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Implementation of consensus-based perioperative care pathways to reduce clinical variation for elective surgery in an Australian private hospital: a mixed-methods pre–post study protocol

Lisa Pagano,[1] Cameron Hemmert ,[2] Andrew Hirschhorn,[3] Emilie Francis-Auton ,[1] Gaston Arnolda ,[1] Janet C Long ,[1] Jeffrey Braithwaite ,[1] Graham Gumley,[3] Peter D Hibbert ,[1,4] Kate Churruca ,[1] Karen Hutchinson,[1] Andrew Partington,[1,5] Cliff Hughes,[1,3] David Gillatt,[3] Louise A Ellis ,[1] Luke Testa,[1] Romika Patel,[1] Mitchell N Sarkies [1,2]

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For numbered affiliations see end of article.

Correspondence to
Dr Lisa Pagano;
lisa.pagano@mq.edu.au

ABSTRACT

Introduction Addressing clinical variation in elective surgery is challenging. A key issue is how to gain consensus between largely autonomous clinicians. Understanding how the consensus process works to develop and implement perioperative pathways and the impact of these pathways on reducing clinical variation can provide important insights into the effectiveness of the consensus process. The primary objective of this study is to understand the implementation of an organisationally supported, consensus approach to implement perioperative care pathways in a private healthcare facility and to determine its impact.

Methods A mixed-methods Effectiveness-Implementation Hybrid (type III) pre–post study will be conducted in one Australian private hospital. Five new consensus-based perioperative care pathways will be developed and implemented for specific patient cohorts: spinal surgery, radical prostatectomy, cardiac surgery, bariatric surgery and total hip and knee replacement. The individual components of these pathways will be confirmed as part of a consensus-building approach and will follow a four-stage implementation process using the Exploration, Preparation, Implementation and Sustainment framework. The process of implementation, as well as barriers and facilitators, will be evaluated through semistructured interviews and focus groups with key clinical and non-clinical staff, and participant observation. We anticipate completing 30 interviews and 15–20 meeting observations. Administrative and clinical end-points for at least 152 participants will be analysed to assess the effectiveness of the pathways.

Ethics and dissemination This study received ethical approval from Macquarie University Human Research Ethics Medical Sciences Committee (Reference No: 520221219542374). The findings of this study will be disseminated through peer-reviewed publications, conference presentations and reports for key stakeholders.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The pragmatic nature of the study will deliberately make use of existing practice structures and approaches to implement the consensus pathways and to obtain patient-related outcomes.
⇒ Multiple forms of qualitative data collection will be used to ensure rigour and a diverse range of perspectives will be gathered.
⇒ An understanding of the barriers and facilitators to adopting new standardised processes of care will be obtained which will provide a deeper understanding of the experiences of implementation at different time periods across multiple surgical cohorts.
⇒ Due to the pragmatic nature of the study, pre–post comparison of some clinical outcomes will be limited to a smaller sample size from one surgical cohort only.

INTRODUCTION

Addressing clinical variation is a fundamental component of health system improvement. While in some circumstances variation can be beneficial (eg, when it represents innovation, or responses to individual patient need or preference), variation in healthcare processes that are unrelated to patient needs or those that differ from evidence-informed guidelines can compromise patient care, create inefficiencies and contribute to health inequality.[1 2] This is a growing problem both in Australia and internationally, where on average, 60% of recommended care according to best practice guidelines is delivered to patients.[3–7] In addition, 30% of all care provided could be considered 'low value' or waste, and 10%

results in some form of iatrogenic harm.[1 4 5] For example, care processes and outcomes for certain surgical patient cohorts have been found to differ substantially between hospitals in both public and private sectors.[8] Data from Australia and the USA demonstrate a high degree of variation in length of stay (LOS), rates of transfer to inpatient rehabilitation following hip and knee arthroplasty,[9] and specific to private hospitals, higher unplanned stay (>2 hours) in recovery after surgery.[8] Considering the increasing number of elective surgeries and associated hospitalisations undertaken in private hospitals in Australia[10] and elsewhere,[11–13] reducing unwarranted clinical variation in these settings is critical to generating higher value care, improving patient outcomes, and reducing healthcare expenditure.

A number of studies have examined ways to reduce unwarranted clinical variation, such as through the implementation of evidence-based perioperative care pathways for surgical cohorts.[14–16] Enhanced recovery after surgery models are one such example involving the implementation of multimodal, evidence-based perioperative pathways designed to achieve early recovery and optimal patient outcomes.[17] However, despite many studies demonstrating the efficacy of some strategies in reducing variation, the optimal methods of developing and implementing such strategies into complex healthcare systems remain unclear. More evidence is needed on how best to implement and sustain these changes, as well as the barriers and facilitators to different methods of implementation to reduce unwarranted variation.

Evidence-informed perioperative care pathways designed to standardise the management of surgical patients to the best evidence-informed practice have been shown to reduce variation and improve patient outcomes.[18] Perioperative care refers to the care of patients before, during and after surgical procedures involving anaesthesia.[19] Care leading up to a surgical procedure involves the reduction of modifiable risks, often in a preoperative clinic, through patient education, medication optimisation and other prophylactic treatments. After surgery, the focus is on expediting recovery and minimising the risk of complications by optimising such things as pain relief, antibiotic regimens to reduce infection risks, anticoagulation protocols to avoid blood clotting and early mobility to return to normal function. Private hospitals in most countries have historically relied on accredited medical practitioners to individually develop their own perioperative care protocols using a combination of their experience, past practice and clinical practice guidelines.[20] Such protocols, when implemented as frontline care, can create variation in care delivery based on provider preferences.

Implementing changes to patient care is complex and challenging, requiring concerted efforts over time. This challenge is well documented and usually involves the provision of resources to support change efforts, shifting professional roles and altering cultural norms.[21 22] Rather than a 'one size fits all' approach, pathways need to be developed to suit the particular needs of the patient cohort and surgical discipline, as well as local resources available. However, there is no universal approach to implementing these pathways. In many private hospitals, medical practitioners tend to operate with a high degree of professional autonomy, which necessitates a consensus-building approach between providers for any standardisation of care processes.

Objectives

The primary objective of this study is to determine successful processes to implementing perioperative care pathways in a private hospital setting using an organisationally supported consensus approach for surgical cohorts, including (1) spinal surgery; (2) radical prostatectomy; (3) cardiac surgery; (4) bariatric surgery and (5) hip and knee replacement surgery. The secondary objective is to assess the impact on administrative and, where possible, clinical and patient-reported outcomes. We hypothesise that a consensus-based approach to care pathway development and implementation will lead to high levels of fidelity to best practice perioperative care processes and improve patient outcomes.

METHODS

Study design

This protocol follows the 'SPIRIT 2013 Statement: Defining standard protocol items for clinical trials' guidelines for reporting (see online supplemental file 1). A mixed-methods Effectiveness-Implementation Hybrid (type III) pre–post study will be used to evaluate the implementation of evidence and consensus-based perioperative pathways, prioritising assessment of effectiveness of the implementation strategies. While improving clinical outcomes is an important goal of any change process, standardisation of perioperative pathways has already been demonstrated to confer benefit to clinical outcomes.[14 23–26] As such, clinical outcomes will be considered secondary in this study. The perioperative care pathways will be implemented once consensus has been reached and outcomes will be compared with those observed before pathway development and integration into routine care, as a control period.

Study setting

The study will be conducted over a 2 year period from October 2022 to December 2024 at Macquarie University Hospital (MUH). MUH is located in Sydney, Australia and is a university-owned, private teaching hospital that focusses on clinical care, teaching and research. MUH comprises 144 beds, 16 operating theatres and is staffed by over 200 surgeons and other health professionals.

Eligibility criteria

Hospital staff and patients will be considered as study participants for the surgical cohorts: spinal surgery, radical prostatectomy, cardiac surgery, bariatric surgery and hip

and knee replacement surgery. Data from hospital staff participants will primarily be used to examine the implementation of perioperative care pathways. Administrative data and data from consenting prostatectomy patients will be used first, to conduct a process evaluation and second, to evaluate impacts on patient-related outcomes.

Hospital staff

Local hospital staff involved in the delivery of clinical care or development and implementation of care pathways (ie, both clinicians and non-clinical staff) will be considered eligible to participate in the implementation component of this study.

Patients

Those admitted during the relevant study periods, seeking care for any of the clinical cohorts of interest will be considered eligible for this study.

There are no specific exclusion criteria for this study.

Intervention

Development and implementation of the cohort-specific standardised perioperative pathways will follow a six-step process nested within four implementation stages using the Exploration, Preparation, Implementation and Sustainment (EPIS) framework.[27] The EPIS Framework guides projects through key stages of the implementation process and highlights important factors influencing implementation success within the broader 'outer context' (system) and the proximal 'inner context' (organisation) across each EPIS stage. The proposed implementation strategies are summarised in table 1. The general implementation strategies will be tailored to each new patient cohort utilising a consensus-building approach. Our implementation science approach will examine this consensus-building process to support successful implementation of the pathways.

Stage 1: exploration

The exploration stage will aim to understand the existing and emerging needs of both clinicians and patients, and to identify the optimal modifications and supports required for the implementation strategy to address those needs. This could include modifications to existing information technology processes or the introduction of organisational support and educational resources for staff members to implement the pathways. To achieve this objective, a care pathway implementation support team will be established comprising members of the research team and key hospital stakeholders. Stakeholders will include a coalition of both clinical partners, such as clinical education coordinators, and non-clinical partners, such as hospital administrators, to ensure that a wide breadth of expertise are included. The primary goal for the team will be to act as a vehicle for organisational leadership that builds capacity in clinical improvement and implementation science methodology. Individual roles within the team will be clarified across the project to reduce the risk of any duplicative efforts and improve the visibility of activities across different patient cohorts where pathways will be implemented. The team will meet monthly for the duration of the study to discuss goals and action items relating to the project to facilitate implementation of the perioperative pathways. For example, an important aim for the support team will be to reduce

Table 1 Overview of implementation strategies

Implementation stage	Implementation strategy	Description
Exploration	Build a coalition	Recruit and cultivate relationships with partners in the implementation effort by formally establishing a care pathway support team
Preparation	Conduct local consensus discussions	Establish a structure for local providers and other stakeholders to form cohort-specific clinical consensus groups to discuss the processes of care and standardisation of pathways
	Codevelop a formal implementation blueprint	Codevelop a formal blueprint for iterative care pathway prioritisation and implementation
Implementation	Develop and implement care pathway toolkits	Develop, test and introduce quality improvement tools and educational materials
	Audit and provide feedback	Embed a comprehensive system audit around care variation, clinical and process outcomes over specified time periods and disseminate to clinicians and administrators to monitor, evaluate and modify provider behaviour
Sustainment	Facilitate relay of clinical data to providers	Undertake formal monitoring and evaluation and develop a reporting structure and channels of communication for care pathway development, implementation and outcomes

the time-burden for clinicians during pathway implementation and to establish actions that will minimise potential time pressures.

Stage 2: preparation

The objective of the preparation stage is to use a consensus-building approach to develop and standardise perioperative care pathways for each surgical cohort, and to use learnings from the hip and knee replacement surgery cohorts retrospectively to facilitate successful implementation. During this stage, perioperative pathways will be drafted by a clinician–researcher in a hospital leadership position (AH) and senior management staff, based on a combination of 'current' surgeon clinical guidelines and evidence-based practice. Clinical consensus groups will then be established for each cohort by the clinician–researcher. These groups will include multidisciplinary representation such as surgeons, anaesthetists, nursing and allied health and will be led by the discipline heads. Clinical consensus groups will attend regular meetings facilitated by the clinician–researcher to discuss components of care to be included in the standardised perioperative pathways, including acceptable bounds of variation in practice. The pathways will optimise components of care differently across cohorts based on current evidence and joint medical decision making, including, but not limited to, preoperative optimisation, postoperative analgesia, surgical antibiotic prophylaxis, anticoagulation protocols and mobilisation after surgery. An 'informal' approach will be utilised to achieve consensus on the perioperative pathways where a set of predefined components will be discussed at each meeting and agreed on by group members using both evidence and their own perspectives to inform discussion.[28] Items will be documented by the facilitator and relevant documentation will be sent to each group member for further review as required following each meeting. Following this process, pathways will be circulated by each group member to their individual teams for feedback and critical modifications will then be made by the consensus groups at additional meetings which will facilitate implementation during the next two stages.

An additional goal of this phase will be to establish consensus from both the taskforce and clinical consensus groups on a plan to implement the pathways. A draft implementation plan will be created by the task force. This plan will be reviewed by the clinical consensus groups for modifications as required and each member will serve as 'champions' to drive implementation. Components of the implementation plan may include education and training sessions for nursing and allied health and establishing audit and feedback processes on the wards.

A separate stakeholder engagement group will be formed to represent the views of patient representatives, engage frontline clinical staff in implementation and facilitate rapid feedback regarding implementation challenges to the care pathway implementation support team. Researchers involved in qualitative data collection will observe this process through naturalistic observation however, they will not have a role in determining components of the pathways. During this stage, learnings obtained from implementation of pathways for the hip and knee replacement cohort will also be analysed by the research team to further understand the process of implementation using a consensus approach.

Stage 3: implementation

In the implementation stage, installation of the care pathways will be guided by the planned implementation supports formalised in the preparation phase. It will be critical to monitor the implementation process during this stage and adjust supports accordingly. Care pathway toolkits including education and documentation resources will be finalised and disseminated to clinical staff and patients at this stage to foster prompt widespread practice change. Further monitoring of the degree of engagement and cohesion between clinical leadership and frontline clinical staff will be achieved using participant observations. Particular attention will be paid to the capacity of frontline clinical staff to absorb and apply new care pathways, avoiding 'bottlenecks' between care pathway development and implementation. This stage will also be supported by an iterative audit and feedback process and data analytics to identify gains made and update external benchmarking comparisons over time. Audit and feedback will relate to process (implementation) outcomes, health services outputs and patient-level outcomes and this feedback will be communicated with staff at regular discipline meetings.

Stage 4: sustainment

The sustainment stage involves the continued application of the structures and processes of the care pathways to realise tangible improvements in patient outcomes. At this stage, care variation reduction becomes a standing item on regular Patient Safety and Quality Committee meeting agendas. 'Roadshow' presentations to the stakeholder engagement groups, frontline clinical staff and hospital leadership groups can continue bidirectional communication and feedback loops to identify new areas of care variance prioritised for future care pathways. We also plan to translate our findings via policy maker round tables and engagement and training with other private hospitals.

Recruitment

Semistructured interviews and focus groups with hospital staff

A purposive sample of staff who have been previously involved in the development of perioperative pathways or provision of care for the hip and knee replacement surgical cohorts, and staff currently involved in the development and implementation of the new pathways for the four new surgical cohorts will be recruited. Staff will be identified by MUH coinvestigators. Research staff not employed by MUH will approach the identified staff members either by email invitation or face-to-face to

Table 2 Summary of primary outcome measures

Acceptability	Provider knowledge and satisfaction with aspects of the perioperative pathways and their implementation will be collected via qualitative interviews and participant observation
Appropriateness	Appropriateness will be assessed both retrospectively based on the experiences piloting the intervention for the hip and knee replacement cohorts using qualitative interviews, as well as for the four prospective cohorts using participant observation
Feasibility	Feasibility will be measured both retrospectively using pilot data from the hip and knee replacement cohorts and prospectively for the four new cohorts of interest using interviews and participant observation
Adoption	Participant observations of the clinical consensus-building process will be used to measure the reasons pertaining to the intention, initial decision or action to integrate the perioperative care pathways into routine clinical practice
Fidelity and sustainment	Regular audits of adherence to the care pathways will provide an indication of variations to practice over time, including potential modifications and tailoring of the pathways by frontline staff (eg, nurses) to better fit within their work routines
Penetration	Penetration will be assessed by the number of eligible patients who receive the care pathway as intended according to planned audits

request their participation in the interviews, indicating that they have been identified by the research team as a key stakeholder in the development and implementation of the pathways. This approach is designed to avoid the potential impact of any existing relationships between hospital staff and coinvestigators. A brief explanation of the study and a written participant information form will be provided to the staff members. Staff members will be provided with time to review the information and ask any questions of the research staff prior to their decision to consent to participate in the interviews and focus groups, or not.

Participant observations with hospital staff

Staff attending relevant meetings will be recruited, such as planned support team project meetings, clinical consensus group meetings, stakeholder engagement group meetings, patient safety and quality committees and ward-based clinical meetings. Attendance of these meetings by external staff will be through invitation from hospital coinvestigators. Study information and a participant information form will be provided prior to the initial meeting where participant observations will take place.

OUTCOMES

Primary outcomes

A summary of the primary outcome measures for this study can be found in table 2. Implementation outcomes including acceptability, appropriateness, feasibility, adoption, fidelity and sustainment and penetration will be used to understand the impact of the implementation strategies and implementation using a consensus-building approach on secondary outcomes.[29]

Secondary outcomes

Secondary outcomes assessed will include both process outcomes and clinical outcomes:

- Hospital or intensive care unit LOS for each cohort collected from routine administrative data systems.
- Patient-reported experience measures (PREMs) collected via patient surveys.
- Patient-reported outcome measures (PROMs) collected via patient surveys for example, health-related quality of life questionnaires.
- Discharge destination collected from routine administrative data systems.
- Hospital-acquired complication rates collected from routine incident reporting systems.
- Hospital readmission rates collected from routine administrative data systems.

Selected PREMs and PROMs for the prostatectomy cohort are currently routinely collected at some site hospitals by specialist nurse practitioners and recorded in the patient's medical records. These include the Prostate Cancer Distress Screen,[30] the International Prostate Symptom Score,[31] Incontinence Questionnaire-Urinary Incontinence Short Form[32] and the Sexual Health Inventory for Men.[33] Research staff will assist with sending out surveys (see online supplemental file 2), prior to the routine 6 month follow-up assessment for up to 50–100 patients both before and after pathway implementation where patients consent, standardising an existing clinical interaction for comparison. Specific PROM and PREM measures for the remaining pathways will be determined during the consensus building process and if agreed, these measures will only be collected for research purposes where patients consent, prospectively.

Data collection

Qualitative interviews and focus groups

Semistructured one-on-one interviews or focus groups will be conducted over a 12 month period with key clinical and non-clinical hospital staff and patient/consumer representatives, focussing retrospectively on the pilot hip and knee replacement cohorts and prospectively

for each of the four new cohorts. Interview guides will be piloted prior to data collection and will include questions pertaining to participants knowledge and experiences of implementing the standardised perioperative pathways, as well as barriers and facilitators to this process (see online supplemental file 3 and online supplemental file 4 for planned interview guides). Interviews and focus groups will be conducted by one experienced qualitative researcher (LP) via videoconference or face-to-face at participants' preferred time and location, lasting between 30 and 60 min. The researcher will conduct all interviews in a private room suited to the interviewee, where interviews will be digitally recorded and transcribed verbatim. Field notes will also be made by the interviewer including initial thoughts, interpretations and analysis of the data collected. Audio and written data will be immediately saved in a password-protected file on an encrypted password protected computer.

Qualitative participant observation

Data collectors will conduct naturalistic participant observations within the planned support team project meetings, clinical consensus group meetings, stakeholder engagement group meetings, patient safety and quality committee and ward-based clinical meetings.[34] Each observation session is anticipated to last between 1 and 2 hours. Fieldnotes will be taken to spatially contextualise events within the study aims.[35] These observations will not be guided by a predetermined schedule, but rather, they will inductively evolve in real-world practice environments. This includes how staff converse with one another, how they plan and make decisions together about perioperative care (ie, implementation, communication pathways and leadership), and how decision-making processes evolve and take shape across different meetings with different stakeholders.

Quantitative clinical outcomes data

Data on clinical outcomes will be collected from administrative databases. These data include measures such as hospital LOS, discharge destination, acquired complications and readmission. Data from routine administrative databases have high levels of agreement with the medical record for both LOS (93%) and discharge destination (91%) data, but some limitations are acknowledged when capturing acquired complications.[36 37] Those data not routinely collected within existing administrative databases will be collected prospectively or via retrospective electronic medical review.

Sample size

Qualitative data pertaining to the implementation of the perioperative clinical pathways will use the concept of theoretical saturation to determine the observation and interview sample size.[38] Based on prior studies, we anticipate conducting 30 interviews and 15–20 meeting observations.[39 40] Staff will be recruited using convenience time-frame sampling which removes opportunistic recruitment of staff and patients, and any researcher or hospital selection bias.

For quantitative data, a power calculation was undertaken for each of the four cohorts based on the mean and SD of LOS for each site hospital in the 2020 and 2021 financial years, an estimated important reduction in LOS, two sided α=0.05 and 80% power. For spinal surgery, for example, reduction of mean LOS from 4.28 (SD 4.66) to 2.78 (the peer group average) required 152 patients preintervention and postintervention, which is achievable with 12 months' follow-up. Bariatric surgery, on the other hand, requires only 6 months. Overall, MUH LOS for cardiac surgery is in line with its peer group, so for this cohort, the target is intensive unit LOS, which is higher than that of peers. The cohorts requiring longer follow-up periods will be prioritised for earlier intervention where feasible. It is important to note that the research team does not view LOS as the most important clinical outcome for these four cohorts; it is used for sample size estimation because it is an administrative outcome where there is a prospect of measuring relevant quantitative change in the time available to the study. Moreover, relevant data on means and SD routinely available, permitting sample size calculation.

DATA ANALYSIS

Qualitative

Qualitative interview and observation analysis

Fieldnotes and interview transcripts will be imported into Nvivo V.20 for data management. Data will be analysed thematically[41 42] by two experienced qualitative analysts (primary and secondary) (LP and MS or EFA) working together to ensure that the process is rigorous, and to enable them to discuss the major and minor themes arising inductively and their concomitant categories until consensus agreement can be achieved. The secondary analyst will examine a subset of the complete data set, to ensure methodological veracity during the analytic process.

Quantitative

Quantitative analysis of clinical endpoints

Data will be analysed by three researchers (LP, GA and MNS) using SPSS. Descriptive statistics will be used to summarise demographic data. For LOS, historical data will be sourced from administrative databases to identify any secular trend and take this into account in attributing any pre–post change to intervention. For other clinical outcomes, PREMs and PROMs will be descriptive only and restricted to 50–100 patients from the prostatectomy cohort and any other cohort where these outcomes are available, while hospital acquired complications and hospital readmission rates will be compared preintervention and postintervention. The estimated between-group difference and the 95% CI will be reported and for significant testing, p<0.05 will be considered statistically significant.

Patient and public involvement

Input and feedback was obtained from the site hospital's Clinical Leadership Committee and the Clinical Disciplines on aspects of the study design, such as the planned implementation strategies and outcome measures. Patients were not involved in the design of this study, however, patient consumer input and feedback will be sought from the site hospital's consumer advisory committee where resources for patients are developed.

Ethics and dissemination

Approval to conduct this study has been obtained from the Macquarie University Human Research Ethics Medical Sciences Committee (Reference No: 520221219542374). Research governance authorisation has been provided by the MQ Health Clinical Research Executive. A waiver for consent will be sought from participants for data obtained in this study. PROMs/PREMs data being collected for clinical purposes will seek informed patient consent for deidentified data to be used for research purposes. The findings of this study will be disseminated through peer-reviewed publications, conference presentations, and summaries or reports for key stakeholders and partners in the field.

Author affiliations
[1]Australian Institute of Health Innovation, Faculty of Medicine, Health and Human Sciences, Macquarie University, Sydney, New South Wales, Australia
[2]School of Health Sciences, Faculty of Medicine and Health, University of Sydney, Sydney, New South Wales, Australia
[3]MQ Health, Faculty of Medicine, Health and Human Sciences, Macquarie University, Sydney, New South Wales, Australia
[4]IIMPACT in Health, Allied Health and Human Performance, University of South Australia, Adelaide, South Australia, Australia
[5]Flinders Health and Medical Research Institute, Flinders University, Adelaide, South Australia, Australia

Twitter Janet C Long @JanetCLong and Louise A Ellis @LouiseAEllis

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ORCID iDs
Cameron Hemmert http://orcid.org/0000-0003-3824-9138
Emilie Francis-Auton http://orcid.org/0000-0001-9632-2298
Gaston Arnolda http://orcid.org/0000-0003-4948-7633
Janet C Long http://orcid.org/0000-0002-0553-682X
Jeffrey Braithwaite http://orcid.org/0000-0003-0296-4957
Peter D Hibbert http://orcid.org/0000-0001-7865-343X
Kate Churruca http://orcid.org/0000-0002-9923-3116
Louise A Ellis http://orcid.org/0000-0001-6902-4578
Mitchell N Sarkies http://orcid.org/0000-0001-7318-3598

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page No.
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Ethics protocol
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	23
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6-7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-17
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	16-17
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17-18
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	17-18
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15-17
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16-18
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Ethics protocol
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	22
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	22
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13, 22
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	22

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Ethics protocol
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Ethics protocol
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Ethics protocol
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Reference: Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207.

MQ Health
MACQUARIE UNIVERSITY
HEALTH SCIENCES CENTRE

PROSTATE CANCER DISTRESS SCREEN

The experience of prostate cancer is for many men a difficult time. I would like to ask you a few brief questions to check how you have been feeling and ask about your main concerns. Thinking about how you have been feeling over the past week including today, how distressed do you feel on a scale of '0', no distress to '10', extreme distress? (circle)

0 1 2 3 4 5 6 7 8 9 10

No distress Extreme distress

This is a list of problems that some men with prostate cancer experience. Do any of these problems apply to you? (Read the list below, tick if yes)

Practical Problems
- Work ☐
- Financial/Insurance ☐

Family Problems
- Partner ☐

Emotional Problems
- Depression ☐
- Uncertainty about the future ☐
- Nervousness ☐
- Sadness ☐
- Worry ☐
- Loss of interest in usual activities ☐

Treatment Problems
- Understanding treatments ☐
- Making a decision ☐
- Information about my illness ☐

Physical Problems
- Pain ☐
- Fatigue ☐
- Sexual ☐
- Urinary ☐
- Bowel ☐
- Hot Flushes ☐
- Weight Gain ☐
- Weight Loss ☐
- Loss of Muscle Mass ☐
- Memory/Concentration ☐
- Sleep ☐

Other Problems (please list)

_____

_____

_____

Which of these are the **most important concerns** for you right now? (Please list)

_____

Which of these concerns would you like help with?

_____

For men with a rating of ≥4 consider further assessment and referral to appropriate support services.

Person completing form: **Date:**___ /___ /___

MQ HEALTH PHYSIOTHERAPY
Macquarie University Clinic
Suite 307, Level 3, 2 Technology Place
Macquarie University NSW 2109

T: +61 2 9812 3850
F: +61 2 9812 3851

E: physiotherapy@mqhealth.org.au
mqhealth.org.au/clinics/physiotherapy

ABN 56 606 405 270

MQ Health
MACQUARIE UNIVERSITY
HEALTH SCIENCES CENTRE

ICIQ-UI-SF: CONFIDENTIAL

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1. How often do you leak urine? (Tick one box)

never ☐
about once a week or less often ☐
two or three times a week ☐
about once a day ☐
several times a day ☐
all the time ☐

2. We would like to know how much urine <u>you think</u> leaks. How much urine do you usually leak (whether you wear protection or not)? *(Tick one box)*

none ☐
a small amount ☐
a moderate amount ☐
a large amount ☐

3. Overall how much does leaking urine interfere with your everyday life?
Please circle a number between 0 (not at all) and 10 (a great deal)

0	1	2	3	4	5	6	7	8	9	**10**
not at all										a great deal

4. When does urine leak? (Please tick all that apply to you)

never – urine does not leak ☐
leaks before you can get to the toilet ☐
leaks when you cough or sneeze ☐
leaks when you are asleep ☐
leaks when you are physically active/exercising ☐
leaks when you have finished urinating and are dressed ☐
leaks for no obvious reason ☐
leaks all the time ☐

Thank you very much for answering these questions.

MQ Health
MACQUARIE UNIVERSITY
HEALTH SCIENCES CENTRE

International Prostate Symptom Score (IPSS)

Patient Name: **Date of Birth:** **Age:** **Today's Date:**

Determine Your BPH Symptoms **Circle your answers and add up your scores at the bottom.**

Over the past month	Not at all	Less than one time in five	Less than half the time	About half the time	More than half the time	Almost always
Incomplete emptying- How often have you had the sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
Frequency- How often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
Intermittency- How often you have found you stopped and started again several times when you urinated?	0	1	2	3	4	5
Urgency- How often have you found it difficult to postpone urination?	0	1	2	3	4	5
Weak stream- How often have you had a weak urinary stream?	0	1	2	3	4	5
Straining- How often have you had to push or strain to begin urination?	0	1	2	3	4	5
Sleeping- How many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	None 0	One Time 1	Two Times 2	Three Times 3	Four Times 4	Five or More Times 5
Add Symptom Scores:	+	+	+	+	+	

Total International Prostate Symptom Score= ___

1-7 mild symptoms - 8-19 moderate symptoms - 20-35 severe symptoms

Regardless of the score, if your symptoms are bothersome you should notify your doctor.

Quality of Life (QoL)	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatis-	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6

MQ Health
MACQUARIE UNIVERSITY
HEALTH SCIENCES CENTRE

Sexual Health Inventory for Men (SHIM)

Instructions

Each question has five possible responses. Circle the number that best describes your own situation. Select only one answer for each question.

Over the last six months:

1. How do you rate your confidence that you could keep an erection?

1	2	3	4	5
Very low	Low	Moderate	High	Very high

2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)?

1	2	3	4	5
Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (more than half the time)	Almost always or always

3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

1	2	3	4	5
Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (more than half the time)	Almost always or always

4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

1	2	3	4	5
Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult

5. When you attempted sexual intercourse, how often was it satisfactory for you?

1	2	3	4	5
Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (more than half the time)	Almost always or always

SUPPLEMENTARY FILE 3

Topic Guide: Staff interviews

Title	Implementation of evidence and consensus-based perioperative care pathways
Principal Investigator	Dr Mitchell Sarkies, Senior Research Fellow and NHMRC Emerging Leadership Fellow, Australian Institute of Health Innovation, Macquarie University mitchell.sarkies@mq.edu.au
Co-investigators	A/Prof Andrew Hirschhorn, Prof Jeffrey Braithwaite, Dr Gaston Arnolda, Dr Emilie Francis-Auton, Dr Janet Long, Ms Lisa Pagano

The semi-structured interviews will be conducted retrospectively for key clinical and non-clinical hospital staff who were previously involved in the development of perioperative pathways for the elective hip and knee replacement surgical cohorts; and prospectively for staff currently involved in the development and implementation of new pathways. The aims of the interview are to:

- Determine the experiences of staff involved in implementing standardised peri-operative pathways.
- Explore the stakeholder knowledge of the care pathways within the hospital setting.
- Assess the integrity, fidelity to and feasibility of the intervention.
- To understand the key barriers and facilitators to implementation of standardised peri-operative pathways from the perspective of both clinical and non-clinical hospital staff.
- To synthesize data from both patient groups to gain a broader understanding of how standardised care pathways are implemented and the impact of these pathways.

QUESTIONS:

Thank you for taking part in this interview to examine the implementation of standardised peri-operative surgical pathways at Macquarie University Hospital. The questions will focus on your experiences, familiarity with the pathway, perspective on whether they're being adhered to, and any barriers or facilitators to their implementation.
Participation in this interview is voluntary and if at any time you do not wish to continue, please let me know. Participation or refusal to participate will not affect your employment. With your permission, this interview will be audio recorded so that it can be transcribed and analysed. Do you have any questions before we start?

1. Demographic questions:

- Can you please introduce yourself and your role at Macquarie University Hospital?
- How long have you worked in healthcare?
- How many of those have been at Macquarie University Hospital?

2. What was your experience/what has been your experience implementing the [SURGICAL COHORT] peri-operative pathway/s?

3. How familiar are you with the particulars of the clinical pathway/s? Can you talk through some of the changes from previous practice?
    - What worked?
    - What didn't work

4. What are your views on the standardised clinical pathways that were implemented/are being implemented?

- Strengths
- Weaknesses

5. Did you and other clinicians tend to follow the new processes/procedures?
    - Why do think that is?

6. What challenges, if any, did you encounter in implementing the clinical pathways?

Prompts;

- Workload and time
- Staffing
- Personal preference/views
- Inter-professional collaboration
- Other

7. What was important to facilitating the implementation of the clinical pathways?

Prompts;

- Organisation
- Resources
- Staffing/Inter-professional collaboration
- Support/Monitoring of fidelity/quality

- Other

8. Were there any other lessons learned about implementing standardised clinical pathways?

Additional probing question:

9. What are your suggestions to improve future implementation of standardised clinical pathways for [SURGICAL COHORT] surgery?

10. What do you see as the effects and value of implementing standardised clinical pathways for [SURGICAL COHORT] surgery?

11. Overall, how feasible is/was it to implement standardised clinical pathways for [SURGICAL COHORT] surgery at Macquarie University Hospital or private hospital settings more generally?

12. Is there anything else you would like to add that has not been covered here?

SUPPLEMENTARY FILE 4

Topic Guide: Surgeons

Title	Implementation of evidence and consensus-based perioperative care pathways
Principal Investigator	Dr Mitchell Sarkies, Senior Research Fellow and NHMRC Emerging Leadership Fellow, Australian Institute of Health Innovation, Macquarie University mitchell.sarkies@mq.edu.au
Co-investigators	A/Prof Andrew Hirschhorn, Prof Jeffrey Braithwaite, Dr Gaston Arnolda, Dr Emilie Francis-Auton, Dr Janet Long, Ms Lisa Pagano

The semi-structured interviews will be conducted retrospectively for key clinical and non-clinical hospital staff who were previously involved in the development of perioperative pathways for the elective hip and knee replacement surgical cohorts; and prospectively for staff currently involved in the development and implementation of new pathways. The aims of the interview are to:

- Determine the experiences of staff involved in implementing standardised peri-operative pathways.
- Explore the stakeholder knowledge of the care pathways within the hospital setting.
- Assess the integrity, fidelity to and feasibility of the intervention.
- To understand the key barriers and facilitators to implementation of standardised peri-operative pathways from the perspective of both clinical and non-clinical hospital staff.
- To synthesize data from both patient groups to gain a broader understanding of how standardised care pathways are implemented and the impact of these pathways.

QUESTIONS:

1. Demographic questions:

- Can you please introduce yourself and your role at Macquarie University Hospital?
- How long have you worked in healthcare?
- How many of those have been at Macquarie University Hospital?

- *Can ask further about elements of their role as needed*

2. What was your experience/what has been your experience implementing the [SURGICAL COHORT] peri-operative pathway/s?

3. How familiar are you with the particulars of the clinical pathway/s? Can you talk through some of the changes from previous practice?
    - What worked?
    - What didn't work?

4. What are your views on the standardised clinical pathways that were implemented/are being implemented?
    - Strengths
    - Weaknesses

5. What are your perceptions of why MQ health was looking to standardise pathways? Alternate question - What do you think about the organisation's approach to try to reduce clinical variation through standardising clinical pathways?

Prompt – do you see clinical variation as being an issue?

6. Option 1: What challenges, if any, did you encounter in implementing the clinical pathways?

   Option 2: What challenges do you think clinicians would face when attempting to implement consensus-based clinical pathways?

Prompts;

- Workload and time

- Staffing
- Personal preference/views/autonomy
- Inter-professional collaboration
- Other

7. Option 1: What was important to facilitating the implementation of the clinical pathways?

Prompts;

- Organisation
- Resources
- Staffing/Inter-professional collaboration
- Support/Monitoring of fidelity/quality
- Other

8. What do you see as the effects and value of implementing standardised clinical pathways for [SURGICAL COHORT] surgery?

9. How would you measure the success of a clinical pathway of the [SURGICAL] clinical cohort?

10. Overall, how feasible is/was it to implement standardised clinical pathways for [SURGICAL COHORT] surgery at Macquarie University Hospital or private hospital settings more generally?

11. Is there anything else you would like to add that has not been covered here?