged as factors influencing patient's DM role preference: trust in HCPs, responsibility for diabetes care, level of knowledge and awareness, involvement of family and personal characteristics.

Table 5.4.2 Characteristics of participants. Values are numbers unless stated otherwise

Characteristic	Participants (n=22)
Male	13
Mean (SD) age (years)	54.68 (9.29)
Age range	28-67
Healthcare setting	
- Public university hospital based primary care clinic	8
- Public healthcare clinics	7
- Private specialist clinic	7
Location	
- Urban	19
- Semi-urban/ Rural	3
Language interview was mainly conducted in	
- Malay	11
- English	8
- Chinese	3
Ethnicity	
- Malay	6
- Chinese	5
- Indian	11
Highest level of education	
- No formal education	3
- Primary	7
- Secondary	6
- Tertiary	6
Decision-making role preference	
- Active role (patient prefers to make the decision)	10
- Collaborative role (patient prefers to share the decision with the doctor)	1
- Passive role (patient prefers the doctor to make the decision)	6
- Unsure/ researcher unable to determine	5

1) Patient's trust in HCP

Levels of trust in the HCP were an influence on patients preferring either active or passive roles. Patients who preferred passive roles did so because they trusted the professional training of the doctor and left the decision to the doctor. The doctor was viewed as an authority on the disease who knew the best course of treatment.

I don't think much about it (the decision); I leave it to the doctors. They are the- that's why I told Dr. S that she's, on disease, an authority, let her decide.

Patient F4, Female, 61 years old, public university hospital diabetic clinic.

Conversely, patients preferred an active DM ROLE PREFERENCE if they had a low level of trust in doctors. One patient said he mistrusted the doctor, and felt that the diagnosis was vague and inaccurate. He only went to doctors as it was necessary for obtaining prescriptions.

I make (the decisions) myself...doctors, I don't take so much interest (in) doctors, because they're not telling me the right thing. If you (the doctor) telling right, what sickness I'm suffering from, or what's the problems with me, then I don't mind. But to me, I feel they're very vague and don't want to tell me. So I don't really follow their words and... I'm just going doctor for the sake of getting medicine, that's all.

Patient M10, Male, 55 years old, public hospital based clinic.

2) Responsibility for diabetes care

The roles and responsibilities played by various parties during insulin initiation influenced patients' DM role preferences. Patients considered their own role as well as the roles of their families and doctors.

An active role was preferred if patients felt that the responsibility of decision making and injection administration was their own. Firstly, patients preferred an active role if they felt that the final say in the decision was theirs and not the doctors. Although the doctor provided professional opinion and monitored the patient's treatment, the patient would have to agree to insulin as the next course of treatment.

(I prefer to make the decisions) myself...the doctor just gives his opinion. If I accept, the reality is that I have to do it myself. That's all.

Patient M2, Male, 61 years old, public health clinic.

(The decision is) mine. Even if the doctor decides to give the insulin he must have my approval. That means I must agree before it happens. He can suggest, then I'll see if I accept or not. His (the doctor's) responsibility is to follow through with the treatment, or advise us to do this, which medicine is important to eat or even to take insulin, like that *lo*.

Patient M8, Male, 60 years old, private clinic.

Patients who knew that they would be self-administering insulin made the decision themselves as they knew that the administration of insulin would be their own responsibility. Although there was potential help from family members, they preferred to inject the insulin on their own.

I made decision myself, they said I have to do it; ok I'll do it, no problem. I didn't like my wife jabbing me you know because I'd rather do it myself you know that some people they prefer to have other people jab them you know.

Patient M1, Male, 47 years old, public hospital-based clinic.

Only one patient expressed a preference for a collaborative role. The patient realized that both doctor and patient had roles to play in insulin initiation; the doctor provided medical advice while the patient was responsible for self-monitoring of her diabetes.

Err... I think (the decision on who should start insulin is) 50:50, the doctor will also advise me isn't it, you see? I think is 50:50. I also feedback to the doctor. Ahh... because I monitor my diet, I monitor my reading, you see. So like every morning ahh... I take one piece of wholemeal and ahh... Nescafe without sugar, the reading also that high, you see. What you (doctor) want me to do, you see?

Patient F8, Female, 57 years old, private clinic.

3) Level of knowledge and awareness

Some patients admitted feeling not that they did not know anything about medicine and accepted the doctor's recommendations.

Because I know nothing about medicine field. Of course the doctor told me about insulin mahh... He proposed to me, then I just accept *lohh*.

Patient M13, Male, 43 years old, private clinic.

For some patients, collaboration was aided by the patient's knowledge about the disease. One patient requested her doctor to initiate insulin when oral medication failed

to control her diabetes: *“My (blood sugar) reading didn’t come down, then I told Dr H maybe should start on insulin, you see. He said yes... because I heard so many stories ahh, if the drugs cannot work then you have to take insulin, you see.”*(Patient F8, Female, 57 years old, private clinic).

4) Involvement of family

Some patients would discuss the doctor’s advice with their spouse before deciding on whether to start insulin.

No uh...doctor was telling to me (about insulin), then I went and tell my wife... My wife said, just uh what the doctor say is good means, just carry on follow the suggestion lah. Then I have to follow the doctor what he said after her... I have to follow lah.

Patient M3, male, 63-year old, public health clinic

When it came to actual decision-making, patient’s families played an active role in making the decision by gathering health information, sitting in with the consultations, and voicing their opinion on insulin.

If she (the patient) decides then, she should consult, because we (the family), we usually take her, to visit the doctor, so we seek the doctor’s advice, he’s also involved so we ask him whether whatever action, can we do this, we let her know. Because we also read the papers, magazines, surf the net, so from there we get *all* sorts of information then we just share with her.

Patient’s daughter (Patient F7, female, 63-year old, private clinic)

However, some patients preferred not to involve the family or peers when make decisions for their health. Patients did not involve others because they felt that health is a personal topic that should not be discussed with others. Although the patient below discussed the decision about insulin with his wife, he said that he would not discuss the topic with his friends due to a code of social conduct, whereby health issues were considered private and it was important to maintain his image of masculine normality.

Never say anything (to others)...because my people, friends, friends all their personal thing...they for keeping personally... they secret never leak out. I also don't want...I got sick *lah*, I got all this all, I don't want to say. I want to just like normal, man *lah*... I want uh just like normal *lah* man *lah*...I just take the medicine, I control the sugar. I'm a man *lah*..normal man.

Patient M3, male, 63-year old, public health clinic

Family dynamics were found to influence DM role preferences. Patients pointed out that they needed opportunities to discuss decisions and their role in the family. One patient's role as the 'head of the family' dictated his freedom to make his own health-related decisions.

Our family is only together once in a while...As the head of the family I would want my own liberty to do things *ma*. If, if it's about my own thing then I must do it myself, make decisions.

Patient M8, male, 60-year old, private clinic

Another patient noted that she did not want to involve her husband as he was busy with his work.

...he (patient's husband) doesn't know anything. He's busy with his work, you see. There's no point discuss, he's not doctor, he's not medical person, you see, he won't know anything.

Patient F8, female, 57-year old, private clinic

Patient views on the treatment played a part in deciding whether or not to include others in their decision. Patients did not include others if insulin was viewed as a routine part of diabetes treatment, which was not a major decision.

Interviewer: Who else did you involve in the decision?

Patient: Me and me myself. Nothing *lah*...I don't see it's anything so big *la*. It's just like today you're saying you must take Metformin, tomorrow you're saying you have to add Diamicron, so what?

Patient F1, female, 58-year old, public university hospital primary care clinic

5) Personal characteristics

Individual traits such as socio-economic background and personality type influenced patients DM role preference. Patients with low education levels often had difficulty understanding and articulating their preferred DM role preference. In terms of personality type, one patient noted that taking an active decision making role was a consistent trait across other types of decision making scenarios.

All my life, I make the decision. Even with my husband the final say will be mine, I'm a very, what do you call it, very strong will- like a man all my life. Even when I was a (high school) student, I'll be the school captain those days even with my health, that time also.

Patient F4, Female, 61 years old, public hospital based clinic.

In general, patients who were more educated were better able to articulate their DM role preference whilst patients who were less educated had difficulty responding to questions about preferences. In the following example, the patient did not reply to the interviewer's question about decisional making preference but instead described how the insulin initiation process was conducted.

Interviewer: Who should make the decision, for injection? The doctor makes the decision, you make the decision, or your family makes the decision?

Patient: Oh, my family is not like this. Ah...I am taking the injection. But my mom has diabetes as well. But my mom doesn't take injections.

Interviewer: No injections...so the decision to take injections, who should make that decision? You or the doctor?

Patient: The doctor gave me (the injections).

Patient F3, Female, 48 years old, public health clinic.

Discussion

This study gives insight into patient's views on their preference for an active, collaborative or passive role during insulin initiation. Our study identified five categories of factors that influenced patient DM role preferences: trust in HCPs, perceived responsibility, level of knowledge, perceived family involvement and personal characteristics. Caress *et al's* study on patients with chronic asthma reported similar themes, whereby respondents cited level of knowledge; trust; duration of condition; severity of condition at the decisional juncture; lifelong nature of asthma; a

perception that “it is my body”; characteristics of the individual and their response to health professionals as influencing role preference (Caress, *et al.*, 2002).

In terms of preferences between active and passive roles, the majority of the patients in both private as well as public sectors preferred an active role. Thus, it is not only ‘paying customers’ that want to have a say in treatment options. Previous studies report that even in an entirely public-funded healthcare system, patients still exercised a ‘consumerist’ mentality and desire active participation in decision making (Caress, *et al.*, 2002). This raises the question of how best to assess patient’s DM role preferences in a consultation as it is hard to differentiate active, collaborative and shared patient DM role preferences based on consultation behaviour alone (Kumar *et al.*, 2010). Engaging patients in open discussion about decision-making preferences is more effective than relying on interpreting communication behaviour (Kumar, *et al.*, 2010). This may prove challenging in Malaysia where barriers to insulin initiation include the lack of time in consultations, low manpower resources and substantial language barriers (Y. K. Lee, Lee, & Ng, 2012).

Other studies have reported that in general, patients who prefer a passive role have above-average trust in their doctor (Kraetschmer, *et al.*, 2004; Loeffert, *et al.*, 2010). Levels of trust increase in response to a positive perception of doctor’s decision making style and the establishment of the doctor-patient relationship over time (Loeffert, *et al.*, 2010). Our study shows that the converse is also true; patients who have low levels of trust in doctors prefer a more active role. In such instances, patients may view doctors as gatekeepers (providing access to medication) rather than caregivers. Counselling during the consultation may be needed to establish a more therapeutic doctor-patient relationship. Level of trust may also be related to patient knowledge; patients with low

levels of knowledge feel that they should adopt a passive role and concede decision making control to the more expert doctor (Caress, *et al.*, 2002).

Perceived responsibility was related to self-administration of insulin. An active role was preferred if patients perceived that they would be responsible for administering injections and managing the treatment regime. Compared to acute health conditions, chronic conditions involve a higher degree of self-management and patients are more aware of how future consequences would affect them. Similarly, asthma patients also preferred an active role if they perceived that it was “‘their body’ into which treatment would be ingested” (Caress, *et al.*, 2002). Potential conflict arises as chronic disease management can be routine and doctors may lapse into an automatic step-up regime for their patients without taking the effort to involve patients in the treatment decisions.

Under the theme of perceived family involvement, most patients did not wish to involve significant others in their decision to take insulin. Male patients especially were influenced by masculine roles (e.g. toughness and family headship) in preferring individualistic decision making. In contrast, 100% of eighty men with prostate cancer reported preferring a collaborative role with their partners (Davison, *et al.*; 2002). Two possible explanations can be given for this. Firstly, the characteristics of the disease and subsequent choices are different. Cancer carries a greater urgency, and it uses up more resources, whilst insulin can be delayed and is a part of long-term chronic care.

Secondly, the cultural notion of family headship could influence Asian men to make the decision alone, despite the emphasis in Asian culture on communal caregiving (e.g. familial obligation, extended family support) (Kong, 2007).

In this study, verbal communication about decisional preferences elicited little more than descriptions about the consultation experience. Strategies to aid patients in

expressing DM role preference such as providing card sorts and computer aids may be helpful (Neufeld, Degner, & Dick, 1993). However, modifications such as graphical representations of DM role preference will be needed for patients with low literacy levels. Besides the use of aids, doctors should aim to practice a more participative communication style to facilitate patient's expression of DM role preference. Healthcare professionals can help alleviate barriers to service-user participation by assessing if a preference for autonomy is due to a lack of trust (Kraetschmer, *et al.*, 2004), ensuring patients are not disempowered by a lack of knowledge (Caress, *et al.*, 2002; Kraetschmer, *et al.*, 2004) and supporting patients who feel 'abandoned' or worried about participating (Elwyn, *et al.*, 2012).

Only one patient was able to state that she preferred a collaborative role. One reason for this could be because we did not include a 'shared' role item prompt in the DM role preference interview guide as we were unaware of the spectrum of DM role preference at the time of guide development (refer to Table 2). However, the fact that most patients (16 out of 22) were able to express a DM role preference for either active or passive roles shows that the DM role preferences in Malaysia may still be heavily skewed towards either doctor or patient control, with little conceptualization of the patient-doctor encounter as being a collaborative partnership. Thus, even if shared decision making were to be advocated as an ideal option, patients may find expressing their preferences surprising, unsettling and hard to comprehend (Elwyn, Frosch, & Rollnick, 2009a).

Limitations

The study had a number of limitations. Firstly, allocation of patient's DM role preference was done through verbal elicitation. A clearer preference would have been

obtained by asking patients to choose using a range of vignettes or preferences.

However, this does not affect validity as this was a qualitative study and no statistical analyses were performed on the correlation between DM role preference and factors.

Furthermore, verbal elicitation of DM role preference was useful in uncovering potential communication barriers in consultations and these barriers are reported.

Secondly, the study has low generalizability as it focuses specifically on insulin initiation. As discussed above, decisional context may influence preferences for DM role preference and partner involvement.

Thirdly, the study results are skewed to either patient- or doctor-only decision making preferences as a collaborative role option was not offered to participants. The impact of this in the research methodology is discussed in the last paragraph of the discussion section above.

Strengths

The studies strengths are that we explored DM role preferences within a diverse sample involving different ethnicities, languages and healthcare systems. Previous qualitative studies have been conducted in western, largely mono-cultural, single healthcare system contexts. Our study reports a range of DM role preference in both public and private healthcare systems and inference is made that patient decision making roles are skewed to either doctor or patient with little conceptualization of a collaborative partnership.

Conclusions

Patient DM role preferences are influenced by views of the doctor-patient relationship, societal roles amongst family and peers, and their knowledge of the disease. Most patients in Malaysia have a pre-existing decision making role preference. However, few

patients in Malaysia view the doctor-patient relationship as a collaborative partnership and more research needs to be done on encouraging shared decision making in Malaysian healthcare practice.

Chapter 5.5: Exploring patient values in medical decision making: A qualitative study

Yew Kong Lee, Wah Yun Low, Chirk Jenn Ng

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Author contributions:

YKL, WYL and CJN were involved in developing the interview topic guides used for data collection and analysis of the data. YKL conducted 17 out of the 21 interviews.

YKL led the preparation and critical review of the manuscript.

Abstract

Background

Patient decisions are influenced by their personal values. However, there is a lack of clarity and attention on the concept of patient values in the clinical context despite clear emphasis on patient values in evidence-based medicine and shared decision making. The aim of the study was to explore the concept of patient values in the context of making decisions about insulin initiation among people with type 2 diabetes.

Methods and Findings

We conducted individual in-depth interviews with people with type 2 diabetes who were making decisions about insulin treatment. Participants were selected purposively to achieve maximum variation. A semi-structured topic guide was used to guide the interviews which were audio-recorded and analysed using a thematic approach. We interviewed 21 participants between January 2011 and March 2012. The age range of participants was 28-67 years old. Our sample comprised 9 women and 12 men.

Three main themes, ‘treatment-specific values’, ‘life goals and philosophies’, and ‘personal and social background’, emerged from the analysis. The patients reported a variety of insulin-specific values, which were negative and/or positive beliefs about insulin. They framed insulin according to their priorities and philosophies in life. Patients’ decisions were influenced by sociocultural (e.g. religious background) and personal backgrounds (e.g. family situations).

Conclusions

This study highlighted the need for expanding the current concept of patient values in medical decision making. Clinicians should address more than just values related to treatment options. Patient values should include patients' priorities, life philosophy and their background. Current decision support tools, such as patient decision aids, should consider these new dimensions when clarifying patient values.

Introduction

Patient decisions are influenced by their personal values; however, there is a lack of clarity and attention on the concept of patient values in the clinical context. This is despite clear emphasis on patient values in evidence-based medicine (EBM) and shared decision making (SDM) (Elwyn *et al.*, 2012; Makoul & Clayman, 2006; O'connor, 2001; Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000). EBM advocates that patients and clinicians make a choice together after considering the best available evidence, the clinician's experience and the patient's values (Barratt, 2008; Makoul & Clayman, 2006).

Current definitions of patient values are often vague (e.g. patient values are “the features that matter most to patients (International Patient Decision Aids Collaboration, 2006)”, “the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient” (Sackett, *et al.*, 2000)) or too narrow. For instance, international standards for patient decision aids narrow the scope of value clarification methods to patient views on physical, psychological and social effects, and the positive and negative features that matter most to patients (Elwyn *et al.*, 2009b).

To date, most studies on the patient role in shared decision making have focused on measurable patient outcomes, such as more accurate risk assessment (Carling *et al.*, 2009) or increased patient involvement during consultations (Couet *et al.*, 2013). Little research has been conducted on how patients actually choose between options and the patient voice is missing from the conversation (The PLoS Medicine Editors, 2007; 2009).

Previous studies have reported that values function as a filter through which patients interpret clinical evidence (Charles, Gafni, & Whelan, 1997; Lockwood, 2004; Reyna, 2008) and make treatment choices (Karel, 2000; Lockwood, 2004). Understanding how values influence patient decision making is particularly relevant to preference-sensitive decisions where there are trade-offs or when there is no one best option. Insulin initiation is one such example of a ‘difficult’ decision which is influenced heavily by patient values (Lee, Lee, & Ng, 2012; Polonsky, Fisher, Guzman, Villa-Caballero, & Edelman, 2005). This is particularly important in the context of diabetes which is reaching epidemic proportion and has significant morbidity and mortality (Whiting, Guariguata, Weil, & Shaw, 2011).

This study used insulin initiation as an exemplar to explore patient values and proposed to create a new model to explain patient values in the context of decision making. It aimed to explore and define patient values because this may help clinicians to understand and address patient concerns and expectations when making decisions.

Methods

Ethics Statement

This study received ethics approval from the Medical Research and Ethics Committee, Ministry of Health, Malaysia (Ref No: NMRR-10-1233-7299) and the Medical Ethics Committee, University of Malaya Medical Centre, Kuala Lumpur (MEC Ref No: 841.6).

Methodological approach

Due to the lack of literature on values from patients’ perspective, and the exploratory nature of the study, a qualitative study design was chosen (The PLoS Medicine Editors,

2007). We conducted individual semi-structured in-depth interviews to explore each patient's values within their experience of insulin initiation. This study formed part of a larger three-year project to develop a decision support tool for clinicians and patients who are making decisions about insulin therapy.

Conceptual framework

Our study was developed from the perspective of a SDM model. We used the Ottawa Decision Support Framework (ODSF), an SDM implementation framework, as the conceptual framework within which patient values are nested (A. M. O'Connor, 2006; A. M. O'Connor *et al.*, 1999). The ODSF identifies the decisional needs of patients as values, decisional conflict, knowledge and expectations, support and resources, decision characteristics, and, personal characteristics. Patient values are defined in the ODSF as the “desirability or personal importance of outcomes of options” (A. M. O'Connor, 2006). We developed a topic guide with 16 questions exploring two main decisional attributes: barriers and facilitators to insulin initiation and barriers and facilitators to decision making; the former focused on patient's perceptions about insulin itself, while the latter explored the patient's experience of the decision making process. In order to explore in-depth the topic of values, we then incorporated Schwartz's theory of values, which is a psychological theory relating to the priority and function of human values (S. H. Schwartz, 2006). In this theory, the five key attributes of values are: “(1) values are concepts or beliefs; (2) values pertain to desirable end states or behaviors; (3) values transcend specific situations; (4) values guide selection or evaluation of behavior and event; and (5) values are ordered by relative importance” (S. H. Schwartz & Bilsky, 1987). Table 5.5.1 shows the seven questions in our topic guide which explored these five attributes in the context of insulin initiation.

Setting

This study was conducted in Malaysia, which is an upper-middle-income, multi-cultural country comprising three main ethnicities (Malay, Chinese and Indian) (The World Bank, 2012). Malay is the official language but English is widely spoken in urban areas. Malaysia has a dual healthcare system. The public sector consists of government-subsidized hospitals and health clinics, which serve the majority of the population; the private sector comprises fee-for-service hospitals and clinics. Patients are free to choose where they prefer to receive treatment.

Malaysia has the tenth-highest prevalence rate of diabetes in the world (International Diabetes Federation, 2009a; Letchuman *et al.*, 2010) and 70-80% of the Malaysian patients in the primary care setting fail to achieve target HbA1c levels of $\leq 7.0\%$ (Ismail *et al.*, 2011; Mafauzy, 2005). The Malaysian clinical practice guideline recommends insulin initiation in patients with type 2 diabetes mellitus who are poorly controlled despite taking optimal oral glucose-lowering drugs (Ministry of Health, 2009). However, insulin uptake remains poor (Letchuman, *et al.*, 2010).

Sampling

Our sample included a range of patients at various stages of decision making. Patients with type 2 diabetes who were still considering insulin or had made a decision about insulin within the past 1 year were included in this study. We decided on this range considering the range of patients' decision making times is varied for insulin initiation. Unlike one-off medical decisions (such as screening tests or surgery), insulin initiation is a decision that may be considered over a prolonged period of time; patients may change their views about insulin before, during, and after initiation (Goodall, Sarpong,

Hayes, & Valentine, 2009). Clinicians recruited patients whom they had recently advised to start insulin.

Purposive sampling was used whereby we recruited non-randomized participants with specific characteristics in order to achieve maximal variation based on three factors: healthcare setting, patients' decision about starting insulin, and their ethnicity. To achieve a broad socio-demographic spectrum in the sample, we recruited patients from public and private, as well as rural and urban settings. We sought patients who were open to insulin as well as averse to it. We included patients who were reluctant to initiating insulin therapy as well as patients who were motivated to initiate insulin therapy. As the interviews progressed, we constantly reviewed the sample characteristics and updated the clinicians on the types of patients we were interested in.

Data collection

An interview topic guide was developed based on literature review, conceptual framework and expert opinion (Table 5.5.1). The topic guide was pilot-tested and iteratively modified based on themes that emerged during both pilot and subsequent interviews. Both the participant information sheet and topic guide were translated into Malay and Chinese by researchers who were fluent in these languages. Before each interview, participants were given an information sheet and written consent was obtained to participate in the study.

Semi-structured in-depth interviews were conducted with patients in their preferred language (English, Malay or Chinese). Interviews were conducted by three researchers trained in qualitative research methods (YK, CJ, and PY) and each lasted 30-45 minutes. Researchers arranged to interview patients at a time and location of their

convenience, including their homes or workplaces if patients were unable to travel due to work commitments or infirmities. Participants were reimbursed for their time and travel. Although the patients were informed that they would be participating in an individual interview, four were accompanied by family members. In such instances, care was taken to avoid having the family members dominate the discussion by consciously focusing questions on the patient.

Table 5.5.1 Semi-structured interview topic guide and corresponding value attribute in Schwartz’s Theory of Values

Interview questions	Corresponding value attribute in Schwartz’s Theory of Values (if any)
<i>Part 1: Introduction and rapport building</i>	
Q1. Can you tell me about your history of diabetes	
<i>Part 2: Focusing on beliefs about insulin and values</i>	
Q2. Have you been asked to start insulin? By whom?	
Q3. What has been going through your mind since you were advised to start insulin?	Values are concepts or beliefs. We probed the patient’s beliefs about insulin such as negative or positive perceptions, and sources of beliefs.
Q4. Where do you get your ideas/ beliefs about insulin from?	

Table 5.5.1, continued

Q5. Is starting insulin a difficult decision for you? Why or why not?	Values guide selection or evaluation of behaviour and events. We explored if patients were motivated to start or avoid insulin and their reasons for doing so.
Q6. Are you motivated to start insulin? Why or why not?	
Q7. Have you received any information about starting insulin?	
Q8. What are important priorities to you at this stage of life?	Values pertain to desirable end states or behaviours. We explored patients' life priorities as an operational definition of desirable end states.
Q9. Do these influence your decision to start insulin?	
If yes, how so? If no, why not?	Values are ordered by relative importance. We probed if patients valued some priorities over others, and if priorities had changed over time with different stages in life.
	Values transcend specific situations. We explored if non-health related priorities influenced patients' decisions about insulin.

Data analysis

English and Malay interviews were transcribed verbatim while Chinese interviews were translated into English for analysis. Malay interviews were not translated as all researchers were familiar with the language. A thematic analysis approach was used for data analysis, based on Strauss and Corbin's method of open, axial and selective codes (Strauss & Corbin, 1990). Three researchers (YK, WY, and CJ) independently coded two interviews line by line to develop an initial list of codes (open coding). A process of constant comparison was employed whereby subsequent interviews were coded using this list and new themes which emerged from new interviews were added to the list upon consultation with the research team. Any discrepancies in the coding process were resolved by discussion during monthly research meetings.

Codes were organised and re-organised into broader categories based on thematic similarities between codes (axial coding). Selective coding was conducted to generate central or core categories based on connecting and consolidating axial codes. All codes were checked by two researchers (YK, CJ) to ensure consistency of coding and consensus on axial and selective codes.

Data collection was stopped when data saturation was reached. Evidence of data saturation was obtained when no new axial or selective codes emerged from the data, showing that the core categories had already been captured. A secondary saturation criterion was based on the saturation of open codes, as there was evidence of repeated coding within the same codes.

Data analysis was facilitated by the use of Nvivo9 software to manage transcripts, themes and quotes, while keeping in mind the context of the quotes within individual interviews.

Results

Sample characteristics

A total of 21 patients were interviewed between January 2011 and February 2012 from five different healthcare locations (one public hospital-based primary care clinic, three public health clinics, and one private clinic). Table 5.5.2 details the range of patients interviewed. Although most patients were from an urban setting, they came from diverse socio-economic background. We achieved good variation in our sample in terms of healthcare setting, patients' decision about starting insulin, and ethnicity. Three core categories of themes emerged: 1) Insulin-specific values, 2) Life goals and philosophies and 3) Socio-cultural values and personal background.

Table 5.5.2 Characteristics of participants. Values are numbers unless stated otherwise.

Characteristic	Participants (n=21)
Male	12
Mean (SD) age (years)	55.24 (9.14)
Age range (years)	28-67
Status of insulin use	
Not currently on insulin	13
Already using insulin	8
Healthcare setting	
University hospital based primary care clinic	7
Public healthcare clinics	8
Private clinic	6
Language used during interview	
Malay	9
English	10
Chinese	2
Ethnicity	
Malay	6
Chinese	5
Indian	10
Decision about insulin	
Keen to start insulin	10
Not keen to start insulin	8
Undecided	1
Not applicable (previous insulin users- gestational diabetes (n=1) and short-term insulin use(n=1))	2

TREATMENT-SPECIFIC VALUES

When making decisions whether or not to start insulin, patients had specific beliefs and feelings about insulin (treatment-specific values). Examples of participants' perceived advantages and disadvantages of insulin are reported in Table 5.5.3.

Table 5.5.3 Beliefs and feelings about insulin

Themes	Participant quotes
BELIEFS ABOUT INSULIN	
Positive beliefs about insulin	
Improve control of diabetes	<p>“To me, I feel that maybe the (oral) drug does not help, then have to use the insulin. I was prepared because I see that my reading, ah, never come down”</p> <p><i>F8, female, 57 y.o., private general practice</i></p>
Prevent diabetes-related complications	<p>So I’m thinking, if I’m sixty years old, how long more can I live? Can I put ten more years, can I put twenty years? So why wait till, you know, when my diabetes is very bad and then put full dose of insulin. Try it now and see.</p> <p><i>F4, female, 61 y.o., public hospital-based primary care clinic.</i></p>
Minimal side-effects	<p>“Insulin is what our body is producing, you see, rather than all these chemicals going into the body. So it’s just that we take the insulin, it’s easy, direct, no...side effects. I mean, there should be minimal side effects.”</p> <p><i>F4, female, 61 y.o., public hospital-based primary care clinic.</i></p>
Enable the patient to lead normal lifestyle	<p>“[The doctor] said we give you insulin, means you can eat, no need to control (your diet). You don’t want to eat, or you want to eat, this (insulin) is better. That’s why I said, straightaway said I want it”</p> <p><i>M3, male, 63 y.o., public health clinic.</i></p>
Convenience of once-daily injections	<p>“[Insulin] is convenient. If you’ve injected in the morning then at night you don’t have to inject”</p> <p><i>M12, 61 y.o., private general practice</i></p>
Medication adherence is improved	<p>“But if you take insulin every day, you won’t forget. Tablets sometimes you forget. Insulin you know that when you wake up in the morning, you have to inject. Oh, it’s time to eat, it’s time to inject. For tablets, you’re working, working, working and then you have this tablet and that tablet, take half hour after meal, you forget. You go to a restaurant, at that time, you</p>

Table 5.5.3, continued

	<p>take your tablets, and you need water, right? Ah, you have to look for water. For him (insulin-users) you don't have to, no need to look for water, just inject insulin.” <i>F6, female, 58 y.o., public hospital-based clinic</i></p>
<p>Negative beliefs about insulin <i>Injection-specific beliefs</i> Scarring</p>	<p>“I don't want to start the insulin. My main concern is the injection and the scar. Everyday injecting, you know, I'm worried it will leave a scar. Because, diabetic people, when you have small injuries, you'll get black scars, I think my legs have got some.” <i>M10, male, 55 y.o., public hospital-based clinic</i></p>
<p>Risk of infections</p>	<p>“I'm afraid of, if I start injections tomorrow, will I get any side-effects? Usually, for people with diabetes, when they get a wound, it gets infected, right? Ah, I've seen a friend, his leg got cut by a wire, infected and pus-filled.” <i>M7, male, 67 y.o., public hospital-based clinic</i></p>
<p>Easier to forget to take injections</p>	<p>“And then, if they (people who take insulin) missed one day, also it's a problem. So that's the reason why I don't want to take insulin, I've been taking medicine for all this while. Medicine is a habit to me, every day I take, I'm reminded to take. Insulin, no, I mean, you might forget.” <i>M10, male, 55 y.o., public hospital-based clinic</i></p>
<p>Interference with current lifestyle</p>	<p>“The way the nurses, the dieticians and the diabeticians and the doctors told me look you must align yourself so they have here 4 meals or 3 meals or whatever and the insulin jabs would correspond to meals. I never take regular meals and the thing is like um... when we have problem with diabetes it's simply because we cannot cope with that huge amount of glucose in our body so human beings physiologically shouldn't eat big meals you see we only supposed to have small parts throughout the day. But that was what I was trying to do and then the way that they told me is just that...is contrary to what I've been doing.” <i>M1, male, 47 y.o., public hospital-based clinic</i></p>

Table 5.5.3, continued

Injection- and needle-phobia	<p>“It’s just that the jabs bothered me at that time. The thing is I don’t like poking myself... that’s normal and the thing is you know like uh... you... doing it 4 times a day you know it’s not easy and I mean it was like you have to do it really... I mean sort of like I don’t know you have to have a very good angle to it and then you won’t feel anything and there are some parts that you, there are some places where you cannot just push it through.”</p> <p><i>M1, male, 47 y.o., public hospital-based clinic</i></p>
	<p>“I’m really afraid of needles. And my daughter told me, how about the needles, right. It’s tiny, you better be careful, if it breaks.”</p> <p><i>F3, female, 48 y.o., public health clinic</i></p>
Preference for oral tablets or lifestyle intervention	<p>“I feel that I can control my own body. That’s all I think about. When I can’t control (my diabetes), my body doesn’t have enough exercise, that’s the time that I will take insulin. So, now, I have enough exercise, I can control. That’s all.”</p> <p><i>M6, male, 56 y.o., public health clinic.</i></p>
Social stigma attached to injections	<p>“Will I look like a drug addict? That’s the reason I don’t want to take insulin. It’s just like a drug addict, you know, on the road. They inject themselves, you know, to make them high. This insulin also you have to inject yourself. So you look like a drug addict. I’m not a drug addict, because I only smoke, that’s the only thing I do. So I don’t want to go into the stage where injection, injection, injection.”</p> <p><i>M10, male, 55 y.o., public hospital-based clinic</i></p>
<i>Insulin-specific beliefs</i> Unsure about the origin	<p>“I think, quite a number of my friends were not, maybe SPM (high-school) level ah, don’t know that insulin is a natural body made product. They think it’s a very strong medicine, that kind of attitude.”</p> <p><i>F4, female, 61 y.o., public hospital-based clinic</i></p>
Damaged organs	<p>“I told (my friends) I got to take injections and all that. They err, they said, you inject here, the behind gets spoilt. (Interviewer: Behind? Kidneys?). Yeah, sooner or later its spoilt. My aunties use it, injections. They said kidneys</p>

Table 5.5.3, continued

	<p>have a lot of problem. That's why they say, just take oral tablets. Don't take injections, just eat medication, let go of bad habits, reduce your food and all that.”</p> <p><i>M4, male, 53 y.o., public health clinic</i></p>
Fear of hypoglycemic events	<p>[Interviewer: So previously, was it your work that caused you to stop insulin?] No, it was the sweat, I have the sweat. So every night, I have to...shivering and wake up. So I was panic, you know. So I stopped it.”</p> <p><i>M11, male, 57 y.o., private general practice</i></p>
FEELINGS ABOUT INSULIN	
Positive feelings about insulin	
Normalization	<p>“Insulin is better, I think so, means, I'll recommend insulin. Because now I see all the people taking insulin, later on, I also take, it's better.”</p> <p><i>M3, male, 63 y.o., public health clinic</i></p>
Acceptance	<p>“So I have no choice in that (insulin)...and it's just that when they found that the levels were not good, that's when they said it would be better to start on the insulin. Because they gave this very good analogy saying that it is like throwing salt into the sea. You see... when you throw salt into the sea there's no effect. So that's the kind of analogy...so I have to change.”</p> <p><i>F1, female, 58 y.o., public hospital-based clinic</i></p>
Negative feelings about insulin	
Severity of diabetes	<p>“My response (to starting insulin) was that my diabetes was not that serious ah. As I said, I will not take it for the time being, I want to observe for a while and see how it goes. [Interviewer: You feel, that if other people take insulin, under what conditions do you think it is important to take insulin?] It is very serious already, when no cure from medicine, then only take this insulin, isn't it?”</p> <p><i>M8, male, 60 y.o., private general practice</i></p>
Denial (patient had been advised by doctor to start insulin)	<p>“Interviewer: So, it was Dr. H who asked you to start insulin, right?</p> <p>Pt M11: No, he didn't, he didn't.</p> <p>Interviewer: Oh...sorry.”</p> <p><i>M11, male, 57 y.o., private general practice</i></p>

Table 5.5.3, continued

Frustration or failure	<p>“I think it’s basically attitude change but it’s rather a difficult step <i>lah</i>, that transition (to insulin) was difficult. For me, it’s like failing an exam. I tried with so many medications as each time she increases the medications I get depressed. Very sad, ah, it’s getting bad, it’s getting bad.”</p> <p><i>F4, female, 61 y.o., public hospital-based clinic</i></p>
Feeling punished or threatened	<p>“She (the doctor) say...she scare, she want to scare me. She said, “So high your reading! 10 point something, just now it was like that. 10 point something, you so high, I must put you on insulin all that”. I said, please don’t do that, I say.”</p> <p><i>F5, female, 66 y.o., public hospital-based clinic</i></p>

Beliefs about insulin

The most commonly mentioned advantage was that insulin would help control diabetes and thus prevent diabetes complications. Some thought that insulin would replace oral glucose-lowering tablets (fewer medications) while others believed that insulin had fewer side-effect than tablets. Furthermore, some were reluctant to increase their daily number of oral tablets. One participant had the misperception that insulin was only injected once a week.

However, the majority of participants had negative perceptions about insulin. They expressed doubt over the origin of insulin; concern over insulin side-effects (e.g. hypos); believed that insulin might cause kidney failure and impair pancreatic function. Cost of insulin was also a concern for patients from poor socio-economic backgrounds and private patients whose insulin was subsidised by their employers.

When I am working, the cost (of insulin) can probably be covered. But, when I'm not working? Who wants to cover? Like I say, insulin isn't bad, it's good. But, it's the cost. Cost and for me, how long you want to stick to that kind of medicine. It's expensive, I know, and that one (insulin) is indeed expensive.

F9, female, 43 years old (y.o.), private general practice.

Moreover, patients had injection-related concerns including: pain, fear of needle, scarring from injections, lifestyle interference, infection at injection sites, forgetting to inject and insulin storage. Some participants were not aware that finer, less-painful needles were available. Two participants were afraid that the needle would break during injections.

Feelings about insulin

Participants also reported positive and negative affection about starting insulin. When advised to start insulin, some patients felt that their diabetes was worsening while others denied the need for insulin. They were not confident to self-inject; there was a sense of frustration or personal failure and felt that they were being punished for not controlling their diabetes. Conversely, some had a more positive affection about insulin initiation. They considered insulin initiation as a natural disease progression. They also gained confidence in insulin therapy by discussing with peers who used insulin.

LIFE PRIORITIES AND PHILOSOPHIES

When asked what was important in life that might influence their decision making, the participants' responses could be coded into two categories: life priorities and general philosophies.

Life priorities

Life priorities were specific goals in life. Three types of life priorities emerged from the interviews: health, finance and career.

Health

Health was a major priority for four participants. Two participants said that health was more important than finance. They said, “It’s OK, we can spend a lot of money. Waste money even, if it’s to look for medicine. We want to look after our body.” (M4, male, 53 y.o., public health clinic) and “Even if I have a lot of money, if we are not healthy, it’s unacceptable” (M7, male, 67 y.o., public hospital-based clinic). One patient said that awareness of risk of diabetes complications “puts you at fear, [you could be that close to] death” (M9, male, 28 y.o., public hospital-based clinic).

Career/ Employment

Interviews with patients who put priority on career or employment served to illustrate how different patients expressing a similar priority could frame insulin either positively or negatively. For example, one patient viewed insulin positively as he believed it helped him to control blood glucose spikes that had hindered his concentration during work. The other patient viewed insulin negatively as it would interfere with his work schedule.

“Establishing myself in terms of career ...my sugar is under control and then I can still hope for the future in terms of careers prospects because I don’t get the sugar spikes anymore, you know” (*positive view of insulin*)

M9, Male, 28 y.o., public hospital-based clinic

“I feel good if I go to work...it’s difficult for me to take insulin in the morning, because I have to leave for work at 5 am. We have to think about this as well.”

(negative view of insulin)

M6, Male, 57 y.o., public health clinic

Finance

Finance was a priority mentioned by three patients. Insulin-related costs were a concern for them. The need for a self-monitoring blood glucose (SMBG) meter caused one patient to say, “My priority is surely (pause) finance. Doctor A told me to buy the diabetes monitor; she said it’s sold here. The problem is...I can’t afford it. It’s hard being a taxi driver, because taxi rental is fifty ringgit (GBP 10) everyday” (M5, male, 44 y.o., public health clinic).

Hierarchy of Life Priorities

A hierarchy of priorities existed for participants. For example, health was more important than finance. However, priorities were sometimes co-related; one participant reasoned that health was important because it helped to achieve her financial goals.

“I was thinking, like, if I want to save my money, I must take care of my health. Hah, that’s why I go for exercise, you see. Exercise is important. And diet. That’s my concerns.”

F9, female, 43 y.o., private general practice

Life Philosophies

Some patients framed insulin according to their life philosophy. In contrast to life priorities, which are concrete goals that are important to the patient, life philosophies are related to patients' worldviews and ethical beliefs about what are morally desirable.

Avoiding Suffering

Avoiding suffering was a recurring theme. One participant stated that his view on life was to "die happy" and that he would consider taking insulin because he didn't want to "suffer and die" (M3, male, 63 y.o., public health clinic).

Another said that "If my suffer(ing)s are very major, I'm going to be dependent on anybody, I might as well go kill myself, instead of living with all the suffering and whatever nonsense that's going on." (M10, male, 55 y.o., public hospital-based clinic).

Another participant associated suffering with death by saying she prayed that "Please help me, I don't want to suffer pain. If I live, just let me live normally. When I die, don't let me suffer pain or anything, don't let me die that way" (F6, female, 56 y.o., public hospital-based clinic).

Fatalism

Some participants refused insulin treatment as they felt that everyone was fated to die one way or another.

"About dying, I'm not worried about it because these things they come naturally. Die means you die, no helping it. You inject until he dies, also die in the end, it's like that. So there is nothing to worry about."

M8, male, 60 y.o., private general practice

Not Being a Burden

Not burdening others was the most important philosophy for one lady. She explained that “I don’t want to be a burden to anybody and as well as to myself. I want to be independent, and a helpful person. That’s the thing that’s making me agree to insulin” (F4, 61 y.o., public hospital-based clinic).

SOCIO-CULTURAL VALUES AND PERSONAL BACKGROUND

Patients’ decision to start insulin was also shaped by their larger social environment, belief system (e.g. religion), and personal background (e.g. family context).

Religion

Religious values were a factor that influenced patients’ views about insulin. Four participants were concerned that the use of insulin might conflict with their religious beliefs. A Muslim patient was concerned about the purity (‘halal’) of insulin and needed assurance from a Muslim clinician. A Hindu patient illustrated how insulin injections could potentially desecrate holy sites as religious rules forbade blood being spilled inside temples.

I wouldn’t like to be in a (Hindu) temple, take out my needle and jab, I don’t think it’s nice. Because that’s supposed to be a spiritual, clean place. So my son-in-law was, like, arguing with me that day and said the blood doesn’t come out. In a spiritual place, blood shouldn’t come out as if it will fall on the floor of the temple, it’s a very big (pause) sin.

F4, female, 61 y.o., public hospital-based primary care clinic.

Personal and family background

The following example illustrates how a 66 year-old woman's family context influenced her decision to avoid insulin. For this patient, her insulin-specific belief was the perception that insulin was expensive.

“I feel I want to save money. Insulin is expensive; I don't want to take it.”

F5, female, 66 y.o., public hospital-based clinic

When asked what was important to her in life, she said that her life priority was on work. This was related to her view that her children were unable to support her.

“I am mostly thinking about work. My son in law, children...how much money can they give? My daughter has her own family, my son also has his own family.”

Finally, when probed why work was prioritised, it emerged that this was due to her tight financial situation. She had to work to support her family and provide for her children's studies after her husband became ill.

“I suffer a lot. My husband retired at fifty-five. Because the doctor asked him to stop working, that time he has a heart problem. That's why every cent I earned, I give it to my son and daughter to study.”

Discussion

This study aimed to explore patient values and what role it plays when making a health decision. The study identified a range of patients' positive and negative perceptions of insulin as well as life priorities and philosophies that influenced patients' decision making. Through analysis of patient narratives, we illustrate how patients' personal

background also influenced their decision about insulin. The study expands the current definition of patient values as treatment preferences to cover a broader dimension including personal life goals and philosophies.

The strength of this study is that the theoretical framework was drawn from a social science theory of human values. By broadening our scope of values to those outside of healthcare, we illustrate how priorities such as career achievement and ethical convictions are influential in patient decision making. Thus, the complex interactions between treatment-specific beliefs, goals and contextual background that emerged from the data are more holistic and, we believe, provide a more accurate representation of actual patient values.

The limitations of our study are that the specific themes from this study may not be transferable to other conditions. Patient values are shaped by local culture and norms. Therefore, priorities and philosophies identified in this sample of patients may not be similar to patients elsewhere.

The first category of values comprised of beliefs and feelings about insulin. These influenced patients' view of insulin as being either positive or negative. Firstly, patients have a set of cognitive beliefs about the perceived advantages and disadvantages of insulin (refer to Table 5.5.3). Not all of these beliefs are correct; patients also reported misperceptions about insulin. Besides cognitive concepts of insulin, patients also expressed an affective concept of insulin i.e. how insulin made them feel. Denial, punishment or lack of self-efficacy would influence patients to view insulin negatively.

Our study reports that patients in Asia share similar beliefs about insulin as those in the west, such as the fear of injections (Goderis *et al.*, 2009; Karter *et al.*, 2010),

inconvenience when using insulin (Hunt, Valenzuela, & Pugh, 1997; Polonsky, *et al.*, 2005), fear that insulin will cause organ damage (Karter, *et al.*, 2010; Larkin *et al.*, 2008), and feeling a sense of failure or punishment (Hayes, Fitzgerald, & Jacober, 2008; Karter, *et al.*, 2010). However, while most studies only highlight medically-related barriers concerning the efficacy and side-effects of insulin (Khan, Lasker, & Chowdhury, 2008), our study underlines the importance of exploring non-medical beliefs as potential barriers during insulin initiation. Some examples in our study include religious beliefs about blood, and patients' fear of social stigma from associating drug use with injection scars. Such socio-cultural and religious concerns may be factors for higher insulin refusal rates in Asian populations (42-52%) (Ahmed *et al.*, 2010; Khan, *et al.*, 2008; Nur Azmiah Z, Zulkarnain AK, & A, 2011) compared to the west.

Besides insulin-specific beliefs, other non-health beliefs also influenced patients' decisions. Patients would consider if insulin agreed with their system of life goals and philosophies. In other words, the choice about insulin was interpreted according to the patient's worldview. Previous literature has highlighted different types of patient values that should be considered when making a healthcare decision (Petrova, Dale, & Fulford, 2006). Schwartz *et al* have reported that from a list of seven 'life goals' (family, wealth, job, education, health/fitness, travel, and personal fulfilment), participants were significantly more willing to trade off achieving family goals for health or life years compared to other goals (A. Schwartz, Hazen, Leifer, & Heckerling, 2008). Such value typologies however face the limitation of being either conceptual or hypothetical. Our study adds to the literature by reporting on patients actually used values when considering insulin. Besides weighing the pros and cons of insulin from a medical

perspective, patients also viewed if insulin would be congruent with their worldview, which includes their life goals and philosophies.

Implications for practice

Currently, patient education remains the cornerstone of counselling patients who are resistant to insulin (Brod, Kongso, Lessard, & Christensen, 2009; Davis & Renda, 2006; Fu, Qiu, & Radican, 2009). The majority of the interventions focus on motivating patients to start insulin by changing their perceptions about insulin (e.g. normalization of insulin) and challenging negative perceptions about insulin use. There is little discussion about decision support and whether the treatment agrees with patients' values. One reason for this is the assumption that both HCPs and patients share similar values (Petrova, *et al.*, 2006). This study shows that patient values may not be congruent with health-seeking goals. Thus, besides addressing patients' negative perceptions, HCPs must also explore patients' underlying value motivations (Mulley, Trimble, & Elwyn, 2012).

From our analysis, patient values comprise three key categories: treatment-specific values; life priorities and philosophies; and socio-cultural and personal background. In Figure 5.5.1 we propose a conceptual model whereby these components form the content of the model and are arranged in three layers. The need to elicit patient values in medical decision making arises within the context of a specific medical decision. As such, the arrangement of the layers in the model was based on how closely related the value categories were to the medical decision being discussed. Whereas the first layer (treatment-specific values) are beliefs that are specific to the treatment (e.g. "I am afraid of insulin injections because they are painful."), the second (life priorities and philosophies) and third (socio-cultural and personal background) layers are trans-

situational, meaning that they are applied to other areas besides health. The second layer is the patient's personal, individual beliefs (which may also include health as a priority) while the third layer comprises of cultural and contextual influences. This model expands on the current scope of patient values in EBM (Lockwood, 2004; Sackett, *et al.*, 2000) and SDM (Barratt, 2008) to also include life priorities and philosophies (or a patient's worldview). In the centre are treatment-specific beliefs which depend on the medical context, while layers further from the centre are more deep-seated and trans-situational, and more importantly, also influence the treatment choice.

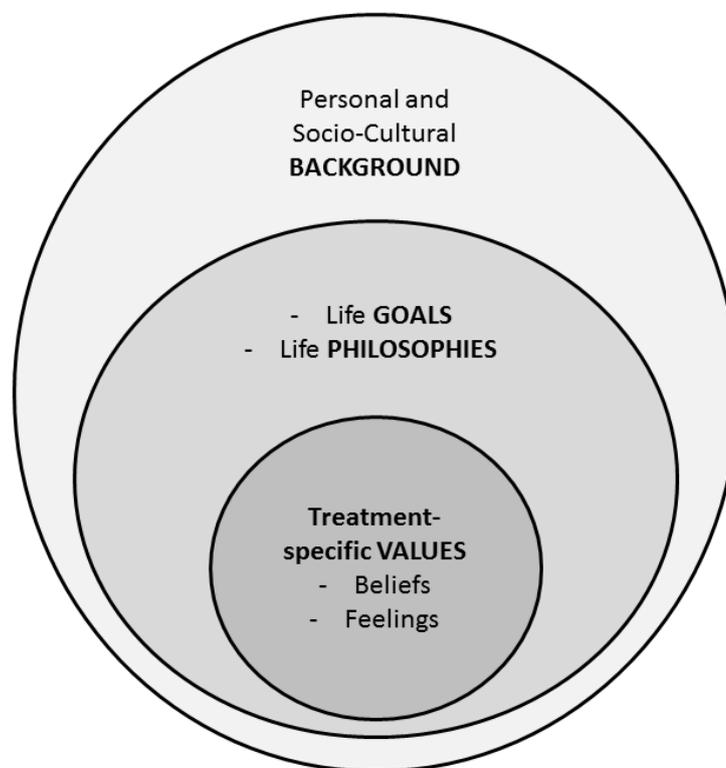


Figure 5.5.1 A conceptual model of patient values

Recent literature has expressed the need to consider the broader communicative and relational contexts when practicing SDM (Matthias, Salyers, & Frankel, 2013). When supporting patients in making decisions, clinicians need to address more than just

beliefs and feelings about the treatment options. A deeper understanding of patients' life priorities and background are essential, particularly when making decisions about treatments. From our study, we suggest that assessing these values involves competencies in eliciting and analysing patient narratives (Charon & Wyer, 2008; Greenhalgh, 1999; Meisel & Karlawish, 2011; Nunn, 2011). Understanding patient narratives is especially important for long-term care of chronic diseases which are heavily influenced by factors such as prior and current life experiences, resources, and explanatory models of illness (Ban, 2003).

Further research needs to be done on a number of aspects. Firstly, how generalizable is the proposed conceptual model of patient values? More studies should be conducted in different healthcare decisions, locations and cultures. Secondly, would an intervention targeting goals and philosophies be more effective than management programmes focusing on improving patient perceptions about insulin? One example would be value self-confrontation, (S. H. Schwartz & Inbar-Saban, 1988) where a patient with poor glycaemic control could be shown how their set of values differs from that of patients with good glycaemic control.

Conclusion

In this paper, we introduce a comprehensive model of patient values based on actual patient perspectives. This model fits well with the practice of EBM and SDM by helping clinicians to understand how patients also consider other non-health values when making a treatment decision. Further study needs to be done to explore the applicability of this model in other contexts.

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Competing interests

The authors declare that they have no competing interests.

Ethics statement

This study received ethics approval from the Medical Research and Ethics Committee, Ministry of Health, Malaysia (Ref No: NMRR-10-1233-7299) and the Medical Ethics Committee, University of Malaya Medical Centre, Kuala Lumpur (MEC Ref No: 841.6).

Abbreviations

CJ- Chirk Jenn Ng

EBM – evidence based medicine

ODSF – Ottawa Decision Support Framework

PY – Ping Yein Lee

SDM- shared decision making

WY – Wah Yun Low

YK – Yew Kong Lee

y.o. – years old

Chapter 6: General discussion and conclusion

This thesis has aimed to explore a simple, yet unanswered, question: What are patient values in medical decision making? The research has spanned three systematic/situational reviews, five research publications and numerous conference presentations. Chronologically, the research roughly progressed as such:

- 1) **systematic reviews** identified current views and research gaps on three areas: patient involvement in medical decision making in Malaysia; definitions of patient values in medical decision making; and barriers and facilitators to insulin initiation in type 2 diabetes;
- 2) **interviews with HCPS** identified the range of patient, HCP and system factors influencing insulin initiation in Malaysia;
- 3) **interviews with patients** identified the various types of values which influenced their decision to initiate insulin;
- 4) **grounded theory analysis of patient values** resulted in a conceptual model of patient values.

The final chapter of this thesis serves as summary and discussion of the body of research reported in the five chapters of this thesis. This chapter is not so much a reiteration of the results that have already been presented or repetition of the discussion sections of each individual paper, but rather a critical summary of the main themes in the investigation of patient values in SDM.

In discussing the common themes in the various papers the following points are pertinent: What do the results say about the challenges to insulin initiation in Malaysia and what strategies can help to address these issues? How can the patient values model

benefit SDM practice and how does the model of patient values fit in with current developments in SDM?

6.1 The challenge of timely insulin initiation in Malaysia

Using three sources (a systematic review, HCPs in Malaysia, patients with type 2 diabetes) this thesis identified a range of patient, HCP and system barriers to insulin initiation (Table 6.1). Healthcare in Malaysia operates within a complex multicultural, dual-sector context and a wide range of barriers to insulin initiation emerged from the study. In Malaysia, patients' barriers include culture-specific barriers such as the religious purity of insulin, preferred use of complementary medication and perceived lethality of insulin therapy (Chapter 5.1, Chapter 5.5). Malaysian HCPs cited negative attitudes towards insulin therapy and the 'legacy effect' of old insulin guidelines (previously, insulin was only initiated in a hospital setting); while system barriers highlighted the lack of resources (e.g. a lack of diabetes nurse educators), language and communication challenges, and lack of access to resources, especially for the private health sector (Chapter 5.1, Chapter 5.2).

These barriers are already being addressed by measures being undertaken by policymakers and HCPs. Policy initiatives aimed at addressing these barriers included an insulin-specific practice guideline and plans to subsidize SMBG costs (Chapter 1.6.3). HCPs who operate in the private healthcare sector utilized the help of NGOs and pharmaceutical companies to train patients (Chapter 5.2) and HCPs utilized various strategies to guide patients to start insulin if they were hesitant to do so (Chapter 5.3).

In the clinical consultation, it is important to differentiate between issues which influence the decision making process and barriers to implementing the chosen option.

For the former, barriers to making an informed shared decision are reported in this thesis. These include patient misconceptions about insulin, negative HCP attitudes about insulin, and communication barriers between the HCP and patient. On the other hand, assuming a patient has decided to start insulin, they may encounter barriers to implementing their choice. For example, they may not be able to afford the cost of SMBG monitoring, or they may require daily assistance as they are unable to self-administer insulin. In the Ottawa Decision Support Framework (O'Connor, 2006), HCPs need to consider how to support both the decision making process (through shared decision making) as well as the implementation of the choice (e.g. through referral to the appropriate health services).

Table 6.1 Comparison of barriers to insulin initiation from HCP interviews, patient interviews and systematic review

Source	HCP-reported barriers (Lee, Lee & Ng, 2012a; Lee, Lee, & Ng, 2012b)	Patient-reported barriers (Chapter 5.5)	Barriers in the systematic review (Chapter 3.1)
Patient barriers	<ul style="list-style-type: none"> • Negative beliefs about insulin <ol style="list-style-type: none"> 1. Fear of side effects and pain 2. Misconceptions about insulin <ul style="list-style-type: none"> o Insulin is lethal o Insulin is a punishment o Insulin is a stigma o Insulin is a medication for old people o Insulin causes sexual dysfunction • Prefers alternative treatment • Lack of knowledge • Lack of self-efficacy • Socio-cultural factors <ol style="list-style-type: none"> 1. Negative influence from family members 2. Insulin is unlawful for Muslims 	<ul style="list-style-type: none"> • Negative beliefs and feelings about insulin <ol style="list-style-type: none"> 1) Injection-specific beliefs <ul style="list-style-type: none"> o Scarring o Risk of infections o Easier to forget to take injections o Interference with current lifestyle o Injection- and needle-phobia o Preference for oral tablets or lifestyle intervention o Social stigma attached to injections 2) Insulin-specific beliefs <ul style="list-style-type: none"> o Unsure about the origin o Damaged organs o Fear of hypoglycaemic events 3) Negative feelings about insulin <ul style="list-style-type: none"> o Severity of diabetes o Denial (patient had been advised by doctor to start insulin) 	<ul style="list-style-type: none"> • Negative beliefs and attitudes about insulin <ol style="list-style-type: none"> 1. Negative perception of insulin 2. Negative attitudes 3. Fear of needle and pain 4. Side effects of insulin 5. Emotional barrier • Barriers in administering <ol style="list-style-type: none"> 1. Barriers in administering 2. Hassle of home glucose monitoring 3. Lack of self-efficacy/skills • Lack of knowledge/Misconception about insulin side effects • Socio-cultural factors <ol style="list-style-type: none"> 1. Social factors 2. Inconvenience 3. Interference with social and work activities

Table 6.1, continued

		<ul style="list-style-type: none"> ○ Frustration or failure ○ Feeling punished or threatened <ul style="list-style-type: none"> ● Socio-cultural factors <ol style="list-style-type: none"> 1. Religious values 2. Personal and family background 	<ol style="list-style-type: none"> 4. Stigma and discrimination 5. Lack of social support 6. Socio-demographic factor
HCP barriers	<ol style="list-style-type: none"> 1) Negative attitudes towards insulin 2) Lack of motivation and confidence 3) Training-related barriers 4) Conflicting advice from the HCPs 	-	<ol style="list-style-type: none"> 1) Negative attitudes 2) Lack of doctor-patient relationship 3) Communication barriers 4) Not involving patients in decision making
System barriers	<ol style="list-style-type: none"> 1) Lack of continuity of care 2) Lack of manpower 3) Lack of resources 4) Language barriers 5) Lack of collaboration between the private and public sectors 	-	<ol style="list-style-type: none"> 1) Lack of diabetes services 2) Lack of education resource

6.2 The patient values model: Contributing to larger patient-centred conversations

The results show that SDM is still a novel concept, both in individual consultations and at policy level. In HCP-patient consultations, Chapter 5.3 highlights that HCPs often use a paternalistic approach when initiating insulin while Chapter 5.4 reveals examples of how insulin consultations are skewed to either doctor- or patient-only decision making. A situational review of SDM in Malaysia (Chapter 2.0) showed that SDM was poorly researched and implemented in policy, research and practice. There is potential for growth in SDM implementation in all these areas within the Malaysian context (Table 2.1).

Besides efforts to promote awareness of SDM in Malaysia, another important effort is to integrate SDM as a component of the larger patient-centred care paradigm. This can be done as SDM shares components with other patient-centred practice models, specifically EBM (Barratt, 2008). For example, both SDM and EBM recognize that incorporating both evidence and preferences into practice is challenging (Barratt, 2008). Rather than an 'either/or' mentality, a 'both/and' approach should be encouraged whereby SDM and other models identify common areas and gaps to be investigated, thereby progressing the larger patient-centred care agenda.

One such area is patient values, for which a systematic review showed that there is a lack of clear definition (Chapter 3.2). The first model of patient values derived from the systematic review (Figure 3.2.2) provides an overview of how values have been defined in the literature. However, it has limitations as it seeks to combine various sources and themes into a single framework and is thus largely based on HCP perspectives of what patient values mean. Certainly, a truly patient-centred model should be one that is based on patient-derived data, and focused on an actual exemplar. Thus, the second model in

Chapter 5.5 (Figure 5.5.1) is derived from actual patient data in the context of insulin initiation in type 2 diabetes.

The second model of patient values (Chapter 5.5) is especially relevant as patient values are a key concept in both SDM (Chapter 1.2) as well as EBM (Sackett, 2000). The model identifies three categories of values that influence a medical decision. Two points can be noted about the model. The first is that the model and its components fit well with existing models of patient-centred models. For instance, the three layered components of the patient values model (treatment-related values; life goals and philosophies; socio-cultural values) bear similarities with the model of illness and disease proposed in the bio-psychosocial model, which also takes into account not just health beliefs, but also emotions and the larger social context (Engel, 1980). The bio-psychosocial model however is a general model from which doctors can empathise with the whole patient illness experience. The patient values model adds specific clarity to patient-centeredness by focusing on the role of values during preference-sensitive decision making, thus being useful for doctors who have reached a stage of deliberation of options in their consultations with patients. Research wise, by documenting the developmental process of the model along with the actual patient quotes, readers are able to understand for themselves how the model was developed from patient perspectives using insulin initiation as the exemplar (Chapter 5.5.).

Within the field of SDM, the model of patient values contributes to current discussion on the little-understood, yet influential, role of intuitive processes in patient decision making (Fagerlin *et al.*, 2012), a research gap which was highlighted in Chapter 1.2. Early SDM literature noted that values function as an interpretive filter (emphasis in bold added):

*“Patients interpret information on average treatment outcomes in order to make them personally meaningful within the decision-making context they are in. In so doing, **their own values and beliefs act as filters** in processing what information is allowed in and how it is understood” (Charles, Gafni, & Whelan, 1999).*

The proposed model of patient values informs this statement by showing how patients perceived insulin initiation through three types of filters, or lenses. The model sheds light on the complex perspective that patients have on a medical decision. Existing models of patient values in literature have been criticised for being based on HCP or researcher perspectives only (Karel, 2000). In consultations, patient views are often confined to a narrow scope (e.g. health-related categories), and without a definition of patient values, there is the risk that patients and doctors have different assumptions of what it means to incorporate values into decision making. This can lead to differing expectations and poor patient-doctor partnerships. Indeed, in this study, only one patient expressed a desire for a collaborative decisional role, which may indicate that the concept of the patient-practitioner relationship as a partnership is lacking in Malaysian society (Chapter 5.4). The model and the quotes are one example of the oft-missing patient voice that needs to be included in the consultation.

6.3 Methodological considerations

Exploration of barriers faced by HCPs when initiating insulin was done using a qualitative methodology. The choice of a qualitative methodology was to explore the area of insulin initiation as no results of previous studies (at the time of study design conception) were available in Malaysia.

Criticisms of qualitative methods are the subjectivity of data interpretation and the lack of generalizability of results. In order to reduce the risk of biased interpretation, three researchers come to consensus on the codes for both patient and HCP data.

Discrepancies in interpretation of transcripts and code names were discussed between researchers and any changes made to the coding structure were done with agreement.

The strength of this study lies in the use of multiple conceptual frameworks to develop the HCP and patient interview topic guides. As the results were later used to develop a complex intervention (the DMIT insulin PDA), a solid literature and theory base was needed to minimise the risk of the intervention leaving out important factors. The conceptual framework involved two systematic reviews, one SDM implementation model and a psychological theory of values. Researchers were able to define the depth (e.g. exploring the five key attributes of patient values) as well as the breadth (e.g. exploring the patient, HCP and system barriers to insulin initiation) required for in-depth interviews and focus group discussions.

6.4 Implications for practice and research

The implications of the patient values model for practice are in PDA development as well as clinical practice. In terms of PDA development, developers should check if all three types of values are elicited in the values clarification sections of PDAs.

Findings from the study were used to inform the development of the “Making Choices: Should I Start Insulin?” PDA (DMIT Group, 2012). Treatment-specific beliefs are the first category of values that need to be addressed and real-life patient quotes were used to develop the “What are your concerns?” introduction pages to the PDA (Appendix L). These quotes were also used to illustrate the ‘Patient FAQs’ section in the HCP Training

Guide where sample responses to these concerns were provided for HCPs (Appendix M).

Secondly, patient's personal and socio-cultural values were elicited in the "What is Important to You?" values clarification section of the PDA. These concerns included concerns "about the cost of insulin treatment", "how other people will think of me using insulin" and "that my family may not agree with me starting insulin". However, the model of patient values was not explicitly used to design the values clarification section of the PDA as the analysis of the patient data had not been completed when the PDA design was being finalised.

Future research should focus on the transferability of the patient values model to other healthcare contexts. Transferability is defined as "the range and limitations for application of the study findings, beyond the context in which the study was done" (Malterud, 2001), which in this study is the application of the patient values model in other healthcare contexts besides insulin initiation. The key to transferability of qualitative research is how much the result of the study advances theoretical understandings which can be applied to multiple situations (Kuper, Lingard & Levinson, 2008). As an initial assessment, because the model was developed from grounded theory practice, the patient values model contains general categories of values which can potentially be applied to other medical decisions besides insulin initiation. Given that patient values are an integral, yet undefined, component of SDM and EBM, the patient values model helps to inform both these practice models by providing a simple and systematic model of the types of beliefs that influence patients' decisions. One way in which the model can inform general medical practice is that HCPs can use the model of patient values to explore values during consultations, especially in

situations where HCPs do not have prior knowledge of a patient (such as first time consults). For example, HCPs could sequentially explore patient's negative and positive perceptions of the options, and then move on to how the option may affect their life priorities and finally discuss the patient's socio-cultural environment. This general model of patient values is flexible enough to be adapted for use in various medical decisions and should prove useful as a tool as part of patient-centred care or communication skills training in medical curricula.

The results underscore the role of culture and society on values in medical decision making, especially within a multicultural Asian context. The plurality of socio-cultural beliefs, languages and healthcare systems (including alternative medicine) make practicing SDM challenging in these contexts. This study highlighted the need for expanding the current concept of patient values in medical decision making. Clinicians should address more than just values related to treatment options and definitions of values should include patients' priorities, life philosophy and their background.

One other area of potential research is to investigate how and why values may change over time. Two models of patient values were produced in this thesis: the first based on the systematic review of patient values (Chapter 3.2); and the second based on the patient interviews (Chapter 5.5). The lists of values for both models are quite similar; however the list from the patient interviews is broader than the model from the systematic review as it also includes more abstract non-health related priorities (such as life goals). One difference between the models was that the dimension of longitudinal stability in the systematic review was not present in the patient interviews as patients were only interviewed once in the study and the study was unable to capture how values changed and the reasons for this change. Future research can investigate the longitudinal

stability of the value structures of actual patients and identify factors which predicate value changes.

Another area of research is evaluating the validity of the model of patient values.

Studies can try to measure the effect of each category of values on patient decisions on different types of decisions in various health decisions. For example, a questionnaire could be developed to measure the importance that patients place on each category of values using a Likert scale. These scores could then be correlated with patient willingness to initiate insulin to find out which categories are most strongly correlated with the behaviour. The same measures can be repeated with other health behaviours and regression analyses can be performed to find out which of the three value categories is the strongest predictor in various health decisions. Validation studies of the patient values model on other areas of healthcare decision making such as acute illness or surgery choice should be carried out to explore the transferability of the model to other decision making areas.

Adapting the patient values model to clinical practice would be another potential area of research. Such adaptation would help facilitate the practice of SDM as perceptions that SDM will positively impact the clinical process and improve patient outcomes are the second and third most common facilitators after personal HCP motivation to practice SDM (Gravel, 2006). Indeed, using the patient values model within a SDM framework to explore patient concerns will help achieve many of the perceived benefits of SDM such as: helping patients address all their concerns, providing HCPs with more background information to better judge patients' needs and preferences, and improving patient satisfaction by reducing their worries and increasing their understanding of the disease (Gravel, 2006). Possible innovations include adapting the model into a patient

questionnaire to be filled by the patient while waiting to see the doctor or a web-based smartphone app that allows patients to highlight their values and concerns to the doctor when making an appointment.

The patient values model also fits well with current ideas on health literacy and can be taught to patients to improve their communication with HCPs. The concept of health literacy has moved beyond the original definition which only included patient ability to perform health-related reading and computational skills (Simonds, 1974). Health literacy is now seen as going beyond just cognitive skills, to also include the patients social skills (e.g. communication, negotiation, organization) and Nutbeam conceptualizes health literacy as an action oriented concept, rather than just an intellectual one (Nutbeam, 2000). Indeed improving health literacy is seen as a form of patient empowerment. For example, Kwan et al (2006) define health literacy as *“People's ability to find, understand, appraise and communicate information to engage with the demands of different health contexts to promote health across the life-course”*. The patient values model fits well into the current view of health literacy as it helps patients to interpret information and choose options according to what is important to them. One goal of health literacy is active involvement of patients in consultations (Edwards et al, 2012). Using the patient values model as a framework for patients to think about and communicate their personal values will help patients to more accurately communicate their needs and concerns to HCPs.

6.5 Limitations

Although the patient values model describes general categories of values which likely are also influential in other disease conditions, without further study, the transferability of the model to other disease conditions remains the main limitation of this study. Some

factors which may limit the transferability of the model are treatment reversibility, acute vs. chronic conditions, and socio-cultural values. Treatments which are non-reversible (e.g. surgery) may involve other types of values (e.g. decisional regret) which were not elicited in this study. Another dimension is the length of treatment: type 2 diabetes is a chronic condition which prompts patients to consider long-term effects of the treatment (e.g. lifelong costs, impact on career) while more acute conditions may involve different concerns. Finally, the socio-cultural values in the study are from a Malaysian context and culture will differ in other settings.

6.6 Conclusion

The “patient revolution” of patients being actively involved in many, if not all, facets of healthcare is gaining strong support in policy and research (Richards, Montori, Godlee, Lapsley & Paul, 2013). Patient participation in healthcare is driven by two currents; evidence that increased patient participation improves health system efficacy (e.g. reducing overmedication), and secondly, concern that the doctor-patient relationship needs to more closely resemble a partnership rather than a paternalism (Barratt, 2008; Richards, Montori, Godlee, Lapsley & Paul, 2013).

Putting patients at the centre of healthcare benefits from practice models that help patients and HCPs understand, and negotiate together, the roles that each plays in the medical encounter. These models identify the components (e.g. information, training, needs, preferences, values, identities, roles) that each party brings to the encounter, and how these should be incorporated to form a patient-doctor partnership. This thesis has developed a model of patient values that identifies the three main categories of values from a grounded theory of patient values in insulin initiation.

Interest in SDM has only just begun in Malaysia. Most patients are not yet able to make informed choices due to the prevalence of misconceptions, the lack of patient education resources and the problems of cross-cultural communication (Chapter 5.1). Some HCPs still prefer a paternalistic style and as in the case of insulin are hesitant to recommend some treatments (Chapter 5.3). Patients in Malaysia's multicultural setting hold to a plethora of values and beliefs and current definitions of patient values do not include these larger worldviews. The patient values model represents my contribution to the efforts of a small group of Malaysian practitioners and researchers who are committed to understanding and resolving the challenges and barriers to implementing SDM in a resource-limited, multi-cultural setting.

In SDM, the patient values model identifies the categories of values which should be considered in value clarification methods, and may be useful for guiding practice (a 'rough guide' to eliciting patient values in various types of medical decisions) and improving SDM training (illustrating what are patient values in medical curricula).

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APPENDICES

APPENDIX A: The Decision Making in Insulin Therapy (DMIT) Project

A.1 Introduction to DMIT (<http://www.dmit.edu.my>)

Malaysia has the highest prevalence rate of type 2 diabetes (11.7%) in the Western Pacific region and this figure is projected to rise to 13.3% by 2030 (International Diabetes Federation, 2011). The majority of patients in Malaysia have poor glycaemic control; only about 20% of them have HbA1c levels of less than 7% (Chan, Ghazali *et al.*, 2005; Mafauzy, 2005; Ismail, Chew *et al.*, 2011). This leads to an increase of micro and macro vascular complications which impose heavy burden on Malaysia's stretched healthcare system (Ibrahim, Aljunid *et al.* 2010; Zhang, Zhang, *et al.* 2010), where cardiovascular disease already accounts for the highest number of hospital deaths in the country (Ministry of Health 2010).

Despite the availability of many treatment options (Ministry of Health 2009), blood glucose control remains poor (Chan, Ghazali *et al.*, 2005; Mafauzy, 2005; Ismail, Chew *et al.*, 2011). One reason is the delay in stepping up treatment regimen such as insulin therapy (Donnon PT, Steinke DT *et al.*, 2002). There are many barriers in starting insulin treatment (Polonsky and Jackson 2004; Polonsky, Fisher *et al.*, 2005) and few interventions have been developed to help patients and clinicians overcome these barriers.

A.2 Overview of the DMIT project

Thus, the project aimed to develop a decision support tool to help HCPs and patients participate in SDM during insulin initiation. This complex intervention was developed based on the needs of stakeholders (patients, clinicians and policy makers), current best evidence and decision support theories (UKMRC, 2008). This practical decision-

making tool would be evaluated for implementation in the primary care setting across Malaysia.

- Development and pilot-testing of the tool took place over three phases between September 2010 and August 2013 (Figure A.1). Overall project development was based on the conceptual frameworks of the Ottawa Decision Support Framework (ODSF) (O'Connor, Tugwell *et al.*, 1998) and the UKMRC complex intervention framework (UKMRC, 2008). A decision-making tool was developed by the research team using the needs of the clinicians and patients (findings from Phase 1); evidence from the systematic review; and decision support theories. This tool was in the form of a 16-page PDA booklet entitled “Making Choices: Should I Start Insulin?” (Figure A.2) (DMIT Group, 2012).

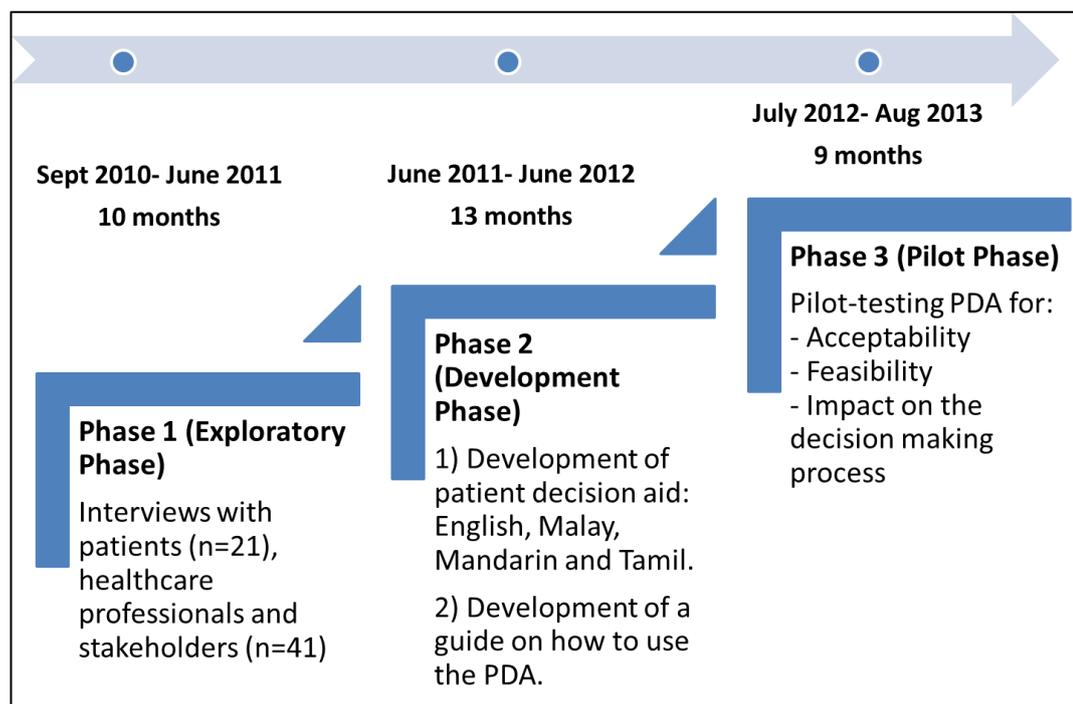


Figure A.1: Exploratory, Development and Pilot phases of the DMIT Project

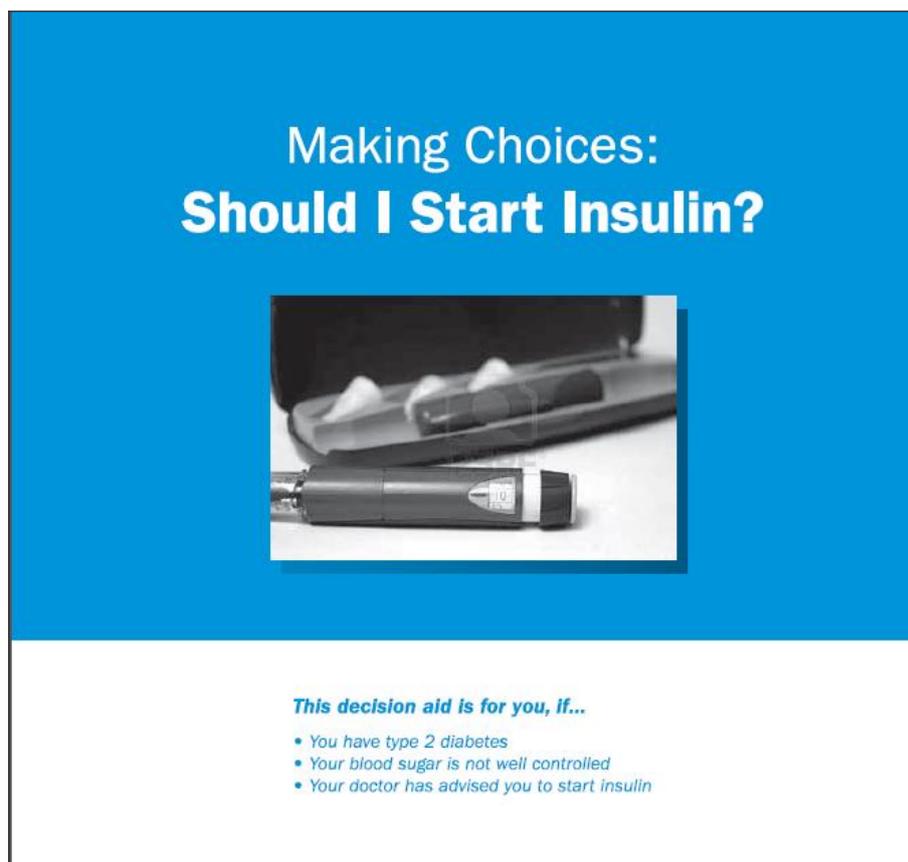


Figure A.2: ‘Making Choices: Should I Start Insulin’ PDA

Source: DMIT Group, 2012

A.3 Role in DMIT and publications

My role in the project was an evolving one. Although I initially joined as a research assistant in September 2010, I received a scholarship from the University of Malaya in October 2010 which converted me to a full time PhD student. Thus another research assistant was recruited and I functioned as a co-researcher and overall project co-ordinator for Phase 1 (Exploratory Phase) of the project. As my PhD focused on patient decision making values, I conducted almost all the 21 patient interviews and analysed the data. During Phase 2 (Development Phase), I focused on the publication of data from Phase 1 as part of my PhD scholarship requirements. Papers published in my PhD

are from the Phase 1 data collection period. More papers were written up for Phase 2 and 3 but these will only be published after the period of my PhD.

Although less involved in overall co-ordination for Phase 3 (Pilot testing Phase), I was still very much involved in developing the assessment tools for evaluating the PDA, facilitating the training workshops (involving one-hundred and one HCPs) and interviewing patients (n=18) and HCPs (n=13) about their experience with using the PDA in clinical consultation.

A.4 Funding and Research Team

DMIT was funded by a University of Malaya Research Grant (Reference number UMRG236/10HTM) and the principal investigator Prof Dr Ng Chirk Jenn is from the Department of Primary Care Medicine, University of Malaya. Besides Dr Ng, the research team comprised seven co-researchers from university, government primary care and private practice settings and one research assistant.

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APPENDIX B: Interview Topic Guide – Healthcare Professionals

Part 1 – Needs Assessment for Decision Making

General – Starting Insulin

1. Can you tell me on average how many diabetic patients you see in one week?
2. What decisions do these patients have to make about their diabetes?

Let's focus on: whether to start insulin.

Patient's Decision Making

3. Is starting insulin a difficult decision for your patients?
 - a. If yes, why is it difficult for them? What difficulties do patients face when deciding whether to start insulin?
 - b. If no, why not?
4. How do they feel when they are making this decision?
5. What are the things that patients consider before they decide whether or not to start insulin?
 - a. Information, what information,
 - b. Values,
 - c. Influence from others: how others do it, support from others, handling pressure
6. What kind of help do they need to make this decision?
 - a. information, support
7. Who else, besides your patient, are involved in making this decision?
 - a. family, friends
 - b. how are they involved in the decision making

HCP's Support

8. Who are the patients whom you would advise to start insulin?
9. If a patient refuses to start insulin, what other options do they have?
 - a. What are the advantages and disadvantages of these options?
10. How do you help patients to start insulin?
11. What role do you play in the decision making process?

12. How do you explain the risks and benefits of insulin to your patients?
13. What barriers do you face when advising them to start insulin?
 - a. Talking about risks and benefits,
 - b. Exploring values, ideas, concerns and expectations
 - c. Coaching them how to make decisions
 - d. Motivating them
14. What kind of help do you need to overcome these barriers?
15. Could you share an example of successfully advising your patient/s to start insulin?
 - a. How did you do it? (For insulin prescribing doctors)

Decision Support

16. There are different ways of helping patients to make decisions about starting insulin. I would like to hear your opinion whether they will work with your patients.
 - Counselling with healthcare professionals (doctors, nurses, others healthcare professionals)
 - Discussion group of people facing the same problem
 - Information materials – content, format and who should prepare these information
 - Patient decision aid (show them the decision aid and ask for their comments)

End of Interview

APPENDIX C: Interview Topic Guide – Patients

General – Diabetic treatment

1. How long have you had diabetes?
2. How do you feel about having diabetes?
3. What have you done to try and control your diabetes?

Let's focus on: the decision whether to start insulin.

Patient's Decision Making

4. Have you been asked to start insulin?
 - a. Who has advised you to start insulin?
 - b. When was that?
 - c. What stage are you at now in starting insulin?

Already started, Agreed but not started, Still considering, Refuse to start.

5. What do you know about insulin?
6. What has been going through your mind since you were advised to start insulin?
7. Where do you get your ideas/ beliefs about insulin from?
 - a. *Friends*
 - b. *Family*
 - c. *Direct experience*
 - d. *Cultural beliefs*
8. Is starting insulin a difficult decision for you?
 - a. If yes, why is it difficult?
 - b. If no, why not?

*Probe emotional barriers related to insulin:
negative feelings and phobias(e.g. depression, anxiety and embarrassment, feelings
of failure, lack of confidence, needle phobia)*

** If patient is unable to identify barriers to starting insulin, then ask:*

Are these barriers (*halangan*) to starting insulin for you?

Probe with list of barriers from HP:

- a. *Prefer Complimentary and Traditional medicine*

- b. *Conflicting information*
- c. *Fear of needles and pain*
- d. *Fear of side effects (hypo, weight gain)*
- e. *Lack of knowledge*
- f. *Self-efficacy*
- g. *Visual impairment*

9. Have you received any information about starting insulin?
- a. What information would you like to have?
 - b. Who should discuss with you about starting insulin?
 - c. Are you satisfied with the information provided so far? Why or why not?
10. Do you have other options besides insulin?
- a. If yes, what are they?
 - b. How do you choose between options?
11. Are you motivated to start insulin?/ Adakah anda rasa bersemangat untuk memulakan insulin?
- a. If yes, what motivates you to start insulin?
 - b. If no, why not?

Probe motivating beliefs about insulin:

Effectively managing diabetes, concern over worsening blood glucose, know of others who manage their diabetes well with insulin

12. What are the things would help you to make a decision whether or not to start insulin?
- More information - what information
 - Support from others – healthcare professionals, family, friends, people who have used insulin

Prompts: side effects, risks and benefits

13. What are important priorities (*keutamaan*) to you at this stage of life?

Examples: Health, money, family

- a. Does this influence your decision to start insulin?
- b. If yes, how so?

c. If no, why not?

14. Who else is involved in making this decision? What are their roles?

a. doctors,

b. family and

c. friends

15. Who do you think should make the decision about you starting insulin?

a. Yourself

b. Doctors

c. Family

d. Others

Decision Support

16. Here are some ways to help patients make decisions – what do you think?

- Counselling by healthcare professionals
- Discussion group of people facing the same problem
- Information materials – content, format and who should prepare these information

End of Interview

APPENDIX D: Coding Tree (HCPs)

D.1 Codes describing the barriers to insulin initiation

Name	Sources	References
Barriers in insulin initiation	5	17
HP Barriers in initiating insulin	0	0
HP Barriers- Attitudes	6	12
HP Barriers- Confidence OR Self-efficacy	6	11
HP Barriers- Lack of motivation	3	4
HP Barriers-Training	7	16
Language Barriers	2	8
Px Barriers in initiating insulin	2	7
Px Barrier - Complimentary Medicine	5	7
Px Barrier - Cost of needles and strips	1	1
Px Barrier - denial	8	15
Px Barrier - Mental Illness	1	1
Px Barrier- Conflicting Information from HP	4	5
Px Barrier- Fear of needles and pain	16	48
Px Barrier- Hypo	8	11
Px Barrier- Inconvenience	13	29
Px Barrier- Knowledge	8	24
Px Barrier- Lack of family support	4	4
Px Barrier- lipohypertrophy	1	1
Px Barrier- Perception of insulin initiation	16	76
Px Barrier- Self-efficacy	3	4
Px Barrier- Visually impaired	6	7
Sys Barrier in initiating insulin	0	0
Sys Barrier- Fast Turnover & Continuity of Care	4	5
Sys Barrier- Lack of Manpower	9	23
Sys Barrier- Lack of Resources	12	57
Views of barriers in insulin initiation	2	2

D.2 Codes describing policies related to diabetes and insulin

Name	Sources	References
Diabetes Program and Policy	0	0
Govt agencies and bodies	0	0
Diabetes Steering Committee	1	2
Diabetes Unit Setup	1	2
Polices concerning Diabetes	0	0
CPG and Support Materials	2	10
Diabetes Treatment Adherence Clinic	2	7
National Diabetes Plan	1	1
Public Health	4	6
QA for Diabetes	2	6
Target levels for diabetes	4	5

D.3 Codes describing problems faced by patients who are using insulin therapy

Problems faced by patients on insulin therapy	12	53
Adherence to treatment regime	7	15
Change of types of insulin and pens	1	1
Difficulty in blood sugar control	5	10
Dropouts	3	9
Monitoring of blood sugar	5	6
Awareness of importance of self monitoring	1	1
Cost of glucometer, strips etc	4	7
Fear of pricking	1	1
Inconvenience in getting the glucometer and strip	4	4
No regular follow-up after initiation	2	2
Side effects	2	3
Teaching of insulin titration	4	7

D.4 Codes related to HCP strategies to initiate insulin in patients with type 2 diabetes

Name	Sources	References
Strategies focused on HP	0	0
Assessment of Px bkgrd before insulin initiation	7	12
Clinical Guide and Support Material	5	12
Mental Preparation	1	1
Training	6	17
Strategies focused on Px	2	5
Empathy	5	8
Follow-up Px	9	17
Gadgets and Tools	15	43
Good Patient-Doctor Relationship	8	17
HP's advice for patient on insulin initiation	16	134
Negotiation with Px	11	22
Px Education Materials	9	17
Px who refused insulin	1	1
Affects Clinic Audit Performance	1	1
Referral	5	5
Signing dissent	1	2
Px-Px communication	1	1
Support	0	0
Family Support	6	10
Involving family in the decision making process	4	10
Types of patient	3	4
Peer Support	7	9
Strategies focused on Team OR System	0	0
Financial Support	2	5
Insulin campaign	1	2
Involvement of other organizations OR companies	7	17
Multidisciplinary Team	9	18

APPENDIX E: Coding Tree (Patients)

E.1 Codes describing the values of patients during insulin initiation

E.1.1 Life Philosophies and Priorities

Name	Sources	References
[-] Patient's values	0	0
[-] Insulin-related values	2	2
[-] Life philosophies	0	0
[-] Negative towards insulin	0	0
As long as I'm happy it's fine	1	2
Death_fated to die anyway	2	2
I don't want my life to be tied to medicine	1	1
Lack of motivation to engage in health-seeking behaviour	1	2
[-] Positive towards insulin	0	0
Does not want to burden others	1	1
Does not want to suffer_positive	1	1
[-] Life priorities	0	0
[-] Negative towards insulin	0	0
Employment as a priority_negative	2	3
Financial priorities	6	9
Loss of status or face	2	2
[-] Positive towards insulin	0	0
Employment as priority_positive	1	1
Health	5	7
[-] Priorities not explicitly linked to insulin DM	0	0
Health as a priority	6	9

E.1.2 Insulin-specific perceptions

<input checked="" type="checkbox"/> Insulin-specific perceptions	0	0
<input checked="" type="checkbox"/> Emotional	0	0
<input checked="" type="checkbox"/> Negative	0	0
<input checked="" type="checkbox"/> Denial	4	7
<input checked="" type="checkbox"/> Fear of unknown	1	2
<input checked="" type="checkbox"/> Feel punished OR threatened	1	5
<input checked="" type="checkbox"/> Frustration OR failure	2	3
<input checked="" type="checkbox"/> Lack of self efficacy	2	2
<input checked="" type="checkbox"/> Severity of disease	10	23
<input checked="" type="checkbox"/> Social stigma	1	1
<input checked="" type="checkbox"/> Positive	0	0
<input checked="" type="checkbox"/> No other choice	3	7
<input checked="" type="checkbox"/> Normalization of insulin	2	3
<input checked="" type="checkbox"/> Role models	1	1
<input checked="" type="checkbox"/> Factual	0	0
<input checked="" type="checkbox"/> Negative	0	0
<input checked="" type="checkbox"/> Cost of insulin OR other cost factors	4	10
<input checked="" type="checkbox"/> Cultural or religious beliefs that conflict with insulin use	4	5
<input checked="" type="checkbox"/> Injection-related	0	0
<input checked="" type="checkbox"/> Afraid of missing dose	1	2
<input checked="" type="checkbox"/> Fear of diabetic infection from injection site	1	1
<input checked="" type="checkbox"/> Interferes with lifestyle	1	1
<input checked="" type="checkbox"/> Issues w SMBG	1	1
<input checked="" type="checkbox"/> Needle phobia	13	27
<input checked="" type="checkbox"/> Needle will break	2	2

E.1.2 Insulin-specific perceptions, continued

<input type="radio"/>	Pain	7	12
<input type="radio"/>	Scarring from injections	1	2
<input type="checkbox"/>	<input type="radio"/> Insulin-related	0	0
<input type="radio"/>	Concern over origins of insulin product	2	2
<input type="radio"/>	Fear of addiction	1	1
<input type="radio"/>	Fear of side effects in general	2	3
<input type="radio"/>	Hypos	1	1
<input type="radio"/>	Insulin will cause pancreas to get lazy	1	2
<input type="radio"/>	Kidney failure is caused by insulin	1	4
<input type="checkbox"/>	<input type="radio"/> Prefers other treatments	0	0
<input type="radio"/>	Only requires insulin if not exercising	1	1
<input type="radio"/>	Prefers to continue on tablets OR lifestyle intervention	7	17
<input type="radio"/>	Prefers to try alternative medicine	2	2
<input type="radio"/>	Unable to understand Dr's advice about insulin	1	1
<input type="checkbox"/>	<input type="radio"/> Positive	0	0
<input type="radio"/>	Able to live a normal life	3	3
<input type="radio"/>	Avoid complications of diabetes	6	9
<input type="radio"/>	Does not want to increase OHAs	1	1
<input type="radio"/>	Improve one's health or diabetes control	14	20
<input type="radio"/>	Injection helps with medication adherence	1	1
<input type="radio"/>	Insulin is not permanent	 1	1
<input type="radio"/>	Need insulin only once a day OR week	2	2
<input type="radio"/>	Tablets have more side effects	4	6

E.1.2 Personal and socio-cultural background

Name	Sources	References
Personal and sociocultural background	2	6
Cultural OR Religious Beliefs	6	8
Education	1	1
Family background	8	18
Experience with insulin	14	27
Family believes that insulin will make patient depressed	1	1
Interaction with HCPs	3	3
HCPs advice to start insulin	4	8
Lifestyle issues	11	21
Medical History	6	9
Needle familiarity	3	4
Personal experience with insulin	3	7
Negative side effects of insulin	0	0
Hyperlipidimia	1	1
Hypo	3	4
Injections	5	6
Weight gain	1	1
Previous experience with insulin	7	14
Person who initiated	6	8
Pt Education about insulin	1	1
Type of previous insulin regime	6	8
Peers	9	12
Self image and personality attributes	4	7
Social discrimination	5	5
Support (or lack of) for insulin	0	0
Family OR Friend Support	5	12

E.2 Codes describing the decision-making context of insulin initiation

Name	Sources	References
Decisional context- Diabetes, health practices, interaction w HPs	0	0
Cultural or religious background	2	3
Diabetes	21	135
Beliefs about diabetes	12	23
Disease management	21	59
Duration of disease	14	14
Impact on person OR lifestyle	10	14
Symptoms of diabetes	15	25
Health beliefs and practices	0	0
Alternative medication	11	22
Cost factors	3	4
Health beliefs	8	20
Interaction with HCPs	16	45
Conflicting advice from HCPs	2	2
Information overload	1	1

E.3 Codes describing the decision-making process of patients

Name	Sources	References
Decision making	0	0
Decision making strategies	0	0
Comparing pros and cons	2	2
Comparisons with others on insulin	3	3
Facing a challenge head-on	1	1
Finds health advice a hindrance	1	1
Follow Dr's advice	5	9
Peer discussion	10	13
Problem solving approach	1	2
Wait and see approach	1	1
Decisional role preference	22	40
Information about insulin	20	73
Format of informational material	8	12
Information needs about insulin	19	43
Information seeking behaviour	11	17
Stage of decision making about insulin	9	11
Time taken to make decision	1	2
Values and Decision making	0	0
Personal values	0	0
Liberty and independence- the individual should make their own decision	1	1
Time factor- how values change over time	3	3
Social norms and values	0	0
Social conformity- wants to appear normal so does not discuss decision	1	1
Social position- having the power to make own decisions	1	1

APPENDIX F: Ethics Approval



PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN
OFFICE OF THE DEPUTY DIRECTOR-GENERAL OF HEALTH
(PENYELIDIKAN & SOKONGAN TEKNIKAL)
(RESEARCH & TECHNICAL SUPPORT)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
Ara 12, Blok E7, Parsel E, Presint 1
Level 12, Block E7, Parcel E, Precinct 1
Pusat Pentadbiran Kerajaan Persekutuan
Federal Government Administrative Centre
62590 PUTRAJAYA

Tel : 03 88832543
Faks : 03 88895184

JAWATANKUASA ETIKA & PENYELIDIKAN
PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Ruj. Kami : (2) dlm.KKM/NIHSEC/08/0804/P11-217
Tarikh : 1 Jun 2011

Associate Prof Dr Ng Chirk Jenn
Fakulti Perubatan
Universiti Malaya

Tuan,

NMRR-10-1233-7299

Developing And Pilot-Testing An Intervention For Patients With Type 2 Diabetes Who Are Making Decisions About Starting Insulin Therapy

Lokasi Projek: Klinik-klinik Kesihatan Kuala Lumpur , Selanagor, Negeri Sembilan

Dengan hormatnya perkara di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia (KKM) tiada halangan, dari segi etika, ke atas pelaksanaan kajian tersebut. JEPP mengambil maklum bahawa kajian tersebut tidak mempunyai intervensi klinikal ke atas subjek dan hanya melibatkan pengumpulan data melalui temuramah sahaja.

3. Segala rekod dan data subjek adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta prosedur mengenai *data confidentiality* mesti dipatuhi. Kebenaran daripada Pengarah hospital di mana kajian akan dijalankan mesti diperolehi terlebih dahulu sebelum kajian dijalankan. Tuan perlu akur dan mematuhi keputusan tersebut.

4. Laporan tamat kajian dan sebarang penerbitan dari kajian ini hendaklah dikemukakan kepada Jawatankuasa Etika & Penyelidikan Perubatan selepas tamatnya kajian ini.

Sekian terima kasih.

BERKHIDMAT UNTUK NEGARA

Saya yang menurut perintah,

(DATO' DR CHANG KIAN MENG)
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia



**UNIVERSITI
M A L A Y A**

PUSAT PERUBATAN UM

**MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE**
ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE: 03-79493209 / 2251 FAXIMILE: 03-79492030

NAME OF ETHICS COMMITTEE/IRB: Medical Ethics Committee, University Malaya Medical Centre	ETHICS COMMITTEE/IRB REFERENCE NUMBER: 950.45
ADDRESS: LEMBAH PANTAI 59100 KUALA LUMPUR	
PROTOCOL NO (if applicable): TITLE: Developing and pilot-testing an intervention for patients with type 2 diabetes who are making decisions about starting insulin therapy	VERSION NO.:
PRINCIPAL INVESTIGATOR: Assoc. Prof. Ng Chirk Jenn	SPONSOR:

The following item have been received and reviewed in connection with the above study to be conducted by the above investigator.

- | | |
|--|---------------------|
| <input checked="" type="checkbox"/> Application for Amendment/Information to Research Project (form) | Ver date: 12 Sep 12 |
| <input type="checkbox"/> Annual Study Report/Study Closure Report | Ver date: |
| <input type="checkbox"/> Serious Adverse Event Report | Ver date: |
| Other documents:- | |
| <input checked="" type="checkbox"/> Participant Information Sheet & Consent Form | Ver date: 11 Sep 12 |

and the decision is :

- Approved
 Modification requested (item specified below or in accompanying letter)
 Rejected (reasons specified below or in accompanying letter)
 Noted

Comments:

Investigator are required to:

- 1) follow instructions, guidelines and requirements of the Medical Ethics Committee.
- 2) report any protocol deviations/violations to Medical Ethics Committee.
- 3) provide annual and closure reports to the Medical Ethics Committee.
- 4) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and the Declaration of Helsinki.
- 5) obtain permission from the Director of UMMC before starting research that involves recruitment of UMMC patients.
- 6) ensure that if the research is sponsored, the usage of consumable items and laboratory tests from UMMC services are not charged in the patient's hospital bills but are borne by the research grant.
- 7) note that he/she can appeal to the Chairman of MEC for studies that are rejected.
- 8) note that Medical Ethics Committee may audit the approved study.
- 9) ensure that the study does not take precedence over the safety of subjects.

Date of approval: 09 OCTOBER 2012
Date of notification:

c.c Head
Department of Primary Care Medicine

Deputy Dean (Research)
Faculty of Medicine

Secretary
Medical Ethics Committee
University Malaya Medical Centre


.....
PROF. DATUK LOOI LAI MENG
Chairman
Medical Ethics Committee

APPENDIX G: Participant Information Sheet (Healthcare Professional)

Please read the following information carefully, do not hesitate to discuss any questions you may have with the researcher.

Study Title

Developing and pilot-testing an intervention for patients with type 2 diabetes who are making decisions about starting insulin therapy

Introduction

We would like to invite you to take part in a research study. This study will find out the problems faced by healthcare professionals and their patients with type 2 diabetes who need to make decisions about starting insulin therapy.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully and talk to the researcher if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

When patients are advised to begin insulin therapy by their healthcare providers, they often find the decision difficult as there are many factors to be considered. Healthcare professionals help patients make informed decisions by advising them on the risks and benefits of the treatment, and also helping them to evaluate how they feel and think about the treatment.

Therefore, the purpose of this study is to find out the barriers, motivators and needs of patients that you have encountered in the course of advising a patient to start insulin therapy.

This information will then be used to help create a practical decision-making tool which doctors and nurses can use to help patients make informed choices about insulin therapy.

A total of 30 healthcare professionals will be interviewed for this study.

What are the procedures to be followed?

If you agree to take part in this study, you will be invited for a session in which a researcher will conduct an in depth interview. During the session, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by a simple questionnaire about your background (10 minutes).

You will participate in a one-to-one interview. The researcher will ask questions about topics related to making decisions about insulin therapy. He/ she will record the conversation using an audio voice recorder. The purpose of the recording is to allow the

researcher to collect information discussed during the interview, which is important for them to analyse later. The one-to-one interview will take about 30 minutes.

All information collected during the course of the research will be kept strictly confidential. Any information that contains your name, telephone and address will be removed so that you cannot be identified.

Who should participate in the study?

Healthcare professionals working in the primary care setting (private or public sectors) who have discussed insulin initiation with their type 2 diabetes patients in the past six months.

Who should not participate in the study?

You should not participate in this study if:

1. you are not practicing in a primary care setting
2. you have not advised patients with type 2 diabetes regarding starting insulin treatment in the past six months

What will be benefits of the study:

(a) to you as the participant?

You will be able to contribute significantly to the development of a practical tool that will help doctors and patients manage diabetes better by making informed decisions about insulin therapy.

You will be given RM 100.00 to compensate for your travel and time to attend the interview.

(b) to the researcher?

The researcher will be able to develop a decision-making tool that will be used by healthcare professionals and patients in making informed-choices about insulin therapy. With better control of diabetes, many patients can live normal lives without the complications associated with diabetes.

The researcher will also be able to contribute to the larger body of medical knowledge in the field of diabetes, healthcare professional-patient communication, and development and implementation of decision-making tools.

What are the possible drawbacks?

During the interview, sometimes, you may be asked questions about your patients that you feel are sensitive or which you are uncomfortable to disclose. You can refuse to answer any questions which you feel uncomfortable with, or you can stop the interview anytime.

Can I refuse to take part in the study?

Yes. This study is voluntary and you can refuse to take part at any stage of the study.

Who should I contact if I have additional questions during the course of the study?

Doctor's Name: Dr Ng Chirk Jenn Tel: 03-7949 2621

Research assistant's Name: Mr Lee Yew Kong Tel: 012-609 2018

APPENDIX H: Participant Information Sheet (Patient)

PATIENT INFORMATION SHEET

Please read the following information carefully, do not hesitate to discuss any questions you may have with your Doctor.

Study Title

Developing and pilot-testing an intervention for patients with type 2 diabetes who are making decisions about starting insulin therapy

Introduction

We would like to invite you to take part in a research study. This study will find out the problems faced by people with type 2 diabetes who need to make decisions about starting insulin therapy.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

When patients are advised to begin insulin therapy by their doctor, they often find the decision difficult as there are many factors to be considered. Informed decision-making on insulin therapy not only requires you to know the risks and benefits of the treatment, it also depends on how you feel and think about the treatment. Sometimes, you may not have had opportunity to discuss this information in detail with your doctor or nurse.

Therefore, the purpose of this study is to find out the problems you have encountered when you are making a decision about insulin therapy.

This information will then be used to help create a practical decision-making tool which doctors and nurses can use to help patients make informed choices about insulin therapy.

A total of 30 patients will be interviewed for this study.

What are the procedures to be followed?

If you agree to take part in this study, you will be invited for a session in which a researcher will conduct an in depth interview. During the session, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by a simple questionnaire about your background (10 minutes).

You will participate in a one-to-one interview. The researcher will ask questions about topics related to making decisions about insulin therapy. He/ she will record the conversation using an audio voice recorder. The purpose of the recording is to allow the researcher to collect information discussed during the interview, which is important for them to analyse later. The one-to-one interview will take about 30 minutes.

All information collected during the course of the research will be kept strictly confidential. Any information that contains your name, telephone and address will be removed so that you cannot be identified.

Who should enter the study?

People with type 2 diabetes who are advised to start insulin treatment.

Who should not enter the study?

You should not participate in this study if:

- You do not have type 2 diabetes
- You have not been advised by your doctor to start insulin
- You are already taking insulin

What will be the benefits of the study:

(a) to you as a participant?

You will be able to contribute to the development of a practical tool that will help doctors and patients manage diabetes better by making informed decisions about insulin therapy.

You will be given RM 50.00 to compensate for your travel and time to attend the interview.

(b) to the researcher?

The researchers will be able to develop a decision-making tool that will be used by doctors and patients in making informed-choices about insulin therapy. With proper management of diabetes, many patients can live normal lives without the complications associated with diabetes.

The researchers will also be able to contribute to the larger body of medical knowledge in the field of diabetes, doctor-patient communication, and development and implementation of decision-making tools.

What are the possible drawbacks?

During the interview, sometimes, you may be asked questions about certain topics which are sensitive or may upset you. You can refuse to answer any questions which you feel uncomfortable with, or you can stop the interview anytime.

Can I refuse to take part in the study?

Yes. This study is voluntary and you can refuse to take part at any stage of the study.

Your treatment and follow-up at the clinic will not be affected if you refuse to take part in this study.

Who should I contact if I have additional questions during the course of the study?

Doctor's Name: Dr Ng Chirk Jenn Tel: 03-7949 2621

Research Coordinator's Name: Mr Lee Yew Kong Tel: 012-609 2018

APPENDIX I: HCP & Patient Participant Consent Form



Study Number: MEC Ref No 806.21

Participant Identification Number for this trial:

CONSENT BY PARTICIPANT FOR RESEARCH

Title of Project: Developing and pilot-testing an intervention for patients with type 2 diabetes who are making decisions about starting insulin therapy

Name of Researcher: Dr Ng Chirk-Jenn

Please initial box

1. I confirm that I have read and understand the information sheet dated _____ (version _____) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I agree to have my:

Interview recorded

Focus group discussion recorded

4. I agree to take part in the above study.

Name of Participant

Date

Signature

IC No:

Name of Person taking consent

Date

Signature

When completed, 1 copy for participant; 1 copy for researcher site file

DMIT_Consent Form Qualitative_HR/ Version 1/01112010

APPENDIX J: HCP demographic information form

- Name
- Age
- Sex
- Address
- Email
- Telephone number
- Workplace
 - () Private sector () Government sector
- Position
- Years of practice since graduation
- Postgraduate training
 - () Yes () No
- How many patients with type 2 diabetes have you seen in the past one month?

- Do you initiate insulin with your patients?
 - () Yes () No
 - If yes, how many of your patients are on insulin? _____

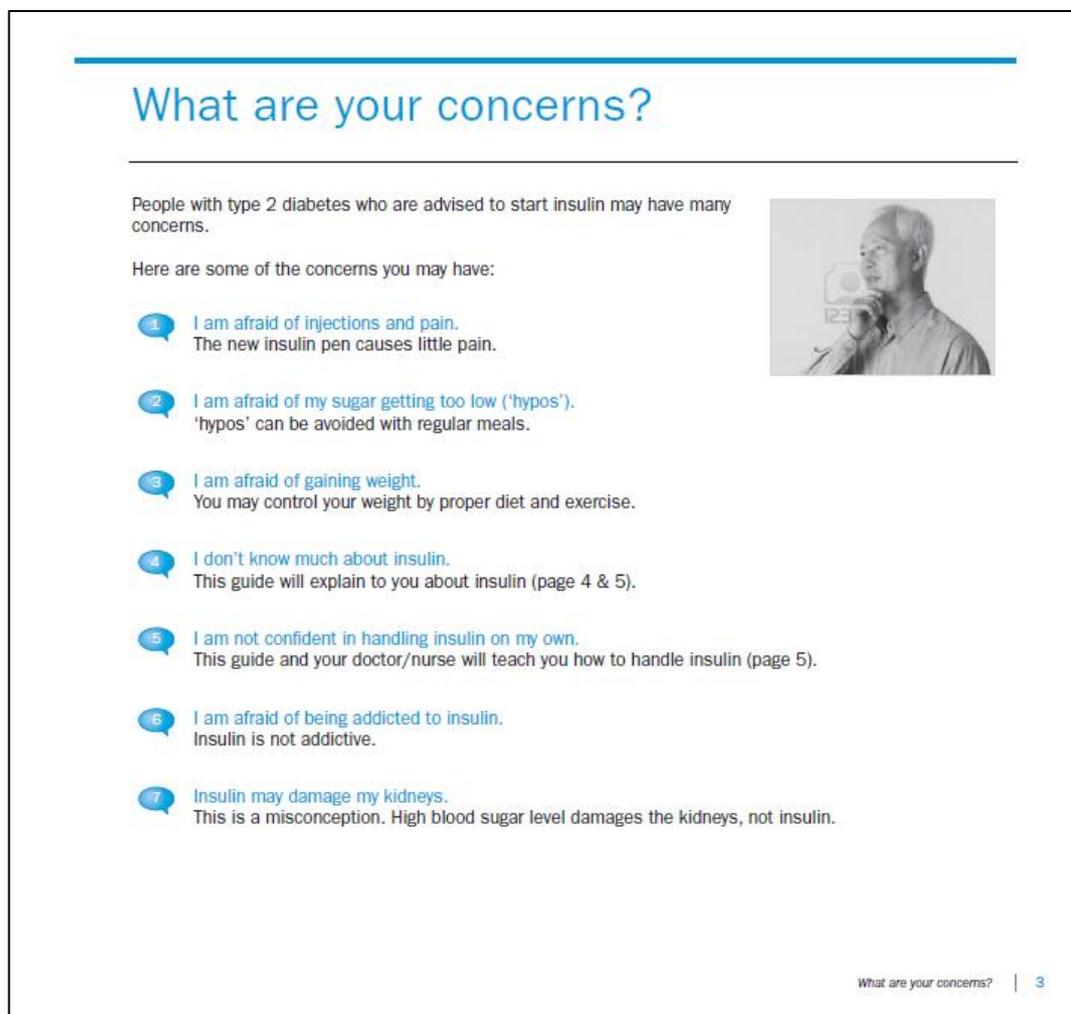
APPENDIX K: Patient demographic information form

- Name
- Age
- Sex
- Address
- Occupation
- Education
 - () None () Primary () Secondary () Diploma () Tertiary
 - () Postgraduate
- When were you first diagnosed with diabetes? _____
- Are you currently on insulin? Yes/ No

If yes, how long have you been on insulin? _____

APPENDIX L: ‘What are your concerns?’ section of the DMIT Insulin PDA

The section “What are your concerns?” on pages 3 and 4 of the PDA (DMIT Group, 2012) provides a list of concerns is based on actual patient concerns from interviews with patients and HCPs. This section entitled is the first page of content in the PDA. The section addresses patients’ possible concerns in order to engage patients on a personal level and to encourage them to read the PDA for themselves by directing them to content in the PDA which addresses their concerns.



What are your concerns?

People with type 2 diabetes who are advised to start insulin may have many concerns.

Here are some of the concerns you may have:

- 1** I am afraid of injections and pain.
The new insulin pen causes little pain.
- 2** I am afraid of my sugar getting too low ('hypos').
'hypos' can be avoided with regular meals.
- 3** I am afraid of gaining weight.
You may control your weight by proper diet and exercise.
- 4** I don't know much about insulin.
This guide will explain to you about insulin (page 4 & 5).
- 5** I am not confident in handling insulin on my own.
This guide and your doctor/nurse will teach you how to handle insulin (page 5).
- 6** I am afraid of being addicted to insulin.
Insulin is not addictive.
- 7** Insulin may damage my kidneys.
This is a misconception. High blood sugar level damages the kidneys, not insulin.

What are your concerns? | 3

Figure L.1 ‘What are your concerns?’ section of insulin PDA

Source: DMIT Group, 2012

What are your concerns?

- 8 Starting insulin means that my diabetes is very serious.
Insulin is started to control your diabetes and prevent it from getting serious.
- 9 I am confused. Different people tell me different things.
This guide provides information to clear your doubts.
- 10 I don't think my diabetes is that serious to need insulin.
You need insulin because your diabetes is not well controlled despite taking tablets.
- 11 I am worried that insulin treatment is too expensive.
The cost of insulin treatment varies. Your doctor will advise you accordingly.
- 12 I am worried that insulin is not halal.
All insulin in Malaysia is halal.
- 13 Will I feel better with insulin?
Yes, your diabetes symptoms will improve.

The following sections of this booklet will help to address some of these concerns. You may also want to clarify these concerns with your doctor or nurse before making a decision.

Figure L.1, Continued

References

DMIT Group. (2012). *Making Choices: Should I Start Insulin?* Kuala Lumpur: UM Press.

APPENDIX M: ‘Patient scenarios and relevant responses from the insulin PDA’

section in the DMIT HCP’s Guide to the Patient Decision Aid

Pages 12-14 of the HCP’s Guide provide a list of common issues faced during insulin initiation. These issues are based on actual patient quotes from the patient interviews. A sample response for HCPs as well as the section in the PDA which addresses these concerns is provided.

PATIENT SCENARIOS AND RELEVANT RESPONSES FROM THE INSULIN PDA		
<p>Often, at the point of decision to initiate insulin for patients, patients will raise a few issues that worry them. The following are real patient scenarios from our study. Suggestions are given on how to address patients’ concerns by using the PDA.</p>		
Issue	Patient quotes	Sample response
Fear of needle	<p><i>“It will be quite painful. Everyday pain like that I will die!”</i></p> <p><i>“The thing is I don’t like poking myself”</i></p>	<p><i>“Insulin pens have fine needles. Most people experience very little pain with the injections.”</i></p> <p><i>“You can consider asking family member to do it for you, but most patients have no problem injecting themselves after a while.”</i></p>
Interfere with lifestyle I) Lifestyle changes II) Inconvenience of Insulin administration III) Holiday (storage)	<p><i>“I have to leave for work at 5am. So morning is difficult for me. Night time is ok.”</i></p> <p><i>“Very inconvenient, when we want to go out everywhere. Like when I go abroad how to bring?”</i></p>	<p><i>“Injecting insulin does not take long when you are familiar with it. Insulin is given by injection using an ‘insulin pen’. For most people, one insulin injection at night is all that is needed. You can set the insulin dose you require by turning a dial on the insulin pen.”</i></p> <p><i>“You can travel with the insulin pen without needing special storage.”</i></p>
Believe that diabetes is not yet serious	<p><i>“I feel that my diabetes is not that serious. I want to observe for a while and see how it goes.”</i></p>	<p><i>“Your blood sugar level remains high despite taking tablets and following healthy diet and exercise. This is because your pancreas is not producing enough insulin. In the long term, if the blood sugar is not well controlled, you may get complications such as blindness, heart attack, stroke, kidney failure, nerve damage and losing your toes or legs. These complications will affect your quality of life.”</i></p>

Figure M.1 ‘Patient scenarios and relevant responses from the insulin PDA’ section

Source: DMIT Group, 2012

Issue	Patient quotes	Sample response
Wants to continue with tablets/lifestyle	<p>"I think I can control my own body. When I cannot control the sugar, it's because I don't do enough exercise. Now I have done enough exercise, I can control my sugar."</p> <p>"Doctor give me tablets is enough already."</p>	<p>"Your blood sugar level remains high despite taking tablets and following healthy diet and exercise. This is because your pancreas is not producing enough insulin. In the long term, if the blood sugar is not well controlled, you may get complications such as blindness, heart attack, stroke, kidney failure, nerve damage and losing your toes or legs. These complications will affect your quality of life."</p>
Cost of insulin	<p>"Injection is very expensive"</p>	<p>"The cost of insulin treatment varies (ref to trainer's guide pg XX). Your doctor will advise you accordingly."</p> <p></p>
Fear of addiction	<p>"I don't want to be a drug addict. Insulin is like a drug addict."</p>	<p>"Insulin is not addictive. Unlike recreational drugs, insulin is a hormone and is not addictive."</p> <p></p>
Scarring from injection	<p>"Every day injecting. I am worried it will leave a scar."</p>	<p>"Insulin pens have fine needles. Insulin is injected into the skin of your abdomen or the outer part of your thigh. So if you have injected at different sites as your doctor would have advised you, you will not have scars."</p> <p></p>
Concerns over origin of insulin	<p>"Is insulin from porcine sources?"</p>	<p>"All insulin in Malaysia is halal."</p> <p></p>
<p>Misconceptions</p> <p>I) Insulin cause pancreas to get lazy</p> <p>II) Insulin leads to complication</p> <p>III) Kidney failure due to insulin</p>	<p>"I thought insulin means very bad already lah"</p> <p>"If you don't use your leg for a while, you will have this thing called muscle atrophy. So I was thinking along those lines, the pancreas will go on vacation and become lazy if you use insulin."</p> <p>"Having insulin injection, after a while, the kidney will be damaged."</p>	<p>"This is a misconception. High blood sugar level damages the kidneys, not insulin. Insulin is a hormone produced by the body and it helps to remove sugar from the blood and store it in muscle and fat. In diabetes, the blood sugar level is high because the body does not produce enough insulin or it does not respond to insulin properly. Your blood sugar level remains high because your pancreas is not producing enough insulin in the long term, if the insulin is insufficient, your blood sugar will not be well controlled, and you may get complications such as blindness, heart attack, stroke, kidney failure, nerve damage and losing your toes or legs."</p> <p></p>

Figure M.1, Continued

Issue	Patient quotes	Sample response
Fear of side effects	"A few years ago, I was admitted and they started me on Insulin. At that time, every night I sweat and wake up, so I stopped. Now, I know my sugar is not controlled, but I don't want to have that feeling again."	"What you are describing is 'hypos'. Insulin may cause 'hypos'. This happens when you skip meals, are not eating enough or exercise too hard. You may feel dizzy, sweaty, cold, confused, shaky and weak. If this happens, you need to take something sweet such as sweets and sugary drinks. You can avoid 'hypos' by eating on time. If it happens too often, inform your doctor and he will adjust the insulin dosage, then you will not be having 'hypos'." page 6
Stigma	"Once we have to inject, other people will see it, there is nothing we can do. Everyone will know we have diabetes."	"Diabetes is a common chronic disease. So having diabetes is just like having other illnesses such as heart disease that we need to be treated to remain well. So you need not worry about how people look at it."
Want to try alternative medicine	"I have come across a traditional medicine in the form of a drink. I want to try that out first."	"There is a lack of scientific evidence of the benefits and harms of alternative treatment." page 11
Cannot understand doctor's advice	"Whatever the doctor says I can't understand. That's my problem."	"This decision aid will help you to understand about insulin. Please discuss any worries with me."

Figure M.1, Continued

References

DMIT Group. (2012). *Making Choices: Should I Start Insulin? Healthcare Professionals' Guide to the Patient Decision Aid*. Kuala Lumpur: UM Press.

APPENDIX N: Permissions to include manuscripts already published

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- 1) A qualitative study on healthcare professionals' perceived barriers to insulin initiation in a multi-ethnic population, *Yew Kong Lee, Ping Yein Lee, Chirk Jenn Ng, Published in BMC Family Practice 13:28 (Chapter 5.1)*
- 2) How can insulin initiation delivery in a dual-sector health system be optimised? A qualitative study on healthcare professionals' views, *Ping Yein Lee, Yew Kong Lee, Chirk Jenn Ng, Published as BMC Public Health 2012;12(1):313 (Chapter 5.2)*
- 3) An overview of patient involvement in healthcare decision-making: A situational analysis of the Malaysian context, *Chirk Jenn Ng, Ping Yein Lee, Yew Kong Lee, Boon How Chew, Julia P Engkasan, Zarina Ismail Irmis, Nik Sherina Hanafi, Seng Fah Tong, Published as BMC Health Serv Res, 13(1), 408. doi: 10.1186/1472-6963-13-408(Chapter 2.0)*

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