Evaluation of preprinted consent forms for retinal detachment repair surgery: a short report

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INTRODUCTION
Autonomy as a pillar of medical ethics is a foundation on which the doctor–patient relationship is established. The consent process for surgery is an example of patient autonomy that is directly exhibited. The consent process should be undertaken vigilantly and with evaluation. It should not be equated to a tick-box exercise, as explained in the Montgomery versus Lancashire Health Board case.1 Retinal detachment surgery repair conducted at the Birmingham Midland Eye Centre currently follows a protocol of consent with handwritten forms completed by an ophthalmologist with the patient present. Local issues arose with legibility, missing information and high variability in the documentation. A Comparative analysis with national opinion; the Medical Defence Union stated within ophthalmology allegations commonly centre on an inadequate consent process.2 Consequent to these findings, a process of improvement was embarked on in the way of a quality improvement project (QIP). This QIP conformed to the Standards for Quality Improvement Reporting Excellence or SQUIRE V.2.0 guidelines.3

Following a literature search, use of a preprinted consent form was found to be successful in orthopaedic surgery, as well as finding numerous improvements with the interventions, such as improved legibility, reduced human error variation and less medical jargon.4 No analysis of such measures has been found for retinal detachment surgery repair, and subsequently, this paper aimed to report on such implementation.

METHODOLOGY: FIRST CYCLE
Senior clinicians noticed several patients had expressed concerns with the current (preprinted) consent forms, namely, their illegibility and lack of risk factor documentation within the consent form. Consequently, a cross-sectional survey was carried out to detect the nature of the underlying issues. This survey questioned patients who provided consent for retinal detachment repair surgery in a specialist tertiary care centre. Patients were offered an anonymous questionnaire consisting of 29 separate questions that aimed to contextualise patients’ understanding of the consent process, consent form information and procedure-specific risks. Fifty patients completed the questionnaire and results were analysed in a double-blinded fashion. The project was registered in the local audit register. The outcomes measured in the questionnaires were

► Patient’s knowledge of consenting process-average score based on a quiz within the questionnaire
► Patient’s wishes documented in the consent form.
► Patients felt all risks are documented in the consent form.
► Patients felt risks were made clear to them.
► Patients felt they understood the consent form wholly.

These outcomes were based on the General Medical Council (GMC) standards5:

44. Before accepting a patient’s consent, you must consider whether they have been given the information they want or need, and how well they understand the details and implications of what is proposed.
28. Clear, accurate information about the risks of any proposed investigation or treatment, presented in a way, patients can understand, can help them make informed decisions.

Results: first cycle
Fifty patients completed the questionnaire. Just over half of the patients understood the consent form wholly, and only 50% felt the consent form was legible. Twenty-two per cent of the participants agreed not all the risks...
discussed were documented. When quizzed about the consenting process, the average score was 57%.

Methodology: second cycle
Following discussions with two independent vitreoretinal surgeons, it was decided that a new preprinted consent form should be trialled (see online supplemental material). This was hoped to solve issues with legibility and would ensure all risks are already included. A preprinted consent form was designed by the senior author and trialled.

A second cycle of data collection was undertaken to assess the new preprinted consent forms using the same questionnaire with five questions amended to include the term preprinted procedure-specific consent form.

A simple randomisation process via coin toss selected patients for the new preprinted consent forms. These patients were unaware of the existence of handwritten consent forms or even that a new consent form was being trialled. The results were compared with the first cycle. The average score when quizzing the participants on the consenting process did not improve significantly with the new consent form.

From these results, one can conclude that the preprinted consent forms are an improvement in the consenting process as they are easier to understand; they make the risks clearer to the patient; and they document the patient wishes more effectively. Ninety-four per cent of the participants agreed they preferred preprinted forms over handwritten ones.

These findings were presented to ophthalmologists at the local quality improvement meeting, where it was decided to incorporate preprinted consent forms into departmental practice. This is now in use as local standard practice for retinal detachment surgery.

RESULTS
Participants were patients undergoing retinal detachment. The results are listed in Table 1.

<table>
<thead>
<tr>
<th>Handwritten forms, % (n)</th>
<th>Preprinted forms, % (n)</th>
<th>Difference</th>
<th>Statistical test (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients felt they understood the consent form wholly.</td>
<td>56 (28)</td>
<td>76 (38)</td>
<td>20% (1.43–36.78)</td>
</tr>
<tr>
<td>Patients felt risks were made clear to them.</td>
<td>42 (23)</td>
<td>98 (49)</td>
<td>56% (39.82–68.73)</td>
</tr>
<tr>
<td>Patients felt all risks documented.</td>
<td>78 (39)</td>
<td>84 (42)</td>
<td>6% (-9.56 to 21.30)</td>
</tr>
<tr>
<td>Patients’ wishes were documented.</td>
<td>18 (9)</td>
<td>66 (33)</td>
<td>48% (29.15–62.19)</td>
</tr>
<tr>
<td>Score on knowledge regarding consenting process (%)</td>
<td>57</td>
<td>62*</td>
<td>5</td>
</tr>
</tbody>
</table>

*SD.
†t-Value (p value).

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DISCUSSION
This project found preprinted consent forms improve patient experience and understanding. One of the key features is legibility, which can be poor in handwritten consent forms. The reason for this may be time pressure on clinicians. By introducing preprinted consent forms, legibility is markedly improved. As there is less to write, the consenting process is more efficient, and clinicians have a lesser time burden.

The study design aimed to capture the subjective experiences of the participants. Patients’ experience of the consent form is a subjective experience, and their understanding of the consent form was assessed in a subjective fashion. Owen et al employed a more objective approach to measure improvement as they measured legibility and information within consent forms retrospectively. The principal limitation of this subjective approach is that one cannot objectively conclude preprinted consent forms to be more effective. However, the evaluation of patients’ experience clearly concluded preprinted consent forms to be superior in the patient’s point of view. As a result, the benefit of a subjective design is patients’ perspectives are understood when determining the quality of consent.
and subsequently acting on these viewpoints in a safe and efficacious manner.

There are numerous learning points to hallmark from this project.

Despite the data collection being carried out during the COVID-19 pandemic, there was little hindrance to the data collection. This was because fortuitously, retinal detachment surgery continued at this tertiary centre during the first wave of the pandemic. Second, designing the consent form was an efficient process due to the combined experience and familiarity with retinal detachment surgery, possessed by the senior authors.

Among the key problems faced was incorporation of the novel form into common use within common practice. We addressed the first step of incorporation by presenting the findings to the local team.

Although regular monthly quality improvement meetings were initially cancelled, these meetings were reinstated in a remote fashion. The findings were presented and incorporation into departmental practice was accepted. The second step was to organise a provider of the consent forms who will regularly print the consent forms to prevent shortages in clinical practice. Although a laborious process initially, this preprinted consent form was added as a stock template which streamlined the process. Strong communication with stock managers was vital throughout the implementation of the new consent forms, and as a result, deliveries were easily arranged, and the stock was placed in a location easily accessible by clinicians.

We hypothesise the findings of this study are applicable to other surgical procedures in ophthalmology; however, further data collection to empirically prove this will be required. The Royal College of Ophthalmologists also advise the use of procedure-specific prepopulated consent forms.

Approximately three-quarters of respondents agreed to reading the consent form and understanding the content. However, some patients were not able to read the questionnaire due to poor vision; instead, the questionnaire was read out to them. This questions their ability to read the preprinted consent forms. Perhaps, more innovative ideas are required to aid the consenting process for ophthalmology patients.

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REFERENCES
Consent Form 1

Patient Agreement to Investigation or Treatment

Patient details (or pre-printed label)

NHS Organisation .......................................................... Patient’s first names ..........................................................

Surname/Family name .............................................. Responsible health professional ..........................................................

Date of Birth .......................................................... Job title ..........................................................

NHS number (or other identifier) ........................................ Special requirements ..........................................................

Gender □ Male □ Female (eg other language/other communication method)

Name of proposed procedure or course of treatment (include brief explanation if medical term not clear) ........................................ Retinal Detachment Repair Surgery

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits ..........................................................

Significant, unavoidable or frequently occurring risks ..........................................................

Total blindness / Retinal re-detachment / Further surgery / Laser / High or Low eye pressure / Distortion / Double vision / Cataract or no lens / Corneal decompensation / Macular oedema / Sympathetic ophthalmia (very rare)

Any extra procedures which may become necessary during the procedure □ blood transfusion □ other procedure (please specify) ..........................................................

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I am taking responsibility for this patient’s consent because: □ I am competent to carry out the procedure □ I have been trained in consent for the procedure in accordance with the delegated consent process. If you cannot tick either of the boxes then you should not be taking consent.

Information Provision

The following leaflet/tape has been provided ..........................................................

This procedure will involve: □ general and/or regional anaesthesia □ local anaesthesia □ sedation ..........................................................

Signed .......................................................... Job title .......................................................... Date ..........................................................

Name (PRINT) ..........................................................

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she has no further questions and wishes the procedure to go ahead. 

Signed .......................................................... Date ..........................................................

Name (PRINT) ..........................................................

Important notes: (tick if applicable)

□ See also advance directive/living will (eg Jehovah’s Witness form)

□ Patient has withdrawn consent (ask patient to sign/date here) ..........................................................

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe she/he can understand.

Signed .......................................................... Date ..........................................................

Name (PRINT) ..........................................................

□ Trust Staff □ Name of Agency ..........................................................

Copy accepted by patient: yes / no (please ring)

GOLD COPY: CASE NOTES WHITE COPY: PATIENT
Guidance to health professionals (to be read in conjunction with consent)

What a consent form is for
This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver - if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoire to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent
See the Department of Health's REFERENCE GUIDE TO CONSENT FOR EXAMINATION OR TREATMENT, SECOND EDITION, for a comprehensive summary of the law on consent (also available at www.doh.gov.uk/consent).

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form
If the patient is 18 or over and lacks the capacity to give consent, you should use form 4 (Form for adults who lack the capacity to consent to investigation or treatment) instead of this form. A patient lacks capacity if they have an impairment of the mind or brain or disturbance affecting the way their mind or brain works and they cannot:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh that information as part of the decision-making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign this form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court appointed deputy.

Information
Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about "significant risks which would affect the judgement of a reasonable patient". "Significant" has not been legally defined, but the GMC requires doctors to tell patients about "serious or frequently occurring" risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. In Chester v Afshar, a majority of the House of Lords held that a neurosurgeon who failed to warn a patient of the small risk of injury inherent in spinal surgery, even if properly performed, was liable to the patient when the risk materialised, even though the risk was not increased by the failure to warn and the patient had not shown that she would never have had an operation carrying the same risk.

You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.