Title

Improving Surgical patient Comprehension and communication Support with patient information cards: a pilot randomised control trial (IScomS)

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Background and Research Question

Surgical specialties by nature require early and succinct morning ward rounds to facilitate the operating lists, clinics, consulting and inpatient care required on a daily basis. As a general rule, ward rounds are complete within an hour. One study found that surgeons spend an average of 48 minutes on ward rounds per day; another in New Zealand showed an average of 2:57 minutes per patient bedside visit.[1] This small allotment of time is often inadequate for some patients to gain a full picture of their diagnosis and planned management, often part of a consenting process- so these patients are often reviewed later in the day by a team member to give the conversation more time. Multiple studies have found that a small minority of patients are given explanation about clinical details on the ward round.[2]

The question, "Why am I here/what's happening?" is heard too often. Patient-centred care is at the heart of the Medical Board of Australia code of conduct, defining good medical practice. If patients can take an active role in their care this allows for enhanced quality of life, adherence to medical plans and improved outcomes.[3-5] Numerous approaches have been trialled to address the needs of both the surgical team and the patient- to balance the requirement of more available communication to improve patient comprehension with a strictly limited period of time, often in the context of consenting for procedures but it remains a difficult balancing act. [6, 7]
Ward round quality has unsurprisingly been linked to the quality of patient outcomes[1, 8]; here we propose a study to see if a written information card can improve patient comprehension and therefore improve standards of patient-centred care and ward round functionality.

Aims and Objectives

Primary objective

To assess and improve the knowledge and comprehension of surgical patients regarding their care in John Hunter Hospital Urology department- including diagnosis, planned investigations, estimated discharge date and follow up plan.

Secondary aims

Ascertain if the addition of a patient information card can improve communication of routine clinical care, and based on feedback from this pilot study, look to establish supplementary sources of information that may be useful to patients, for example a local Urology service website with comprehensive information sheets and other relevant links or the use of a phone app with a similar purpose.

Study Design

Setting and Intervention

This is a proposed pilot randomised control trial. Admitted Urology patients to E2 would be randomised to one of two groups: one given routine clinical care and the second group given routine care with the addition of a patient information card on the first post-admission morning ward round.

Randomisation would be completed prior to the start of the morning ward round for new admissions, based on a pre-allocated randomised sequence which would be assigned to the included patients by the order of admission.

The patient information card could be updated by the team in collaboration with the patient on ward rounds or other clinical reviews throughout their admission.

All patients would be provided with a consent and survey (see proposed form attached) upon admission to the ward by the nursing staff, which the patient may fill out after the first ward round. A second survey would be provided by the nursing staff to those participating in the study just before discharge, and collected prior to leaving.

Eligibility

Inclusion

All patients aged 18 years and over who are admitted under the Urology team at the E2 ward at John Hunter Hospital until at least 100 patients are included in the study. Patients with non-English speaking background would have the documents translated into another language on a case-by case basis if that is the patient's preference, with otherwise routine clinical care (including translators). Patients who identify as Indigenous would be offered the assistance of an Indigenous liaison officer.

Exclusion

Patients that are not willing to contribute their information to the study will be excluded from participation. Furthermore, patients deemed to lack competency from a medical standpoint (including dementia, delirium and acute mental illness) and non-literate patients in order to standardise the assessment for this pilot study.

Data gathering

Prior to the commencement of the pilot study, a baseline assessment of ward round practice and communication would be completed, with data gathered over the course of a week. For each patient admitted during this time, the following information would be gathered by investigators:

- Minutes spent on day 1 post admission ward round per patient
- Ward round checklist completed for at least one day during inpatient stay, with the use of a template sticker in the patient notes (attached).

Relevant data will be obtained by the treating team members from the digital medical records of patients held at JHH by accessing the Clinical Applications Portal (CAP). Collected information will be entered into a REDCap database and will consist of the following items, as assessed by the medical record post-discharge for baseline demographics and comparison with patient reported outcome measures:

- Age (years)
- Sex
- Diagnosis
- Investigations completed during admission and indication
- Length of stay (days)
- Admitting consultant
- Follow up planned

Data collected by survey: Patient completion of the following (see attached proposed post-admission and upon discharge surveys) for patient reported outcome measures:

- Diagnosis
- Investigations planned/completed
- Treating consultant or registrar
- Follow up planned
- Understanding of medical diagnosis and care provided
- Satisfaction with care provided
- Opportunity for open feedback- with the option to instead submit an anonymous formal complaint or compliment form to the hospital associated with this if that is their preference.

Sample size

This study will be a pilot to assess feasibility, required sample size will be assessed further following initial analysis.

Recruitment

Adequate participant enrolment to reach target sample size is expected with routine admission procedures.

Allocation

Group allocation will be random with computer-generated sequences and assigned by an investigator on the clinical team to included patients in order of admission prior to their first post-admission ward round and intervention. The ID and computer-randomised group allocation will be created by an investigator not directly involved in clinical data collection (in data analysis alone), maintaining concealment. Allocations will be accessible through REDCap as each patient is admitted and included in the study by the treating investigators.

Blinding

Patients will be blinded to the exact intervention, although we will consider complete blinding not possible to achieve due to the nature of the intervention and in the hospital setting with shared hospital bays where patient communication is possible between groups as beds are allocated according to clinical need. The investigator assisting in randomisation/allocation, data analysis and management will be blinded to patient identities, while the investigators involved in data collection will not be blinded due to the nature of the intervention. Statisticians involved in data analysis will be blinded.

Data Handling and Record Keeping

A study database will be utilised to store study data via the HMRI REDCap system, which is a secure online system for research data hosted on the servers of HMRI. The websites are secured via Secure Socket Layer encryption (SSL (HTTPS) 256bit secure channels) and all environments are secured by individual user password access controlled.

Data will be made available to the Clinical Research Design and Statistics Support Service (CReDITTS) for statistical analysis, with all data supplied in a de-identified manner. All results will be presented and published in a grouped manner.

Data Analysis

Simple statistical tests including qualitative analysis will be conducted to test for significant differences between the two groups. Statistical analysis will be performed by the Clinical Research Support Unit at Hunter Medical Research Institute.

Data monitoring

Adverse outcomes are not anticipated due to the nature of the intervention, however if patients are distressed by the information card or data collection survey they are able to withdraw at any time.
Auditing trial conduct may be completed by a senior member of the treating investigators as required.

Ethics Compliance

This project will be conducted according to the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (54) in compliance with applicable laws and regulations. The project will be performed in accordance with the NHMRC Statement on Ethical Conduct in Research Involving Humans (© Commonwealth of Australia 2007 (and updated 2018) (55) and the principles laid down by the World Medical Association in 2008. The Investigators shall comply with the protocol.

Ethics approval will be sought from Hunter New England Human Research Ethics Committee, a NSW Health Lead HREC and registered with REGIS and the clinical trials registry. The study will be conducted in accordance with applicable Commonwealth and State Privacy Acts and Regulations.

Informed Consent

A consent form will be provided to each patient with their survey, and the opportunity provided to ask questions (please see attached form as an example).
Each admitted participant will be informed that involvement in the study is voluntary and that they may decline or withdraw their information from the study at any time without prejudice or without providing a reason. The Patient Information Sheet will clearly state a contact number and email should the participant wish to withdraw at a later time.

Protocol amendments

Any protocol or study design amendments prior will be communicated directly to all investigators and relevant parties (including trial participants, ethics committee and registry). Any protocol amendments will not be implemented until ethical approval is obtained.

Privacy and confidentiality

Each patient will be allocated a unique REDCap identifier to maintain privacy and confidentiality within the database.
A separate log of patients will be maintained by the Surgical Research team which will link patients' MRN with the unique REDCap identifier. This log will be maintained in the Surgical

Research file share maintained on a HNE computer, and only relevant research staff will have access to this log via username and password.

Declaration of interests

The investigators have no sources of funding, study sponsors or competing interests to declare.

Dissemination of Results

The data will be anonymised at the time of data entry and stored in HMRI REDCap system. After 24 months or at completion of publication the data with be electronically deleted. The Investigators shall have sole authorship of any publication/s resulting from this research. Results of this project may be presented and published in peer-reviewed scientific and or medical journals and conferences.

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