

Regional Consent Audit

August 2007

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Finally my sincerest thanks to the patients who took the time and effort to complete the Patient Questionnaire which provided such valuable information about the patient experience of consent.

Paddie Blaney

Chair Regional Consent Steering Group

EXECUTIVE SUMMARY

“Patients have a fundamental legal and ethical right to determine what happens to them. Valid consent to treatment is therefore absolutely central in all forms of health care, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health care professionals and patients.”

Good Practice in Consent: Implementation Guide for health care professionals, March 2003.

The multi-professional Regional Consent Audit Steering Group, chaired by Ms Paddie Blaney, Chief Executive of NIPEC¹, was set up in September 2006 with the aim of identifying that regional consent practice was carried out effectively, to provide guidance on completion of the audit stages; to arrange a regional workshop to agree an action plan if required and to provide a report on the Regional Audit of Consent to the Chief Medical Officer (CMO), Department of Health, Social Services & Public Safety (DHSSPS NI) by March 2007.

Consent is an important aspect of professional practice across all health and social care settings, however in order to audit professional practice of formal written consent the Regional Consent Steering Group agreed that the regional audit should focus on consent to operative procedure and that there would be three strands to the audit; one looking at the quality of information leaflets, one reviewing audit information already produced by Trusts and lastly one surveying patients’ experience of consent practice over a two day discharge period.

Following the correlation of the data and identification of initial recommendations a regional workshop was arranged to enable Trusts to inform and subsequently own the recommended actions arising from the audit.

Some themes emerged across all three strands of the audit, reflecting both good practice and areas for enhancement in the consent process such as; ensuring that Trusts had embedded sound consent practices across all health and social care settings, that consent training is included in all relevant professional training and education and that consent is seen as a process of providing information and agreeing a decision. In addition it is important that capacity issues are well understood, that information about alternative

¹ Northern Ireland Practice & Education Council for Nursing & Midwifery

management options, anaesthetic, recovery benefits and risks of procedures are addressed. There was also a need to review the current documentation to ensure that it supported the best of consent practice.

The audit also identified areas for enhancement in relation to written information leaflets. Leaflets should provide up-to-date information needed to support the consent process and should include contact details for people wanting further advice.

In order to provide a more standardised approach to organisational audits a regional organisational audit tool was developed based on the assortment of different audit tools supplied. Various elements of the patient's experience of consent practice were also identified as necessary in order to ensure a positive consent experience.

BACKGROUND

In March 2003, the Department of Health Social Services & Public Safety (DHSSPS) issued guidance on consent "*Good Practice in Consent*" which stated, "*The Department of Health, Social Services and Public Safety (DHSSPS) recognizes that consent procedures are of central importance and must recognise the rights of each individual. Seeking consent to treatment and care should be about enabling people to make health and social care choices which are right for them, and recognizing that different people will make different choices in apparently similar situations*".

As patients and staff move between different Health & Social Care (HSC) organisations throughout Northern Ireland it is important that both the consent forms and the information used across the HSC is standardised. The DHSSPS have issued standard consent forms and guidelines, but the information regarding individual procedures is decided on locally.

Following the Regulation & Quality Improvement Authority (RQIA) Report - "*Review of the Lessons Arising from the Death of Mrs Janine Murtagh*" (October 2005) it was recommended that "*A Regional review of the application of the DHSSPS (April 2004) Reference guide to consent for examination, treatment or care should be carried out*".

In response to this the Regional Multi-professional Audit Group (RMAG) were approached to fund a Regional Audit of Consent, headed by a multi-professional Audit Steering Group made up of members across the service, see Appendix 1 for membership.. The terms of reference of this Consent Audit Steering Group were to:

1. To ensure that the Regional Audit of Consent practice is carried out effectively.
2. To provide guidance on completion of the audit stages.
3. To arrange a regional workshop to agree regional action plan as required.
4. Provide a report on the Regional Audit of Consent to the Chief Medical Officer (CMO), Department of Health, Social Services & Public Safety (DHSSPS) (NI) by the end of March 2007.

Standards Used

The regional audit was informed by standards used by the NHS Litigation Authority Clinical Negligence Scheme and Departmental Guidance – Good Practice in Consent issued in 2003. It was agreed to examine three areas in relation to consent; standards of written information for a number of interventions in relation to consent; analyse organisational consent audits that had already been undertaken: and to survey patients on their experience of consent following operative procedures over a two day discharge period.

Information Leaflets

Written information, supporting oral information, can be especially helpful for patients who are due to undergo planned treatment. They can be given the information to read, and have time to discuss it with their family, carers or healthcare professionals before giving consent to the treatment. There is evidence that leaflets specific to a condition are read by patients (Mayberry, 1988), and evidence that patients receiving written information are more satisfied with the information they are given (Edwards, 1990).

Consent for a treatment must be based on the patient having the information they need to make a valid decision. This information should include details of the procedure planned, including how the patient should prepare for the procedure, what they might experience during or after the procedure, common or serious side effects, the likely benefits and probability of success, and alternative options to the proposed treatment. (GMC, 1998, DHSSPS, 2003).

✓ *The quality of information leaflets would be Strand 1 of the Regional Audit.*

Organisational Audits, including audits of consent forms

The introduction of standardised consent forms for use across the HPSS in 2004 linked with additional training on consent processes by Trusts. Consent forms are used to record written consent for major interventions such as surgery. They act as a record of the consent process, and areas of good or bad practice may become evident through looking at the completion of these forms.

Many Trusts have already carried out audits looking at the completion of consent forms, and other aspects of consent. Although each Trust developed its own audit criteria and audit tools, informal contact with medical directors and audit managers indicate that these various audits looked at similar issues such as legibility, identification of patient and professional, date of signing, clarity about what procedure was consented to, additional information provided about benefits and risks, and provision of leaflets.

Use of a common tool for future use in audits of this activity would allow easy collation of data, and benchmarking between Trusts

✓ *An examination of existing Trust Audits, including standards audited and results would be Strand 2 in the Regional Audit.*

Patient Experience

Patients facing major operations want good information, which may be provided in a number of ways including talking to health professionals, leaflets, videos and interactive computer programs (Coulter, 1999).

There is recognition that different patients will want different levels of detail in the information they get (DHSSPS, 2003). Patients' anxieties may relate to problems with managing family and personal life as much as concerns about treatment outcome or pain (Fitzpatrick, 1984). There is also evidence that patients have difficulty understanding the concept of risk of side effects or poor outcomes (Coulter, 2004, Calman, 1997).

It may require complex research to consider patients understanding and recall of the information provided, but it should be possible to audit the patient experience of the consent process by asking if they felt they received sufficient, appropriate information, time to consider the decision and what they would change if faced with the same situation again (Howler, 2004)

✓ *Patient experience of the consent process would be surveyed as Strand 3 of the Regional Audit).*

REFERENCES

Calman,C., Royston,G. (1997) "Risk language and dialects" British Medical Journal vol. 315:
pp939-942

Coulter, A., Entwistel, V., Gilbert, D. (1999) Informing Patients: An Assessment of the Quality of Patient Information Materials. London: King's Fund

Coulter, A. (2004) The Autonomous Patient. London: The Nuffield Trust

DHSSPS (2003) Good Practice in Consent: Consent for Examination, Treatment or Care. Belfast: DHSSPS

Edwards, M. (1990) "Satisfying Patients' Needs for Surgical Information". British Journal of Surgery vol. 77. pp 463-5

Fitzpatrick, R. (1984) "Satisfaction with Health Care" in Fitzpatrick, R. et al, (eds) The Experience of Illness. London: Tavistock

GMC (1998) Seeking Patients' Consent: The Ethical Considerations. London: GMC

Howler, M.H. et al (2004) "Patients Views of the Consent Process for Adult Cardiac Surgery: Questionnaire Survey" Scandinavian Cardiovascular Journal vol. 38 pp 363-8

Mayberry, J. (1988) "Information Booklets for Patients with Inflammatory Bowel Disease" International Disability Studies. Vol. 10 pp 179-80

AUDIT APPROACH

Aim of the Audit

People have a fundamental legal and ethical right to determine what happens to them. Valid consent is central in all forms of health and social care, from providing help with washing and dressing, to undertaking major surgery. Seeking consent is a process of providing information, discussion and decision making. The aim of the regional audit was to focus on the area of consent for operative treatment and to look at the three strands identified above across all 18 Health and Social Services Trusts in Northern Ireland.

Audit Methodology

Strand 1 – Information Leaflets

Trust Audit Managers were asked to provide patient information leaflets on six common procedures if they were carried out within their Trust (copy of Patient Information Leaflet request form see Appendix 2). Each leaflet was then assessed using a proforma audit tool (see Appendix 3).

Strand 2 – existing Trust Consent Audits

Each Trust was asked to provide copies of any existing data on audits carried out from January 2005 to December 2006. Trusts were asked to supply a copy of the audit tool used as well as the data collected. It was recognized that not every audit would have looked at all the same elements of consent, but it would be possible to highlight key elements of good or poor practice by collating information from several audits.

Strand 3 – Patient Experience

While acknowledging that consent occurs across the whole range of health and social care, people who had undergone surgery requiring inpatient treatment would be an identifiable group for an audit, and will have given formal consent. To enable a “snapshot” of patient experience of the consent process, all patients being discharged from in-patient wards on 29 and 30 November 2006, who had undergone a surgical procedure during that admission, were asked to complete a questionnaire (see Appendix 4).

Trusts were provided with the questionnaire and a return envelope and asked to issue and collect them from patients prior to discharge. These forms were then returned to the DHSSPS for centralised analysis.

AUDIT FINDINGS

Strand 1 - Audit of Patient Information Leaflets

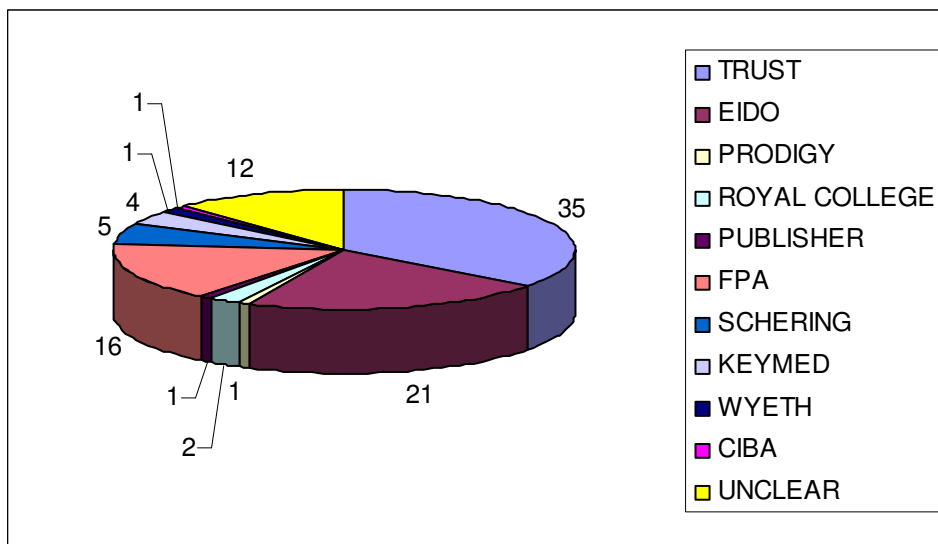
Patient information leaflets can act as a useful supplement to discussions between patients and healthcare professionals. In this strand of the audit six common procedures were chosen and all Trusts were asked to indicate if they carried out the procedures, and if so did they use patient information leaflets. Trusts were asked to send the leaflets, and these were audited against criteria covering details about their origin, evidence of being up to date and provision of contact details, as well as information about the procedure, including its risks, benefits, and alternatives. The leaflets were requested for six common procedures. They were hernia surgery, hysterectomy, cataract surgery, upper gastrointestinal endoscopy, insertion of intrauterine device, and dental extraction.

In total 99 leaflets were provided by 16 Trusts. Most Trusts provided patient information leaflets for all procedures they undertook. Four Trusts indicated they carried out either hernia surgery or hysterectomies, but did not have patient information leaflets on these procedures.

Origin of leaflets

The origin of the information leaflets is a potential quality indicator and this was recorded as part of this audit strand - see Chart A.

Chart A



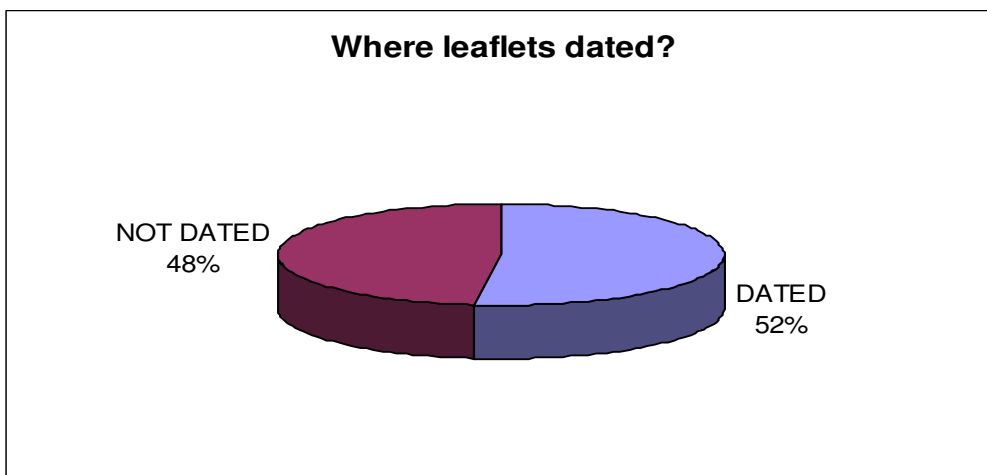
- Almost half of the leaflets were created by the Trust (34 definite, 8 probably Trust).
- EIDO is a commercial company providing patient information leaflets.
- Several leaflets were developed by independent/ professional bodies
- PRODIGY is an NHS website providing clinical summaries
- Royal Colleges provide professional leadership in each speciality
- Family Planning Association is a national charity. Many of its leaflets were produced in association with Department of Health
- Several commercial companies' leaflets were used
- Schering, Wyeth and CIBA (which became part of Novartis) are pharmaceutical companies and Keymed make endoscopes

Quality Indicator: Leaflets are dated

Background

Clinical practice changes over time. The procedure and alternatives may change. Knowledge about benefits and risks increases as experience grows. It is therefore good practice to show either a date of creation, or a date for the information to be reviewed - see Chart B.

Chart B



Comment

Just over half of the leaflets in this audit had either a date of production or a review/expiry date. Leaflets produced by Trusts (or where origin was unclear) were less likely to be dated than those from other sources. The earliest date noted was on a leaflet that had been produced in 1997 and stated it was due for review in 1998.

Quality Indicator: Contact details were given

Background

One of the advantages of providing written information for patients is that it allows them to read the information in their own time. They may then have questions to ask, and it is helpful if they are given a contact. Patients may also have concerns after a procedure, and should know who to contact - see Chart C.

Chart C



Comment

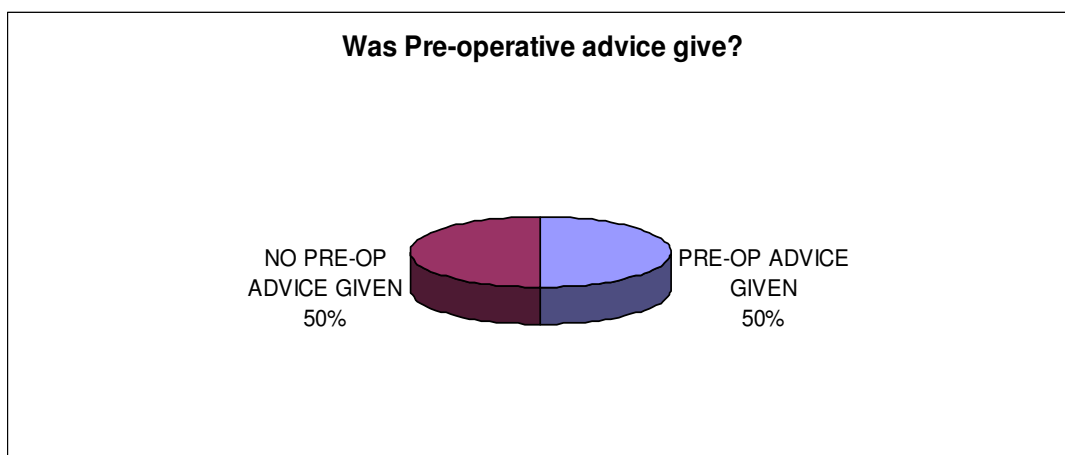
Only about 60% of leaflets had contact details for patients who had questions or developed problems after their procedure.

Quality Indicator: Pre-operative advice was given

Background

For many treatments or procedures patients would benefit from advice on things they can or should do before the procedure. Long term advice such as stopping smoking, or losing weight might be appropriate before planned surgery. More immediate advice might include what to eat or drink and whether to take regular medication in the 24 hours before the procedure - see Chart D.

Chart D



Comment

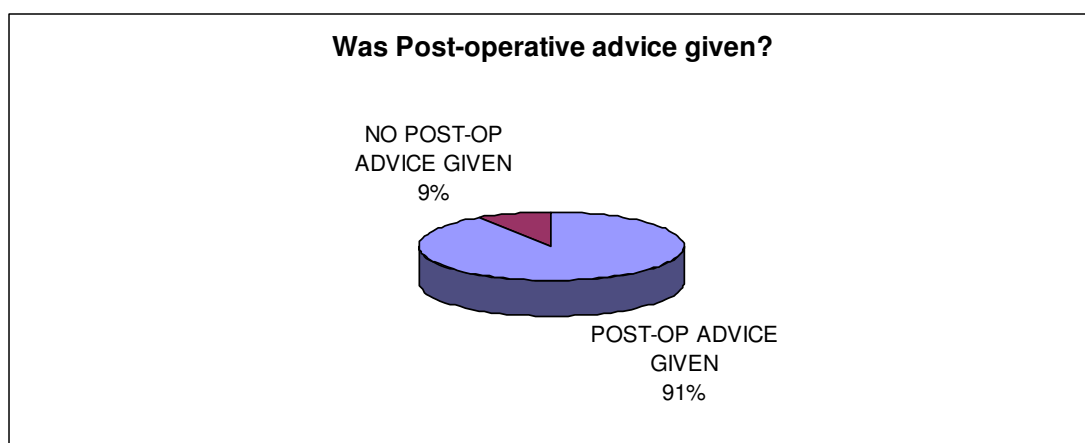
Half the leaflets included advice for patients preparing for the procedure

Quality Indicator: Post-operative advice was given

Background

Post-operative information might include practical issues like driving home, eating and drinking, returning to work. There may be information about common side-effects and how to manage them, or advice about signs and symptoms that require the patient to be seen, and who to contact if they have concerns - see Chart E.

Chart E



Comment

Around 90% of leaflets included advice for patients after their procedure.

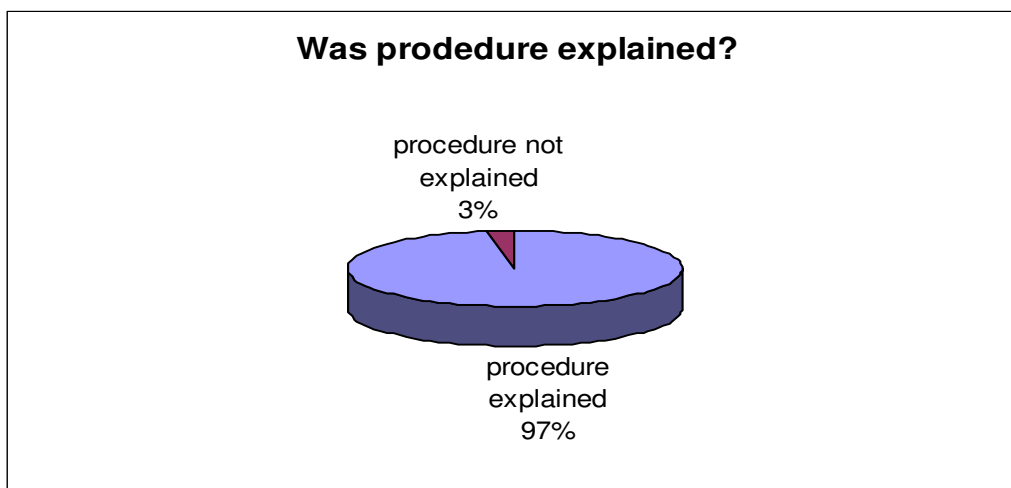
Twenty four of the patient information leaflets included in the audit only contained very simple admission or discharge information. These were excluded from the following sets of data.

Quality Indicator: The procedure was explained

Background

Patients need to understand the nature and scope of the procedure if they are to make a decision whether to consent or not - see Chart F.

Chart F



Comment

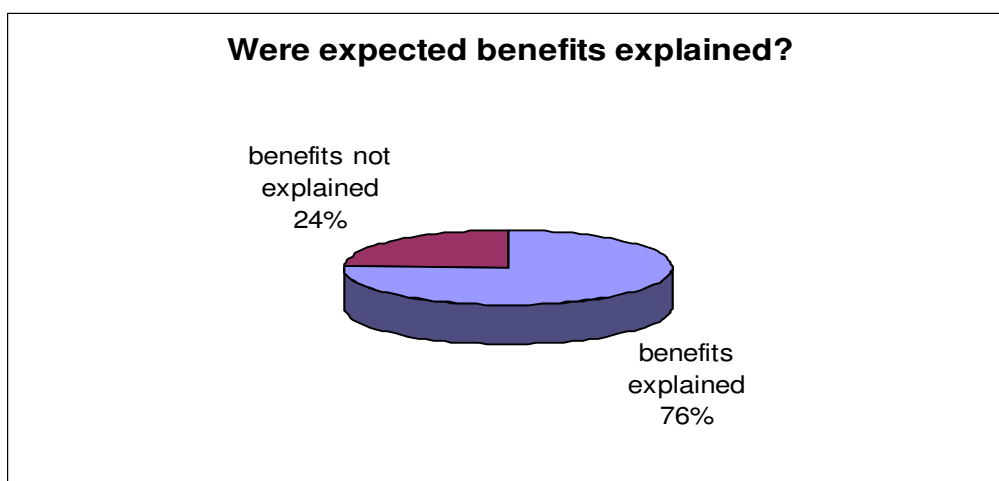
Almost all leaflets explained the procedure

Quality Indicator: The purpose or benefits of the procedure were mentioned

Background

Procedures may be carried out for diagnostic, preventative or treatment reasons, or a combination of reasons. Patients should also understand the purpose of the procedure before consenting to it - see Chart G.

Chart G



Comment

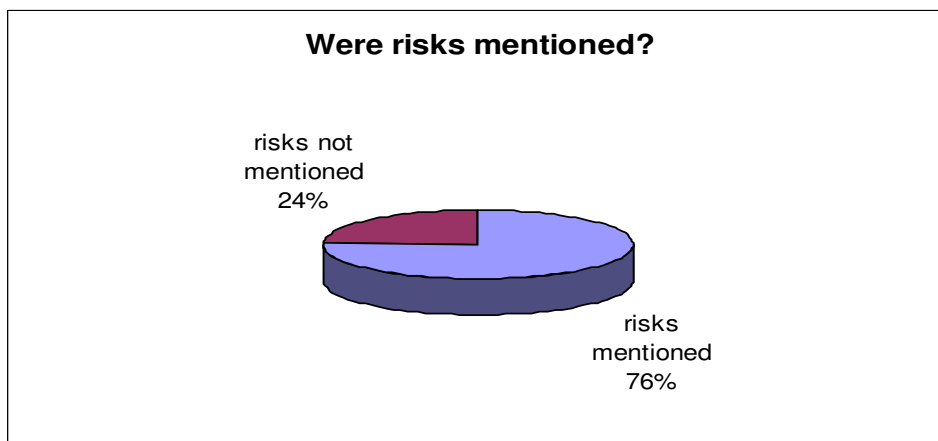
About three quarters of the leaflets described the purpose or expected benefits for the procedure.

Quality Indicator: Risks of the procedure were mentioned

Background

All procedures carry some risk of complication. Patients need to know about the most common and most serious (even if rare) complications to allow them to give consent for a procedure - see Chart H.

Chart H



Comment

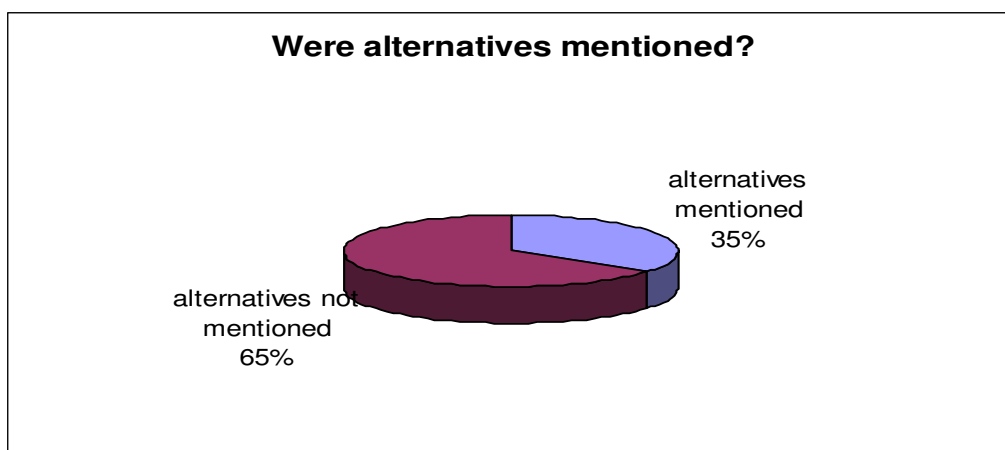
About three quarters of leaflets mentioned risks related to the procedure. This may have included listing the most common or serious complications, or giving the statistical chance of certain complications.

Quality Indicator: Alternatives to the procedure were mentioned

Background

For a patient to make a properly informed decision to have a procedure or any other treatment, they must be aware of alternative treatments that are available. This should include the option of no treatment. Leaflets may be used after the patient and clinician have discussed options and agreed on a procedure. In these cases it may be unnecessary to give detail about alternatives, but it may be helpful for leaflets to remind patients that they can discuss alternatives with their clinician - see Chart I.

Chart I



Comment

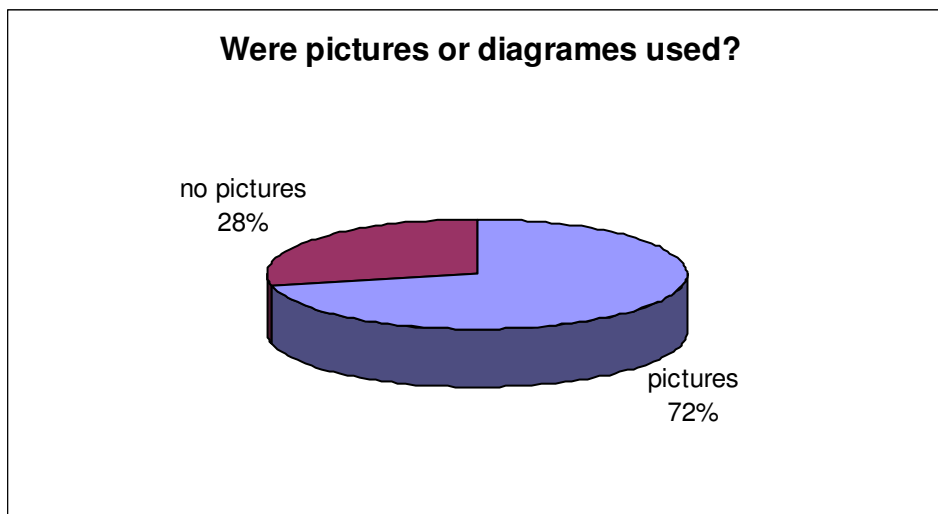
Only about a third of leaflets described alternatives, including the option of no treatment.

Quality Indicator: Pictures or diagrams were used in the leaflets?

Background

Where appropriate pictures and diagrams can help to explain procedures - see Chart J

Chart J



Comment

Almost three quarters of leaflets used pictures or diagrams. This ranged from a single diagram to a whole "picture story".

Strand 2 - Existing Trust Consent Audits

Eight Trusts indicated that they had already undertaken consent audits. These audits variously included information on a number of quality indicators such as; completion of consent forms, recording of consent in notes, staff questionnaires, patient questionnaires, patient focus groups and practical aspects such as availability of consent information. Eight audits looked at the information contained in the patients' chart or consent form. The number of cases looked at by each Trust varied from 10 to over 300. There were several areas that most Trusts included in their audit - see Table A below:

Table A

Quality Indicator Examined	Trust Audits including this area
Patient's identity should be on the consent form	6 Trusts audited this standard
Proposed procedure/treatment is documented	7 Trusts audited this standard
Intended benefits are noted	7 Trusts audited this standard
Intended Risks are noted	7 Trusts audited this standard
Additional procedures are documented	6 Trusts audited this standard
Patient received information via leaflet/tape	7 Trusts audited this standard
Type of anaesthesia is recorded	5 Trusts audited this standard
Patient signed the form	6 Trusts audited this standard
Patient's name and date is recorded on the form	6 Trusts audited this standard
Consenting Professional signed the form	All 8 Trusts audited this standard
Contact details are given to patient for future reference	6 Trusts audited this standard
Appropriate form should be used	6 Trusts audited this standard
Consent form is in the patient's chart	6 Trusts audited this standard
Patient is given a copy of the consent form	6 Trusts audited this standard
Consent recorded	4 Trusts audited this standard
Abbreviations not used	4 Trusts audited this standard
Usage of samples discussed	3 Trusts audited this standard
Professional saw advance directive/living will	3 Trusts audited this standard
Patient withdrawal of consent noted	3 Trusts audited this standard

Only 2 Trusts included questions specifically about Form 4. This is the form used to record the professional's decision making for adults who are not capable of giving or withholding consent - see Table B below.

Table B

Form 4 Quality Indicators	Trusts including this area
Was address of relative/friend involved in discussion documented	2 Trusts audited this standard
How doctor came to lack of capacity decision documented	2 Trusts audited this standard
Two signatures present	2 Trusts audited this standard

Several Trusts provided conclusions based on their audits and these were very similar across Trusts:

- Patient identification was generally good, although in a small number of cases the hospital number was missing
- Risks and benefits were recorded in the majority of cases
- Documentation of patients having received additional information (eg. leaflets or tapes) was recorded
- Only a small number of forms did not have a professional signature
- Record of discussion was not always documented
- A significant number of cases had procedures abbreviated
- The patients' name was not always printed on the form
- In a few cases the side marked for surgery was incorrectly documented
- Additional procedures not always discussed at consent taking
- Forms are not always dated
- The use of stickers on forms make it difficult to complete correctly
- Patients are not always given/offered copy of the form

Recommended Actions made by Trusts following their audit included:

- All patients should be offered a copy of the completed consent form for their own information
- It should be documented if the patient refuses a copy of the consent form
- Forms should be checked for completion prior to patient leaving ward for procedure

The audits illustrate that all aspects of the Consent form were being completed. The area with least consistency was contact details for healthcare professionals, in some audits only 9.1% completed this. All forms were signed and dated.

Five audits looked at how the consent process was carried out in practice, including staff questionnaires.

There was little consistency across Trusts in the questions that were asked, but most did ask some question about staff training in consent. Results showed variable provision of training between Trusts, between different professions and between different grades of staff. This ranged from training having been provided for 9% of all doctors in one Trust, to 100% of consultants in another Trust.

Other learning points that emerged from the audits were

- Staff asked to take consent for procedures that they are not familiar with
- Lack of time for the consent process
- Difficulty using the forms
- Lack of availability of consent forms or information leaflets.

Two Trusts sent audits including patient questionnaires. One Trust sent findings from a series of patient focus groups. Although the focus groups had taken place in 2002, the findings were still of interest, and largely consistent with the more recent surveys.

The key themes emerging from the patient surveys and focus groups are:

- All the patient surveys and focus groups were based on patients who had surgery
- Most people found staff helpful
- Most people found having a booklet to refer to helpful
- People like to have information before their admission
- Most people felt they had enough information about their surgery to give consent
- Some people felt they would like more information about the anaesthetic
- People felt less well informed about recovery e.g. need for aids or adaptations, ability for childcare, return to work than they were about the actual surgery.

Strand 3 - Patient Questionnaires

Of the questionnaires distributed on the two discharge dates chosen a total of 278 replies were received. Out of this number 269 chose to answer the questions with only six refusing to respond. Three were also declared invalid, as the questions were not answered correctly. (Some people also left blank answers which is why in some cases the totals do not add up to the same figure.) Unfortunately Trusts were not asked to record the number of questionnaires issued.

There is anecdotal evidence that clinicians feel that particularly older patients can be overwhelmed by detailed information before a procedure and therefore the results shown below and have been broken up into three age groups. The 269 replies consisted of:

- 37 from people aged under 25
- 152 from people aged 25-64
- 78 from people aged over 65

See Appendix 5 for a Table giving the overall results for each question in the different age groups. Differences in the answers given by different age groups are commented on separately in the questions below.

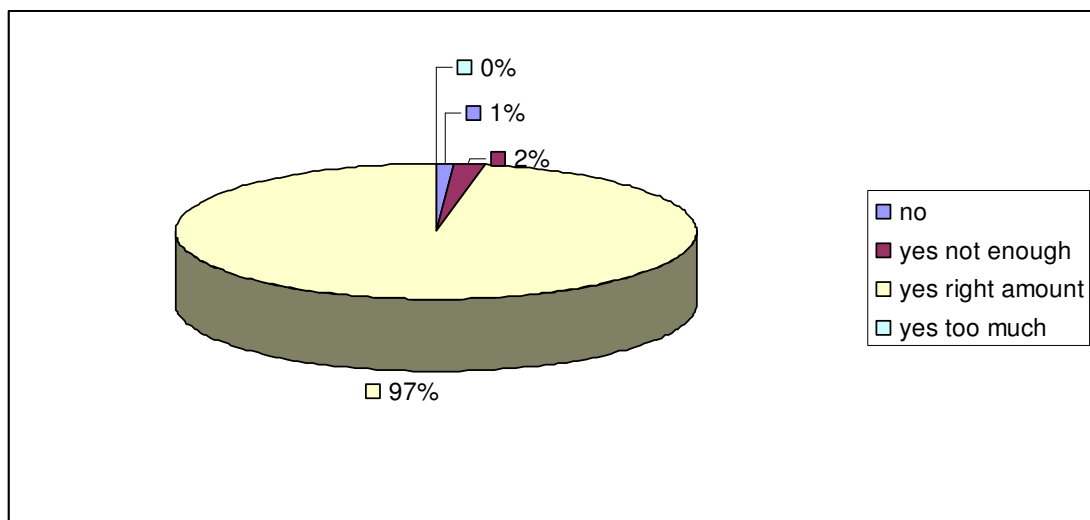
Questions related in the main to aspects of the patient's experience of the consent process.

Quality aspect: Informed of reason for operation and given enough information?

Background

For those that had an operation, were they informed of the main reasons for the operation and if so were they given enough detail about the reasons to make their decisions? – see Chart 1.

Chart 1



Comment

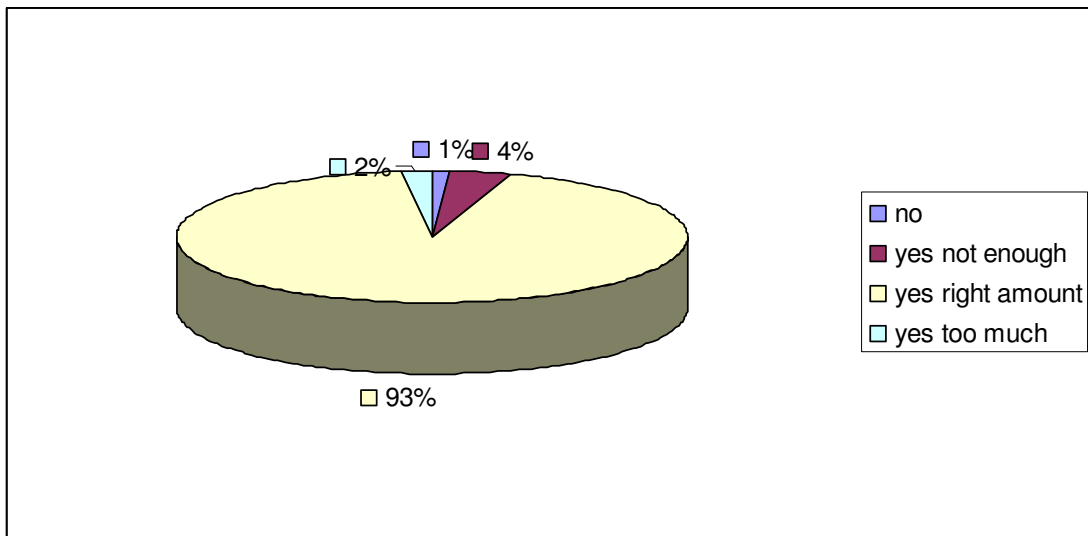
Overall 99% of patients were given information about the reasons for their operation with 1% not being informed. Out of this 99% total, 97% received the right amount of information with 2% feeling they did not receive enough.

Quality aspect: Given enough information about risks and side effects?

Background

For those that had an operation, did they receive information about the main risks, side effects and complications and if so were they given enough detail? – see Chart 2

Chart 2



Comment

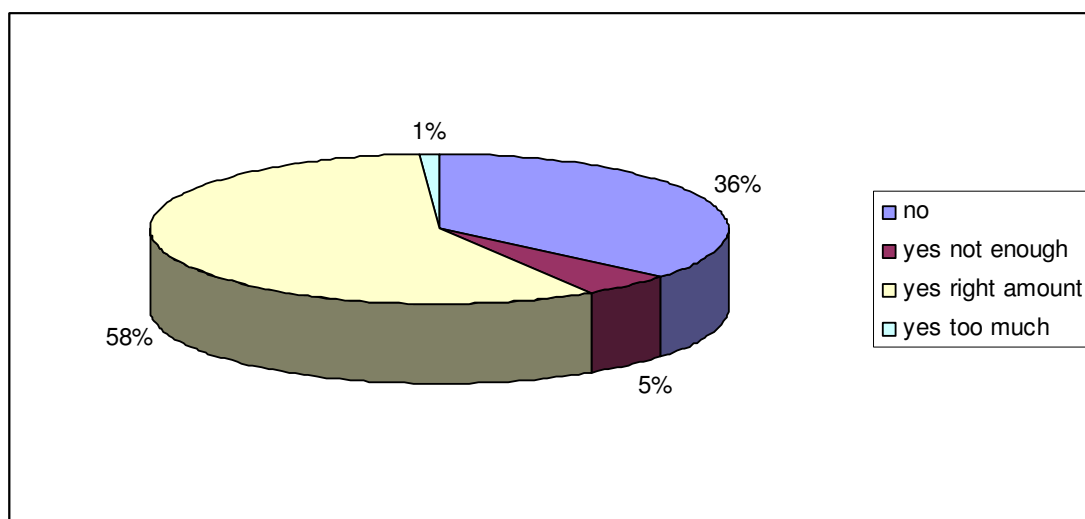
In total 99% of people were given information about the risks and side effects of their operation with 1% not being given information. From the 99% that answered yes, the majority (93%) felt they had received the right amount of information to help make decisions, 4% felt they had not been given enough information and 2% felt they had been given too much.

Quality aspect: Given enough information about alternatives if applicable?

Background

For the people who had an operation, were they given any alternatives to having the operation and if so were they given enough detail about the alternatives to make decisions? – see Chart 3.

Chart 3



Comment

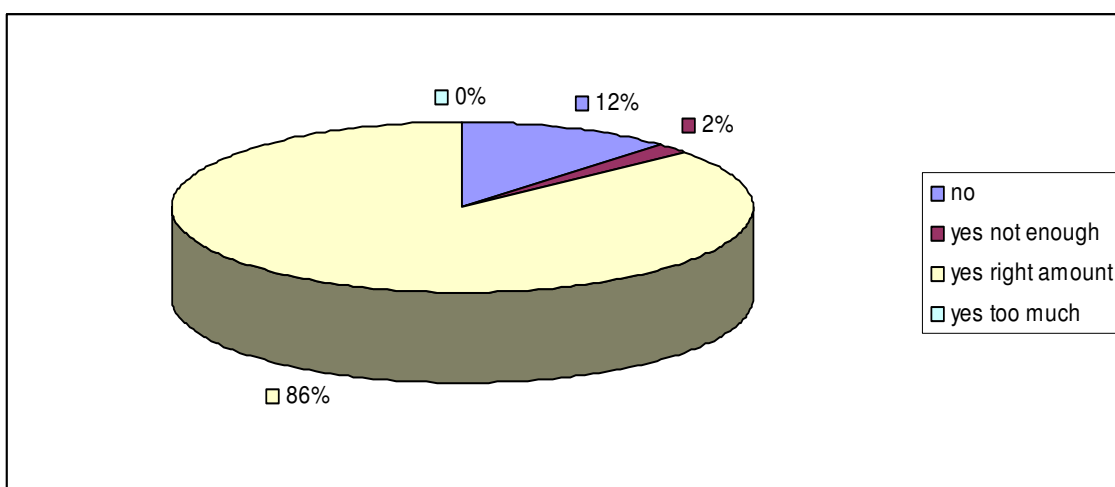
Overall almost two thirds of patients (64%) were given alternatives to having their operation with 36% not receiving information about alternatives. Out of the 64% that received information, 5% felt that it was not enough, 1% felt that it was too much with the majority (58%) feeling they had been given the right amount of information.

Quality aspect: Given enough information about reasons for anaesthetic?

Background

For those that had an operation, were they given information about the reasons for any anaesthetic and if so were they given the right amount of information? – see Chart 4.

Chart 4



Comment

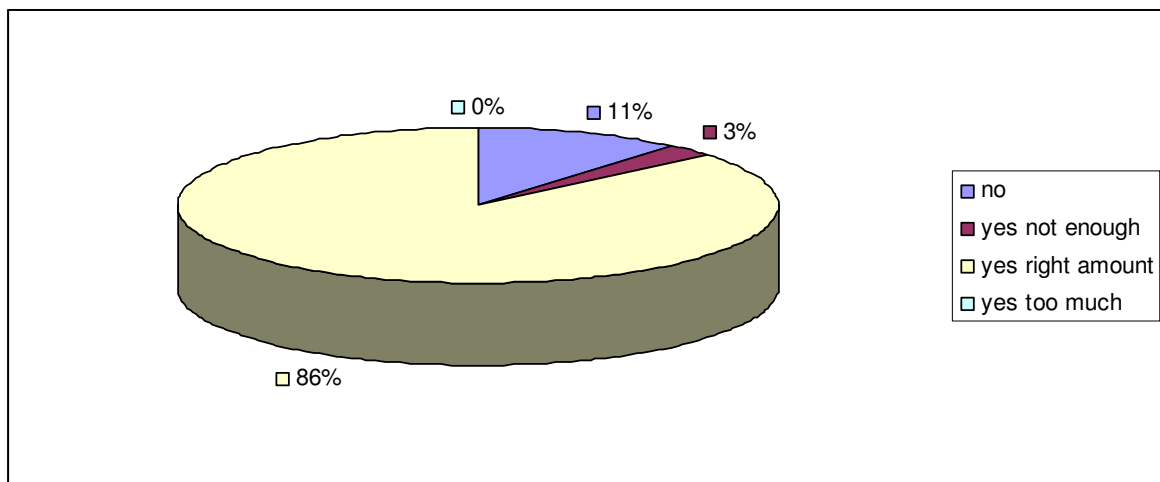
A total of 88% of patients were given information about the anaesthetic that may be used for their operation with 12% not being informed. From those 88% that answered yes, 86% were satisfied that they received the right amount of information with 2% feeling they were not given enough.

Quality aspect: Given enough information about recovery?

Background

For people who had an operation, did they get information about what their recovery would be like after the operation and if so were they given enough information? – see Chart 5.

Chart 5



Comment

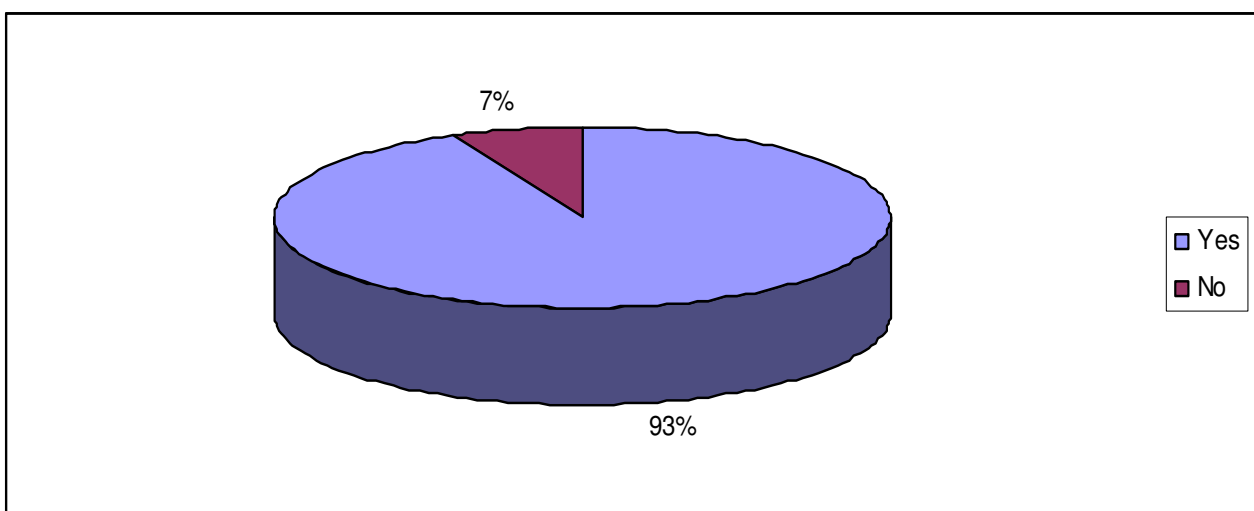
In total 89% of people received information about what their recovery would be like after their operation with 11% not receiving information. Out of the 89% of patients that received information, 86% felt that they had been given the right amount with 3% feeling they had not been given enough.

Quality aspect: Given time to ask questions and discuss operation?

Background

For people who had an operation, did they have enough time to ask questions and discuss before the operation? – see Chart 6

Chart 6



Comment

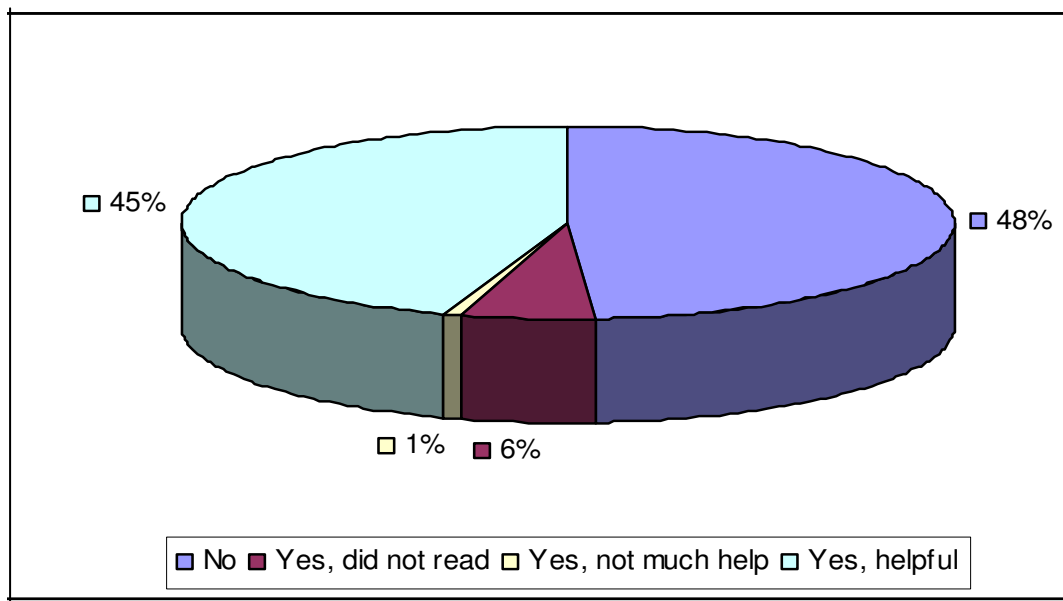
Of people who had an operation 93% were satisfied (7% not satisfied) that they had enough time to ask question before their operation.

Quality aspect: Given written information to help decision?

Background

For people who had an operation, were they given information leaflets or booklets to help make decisions? – see Chart 7.

Chart 7



Comment

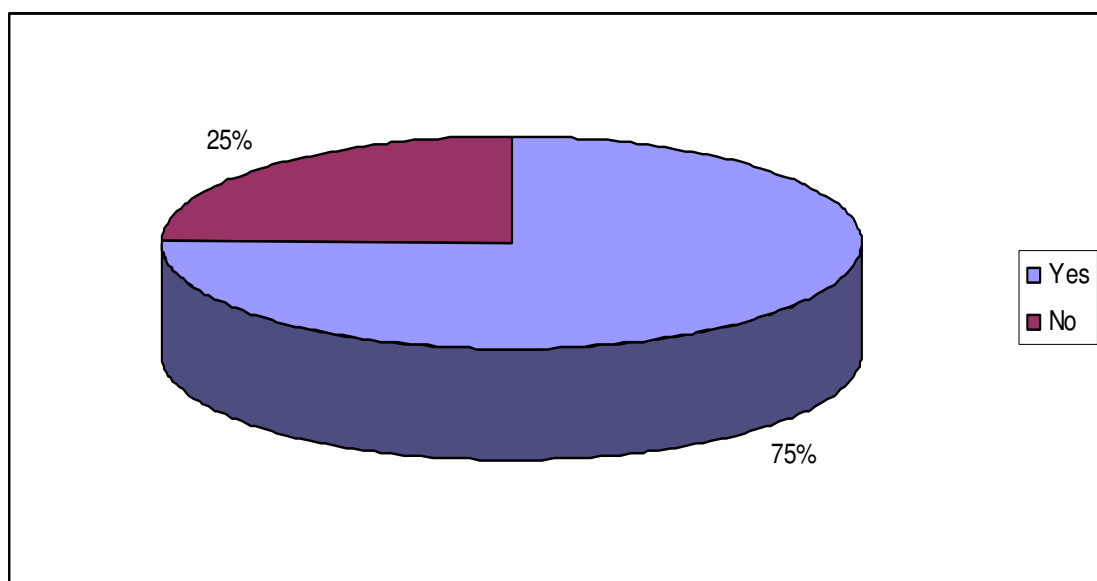
Of the 52% of people given leaflets, the highest proportion (56%) of people finding them helpful came from the over 65's while the lowest proportion (31%) came from the under 25's.

Quality aspect: Given information before admission?

Background

For people who had an operation, were they given information about the operation before being admitted? – see Chart 8.

Chart 8



Comment

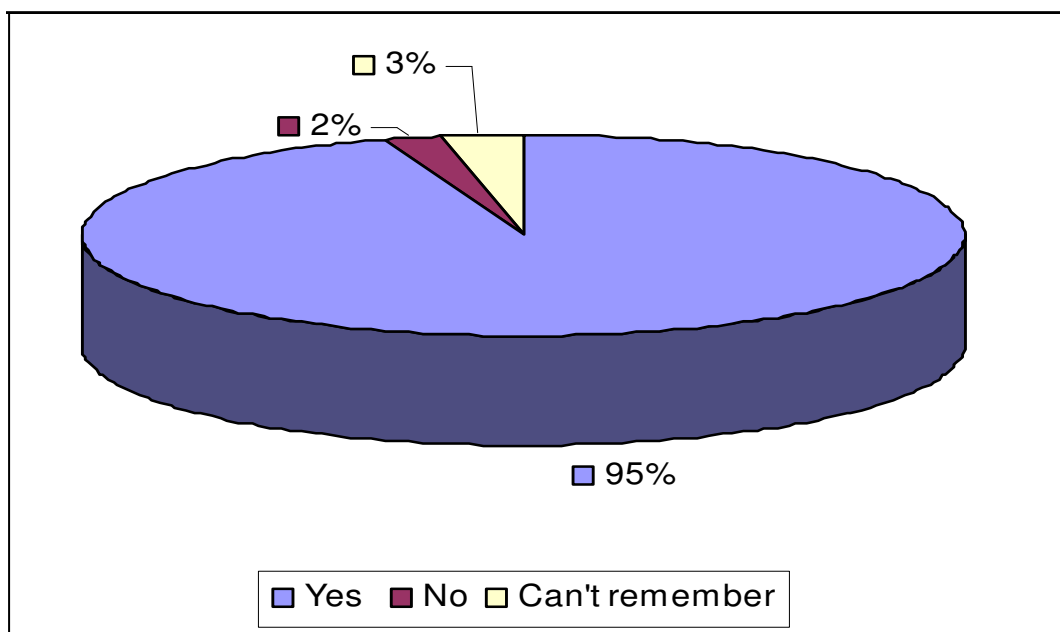
Of those that answered this question $\frac{3}{4}$ were given information about their operation before being admitted to hospital with $\frac{1}{4}$ not receiving information. Responses were similar across all 3 age bands.

Quality aspect: Signed a consent Form?

Background

For those that had an operation, did they sign a consent form? – see Chart 9.

Chart 9



Comment

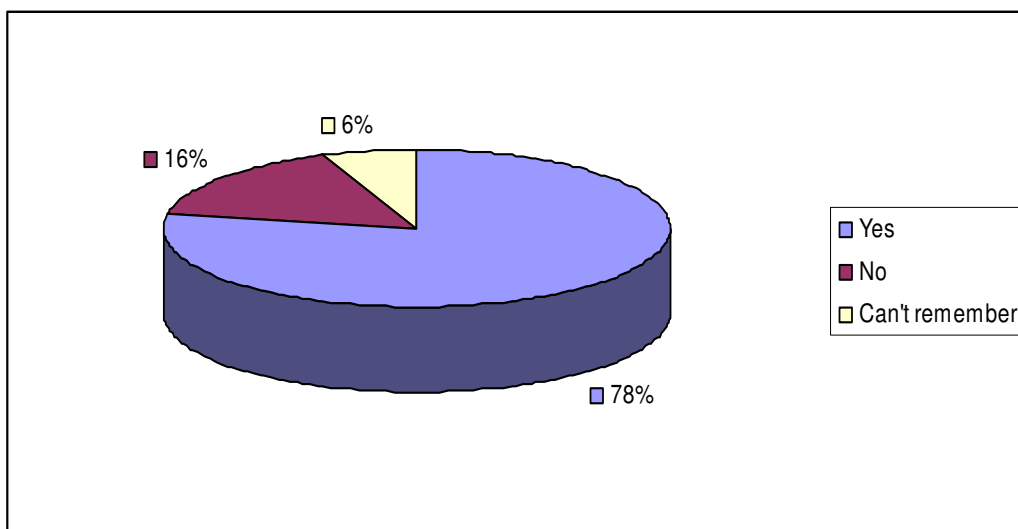
Overall 95% of patients that had an operation signed a consent form, with 2% failing to do so and 3% unable to remember whether they did or not.

Quality aspect: Read form or had it read?

Background

For those that signed a consent form (answered Yes to question 12), how many read it or had it read to them before signing? – see Chart 10.

Chart 10



Comment

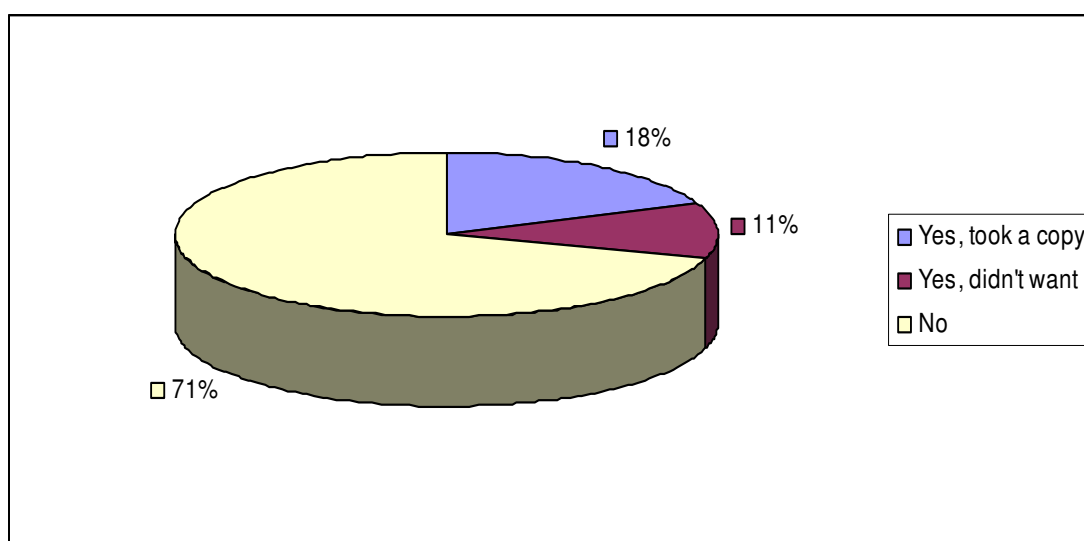
Of those that answered this question 78% said they read the consent form before signing it, 16% failed to read it and 6% cannot remember. The majority of under 25's (94%) read the consent form with the 25-64 and over 65 age bands having higher proportions of those that did not read the form, or could not remember, with only 77% of 25-64 and 72% of over 65 stating they had read the form or had it read to them.

Quality aspect: Offered a copy of consent form?

Background

For those that signed a consent form, were they offered a copy of it? – see Chart 11.

Chart 11



Comment

More than 70% of people were not offered a copy of the consent form, while only 18% of all people were offered a copy and took it and 11% were offered a copy but chose not to take it. The under 25 age band had the highest proportion (31%) of those taking a copy with the 25-64 age group having the highest proportion (74%) not offered a copy.

The questionnaire also gave space for further comments and 56 people added comments in this section, of which three were none specific comments e.g. “none”, “emergency c/section”. Of the other comments:

1 was negative about the questionnaire

“What a waste of resources!”

8 made negative comments including:

“It can be extremely difficult to read the surgeons comments and this makes things difficult when trying to explain what is involved to relatives anxious for information as to what is to occur”

“Had to ask for leaflet to take home. Wasn't told what to do when I got home”

“Some doctors could do with a little smile more often which would make patients feel a little more at ease to ask more questions about their condition, operation, after care.”

44 made positive comments including:

“I had absolutely no worries about my operation as everything was explained to me in a very positive way”

“The staff were very helpful and pleasant. They were full of information and were able to answer my questions.”

“I felt that I was well informed on all aspects of anaesthetic and operation and I felt that because of the explanations I was much more at ease.”

“The staff communicate very well; this made it easy for me and them.”

“I was given details in classes about this operation in case it could happen (emergency c section.) When the situation arose and I had to have one I felt that everything was explained to me in a calm and professional manner.”

“Found staff very kind and honest and give plenty of advice and help”

“I think the staff, surgeon and anaesthetists were very good explaining everything to me and making sure I understood everything which was being explained. They were also very good about my after care following the operation and still explaining what stages I would be going through and being very patient”

“Everything was fully explained and the care and attention I received from everyone during my stay was excellent. I was very anxious about coming into hospital and having the surgery. I would like to thank everyone who looked after me for their support and for making me feel less anxious and confident I would get through OK.”

WORKSHOP AND RECOMMENDED ACTION

In keeping with the audit cycle, standards of good practice had been identified and aspects of consent practice had been measured. The next stage is to agree an action plan but as this was a regional audit the steering group sought regional involvement in drafting the recommended actions via a facilitated² workshop.

The steering group initially identified a number of areas for recommendations both generally and specific to the three strands of the audit project and these were shared in draft form with invitees to a regional workshop. The workshop was held in March 2007 to share the findings of the Regional Audit of Consent and allow key stakeholders to shape the final recommendations for the consent process across Northern Ireland.

The afternoon workshop was well attended and had representation from all 18 HPSS Trusts across Northern Ireland including: Medical Directors, Directors and Assistant Directors of Nursing, Consultant Nurses, Senior Nurse Managers, Audit Managers, Governance representatives, Consultant Anaesthetists and Surgeons. Following presentations of the findings of the audit delegates were asked to consider draft recommendations.

Delegates were allocated to tables to consider the recommendations and determine the actions required for their implementation. In the first table exercise delegates were asked to discuss and consider if the recommendations were appropriate and complete, identifying any further additions or deletions required. Following feedback from individual groups, other delegates were encouraged to add any additional comments which were recorded. Whilst groups were in agreement that the recommendations were appropriate, a number of changes and additions to the content were suggested which followed broad themes around expansion of definitions, context and guidance. It was generally felt that a regional approach was required in order to clarify such issues as: when the consent process should begin for a patient or client, the standard of information and content, and the need for local application to supplement the regional processes. There was a general consensus that no recommendations should be deleted. For further breakdown of responses please see Appendix 6.

² The workshop was facilitated by two Professional Officers from NIPEC; Cathy McCusker and Angela Drury

The second Table exercise required the delegates, in their groups, to consider what actions were required for implementation of the recommendations at both a Regional and a Trust level. They were then asked to prioritise actions and to identify the barriers to implementation, feeding back to the main group in a similar manner to the first table exercise. Copies of the Regional Audit Tools, inclusive of the template patient questionnaires were circulated to the tables during Exercise 2 (see Appendices 8, 9 and 10).

A regional approach was consistently identified throughout the workshop as essential to ensuring the recommendations from the Regional Audit of Consent are implemented. There was also a request for wide dissemination of findings from the Report which should be supported by updated training and review of the consent process and relevant documentation including leaflets and audits.

It was recommended that there should be a regional directive to ensure that Trusts make the auditing of consent a priority. Whilst delegates did not reject the tools presented, it was generally recognised that further work would be required to amend the audit tools, to ensure their applicability regionally and across all care settings. Regional audit tools should be designed to allow for local adaptation. It was suggested that Regional Audits should be scheduled, reflecting the need for audit to be 'regular'.

Barriers were broadly themed under resources, organisational barriers and the provision of information at both Trust and Regional levels. For further breakdown of responses please see Appendix 7.

The afternoon provided a good opportunity for individuals engaging in the consent process with patients/clients and individuals responsible for ensuring governance principles are effectively applied in organisations, to work together to agree the Regional Audit of Consent Report Recommended Action Plan. Delegates provided expert opinion and discussion, recommending appropriate amendments and priority actions.

Final Recommended Actions

Recommended Actions: General

Some themes emerged across all three strands of the audit, reflecting both good practice and areas for enhancement in the consent process.

1. Trusts should ensure good practice in consent is embedded in health and social care practice.
2. Trusts and training organizations should ensure consent is included in training for all relevant staff, with training for intervention specific consent as well as the consent process.
3. Emphasis should be placed on the fact that consent is a process of providing information and agreeing a decision.
4. Professionals should be aware of the importance of patients' capacity to give consent and appropriate action to take if there are capacity issues.
5. Information about alternative management options, anaesthetic and recovery should be included in the consent process, as well as information about proposed management and the benefits and risks of procedures.
6. The current consent form should be reviewed to ensure it supports good practice and provides evidence of issues discussed in the consent process.

Recommended Actions: Information Leaflets

7. Ownership of information leaflets should be clear, eg produced by Trust or leaflet provider. Trusts should ensure that commercially provided leaflets provide unbiased information for patients.
8. Date or version control should be on each leaflet.
9. Contact details should be available on all information.

10. Information leaflets should provide information covering the key areas, eg, benefits, risks and alternatives available.
11. Language used in leaflets should be easy to understand. Consideration should also be given to patients' cultural diversity and disability.
12. Leaflets should be audited to ensure consistency and accuracy of information. (see Appendix 8 for model audit tool)
13. Consideration should be given to the introduction of a regional database/register of information leaflets.

Recommended Actions: Trust Audits

14. Trusts should ensure the whole consent process, and its context is included in audit. This should be across all services and include policy, practice, training, staff and patient opinion.
15. An agreed standardized set of audit tools should be used regionally to maximize consistency. This could still be supplemented by specific audits tailored to meet local requirements. (See Appendices 8, 9, 10 and 11 for model audit tools).
16. Audits of consent forms should include appropriate use of Form 2 (Children) and Form 4 (Adults who are unable to Consent).
17. Trusts should show the completeness of the audit cycle through re-audit on a regular basis.
18. There should be regional sharing of learning from audits to include problem areas as well as areas of good practice.

Recommended Actions: Patient Experience

19. Trusts should obtain patient feedback on the consent process. This could be through focus groups or questionnaires.

20. Trusts should ensure that where written patient information is available, it is offered to patients
21. Trusts should ensure that information about interventional procedures should include alternatives, anaesthetic and recovery as well as the proposed procedure and its risks and benefits.
22. Patients should be given a copy of the consent form.
23. Consideration should be given to the setting up of a Regional Patient Information Website which would standardize information being given to patients. It is important however, to note that this should not take the place of any professional/patient communication.

Appendices

1	Steering Group membership
2	Patient information Leaflet request form
3	Audit Tool Proforma: Patient Information Leaflets
4	Audit Patient Questionnaire
5	Table of results from patient questionnaire by age ranges
6	Responses from Workshop Table1 Exercise
7	Responses from Workshop Table 2 Exercise
8	Model patient information leaflet audit tool
9	Model consent policy and practice audit tool
10	Model consent form audit tool
11	Model Patient Questionnaire

THE STEERING GROUP

Ms P Blaney, Chief Executive, NIPEC (Chair)

Dr D Connolly, Medical Director, Greenpark Healthcare Trust

Dr R McMillen, Consultant Gynaecologist, Antrim Area Hospital

Mrs A Hickey, Nurse Endoscopist, Ards Hospital

Dr P Donnolly, Royal Victoria Hospital

Miss Nicola Porter, Regional Audit Facilitator DHSSPS

Dr Heather Neagle, Medical Officer DHSSPS

REGIONAL CONSENT AUDIT: PATIENT INFORMATION LEAFLETS

Please indicate which of the following forms your Trust provides for patients prior to procedures.

Procedure	Does your Trust carry out this procedure? Yes/No	If your Trust carries out the procedure do you have an information leaflet Yes/No	Current leaflet sent Yes/No
Hernia repair			
Upper GI endoscopy			
Hysterectomy			
Insertion of intra-uterine contraceptive device (IUCD or "coil")			
Cataract surgery			
Tooth extraction			

Please send completed table and copies of current leaflets to:

REGIONAL CONSENT AUDIT

Room C3.14

Castle Buildings

Stormont Estate

BT4 3SQ

AUDIT TOOL FOR PATIENT INFORMATION LEAFLET

QUESTION	DIRECTIONS	RECORD ANSWER IN THIS COLUMN
Title of leaflet	Record title as it appears on leaflet	
Is the leaflet unique to the Trust, or developed by another organisation e.g. a Royal College?	Record either Trust / Name of organisation	
Is leaflet dated?	Record either YES/NO	
Date of leaflet if shown	Use format as it appears on leaflet	
Is the procedure or condition explained?	YES/NO	
Are benefits of planned intervention mentioned?	YES/NO	
Are risks of planned intervention mentioned?	YES/NO	
Are alternatives to planned intervention (including no intervention) mentioned?	YES/NO	
Is there advice about pre-op preparation or post-op care?	YES/NO	
Is a follow-up contact provided?	YES/NO	
Are pictures/ diagrams used	YES/NO	

AUDIT PATIENT QUESTIONNAIRE

A questionnaire about your opinions of getting information and giving consent for an operation

Why we are asking you to fill in this questionnaire

Every day, doctors and nurses in this hospital give people information before those people decide about having an operation. Usually then people will be asked to sign a consent form as a record of their decision.

This questionnaire is to help us find out if people feel they were given the right amount of information for them.

The information we get from all your replies will help us to improve how we give information and get people's consent.

What we are asking you to do

We would like you to tick your answers to each question. It should take about 5 minutes to complete the questionnaire.

Then just put the questionnaire into the envelope provided and give it back to the staff on the ward.

What will happen to the questionnaires?

The questionnaires from all hospitals will be sent to the Department of Health, Social Services and Public Safety (DHSSPS) in Belfast.

Once all the information has been looked at in the DHSSPS, it will be used to let doctors and nurses know if people generally feel they were given the right amount of information to make decisions about operations.

Please be honest about your opinions

You are not asked to give your name, and there will be no way for anyone to trace your questionnaire back to you.

No one in the hospital will look at the forms before they are sent to the DHSSPS.

We want your honest opinions to help us do things well

Patient Opinion Questionnaire

Please tick one answer for each question

Are you willing to answer some questions about getting information and giving consent for an operation?

- Yes – please answer the questions below
- No – do not answer the questions, but please still put the form in the envelope and give it back

Did you have an operation during this stay in hospital?

- Yes
- No

Did you get information about the main reasons for your operation?

- Yes
- No

Did you get information about the main risks, complications or side effects of your operation?

- Yes
- No

Did you get information about any alternatives to having your operation, including not having any operation?

- Yes
- No

Did you get information about the reasons for any anaesthetic you needed, including any risks and alternatives?

- Yes
- No

Did you get information about what your recovery would be like after the operation, for example how long you could expect to be in hospital or any help or changes you would need when you go home?

- Yes
- No

Do you think the information you got before your operation gave you the right amount of detail to make decisions? Tick one box for each area of information.

	Not enough detail	Right amount of detail	Too much detail
Reasons for the operation			
Risks of the operation			
Alternatives to the operation			
Anaesthetic for the operation			
Recovery from the operation			

Did you have enough time to ask questions and discuss your decisions before your operation?

- Yes
- No

Were you given information leaflets or booklets to help you make your decisions?

- No
- Yes, but I did not read them
- Yes, but they were not much help
- Yes, and they were helpful

Did you get information about this operation before you were admitted to hospital? (For example at an out-patient clinic or pre-assessment clinic)

- Yes
- No

Did you sign a consent form for any treatments?

- Yes
- No
- I can't remember

Did you read the consent form (or have it read out to you) before you signed it?

- Yes
- No
- I can't remember

Where you offered a copy of the consent form?

- Yes, and I took a copy
- Yes, but I did not want a copy
- No

What age group are you in?

- Under 25
- 25 to 64
- Over 65

If you have any other comments about the information you were given, or your experience of giving consent, please write them in the box on the next page.

TABLE OF RESULTS FROM PATIENT QUESTIONNAIRE BY AGE**RANGES**

		<25	25-64	65+
Are you willing to answer questions about operation?	yes	37	152	78
	no	0	0	0
Did you have an operation during this stay?	yes	36	146	77
	no	1	6	1
Did you get info about reasons for operation?	yes	36	147	77
	no	1	3	1
Did you get info about risks of operation?	yes	36	148	71
	no	1	1	1
Did you get info about alternatives to operation?	yes	21	96	41
	no	14	49	28
Did you get info about anaesthetic you needed?	yes	30	128	64
	no	6	16	10
Did you get info about recovery post-op?	yes	30	132	68
	no	7	15	8
Was the info you got pre-op covered in enough detail regarding reasons for operation?	not enough	0	5	2
	right amount	34	138	69
	too much	0	0	0
With regards to the risks of the operation?	not enough	1	6	3
	right amount	33	135	61
	too much	1	0	3
With regards to alternatives to the operation?	not enough	12	27	6
	right amount	22	104	49
	too much	0	0	1
With regards to anaesthetic needed for operation?	not enough	4	9	4
	right amount	31	131	62
	too much	0	0	1
With regards to recovery from the operation?	not enough	6	14	7
	right amount	29	127	61
	too much	0	0	0
Did you have enough time to ask questions pre-op?	yes	34	136	71
	no	3	12	5
Were you given information leaflets to help make decisions?	no	24	80	20
	yes, did not read	2	3	10
	yes, not much help	0	0	2
	yes, helpful	11	63	41
Did you get info about operation before being admitted?	yes	27	109	59
	no	9	40	16
Did you sign a consent form for any treatments?	yes	34	144	69
	no	1	2	3
	can't remember	1	5	3
Did you read the consent form before signing?	yes	33	112	50
	no	2	30	13
	can't remember	2	10	10
Were you offered a copy of the consent form?	yes, took a copy	10	25	10
	yes, did not want	3	12	12
	no	21	108	48
What age group are you in?	under 25	37	0	0
	25-64	0	152	0
	over 65	0	0	78

**ORIGINAL AND AMENDED RECOMMENDATIONS FROM TABLE
EXERCISE 1**

Original Recommendation	Suggested amendments
1. Trusts should ensure good practice in consent is embedded in clinical practice.	Trusts should ensure good practice in consent is embedded <u>in all Health and Social Care</u>
2. Trusts should ensure consent is included in training for all relevant staff.	Trusts <u>and</u> Educational Bodies (NIMDTA, NIPEC, Universities) should ensure consent is included in training for all relevant staff.
3. Information about alternative management/ treatment options should be included in the consent process. 4. Information about anaesthetic should be included in the consent process. 5. Information about recovery period should be included in the consent process.	Guidance is required on when the consent process should commence. It was suggested that this should be from the start of patient care.
6. Ownership of information leaflets should be clear e.g. produced by Trust or leaflet provider. Trusts should ensure that if they use commercially provided leaflets, these provide unbiased information for patients. 7. Date or version control should be on each leaflet. 8. Contact details should be available on all information.	No change
9. Information leaflets should provide information covering the key areas, e.g., pre & post operative information, benefits, risks and alternatives available.	Direct individuals to adopt a balanced approach when giving information to patients/clients about risks.
10. Leaflets should be audited to ensure consistency. (see Appendix 4 for model audit tool)	Leaflets should be audited to ensure consistency <u>accuracy and that they are up-to-date.</u>
11. Trusts should ensure the whole audit process, and its context is included in audit, including policy, practice, training, staff and patient opinion, as well as completion of consent forms.	This recommendation requires rewording to facilitate understanding.

12. An agreed standardized set of audit tools should be used regionally to maximize consistency (See Appendix 5 for model audit tools and questionnaires).	Direct individuals that the regional audit tools provide a minimum standard of audit and may be supplemented with additional criteria for local application.
13. Form 4 use should be included in consent form audits, as it records decision making for a vulnerable group	There should be reference to the practical difficulties associated with the use of Form 4.
14. Trusts should show the completeness of the audit cycle through re-audit on a regular basis	No change
15. Patients should be offered a copy of the consent form.	Changes to enable future audit of consent to establish if patient was offered a copy of the consent form.
16. Trusts should ensure that information is given to patients on alternatives, anaesthetic and recovery as well as the proposed procedure and its risks and benefits.	Alternatives need to be clarified e.g. surgical/anaesthetic/ which hospital. For elective admissions, information should be provided in advance – can measure in future audits date of consent with date of operation
17. Trusts should ensure that where written patient information is available, it is actually offered to patients.	Changes to enable future audit of consent to establish if patient was offered written information
18. Trusts should get patient feedback on the audit process. This could be through focus groups or questionnaires	No change

Implementation Plan: Prioritised Actions Required at Regional and Trust Level from Table Exercise 2

Regional	Trust
Areas of Good Practice - Recommendations 1 & 2	
<ol style="list-style-type: none"> Needs to be part of the Curriculum for all Health and Social Care Professions More Clarity about what is 'Regular' audit of consent and include guidance for social care 	<ol style="list-style-type: none"> Induction Package and regular mandatory training Appraisal for individuals obtaining consent Regular audit in the range of Health and Social care arenas Training should include issues around capacity
Areas where Consent Process could be enhanced - Recommendations 3, 4 & 5	
<ol style="list-style-type: none"> Dissemination of Report of Regional Consent Audit Amendment to the Regional Consent Forms Guidelines on standardisation/clarity of when the consent process should start – who, when, where and the competence of the individual obtaining consent Clarity and guidance as to which minor procedures require consent and which do not 	<ol style="list-style-type: none"> Amendments to Trust Consent policies to reflect the recommendations of the Regional Audit of Consent Report Training
<ol style="list-style-type: none"> The forms should be reviewed to ensure it maximises its potential for supporting the process. This should include relevance to the social care setting and follow the patient pathway as well as the consent process Redesign the form to track the process (retained in the record) checking with the patient at each stage that they have been provided with and understand information. The form can be kept simple and may need to be signed by different people along the pathway with final signing of consent by for example Consultant in charge of the patient's care. 	<ol style="list-style-type: none"> Staff should be made aware of the Regional Audit Report recommendations Trust Board to agree recommendations Training at Department Level Need to ensure that the consent process is owned by a single individual within a Trust eg Head Nurse
Information Leaflets – Recommendations 6 – 10	
<ol style="list-style-type: none"> Ideally patient information leaflets should be reviewed regionally but realistically it will be undertaken by Trusts – but it carries resource implications Regional Lead Agree standards regionally for consistency Regional internet website for information on leaflets to be accessed 	<ol style="list-style-type: none"> New Trusts should undertake a review of patient information leaflets to implement the recommendations. This carries a resource implication <ul style="list-style-type: none"> Who is going to do this within Trusts There is no commercial interests Funding, printing issues eg pictures Re Recommendation 10 who will audit leaflets to ensure consistency eg proofing committee so the leaflet meets requirements

	of Appendix 4
<ol style="list-style-type: none"> 1. Regional identified lead 2. Regular regional audit (specified time) 3. Information leaflets should be regional 4. Plain Language Commission for all leaflets 5. Take account of cultural diversity/disability 6. Training/Education for all Health and Social Care staff 7. Consent Process/Timing 8. 'Who Takes Consent' important all Health and Social Care Staff 	
Trust Audits – Recommendations 11 – 14	
<ol style="list-style-type: none"> 1. Development and issuing of standardised audit tools to ensure consistency 2. Development of some type of standard and targets for achievement 3. Potential for regional monitoring of audits and results. Return centrally with feedback mechanism regionally 	<ol style="list-style-type: none"> 1. Consent Audits part of the core of the Trust's annual audit programme 2. Ensure audit cycle is completed 3. prioritise specific areas within consent process as appropriate
<ol style="list-style-type: none"> 1. Develop core regional audit tool, but allow some flexibility for local variation. Tool may need to be client group specific eg learning disability, occupational health etc 2. Regional request for Trusts to make consent audit a priority taking into account capacity 3. Centre to facilitate collation of results to allow benchmarking and sharing of good practice 	<ol style="list-style-type: none"> 1. Ensure consent is part of the Trust annual audit plan and identify how frequent "regular" is. Each Trust to submit audit results to centre. 2. Trust needs to identify where Form 4 is used and how this could be audited 3. Trust should identify who should be involved in undertaking the audits – who is responsible for implementing recommendations arising and follow-up audits/action plans
Patient Experience – Recommendations 15 - 18	
<ol style="list-style-type: none"> 1. Information on internet/give web address 2. Training at undergraduate level 3. Department of Health information leaflets to cover 'basic' standard operations, anaesthetics 	<ol style="list-style-type: none"> 1. Recommendation 16 & 17, standardise methods to deliver information 2. Recommendation 15, local training 3. Co-ordination of information from different sources eg. Oncologist, surgeon/physician all involved in same case. Information pack at initial OPD 4. Recommendation 18, Comment cards for all. Focus groups do not always represent the masses. A regular questionnaire, eg yearly or every 2-3 years
<ol style="list-style-type: none"> 1. Recommendation 16 Provision of Training/feedback for people taking consent 2. Recommendation 16, Develop pathways/information leaflet based on specialties of care <p>Recommendations 15 & 17, Development of a check list to show forms/information has been offered or amend consent forms to reflect this</p>	<ol style="list-style-type: none"> 1. Recommendation 17, Training on ensuring leaflets are provided

MODEL AUDIT TOOL FOR PATIENT INFORMATION LEAFLET

QUESTION	DIRECTIONS	RECORD ANSWER IN THIS COLUMN
Title of leaflet	Record title as it appears on leaflet	
Is the leaflet unique to the Trust, or developed by another organisation e.g. a Royal College?	Record either Trust / Name of organisation	
Is leaflet dated?	Record either YES/NO	
Date of leaflet if shown	Use format as it appears on leaflet	
Is the procedure or condition explained?	YES/NO	
Are benefits of planned intervention mentioned?	YES/NO	
Are risks of planned intervention mentioned?	YES/NO	
Are alternatives to planned intervention (including no intervention) mentioned?	YES/NO	
Is there advice about pre-op preparation or post-op care?	YES/NO	
Is a follow-up contact provided?	YES/NO	
Are pictures/ diagrams used	YES/NO	
Overall impression (ease of understanding, layout, content) **subjective**	Excellent/ Average/ Poor	

MODEL CONSENT POLICY & PRACTICE AUDIT TOOL

CRITERIA	EVIDENCE examples	MEASURE
POLICY		
There is a consent policy	Written policy	Yes / No
Staff are aware of consent policy	Staff questionnaire	% staff aware
More detailed policy/procedures are available on consent for staff working with children, young people, people with impaired capacity	Policy, procedures, guidance, assessment tools, evidence of training	Yes / No
ENSURING GOOD PRACTICE		
Staff have had appropriate training in consent	Training records Part of induction training Staff questionnaire	% staff trained
Patients/users are content with consent process	Questionnaires, focus groups, complaints/compliments – see <i>draft model patient consent questionnaire</i>	Yes / No
USER INFORMATION		
Written information about consent is available for users	DHSSPS consent leaflets or Information leaflets with section on consent	Yes / No
Written information about service or procedure is available for users	Information leaflets – see <i>draft model consent leaflet audit</i>	Yes / No
Information is available in appropriate formats	Pictures, translations, interpreting services, audio/video tapes	Yes / No
RECORDING CONSENT		
Discussions / decision making recorded	Evidence of discussions and decisions in care plans or notes	% Satisfactory
DHSSPS consent forms are available	All appropriate forms readily available	Yes / No
Consent forms are completed appropriately	All sections completed – see <i>draft model consent form audit</i>	% Satisfactory

MODEL CONSENT FORM AUDIT TOOL

Type of Consent Form

Hospital Number: _____	Inpatient/Outpatient (Delete as appropriate)
Specialty _____	Consultant _____
Consent form used?	1 2 3 4
Was correct consent form used (based on explanation below)	Yes / No

Consent form 1(pink): For patients who are able to consent for themselves.

Consent form 2(yellow): For those with parental responsibility, consenting on behalf of a child/young person.

Consent form 3(white): For patients consenting for themselves and for those with parental responsibility, where the procedure does not involve any impairment of consciousness.

****The use of this form is optional****

Consent form 4(green): For adults who lack the capacity to consent to a particular treatment. As no-one else can give consent on behalf of such patients, they may only be treated if that treatment is believed to be in their 'best interests'

Person Giving Consent

Was consent form signed by patient/guardian	Yes / No
Who signed the consent form?	Patient / Carer / Parent / Guardian / Other (Please Specify) _____
Was Name printed?	Yes / No
Was the consent form dated?	Yes / No

Details about Procedure

Name of procedure _____		
Was the procedure abbreviated on the consent form? Yes / No		
When was consent obtained?	Date: _____	
When was the procedure carried out?	Date: _____	
Does the consent form record discussions about:	Benefits	Yes / No
	Risks	Yes / No
Was side/site clearly documented?	Yes / No / N/A	
If NO , please comment _____		

Was additional information provided to the patient (eg.leaflet/tape)	Yes / No
If YES , please specify what type of information was given: _____	

Professional Gaining Consent

Was the name of person obtaining consent printed	Yes / No
Was the Job Title of person obtaining consent documented	Yes / No
Please state _____	
Was the Signature of person obtaining consent present	Yes / No
Date Recorded _____	
Was health care professional taking consent the same as the health care professional performing the procedure?	Yes / No
Was an interpreter used	Yes / No / N/A
Did the person giving consent accept a copy of the form?	Yes / No

Confirmation or Withdrawal of Consent

Was consent confirmed if form was signed in advance?	Yes / No / N/A
Was consent withdrawn?	Yes / No
If person withdrew consent was this signed and dated?	Yes / No

Form 4 Only

Was doctors decision regarding lack of capacity documented?	Yes / No
Does the form record input by family/other?	Yes / No
Was a second opinion sought?	Yes / No

MODEL PATIENT QUESTIONNAIRE

A questionnaire about your opinions of getting information and giving consent.

Why we are asking you to fill in this questionnaire

Every day, health and social care staff give people information before those people decide about treatment or care. Treatments include operations, medicines, nursing care, physiotherapy, occupational therapy, speech therapy. Care includes help with dressing, washing, home-help, going to day centre or living in a residential or nursing home.

This questionnaire is to help us find out if people feel they were given the right amount of information for them.

The information we get from all your replies will help us to improve how we give information and get people's consent.

What we are asking you to do

We would like you to tick your answers to each question. It should take about 5 minutes to complete the questionnaire.

**Trusts should insert how the questionnaire is to be returned*

What will happen to the questionnaires?

Once all the information has been looked at, it will be used to let staff know if people generally feel they were given the right amount of information to make decisions.

Please be honest about your opinions

You are not asked to give your name, and no-one will trace your questionnaire back to you.

We want your honest opinions to help us do things well

Your opinion about getting information and giving consent

Please tick one answer for each question

Are you willing to answer some questions about getting information and giving consent?

- Yes – please answer the questions below
- No – do not answer the questions, but please still return the questionnaire

Are you the patient or client, or are you a family member or carer?

- Patient or client
- Family member or carer

What age group are you in?

- Under 25
- 25 to 64
- Over 65

What is the main type of condition you (or the person you care for) are being treated for?

- A long-standing problem
- A new problem
- A combination of new and long standing problems

Did you get information about the main reasons for the planned treatment or care?

- Yes
- No

Did you get information about any risks from the planned treatment or care?

- Yes
- No

Did you get information about any alternatives, including not having any treatment or care?

- Yes
- No

Did you get information about what recovery to expect, for example how long treatment or care would last, or any help or changes you would need at home?

- Yes
- No

Do you think the information you got before gave you the right amount of detail to make decisions? Tick one box for each area of information.

	Not enough detail	Right amount of detail	Too much detail
Reasons for treatment or care			
Risks of treatment or care			
Alternative treatment or care			
Recovery			

Did you have enough time to ask questions and discuss your decisions?

- Yes
- No

Were you given information leaflets or booklets to help you make your decisions?

- No
- Yes, but I did not read them
- Yes, but they were not much help
- Yes, and they were helpful

Only answer the following questions if you had an operation during this hospital admission

Did you get information about this operation before you were admitted to hospital?

(For example at an out-patient clinic or pre-assessment clinic)

- Yes
- No

Did you get information about the reasons for any anaesthetic you needed, including any risks and alternatives?

- Yes, but I would have liked more detail
- Yes, I had about the right amount of detail
- Yes, but there was too much detail
- No

Did you sign a consent form for any treatments?

- Yes
- No
- I can't remember

Did you read the consent form (or have it read out to you) before you signed it?

- Yes
- No
- I can't remember

Where you offered a copy of the consent form?

- Yes, and I took a copy
- Yes, but I did not want a copy
- No

Was your operation an emergency?

- Yes
- No

If you have any other comments about your experience of getting information and giving consent, please write them on the next page.

