Ir J Med Sci
DOI 10.1007/s11845-014-1160-x

ORIGINAL ARTICLE

Content, accuracy and completeness of patient consent in a regional vascular surgery unit

D. McGrogan · D. Mark · B. Lee · M. E. O'Donnell

Received: 31 January 2014 / Accepted: 3 June 2014

Abstract
Objective Although the General Medical Council has published guidelines for procedural consent, there is evidence to suggest that deficiencies still occur in completion demographics, documentation of procedural risks and information regarding alternative therapies. We assessed the accuracy and completeness of vascular consent within our unit.
Methods A retrospective review of patients undergoing vascular intervention between February 2010 and 2011 was performed. Patient chart examination included the analysis of consenting doctors' grade, responsible vascular consultant, completeness of procedural entry, documentation of correct side, use of abbreviations, discussion of benefits and complications, additional information and overall legibility.
Results 323 patient consent forms were reviewed (male 203, mean age 68.0 years, elective surgery 241) including 50 AAA repairs, 27 carotid endarterectomies, 88 peripheral arterial reconstructions, 96 amputations and 69 elective varicose vein surgeries. 294 (91 %) consent forms were completed by a specialist registrar or above with 286 (88.5 %) forms having the responsible consultant documented. 85.4 % of patients were consented within 48 h of surgery. 245 (75.9 %) consent forms had legible printed names. However, only 75 (23.2 %) had a legible signature. 306 (94.7 %) consent forms had the procedure documented in full but 165 (51.0 %) had used abbreviations. 103 (31.9 %) had documentation of the intended benefits of surgery whilst 293 (90.7 %) had documentation of potential complications. Three patients had documented evidence of receiving written information and one patient received a copy of the consent form. Of those surveyed, procedural mortality was discussed in 62.5 % of open and 47.3 % of endovascular AAA repairs. Stroke was documented in 96.3 % of consent forms for carotid endarterectomy. Scarring was included most commonly in patients undergoing venous procedures.
Conclusion Vascular consent is a complex process involving a number of discussions and meetings with patients. Our unit has demonstrated compliance of nearly 90 % for all consent-related processes and remains consistent with current GMC guidance. However, further improvement including the documentation of intended benefits, provision of additional written information whilst reducing the use of abbreviations is desired.

Keywords Consent · Patient · Surgery · Vascular

Association of Surgeons of Great Britain and Ireland 2013 International Surgical Congress, Glasgow, UK, 1st–3rd May 2013 and Society for Clinical Vascular Surgery, California, United States, 18th–22nd March 2014.

D. McGrogan · D. Mark · B. Lee · M. E. O'Donnell
Department of Vascular and Endovascular Surgery, Royal Victoria Hospital, Belfast, Northern Ireland

M. E. O'Donnell
Sport and Exercise Sciences Research Institute, Faculty of Life and Health Sciences, University of Ulster, Jordanstown, Northern Ireland

M. E. O'Donnell (✉)
Division of Vascular and Endovascular Surgery, Mayo Clinic, Phoenix, AZ, USA
e-mail: modonnell904@hotmail.com

Introduction

Optimisation of patient consent in the hospital environment remains vital for patient safety and wellbeing. As an

Published online: 19 June 2014

independent regulator of doctors in the UK, the General Medical Council (GMC) has previously issued generic consent guidelines in 2008 for registered medical practitioners—"consent: patients and doctors making decisions together" [1]. These guidelines examined basic components of patient consent with an emphasis on the importance of adequately trained and qualified personnel to provide a clear and accurate dissemination of information. Adverse outcome documentation was further described including procedural side effects, complication rates and failure to achieve desired objectives [1].

Guidelines for medical record documentation published by the World Health Organisation (WHO-SEARO) coding workshop in 2007 state that "documentation and record keeping is a fundamental part of clinical practice" [2]. Correct documentation was suggested as a means to further delineate clinical accountability whilst acting as a record of an individual's professional practice [2]. Crawford et al. [3] presented the CRABEL score which was designed as a quick and easy assessment tool of the quality of medical record keeping with the purpose of standardising the audit of medical records and improving their quality. These authors also included an assessment of patient consent where patient name, hospital number, operation in full, risks/complications and signature documentation were deemed absolute requirements for inclusion in the patient's records [3]. The Queensland Government in Australia remain the only legislative body to incorporate specific procedural complications in the formal consent process [4].

Previous researchers have investigated individual aspects pertaining to the consent process. Black et al. [5] identified a significant improvement in consent performance in consultants compared to trainees during their assessment of competency when consenting patients for carotid endarterectomy. Interestingly, the authors highlighted that this improvement occurred independently of any formalised training process [5]. Berman et al. [6] analysed the patient's perspective of informed consent for repair of abdominal aortic aneurysms where effective communication improved patient's understanding of their options for surgery and helped facilitate decision-making processes for both the patient and their families. These authors identified deficiencies in dissemination of clinical information relating to available alternative therapeutic options. It was also noted that different patients desired different depths of information content regarding the procedure and that the patient's trust in that particular surgeon had a significant impact on the overall informed consent process. In assessing junior doctors' perceptions of the consent procedure, Houghton et al. [7] reported that 37 % of junior doctors admitted to gaining consent for procedures of which they had little understanding. This poses a potential medico-legal issue in that patients may have grounds to claim that they were not fully informed about specific complications and that whilst not a definitive defence, documentation of risks explained may help to form a platform for defence of practice. In addition, Carter et al. [8] suggested that the implementation of clinical audit in the review of the consent process appeared to improve the overall process of informed consent when assessed in New Zealand vascular surgery patients.

Currently, there are no explicit guidelines regarding patient consent for major vascular operative intervention in Great Britain and Ireland. The main objective of this study was to assess key aspects of patient consent within our tertiary vascular surgical practice particularly relating to consent content, accuracy and completeness.

Methods

All patients undergoing a vascular surgery intervention at the regional vascular and endovascular unit in the Belfast City Hospital were assessed in this study between February 2010 and 2011. Surgical caseload was identified through analysis of the Belfast Health and Social Services Trust Theatre Management System. Patients undergoing core vascular procedures including aortic aneurysm, carotid, peripheral arterial and amputation surgeries as well as varicose vein operative interventions were included in the study. Miscellaneous surgeries including wound washout/debridement, arteriovenous fistula formation, fasciotomies and percutaneous interventional radiological procedures were excluded. Office-based radiofrequency vein ablations were also excluded as they were not formally recorded on the theatre management system.

Following patient identification, the clinical case notes were reviewed to identify patient demographics, clinical diagnosis and operative intervention performed. The patient's consent form was assessed for all aspects of information pertaining to: completion demographics including responsible staff member and timeframe for consent completion; documentation of patient details and overall legibility; procedural descriptives including type, laterality and use of abbreviations for the surgical procedure; complication documentation and supporting information provision.

The data for this study were collected by two second year core surgical trainees, DMG and DM, supervised by MEOD. Interpretation of consent documentation and overall legibility was performed by DMG and DM using guidelines and processes derived from the 2007 WHO-SEARO workshop and the Crawford–Beresford–Lafferty (CRABEL) model. The CRABEL score provides a mechanism during the auditing of medical notes where five points may be assigned for correct consent documentation

including one point each for the patient's name; hospital identifier number; consultant in charge of care; date/time; and clinician demographics (name, designated title and pager number). Additional points may be awarded for subsequent chart entries based on overall legibility [3]. An overall CRABEL score for this study was then calculated for each consent form based on five key areas including patient name, hospital number, operation in full, inclusion of risks/complications and signature [3].

Results

Surgical caseload

From February 2010 to 2011, a total of 729 operations were performed on 613 patients. One hundred and eighty-eight procedures were excluded from the final analysis leaving 541 core vascular procedures performed on 478 patients during the study period. Two hundred and ninety-one patient charts were retrieved successfully for review from the medical records department accounting for 323 procedures. The majority of patients was male ($n = 203$, 69.7 %) with a mean age of 68.0 years. Of these 291 patient charts assessed, 111 patients had a history of previous vascular intervention including 12 abdominal aortic aneurysm (AAA) repairs, 33 peripheral arterial reconstruction, 3 carotid endarterectomies (CEA), 42 lower limb amputation procedures, 14 varicose vein operations and 53 lower limb percutaneous revascularisation interventions. Forty-six patients had a combination of these procedures.

Two hundred and forty-one (74.6 %) of the 323 procedures were deemed elective or semi-elective. These included 30 (20 elective) open and 20 (17 elective) endovascular AAA repairs, 27 (19 elective) CEA, 88 (57 elective) peripheral arterial reconstructions, 96 (59 elective) amputations and 69 elective varicose vein surgeries. Seven patients were consented for a combination of procedures: EVAR + amputation ($n = 2$) and peripheral arterial reconstruction + amputation ($n = 5$). The consent forms for 6 (1.9 %) patients could not be traced whilst a further patient had documentation of verbal consent clearly recorded in the clinical notes by the vascular consultant for an elective EVAR.

Completion demographics

Two hundred and eighty-six (88.5 %) consent forms had the responsible consultant documented. Three hundred and thirteen (96.9 %) consent forms had the grade of consenting doctor documented. Forty-six (38 elective) procedures were consented by consultants, 248 (183 elective) by specialist registrars, 14 (9 elective) by core surgical trainees and 5 (3 elective) by foundation year two doctors. Three hundred and sixteen (97.8 %) consent forms had the date of consent documented. One hundred and seventy-three (132 elective) consent forms were completed on the day of procedure, 103 (74 elective) 1 day before, 17 (11 elective) 2 days before, 13 (11 elective) 3 days before, 4 (4 elective) 4 days before, 4 (2 elective) 5 days before, 1 (both elective) each 6 and 7 days before.

Documentation of patient demographics and overall legibility

Patient demographics were documented on all consent forms manually by the clinician ($n = 9$, 2.8 %) or with pre-printed addressograph labels ($n = 308$, 95.3 %). Manual completion of demographic data was only performed during the consent for ruptured aortic aneurysm repair. Written details included name, surname, date of birth and identifying health and care and/or unit number for each patient whilst the pre-printed addressographs also included the patient's address. None of the consent forms had documentation of the Health and Social Service Trust or patient's general practitioner. No other types of pre-printed labels were used at any stage within the Belfast Health and Social Services Trust.

During the analysis of additional handwritten information pertaining to procedure-specific details within the main body of the consent form, i.e. documentation of responsible consultant, procedure, intended benefits, potential complications, DMG and DM identified that all reviewed consent forms contained information considered legible enough for complete interpretation. Two hundred and forty-five (75.9 %) consent forms had legible printed names of the consenting clinician whilst only 75 (23.2 %) of these had a legible signature. None of the consent forms had a documented General Medical Council number next to the signature.

Procedural descriptives

306 (94.7 %) consent forms had the procedure documented in full. One hundred and sixty-five (51.0 %) had abbreviations used for other details within the consent form including abdominal aortic aneurysm abbreviated to AAA ($n = 5$), common femoral artery as CFA ($n = 2$), arterial bypass abbreviations such as fem/fem or fem/pop ($n = 5$) and below knee abbreviated to BK ($n = 1$). Thirty-one patients undergoing venous operations had abbreviations for the long saphenous vein (LSV), sapheno-femoral (SFJ) and sapheno-popliteal (SPJ) junctions. One hundred and ten forms had DVT/PE used to abbreviate thromboembolic risk, 11 had the abbreviation CVA documented for cerebrovascular

Table 1 General and specific procedural-related complications associated with aortic, carotid, peripheral arterial, amputation and varicose vein surgeries

General procedural complications						
Operation	Open AAA $n = 24$ (%)	Evar $n = 19$ (%)	Carotid $n = 27$ (%)	Peripheral $n = 88$ (%)	Amputation $n = 96$ (%)	Venous $n = 69$ (%)
Bleeding	19 (79.2)	16 (84.2)	26 (96.3)	85 (96.6)	25 (26.0)	67 (97.1)
Bruising	2 (8.3)	5 (26.3)	8 (29.6)	22 (25.0)	9 (9.4)	21 (30.4)
CVA	2 (8.3)	1 (5.3)	26 (96.3)	0	2 (2.1)	0
MI	15 (62.5)	7 (36.8)	8 (29.6)	28 (31.8)	11 (11.5)	1 (1.4)
Death	15 (62.5)	9 (47.3)	9 (33.3)	27 (30.7)	16 (16.7)	0
Respiratory infection	9 (37.5)	8 (42.1)	5 (18.5)	29 (33.0)	11 (11.5)	7 (10.1)
Thromboembolism	9 (37.5)	10 (52.6)	5 (18.5)	44 (50.0)	15 (15.6)	47 (68.1)
Wound infection	17 (70.8)	14 (73.7)	18 (66.7)	77 (87.5)	77 (80.2)	57 (82.6)
Wound scar	1 (4.2)	1 (5.3)	1 (3.7)	1 (1.1)	7 (7.3)	20 (29.0)

Specific procedural complications					
Open AAA	Evar	Carotid	Peripheral	Amputation	Venous
Urinary retention 1 (4.2)	Endoleak 3 (15.8)	Cranial nerve injury 20 (74.1)	Distal ischaemia 26 (29.5)	Additional surgery 31 (32.3)	Chronic pain 17 (24.6)
Distal ischaemia 16 (66.7)	Graft infection 3 (15.8)	Numbness 1 (3.7)	Future amputation 28 (31.8)	Chronic pain 13 (13.5)	Deep vein injury 2 (2.9)
Bowel injury 4 (16.7)	Graft occlusion 3 (15.8)	Patch infection 1 (3.7)	Future intervention 21 (23.9)	Failure to regain mobility 1 (1.0)	Failure to improve symptoms 3 (4.3)
Graft infection 4 (16.7)	Re-intervention 4 (21.1)	Respiratory compromise 1 (3.7)	Graft infection 8 (9.1)	Long-term wound care 42 (43.8)	Further surgery 2 (2.9)
Graft ischaemia 4 (16.7)	Renal failure 8 (42.1)	Swallowing difficulties 1 (3.7)	Graft occlusion 24 (27.3)	Phantom pain 10 (10.4)	Nerve injury 48 (69.6)
Ileus 1 (4.2)			Limb oedema 3 (3.4)	Proximal amputation 5 (5.2)	Numbness 12 (17.4)
Renal failure 10 (41.7)			Long-term wound care 7 (8.0)		
			Nerve injury 23 (26.1)		
			Procedural failure 15 (17.0)		
			Seroma 2 (2.3)		
			Use of synthetic material 1 (1.1)		

AAA abdominal aortic aneurysm, *CVA* cerebrovascular accident, *EVAR* endovascular aortic aneurysm repair, *MI* myocardial infarction

accident-stroke and 17 had MI used for myocardial infarction. Where laterality was relevant only one consent form had the side abbreviated to a single letter whilst three patients had bilateral abbreviated to B/L or BL. Only four consent forms used numerical figures to identify digits. Twenty-five consent forms had more than one abbreviation used.

One hundred and three (31.9 %, 78 elective) consent forms had documentation of the intended benefits of surgery. Two hundred and ninety-three (90.7 %, 224 elective) had documentation of potential complications. Of the remaining 30 consent forms, only 10 had no complications documented whilst 14 patients had a form 4 completed (used for adults who lack capacity to consent to examination, treatment or care). As stated previously, six procedures had no documented evidence of consent, all of whom underwent emergency repair of a ruptured abdominal aortic aneurysm.

Complication documentation

A further analysis was completed to explore documentation of both general and procedure-specific complications for each of the core procedures (Table 1; Fig. 1).

Open AAA repair

General complications included bleeding, myocardial infarction, death and wound infection whilst procedure-specific complications most commonly documented included renal failure and distal ischaemia.

Endovascular AAA repair

Similar to open AAA repair, bleeding and wound infection were commonly discussed during the consent process. However, it was noted that the more significant complications of myocardial infarction and death were discussed less frequently whilst more emphasis was placed on respiratory infection and venous thromboembolic complications compared to open AAA repair. Renal failure was the most common procedure-specific complication discussed as well as endoleak, graft complications and re-intervention.

Carotid endarterectomy

Bleeding and cerebrovascular accident were included in nearly all consent forms whilst wound infection, myocardial infarction, death, respiratory and venous

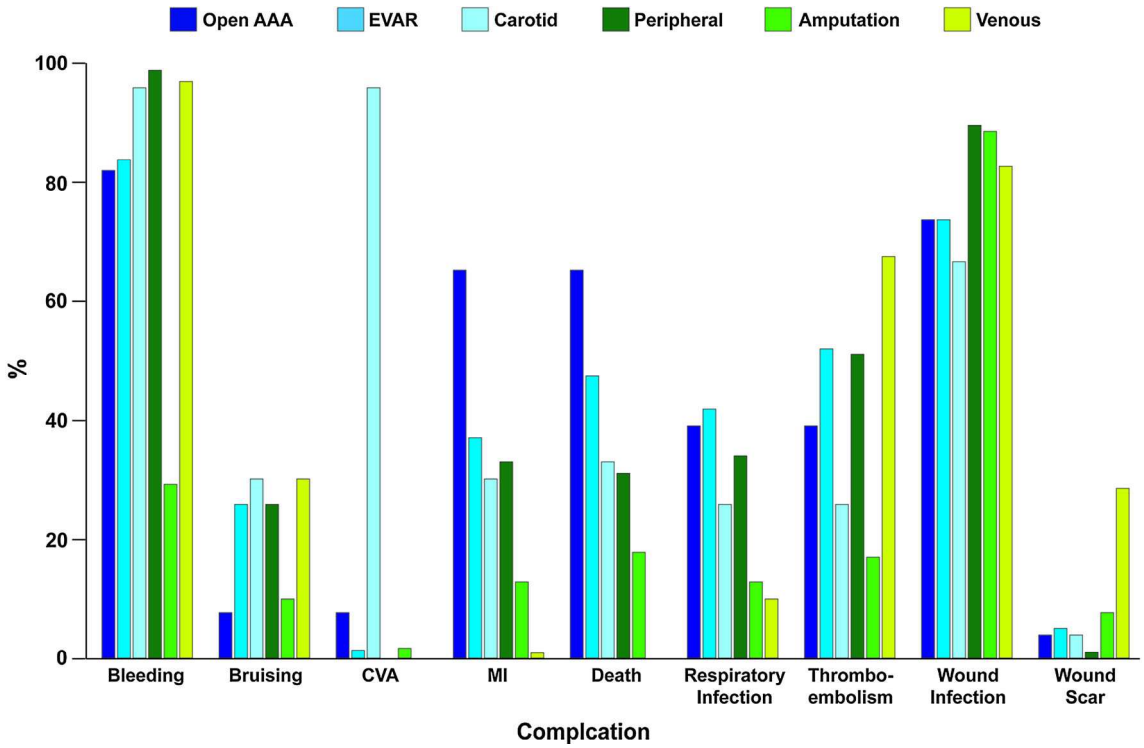

Fig. 1 General complications associated with aortic, carotid, peripheral arterial, amputation and varicose vein surgeries (*CVA* cerebrovascular accident; *MI* myocardial infarction; % percentage of consent forms which included the particular complication)

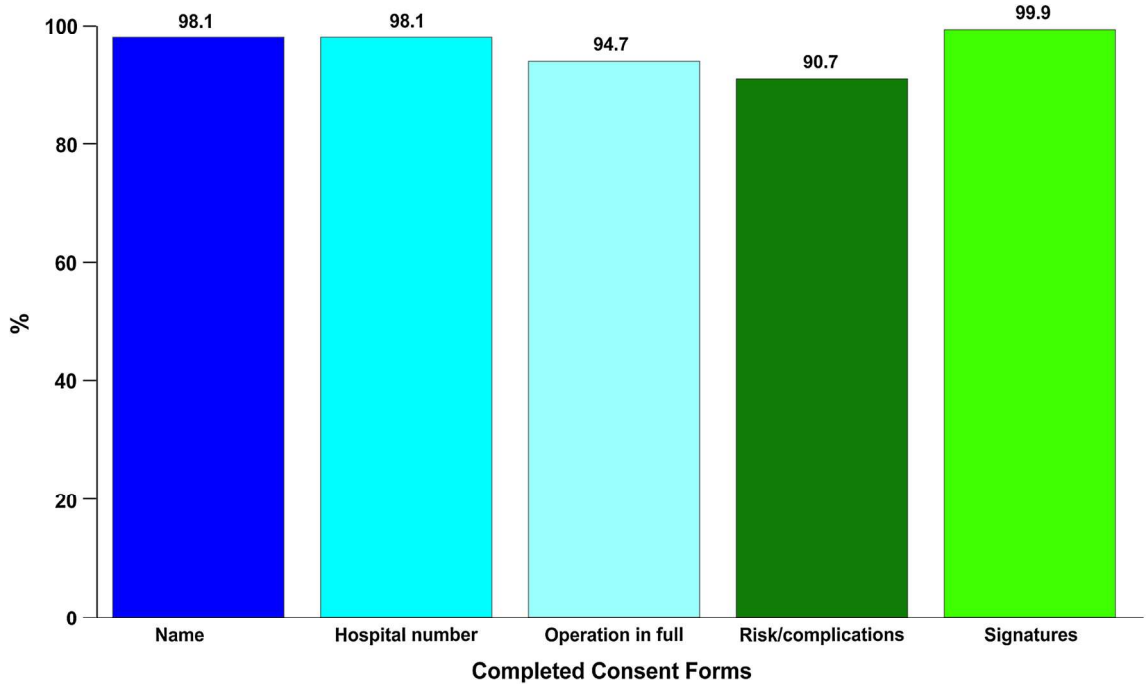

Fig. 2 Consent form documentation compliance assessed using the overall CRABEL score derived from five key areas including patient name, hospital number, operation in full, inclusion of risks/complications and signature

thromboembolism complications were documented in a third of all consent forms. Cranial nerve injury was the most commonly described procedural-related complication.

Peripheral arterial reconstruction

Bleeding, wound infection, venous thromboembolism as well as cardiac and respiratory complications were discussed whilst procedure-specific complications included distal ischaemia, future interventions, graft complications, nerve injury, procedural failure and long-term wound care.

Amputation

Wound infection was the most common general complication included for amputation surgery. Requirement for additional surgery and long-term wound care were the most common procedure-specific complications discussed.

Varicose vein surgery

Bleeding, wound infection and venous thromboembolism were discussed most frequently whilst wound scarring discussions occurred more frequently than any other procedure. Procedure-specific complications included nerve injury and chronic pain following the venous intervention.

Supporting information

Only three consent forms had documented evidence confirming the provision of additional written information pertaining to the procedure provided to the patient. Only one patient had documentation of receipt of a copy of the consent form. None of the consent forms indicated that the patient had received information regarding the post-operative recovery process.

CRABEL score analysis

Assessment of the CRABEL score was performed for each of our completed consent forms excluding those patients that had no forms for review ($n = 7$) and those which had a form 4 completed ($n = 14$). Completion of name and hospital number was recorded in 98.1 % of consent forms, full operation documentation in 94.7 %, risks/complications in 90.7 % and signatures were found on 99.9 % of completed consent forms (Fig. 2).

Discussion

The GMC document "consent: patients and doctors making decisions together" has stated that the individual undertaking the procedure is responsible for gaining the consent of the patient either in person or via another delegated

individual provided that they are suitably trained and qualified, have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved with the procedure itself; whilst understanding and agreeing to act in accordance with detailed guidance within the GMC booklet itself [1]. In our unit, 88.5 % of consent forms had the responsible consultant documented reflecting the importance assigned to overall responsibility for vascular interventions. 96.9 % of consent forms had the grade of consenting doctor documented with 91.0 % being consented by a consultant (14.2 %) or surgical registrar (76.8 %). This trend was also identified amongst emergency vascular interventions ($n = 80$) where 91.2 % of cases were consented by surgical registrar or above.

Although there are no explicit criterion to evaluate competency for procedural-based clinicians, previous researchers have suggested that consultants and registrars were most capable at gaining informed consent and that there was a deficiency of knowledge in other members of the surgical team to adequately gain informed consent [9]. Other specialities have had similar experiences. Temple-Doig et al. [10] attributed a higher proportion of consent completion by interventional radiology consultants due to perceived deficiencies in overall exposure of interventional procedures by radiology trainees compared to their surgical counterparts. Black et al. [5] also reported that vascular consultants had higher performances gaining patient consent compared to junior or senior surgical trainees. Despite their findings, these authors acknowledged that such abilities to perform patient consent occurred despite a generalised lack of formal training [5]. Similar to Black et al. [5], senior staff in our unit did not report any formal consent training where capability to consent was simply based on experiences gained during the completion of such vascular procedures over many years. Surgical trainees in Northern Ireland now have opportunities to receive formal consent training regarding patient consent at regional generic teaching sessions combined with additional supervision and formal assessment of their abilities through completion of direct observational of procedural skills (DOPS) and procedural-based assessments (PBA) for their Intercollegiate Surgical Curriculum Project (ISCP) portfolios [11].

Currently, there remains very little published information regarding the appropriate timing of consent. The GMC delineates that the patient's consultant physician performing the procedure remains responsible for correct dissemination of information in an appropriate time frame prior to the commencement of any invasive investigative or therapeutic modality. The defined length of time prior to the procedure can vary depending on the simple logistics of admission alone particularly with the growing tendency to admit patients on the day of their procedure creating smaller windows of opportunity for consent. In our unit, 173 (76.3 % elective) and 103 (71.8 % elective) procedures were consented on the day of and day prior to their procedure respectively equating to 276 procedures (85.4 %) patients consented <48 h of their procedure, 74.6 % of which were elective.

The WHO-SEARO coding workshop 2007 states that appropriate documentation promotes a high standard of clinical care and provides evidence that the clinician has met their duty of care and taken all reasonable decisions and actions to provide the highest standard of care [2]. In our study, the majority of completed consent forms had printed addressographs whilst only 2.8 % had handwritten demographic details where all five sections were fully complete. This highlights the diligence of paramedical staff within the Belfast Trust to ensure that addressographs are available for use in the vast majority of patients including emergencies. Post-hoc analysis identified only 17 consent forms out of a potential 305 completed forms which failed to reach a CRABEL score of 5 out of 5 with completion rates of greater than 90 % for each of the CRABEL consent parameters (Fig. 2).

Overall, the two data collectors DMG and DM reported that overall legibility and subsequent documentation of written information in the body of the consent forms (consultant, procedure, intended benefits and risks) to be of a high standard with no significant difficulties with interpretation of handwritten information including abbreviations. We found that 75.9 % had legible printed names whilst only 23.2 % of consent forms had a legible signature. None of the consent forms had the doctor's GMC number documented next to their signature. Although it is acknowledged that the current design of consent forms in Northern Ireland has no designated space for GMC numbers at present, this may be an issue to consider in future publications.

In 2002, the Department of Health (Northern Ireland) published the consent for examination or treatment for a competent adult form (form 1—pink colour) [12]. Our study identified that 94.7 % of consent forms had the proposed procedure documented in full, 31.9 % had documentation of intended benefits and 90.7 % had documentation of potential complications. All completion deficiencies in the proposed procedure (5.3 %) or complication (9.3 %) sections occurred in emergency surgeries. Although 43.7 % (45/103) of consent forms without documentation of intended benefits were emergency surgeries, the majority were consents for elective procedures. Our experience suggests appropriate adherence to current guidelines regarding inclusion of the actual proposed procedure and completion of the potential complications sections of the consent form. It remains unclear why documentation of intended benefits of the surgery completion rates was so low particularly as patients undergoing

surgery often have unrealistic expectations [13]. It is postulated that written omission merely reflects a predominant emphasis in our unit on the verbal description of procedural indications and potential benefits whilst accurate completion of the proposed procedure and complications sections reflects a medico-legal necessity. Following an assessment of the actual consent form, the authors also noted that sections for patient diagnosis or alternative treatment options are not yet included.

During the study period, 51.0 % ($n = 165$) of consent forms had used abbreviations. The WHO-SEARO coding workshop states that whilst "abbreviations and symbols can be an effective and efficient form of documentation, abbreviations that are obscure, poorly defined and open to broad interpretation or have multiple meanings can lead to confusion and error in relation to patient care". Although there are no current explicit recommended abbreviations for medical practice, online medical dictionaries do list current common medical abbreviations. With the exception of "fem/fem", "fem/pop" and "B/L", all the abbreviations identified in this study were easily identifiable online. Interestingly, the Cambridge publication "Professional English in Use: Medicine 2008" failed to observe the abbreviation AAA for abdominal aortic aneurysm [14]. Although the authors identified a significant proportion of abbreviations used within the consent forms assessed in this study, it remains important to emphasise that delivery of clinical information to the patient should still remain clear, transparent and understandable especially when signatory confirmation is required. Consent forms should therefore try to avoid or minimise the use of abbreviations unless such terms have been explained to the patient in full. Despite the completion of the patient's signature on each consent form, it remains unclear whether every patient had complete understanding of the issues pertaining to the procedure particularly if abbreviations were used.

Reported general and procedure-specific complications identified in our study appear consistent with previous published reports. Berman et al. [15] surveyed expert opinion from the "International Society for Vascular Surgery" regarding the importance of discussing various complications during the consent of patients for open and endovascular repair of abdominal aortic aneurysms and reported that mortality, myocardial infarction, renal failure and impotence were weighted most heavily. Of those surveyed, procedural mortality was discussed in 97 % of open and 94 % of endovascular AAA repairs. Other co-morbidities discussed in their publication included myocardial infarction (67 % open and 58 % EVAR), renal failure (48 % open and 53 % EVAR) and impotence (62 % open and 32 % EVAR). A varying degree of importance was reported for other complications during AAA repair including stroke risk which was discussed by less than a third of surgeons. This variation in expert opinion is similarly reflected in our unit's inclusion of mortality (62.5 % open, 47.3 % EVAR), myocardial infarction (62.5 % open, 36.8 % EVAR) and renal failure (41.7 % open, EVAR 42.1 %). Our unit's inclusion of impotence and stroke in the consent form was lower than that of the American survey. Impotence was not recorded in any of the consent forms reviewed whilst stroke risk was recorded in only 8.3 % of open and 5.3 % of EVAR operations. In their simulated assessment of surgeon's abilities to consent, Black et al. [5] used ten items felt by local experts to be important for carotid endarterectomy consent including risk of stroke, scarring, cranial nerve damage, bleeding, infection and myocardial infarction. In our study, stroke was documented as a complication in 96.3 % of consent forms, scarring in 3.7 %, cranial nerve damage in 74.1 %, bleeding in 96.3 %, wound (66.7 %) and respiratory tract (18.5 %) infection and myocardial infarction in 29.6 %. In addition to the actual percentage documentation of each complication for each procedure, we also identified variations amongst different surgeons and also amongst the same surgeons consenting different patients. We feel this reflects the adaptability of the consent process to cater for each patient as an individual rather than as a collective dataset for each procedure. We also identified the omission of stroke risk in one consent form for a carotid endarterectomy which is unacceptable.

A number of national publications have previously discussed the role of written information provision during the consent process [16, 17]. The ability to enhance the consent process through provision of well-crafted booklets was discussed as a potential modality to make consent more "user friendly". In our unit, we could find evidence that only three patients had received written information and that only one patient had received a copy of their consent. We could find no evidence in our study that documentation of information regarding the post-operative recovery process had been provided to any patient. However, during a subsequent assessment of both outpatient clinic and ward-based environments, the authors were able to identify clearly displayed and freely available patient booklets with information pertaining to all the vascular procedures and their clinical sequelae. Although this study identified that actual provision of a copy of the consent form to the patient as well as delivery of additional information was not documented, the authors report that clinicians within our department routinely advise patients verbally of the additional documentation available in the clinical environment.

We acknowledge limitations relating to this study where it is merely representative of a single units' experience over a pre-defined time period. It must also be noted that gaining patient consent for surgical intervention is a process, not

simply a signed consent form and that a signed consent form does not necessarily indicate informed consent. As an objective review of data inclusion in written consent forms, this study has not formally assessed patient understanding. A synchronous assessment of the full consent process particularly verbal information dissemination and patient understanding would serve to improve overall consent validity. Further study may also address the overall patient experience from the initial out-patient consultation through to hospital discharge with additional inclusion of actual patient understanding.

The authors also acknowledge that no specific criterion for complication documentation was defined during calculation of the CRABEL score. The lack of research into expert opinion regarding the vascular consent process and inclusion of complications in the UK is apparent. The authors are currently conducting a National Survey of Vascular Consent in Great Britain and Ireland.

Conclusion

Vascular consent is a complex process involving a number of discussions and meetings with patients. Our unit has demonstrated compliance of nearly 90 % for most consent-related processes and remains consistent with current GMC guidance. However, further improvement including the documentation of intended benefits, provision of additional written information whilst reducing the use of abbreviations is desired.

Acknowledgments The authors acknowledge Ms. Bonnie Schimek from the Mayo Clinic who provided assistance with all the figures.

References

1. General Medical Council (2008) Consent: patients and doctors making decisions together. http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp. Last accessed 12 May 2014
2. WHO-SEARO workshop (2007) Guidelines for medical record and clinical documentation. http://www.searo.who.int/LinkFiles/2007_Guidelines_for_Clinical_Doc.pdf. Last accessed 15 May 2013
3. Crawford JR, Beresford TP, Lafferty KL (2001) The CRABEL score: a method for auditing medical records. Ann R Coll Surg Engl 83(1):65–68
4. The State of Queensland (Queensland Health) (2012). http://www.health.qld.gov.au/consent/html/sub_specialties/vascular.asp. Last accessed 12 May 2014
5. Black SA, Nestle D, Tierney T, Amygbalos I, Kneebone R, Wolfe JHN (2009) Gaining consent for carotid surgery: a simulation-based study of vascular surgeons. Eur J Vasc Endovasc Surg 37(2):1334–1339
6. Berman L, Curry L, Gusberg R, Dardik A, Fraenkel L (2008) Informed consent for abdominal aortic aneurysm repair: the patient's perspective. J Vasc Surg 48(2):296–302
7. Houghton DJ, Williams S, Bennett JD, Back G, Jones AS (1997) Informed consent: patients' and junior doctors' perceptions of the consent procedure. Clin Otolaryngol Allied Sci 22(6):515–518
8. Carter K, Roake JA, Buckenham T, Frampton CM, Lewis DR (2008) Informed consent for vascular intervention: completing one audit loop. NZ Med J 121(1269):57–63
9. Soin B, Smellie WA, Thomson HJ (1993) Informed consent: a case for more education of the surgical team. Ann R Coll Surg Engl 75(1):62–65
10. Temple-Doig L, Gordon M, Buckenham T, Roake J, Lewis D (2005) Informed consent for vascular intervention. N Z Med J 118(1221):U1630
11. Intercollegiate Surgical Curriculum Programme. https://www.iscp.ac.uk/surgical/curr_intro.aspx. Last accessed 12 May 2014
12. Department of Health (UK) (2001) Good practice in consent implementation guide: consent to examination or treatment. London: Department of Health publications. Available at http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Consent/ConsentGeneralInformation/fs/en. Last accessed 15 May 2013
13. Palfreyman SJ, Drewery-Carter K, Rigby K, Michaels JA, Tod AM (2004) Varicose veins: a qualitative study to explore expectations and reasons for seeking treatment. J Clin Nurs 13(3):332–340
14. Glenndinning E, Howard R (2007) Professional English in Use: Medicine. Cambridge University Press, Cambridge
15. Berman L, Dardik A, Bradley EH, Gusberg RJ, Fraenkel L (2008) Informed consent for abdominal aortic aneurysm repair: assessing variations in surgeon opinion through a national survey. J Vasc Surg 47(2):287–295
16. Campbell B (2004) New consent forms issued by the Department of Health. Ann R Coll Surg Engl 86(6):457–458
17. Langdon IJ, Hardin R, Learmonth ID (2002) Informed consent for total hip arthroplasty: does a written information sheet improve recall by patients? Ann R Coll Surg Engl 84(6):404–408