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OXFORD INFORMED VIDEO CONSENT TOOL (OXIVCT): A PILOT STUDY OF INFORMED VIDEO CONSENT IN SPINAL SURGERY AND ITS IMPACTS ON PREOPERATIVE PATIENT SATISFACTION.

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OXFORD INFORMED VIDEO CONSENT TOOL (OXIVCT): A PILOT STUDY OF INFORMED VIDEO CONSENT IN SPINAL SURGERY AND ITS IMPACTS ON PREOPERATIVE PATIENT SATISFACTION.

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ABSTRACT

Objectives: A 'three-legged stool' approach to consent, advocated by British Association of Spinal Surgeons (BASS) calls for updates in consenting practice. This study investigates the utility and acceptability of a personalised video consent tool to enhance patient satisfaction in the preoperative consent giving process.

Design: Pilot study using questionnaires to assess video consent and its impacts on preoperative patient satisfaction.

Setting: A single centre, pilot study of individuals undergoing surgery at a regional spinal centre in the UK.

Outcome measure: As part of preoperative planning, a self-administered questionnaire regarding patient satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods was completed.

Participants: 20 participants with a mean age of 56 years (*SD* = 16.26). who watched their personalised consent video at least once prior to consenting for surgery.

Results: Median number of video views were 2-3 times. 85% of patients watched the video with next of kin and family members. 80% of participants reported that the video consent tool helped to their address preoperative concerns. All participants stated they would use the video consent service again. All would recommend the service to others requiring surgery. Implementing the video consent tool did not endure any significant time or costs.

Conclusions: Introduction of a video consent tool was a positive adjunct to traditional consenting methods. Patient – clinician consent dialogue can now be documented. A randomised controlled study to further evaluate the effects of video consent on patients' retention of information, pre and postoperative anxiety, PROMS and length of stay is in process.

Key Words: Video consent, Informed consent, Patient satisfaction, Spinal surgery.

ARTICLE SUMMARY

What this pilot study adds to the literature:

1. First report of a personalised consent tool in preoperative care (currently deficient in the published literature)
2. First report of a multimedia consent adjunct used outside of the clinical environment, allowing patients to review their consent dialogue at a time and place convenient to them.
3. First report of a personalised consent adjunct promoting shared decision making and promoting patient empowerment.
4. First report of a correlation between frequency of interaction with multimedia consent adjuncts and patient satisfaction levels.
5. First report of multimedia to document the patient – clinician consent conversation

Strengths and limitations of this study

The strengths of the study have been outlined above. Although this pilot has achieved its overall aim, it is important to acknowledge the limitations. As a small non-randomised study, further work is needed to provide robust conclusions. While the quantitative data collected yielded statistical data, the introduction of qualitative data collection methods could provide further insights into patient satisfaction and experience.

INTRODUCTION

Informed consent is a legal and ethical principle which is required prior to any intervention that may violate autonomy. The *Montgomery v Lanarkshire* judgement (1) initiated a change in how healthcare professionals obtain informed consent. Montgomery (1) confirms the shift from an already eroding paternalistic approach to consent set by *Bolam v Friem Hospital Management Committee,(2),* to the adoption and acknowledgment of a person-centred approach seen in *Sidaway v Bethlem Royal Hospital (3), De Freitas v O'Brien (4)* and *Bolitho v City & Hackney HA (5).* Others concur that *Montgomery* marked a decisive shift in the legal test of duty of care, from the perspective of the clinician to that of the patient (6).

In acknowledgement of the recent changes in consenting practice, the British Association of Spinal Surgeons (BASS) recently published consent guidelines (7). BASS advocates a 'three-legged stool' model to informed spinal consent. The three pillars of this model are: 1) provide

patient information, 2) engage in and document patient centred dialogue and 3) provide procedure specific information. However, there is currently a gap in consenting practice relating to documenting the preoperative consent conversations. Preparing to undergo surgery is a stressful event for both patients and their families, often important information discussed within the consent consultation is forgotten (8). By providing patients access to a tool that captures their consent conversation, it is proposed that the video will provide them with an opportunity to reflect and revisit the previously discussed dialog, prior to consenting to treatment. The addition of this step to the preoperative consenting process may safeguard patients from medical coercion and promote autonomy to make an informed decision about their care, while reducing potential litigation claims.

Enhancements in digital technology are driving changes in information practices, which has influenced how informed consent may be delivered (9), examples include the use of iPads to deliver consent information (10) to the use of a smartphone app's to assist informed consenting practice (11). The acceptance of multimedia technology in preoperative consenting has been demonstrated across a variety of surgical disciplines, foot & ankle surgery (12), spinal surgery (13), vascular surgery (14), ophthalmic surgery (15), gastrointestinal surgery (16) and urological surgery (17). Notably, such preoperative multimedia consent technologies are often generic and not patient specific. There is currently a lack of research regarding the use of personalised multimedia consenting adjuncts within surgery.

In order to improve service delivery and comply with the updated guidelines, we piloted a video consent tool as an adjunct to traditional consenting methods for patients attending a spinal Preoperative Outpatient Assessment Clinic (POAC). To our knowledge the use of an informed video consent tool has not been used before in spinal surgery. The aims of the study were to evaluate acceptability of a novel consent tool as an adjunct to traditional verbal and written consent in patients attending a spinal POAC, while providing documentary evidence of the patient – clinician consent conversation, which now forms part of the medical notes, improve patient experience and enhance patient satisfaction within the preoperative consent process and generate an evidence base for future research.

METHODS

Procedure

We conducted a single centre, non-randomised, non-comparative pilot study in patients undergoing a spinal procedure at a spinal centre in the UK. A flowchart of the study procedure is outlined on Figure 1. All participants who agreed to take part were consented by fellowship trained Consultant Spinal Surgeons using verbal and written consenting methods in addition to a precis of the consent consultation being recorded. Participants were all informed that their participation was voluntary and they were free to withdraw at any time. The precis was conducted in a structured way and consisted of the following, a discussion around the patients reasoning for choosing surgery, followed by an overview of the surgical procedure, its intended benefits and associated risks ending with an opportunity for the patients' to check their understanding by asking questions.

A password protected email and a hospital trust approved web transfer service was used to send the personalised consent videos to study participants. Participants reviewed their personalised consent consultations at home with their family or friends. Participants had the option to forward their personal consent videos to family members outside of the UK. All, participants were invited to contact the spinal team, to seek clarity or ask further questions regarding the video content (two participants utilised this service). The recorded consent was stored securely within the patient's electronic health records, accessible only to the research team. Participants were asked to contact the spinal team once they had reviewed the consent conversation, acknowledging the risks and benefits of the proposed treatment. Prospective data from patients was obtained in the form a self-administered questionnaire regarding patient satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods. Participants were invited to complete the measure following the consent consultation and after reviewing their personalised consent video.

Participants

Participants were recruited over a four month period (September to December 2017).
Twenty two people were approached to take part, two declined, twenty volunteered. (n=20). Participants did not receive a honorarium for taking part in the study. Study inclusion criteria were: all participants must be over the age of 18 years of age and have capacity to make informed decisions. Participants were also required to have an active email address with access to the internet. Participants were excluded from the study if they lacked capacity to make informed decisions or if they had any visual or hearing impairments which may inhibit their ability to review their consent video.

Assessments

Electronic Self-Administered Questionnaires (SAQ) were distributed via email to patients who agreed to partake in the study. Participant demographics, which included gender, age, number of times the video consent tool was viewed as well as who they watched it with was collected. In addition to this, quantitative data was collected via the validated CSQ-8 tool (18) . The tool consists of eight questions, each constructed with a four point Likert scale reply.

Data was collected at one point, post consent consultation. The minimum achievable satisfaction score is 8, indicating poor satisfaction, a maximum score of 32 would indicate high levels of satisfaction (19, 20). The CSQ-8 tool has been extensively tested for reliability and validity (19-21), to date it has been translated into more than 30 languages since its first launch in the early 1980's (22).

Data analysis

The data collection period finished once 20 completed SAQ's were received. Normality of data was assessed using a Kolmogorov-Smirnov test. Descriptive, bivariate and inferential statistics were calculated and reported using two-tailed methods with the assistance a statistical program from IBM, SPSS 24 for Microsoft© Windows version 10.

Patient and Public Involvement

Patients were not involved in the development or design of this pilot study. However we do plan to enlist patient help when disseminating our research findings. We aim to include patient involvement when designing subsequent studies involving OXIVCT.

RESULTS

Descriptive information

Over a four-month period, 20 participants (10:10, male: female) deemed suitable candidates for spinal procedures were recruited into the study. The mean age of participants was 56 years (*SD* = 16.26), range 27 years to 81years. Participant demographics can been seen in Table 1.

Patient satisfaction

The mean patient satisfaction score (CSQ-8) was 30.2 out of a maximum 32, indicative of high patient satisfaction. The CSQ-8 scores by gender and age can be seen in Table .2.

A two-way between groups analysis of variance was conducted to explore the impact of gender and age on patient satisfaction levels, as measured by the CSQ-8 scale. Participants were divided into five groups depending on their age (Group 1: 25-34 years, Group 2: 45-54 years, Group 3: 55-64 years, Group 4: 65-74 years and Group 5: 75-99 years) The interaction effect between gender and age was not statistically significant .
High patient satisfaction levels were reported across a broad range of spinal procedures, seen in Table.3.These ranged from spinal nerve root blocks to complex deformity correction surgery.

The CSQ-8 responses generated several significant trends, a strong positive relationship between meeting patients 'preoperative consenting needs and helping them to deal more effectively with their preoperative concerns was reported (p=.028), with 80 % reporting that the tool helped a great deal. All participants reported that they would recommend the video consent tool to others preparing for surgery. When asked "if future treatment were required, would you use the service again?", all participants said yes. A significant positive relationship between the quality of the service participants received versus the service they expected was observed ($p = 0.008$).

Engagement with the tool

All participants watched their consent video at least once prior to consenting for surgery, with a mean number of viewings of 2-3 times. Eighty-five percent of the participants watched their consent video with family and friends. Two participants sent their consent videos to their children, who lived in the USA and Australia. 15% of participants reported watching their video alone. Those who watched the video 4 to 5 times on average reported higher satisfaction scores. Approximately 13 additional minutes were required compared to the traditional process to complete the video recording process The mean recording time was 13 minutes and 15 seconds, with a range of 6 minutes and 21 seconds, to 20 minutes and 55 seconds. Introduction of the video consent tool did not endure any significant costs as the technology already existed within the Trust.

DISCUSSION

The main findings of our study were that participants were overall 100% satisfied with the tool and the service. All patients reported that that would use the service again, if needed and 100% of participants reported that would recommend the service to others requiring surgery.

The mean CSQ-8 satisfaction score reported in this study was 30.2, with scores above 24 considered as achieving high levels of satisfaction (21) Compared to previous studies examining multimedia consent processes (17, 23), the personalised consent tool used in the present study is equal to, if not more effective than, the existing methods.

Our preliminary results suggest that participants' age or gender did not affect patient satisfaction levels with the use of the video consent tool in the preoperative setting. This finding is consistent with studies (12, 24, 25).Busy preoperative clinics, poor communication techniques, unanswered questions, anxiety and poor comprehension are all barrier to patients not retaining information (26).

Our study has shown that the use of personalised video tool can allow patients to process and review complex information previously discussed by the surgeon, from the comfort of their own home. Participants, had the opportunity to email the spinal service for further clarity of the video content, two participants utilised this service.

Introduction of the video consent tool did not require significantly more clinician time. The ability to watch the video with family members, or even to securely send family members the video, allowed for shared decision making and aided a person-centred approach to care, empowering participants to manage their own medical information. This is important for patients outcomes as shared decision making facilitates increased patient satisfaction levels (27, 28). All patients engaged with their personalised consent adjunct twice on average before consenting to surgery. To our knowledge, multiple interactions of a consent adjunct have not been reported in the literature (29). This project found that, the more times participants watched their consent video the more satisfied they became with their consent process. With the highest satisfaction scores in those who engaged with the video tool the most (4 to 5 times). Moreover, as the majority of studies using multimedia tools as an adjunct to informed consent do not personalise their content (27, 29), This is the first time that the use of a personalised multimedia tool has been reported in the literature. Due to the relative ease in setting up the pilot, other surgical disciplines within the trust have expressed interest in rolling out OXIVCT across their departments.

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CLINICAL IMPLICATIONS

This study demonstrates that a personalised video consent tool is feasible to administer during the preoperative consent process for spinal surgery procedures and that the intervention produced high satisfaction scores. Overall, we found approximately thirteen additional minutes

were required compared to the traditional process to complete the video recording process. This indicates that this procedure would be acceptable for use. Introducing OXIVCT into clinical practice has numerous benefits such as, documentary evidence of the clinician – patient consent conservation, which may reduce medicolegal cases associated informed consent.

It can be used as an educational tool for undergraduate medical teaching and could acts as a patient resource / decision aid, useful when analysing potential benefits and risks associated with surgery.

While concerns over additional time, potential costs and practicality as to achieving this process are valid, we have found them not to be a significant barrier to delivering this service. Providing one has access to a digital recording device such as a smartphone that can transfer and store data securely, then the process is relatively simple. We recognise that patients need to have access to the internet and may require help if not familiar using this sort of technology; however, as 85% of UK adults have a smartphone (30) and access to the internet in this is not an insurmountable barrier. While we have not undertaken a cost analysis, for this pilot there have been no significant costs as the technology already exists within the NHS Trust. We would therefore recommend video consenting as a new bench mark in the consenting process. Based on this study, we recommend a randomised controlled trial and evaluate the full impact of this process on outcome measures such as information retention, length of stay and litigation claims.

FUTURE RESEARCH

The findings from this pilot provide a foundation for potential future research projects.

A larger more diverse sample size to include younger (kids/teens) and older (75yrs +) people could add to the validity. There has been interest from other departments, further research could look at its utility in other surgical disciplines. Phase 2 of this pilot study has led to the development of a randomised controlled study to further evaluate the effects of OXIVCT on patients' retention of information, pre and postoperative anxiety, PROMS and length of stay.

CONCLUSION

If patient satisfaction is a measure of quality (31) this study shows that the introduction of a personalised consent tool can have positive impact on the quality of service patients receive. The provision of informed care can be facilitated by the introduction of a personalised video

tool, as it promotes patient autonomy, shared decision making and empowers patients to manage their own health.

AUTHOR CONTRIBUTIONS:

GM, CT and JR made substantial contributions to the conception of the study.GM analysed and interpreted the data for the study. GM, CT, DR and JR drafted the article and revised it critically for important intellectual content. JR, gave final approval of the version to be published and agreed to be accountable for all aspects of the article in ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved. GM, JR and DR contributed to acquisition of the data.

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Competing interests: None

Disclaimer: This study has been presented via podium presentation at the 41st Annual Scientific Meeting of the Singapore Orthopaedic Association and at the Joint British Scoliosis Society / Irish Spine Society Meeting, 2018.

Patient consent: Obtained

Ethics approval: Oxford Brookes University, Faculty of Health Sciences Research Ethics Committee (FREC2016/57).

Data sharing statement: We welcome data-sharing requests from researchers interested in OXIVCT. Please contact GM (gerard.mawhinney@ouh.nhs.uk) directly to explore further.

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WORD COUNT: 2808

TABLES

Table.1. Demographics of Study Participants

Demographic		N (%)
Gender	Male	10 (50%)
	Female	10 (50%)
	Mean age	56
	Range	27 -81
Participant Age (years)	25 - 34	2 (10%)
	35 – 44	0 (0%)
	45 – 54	6 (30%)
	55 – 64	5 (25%)
	65 – 74	4 (20%)
	75 – 99	3 (15%)
Frequency of viewing consent video	Once	7 (35%)
	2 to 3 times	10 (50%)
	4 to 5 times	3 (15%)
Video watched (with)	Alone	3 (15%)
	Next of Kin	11(55%)
	Children	2 (10%)
	Other family members	6 (30%)
	Friends	2 (10%)

Table. 2. Mean CSQ-8 Scores by Age and Gender

Demographic	Mean CSQ-8 Score (Maximum score 32)	Range (*SD*)
Gender		
Male	30	26 – 32 (*2.2*)
Female	30.4	29 – 32 (*1.07*)
Total Mean	30.2	26 – 32 (*1.70*)
Participant Age (years)		
25 - 34	31	30 – 32
35 - 44	-	-
45 – 54	30.16	26 - 31
55 – 64	29	26 – 31
65 – 74	30.25	28 – 32
75 – 99	31.66	31 – 32

Table.3. Overview of consented surgical procedures

Variety of Surgical Procedures	N = 20
Deformity correction	3
Lumbar degenerative	6
Nerve root block	3
Removal of metalwork	1
Tumour surgery	7

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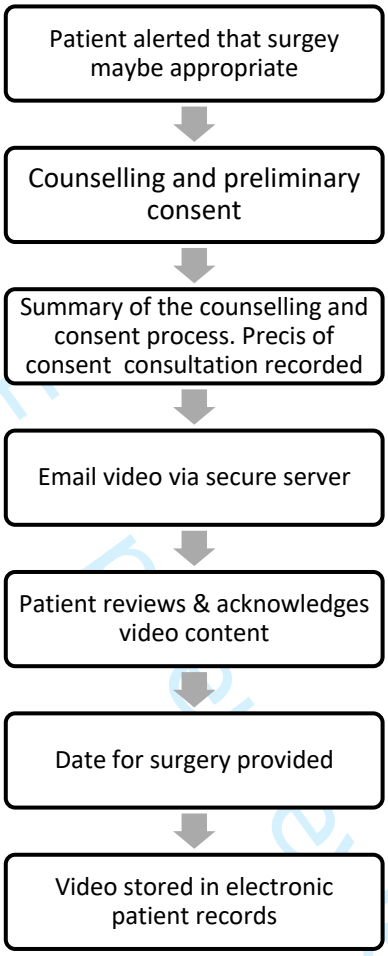
Figure.1. Summary of study procedure.



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ABSTRACT

Objectives: The British Association of Spinal Surgeons (BASS) has recently called for updates in consenting practice. This study investigates the utility and acceptability of a personalised video consent tool to enhance patient satisfaction in the preoperative consent giving process.

Design: A single centre, prospective pilot study using questionnaires to assess acceptability of video consent and its impacts on preoperative patient satisfaction.

Setting: A single National Health Service (NHS) centre with individuals undergoing surgery at a regional spinal centre in the UK.

Outcome measure: As part of preoperative planning, a self-administered questionnaire regarding patient satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods was completed.

Participants: 20 participants with a mean age of 56 years (*SD* = 16.26) undergoing spinal surgery.

Results: Median number of video views were 2-3 times. 85% of patients watched the video with next of kin and family members.

80% of participants reported that the video consent tool helped to their address preoperative concerns. All participants stated they would use the video consent service again. All would recommend the service to others requiring surgery. Implementing the video consent tool did not endure any significant time or costs.

Conclusions: Introduction of a video consent tool was found to be a positive adjunct to traditional consenting methods. Patient – clinician consent dialogue can now be documented. A randomised controlled study to further evaluate the effects of video consent on patients' retention of information, pre and postoperative anxiety, patient reported outcome measures as well as length of stay may be beneficial.

Key Words: Video consent, Informed consent, Patient satisfaction, Spinal surgery.

ARTICLE SUMMARY

- Development of a personalised video informed consent tool.
- A novel method to document the patient – clinician preoperative consent conversation.
- Prospective data gathered from self-administrated patient satisfaction questionnaires.
- Participants recruited,10 male, 10 female, mean age of 56, all undergoing spinal surgery.
- An individualised consent adjunct used to promote patient autonomy and shared decision making.

INTRODUCTION

Informed consent is a legal and ethical principle which is required prior to any intervention that may violate autonomy. The *Montgomery v Lanarkshire* judgement (1) initiated a change in how healthcare professionals obtain informed consent. Montgomery (1) confirms the shift from an already eroding paternalistic approach to consent set by *Bolam v Friem Hospital Management Committee,(2),* to the adoption and acknowledgment of a person-centred approach seen in *Sidaway v Bethlem Royal Hospital (3), De Freitas v O'Brien (4)* and *Bolitho v City & Hackney HA (5).* Others concur that *Montgomery* marked a decisive shift in the legal test of duty of care, from the perspective of the clinician to that of the patient (6).

Informed consent has gained accelerated momentum following the Montgomery judgement. In acknowledgement of the recent changes in consenting practice, the General Medical Council (GMC), the Royal College of Surgeons (RCS) and other professional organisations, such as The British Association of Spinal Surgeons (BASS), have issued best practice guidelines on obtaining informed consent (7). However, despite the release of updated guidelines there is currently a gap in consenting practice relating to documenting the preoperative consent conversation.

Preparing to undergo surgery can be a stressful event for both patients and their families, often important information discussed within the consent consultation is forgotten (8). By providing patients access to a tool that captures their consent conversation, it is thought that the video will provide patients an opportunity to reflect and revisit the previously discussed dialog, prior to consenting to treatment. It encourages a bespoke individualised approach as indicated by Montgomery (1). The addition of this step to the preoperative consenting process may safeguard patients from medical coercion and promote autonomy to make an informed decision about their care, while reducing potential litigation claims.

Enhancements in digital technology are driving changes in information practices, which has influenced how informed consent may be delivered (9), examples include the use of iPads to deliver consent information (10) to the use of a smartphone applications to assist informed consenting practice (11). The acceptance of multimedia technology in preoperative consenting has been demonstrated across a variety of surgical disciplines, foot & ankle surgery (12), spinal surgery (13), vascular surgery (14), ophthalmic surgery (15), gastrointestinal surgery (16) and urological surgery (17). Notably, such preoperative multimedia consent technologies are often generic and not patient specific. There is currently a lack of research regarding the use of

personalised multimedia consenting adjuncts within surgery.

In order to improve service delivery and comply with the updated guidelines, we piloted a video consent tool (OxVIC) as an adjunct to traditional consenting methods for patients attending a spinal Preoperative Outpatient Assessment Clinic (POAC). Each consent video contained indications for surgery, associated risks and benefits, alternative treatment options and a section for patients to ask questions or clarify points. To our knowledge, the use of a video informed consent tool has not been used before in spinal surgery.

Our study aims were to evaluate acceptability of a novel consent tool (OxVIC), as an adjunct to traditional (written and verbal) consenting methods. Provide documentary evidence of the patient – clinician consent conversation, which now forms part of the medical notes. Improve patient experience and enhance patient satisfaction within the preoperative consent process, while generating an evidence base for future research.

METHODS

Ethical approval for this project was obtained from the Health and Life Sciences Faculty Research Ethics Committee (FREC) Oxford Brookes University, Oxford, England (FREC2016/57). In addition to the video consent process described below, written

informed consent was additionally obtained from all participants.

Procedure

We conducted a single centre, non-randomised, non-comparative pilot study in patients undergoing a spinal procedure at an NHS spinal centre in the UK. A flowchart of the study procedure is outlined on Figure 1. Prior to consenting to take part, all patients received a Participant Information Sheet (PIS). The PIS outlined that if patients agreed to take part they would receive the " gold standard" (verbal and written) in consent information. In addition to this they would also receive a consent adjunct in the form of a personalised video. All participants who agreed to take part were consented by fellowship trained Consultant Spinal Surgeons using verbal and written consenting methods in addition to a summary of the consent consultation being recorded. A researcher, independent of the surgical team provided participants with patient information sheets prior to consenting. Participants were all informed that their participation was voluntary and they were free to withdraw at any time. The summary was conducted in a structured way and consisted of the following, a discussion around the patients reasoning for choosing surgery, followed by an overview of the surgical procedure, its intended benefits and

associated risks ending with an opportunity for the patients' to check their understanding by asking questions.

A password protected email and a hospital trust approved web transfer service was used to send the personalised consent videos to study participants. Participants reviewed their personalised consent consultations at home with their family or friends. Participants had the option to forward their personal consent videos to family members outside of the UK. All, participants were invited to contact the spinal team, to seek clarity or ask further questions regarding the video content (two participants utilised this service). The recorded consent was stored securely within the patient's electronic health records, accessible only to the research team. Participants were asked to contact the spinal team once they had reviewed the consent conversation, acknowledging the risks and benefits of the proposed treatment. Prospective data from patients was obtained using a self-administered questionnaire regarding patient satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods. Participants were invited to complete the measure following the consent consultation and after reviewing their personalised consent video.

Participants

Participants were recruited over a four month period (September to December 2017).

Twenty two people were approached to take part, two declined, twenty volunteered. (n=20). Participants did not receive a honorarium for taking part in the study. Study inclusion criteria were: all participants must be over the age of 18 years of age and have capacity to make informed decisions. Participants were also required to have an active email address with access to the internet. Participants were excluded from the study if they lacked capacity to make informed decisions or if they had any visual or hearing impairments which may inhibit their ability to review their consent video.

Assessments

Electronic Self-Administered Questionnaires (SAQ) were distributed via email to patients who agreed to partake in the study by a researcher independent of the surgical team. Data were collected at one point, post consent consultation. Participant demographics, which included gender, age, number of times the video consent tool was viewed and who they watched the video with, were collected. In addition to this, participants completed the validated CSQ-8 tool (18) online. The CSQ-8 consists of eight self-report questions, each constructed with

a four point Likert scale reply. The minimum achievable satisfaction score is 8, indicating poor satisfaction, a maximum score of 32 would indicate high levels of satisfaction (19, 20). The CSQ-8 tool has been extensively tested for reliability and validity (19-21), to date it has been translated into more than 30 languages since its first launch in the early 1980's (22). The CSQ-8 has been found to be acceptable for use in previous studies examining patient satisfaction with consenting methods (17, 23).

Data analysis

The data collection period finished once 20 completed SAQ's were received. Normality of data were assessed using a Kolmogorov-Smirnov test. Descriptive, bivariate and inferential statistics were calculated and reported using two-tailed methods with the assistance a statistical program from IBM, SPSS 24 for Microsoft© Windows version 10.

Patient and Public Involvement

Patients were not involved in the development or design of this pilot study. However we do plan to enlist patient help when disseminating our research findings. We aim to include patient involvement when designing subsequent studies involving the Oxford Video Informed Consent tool (OxVIC).

RESULTS

Descriptive information

Over a four-month period, 20 participants (10:10, male: female) deemed suitable candidates for spinal procedures were recruited into the study. The mean age of participants was 56 years (*SD* = 16.26), range 27 years to 81years. Participant demographics can been seen in Table 1.

Patient satisfaction

CSQ-8 data were normally distributed. The mean patient satisfaction score (CSQ-8) was 30.2 out of a maximum 32, indicative of high patient satisfaction. The CSQ-8 scores by gender and age can be seen in Table .2.

A two-way between groups analysis of variance was conducted to explore the impact of gender and age on patient satisfaction levels, as measured by the CSQ-8 scale. Participants were divided into five groups depending on their age (Group 1: 25-34 years, Group 2: 45-54 years, Group 3: 55-64 years, Group 4: 65-74 years and Group 5: 75-99 years) The interaction effect between gender and age was not statistically significant .

High patient satisfaction levels were reported across a broad range of spinal procedures, seen in Table1. These ranged from spinal nerve root blocks to complex deformity correction surgery.

The CSQ-8 responses generated several significant trends, a strong positive relationship between meeting patients 'preoperative consenting needs and helping them to deal more effectively with their preoperative concerns was reported (p=0.028), with 80 % reporting that the tool helped a great deal. All participants reported that they would recommend the video consent tool to others preparing for surgery. When asked "if future treatment were required, would you use the service again?", all participants responded yes. A significant positive relationship between the quality of the service participants received versus the service they expected was observed (p = 0.008).

Engagement with the tool

All participants watched their consent video at least once prior to consenting for surgery, with a mean number of viewings of 2-3 times. Eighty-five percent of the participants watched their consent video with their next of kin, which includes partners and other family members, their children or friends. Two participants sent their consent videos to their children, who lived in the USA and Australia. 15% of participants reported watching their video alone. Those who watched the video 4 to 5 times on average reported higher satisfaction scores. Approximately 13 additional minutes were required compared to the traditional process to complete the video recording process.

The mean recording time was 13 minutes and 15 seconds, with a range of 6 minutes and 21 seconds, to 20 minutes and 55 seconds. Introduction of the video consent tool did not endure any significant costs as the technology already existed within the Trust.

DISCUSSION

The main findings of our study were that participants were overall completely satisfied with the video consent tool and the service. All patients reported that that would use the service again if needed and that they would recommend the service to others requiring surgery.

The mean CSQ-8 satisfaction score reported in this study was 30.2, with scores above 24 considered as achieving high levels of satisfaction (21) While it was beyond the scope of this exploratory pilot study to examine to how the video consent tool compared to other methods of consent, such as audio recording of consent, participant scores on the CSQ-8 in the present study indicate that the personalised video consent tool may be equal to, if not more effective than, the existing methods (e.g. audio recording alone) (17, 23). However, additional research is needed to further explore this possibility. Our preliminary results suggest that participants' age or gender did not affect patient satisfaction levels with the use of the video consent tool in

the preoperative setting. This finding is consistent with previous studies (12, 24, 25).

Busy preoperative clinics, poor communication techniques, unanswered questions, anxiety and poor comprehension are all barrier to patients not retaining information (26). Our study indicates that the use of personalised video tool may allow patients to process and review complex information previously discussed by the surgeon, from the comfort of their own home. Participants had the opportunity to email the spinal service for further clarity of the video content and two participants utilised this service.

Introduction of the video consent tool did not require significantly more clinician time. The ability to watch the video with family members, or even to securely send family members the video, allowed for shared decision making and aided a person-centred approach to care, empowering participants to manage their own medical information. This is important for patients outcomes as shared decision making facilitates increased patient satisfaction levels and potentially reduces illness uncertainty (27, 28).

All patients engaged with their personalised consent adjunct twice on average before consenting to surgery. To our knowledge, multiple interactions of a preoperative consent adjunct have not been reported in the literature (29). All patients were happy to recommend OxVIC to others requiring preoperative surgical consent, indicating they were satisfied

and it would be acceptable for further use. This project found that, the more times participants watched their consent video, the more satisfied they became with their consent process. With the highest satisfaction scores in those who engaged with the video tool the most (4 to 5 times). Moreover, as the majority of studies using multimedia tools as an adjunct to informed consent do not personalise their content (27, 29), this is the first time that the use of a personalised multimedia tool has been reported in the literature.

Clinical implications

This study indicates that a personalised video consent tool is feasible to administer during the preoperative consent process for spinal surgery procedures and that the intervention produced high satisfaction scores. Overall, we found approximately thirteen additional minutes were required compared to the traditional process to complete the video recording process. This suggests that this procedure would be acceptable for use. Particularly in complex consultations where decision-making and communication might be more challenging for both the clinician and the patient.

While concerns over additional time, potential costs and practicality as to achieving this process are valid, we found them not to be a significant barrier to delivering this service. Provided one has access to a good quality digital recording

device, such as a smartphone that can transfer and store data securely, then the process can be straightforward.

We recognise that patients need to have access to the internet and may require help if not familiar using this sort of technology; however, as 85% of UK adults have a smartphone (30) and access to the internet in this is not an insurmountable barrier. While we have not undertaken a cost analysis, for this pilot there have been no significant costs as the technology already exists within the NHS Trust.

Introducing OxVIC into clinical practice has numerous benefits such as, documentary evidence of the clinician – patient consent conservation, which may reduce medicolegal cases. It may be used as an educational tool for medical teaching and could act as a patient resource / decision aid, useful when analysing potential benefits and risks associated with surgery.

We would therefore suggest video consenting as a new bench mark in the consenting process. Based on this study, we recommend a randomised controlled trial to evaluate the full impact of this process on outcome measures such as information retention, length of stay and litigation claims.

Strengths and limitations

This study has several strengths and weaknesses. Among the strengths was the development of a novel method to document the patient – clinician consent conversation. To our knowledge, this

study is the first of its kind to provide preoperative patients with a personalised multimedia consent adjunct (OxVIC). Furthermore, OxVIC allows patients to review their consent conversation with family members and friends away from the clinical area, promoting shared decision making and patient autonomy. Among the weaknesses is the limited diversity of the sample (e.g. spinal surgery patients). Further studies could include the patient perspectives from other surgical specialities. In addition, quantitative data gathered within this pilot could be supported by the addition of qualitative research methods. While a standard NHS/Trust surgical consent form was used to promote surgeon adherence to standard information giving, the consent videos were not independently reviewed for validation purposes prior to patient access. The potential for standardisation should be considered in future studies of multimedia consenting. Finally, concerns regarding cost and additional consenting time could be perceived as a potential limitation. However, the ability to document the patient-clinical conversation and its potential application to medio-legal practice may outweigh such concerns. This needs to be considered in future feasibility studies.

Future research

The findings from this pilot provide a foundation for potential future research projects.

A larger more diverse sample size to include younger (<25 years) and older (75yrs +) people could add to the validity. Moreover, there is scope for the tool to be included in other specialities and further research should examine the acceptability of video consenting tool in multiple surgical disciplines. A double blinded, randomised control trial to definitively test the efficacy of OxVIC across different surgical specialities is in process.

Conclusion

If patient satisfaction is a measure of quality (31) this study indicates that the introduction of a personalised consent tool may have a positive impact on the quality of service patients receive. The provision of informed care could be facilitated by the introduction of a personalised video tool, as it promotes patient autonomy, shared decision making and empowers patients to manage their own health.

AUTHOR CONTRIBUTIONS:

GM, CT and JR made substantial contributions to the conception of the study. GM analysed and interpreted the data for the study. GM, JR and DR contributed to acquisition of the data. GM, CT, VW, DR and JR drafted the article and revised it critically for important intellectual content. All authors gave final approval of the version to be published and agreed to be accountable for all aspects of the article in ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

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Competing interests: None

Disclaimer: This study has been presented via podium presentation at the 41st Annual Scientific Meeting of the Singapore Orthopaedic Association and at the Joint British Scoliosis Society / Irish Spine Society Meeting, 2018.

Patient consent: Obtained

Ethics approval: Oxford Brookes University, Faculty of Health Sciences Research Ethics Committee (FREC2016/57).

Data sharing statement: We welcome data-sharing requests from researchers interested in OxVIC. Please contact GM (gerard.mawhinney@ouh.nhs.uk) directly to explore further.

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WORD COUNT: 3155

Table.1. Demographics of Study Participants

Demographics		Sample statistics
Gender, N(%)	Male	10 (50%)
	Female	10 (50%)
Participant age (years) *SD* = 16.26 Mean age – 56 years	25 – 34	2 (10%)
	35 – 44	0 (0%)
	45 – 54	6 (30%)
	55 – 64	5 (25%)
	65 – 74	4 (20%)
	75 – 99	3 (15%)
Range	27 – 81	
Variety of Surgical Procedures		3
	Deformity	6
	correction	3

	Lumbar degenerative Nerve Root block	1
	Removal of metalwork	7
	Tumour surgery	
Frequency of viewing consent video	Once	7 (35%)
	2 to 3 times	10 (50%)
	4 to 5 times	3 (15%)
Video watched (with)	Alone	3 (15%)
	Next of Kin	11(55%)
	Children	2 (10%)
	Other family members	6 (30%)
	Friends	2 (10%)

Note. *SD* = standard deviation.

Table. 2. Mean CSQ-8 Scores by Age and Gender

Demographic	Mean CSQ-8 Score (Maximum score 32)	Range (*SD*)
Gender		
Male	30	26 – 32 (*2.2*)
Female	30.4	29 – 32 (*1.07*)

Total Mean	30.2	26 – 32 (*1.70*)
Participant Age (years)		
25 - 34	31	30 – 32
35 - 44	-	-
45 – 54	30.16	26 - 31
55 – 64	29	26 – 31
65 – 74	30.25	28 – 32
75 – 99	31.66	31 – 32

Figure legend: Figure.1. Provides an overview of the Oxford Video Informed Consent Tool (OxVIC).

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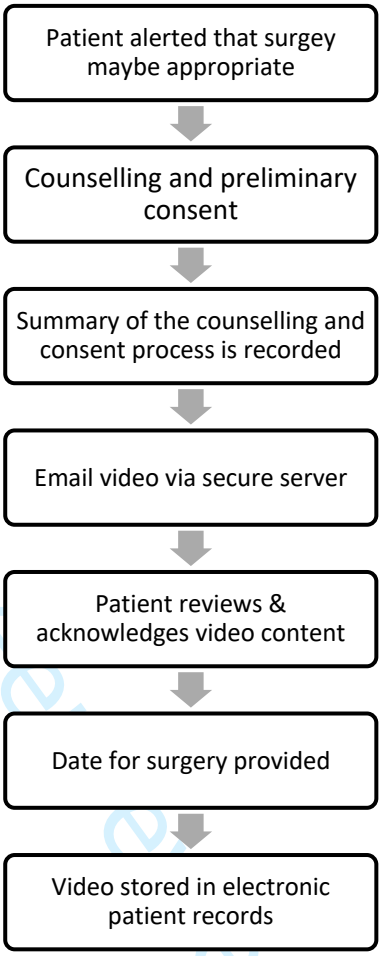
Figure.1. An overview of the Oxford Video Informed Consent Tool (OxVIC) process



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THE OXFORD VIDEO INFORMED CONSENT TOOL (OXVIC): A PILOT STUDY OF INFORMED VIDEO CONSENT IN SPINAL SURGERY AND PREOPERATIVE PATIENT SATISFACTION.

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ABSTRACT

Objectives: The British Association of Spinal Surgeons recently called for updates in consenting practice. This study investigates the utility and acceptability of a personalised video consent tool to enhance patient satisfaction in the preoperative consent giving process.

Design: A single centre, prospective pilot study using questionnaires to assess acceptability of video consent and its impacts on preoperative patient satisfaction.

Setting: A single National Health Service (NHS) centre with individuals undergoing surgery at a regional spinal centre in the UK.

Outcome measure: As part of preoperative planning, study participants completed a self-administered questionnaire (CSQ-8), which measured their satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods.

Participants: 20 participants with a mean age of 56 years (*SD* = 16.26) undergoing spinal surgery.

Results: Mean patient satisfaction (CSQ-8) score was 30.2 / 32. Median number of video views were 2-3 times. 85% of patients watched the video with family and friends. 80% of participants reported that the video consent tool helped to their address preoperative concerns. All participants stated they would use the video consent service again. All would recommend the service to others requiring surgery. Implementing the video consent tool did not endure any significant time or costs.

Conclusions: Introduction of a video consent tool was found to be a positive adjunct to traditional consenting methods. Patient – clinician consent dialogue can now be documented. A randomised controlled study to further evaluate the effects of video consent on patients' retention of information, pre and postoperative anxiety, patient reported outcome measures as well as length of stay may be beneficial.

Key Words: Video consent, Informed consent, Patient satisfaction, Spinal surgery.

ARTICLE SUMMARY

Strengths and limitations of this study

- The development of a personalised video consent tool used to promote patient autonomy and shared decision making.
- An exploratory pilot study in spinal surgery, future research will explore the use of OxVIC across different surgical specialities.
- Prospective quantitative data gathered from 20 participants, the introduction of a qualitative research element is planned for phase two of this study.
- A novel method to document the patient-clinician preoperative consent conversation.

INTRODUCTION

Informed consent is a legal and ethical principle that is required prior to any intervention that may violate autonomy. The *Montgomery v Lanarkshire* judgement (1) initiated a change in how healthcare professionals obtain informed consent. Montgomery (1) confirms the shift from an already eroding paternalistic approach to consent set by *Bolam v Friem Hospital Management Committee,(2),* to the adoption and acknowledgment of a person-centred approach seen in *Sidaway v Bethlem Royal Hospital (3), De Freitas v O'Brien (4)* and *Bolitho v City & Hackney HA (5).*

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Preparing to undergo surgery can be a stressful event for both patients and their families, often important information discussed within the consent consultation is forgotten (8). By providing patients access to a tool that captures their consent conversation, it is thought that the video will provide patients an opportunity to reflect and revisit the previously discussed dialog, prior to consenting to treatment. It

encourages a bespoke individualised approach as indicated by Montgomery (1). The addition of this step to the preoperative consenting process may safeguard patients from medical coercion and promote autonomy to make an informed decision about their care, while reducing potential litigation claims.

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In order to improve service delivery and comply with the updated guidelines, we piloted a video consent tool (OxVIC) as an adjunct to traditional consenting methods for patients attending a spinal Preoperative Outpatient Assessment Clinic (POAC). Each consent video contained indications for surgery, associated risks and benefits, alternative treatment options and a section for patients to ask questions or clarify points. To our knowledge, the use of a video informed consent tool has not been used before in spinal surgery.

Our study aims were to evaluate acceptability of a novel consent tool (OxVIC), as an adjunct to traditional (written and verbal) consenting methods. Aim to provide documentary evidence of the patient – clinician consent conversation, which now forms part of the medical notes. Improve patient experience and enhance patient satisfaction within the preoperative consent process, while generating an evidence base for future research.

METHODS

Ethical approval for this project was obtained from the Health and Life Sciences Faculty Research Ethics Committee (FREC) Oxford Brookes University, Oxford, England (FREC2016/57). In addition to the video consent process described below, written informed consent was additionally obtained from all participants.

Procedure

We conducted a single centre, non-randomised, non-comparative pilot study in patients undergoing a spinal procedure at an NHS spinal centre in the UK. A flowchart of the study procedure is outlined on Figure 1. Prior to consenting to take part, all patients received a Participant Information Sheet (PIS). The PIS outlined that if patients agreed to take part they would receive the " gold standard" (verbal and written) in consent information. In addition to this they would also receive a consent adjunct in the form of a personalised video.

All participants who agreed to take part were consented by fellowship trained Consultant Spinal Surgeons using verbal and written consenting methods in addition

to a summary of the consent consultation being recorded. A researcher, independent of the surgical team provided participants with patient information sheets prior to consenting. Participants were all informed that participation was voluntary and were free to withdraw at any time. The summary was conducted in a structured way and consisted of the following: a discussion around the patients reasoning for choosing surgery, followed by an overview of the surgical procedure, its intended benefits and associated risks ending with an opportunity for the patients to check their understanding by asking questions.

A password protected email and a hospital trust approved web transfer service was used to send the personalised consent videos to study participants. Participants reviewed their personalised consent consultations at home with their family or friends. Participants had the option to forward their personal consent videos to family members outside of the UK. All, participants were invited to contact the spinal team, to seek clarity or ask further questions regarding the video content (two participants utilised this service). The recorded consent was stored securely within the electronic health record, accessible only to the research team.

Participants were asked to contact the spinal team once they had reviewed the consent conversation, acknowledging the risks and benefits of the proposed treatment. Prospective patient data were obtained using a self-administered questionnaire regarding patient satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods. Participants were invited to complete the measure following the consent consultation and after reviewing their personalised consent video.

Approximately 13 additional minutes were required compared to the traditional process to complete the video recording process. The mean recording time was 13 minutes and 15 seconds, with a range of 6 minutes and 21 seconds, to 20 minutes and 55 seconds. This was dependant of the complexity of the proposed treatment and its associated risks and benefits. Introduction of the video consent tool did not endure any significant costs as the technology already existed within the Trust.

Participants

Participants were recruited over a four month period (September to December 2017).

Twenty two people were approached to take part, two declined, twenty volunteered (n=20). Participants did not receive a honorarium for taking part in the study. Study inclusion criteria were: over the age of 18 years of age; have capacity to make informed decisions; and have an active email address with access to the internet. Participants were excluded from the study if they had any visual or hearing impairments which may inhibit the ability to review the consent video.

Assessments

A researcher independent of the surgical team distributed electronic Self-Administered Questionnaires (SAQ) to participants who agreed to partake in the study, data were collected at one point, post consent consultation. Participant demographics, which included gender, age, number of times the video consent tool was viewed and who they watched the video with, were collected. In addition to this, participants completed

the validated CSQ-8 tool. The CSQ-8 tool consists of eight self-report questions, each constructed with a four point Likert scale reply (18). The minimum achievable satisfaction score is 8, indicating poor satisfaction, a maximum score of 32 would indicate high levels of satisfaction (19, 20). The CSQ-8 tool has been extensively tested for reliability and validity (19-21); to date it has been translated into more than 30 languages since its first launch in the early 1980's (22). The CSQ-8 has been found to be acceptable for use in previous studies examining patient satisfaction with consenting methods (17, 23).

Data analysis

The data collection period finished once 20 completed SAQ's were received. Normality of data were assessed using a Kolmogorov-Smirnov test. Descriptive, bivariate and inferential statistics were calculated and reported using two-tailed methods with the assistance a statistical program from IBM, SPSS 24 for Microsoft© Windows version 10.

Patient and Public Involvement

Patients were not involved in the development or design of this pilot study. However, following this preliminary pilot study, patient involvement will be included in the development of subsequent studies utilising OxVIC.

RESULTS

Descriptive information

Over a four-month period, 20 participants (10:10, male: female) deemed suitable candidates for spinal procedures were recruited into the study. The mean age was 56 years (*SD* = 16.26), range 27 to 81years. Participant demographics can been seen in Table 1.

Patient satisfaction

CSQ-8 data were normally distributed. High patient satisfaction levels were reported across a broad range of spinal procedures. The mean patient satisfaction score (CSQ-8) was 30.2 out of a maximum 32, indicative of high patient satisfaction.

The CSQ-8 scores by gender and age can be seen in Table .2. A two-way between groups analysis of variance was conducted to explore the impact of gender and age on patient satisfaction levels, as measured by the CSQ-8 scale. Participants were divided into five groups depending on their age (Group 1: 25-34 years, Group 2: 45-54 years, Group 3: 55-64 years, Group 4: 65-74 years and Group 5: 75-99 years) The interaction effect between gender and age was not statistically significant (p = 0.155).

The CSQ-8 responses generated several significant trends, a strong positive relationship between meeting patients 'preoperative consenting needs and helping them to deal more effectively with their preoperative concerns was reported (p = 0.028), with 80 % reporting that the tool helped a great deal. All participants reported that they would recommend the video consent tool to others preparing for surgery. When asked "if future treatment were required, would you use the service again?", all participants responded yes. A significant positive relationship between

the quality of the service participants received versus the service they expected was observed ($p = 0.008$).

Engagement with the tool

All participants watched the consent video at least once prior to consenting for surgery, with a mean number of viewings of 2-3 times. Eighty-five percent of the participants watched the consent video with friends and family, which included next of kin, partners, children and other family members. Two participants sent the consent videos to their children living overseas. 15% of participants reported watching their video alone. Those who watched the video 4 to 5 times on average reported higher satisfaction scores.

DISCUSSION

The main findings of our study were that participants were overall completely satisfied with the video consent tool and the service. All participants reported that that would use the service again if needed and that they would recommend the

service to others requiring surgery. The mean CSQ-8 satisfaction score reported in this study was 30.2, with scores above 24 considered high levels of satisfaction (21).

It was beyond the scope of this exploratory pilot study to examine how the video consent tool compared to other methods of consent, such as audio recording of consent. Nonetheless, participant scores on the CSQ-8 in the present study indicate that the personalised video consent tool may be equal to, if not more effective than, the existing methods (e.g. audio recording alone) (17, 23). However, additional research is needed to further explore this possibility. Our preliminary results suggest that participants' age or gender did not affect patient satisfaction levels with the use of the video consent tool in the preoperative setting. This finding is consistent with previous studies (12, 24, 25).

Busy preoperative clinics, poor communication techniques, unanswered questions, anxiety and poor comprehension are all barrier to patients not retaining information (26). Our study indicates that the use of personalised video tool may allow patients to process and review complex information previously discussed by the surgeon,

from the comfort of their own home. Participants had the opportunity to email the spinal service for further clarity of the video content and two participants utilised this service.

Introduction of the video consent tool did not require significantly more clinician time. The ability to watch the video with family members, or even to securely send family members the video, allowed for shared decision making and aided a person-centred approach to care, empowering participants to manage their own medical information. This is important for patients outcomes as shared decision making facilitates increased patient satisfaction levels and potentially reduces illness uncertainty (27, 28).

All patients engaged with their personalised consent adjunct twice on average before consenting to surgery. To our knowledge, multiple interactions of a preoperative consent adjunct have not been reported in the literature (29). All patients were happy to recommend OxVIC to others requiring preoperative surgical consent, indicating they were satisfied and it would be acceptable for further use.

This project found that, the more times participants watched their consent video, the more satisfied they became with their consent process. With the highest satisfaction scores in those who engaged with the video tool the most (4 to 5 times). Moreover, as the majority of studies using multimedia tools as an adjunct to informed consent do not personalise their content (27, 29), this is the first time that the use of a personalised multimedia tool has been reported in the literature.

Clinical implications

This study indicates that a personalised video consent tool is feasible to administer during the preoperative consent process for spinal surgery procedures and that the intervention produced high satisfaction scores. Overall, we found approximately thirteen additional minutes were required compared to the traditional process to complete the video recording process.

This suggests that OxVIC would be acceptable for use, particularly in complex consultations where decision-making and communication might be more challenging for both the clinician and the patient.

While concerns over additional time, potential costs and practicality as to achieving this process are valid, they did not appear to be a significant barrier to delivering this service. Provided one has access to a good quality digital recording device, such as a smartphone that can transfer and store data securely, then the process can be straightforward.

We recognise that patients need to have access to the internet and may require help if not familiar using this sort of technology; however, as 85% of UK adults have a smartphone (30) and access to the internet in this is not an insurmountable barrier. Future studies exploring clinician experiences of obtaining patient consent via OxVIC would also be useful to ensure that any concerns or barriers to use that were not identified in the present study are considered and acceptably addressed.

While we have not undertaken a cost analysis, for this pilot there have been no significant costs as the technology already exists within the NHS Trust. Introducing OxVIC into clinical practice has numerous benefits such as, documentary evidence of the clinician – patient consent conservation, which may reduce medicolegal cases.

It may be used as an educational tool for medical teaching and could act as a patient resource / decision aid, useful when analysing potential benefits and risks associated with surgery.

We would therefore suggest video consenting as a new bench mark in the consenting process. Based on this study, we recommend a large-scale study to evaluate the full impact of this process on outcome measures such as information retention, length of stay and litigation claims.

Strengths and limitations

This study has several strengths and weaknesses. Among the strengths was the development of a novel method to document the patient – clinician consent conversation. To our knowledge, this study is the first of its kind to provide preoperative patients with a personalised multimedia consent adjunct (OxVIC). Furthermore, OxVIC allows patients to review their consent conversation with family members and

friends away from the clinical area, promoting shared decision making and patient autonomy.

Among the weaknesses is the limited diversity of the sample (e.g. spinal surgery patients). Further studies could include the patient perspectives from other surgical specialities. In addition, quantitative data gathered within this pilot could be supported by the addition of qualitative research methods. While a standard NHS/Trust surgical consent form was used to promote surgeon adherence to standard information giving, the consent videos were not independently reviewed for validation purposes prior to patient access. The potential for standardisation should be considered in future studies of multimedia consenting.

Finally, concerns regarding cost and additional consenting time could be perceived as a potential limitation. However, the ability to document the patient-clinical conversation and its potential application to medio-legal practice may outweigh such concerns. This needs to be considered in future feasibility studies.

Future research

The findings from this pilot provide a foundation for potential future research projects. A larger more diverse sample size to include younger (<25 years) and older (75yrs +) people could add to the validity. Moreover, there is scope for the tool to be included in other specialities and further research should examine the acceptability of video consenting tool in multiple surgical disciplines. A larger study to definitively test the efficacy of OxVIC across different surgical specialities is in process.

Conclusion

If patient satisfaction is a measure of quality (31) this study indicates that the introduction of a personalised consent tool may have a positive impact on the quality of service patients receive. The provision of informed care could be facilitated by the

introduction of a personalised video tool, as it promotes patient autonomy, shared decision making and empowers patients to manage their own health.

AUTHOR CONTRIBUTIONS:

GM, CT and JR made substantial contributions to the conception of the study. GM analysed and interpreted the data for the study. GM, JR and DR contributed to acquisition of the data. GM, CT, VW, DR and JR drafted the article and revised it critically for important intellectual content. All authors gave final approval of the version to be published and agreed to be accountable for all aspects of the article in ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

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Patient consent: Obtained

Ethics approval: Oxford Brookes University, Faculty of Health Sciences Research Ethics Committee (FREC2016/57).

Data sharing statement: We welcome data-sharing requests from researchers interested in OxVIC. Please contact GM (gerard.mawhinney@ouh.nhs.uk) directly to explore further.

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Table 1. Demographics of Study Participants

Demographics		Sample statistics
Gender, N(%)	Male	10 (50%)
	Female	10 (50%)
Participant age (years) *SD* = 16.26	25 – 34	2 (10%)
Mean age – 56 years	35 – 44	0 (0%)

	45 – 54	6 (30%)
	55 – 64	5 (25%)
	65 – 74	4 (20%)
	75 – 99	3 (15%)
Range	27 – 81	
Variety of Surgical Procedures	Deformity correction	3
	Lumbar degenerative	6
	Nerve Root block	3
	Removal of metalwork	1
	Tumour surgery	7
Frequency of viewing consent video	Once	7 (35%)
	2 to 3 times	10 (50%)
	4 to 5 times	3 (15%)
Video watched (with)	Alone	3 (15%)
	Family and friends	17(85%)

Note. *SD* = standard deviation.

Table 2. Mean CSQ-8 Scores by Age and Gender

Demographic	Mean CSQ-8 Score (Maximum score 32)	Range (*SD*)
Gender		
Male	30	26 – 32 (*2.2*)
Female	30.4	29 – 32 (*1.07*)
Total Mean	30.2	26 – 32 (*1.70*)
Participant Age (years)		
25 - 34	31	30 – 32
35 - 44	-	-
45 – 54	30.16	26 - 31
55 – 64	29	26 – 31
65 – 74	30.25	28 – 32
75 – 99	31.66	31 – 32

Figure legend: Figure.1. An overview of the Oxford Video Informed Consent Tool (OxVIC) process

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Figure.1. An overview of the Oxford Video Informed Consent Tool (OxVIC) process