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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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VALID AND INFORMED CONSENT IN ORTHOPAEDIC SURGERY: A MULTICENTRE, REGIONAL SERVICE EVALUATION OF CURRENT UK PRACTICE

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Abstract.

Background: In recent years, there has been increasing focus upon tailoring the consent process to reflect patients' individual needs and concerns. Meanwhile, clinical litigation costs for 'failure to warn' as part of 'informed consent' remain staggeringly high. We aimed to investigate the validity of the patient consent process in elective lower limb arthroplasty surgery regionally, with a view to ascertaining how it could be improved.

Methods: Regional data across the East of England was collected retrospectively from seven hospital trusts (fifty data sets per hospital) in 2021 and analyzed against predetermined criteria. Data analyzed included operation notes, patient records and clinic letters.

Results: A total of 165 elective knee and 173 elective hip replacement cases were included in the final analysis. Capacity criteria (defined as the ability to understand, retain, weigh up and communicate a decision) were fulfilled in 11.6% of hip and 13.9% of knee replacement surgeries, despite Consent Form 1 (a form commonly used in England to consent adults, deemed to have capacity, for surgical procedures) being completed in 94.8% and 88.5% of these same cases. Procedure-specific consent was obtained in 74.0% and 72.1% of cases, respectively, whilst 'Type' and 'Brand' of implant were rarely consented for. Alternative treatment options were offered in 67.1% of hips and 62.1% of knee cases. Separate consent clinics were offered in 55.5% of hip and 57.6% of knee cases.

Conclusions: This study demonstrates that there is room for improvement within the current consent process. We propose digitalization, utilizing interactive multimedia and audio-visual demonstrations to explain surgical procedures, as a dynamic and versatile adjunct to the consent process.

Categories: Orthopaedics, Quality Improvement, Healthcare Technology

Key words. clinical negligence, knee surgery, hip surgery, orthopaedics, valid and informed, consent, lower limb arthroplasty.

Introduction.

The Montgomery ruling has led to an immense shift in our collective understanding of 'informed consent' and shared decision making. It deviates significantly from the previously applied 'Bolam test' and has led to landmark changes in our approach to the consent process [1].

The General Medical Council (GMC) recently released a document on 'Decision Making and Consent' in November 2020, which reinforces both the relevance and clinical implications of this ruling [2]. The document outlines guiding principles surrounding the multifaceted process of consent. Communication clearly plays a crucial role in the delivery of optimal patient-centred care, not only as an effective means of reducing clinical litigation claims, but also to improve patients' experiences within the healthcare setting [1,2].

Various approaches to obtaining consent have been proposed, from the use of separate consent clinics and remote video consultations, to pre-printed, standardised consent forms [3,4].

Within Trauma and Orthopaedic Surgery alone, consent-related litigation claims accounted for over £1.2 billion of all cases of damage related pay-outs between 2008 and 2019 [5]. Both the Royal College of Surgeons (RCS) and the GMC have recognised the significant medico-legal burden levied secondary to consent-related litigation issues [2,6,7]. Overall, there are clearly heavy healthcare and socioeconomic implications incurred from litigation claims [5,8].

Although there have been previous, smaller studies examining the usefulness of individual consent methods (such as the hand-

written consent form) [3,9], our research has not highlighted any recent large, multi-centre study examining current consent processes used in Orthopaedic surgery for elective lower limb arthroplasty procedures, hoping to identify and evaluate failings in the current process, in order to ascertain how it can be improved [2].

This article was previously presented as a poster at the 2023 EFORT International conference poster walk in Vienna (24-26th May 2023); as a poster presentation at the 2022 ASiT annual conference in Aberdeen on 4th-6th March 2022; at the 2022 SICOT Young Surgeons' International Meeting and CTOC Cambridge Club Combined Collaboration as a poster presentation on 30th June-1st July 2022 and as an oral free paper presentation at the 2022 SICOT Kuala Lumpur International Orthopaedic World Congress (28-30th Sept 2022). This article has also been published as an abstract in the 2022 BJS Oxford Academic [10].

Materials and Methods.

Hospitals were recruited through the Orthopaedic Research Collaborative East Anglia (ORCA).

Seven hospital trusts across the East of England collected fifty data sets each for elective lower limb arthroplasty procedures (n = 350). Data for the month commencing 1st of May 2021 was collected retrospectively and the final data sheet stored in an anonymised format.

Data standards followed principles laid out by the Royal College of Surgeons and GMC, as shown below in Table 1.

Data collected for analysis included: 'Type of Procedure' consented for; discussion of 'Alternatives, Risks and Benefits' of the procedure; the availability of separate consent clinics; patient information leaflets and documentation demonstrating satisfactory fulfilment of capacity criteria.

As a means of regulating and standardising the data collection process regionally, data standards were discussed and agreed upon prior to data collection. Regular weekly meetings held across participating hospitals allowed any queries relating to the data collection process to be addressed promptly.

Data for all eligible patients meeting the inclusion criteria was collected. This included patients of age >16 years, patients undergoing elective hip and knee arthroplasty procedures and patient records (all available paper/electronic records, clinic letters, consent forms and operation notes). Incomplete data and non-elective (trauma cases) were excluded from the final analysis.

Regional results were analysed quantitatively to evaluate the validity of the patient's consent journey.

Characteristics of the Seven Participating Hospital Trusts.

A total of seven hospitals were involved in this audit, within the East of England region: Norfolk and Norwich University Hospital, Addenbrooke's (Cambridge University Hospitals Trust), Princess Alexandra Hospital NHS Trust (Harlow), Lister Hospital NHS Trust, James Paget University Hospital, Colchester General Hospital Foundation Trust and Broomfield Hospital, NHS Foundation Trust (Chelmsford).

Table 1. *Data standards followed principles laid out by the Royal College of Surgeons and GMC.*

Data Standards
Procedure
Date of procedure
Date of consent for procedure
Type of implant consented for
Brand of implant consented for
Were alternative treatment options offered?
• What were the alternative treatment options offered?
• How were the alternative treatment options documented?
Was there a separate 'consent clinic' prior to surgery?
Were the benefits of treatment discussed?
• What benefits were discussed?
Were the risks of treatment discussed?
• What risks were discussed?
Where was the discussion of 'risks and benefits' of treatment documented?
Was a copy of the clinic letter sent to the patient?
Did the patient sign a procedure-specific consent form?
Is there a record of a patient information leaflet being given and documented in the clinic letter(s)?
Is the name of the leaflet and version/date documented?
How was the patient information leaflet given?
Was a capacity assessment carried out and documented?
Does the patient have capacity (has signed consent form 1)? Capacity for which patients were deemed able to provide informed consent was assessed through fulfilling the following four criteria:
• Was the patient's understanding of the procedure assessed and documented?
• Was the patient's ability to retain information concerning the procedure assessed and documented?
• Was the patient's ability to weigh up information concerning the procedure assessed and documented?
• Was the patient's ability to communicate information regarding the procedure assessed and documented?

Six hospitals are designated trauma units, whilst the seventh participating hospital, Addenbrooke's, serves as the East of England's level 1 designated major trauma centre, as well as a teaching hospital [11,12].

Norfolk and Norwich University Hospital is a tertiary centre and is renowned for being one of the biggest teaching trusts in the country, affiliated with the University of East Anglia for research [13,14].

The Princess Alexandra Hospital, Harlow provides a full range of general acute services, with access to complex and revision lower limb arthroplasty procedures, including hip arthroscopy services [15,16].

Lister Hospital is a district general hospital which provides a range of general and specialist services and is a teaching hospital [17,18].

James Paget University Hospitals Foundation Trust is a university hospital foundation trust which offers a full range of general acute services [19].

Colchester Hospital offers a range of Orthopaedic services, including hip and knee arthroplasty surgery [20].

Broomfield hospital provides a variety of services including elective surgery in most specialties and has an internationally renowned Burns Unit [21].

Ethics and Consent.

The study protocol was reviewed and approved locally by each hospital trust and was registered with local clinical governance teams. ORT_21-22_A02 was the approval registration audit number for our lead hospital trust, Norfolk and Norwich University Hospital.

Ethics Committee approval was assessed using the Health Research Authority decision tool and found to not be formally required. Patient demographics and data regarding the consent process were recorded in line with the NHS Caldicott Principles and Data Protection Act (1988), with project registration as per guidance from local clinical governance teams.

Statistical Analysis.

Regional anonymised data was tabulated in a spreadsheet and statistical analysis was conducted using Microsoft Excel (2019) in accordance with Data Protection Laws. Data analysis performed included using Excel algorithms such as 'Countif', 'Sumproduct', search algorithms and 'Helper cell' arrays to allow data graphs to be generated within Excel.

Results.

Specifics:

A total of 173 hip and 165 knee cases were included in the final analysis (n = 338). 7 data sets were excluded: 2 hip and 5 knee replacements were excluded due to incomplete data records, whereby their inclusion would have limited data interpretation and analysis.

Additionally, 1 centre was unable to reach the required 25 knee replacements by the deadline for data collection and so the total fell a further 5 knee replacements short of the expected 350.

The mean age of patients at the time of their hip replacement was 71.7 years and the mean age of patients undergoing a knee replacement was 70.1 years (2 data entries were excluded from the data set for hips due to invalid data entry for 'date of birth').

Brand and Type of Implant:

From the combined data (for all hip and knee replacements), 'Type' and 'Brand' of implant were consented for in 80 (23.7%) and 13 (3.8%) of all cases, respectively.

The type of implant was consented for in only 48 (27.7%) of hip implants and 32 (19.4%) of knee implants.

The actual brand of implant was consented for in 4 (2.3%) of hip and 9 (5.5%) of knee implants. For all cases, this totalled 13 (3.8%).

A procedure-specific consent form (a form individualised to the specific procedure to be undertaken) was utilised in 247 (73.1%) of all cases, with 128 (74.0%) of hip and 119 (72.1%) of knee cases.

Risks/Benefits and Alternatives:

Alternative treatment options were documented as being offered in 116 (67.1%) cases for hip and 101 (62.1%) cases for knee surgery. For all cases of hip and knee surgery, this formed 217 (64.2%) of patients having alternative options offered.

The specific benefits of the proposed surgical intervention were documented in 279 (82.5%) of all cases, with this being divided between 146 (84.4%) of hip cases and 133 (80.6%) of knee cases.

'Risks of treatment' were documented in 160 (92.5%) of hip cases and 148 (89.7%) of knee cases, making a total of 308 (91.1%) for all cases of lower limb arthroplasty.

Figure 1 details the specific alternatives to surgical intervention that were documented as having been discussed. Notably, no alternatives were documented as being offered in over a third of cases for both hip and knee surgery. Common alternatives to surgery suggested to patients included analgesia, conservative (non-operative management) and physiotherapy.

Figure 2, above, details the benefits of treatment, for which the most commonly cited benefit, was decreased pain, followed by improved mobility. Improved function was another benefit of treatment mentioned for both hip and knee surgery. In 9.1% of cases of knee surgery, the more generalised, non-specific term, 'improvement to symptoms' was offered as a benefit of surgery. In more than 10% of cases of hip and knee procedures the benefits of surgical management were not documented.

Figure 3, below, details the specific risks of surgery documented as being discussed prior to hip arthroplasty surgery. The most commonly discussed risks included: infection, thromboembolism and neurovascular injury/limp. Of note, blood transfusion and medical complications secondary to surgery were not commonly mentioned, although anaesthetic risks were often highlighted (in 75.1% of cases).

Figure 4 details the risks of treatment discussed for knee arthroplasty. For both hip and knee data sets, there was great variation in the breadth of risks discussed, as well as variation in the frequency of which such risks were discussed with patients. As for hip surgery, infection was, again, commonly highlighted as a surgical risk, however knee surgery emphasised stiffness to a greater degree than for hip surgery. Thromboembolism, pain, neurovascular injury and anaesthetic risks were, again, highlighted as common risks of surgery for knee, as for hip surgery. Interestingly, in directly comparing percentage parameters for each of these risk factors (thromboembolism,

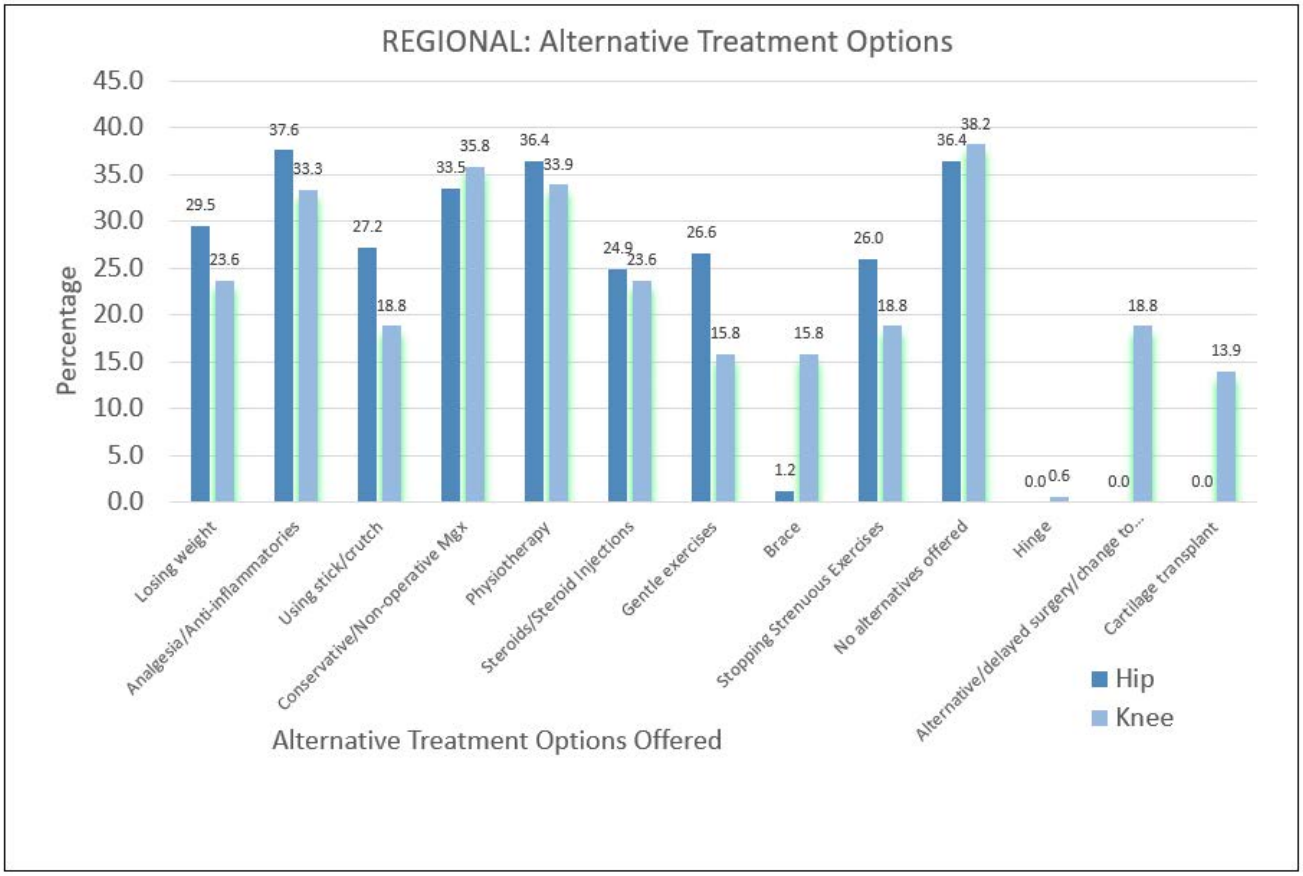

Figure 1. *Regional Alternative Treatment Options for Hip and Knee Arthroplasty Surgery.*

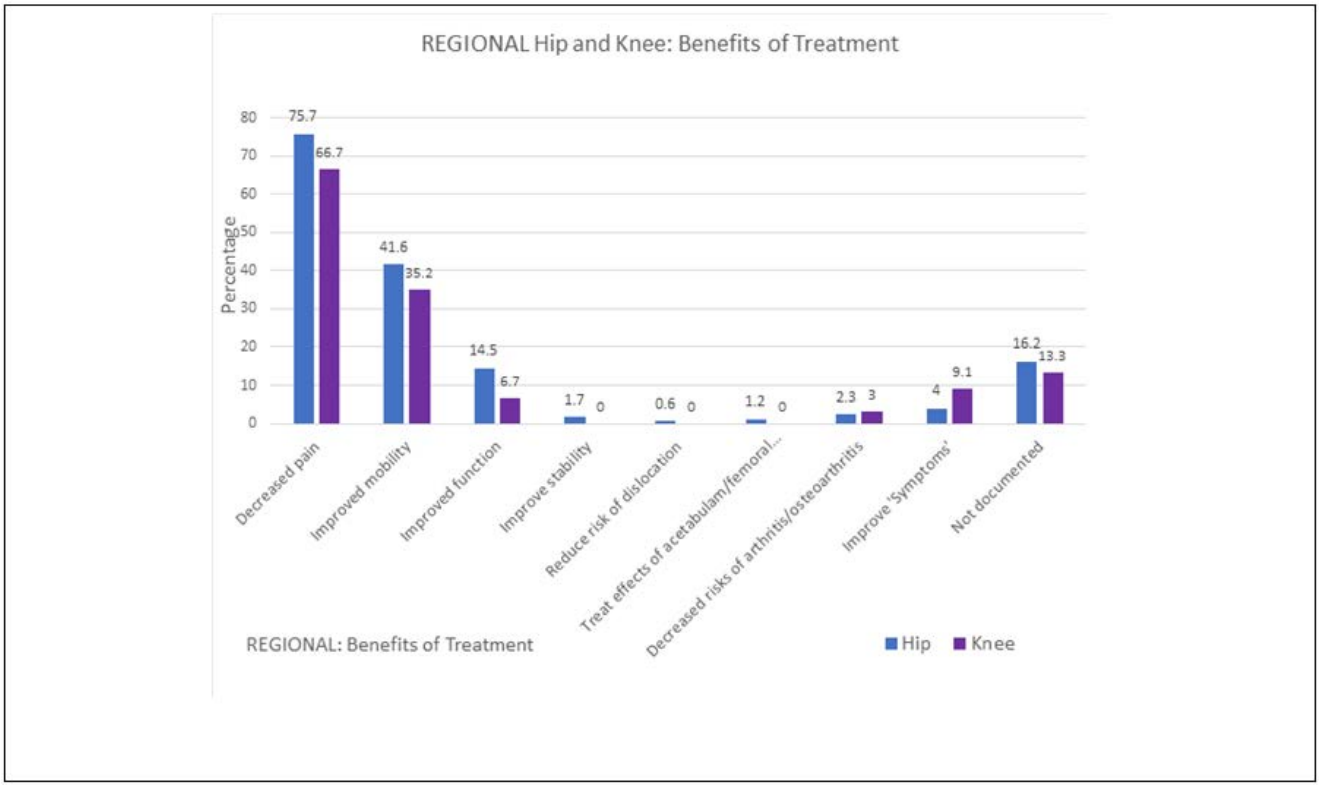

Figure 2. *Regional Benefits of Treatment.*

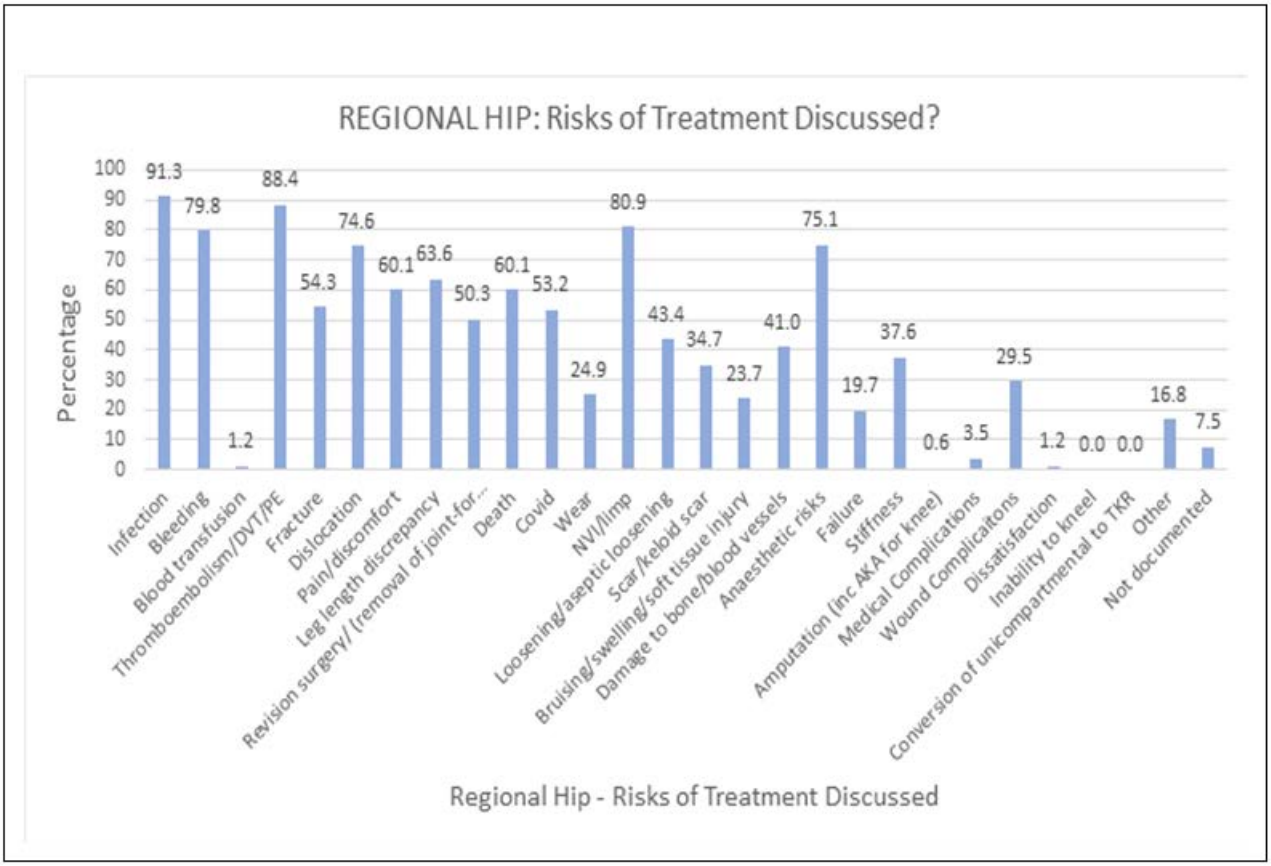

Figure 3. *Regional Hip Results: Risks of Treatment Discussed.*

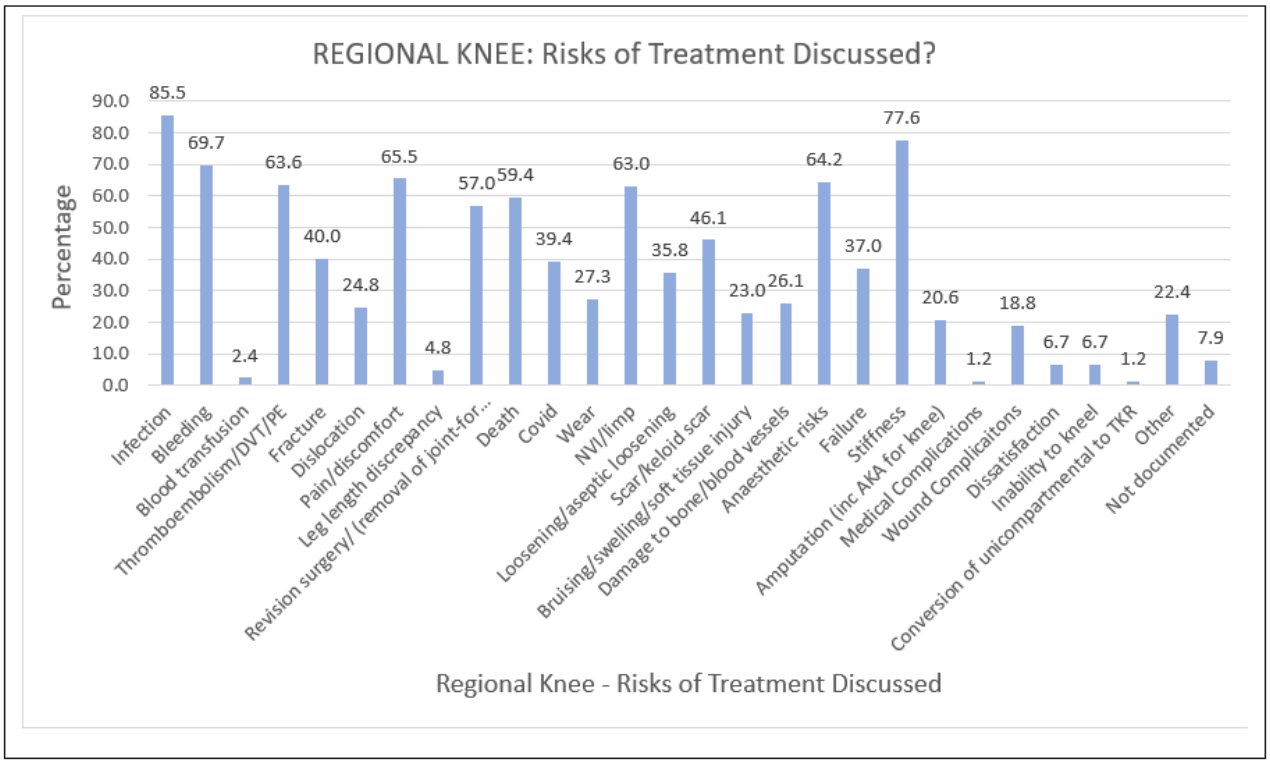

Figure 4. *Regional Knee: Risks of Treatment Discussed.*

pain, neurovascular injury and anaesthetic risks), these risks were more frequently documented for hip surgery than for knee surgery.

The methods of documentation for 'Alternative' interventions are summarised in Figure 5, for regional hip data. The most common method to document alternative treatment options was via clinic letters. In almost 40% of cases, alternative options were not documented for hip arthroplasty procedures. The consent form was another method of documenting alternative treatment options discussed with patients, as in 23.1% of cases.

Figure 6 shows how alternative interventions for regional knee data were documented. Most commonly, alternatives were not documented, in cases where alternatives were documented, clinic letters, were the most common methods of documenting alternative options for knee arthroplasty, thus being a popular method of documentation for both hip and knee surgery.

The documentation concerning 'Risks and Benefits' of interventions is summarised below in Figure 7, for regional hip data. The most common method for documenting these cases was via the consent form (67.6%), however patient clinic letters remained a popular method. In 8.1% of cases documentation of risks and benefits was not present.

Regional knee data, displaying where the risks and benefits of treatment were documented is conveyed in Figure 8, with knee replacement data mirroring similar trends as for hip arthroplasty data, where consent forms were the most popular method of documenting risks of surgery, followed by patient clinic letters. Again, in almost 10% of cases, risks and benefits were not documented.

Percentage figures for Figures 7 and 8 exceed 100% due to documentation of 'Risks' and 'Benefits' of treatment for some patients being documented in multiple formats, which were not mutually exclusive, for example a patient could have risks/benefits documented, both in their consent form and in their patient clinic letter, leading to overall percentage figures totalling greater than 100%.

Pre-operative Consent

Pre-operative consent in a clinic was undertaken in 96 (55.5%) of hip cases and 95 (57.6%) of knee cases respectively, with remaining cases consented for on the day of surgery. For the combined hip and knee data, this meant that 191 (56.5%) of all cases assessed had a separate 'consent clinic'.

For hip operations, the average time between consent for procedure and time to operation was 106 days. For knee operations, the average time was 114 days, whilst on the waiting list for surgery. There were 20 data exclusions: 4 hip and 16 knee procedures, due to invalid data entry (with regards to dates). For the combined data of all lower limb hip and knee arthroplasty cases, this meant that the average time between consent and surgery was 109.9 days.

In both hip and knee clinics only 59 and 56 respectively, (rounding to 34.1%) of consultations subsequently sent a copy of the clinic letter to the patient. For all cases this totalled 115 (34.0%).

Patient Information Leaflets:

In 56 (32.4%) of hip case consultations, patients were provided with a surgical information leaflet. For all patients undergoing

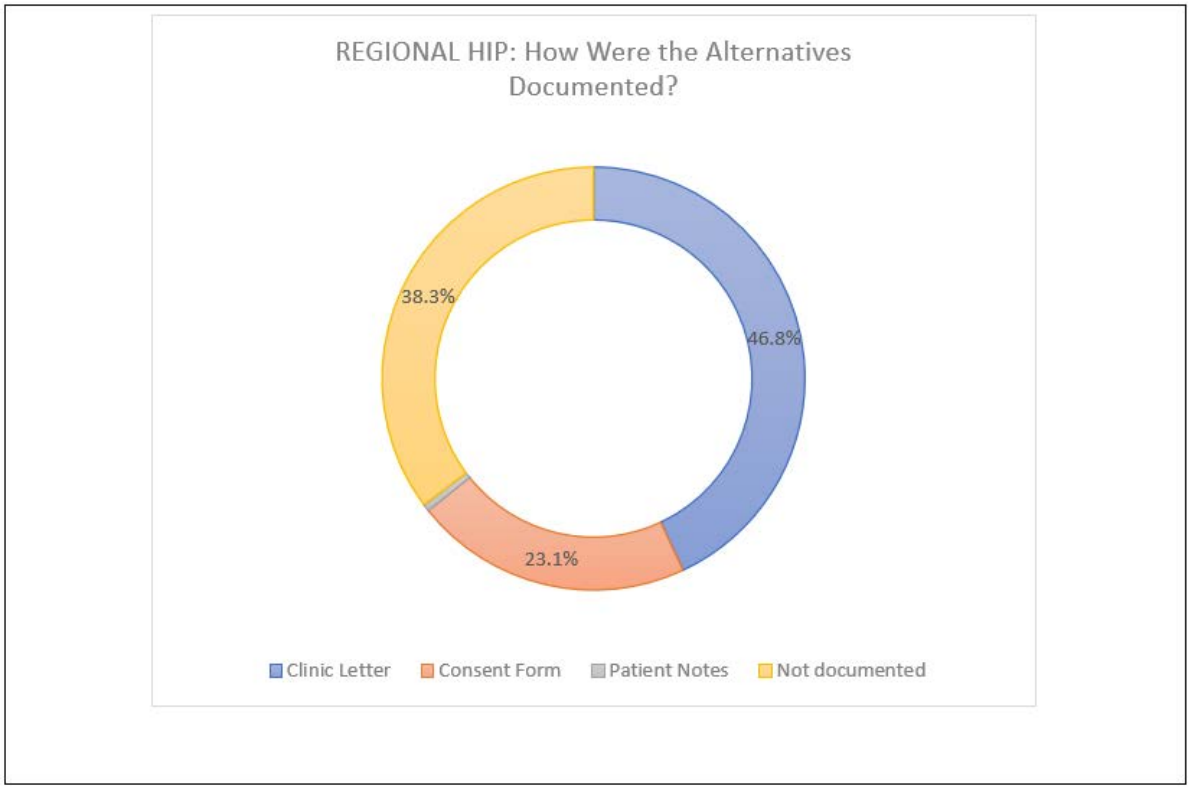

Figure 5. *Regional Hip: How Were the Alternatives Documented?.*

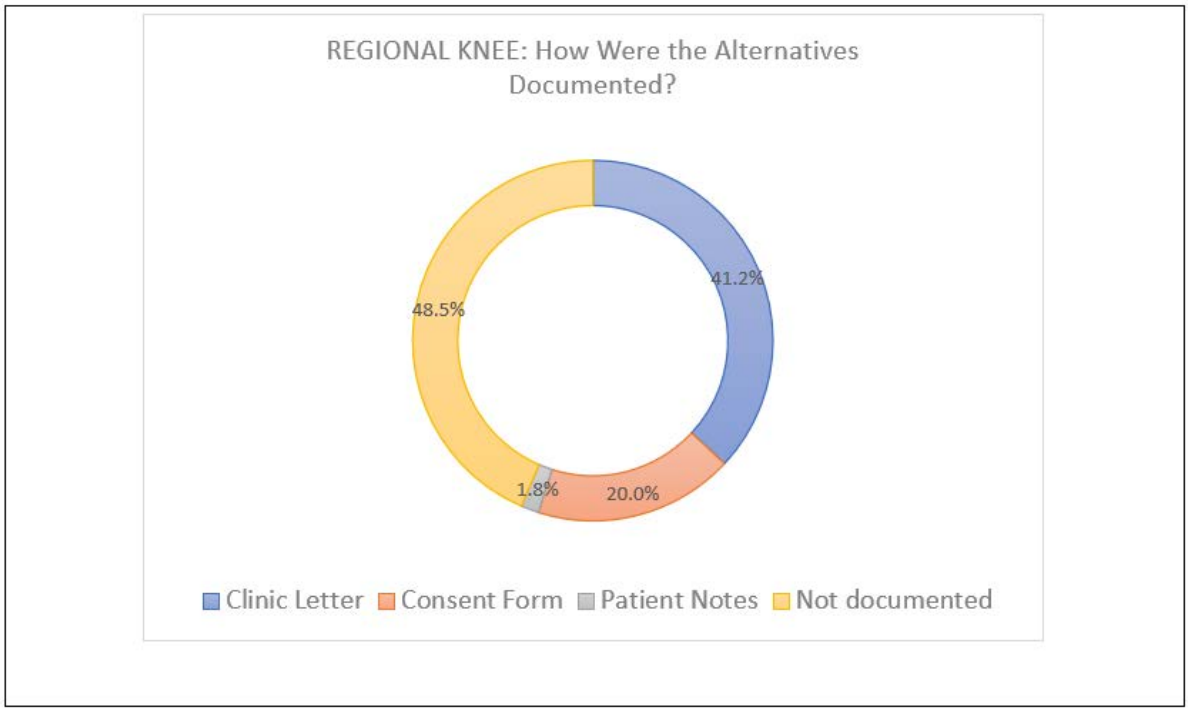

Figure 6. *Regional Knee: How Were the Alternatives Documented?.*

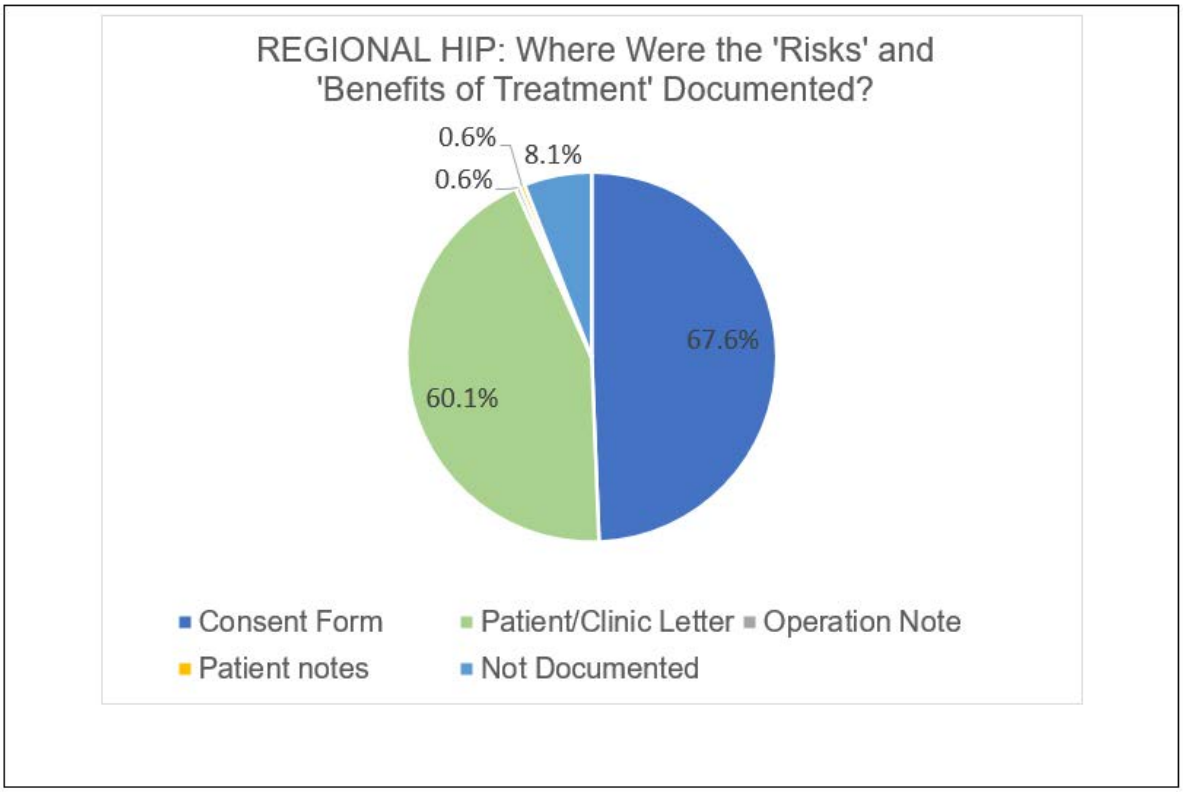

Figure 7. *Regional Hip Results: Where Were the 'Risks' and 'Benefits' of Treatment Documented?.*

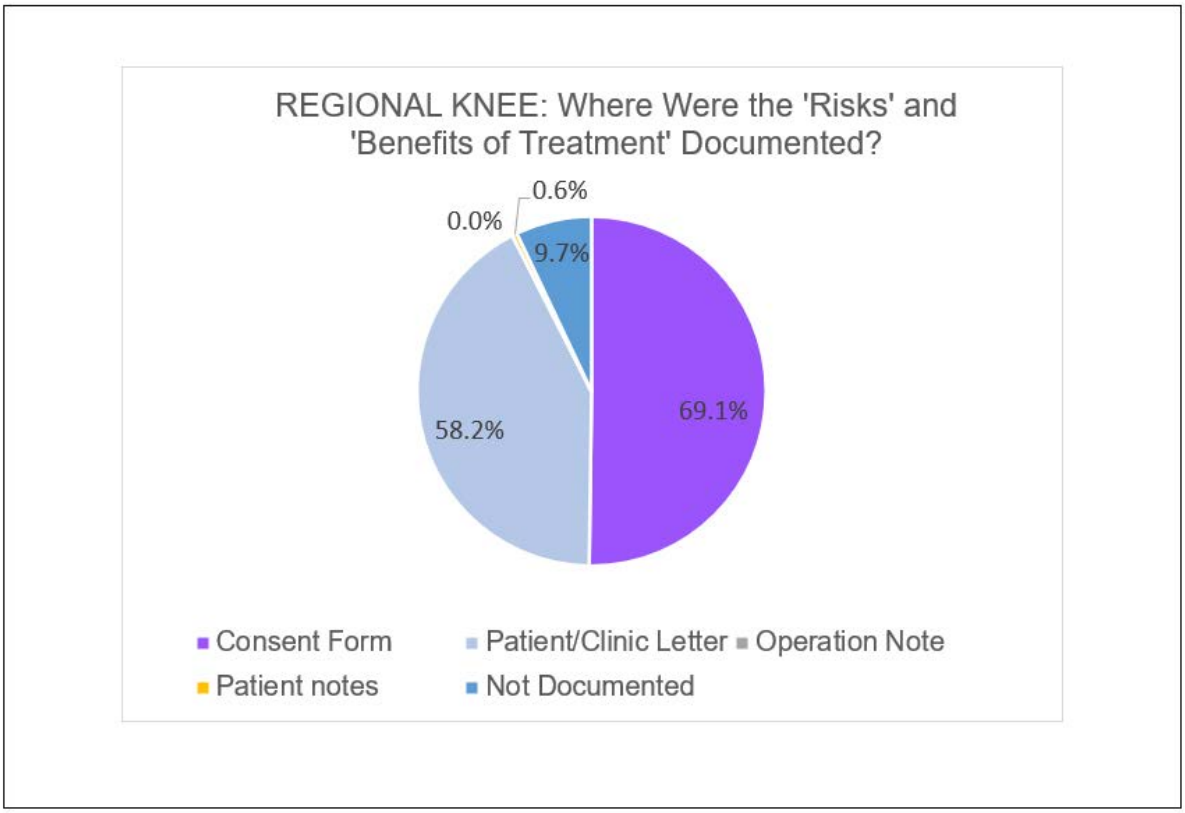

Figure 8. *Regional Knee Data: Where 'Risks' and 'Benefits' of Treatment Were Documented.*

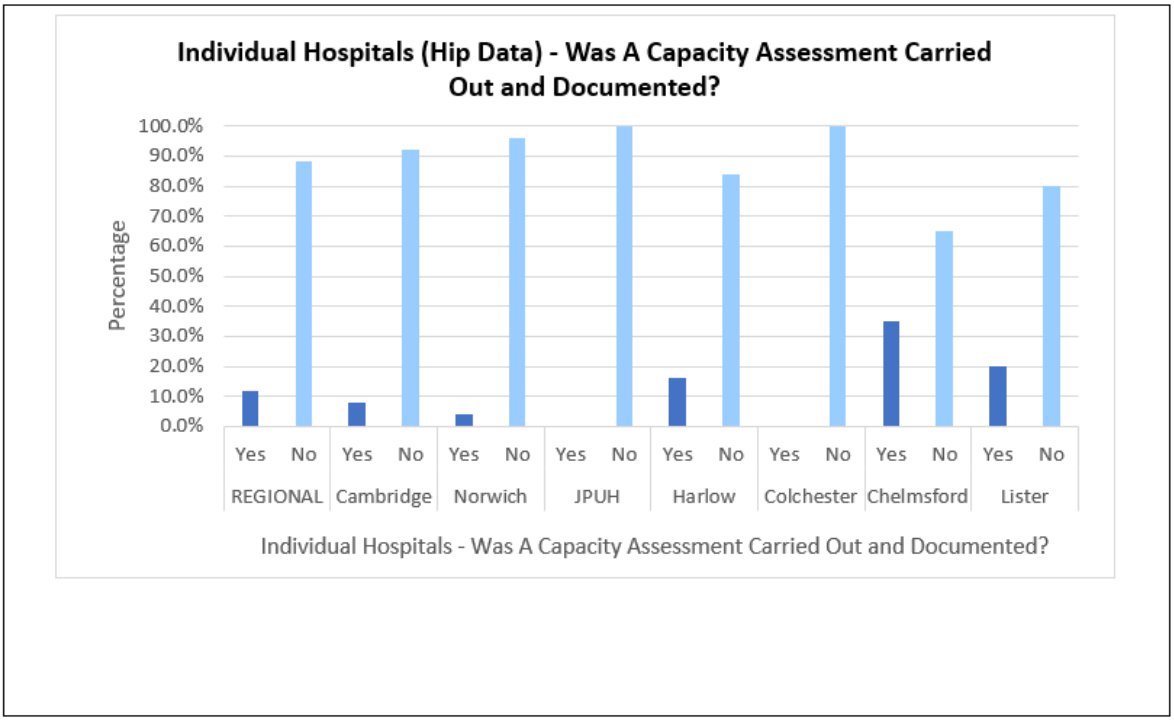

Figure 9. *Individual Hospitals (Hip Data) - Was A Capacity Assessment Carried Out and Documented?*

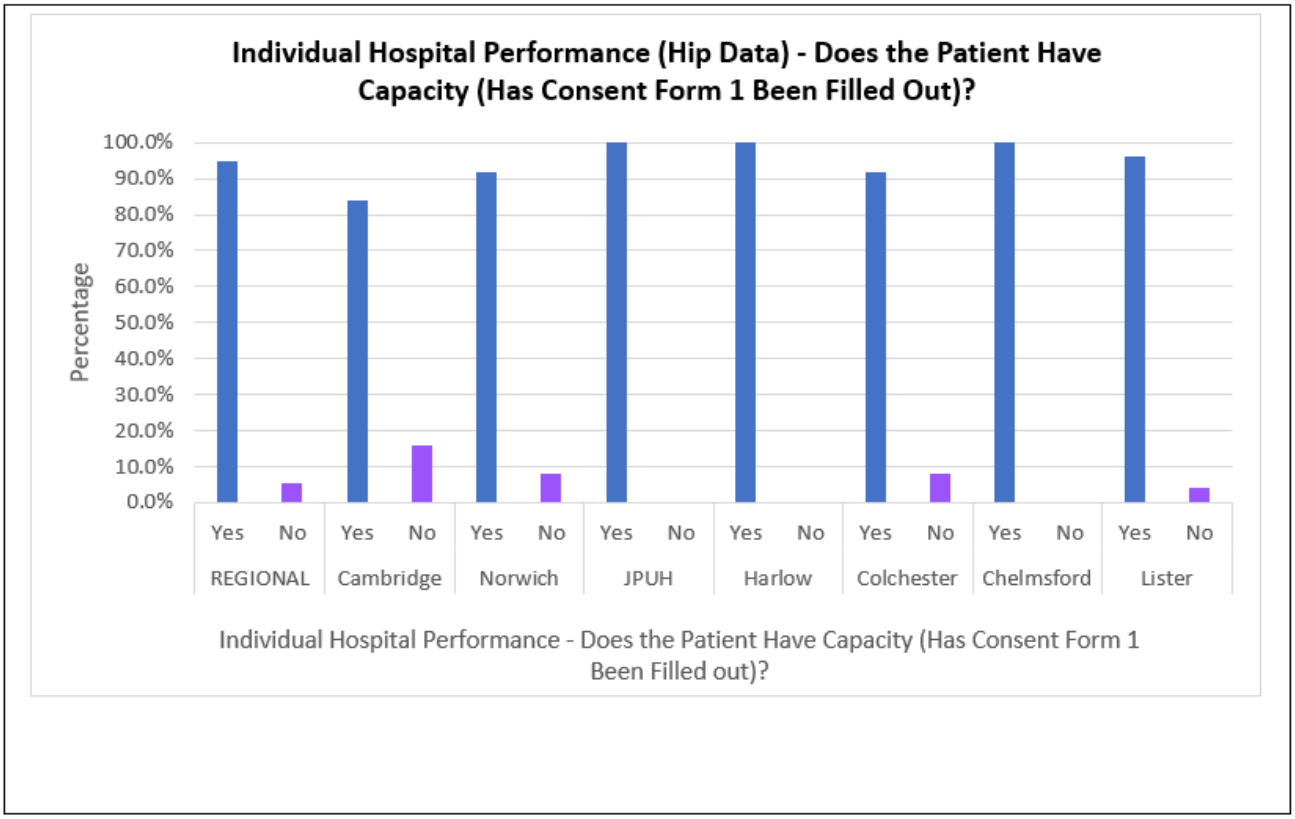

Figure 10. *Individual Hospital Performance (Hip Data) - Does the Patient Have Capacity (Has Consent Form 1 Been Filled Out)?*

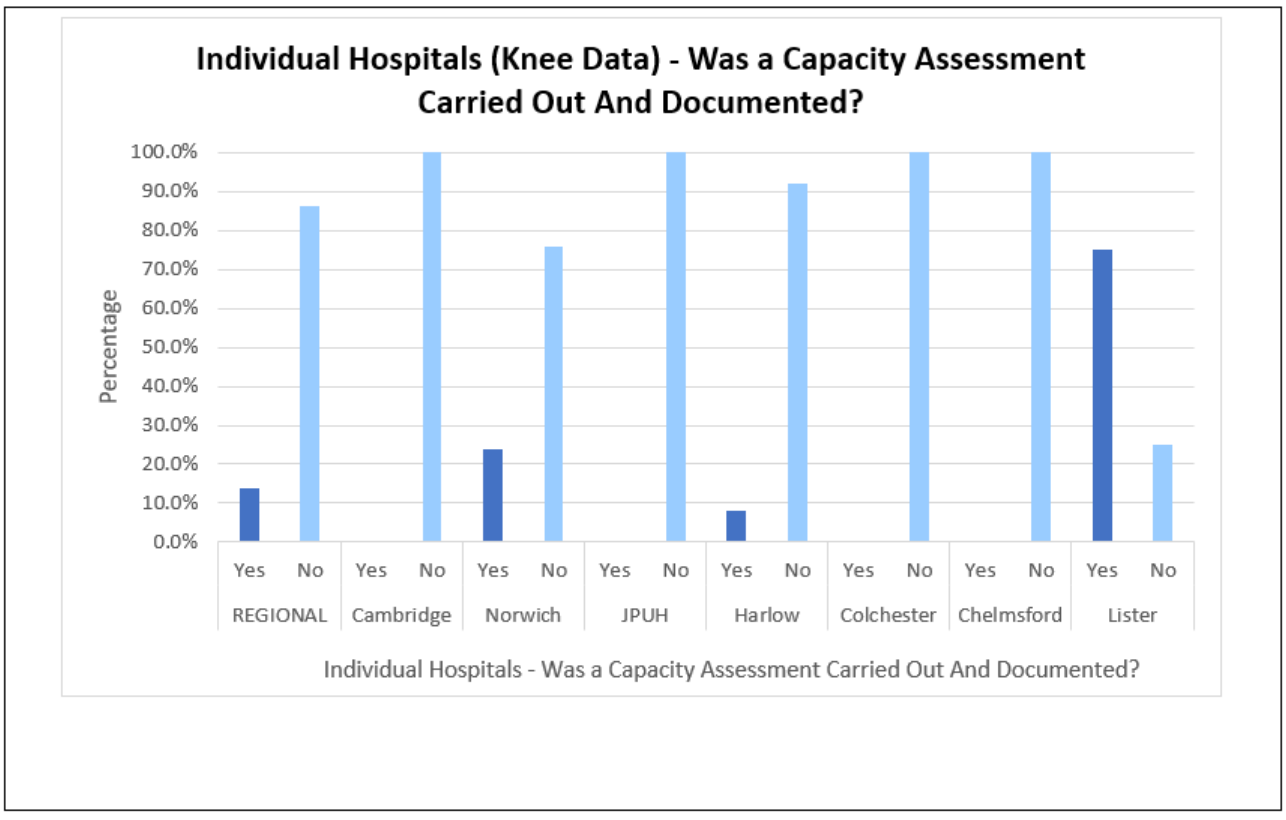

Figure 11. *Individual Hospitals (Knee Data) - Was a Capacity Assessment Carried Out and Documented?*

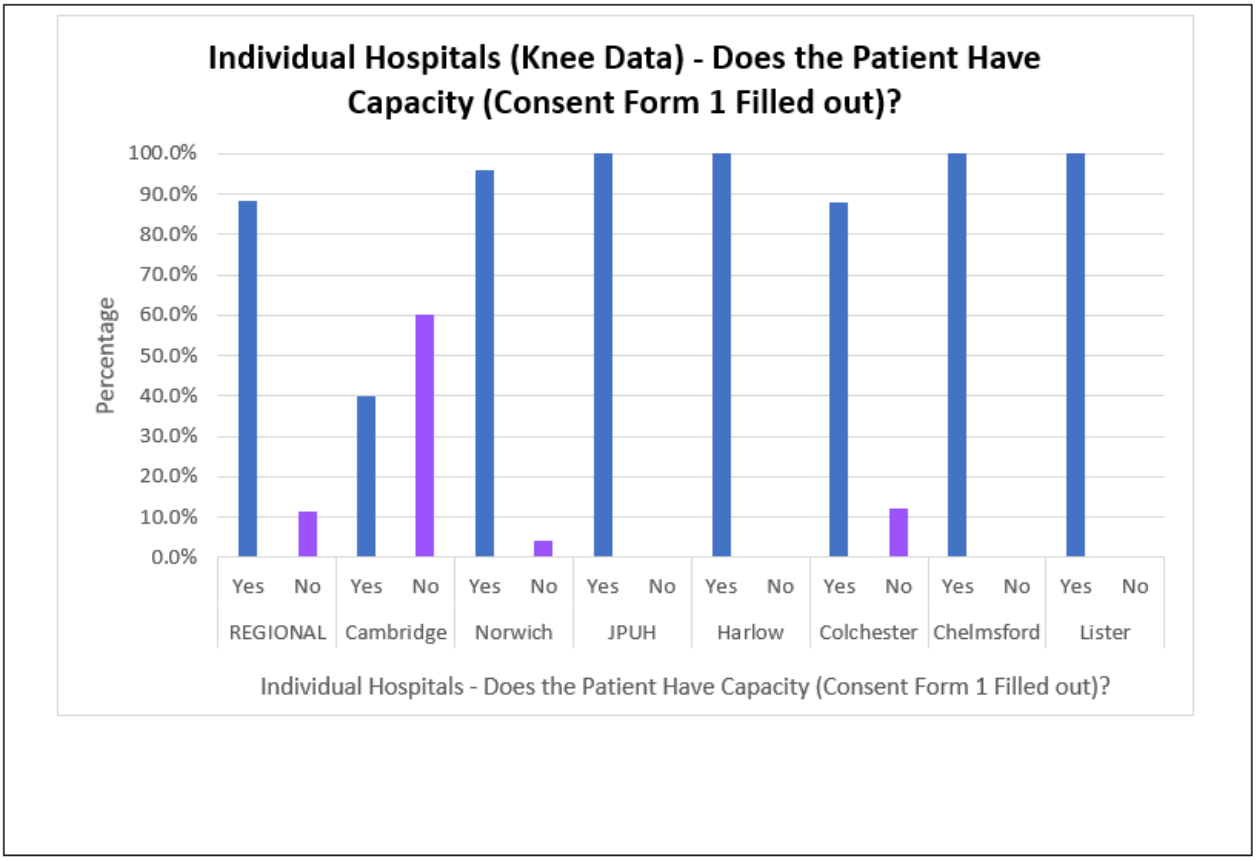

Figure 12. *Individual Hospitals (Knee Data) - Does the Patient Have Capacity (Consent Form 1 Filled out)?*

hip surgery, 53 (30.6%) were provided with a written paper leaflet and 6 (3.5%) received a leaflet online/via registry.

49 (29.7%) cases of knee consultations provided a patient information leaflet. Of all patients undergoing knee arthroplasty procedures, 32 (19.4%) were given a written paper leaflet and 4 (2.4%) received an online version/registry.

The version of leaflet provided to patients was documented in 32 (18.5%) of all patients undergoing hip arthroplasty procedures. For knee data, the leaflet version was documented in 6 (4.5%) of all knee cases.

In all cases of hip and knee surgery, the combined data showed that 105 (31.3%) provided a leaflet to patients in clinic, with the leaflet version and name being recorded in 38 (11.2%) of all arthroplasty cases.

Capacity:

20 (11.6%) of hip and 23 (13.9%) of knee cases were documented as fulfilling capacity criteria satisfactorily (in other words, the pre-requisite four criteria, required in order for a patient to be deemed 'to have capacity', were fulfilled).

In comparison, 164 (94.8%) of hip cases had consent form 1 completed (i.e. the procedure was undertaken, with the assumption that patients had full capacity) and 146 (88.5%) of knee cases had consent form 1 completed within the patient's records.

Overall, this meant that only 310 (91.7%) of all hip and knee cases had consent form 1 completed, despite only 43 (12.7%) of all procedures having had a full capacity assessment carried out and documented.

McWilliams et al. [22] noted that between 1995 and 2010, for lower limb arthroplasty surgery, there were a total of 1527 clinical claims for hip and knee arthroplasty surgery, 1004 for hip arthroplasty and 523 for knee arthroplasty, amounting to claims costs of £41.5 million and £21 million respectively [22].

It Is relevant to note, that although litigation attracts high financial costs, with 1527 claims for lower limb surgery, the National Joint Registry records that the total number of hip and knee replacements surgeries performed, since the registry began data collection in 2003 amounts to greater than 1.5 million hip replacements procedures and more than 1.66 million primary knee joint replacement procedures [22,23].

Reasons for litigation were most commonly for neurological deficit post hip arthroplasty, and related to infection post knee arthroplasty, for which we comparatively note in our regional hip data sets, was only discussed as a risk in 80.9% of all cases. McWilliams et al. [22] reported that vascular complications resulted in the highest cost per claims in both groups for hip and knee surgery. For our regional hip data, risks for vascular complications were discussed as follows: bleeding (79.8%), blood transfusion (1.2%), thromboembolism/DVT/PE (88.4%), bruising/swelling/soft tissue injury/tendon/ligaments (23.7%), damage to bone/blood vessels (41.0%), amputation (0.6%). For our regional knee data vascular complications were discussed

as follows: bleeding (69.7%), blood transfusion (2.4%), thromboembolism/DVT/PE (63.6%), neurovascular injury/peroneal nerve damage/foot drop/limp/numbness (63.0%), bruising/swelling/soft tissue injury/tendon/ligaments (23.0%), damage to bone/blood vessels (26.1%), amputation (20.6%). It is therefore interesting to note the low percentage levels of discussion for risks of certain vascular complications, in view of the high cost per claims that vascular injury attracts in clinical litigation claims [22].

Reasons for litigation interestingly remained unchanged over time for hip replacements [22].

Although large increases in number of operations were performed, McWilliams et al. [22] also noted that this did not correlate with a corresponding relative increase in litigation rates [22].

As seen above in figures 9 to 12, there did not appear to be a correlation between capacity criteria being assess and documented (or indeed consent form 1 being completed) and the characteristic type of hospitals. There does not appear to be a consistent correlation between results in 'teaching' compared to 'non-teaching' hospitals, for hip and knee data.

Discussion.

A robust, patient-centred consent process provides patients with accurate, comprehensive information and the time necessary to reach an informed decision. This is important, not only to meet professional, ethical and legal requirements, but, crucially, as a means of safeguarding patient safety and satisfaction [24,25].

The results of this study across a regional deanery have demonstrated less than satisfactory consent processes using conventional consent standards for elective hip and knee arthroplasty procedures.

Patients were consented for 'Brand' and 'Type' of implant infrequently (3.8% and 23.7% of all cases) and almost half of all patients were only consented on the day of surgery (43.5%). Of those that consented in clinic prior to the day of surgery 115 (34.0%) of all lower limb cases received a copy of the clinic letter. Unsurprisingly, this led to an overwhelming majority of patients who were unable to demonstrate the successful retention of information required in order to 'have capacity'.

The case of Thefault v Johnston (2017) [26] emphasised the importance of patients having sufficient time to make their decisions [26]. Consent clinics provide an invaluable source of time and space, over which a patient can reflect and deliberate over the various surgical options provided (including non-operative interventions) and have been shown to be beneficial to the consent process [24-26], however we have demonstrated that this is not widespread practice.

Regional results for all cases of lower limb arthroplasty demonstrated that, surprisingly, only 43 (12.7%) of patients had a formal capacity assessment carried out and documented, despite Consent Form 1 being completed in 310 (91.7%) of cases.

In more than 10% of knee cases, a consent form 1 document could not be found at the time of data collection. Given that lower limb arthroplasty procedures are likely to be performed in patients with comparatively fewer significant medical comorbidities, we venture that this remaining 11.5% is more likely to be the result of missing documents. Digitalisation, where there is an electronic record or 'paper trail', would be beneficial in reducing such incidences of data loss in the future.

Alternative treatment options were offered in only 217 (64.2%) of all cases, whilst 'risks and benefits' were discussed in 308 (91.1%) and 279 (82.5%) of cases respectively.

The regional findings for the subsets of both hip and knee arthroplasty data are similar. Poor consent practices can lead to reduced patient safety and satisfaction, increasing litigation risks and, thus, financial burden [27,28].

To the authors' knowledge, this is the largest study to date investigating the quality of written consent forms in lower limb arthroplasty procedures. However other studies have also corroborated these findings and found the consent process to be suboptimal in lower limb arthroplasty [27,29].

Studies of other surgical specialties [3], outside of Trauma and Orthopaedics, have reached similar conclusions. Knight et al. [3] also found consent processes to be sub-optimal in their national, multicentre study in Scotland, noting patients were sent a copy of their clinic discussion in only 4.2% of cases [3].

Our own analysis of regional data, relating to the completion of consent forms, has revealed wide variation in the quality of documentation of risks and benefits (complication risks, in particular), findings which are reflected in other studies [9,27,29-31]. The root cause of this variation is thought to stem from the often 'ad hoc' bedside nature of consent form completion. Obtaining consent often relies upon surgeons immediate, precise memory recall of surgical procedures in time-pressured situations - the very nature of which, results in a process susceptible to error (as opposed to 'genuine' variability in anticipated surgical complications across different surgical institutions) [9,32]. Across other hospitals, various methods have been employed to address this issue, including introducing pre-printed procedure-specific complication stickers, electronic or pre-printed standardised consent forms (with pre-filled 'risks and benefits') [9,31,33-35]. Our study has shown that despite this, 1 in 4 patients are still not consented on procedure-specific consent forms.

Studies [32] investigating the use of pre-printed, standardised consent forms (such as British Orthopaedic Association (BOA) endorsed 'OrthoConsent' forms [36]) as an adjunct to the normal consent process, have found standardised consent to be significantly superior to handwritten consent forms alone. Diagrammatic data representation has been suggested as a further method of improving patients' understanding of surgical procedures, in order to achieve informed consent [32].

Other issues concerning handwritten consent forms include those relating to legibility. Thakkar et al. [34], noted that although, handwritten consent forms for hip fracture surgery were legible, they were written at 'high reading grades', and therefore were not immediately understandable to all members of the public. Given the significantly high morbidity and mortality rate associated with neck of femur fractures [31], the need for clear, comprehensive consent form information could not be greater. Standardised consent forms, such as 'OrthoConsent', with a reading age of 14 [36], allow a greater proportion of the population to understand the medical terminology used, highlighting an important, additional advantage supporting the use of standardised consent forms [32].

Beyond the use of standardised, paper-based consent forms, some studies [30,33] have gone one step further, beyond this, to consider how consent would benefit from a digitalised process.

Issa et al. [30] described the benefits of electronic consent forms, noting that they allowed for standardisation of documentation (particularly 'risks and benefits' of surgical procedures) and were both legible, as well as, comprehensible. Unsurprisingly, when compared to paper-based consent forms, patient satisfaction was higher with electronic forms, with 96.1% preferring the new system.

In addition to this, interactive multimedia tools have been shown to have an even greater impact than videos alone in obtaining consent [33].

Digital consent has the potential to revolutionise the consent process. It recognises that surgical consent is a complex process that cannot be achieved effectively during a single, 'once-only' event on the day of the procedure. In contrast to current practices, it allows patients to participate in an ongoing process of consent, up until the operation date, and thus sits in accordance with known GMC principles regarding consent [37-39].

Digital consent ensures that the information provided to patients is accurate, comprehensive and comes from a suitably trained professional [9,33,40]. Error rates in digital consent have been found to be lower than paper-based consent [40], therefore digitalisation is likely to reduce litigation risks and avoid the financial penalties they necessitate.

Healthcare alone generates a significant proportion (4-5%) of the world's greenhouse gases [41]. A further benefit of digital consent would include a reduced carbon footprint, through decreased reliance upon paper and faxing/filing systems [40].

There are clearly many advantages to digitalising the consent process. However, digital consent is not without challenges, including the initial start-up costs of acquiring and running digital software (including software integration with existing electronic health records). Digitalisation means that IT issues can affect the system function. Patients must be digitally literate to benefit and, as with all new systems, it requires educating health professionals about the software prior to implementation, where professionals may need time and training to adapt to the new system [40].

Despite these challenges, digitalisation would seem to have more benefits than drawbacks. At the very minimum, it provides a useful adjunct which can reduce litigation risks by helping patients make informed decisions, in a manner which increases clinical efficiency without dramatically increasing workload [40].

Limitations of this study.

Study limitations included findings being applicable to Trauma and Orthopaedics elective surgical procedures, within the region of East Anglia. There is further scope, however, to extrapolate this study to encompass other specialties, both medical and surgical and expand to a national scale.

Results are additionally based upon elective, as opposed to acute, trauma cases, wherein clinical urgency and patient deterioration may necessitate a more streamlined consent process.

Finally, the method of retrospective data collection was highly dependent on the clinical systems and record keeping abilities of each individual trust and thus would have been subject to variation.

Conclusion.

To conclude, this study has demonstrated that current consent processes, using handwritten forms, are suboptimal for elective lower limb arthroplasty procedures.

We believe that failings in the current system could be addressed, and dramatic improvements made, via the implementation of digital consent. Digitalisation has the potential to revolutionise the consent process and promises to play a prominent role in many exciting future developments, allowing us to remain ever relevant to the changing modern era.

Conflicts of Interest Declaration.

The authors declare no conflicts of interest or financial benefits were accrued with regards to this work.

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