The Service Profit Chain Customer Value Equation – an application to Health Care

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Abstract

The assessment of value in health care is most often considered from a population perspective, using techniques such as burden of illness and economic evaluation. While necessary, such techniques are not sufficient to maximise health benefits from the perspective of the individual.

The Service Profit Chain is a model by which better outcomes for both service providers and customers can be achieved. A core component, the Customer Value Equation, describes the perceived value of a service to an individual as: outcomes plus perceptions of the quality of service delivery (process quality) / monetary fees plus access costs (such as time).

Based on a series of studies using real-world data, this thesis discusses applicability of these ideas to the health care environment, focusing on process quality and the relationship between clinicians and their consulting patients.

Patients must be equal partners in the decision-making process; where this occurred, outcomes were generally better. Engagement, empathy and good communication between clinician and patient were shown to be necessary factors to maximise outcomes. Disconnects between clinical and patient regarding disease severity, recognition of symptoms and side-effects, and perceived lack of communication were all associated with worse quality of life, lower satisfaction and lower adherence to treatment plans.

Policy implications arising from the research findings are discussed, including equipping clinicians to better understand the objectives and needs of their patients, improving clinical-patient communication, more widespread use of models of care such as Shared Decision Making, and developing tools to measure satisfaction with the care process.

This thesis demonstrates the advantages of real-world data regarding the measurement of process activity and outcomes, highlighting the value of any data source able to capture both clinician and patient perspectives of the same health care encounter. This allows assessment of value from the individual patient perspective which, together with population measures of value, will enable the maximisation of value of health care interventions.

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Without the opportunity to attend the Omnicom University Programme, I would never have had the idea for this PhD subject, since this is where I was introduced to the Service Profit Chain concept. It was whilst attending this Programme that I had the opportunity to discuss my PhD plan with Professor Leonard A. Schlesinger (Harvard Business School), who gave me so much food for thought and study material to consider as I was coming to decisions on the direction of the thesis.

I would also like to than the following for advice and encouragement at various stages: Dr Daniel Green, Dr Fritha Hennessy, Dr Victoria Davis, my brother Robert Piercy and not least Dr Cees Verboom (ex-Solvay Pharmaceuticals) who told me I needed to get a PhD in the first place!

This thesis is dedicated to my daughter Siobhan Chandler-Piercy.

Table of Contents

List of Tables

List of Abbreviations

AD	Atopic Dermatitis
AML	Advanced Myeloid Leukaemia
ARRA	The American Recovery and Reinvestment Act
CD	Crohn’s Disease
CVE	Customer Value Equation
DSP	Disease Specific Programme
DLQI	Dermatology Life Quality Index
EASI	Eczema Activity and Severity Index
EMA	European Medicines Agency
EPhMRA	European Pharmaceutical Market Research Association
EQ5D	EuroQol 5 - Dimension
EU	European Union
FACT-Leu	Functional Assessment of Cancer Therapy – Leukaemia
FDA	Food and Drug Administration
FLT3	FMS-like Tyrosine Kinase 3
GI	Gastro-Intestinal
GLP1-RA	Glucagon-like Peptide-1 Receptor Agonists
GP	General Practitioner
HAQ-DI	Health Assessment Questionnaire-Disability Index
HCRU	Health Care Resource Utilisation
HES	Hospital Episode Statistics
HIPAA	Health Insurance Portability and Accountability Act
HRQoL	Health Related Quality of life
IBD	Irritable Bowel Disease
ICER	Incremental Cost-Effectiveness Ratio

ICH-CAHPS	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
i-QoL	Incontinence Quality of Life
NCC	Nephrologists Communication and Caring (subscale of ICH-CAHPS)
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OAB	Overactive Bladder
OAB-Q	Overactive Bladder Questionnaire
OPCS	Office of Population Censuses and Surveys
OR	Odds Ratio
PI	Provision of Information (subscale of ICH-CAHPS)
PRF	Patient Record Form
PROM	Patient Reported Outcome Measure
PSC	Patient Self-Completion
QALY	Quality Adjusted Life Year
QCO	Quality of the Dialysis Centre and Operations (subscale of ICH-CAHPS)
RA	Rheumatoid Arthritis
RCS	Royal College of Surgeons
RCT	Randomised Controlled Trial
RWD	Real World Data
RWE	Real World Evidence
SDM	Shared Decision Making
SPC	Service Profit Chain
T2DM	Type 2 Diabetes Mellitus
UC	Ulcerative Colitis
UI	Urinary Incontinence

USA	United States of America
USRDS	The United States Renal Data System
WHO	World Health Organisation
WPAI	Work Productivity and Activity Impairment

1. Introduction and Background

1.1. Introduction

One of the key goals of administering or prescribing medications, and one of the aims of health care in general, is to improve the health of the population (Berwick et al., 2008). On an individual level, this can mean increasing life expectancy or improving Health Related Quality of Life (HRQoL); which on a population basis can imply maximising the health and welfare of the population (Tengland, 2006). However, since resources will always be scarce compared to the unlimited wants of the population and the potential capacity of health care to meet these wants (Gray, 2017), choices must be made regarding what treatment alternatives might be available, and in the context of an individual patient, which of these available treatment options might be the most suitable.

So, how are choices made? Firstly, interventions such as drug treatments need to work, otherwise they are at best, a waste of resources and at worst, harmful. Ensuring that interventions work and that they are safe is the focus of regulatory bodies such as the European Medicines Agency (EMA) in the European Union (EU) and the Food and Drug Administration (FDA) in the United States of America (USA). The concerns of these bodies therefore are primarily treatment safety and efficacy (FDA, 2019).

Even if ineffective and unsafe treatments are removed, there are still many more treatment possibilities than society can afford. The issue of choice and affordability is the primary concern of health care payers. A fundamental objective for payers is efficient resource allocation, since payers only have a limited budget to purchase health care for their populations. Their focus is to ensure that value for money is achieved, hence the need to ensure that treatments are not only effective but also cost-effective (Zannad et al., 2017).

Value, as a concept in health care, has been defined as “the equitable, sustainable and transparent use of the available resources to achieve better outcomes and experiences for every person” (Hurst et al., 2019 p8). But defining value is not straightforward and there appears to be no consensus on what “value” actually means (Neumann et al., 2018). One common theme relates to outcomes achieved for money spent (Porter, 2010), however this viewpoint does not make reference to how much money gets spent in total or who the money gets spent on. In addition to the technical efficiency of ensuring the most is achieved for a given budget, consideration of resource allocation and equity are also important.

Many value frameworks are focused on payers and decision-makers, although the techniques used can be very different regarding the scope. Economic evaluation, and in particular, the techniques of cost-effectiveness and cost-utility analysis are the most used metrics in health technology assessments, but these can have their limitations (Neumann et al., 2018). For example, Quality Adjusted Life Years (QALYs) may not cover all health-related factors important to a patient, or incorporate individual preferences regarding disease severity, access to health care, unmet need or equity. The perspective of the value assessment is also important, which can range from the narrow perspective of health care costs to the full societal impact of an intervention (Garrison et al., 2018), with the preferred perspective depending on the context in which the decision is being made. More broadly, as well as QALYs and costs, elements and definitions of value can also include productivity, reductions in uncertainty, the value of hope, equity, factors influencing patient behaviour and the underlying severity of disease/unmet need (Lakdawalla et al., 2018). Ultimately, however, these values all relate to value on a population basis, which is how payers make decisions. Assessments of outcomes and effectiveness of treatment are most often made using evidence derived from clinical studies using study population means. However, the mean outcome will not necessarily reflect that of a given individual within that population, some will have better outcomes and others will have outcomes which are not so favourable. But decisions such as licensing of health technology and on cost-effectiveness will be made using population means.

There is another way of considering value, one which focuses on the individual sense of value that a patient receives as a result of the treatment provided. This value relates to not only how well the treatment works in that individual, but also to the perception of the value of the treatment from their perspective. One method of considering value to an individual is the Service Profit Chain (SPC). The SPC is a business model developed by researchers from Harvard University (Heskett et al., 1997). The basic principles of the model imply direct and strong relationships between the perceived value of goods and/or services delivered, customer satisfaction, and the capability of the service provider to provide those goods or services (Heskett et al., 1994). The SPC is a model which is applicable to service industries in general as it underlies the basis of customer-provider interaction, with the best results obtained where the value derived by customers results in customer satisfaction.

1.2. The Service Profit Chain

The SPC has been developed as a model by which better outcomes for both service providers and customers can be achieved (Heskett et al., 1997). In a general context, good outcomes for service providers mean profits or growth, which is achieved through satisfied and loyal customers (Heskett et al., 1997). A key element of loyalty is customer satisfaction, which in turn is linked to the perceived value to the customer of the service provided. It also states that the ability of a service provider to deliver value is linked to the capability of the employee and their own job satisfaction (Heskett et al., 1997, Heskett et al., 2003).

Heskett et al (1997) summarised the SPC as follows:

1. A primary driver of profitability is client loyalty and viral behaviour. Retaining existing customers is both easier and more profitable than having to chase new customers.
2. Loyalty is influenced by client satisfaction. A satisfied customer will be a loyal customer.
3. Satisfaction results from the true value delivered to clients. Customers seek results, not just products or services. Value is achieved by satisfied, productive and loyal employees.
4. Employee satisfaction is determined by the capability to deliver what the customer values as well as by technical skill.

The end goal though for health care services is improved patient health outcomes; although in commercial health systems, growth and profit are also aims of service providers. Efficiency of service delivery and value for money are also important in health care. All these aims can be best achieved if the patient is satisfied with the result of the interaction with their service provider.

Integral to the SPC model is the value provided in the mind of the client, or patient. This was set out by Heskett et al (1997) as the Customer Value Equation (CVE):

$$\text{Value in the mind of the client} = \frac{\text{Results} + \text{Process Quality}}{\text{Client Access (Relationship) Costs} + \text{Fees}}$$

From Heskett et al. The Service Profit Chain. The Free Press 1997

Where:

- Results: customers desire results, not products or services (health; not health care).
- Process Quality: the way in which the service is delivered. Important factors include dependability, responsiveness and empathy. Whether the service provider understands the needs of the customer is also important.
- Client Access (Relationship) Costs: includes convenience, time spent, including waiting time, and ease of access (technological, geographical).
- Fees: the monetary cost of the service.

The CVE relates directly to value in the mind of the consumer. In the context of health care, the CVE can be characterised in the following way. Results, naturally, relate to the success of the treatment, the change in health in the physical or psychological health of the patient. Process Quality is the way in which the service is provided and ties in with the user experience and the confidence the patient has in their service provider and in the care environment. It will therefore include the interaction between service provider and service user, the clinician and the patient. Acquisition costs relate to issues associated with accessing health care. These include elements of direct or indirect cost to the patient other than the direct cost of the treatment or medication such as the time, convenience, effort and other non-monetary costs of arranging and attending the consultation, carrying out any follow-on actions or making any recommended lifestyle changes. Fees are the monetary costs paid by the individual – but from a societal perspective, health sector costs, paid by a tax-based health care system such as in the National Health Service (NHS) or by a health insurer, can also be included.

Thus, in the mind of the patient, the value equation can be re-formulated as follows:

$$\text{Value in the mind of the patient*} = \frac{\text{Health Gain + Delivery Experience}}{\text{Access Issues + Out of Pocket Costs}}$$

There is no reason therefore why these SPC principles should not work just as well in the health care environment (Kravitz, 2010) as they would in any other service sector such as financial, transportation or telecommunication. In health care, the objectives are health gain, or improvement in health outcomes (although in private health care systems the incentives of profit and growth for service providers will still apply). To obtain positive outcomes, and to maximise the value of the treatment plan to the patient, clinicians must make good decisions, but patients must also play their part by following treatment plans and carrying out any other recommended actions. This is most likely if the patient has a good experience regarding the delivery of the service and is satisfied with the encounter. The importance of satisfaction suggests that delivery of good care is broader than the technical aspects of diagnosis, management and treatment: it must also encompass the buy-in of the patient (Sharan et al., 2016). Value to the individual is therefore perceived to be more than the relationship between costs and outcomes (however outcomes are defined and whatever aspects of cost are included); the quality of the patient experience must also be taken into consideration given the role this can play in satisfaction, engagement and adherence.

1.3. Aims of the thesis

In this thesis I will focus on one particular aspect of the Service Profit Chain: the Customer Value Equation. Other aspects of the SPC, such as customer loyalty and employee capability will not be discussed in this thesis.

The aim will be, in the context of the CVE, to demonstrate the importance of connect/disconnect between patient and physician, communication and patient engagement and their relationship to outcomes, satisfaction and adherence. This is integral to the process quality element of the Value Equation.

Using evidence from studies of real-world data, I will argue that where there is a disconnect between physician and patient, this can result in lower satisfaction, lower engagement and less favourable health outcomes. This means that whatever health care resource allocation decisions are made, based on economic evaluation or other criteria, wherever there is a disconnect the value associated with those decisions may not be realised by individual patients. This means that the value of the intervention to society will not be maximised.

It should be noted that while the CVE, and indeed the Service Profit Chain as a whole, was developed in North America and that while the application of the model has most generally been applied as a business model, this thesis will discuss the applicability of these principles to the National Health Service (NHS) in the United Kingdom.

1.4. Structure of the thesis and papers to be presented

During his career, the writer has published over 50 papers in Health Economics and Outcomes Research which focus on value, HRQoL and patient satisfaction (see Appendix 1 for full citation list). The eight papers presented in this thesis, selected from the 41 publications available at the time of enrolment, will explore elements of the SPC relating to the CVE. These have been selected as together they argue that in order for value to be maximised then real world practice must consider individual as well as population perceptions of value; and also provide evidence of how sub-optimal outcomes may be observed should real world practice not be consistent with SPC principles regarding value. The writer has authored other papers that could have also been included in the thesis. However, the aim was to select papers that covered different aspects of the SPC and in particular to include papers that related to perceptions of value either from a system perspective or from an individual perspective. It was also the intention to include evidence based on a wide variety of disease areas to show that SPC thinking is consistent regardless of condition and setting. The eight papers finally selected are shown in Table 1 below.[1]

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[1] It will be noted that the writer of this thesis is not the first or senior author on the papers presented. The reasons for this are that all but one of these papers were developed in partnership with a pharmaceutical company. The pharmaceutical company will generally want a “Key Opinion Leader” physician included; the “rules of engagement” are generally that the pharmaceutical client mandates that such Key Opinion Leaders are given positions of first and/or senior author regardless of contribution. Data vendors, such as the writer’s employer, Adelphi Real World, often have to accept places in the middle of the author list (and in some cases can be excluded altogether regardless of contribution due to pharma company policies).

Table 1. Papers presented in this thesis

Paper, in order of presentation	Chapter/Section
Tang DH, Colayco DC, Khalaf KM, **Piercy J**, Patel V, Globe D, Ginsberg D. Impact of urinary incontinence on healthcare resource utilization, health-related quality of life and productivity in patients with overactive bladder. BJU Int. 2014;113(3):484-491.	Chapter 3 Section 3.2
Ryan J, **Piercy J**, James P. Assessment of NICE guidance on two surgical procedures. Lancet. 2004 May 8;363(9420):1525-6	Chapter 3 Section 3.3
Wei W, Anderson P, Gadkari A, Blackburn S, Moon R, **Piercy J**, Shinde S, Gomez J, Ghorayeb E. Discordance Between Physician- and Patient-Reported Disease Severity in Adults with Atopic Dermatitis: A US Cross-Sectional Survey. Am J Clin Dermatol. 2017 Dec;18(6):825-835	Chapter 4 Section 4.2
Horvath Walsh LE, Rider A, **Piercy J**, Pike J, Wilson S, Pandya BJ, Medeiros BC. Real-World Impact of Physician and Patient Discordance on Health-Related Quality of Life in US Patients with Acute Myeloid Leukemia. Oncol Ther. 2019;7(1):67-81	Chapter 4 Section 4.3
Peterson S, **Piercy J**, Blackburn S, Sullivan E, Karyekar CS, Li N. The multifaceted impact of anxiety and depression on patients with rheumatoid arthritis. BMC Rheumatol. 2019 Oct 28;3:43.	Chapter 4 Section 4.4
Sullivan E, **Piercy J**, Waller J, Black CM, Kachroo S. Assessing gastroenterologist and patient acceptance of biosimilars in	Chapter 5 Section 5.2

It will also be noted that during this thesis the writer draws on and cites other published papers in which he has been an author as supporting evidence or which cover related themes. A full list of publications is presented in Appendix 1.

ulcerative colitis and Crohn’s disease across Germany. PloS One. 2017 Apr 14;12(4):	
Sikirica MV, Martin AA, Wood R, Leith A, **Piercy J**, Higgins V. Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes. Diabetes Metab Syndr Obes. 2017 Sep 29;10:403-412	Chapter 5 Section 5.3
Wood R, Paoli CJ, Hays RD, Taylor-Stokes G, **Piercy J**, Gitlin M. “Evaluation of the CAHPS-ICH Hemodialysis Survey.” Clin J Am Soc Nephrol 2014;9:1099-1108	Chapter 6 Section 6.2

The writer’s role in these papers has been varied, but in all the papers the writer had responsibilities for designing the analysis, interpreting the results and writing/editing the papers. Details of contribution to each paper are included in Appendix 2. As explained in the footnote on the previous page, the author order itself is not reflective of overall contribution but tends to be a “political” decision made by the funder of the paper.

The papers presented in this thesis will demonstrate that the nature of value needs to be extended beyond the notion of traditional economic evaluation. Techniques such as economic evaluation deal with value from a population perspective, whilst the CVE concentrates on individual perceptions of value. It will be shown that economic evaluation is a necessary but not a sufficient condition to capture the perceived value of a health care intervention to a patient and by implication, to a population. Indeed, the first two papers, presented in Chapter 3, (Tang et al., 2014, Ryan et al., 2004) take a population perspective on the assessment of the value of specific existing or potential new health care interventions. They focus respectively on assessments of burden of illness and the quantification of unmet needs and on the impact of guidance based on economic evaluation developed by the National Institute for Health and Care Excellence (NICE[2]). In these papers, process quality and relationship costs are not considered, implying techniques such as burden of illness and

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[2] Formerly the National Institute for Clinical Excellence

economic evaluation are necessary but not sufficient for the value of an intervention to be assessed from a patient-centric perspective.

The next five papers in Chapters 4 and 5 focus on value from the perspective of the individual. They consider other aspects of the value equation, the process quality of the encounter in terms of shared understanding (or not) between physician and patient; and to some extent the acquisition cost in terms of time, effort and lifestyle changes to the patient. An essential aspect of process quality is the physician-patient interaction.

The three papers presented in Chapter 4 (Wei et al., 2017, Horvath Walsh et al., 2019, Peterson et al., 2019), explore the prevalence and nature of disconnects between patients and physicians and the consequent impact on health outcomes. The first paper (Wei et al., 2017) considers disconnect from an overall disease perspective, assessing the incremental effects on HRQoL in situations where the patient rates their disease as more severe than the physician. The degree of concordance between physical symptoms experienced and reported by the patient and the awareness of these same symptoms by their physician is assessed in the second study (Horvath Walsh et al., 2019) whilst the third paper (Peterson et al., 2019) addresses the issue of invisible symptoms. All these papers assess the incremental effect of a lack of recognition of the presence and importance of disease severity and symptomatology on HRQoL.

The two papers presented in Chapter 5 describe examples where divergence from the SPC model is associated with patient dissatisfaction and treatment discontinuation. The first paper (Sullivan et al., 2017) explores the consequences of a lack of engagement with the treatment alternative and its effects on satisfaction and perception of outcomes; the second paper (Sikirica et al., 2017) discusses differences between patients and physicians in perceptions and relative importance of, treatment side-effects in relation to dissatisfaction and discontinuation of medication.

Chapter 6 returns to the central theme of process quality and the CVE. If value is to be increased through enhancing the patient experience, there will need to be a way of measuring it. The final paper presented (Wood et al., 2014) discusses the properties of a method of achieving this through measuring the quality of the interaction between service provider and service user, showing that if such techniques are employed, better quality of care and better outcomes can be achieved.

The final two Chapters pull together the themes covered in the thesis. These discuss the lessons that can be learned from the research presented, suggest areas where further research is needed and draw out learnings from a policy perspective.

1.5. Data Sources used in the papers presented in this thesis

Each of the papers draws on Real World Data (RWD). RWD relate to the health of patients and also to the delivery of healthcare in routine clinical practice. They can be obtained through observational or non-interventional studies but RWD can also include pre-existing data collected for administrative purposes, medical records and claims databases (Anderson et al., 2023).

The value of RWD in assessing the application of the SPC to health lies in the nature of the data themselves. RWD, by definition, measure routine encounters between patients and their physicians, and it is the encounter between patient and physician which is at the heart of the CVE. It is also necessary, if any conclusions regarding the applicability of the SPC to health care are to be generalisable, to have large sample sizes from which conclusions can be drawn, ideally in different health care systems and across different disease areas. This rules out the possibility for the author to have undertaken specific primary data collection to address this topic, as sample sizes would have been small and localised so would be difficult to generalise.

Seven of the eight papers used data drawn from the Adelphi Disease Specific Programmes (DSPs). The strength of the DSP for real world research is that, using evidence collected directly from both clinicians (typically physicians) and patients, each DSP provides a holistic contemporary view of disease management and treatment patterns, independent of clinical practice guidelines or protocols. It is an independent data source, owned by Adelphi Real World, so not beholden to any pharmaceutical company. Data are not collected with any pre-set hypothesis in mind.

Each DSP is a large, multinational surveys of physicians and their patients presenting in a real-world clinical setting (Anderson et al., 2008). The validity of the DSPs in comparison with large scale epidemiological data (Babineaux et al., 2016) and the consistency of the DSP between successive waves of the same DSP have been established (Higgins et al., 2016).

Data are captured as follows:

- Physicians complete a record form (PRF) for consecutively consulting patients who visit them for routine care during the data collection period. This contains detailed questions on patient demographics, their clinical status including disease severity and symptoms, test results (where these exist and are readily available), treatment history including reasons for choice of therapy, drug switches and discontinuations with reasons, consultation history, hospitalizations, concomitant conditions, physician perceived satisfaction with disease control and physician perception of patient knowledge and engagement with their disease.
- The same patients are then invited to fill out a self-completion form (PSC), providing information on demographics, reasons for consultation, perceptions on disease severity and symptoms, treatment satisfaction, attitudes and feelings toward their condition. They also complete validated Patient Reported Outcome Measures (PROMs) for example the EQ-5D (EuroQol, 1990) and Work Productivity and Activity Impairment (WPAI) questionnaires (Reilly et al., 1993) together with disease specific PROMs according to their condition and provide evidence regarding the overall impact of their disease on their lifestyle.

Each DSP complied with relevant legislation at the time of data collection, including as appropriate the US Health Insurance Portability and Accountability Act 1996 (HIPAA, 1996), the Health Information Technology for Economic and Clinical Health Act legislation (ARRA, 2009) and in accordance with the European Pharmaceutical Marketing Research Association guidelines (EPhMRA, 2019). All physicians and patients were given information about the research and consented to participate on the understanding they would be providing information which would be anonymized and aggregated prior to analysis and publication.

The specific value of DSP data regarding the objectives of this thesis relate mainly to the fact that data are captured from both physicians and patients. The ability to match each PSC to a physician completed form regarding the same patients is the most important factor. This is because there are a number of themes concerning perception of the condition, symptoms and satisfaction about which both the physician and the patient are asked the same question, thereby allowing responses to be compared. Only through this data collection methodology can differences in the perception of the condition, symptoms or satisfaction be identified.

In addition, the collection of many variables results in the DSP being a rich source of data and therefore enables many different questions to be addressed. The data collection methodology and the two surveys (PRF, PSC) are identical in each country included, other than minor differences associated with population ethnicity and the method of payment for health care services (insurance, etc.). This is important since it is possible to combine, analyse and compare data across countries regarding treatment patterns, management practices and PROMs.

The remaining paper (Ryan et al., 2004) drew upon Hospital Episode Statistics (HES) data (NHS, 2019a), a dataset of hospital-based activity in the whole of England. HES are collected for administrative purposes; the primary aim being to record and monitor hospital activity in the NHS in England, although more recently outpatient and accident and emergency attendances have also been included. As well as providing evidence for health services planning, the data can also be used for research purposes, for example understanding patterns of disease (Thwaites and Piercy, 2004, Sweiss et al., 2022) , assessing geographical variations in health care provision (Palser et al., 2018), and estimating the natural history and burden of disease (Harris et al., 2022).

Data contained in HES include demographic and geographic information; clinical information relating to diagnoses and procedures undertaken; and administrative information such as dates of admission, discharge and lengths of stay. While HES data were not specifically designed for health services research, the wealth of variables and representativeness of the data (the whole of England is included) makes the data a perfect source of information for assessing hospital-based activity in these countries. Given the variables collected and their definitions remained unchanged over the period covered in the research presented, HES provided the ideal data source for the longitudinal analysis undertaken. An important limitation of HES is that it does not cover primary care, but for the question addressed in the research presented, this is not a limitation as primary care data are not relevant.

1.6. Summary

This Chapter has introduced the SPC, the customer value equation and their application to service industries. It has also introduced the papers to be presented in this thesis, and the data sources used in the papers have been described. The next Chapter, the literature review, focuses on the application of the SPC in the context of health care. Two specific case studies of the SPC in health care specific settings taken from the literature are discussed homing in on the customer value equation and process quality. The review will also include more general evidence relating to process quality, patient-physician discordance or disconnects, the implications of disconnect on satisfaction and adherence to medication, and the importance of patient engagement and empowerment.

2. Literature Review

2.1. Introduction

This Chapter reviews the published literature of relevance to the SPC concept in health care. The review consists of three sections. The first two sections cover literature and case studies relating directly to the SPC in the field of health care. The next section is more general, covering related issues such as the existence and consequences of disconnects between physician and patient, the importance of patient engagement and empowerment and the relationship to adherence and to outcomes of care. Finally, since the papers presented all make use RWD, the literature review will discuss the role RWD can play in providing evidence concerning the delivery of clinical practice and the outcomes of treatment alternatives.

2.2. The Service Profit Chain in Health Care

Modern medicine has always been a service industry. The delivery of good care extends beyond the purely technical aspects of selecting the correct management approach, performing a complex procedure or prescribing the right drug (Sharan et al., 2016). Managing relationships with customers (patients) is becoming increasingly important as more emphasis becomes placed on value in health care and not just from the perspective of cost-effectiveness. A key element of value, one which is core to the SPC, is the patient experience. While this is essential in a commercial environment where providers have to compete for business, it is also being recognised as an essential component of value in publicly run health care systems such as the NHS in the UK (Hurst et al., 2019). Clearly defined and well-implemented processes leading to enhanced patient experiences can make positive differences in any health care practice environment (Fibuch and Ahmed, 2017), but also by inference, in any health care setting. On the other hand, negative experiences such as nonchalance and disrespect can negatively affect care outcomes (Wessel et al., 2012). But what is the patient experience? It reflects events in the patient journey and encompasses not only satisfaction and engagement but also the setting and meeting of appropriate expectations (Wolf, 2014). These are important concepts in the context of this thesis.

It is also important to consider the nature of value itself. In the context of decision-making regarding the availability and reimbursement of treatments and health care interventions in general, value is considered to be the relationship between quality and cost where quality reflects patient outcomes and cost is the cost of providing the treatment and associated diagnostic, testing and monitoring services (Ken Lee et al., 2016).

Value can be defined from different perspectives (Landon et al., 2021). It can be as broad as ensuring the right people access the right care (Porter, 2010), or as well defined as individual health outcomes achieved per unit of currency spent (Gray, 2017). But, although this latter definition pays lip service to value on an individual basis, the decisions taken about offering a treatment are still taken on a population basis since reimbursement decisions are made in the light of expected benefit using population based measures of effectiveness – which in the case of clinical studies consists of the average benefit (however measured) across all the study participants. True value to the individual will take into account not only the expected clinical value of the treatment (which is at least to some extent uncertain at the outset of treatment), but in the opinion of the author, the individual circumstances of the person, their perceptions of the care offered, satisfaction with the care provided and the care process itself. It is this concept which will be the lens through which value will be considered in this thesis.

Intuitively physicians have always recognised the value of the physician-patient relationship and the correlation between this and a good outcome for the patient (Belasen and Belasen, 2018). In a competitive environment, such as the USA, physicians have to compete for patients so need to differentiate themselves through the delivery a service beyond that of the health outcomes of the treatment (Sharan et al., 2016). Understanding the principles of customer service that underpin the SPC can help physicians succeed in the transition to a pattern of care which optimises the value for the individual patient as well as for the health care system, even in non-competitive environments.

Few papers have directly studied the SPC in a health care context. One such study was conducted in China (Lei and Jolibert, 2012). 630 inpatients from 6 major hospitals in Shanghai completed surveys to assess the relationships between perceived service quality, patient satisfaction and subsequent loyalty to the provider. Loyalty was defined in the paper as whether based on their experience the patient would recommend this hospital to other people. Using structural equation modelling to test several theoretical models regarding the relationship between service quality, patient satisfaction and loyalty, the authors found the strongest association corresponded directly with the directionality of the SPC framework in that patient satisfaction is a result of perceived quality of service and that it drives patient loyalty. The model emphasized the distinction between quality and satisfaction, demonstrating that quality was indeed an antecedent of satisfaction. Other models, such as quality and satisfaction simultaneously influencing loyalty, or with satisfaction driving quality and loyalty, were not supported by the evidence. The driver, therefore, is process quality. Indeed, when outcomes and fees are similar across providers, then process quality can be a big differentiator in the choice of provider, particularly in environments where patients have the ability to choose.

There are important limitations to the Chinese study. Firstly, it was conducted in a specific setting, thus limiting generalisability. It was also conducted while the patients were still receiving care, so not only may patients have been a little guarded in their answers, but also the final outcome of care may not have been known. By removing outcomes though, the research can focus directly on process quality. Another important limitation is that all the subjects were inpatients, whereas most health care is provided in an outpatient and primary care setting. Further research in outpatient settings and in other health care systems would be instructive to confirm the generalisability of the relationship identified. It should also be noted that the model did not consider all aspects of the value equation, effectively assuming similar outcomes and costs across institutions. Should significant differences in either have been observed, then the results may differ – the best in-hospital user experience may not correlate with the best outcomes. However, the model itself does provide valuable insights regarding the relationship between process quality and satisfaction. The examples in the next section discuss two other case studies where SPC principles have been applied.

But before discussing these case studies, a couple of important limitations need to be discussed regarding the SPC. Firstly, the SPC is a theory concerning relationships between employee capability, customer satisfaction, loyalty and profitability. It suggests that successful and profitable service providers are those which foster loyalty, but assumes that customers i.e. patients, can change service provider. But this is not a feature of the health care system in the UK. So, unlike the scenario described in the Chinese study described above, in the UK the applicability to assess this aspect of the SPC model may be limited, but this is outside the scope of this thesis.

The CVE implies that the method of promoting loyalty and profitability (health gain) is to maximise the perceived value of the service offered. The CVE states that perceived value is based on results, process quality, access costs and fees (Heskett et al., 1997). But in health care, results, unlike acquisition of goods or services, are associated with uncertainty. While the mean outcome (or result) from treatment can be assessed on a population level, there is uncertainty therefore regarding the outcomes or perceived value for each individual patient.

This makes the theory hard to test on an individual patient basis. The perceived value of a health care intervention would be determined overwhelmingly by the effectiveness of the intervention, and this is often surrounded in uncertainty. While other elements of the CVE do not have issues surrounding uncertainty, their effects may be relatively small in comparison. No amount of empathy, understanding and ease of access to a service will compensate if the treatment itself is ineffective.

However, one reason for medication ineffectiveness is a lack of adherence to the treatment plan, and this is something that can be affected by the quality of the health care encounter, as will be discussed in the literature review in Section 2.4 and which will be explored further in the papers presented in Chapters 4 and 5. Furthermore, process quality can be measured, the paper presented in Chapter 6 discusses one method of measuring aspects of process quality (and also factors affecting access to services) which may be important to patients. So, on a population basis, if an intervention to improve process quality is introduced and measured, its effects on adherence can be tested, and as long as the sample is sufficiently large, effects on population outcomes can also be measured. Therefore, although the CVE is concerned with perceived value on an individual basis, testing the theory would need to be done on a population basis to account for uncertainty associated with the effectiveness of the medical intervention itself.

The CVE focuses on perceived value as a function of result, process quality, acquisition cost and fees. But alternative measures of value exist. Indeed, “well-being” is a concept of value that has been suggested as a modifier to the SPC framework (Hogreve et al., 2017). The nature of well-being though is not easy to define and can include emotional stability, optimism, resilience self-esteem and as well as happiness and health (Ruggeri et al., 2020). This can make well-being is difficult to assess, and consequently is not widely used in health care decision-making due to a perceived lack of sensitivity (Brazier et al., 2017). Also, well-being does not resolve the problem of uncertainly in the outcome of a treatment so will not resolve the problem of uncertainty in estimating perceived value on an individual basis.

The author's modification of the CVE from "result" to "health gain" does not resolve the limitation regarding uncertainly, but the concept of health gain is at least measurable and comparable using generic measures of health such as the SF-36 (Ware and Gandek, 1998) and the EQ-5D (Rabin and de Charro, 2001). Such measurement of health gain is essential to assess the effectiveness of any intervention designed to improve process quality in a health care system such as the NHS so would be necessary to empirically test the CVE aspect of the service profit chain.

2.3. The Service Profit Chain in action

Two well documented examples of the SPC in action are the Shouldice Hospital (Canada) and Athenahealth (USA). There are others, but these examples represent case studies of SPC principles in hospital and community settings respectively. Both case studies focus on the customer value equation. The first demonstrates the relevance of process quality whilst the second considers user experience regarding ease of access to services and the implicit hidden costs of health care. In both cases, specific costs and clinical outcomes are not discussed in detail; the focus is on the experience of the patient and the perceived value of the services provided.

Both these examples of the SPC in action are drawn from North America. Owing to the nature of health care in the USA (and to some extent in Canada) there is a greater imperative for care providers to compete for patients. To remain sustainable (and profitable), providers need to provide a customer-friendly service, an essential element in the SPC. This has resulted in the SPC model being assessed in these environments. In the UK, service providers do not have such incentives; since patients are required to register with a single provider (GP Practice) to access health care and these providers do not compete for patients. Therefore, although the patient perspective is still important in the UK, to the best of the author's knowledge, provider/patient interactions have not been studied in the specific context of the SPC.

2.3.1. Shouldice Hospital – providing value through enhancing patient experience

The Shouldice Hospital, based in Ontario, Canada, claims to be the world's leading centre of excellence for hernia repair, to quote from the hospital website [About Shouldice Hernia Clinic | Hernia Repair and Treatment Hospital Canada] a "99% lifetime success rate for repairing primary hernias" (Shouldice, 2020). The Shouldice Hospital specialises in one procedure, external abdominal hernias performed on uncomplicated non-obese patients, undertaken using the "Shouldice method" (Shouldice, 2010), a novel technique that has achieved comparable outcomes to standard mesh-based methods (Kockerling et al., 2018, Amato et al., 2012). The key principle in the Shouldice method is to encourage movement as soon as the procedure is completed. The hospital ethos and environment is designed to allow this (Shouldice, 2020). As well as contributing to earlier return to normal activity, this movement encourages patients to mingle, to support each other establishing a peer-to-peer support network based on a shared positive experience (Davidow and Uttal, 1989). The "after sales service" - annual check-ups - is free, coinciding where possible with reunions for past patients. These factors, together with a lower risk of any recurrence of the problem requiring subsequent surgery (Malik et al., 2016a), contribute to the lasting positive experience provided by the Shouldice hospital and high perceived value of the service, which is a key factor in their willingness to refer others, a textbook example of SPC viral marketing principles (Heskett, 1983).

Regarding service provision, staff experiences are also positive, workload is sustainable and peer-to-peer support, development of individual technique, continuous learning and regular appraisals are all encouraged. These elements result in capable and satisfied staff, a necessary precursor to high customer satisfaction and good clinical outcomes (Malik et al., 2016b).

The Shouldice experience demonstrates the applicability of the SPC model to a health care environment in that it links user experience to perceived value and outcomes. However, one of the reasons why Shouldice is so successful is that it focuses on a single elective procedure, a luxury not generally afforded in most health care settings. Moreover, no evidence is available concerning how other (competitor) hospitals perform regarding satisfaction and outcomes, limiting the ability to draw definitive conclusions about the comparative benefits of the Shouldice experience. Although the generalisabity of the Shouldice may be limited, certainly in primary care environments; the core principles of staff satisfaction, patient engagement and the provision of positive care experiences are likely applicable to any health care setting. The next example discusses the same core principles in a primary care setting.

2.3.2. Athenahealth – The value of Patient Engagement

Athenahealth provides network-enabled services for point-of-care mobile apps, marketing their services primarily to physician networks in the USA. The offer is based on the premise that the most successful organisations are those who can best to understand the behaviour and expectations of patients as customers. Three aspects of care promoted by athenahealth appear to align with the SPC model: enhancing provider capability, driving patient retention through improving patient experience and satisfaction and increasing patient engagement (athenahealth, 2014).

Provider capability drives service value and customer loyalty. Physicians performing at their best are most likely to be engaged, satisfied and productive (Clain and Novotny, 2017). Such physicians are most likely to empower patients to achieve optimal outcomes (Schlesinger, 2017a, Schlesinger, 2017b). A key element is sustainable job design, provision of feedback, continuing education and training; attributes which should be strived for in any health system.

An essential marker of success for service providers in the USA is recruiting and retaining customers. While goals of profitability do not apply in socialized health systems, SPC principles of maximising process quality whilst minimizing access/relationship costs are relevant in all settings. Providers must provide service value, offering high quality patient experiences such as fast, simple and convenient service - factors becoming increasingly important in the health care industry, with new entrants such as Amazon accelerating this trend through the use of mobile technology.

Associated with this is enhancing patient engagement. To promote engagement, athenahealth provides automated messages to patients, an on-line portal, call support when needed to make/cancel appointments and outreach campaigns designed to promote positive health seeking behaviour and health lifestyles. But why is active patient engagement so important? Patients who are passive are three times more likely to have unmet medical needs and twice as likely to defer care (Hibbard and Cunningham, 2008). Engaged patients were also more likely to rate their self-perceived health status as very good or excellent. Transforming patients from passive into active participants with sufficient knowledge to fulfil their responsibilities is a way to enable the best health outcomes possible to be achieved (Schlesinger and Fox, 2016).

However, for patients to gain access to the full range of services provided through the athenahealth platform, patients must have access to, and be confident in using, the technology required such as computers and handheld devices. Virtual models of care therefore may not be ideal for every patient and challenges such as language, literacy, access and willingness to embrace new technologies have been highlighted (Jonnagaddala et al., 2021). In particular, the so-called digital divide may have exacerbated inequalities in access to health care (Ramsetty and Adams, 2020). In such circumstances, the costs of accessing health care may become too great for some patients to bear in terms of both paying for devices and a lack of the skills or education necessary to use them appropriately (Watts, 2020). Making the user experience as easy and friendly as possible will be essential to driving value on an individual perspective whilst enabling access for all will be fundamental on a population basis. The philosophy embodied by organisations such as athenahealth are potential models for all health care delivery systems, although care must be taken to ensure that people do not get left behind in the drive towards technology.

It is also likely that concerns around privacy exist, particularly in disadvantaged or ethnically diverse communities. Participants may be reluctant to share data or to use mobile health apps in certain circumstances as they do have concerns about such data potentially being used for targeted advertisements, becoming available to other third parties (potentially insurers) or even becoming publicly available (Grande et al., 2021). Such obstacles will need to be overcome before such a model can be effective for all.

The athenahealth experience has taken on a much greater relevance in the last few years. The COVID-19 pandemic has changed the way health care services are accessed and how health care is provided. For example, the use of digital health interventions and telemedicine has increased dramatically because of the need to reduce the risk of contagion (Schlieter et al., 2022). Physicians have changed prescribing habits (Ladani et al., 2020), reduced in-person consultations (Rose et al., 2021) and changed the way that health care is delivered in general. Such changes are, in part, likely to become the “new normal” (Drake et al., 2022).

The two case studies presented in this Chapter have demonstrated that principles of the SPC model can be applied in the health care environment and can result in good patient outcomes. Such principles can be expected to hold in any health care system as long as patients value the health care being provided to them, even in situations where they may not directly pay for the care provided. This theme will be explored further in the Discussion (Chapter 7).

2.4. Patient Perspectives as they relate to Process Performance

Given the paucity of peer-reviewed literature regarding the SPC in health care, this section of the literature review focused on specific links within the chain, notably the importance of patient perspectives, the connection between patients and their doctors, the importance of empowerment and engagement, and the relationship of these factors to adherence and outcomes. These factors are closely associated with process quality, a core component of the CVE.

Physicians and patients can have very different objectives regarding health care. Physicians are trained to look to measurable clinical outcomes (Powers et al., 2017). Typically, these will take the form of clinical outcomes that can be measured such as laboratory values, mobility challenges and visual outcomes (Dannenberg et al., 2016). Objective setting is reinforced by standards, guidelines and targets set out by physician associations such as “Treat to Target” in rheumatoid arthritis (Wabe and Wiese, 2017) or “Treat to Goal” in dyslipidaemia (Jellinger et al., 2017). Patients, however, may view other factors as important, for example, symptom control, pain and overall quality of life (Golder et al., 2018). Such factors may not always overlap with the goals of the clinician.

That patient objectives are taken into consideration and that the patient should be central to the decision-making process is a principle which is becoming widely recognised. In the NHS Long Term Plan (NHS, 2019b), there is a commitment to shared decision making (SDM) and personalised care; building the knowledge, skills and confidence for patients to live well with their condition and to empower them to have greater choice and control over the care they receive (NHS, 2019d). More generally, the SDM model has been well documented as a core component of satisfaction and adherence (Mahlich et al., 2019, Lofland et al., 2017), although historically there has been little guidance regarding its implementation (Elwyn et al., 2012).

However, it is an important tool in enhancing the patient experience, promoting engagement and maximising the perceived value of the health care encounter.

There is a substantial and increasing body of evidence which discusses issues associated with the disconnect between physician and patient, including the recognition and understanding of the patient's condition (Liker et al., 2009), understanding the most important aspects of the disease (Price et al., 2013), the differing objectives of the physician and patient (Allegretti et al., 2010) and satisfaction with treatment (De Mits et al., 2016). Where disconnects exist, there can be negative implications on health care resource utilisation (HCRU), adherence and outcomes both in the short and long term (Boyer et al., 1996, McCabe and Healey, 2018).

The patient-physician interaction is essential to both satisfaction and empowerment. Core elements of the physician-patient relationship include trust, knowledge, regard and loyalty (Ridd et al., 2009). If these elements are not in place, the relationship is impaired and patient satisfaction outcomes can be affected (Chipidza et al., 2015). Indeed, any patient-provider disconnect can interfere with the doctor-patient relationship and harm the user experience. An essential part of the physician's capability to promote adherence and deliver positive outcomes is therefore their ability to communicate with the patient (Zolnierek and Dimatteo, 2009). Physicians need the ability to develop a rapport with the patient, to understand both visual and verbal cues, to empathise with the patient and to provide a positive reappraisal focusing on the patient's personal resources, solutions to their problems and understanding their ability to cope (Finset and Mjaaland, 2009). All these steps can lead to a positive impact on outcomes.

Patient empowerment is also recognised as being essential to the provision of more effective care. Patients should be empowered and able to make the best decisions about their care (Verma, 2018), with the knowledge and ability to make informed choices, so taking control of their own health and management of their disease (Mesko et al., 2019). It can have many benefits, including quicker recovery time, and is associated with less anxiety and increased adherence with treatment plans (Schlesinger and Fox, 2016).

Patient empowerment is a key factor in adherence (Webb et al., 2001, Hernandez-Tejada et al., 2012), health and clinical outcomes (Rappaport, 1981, Rappaport, 1987, Zimmerman and Rappaport, 1988). The relationship between adherence and outcomes is intuitive (Hays et al., 1994, Vik et al., 2004), and has been demonstrated empirically by many authors. A systematic review of the relationship between empowerment and adherence showed that high levels of empowerment promoted medication adherence (Nafradi et al., 2017). Key components of empowerment include the ability of a patient to implement behaviours or instructions (Bandura, 1977). It is also important whether the reinforcement for health related behaviour is internal, the belief that control over health is associated with any actions the patient might take, rather than being determined by external factors such as chance or fate – or solely by physicians (Rotter, 1966). Adherent behaviour is further reinforced if the patient believes in the medication (Horne and Weinman, 1999), is satisfied with the information provided (Horne et al., 2001) and receives consistency of information (Carpenter et al., 2010). While typically the focus, adherence (or non-adherence) is not restricted to medication use; it has been estimated, for example, that over 40% of Type 2 Diabetes Mellitus (T2DM) patients do not receive the specified number of health checks per year and even more do not accept structured education about their diabetes, even when it is offered (Whicher et al., 2020).

Other than empowerment, adherence is affected by many factors. These include patient demographics, family and social support, economic factors, stigma associated with the condition and the asymptomatic nature of some conditions (Kardas et al., 2013). Health care system factors are also important: poor access to health care, unclear instructions about drug administration, poor communication and a lack of follow-up are barriers to adherence. While that prediction of non-adherence in a given individual may be difficult, it is clear that the physician-patient interaction plays an important part in improving adherence (Kardas et al., 2013). Linked to this is patient satisfaction, both with the medication and with the health care interaction. Satisfaction with medication has also been demonstrated to have a positive impact on adherence in many disease areas including asthma (Plaza et al., 2018), HIV (Dang et al., 2013), multiple sclerosis (Haase et al., 2016) and diabetes (Garcia-Perez et al., 2013), as has satisfaction with the health care interaction (Hefner et al., 2018), especially in the older population (Peck, 2011). Satisfaction with such interaction is a key component of process quality, so integral to the CVE.

The consequences of non-adherence can be significant, as this can affect health care outcomes and overall health care costs (Iuga and McGuire, 2014). Costs of non-adherence are substantial, estimated to be between 3% and as much as 10% of total health care costs in the

USA (IMS, 2013). A recent systematic literature review suggested a median proportion of hospital admissions associated with non-adherence to be more than 4%; almost all of these were considered preventable (Mongkhon et al., 2018). Using the medicines possession ratio as an indicator, annual adjusted disease specific non-adherence median costs for all causes were estimated as $17,132 per patient (2015 US$) ranging from $6,689 in respiratory medicine to $41,402 in osteoporosis (Cutler et al., 2018). In the UK, in 2015 the costs of wasted medicines alone associated with non-adherence has been estimated at £300m – excluding additional physician visits, tests, subsequent hospitalisations and other costs associated with worsening health states (Oswald, 2018).

In summary, health outcomes are maximised when patients and physicians are aligned, patients feel satisfied with both the interaction with the physician and with their medication, and where good communication exists between patient and physician. All these factors are associated with positive health experiences, indicative of good process quality and essential to maximise the value of interventions. If such factors are in place, patients are more likely to and feel empowered to play their part, adhering to treatment plans and maximising the chances of positive outcomes such as improved wellbeing, quality of life, ability to perform usual activities – and of course, cost savings associated with the potential avoidance of more expensive treatment at a later date.

2.5. Real World Data and Real World Evidence

RWD are data relating to a patient's health. However, RWD can also relate to the delivery of health care (Chodankar, 2021). As mentioned in Section 1.5, RWD cover both primary data collected directly from patients and physicians in routine settings such as observational research, registries, ethnographic studies and market research; and existing data sources such as medical records, administrative and claims data.

Real world data sources are essential to assess what happens in routine care settings and the need for such data has never been stronger (Anderson and Piercy, 2015). However, collecting data is not sufficient for providing insights into health care outcomes or service delivery, it is the analysis and interpretation of RWD that provides Real World Evidence (RWE). RWE provides the evidence regarding the use and possible benefits/risks of a medical intervention (Orsini et al., 2020).

To generate high quality and reliable RWE, the study design and the transparency of the research is just as important as the data collection (Berger et al., 2017). When using RWE it is important to ensure that the data collected are suitable of the purposes to which they will be used, analysis plans are clear, the research is free from bias and that limitations are addressed (Burns et al., 2022).

Randomised controlled (clinical) trials (RCTs), however, have historically been perceived as the gold standard of evidence generation (Barton, 2000, Cartwright, 2007). They are experiments which determine whether an intervention is effective in a specific patient sample (Mulder et al., 2018). The randomisation process, while not perfect, allows a fair comparison to be made between alternatives, thus providing internal validity. However, clinical trials are conducted as experiments in controlled settings with pre-defined protocols and analysis plans, where participants are often paid to provide the necessary information. They may not reflect real world practice for several reasons. Firstly, real world practice is not protocol driven; patients are not required (and incentivised) to present at regular intervals for assessments and monitoring. Secondly, the level of testing prevalent in clinical trials is not so widespread in the real world. This will be explored further in Chapter 4. Patients enrolled in clinical trials are also more likely to be motivated and therefore to be fully adherent, both regarding attending scheduled visits/assessments and also in taking the medication as detailed. It is also the case that in general, clinical trial inclusion criteria are established to minimize the number of comorbid conditions that participants may have. Again, this is not the case in real world practice. The degree to which clinical trials are generalisable though is therefore limited, as while internally valid, trials may not be externally valid. It is necessary for physicians to know how an intervention will work in their particular setting (Fortin et al., 2006), and clinical trials may not provide this information.

RWD are different to, and complement data from, RCTs (Suvarna, 2018). The aim of RWD and RWE is to improve health care decision making (Berger et al., 2017). Firstly, RWD sources can contain large number of observations both in terms of patients and data collected per patient (Rogers et al., 2021). RWD offer large sample sizes in diverse populations (Blonde et al., 2018) including patients with multiple comorbidities. RWD provides external validity, which suggests results are applicable to the wider population (Barnish and Turner, 2017). Due to the sample size, RWD can also be used to track rare events and monitor adverse events in general (Berger et al., 2017).

RWD is becoming accepted by regulators such as the FDA; most notably as external control arms adjunct to single-arm RCTs, or as historical controls in diseases where the total patient population may not be large (Feinberg et al., 2020). Examples include regulatory submissions for Tacrolimus and Zolgensma in the USA, where RWD were used to provide historical controls to compare with the intervention, or to research the natural history of the condition in question to provide context to the intervention (Concato and Corrigan-Curay, 2022).

In addition to the above, another use of RWD is to observe how a treatment performs outside a controlled environment. In doing so, RWD studies can include patients who have conditions which might exclude them from participating in an RCT and will certainly include patients who are not fully adherent to their treatment programme. This is because the focus of RWD is to record what happens in routine practice and not in a controlled environment. It is therefore possible that due to issues such as adherence, whether this be taking medication as prescribed, attending appointments or making any necessary lifestyle changes, outcomes observed in RCTs may not be replicated in real world settings. If the principles of the SPC approach can be applied and can be shown to improve engagement and adherence, then it can be expected that outcomes (as measured by RWD) may be closer to those observed in clinical trials, taking into account patient characteristics.

The key limitations of RWD relates directly to the limitation of the data sources. Primary data collection such as registries, on the other hand, provide valuable information about patient and disease monitoring, the effects of medical care and about health care planning (Pop et al., 2019). However, they are time consuming and expensive to set up and run. More importantly, but may not be generalisable to address questions other than those associated directly with the objectives of the registry, i.e., the evaluation of specific outcomes and the assessment of specific treatment plans and medications, which can limit their use in addressing more general questions (Richesson and Vehik, 2010). Equally importantly, researchers need to be aware of issues of generalisability in setting up primary data collection real world studies due to small sample sizes in specific study populations.

On the other hand, RWD sources routinely collected by health care systems (i.e. secondary data sources) are typically much larger in sample size. However, they are not designed to facilitate research, but generally to monitor activity and/or to allow for billing. Administrative data, such as UK HES data for example, will include the minimum number of variables to achieve the objective of monitoring process activity, the purpose for which it was designed. Data from electronic medical records, whilst providing more detailed information regarding demographic and clinical characteristics, may not be as generalisable and will not necessarily provide all variables of interest. For example, up to date information regarding Body Mass Index is not routinely recorded in medical records in the UK, although obesity is a public health issue of increasing importance (Bhaskaran et al., 2013).

Analysis of RWD also has its challenges. Since such data were not designed for research, without an appropriately specified and *a priori* analysis plan, the lack of specific hypotheses can lead to potential accusations of data mining (Sherman et al., 2016, Segal et al., 2016), particularly in the case of secondary database studies. In all cases, researchers need to be mindful of bias and take this into account when analysing real world data (Al-Sahab et al., 2023).

Ultimately though, it is increasingly evident that evidence from both clinical trials and the real world is necessary if the best decisions are to be made (Swift et al., 2018). This thesis though does not discuss the efficacy of any intervention. Rather, it uses real world data to address issues which cannot be assessed in a trial environment, the relationship between the physician and the patient and the subsequent impact on outcomes.

2.6. Conclusion

The CVE highlights the relationship between process quality and user experience, satisfaction with health care services and the perceived value of the service provided. Satisfaction results from perceived service quality; engagement and empowerment are linked to satisfaction; and perceived value follows from this. The same factors are associated with adherence to treatment plans, essential if the best outcomes for the patient (and by implication for society) are to be obtained. The patient experience is at the core of all these concepts.

The papers that will be presented in subsequent Chapters will explore the concepts discussed in the literature review; disconnects between physician and patient; the consequences of disconnect in terms of adherence and HRQoL, and suggestions for enhancing the patient experience and process quality associated with the patient-physician interaction.

However, before considering value at an individual level in later Chapters, the next Chapter will discuss value at the population level. It assesses the role of population burden of illness studies and their link to unmet needs; and the use of economic evaluation as a tool to guide clinical decision making.

3. Value from a population perspective: Burden of Illness and Economic Evaluation

3.1. Introduction

This Chapter focuses on two themes which are common in considering value on a population level: estimation of the burden of disease from a resource use and humanistic perspective; and the use of health technology assessment to drive and inform clinical practice.

Burden of illness studies aim to quantify the consequences of a defined disease in a community. They can include assessments of economic impact, quality of life, disability, caregiver/support requirement and mortality (Jo, 2014). As such, they can help in the assessment of unmet needs, identify treatment gaps, and assist in decision-making (Johnston et al., 2019). Economic evaluations, when used in the context of health technology assessment, through the consideration of the costs and benefits of health care interventions provide evidence regarding their cost-effectiveness, so can be used to inform resource allocation.

3.2. Population need as an indicator of value: Burden of Illness. (Tang et al., 2014)

Tang DH, Colayco DC, Khalaf KM, ***Piercy J,*** *Patel V, Globe D, Ginsberg D. Impact of urinary incontinence on healthcare resource utilization, health-related quality of life and productivity in patients with overactive bladder. BJU Int. 2014;113(3):484-491*.

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Overactive bladder syndrome (OAB) is a common condition (Irwin et al., 2011) associated with significant economic (Irwin et al., 2009) and HRQoL burden (Coyne et al., 2011). The aim of this paper was to evaluate and compare the incremental impact of urinary incontinence (UI) in patients with OAB on HRQoL and work productivity against OAB patients who were continent.

Data were drawn from the Adelphi DSP in OAB conducted between October 2010 and March 2011 in France, Germany, Spain, UK and the USA. After confirmation of diagnosis, physicians provided data on patient demographics, clinical characteristics, disease management, and symptoms as well as surgical and pharmacological treatment. Patients provided information on HRQoL, including completing the disease specific Incontinence Quality of Life questionnaires [I-QOL] (Schurch et al., 2007) and Overactive Bladder (OAB-q) questionnaires (Coyne et al., 2002); the EQ5D-3L (EuroQol, 1990) and the Work Productivity and Activity Impairment (WPAI) questionnaire (Reilly et al., 1993). Patients also reported use of incontinence pads and number of times they had visited their physician over the previous three months. Multivariate ordinary least squares regression analysis was used to estimate the association between continence status and HRQoL / HCRU, with multiple imputation and median imputation being performed to impute variables with missing values.

1730 patient were included in the analysis, 71% of whom were incontinent. Compared with patients who were continent (all p<0.001), incontinent patients experienced worse quality of life as measured by the EQ5D, the I-QOL, OAB-q (both the symptom severity score and overall HRQoL score), greater activity impairment and overall work impairment. Patients with UI were also less likely to be in employment, more likely to have received surgery and to have required incontinence pads. They were also more likely to have switched their anticholinergic medication due to safety or efficacy reasons – a sign perhaps of dissatisfaction with the original medication. The negative impact on HRQoL and HCRU increased as the number of incontinence episodes per day increased.

The key strength of the paper, as is the case with all the following papers, was that it was based on RWD. This is particularly important where HCRU is measured. RWD records what happens in actual clinical practice, without (clinical trial) protocols governing medication, frequency of consultation, testing and hospital visits. Another major strength of the study was that patients were recruited by physicians leading to accurate identification of patients as OAB with or without UI. Analysis was also simplified by dichotomising patients reported by their physician to be either as continent or incontinent, unlike other research which set arbitrary thresholds of continence (Coyne et al., 2008).

However, although it was possible to quantify associations between UI and measures of burden such as HRQoL and resource utilisation, due to the nature of the DSPs being point-in-time, it was not possible to attribute cause and effect relationships. These associations could have been strengthened if a propensity matching technique (Austin, 2011) had been used to match continent and incontinent patients for age, disease duration, gender and concomitant conditions. Such techniques have subsequently been used in other analyses by the writer of this thesis using the same data source (Andersson et al., 2016).

Although out of scope for the study objective, it would have been possible to undertake additional analysis to identify specific subgroups of patients with the greatest unmet need; or to identify specific features or symptoms causing the most impact. This would have made the analysis potentially much more insightful since it would offer insights regarding aspects of the condition that might be most important to a patient. One such feature in OAB patients is nocturia, a condition where patients wake up in the night to urinate (Zeng et al., 2019). Compared with patients without the condition, nocturia patients experience lower HRQoL, worse work productivity and greater activity impairment (Andersson et al., 2016); with an increasing number of night-time voids being associated with deterioration of overall HRQoL. Significant differences were observed between 0–1 and with greater than 2 voids ($p < 0.001$). Specifically, nocturia was also associated with a modest but statistically significant deterioration in utility of 0.0134. However, it is not necessarily the nocturia itself that causes the greatest burden, rather the associated sleep fragmentation (Coyne et al., 2003). Further research involving the use of wearable technology could shed further light, identifying exactly how many and for how long night-time disturbances to sleep occur.

Further analysis that would be particularly insightful and one which would certainly enlighten the physician-patient conversation, would be to study exactly what factors are affecting quality of life. Is it the nocturia, or perhaps the lack of sleep that results from night-time waking / voiding (Holm-Larsen, 2014)? Studying drivers of HRQoL (using regression analysis) would enable physicians to focus on what matters most.

This research highlights that, rather than just reporting the association between a condition and patient impact, analysis of what drives the impact can be particularly insightful. It is incumbent on physicians to look beyond the obvious and consider what issues of importance might lie behind a common and easily manageable condition. Enhanced understanding of the patient's condition would increase the physicians' capability to understand the challenges faced by the patient and to focus effort on aspects that matter most and have the greatest impact on the patient. Implications could be significant if the consequences of the condition can be managed as well as treating the cause. Real value would then be provided for the nocturia patient. This will be true of all conditions, not just OAB: health care providers need to look for the factors associated with the condition that have the greatest incremental impact on HRQoL and resource utilisation.

Burden of illness studies are not however economic evaluations and since they are descriptive and not comparative, they tell us nothing about the cost-effectiveness of the standard of care described. However, understanding and quantifying burden of illness, in addition to highlighting unmet needs, can also have a role in setting the scene for more formal economic evaluation, the subject of the next paper.

3.3. Value in the context of economic evaluation. (Ryan et al., 2004)

*Ryan J, **Piercy J,** James P. Assessment of NICE guidance on two surgical procedures. Lancet. 2004 May 8;363(9420):1525-6*

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Assessment of NICE g

The objective of this research was to understand the effect that NICE guidance had on treatment choice and decision making in the NHS (excluding Scotland[3]). The first two guidance documents published related to two surgical procedures namely the routine extraction of wisdom teeth and the selection of prostheses for total hip replacement, both published in 2000 (NICE, 2000a, NICE, 2000b). The guidance suggested there was no evidence to support the removal of healthy wisdom teeth, so a formal economic evaluation was not necessary. The guidance relating to hip replacement suggested there was no evidence on

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[3] NICE guidance covers England; Wales, subject to Welsh legislation https://www.gov.wales/national-institute-health-and-care-excellence-nice-guidelines ; and Northern Ireland, subject to local review. https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hsc-sqsd-13-22.pdf It does not cover Scotland.

cost-effectiveness for cementless or hybrid prostheses, although updated guidance did include an economic evaluation as part of the assessment process (NICE, 2014).

Choices regarding resource allocation must be made firstly at a population then at an individual level. At a population level, this is the task of organisations such as NICE. The role of NICE was, and still is, to “produce evidence based guidance and advice for health, public health and social care practitioners” (NICE, 2020). Based on technology appraisals plus inputs from other stakeholders (including patients), NICE recommends which new technologies or medicines are eligible for funding within the NHS. A positive recommendation means that mandatory funding must be made available within three months of the appraisal subject to overall budget impact (NICE, 2019). Although NICE guidelines promote value for money in the provision of health care services by assessing whether health care treatments are clinically effective and cost-effective thereby influencing the choice of treatment alternatives available to a physician, its role is not to make individual treatment choices on behalf of physicians. Therefore, a positive recommendation does not mean that a technology must automatically be used in every situation, while a negative recommendation does not say a technology can never be used. Decisions can also be based on other criteria as discussed in this paper.

Using routinely available data from the HES standardized hospital minimum dataset in the England, the authors conducted a multiple regression analysis on time-series monthly activity data. Using Office of Population Censuses and Surveys (OPCS-4) codes (NHS, 2020), the authors were able to identify the procedures appropriately to detect changes in trends. There was a single code to define the surgical removal of impacted wisdom teeth regardless of reason. However, since it could reasonably be assumed that the removal of diseased teeth would remain constant, the analysis would be able to detect changes in the numbers of removal of disease-free teeth. Regarding total hip replacements, separate codes existed for cemented and non-cemented prostheses. For each procedure, a dummy variable to indicate pre-and post- NICE guidance periods was employed. The period of analysis included three years of activity before the implementation of the relevant NICE guidelines and two years after their introduction to ensure that there was sufficient time for the guidance to be disseminated and for the recommendations to influence clinical practice.

The authors noted a consistent downward trend in wisdom teeth extractions over the whole five-year period, with the most significant change observed from late 1998 onwards. However, since this trend was observed pre-NICE guidance, it could be argued that the recommendations of a professional body, the Royal College of Surgeons (RCS, 1997) had a more direct influence. No separate change in trend was observed after the introduction of the NICE guidance, although it was possible this guidance could have reinforced the professional body guidelines. Neither was any significant change in the proportion of cemented to uncemented primary total hip replacements detected as a result of the NICE guidance. Although there was a consistent move towards non-cemented prostheses, the authors suggest this could result from more evidence becoming available regarding the use of non-cemented prostheses. In both cases, therefore, the authors concluded that NICE guidance did not have an independent effect on surgical activity. It should also be noted that while changes in trends could be identified, reasons for change could not be ascertained – this would require a separate study of physicians' attitudes and reasons for choice of treatments.

This study was the first to assess the impact of NICE guidance using a nationally representative data set, validated for use in health service evaluation (Thwaites and Piercy, 2004). Including data from 88 teaching and non-teaching NHS hospital trusts, at the time of analysis the data set accounted for 48% of all impacted wisdom teeth extractions and 40% of all total hip replacement procedures. This makes it generalisable to the whole of England. There is always one limitation with administrative data sets; they are only as good as the coding. However, as data from the same hospitals were used throughout the analysis period, any systematic bias due to coding or coding errors would be minimised.

Since the paper was published, new guidance has been issued regarding total hip replacement (NICE, 2014), focusing on long term clinical benefits and failure rates, not on any specific form of prosthetic hip. There has been no further guidance in relation to wisdom teeth extraction, though trends identified in our paper suggested that removal of disease-free wisdom teeth would cease to be a cause for concern.

It must be made clear that NICE guidance has evolved since those first appraisals published in 2000. With over 800 technology appraisals now conducted, the use of economic evaluation in a wider context (together with the inclusion of HRQoL data) is better understood and more accepted. Indeed, there is more recent evidence to suggest that guidelines are now being successfully implemented (Lowson et al., 2015). To some extent, this could be a function of familiarity and acceptance. However, Lowson et al. suggest that organisational barriers and resource limitations means that implementation may not always be totally effective and that improvements in dissemination might be valuable in increasing guidance uptake.

The paper discussed a way of measuring change in health care practice, but how do we know what change is good change? Process measures, the act of accounting for what takes place, can assess whether differences in practice have occurred. However, they offer only a limited perspective on the value of the service being offered or the outcomes associated with the change in practice. Just because an activity is recorded does not mean that the best course of action has been taken. This is a key limitation of the analysis of administrative data such as HES: while such data tell us what happens and provide evidence of resource use and cost, they do not tell us anything about the process quality associated with the treatment, nor about the outcome (other than survival to discharge and short-term readmission rates). Nor can these data inform whether patients are engaged, satisfied or whether their HRQoL is improved. Information from patients is required to answer these questions. This is discussed further in Section 3.4.

However, the fact that such activity data are easy to collect, consistent over time and allow longitudinal comparisons to be made, they do have value in measuring change. Governments and health authorities can point to increases in volume of activity, increased procedures and also to these procedures being undertaken more efficiently, for example, requiring shorter lengths of hospital stay, and resulting in fewer readmissions. So one can learn to some degree about technical efficiency from process measures of activity. But without outcomes data, such data can only tell part of the story regarding value in health care delivery.

3.4. Application to the SPC

One aim of burden of illness analyses is to estimate the economic impact of a particular disease (Ramsey and Sullivan, 2003). They traditionally focus on resource use, often taking a payer or societal perspective of burden or cost. As such, they measure problems, but not the value of solutions (Mooney and Wiseman, 2000). They do, however, identify unmet needs, highlighting areas where new treatment alternatives might be beneficial (Taylor et al., 2016). Patients or subgroups of patients with the greatest disease burden can be considered to have the greatest unmet need – and the greatest capacity to benefit from new treatments (Quigley et al., 2006).

Burden is a multi-faceted concept. Addressing burden from a resource use or cost perspective does not automatically address the most important needs of the patient population. It is necessary to identify specific aspects of a condition that have the greatest impact on a patient's quality of life, their ability to work or to perform normal activities. Asking patients directly what the most important benefits of treatment are would be a logical extension of burden of illness studies and might provide such insights. However, where PROMs are included in burden of illness studies, they address HRQoL associated with being in a particular disease state, so do not consider the value of the health care experience. Indeed, there is evidence that patient satisfaction with treatment can also be an effective indicator to measure the success of health care services (Prakash, 2010). Efforts to improve satisfaction of patients can thus have a direct effect on the outcomes of the treatment, and therefore the value of the service provided.

Burden of illness studies are not economic evaluations. The principles of economic evaluation involve comparing two or more discrete courses of action (Drummond et al., 2015). One of these, the baseline against which alternatives can be assessed, will typically be the current standard of care (Cohen and Reynolds, 2008). The generic formula for assessing cost-effectiveness (regardless of how effectiveness is measured) is the Incremental Cost-Effectiveness Ratio (ICER), which is the incremental change in costs of the new intervention divided by the incremental change in the effectiveness or outcome (Cohen and Reynolds, 2008).

However, economic evaluations, such as those discussed in the paper presented, are generally context specific, even where standard measures are used. The most routinely used outcome measure in economic evaluation is the Quality Adjusted Like Year, or QALY (Whitehead and Ali, 2010) since this enables comparison of health outcomes across conditions. But limitations remain: the QALY does not take equity or fairness into account (Whitehead and Ali, 2010), and debates persist concerning whether QALYs are the same in all circumstances (Soares, 2012) and even around valuation systems (Devlin et al., 2018). Equally importantly, economic evaluation focuses on the results of treatment, regardless of how the results are measured. It does not generally take into account the patient experience, as satisfaction is not routinely included in economic evaluation. Furthermore, economic evaluations, as standalone pieces of research, relate to cost-effectiveness measured against a monetary threshold. They do not explicitly address unmet needs related to a condition, only the relative cost-effectiveness of alternative ways of treating the condition. The need for assessments of disease burden and unmet need is most clear in rare diseases, where drugs are unlikely to meet cost-effectiveness thresholds due to the high prices necessitated by high development costs and limited market size. In such case, burden of illness analysis and quantification of unmet need will be necessary to inform those tough political resource allocation decisions regarding willingness to pay for such medications.

The principles of the SPC place the customer at the centre of the decision-making process. So, are the ideas of burden of illness and economic evaluation, which deal with populations, consistent with individual perceptions of value?

From Chapter 1, the CVE was summarized as follows:

$$\text{Value in the mind of the client} = \frac{\text{Results + Process Quality}}{\text{Client Access (Relationship) Costs + Fees}}$$

From Heskett et al. The Service Profit Chain. The Free Press 1997

The ICER can be written as (from Cohen and Reynolds, 2008).

$$\mathrm{CE\,ratio} = \frac{\mathrm{Cost}_{\mathrm{New}} - \mathrm{Cost}_{\mathrm{Reference}}}{\mathrm{E}_{\mathrm{New}} - \mathrm{E}_{\mathrm{Reference}}}$$

Thinking of effectiveness as the results, of the incremental costs as the fees, two aspects of the value equation are present in the ICER, although the SPC concept of value is in effect the reciprocal of the ICER.

Economic evaluation, therefore, as well as providing a means to assist with resource allocation by assessing whether a technology (or service) is cost-effective, is not inconsistent with and in fact is an essential part of the value equation. However, other aspects of the value equation such as the process quality and the relationship costs, are missing. Economic evaluation can therefore be thought of as necessary in the CVE, but not sufficient for the identification of the true value of an intervention for any given individual.

3.5. Summary

These papers have discussed ways of assessing the burden of disease and of measuring change in health care practice. Burden of illness studies are valuable in assessing the impact of diseases and informing unmet needs. Economic evaluations help guide the decision-making process regarding what treatment alternatives should be available and in what circumstances. Both are valuable at a population level.

But while burden of illness studies and economic evaluation have vital roles to play in assessing unmet needs and informing decision making and resource allocation at a population level, the application of these techniques alone, although necessary, may not be sufficient to maximise health benefits from the perspective of the individual. The patient voice and patient experience is an essential element of driving value on an individual level, as implied in the customer value equation. Understanding the patient voice is the subject of the next two Chapters.

4. Patient-Physician Disconnects

4.1. Introduction

A key aspect of the SPC and of customer service in general is the ability to provide what the customer actually wants rather than what the provider thinks the customer wants, or what they think the customer should have. In the context of health care, this involves physicians recognising the factors associated with a condition that might be most important to the patient and addressing these in a way which maximises the patient's experience of the service provided.

The three papers presented in this Chapter focus on how failure to recognise particular aspects of a condition can result in a disconnect between patient and physician and how this can impact health outcomes. This suggests that if the process quality is not right, then not only can the patient be dissatisfied, but the outcomes that might be expected of the intervention might not be achieved. The first paper (Wei et al., 2017) considers disconnects in overall disease severity; the other two papers (Horvath Walsh et al., 2019, Peterson et al., 2019) highlight the impact of disconnects regarding specific physical and psychological aspects of a condition respectively.

4.2. Disconnect in Patient Severity (Wei et al., 2017)

Wei W, Anderson P, Gadkari A, Blackburn S, Moon R, ***Piercy J****, Shinde S, Gomez J, Ghorayeb E. Discordance Between Physician- and Patient-Reported Disease Severity in Adults with Atopic Dermatitis: A US Cross-Sectional Survey. Am J Clin Dermatol. 2017 Dec;18(6):825-835*

2017-04 AJCD Wei.
Discordance between

Atopic Dermatitis (AD) is a severe form of eczema, characterized by intense pruritus or itch. In general, onset is in childhood/early adulthood; and in the current absence of a cure, lifetime treatment is required (Raimondo and Lembo, 2021). It is associated with a significant multi-dimensional burden on the patient which in addition to the physical skin symptoms can include lack of sleep, anxiety/depression and reduced function and productivity (Dalgard et al., 2015, Simpson et al., 2016). The paper had several objectives, focusing on assessing the level of disconnect, factors associated with this disconnect, and estimation of the associated potential additional burden.

Data were drawn from the Adelphi DSP in AD conducted between October 2014 and March 2015 in the USA. Physicians provided data on demographics, clinical characteristics, symptoms including perceptions of sleep disturbance and itch and the impact on their interference with daily activities, disease management and treatment. Physicians also provided elements required to derive the Eczema Area and Severity Index (EASI) score (Leshem et al., 2015). Patients provided information on HRQoL, including completing the Dermatology Life Quality Index (DLQI) (Finlay and Khan, 1994) EQ5D-3L (EuroQol, 1990), and the WPAI questionnaire (Reilly et al., 1993). Both physician and patients provided their own subjective assessments of disease severity, classified into mild, moderate or severe.

The level of concordance between physician and patient with regard to disease severity was assessed using the kappa statistic measure of inter-rater agreement (Cohen, 1988). The authors then compared the HRQoL of patients whose assessment of severity aligned with their physicians with matched patients who were not aligned.

In total, data were available relating to 1196 patients, 678 of whom filled out a PSC and were therefore eligible for inclusion in the analysis. Physicians (n=202) and patients were in agreement regarding perceptions of disease severity in 465 cases (68.6%). Disconnect was observed in 213 cases (31.4%). Patients rated their disease as more severe in 76 cases (11.2%) and less severe in 137 cases (20.2%). The weighted Kappa was 0.52 (Confidence Interval 0.518-0.525) suggesting a moderate level of agreement.

Bivariate analysis was used to assess the relationship between concordance and disconnect and a range of physician and patient reported measures (Table 2).

Disconnect was observed in approximately one third of matched patient-physician pairs. A potential reason for this could be that respective reference frames are different. A patient generally has a reference base of one – themself – and therefore only their previous experiences to compare against. In contrast, a physician, particularly a specialist, will see many patients, so can consider the severity of this patient in the context of all the other patients they will see. An individual patient’s experiences also could be coloured by their direction of travel: if the patient is improving, they may well report the current condition as “mild” simply because they feel better than they were. This does not mean their condition is clinically mild – hence the possibility of physician suggesting a higher level of severity. Equally, a patient with a new or worsening condition may rate themselves as severe, when they may be only clinically mild.

Table 2. Impact of Discordance on Patient Reported Outcome Measures

Severity Rating (n=678)	Matched	Patient Rated Higher	Physician Rated Higher	
Dermatology Life Quality Index	7.0	9.7	5.7	P<0.001
EQ-5D-3L	0.89	0.81	0.89	P<0.001
WPAI: Overall Work Impairment	20.2	29.3	19.2	P=0.031

One of the main reasons physicians may consider AD as more severe is the emphasis they put on sleep disturbance. Indeed, physician reported sleep disturbance is more common in cases where physicians report a higher disease severity. It is clear that sleep disturbance can lead to lower HRQoL (Mann et al., 2020) and can impact on work productivity and activity impairment (Hendricks et al., 2019). However, for a physician to recognise sleep disturbance, the patient would have had to mention it, since sleep disturbance is an invisible symptom of AD. This fact may lead a physician to place a high importance on this factor.

Factors associated with disconnect were presence of AD on the head and neck and permanent scarring. These are highly visible factors – ones which are important to a patient, and which are easy to spot. Physician recognition of the importance of visible symptoms, even though a patient may be generally mild, could lead to higher patient satisfaction and therefore a greater service value. Such factors are often included in PROMs. Based on these PROMs, further investigation could focus on reasons for dissatisfaction and disconnect. This could expose issues of importance that may not be being discussed and addressed during consultations. Profiling the types of patients who report a disconnect compared to those who are aligned patients in terms of demographics, clinical status (severity, symptoms) and feelings could highlight areas to focus on during the consultation.

A secondary objective of this study was to investigate physicians' awareness and routine use of AD specific PROMs. Although dermatologists had a better knowledge of PROMs than did Primary Care Physicians or internists, even amongst these specialists, awareness of some key measures was low. For example, 73% of dermatologists were not aware of the Pruritis 5-Dimension scale which measures the key symptom of itch (Elman et al., 2010), whilst 52% were not aware of the Patient-Orientated Eczema Measure (Charman et al., 2004) – commonly used in clinical trials. Use of the tools was even lower; less than 5% of physicians reported they commonly used PROMs in patient assessment. Even the physician completed EASI score was commonly used by only 21% of dermatologists and 17% of physicians overall. Given the impact on the patient may be greater where the AD is in visible areas such as head and neck, hands and upper/lower limb extremities (Lio et al., 2020), increased use of such measures could be a reminder of the need to consider more than simply body surface area and general severity. Even if advanced systemic treatments may not be targeted to specific locations on the body, an understanding of and empathy with the problems is likely to increase engagement, satisfaction and patient experience.

In this study, the presence and importance of itch and sleep disturbance were assessed by the physician. Although these issues were also addressed in the patient completed DLQI, additional matched questions to the patient assessing the interference of itch and sleep on daily activities could have been completed by the patient. Nevertheless. use of PRO tools could be an important area for further research with objectives of reducing disconnect and increasing HRQoL.

This paper focused on disconnect in overall severity. The next paper homes in on disconnect at a more micro level of individual symptoms.

4.3. Physician and Patient Discordance in in Symptom Recognition (Horvath-Walsh et al., 2019)

*Horvath Walsh LE, Rider A, **Piercy J**, Pike J, Wilson S, Pandya BJ, Medeiros BC. Real-World Impact of Physician and Patient Discordance on Health-Related Quality of Life in US Patients with Acute Myeloid Leukemia. Oncol Ther. 2019;7(1):67-81*

2019-04 Oncol Ther.
Real World Impact of

Acute Myeloid Leukaemia (AML) is the second most common type of leukaemia in the USA (Siegel et al., 2018). AML has a poor prognosis, particularly for older patients (Oran and Weisdorf, 2012) and those with fibromyalgia syndrome-like tyrosine kinase-3 (FLT3) mutation (Schlenk et al., 2008). For patients whose life expectancy is shorter and for whom a likelihood of a cure is lower, improvements in HRQoL may be particularly important (Storey et al., 2017). The objectives of this study were to understand the impact of a range of factors that might influence HRQoL and to assess how HRQoL may vary in patients with different clinical and treatment characteristics. Indeed, the authors also found decrements in HRQoL associated with specific clinical factors, as did the use of treatment alternatives such as hypomethylating agent monotherapy in patients with low treatment intensity, findings consistent with other studies (Kurosawa et al., 2015, Korol et al., 2017). A secondary objective, and the important one in the context of this thesis, was to assess the degree of discordance in recognition of symptoms experienced by the patient and reported by their physician as well as the impact on HRQoL recording of these same symptoms by their physician.

Data were drawn from the Adelphi DSP in AML conducted between February and March 2015 in the USA. Physicians provided data on demographics, clinical characteristics, the presence or absence of a range of symptoms, disease management and treatment patterns. Patients provided information on HRQoL, including completing the Functional Assessment of Cancer Therapy – Leukaemia (FACT-Leu) (Cella et al., 2012) EQ5D-3L (EuroQol, 1990), and the Cancer Therapy Satisfaction Questionnaire (Abetz et al., 2005).

The differences and level of concordance between physician and patient with regard to the presence of key symptoms was assessed using the Kappa statistic measure of inter-rater agreement (Landis and Koch, 1977) Since physicians did not rate symptoms by severity, concordance analysis was conducted in respect of presence or absence of symptoms only.

In total, 82 patients were included in the analysis. Agreement on individual symptoms varied significantly, with low kappa scores (suggesting low levels of agreement) observed for all symptoms other than for fever..

Lower HRQoL was associated with patient-physician disconnect in relation to specific symptoms of bleeding, weight loss and appetite loss. Similarly, disconnects regarding fever, weight loss and appetite loss were associated with significantly lower patient treatment satisfaction scores. While it could be expected that patients report more symptoms than those noted by the physician, this study not only assessed the disconnect but sought to quantify its impact on HRQoL. This advancement of knowledge is an important new finding.

The analysis also had limitations. Patient assessments were obtained though the "Additional Concerns" section of the FACT-Leu which asks patients to provide responses on a scale of 0 - 4 where a score of 0 represents "not at all", and 4 represents "very much. Physicians provided responses using a pre-coded list and were not asked to rate the severity of the symptoms. Considering the fact that presence of mild symptoms may not be seen as sufficient to warrant recognition by the physician, the concordance analysis only took into account the presence of symptoms when the patient was "quite a bit" or "very much" bothered. However, a sensitivity analysis using a more stringent cut-off based solely on physician reported presence or absence of symptoms corroborated the findings, so this limitation was not viewed to be of importance.

It should be noted that the number of respondents was small. However, despite the small sample size it was still possible to identify associations between patient sub-groups and HRQoL, although more advanced statistical methods (precluded by sample size) such as propensity matching could have definitively ruled out potential confounding factors such as age, sex and concomitant conditions.

This paper focused on symptoms of AML. The study did not, however, account for overall disease severity. It is likely that physicians may focus on the disease itself rather than on specific symptoms, some of which may in fact be side-effects associated with treatment. Much larger studies might be required to untangle these dual issues of symptoms and treatment-induced side-effects.

However, the findings suggest that it is important for physicians to recognise and react to issues (symptoms) which can adversely affect the quality of life of the patient. Again, it is likely that the use of PROMs in clinical consultations could improve the process quality of the health care interaction by enabling physicians to have a better understanding of the patient's health state and HRQoL through the highlighting of any specific factors that might be driving a worse HRQoL; recognition of these factors could improve patient satisfaction and experience. It should be noted that this paper focused on visible symptoms. However not all signs and symptoms are physical or observable. The next paper reports the under recognition and associated consequences of psychological symptoms in a condition which has very real physical manifestations.

4.4. The Burden of unrecognised symptoms (Peterson et al., 2019)

*Peterson S, **Piercy J**, Blackburn S, Sullivan E, Karyekar CS, Li N. The multifaceted impact of anxiety and depression on patients with rheumatoid arthritis. BMC Rheumatol. 2019 Oct 28;3:43*

Peterson et al
depression in RA BMC

Rheumatoid Arthritis (RA) is a chronic autoimmune inflammatory disease that is associated with significant implications for HRQoL. The invisible symptoms of anxiety and depression are particularly important, since the prevalence of anxiety/depression in RA patients can exceed their prevalence in the general population (Matcham et al., 2013). The primary objective of this study was to assess the under-recognition and incremental impact of anxiety and depression in RA patients in the USA and Europe.

Data were drawn from the Adelphi DSP in RA, a study conducted in Europe and the USA between January and June 2014. Physicians provided data on demographics, clinical characteristics and symptoms. Patients provided data on symptoms, degree of pain, treatment satisfaction, details of / effects on employment, besides filling out validated PROMSs; the EQ5D (EuroQol, 1990), the Health Assessment Questionnaire Disability Index (HAQ-DI) (Bruce and Fries, 2005) and the WPAI (Reilly et al., 1993). Both physicians and patients reported the presence or absence of anxiety and/or depression. Physicians directly reported the presence of anxiety and/or depression, whilst patient reported anxiety and depression was captured from the relevant EQ5D dimension.

The analysis included 1015 patients, 408 in the USA and 607 in Europe. 390 patients (38.4%) reported anxiety and/or depression, whilst physicians reported only 180 (17.7%) patients as having these conditions. In 118 (11.6%) cases both patient and physician recorded anxiety/or depression; in 262 (25.8%) cases patients reported but physicians did not and in 62 (6.1%) cases physicians reported whereas patients did not. For the remaining 573 (56.5%) of patients, neither party reported anxiety or depression. Multiple regression analysis suggested that more patients with anxiety and/or depression experienced treatment dissatisfaction (Odds Ratio [OR] 2.28), had greater impairment in both work and usual activity (increased coefficients of 11.8 and 14.8 on a 0-100 scale respectively), were more likely to be unemployed (OR 1.74) and experienced greater levels of pain (4.1 vs 2.8 on a 0-10 scale), all $p<0.05$. These effects show the incremental burden of these conditions in RA, highlighting the importance of their recognition and treatment.

This study has shown that these conditions result in a significant incremental burden in RA patients. We also found that the prevalence of anxiety and/or depression is more common in the RA population than in the general population (18.9% depression, 14.8% anxiety) (Olfson et al., 2000) and that it is under-reported by physicians (Li et al., 2019), (Sruamsiri et al., 2017).

When considering the implications of our findings, it is necessary to address an important limitation of the research, namely the differences in the method of recording the presence of anxiety and/or depression between physicians and patients. Physicians reported these separately as concomitant conditions. Estimates of patient reported depression were collected through their responses to the anxiety/depression dimension of the EQ5D, which does not capture underlying prevalence, simply asking patients to record whether they feel anxious or depressed on that day. This could lead to over-estimate of patient reported anxiety and/or depression, therefore inflating the disparity in reporting between physician and patient. However, our findings are corroborated by other research, as other studies have found similar levels of anxiety and depression in RA patients (Isik et al., 2007), with rates much higher than that found in the general population (Matcham et al., 2013). Other studies have not only documented the underreporting of these conditions in RA patients (Sleath et al., 2008), but identified consequences of these conditions in terms of higher disease activity (Scott et al., 2018) and estimated increased health care costs (Michaud et al., 2003). The importance and the novelty of our research is that for the first time, the *incremental* burden of under-recognised anxiety and/or depression has been quantified.

It is possible that there may be other reasons for a higher level of anxiety/depression in the study population. Such factors include income, education, alcohol consumption, smoking status and treatment for other conditions, factors that were not considered in our study. In future research, taking these factors into account might allow a more causal relationship between anxiety/depression and outcomes such as HRQoL and satisfaction with treatment/disease control to be established. Regardless of these limitations, these factors of anxiety and depression are important in patients with RA and their under-recognition is associated with worse patient outcomes. Additional research might focus on whether the prevalence of invisible symptoms is related to specific patient demographic and disease factors, including time since diagnosis, symptoms, pain; this enables predictions to be made regarding which patients are most likely to encounter this problem. Profiling patients with or without anxiety or depression would be a good beginning to this research.

The results are generalisable to any chronic condition. In addition to the physical symptoms of a condition (such as RA), physicians need to be aware of invisible symptoms too. Psychological symptoms are particularly important and although these may not be directly associated with the condition, they may be more prevalent in its’ presence. Physicians need to treat patients holistically rather than just managing the obvious symptoms of the condition they are dealing with at the time (Hahn, 1982). Symptoms that are not recognised will remain untreated, resulting in consequences for the patient regarding their HRQoL, ability to function and overall well-being. Furthermore, untreated symptoms and unrecognised concomitant conditions can have consequences not just in the immediate term, but also for future long-term outcomes and costs. If conditions are allowed to worsen, inevitably the cost of treatment in the future will rise. Appropriate training, or encouragement of multidisciplinary working, would enable conditions to be recognised earlier rather than later; and appropriate treatment of concomitant conditions at the appropriate time would enhance the overall value of the treatment in terms of cost effectiveness and value for money, as well as enhancing the patient experience. This is particularly important when considering the possibility of invisible conditions such as anxiety and depression arising as a consequence of a physical disease.

4.5. Application to the SPC

A key aspect of the SPC Customer Value Equation is process quality. Process quality is a measure of the way in which a service is delivered, so relates directly to the customer experience and to satisfaction. Satisfaction is most likely to occur when patients and physicians are aligned and when the physician is showing attentiveness and knowledge of the patient's circumstances (Simsekler et al., 2021). Disconnect suggests that since the patient's needs may not be fully understood or recognised; this could have an impact on patient perception of process quality. Fundamentals of process quality are that service providers understand customer needs, are responsive to those needs and can provide confidence that these needs are being met.

The three papers described in this Chapter addressed different aspects of disconnect between physician and patient. This first paper focuses on the concordance/disconnect in patient severity of AD. Instead, aspects of the condition such as sleep disturbance demonstrated significance. The second and third papers discussed disconnect regarding the prevalence and potential importance of physical and psychological symptoms respectively. In both cases it was observed that patients were more likely to report experiencing symptoms than their physicians. In each case, the lack of concordance had detrimental effects both on HRQoL and satisfaction with treatment.

Based on the findings from these three studies, it is not sufficient merely to diagnose the condition that the patient is suffering from; the best outcomes can only be obtained if physicians and patients concur regarding the severity of the condition and about the presence and importance of both visible and invisible symptoms. To achieve greatest patient satisfaction and to maximise value to the patient, physicians also need to recognise what *aspects of the condition* are of most importance to the patient. It is this recognition of and empathy with the most important symptoms in the mind of the patient that is key to process quality and patient experience.

Several reasons for the lack of concordance can be hypothesised. Firstly, there may simply be a lack of communication between the physician and the patient; a physician may not recognise the presence of a symptom, particularly if it is not directly observable. Secondly, physicians may be aware of the symptom, but not place as much emphasis on it as the patient.

Thirdly, the focus and objectives of the physician may simply be different to those of the patient. Whatever the reason though, discordance results in sub-optimal outcomes for the patient and a lower return on the investment made in the health care for those patients.

One way of identifying patient needs could be the routine use of validated PROMs. However, as was observed in the first study presented in this Chapter (Wei et al., 2017) physicians may not be familiar with PROMs, or even if they are familiar, rarely use them in routine clinical practice. This lack of knowledge or comfort in using PROMs suggests a potential lack of knowledge regarding the elicitation of what is important to the patient. If the physician does not establish what is most important to the patient, not only might process quality be compromised, so might the capability of the physician to deliver what the patient values. Incorporation of PROMs into patient assessment processes could help physicians to ask the "right" questions. Decisions regarding the most appropriate treatments can then focus not only on the condition but also on specific factors of the condition which drive poor HRQoL.

These studies have highlighted disconnect between physicians and patients in three conditions: Atopic Dermatitis, Acute Myeloid Leukemia and Rheumatoid Arthritis. However, disconnect and discordance is relatively common, not just in terms of severity but also in recognition of symptoms. It has been observed across a number of chronic conditions, including osteoarthritis (Bushmakin et al., 2011), Diabetic Peripheral Neuropathy (Taylor-Stokes et al., 2011) and Psoriasis (Paul et al., 2015). In all cases, disconnect had a negative impact on outcomes/HRQoL.

Another important and related element is physician capability. This can be achieved by appropriate patient co-management. The third paper presented in this Chapter (Peterson et al., 2019) highlighted the under-recognition of anxiety and depression. A study conducted in the UK (Dures et al 2014) found that rheumatology units self-report a lack of access to psychological support, with both time constraints and training highlighted as barriers to the provision of this service. Enhanced availability of this would provide the possibility to recognise the presence of psychological disorders and to improve outcomes in the 25% of RA patients who suffer with unrecognised anxiety and/or depression.

So, what are the implications of these three studies? Disconnects occur when patients and physicians do not share a common understanding on issues such as disease severity, the importance of symptoms or the recognition of the impact of the condition on the patient's overall health. A truly capable physician would ensure that all important concomitant conditions are recognised and managed appropriately, if not by self, then through co-management with other physicians. The key to reducing disconnect is not only communication, empathy and recognition of what is important to the patient, but also the confidence to manage patients as part of a multi-disciplinary team.

One reason that symptoms and concomitant conditions can be unrecognised is an unintended consequence of organising physicians into specialties and subspecialties, with different groups of physicians and other health care professionals working independently from each other. While this structure makes sense from an organisational perspective for example with regard to peer support (ongoing training, doctor rotations and support of junior staff to name but a few reasons), it does highlight a need for cross-discipline collaboration for individual patients where this makes sense. Traditionally, the way to obtain a different opinion is to refer the patient to a clinician in a different specialty. This can cause unnecessary administration, delay to the patient and is unlikely to enhance the patient treatment experience. Indeed, as well as delays to treatment, referrals mean more consultations and greater access costs in time and money for the patient – this is a direct negative in the CVE and reduces the overall value of the care experience. Extra consultations will also result in greater costs to the health care system. Hence, the need for multi-disciplinary working from the get-go; and any policy recommendations to this effect can only enhance the patient experience. Increasing value by improving the process quality of overall health care interactions – and training physicians regarding the signs they need to look for in issue recognition - would lead to more positive patient experiences, increased satisfaction and HRQoL. Widespread adoption of shared decision making, as discussed in Section 7.2, would be one approach to consider.

4.6. Summary

The papers in this Chapter have shown how health outcomes can be worse if there is disconnect between doctor and patient.

In the context of the SPC, to address this problem, physician capability needs to extend beyond the obvious physical symptoms of the condition. Physicians need to consider not only overall disease severity but also to recognise specific visible / invisible symptoms or conditions and to act on these. Goals of physicians need to align more closely with goals of patients. A more holistic view of the patient’s condition is necessary to maximise patient satisfaction and outcomes, together with the physician’s ability to communicate or engage with the patient and identify issues of concern. One method of achieving this might be a more widespread knowledge and use of PROMs since these offer insights not only into the patient’s health state but can show what might be driving their HRQoL. These insights may also lead to the physicians asking more pertinent questions to the patient during their consultation.

If the physicians’ capability to recognise and act on these problems is increased, then so will the perceived value of the interaction in the mind of the patient. Enhancement of physician capability through training (or through provision of appropriate resources in a shared care, co-management or similar environment) has the potential to result in better engagement, satisfaction and outcomes.

However, it is not the presence of discordance *per se* that is important, it is the effect of the discordance that matters. This is the subject of the next Chapter.

5. Patient Engagement

5.1. Introduction

The previous Chapter discussed the association between patient-physician disconnect in terms of disease severity, symptoms and HRQoL. However, recognition of needs is only the first step. While this should lead to appropriate therapy choices, this may not be sufficient to maximise the value of the health care encounter and ensure optimal outcomes. As discussed in Section 2.4, communication is an essential part of the physician's capability to promote adherence (Zolnierek and Dimatteo, 2009), indeed, poor communication can be a barrier to adherence (Kardas et al., 2013). Value is maximised where trust, rapport, empathy between physician and patient is established (Finset and Mjaaland, 2009); all of which is underpinned by clear and positive communication. Good communication will not solve every problem related to adherence and outcomes and in itself will not maximise the value of the treatment, but it is a necessary first step. By communicating effectively with their patients, physicians can empower them with sufficient knowledge and understanding to follow the treatment plan and to maximise the change of a good outcome (Street et al., 2009).

This Chapter discusses two situations where communication and knowledge are important. The first paper (Sullivan et al., 2017) describes a situation where patients are asked to accept a switch in medication even when this may not be for clinical reasons. The second paper (Sikirica et al., 2017), in the context of a specific drug, studies the reasons for medication discontinuation combined with an analysis of problems experienced by patients still receiving treatment. Both papers show the necessity of providing information and setting expectations regarding their therapy.

5.2. The importance of communication in medicine acceptance (Sullivan et al., 2017)

*Sullivan E, **Piercy J**, Waller J, Black CM, Kachroo S. Assessing gastroenterologist and patient acceptance of biosimilars in ulcerative colitis and Crohn's disease across Germany. PLoS One. 2017 Apr 14;12(4):*

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Crohn’s Disease (CD) and Ulcerative Colitis (UC) are types of Inflammatory Bowel Disease (IBD), chronic conditions of the digestive system (Baumgart and Carding, 2007) which can have a significant impact on HRQoL (Mao et al., 2017). Both can be treated with biologic medication (Danese et al., 2015). Since 2013, biosimilar products have been approved by the EMA for use in the EU use in IBD alongside other indications approved for the bio-originator (Beck and Reichert, 2013). Biosimilars are copies of already authorised drugs, similar in quality, safety and efficacy to the reference drug (EMA, 2014). Two infliximab biosimilar compounds were launched in Germany in early 2015. This study examined motivations and preferences of both physicians and patients regarding biosimilar and bio-originator compounds. Key objectives were the exploration of IBD patient acceptance of biosimilars and to understand patient satisfaction and concerns with biosimilars in relation to treatment with bio-originators.

Data for this analysis were drawn from the Adelphi DSP in Biosimilars conducted between December 2015 and March 2016 in Germany. Four groups of patients were studied: two groups receiving a biosimilar either with or without a prior bio-originator and two groups receiving a bio-originator initiated either before or after February 2015, the date when the biosimilars were approved for use in Germany.

Physicians provided data on their prescribing behaviour and attitudes towards biosimilars. Patients provided information on demographics, health status, satisfaction and compliance with current treatment together with perspectives on biologic and biosimilar therapies.

In all, 25 gastroenterologists provided data on 136 patients (69 CD; 67 UC across the four groups). Key findings were that patients who were switched from a bio-originator were less likely to accept a biosimilar without reluctance than those who had not (43% vs 60%), particularly if there was no clinical need for the change. In addition, 10% of biologic naïve and 18% of bio-originator experienced patients refused treatment with a biosimilar.

While satisfaction with treatment and with symptom control was generally high for all patients, the authors observed a greater level of satisfaction in patients receiving bio-originators (91% vs 79% for overall treatment; 87% vs 69% for symptom control). Concerns regarding side-effects and long-term effects were greater for biosimilars, particularly in those who were switched from a biologic. A greater proportion of patients receiving biosimilars felt they did not know enough about the drug; though such concerns were also more common in patients prescribed a bio-originator before February 2015 (when there was less experience of biologic drugs). These results were similar to those observed in a parallel study in rheumatoid arthritis in which the writer of this thesis was also an investigator (Waller et al., 2017).

Although there had been studies examining physician attitudes towards biosimilar products (Zelenetz et al., 2011, Weise et al., 2014, Aapro, 2012), these had focused on oncology, where experience with biosimilar products was greater. To the best of the author's knowledge this was the first study in IBD and one of the first anywhere systematically to capture the patient perspective. As the research was carried out within a year of the introduction of biosimilar products, sample sizes were too small to carry out statistical testing confidently. Since then, there have been big increases in the use of both biologics and biosimilars. As this experience increased, it is likely that physician comfort levels in prescribing and explaining them, plus greater patient awareness, may have increased the acceptance of both bio -originator and biosimilar drugs.

One potential limitation to the generalisability of the study was the choice of physicians. The inclusion criteria specified that each gastroenterologist had to be managing at least one patient in each of the four specified groups. Not only does that suggest that only gastroenterologists with relatively large workloads could be included, but it also implies that these physicians were more likely to have a greater understanding and to be early adopters of biosimilar therapy. It would have been enlightening to have also included physicians with less experience or who did not prescribe biosimilars in the physician survey, since they may have less favourable perceptions of biologic/biosimilar therapies.

This paper focused on one particular class of drug in one condition in one country. However, similar situations are likely to occur when any biosimilar is introduced to the market in any country and where patients are switched from existing treatments for reasons other than lack of efficacy or tolerability. As with generic drugs, biosimilars are seen by payers as a method of controlling cost since they are much cheaper than the branded bio-originator but, as the name suggests, effectiveness is similar (Kvien et al., 2022). Therefore, given the push towards biosimilar prescribing, physicians need to communicate clearly that the chosen treatment alternative is appropriate, they must engender confidence in the treatment choice and explain the value of this course of action to the patient. Given that gastroenterologists, particularly in Germany, may themselves be uncomfortable with biosimilar adoption (Bernasko and Clarke, 2021), this may require a degree of physician education and although this may have been improved with supportive data from infliximab biosimilars in IBD (Bhat and Qazi, 2021), it is clear that if a physician is not convinced about this treatment alternative then explaining the choice to a patient can be expected to be problematic. Should the patients feel they are receiving a generic (cheap) alternative, their perceived value of the treatment and their satisfaction with the result of the health care encounter may be lower (Dunne, 2016). They may be less likely to accept and adhere to the treatment, reducing the effectiveness of the medication prescribed; or they may stop taking the drug altogether. Indeed, discontinuation with a treatment plan is the subject of the next paper.

5.3. Therapy Discontinuation (Sikirica et al., 2017)

Sikirica MV, Martin AA, Wood R, Leith A, ***Piercy J****, Higgins V. Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes. Diabetes Metab Syndr Obes. 2017 Sep 29;10:403-412*

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Diabetes is a chronic disease affecting 8.5% of the global population. Early diagnosis and treatment increase the likelihood of favourable outcomes (WHO, 2016). Oral antidiabetic therapy is generally the first line treatment, though add-on treatments can be used where necessary. The most common injectable therapy is insulin, but other drugs, notably the Glucagon-like peptide-1 receptor agonists (GLP1-RA), can also be prescribed (Chamberlain et al., 2016). GLP1-RAs improve glycaemic control without the risk of hypoglycaemia and weight gain associated with insulin. However, these medications have been shown to have high discontinuation rates in the first year after initiation (Davidson, 2013, Fabunmi et al., 2009). The implications of discontinuation are clear; without treatment, achieving control of the condition is compromised, leading to excess risk of diabetes related complications and health care costs (Roborel de Climens et al., 2020). Objectives for this study included understanding the reasons for discontinuation of GLP1-RAs and identifying problems experienced by patients still receiving GLP1-RA medication.

Data for this analysis were drawn from the Adelphi DSP in Diabetes conducted in 2014 in the USA and Europe. Physicians provided patient-specific data on demographics, clinical characteristics, symptoms and treatment, including reasons for choice of and for switching between drugs. They also completed a survey which included exploring their perceptions of problems associated with GLP1-RAs. Patients provided information on their experiences and perceptions of Type-2 Diabetes Mellitus (T2DM) treatment. Specifically, patients who were currently receiving GLP1-RAs were asked whether they were experiencing problems while using this treatment and how bothered they were on a 4 point scale (not at all, somewhat, very, extremely bothered); or if they had stopped taking them, what the reasons were for stopping.

Overall, 443 physicians provided data for 2173 patients; 1396 currently receiving and 777 who had discontinued GLP1-RA therapy. Physicians reported the main reasons for discontinuation were lack of blood glucose control (45.6%), nausea/vomiting (43.8%) and gastrointestinal side-effects (36.8%). In 17.6% of cases, patient request was cited as a reason for discontinuation. For patients, the main reasons were different; nausea (64.4%), vomiting (45.4%) and a preference for oral rather than injectable medicines (39.7%). In total, 34.5% of patients stated that inadequate blood sugar control was the reason for discontinuation. For patients currently receiving GLP1-RA drugs, the main problems that patients reported were a preference for oral over injectable medication (56.0%), nausea (38.1%), the drug did not help them lose weight (25.4%) and gastro-intestinal (GI) side-effects (22.0%). Patients reported the problems that bothered them most were difficulty in meal planning (55.6%), vomiting (51.6%) and weight gain (50.0%). These are all problems which physicians need to consider when planning treatment strategies. A similar range of problems were also reported by the physician, although the reported prevalence of problems was typically around 50% lower.

As discussed in the literature review in Chapter 2, RWD are essential to understand the long-term effectiveness of treatment in everyday care. Clinical trials have higher adherence rates which can lead to greater clinical benefits than those observed in real world populations (Cefalu et al., 2014). While trials have demonstrated that GLP1-RAs are effective at controlling diabetes (Trujillo et al., 2015), they have also highlighted adverse events, the most common being the same GI events observed in our study.

Another strength was the sample size and geographic spread, including over 2,000 patients in six countries. We observed similarities between USA and EU patients regarding both reasons for discontinuation and current problems experienced – other than cost which featured much more heavily in the USA. This suggests that our findings are generalisable to most health care environments. Being able to directly compare physicians and patients' perceptions about the reasons for discontinuation and the problems associated with GLP1 RAs is also a key feature of our research.

Limitations to this study must be acknowledged. Almost half of the patients in the discontinuation analysis had stopped taking GLP1-RAs more than 6 months previously. Recall of the reasons for discontinuation may therefore be less sharp than in the immediate aftermath. However, there is a consistency between the reasons for discontinuation and the problems currently being experienced by patients receiving GLP1-RAs, lending validation to the findings. However, it is possible that a survey of patients at or just after discontinuation would provide more immediate insights.

The sole focus of the study was GLP1-RA therapies. Therefore, these findings were not placed in the context of anti-diabetic therapies in general, nor was the prevalence of side-effects compared against other anti-diabetic therapies. Such wider analysis could be undertaken using the same data source, since the GLP1-RA patients represented only a fraction of the entire DSP sample. Alternatively, comparisons could be made through literature review and indirect treatment comparison. However, the focus of this analysis was specifically GLP-RAs, not a comparative analysis of the side-effects of all anti-diabetic drugs.

Additional analysis of the current data could provide further insights. Given the data set contains variables relating to both the duration of current and previous treatments, it would be instructive to add a time dimension to the analysis - how long does it take for problems to be encountered and for discontinuation to occur – and whether problems become less bothersome the longer the patient remains on treatment. Or, whether the reasons for discontinuation change depending on how quickly the discontinuation occurs. The fact that there is evidence to suggest these problems subside over time (Cefalu et al., 2014) only highlights the importance of setting patient expectations about the treatment process, both during the initial consultation and in subsequent consultations should the patient be experience tolerability issues.

In the CVE, value is maximised not only in terms of the relationship between outcomes (results) and fees (direct costs), but also by process quality and maximising the user experience. Value is reduced if the user experience is poor, especially if the patient experiences adverse events, or if there are costs to the patient in terms of disruption of usual activities or the need to modify lifestyle choices. The finding that patients experienced bother with meal planning and with weight gain while receiving the medication are examples of how value can be compromised, particularly if these issues are unexpected. Good communication between the physician and the patient is essential if such issues are to be managed and appropriate expectations of the treatment established at the outset of the treatment process. The issue of physician-patient communication is addressed more generally in Section 7.3.

Dissatisfaction with and discontinuation of medicines have consequences for both the patient and the health care system. The literature review in Chapter 2 highlighted some direct costs associated with nonadherence to medication, but this is only likely to be the tip of the iceberg. Patients cannot benefit from treatments they do not take, so their health status and quality of life cannot be improved. But once dispensed, medications have to be paid for, either by the individual or by the health care system, so costs are incurred without any benefit at all. On top of this, there is also the opportunity cost to the health care system as the funds used could have been allocated to other patients and other treatments. So, as well as failing to derive benefit themselves, the non-adherent patient also punishes other patients who are not now able to be treated since money cannot be spent twice. In addition, not taking the medicine can also have unfavourable long-term consequences for the patient. The condition they suffer from is unlikely to improve or resolve without treatment; for chronic conditions, delays will only result in patients getting worse and being harder and more expensive to treat in the future. Policy initiatives aimed at cutting waste by improving adherence would therefore be of value, especially in systems where the patient does not pay for the treatment (so may value the medication less). If increasing engagement can increase adherence, then this can only be a good thing. This is where SPC principles, particularly those associated with the CVE, can be applied, namely enhancing the patient experience, setting realistic expectations of both outcomes and potential side-effects, and reducing disconnect between the patient and their physician.

5.4. Application to the SPC

The papers presented in this Chapter have focused on potential effects of disconnect between physician and patient. The CVE would suggest that the problems of lower satisfaction with therapy, low adherence and discontinuation observed in the papers can arise if the overall patient experience is not good.

In each case, issues are more likely to occur if patients do not feel engaged with their treatment and/or do not have sufficient information regarding both positive and negative aspects of treatment. Establishing appropriate patient expectations considering both treatment benefits and side-effects is also important.

In the case of biosimilars, the evidence suggested that the perceived overall value felt by patients prescribed biosimilar medication was lower. Reasons for this included a lack of knowledge and consequently a lack of confidence in the drug, potential side-effects, and perceived long-term problems. Negative perceptions were strongest in patients had previously received a bio-originator but who subsequently were prescribed a biosimilar, resulting in reduced satisfaction and greater concerns with biosimilar medication. One plausible explanation is that because the cost of biosimilar medications is lower, the patient believes that the quality may also be lower (Dunne, 2016).

But biosimilar agents confer significant cost saving benefits to payers (Leonard et al., 2019). To ensure perceived value of treatment is maintained, it is essential that the value of biosimilars is explained to both physician and patient (Kim et al., 2017). Mistrust of generic medications in general is still a problem in some patients, with familiarity and trust in brand-name goods remaining a barrier to generic use even though effectiveness has been demonstrated to be comparable (Desai et al., 2019). The fact that we observe this mistrust extending to biosimilars is not therefore unsurprising. Indeed, some physicians still remain sceptical themselves (Barsell et al., 2017), though this can be expected to reduce over time. The increased use of biosimilars depends on the willingness of physicians to prescribe them (Leonard et al., 2019). Addressing gaps in the knowledge of biosimilars is the key to facilitating prescribing changes and empowering physicians to discuss and explain such products to their patients and to convince them that the value of these products is comparable with that of brand name bio-originators despite their lower cost.

Communication is also important in situations where side-effects are both common and expected. While the reasons stated by physicians and patients for discontinuation of diabetes medicines were broadly similar, physicians focused primarily on measurements (blood glucose control) whereas patients prioritised how they felt (nausea, vomiting). The higher levels of reporting of side-effects by patients than by physicians suggest some problems go unrecognised or are viewed by the physician as acceptable in relation to the clinical benefits of the treatment. Disconnects in the expectation of tolerability issues surrounding the medication can lead to dissatisfaction and discontinuation should patients view the experience on medication sufficiently bothersome or the cost to their lifestyle sufficiently great. The need therefore for physicians to explain fully the consequences as well as the benefits of the medication are crucial to setting expectations and convincing them of the value of engaging in the treatment plan.

Engaging patients is especially important where the patient may have alternative preferences regarding their medicine and where these preferences can be met by products available in the market. In the diabetes study, 56% patients and 33% of physicians reported a preference for oral medications over injectables. It is plausible that physicians may be underestimating the strength of patient preference for oral medications or overriding these concerns in the pursuit of greater efficacy.

Adherence is indeed a particular problem in GLP1-RA diabetes medication (Divino et al., 2014), so given GI side-effects are a likely contributor to non-adherence to GLP1-RAs (Sanyal and Majumdar, 2013) and to diabetes medication in general (Florez et al., 2010), it is important this issue is recognised and addressed. The same hold true for all medications regardless of therapy area, since although discontinued medicines cannot provide treatment benefit they are certainly a cost to the health sector - indeed the costs of wasted medicines alone has been estimated at £300m in the UK (Oswald, 2018).

An essential component of the process quality of the health care encounter is the communication between the physician and the patient. It is especially important in the two situations described in this Chapter, where there is potential for patients to think they may be getting a cheaper (so lower value) substitute product rather than the brand-name original, or where there is the potential for discontinuation due to lifestyle restrictions/unpleasant side-effects. The common theme is lower engagement with the treatment plan, causing dissatisfaction or discontinuation, a logical result of lower perception of value and unrealistic expectations.

But communicating with every patient may not be so easy. Discussion of the athenahealth case study in Section 2.3 highlighted the potential for technology to create inequality. Indeed, ability to access technology has always been incorporated into the CVE framework as a potential access cost or barrier to access (see Section 1.2 above). With the increases in remote consultation, online booking and monitoring of their condition, inability of patients to access or use technology such as computers, tablets, smart devices or even the internet may therefore exacerbate any pre-existing inequality. Indeed, a large scale study in an older population in the USA showed that people of increasing age and of black, Latino or Filipino race/ethnicity were less likely to use online portals, thus increasing existing disparities in health care and health status (Gordon and Hornbrook, 2016). Technology is important in health care delivery and outcome, but it is important that this equitable across different populations (Saeed and Masters, 2021).

Health literacy and spoken language are also important when considering communication. There is evidence that poor health literacy is associated with lower communication quality (Wynia and Osborn, 2010) and lower satisfaction with care among patients (Altin and Stock, 2016). Both issues are likely to lead to less favourable health outcomes. Language itself can be an even bigger barrier, since communication errors between practitioner and patient are increasingly likely when one is speaking a secondary language (Meuter et al., 2015). Both literacy and language are factors that physicians and health care professionals in general must consider when communicating with patients.The importance of the connection between physicians and patients is essential to process quality. This has been recognised for many years (Stavropoulou, 2011). involvement in the decision-making process, treating patients as equals and ensuring all important issues have been addressed when prescribing were significant factors in determining adherence. Discussing potential issues and offering realistic expectations may therefore set realistic patient expectations and thereby promote adherence. Such focus on patient concern lies at the heart of maximising the perceived value of the product from their perspective.

5.5. Summary

The two papers presented in this Chapter described situations where the choice of medication, while appropriate for the clinical context, may not be the first preference of the patient. The first paper (Sullivan et al., 2017), considers patients who were asked to accept a cheaper biosimilar rather than an original biologic product. Such patients may feel they are getting a copy rather than an original and perceive the copy to be inferior. The second paper studies patients prescribed an injectable medicine with a known side-effect profile which may be uncomfortable for patients. In both cases, it is necessary for physicians to communicate all aspects, both positive and negative, of the treatment choice. In the SPC model, it is stated that “service quality can be enhanced by meeting or exceeding customer (patient) expectations or taking steps to control such expectations” (Heskett et al., 1997). Communication of both the benefits and of the potential side-effects of treatments and/or discussions around why it may be necessary to provide a drug which the patient may not feel as a first preference, is essential to set the right expectations for the patient. Setting appropriate expectations is also likely to result in higher satisfaction and adherence. But how can satisfaction of the process quality of care be measured? The next Chapter explores the validity of a measure designed to do exactly that.

6. Measuring Process Quality - Including the Patient Voice

6.1. Introduction

The papers in the previous two chapters have assessed the implications of disconnects between physician and patients in terms of HRQoL, satisfaction and adherence to treatments provided. They have focused on the need for physicians to understand the holistic needs of the patient in front of them, recognising and acting on factors that the patient might perceive as most important. The value of understanding, empathy and engagement has been outlined. I have also highlighted that for the perceived value of a health care intervention to be maximised, patients need to be empowered with the capability to fulfil their obligations. This suggests the patient experience is important – but what drives it, and can it be measured?

6.2. Assessing the Patient Experience (Wood et al., 2014)

Wood R, Paoli CJ, Hays RD, Taylor-Stokes G, ***Piercy J****, Gitlin M. "Evaluation of the CAHPS-ICH Hemodialysis Survey." Clin J Am Soc Nephrol 2014;9:1099-1108*

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The objective of this study was to evaluate the psychometric properties of a survey, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS), designed to evaluate consumer assessment of end-stage renal disease health care providers. The aim of the tool is to assess patient experiences of care (Weidmer et al., 2014) and to provide feedback on service quality, which, if taken on board by providers, can be used to improve the customer (patient) experience. If patients are not satisfied with the way in which the service is delivered, their perception of the quality will be low, and outcomes affected.

Data for this analysis were drawn from the Adelphi DSP in Chronic Kidney Disease conducted between February and March 2012 in the USA. Nephrologists provided data on patient demographics, clinical characteristics, and patient management. The study population comprised patients currently receiving centre haemodialysis. Each nephrologist also provided details of their dialysis centre including the size of the facility, staff-patient ratio and waiting times. They also provided clinical and demographic details for each patient included in the research. Patients provided information regarding their consultation history and symptoms and completed the ICH-CAHPS.

The ICH-CAHPS instrument (AHRQ, 2019) has three multi-item scales: assessing nephrologists communication and caring (NCC); quality of the dialysis centre and operations (QCO); and the provision of information (PI). Three general questions ask patients for global ratings regarding their doctor, dialysis centre staff and about the facility itself. Analysis focused on evaluation of item-scale convergence, discrimination and reliability for multi-scale items plus floor and ceiling effects for all scales. To assess reliability, the extent to which patients attending the same facility shared similar experiences was tested.

In all, 404 patients attending 76 dialysis centres were included in the analysis. The authors found that item-scale correlations and internal consistency reliability estimates provided support for the NCC and the QCO composites. In contrast, the PI composite had a low internal consistency and reliability. Minimal floor effects were identified in all scales, but ceiling effects were variable, suggesting the ICH measure may be limited in the ability to distinguish between patients having the most positive experiences of care, although negative perceptions can certainly be identified. Regarding factors pertaining to the process quality of care, the study found that lower patient to provider ratios, the provision of information and shorter time spent in the facility waiting room were most important.

The survey included a robust number of patient responses. Demographics were broadly representative of the whole USA patient cohort when compared with national census data captured in the USA Renal Dialysis Data System in 2012 (USRDS, 2012). It could be argued however that the relatively limited number of facilities included in the survey could limit the generalisability across all 7,500 plus dialysis facilities in the USA. Furthermore, we were unable to compare patients who did not choose to participate. However, these factors are not important in relation to testing whether the assessment tool works, which was the main objective of the paper

The ICH-CAHPS provides a valuable step forwards in the assessment of the patients perceived quality of care. Factors identified as strong correlates of the perception of care such as staffing ratios and the information provided to patients might be directly related to service quality and therefore to the perceived value of the service provided. However, as measurements are setting specific, further research in other disease areas and other care settings would be necessary to test the replicability of our findings. Further research could also focus in on specific items reflecting particular aspects of care as markers for quality improvement and on the correlation between measures of process performance and measures of clinical and patient related HRQoL outcomes. Clinically meaningful differences also need to be identified – a research question highlighted by the authors but which, to the best of the writer's knowledge, has not yet been reported.

There have been a number of PROMs developed to attempt to measure patient satisfaction, such as the general Treatment Satisfaction Questionnaire for Medication (Atkinson et al., 2004), the Feeling of Satisfaction with Inhaler-10 (Perpiñá Tordera et al., 2008) used in the respiratory area and the Cancer Therapy Satisfaction Questionnaire (Abetz et al., 2005). However, these PROMs focus on the treatments provided or the method of administration of those treatments, and not on the interaction between the patient and the health care provider. Satisfaction with medications is only part of the story; the whole picture needs to include the overall care package and management of the patient, including health care encounters. This is of particular importance in systems such as the UK, where the patient has to register with a physician (general practitioner) and where it is not straightforward to change providers. In such systems, health care professionals do not have to compete for patients (and therefore income) so there is less direct financial incentive to provide the highest quality of care. But the overall care experience does influence patient engagement and subsequent behaviours, so needs to be maximised.

The value of instruments such as the ICH-CAHPS lies in their ability to assess satisfaction with the whole care experience. This includes quality of the care environment, communication between provider and patient and waiting times. Tying payments to results of measures such as ICH-CAHPS can incentivize providers to improve aspects of care with which the patient may not be satisfied. Use of quantitative tools to measure overall satisfaction is a potential next step. Indeed, ratings are commonplace in the UK education sector, with schools promoting themselves on the back of favourable Ofsted[4] assessments, so the principle of assessing

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[4] Ofsted is the Office for Standards in Education, Children's Services and Skills. Their purpose is to inspect services providing education and skills for learners of all ages.

public services has been established. Whether the ICH-CAHPS is the right tool for use in the UK is a question that would need to be addressed, but the principle is clear; overall service quality can and should be measured, and policy initiatives to achieve this would be expected to result in higher standards of overall care. All that is required is the political will to enact such a system.

6.3. Application to the SPC

This paper is potentially the most important paper to be presented in relation to the CVE as it sets out a potential method of measurement. The paper outlined a method of objectively quantifying the user experience in a systematic and scientific fashion, specifically dealing with issues that are important to the patient and that cover process quality. The sub-scales of the tool capture aspects of process quality that directly influence patient perception of value and satisfaction. Aspects of process quality such as nurse-patient ratios and shorter waiting times were associated with patients being more likely to recommend a facility, as discussed in Chapter 2. This research found that this ease of access in terms of shorter waiting times was positively correlated with perceptions of care, as were favourable staff-patient ratios, another factor indicative of process quality. These results are consistent with other patient experiences of care in the USA (Jha et al., 2008, Kutney-Lee et al., 2009). The Kutney-Lee paper also suggests a relationship between nurse-patient staffing ratios and the likelihood of patients recommending that hospital.

CAHPS surveys have been used successfully in a number of therapeutic areas across different health care settings (Paddison et al., 2013, Anderson et al., 2002, Sangl et al., 2007, Frentzel et al., 2012, Bader and Shugars, 2012). Indeed, there is evidence that communities most likely to benefit from a holistic approach to care are those that might otherwise be perceived as disadvantaged (Bagchi et al., 2012). These were the same patient communities that were suggested to have had a worse global care experience in the analysis presented in the paper. Understanding patient needs holistically, including cultural needs, is fundamental to providing the greatest value to the patient and maximising the value of the health care intervention.

An institution that can score highly on measures such as CAHPS will be an institution that not only meets the patients' clinical needs well but also one which will maximise the care experience and overall satisfaction. This is the philosophy espoused in the Shouldice Hospital case study presented in Chapter 2, where that institution's aims included not only the provision of high quality clinical care but also to make the patient experience so positive, thus differentiating themselves from rival institutions with respect to the overall value provided to the patient over and above the clinical outcome. Such institutions are those most likely to be successful; whatever definition of successful is chosen, for example health outcomes, profit, growth, patient, and health care professional satisfaction etc.

However, both process quality and user experience are factors which can get overlooked when assessing the value and cost-effectiveness of care using traditional measures of economic evaluation, since such analyses focus primarily on costs and results, often ignoring how the outcome is achieved. Yet such factors will lead to higher perceived value to the patient, essential to promote patient satisfaction and engagement so should take a more central place in the provision of health care services. Perhaps it is a weakness of the use of health care evaluation that formal techniques of economic evaluation are often limited to drugs and diagnostics, whilst the majority of care provision such as that provided directly by health care practitioners can be overlooked (Neumann et al., 2018). Addressing this could result in both better service quality and perceived value of the treatment for the patient at the point of their engagement with the health care system, and consequently improved value in the whole health care system. This paper has demonstrated the validity and relevance of an instrument to measure satisfaction with the care experience in one disease area in one country, and while not perfect, the ICH-CAHPS methodology is one potential step forward in undertaking such evaluations.

6.4. Summary

The three aspects of care discussed in this final paper, communication and caring, quality of care, provision of information, are essential aspects of the CVE. Communication and caring, plus provision of information in a way the patient can understand are fundamental to process quality and should be core components of physician capability. However, as was shown in other papers in this thesis, these aspects are not always in evidence - if patients do not perceive they have received value, dissatisfaction is the result and outcomes are less favourable.

Indicators of satisfaction, such as the ICH-CAHPS are increasingly being used to determine reimbursement for health care services, providing strong incentives to encourage process quality. There is no reason why this framework cannot be used in any health care situation, linking aspects of funding to services which provide a high process quality in the perception of the patient.

While these ideas may gain most traction in a private health care environment where there is competition for patients, the same principles could and should be applied also to publicly funded health care systems. Ensuring process quality and enhancing the patient experience would be just as effective in maximising the value of the health care provided regardless of the funding mechanism in place. Indeed, the value associated with the patient experience sits as a key aspect of performance management in the NHS (NHS, 2013). The question remains, how to measure it and how to improve it – the ICH-CAHPS and related tools provide one way to do this.

7. Discussion

7.1. Introduction

The overall aim of this thesis was to discuss the applicability of the Service Profit Chain to the health care environment. The SPC is a business model linking together profitability, customer satisfaction and loyalty, employee satisfaction and capability (Heskett et al., 1997). Customer loyalty is influenced by the perceived value of services provided to customers. It considers results, service quality, non-monetary costs of access to the service and fees (costs).

Examples of the SPC in action range from Southwest Airlines to Au Bon Pain to American Express to IKEA. All these companies are highlighted as embracing the SPC and outperforming their competitors as a result (Heskett et al., 1997). But does the model apply to health care? It is clear that in health care systems where providers have profit as an objective, the SPC model has a direct relevance. The examples of the Shouldice Hospital and the value creation provided by athenahealth are examples of this. But good process quality should apply to all organisations, regardless of funding pathways.

Critical to the SPC is the CVE. It has been shown that health care outcomes are maximised when the patient has the motivation to adhere to their treatment plan. This is most likely if the patient is engaged in the health care process and plays an active part in treatment decisions. Such patients are more likely to be satisfied and value their health care encounters, an outcome most likely if they believe that the process quality of their care is high and their access costs (in ease, time, effort) are low. Fundamental to the CVE and to process quality is the interaction between the physician and their patient.

So, in the context of health care, the SPC as it applies to the health care encounter can be adapted as follows:

1. A primary driver of good treatment outcomes is the patient's willingness and ability to take their medication and follow the instructions of their doctor (patient empowerment).
2. This is more likely if patients are satisfied with the result of their interaction with the health care service. The process and delivery of the health care is a key driver of satisfaction, which is itself an important driver of adherence.

3. Satisfaction results from doctors and patients having shared goals. Shared goals result from the doctor understanding patient needs. Effective communication is essential to achieve this. Process efficiency alone is not enough – perception of service value is also important. Research has shown that more than half the claims made for medical malpractice in the US didn’t involve patient injury or any adverse event but were associated with patient perception of value or because the patient was unhappy with the way the service was delivered (Weiler et al., 1993). Disconnect between physician and patient is indicative of perceived poor service quality and therefore poor value and can result in patient dissatisfaction and lack of adherence to the treatment plan.
4. As with any service industry, service quality is linked to provider job satisfaction. Physician job satisfaction is linked to their capability to provide the best quality health care. Time, training and motivation are essential for physicians to achieve this. Technology can play an important part in this (Menachemi et al., 2009), but this is outside the scope of this thesis.

Essentially, if the patient is at the centre of the care system, they are more likely to feel that the physician is actively engaging with their concerns and their experience is more likely to be positive. The value of the encounter and of the outcome (treatment plan) will be greater than if the patient experience is poor. Effective communication skills are required to achieve this patient buy-in (Hurst et al., 2019); if this is achieved then the likelihood of adherence to the treatment plan is greatest and value is maximised.

7.2. Steps towards a SPC model: Shared decision making

The traditional historical doctor-patient relationship has been described in economic terms as an ‘agency relationship’ where informed agents make decisions for less well informed clients (Mooney and Ryan, 1993) and despite advances in access to information associated with the internet, social media and Patient Advisory Groups, this still remains an issue in health care (Cerovic et al., 2012). In this case, communication between the physician and patient is fundamental for rational and effective prescribing. Better decisions can be made when relevant information is available to both parties, thus breaking down the agency relationship (Steinke et al., 1999).

One way to achieve this is shared decision making (SDM). The principles of SDM include providing patients and their families the autonomy to make difficult decisions after receiving clear and comprehensive information about medical facts and treatment options (Beers et al., 2017). As SDM takes into consideration the patient’s own values and goals, clinicians are better able to guide patients with their health care choices. Essentially, physicians and patients work together to make optimal health care decisions (Elwyn et al., 2012). SDM is indeed being advocated for all patients as one aspect of value-based care (Gustin, 2019).

This process of SDM respects the rights of patients to be fully involved in decisions about their care (Hughes et al., 2018). Therefore, to be effective, it must be driven by patient centred preferences and goals. Important elements include mutual respect, that the patient feels that they are being listened to and that the care they receive is personalised for them. It has been shown to increase health literacy, patient satisfaction and improve care outcomes (Stacey et al., 2017)

Patients have a critical role in their own care, including attending appointments, filling and taking medications, undertaking exercises and making lifestyle changes (Schlesinger and Fox, 2016). Rather than being passive recipients of care, patients will become active partners in their own care, in collaboration with physicians and clinical staff. This degree of alignment between patient needs and treatment choices may enhance satisfaction, adherence and outcomes (Bell et al., 2021). A SDM approach is likely to be of particular benefit when treatment alternatives which might have a lower perceived value, or which are less preferred, are under consideration.

The SDM model resonates with aspects of the SPC. The SDM approach works to rebalance the value equation in favour of providing a higher perceived value to the patient. Where the process/service quality is good and perceived value is high, engagement and patient activation is most likely to occur. Indeed, there is evidence that SDM will make patients more likely to adhere to their treatment, particularly in disadvantaged groups where health literacy may be lowest (Durand et al., 2014, Cornelissen et al., 2020). Indeed, clinician-patient partnerships have even been shown to be particularly effective in mental health conditions where adherence to treatment is notoriously low (Thompson and McCabe, 2012).

Crucially, SDM embraces patient engagement, it is driven by patient centric goals, it encourages good communication and results in care that the patient feels appropriate for their needs. Indeed, in the UK, SDM has been recognised in the NHS as a key component of Universal Personalised Care, with the NHS preparing a summary guide to the concept together with a checklist for its implementation (NHS, 2019c, NHS, 2019d). The SPC model has the same core principles: service quality is determined by the customer, not the provider; it varies between customers and best results are achieved when the individual customer is satisfied with the service provided. By promoting SDM as part of its personalised care strategy and placing the patient's issues and concerns at the centre rather than the periphery of the health care decision making process, the NHS is indeed taking on board principles which mirror those associated with the CVE and the SPC as a whole.

7.3. Communication

Disconnect, dissatisfaction and treatment discontinuation represent failure to achieve optimal health outcomes. A constant in each of these problems is a lack of engagement. Maximising this perceived value of the physician-patient interaction involves promoting patient engagement with their condition and with their treatment plan. Physicians therefore need to recognise not only obvious clinical issues but also have the empathy to recognise specific physical and psychological factors that might be important to the patient and to act on these. One method of assisting physicians to understand the burden of the patient and to recognise what might matter most to them would be to make use of PROMs, symptom scales and measures of health status in regular clinical practice. Analysis and interpretation of results from such measures could provide insight into patient feelings, detect unrecognised problems and inform the discussion between physician and patient. However, appropriate use of such measures could necessitate additional training since tools are not routinely used in every day practice, one reason for which is lack of physician time and knowledge to interpret results (Nguyen et al., 2021). Incorporation of PROMs into routine practice may face practical issues though since the assessments would need to be completed in advance of the consultation and the results be available and to hand. However, since many PROMs are available online and since scoring processes can be automated, this hurdle could be overcome subject to appropriate information technology infrastructure being in place.

Nevertheless, regardless of what aids to understanding are available and in place, physicians still need the capability to communicate clearly with the patients, work in partnership to achieve a consensus regarding the best way forward and empower the patient to adhere to their treatment plan after the consultation is completed. Even in 2022, this is not always achieved, basic misunderstandings still can occur, particularly when medical and lay language does not coincide (Gotlieb et al., 2022). Indeed, the patient's own experience of care reflects the value of these interpersonal aspects of care and can complement their health care outcomes as assessed by more formal HRQoL evaluations (Browne et al., 2010).

SPC principles suggest that the physician-patient relationship should be an equal partnership with both sides contributing to the decision. Indeed, the medical consultation has been conceptualised as a value chain (Finset and Mjaaland, 2009), deconstructed into a series of steps, each adding value to the consultation. The overall goal is engaging the patient; intermediate steps involve establishing rapport and trust, enabling patient disclosure of emotional as well as physical concerns, doctor expression of empathy and demonstration of understanding, and finally, the patient's positive reappraisal of concerns focusing on their personal resources, solutions and potentials for coping. These steps require physicians to have the capability to read both verbal and visual cues but also to communicate well with the patient. This takes both time and a high degree of communication skill; appropriate use of PROMs could provide direction to the consultation and assist physicians to pick up these cues.

These principles are supported by research linking clinician-patient communication to health outcomes (Street et al., 2009). The authors suggest that communication should aim to achieve process outcomes such as trust, mutual understanding, adherence, social support and self-efficacy associated with improved health. Specifically, empathy has also been highlighted as a key determinant of quality in medical care (Neumann et al., 2009). Engagement has indeed been shown to be critical in promoting adherence (Nafradi et al., 2017), as have the use of eHealth tools, particularly when they involve direct patient-provider communication (Lancaster et al., 2018). Patient support programmes can also boost engagement, increase health literacy and improve adherence (Demoly et al., 2016). These examples highlight the value of patient appropriate communication and the role it plays in enhancing the patient experience.

But do physicians have this capability? Historically, communications skills – or "bedside manner" as it used to be known, were part of medical school training (Reeves, 2019). Indeed, in the 1960s, prospective students were formally interviewed as part of the medical school admissions process to ensure they could express themselves in coherent English! However, even then, educators noted that students *"may become so preoccupied with the minutiae of the specialties and with the technologies of the laboratory that they lose sight of the patient as a 'whole person' functioning in a social context"*, and this led some medical educators to search for a counterbalancing element to build into the medical curriculum (Martin et al., 1967). Calls for a more human approach to medical education became particularly significant in the second half of the twentieth century (Bates, 2017), although 50 years after the publication of Martin's paper, the importance of these ideas has not yet been fully recognised (Thompson et al., 2016), although system-wide relationship-centered communication skills training has been shown to improve both physician empathy and patient satisfaction (Boissy et al., 2016). Training in communication and in empathy as well as in recognition of symptoms and problem-solving must become an essential element of improving physician capability to engage patients and improve patient experiences.

7.4. Contribution to knowledge

Broad concepts of assessing value such as burden of illness and economic evaluation are necessary but not sufficient for maximising value in health care. These concepts act at a population level. Applying them without consideration of individual preferences may not maximise value.

The aim of this thesis was to assess how embracing principles of the SPC could lead to better value health care for **individual** patients and therefore for populations. The Customer Value Equation of the SPC sets out a model by which value can be maximised for an individual. It includes not only the results of the treatment; but also considers the way in which the service is delivered (process quality), the acquisition cost to the patient in terms of convenience, ability to undertake the tasks required as well as any financial cost.

The SPC is a known theory in a consumer context. One aspect of this theory, the CVE, focuses on the perceived value of a good or service to an individual. The contribution to knowledge of this thesis is to apply this theory in the specific context of health care. The papers presented have addressed the process quality associated with health care provision, demonstrating that where process quality is less than optimal; satisfaction, adherence and health outcomes are compromised. In this context of the CVE, the papers presented have demonstrated the need to consider value from an individual in addition to a population perspective. Maximising the value of each individual interaction will result in maximising the value of health care from a population perspective based on the treatment decisions taken.

The research has shown that principles such as those incorporated in the Customer Value Equation element of the Service Profit Chain, when applied to health care, can increase the value of the health care provided through maximising the perceived value of the health care encounter, thus improving process quality.

The papers presented have also demonstrated the importance of patient and physician connect/disconnect, the need for clear communication between patient and physician, the importance of patient engagement and ultimately the relationship of these factors to outcomes, satisfaction and adherence. This is integral to the process quality element of the Value Equation.

Taken together, the papers discuss different components of satisfaction and value. They raise issues around the holistic management of patients. The novelty of this research is to suggest that by applying SPC principles, that the value of health care can be assessed and improved like value can be improved in any service industry.

Indeed, given the constraints of publicly funded health care, the onus is on policy makers to maximise the value of every pound, euro or dollar spent, both on a population and on an individual patient basis. At the very least, one could expect to see the level of waste and cost associated with non-adherence to be reduced, but also one could expect greater satisfaction and better health outcomes from the treatments that are provided. To some extent, the Shared Decision Making pathway as part of the NHS Personalised Care objective recognises the importance of maximising perceived value of the health care interaction as this emphasises process quality through the importance of communication and engagement between clinician and patient.

7.5. Strengths and Limitations of the thesis

The key strengths of the papers in this thesis are that they were all based on real world data. As discussed in Section 2.5, RWD has the advantage of reflecting routine clinical practice. Lessons learned from such data are important in understanding issues in routine practice, regarding process quality, satisfaction and outcomes in the general population, not those included in experimental studies, which by definition do not represent everyday clinical practice.

Seven papers used data from the Adelphi DSPs, collected from practicing physicians and their consulting patients in a routine care setting. Real world data sources are the most appropriate to assess what happens in routine care settings, the need for such data to has never been stronger (Anderson and Piercy, 2015). The value of this data source is that evidence is collected from both physician and patient, and that the data can be matched. Collecting data from either physicians and patients alone does not allow agreement or disconnect between patient and physician perspectives to be assessed or the impact observed. Collection of data from physicians or medical charts/records alone, or analysis of databases such as the Clinical Practice Research Datalink or HES, lack a patient perspective. Surveys of patients such as the Health and Wellness Survey cannot provide a physician perspective; and since patients self-identify there is always the issue of professional respondents masquerading as patients since completion is incentivised. A strength of the source data used in the papers presented is the linkage between the clinician and patient perspectives of the same health care encounter. Furthermore, the same questions are asked to physicians and patients in every country where the DSP is run. This consistency of data collection allows direct comparison between countries and across disease areas. Finally, the richness of the data with regard to the number of variables collected allows for examination of a wide range of study questions related to patient management and treatment patterns, the physician-patient interaction, and the subsequent direct link with quality of life.

The other paper used data collected to record and monitor hospital activity in the NHS. Although the patient perspective is not collected, this data source was ideal for analysis of change in clinical practice as due to new guidance, since the data source itself is used for measuring and quantifying activity. Furthermore, as the data source now covers 100% of activity in England, it is truly representative of clinical practice, and the consistency of coding over time allows longitudinal changes to be assessed.

A key limitation of the research is the limitation associated with any real world data source. Administrative data include the minimum number of variables to achieve the objective of monitoring process activity. Electronic Health Records provide more detailed information but do not provide reasons behind physician decision-making. Neither source includes the patient perspective. While the DSPs and similar studies do include data collection directly from patients, data are collected at a single point in time albeit with retrospective data collection from medical records. Whilst it is possible to show associations between data points, these data cannot establish cause and effect. For example, in the study estimating the incremental burden of anxiety and depression in RA (Peterson et al., 2019) it is not possible to prove that it is the presence of anxiety/depression that caused worse HRQoL, or whether worse HRQoL caused the anxiety/depression. However, the fact that the regression techniques control for external factors influencing both HRQoL and anxiety/depression such as age, disease duration, severity, one can be confident that the association is genuine.

Regarding the DSP data, another limitation is the nature of the respondent. Both physician and patient must consent to participate in the research. This may suggest that both parties are motivated by research. Although this is a trait common to all research studies including clinical trials, it is possible that the DSPs include doctors who have more of a research focus (or are willing to participate for the incentives offered). Patients, however, may be motivated by altruism; a common motivation for patients to participate in observational research (Soule et al., 2016). Although, in each DSP patients who do and do not fill out the PSC are demographically and clinically similar, those who do participate are more likely to be motivated and engaged (and health literate) than those who decline.

The analysis conducted in the papers was not designed to assess the relevance or applicability of the SPC model. They do however tell a story which when taken together cover many of the principles fundamental to the CVE: namely outcomes; process quality in the form of the patient experience in the context of the doctor patient interaction; and issues relating to the non-monetary costs of health care such as the requirement to follow the treatment plan and the side-effects of the medication prescribed.

With the exception of the first paper (Ryan et al., 2004), all the papers were funded by the pharmaceutical industry, with the primary purpose being to highlight an area of unmet need in topics relevant to areas of interest to the funding company or to support medicines in the market of under development. However, that does not affect the message in relation to the SPC model – and the evidence provided regarding disconnect, satisfaction, discontinuation does highlight the need for a greater understanding of patient need and of the value of improved communication between doctor and patient.

A second natural limitation of the papers in terms of the SPC is that the analysis plans originally established for each of the papers included only those topics of immediate interest to the funder. It was not the aim of the research to explore wider policy issues although the general principles are widely applicable. Indeed, this is often the case when RWD are analysed, such data are usually collected for purposes other than to address the research question set especially for claims and administrative data.

7.6. Learning experience – and an agenda for future research

The papers included in this thesis have been prepared during different stages of the writer's career journey. The papers in the Chapter 3 were developed at an earlier stage, when the writer's career was focused more on hospital data analysis (and capacity planning) and economic evaluation.

Regarding the analyses undertaken in the papers presented, in each case, the analyses reported barely scratch the surface of what is possible. The analyses were developed to address specific research questions. Initially, earlier papers related to population-based issues such as economic evaluation and burden of illness; more recently published papers included patient perspectives, disconnect between patient/physician and recognition of the importance of individual aspects of a condition paving the way for individual centric care. This parallels increases in the writer's knowledge and awareness of the importance of the patient perspective.

Although not designed for this purpose, the implications resulting from each the papers offer evidence regarding the use of SPC principles to guide health care delivery. Each paper though is limited in scope; and the data sources used could be exploited further to address issues raised in each of the papers. As has been discussed in relevant Chapters, further research ideas identified include:

- Studying drivers of HRQoL – enabling physicians to focus on what matters most.
- Examining reasons for patient dissatisfaction and patient-clinician disconnect, with the aim being to expose issues of importance that may not be being discussed and addressed during consultations. However, this would need additional questions to be asked on data collection.
- Similarly, adherence is an issue which needs further analysis. An understanding of factors which are associated with adherence, and non-adherence, could help clinicians identify the types of patients who are less likely to adhere. This information would enable the clinician to take steps to encourage the patient to remain adherent.
- Studying whether the prevalence of invisible symptoms is related to specific patient demographic and disease factors, including time since diagnosis – enabling predictions to be made regarding which patients are most likely to encounter this problem.
- Adding a time dimension to the reasons for discontinuation and disconnect. Knowing how long it takes for problems to occur would enable physicians to anticipate them and set expectations accordingly.
- Research into identifying particular aspects of care as markers for overall quality improvement; also studying the correlation between measures of process quality and measures of clinical and patient related outcomes.

All these analyses would enhance the ability of the physician to engage and empathise with the patient. All are transferrable to and replicable across any disease area.

One further area which has not been addressed at all in the papers in this thesis is to ask patients directly what they think the most important benefit would be regarding their treatment. This is a general weakness of any research that does not ask the patient directly for their views. In recognition of this, such a question has been developed and added to all Adelphi DSPs since 2018 and is answered by both physicians and patients, a development led by the writer of this thesis. This question asks “Other than a cure, what is the single most important benefit that a drug treatment could provide?” – essentially asking what factor(s) associated with the condition are most important to the patient. The first publication from this perspective was presented at the 2020 Annual Congress of the International Society of Pharmacoeconomics and Outcomes Research (Higgins et al., 2020), and more recently in a study of patient / physician symptom concordance in hepatocellular carcinoma which demonstrated clear differences in perspectives regarding “what matters most” (Leith et al., 2022). Both studies included as an author the writer of this thesis. As evidence becomes available from other disease areas, further analyses are planned, ultimately including cross-disease analysis and whether preferences change over time. Such information enables a first-hand understanding of exactly what patients at all stages of their condition and treatment pathway think is most important about their conditions – enabling physicians to identify it and act on it. Indeed, the FDA and other regulatory bodies are now very much considering the patient voice in decisions about what treatments are licensed and offered, encouraging the use of PROMs in both new drug (Perfetto et al., 2015, Crossnohere et al., 2020, Hines et al., 2019), and new device assessments (Matts et al., 2022). This is indeed a welcome development in patient-centric care and one which fits well with patient perceptions of value.

This thesis has also suggested that the key to improving value would be to improve the patient, or customer, experience. Measures such as the ICH-CAHPS as described previously would be one method of addressing patient experience in the context of satisfaction with services. However, satisfaction is about more than the user experience; factors such as expectations are also important. Communication and engagement are essential to setting expectations as well as factors in the user experience, so represent controllable factors which will help determine perceived patient value.

Finally, it is recognised that to quantify the potential gains if SPC principles are followed, there needs to be a way to measure them. Other than measuring process quality as outlined above, true value can only be obtained for an intervention is the patient is engaged, or at least adherent. Measurement of adherence is not straightforward there is no agreed gold standard regarding how this should be measured; indeed most existing questionnaires have been designed to focus on oral daily medication (Bentley et al., 2022). To this end, the author has directed the development of a new adherence questionnaire, the Adelphi Adherence Questionnaire (ADAQ^{TM}), designed to be both condition and medication agnostic. This PROM has been developed from first principles and validated in line with FDA approved methodology (Bentley et al., 2022).

Thus, in light of the relevance of the customer value equation and particularly in the context of a post-COVID world which has resulted in increases in the use of telemedicine and remote consultation in health care delivery, there has never been a greater need to ensure that the patient experience is positive. The ability to ensure a positive patient experience and for physicians to communicate effectively should be at the heart of health care professional training.

8. Summary, Policy Implications and Conclusions

8.1. Summary

The overall aim of this thesis was to discuss the applicability of the Service Profit Chain to the health care environment. The SPC is a business model linking together profitability, customer satisfaction and loyalty, employee satisfaction and capability (Heskett et al., 1997).

The key to the whole SPC framework is the patient perception of value, stated clearly in the CVE. This addresses what factors drive value in the mind of the customer, providing clues regarding of how the perceived value of a service can be assessed. Considering value solely in the context of burden of illness studies and economic evaluation will miss elements important to an individual patient such as process quality and the user experience. Too often this has been ignored in the past in health care with physicians focusing on measurable results, payers on cost effectiveness and cost containment and regulators on safety and efficacy. Even wider definitions of value such as those suggested by the International Society for Pharmacoeconomics and Outcomes Research (Lakdawalla et al., 2018) may be insufficient for consideration of value on an individual level since these definitions still focus on populations.

Placing the patient at the heart of the decision-making process both at the level individual interaction with health care services and on a national level would result in better engagement and lead to more favourable outcomes. To achieve this, the principles enshrined in the CVE may not be a bad place to begin. After all, it is the perception and wants of the customer that matter – not those of the provider. The implementation of shared decision making as routine is a first step along this road to allowing the patient voice to be heard.

The papers included in the thesis have demonstrated:

- There are disconnects between doctor and patient in terms of disease severity and understanding which aspects of the condition may cause the greatest patient burden.
- Doctors may not recognise or fully appreciate the most important symptoms of the patient's condition especially if they lie outside the measurable or visible aspects of the condition.

- Such disconnects or lack of appreciation of what is most important to the patient can result in patients experiencing a lower quality of life than in a situation where both physician and patient are on the same page.
- This lack of connection between physician and patient can result in a worse patient experience, lower satisfaction, a lack of engagement in or buy-in to the treatment plan and consequently in lower adherence to or discontinuation of medication.
- The importance of communication and the development of a bond of empathy and trust between the physician and the patient.

These elements are all part of overall process quality. If process quality is less than optimal, the consequences can include sub-optimal outcomes. Customers buy results; patient attend medical care because they want the result of feeling better, to have their condition alleviated, controlled or cured. If the doctor-patient interaction is poor or of low quality in the mind of the patient, they may not agree with the recommendations, follow the advice, make the necessary lifestyle changes or even take the medication at all.

It should be noted though that addressing the CVE is a method of maximising the value of an individual encounter. It does not inform issues of assessing unmet needs, resource allocation, the cost-effectiveness of treatment or provide information to guide macro-level choices about what treatments should be available. These questions remain the domain of economic evaluation, also a necessary component for ensuring value in health care. Ultimately, both economic evaluation and SPC principles are necessary to improve value in health care, but in isolation neither are sufficient. Both must be used in parallel; evaluation to inform the big picture decisions about treatment availability; the customer value equation to drive maximum value from the individual health care encounter.

8.2. Policy implications

The findings presented in this thesis have implications for patients, physicians and health policy. For patients, as the recipients of care, better engagement and experience should result in the most appropriate treatment being offered, greater satisfaction with the care process and an increase in perceived value of the treatment provided. This in turn should result in higher adherence, better outcomes and improved quality of life.

To achieve this however, the patient-physician interaction needs to be enhanced. Simple ways of achieving this could include:

- Communication training – enabling physicians not only to elicit the true nature of the problem and also information about what matters most to the patient, but also, to provide clear explanations of the benefits of treatment and to manage patient expectations appropriately.
- Training in and use of PROMs. While this may not be practical in general practice owing to the wide variety of conditions seen by general practitioners, this is certainly possible in a specialist environment, the environment in which much of the research presented in this thesis was undertaken. Greater use of disease specific PROMs would afford an enhanced understanding of the individual patient's health status, highlighting the presence of symptoms, the degree of bother and the impact on activities of daily living. Using the results of the assessments, physicians will have greater insights into the condition and how it affects the patient, so can make treatment decisions and take actions based on more detail that can be revealed in a routine conversation alone. This is particularly important where symptoms can be non-visible (such as anxiety or depression) or symptoms that a patient may be reluctant to mention.
- More widespread use of multidisciplinary teams. With physicians routinely being organised into specialties, there is a tendency for specialties to become islands. Bridges between them need to be built and reinforced, enabling patients to obtain maximum benefit with minimal access cost.

Regarding health policy, the implications of this research suggest the following:

- Ensuring patient communication becomes a more important part of health care professional training. Technical skill is necessary to make correct decisions, but communication of reasons behind decision-making, empathy and techniques in enabling patient engagement are also important to maximise adherence and therefore individual outcomes.

- Rolling out Shared Decision Making, providing physicians with the necessary training to embrace the concept and employ to the degree that SDM becomes a natural and automatic part of the patient management plan.
- Developing and rolling out measures of performance satisfaction such as the ICH-CAHPS instrument, with the specific aim of measuring factors relating to the patient experience; including access to care, the quality of facilities, communication and the satisfaction with the care experience.

8.3. Conclusions

It is accepted that we will never realise the goals of health care's Triple Aim — reducing costs, improving the health of populations, and improving the patient experience (Berwick et al., 2008) without putting patients at the centre of their care (Schlesinger and Fox, 2016).

The relationship between the patient and the physician is fundamental to successful health care. Communication is central to this relationship. The relationship, or partnership, must become one of equals, with the patient voice carrying weight in a (shared) decision-making process. This will maximise the perception of the value of the interaction from the perspective of the patient, the most important person in the health care industry. Indeed, only when patients, physicians and staff are all working together, fully engaged and enabled to do what each does best, will society achieve the clinical and economic outcomes we are all aiming for (Schlesinger and Fox, 2016). Applying the principles of the SPC in terms of the relationship between service provider and customer – the physician and the patient – provides the opportunity promote health literacy, engagement, satisfaction, adherence: all necessary to get closer to the Triple Aim of health care.

There is an old proverb which states that if you look after the pennies, the pounds will take care of themselves. This is exactly why health services need to consider the CVE as essential to providing value. Ensure that perceived value is maximised for each patient, then the health care industry has the greatest chance to provide value to society.

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10. Appendix 1. Peer Review Publication List

At the time of admission to MMU, the writer had been an author on a total of 41 peer review manuscripts. The selection of papers for inclusion in this PhD by Published Work was drawn from that list.

As of December 2022, the author has published a further 15 peer review manuscripts Some of these more recent publications are referred to in this thesis; although there was no consideration to substitute for papers selected for inclusion in the thesis.

Peer review publications to 2019

Peterson S, **Piercy J**, Blackburn S, Sullivan E, Karyekar CS, Li N. The multifaceted impact of anxiety and depression on patients with rheumatoid arthritis. BMC Rheumatol. 2019 Oct 28;3:43. doi: 10.1186/s41927-019-0092-5. eCollection 2019. PMID: 31673680.

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11. Appendix 2. Declaration of Contribution to Research

An estimated percentage contribution to each of the papers shown is shown in the following table. in addition to fulfilling all the ICJME criteria, the specific contributions listed are where I took specific leadership in particular aspects of the paper.

Paper Number	First Author	% Contribution	Specific Tasks Undertaken
1	Tang	20%	Analysis plan, support analysts
2	Ryan	45%	With James Ryan, developed the study concept Promoted the specific regression technique to be used Drafted the manuscript
3	Wei	20%	Led the development of the analysis concepts, outcomes research analysis
4	Walsh	35%	Outcomes research (PRO) analytics lead
5	Peterson	35%	With Steve Peterson, designed the analysis and selected the outcomes to be addressed Prepared and wrote the manuscript outline
6	Sullivan	30%	Outcomes research analytics lead
7	Sikirica	25%	Led the development of the structure of the paper outcomes research analysis
8	Wood	20%	Study design, outcomes research analysi2

Notes

JP played a leading role in developing the protocol for each of the studies undertaken (except for Paper 1 and 2 where there was no formal protocol)

For all the papers JP was heavily involved in drafting and reviewing at each stage of the manuscript development process; with particular responsibility for discussion and interpretation of the findings.

For papers 2-8, JP was closely involved in data collection; notably as part of the team responsible for drafting the data collection materials and had final responsibility for their sign-off prior to fielding. In particular, for each set of study fieldwork, JP designed questions relating to outcomes research and identified the PROMs used

Paper 1 used an existing data source, identified and sourced by JP as appropriate for the analysis.