



THE UNIVERSITY OF HULL

DECISION MAKING IN SURGERY AND CANCER CARE

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1 MD Summary

Decision making in surgery and cancer care is an interesting, challenging, and yet little explored area of surgical sciences research. This research addresses that paucity. In performing this research, health outcomes research (HOR) literature was comprehensively reviewed. Health outcome measures including quality of life and health-related quality of Life were described, in addition to their measurements. Subsequently health outcome measures in relation to oncoplastic and aesthetic breast surgery were described, and health outcome measures in a number of benign breast and colorectal pathologies were studied.

Decision making in surgery and cancer care was explored using a mixed methodology of quantitative and qualitative studies. To derive a more comprehensive view, different specialties were explored: breast, colorectal, and head and neck surgery. To address socio-cultural factors the qualitative focus group discussions were undertaken in England, Wales, and India.

Quantitative studies included literature reviews, prospective studies, retrospective studies, and questionnaire surveys. Qualitative studies were based on focus group discussions.

The results showed that raw quantitative data is only one of the factors influencing the decision making process (*Diagram 1*). A number of other factors play an important role in the decision making process. These include: health

outcome measures (quality of life, health-related quality of life), clinician factors (knowledge, skill, expertise, judgment), patient factors (socio-economic, education, cultural), nursing factors, translational research, and resource infrastructure.

Important themes and outcomes emerged from the qualitative studies. The focus group discussions showed that decision making in surgery and cancer care varies not only between the developing and the developed world, but also within different regions in the western world. In England, a small minority of patients was driving the decision making process, compared with Wales, where joint decision making is the norm. However, in India decision making is predominantly led by the clinicians and the patient's family members.

As modern health care moves towards a patient centered care approach, evidence based patient choice and patient decision making clearly has a greater role to play, and the cultural and practical issues demonstrated in this thesis must be considered.

Diagram 1. Factors affecting decision making.



Background: Every day, an ever-increasing number of surgical procedures are performed to treat a spectrum of benign, malignant, functional, and aesthetic disorders.

Surgery is obviously not without risk. Clinical decisions should be evidence-based, and involve judgment, experience, expertise, and informed patient choice. Different treatment options carry their own risks of morbidity and mortality, and it is important to assess them considering both quality of life and survival. It is therefore vital to try to attain as comprehensive an evidence base as possible for each treatment option, using both quantitative and qualitative data.

Little is known about what influences decision making in surgery. Clinical decisions are made about patients, and it is paramount that their preferences should be taken into account.

Weighing the treatment options for cancer patients, in terms of quality of life and survival, is a particular issue. Greater understanding of this area would provide information for both patients and clinicians that would enable them to make appropriate individualised decisions on cancer management.

Hypothesis: Clinical decisions are not multi-factorial and are solely based/dependent on hard quantitative research data.

Aims: To evaluate the multi-factorial nature of decision making, and to undertake an exploratory analysis of the factors affecting decision making, and the decision-making process itself, in surgery and cancer care.

Methods: A mixed methodology was used. Quantitative and qualitative studies were incorporated. Quantitative studies included literature reviews, prospective

studies, retrospective studies, and questionnaire surveys. Qualitative studies were mainly based on the concept of grounded theory, utilizing focus group discussions. Grounded theory is a systematic methodology in the social sciences involving the generation of theory from data (1).

Study groups included patients with various benign, malignant, and functional problems in relation to surgery. In order to get a more comprehensive assessment, colorectal, breast, and head and neck specialities were studied. Focus group discussions and postal questionnaire surveys were utilised for the qualitative arm. Care-providing clinicians in breast, colorectal, and head and neck surgery formed the participant group in focus group discussions.

Results: Decision making in surgery and cancer care is influenced by a multitude of factors. It is a complex process dependent on a number of patient and clinician factors, including evidence based practice, research translation (translating the results of research into clinical practice), quality of life, risks of associated mortality and morbidity, infrastructure, and resources. Quality of life seemed to be one of the more important factors when decisions were made in surgery. Increasingly, quality of life and health related quality of life measures are playing an important role in measuring treatment outcomes. The results are summarised below.

A. Health outcome measures

Background knowledge about health outcome measures and their applications in various sub-specialities of surgery have been seen to be important to the decision making process in surgery. Such measures influence both the

clinicians providing care and the patient, during the decision making process. The subsection of this thesis on aesthetic breast surgery may influence the decision making process of the relevant clinicians and patients.

B. Benign breast conditions

Evaluation of reduction mammoplasty data suggested that higher resect weight; increased BMI; older age, and smoking are some of the risk factors associated with complications in reduction mammoplasty. An attempt should be made by clinicians to reduce the risk factor profile for modifiable risk factors, prior to offering patients reduction mammoplasty.

C. Benign colorectal conditions and quality of life

Evaluation of efficacy and acceptability of rectal irrigation (RI) using health outcome measures was undertaken. One hundred and seventy-five patients underwent RI. One hundred and eleven cases were successful, 64 failed. Analysis was done only for successful cases. General standardised questionnaire (GSQ) analysis showed significant improvement in symptoms of straining, incomplete emptying, wind leakage, and urinary leak (95% CI) pre and post RI. SF-36 demonstrated significant differences in physical functioning (PF), social functioning (SF) and general health (GH), pre and post RI (95% CI). Faecal Incontinence Quality of Life Scales (FIQL) analysis showed no statistically significant difference in the quality of life post RI. RI can offer symptomatic improvement to patients with faecal evacuatory disorders where other conservative and pharmaco-therapies have failed. Most patients find the treatment acceptable which was well tolerated and pain free. They chose RI over other treatments.

D. Malignant colorectal, breast, head, and neck conditions

The process of decision making was evaluated using focus group discussions. Common themes and outcomes were generated from the focus group discussions (FGDs) undertaken in England, Wales, and India.

In England, patient decision making in cancer care is gradually becoming more common, although currently only occurs in a minority of cases. This minority of the patient population will play an increased role in decision making, and will possibly drive decision making, in the future. This group, when making decisions, will consider the tradeoffs and risks between survival and quality of life. In the majority of patients remaining, decision making jointly with the clinician seems to be the norm.

In the Welsh population, a drive towards joint decision making can be seen. In the future, patients are likely to have increased involvement and a greater role in decisions about their treatment, within the multidisciplinary team setting.

In contrast, the findings from India (a developing country), show that evidence-based patient choice (EBPC) has not developed to the extent seen in the western world. Decisions seem to be predominantly clinician led. There is not much of an emphasis on quality of life, and there is a clear need for patient groups and a stronger patient voice. It is suggested that in the future, not just in England in Wales, but globally, patients are likely to have increased involvement and a greater role in decisions about their treatment, within the multidisciplinary team setting. The process of decision making is currently slowly evolving and will see metamorphosis in future. However, it is important for clinicians and nurses to play a role in encouraging this change. Decision making in cancer care has to be handled delicately and sensitively, and must

work within the framework both of financial constraints, and the traditions and culture of the society.

The role of radiotherapy in rectal cancer was investigated using a national questionnaire surveys involving members of the Association of Coloproctology of Great Britain and Ireland (ACPGBI). Results suggest that approximately two thirds of consultant surgeons in the UK have yet to implement neo-adjuvant short course radiotherapy as a routine treatment regime. A change in practice in 39% of surgeons following the early dissemination of trial results indicated that colorectal surgeon practice is guided by scientific evidence. Qualitative analysis undertaken of survey results gave rise to various themes and outcomes.

Themes that emerged from thematic analysis are: patient groups, treatment, evidence based practice, professional consensus, and service provision. The desired outcomes that emerged are: to individualize treatment; because the treatment group tends to be elderly, to provide safer and less harmful treatment (attempting to avoid some of the complications associated with radiotherapy); to increase the role of multidisciplinary teams; to overcome a lack of consensus; to increase awareness of current evidence based literature, to address the existing lacunae in evidence based practice; to develop protocols and guidelines; and to shorten the delay in implementing evidence based practice. A need for improvement in service provision, infrastructure, and resources was highlighted.

A further national questionnaire survey with the same group investigated thrombo-prophylactic practice in colorectal surgery. The study revealed that 259 (100%) surgeons routinely used thrombo-prophylaxis. Two hundred and forty three (93.8%) surgeons followed departmental guidelines. The majority of respondents (247, 95.40%) used combined chemo and mechanical prophylaxis, while 12 (4.6%) used chemo-prophylaxis only. Low molecular weight heparin

(LMWH) was the chemotherapeutic agent chosen by the majority (243, 93.8%), whilst 9 (3.5%) chose un-fractionated heparin (UFH). Timing of thromboprophylaxis varied. One hundred and seventy-six (68%) started chemoprophylaxis (CP) on admission, 22 (8.5%) on induction, 38 (14.7%) 6 hrs post-operatively, and 6 (2.3%) 24 hrs post-operatively. The majority 201(77.6%) discontinued CP upon discharge whilst 31 (12.0%) discontinued prior to discharge. Thirteen (5.0%) discontinued on mobilisation, whilst 4 (1.5%) discontinued 6 weeks following discharge. When asked about recommending continuing prophylaxis after hospital discharge 71 (27.4%) did so, whilst 178 (68%) were against it.

Conclusions: Decision making in surgery and cancer care is a challenging cognitive task. The various quantitative and qualitative studies undertaken demonstrated that decision making in surgery and cancer care is multi-factorial, and is not solely dependent on hard quantitative data. It is influenced by a number of factors. These include patient, clinician, and nursing factors, along with quantitative and qualitative data, resource, infrastructure, and translational factors. In addition, emerging models in decision making, for example decision aids, decision trees, and artificial intelligence techniques, may have an increasing role. The identified issues in decision making should be addressed. It is important to individualise the decision making process.

Key words : Association of Coloproctology of Great Britain and Ireland, Cancer, Decision analysis, Decision making, Decision tools, Health outcome measures, Health related quality of life, Mortality, Neoadjuvant radiotherapy, Outcomes, Patient preference, Qualitative analysis, Quality of life,

Questionnaire survey, Rectal cancer, Surgical decision making, Survival,

Themes

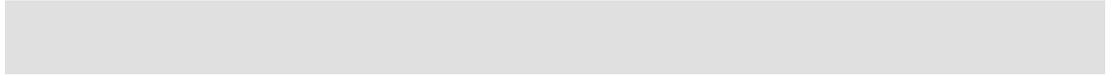
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5 List of abbreviations

ACPGBI - Association of Coloproctology of Great Britain & Ireland

BCS - Breast conserving surgery

CBS - Conservative breast surgery

CRM - Circumferential resection margin

DFS - Disease free survival

FIQL - Faecal incontinence quality of life

GSQ - General standardised questionnaire

LOS - Length of survival

MOS - Medical outcomes study

MRI - Magnetic resonance imaging

NASCRT - Neoadjuvant short course radiotherapy

NQS – National Questionnaire survey

OS - Overall survival

SF-36 - Short form 36

TP – Thromboprophylaxis

TME - Total mesorectal excision

VAS - Visual analogue scales

VTE - Venous thrombo embolism

6 Declaration

I have carried out the research described in this thesis in the Academic Surgical Unit at Castle Hill Hospital, Cottingham. I have undertaken all the field work, data collection, analysis and interpretation of results involved in this thesis, with some help from co-researchers, nurse practitioners, and guidance from supervisors. This thesis has not been submitted to any other Institute.

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Deposit of thesis in accordance with senate minute 131, 1955/6, 141, 1970/71 and 343, 1988/89.

I Narasimhaiah Srinivasaiah hereby consent to a copy of my thesis "DECISION MAKING IN SURGERY AND CANCER CARE", if accepted for the degree of MD in the University of Hull and thereafter deposited in the University library, being available for consultation, interlibrary loan and photocopying at the discretion of the university librarian.

Signature

7 Publications and presentations from thesis

Peer Reviewed Articles

- **Rectal Irrigation in the treatment of Defaecation disorders.** Srinivasaiah N, Marshall J, Gardiner A, Duthie G S. In press, Aug 2011. British Journal of Nursing.
- **Quality Of Life Issues in Aesthetic Breast Surgery - A Review Article.** Srinivasaiah N, Drew PJ, Platt A. Br J Hosp Med (Lond). 2010 Apr;71(4):211-5. PMID: 2039343
- **Radiotherapy in Rectal cancer – Is it time for change?** A qualitative analysis of the national questionnaire survey of members of ACPGBI on preliminary CRO7 results. N. Srinivasaiah and J.R.T. Monson. Colorectal Dis. 2008 Nov; 10(9):873-8. PMID: 18325044
- **How do we manage early rectal cancer?** A national questionnaire survey among members of the ACPGBI after the preliminary results of the MRC CR07/NCIC CO16 randomized trial. N. Srinivasaiah & J.R.T. Monson. Colorectal Disease 2007. PMID: 17764532

Chapters In Books

- **Quality Of Life Issues in Breast Surgery.** Srinivasaiah N and Drew P J. Recent Advances in Surgery (2007) Ed: 30, Chapter 5, RSM Press. ISBN- 9781853157202.

Abstracts : There are 25 or more published in peer review journals

Short articles / Correspondence / Letters

- **Faecal Incontinence.** Srinivasaiah N, Duthie GS. British Journal of Surgery 2007, Feb : 94(2):134 -144 PMID: 17701966

Selected presentations

“A Qualitative Analysis Of A Focus Group Discussion On Patient Decision Making In Cancer Care” – A global perspective. Srinivasaiah N, Appleton B, Monson JR, Hargest R. SARS 2011, Dublin, UK. **(Poster - National)**, 5 - 6th Jan 2011

“Risk factors for complications following Reduction Mammoplasty”. Srinivasaiah N, Drew P J.

- SARS 2011, Dublin, UK. **(Poster - National)**, 5 - 6th Jan 2011
- BAAPS annual meeting, Chester, UK **(Poster – National)**, 18 - 19 Sept 08.

“ThromboProphylaxis (TP) In Colorectal Surgery: A National Questionnaire Survey of the members of the ACPGBI”. Srinivasaiah N, Zadeh R A, Monson J R T. Society of Surgical Oncology, Phoenix, USA. **(Poster – International)**, 5 – 8, March 2009

A Qualitative Analysis Of A Focus Group Discussion On Patient Decision Making In Cancer Care. Srinivasaiah N, Joseph B, Gunn J, Hartley J, Monson J R T. ASCO Annual meeting, Orlando, Florida, USA **(Publish-only abstract – Int)**, 29 May – 2 Jun 09

A Qualitative Analysis Of The Survey Of Members Of ACPGBI On Preliminary CRO7 Results. Srinivasaiah N, Joseph B, Gunn J, Hartley J, Monson J R T. XXII Biennial Congress of the ISUCRS, California, USA **(Oral - Int)**, Sept 13-17, 2008.

Rectal Irrigation (RI) Is A Boon For Chronic Constipation – A Review. Srinivasaiah N, Marshall J, Gardiner A, Duthie G S. XXII Biennial Congress of the ISUCRS, California, USA **(Oral - Int)**. Sept 13-17, 2008

Rectal Irrigation In Disorders Of Faecal Continence - A Review

Srinivasaiah N, Marshall J, Gardiner A, Duthie G S. ASCRS Annual Meeting, St Louis, Missouri, USA (**Poster – International**), 2 – 6 Jun 07

National Questionnaire Survey After The Preliminary Results Of The MRC CR07/NCIC CO16 Randomised Trial.

Srinivasaiah N, Mackey P, Joseph B, Alabi A, Suppiah A, Hartley J, Monson J R T. ACPGBI, Glasgow, UK (**Oral – National**), (**Nominated for The BJS Prize**), 2 – 5 Jul 07

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9 Introduction

Approximately 32.7 million surgical procedures were undertaken in the US during 2006 (2). The spectrum of disorders includes benign, malignant, functional, and aesthetic. Cancer is one of the most important pathologies for which major surgery is undertaken.

Cancer is a major cause of morbidity in the United Kingdom. Each year, more than a quarter of a million people are newly diagnosed with cancer (3), (4), (5), (6). Overall, it is estimated that more than one in three people will develop some form of cancer during their lifetime. Whilst there are more than 200 different types of cancer, four of them, breast, lung, large bowel (colorectal), and prostate, account for over half of all new cases (3), (4), (5), (6).

Cancer was responsible for 26% of all deaths in the UK in 2005 (29% for males and 24% for females) (7), (8), (9).

Disease management poses difficult choices, where the most appropriate treatment option is not always obvious. Different treatment options have their own risks of morbidity and mortality. Weighing them in terms of quality of life and survival is important.

Patient preferences should play an important role in clinical decision making. For this, it is important that actual patient preferences are determined. The literature increasingly demonstrates that surgeons and physicians have divergent preferences for treatment options compared with both their patients and each other (10), (11), (12). Thirty to forty percent of critical medical decisions are made by doctors for their patients (13), (14), (15), (16), (17) . This

rate increases when patients are acutely unwell, elderly, or dealing with cancer (14), (15). When this is the case, it is important to know what influences clinician decision making. Solomon et al (10) in their study titled “What do patients want? Patient preferences and surrogate decision making in the treatment of colorectal cancer.” demonstrated that patients are willing to trade survival for quality of life and can do so differentially between treatment scenarios. They proved that patients’ preferences do not always accord with those of clinicians. They stated that unless patients’ preferences are explicitly sought and incorporated into clinical decision making, patients may not receive the treatment that is best for them.

Cancer psychology is a vitally important part of cancer management. Assessing the treatment options in terms of quality of life and survival is obviously important.

Decisions taken when dealing with benign and functional problems also pose a challenge to the clinician. Decision making is dependent on a number of factors, including evidence based practice, research translation, quality of life, risks of associated mortality and morbidity, infrastructure, and resources. Health outcome measures, including quality of life and health related quality of life measures play an important role in measuring the treatment outcomes. Patient preferences should also be considered, in addition to the available evidence base. Qualitative results gathered from focus group discussions, semi-structured interviews and questionnaire surveys can form a valuable qualitative evidence base. Health outcomes research plays a vital role in building the evidence base to help clinicians and patients with decision making.

Decisions for surgical conditions often rely on the available evidence base. However, in a significant proportion of cases, they are based on clinicians' experience. The last decade has seen subtle changes in the use of patient preferences and joint decision making in clinical care. A variety of instruments including questionnaires, focus group discussions, patient satisfaction surveys and patient questionnaires can potentially inform the decision making process and improve clinical outcomes and health outcome measures.

The author has investigated decision making in surgery and cancer care by using validated quantitative and qualitative methods in a range of surgical conditions (benign, malignant, and functional problems).

Decision making can be regarded as an outcome of mental processes (cognitive process) leading to the selection of a course of action among several alternatives. Every decision making process produces a final choice.

Decision making in surgery and in cancer care has never been easy. In the current political climate, the patient and patient care are the main focus. There is now widespread realisation that patients' views are not optional, but are essential, to achieving high quality care (18). Patients are playing an important role in NHS funded research in England, which is contained and protected in the national advisory group INVOLVE (19). During the years 2008-09, the NHS operating framework took the first step in making patient reported outcomes a mandatory requirement for audit (20). In addition, within the past decade, national surveys of patients' experiences of healthcare have become a feature of NHS regulation (21). Black et al have detailed the importance of patient surveys using questionnaires in their article "Measuring patients' experiences

and outcomes”, thus highlighting the increasing importance being placed on patients’ views of the humanity and effectiveness of their care (22). Patient preferences are beginning to play a role, at least in a minority of cases, with joint decision making achieving rapid progress.

Clinical decision making is multifactorial, involving clinician factors, patient factors, the translational factors involved in translating research to clinical practice, and patient satisfaction surveys.

Clinician factors: Awareness of the available evidence base, experience, clinical judgement, and clinical intuition.

Patient factors: Educational level, sociocultural level, current circumstances, and associated patient co-morbidities.

Research translational factors: Integration of current best evidence from research into clinical policy and practice. This can be done by using new evidence based services to access current best practice and ensure that evidence and policy are applied at the right time. Some of factors, more specifically, involve synthesizing the evidence (COCHRANE Library), creating evidence based clinical policies (development of guidelines), and applying evidence based policy into practice.

Patient satisfaction surveys: Give a strong indication of patient needs based on feedback. Other related factors that might play a role are organizational factors, and those dependant on infrastructure and resources.

Decision Analysis: The last few decades have seen an emergence in Decision Analysis (DA), a discipline comprising of philosophy, theory, methodology, and professional practice, and is necessary for addressing important decisions in a formal manner. The term decision analysis was coined in 1964 by Ronald A. Howard, a professor at Stanford University. He has been instrumental in developing the practice and professional application of DA. He developed a model to help decision making by estimating the risk of mortality and significant morbidity to the patients and then communicating this risk to them. He called the model 'Micro risks for medical decision analysis' (23).

Graphical representation of decision analysis problems commonly use influence diagrams and decision trees. An influence diagram (also called a decision network) is a compact graphical and mathematical representation of a decision situation. A decision tree (or tree diagram) is a decision support tool that uses a tree-like graph or model of decisions and their possible consequences, including chance event outcomes, resource costs, and utility. However, there is a growing controversy over the usefulness of these tools in improving the decision making process. Klien (24) pointed out that people do not make decisions based on decision trees and mathematical probabilities, and that an intuitive style of decision making needs to replace the disaggregated approaches commonly used by most decision analysts.

Nyatanga et al in their article "Intuition in clinical decision-making: a psychological penumbra" concluded that intuition has traceable cognitive and physiological bases. Those working in acute and palliative care, where there

are difficult ethical, as well as clinical, patient situations, can benefit from using intuitive ideas to arrive at complex decisions (25).

Various communication models have been described in the development of decision making. Siminoff and Step, in their article “A communication model of shared decision making: accounting for cancer treatment decisions” (26), present a communication model of shared decision making (CMSDM) that explicitly identifies the communication process as the vehicle for decision making in cancer treatment. They describe socio-communicative processes whereby people enter into a relationship, exchange information, establish preferences, and choose a course of action. In the CMSDM, decisions depend on (a) antecedent factors that have potential to influence communication, (b) a jointly constructed communication climate, and (c) treatment preferences established by both the physician and the patient. In another study “Patient Preferences Versus Physician Perceptions of Treatment Decisions in Cancer Care” (27), by Bruera and colleagues, they conclude that an individual approach is needed, and each patient should be assessed prospectively for decision making preferences. Poor communication between the clinicians and the patients can lead to poor outcome. Barry et al, in their study titled, “Patients' unvoiced agendas in general practice consultations: qualitative study” (28), concluded that steps should be taken in both daily clinical practice, and research, to encourage the voicing of patients agendas.

Annette O'Connor in her review “Decision aids for patients facing health treatment or screening decisions: systematic review” (23), concluded that decision aids improve knowledge, reduce decisional conflict, and stimulate patients to be more active in decision making, without increasing their anxiety. Decision aids have little effect on satisfaction, and a variable effect on decisions.

The effects on outcomes of decisions (persistence with choice, quality of life) remain uncertain.

Kassirer JP in his article “Incorporating patients' preferences into medical decisions” (24), describes that, with time, medical decisions become more and more standardized and codified, and state that one should take care to ensure that critical therapeutic choices are not based exclusively on formal guidelines. Authors stress that decisions need to be individualized, especially when they involve choices between possible outcomes that may be viewed differently by different patients. The author recommends that patient's preferences should be identified scrupulously in the process of medical decision making.

Barton, in an editorial on clinical evidence, posits that future decision support systems may help to tailor information for individuals in their decision making (25).

Overall, a good decision maker should understand all the approaches available in medical decision making, and individualize them according to patient need and preference. In the current political climate, where the mantra of 'patient centered care' is repeated often, clinicians should involve the patient in every stage of their care. In addition, patients have been shown to desire patient centered care, as demonstrated by Little et al (26), (27). The authors answered crucial questions about patient centered medicine: What is it? Do patients want it? Do doctors practice it? What are its benefits? Little et al focused on the first two questions, and demonstrated that patients did indeed want patient centered care.

Patient centered care includes:

- (a) Exploration of the patients' main reason for the visit, concerns, and need for information;
- (b) Seeking an integrated understanding of the patients' world – that is, their whole person, emotional needs, and life issues;
- (c) Finding common ground on what the problem is, and mutually agree on management.
- (d) Enhance prevention and health promotion; and
- (e) Enhance the continuing relationship between the patient and the doctor.

Qualitative research conveys the qualities of patient centred care (28).

Asking patients is an important way to assess this process. However, since clinicians form an integral part of patient care, exploring their thoughts was vital.

There is active interest amongst policy makers and politicians in patient centred care. An analysis and commentary by Epstein et al (29) from the University of Rochester on “Why the nation needs a policy push on patient-centred health care”, described patient centred care, why it matters, and how policy makers can advance it in practice. They highlighted that patient-centred care is determined by the quality of interactions between patients and clinicians. They rightly pointed out that patient centred care improved disease outcomes and quality of life, and that it is critical to address racial, ethnic, and socioeconomic disparities in health care and health outcomes. Policy makers need to look beyond such areas as health information technology to shape a coordinated and focused national policy in support of patient-centred care. This policy should help health professionals acquire

and maintain skills related to patient-centred care, and it should encourage organizations to cultivate a culture of patient-centeredness (29).

Communication can be the Achilles heel of an otherwise good decision making process. Literature suggests that doctors and patients not only talk to each other with different voices (30), but also have communication misunderstandings (31). (32)

Charles et al from Ontario, Canada, describe the importance of doctor and patient communication, in their article “How to improve communication between doctors and patients. Learning more about the decision making context is important” (33), it is recommended that efforts should be made to improve communication between doctors and patients in the treatment decision making process. The team responsible for that article were developing educational interventions targeted at doctors to address these issues. Patient focused interventions, although not mentioned in that article, are also likely to help patients voice their agendas. Charles et al conclude that treatment decision making in the medical encounter is a complex and dynamic process, the course of which is not predictable in advance because no two encounters are exactly the same. They recommend that doctors should practise shared treatment decision making with their patients, and unspoken patient agendas pose barriers to this goal.

A number of approaches to treatment decision making between doctors and patients have been described. They are the paternalistic, the shared, and the informed (or consumerist) approach. Each has different implications for the roles of doctors and patients in communicating information, and for the amount, and flow of information between the two (34). Some approaches are

more amenable in incorporating patients' voices and eliciting patients' agendas than others.

Paternalistic approach: In the 'pure type' of this approach, doctors can make a treatment decision that they think is in their patients' best interest, without having to explore the patient's values and concerns. Instead, the doctor is more likely to want short descriptions of physical symptoms that they can transform into diagnostic categories. In the paternalistic approach, doctors are unlikely to have much interest in discussing patient concerns expressed 'in the voice of the life world' (30).

Informed approach: Here, patients are accorded a more active role in both defining the problem for which they want help, and in determining appropriate treatment. In the pure type of this approach, the doctor's role is limited to providing relevant research information about treatment options and their benefits and risks, so that the patient can make an informed decision.

Shared approach: Doctors commit themselves to an interactive relationship with patients in developing a treatment recommendation that is consistent with patient values and preferences (34). To enable this to happen, the doctor needs to create an open atmosphere in which patients feel able to express all relevant concerns. In this approach, information exchange helps the doctor understand the patient, and ensures that the patient is informed of treatment options and their risks and benefits. It also allows patients to assess whether they can build a relationship of trust with their doctor.

Charles et al says that actual behaviour rarely corresponds to ideal types, and most doctor-patient encounters combine elements from different models (35).

They feel the approach adopted at the beginning of an encounter may change as the doctor gains a better sense of whether the patient has a good understanding of the available treatments.

The authors (33) conclude that there is a need to develop effective interventions to promote better communication. Understanding the reasons for communication problems is important. It will help researchers develop interventions designed specifically to address potentially different types of communication issues (36), (37).

In recent years, there has been increased emphasis on using mixed methodologies for achieving better outcomes from studies. There are techniques designed to combine the results of qualitative and quantitative studies to provide researchers with more knowledge than separate analysis (38). O’Cathain et al (38) describe three techniques for integrating data in mixed methods studies. The three techniques are triangulation protocol, following a thread, and the mixed methods matrix. There is more to be learnt from bringing together data from quantitative and qualitative methods than from using one method alone. It is for this reason that this study adopted a mixed methodology approach.

10.0 Aims of the study

Aims:

- To evaluate health outcome measures in benign, aesthetic, and oncological surgery.
- To evaluate the multi-factorial nature of decision making, and undertake an exploratory analysis of the decision making process in surgery and cancer care, along with factors affecting decision making.

Hypothesis: Clinical decisions are not multi-factorial and are solely based/dependent on hard quantitative research data.

11.0 Materials and methods

A mixed methodology was adopted. Quantitative and qualitative studies were incorporated. Quantitative studies included literature reviews, prospective studies, retrospective studies, and questionnaire surveys. Qualitative studies were based on the concept of grounded theory utilizing focus group discussions. Study groups included patients with various benign, malignant, and functional problems in relation to surgery. Colorectal and breast specialities were studied. Focus group discussions and postal questionnaire surveys were utilised for the qualitative arm of the research. Clinicians in breast, /colorectal, and head and neck surgery formed the participant group in focus group discussions. The various methods used are highlighted below.

Health outcome measures: A series of literature reviews were undertaken.

Benign breast conditions: Risk factors for complications following reduction mammoplasty were evaluated using data from a randomised trial. The effects of resection weight, BMI, age, and smoking on complication rates following reduction mammoplasty were investigated.

Benign colorectal conditions and quality of life: Retrospective reviews based on prospective databases, bowel dairies, quality of life and health-related quality of life instruments were used.

Malignant colorectal, breast, head and neck conditions: National questionnaire surveys and qualitative research tools were used to undertake focus group discussions based on grounded theory.

Questionnaires: Wherever standard externally validated questionnaires were available, they were used. In the absence of externally validated questionnaires, they were developed by expert groups based on the opinions of the members of the academic surgical unit. Questionnaires with psychological components were further validated by the clinical psychologists in the University. The questionnaires developed in-house are illustrated in the respective chapters and appendix.

Analysis: Quantitative analysis was undertaken using the Statistical Package for the Social Sciences (SPSS[®] version 11.5, Chicago, Illinois, USA). Health outcome measures were analysed using dedicated software, the SF36 analysis package (SPSS[®] version 11.5, Chicago, Illinois, USA). Analysis of the

qualitative data was undertaken by a systematic, thematic process, where the data was analysed to derive most commonly reoccurring concepts. These reoccurring concepts are referred to as 'themes'. Repeated analysis leads to saturation of themes. Analysis of themes leads to the evolution of solutions for problems identified in the themes. The solutions carved out of this data are 'outcomes'.

12.0 Results:

Prior to investigating the various disease pathologies and their associated decision making processes, health outcome measures, as the basis of quality of life assessments, were evaluated.

12.1 Quality of life and its measurements

Health is multi-dimensional. Mortality, morbidity, and cost are traditional health indicators. In addition to these, personal assessments of functional status and well-being, customers' reports, ratings of care, services and health plans, are all driving healthcare towards a patient based assessment. Quantification of health indicators is important. Outcomes research relates to quality of life and health-related quality of life. Health outcome measures are becoming increasingly important in health care, and health research.

Methods / data sources: A non-systematic review was undertaken using the available literature. Health outcome measures, quality of life, health related quality of life, breast surgery, cosmetic surgery, and aesthetic surgery, were some of the search terminologies used. An extensive literature search was conducted till November 2006 on Ovid MEDLINE(R) and August 2006 on Pub med. Google scholar was used for non-peer reviewed literature. The Science of Health measurement (an educational series by the Tufts University School of Medicine) was referred to for understanding health outcome measures.

Health and its concepts

In 1948, the World Health Organization (WHO) defined health as 'a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity'. Health is multi-dimensional (physical, mental, and social). It is important to quantify these health indicators or measures.

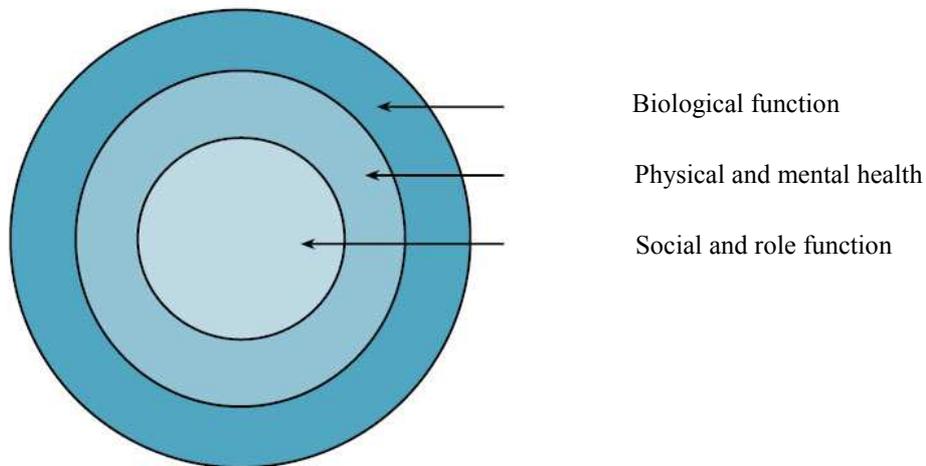
The traditional indicators of health care outcomes are mortality, morbidity, and cost. In addition to these, personal assessments of functional status and well-being, customers' reports, ratings of care, services and health plans are all driving health indicators towards a patient based assessment. Ware et al (39) defined quality of life:

'Quality of life is a state of mind ... how good it is to you, and only you can decide that. If I want to know your quality of life, I have to ask you. I can't know it by observing you; I have to ask you. And that's the way we gather quality of life data. The health-related quality of life is that part of your quality of life that is more affected by disease and health care treatment.'

Health concepts (Ware et al, 1984) (44)

Ware et al defined health as a balance between the biological function, physical and mental health, and the social and role function (*Figure 1*).

Figure 1. Dimensions of health (40)



Disruption in any one of these dimensions of health can compromise functioning and well-being in other areas. Ill health can come from any one dimension, and all of these states must be in balance in order for a person to have perfect health.

Quality of life and health-related quality of life

It is important to understand the distinction between quality of life and health-related quality of life. Quality of life is a global concept with many themes, including overall satisfaction with life as well as the specific domains of life including family, community, work, and health. Health-related quality of life takes into account the values of the individual, narrowing the focus to health concepts, such as functioning, that are affected by disease and treatment (41).

Outcomes research and health surveys

Outcomes research examines the end results of medical interventions, taking into account patients' experiences, preferences, and values. The purpose of assessing outcomes is to provide evidence on which to base clinical decisions. Health surveys are tools used for evaluating various concepts of health, and provide a patient-based assessment of health. They are broadly categorized into generic and specific health measures.

1. Generic Health Measures

Generic health measures assess health concepts that represent basic human values, and are relevant to one's health status and well-being, regardless of age, disease, or treatment group (42). Some of the generic health measures used are shown in *Table 1*. The SF-36 provides an illustrative example:

Medical Outcome Study (MOS): Short Forms (SF-36)

The SF-36 was designed to serve as a core general health measure. It is a 36-item survey, and requires 6 to 9 minutes, on average, to complete. Survey items capture eight health concepts (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health). Scale construction studies support several scoring options, including a profile of health states across the eight concepts, summary measures of physical, and of mental health outcomes, and a single utility index of health. Published scoring algorithms include data quality checks. Results of extensive validity studies have been published, and norm based scoring further improves the interpretation of scores.

2. Specific health measures

Specific measures focus on the particulars of a specific disease or diagnostic group (e.g. cancer), condition (e.g. congestive heart failure), or treatment (e.g. hip replacement), and are designed to capture areas of health specifically affected by that disease or treatment (43). Some of the specific health measures used are shown in *Table 2*.

Table 1. Generic health measures

European Quality of Life Index (EuroQoL) (44)
MOS Short Forms (SF-36 (45) and SF-12 (46))
Nottingham Health Profile (NHP) (47)
Quality of Well-Being Scale (QWB) (48)
Sickness Impact Profile (SIP) (49)
Health Utilities Index (HUI) (50)
Quality-of-Life Index (51)
Subjective quality of life profile (SQLP) (52)
General health questionnaire (GHQ12) (53)

Table 2. Specific health measures

Breast	Breast Evaluation Questionnaire (54)
	Breast Chest Ratings Scale (BCRS) (55)
	Derriford Scale (DAS59) (56)
	Multidimensional Body-States Relations Questionnaire (MBSRQ) (57)

Psychosocial	Psychosocial Adjustment to Illness Scale (58) Courtauld emotional control (CEC) scale (59) Folkman and Lazarus Ways of Coping questionnaire (60) Modified Folkman and Lazarus Ways of Coping questionnaire Profile of Mood States (61) LOT-R – Measure of optimism (62) Hospital Anxiety and Depression Score (63)
Pain	Pain Disability Questionnaire (64) McGill Pain Questionnaire (65) MOS Pain Measures (66)



12.2 Quality of life, Health-related quality of life, and breast surgery

Oncoplastic surgery and quality of life issues

Post surgery, younger women experience a lower quality of life due to the effects of medical treatment (67). The effects of surgery and removal of the breast result in more negative feelings regarding body image (67). Systemic treatments make many younger women experience sudden onset of menopause, and many suffer relationship issues contributing to a high level of sexual concern. Psychosocially, the effect is present in both female patients and their partners. Emotional support from the partner is important for the woman's adjustment to the altered body image. There is encouraging evidence that couple-based psychosocial interventions might be of particular assistance to both parties (67).

In a study carried out in the Far East, looking at the early effect of surgery in women with operable breast cancer on quality of life, patients were interviewed prior to and after the surgery, using the Functional Assessment of Cancer Therapy-Breast quality of life (FACT-B) instrument. There was no significant change in overall quality of life immediately after surgery, probably reflecting strong family and social support for these women. Similar results have been reported by studies from other countries (68).

After breast-conserving surgery, and during subsequent radiation therapy (RT), young women experience changes in quality of life, psychosocial adjustment, and adaptation to survivorship issues. Changes may not reflect what is observed in clinical practice. As such, there is a need to understand and support young women during RT (69).

Schultz et al (70) studied the quality of life issues in long-term survivors of breast cancer. He described the relationship between menopausal symptoms, physiologic health effects of cancer treatment and physical constraints. He concluded that breast cancer and menopause are independent issues, and should not be confused with the quality of life or psychosocial issues of the cancer survivor. Understanding these issues is important before it is possible to provide holistic nursing care.

Casso et al (71) examined the correlates of quality of life of a well-defined group of 5–10 year breast cancer survivors, who were diagnosed between the ages of 40 and 49, using questionnaires. CARES-SF and SF-36 were some of the measures used. Breast-related symptoms, use of adjuvant therapy, lower income, and type of breast surgery were significantly associated with lower quality of life 5 to 10 years post-diagnosis. The authors emphasized that younger long-term survivors have a high quality of life across several standardized measures. The long-term consequences of adjuvant therapy and management of long-term breast-related symptoms are two areas that may be important for clinicians and women with breast cancer to enable understanding and optimizing of long-term quality of life.

A survey done among the British Association of Surgical Oncology members to frame the attitude and perception of breast surgeons in the UK demonstrated age as not a criteria in identifying a patient as elderly in 44% (72). The surgeons surveyed felt that the decision making process was based on multiple factors, used to tailor the most appropriate treatment with the aim of improving quality of life (42%) and quality adjusted survival (40%). No routine elderly care

assessment was utilized (82%). The survey confirmed a lack of knowledge in the management of elderly patients affected by breast cancer.

Reconstructive surgery and quality of life

Reconstructive surgery plays an important role in the physical and emotional outcome amongst breast cancer survivors. The psychosocial impact of primary surgery occurs largely in areas of body image and feelings of attractiveness, with women receiving lumpectomy experiencing the most positive outcome (73). The type of primary surgery has no significance on emotional, social, or role function (73). Beyond the first year following diagnosis, a woman's quality of life is influenced more by her age or exposure to adjuvant therapy, than by her breast surgery (73). In the case of mastectomy, reconstruction will restore lost femininity, sexuality, and normality, in most cases, not because of the procedure but because of elimination of prostheses (74).

Older patients post reconstruction do well when it comes to mental health scores, compared to younger women. Giroto et al (75) studied breast reconstruction after mastectomy in women older than 65 years of age, and looked at its impact on quality of life. The SF-36 outcome measure was used. Older patients scored lower (worse outcomes) in the areas related to physical function. They maintained superior scores (better outcomes) over younger patients in the subscales influenced by mental health.

In breast cancer, apart from improving disease free survival, quality of life, body image, and cosmetic outcome are important issues. Cocquyt VF et al (80) evaluated health-related quality of life and body image in patients treated with

preoperative chemotherapy followed by breast conserving surgery, or skin-sparing mastectomy (SSM) and perforator-flap breast reconstruction.

Participants were evaluated by SF-36 and a study-specific questionnaire. The authors showed that breast conserving treatment or mastectomy with reconstruction may yield comparable quality of life results, but cosmetic outcome was better after SSM and perforator-flap reconstruction. Patients should be offered both options, and clinicians should stress that both are equally effective.

Quality of life, patients' satisfaction, and aesthetic outcome after pedicle or free TRAM (Transverse Rectus Abdominis Myocutaneous) flap breast surgery were studied to evaluate the aesthetic result of breast reconstruction, both objectively and subjectively (76). No statistically significant difference between pedicle and free TRAM flap were seen regarding patient satisfaction with the reconstruction. In the patients' self-assessment of cosmetic outcome, the degree of symmetry was assessed to be higher in the free TRAM flap group. SF-36 revealed no difference between the pedicle and free flap groups. A strong correlation between patient and panel evaluation of cosmetic outcome was seen.

The psychosocial impact of breast surgery has been extensively studied in the West. There is a relative paucity of comparable data in oriental women who are increasingly affected by breast cancer. Fung et al (77) studied the effects that different types of primary breast surgery have on the quality of life of Chinese women. Aspects of quality of life included general psychological well-being, body image, and sexual and social function. The results showed that breast-conserving treatment (BCT) had significantly improved body image scores

compared to mastectomy. The three groups, namely BCT, mastectomy and mastectomy with immediate breast reconstruction, did not differ significantly in the other aspects of quality of life measured.

Nissen et al (78) looked at women's expectations following post mastectomy reconstruction, and factors affecting their quality of life. Qualitative focus groups revealed that women wished they had been better informed about some issues. Ratings of satisfaction were generally high. There were concerns about cosmetic outcome and persistent anxiety about recurrence. Women appreciated information which enabled them to prepare for reconstruction and recovery.

Quality of life after breast carcinoma surgery compared between breast conservation surgery (BCS), mastectomy alone, and mastectomy with reconstruction, was shown to be equally effective for the treatment of early stage breast carcinoma, using the Mischel Uncertainty in Illness Scale, Profile of Mood States, and FACT for Breast Cancer (79). In conclusion, aspects of quality of life other than body image were no better in women who underwent BCS or mastectomy with reconstruction, than in women who had mastectomy alone. Mastectomy with reconstruction was associated with greater mood disturbance and poorer well-being (79).

Harcourt et al (80) have examined the research literature relating to the psychological aspects of breast reconstruction. Particular attention was given to the role of specialist breast care nurses and psychological benefits. There is a lack of studies examining breast reconstruction in terms of relevant psychological constructs, especially in relation to coping and decision-making.

They concluded that existing research into the psychological aspects of breast reconstruction is limited, and not sufficiently conclusive to inform changes to policy and the provision of care.

Complications and quality of life

Lymphoedema and post-mastectomy pain are complications that can have an impact on the QOL. Patients with lymphoedema may experience pain and body image issues. Complete decongestive therapy (CDT) is effective in treating lymphoedema. The FACT-QOL measure and a visual analogue scale for pain showed successful reduction in girth, volume, and pain with increased quality of life. Quality of life and pain are improved by treatment, and continue to improve after the treatment has ended (81).

Pain after quadrantectomy and radiotherapy for early-stage breast cancer affecting quality of life was studied using self-completed questionnaires (82). The outcome measures used were the McGill Pain Questionnaire and a quality of life questionnaire. The authors supported the hypothesis that pain is a frequent sequelae of CBS and radiotherapy, and that such symptoms can cause postoperative psychosocial distress, thus limiting patient adaptation and reducing the beneficial effect of CBS on body image.

Macdonald et al (83) looked at long-term follow-up of breast cancer survivors with post-mastectomy pain at 7-12 years postoperative. Chronic pain and quality of life were assessed using the McGill Pain Questionnaire and SF-36. Quality of life scores were significantly lower in women with persistent post

mastectomy pain syndrome, compared to those women whose pain had resolved.

Psychological factors

In breast cancer, the psychological response, such as a fighting spirit, or an attitude of helplessness and hopelessness, toward the disease has been suggested as a prognostic factor.

Watson et al (84) in a population based study, investigated the effect of psychological response on disease outcome in a large cohort of women with early-stage breast cancer. Psychological response was measured by the mental adjustment to cancer scale, the Courtauld emotional control scale, and the hospital anxiety and depression scale. The authors found that for 5-year event-free survival, a high helplessness/hopelessness score has a moderate detrimental effect. There were no significant results found for the category of 'fighting spirit'. A high depression score is linked to a significantly reduced chance of survival.

Watson et al (85) assessed the psychological responses of helplessness/hopelessness, fighting spirit and depression in early-stage breast cancer patients between 1 and 3 months post-diagnosis. In order to ascertain the effect on cancer prognosis, patients were followed-up for 10 years. There was a continuing effect of helplessness/hopelessness on disease-free survival, but not of depression. Longer follow-up also indicated that a high fighting spirit conferred no survival advantage. The results showed that, in patients who were disease-free at 5 years, baseline helpless/hopeless response still exerted a

significant effect on disease-free survival beyond 5 (and up to 10) years. The effect is therefore maintained for up to 10 years.

Reynolds et al (86) evaluated the association between coping strategies and breast cancer survival among black and white women. An emotion-focused coping strategy was associated with survival. Expression of emotion was associated with better survival, suggesting that the opportunity for emotional expression may improve survival among patients with invasive breast cancer.

In a qualitative study on metastatic disease by Cunningham and Watson (87), common themes emerged. 'Authenticity', or a clear understanding of what was important in one's life; 'autonomy', the perceived freedom to shape life around what was valued; and 'acceptance', a perceived change in mental state to enhanced self-esteem, greater tolerance for and emotional closeness to others, and an affective experience described as more peaceful and joyous. The authors looked at the concept of remarkable survivors. They found a mirrored symmetry between the psychological patterns possibly promoting disease, and the changed adaptations that may lead to longer survival in some cases. The authors suggested that the progression of cancer, or other chronic disease, is favoured by a distorted psychological adaptation, and that healing may be assisted by a reversal of that adaptation in the case of cancer, toward greater authenticity of thought and action (87).

Petticrew (88), in his systematic review, analysed the influence of psychological coping on survival and recurrence in people with cancer and summarised the evidence that psychological coping styles (including fighting spirit, helplessness,

hopelessness, denial, and avoidance) affect survival and recurrence in patients with cancer. He concluded that there is little consistent evidence that psychological coping styles play an important part in survival or recurrence. People with cancer should not feel pressured into adopting particular coping styles to improve survival or reduce the risk of recurrence. Although the relation is biologically plausible, there is at present little scientific basis for the popular lay and clinical belief that psychological coping styles have an important influence on overall or event-free survival in patients with cancer.

Service provision and quality of life

Day case surgery and the role of nurses: Margolese and Lasry (89) compared inpatient to same-day discharge surgery for breast cancer on unselected patients. Outpatient and hospitalized patients reported similar levels of pain, fear, anxiety, health assessment, and quality of life.

Ambulatory patients manifested a significantly better emotional adjustment and fewer psychological distress symptoms. Same-day discharge patients are not at a disadvantage compared to hospitalized patients; i.e. they report faster recovery and better psychological adjustment. Outpatient surgery may thus foster patient emotional well-being better than routine hospitalization.

Education for women being fitted for breast prostheses is best done by nurses who are instrumental in educating women about issues related to breast surgery and in helping to promote psychosocial adjustment.

Prostheses and bras that fit properly are very important in the recovery process, and ultimately improve quality of life (90).

Physical exercise and quality of life

Aerobics and resistance training exercises can improve the quality of life for women recovering from breast cancer treatment. Long-term fatigue with subsequent decrease in quality of life is a serious problem for cancer survivors. Up to 30 per cent may experience this symptom for years after termination of treatment (91).

Complementary and alternative therapies and quality of life

Sanskrit is an ancient language of India. Yoga is a Sanskrit word meaning 'union of the body, mind and spirit'. Studies have shown that breast cancer patients who do yoga tend to enjoy better health, less fatigue and experience less daytime sleepiness. Short yoga programmes, including meditation, relaxation, breathing exercises, stretching, imagery, and physical movements, are shown to be useful at reducing the side effects of breast cancer treatment.

Shannahoff-Khalsa (92) showed that the Kundalini yoga meditation technique for psycho-oncology is a potential therapy for patients with anxiety and depression. A pilot study of yoga for breast cancer survivors (93) showed physical and psychological benefits of lessening the impact of detrimental cancer-related symptoms and treatment side-effects (e.g. fatigue, nausea), and improving overall well-being and quality of life.

Carlson et al (99) investigated the relationships between mindfulness-based stress reduction (MBSR) in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. The participants were enrolled into an 8-week MBSR program that incorporated

relaxation, meditation, gentle yoga, and daily home practice. Demographic and health behaviour variables, quality of life (EORTC QLQ C-30), mood (POMS), stress (SOSI), and counts of NK, NKT, B, T total, T helper, and T cytotoxic cells, as well as NK and T cell production of TNF, IFN-gamma, IL-4, and IL-10 were assessed pre and post intervention. The authors concluded that MBSR participation was associated with enhanced quality of life, and decreased stress symptoms, in breast and prostate cancer patients. This study is the first to show changes in cancer-related cytokine production associated with programme participation.

In another study, Carlson (94) concluded that MBSR program enrolment was associated with enhanced quality of life and decreased stress symptoms in breast and prostate cancer patients, and resulted in possibly beneficial changes in hypothalamic-pituitary-adrenal axis functioning.

Health outcome measures specific to breast cancer

There are a few generic and specific health outcome measures associated with breast surgery. Reliable and valid assessment instruments in cosmetic surgery are a vital factor in assessing patient satisfaction with physical appearance. Appearance and satisfaction assessments are needed to adequately evaluate quality of life. The Breast Evaluation Questionnaire was designed to assess satisfaction with breast attributes. It is a 55-item with subscales including comfort not fully dressed, comfort fully dressed, and satisfaction with breast attributes. The assessment is easy to administer and interpret, and is

recommended for assessing outcomes among breast augmentation patients, breast reconstruction patients, mastectomy patients, lumpectomy/breast-sparing surgery patients, breast reduction patients, and patients who have sustained trauma or injury to their breasts (54).

Ching et al (55), in their literature review on measuring outcomes in aesthetic surgery, identified body-image and quality of life measures to be of the greatest value in determining cosmetic surgery outcomes. These conclusions were based on a critical evaluation of the feasibility, validity, reliability, and sensitivity to change of these measures. The Multidimensional Body-States Relations Questionnaire (MBSRQ), a psychological assessment of body image, was selected as a potential candidate for further study. The Breast Chest Ratings Scale (BCRS) was said to be useful in the assessment of breast surgery. The Derriford Scale (DAS59), an instrument that assesses appearance-related quality of life, was also selected. In addition, the authors recommend the use of a generic, utility-based quality-of-life instrument, such as the Health Utilities Index (HUI) and EuroQoL (EQ-5D).

12.3 Benign breast conditions

12.3 a: Quality of life issues in aesthetic breast surgery

Introduction

Evaluation of quality of life is an important measured outcome in the field of breast surgery. Measuring health-related quality of life is also an important endpoint in aesthetic surgery. However, not all surgeons are familiar with the basic concepts and uses of quality of life assessments. The following is a review of the existing literature on quality of life issues in aesthetic breast surgery.

Methods / data sources: An extensive literature search was conducted from January 1996 to November 2006 on Ovid MEDLINE(R) and January 2000 to August 2006 on PubMed. Google scholar was used for non peer reviewed literature. Search terminologies used for literature search included breast surgery, cosmetic surgery, aesthetic surgery, and quality of life. Studies relating to cancer were not considered. The Science of Health measurement (an educational series by the Tufts University School of Medicine) was referred to for understanding health outcome measures.

Health and its concepts

A detailed description of health and its concepts has been given in chapter 12.1. The earlier chapter also describes quality of life and health-related quality of life in detail. The remit of the current chapter is to undertake an exercise to look into the quality of life issues in aesthetic breast surgery.

Aesthetic surgery

Reduction, augmentation mastopexy, and correction of asymmetry are common aesthetic procedures performed on the breast.

Reduction mammoplasty and quality of life:

In 2007 there were 3,402 reduction mammoplasty procedures in the UK (95).

Macromastia interferes with the patient's physical, social and emotional health.

The physical issues include pain, discomfort, poor posture, under breast rashes, and tiredness. Feeling tired, worn out, depressed or nervous, having issues with undressing, fear of being teased by the partner, and suffering social

embarrassment are some of the emotional and psychological issues involved.

Breast reduction improves quality of life, physical and psychosocial issues (96), (97) along with providing a long term improvement in health status (98). This could be put into context with other procedures, such as total hip replacement which has been proven to benefit quality of life (99).

Brown and Khan showed that patient satisfaction with breast reduction was

high, with major improvement in psychological well-being and physical benefits.

All patients noted improvement with breast, neck, and back pain, and with under breast rash, and shoulder grooving (100). Reduction mammoplasty is shown to offer substantial relief of macromastia associated symptoms, with a low complication/revision rate (101) along with significant improvement in all quality-of-life factors (108).

Iwuagwu et al in a RCT, assessed the effects of bilateral breast reduction on anxiety and depression in women with macromastia. The Hospital Anxiety and Depression Score showed significant improvements ($p < 0.001$) in symptoms of anxiety and depression, and improvement in symptoms of clinical depression (102). There were highly significant differences in quality of life and psychosocial functioning between groups in scores measured on the Functional Assessment of Non-Life Threatening Conditions version 4, EuroQoL, and both mental and physical scales of Short Form 36 ($p < 0.001$). The Eysenck Personality Questionnaire-Revised demonstrated a statistically significant increase in extroversion and emotional stability in the early treatment group. The authors concluded that reduction mammoplasty significantly improved quality of life, and increased extroversion and emotional stability(103). Reduction mammoplasty was also responsible for physiological improvement in pulmonary function (104).

Augmentation mammoplasty and quality of life:

In 2007, a total number of 6,497 augmentation mammoplasty procedures were undertaken in the UK (95). The number of 18-year-olds in the United States, who underwent breast-implant surgery, rose from 3,872 in 2002 to 11,326 in 2003, according to the American Society for Aesthetic Plastic Surgery. Breast augmentation is the third most commonly performed cosmetic surgical procedure in the United States. In 2005, 291,000 breast augmentation procedures were performed (105) in USA.

Studies have shown improvement in the subjective quality of life and mental health after bilateral breast augmentation on the basis of indices of patient satisfaction and psychological evaluation. Chahraoui et al (106), using the

subjective quality of life profile (SQLP) and the general health questionnaire (GHQ12), along with interviews, revealed the benefits of cosmetic surgery for the patients' subjective quality of life. The subjects' mental health and quality of life improved in a number of dimensions: physical health, pain, physical appearance, social life, and inner life. The study also showed that improved physical health during the postoperative period was associated with the quality of the relationship with the doctor, whereas deterioration in health was associated with excessively high initial expectations concerning the relationship with doctors, and physical health.

Mastopexy for asymmetry:

Mastopexy, or breast lift, is a procedure designed to improve the appearance of sagging or ptotic breasts (107) . The prevalence of breast ptosis is difficult to estimate, but the frequency of mastopexy clearly is increasing. In 1992, the American Society of Plastic Surgeons reported that fewer than 8000 mastopexies were performed. The 2004 report indicates that more than 98,000 mastopexies were performed in the United States alone (107) .

A retrospective review by Spear et al (108) highlighted that the end results of augmentation and mastopexy depend on a number of factors that must work in harmony to yield an excellent result. The authors reported that what is aesthetically pleasing to the surgeon may not be pleasing to the patient, and vice versa. Acknowledging the complex nature of the patient's problems and the surgical procedure, they concluded that overall results of one-stage breast augmentation and mastopexy are good, and the patients generally are satisfied

Mental health benefits of aesthetic surgery:

The mental health benefits of breast augmentation and reconstruction are widely acknowledged and supported by surveys, but objective research does not support those claims. From 2001-2006, five studies were published indicating an increase in deaths from suicide among women with breast augmentation (109). Most studies compared women with implants to women in the general population, raising questions about whether women who choose plastic surgery have other traits (age, race, social class, low self-esteem) that make them more likely to commit suicide than other women. However, a study by scientists at the National Cancer Institute found a higher suicide risk among breast implant patients compared to other plastic surgery patients, although the women were similar in terms of age, race, social class, health status and health habits (109). All these studies do not determine whether women choosing breast augmentation are less psychologically healthy than other women before surgery, or if the mental health problems contributing to suicide are related to pain or other complications from breast augmentation.

In the only studies that objectively compared women before breast implants to two years later, the women who undergo breast augmentation or reconstruction have the same or lower scores on most tests of self-esteem and quality of life two years after getting silicone breast implants compared to those same women just before surgery (110).

Psychosocial issues, psychologists, and quality of life:

It is known that psychological factors are important in aesthetic surgery for a good outcome. While most people do well, some do badly. It is important to pick

up the right people for surgery. Selecting patients for aesthetic procedures is a challenging task.

Aesthetic surgery has positive effects on psychological and psychosocial functioning including improvements in body image and quality of life. However unrealistic expectations or a history of depression and anxiety are predictors of poor outcome.

Degree of deformity, patient expectations and outcome:

With increased degree of deformity and low patient expectation, bilateral breast reductions do well, with a very good outcome and generally resulting in a happy patient. With minimal deformity and a very high patient expectation, mastopexy patients will have poor outcome, resulting in an unhappy patient. Patients with bilateral breast augmentations lie half way between this, with moderate deformity and reasonable patient expectations, resulting in a satisfied patient. Research studies (111), (112) suggests that patients who are dissatisfied with surgery may request repeat procedures, or experience depression and adjustment problems, social isolation, family problems, self-destructive behaviours, and anger toward the surgeon and his or her staff.

Honigman et al (111) state, 'While most people do well in terms of psychosocial adjustment after cosmetic procedures, some do not, and the field needs to be aware of this and to arrange screening for such individuals'.

Psychologist Diana Zuckerman states, 'Cosmetic surgery affects patients' relationships, self-esteem and quality of life. These are fascinating issues for psychologists to look at from the cultural phenomena, to the interpersonal phenomena, to the mental health and self-esteem issues.' (113).

David Sarwer, another psychologist, is of the opinion that plastic surgery issues will affect clinician psychologists more and more, and the area will offer new roles for them, such as conducting pre- and post-surgical patient assessments. He stresses that with the growing popularity of plastic surgery, it will become important for psychologists to be able to talk with patients about their appearance concerns and make decisions on patients being good or bad candidates for cosmetic surgery (113).

In a recent study, Sarwer et al (112) found that a year after receiving cosmetic surgery, 87% of patients reported satisfaction following their surgery, including improvements in their overall body image and the body feature altered. They also experienced less negative body image emotions in social situations.

In contrast, this group (114) has also shown a link between plastic surgery and poor post-surgical outcomes for some patients, particularly for those with a personality disorder, or those who have body dysmorphic disorder (BDD) where they repeatedly change or examine the offending body part to the point that the obsession interferes with other aspects of their life. The majority of BDD patients who have cosmetic surgery do not experience improvement in their BDD symptoms, often asking for multiple procedures. Psychologists can help plastic surgeons identify patients who may not adjust well psychologically or psychosocially after surgery. Empirically based screening questionnaires are used in certain centres around the world to help plastic surgeons select cosmetic surgery patients likely to experience

positive psychosocial outcomes. More psychologists will begin to examine issues related to cosmetic surgery, because of its increasing popularity and the link between appearance, body image, and many psychiatric disorders, such as eating disorders, social phobia, and sexual functioning.

Cook et al (115), in their recent systematic review on aesthetic surgery as an effective psychotherapeutic intervention, concluded that there is neither good evidence to justify elective cosmetic surgery in the absence of physical need, nor there is strong enough evidence to justify withholding cosmetic surgery. They suggested several improvements in study designs whereby future prospective cohort studies could provide higher standards of evidence.

Service provisions and quality of life

Apart from surgery, other factors also play a role in patient's psychosocial adjustment.

Role of nurses: Patient education for women with breast prostheses is best done by nurses who are involved in educating women about issues related to breast surgery and in helping to promote psychosocial adjustment. Nurses should ensure that patients considering breast surgery understand the risks involved (116).

Health outcome measures specific to breast surgery

There are a few generic and specific health outcome measures used in breast surgery. Reliable and valid assessment instruments in cosmetic surgery are a vital factor in assessing patient satisfaction with physical appearance.

Appearance and satisfaction assessments are needed to adequately evaluate quality of life related to changes in the female breast across a variety of surgical interventions.

The Breast Evaluation Questionnaire (54) was designed to assess satisfaction with breast attributes. The Breast Evaluation Questionnaire is a 55-item scale, with subscales addressing comfort when not fully dressed, comfort fully dressed, and satisfaction with breast attributes. The assessment is easy to administer and interpret, and is recommended for assessing outcomes among breast augmentation patients, breast reconstruction patients, mastectomy patients, lumpectomy/breast-sparing surgery patients, breast reduction patients, and patients who have sustained trauma or injury to their breasts.

The Derriford Appearance Scale (DAS59) (56) is a psychometric scale for the evaluation of patients with disfigurements and aesthetic problems of appearance. The DAS59 has been designed and developed to meet the need for an objective measure of the spectrum of psychological distress and dysfunction that is characteristic of disfigurements, deformities and aesthetic problems of appearance.

Ching et al (55), in their literature review on measuring outcomes in aesthetic surgery, identified body-image and quality of life measures to be of the greatest value in determining cosmetic surgery outcomes. These conclusions were based on a critical evaluation of the feasibility, validity, reliability, and sensitivity to change of these measures. The Multidimensional Body-States Relations Questionnaire (MBSRQ), a psychological assessment of body image, was selected as a potential candidate for further study. The Breast Chest Ratings Scale (BCRS) was said to be useful in the assessment of breast surgery. The

Derriford Scale (DAS59), an instrument that assesses appearance-related quality of life, was also selected. In addition, the authors recommend the use of a generic, utility-based quality-of-life instrument, such as the Health Utilities Index (HUI) or EuroQoL (EQ-5D).

Conclusion: The magnitude of aesthetic breast surgery is on the rise.

Reduction mammoplasty and augmentation mammoplasty have increased significantly in the last decade. Understanding the concepts of health outcome measures is important. Evaluation of quality of life and health-related quality of life are important measured outcomes. Understanding the concepts of health outcome measures is important. Applying them to the clinical practice of aesthetic breast surgery is vital for good surgical practice.

12.3 b: Risk factors for complications following reduction mammoplasty

Introduction: Macromastia interferes with patient's physical, social and emotional health.

A number of operations have been described to reduce breast volume. The inferior pedicle technique is the procedure most commonly used by plastic surgeons in the western world (117), (118). However, there are some recognised complications with every technique used. These include the general complications of surgery, such as chest infection, deep vein thrombosis and thrombo-phlebitis. More specific complications include wound infection, seroma, haematoma formation, altered breast skin sensation, fat necrosis, wound dehiscence, poor wound healing especially involving the T- junction, and scar formation. Others specific and serious complications include skin necrosis, glandular flap necrosis, and nipple/areola necrosis.

The complication rates following reduction mammoplasty vary in different series from 7 to 53% (119), (120), (121), (122), (123). Although a number of factors such as resection weight, age, BMI, and smoking have been implicated as risk factors, there is paucity in prospective data examining these factors as risk factors for complications following reduction mammoplasty.

Aim: To determine the effects of resection weight, BMI, age and smoking on complication rates following reduction mammoplasty.

Methods: Ethical approval was granted from the Humber Research Ethics Committee bearing no. LREC Ref 07/02/130 for research project titled 'Quality of life biomechanical and cost effectiveness of reduction mammoplasty – a prospective randomised controlled trial'. The data for the study detailed below

was gathered from this original study. Data was gathered as a part of randomised control trial examining psycho-social and quality of life benefits of reduction mammoplasty. Sixty-seven consecutive female patients referred to either the Hull Breast Unit or Hull Plastic and Reconstructive Surgery Unit who underwent inferior pedicle reduction mammoplasty were recruited. Complications were recorded prospectively. Patients were selected based on the inclusion and exclusion criteria. All female patients requesting bilateral reduction mammoplasty for symptoms of macromastia, who gave written informed consent to participate in the study, were included. The exclusion criteria were patients with male gynaecomastia, unilateral reduction mammoplasty, or candidates for breast conservation surgery (breast cancer patients). All patients had a standard anaesthetic regimen given by a single consultant anaesthetist, and underwent inferior pedicle bilateral breast reduction by a consultant surgeon. All patients received the same post-operative wound care and pain management. Outpatient care also followed a routine protocol of a week post-operative review; subsequently, those that required more intensive wound care were seen accordingly. In addition to the basic demographics, data gathered included resection weight, BMI, age, and smoking status. Smoking status was categorised into current smoker, ex-smoker, and never smoked. Prospective records of all complications were noted. SPSS was used for purposes of statistical analysis (SPSS[®] version 11.5, Chicago, Illinois, USA).

Results: Of the 67 patients, 16 (23.9%) had complications (*Table 3*). Higher resect weight, increased BMI and older age are associated with high rate of complications with significance reaching P values of $p < 0.001$, $p = 0.034$ and $p = 0.004$ respectively (*Table 4*).

Table 3. Complications after reduction mammoplasty.

Sl No.	Age	Res. Wt. (gms)	BMI	Smoking	Complications
1.	57	880	30	Never	Minor- T junction breakdown
2.	55	1243	26	Never	Major-MRSA wound infection
3.	62	2874	31	Current	Minor-dusky nipples initially-recovered
4.	41	1187	32	Never	Minor(excision dog ears)
5.	46	1336	31	Current	Major fat necrosis / wound infection
6.	21	2163	34	Never	Major - non healing T-junction / wound infection
7.	52	2216	29	Ex – smoker	Minor – Wound infection
8.	38	2446	34	Current	Major - wound infection MRSA
9.	63	1549	26	Current	Major – haematoma
10	42	2468	36	Never	Minor rev. scar
11	27	714	27	Never	Minor fat necrosis
12	50	1878	29	Never	Minor – T junction breakdown
13	64	1596	33	Never	Minor - wound infection
14	56	-	27	Ex – smoker	Minor – wound infection
15	38	1744	36	Ex – smoker	Minor - wound infection
16	47	3603	35	Current	Major - wound infection / fat necrosis

Table 4. Effect of resection weight / BMI / age on complications.

Mean value (SD)	No complications (n=51)	Complications (major or minor) (n=16)
Resect weight	1,253 (SD 469.5)	1,813** (SD 763.7)
BMI	27. 9 (SD 4.4)	30.5* (SD 3.3)
Age (in years)	36.9 (SD 11.5)	47.1** (SD 12.7)

* Significant difference at 95% confidence interval

** Significant difference at 99% confidence interval

Effect of smoking and complications.

Among the 67 women who had surgery, 9 (13.4%) are current smokers, 20 (29.9%) are ex-smokers and 38 (56.7%) have never smoked. The incidence of complications is highest amongst current smokers, and lowest amongst those who have never smoked (*Table 5*).

Table 5. Effect of Smoking on complications.

	Current smoker (n=9)	Ex-smoker (n=20)	Never smoked (n=38)
No complications	4 (44.4%)	16 (80%)	31 (81.6%)
Complications	5 (55.6%)	4 (20%)	7 (18.4%)

When comparing the current smokers with those who are not currently smoking, there is a 37% difference in the occurrence of complication (*Table 6*). The chi squared test shows that this is a significant difference ($p < 0.01$) at 99% confidence interval.

Table 6. Effect of current smoking on complications

	Current smoker (n=9)	Not current smoker (n=58)
No complications	4 (44.4%)	47 (81.0%)
Complications	5 (55.6%)	11 (19.0%)

Major complications: Among the 67 who had surgery, 6 had major complications culminating in either operative treatment, or prolonged wound care and adjunctive antibiotic treatment. Two patients had MRSA wound infection and breakdown of the T-junctions, which required prolonged wound care and antibiotic treatment for 8-12 weeks. The wounds have now healed and

the scars have become less obvious over the ensuing months; both women did not require any further surgery. Another patient developed a breakdown of both T-junctions with non-healing of the wounds. She required prolonged wound care on a daily basis. Despite having healthy granulation tissue, complete healing was difficult to achieve, she eventually underwent split skin graft treatment with good result. Two heavy smokers developed severe fat necrosis with loss of volume, with superadded wound infection which also required prolonged wound care and debridements of tissue. A female patient developed a large haematoma approximately a week post operation, this was managed by several episodes of percutaneous ultrasound guided aspiration, this complication has resolved satisfactorily.

Minor Complications: Ten women had minor complications. Of these, four were women with low grade wound infection, all of which responded to antibiotics, two women required minor revision of the scar, mostly for 'dog ears' in the lateral aspect of the horizontal scar, Two women had minor T-junction breakdown that required no surgery, and eventually healed satisfactorily, One patient had a solitary area of fat necrosis measuring approximately 4cm x 4cm which required excision using a vacuum assisted breast biopsy device, another woman who had a massive resection (2874 gram-specimen weight) developed a dusky and pale right nipple in the immediate post operative period, but the colour rapidly improved over the next few days in the post-operative period.

Multivariate analysis of all complications and development of risk prediction model:

Logistic regression is used to predict the likelihood of a patient developing complications given the information collected concerning the independent variables (smoking, BMI etc). The variables included in the multivariate analysis are current smoking status, past smoking status, BMI (actual value), age (in years), and resect weight (actual value).

The model works well at predicting levels of complication giving a significant model. The details are shown below (*Table 7*). The model includes both age and resect weight, but does not include either of the smoking variables or the BMI.

Table 7. Risk prediction model.

	Model details	
	<i>B (SE)</i>	<i>Exp B</i>
Included in model		
Resect Weight	0.001* (0.001)	1.001
Age	0.06* (0.03)	1.061
Constant	-5.90* (1.60)	0.003

Note $R^2 = 0.198$ (Cox & Snell), $\chi^2 = 14.6$, $p < 0.001$. * $p < 0.05$, ** $p < 0.01$

The model shows that the likelihood of a patient developing a complication following surgery increases for older patients, and increases with the size of resect. This is shown by a value of Exp B greater than 1.

Discussion: There are a number of techniques in use for reduction mammoplasty. The inferior pedicle technique is the procedure most commonly

used by plastic surgeons, from a survey of board certified plastic surgeons in America (117). A questionnaire survey by Iwuagwu et al looking at the current trends in reduction mammoplasty in UK and Ireland demonstrated that nearly 67% of the consultant surgeons used the inferior pedicle technique (118).

The reported complication rates for reduction mammoplasty range from 5% (117) to 53% (124). Complications following breast reduction can be broadly categorised into local vs. systemic, early vs. late, or major vs. minor. Ferreira (125) categorised them into early complications (i.e. haematoma, seroma, wound dehiscence, infection, and necrosis) and late complications (i.e. problems of volume, shape, symmetry, areola and scars).

An overall view of some of the important studies highlights the risk factors associated with complications following reduction mammoplasty. In a 9-month prospective, multi-centre trial from the BRAVO study, analysis of complication data showed an overall complication rate of 43%. Complication data revealed resection weight correlated with increased risk and absolute number of complications. Delayed healing correlated directly with resection weight, and inversely with increasing age (123). It has been suggested that the complication rate of reduction mammoplasty is directly correlated with the amount of breast tissue resected (126). A higher mean BMI predicted delayed healing, wound dehiscence, and infection (127). Mandrakes et al (128) in their study looked at 371 patients who had inferior pedicle reduction mammoplasty over 10 years, with an overall complication rate of 11.4%. Their specific complications were haematoma 0.3%, nipple and/or pedicle necrosis 0.8%, wound dehiscence 4.6%, fat necrosis 0.8%, carcinoma 0.5%, loss of sensitivity of the nipple 1.3%, hypertrophic scars 3.3%, dermoid cysts 0.3%, and marked lower fullness 0.3%.

Zubowski et al (126), in their attempt to derive a relationship between obesity, specimen weight, and complications in reduction mammoplasty, conclude that obesity and specimen weight are both associated with a higher incidence of complications. The authors retrospectively reviewed 395 patients who underwent reduction mammoplasty over a 10-year period, and showed a statistically significant increase in complication rate in the obese ($p=0.01$), and demonstrated a stronger linear relationship between specimen weight per breast and incidence of complications.

A number of studies have indicated that smokers are at increased risk of developing complications compared to the non smokers. Bikhchandani et al (122) showed that smokers were 2.3 times more likely to develop any complication. This is similar to the results from Schumacher (129), who reported the incidence of wound complications to be 3.4 times higher in smokers. Chan et al (130), in their study on smoking and wound healing problems in reduction mammoplasty, suggested introduction of urine nicotine testing at the preadmission clinic, and prior to the operation, to provide objective verification of patients' smoking history, minimize morbidity, and enable healthcare cost savings.

Reduction mammoplasty is a procedure with potential for complications, the complications in the author's series being comparable to other published series in the literature and is in the mid range. Complications are particularly likely to occur in operations that involve larger resections of breast tissue, high BMI, older patients, and smokers.

Thus in this study, of the 67 patients who had already undergone surgery, there was a 9% incidence of major complication and 18% incidence of minor complication. None of the women complained of altered skin sensation,

although all were warned of this risk prior to surgery. Although previous studies have demonstrated the risk factors for complications following reduction mammoplasty, the prospective RCT nature of this study strengthens and reinforces the previous evidence.

Patients should be adequately counselled beforehand about possible complications. They should be strongly encouraged to modify the reversible risk factors by reducing weight, and stopping smoking. The relationship between smoking status and complications emphasises the importance of stopping smoking in the peri-operative period, until the wounds have completely healed. Health education, professional counselling, de-addiction services, and active exercise programmes should all be utilised. Clinical preventive services, which include risk factor education and counselling by primary care physicians, can improve short-term health-related behaviour of patients (131). Health advocates might play an important role by increasing patient's receipt of preventive recommendations by assisting in patient education, referral, and encouraging physician recommendations (132). The role of counselling in stopping smoking cannot be overemphasised.

Conclusion: Reduction mammoplasty is a procedure associated with complications. It is therefore necessary for every attempt to be made to modify the possible risk factors for complications following reduction mammoplasty. Higher resect weight, increased BMI; older age, and smoking are some of the risk factors. Patients should be adequately counselled about losing weight and stopping smoking by active counselling services. Clinical preventive services and health advocates might have an increased role to play in the coming future. Whether adopting smoking abstinence in the peri-operative period should be an

essential eligibility criterion for breast reduction is an issue that needs consideration.

12. 4. Benign colo-rectal conditions and quality of life

12.4 a: Rectal irrigation in the treatment of evacuation disorders

Introduction:

Disorders of faecal continence present through a wide spectrum of symptoms and aetiologies (133). A recent review (134) highlighted the social and psychological distress along with impairment of quality of life that faecal continence disorders cause. The underlying anatomical and patho-physiological changes are complex, often incompletely understood, and cannot always be determined. As a consequence, many medical, surgical, and behavioural approaches have been described, with no panacea (134).

The problem persists widely in the community and the patients represent a diverse group. A systematic review reported a prevalence of 0.4–18% for faecal incontinence in community dwelling adults (135). The prevalence is approximately 50% among the institutionalised, with an annual incidence of 20% developing incontinence (136). Most of the patients are managed through conservative and pharmacological methods. However, there exists a group of patients which do not respond to either treatment. An important measure of severity of faecal continence disorders is its effect on quality of life. More than 50% of patients with major faecal incontinence report a significant negative impact on quality of life (137). There are various therapies which can be tried to relieve the patients of their symptoms, and improve their quality of life. Rectal irrigation (RI) is one such therapeutic method (138). The colo-rectal unit in Hull has been offering RI since 2002. The following are the results of an evaluation into such treatment.

Aims and objectives: The aims of this study were:

- To evaluate the efficacy and acceptability of rectal irrigation in the treatment of patients with disorders of faecal continence.
- To assess the health outcome measures, namely the generic quality of life measure SF-36, health-related quality of life measure faecal incontinence quality of life (FIQL), and generic standardized questionnaire (GSQ).

The generic standardized questionnaire looked into various symptoms of faecal continence disorders. The efficacy of rectal irrigation was evaluated by examining self reported improvement of symptoms in response to rectal irrigation in terms of GSQ and the visual analogue scale (VAS). The general and specific health outcome measures namely SF-36 and FIQL evaluated the acceptability.

Patients and methods:

The study was a review of a prospective database of patients who had RI between 2002 and 2005. Symptom quantification determined efficacy of RI using general standardized questionnaires (GSQ). The acceptability of RI was determined using the general health outcome measure SF-36, and health related quality of life questionnaire FIQL. In addition, patient bowel diaries were looked into. All patients deemed suitable were referred to the Rectal Irrigation clinic. They were seen by a consultant surgeon who assessed their suitability for rectal irrigation after a detailed history, examination and investigation. The patients were predominantly those who had either no improvement or minimal improvement after using pharmacological agents and conservative measures prior to surgical intervention.

These patients were further referred to a colorectal nurse practitioner for explanation and to obtain informed written consent. The nurse practitioner

would spend time with them explaining RI and the technicalities associated with it. Patients would be sent home after the informed consent was gained, with patient dairies and questionnaires to fill in. After three weeks, the patients would return the pre irrigation questionnaires, and start rectal irrigation. RI would be either gravity assisted or pump assisted. 6 weeks post RI the questionnaires were returned. Patients quantified their symptoms (before and after RI) to determine the efficacy of RI.

The questionnaires used included general health outcome measure SF36, Health related quality of life measure for faecal incontinence FIQL (Faecal incontinence Quality of Life) and a general standardized questionnaire exploring the symptomatology of faecal continence disorders.

Health outcome measures: SF-36 is a general health outcome measure. It includes both physical and mental component scores. The eight health concepts captured by the questionnaire are physical functioning (PF), physical health (PH) / role physical, emotional problems (EP) / role emotional, energy fatigue (EF) / vitality, emotional wellbeing (EW) / mental health, social functioning (SF), pain (P) / bodily pain, and general health (GH).

FIQL questionnaire: This is a health related quality of life questionnaire. The four health concepts captured by the questionnaire are lifestyle, coping behaviour, depression/self perception, and embarrassment.

General standardized health questionnaire: The general standardized health questionnaire was developed in the academic surgical unit in Hull. It was

internally validated. It assessed the common symptoms associated with faecal continence disorders. This tool was used to compare the symptoms of faecal continence disorders pre and post RI. The symptoms included frequency of bowel movement, consistency of the stools, mucous leakage, liquid leakage, solid leakage, wearing pad for bladder symptoms, wearing pad for bowel symptoms, swollen area between anus and vagina, feeling of bowel pushing forwards into vagina, rush to pass water, need to self help to empty the bowel, micturition urgency, frequency of straining at stools, feeling of incomplete emptying, wind leakage, pressure application on the area between the anus and vagina, leak urine on coughing, sneezing, urgency to empty the bowels, and bowel problems affecting life.

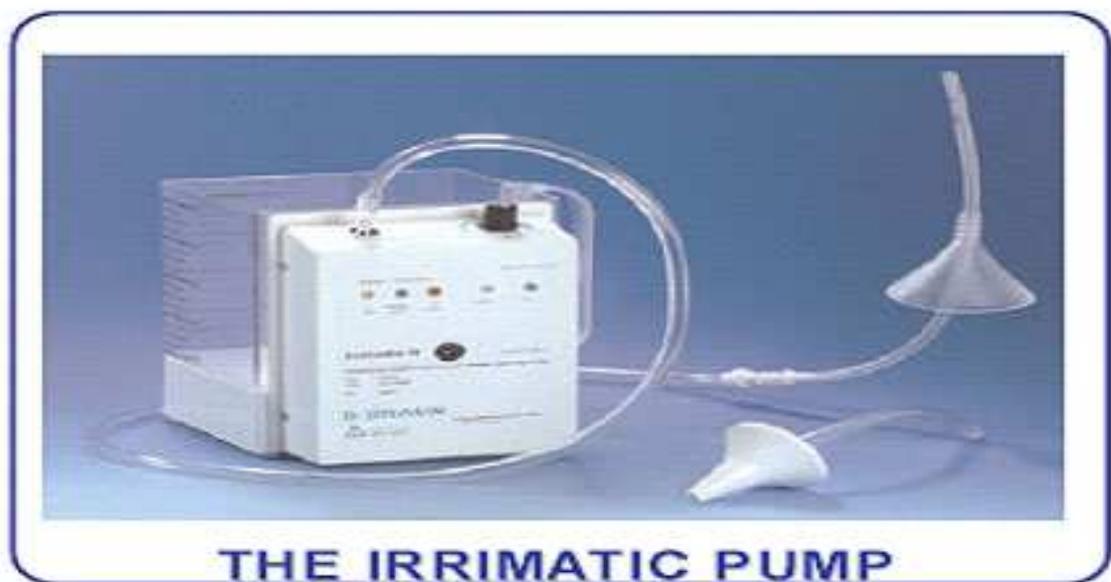
The efficacy of RI was determined by using the GSQ. The acceptability was assessed using a general quality of life questionnaire SF-36 and specific health related quality of life questionnaire for faecal incontinence (FIQL - Rockwood). Data regarding presenting symptoms, previous therapies, surgeries were obtained. There were reminders sent to non responders who failed to return the questionnaires. A review was undertaken using the prospectively maintained database and RI folders.

The broad overlap in symptoms and etiologies made this diverse group particularly challenging to study and treat. For the purposes of this paper, the definitions for continence disorders have been kept deliberately broad. The patients were divided into two categories, depending on their primary symptom of either incontinence or constipation. The term incontinence is used to describe the involuntary escape of faeces, and includes those patients with primary sphincter problems, patients with rectal compliance problems, leading to urge

incontinence, and patients who describe faecal soiling (139) Constipation is defined as the inability to evacuate the rectum when desired, and includes with obstructed defaecation and dyssynergic defaecation (140).

Technique of RI : The equipment used were Coloplast stoma irrigation set for gravity assisted RI which included a hook, water bag, stoma irrigation cone, tubing, connector, and lubricant, or a pump assisted irrigation set which was Irrimatic pump from B Braun (*Figure 2*). Apart from the hook these items are available on prescription or via nurse specialist from Coloplast and B Braun.

Figure 2. Irrimatic rectal irrigation set



Initially patients undertook irrigation on a daily basis, using 1.5l of tap water at body temperature. Irrigation was commenced sitting on the toilet with the water bag hanging on a hook with the bottom of the water bag just above head height. The cone was lubricated and inserted into the anus holding it firmly, in order to give a good seal. Between 300 and 500 mls of water was instilled under gravity in a gravity assisted method, or the same amount using a pump, where the

pump was at ground level. Patients were informed that the irrigation process should be gentle and should not be uncomfortable in any way. Once the water flow had stopped, patients waited for 1–2 minutes before removing the cone, resulting in an immediate evacuation of water and stool. This irrigation process was undertaken three times. Normally, the first irrigation is followed by hard pellet-like / semisolid cleanse, the second by a brown fluid and the third by near normal clear water.

Patients were told to expect an urge to defaecate 10–15 mins after the third irrigation, but should not experience the urge to defaecate again for 12–24 hours. Once proficient, patients were encouraged to adopt the volume of water and frequency of irrigation to suit their own needs. All patients were provided with both verbal and written instructions, and contact numbers for help and advice. Specialist nurses offered regular follow-up for as long as needed.

Data collection: Patients were given dairies and questionnaires to fill in.

Dairies consisted of incontinence and bowel movement details. The questionnaires constituted the generalized standardized questionnaire, general health outcome measure SF-36, and health related quality of life questionnaire FIQL. In addition, a linear scale was used to quantify reduction in the severity of the symptoms after rectal irrigation to produce a visual analogue score (VAS).

Statistical analysis: An SPSS and SF-36 analysis package was used for analysis (SPSS® version 11.5, Chicago, Illinois, USA).

Results:

A total of 175 patients' data was collected for this study. 111 cases are successful cases, and 64 cases are failed cases. The patient groups are

predominantly female (n=154, 88%) with similar proportions of female patients in both the successful (n=97, 87.4%) and failed cases (n=57, 89.1%). The mean age of the patient group was 52.6 years (SD 15.08)

SF-36, FIQL, and general standardized questionnaires were analysed pre and post RI. Analysis is done only for the successful ones.

SF-36: 71 of the 111 patients completed the SF-36 questionnaire pre treatment and 43 of these patients also completed the questionnaire post treatment.

Subscales are calculated on a score of 0 to 100, with 0 being the 'worst' score and 100 being the 'best'. The higher scores mean a better quality of life.

Table 8: shows the median pre RI and median post RI for each of the subscales. There has been an improvement in quality of life post RI.

Table 8. SF36 (pre and post RI)

SF-36 sub-scale	Pre-RI median value (IQR)	Post-RI median value (IQR)
Physical function (PF)	66.6 (32.5, 88.1)	75 (40, 100)
Physical health (PH)	12.5 (0,100)	50 (0, 100)
Emotional problems (EP)	33.3 (0,100)	66.6 (0,100)
Energy fatigue / vitality (EF)	37.5 (15, 50)	40 (25,50)
Emotional wellbeing / mental health (EW/MH)	55 (40, 60)	60 (50, 75)
Social functioning (SF)	50 (25, 75)	62.5 (50, 87.5)
Pain (P)	40 (22.5, 67.5)	55 (32.5, 90)
General health (GH)	45 (20, 65)	50 (33.3, 75)

Comparison of various components of SF-36 pre and post RI using non parametric tests showed a significant difference in PF, SF and GH (95% CI) as shown in *Table 9*.

Table 9. SF-36 components pre and post RI using non parametric tests

SF-36 sub-scale	Negative ranks	Positive ranks	Tied ranks	Z value	(** 95% CI, * 90% CI)
PF	8	20	14	-2.34	0.020**
PH	8	12	20	-1.68	0.093*
EP	9	7	25	-0.08	0.937
EF	18	15	8	-0.40	0.693
EW	14	23	4	-1.84	0.066*
SF	10	25	7	-2.17	0.030**
P	13	19	10	-1.87	0.061*
GH	14	25	3	-1.97	0.049**

* Significant difference at 95% confidence interval.

** Significant difference at 99% confidence interval.

Wilcoxon signed rank test demonstrated a significant difference in PF, SF and GH between the pre and post treatment. The table also shows that there are positive shifts in sub-scales PH, EW and P (these differences are significant at the 90% confidence level but not at the 95% confidence level).

FIQL questionnaire: 32 of the 111 patients completed the FIQL questionnaire pre RI, and 22 of these patients also completed the questionnaire post RI.

Table 10 below shows the median value pre and post RI for each of the subscales. The post median value is equal to or higher than the pre measure.

This suggests that there has been a slight improvement in quality of life measured by the FIQL questionnaire post RI. Non parametric tests are shown in *Table 11*.

Table 10. FIQL components pre and post RI

FIQL sub-scale	Pre-RI median value (IQR)	Post-RI median value (IQR)
Lifestyle	2.9 (2.0, 3.8)	3.1 (2.4, 3.5)
Coping	2.3 (1.5, 3.7)	2.9 (1.7, 3.1)

Depression	3 (2.3, 4.0)	3.1 (2.3, 4.1)
Embarrassment	2.7 (1.3, 3.8)	2.7 (1.7, 3.7)

Table 11. FIQL components pre and post RI using non parametric tests

FIQL sub-scale	Negative ranks	Positive ranks	Tied ranks	Z value	(**95% CI, *90% CI)
Lifestyle	5	5	0	0.000	1.000
Coping	5	5	1	-0.15	0.878
Depression	7	7	0	-1.16	0.245
Embarrassment	4	3	3	-0.17	0.863

Wilcoxon signed rank test demonstrates no significant difference in any of the 4 quality of life subscales of FIQL. This may be due to the large numbers of missing data and 'not applicable' answers to the individual items on the questionnaire.

General Standardized questionnaire: 72 of the 111 patients completed the general standardized questionnaire pre RI and 43 of these patients also completed the questionnaire post RI. The Questionnaire and responses for the GSQ pre and post RI are shown in Appendix 1.

The standard questionnaire demonstrates no significant difference between the pre and post RI in frequency of bowel movement, consistency of the stools, mucous leakage, liquid leakage, solid leakage, wearing pad for bladder symptoms, wearing pad for bowel symptoms, swollen area between anus and vagina, feeling of bowel pushing forwards into vagina, rush to pass water, need to help yourself empty the bowel, and ever not make it in time to pass urine. A significant difference was noticed pre and post RI in the following symptoms, frequency of straining at stools, feeling of incomplete emptying, wind leakage,

pressure application on the area between the anus and vagina, leak urine on coughing, sneezing. No significant difference between the pre and post RI at the 95% CI, but a significant difference was found at 90% CI in urgency to empty the bowels, and bowel problems affecting life.

The Visual Analog Scales (VAS)

Sixty-eight of the 111 patients completed the VAS questions pre RI and 42 of these patients also completed the questions post RI. Evaluation of the two visual analog scales, one for bowels (*Image 1*) and one for urinary functions (*Image 2*) shows that there appears to be a reduction in the severity of the problem.

Image 1. Reduction in the severity of the bowel problems affecting quality of life.

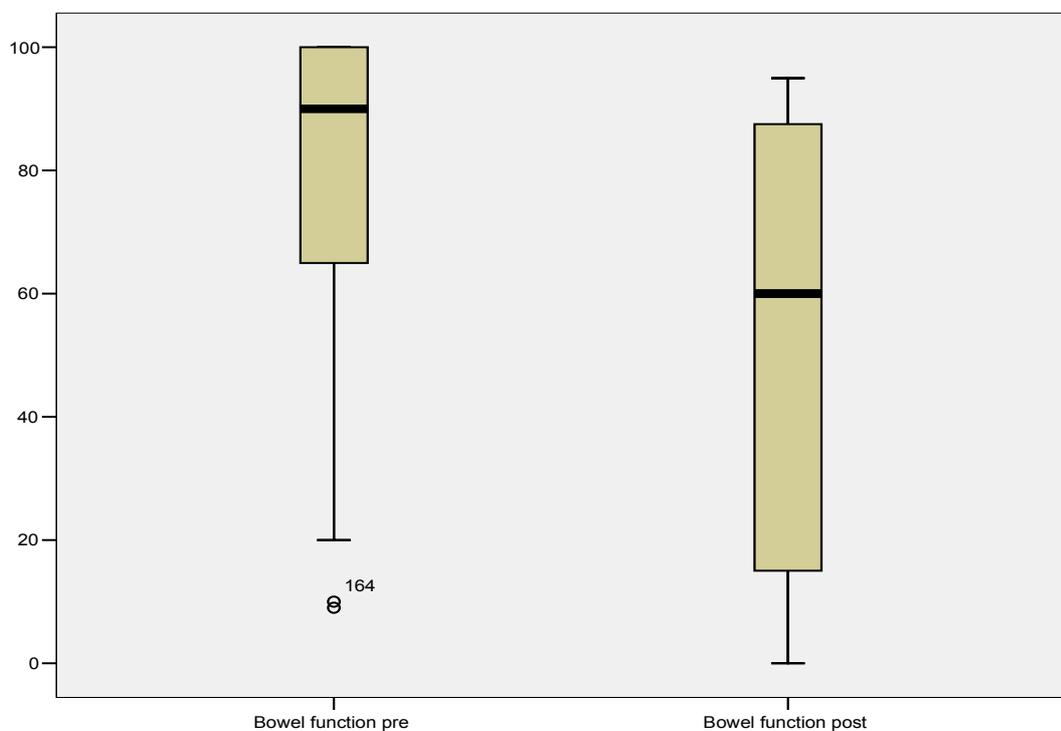
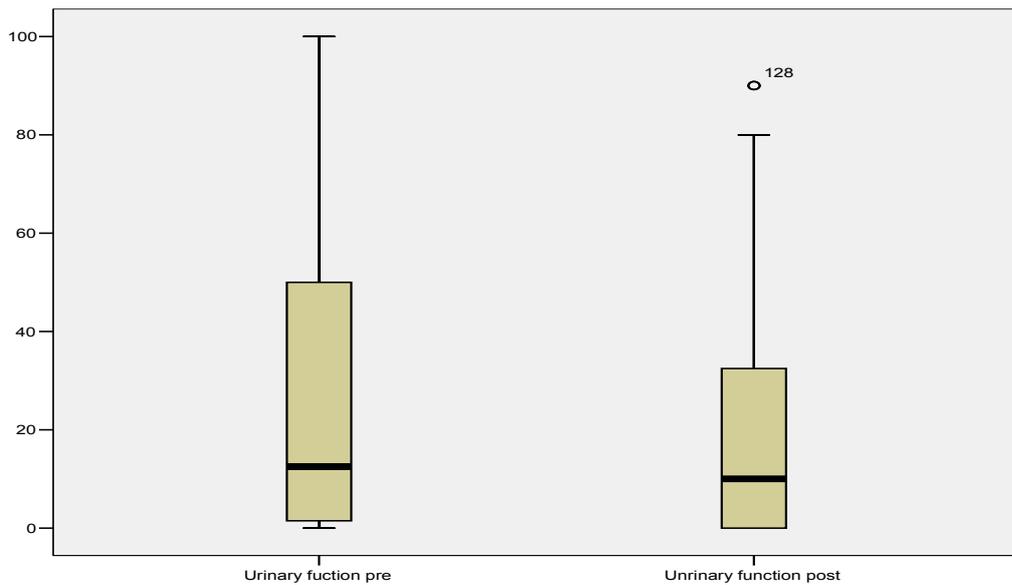


Image 2. Reduction in the severity of the bladder problems affecting quality of life.



The median value for severity of bowel function affecting quality of life pre treatment is 90 (IQR, 80 to 100) and post treatment is 65 (IQR, 15 to 90). The median value for severity of urinary function affecting quality of life pre treatment is 12.5 (IQR, 0 to 50) and post treatment is 10 (IQR, 0 to 28.75).

The Wilcoxon signed rank test is used to see if patients are recording a difference in the severity of their problems between pre and post RI on the VAS scales. *Table 12* shows greater proportion of patients recording an improvement pre to post RI than a worsening of their problems.

Table 12. Wilcoxon signed rank test shows improved Bowel and Bladder function post RI on the VAS

VAS	Negative ranks	Positive ranks	Tied ranks	Z value	(95% CI)
Bowel function	28	5	6	-3.579	0.000**
Urinary function	19	7	14	-2.329	0.020**

Discussion:

History: Using water to cure ailments is not new to clinical practice. In 1923, Dr. Benedict Lust described hydrotherapy as 'The Fountain of Youth; or, Curing by Water. How you may quickly overcome acute and chronic illness by the use of the biological blood washing bath' (141). A rectal irrigator was in use during the early sixties (142). RI can also be seen in ancient medical papyri (143).

Transrectal irrigation with tap water is shown to be a safe method to resolve constipation and faecal incontinence in children with myelomeningocele and neurogenic bowel dysfunction (144). RI has been shown to benefit a whole spectrum of pathologies from organic, inflammatory, to functional. RI with short-chain fatty acids has shown to benefit distal ulcerative colitis in terms of reduction of disease activity to total resolution of the symptoms (145) . RI has been shown to reduce symptoms in functional bowel disorders (146) .

Irrigation of the rectum has been tried in various ways. The Enema Continence Catheter (ECC) consists of a rectal catheter with an inflatable balloon, and has been shown to reduce symptoms in most children suffering from faecal incontinence or constipation, and in some adults with faecal incontinence (147). Rectal impaction in children was treated with pulsed-irrigation enhanced-evacuation procedure with good outcome (148). Crawshaw et al showed from their retrospective study that RI relieves patients with faecal continence disorders of their symptoms, and improves their quality of life (138). Patients with spina bifida who have faecal incontinence can be managed by means of a large-volume saline enema (149). Studies have also evaluated long-term results of transanal irrigation for defecation disturbances, and have concluded that

transanal irrigation is simple and safe for long-term treatment for defecation disturbances, and shows the greatest benefit in patients with neurogenic bowel dysfunction (150). Gosselink et al evaluated the long term outcomes of retrograde colonic irrigation. Their overall success-rate was 45% (151). Koch et al showed that retrograde colonic irrigation as was an effective treatment for evacuatory disorders and demonstrated improved health outcome measures (152).

In the context of this study, RI seems to help with both constipation and faecal incontinence. Predominant benefits are for those patients with outlet obstruction i.e. Intusseption, rectocoele, enterocoele etc. In patients with incontinence, RI helps by washing out the rectum, thereby giving them a window period for their activities, and thereby improving functional outcome. RI is of two types, one gravity assisted, the other pump assisted. The principle in both is the same, cleansing the rectum using tepid tap water under minimal pressure. The efficacy of both is good, though there is a study ongoing comparing the two.

Technique: The volume of water that is used is around 1.5 lts. The water should be lukewarm tap water. The apparatus consists of a water container, plastic tubing, a funnel, and a connector. The funnel slides into the anal canal with lubrication using a water soluble gel or plain tap water. In the manually operated system, the stop valve must be on when the funnel is inserted into the rectum. Once it is in place the stop valve can be released which will infuse the rectum with water under pressure. An amount of 500mls is infused, and the patient must wait for a few minutes or till there is an urge for defecation before beginning the defecation process.

Complications from the procedure are rare, although a few reports from similar procedures to RI have been documented in the literature. Retrograde irrigation enemas common in the treatment of chronic constipation in elderly have caused perforations (153), and a case of colorectal perforation due to self-administered retrograde water enema in a 55 year-old, for treatment of chronic constipation, has been reported (154).

Disorders of faecal continence cover a spectrum of conditions, from faecal incontinence, idiopathic constipation, to dyssynergic defaecation (139),(140). Patients can experience symptoms varying from urgency of defaecation and incontinence, to difficulty initiating defaecation and constipation. Sometimes the symptomatology can be overlapping, and around 30% of patients presenting with faecal incontinence also complain of difficulty evacuating their bowel (133),(155). It can be seen therefore that this paper attempts to study a rather amorphous population, who have exhausted other avenues of pharmacotherapy and conservative management that is hard to categorize and treat, because of the wide variety of symptomatology and etiology.

There are difficulties in interpreting the results offered here, but this should not detract from the overall message that in this study population, patients had an improvement in their symptoms as indicated by the GSQ, and an improvement in the general quality of life measure SF36 and a minimal improvement in the health-related quality of life questionnaire FIQL, though not statistically significant. The VAS has not only demonstrated a clear benefit in terms of reduction of the severity of the symptoms in bowel function but also, to a limited

extent, in bladder function where there existed an associated bladder dysfunction.

The number of people suffering from such symptoms in the general population is difficult to accurately quantify. Surveys suggest faecal incontinence affects over 1% of the population, with 0.7% having symptoms which impact on quality of life (156), and 2.6% suffering from some form of anal incontinence. For those reporting some faecal incontinence, 10% experience the problem at least weekly, yet only 36% had consulted their general practitioner (157). Self-reported data on constipation suggests that 10% of women and 2% of men experience constipation, and, in an English population, 52% of women and 39% of men, reported regular straining to stool (158). There do not appear to be any figures available to give an indication of the numbers affected by incomplete evacuation. Such data are derived from those who have consulted a member of the health care team, or who have been approached and will admit to this problem. There may be many more too embarrassed to report these symptoms (159).

Current study: The study looks at a complex problem in a difficult group of patients. The study is a retrospective review of a prospective database of patients who underwent RI for various evacuatory disorders. However, there are a few limitations which need highlighting. The analysis has been carried out only on successful cases, providing no information on cases that failed, and the reasons for failure. Analysis was not undertaken on an intention to treat basis, and this could have led to bias in statistical analysis. The poor return of completed questionnaires may reflect patient embarrassment due to the nature of the problem. Though there was noticeable improvement in the health-related

quality of life questionnaire FIQL, it failed to reach statistical significance due to small numbers and too many responses of 'Not applicable'. There could be a bias in the results to a more favorable outcome, as patients who have had an unfavorable experience or outcome from rectal irrigation may be less likely to respond to the questionnaire. Alternatively, those patients who are still using the technique and anticipate a need for further input from the Coloproctology clinic might be more motivated to respond. The questionnaire was a 'snap shot', documenting the patient condition at a single time point, asking them to recall their previous symptoms which in turn could bias these results. The complex symptomatology of this heterogeneous group makes quantitative assessment difficult, hence adding the visual analogue scale to rate the reduction in severity of the symptoms post RI. Overall rectal irrigation produced an improvement in self-reported bowel function in this non-selected group with multiple pathophysiologicals. An attempt to measure the quality of life both generic as well as specific using SF36 and health-related quality of life- FIQL has been made. Instruction in rectal irrigation requires the input of a specialist nurse, and the symptomatic improvement we have noted may be due in part to a placebo effect from the patient-specialist interaction. Studies examining the effect of biofeedback on faecal incontinence compared to simple sphincter exercises alone suggest that biofeedback produces better results, but whether this due to a placebo interaction with the therapist rather than the treatment itself is debatable (155). Initial results suggest intensive nursing input plays an important role in the treatment of these patients. However, the sustained improvement in bowel control noted in the patients responding to RI in this study suggests the beneficial effect is more than just a placebo effect. If the benefit was a simple placebo effect one would expect to see the improvement in

symptomatology diminish over time, as the input from the specialist nurse reduced.

RI is a method of management that is time consuming, and therefore requires commitment from the participants. It has no apparent side-effects and can be discontinued or recommenced at any time. It is cheap; kits cost £20 and last approximately 6 months for gravity assisted kit. The pump assisted kit costs £300, and lasts for a few years. Both kits are easily supervised by nursing staff, thus freeing time at otherwise busy colorectal clinics.

Summary: The study demonstrates quality of life improvement in the subscales of PF, SF and GH significantly (95% CI), and PH, EW and P (90% CI) using the generic quality of life measure. Health-related quality of life measure FIQL shows slight improvement in quality of life, though statistically not significant. This might be due to the large numbers of missing data. The standard questionnaire demonstrates no significant difference between the pre and post RI in frequency of bowel movement, consistency of the stools, mucous leakage, liquid leakage, solid leakage, wearing pad for bladder symptoms, wearing pad for bowel symptoms, swollen area between anus and vagina, feeling of bowel pushing forwards into vagina, rush to pass water, need to help yourself empty the bowel, and ever not make it in time to pass urine. A significant difference was noticed pre and post RI in the following symptoms, frequency of straining at stools, feeling of incomplete emptying, wind leakage, pressure application on the area between the anus and vagina, and leak urine on coughing and sneezing. At 90% CI there was improvement in urgency to empty the bowels, and bowel problems affecting life.

Conclusion: RI can offer symptomatic improvement to patients with faecal evacuatory disorders where other conservative and pharmaco-therapies have failed. Most patients find the treatment acceptable which was well tolerated and pain free. The use of RI via either the gravity assisted or pump assisted kit, as an intermediary treatment post conservative and pharmacotherapy and pre surgery is therefore recommended.

12.5 Malignant colorectal conditions

Decision making processes in malignant colorectal conditions were methodologically evaluated using mixed methods. Qualitative tools used included focus group discussions, and quantitative studies were in the form of questionnaire surveys.

Methodological approach (qualitative): The qualitative study design, given the exploratory nature of the inquiry and the limited existing evidence on decision making in surgery and cancer care, was adopted. Focus groups were used to capitalise on group interactions, and to elicit rich experiential data by exploring participants' knowledge and experiences (160). In addition, focus groups are suitable for examining how knowledge and, more importantly, ideas develop and operate within a given cultural context (161).

Focus group: A focus group is a formal discussion with 8–12 people on a specific topic. The group is facilitated by a moderator who keeps participants focused on the topic of interest. The purpose of a focus group is to collect in-depth information from a group of people who represent the population of interest. This useful, qualitative research tool has been an underutilized research technique for improving theory and practice in health education (162), (163).

Sampling and data collection: Three focus group discussions were held. Focus groups constituted members of the academic surgical unit, colorectal multidisciplinary team, and the head and neck tumour board. To maximise the

socio-demographic and cultural diversity, and attain a global perspective of the patient populations focus group discussions were held in England (Hull), Wales (Bridgend) and India (Bangalore). Purposive sampling was used to select focus groups from healthcare professionals who make surgical and cancer care decisions routinely.

The stimulus material (Appendix 4) for use in focus group discussions was developed following a review of the literature. Abstracts of the relevant papers on decision making and patient preferences were used. In addition, there were standard questions used by the moderator of the focus group discussion, in this case the researcher. The abstracts and the questions used as stimulus material are illustrated in Appendix 4.

The focus group discussion was always preceded by a standard presentation by the researcher on the focus group discussions and a brief introduction to decision making in surgery and cancer care. This was followed by distribution of stimulus material, with time to read the abstracts. The researcher would initiate the discussion and moderate the session.

Analysis: With the consent of participants, the focus groups were tape recorded and transcribed verbatim. The data was anonymised. Qualitative data analysis is a notice, collect, and think process (164). Interesting findings on the transcribed data were marked and coded alphabetically or numerically, as appropriate. The codes were then sorted and sifted through the data. Codes were summarized, synthesized, and sorted from many observations made from the data. The thinking process involved searching for types, classes, sequences, processes, patterns, or wholes. This process led to a reconstruction

of the data in a meaningful and comprehensible fashion, identifying recurrent concepts as themes. Two researchers read the transcripts individually (NS: author and BJ: co-researcher), and independently noted down the core themes that emerged. The notes were compared, and any discrepancies were resolved by consensus. Each researcher took the lead to identify sub themes (NS analysed the themes). Solutions were carved out for the problems identified from the focus group discussions, and these were called 'outcomes'.

Anonymised quotations were considered within the context of the focus group discussions, and the important ones with key messages are part of this document. The quotations have been selected to illustrate the themes raised by participants and they are indicative both of typical responses and of the diversity of views obtained. Following the initial pilot focus group discussion in England, further focus group discussions were held in Wales and India.

12.5 a 1: A qualitative analysis of a focus group discussion on decision making in cancer care – An English perspective.

Introduction and background:

Cancer accounted for 28 per cent of all deaths in males and 23 per cent in females in England in 2003 (165). In 2006, 293,601 people were diagnosed with cancer in the UK (166). Cancer management poses difficult choices in which the most appropriate treatment option is not always obvious. Different treatment options have their own risks of morbidity and mortality, weighing them in terms of quality of life and survival is important. Patient preferences should play an important role in clinical decision-making (167). The literature increasingly demonstrates that clinicians have divergent preferences for treatment options compared with their patients and with each other (10), (11) , (12). Thirty to forty percent of the critical medical decisions are made by doctors for their patients (13), (14), (15), (16), (17). This rate increases when patients are acutely unwell, elderly or dealing with cancer (14), (15).

Cancer psychology is a vitally important part of cancer management. Qualitative research is a gateway to explore this. Weighing the treatment options in terms of quality of life and survival is important. Analysis of this area would provide information for patients and clinicians that would allow them to make appropriate individualized decisions on cancer management.

Aims: The aim was to explore the thoughts of surgical colleagues about ‘patient decision making in cancer care’ and to identify factors that may have a role to play in decision-making in England.

Design: Qualitative study.

Participants and methods:

A prospective study was carried out at the academic surgical unit attached to the University of Hull, with robust research activity. Work was undertaken in collaboration with Hull and East Yorkshire NHS Trust. Members of the academic surgical unit formed the pilot focus group. Qualitative methods were used based on grounded theory. The study explored the thoughts and attitudes of the care providing clinicians about 'patient decision making in cancer care'. The participating members were briefed in advance about the research project. A pilot focus group discussion was held during a dedicated research morning in the academic surgical unit. The pilot focus group discussion explored clinicians' opinions and thoughts about patient decision making in cancer care. Focus group discussion involved members of the academic surgical unit. There were four surgical consultants, among whom were professorial chairs of colorectal and breast surgery. The remaining members of the focus group included two colorectal consultants, three surgical registrars and three surgical research fellows. The characteristics of participants in the focus group are as illustrated in *Table 13*.

Table13. Characteristics of participants in focus group.

Characteristic (job title)	Focus group participants (n=10)
Professors	2 (colorectal, breast)
Surgical Consultants	2 (colorectal)
Surgical Registrars	3
Surgical research fellows	3

The focus group discussion was moderated by the chief investigator and the co-investigator. Stimulus material in the form of abstracts from published papers relevant to decision making and patient preferences were given to the members. The focus group discussions were audio taped and transcribed by surgical secretaries. All the quotations were anonymised for confidentiality purposes.

Qualitative methodology was adopted for analysis. Thematic analysis using a framework approach was done, thereby identifying themes and outcomes. Two surgical research fellows analysed the data separately for accuracy and repetitiveness of the themes and outcomes.

Data collection:

Data was gathered from focus group discussions. Data was audio taped and transcribed by surgical secretaries. Quotations were anonymised for confidentiality reasons.

Analysis:

Thematic analysis of the collated data was done using the framework approach thereby identifying themes and outcomes. Analysis of qualitative research data was carried out using a validated technique.

Results: The emerging themes and outcomes are shown in *Table 14*.

Table 14. Emerging themes and outcomes

Emerging themes	Derived outcomes
Evidence based clinical practice	To increase evidence base
Knowledge	To increase the clinician and patient knowledge
Patient information and decision making	Provide adequate information
	Decisions to be based on patients best interest
Risk and communication	Communicate risk in an understandable manner
	Take patients views, knowledge and demands into consideration
Consent	
Socioeconomic factors	
Patient empowerment	

Figure 3. Emerging themes

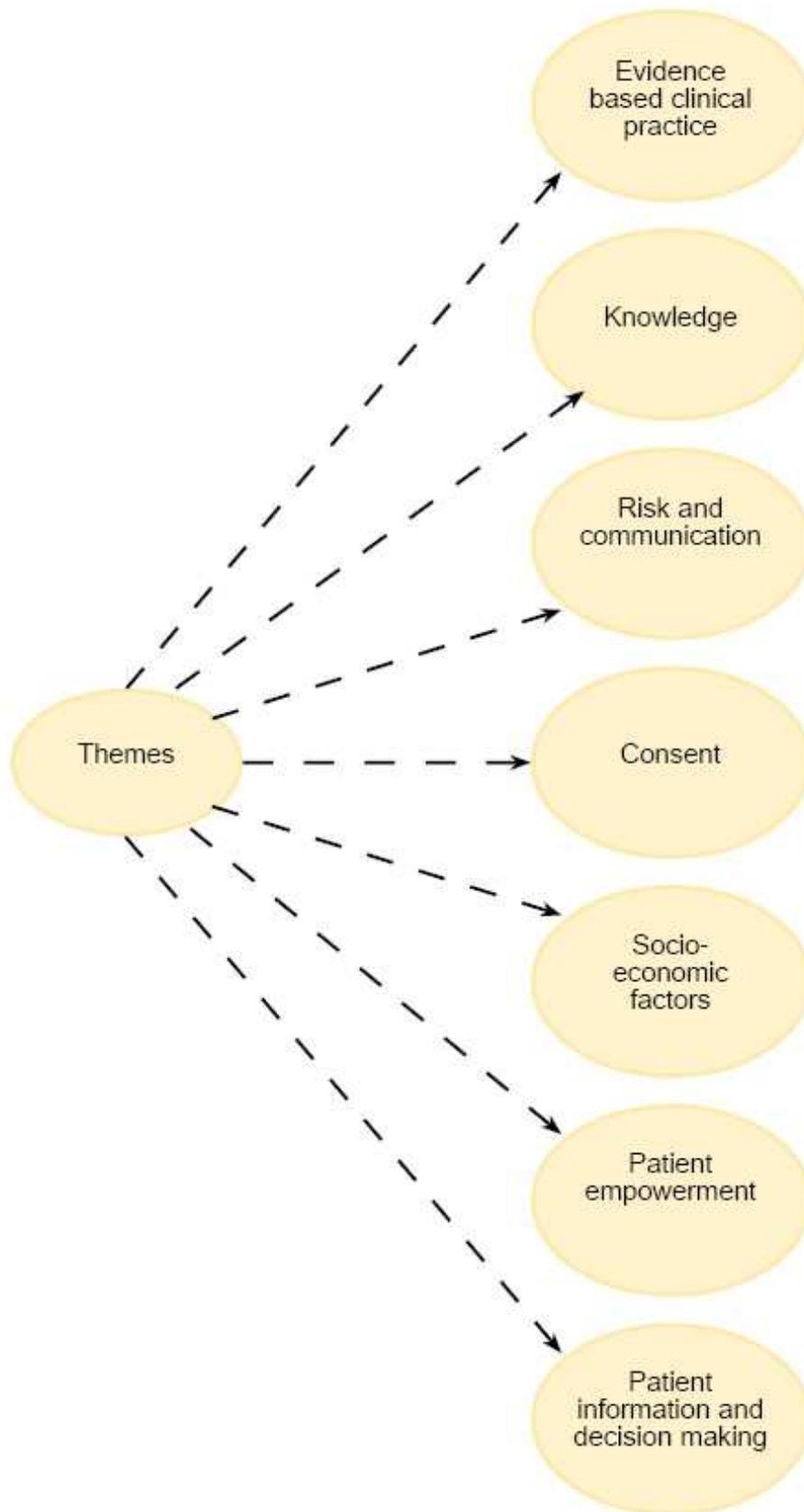
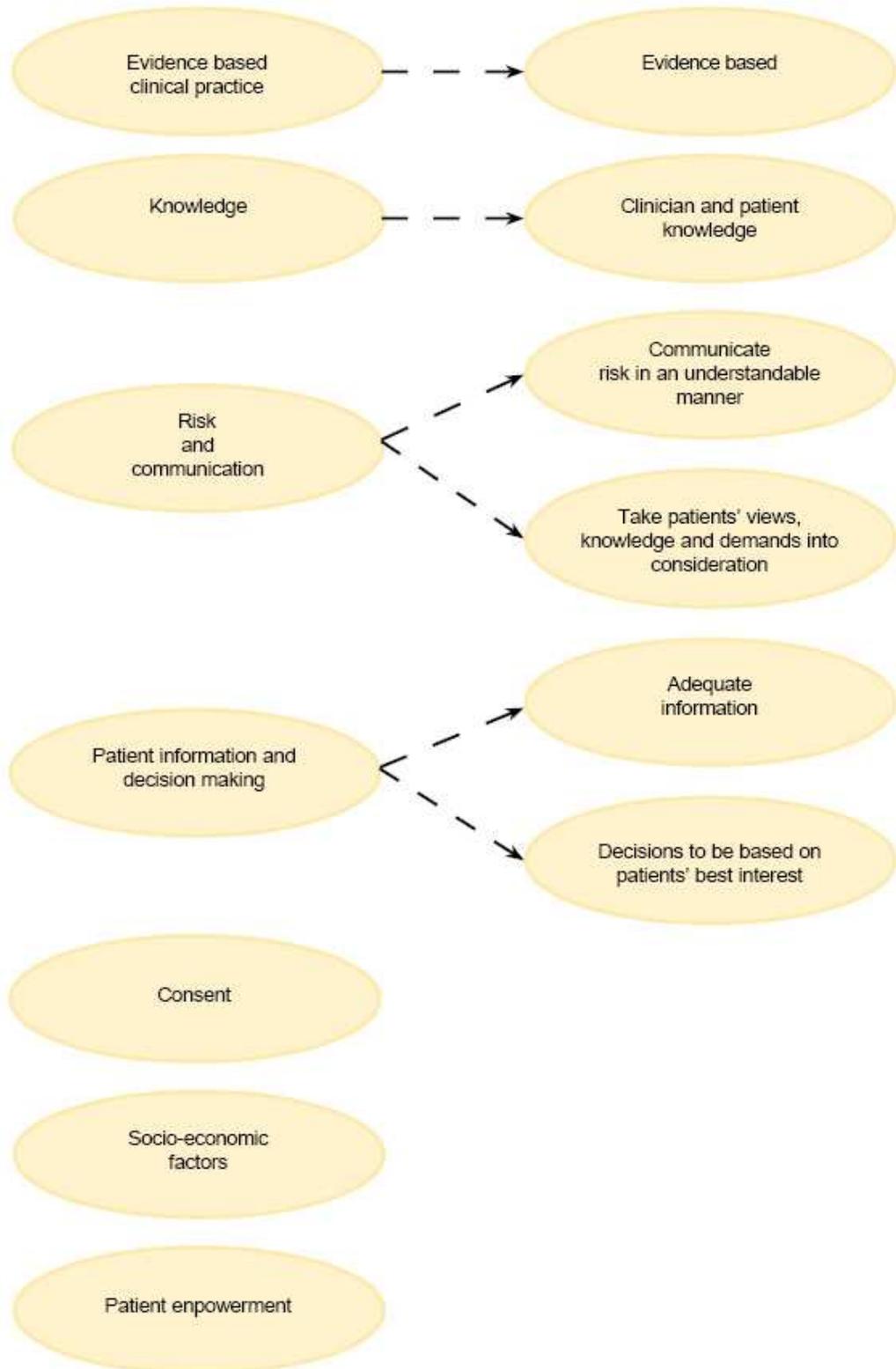


Figure 4. Derived outcomes



Patient decision making (PDM)

Patient autonomy, empowerment and role in decision making are very topical. The majority of the cancer patient population want the cancer to be totally taken out, irrespective of the risk of mortality and morbidities associated with. A very small percentage of the population really weigh the benefits and risks when there is more than one treatment for the same disease pathology. The majority of the population trust the traditional procedures, although these are still associated with major risks.

(Respondent)R-1: *“Tell what we know”, “in majority there is no decision to be made”, “needs cancer to be taken out, majority agree”. “A small percentage have a real alternative option.”*

Evidence based clinical practice (EBCP)

The team members were asked what they understood by the term ‘evidence based clinical practice’. Few of them had a defined answer. However, everybody agreed on the need to follow good evidence.

R-3: *“Informing patients and consent”, “Decision making based on current evidence and multidisciplinary team process”, “unusual for patients wanting trial data and outcomes.”*

Knowledge and risk

Clinician knowledge, technical skill and communication are important aspects of being a good clinician. Even when knowledge and skill have been acquired, poor communication can lead to patient harm.

R-2: *“You have to respect and understand what the clinician understands and knows. Having spent many years trying to teach some registrars and consultants what risk is, and how to communicate risk, I can assure you that the vast majority have absolutely no idea about how to communicate it. If the clinician does not know how to communicate risk, how on earth do you expect the patient to understand differences in risk?”*

Patient information

R-2: *“It’s how you inform them, that makes their choice; I don’t think anybody ever gets unbiased information.”*

Decision making

R-2: *“You do not lay all the data out to them and say, ‘You make the choice’. You steer them in a direction and they choose ... that direction [in] the vast majority of cases.”*

R-2: *“One patient said to me, ‘Don’t tell me! Just do to me what you think is right, and I will go with it.’”*

R-5: *“Nobody can make a decision and they are least well suited at that time to make an objective decision, its all ‘smoke and mirrors’.”*

R-2: *“I don’t believe they do have a choice. From the minute they turn up they have got the disease, they come to someone they put their trust in to sort them out.”*

VQ- Socioeconomic factors

R-2: “I think it’s cultural as well!”

Informed Consent:

There exists a dilemma in what is termed as ‘fully informed consent’. Some of the questions that arise in the process of acquiring consent are: How much information is to be given? What is adequate information? What if the person receiving the information refuses to receive full information?.

On the other hand, if the patient decides on a procedure and insists on it, is the clinician obliged to provide that service? If the patient requests for the clinician’s performance statistics, is there a system to provide that information along with the national averages. These are some of the issues that need consideration.

13. Discussion:

Decisions: When making decisions it is important that patients' views are taken into account, an understanding of their level of knowledge and demands is important.

PDM in cancer care: Although patient decision making in cancer care is a passive process in the majority of the population, active decision making is slowly evolving – albeit in a minority. This minority requires in depth knowledge of the disease process, available treatment options, and the complications associated with it.

The future: With increasing active involvement and participation of this minority of patients, they will play an increased role when making decisions in the future.

Tradeoffs and risks: Tradeoffs and risks between survival and quality of life will be considered when decision making in the minority group of patients who take active part making decisions about their treatment.

Bias reducing factors: To overcome the bias that may be associated with gathering data, a second moderator was involved in the focus group discussion. This second moderator also took part in thematically analyzing the qualitative data, to overcome bias. The themes and outcomes from both researchers were compared to derive reoccurring themes and outcomes.

Conclusions:

It is important that patients' views, knowledge and demand are all taken into account when decision making. Patient decision making in cancer care is slowly increasing, although it is still only present in a minority of patients. This minority of the patient population will play an increased role in current decision making, and will possibly drive decision making in future. Tradeoffs and risks between survival and quality of life will be considered by this active minority.

12.5 a 2: A qualitative analysis of a focus group discussion on decision making in cancer care – A Welsh perspective

Introduction and background:

In addition to the background described in the above chapter, it is important to emphasise that there is a significant educational and socio-economic variation between England and Wales. There is also a discrepancy in the healthcare provision between the two regions.

Aims and objectives:

The aim is to explore the thoughts of surgical colleagues about patient decision making in cancer care and to identify factors that may have a role to play in decision-making in Wales.

Design: Qualitative study.

Participants and methods: This is a prospective study that was carried out at Princess of Wales hospital, Bridgend, attached to Abertawe Bro Morgannwg (ABM) University Health board in Wales. A qualitative study by methodology, focus group discussions were used as a research tool.

The study explores the thoughts and attitudes of the care providing clinicians about patient decision making in cancer care. They are members of the colorectal cancer multidisciplinary team. The participating members were briefed in advance about the research project.

A focus group discussion was held during a dedicated research afternoon in the multidisciplinary team meeting room. The focus group discussion explored clinicians' opinions and thoughts about patient decision making in cancer care. Focus group discussion involved members of the colorectal multidisciplinary team. There were three surgical colleagues in addition to the researcher, pathologists, radiologists, medical oncologists, and colorectal nurse practitioners. The characteristics of participants in the focus group are illustrated in *Table 15*.

Table 15. Characteristics of participants in focus group.

Characteristic (job title)	Focus group participants (n=15)
Surgical Consultants	2 (Colorectal)
Surgical Registrars	2
Oncologists	2
Radiologists	3
Pathologists	2
Specialist nurse practitioners	2 (Colorectal)
Allied health professional	2 (MDT coordinators)

A brief PowerPoint presentation was given on qualitative research. This was followed by a focus group discussion. The focus group discussion was moderated by the chief investigator and the co-investigator. Stimulus material in the form of abstracts from published papers relevant to decision making and patient preferences were given to the members. The focus group discussions were audio taped and transcribed by surgical secretaries. All the quotations were anonymised for confidentiality purposes.

Qualitative methodology was adopted for the analysis. Thematic analysis using a framework approach was done by identifying themes and outcomes. Two clinicians skilled in qualitative research analysed the data separately for accuracy and repetitiveness of the themes and outcomes.

Data collection: Data was gathered from focus group discussions. Data was audio taped and transcribed by surgical secretaries. Quotations were anonymised for confidentiality reasons.

Analysis: Thematic analysis of the collated data was done using the framework approach, thereby identifying themes and outcomes. Analysis of qualitative research data was carried out using a validated technique.

Results:

Themes that emerged revolved around patient, clinician, and nursing factors. Patient factors included evidence based patient choice, patient individuality, socioeconomic factors, autonomy/empowerment, beliefs, trust in clinicians, information, experiences, and decision making. Clinician factors were efficacy of risk communication, consent, steering decision making process, and continuity of care and support. There were a number of themes arising from the nursing perspective, included continued care, keeping patients informed, being a good communicator, providing information, helping in decision making, and providing help as and when required.

Outcomes derived are to individualise treatment based on patient factors and in the patient's best interest, to take patients' views, knowledge and demands into consideration, to tailor information to patient's need, and to direct them to

evidence based, reliable, speciality based websites. Further outcomes were to communicate risk in an understandable manner, which should include the consenting process and risk communication training for clinicians. Provision of continuing care, support with the decision making process, and availability of help when required were some of the other outcomes.

The emerging themes and outcomes are shown in *Tables 16* and *17*.

Table 16. Emerging themes

Emerging Themes	
Patient factors	Evidence based patient choice
	Patient individuality
	Socioeconomic factors
	Autonomy/empowerment
	Beliefs/trust in clinicians
	Information
	Experiences and decision making
Clinician factors	Efficacy of risk communication
	Consent
	Steering decision making process
	Continuity of care and support
Nursing factors	Continued care
	Keeping patients informed
	Being a good communicator
	Providing information
	Helping in decision making
	Providing help as and when required

Table 17. Emerging outcomes

Emerging outcomes	
Patient factors	Individualise treatment based on patient factors and in patient's best interest
	Take patient's views, knowledge and demands into consideration
	Tailor information to patients need
	Direct patients to evidence based, reliable, speciality based websites
Clinician factors	Communicate risk in an understandable manner including the consenting process
	Risk communication training for clinicians
Nursing factors	Provide continuing care
	Provide support with decision making process
	Availability of help when required

Factors affecting decision making:

Evidence based patient choice (EBPC):

R: "I personally would explain to my patients, and try to give them enough information for them to make a decision based on their own beliefs, but if you know what the evidence shows as best practice, you do tend to try and steer them in that direction. However, I think as long as you give them enough opportunities to ask the questions that they want to ask and you can answer them as truthfully as you can, then you know you have given all the information you can to enable them to make their own decisions."

R: "Going back to pathology, we talked about the evidence base ... You tend to get reports from pathologists, and ... the reports were taken almost as dogma, and the problem is that there is an awful lot in pathology we do not know, we do not understand. There are lots of situations we come up with where we squeeze

them into these classifications; we squeeze cases into staging things and they don't really go because the evidence isn't there."

R: "For many common clinical diseases we just don't have the pathological understanding of how those diseases behave. It is an assumption. There is no evidence base for it. So I really wonder even where you have got what you are thinking is solid evidence, e.g. the path report - there is an awful lot of shaky ground under that, so I do worry about this ... taking our reports as being the only bit of concrete you have got; it is probably the crumbliest bit of concrete you have got, actually."

R: "About patient choice? Well, we're actually not, as you know, directly involved. I have likened this before to a bit like World War II bomber pilots – we write our bombs, which are our reports and by the time they go off we are nowhere to be seen, we are gone, and we don't see the effects."

Patient factors:

Individualize treatment:

R: "I think we need to take a step back, because you cannot just characterise patients into groups and I think that's the danger of modern medical practice, particularly in the NHS."

R: "You cannot follow a flow chart for every single patient, the patients carry a lot of baggage with them. That is a prime example of ... saying you are completely making a subjective scenario completely objective, and you are

labelling a tumour essentially, and that tumour is attached to someone with a lot of circumstances with an age and lots of other factors that you need to take into account, and I think that is the danger, and that is what's happening a lot. A prime example we had earlier; a patient who is too large to have any surgery, but the protocol means he gets followed up ... in a year with a CT. What we can do about it? Nothing! What's the point, but that's the protocol."

Socio-economic/geographic factors:

R: "There are differences and the differences socio economically ... [are] important because expectations are different, patient groups are different."

R: "You know the patient populations are very different, aren't they?"

Patients own beliefs:

R: "I personally would explain that to my patients, and try to give them enough information for them to make a decision based on their own beliefs."

Trust and belief in clinicians:

R: "Patient groups are different because a certain group of patients (although they are fewer these days), they sort of say, 'Anything you say, you know I will do, doc.', and some don't want any information at all, so any efforts you make to explain to them what you are going to do, or what the best test is, or what the best treatment is, you spend half an hour talking to them and they will turn around and tell you, 'Well, it's up to you, what do you think is the best thing to do?'"

Information/internet:

R: “Some patients will ... have trawled through the internet and have a whole raft of information with them, some of it false, and some of it correct, and again you know they are going to be influenced by what they have read on the internet, and how you actually present that data to them. So, I don’t think there are any hard or fast rules really as to what we can do.”

R: “Are we giving them too much information?”

R: “I was just going to say that as well!”

R: “Some take in only half of the information, don’t they? – They get information overload, ... There is a big issue around patient choice, but can they actually compute all that information and make logical sense out of it?”

R: “Yes! I think it is part of our job to try to help them through that whole mêlée of information, and try to make sense of it, because sometimes you can give them too much information and they are sitting there thinking, ‘Well, where do I go next?’ and, as you said, the ones that have gone against the multidisciplinary team decisions have been ones where patient choice has come into it, so one would question whether the patient fully understands the implications of their decision making in that context because they can’t cope with all the information.”

R: “Having had personal experience with going through this process recently, the first thing I would say is, you are absolutely right, it is too much information. The situation I was in with two medical professionals having to assess the information was extremely difficult, there was too much there, we did use the internet, and got totally confused, because two very different sites were actually saying completely opposite things, so it is confusing for professionals, let alone people who do not have a medical background.”

R: “But I think it is daunting to have to look at all this information, and, as I said, [particularly so] when you have got clearly very professional outfits on the internet giving totally different advice, you know, 180° different from each other.”

R: “You can try to steer them towards reputable sites, such as Cancerbackup.”

R: “Yes, certainly ... on our information leaflets that we give them at diagnosis, we have got recommended websites that they should look at rather than randomly googling sites all day.”

Patient rights / autonomy:

R: “I mean nobody can force a patient to do something they don’t want to do.”

Other patient experiences:

R: “Having gone through personally with my dad with this, one thing patients do look at is what has happened to somebody else with a similar problem. That strikes them as more important than anything that comes of the internet, or some details from the clinic, e.g. one of the relatives or somebody who has recently had a lap surgery and say came through well ... that’s very important.”

R: “However good the surgery or any intervention is, if they are seeing somebody who has had a bad experience, they tend to avoid it as well. It is probably quite an important point.”

Clinician factors:

Risk communication:

R: “What the approach for the colonoscopy and polypectomies is, is we always send an information pack to the patient with a consent form, so that the patient has [plenty of] time at home to read the information available, about the risk of the colonoscopy with or without polypectomy. This information is provided before they sign the consent, so they are aware of the risks.”

R: “Are they actually 100% sure what the risks are, or what is the actual the risk? I doubt it, the surgical chance of perforation is 1 in 2000. It doesn't mention that if you have a polyp that becomes 1 in a 1000, or 1 in 500. So the information is there, but I don't think the patient takes it seriously unless you do something that goes wrong, then they take it more seriously.”

R: The other thing I would mention when we are talking about risk is that the consent form that was signed – the benefits had one entry – possible risks had 40, and, as my wife commented, how the hell do you get anyone to sign one of these I do not know, so, again, I think there is a lot of information overload. How patients manage with it, particularly patients who do not have any medical understanding, is quite beyond me, I find it difficult enough even with medical understanding.”

Steer DM process:

R: “I think it is largely in certain patient groups, how you phrase the information that you give them really.”

R: “There will be certain patients who have made up their minds before they even come and see you about what they want to do, and what they don't want to do. For the ones that haven't, it very much depends on what track you take, and how you steer them, because there are obviously certain cases where you

don't really know what the right answer is, because there is no evidence to tell you."

R: "If you know what the evidence shows as best practice, you do tend to try and steer them in that direction, but I think as long as you give them enough opportunities to ask the questions that they want to ask, and you can answer them as truthfully as you can, then you know you have given all the information you can to [enable them to] make their own decisions."

Continuity of care/giving more time/decision making:

R: "I have patients who, half-way through their chemotherapy, are then ready to discuss the possibilities of what they were meant to do, and you know, you have to sit down with them and make more time then, and usually they will realise that they have made the right decision, but that's when they're ready to make it, two months later because they have kind of got to grips with things and it is too late to make the decisions they needed to make earlier."

Nursing factors:

Continuity of care:

R: "I think from a nursing point of view it is very important for us in colorectal surgery to see all patients at diagnosis in endoscopy, bowel screening, and obviously in clinic."

Keeping patients informed:

R: "We make it very clear to the patient so that [they understand] any information that is given to them, and that they understand what they are being

told, e.g. 'you are being discussed at MDT.' What does MDT mean to a patient? It could mean a medical terminology; they might be thinking it is something to do with their cancer. But if you sit down and explain to them that it is a meeting, and that we all meet, and so from a very early stage we are explaining all the basics to them, from diagnosis, so when we ring them following MDT we tell them the result and what is happening next, they are informed all the way along. I think our patients would probably be less likely to look on the internet and things like that because we are keeping them informed all the way along their journey, so that they should hopefully not feel the need to look on the internet because I hope that they would feel that we are giving them sufficient information. As nurses we support them when we are seeing them with the consultant, and then we will take them off, so, like you were saying earlier what do the patients take in at that consultation? Probably nothing, hence why we are there to take them aside, and go through it all”.

Avoid medical jargon:

R: “We make it very clear to the patient so that [they understand] any information that is given to them; that they understand what they are being told e.g. 'You are being discussed at MDT.' What does MDT mean to a patient? It could mean a medical terminology; they might be thinking it is something to do with their cancer?”

Helping decision making:

R: “I think if you are meeting [the patients] continuously along that journey, you can ... get them on your side and steer them away from that, but if you just leave them to it ... I think you get the patient that doesn't want to know anything,

or will just go with whatever the doctor tells them, or you get the patient that feels that they have got to get all this information that is out there to make the best decision, and they just get totally confused, and they end up probably making worse decisions because they get so confused. So I think we play a big role in that certainly.”

R: “Absolutely, and it’s like the debate about having a low anastomosis and no stoma, and then being incontinent ... and then there are a lot of these decisions that patients have to make, and when they are looking on the internet at having these ultra low anastomosis, there is a lot of stuff out there that they don’t understand, that needs explaining further.”

Journey of decision making:

R: “I honestly don’t know ... I’ve thought about it and wondered how you could improve it, it’s just the [mindset] at the moment within the NHS that you have to give everything, and particularly you have to give all the possible complications, no matter how uncommon they might be and, granted, if it does happen with somebody it is 100%, you know, they have got it, that’s it, it doesn’t make any difference, but actually 1 in a 1000 to them is a 100%.”

R: “But I think it is daunting to have to look at all this information and, as I said, even when you have got clearly very professional outfits on the internet giving totally different advice, you know, 180° different from each other. Well, how do you reconcile that, even as the professionals we find that difficult. How the public reconcile that is quite beyond me, I really don’t know.”

Discussion: Multidisciplinary teamwork is a process where decisions are made about an individual. Literature suggests that there is a drop out on the multidisciplinary team decisions, and that not all multidisciplinary team decisions are implemented (168) . One of the possible ways, the multidisciplinary team process could be improved in terms of efficacy and efficiency is to bring these patients to the multidisciplinary team meetings so that they could choose their treatment. This should be undertaken only where there is a conflict in decision making. Given the time pressure, it might sound impractical, however, if it can save time and resources in following clinics, it might be worthwhile.

Family members can certainly play a significant role in helping the patient arrive at a decision. Again, this varies with socio-cultural differences. With an increasing ethnic population in the UK, this is something that we encounter more and more, particularly amongst the Asian population.

There has been an overwhelming discussion about the redundant, inappropriate information available on the internet. The outcomes derived suggest that the patients should be diverted to reliable speciality based websites, from the specialist societies. Also, the speciality journals publish website reviews on specific pathologies which can prove to be very useful.

There was an emphasis on the role of nurses, from breaking bad news to maintaining communication, in addition to the provision of help when necessary. Given the skill and the experience of the nursing colleagues, it might be a good idea to consider the concept of decision making liaison nurses. It should be recommended that the breast/colorectal/upper gastrointestinal nurses take up the roles of decision making liaison nurses, after adequate training.

One of the important themes generated from the focus group discussion was the process of risk communication and the consent process. The clinicians felt the consent process to be tedious and labour intensive paperwork.

Having undertaken the focus group interviews in England, Wales and India, detailed below, an overwhelming factor is the role of socio-economic and cultural factors in decision making. In this globalised world, with a cross-cultural population, it is important to take into account the patient's socio-cultural factors in the decision making process.

One of the other convergent themes from all the focus groups was the way decisions were steered in line with the clinician's preference. Generally speaking, in Wales there is a preference towards joint decision making.

Conclusions:

Decision making in cancer care is a complex physical and cognitive process based on evidence base, patient needs, clinician experience, judgement and, more importantly, patient preference. The focus group discussion demonstrates the importance of the members of the multidisciplinary team in the decision making process for an individual patient, with a drive towards joint decision making in the Welsh population. In the years to come, patients will probably have an increased involvement and role within the multidisciplinary team setting, when decisions are made about them.

12.5 a. 3: A qualitative analysis of a focus group discussion on decision making in cancer care – An Indian perspective

Introduction and background:

It is vital to mention that there exists a wide variation in healthcare provision between UK and India. Not only this, but within India itself there exists significant variation, in relation to educational, social, economic and religious factors, which certainly has implications for the decision making process.

Cancer psychology is a vitally important part of cancer management. Qualitative research is a gateway to exploring this. Weighing the treatment options in terms of quality of life and survival is important. Given the globalisation of healthcare seen in the last decade, the exploration of the decision making process in a developing nation was deemed highly appropriate.

Aims and objectives:

The aim is to explore the thoughts of surgical colleagues and care providing clinicians about patient decision making in cancer care in developing countries, with special reference to India. The secondary objective was to identify factors that may have a role to play in decision making in India.

Design: Qualitative study.

Participants and methods: This was a prospective qualitative study. The exercise was carried out at Kiran Mazumdar Shah Cancer Centre. The hospital is a tertiary referral centre for cancer services in the southern city of Bangalore, India. A qualitative study by methodology, a focus group discussion was undertaken with the members of the head and neck tumour board. The study

explores the thoughts and attitudes of the care providing clinicians about patient decision making in cancer care. The participating members were briefed in advance about the research project. The focus group discussion was held prior to a scheduled tumour board meeting. The characteristics of participants in the focus group are illustrated in *Table 18*.

Table 18. Characteristics of participants in focus group.

Characteristic (job title)	Focus group participants (n=12)
Professors	1 (Head and neck)
Surgical Consultant /Senior lecturer	1 (Colorectal)
Clinical oncologists	3
Surgical Registrars	4
Allied health professional	3 (Psychosocial workers)

The focus group discussion explored clinicians' opinions and thoughts about patient decision making in cancer care in an Indian context. The focus group included head and neck surgeons, oncologists, radiotherapists, psychosocial workers in addition to a senior lecturer and surgeon from Cardiff University, along with the chief investigator, who was running the focus group discussion. The focus group discussion was moderated by the chief investigator and the co-investigator. Stimulus material in the form of abstracts from published papers relevant to decision making, and patient preferences were given to the members. The focus group discussion was audio taped and transcribed. All quotations were anonymised for confidentiality purposes. Qualitative methodology was adopted for analysis. Thematic analysis using a framework approach was done to identify themes and outcomes. Two surgical research

fellows analysed the data separately for accuracy and repetitiveness of the themes and outcomes.

Data collection:

Data was gathered from focus group discussions. Data was audio taped and transcribed. Quotations were anonymised for confidentiality reasons.

Analysis:

Thematic analysis of the collated data was done using the framework approach, thereby identifying themes and outcomes. Analysis of qualitative research data was carried out using a validated technique.

Results:

The emerging themes and outcomes are shown in *Table 19*.

Table 19. Emerging themes and outcomes

Emerging themes	Derived outcomes
Patient factors	
Cost and affordability	Shift from health care provider and to health care Insurer
Quality of life	Raising awareness of health outcome measures
Patient choice and demand	Respect patient choice/demand/trust and beliefs
Trust and beliefs	
Patient knowledge	Raise patient knowledge
Socio-economic and educational status	Consider socio-economic / educational status while decision making
Family and social support	
Clinician and clinical factors	
Communication, risk and consent	Train clinicians in risk communication/consent
Patient advocate	Encourage patient groups/voice
Information technology	Direct patients to evidence based, reliable, speciality based websites
Clinician knowledge	Raise Clinician knowledge
Psychosocial workers/nursing	
Sharing and support	Increase nursing input in patient care

Quotations:

Cost and affordability:

R: “Money is the first thing ... actually the most important factor, if they cannot afford the treatment, there is no point in telling [the patient about it].”

R: “When the patient comes to the hospital in Britain, nobody talks of money. Here, the first thing is how much it costs.”

Quality of life:

R: “They do not talk about quality of life.”

R: “The best option, whether it is debilitating or low quality of life, we have to offer it. He has an option of refusing it, but just because you may not like it, we should not refuse that option.”

R: “When the patient comes to the hospital in Britain, nobody talks of money. Here, the first thing is how much it costs. They do not talk about quality of life that is all.”

Case complexity and choice of therapy:

R: “If there is a clear-cut answer to a problem, there is no discussion. A discussion comes when there are multiple options.”

Ease of communication:

R: “Patients feel [more] comfortable communicating with doctors than nurses.”

Decision making:

R: “They know what was discussed here, that will be conveyed to the patient and then we come up with a decision.”

Patient choice and demand:

R: “We will have some definite plan that was made, and sometimes the patient has a completely opposing treatment plan, and we strongly feel that patient needs to be counselled, therefore we try our best to counsel, but sometime the patient will be against us.”

R: “We have had a few patients who come demanding for a particular type of therapy.”

R: “I mean it is not really uncommon for people to come with some particular treatment in their mind, it need not be the best possible option.”

Trust and beliefs:

R: “Totally curable, but patient is going to go for Siddha ayurvedic treatment. We tried to explain that this is curable, but he is against it, we cannot force the patient, but we said we will keep an eye on the patient. I am helpless.”

R: “I have belief in surgery, but sometimes belief is what patients [have too]. So, all of us have certain bias based on it. Patients have their own perspective about life and treatment.”

R: “A man working at a vice president level in an IT company is telling me that his uncle told him that radiotherapy will disfigure her, so she did not take radiotherapy, now she is left with an expected life survival of three months. So, it is an interesting concept, but there are lots of social issues attached to it and

we will be very happy to choose the patients who get involved during decision making.”

R: “One of our very senior oncologists is considered as God in India. They will go and touch his feet, the only thing he does is to tell to them, they will be cured. We know that he is giving the patient hope. He sells hope. He is so popular that he travels across India. He sees patients in the airport, anywhere and everywhere, and he is God, people love him.”

Evidence-based patient preferences, patient choice, or patient decision making:

Financially driven:

R: “In India, it is a completely different scenario. Our practice is a very bad practice. If he does not like me or the other surgeon, there are enough renowned hospitals in the city where patients can go and if, you know, there are hospitals where the doctors will do whatever the patient say. So, it is a completely different concept.”

R: “That is exactly opposite what happens in India. The patient has enough and more choices. We see so many patients who shop around the whole of the country and then come to us.”

Affordability:

R: “Affordability is the first thing that is actually the most important factor, if they cannot afford the treatment, there is no point in telling them the various options.”

R: “When the patient comes to the hospital in Britain, nobody talks of money. Here, the first thing is how much it costs. They do not talk about quality of life.”

Socio-economic and educational status:

R: “The level of understanding and education, it is very different among patients. Dr [X] has worked in a centre where the financial status of the patients was very different, so I am sure he has a prospective of that, compared to this hospital where we see more of humble background patients.”

R: “You know, lot of patients are not educated. They do not understand what is happening. In fact, they do not know what is happening with them.”

Clinician and patient knowledge:

R: “So, to involve them, you know, you can make a decision if you have knowledge. We see some patients who do extensive internet search, come to us and seek treatment. That may or may not be the right treatment for them. If somebody does not have the knowledge, it is very difficult to make the patient understand the whole process.”

R: “I am talking about patients’ knowledge. See, day before yesterday I saw one patient, a man working at a senior position in IT Company, somewhere in his 50s, came to me with his wife’s records. She had recurrent astrocytoma grade 3, operated one year back. She did not receive any radiotherapy, because his uncle told him that radiotherapy will disfigure her.”

Family and social support:

R: “They do not understand what is happening with them. There is a decision maker in the family who takes all the decision.”

R: “Sometime I do not communicate everything to the patients; difference being family psychology in India is different from UK.”

R: “Here sometimes, there is one leader in the family, or we might talk to that particular person and then they will communicate gradually to the patients. So, we may not deliver everything to the patient. The family network is very, very strong in India.”

Information technology:

R: “They could do internet search. Most of the search is done on websites like Google, which will not give you what is the best therapeutic option for the patient. It will just give some kind of a treatment and majority of the patients come with treatment options which are not actually significant.”

R: “We see a lot of patients who come [asking for] interesting drugs or techniques which are in phase 1 and phase 2 trials, because that is what forms headlines in newspapers or articles. So, we always face this problem.”

R: “We did try to divert them to more reliable sites. We offered them what we have.”

Analysis of multidisciplinary team/tumour board meetings:

R: “I think that it is the rule for the Tumour Board to make the right decision. Of course, the patient has choices to schedule the treatment.”

Patient advocate:

R: “As a clinician, we have a tradition of making the right decision for the patient.”

R: “The ultimate aim of the clinician is to work for the patient, but at the same time, it is our job to make right decision.”

Communication with patients/risk communication:

R: “We fight for the patient, we try to bring the family and discuss in detail, and communication can be a problem.”

R: “Let’s say that, I have a break in my communication, sometimes you do not gel well with the patient, and then I feel that you should seek a colleague’s help.”

R: “I think that we cannot ask the nurse to communicate for you.”

R: “But, we cannot delegate a nurse to communicate fully, that is not we are working for. We should make time for communication with patients.”

R: “In fact, the initial communication is the key, you can step aside after the treatment is initiated, but if the initial communication is lacking, I think there is a major error.”

R: “If time is an issue, increase the manpower.”

R: “Nurses in the UK know the patient very well, but some patients need things to be told 10 times for them to remember. That is where those nurses kick up that extra number of conversations.”

R: “I will say what the expected complications or sequela of the treatment are.”

Nurses:

R: “In India, the role of nurses in communication with regard to the cancer care is minimal. Most of it is done by the clinicians.”

R: “I think that we cannot ask the nurse to communicate for you.”

R: “But, we cannot delegate nurses to communicate fully. That is not we are working for.”

R: “Nurses in the UK know the patient very well, but some patients need things to be told 10 times for them to remember. That is where those nurses kick up that extra number of conversations.”

Medical social workers:

R: “Medical social worker, he plays the same role in communication as a specialist nurse practitioner. His background is science graduate, he has done a Masters in medical social work, and when they, he/she, comes to us, he may not have much experience in cancer, and they sit with us in the Tumour Board meetings, and learn what is necessary.”

Sharing and support:

R: "We do not have, but we are trying to develop patient support groups."

Patient voice:

R: "I think we need the patient voice to say what is important."

Individualisation of treatment:

R: "We have to individualize treatment."

Consent:

R: "The consent process is not very, very strict. We would tell everything, but we do not write down all the possible complications. I heard [that in the] US that they write down every possible individualized consent form, write everything possible. You can imagine that consent form."

R: "That will protect you, medico-legally to certain extent."

Discussion:

There is some literature available on the delivery of pain relief and palliative care in developing countries, but very little data on decision making. A search of the literature revealed a number of ethical dilemmas and challenges that professionals, cancer patients, and their families encountered during palliative care. It was noted that patients' preferences and decisions are influenced by family members (169). When making decisions, it is important that patients' views are taken into account, in addition to their level of knowledge and demands.

Patient choice has not developed to any large extent in the developing world. This is due to a number of factors, including cost and affordability, illiteracy, tradition, and lack of awareness. There is also a spiritual aspect in the decision making process. There does not seem to be much of an emphasis on quality of life.

There has been an enormous amount of discussion about the redundant information available on the internet, especially on search engines such as Google. The consensus is that most of the available information is unreliable, and it is important for the care providing clinicians to direct patients to appropriately reliable speciality websites, and web publications from the relevant medical societies (such as ASCRS, ACPGBI, BASO, ASGBI.)

Evaluation of the quality of multidisciplinary team Tumour board decision-making is important. The proportions of decisions implemented are grossly unknown. One such study was from Wood et al, a group in Bristol who evaluated the treatment decisions of the colorectal cancer multidisciplinary team (168). This study examined multidisciplinary team decision-making by studying whether multidisciplinary team treatment decisions were implemented, and investigated the reasons why some decisions changed after the meeting. The vast majority of colorectal multidisciplinary team decisions were implemented, and when decisions changed, it was mostly because of patient factors that had not been taken into account. This raises the question whether involvement of patients in the multidisciplinary team process would help with better decision making.

Attitudes of clinicians differ towards the nurses with respect to the roles they can undertake in the developing world. In the western world, nurses are in the forefront of patient care. This does not seem to be the case in the developing world. Some of the responsibilities of the specialist nurses are undertaken by the medical social workers. Medical social work is a sub-discipline of social work, also known as hospital social work. Medical social workers typically work in a hospital, skilled nursing facility, or hospice, have a graduate degree in the field, and work with patients and their families in need of psychosocial help. Medical social workers assess the psychosocial functioning of patients and families, and intervene as necessary. Interventions may include connecting patients and families to necessary resources and supports in the community, providing psychotherapy, supportive counselling, or grief counselling, or helping a patient to expand and strengthen their network of social supports. Medical social workers typically work on an interdisciplinary team with professionals of other disciplines (such as medicine, nursing, physical, occupational, speech, and recreational therapy).

Bias reducing factors: To overcome bias that may be associated with gathering data, a second moderator was involved in the focus group discussion. The second moderator also took part in thematically analyzing the qualitative data, to help overcome bias. The themes and outcomes from both researchers were compared to derive reoccurring themes and outcomes.

Conclusions:

Decision making in cancer care is a complex physical and cognitive process

based on evidence, patient needs, clinician experience, judgement, and patient preference. In India (a developing country), evidence based patient choice (EBPC) has not developed to a large extent, when compared to the western world. Decisions seem to be predominantly clinician led. Attitudes of clinicians differ towards the role of nurses. There is not much of an emphasis on quality of life, and there is a clear need for patient groups and a patient voice. In the future, patients should have increased involvement in decisions made about them. The process of decision making is slowly evolving, and will see metamorphosis in future. It is important for the clinicians and nurses to play a role leading to this change. Decision making has to be handled delicately and sensitively in cancer care, within the framework of the traditions and culture of the society and financial constraints.

12.5 a. 4: Decision making in surgery and cancer care – A comparative analysis between England, Wales and India.

Healthcare is in a rapid globalisation phase. As a result, it is imperative to look into the decision making process in the developed, developing, and the underdeveloped world. From the focus group discussions in the developed and the developing world, there were interesting diverging and converging themes. *Table 20* and *Chart 1* illustrate this. There has been increased activity with respect to decision making all around the world. Pope, from the Health law institute in Delaware, USA, in his article ‘Legal briefing: informed consent’ highlights the importance of shared decision making (170). The findings from the study presented here suggest that the majority in the developed world are in favour of joint decision making, although for a small minority there is a significant element of patient decision making in surgery and cancer care. In comparison, the study from India indicates that, in a majority, it is the clinicians who lead the decision making.

Table 20. Converging and diverging themes between developed and developing countries.

CONVERGENT THEMES	DIVERGENT THEMES
Patient factors	
Patient individuality	Cost and affordability
Educational, socioeconomic and cultural factors	Patient choice
Patient empowerment	Trust and beliefs
	Role of family members in DM
	Less emphasis on quality of life
	Lack of patient voice/groups
Clinician & clinical factors	
Evidence based clinical practice	Demand for good/famous clinicians
Clinician knowledge	Alternate forms of medicine
Information and consent	Low emphasis on consent
Risk and communication (training)	

Steering decision making process	
Patient advocate	
Information technology	
Nursing care	
Continuity of care and support	Role of psychosocial workers
Providing help when required	No role of specialist nurses

The common convergent themes were patient Individuality, patient empowerment, and educational, socioeconomic, and cultural factors. Themes related to clinician and clinical factors included evidence based clinical practice, clinician knowledge, information and consent, risk communication, steering decision making process, patient advocacy and information technology. Continuity of care and support, and providing help when required are two of the nursing care related themes.

The divergent themes included cost and affordability, patient choice, trust and beliefs, the role of family members in decision making, decreased emphasis on quality of life, and a lack of patient voice/groups. Demand for good/famous clinicians, alternate forms of medicine, and decreased emphasis on consent, are some of the clinician related divergent themes. The role of psychosocial workers, and the lack of specialist nurses, were the nursing related divergent themes.

The derived outcomes included: increase the evidence base, clinician and patient knowledge; provide adequate information, tailor information to patients needs, and direct them to evidence based, reliable, specialty based websites. It is important to take patient's views, knowledge and demands into consideration. Risk should be communicated in an understandable manner, including the consenting process, and risk communication training should be given to clinicians. Individualized decisions should be taken based on patient factors and

best interests. Continuing care, and support with the decision making process should be provided, and help should be made available when required. From a perspective of a developing country, the outcomes in addition to the above included changing role of the government from being a health care provider to health care insurer, increasing awareness of health outcome measures, respecting patient choice/demands/trust and beliefs, and encourage patient groups/voice.

Conclusion:

Decision making in cancer care is a complex physical and cognitive process based on the evidence base, patient needs, clinician experience, judgment and patient preference. Patient decision making in cancer care is slowly evolving in England. Time is a factor and in the future, patients will play an increased role in choosing their treatments, taking into account tradeoffs and risks between survival and quality of life.

In Wales, the focus group discussions demonstrate the importance of the members of the multidisciplinary team in the decision making process for an individual patient, with a drive towards joint decision making. In the future, patients will probably have an increased involvement and role within the multidisciplinary team setting, when decisions are made about them.

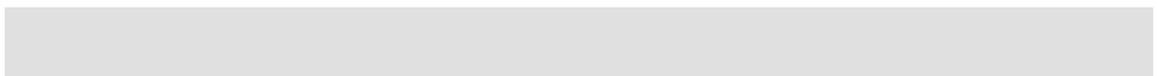
In India (a developing country), evidence based clinical practice has not developed to a large extent, when compared to the western world. Decisions seem to be predominantly clinician led. Attitudes of clinicians differ towards the role of nurses. There is not much of an emphasis on quality of life and there is a need for patient groups/patient voice. In the future, patients will have an

increased involvement/role within the multidisciplinary team setting. The process of decision making is slowly evolving and will see metamorphosis in future. It is important for clinicians and nurses to play a role leading to this change.

Discussion:

There are a number of reasons for the variation seen amongst the clinicians in England, Wales, and India. The majority of the differences are due to the socio-economic variation. There are certainly lessons to be learnt from the comparison.

In Indian, trust and beliefs play a significant role in decision making. The background to this could be because of the role of alternative medicines in India. In Western culture, 'alternative medicine' is any healing practice 'that does not fall within the realm of conventional medicine' (176). The American National Centre for Complementary and Alternative Medicine (NCCAM) cites examples including naturopathy, chiropractic medicine, herbalism, traditional Chinese medicine, Ayurveda, meditation, yoga, biofeedback, hypnosis, homeopathy, acupuncture, and nutritional-based therapies, in addition to a range of other practices (171) . A 1998 systematic review of studies assessing its prevalence in 13 countries concluded that about 31% of cancer patients use some form of complementary and alternative medicine (172).



12. 5 b National questionnaire survey of the members of the ACPGBI after the Preliminary results of the MRC CR07/NCIC CO16 randomised trial

How do we manage early rectal cancer? A National Questionnaire survey among members of the ACPGBI after the Preliminary results of the MRC CR07/NCIC CO16 randomised trial.

Introduction:

Colorectal cancer is the second most common cause of death from malignant disease in the United Kingdom, with about 20,000 deaths each year. Around one million new cases (9% of all cancers) are diagnosed each year worldwide (173). As the UK population ages, the incidence is predicted to rise. The current gold standard treatment is surgical resection of the primary tumour. Reported recurrence rates following surgical resection of rectal cancer vary widely from 3–50% (174) (175). It is well accepted that involvement of the circumferential resection margin predicts a high rate of local recurrence.

Improvement in the surgical technique (176) and delivery of radiotherapy (177), (178), (179) are proving to be of benefit in terms of local control and prevention of local recurrence. The benefit of neo-adjuvant short course radiotherapy is currently the subject of considerable international debate (180).

Although low rates of local recurrence have been reported following total mesorectal excision alone, increasingly, a number of randomised controlled trials have demonstrated improved 5 year disease free and overall survival for pre-operative radiotherapy, compared to post operative regimes (181), (182), (183). Nevertheless, there remains a wide variation in the use of radiotherapy throughout the UK (184).

Increasingly, a number of RCTs have favoured preoperative over post-operative radiotherapy in reducing the local recurrence (185), (186), (187). In the absence of a clear consensus with regard to use of neo-adjuvant radiotherapy, the CRO7 trial was set up and funded by the Medical Research Council.

The CRO7 trial included all patients with operable adenocarcinoma of the rectum <15 cm from the anal verge, with no metastases. Patients were randomized either to receive pre-operative RT 25 Gy in 5 fractions, followed by surgery or surgery with use of adjuvant chemo radiotherapy, should the circumferential margin be positive on pathological examination of the resected specimen. Both groups received adjuvant chemotherapy according to local policy.

The preliminary results from the trial demonstrated that patients with resectable tumours benefited from preoperative radiotherapy whatever the stage and position of the cancer (188), in terms of both local recurrence and disease free survival .

In the light of these preliminary results, a national questionnaire survey to assess the current pattern of practice in the UK was undertaken by the author. The aim of this study was to determine any change in current practice consequent to the early dissemination of the trial data, in advance of the publication of the full paper.

Materials and methods: A national questionnaire survey amongst the Association of Coloproctology of Great Britain and Ireland (ACPGBI) members.

The ACPGBI is the sub-specialty association for colorectal surgery in the UK. A specifically designed postal questionnaire was distributed among all 400 active consultant members of the ACPGBI. This is a 14-item questionnaire enquiring on clinical management of operable rectal cancers, use of neo-adjuvant short course radiotherapy, and the influence of preliminary results of CRO7 on their practice (see questionnaire in Appendix 2). The questionnaire, along with a personalized covering letter and a self addressed stamped envelope were posted. No reminders were sent for unreplied questionnaires. All the questionnaires were anonymised. The questionnaire was developed using expert opinions in the field of colorectal surgery, and was internally validated amongst the members of the academic surgical unit at Hull.

Results:

Of 400 questionnaires, 200 (50%) were returned fully completed. 166(83%) of surgeons did not routinely use neo-adjuvant short course radiotherapy (NASCRT) in clinically operable rectal cancers (T1/T2) <15cm from anal verge with no metastases (the CR07 eligible cohort). Sixty-four (32%) used NASCRT for T3 cancers routinely, whereas 76(38%) used neo-adjuvant long course radiotherapy instead.

One hundred and fifty-six (78%) of the surgeons felt the height of the tumour from the anal verge influenced their decision on NASCRT, while 104(52%) felt position was important (anterior/posterior). Positive circumferential resection margin (CRM) on MRI was a deciding factor for 185(92.5%) of surgeons in favour of neo-adjuvant therapy. Post-operatively in patients who have not had pre-operative radiotherapy, 154(77%) recommended radiotherapy, and 155(77.5%) recommended chemotherapy if the CRM was positive on final pathology.

Seventy-eight (39%) of the surgeons had changed their practice after the preliminary results of the CRO7 were published, by adopting neo-adjuvant short course radiotherapy for treating early rectal cancers.

There is significant variation in the treatment of patients who have had pre-operative short course radio-therapy and those who, post-operatively, have CRM involvement. Ninety-four (47%) of the surgeons opted for post operative adjuvant chemotherapy, while 24 (12%) chose either radiotherapy or chemo- radiotherapy. Ten (5%) of the surgeons decided to follow up the patient with 'watchful waiting'.

For patients who had preoperative long course radiotherapy, 145 (72.5%) of surgeons used post operative chemotherapy, while 6 (3%) opted for either radiotherapy or chemo-radio therapy. Nineteen (9.5%) of the surgeons preferred a wait and watch policy.

For 143(71.5%) of the surgeons, chemotherapy was predominantly directed solely by oncologists, while joint decisions through multidisciplinary teams accounted for the remaining 52 (26%). No surgeon made a sole decision regarding adjuvant chemotherapy. The choice of the chemotherapeutic agent varied but was largely 5 FU based regimens, followed by Oxaliplatin and Capecitabine.

Qualitative methodology was adopted to analyze the comments section. Out of 200 fully completed questionnaires, only 52 (26%) of surgeons completed the comments section. A number of themes emerged from thematic analysis. These included:

- Difficult treatment group,
- Individualizing treatment (no one size fits all)
- Concerns about radiotherapy

- Service provisions
- Role of the multidisciplinary team
- Need for full evidence
- Lack of awareness of the evidence
- Role of uniform protocols and guidelines
- Lack of consensus amongst surgeons, oncologists and radiotherapists
- Slowly emerging consensus, and,
- Delay in implementation of evidence based practice.

Discussion:

The CRO7 trial was set up with the objective of evaluating the effect of preoperative short course radiotherapy on operable rectal cancers. The trial involved 69 centers in the United Kingdom, nine in Canada, and one each in South Africa and New Zealand. The early data has been presented at a number of international and UK scientific meetings and published in abstract form only.

The preliminary results showed that pre-operative short course radiotherapy in patients with operable rectal cancer resulted in a lower rate of local recurrence than selective pathology guided postoperative chemo radiotherapy. Patients with resectable tumors benefited from preoperative radiotherapy whatever the size (T stage) and position of the cancer, or the quality of the excision (TME) (188). Quality of surgical removal (TME grade) was directly related to the risk of recurrence. Combining preoperative radiotherapy with the 'best surgery' reduced the risk of recurrence of tumors to 1%.

The trial found that preoperative radiotherapy improves three year survival. The rate of pelvic recurrence after five years was 5% in the preoperative treatment group, across all qualities of surgery, and 17% in the postoperative group. The probability of disease free survival at five years was 75% for those who were treated pre-operatively and 67% for those treated postoperatively.

The MRC CRO7 was designed in 1997, before the wide availability of MRI for staging rectal cancer. Studies suggest that high resolution magnetic resonance imaging could predict tumour at the potential circumferential resection margin if the tumour was within 1mm of the mesorectal fascia on the scan(189), (190), (191). Studies by the MERCURY group suggest high resolution magnetic resonance imaging can accurately predict the surgical resection margin, thus potentially enabling selection of patients for preoperative treatment (192). In the study discussed here, positive CRM on MRI was a deciding factor for 185 (92.5%) of surgeons in favour of neo-adjuvant therapy and MRI will be a major influence on the choice of patients for NASCRT.

In the current survey, the response rate was 50%. Some of the factors that may have influenced the high rate of return are the personalized covering letter and self-addressed envelope (198).

The results from this survey demonstrate a highly variable approach to the use of radiotherapy across the UK, in many instances showing a certain reluctance to adopt evidence based practice. Perhaps when the mature trial data is available, more surgeons would be willing to utilize routine use of SCNART, and a further survey of practice may be warranted after that time. However, the survey does demonstrate that almost 40% of surgeons have already altered

their practice before the publication of full trial data. It is believed that this figure will likely rise even further at that time.

There are many barriers to evidence based clinical practice. One of them is adopting research findings into practice (193).

While this national survey among members of the ACPGBI does show delay in implementing evidence based clinical practice based on previously published data, the results suggest that the MRC trial has already had an impact on clinical practice in the UK.

Conclusion: Even though the CR07 data has yet to be published in full paper format, 39% of surgeons have already altered their treatment policies, suggesting that RCT data of sufficient quality does influence surgical practice. However, the mature trial data are yet to be published, and a further survey of practice is warranted after that publication. CR07 is likely to result in fundamental changes to the management of rectal cancer in the UK.

12.5 c: Qualitative analysis of the National questionnaire survey on CRO7 results.

Introduction:

A consensus has not yet been reached on the role of neo-adjuvant therapy in the management of rectal cancers in colorectal surgical practice. In the light of the preliminary results of the CRO7 trial, a national questionnaire survey was undertaken to assess the current pattern of practice in the UK. The results suggested that despite the evidence of the CRO7 trial supporting the use of NASCRT for operable rectal cancer, approximately two-third of consultant surgeons in the UK have yet to implement this treatment regime routinely. However, 39% of surgeons have changed their practice following the early dissemination of trial results (194).

Change in clinical practice is driven by a number of factors (195), (196) .

Available data is one of them, but may not be the most important factor (197).

Aim: The aim was to explore factors driving change in clinical practice, using the context of radiotherapy in rectal cancer. This study aimed to consider why some clinicians adopt change while others do not. It considered whether change in practice is only guided by scientific evidence, or whether there might be other factors which influence change.

Materials and methods: The study used a national questionnaire survey of the ACPGBI members. A specifically designed postal questionnaire was distributed among all 400 active consultant members of the ACPGBI. This was a 14-item questionnaire asking about the clinical management of operable rectal cancers, and a separate question allowed for comments, suggestions and

thoughts about the issue. Details of the active members of the ACPGBI were gathered from the association's database. A questionnaire, along with a personalized covering letter and a self-addressed stamped envelope were posted during the beginning of the week using second class postage. No reminders were sent. All the questionnaires were anonymised. Qualitative data for this article has been drawn from a subset of results analyzing the comments section of the questionnaire. Qualitative methodology was adopted to analyze the qualitative data to derive themes and outcomes.

Results:

Of 400 questionnaires, 200 (50%) were returned completed. Of these, only 52 (26%) of surgeons completed the comments section. Qualitative methodology was adopted to analyze the comments section. Themes that emerged from thematic analysis are patient groups, treatment, evidence based practice, professional consensus, and service provisions. The outcomes carved out are to individualize treatment, difficult elderly treatment group, provide safer and less harmful treatment due to the complications associated with radiotherapy, increase role of multidisciplinary teams to overcome lack of consensus, increase awareness of the current evidence based literature to address the existing weakness in evidence based practice, develop protocols and guidelines, and shorten the delay in implementing evidence based practice. Service provisions, infrastructure and resource availability should also be improved.

Some of factors responsible for change in the clinical practice are clinical decision making (patient groups, treatment, and professional consensus), evidence based practice/education, research translation, organizational factors,

and infrastructure / resources. Some of them are being elaborated using quotations.

Clinical decision making (patient groups, treatment, and professional consensus).

Patient groups: The general consensus was to tailor the treatment to individual patient need, rather than taking a blanket approach.

R1: *“Always remember to treat a patient as an individual, especially with an ageing population.”*

R21: *“Individualise management, but adjuvant therapies are probably over used.”*

Treatment: Various factors such as age, co-morbidities, functional outcome, and complications associated with the treatment, should be considered before treating.

R37: *“The treatment of rectal cancer is complicated and there is ‘No one size fits all’. Very low recurrence and excellent long term survival is possible with a tailored approach.”*

R18: *“Increased likelihood to offer SC pre-op DXT to T1/T2, but still concerns overall about post treatment morbidity.”*

R36: *“I think that the functional morbidity of both short and long course pre-op radiotherapy has been underestimated.”*

Professional Consensus: Lack of professional consensus and the role of multidisciplinary teams were highlighted.

R7: *“A lot of management is decided by clinical oncologists these days.”*

R31: *“Would prefer to use long course RT in all T3 cancers,(whenever RT indicated, but radiotherapy department still feels evidence not conclusive for proven benefit.”*

R43: *“CRO7 has changed our multidisciplinary team practice with mid and low rectal cancers.”*

R44: *“All decisions are joint with oncologists in the multidisciplinary team on, an individual patient basis.”*

R51: *“DXT for rectal cancer, has been confusing, of late, I believe a consensus is however, beginning to emerge.”*

Evidence based practice/education: There is a gradually evolving evidence base. Though one third of the clinician population has changed their clinical practice based on the preliminary results, the majority of them are waiting to see the full publication.

R12: *“Our local Network Site Specific Groups (NSSG) is waiting to see the full CRO7 publication before changing practice.”*

R13: *“CRO7 has turned practice on its head.”*

R17: *“Still awaiting full backup of CRO7.”*

R25: *“We are about to discuss practice following CRO7 results.”*

R32: *“Policy changed in September 06 to reflect preliminary CRO7 figures.”*

R37: *“The CRO7 results are interesting, but already historical.”*

R45: *“We all know the results are but slow to act on them.”*

R46: *“Would be useful to know CRO7 results.”*

Research translation: The consultants are in various stages of implementing research findings into clinical practice.

R48: *“CRO7 being discussed and network guidelines being changed/formulated.”*

R52: *“CRO7 may change my practice when full information is available in a peer reviewed publication”.*

Organisational factors and infrastructure/service provisions: Lack of adequate infrastructure and resources necessary for providing radiotherapy services is certainly an issue.

R4: *“Difficult to arrange for pre-operative neo-adjuvant DXT due to the fact that [location] is isolated, and it is difficult to arrange travel for patients to UK.”*

Discussion: The preliminary results of CRO7, a large international RCT showed that 'patients with resectable tumours benefited from preoperative radiotherapy whatever the stage and position of the cancer, in terms of both local recurrence and disease free survival' (198). The preliminary results concluded by saying further follow up is required to determine any difference in overall survival. Data suggests that meticulous surgery alone in favourable tumours is not enough. The CRO7 trial is a large international RCT which suggested that most patients should receive preoperative RT of some form - short course/long course. The trial indicated a need for much wider use of short course radiotherapy.

A national questionnaire survey was undertaken to explore the current pattern of practice in the UK and to see if clinical practice had changed from the time the trial was set up to the dissemination of preliminary results as oral presentations and abstracts, awaiting full publication. The results demonstrated that 78 (39%) *changed practice* (194).

Change in clinical practice is driven by a number of factors (195), (196) .

Available data is one of them, although it may not be the most significant one though (197). Thus, it was desirable that the factors driving current practice and the ones influencing change in practice should be explored.

In the current survey, given that no reminders were sent, the return rate was 50%. Although the return rate was reasonable, the number of respondents who answered the comments section was low, at 52 (26%).

The data was analysed using a qualitative approach. Qualitative analysis is a systematic process by which data is analysed to derive the most commonly reoccurring concepts, called themes. The solutions carved out of this data are outcomes. Five themes were consistently derived from the comments section of the questionnaire. Each theme produced outcomes, sometimes one, and sometimes more than one.

Use of radiotherapy, as well as timing, is a highly contentious issue in the management of rectal cancer. The survey results demonstrate highly variable approaches to the use of radiotherapy across the UK, in many instances showing a certain reluctance to adopt evidence based practice. Analysis of the qualitative data illuminates factors influencing changes in clinical practice. Some of them include the non-availability of the mature trial data, barriers to evidence based clinical practice as defined by Haynes et al (193), inadequacy of infrastructure and resources, lack of evidence based practice/education, and inappropriate clinical decision making.

Perhaps when the mature trial data is available, more surgeons would be willing to utilize routine short course neo-adjuvant radiotherapy, and a further survey of practice may be warranted after that time.

There are many barriers to evidence based clinical practice. One of them is adopting research findings into practice. This gap needs to be bridged. It is vital to not only extract the evidence from research, but also to encourage early adoption of it in clinical practice. Haynes et al (193) described the problems in implementing evidence based medicine, and suggested possible solutions. Some of the important solutions are: to integrate current best evidence from research with clinical policy and practice, to use new evidence based services to access current best evidence, and ensure that evidence and policy are applied at the right time.

Working through the various stages of generating evidence from research to making clinical decisions, numerous issues have to be addressed. Some of them are issues relating to the synthesis of the evidence (COCHRANE Library), creating evidence based clinical policies (development of guidelines), and applying evidence based policy into practice. What is noted in the current study is that clinicians are at various phases for research translation, beginning with some who are unaware of the results, all the way through to some who have already implemented the change.

While making clinical decisions the clinician has to take into consideration, along with the evidence, the patient's wishes and circumstances. Other factors that might play a role are organizational factors, infrastructure and resources.

Our national questionnaire survey among members of the ACPGBI after the preliminary results of the MRC CR07/NCIC CO16 randomised trial does show delay in implementing evidence based clinical practice in two thirds of the surveyed consultant surgeons. A possible reason for this is that the evidence generated is going through the phase of synthesizing the evidence and creating evidence based clinical policies, along with other contributing factors responsible for change in practice.

Allery et al (195) showed that doctors recognise organisational factors, education, and contact with other professionals as influential in changing their clinical practice . Education formed a major component, providing one sixth of the reasons for change, and was involved in one third of the changes. The average number of reasons per change was three.

Quantitative studies have provided objective evidence of the effectiveness of continuing medical education programmes in changing physician performance or health care (199), (200), (201), (202).

Wergin et al believe that the impact of continuing education can be understood only within the context of other important intervening variables (203). Graham has emphasized the importance of researching the beliefs of clinicians, if strategies to influence doctors' behaviour are to succeed (204).

Studies have shown that nearly all changes in doctors' clinical behaviour are due to a combination of factors (195). Reasons for change ^are numerous and wide ranging (203), (205).

Kerr et al found that for consultants, the two most frequently mentioned educational reasons for change were reading medical journals and correspondence, and attending scientific meetings (206).

Limitations: Being a questionnaire study, the return rate was reasonable at 50%; however the number of responses for the comments section was only 52 (26%). It is possible that reminders would have helped provide a better response rate (207). Studies have shown that response rates with questionnaire studies are in the range of 50–55% for medical questionnaires (208). Nevertheless, the qualitative nature of the study leads to early saturation of themes and outcomes.

Conclusion: Change in clinical practice in the context of use of radiotherapy in rectal cancer is due to a combination of factors. The reasons for change were numerous and wide ranging. Some of them include:

Clinical decision making: It is vital to provide safe and less harmful treatment, where possible. There is a need to increase the role of multidisciplinary teams, and adopt a tailored approach based on individual patient needs.

Evidence based practice/education: There is a strong feeling among the consultants that they wish to view the CR07 data in full paper format, before they can adopt change. There is also the need to increase awareness of the current evidence based literature.

Organizational factors, infrastructure and resources: Improvement of service provisions is necessary.

Translation of research evidence to clinical practice: It is necessary to overcome the barriers to evidence based practice by synthesizing available research evidence, developing protocols and guidelines, along with shortening the delay in implementing evidence based practice.

In conclusion, change is a slow and complex process influenced not only by data and scientific evidence, but by a number of other factors. Some of the above conclusions will aid the policy makers and opinion leaders in the NHS.

Future: It is intended to repeat the survey following a full publication of the CRO7 trial, and compare the results with this baseline survey.

12.5 d: Thrombo-prophylaxis in colorectal surgery : A NQS of ACPGBI

members

Thrombo-Prophylaxis (TP) In Colo-Rectal Surgery: A National Questionnaire Survey of the Members of the ACPGBI

Introduction:

Colorectal cancer is the second most common cause of death from malignant disease in the United Kingdom (173). There are approximately 30,000 new cases and 20,000 deaths per year in the England and Wales (209). As the UK population ages the incidence is predicted to rise.

Venous thromboembolism associated with malignancy reduces survival (210), (211). Pulmonary embolism is the second most common cause of death in patients with cancer (212), (213), (214), (215). Post operatively, deep vein thrombosis (DVT) and pulmonary embolism are twice and thrice more common respectively, in cancer patients compared to the ones operated for benign causes (210). Post-operation DVT prevalence in colorectal surgery is estimated to be around 20% (216) . Surgery on cancer patients is a significant risk factor for thrombosis. This could be attributed to disruption of Virchow's triad, with prolonged immobilisation etc. Although the rate of prevalence of pre-operative DVT is unknown, it certainly is a risk factor for pulmonary embolism post operatively.

There is no doubt that a standardised thrombo-prophylaxis is vital in this group of patients undergoing surgery. Anecdotal evidence suggests that there is a lack of standardisation and uniformity in thrombo-prophylaxis practice in the UK. A national survey aiming to assess the current practice amongst the active

consultant members of the ACPGBI was undertaken to evaluate whether there is any uniformity in the post-operative thrombo-prophylaxis practice in colorectal surgery, and whether this practice is based on the available guidelines from ACPGBI and NICE.

ACPGBI guidelines from 2007 state that a combination of graduated compression stockings and heparin should be used for thrombo-prophylaxis for patients undergoing colorectal surgery (217). NICE recommends that patients having general surgery with one or more risk factors for venous thromboembolism should be offered mechanical prophylaxis and either LMWH or fondaparinux (218).

A national questionnaire survey aiming to assess the current pattern of thrombo-prophylaxis in post operative major colorectal surgical practice in the UK was undertaken, and the results compared with the available guidelines from ACPGBI and NICE.

Materials and methods: A national questionnaire survey of the ACPGBI members was carried out. A specifically designed postal questionnaire was distributed among all 490 active consultant surgical members of the ACPGBI. This is a 10 item questionnaire enquiring into the current management strategy of post-operative thrombo-prophylaxis in colorectal surgery, and evaluates the influence of recent post-operative thrombo-prophylaxis guidelines from ACPGBI and NICE (see *Appendix 3*). The questionnaire, along with a personalized covering letter and a self addressed stamped envelope were posted during the beginning of the week using second class postage. No reminders were sent.

The data was anonymised prior to dissemination. The questionnaire was developed based on common strategies of thrombo-prophylaxis in practice. It had expert input and was validated amongst the members of the academic surgical unit.

Results: Of 490 questionnaires, 259 (52.8 %) were returned fully completed. 243(93.8%) of surgeons used departmental guidelines for thrombo-prophylaxis in colorectal surgery. All 259 (100%) of them routinely used thrombo-prophylaxis. The majority of them used combined chemo and mechanical prophylaxis at 247 (95.40%), while 12 (4.6%) used chemo-prophylaxis only. As a chemotherapeutic agent of choice, the majority of them opted for LMWH at 243 (93.8%), whilst 9 (3.5%) chose UFH. The time of starting chemo-prophylaxis varied amongst surgeons - 176 (68%) started chemo-prophylaxis on admission, 22 (8.5%) on induction, 38 (14.7%) 6 hrs post-operatively and 6 (2.3%) 24 hrs post-operatively. The majority of them discontinued chemo-prophylaxis upon discharge 201(77.6%), whilst 31 (12.0%) discontinued prior to discharge. Thirteen (5.0%) discontinued on mobilisation, whilst 4 (1.5%) discontinued 6 weeks following discharge.

Use of combinations of agents for mechanical thrombo-prophylaxis was seen. 154 (59.5%) used a combination of TED stockings and Flowtron boots, 10 (3.9%) used TED stockings with foot and ankle pumps, and 9 (3.5%) used a combination of TED stockings, foot and ankle pumps and Flowtron boots. In isolation, TED stockings were used by 56 (21.6%) and Flowtron boots by 19 (7.3%). More than half, 137 (52.9%), discontinued mechanical prophylaxis upon discharge, 41 (15.8%) discontinued on mobilisation. While 23 (8.9%)

discontinued 6 weeks after discharge, 18 (6.9%) did so prior to discharge. Twenty-two (8.5%) respondents chose not to answer this question. When asked about recommending continuing prophylaxis after hospital discharge 71 (27.4%) did so, whilst 178 (68%) were against it.

Discussion: A large evidence base has favoured post-operative thromboprophylaxis for many years, with wide international variation in the different approaches.

In the current survey, the response rate was nearly 53%. It is believed that some of the factors that favoured a better return rate were the personalized covering letter, the inclusion of the self-addressed envelope, and the posting during the beginning of the week using second class postage (219).

These results demonstrate a highly variable approach to the use of thromboprophylaxis across the UK. Translation of research evidence to clinical practice does take time, and there are many barriers to evidence based clinical practice. One of them is adopting research findings into practice (193).

There are recent NICE guidelines on venous thromboembolism prophylaxis. NICE guidelines from January 2010 (220) recommend a combined thromboprophylaxis for gastro-intestinal surgical procedures with increased risk of venous thromboembolism and low risk of major bleeding. The mechanical venous thromboembolism prophylaxis should commence at admission, and continue until mobility is no longer significantly reduced. The mechanical venous thromboembolism prophylaxis includes anti-embolism stockings (thigh or knee length), foot impulse devices, or intermittent pneumatic compression

devices (thigh or knee length). For chemo-prophylaxis fondaparinux, LMWH, or UFH (for renal failure patients) is recommended to be continued until mobility is no longer significantly reduced (generally 5–7 days).

The current guideline also lays emphasis on patient centred care (220). The document states that ‘Treatment and care should take into account patients’ individual needs and preferences. Good communication is essential, supported by evidence-based information, to allow patients to reach informed decisions about their care. If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care’.

Questionnaire: This was a simple study designed using a 10 item questionnaire. It inquired into the current management strategy of thrombo-prophylaxis in colorectal surgical practice. There are limitations. It is a very short questionnaire with a yes/no response to many of the questions.

It did not allow an assessment of ‘always, sometimes, occasionally, never’ for certain indications. Reasons were not asked as to why respondents did or did not use a specific agent, or what information would lead people to change practice.

Limitations of the study:

The study did have the limitations of a questionnaire study in that the response rate was only 53%. The responses may not be representative of the whole membership that was surveyed. Also, reminders were not sent; these could have improved the response rate.

Conclusion: In this national survey questionnaire, a small percentage of the

consultants are using chemo-prophylaxis in isolation. In a majority, thrombo-prophylaxis is not continued post-operatively for the recommended period of time as per guidelines. Although current thrombo-prophylaxis practice is acceptable, the use of available national guidelines would further improve the thrombo-prophylaxis practice. However, patient compliance and resources are factors that need consideration.

Future: It would be useful to gather data pertaining to causes of cancer related mortality in the community. This would help in targeting thrombo-prophylaxis use in a better way.

13.0 Discussion

Here is an outline of the various studies that link to the central concept of decision making in surgery and cancer care.

A. Health outcome measures.

12.1 Quality of life and its measurements:

12.2 Quality of life, health-related quality of life and breast surgery:

The background knowledge about health outcome measures and their applications in various sub-specialities of surgery is important in the decision making process in surgery. They influence care providing clinicians as well as the patients in the decision making process. The subsection on health outcome measures in reconstruction and aesthetic breast surgery would influence the relevant clinicians and the patients in the decision making process.

B. Benign breast conditions

12.3 a: Quality of life issues in aesthetic breast surgery :

This section reviews studies involving health outcome measures in aesthetic breast surgery. The work undertaken has tried to create an awareness of health outcome measures in aesthetic breast surgery. This should help clinicians decide when and to whom to offer aesthetic procedures. It will also make them consider the psycho-social issues and body dysmorphic disorder before decision making.

12.3 b Risk factors for complications following reduction mammoplasty:

Higher resect weight, increased BMI, older age, and smoking are some of the risk factors associated with complications in reduction mammoplasty. It is therefore necessary that every attempt is made to reduce modifiable risk factors. Patients should be adequately counselled about losing weight and stopping smoking. Clinical preventive services and health advocates might have an increased role to play in the coming future. These factors should help the clinicians and patients in decision making for reduction mammoplasty.

12.4 . Benign colorectal conditions & quality of life

12. 4 a. Rectal irrigation in the treatment of disorders of faecal continence

Management of evacuatory disorders can be a true challenge. Reflected in this chapter are the generic and specific health outcome measures in relation to rectal irrigation in the treatment of faecal continence disorders. Rectal irrigation can offer symptomatic improvement to patients with faecal evacuatory disorders where other conservative and pharmaco-therapies have failed. Most patients find the treatment acceptable. This will help clinicians to provide information to the patients on the effectiveness and efficacy of rectal irrigation, and to make better decisions in the management of faecal continence disorders.

12.5. Malignant Colorectal, Breast, Head and Neck conditions

12.5 a. 1- 4 : A qualitative analysis of a focus group discussion on decision making in cancer care

Qualitative research based on grounded theory was used to organise focus group discussion to evaluate the decision making process. This was undertaken amongst the care providing clinicians. The focus groups

discussions have added an enormous amount of information to this work. They enabled the identification of the various factors playing a role in decision making, and in particular the role of clinicians, nurses and the patients themselves. It was interesting to analyse what clinicians felt about patient decision making in surgery and cancer care.

The generated themes and outcomes were certainly thought provoking. Common themes and outcomes were generated from the focus group discussions undertaken in England, Wales and India. Decision making in cancer care is a complex physical and cognitive process based on evidence, patient needs, clinician experience, judgement and patient preference. Patient views, knowledge and demands are all taken into account, along with socio-cultural differences. In England, patient decision making in cancer care is slowly growing, albeit currently only occurring in a minority of cases. This minority will play an increased role in decision making in the future and will possibly come to drive decision making. Tradeoffs and risks between survival and quality of life will be considered in decision making in this minority.

In the Welsh population, a drive towards joint decision making is seen. In the future, patients will probably have an increased involvement and role within the multidisciplinary setting. In contrast, the finding from India show that evidence based patient choice has not developed to a large extent, when compared to the western world. Decisions seem to be predominantly clinician led. Attitudes of clinicians differ towards the role of nurses. There is not much of an emphasis on quality of life, and there is a need for patient groups and a stronger patient voice.

Globally in future, patients will probably have an increased involvement/role within the multidisciplinary team setting. The process of decision making is

slowly evolving and will see metamorphosis in future. It is important for clinicians and nurses to play a role leading to this change. Decision making has to be handled delicately and sensitively in cancer care, within the framework of the traditions and culture of the society, and financial constraints.

Questionnaire surveys play an important role in research translation, in addition to assessing the current pattern of practice.

12. 5 b – d : National questionnaire surveys of the members of the ACPGBI

The above questionnaire surveys assessed the translational practice which is vital for implementation of research evidence into clinical practice. Evaluation of the current practice of neo-adjuvant short course radiotherapy in rectal cancer and thrombo-prophylaxis in colorectal surgery were undertaken. The above studies gave an insight into the factors delaying the implementation of evidence based practice. Translational research is something that should be concentrated on to bring change to the way we practice, taking care of other factors. Some of the key lessons learnt were: provide safe and less harmful treatment, increase the role of multidisciplinary teams, and adopt a tailored approach based on individual patient needs. A need to increase awareness of the current evidence based literature, A need to improve service provisions, and to overcome barriers to evidence based practice by synthesizing available research evidence, developing protocols and guidelines, along with shortening the delay in implementing evidence based practice, was highlighted. Change is a slow and complex process influenced not only by scientific data and scientific evidence, but by a number of other factors. Some of the above conclusions will aid policy makers and opinion leaders in the NHS. In addition, they provide significant help in decision making amongst clinicians.

Decision making in surgery and cancer care is an important, challenging field in its own right. Clinicians have to consider that clinical decision making is a complex process driven by a multitude of factors. Some of these are evidence based quantitative data, health outcome measures, clinician factors, patient factors, themes and outcomes generated from the qualitative data, translational factors, evidence based guidelines, feedback from audits, surveys and questionnaire studies, infrastructure/resources and nursing factors. Within the above factors, there is an extensive variability in terms of clinician knowledge, experience, intuition and judgement. The patient factors include education, patient circumstances, socio-cultural factors, trust-beliefs and patient preferences. Nursing colleagues not only have a role to play in communicating and supporting patients, but also take a role in their decision making. In addition, infrastructure and resources also play a role.

Emerging models in decision making are the use of decision aids and decision trees. There are a number of issues that need to be addressed. Some of them involve education and training clinicians in the process of risk communication and the consenting process. Building a robust evidence base by undertaking good prospective studies, creating awareness of health outcome measures amongst clinicians, improving clinician and patient knowledge, considering patient factors when decision making and improving infrastructure and resources will assist in addressing these issues. It is very likely that the evidence provided here help opinion leaders and managers in the NHS to allocate funds and resources for better patient care.

It is important to individualise decision making. Decision aids, decision trees, discharge liaison nurses and an active role by patients in the multidisciplinary

team process are some of the things clinicians will encounter more. Because of this, clinicians should act as catalysts and leaders for this improved decision making in surgery and cancer care.

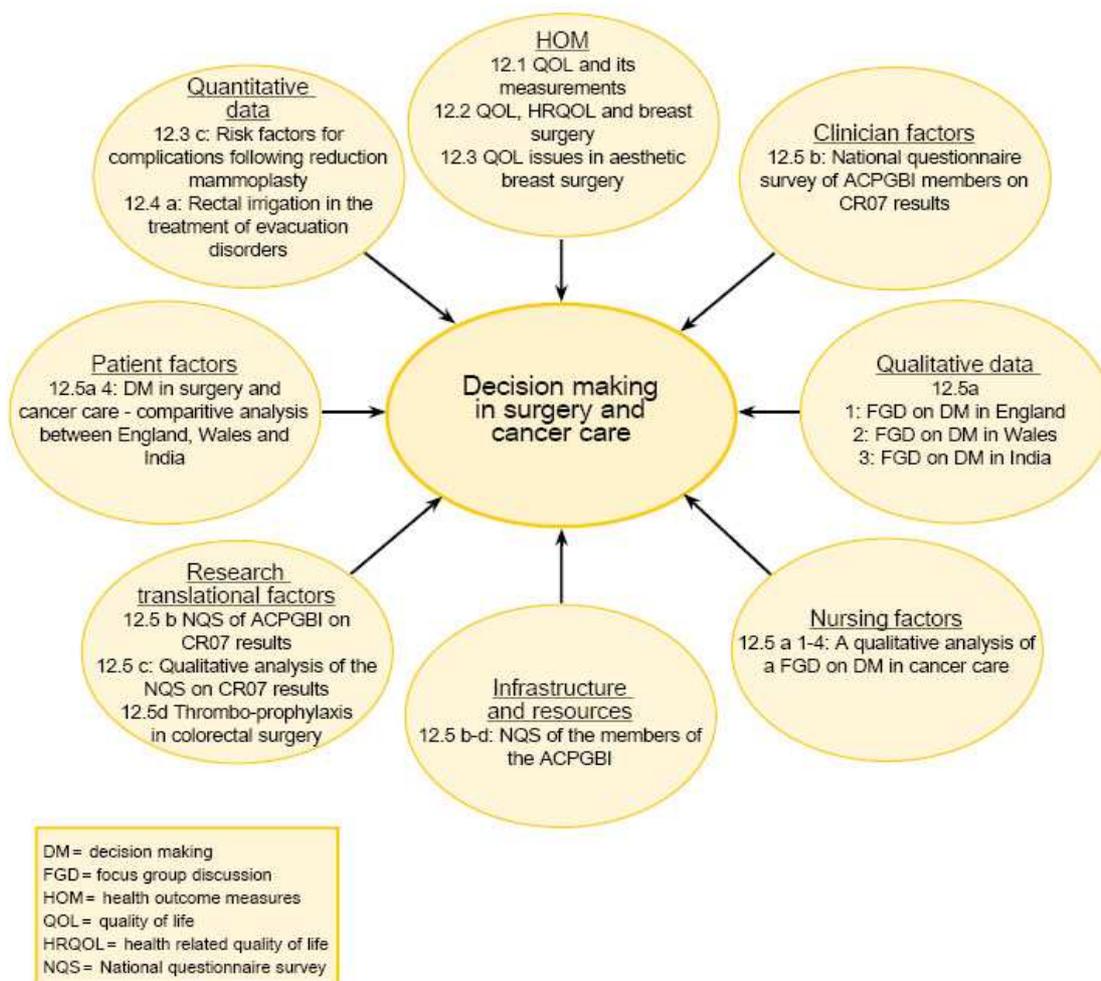
Diagram 2 illustrates the multi-factorial nature of decision making. The results of these studies have demonstrated that decision making does not rely just on the hard quantitative data, but is an amalgamation of a number of factors. This disproves the hypothesis that clinical decisions are not multi-factorial and are solely based/dependent on hard quantitative research data. The quantitative evidence base is only one of the factors aiding decision making. There are, as has been shown, a number of other factors which are less explored, yet still play an important role in decision making.

The chapters on health outcome measures, and their relevance to oncology and aesthetics demonstrate their importance in decision making. The reviews and questionnaire studies have generated quantitative data. Focus group discussions have provided an enormous amount of qualitative data.

The work undertaken has demonstrated the interplay between clinicians, nurses, patients and their families in the decision making process. Research translational factors, infrastructure and resources are other factors that play a role in decision making. The clinician factors (knowledge, skill, expertise, judgment), patient factors (socio-economic, education, cultural) and nursing factors all play a vital role in the whole process of decision making.

Decision making is a dynamic process and clinicians need to understand this multi-factorial process well, enabling the adoption and training required to help patients in decision making, whilst not forgetting that the patient is at the centre of the whole process.

Diagram 2. Multifactorial nature of decision making.



This work is timely in shedding light on current practice in decision making in surgery and cancer care, and the role patients play within this process, an issue that has taken a centre stage with the patient at the heart of healthcare. The evidence that has been generated can be used to improve the decision making process in everyday practice. Based on the work undertaken, it is not only important to generate scientific data, but also look into all the factors that have an impact on clinical decision making. Translational research is important for

implementing research evidence into clinical practice, infrastructure and resources need consideration, along with the continued medical education of clinicians, involving training on risk communication, keeping up with audit and research, seeking patients opinions and measuring health outcome measures. These should all be a part of the process in improving the decision making process. Healthcare is in a globalisation phase. It is important to understand and respect the cultural variation that exists in different parts of the world while decision making.

To the best of the author's knowledge, this study is the first to explore how clinical decisions are made in a developing country and to compare this process with the west.

14.0 Conclusions

In conclusion, the results from our studies show that the *decision making process is multi-factorial*. Quantitative data is only a contributing factor in the process and it is vital that qualitative data, nursing factors, patient factors, translational research, health outcome measures, infrastructure and resources, socio-economic and cultural factors, in addition to patient preferences are considered in the decision making process. Currently, in the western world, the majority of decisions are made jointly between the clinicians and patients, although there is a small minority of patients who are leading the process. In the developing world, decisions currently seem to be clinician led.

15.0 Thesis – Limitations

The lack of research in the area of decision making in surgery and cancer care was certainly a disadvantage, leaving a minimal foundation to build on.

Adopting qualitative research methods and tools, which do not sit easily with quantitative methods, into the research was a challenge. It is hoped that the mixed methodology, combining the elements of psychology, sociology and surgery, has been successfully demonstrated.

I would have preferred to involve patients as participants and provide them with hypothetical scenarios, and evaluate the decision making process. In the process, I wanted to adopt the principles of prospective measure of preferences. The prospective measures of preferences (221) bring the concepts of 'Willingness to Trade' and 'Willingness to Gamble'. This would have thrown light on the way patients would trade and gamble the length of survival to quality of life and vice-versa. Unfortunately, this was not possible due to ethical issues.

Involving patient representatives, nursing colleagues and specialist nurse practitioners in this research from the beginning would have made the process easier. In the initial chapters, the literature reviews would have been improved if a systematic approach was adopted, rather than general literature reviews. Focus group discussions involving patients would have given us the patients' views on decision making. However, obtaining ethical approval for this was not possible in the form presented. As highlighted earlier, help from patient representatives, nurses and specialist nurse practitioners is vital in the process.

A sizable portion of this research work is in the form of questionnaire studies. It carries the inherent bias of lack of data from the non-responders. While there was a 50–60% response rate, which is normal for questionnaire surveys, reminders might have increased the response rate.

16.0 The future:

This academic exercise has provided the basis for more thoughts, ideas and stimulation for further work. There are several elements; practical and theoretical, requiring further investigation that has been identified by this thesis: There are issues regarding previously unrecorded cultural and socioeconomic parameters that have been demonstrated by this work. It is clear that even within the UK there are differences that affect the decision making process. This requires further work to evaluate it more clearly as, unlike the USA and Europe, UK patients are not willing to travel to obtain what is perceived as the best treatment, and therefore some form of homogeneity must be maintained if standard treatment opportunities and outcomes are to be equal. If the difference is necessary for socioeconomic or other reasons, the contextual heterogeneity must be recognized in order to facilitate true patient choice.

The role of patients in the multidisciplinary team needs to be explored and developed accordingly, along with further studies into preferences using the concepts of willingness to trade and willingness of gamble, and their influencing factors.

Patient preferences should play an important role in clinical decision making. For this, it is important that actual patient preferences are determined. The literature increasingly demonstrates that surgeons and physicians have divergent preferences for treatment options compared with both their patients and each other (10), (11), (12). Thirty to forty percent of critical medical decisions are made by doctors for their patients (13), (14), (15), (16), (17) . This rate increases when patients are acutely unwell, elderly, or dealing with cancer

(14), (15). When this is the case, it is important to know what influences clinician decision making. Solomon et al (10) in their study titled “What do patients want? Patient preferences and surrogate decision making in the treatment of colorectal cancer.” demonstrated that patients are willing to trade survival for quality of life and can do so differentially between treatment scenarios. They proved that patients’ preferences do not always accord with those of clinicians. They stated that unless patients' preferences are explicitly sought and incorporated into clinical decision making, patients may not receive the treatment that is best for them..... 21

Focus group: A focus group is a formal discussion with 8–12 people on a specific topic. The group is facilitated by a moderator who keeps participants focused on the topic of interest. The purpose of a focus group is to collect in-depth information from a group of people who represent the population of interest. This useful, qualitative research tool has been an underutilized research technique for improving theory and practice in health education (162) , (163)..... 91

SL no.7..... 191

SL no. 08..... 193

Practically, it is clear clinicians need to be educated in communication of risk and informed consent. The recent GMC guidance on consent is an illustration of this (222). Clinicians need to be aware of the complex process of decision making and the factors that may influence it. Only then can clinicians truly begin to form a partnership with patients in order to, not only provide them not only with the care we think they need, but also with the care they actually want.

In the near future, I hope to integrate the available quantitative and qualitative data from my thesis in a systematic manner using the newer techniques of triangulation protocol, following the thread, and mixed methods matrix.

17.0 Appendix

Appendix 1: Questionnaire and responses for the GSQ pre and post RI

		Pre	Post
Q1 How often do you empty your bowel	More than 6 times per day	1.4%	0.0%
	4-5 times per day	11.4%	7.3%
	2-3 times per day	32.9%	14.6%
	Once per day	14.3%	46.3%
	4 times a week	7.1%	9.8%
	2-3 times per week	18.6%	17.1%
	Once per week	2.9%	2.4%
	Less than once per week	11.4%	2.4%

There is no significant difference between the pre and post values, $z=-0.684$, $p=0.494$.

		Pre	Post
Q2 Are your bowel motions mostly...	Liquid	11.3%	2.4%
	semi-solid	22.5%	22.0%
	Formed	25.4%	31.7%
	Soft	21.1%	24.4%
	Hard	14.1%	14.6%
	Pellets	5.6%	4.9%

There is no significant difference between the pre and post values, $z=-0.187$, $p=0.852$.

		Pre	Post
Q3 Ever strain to empty your bowel	Always	52.2%	14.0%
	Daily	20.3%	23.3%
	Weekly	11.6%	18.6%
	Monthly	4.3%	11.6%
	Rarely	8.7%	23.3%
	Never	2.9%	9.3%

There *is* a significant difference between the pre and post values, $z=-3.70$, $p=0.000^{**}$.

		Pre	Post
Q4 Ever feel your haven't completely emptied	Always	69.0%	23.8%
	Daily	23.9%	21.4%
	Weekly	4.2%	23.8%
	Monthly	0.0%	4.8%
	Rarely	1.4%	16.7%
	Never	1.4%	9.5%

There *is* a significant difference between the pre and post values, $z=-3.844$, $p=0.000^{**}$.

		Pre	Post
Q5 Ever need to rush to empty your bowel	Always	10.1%	7.3%
	Daily	14.5%	2.4%
	Weekly	17.4%	19.5%
	Monthly	7.2%	12.2%
	Rarely	30.4%	29.3%
	Never	20.3%	29.3%

There is no significant difference between the pre and post values at the 95% confidence level, but there is at the 90% confidence level, $z=-1.948$, $p=0.051^*$.

		Pre	Post
Q6 Wind leakage	2 or more per day	59.7%	39.5%
	once per day	6.5%	7.9%
	2 or more pre week	8.1%	2.6%
	once per week	3.2%	13.2%
	1-3 times a month	8.1%	18.4%
	Never	14.5%	18.4%

There *is* a significant difference between the pre and post values, $z=-2.533$, $p=0.011^{**}$.

		Pre	Post
Q7 Mucous leakage	2 or more per day	12.5%	0.0%
	once per day	7.1%	7.9%
	2 or more pre week	5.4%	2.6%
	once per week	3.6%	5.3%
	1-3 times a month	16.1%	10.5%
	Never	55.4%	73.7%

There is no significant difference between the pre and post values, $z=-0.366$, $p=0.714$.

		Pre	Post
Q8 Liquid leakage	2 or more per day	12.7%	5.3%
	once per day	3.6%	5.3%
	2 or more pre week	10.9%	5.3%
	once per week	7.3%	7.9%
	1-3 times a month	9.1%	7.9%
	Never	56.4%	68.4%

There is no significant difference between the pre and post values, $z=-0.905$, $p=0.365$.

		Pre	Post
Q9 Solid leakage	2 or more per day	1.8%	2.6%
	once per day	0.0%	2.6%
	2 or more pre week	8.8%	5.3%
	once per week	3.5%	2.6%
	1-3 times a month	14.0%	10.5%
	Never	71.9%	76.3%

There is no significant difference between the pre and post values, $z=-0.144$, $p=0.886$.

		Pre	Post
Q10 Do you ever wear a pad for urinary symptoms	Yes	29.0%	19.5%
	No	71.0%	80.5%

There is no significant difference between the pre and post values, $z=0.000$, $p=1.000$.

		Pre	Post
Q11 Do you ever wear a pad for bowel symptoms	Yes	24.3%	16.7%
	No	75.7%	83.3%

There is no significant difference between the pre and post values, $z=-0.577$, $p=0.564$.

		Pre	Post
Q12 Does your bowel problem affect your life	Yes	88.7%	69.0%
	No	11.3%	31.0%

There is no significant difference between the pre and post values at the 95% confidence level, but there is at the 90% confidence level, $z=-1.941$, $p=0.052^*$.

		Pre	Post
Q13 Ever feel like the area between your anus & vagina is swollen	All of the time	8.9%	3.3%
	most of the time	20.0%	10.0%
	some of the time	42.2%	43.3%
	A little of the time	11.1%	13.3%
	none of the time	17.8%	30.0%

There is no significant difference between the pre and post values, $z=-1.058$, $p=0.290$.

		Pre	Post
Q14 Ever feel your bowel is pushing forwards into your vagina	All of the time	23.3%	3.6%
	most of the time	20.9%	10.7%
	some of the time	39.5%	46.4%
	A little of the time	0.0%	7.1%
	none of the time	16.3%	32.1%

There is no significant difference between the pre and post values, $z=-1.655$, $p=0.100$.

		Pre	Post
Q15 Ever need to apply pressure on the area between the anus & vagina	All of the time	20.0%	0.0%
	most of the time	24.4%	27.6%
	some of the time	28.9%	20.7%
	A little of the time	2.2%	10.3%

time		
none of the		
time	24.4%	41.4%

There *is* a significant difference between the pre and post values, $z=-2.598$, $p=0.009^{**}$.

		Pre	Post
Q16 Ever need to help yourself empty the bowel	All of the time	9.3%	6.5%
	most of the time	25.6%	12.9%
	some of the time	27.9%	19.4%
	a little of the time	20.9%	19.4%
	none of the time	16.3%	41.9%

There is no significant difference between the pre and post values, $z=-1.610$, $p=0.107$.

		Pre	Post
Q17 Do you ever rush to pass water	Always	11.1%	2.6%
	Daily	27.0%	12.8%
	Weekly	0.0%	5.1%
	Monthly	6.3%	12.8%
	Rarely	44.4%	46.2%
	Never	11.1%	20.5%

There is no significant difference between the pre and post values, $z=-1.235$, $p=0.217$.

		Pre	Post
Q18 Do you ever leak urine if you cough, sneeze	Always	21.5%	14.6%
	Daily	13.8%	7.3%
	Weekly	13.8%	2.4%
	Monthly	7.7%	19.5%
	Rarely	21.5%	34.1%
	Never	21.5%	22.0%

There *is* a significant difference between the pre and post values, $z=-2.034$, $p=0.042^{**}$.

		Pre	Post
Q19 Do you ever not make it in	Daily	9.4%	0.0%

time to pass urine

Weekly	1.6%	5.1%
Monthly	3.1%	2.6%
Rarely	43.8%	48.7%
Never	42.2%	43.6%

There is no significant difference between the pre and post values, $z=-0.299$, $p=0.765$.

Appendix 2: Questionnaire – A NQS on preliminary results of CRO7 survey

Questionnaire

Pre - Operative

- Q 1. In clinically operable rectal cancer <15cm from anal verge with no metastases, i.e. T1/T2, do you routinely use Neo – Adjuvant short course DXT ?
Yes No
- Q 2. For T3 rectal cancer do you routinely use Neo Adjuvant short course DXT?
Yes No
- Q 3. For T3 rectal cancer do you routinely use Neo Adjuvant long course DXT?
Yes No
- Q 4. Does your decision to use Neo-adjuvant treatment depend on the Tumour position i.e. height from the anal verge?
Yes No
- Q 5. Does your decision to use Neo-adjuvant treatment depend on whether the tumour is located anterior or posterior
Yes No
- Q 6. Does your decision to use neo-adjuvant treatment depend on +ve CRM on MRI?
Yes No

Post – Operative

- Q 7. In patients who have not had pre-operative DXT, do you routinely give post – operative DXT if the CRM was +ve histologically?
Yes No
- Q 8. Do you give Chemotherapy post – operatively if the CRM was +ve histologically?
Yes No
- Q 9. How do you treat patients who have had pre – operative Short course DXT and post – operatively have CRM involvement?

- Q 10. How do you treat patients who have had pre – operative long course DXT and post – operatively have CRM involvement?

- Q 11. With the preliminary results of the CRO7 trial, has there been any change in your practice?
Yes No
- Q 12. Who is responsible for directing chemotherapy in your unit?
Colorectal Surgeons Oncologists
- Q 13. If you direct the adjuvant chemotherapy, which agent is used as per your local policy?

- Q 14. Please write your comments here

Thank you for your time!

National Questionnaire survey amongst the consultant members of the ACPGBI on Thrombo-prophylaxis (TP) in major colorectal surgery.

Q 1. Are there any departmental guidelines in use for thrombo-prophylaxis in colorectal surgery?

Yes No

Q 2. Do you routinely use Thrombo-prophylaxis for major colorectal resections?

Yes No

Q 3. Which type of TP do you use in your Colo-rectal resection patients?

Chemoprophylaxis Mechanical Both

Q 4. If you use Chemo-prophylaxis which agents do you use? (You can mark more than one).

Aspirin Unfractionated Heparin LMW Heparin Heparin Others

Others

Q 5. When do you start chemoprophylaxis on patients?

On Admission On Induction 6 hours Post-op 24 hours post-op

Q 6. At what stage do you discontinue chemoprophylaxis?

On mobilization prior to discharge Upon discharge 6 weeks after discharge

Others

Q 7. What mechanical devices do you use for Thrombo-prophylaxis? (You can mark more than one)

TED stocking Foot & Ankle pump Flowtron boots Others

Q 8. At what stage do you discontinue mechanical Thrombo-prophylaxis?

On mobilization prior to discharge Upon discharge 6 weeks after discharge

Others

Q 9. "Do you recommend continuing prophylaxis after hospital discharge?"

Yes No

If "Yes", How long for? What agent?

Q 10. Please write your comments here

Thank you for your time and co-operation!

Appendix 4: Stimulus material for focus group discussions (Abstracts of publications and title guide)

SL no. 01

An economic perspective on evidence-based patient choice in surgery.

The aim of the present paper is to provide an economic perspective on current and emerging issues relating to surgical decision-making. The central issue discussed in the paper is choice and how this relates to patient management. The paper explores three factors that may influence the nature of choice; they are--evidence-based medicine, patient involvement in making choices and the role of cost-effectiveness analysis in surgery. Together, these factors are driving a shift from the traditional model of care based on medical beneficence to one based more on individual patient autonomy. This shift has been described as a move towards 'evidence-based patient choice' (EBPC). The concept of EBPC is relatively new and ill defined. Yet it encapsulates what is happening now and what will occur more dramatically in the future; that is, the nature of the relationship between surgeon and patient is changing. We hope that this paper will provoke discussion on the concept of EBPC and cost-effectiveness analysis in surgical decision-making

SL no. 02

What do patients want? Patient preferences and surrogate decision-making in the treatment of colorectal cancer.

PURPOSE: Clinicians often make decisions for their patients, despite evidence that suggests that correspondence between patient and clinician decision making is poor. The management of colorectal cancer presents difficult decisions because the impact of treatment on quality of life might overshadow its survival efficacy. This study investigated whether patients are able to trade survival for quality of life as a means to express their preference for treatment options and to compare their preferences with those expressed by clinicians.

METHODS: Patients undergoing curative surgery for colorectal cancer were interviewed postoperatively to elicit their preferences in four hypothetical treatment scenarios. A questionnaire was mailed to all Australian colorectal surgeons and medical oncologists that asked them to respond as if they themselves were patients.

RESULTS: One hundred patients (91 percent), 43 colorectal surgeons (77 percent), and 103 medical oncologists (50 percent) participated. In all four scenarios, patients were able to trade survival for quality of life. Patients' responses varied between scenarios, both in willingness to trade and the average amount traded. There were significant differences between patients and clinicians. Clinicians were more willing than patients to trade survival to avoid a permanent colostomy in favour of chemo radiotherapy. Patients'

strongest preference was to avoid chemotherapy, more than to avoid a permanent colostomy.

CONCLUSIONS: Patients are able to trade survival as a measure of preference for quality of life and can do so differentially between treatment scenarios. Patients' preferences do not always accord with those of clinicians. Unless patients' preferences are explicitly sought and incorporated into clinical decision-making, patients may not receive the treatment that is best for them.

SL no. 03

Lack of congruence in the ratings of patients' health status by patients and their physicians.

PURPOSE: The purpose of this study was to examine if physician assessments of their patients' health status after the medical encounter are comparable to their patients' self-assessment of their own health.

METHODS: Consecutive patients with musculoskeletal diseases were recruited when they attended 1 of the rheumatology outpatient clinics selected for the study. Five physicians participated in the study, 4 based at an academic centre and 1 in the community. Patients were interviewed after seeing the physician; they completed health status questionnaires (mHAQ and SF-12) and rated their pain, worry about disease, and overall health status on visual analog scales. Standard gamble techniques were used to obtain patient utilities in relation to their health status, "gambling" on the probability of obtaining perfect health from an intervention with varying risks of death. After the medical encounter, physicians were asked to rate their patients' health status with similar instruments and with standard gamble elicitation techniques, blinded to the patients' responses.

RESULTS: A total of 105 patients participated in the study; 70% were female; mean age was 54+/-16 years; 64% had a connective tissue disease, most commonly rheumatoid arthritis; and the other diseases in this group included soft tissue rheumatism, osteoarthritis, or low back pain. Statistically significant

differences were observed between patient and physician ratings for pain, overall health, and standard gamble. On average, physicians rated their patients' health status higher than the patients themselves and were less willing to gamble on the risk of death versus perfect health. Intra-class correlation coefficients (ICC) were low: 0.42 for pain, 0.11 for worry, 0.11 for overall health, and 0.04 for standard gamble utilities. Similar findings were observed when subgroup analysis was performed for individual physicians and for patients with connective tissue diseases. No specific patient characteristic consistently related to increased divergence in the ratings.

CONCLUSIONS: These findings suggest that the communication between physicians and their patients at the time of the medical encounter needs to be enhanced. An understanding of their patients' health perceptions may assist physicians in suggesting appropriate interventions, taking into account their patients' benefit-risk preferences.

Treatment decisions for breast carcinoma: patient preferences and physician perceptions.

BACKGROUND: Patient autonomy and participation in treatment decision making have been encouraged in recent years. However, patients and physicians frequently disagree with regard to the patient's needs and perceptions of their illness. To the authors' knowledge to date only limited research has assessed physicians' perceptions of patients' decision-making preferences. The purpose of the current prospective study was to determine the agreement between patient decision-making preferences and physician perceptions of those preferences.

METHODS: Women with breast carcinoma who were attending their first outpatient consultation with a breast medical oncologist in a university cancer centre were enrolled in the current study. At the end of the consultation, the patients were given a survey regarding their treatment decision-making preferences that included active, shared, and passive roles in decision-making and the patients' attending physicians also were given a survey regarding their perceptions of the patients' decision-making preferences.

RESULTS: Fifty-seven patients had complete data and were analyzed. Approximately 89% of these 57 patients preferred either an active or a shared role in decision making. The agreement between patients and physicians with regard to decision-making preference only occurred in 24 cases (42%). The

majority of covariates such as age, education, and income were not found to be statistically significant with regard to patient preferences or to the proportion of patients and physicians who agreed on the patient's preferences.

CONCLUSIONS: Women with breast carcinoma appear to have a strong desire for involvement in making decisions regarding their treatment. However, physicians do not appear to be consistently able to predict the decision-making preferences of their patients. Enhanced agreement between patient preferences and physician expectations mostly likely will improve communication and patient satisfaction with the treatment decision-making process.

SL no.7

The impact of patients' preferences on the treatment of atrial fibrillation: observational study of patient based decision analysis

OBJECTIVE: To investigate the impact of patients' preferences for the treatment of atrial fibrillation, by using individualised decision analysis combining probability and utility assessments into a decision tree.

DESIGN: Observational study based on interviews with patients.

SETTING: Eight general practices in Avon.

PARTICIPANTS: 260 randomly selected patients aged 70-85 years with atrial fibrillation.

MAIN OUTCOME MEASURES: Patients' treatment preferences regarding anticoagulation treatment (warfarin) after individualised decision analysis; comparison of these preferences with treatment guidelines on the basis of co-morbidity and absolute risk and compared with current prescription.

RESULTS: Of 195 eligible patients, 97 participated in decision making using decision analysis. Among these 97, the decision analysis indicated that 59 (61%; 95% confidence interval 50% to 71%) would prefer anticoagulation treatment-considerably fewer than those who would be recommended treatment according to guidelines. There was marked disagreement between the decision

analysis and guideline recommendations ($\kappa=0.25$ or less). Of 38 patients whose decision analysis indicated a preference for anticoagulation, 17 (45%) were being prescribed warfarin; on the other hand, 28 (47%) of 59 patients were not being prescribed warfarin although the results of their decision analysis suggested they wanted to be.

CONCLUSIONS: In the context of shared decision making, individualised decision analysis is valuable in a sizeable proportion of elderly patients with atrial fibrillation. Taking account of patients' preferences would lead to fewer prescriptions for warfarin than under published guideline recommendations. Decision analysis as a shared decision making tool should be evaluated in a randomised controlled trial.

SL no. 08

Preference-based anti-thrombotic therapy in atrial fibrillation: implications for clinical decision making

BACKGROUND: Patient preferences and expert-generated clinical practice guidelines regarding treatment decisions may not be identical. The authors compared the thresholds for anti-thrombotic treatment from studies that determined or modelled the treatment preferences of patients with atrial fibrillation with recommendations from clinical practice guidelines.

METHODS: Methods included MEDLINE identification, systematic review, and pooling with some reanalysis of primary data from relevant studies.

RESULTS: Eight pertinent studies, including 890 patients, were identified. These studies used 3 methods (decision analysis, probability trade-off, and decision aids) to determine or model patient preferences. All methods highlighted that the threshold above which warfarin was preferred over aspirin was highly variable. In 6 of 8 studies, patient preferences indicated that fewer patients would take warfarin compared to the recommendations of the guidelines. In general, at a stroke rate of 1% with aspirin, half of the participants would prefer warfarin, and at a rate of 2% with aspirin, two thirds would prefer warfarin. In 3 studies, warfarin must provide at least a 0.9% to 3.0% per year absolute reduction in stroke risk for patients to be willing to take it, corresponding to a stroke rate of 2% to 6% on aspirin.

CONCLUSIONS: For patients with atrial fibrillation, treatment recommendations from clinical practice guidelines often differ from patient preferences, with substantial heterogeneity in their individual preferences. Since patient preferences can have a substantial impact on the clinical decision-making process, acknowledgment of their importance should be incorporated into clinical practice guidelines. Practicing physicians need to balance the patient preferences with the treatment recommendations from clinical practice guidelines.

Treatment decision-making and its relation to the sense of coherence and the meaning of the disease in a group of patients with colorectal cancer.

The aims of the present study were to describe the preferred and the actual participating roles in treatment decision-making in relation to patients with newly diagnosed, colorectal cancer and to relate this result to the socio-demographic data, the Sense of Coherence Scale (SOC) and the patients' meaning of the disease. Eighty-six patients were studied. The following instruments were used: the Control Preferences Scale (CPS); the eight Lipowski categories of the meaning of the disease (LCMD); and the SOC. The results showed that 62% of the patients preferred a collaborative role and 28% a passive role in treatment decision-making. Agreement between the preferred and the actual participating roles was achieved by 44% of the patients. Seventy-one per cent of the patients showed an optimistic understanding of their disease. The mean SOC score was 150. There was no statistically significant difference between the CPS groups as regarded the socio-demographic data, the SOC and the LCMD. Conclusion: Socio-demographic data, the perceived meaning of the disease as well as the patients' sense of coherence were not related to the decision-making preferences in the investigated group of patients. Therefore, further investigations are needed to get an understanding of influencing factors of the decision-making preferences.

SL no. 10

Lay constructions of decision-making in cancer.

In recent years there has been increased emphasis on involving people in decision-making about their medical care. However, few studies have addressed the questions of why women with cancer want information, and what they believe to be the important factors influencing their decision-making. In order to examine these questions 20 women with cancer were interviewed via telephone 2 weeks after their first consultation with one of 6 medical oncologists. Recruitment continued until informational redundancy was achieved. While women cited the risk of recurrence, life expectancy, side-effects, and quality of life as influencing their decisions, they placed at least as much emphasis on their personal relationship with the specialist. These 'personal' factors included: feeling that the doctor cared for, understood and respected them; that they could trust and have confidence in the doctor; that the doctor would give them enough time; that they would be listened to; and that the doctor would be open and honest. If these factors were felt to be present, many women were happy to accept the doctor's recommendation, confident that they would receive the optimum treatment. However, many women felt there was no decision to be made: further treatment must be undertaken to reduce risk, and minor variations in the treatment protocol were of little significance. These results underline the importance of establishing patient priorities and concerns before embarking on discussions about treatment.

SL no. 11

Can the standard gamble be used to determine utilities for uncertain health states? An example using postoperative maintenance therapy in Crohn's disease.

The objective of this study was to determine whether patients with Crohn's disease (CD) value the absolute reduction in postoperative recurrence risk attributable to therapy with mesalamine (5-ASA). One hundred subjects evaluated state A (taking 5-ASA; 25% risk of recurrence), state B (not taking 5-ASA; 40% risk of recurrence), and state C (100% risk of recurrence) by rank order, visual analog scale (VAS), and standard gamble (SG). Sixty-five of 91 patients (71%) with completed and usable questionnaires had the same preference order for state A (25% risk), state B (40% risk), and state C (100% risk) on both the VAS and the SG. The mean scores for state A (25% risk), state B (40% risk), and state C (100% risk), respectively, were 67.5, 49.8, and 19.8 on the VAS and 0.977, 0.972, and 0.910 on the SG. Subgroup analyses using stepwise logistic regression showed that risk attitude seemed to be predictive of subjects' preferences for 5-ASA. These results suggest that most subjects seem to value the 15% absolute risk reduction offered by 5-ASA. Furthermore, the SG seems to be a feasible method for measuring utilities for uncertain health states in patients with CD.

SL no. 12

Patient preference for cancer therapy: an overview of measurement approaches.

PURPOSE: In the era of evidence-based medicine and shared decision making, the formal assessment of patient preference for treatments or treatment outcomes has attracted much attention. In this article, the two most common approaches to the evaluation of preference, i.e. utility assessment and probability trade-off assessment are described. The purpose is to provide clinicians with the background knowledge needed to interpret preference studies published in the literature and to judge whether the reported findings are relevant to their own patients.

METHODS: An overview is given of the methods used to assess utilities and probability trade-off scores. Evidence on determinants of such scores is presented. Examples from oncology are provided. Because experience with the treatment plays an important role as a determinant of preferences for both treatments and treatment outcomes, special attention is paid to the interpretation of studies in the light of subject selection. Directions for future research are suggested.

CONCLUSION: The choice of approach and the measuring instrument depend on the goal of the preference assessment. Normal psychological processes, such as coping, adaptation, and cognitive dissonance reduction, cause patients

who are about to undergo a therapy or have experienced a therapy to rate it more favourably than other patients do. This should be remembered when using evidence from the literature to inform patients or for patient decision making.

SL no. 14

Variability in physician opinion on limiting paediatric life support

OBJECTIVE: We conducted this study to investigate how physicians in a paediatric intensive care unit (ICU) currently make decisions to withdraw and withhold life support. Consultation with the patient's primary caregiver often precedes decisions about withdrawal and limitation of life support in chronically ill patients. In these scenarios, the patient's primary caregiver was the paediatric oncologist. To evaluate the influence of subspecialty training, we compared the attitudes of the paediatric intensivists and the oncologists using scenarios describing critically ill oncology patients.

DESIGN: Cross-sectional survey. Each physician was randomly assigned 4 of 8 potential case scenarios.

SETTING: A total of 29 American paediatric ICUs.

PARTICIPANTS: Paediatric intensive care and oncology attendings and fellows.

INTERVENTION: Systematic manipulation of patient characteristics in two hypothetical case scenarios describing 6-year-old female oncology patients presenting to the ICU after the institution of mechanical ventilator support for acute respiratory failure. Cases 1 through 4 described a patient who, before

admission, had a 99% projected 1-year probability of survival from her underlying cancer and suffered from severe neurological disabilities. Cases 5 through 8 described a patient who was neurologically normal before admission and had a <1% chance of surviving longer than 1 year because of her underlying cancer. Each physician was randomly assigned 2 cases from cases 1 through 4 and 2 cases from cases 5 through 8. Within each of these case scenarios, parental preferences (withdraw or advance support or look for guidance from the caregivers) and probabilities of survival (5% vs. 40%) were manipulated. Before distribution, the survey instrument was pilot-tested and underwent a rigorous assessment for clinical sensibility.

PRIMARY OUTCOME MEASURES: Physicians ratings of the importance of 10 factors considered in the decision to withdraw life support, and their decisions about the appropriate level of care to provide. Respondents were offered five management options representing five levels of care: 1) discontinue inotropes and mechanical ventilation but continue comfort measures; 2) discontinue inotropes and other maintenance therapy but continue mechanical ventilation and comfort measures; 3) continue with current management but add no new therapeutic intervention; 4) continue with current management, add additional inotropes, change antibiotics and the like as needed, but do not start dialysis; and 5) continue with full aggressive management and plan for dialysis if necessary. Respondents also were asked whether they would obtain an ethics consultation.

RESULTS: A total of 270 physicians responded to our survey (165 of 198 potentially eligible paediatric intensivists and 105 of 178 paediatric oncologists for response rates of 83% and 59%, respectively). The respondents considered

the probability of ICU survival and the wishes of the parents regarding the aggressiveness of care most important in the decision to limit life-support interventions. No clinically important differences were found when the responses of oncologists were compared with those of intensivists. In six of eight possible scenarios, the same level of intensity of care was chosen by less than half of all respondents. In three scenarios, $\geq 10\%$ of respondents chose full aggressive management as the most appropriate level of care, whereas another $\geq 10\%$ chose comfort measures only when viewing the same scenario. The most significant respondent factors affecting choices were professional status (attending vs fellow) and the self-rated importance of functional neurological status. The majority of respondents (83%) believed that the intensive care and the oncology staff were usually in agreement at their institution about the level of intervention to recommend to the parents.

Topic guides for participants

- Patient decision making in cancer care
- Journey from diagnosis to treatment decision
- Who decides your treatment?
- What matters? Length or quality of life?
- Decision making pathway ... WHO LEADS?
- Patient preference and clinical decision making
- Prospective measure of preferences
 - Time trade off and standard gamble
 - Willingness to trade (WTT) and Willingness to gamble (WTG)
 - Prospective measure of preference – gamble (PMPg)
 - Prospective measure of preference – trade (PMPt)

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