

1. **Title:** Evaluation Of A Personal Outpatient Worksheet And Educational Resource (POWER) Form in a ward setting – A single site, open label, randomised controlled trial
2. **Investigator details**

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1. **Introduction**

The surgical ward round is a chaotic environment but is often the only encounter that a patient has with their treating team. During this daily event clinicians review their patient, assess progress, and determine ongoing management. There are often external demands that impact the amount of time that the treating team can spend with the patient. As the ward round typically occurs first thing in the morning it is competing with emergency and elective operating lists, outpatient clinics, overnight handover, and other on call responsibilities. As a result, the quality of this interaction is vital to ensure that the highest standard of care can be achieved. We have successfully implemented a distraction free *Sterile Cockpit* to the ward round where interim results show promise in improving some aspects of healthcare delivery, however, patients are often confused or unclear about their medical issues.

Increasing patient participation in the clinical consult increases satisfaction, reduces anxiety, and improves clinical outcomes. This process of Shared Decision Making (SDM) promotes this and challenges the traditional authoritarian model of care. The ‘Doctor Knows Best’ approach results in clinicians being unapproachable and intimidating. SDM encourages patients to take ownership of their health and work collaboratively with the clinician to achieve their healthcare goals. This approach empowers patients and gives them greater knowledge and responsibility. Empowered informed patients are more likely to be compliant with treatment, happier with results, and have fewer unplanned admissions.

To address this we propose conducting a Randomised Controlled Trial (RCT) evaluating the impact of an intervention initially designed for the surgical outpatient department – the POWER form. The form is a 5 point prompt sheet/checklist (See appendix A) given to the patient prior to the ward round. It is designed to encourage patients to engage with their team and understand their clinical issues. This intervention will be compared with standard or usual care. Ward round encounters of participants will be audio visually recorded with a small camera. Patient’s will complete a survey after the encounter to assess their understanding, anxiety, and satisfaction and their responses will be compared to the dialogue from the video to evaluate their understanding.

The purpose of this study is to determine if a tool designed for outpatient use can improve patient engagement and understanding during the surgical ward round.

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, such as the POWER form, are inexpensive, simple to implement, and are perceived as more helpful than normal information sheets. These 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. In discussions about end of life and prognosis, prompting documents have been endorsed by doctors and patients.

Analysis of the utility of such documents in the surgical ward round is lacking. How the patient feels about the use of a prompting document during the consultation and whether or not this enhances feelings of empowerment, knowledge, understanding and autonomy within the shared decision-making process is unclear. This study aims to explore if the use of a prompting document can increase patient engagement, empowerment, understanding and information recall.

1. **Purpose**

**5.1 Aims:**

We aim to explore whether a patient prompting document can improve doctor-patient communication during a surgical ward round.

**5.2 Hypothesis**

We hypothesise that the POWER form will:

* Improve patient engagement during the surgical ward round
* Reduce patient anxiety
* Increase patient satisfaction
* Reduce patient length of stay

**Study design**

This will be a randomised controlled trial conducted by the Department of Surgery (UGI and colorectal) in the Surgical wards of The Queen Elizabeth Hospital. We anticipate commencing this project in September 2024 and completing data collection by December 2024.

* 1. **Participants**

**6.1.1 Patient Participants**

**6.1.1 Patient Participants**

Patients admitted to any Surgical Ward at The Queen Elizabeth Hospital. Any patient 18 years or older, who has the capacity to consent to participation, and has signed and understood the consent form.

**6.1.1.a Inclusion Criteria:**

* Patients admitted to a Surgical Ward at The Queen Elizabeth Hospital
* Patients over the age of 18

**6.1.1.b Exclusion criteria:**

* Declining to participate
* Patients held in isolation rooms such as those for multi-resistant organisms, confirmed or potential respiratory tract infections, COVID-19 or gastroenteritis
* Patients under the age of 18

**6.1.1.c Recruitment**

Clinicians caring for the patient will make the first approach to the patient. Only patients on the ward that are under the care of consenting doctors will be approached. This will be done by convenience sampling. Any patient admitted to a General Surgery Ward (Colorectal, Upper GI) at the Queen Elizabeth Hospital in any Surgical Ward are eligible for participation, if they are above the age of 18 and are not held in isolation rooms. Patients will be asked to fill out a brief survey at the cessation of the ward round encounter.

**6.1.1d Randomisation**

Once consent has been obtained by the patient a copy of the signed PICF will be given to the patient. At this time the patient will be randomly allocated to the intervention or the control cohort. Randomisation will be 1:1, stratified by sex, and designed using a digital random generator. Allocation concealment will be achieved using opaque envelopes prepared by investigators not involved in recruitment. This study was powered to 140 videos (70 randomised to control, 70 randomised to intervention), by a senior statistician. It is anticipated that data collection for this project will take approximately three months.

**6.1.2 Staff participants**

**6.1.2a Inclusion criteria**

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
  4. Surgical Registrar
  5. Surgical Resident
  6. Surgical Intern
  7. Surgical ward nurse

**6.1.2b Exclusion criteria**

* Declining to participate
* Patients without capacity to consent

**6.1.3 Other Participants**

Companions of patients will be eligible for inclusion if they are over the age of 18 and have the capacity to consent to participation and have signed and understood the consent form.

**6.2 Informed consent**

Clinicians caring for the patient will make the first approach to the patient in the afternoon before the following day’s ward round. They will explain the study and provide the patient with a Patient Informed Consent Form (PICF) for the patient to read. The following morning before the ward round commences, a research investigator will return to speak to the patient to ask them if they are happy to participate in the study and will collect their signed PICF.

**6.3 Methodology**

**6.3.1 Overview**

1) Recruitment of staff

2) Staff consent

3) Patient / companion consent

4) Ward round encounter is recorded

5) Endpoints on patient perception collected via survey

6) Ward round quality will be collected

The Intervention:

The POWER form is a five point checklist/question prompt sheet that contains the most pertinent information that patients should be aware of regarding their own healthcare. The five items are:

* What is my medical issue (or what do we suspect)?
* What are the treatment options (or further tests)?
* How does this impact my ability to work/eat/exercise?
* What are the risks/benefits of treatment (or what happens if I don’t have treatment)?
* Who is involved in my treatment and when will it occur?

All participants will be invited to attend an information session prior to the commencement of the trial. The purpose of this will be to familiarise staff with the intervention and give them an additional opportunity to ask any questions.

Location:

Audio-visual recording will take place at the Queen Elizabeth Hospital. The small Go Pro camera’s (Hero 10) used for both audio and visual recording in this study are owned by the Surgical Science Research Group, and stored in locked drawers in 6A, The Department of Surgery, The Queen Elizabeth Hospital. Setting up the small camera’s for this study will predominantly be conducted by the associate investigator Dr Matheesha Herath. Other associate investigators (Ellie Treloar, Emma Bradshaw, and Jesse Ey) will assist in setting up the recording equipment.

**6.3.2 Data collection:**

Audio-visual recordings:

The ward round occurs at the patient bedside each morning. Typically, the most senior doctor will lead the ward round, and the most junior doctor will scribe the important information discussed into the patient’s electronic case notes. In this study, each ward round encounter will be audio-visually recorded with a small camera. This camera will be placed on a shelf in the corner of the room encapsulating a wide view of the encounter. The video recording will start as the team enters the room and stop when they exit the room.

If a consented patient is sharing a room with another patient, a surgical blind will be drawn to shield the other patient from the video recording. In this circumstance, to mitigate the risk of recording irrelevant discussions from patients who have not consented to the study and to maintain confidentiality, the audio-visual recording device will be strategically placed on the other side of the room to keep the microphone away from the other patient whilst maintaining optimal video recording.

All videos will be transcribed verbatim and analysed by researchers to assess factors affecting ward round quality such as time taken, questions asked, talk time, and patient perception.

Patient Data Collection:

A patient survey will be given to patients at the end of their surgical ward round encounter. This survey aims to understand patients views on how their surgical ward round encounter was. Patients will be asked by a study investigator to complete the survey after the surgical team has left the room. Patients will be reminded that all answers to the survey will be kept confidential and will not in any way affect the level of care that they will receive at the hospital. Once the patient is finished with the survey, it will be placed in a sealed envelope and labelled with a de-identified number and collected by the research team. If patients do not wish to take part in the survey, they can place the unanswered slip in the envelope, and similarly it will be labelled with a de-identified number and collected by the research team. The de-identified survey will be stored in a locked cupboard in the 6A Department of Surgery until all data collection is finished.

Information relating to the patients admission, and demographic information from Sunrise EMR will also be collected by a member of the research team who is employed at CALHN (Dr Matheesha Herath).

REDCap will be used to collect all data.

**6.4 Analysis**

All audio-visual recordings of the ward round encounter will be reviewed by a member of the research team. This could involve any investigator listed in this application or a medical student from the University of Adelaide under the oversight of the Principal Investigator Professor Guy Maddern and in conjunction with Good Clinical Practice.

For obvious reasons, the content of the footage cannot be de-identified; however, the videos will be de-identified with a randomised number code to protect privacy of participants. This will be done by a research investigator on this protocol.

All videos will be transcribed verbatim and analysed by researchers to assess factors affecting ward round quality such as time taken, interruptions and distractions present, patient perception, length of stay and delayed discharge.

Deidentified data will be given to an experienced Biostatistician on a password-protected hard drive, to perform statistical analysis.

Roles of University students in this Project

Two university students (Ellie Treloar and Jesse Ey) currently enrolled in the Doctor of Philosophy (PhD) in Surgery program will be participating as associate investigators in this study. These two investigators will be involved in consenting patients after a member of the patient’s clinical team has approached them and explained the study. Both investigators will handle any patient data that has been collected from members of the patients treating team. This will occur in the Department of Surgery Office 6A, The Queen Elizabeth Hospital, and in conjunction with Good Clinical Practice.

Medical students from the University of Adelaide may help assist with the data analysis of de-identified results in the future. This will be under the oversight of the Principal Investigator Professor Guy Maddern in the Department of Surgery Office 6A, The Queen Elizabeth Hospital, and in conjunction with Good Clinical Practice.

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 documents containing personal information, including video and audio data obtained during the study will be de-identified and stored securely on a password protected shared departmental drive on the SA Health Network (Q Drive) by a research investigator (Ellie Treloar). This will involve assigning a de-identified number to each patient. A spreadsheet containing only the study ID, the de-identified codes, and one patient identifier will be created and kept in a separate password locked hard drive stored in level 6A Department of Surgery, at the Queen Elizabeth Hospital. A backup copy will be stored in a password-encrypted external hard drive owned by the department of Surgery (CALHN) kept in a locked drawer in the same office.

SA Health staff must comply with the State Records General Disposal Schedule No. 28 which mandates retention of records for a period of 15 years from the date of project completion, unless legislated otherwise. Study documents will be destroyed or deleted, as appropriate, at the expiration of this period by the Principal Investigator.

Data obtained will be available to the research investigators listed. Both identifiable and de-identified data will be accessible to investigators listed on this protocol, including the higher degree students Ellie Treloar and Jesse Ey. This is explained further in section 7.1 regarding roles of university students.

De-identified data may be utilised by a member of the research team listed as an investigator on this protocol Ellie Treloar, Jesse Ey) to obtain additional educational qualifications/a higher degree. It is anticipated that the results of this study (or data obtained from it) will be published and/or presented at medical forums. Any information will be presented in such a way that participants cannot be identified.

**7.1 Roles of University students in this Project**

Two university students Ellie Treloar, Jesse Ey) currently enrolled in the Doctor of Philosophy (PhD) in Surgery program will be participating as associate investigators in this study. Ellie Treloar and Jesse Ey’s primary supervisor is Professor Guy Maddern.

These investigators will be involved in consenting patients after a member of the patient’s clinical team has approached them and explained the study. Both investigators will handle any patient data that has been collected from members of the patients treating team. This will occur in the Department of Surgery Office 6A, The Queen Elizabeth Hospital, under the supervision of Professor Guy Maddern, and in conjunction with Good Clinical Practice.

Other non CALHN investigators (that are not listed as investigators on the protocol), or medical students from the University of Adelaide may assist with the data analysis in the future if the results are de-identified. Results will be de-identified by one of the investigators listed on this protocol. This will be under the oversight of the Principal Investigator Professor Guy Maddern in the Department of Surgery Office 6A, The Queen Elizabeth Hospital, and in conjunction with Good Clinical Practice.

1. **Protocol deviations and Serious Breaches**

If any protocol deviations occur where a procedure or task that is not detailed in the study protocol or Participant Information and Consent Form, they will be reported to the reviewing ethics committee as soon as practicable following the investigators becoming aware of the deviation.   
  
If a serious breach of Good Clinical Practice occurs, or if there is a deviation from the protocol that is likely to affect to a significant degree the safety or rights of a trial participant, or the reliability and robustness of the data generated in the clinical trial, it will be reported to the reviewing ethics committee as soon as practicable following the investigators becoming aware of the deviation.

The principal investigator will use continuous vigilance to identify and report any suspected breaches to the institution responsible for the study (the ‘sponsor’) within 72 hours of becoming aware of the event and report any serious breaches confirmed by the sponsor as occurring at the site to their institution (research governance office) within 72 hours of being notified of the serious breach. 

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**
   1. **Benefits of the Study**

**9.1.1 Participants**

There will be no clear benefit to the participants that choose to participate in this study.

* + 1. **Researchers**

De-identified data may be utilised by a member of the research team to obtain additional educational qualifications/a higher degree.

* + 1. **The local community**

Guidelines for best practice in the surgical ward round are essentially non-existent, are rarely featured in medical textbooks, and subsequently are mainly based on the preferences of practice from each unit’s senior team member. Findings from this study will allow us to gain a better understanding of methods to improve the surgical ward round process.

* 1. **Risks of the study**
     1. **Participants**

There is a risk that privacy may be breached.

* + 1. **Researchers**

Negligible risk.

* + 1. **The local Community**

Negligible risk.

* 1. **Risk Mitigation**

To mitigate this, all video recordings and documents obtained from this study will be kept in a password-protected computer in the Department of Surgery at The Queen Elizabeth Hospital. At the end of the storage period (15 years), all documents and recordings related to this study will be confidentially destroyed.

* 1. **Responsibility for liability of injury**

Not applicable

* 1. **Conflicts of interest**

The authors have no conflicts of interest to declare, this includes having no conflicting financial interests or commercial affiliations to disclose.

**9.6 Other ethical issues**

If unfavourable or disrespectful behaviour is observed by research staff in the audio-visual recordings, this will be managed through the clinical channels that would ordinarily be pursued in the circumstance of such an event, with the assistance and involvement of the Principal Investigators, to ensure patient and/or staff safety. This may include, but is not limited to, use of the SA Health Safety Learning System (SLS).

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, 14 July 2024
* PICF staff version 1.1, 03 June 2024
* CAHLN ethics and governance application form
* TQEH POWER form (2)
* Data Analysis Sheet, version 1 03 June 2024
* Survey of patient V1 03 June 2024

**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