

1. **Title:** A pilot study to assess patient perspective and utility of a patient prompting document in surgical consultation
2. **Investigator details**

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1. **Introduction**

Presenting to a surgical outpatient clinic can be a stressful experience for patients. Disparity in education levels, perceived power imbalances and other factors can result in the patient feeling unsatisfied or confused at the completion of the consultation. We propose a randomised controlled study; whereby, the participant is placed into either the intervention group and will receive a pre-designed patient prompting document, or they are placed in the control group. The outpatient consultation will be audio-video recorded. Within 7 days of the consultation the participant will be contacted by telephone to discuss their experience. The purpose is to analyse the utility of a patient prompting document in improving patient understanding, increased patient empowerment and facilitating successful outpatient consultations.

1. **Background**

Many interventions have been studied in an attempt to enhance doctor-patient communication, shared decision making and increase patient engagement/empowerment. Documents that prompt the patient are inexpensive, are relatively simple to implement, and are perceived as more helpful than normal information sheets (Keinki. C). Prompting documents have been extensively used in oncology where they have been shown to increase the number of questions asked by the patient, reduce anxiety at follow up appointments, and influence patient ability to recall information (Brandes. K). In discussions about end of life and prognosis, prompting documents have been endorsed by doctors and patients (Walczac. A). Analysis of the utility of such documents in presurgical consultation is lacking. How the patient feels about the use of a prompting document during the pre-surgical consultation and whether or not this enhances feelings of empowerment, knowledge, understanding and autonomy within the shared decision-making process is unclear. We seek to explore the patient perspective of a prompting document in terms of the direction and content of the surgical consultation. This study also aims to explore if the use of a prompting document can increase patient engagement, empowerment, understanding and information recall.

1. **Purpose**

We aim to explore whether a patient prompting document can improve doctor-patient communication during a surgical outpatient consultation, and information retention and understanding one week later.

1. **Study design**
2. **Participants**

**Patient Participants**

Patients scheduled for surgical consultations from October 2021- March 2022 at The Queen Elizabeth Hospital. Any patient 16 years or older attending the outpatient surgical clinic, who has the capacity to consent to participation, and has signed and understood the consent form.

**Staff participants**

Staff participants will be eligible for inclusion in this study if employed by CALHN and any of the following criteria apply:

* 1. Surgical Staff Consultant (including heads of units, academic consultant surgeons)
  2. Surgical Visiting Medical Officer
  3. Surgical Fellow

**Exclusion criteria**

* Declining to participate
* Patient who require a translator

**Informed consent**

Written consent to be obtained from candidates who are willing to participate.

**Methodology**

Overview

1. Staff consent
2. Patient are approached via telephone
3. Patient approached in clinic
4. Patient signs consent
5. Patient randomised to receive intervention (prompt sheet) or standard consultation (no prompt sheet)
6. Consultation is recoded
7. Follow up phone to patient to assess recall

**Staff participation:**

Staff will be invited to participate by the lead researcher (GM) at Unit meetings. Staff will be provided with the Information sheet to read and given time to consider their involvement. They will be asked to conduct the consultation as they normally would. They will be informed that some patients may be using a provided prompt sheet but that it is completely up to the patient as to how the prompt sheet influences the discussion (if at all). There is no need or requirement for the consultant to address the prompt sheet unless they wish to.

Staff will be reminded that the desk setup in the consultation room will be recorded and that any activity that requires the patient to undress should occur in the side room.

**How will you approach staff?**

Surgical Staff Consultant (including heads of units, academic consultant surgeons), Surgical Visiting Medical Officers, and Surgical Fellows will be approached during unit meetings.

**Preconsultation:** Patients who are likely to be consented for surgery will be identified and contacted by Matheesha Herath, Guy Maddern or Jessica Reid via telephone call (attached script) to let them know about a potential research trial they may be approached about when they attend the outpatient clinic. Participation is entirely voluntary and will not influence their care or waiting time. When patient attends clinic they will be asked if they are interested in participating and provided with the PICF. If they would like to participate, they will be asked to provide written informed consent. They will be provided with a copy of the PICF to take home.

**Intervention:** The intervention being studied is a patient prompting document. We are testing what effect the use of this prompting document will have on the surgical consultation in regards to engagement, communication and satisfaction.

**Randomisation**: Patients will be stratified by sex. A sealed envelope system will be used to randomise patients. Patient will be randomised in the order they consent to participate. Randomisation will occur in blocks of 4 and 6. The allocation will occur via random number computer generation software. The allocation will be placed in sealed, opaque, tamper proof envelopes. Envelopes will be numbered consecutively. When a patient signs consent, the “next” envelope will be opened and the patient assigned to the experimental group (prompt sheet) or the standard group.

**Consultation:** The consultation commences when the patient enters the room and concludes when the patient leaves the room. The entire clinic appointment will be recorded using 2 GoPros, one focusing on patient, one focusing on consultant. Recording will capture both audio and video data. The cameras will be pointed at the desk in the consultation room. The camera will not capture any physical examinations or situations where the patient might remove any clothing.

**Post consultation follow up:** The patient participant will receive a phone call within 7 days of the consultation by a member of the research team (script attached) to understand information retention and satisfaction with the information received in the consultation.

**Video review phase:** All recordings will be reviewed by a member of the research team. Videos will be assigned a randomised number code to protect privacy or participants. All videos will also be analysed by researchers to look for patient engagement factors such as consultation time, talk time for patient and surgeon, mutual eye gaze). We will also analyse the types of questions asked (open or closed ended), the situation where the question was asked (direct or indirect prompt). We will analyse in terms of use of the intervention (time spent looking at the prompt sheet, patient referring to the prompt sheet, doctor engaging with the prompt sheet, if information was recorded on the prompt sheet)

1. **Confidentiality, data storage and security**

Any information obtained during this research that may identify any participant will remain confidential, and will only be disclosed with participant consent, except as required by law. All documentation and video/audio data obtained during the study will be retained in a securely locked area within the Department of Surgery, The Queen Elizabeth Hospital, accessible only by the study investigators, for a period of fifteen (15) years as required by the Central North Adelaide Health Service’s policy on retention of study data. Electronic data data will be stored on a shared departmental drive with password. Study documents will be destroyed or deleted (as

appropriate) at the end of this period by the Primary Investigator. It is anticipated that the results of this study (or data obtained from it) will be published and/or presented at medical forums. Data obtained may be utilised by a member of the research team to obtain additional educational qualifications/a higher degree. Any information will be presented in such a way that participants cannot be identified.

1. **Publication**

Results of this study will be published in peer-review journals and presented at conferences. Patient confidentiality will be maintained and no identifiable details will be made public.

1. **Ethical considerations**

There will be no clear benefit to the participant by participating in this study. The study will allow us to gain a better understanding of the utility of providing patients with prompting documents in the outpatient department. So as not to alter the behaviour of the participants randomised to the standard group, they will not be aware of the existence of the prompt sheet.

**Risks**

**Patient participant:** There is a risk that privacy may be breached.

**Staff participant:** There is a risk that privacy may be breached.

**Risk mitigation**

All documents and recordings from this study will be kept in a locked area, accessible only to the research team, in the Department of Surgery, at The Queen Elizabeth Hospital. At the end of the storage period, all documents and recordings related to this study will be confidentially destroyed.

There are no conflicts of interest to declare.

1. **Attachments**

All Participant Information Sheets/Consent Forms, copies of all questionnaires, recruitment flyers or information brochures and any other documents relevant to the study must be submitted via email as separate attachments to the application.

The following documents are attached for review:

* PICF patient version 1.2, 30 September 2021
* PICF staff version 1.1, 23 September 2021
* Pre-consultation telephone script
* Post-consultation follow up telephone script
* CAHLN ethics and governance application form
* Question Prompting Document, version 1, 1 September 2021
* Data Analysis Plan, version 1, 30 September 2021

**References:**

1. Keinki C., Momberg A., Clauss K., et al Effect of question prompt lists for cancer patients on communication and mental health outcomes-A systematic review. Patient Educ. Couns. 2021;104(6):1335-1346. doi:10.1016/j.pec.2021.01.012

2. Brandes K., Linn A.J., Butow P.N., Van Weert J.C.M. The characteristics and effectiveness of question prompt list interventions in oncology: A systematic review of the literature. Psycho-Oncology 2015;24(3):245-252. doi:10.1002/pon.3637

3. Walczak A., Butow P., Davidson P., et al Discussing prognosis and end-of-life issues with patients in the final year of advanced cancer: A new question prompt list and a model of patient identified optimising factors. Psycho-Oncology 2011;20(SUPPL. 2):118-119. doi:10.1002/pon.2078