The PACT Study: A time series study investigating the feasibility and acceptability of an integrated, patient-centred model for psychosocial assessment, care and treatment of patients with urological and head and neck cancers.

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Complete List of Authors:	Girgis, Afaf; The University of New South Wales, Translational Cancer Research Unit, Ingham Institute for Applied Medical Research Kelly, Brian; The University of Newcastle, Priority Research Centre for Translational Neuroscience and Mental Health, School of Medicine and Public Health; Hunter New England Local Health District, Consultation Liaison Psychiatry Service, John Hunter Hospital Boyes, Allison; The University of Newcastle, Priority Research Centre for Health Behaviour & Hunter Medical Research Institute Haas, Marion; University of Technology Sydney, Centre for Health Economics Research & Evaluation Viney, Rosalie; University of Technology Sydney, Centre for Health Economics Research & Evaluation Descallar, Joseph; The University of New South Wales, Ingham Institute for Applied Medical Research, South Western Sydney Clinical School Candler, Hayley; The University of New South Wales, Translational Cancer Research Unit, Ingham Institute for Applied Medical Research Bellamy, Douglas; Hunter New England Local Health District, Hunter New England Cancer Network Directorate Proietto, Anthony; Hunter New England Local Health District, Hunter New England Cancer Services
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The PACT Study: A time series study investigating the feasibility and acceptability of an integrated, patient-centred model for psychosocial assessment, care and treatment of patients with urological and head and neck cancers

Professor Afaf Girgis, PhD (corresponding author)
Translational Cancer Research Unit, Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales
Liverpool NSW 2170 Australia
afaf.girgis@unsw.edu.au

Professor Brian Kelly, PhD
Priority Research Centre for Translational Neuroscience and Mental Health
School of Medicine and Public Health, The University of Newcastle
Callaghan NSW 2308 Australia
Consultation Liaison Psychiatry Service
Hunter New England Local Health District
John Hunter Hospital (JHH), Lookout Road
New Lambton NSW 2305 Australia
brian.kelly@newcastle.edu.au

Dr Allison Boyes, PhD
Priority Research Centre for Health Behaviour & Hunter Medical Research Institute
The University of Newcastle, Callaghan NSW 2308 Australia
allison.boyes@newcastle.edu.au

Professor Marion Haas
Centre for Health Economics Research & Evaluation
University of Technology Sydney, Ultimo NSW 2007 Australia
marion.haas@chere.uts.edu.au

Professor Rosalie Viney
Centre for Health Economics Research & Evaluation
University of Technology Sydney, Ultimo NSW 2007 Australia
rosalie.viney@chere.uts.edu.au

Dr Joseph Descallar
Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales, Liverpool NSW 2170 Australia
joseph.descallar@sswahs.nsw.gov.au

Ms Hayley Candler
Translational Cancer Research Unit, Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales
Calvary Mater Newcastle, Edith Street
Waratah NSW 2298 Australia

hayley.candler@unsw.edu.au

Mr Douglas Bellamy
Hunter New England Cancer Network Directorate
Hunter New England Local Health District
JHH, Lookout Road
New Lambton NSW 2305 Australia
douglas.bellamy@hnehealth.nsw.gov.au

Associate Professor Anthony Proietto
Hunter New England Cancer Services
Hunter New England Local Health District
JHH, Lookout Road
New Lambton NSW 2305 Australia
anthony.proietto@hnehealth.nsw.gov.au

The PACT Study team also includes Catherine Adams, Debbie O'Brien, Gai Shylan, Ben Britton, Sandy Grant, Vicky Parker, Chris Wratten, Deanna Sue.

Contact Information
Professor Afaf Girgis, Translational Cancer Research Unit, Ingham Institute for Applied Medical Research, South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales
Liverpool Hospital, Locked Bag 7103, LIVERPOOL BC NSW 1871
T: +61 (4) 12 142 841
F: +61 (2) 9602 3221
E: afaf.girgis@unsw.edu.au

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ABSTRACT

Introduction: Whilst there is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve distress experienced by people affected by cancer, much of this psychosocial morbidity is undetected and untreated, with consequent exacerbated suffering, decreased satisfaction with care, impaired adherence to treatment regimens and poorer morbidity and mortality outcomes. The objective of this study is to develop, implement and assess the feasibility, acceptability and cost of an integrated, patient-centred Psychosocial Assessment, Care and Treatment (PACT) model of care for patients with urological and head and neck cancers.

Methods and analysis: A time series research design will be used to test the feasibility, acceptability and cost of the PACT model of care, newly introduced in an Australian tertiary hospital. The primary outcome is system-level change, assessed through audit of patients' medical records and Medicare claims for follow-up care. The secondary outcomes are acceptability of the model to patients and health care professionals (HCPs) and impact on the knowledge and confidence of HCPs, assessed via patient and HCP surveys at baseline and at follow-up and HCP interviews at follow-up. The intervention cost (tertiary outcome) will be assessed from Medicare and Pharmaceutical Benefits Scheme claims information and information logged pertaining to intervention activities (eg time spent by the newly appointed psycho-oncology staff in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg salaries, training materials, videoconferencing).

Ethics and dissemination: Ethics approval was obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of NSW. Results will be widely disseminated to the funding body and through peer-reviewed publications, HCP and consumer publications, oncology conferences and meetings.

Trial registration: The study is registered with the Australian New Zealand Clinical Trials Registry with registration number ACTRN12613000916741.

STRENGTHS AND LIMITATIONS

Strengths of the study:

- It has been developed specifically to address existing gaps in psychosocial care, and proposes a model of care which will be integrated, high quality, evidence-based, embedded in routine practice, and responsive to individual patients' needs.
- It promotes an active role for frontline staff, as well as improved coordination and continuity of care; particularly for patients in rural and remote areas.
- The lack of research attention on patients with urological or H&N cancers, despite their burden on the Australian community, is addressed.
- The translational capacity of the program is enhanced through the support of a very strong collaborative team, a strong methodology for health services research (including cost analyses, which are often overlooked in interventional research), and strong support for the integration of psychosocial care into routine care. Importantly, this work has substantial potential for translation into other cancer services, beyond the current study.

Limitations of the study:

- The target population is vulnerable and experiencing an acute stressor that may impact on recruitment.
- As the intervention will continue over a twenty-four month period, changes in health professional staff over that time may be substantial. Consequently, some of the health professionals who complete a survey at twenty-four months may be only minimally exposed to the intervention and have diluted perceptions of impact.
- Other health initiatives may be introduced into hospitals in the study area, which could affect the impact of this intervention.

Emotional distress, pain and fatigue are commonly experienced by the majority of cancer patients, while other issues are unique to specific cancer types. Individuals diagnosed with urological cancers (bladder, kidney, prostate, testicles, penis) typically experience urinary and bowel dysfunction, and sexual problems.[1] Those diagnosed with head and neck (H&N) cancers (mouth, jaw, throat, larynx, salivary glands, skin of head and neck including melanoma, thyroid) often experience profound disfigurement and functional disability, changed body image, speech difficulties, nutritional problems, and have higher suicide rates than other people with cancer.[2] Both urological and H&N cancer patients often report negative changes in their intimate and social relationships.[1, 3] Some cancers, including urological and H&N cancers, are more prevalent in rural areas,[4] where people experience major difficulties accessing cancer services, including psychosocial care.[5] There is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve the distress experienced by cancer patients.[6] Nevertheless it is well established that much psychosocial morbidity experienced by cancer patients is undetected and untreated.[7] Failure to address these problems can exacerbate suffering and lead to decreased patient satisfaction with care, impaired adherence to treatment regimens, and poorer morbidity and mortality outcomes.[8]

Recent cancer patient satisfaction surveys in Australia, the United Kingdom and Canada have highlighted problems in coordination of services and limitations in psychosocial care.[9-11] Skills, confidence and beliefs of clinical staff regarding psychosocial aspects of care are important contributing factors.[12] Many health care professionals are not aware of effective evidence-based strategies to address patients' concerns, or underestimate the benefits of attending to psychosocial needs or referring to psychosocial personnel or services. There are few formalised mechanisms for communication between health care providers and systems of care may contribute to patients receiving fragmented and poorly coordinated care;

especially those who reside in rural areas.[8] With well supported stepped care models, the needs of the majority of cancer patients can be met without referral to specialist psychosocial services.[13] Models of care that provide basic psychosocial care delivered by frontline health care providers (eg oncology nurses), with appropriate training and mentorship by psycho-oncology specialists, have demonstrated efficacy and cost effectiveness in terms of the increase in quality-adjusted life-years achieved.[14]

The Institute of Medicine [8] has recommended a model for integrated psychosocial cancer care that comprises: 1) identifying patients' health needs through screening and assessment; 2) linking patients to health services via structured referral, case management and clinical integration of services; 3) supporting patients in illness self-management; 4) coordinating psychosocial and biomedical health care through care coordinators, multidisciplinary team meetings, multidisciplinary care plans and electronic health records; and 5) following up on care delivery by telephone calls or web-based technology to re-evaluate and adjust the patient's care plan.[8] Achieving such a model of care in most specialist oncology services and evaluating its effectiveness represent major challenges.[15-16] These challenges are accentuated in settings where cancer care is integrated into general medical or surgical care, with the absence of dedicated on-site cancer teams. This means that staff may not identify themselves as cancer clinicians and service models are generic to cater for a diverse range of illness groups. Nevertheless this represents the setting in which a significant proportion of cancer patients experience at least part of their treatment. Within this type of care delivery setting, how can effective models of integrated psycho-oncology care be developed, implemented and evaluated? This is one of the key questions this project aims to investigate.

The Hunter New England Local Health District of New South Wales, Australia, includes three tertiary referral hospitals and a total of over 2500 hospital beds servicing a

major metropolitan centre and several large regional centres, as well as many smaller rural centres and remote communities. This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000 inpatient separations per year for cancer related conditions.[17]

The current model of cancer care at the John Hunter Hospital (JHH), the site for this study, includes investigation, diagnosis, surgery and follow-up surveillance. Patients needing radiation or chemotherapy are referred to a nearby specialist cancer service and generally return to the JHH or a regional hospital facility for follow-up and monitoring. In 2012, 124 urology and 69 H&N patients received inpatient cancer care at the JHH. The JHH urology service comprises five senior urologists and four dedicated outpatient nursing staff, and the H&N unit comprises four senior surgeons, one dedicated outpatient nurse and four ward-based nurses. Each inpatient unit comprises 20 nursing staff caring for patients with a range of cancer and non-cancer conditions. For both tumour groups, multidisciplinary team meetings provide a forum to discuss individuals with complex cancers.

Screening for psychosocial needs is not routine and when it is conducted (using pen-and-paper Distress Thermometer and Problem Checklist),[18] the Cancer Care Coordinator discusses the issues with the patient and referrals may be made to allied health care professionals or other agencies, albeit not based on a specific care pathway. Although each unit is supported by dedicated allied health clinicians, the JHH has no dedicated psycho-oncology services; patients requiring psycho-oncology assessment are either referred to generic Liaison Psychiatry, which provides a limited role including advice, inpatient consultation and a restricted level of outpatient assessment, or to the Psycho-oncology service at the nearby cancer hospital, which is a separate service with no shared records and located at a different site to patients' routine outpatient care at the JHH.

Objective

The objective of this study is to develop, implement and assess the feasibility, acceptability and cost of, an integrated, patient-centred model for psychosocial assessment, care and treatment of patients with urological and H&N cancers.

Study Design

A time series research design will be used to test the feasibility and acceptability of the Psychosocial Assessment, Care and Treatment (PACT) model of care (detailed below). While the RCT is often used as the gold standard for assessing the effectiveness of health interventions, it is not always practical in health services research. A time series design will be used, as it is regarded as the strongest quasi-experimental design for evaluating longitudinal effects of interventions [19] and is an acceptable design for inclusion in Cochrane reviews.[20] Time series designs attempt to detect whether an intervention has an effect significantly greater than the underlying secular trend,[20] and are useful in quality improvement research for evaluating the effects of interventions when it is difficult to randomise patients. The study will focus on system-level outcomes as being of primary interest. We will monitor the process, outcomes and costs of establishing the specialised psycho-oncology service, including the development of evidence-based management protocols and referral pathways specifying defined roles for different health professionals within the cancer care setting.

METHODS

Study Setting

The setting for this study is John Hunter Hospital (JHH)/Royal Newcastle Centre; the largest tertiary referral teaching hospital in the Hunter New England Local Health District of

NSW, Australia. It provides the main services for a large sector of the state of NSW, comprising a population of over 850,000 people. It is the main teaching hospital of the University of Newcastle.

Eligibility criteria

Patients

Inclusion criteria are: a) aged 18 years or over, b) diagnosed with a urological cancer or a H&N cancer, and c) receiving inpatient and/or outpatient care at JHH.

Staff

Staff who are employed through the JHH will be eligible to complete the Knowledge and Confidence Survey if they: a) are a nursing or allied health staff member, and b) provide care for patients who are receiving inpatient or outpatient urological or H&N cancer services at this site. Staff will be eligible to participate in interviews to assess the acceptability of the PACT care model if they meet the following inclusion criteria: they a) are a medical, nursing or allied health staff member, b) provide care for patients who are receiving inpatient or outpatient urological or H&N cancer services, and c) have been involved in the PACT care pathway of one or more patients, either on-site at JHH, or through provision of follow-up care, following discharge from JHH.

Intervention

The PACT (**P**sychosocial **A**ssessment, **C**are and **T**reatment) model, targeting patients with H&N or urological cancers, will be developed as part of this study. This model aims to systematise the approach to screening for distress and responding to that distress in a coordinated manner, including facilitating continuity of care for patients who reside some

distance from the acute care setting where they were treated for cancer. The development of this care model includes the following key components:

1) The implementation for inpatients and outpatients of the two surgical units of routine screening for distress, and associated psychosocial care plans.
2) The identification of intervention options for all levels of need, and pathways to specialist psycho-oncology care if required.
3) The addition of dedicated psycho-oncology clinical services (including psychologist, psychiatrist and mental health nurse).
4) The provision of staff development and support to implement such a model (including training in skilled communication to identify and respond to emotional distress), and structured case review for complex or challenging cases. The latter strategies will incorporate oncology clinical staff and others working with cancer patients within urban, regional and remote communities.
5) Videoconferencing to facilitate case review meetings between clinicians at urban and rural sites.

In order to achieve these intervention goals, the following are intrinsic to the service model:

a) A dedicated Clinical Nurse Consultant (CNC), with experience in psycho-oncology and adult education, will coordinate the establishment and delivery of the model, with a special focus on development and implementation of a systematic and structured approach to routine assessment, triage and management of cancer patients' individual physical, psychological and social concerns during active treatment and at follow-up.

b) The CNC, a newly appointed Clinical Psychologist, and two of the investigators with experience in communication skills training (AG, BK) will develop and deliver a communication skills-based training program to support frontline clinical staff (mostly

nursing and allied health care professionals) in implementing the psycho-oncology care model and facilitating within-team communication to enhance continuity of patient care. This training program will be run on numerous occasions to reach as many frontline staff as possible during the intervention period.

c) The CNC and Clinical Psychologist will facilitate the delivery of the care model through the training of frontline staff, provision of clinical assessment and specialised evidence-based care for patients who are referred to the psycho-oncology service, monitoring of progress on psychosocial care plans including with rural clinicians through case reviews, and providing advice as required to rural clinicians to support linking patients to local rural specialised services. Where specialised services are not available, the Clinical Psychologist will collaborate with the local clinician (eg rural clinical nurse) to provide outreach specialist assessment by videoconference. The lead psychiatrist (BK) will provide clinical oversight of the program, participate in staff training, and direct clinical evaluation and treatment of patients with the highest level of distress or complexity.

Clinical practice guidelines recommend routine distress screening of cancer patients (with feedback to health care providers) at periods of increased vulnerability to ensure that those at risk are identified promptly and offered appropriate treatment.[18] As part of the newly developed model of care, all inpatient and outpatient urology and H&N cancer patients will be screened at their first diagnostic or treatment visit and at each subsequent follow-up visit, using the Distress Thermometer (DT) and accompanying Problem Checklist,[13] which will inform the development of a care plan to address the issues identified through the screening and second-line inquiry. The care plan will facilitate provision of care tailored to the specific needs of patients and promote continuity of care across care settings and providers, including with health care professionals (HCPs) in the rural and regional areas.

The screening and problem checklist will act as a trigger for frontline staff to inquire about, and discuss the cause/s of, distress with patients whose distress levels are above the recommended cut-off of 4 or more out of 10.[21] Training for frontline staff will focus on discussing the cause/s of the distress, developing an evidence-based psychosocial care plan to address identified concerns, providing information and/or basic counselling, or referring patients with significant or persistent distress to the psycho-oncology service, and facilitating continuity of care, including linking patients with hospital and community services as required. Long-term sustainability of these service changes will be promoted through organisational leadership and management support, engagement of cancer clinician leaders in each unit in the design and evaluation of the service model, and development of a model with the aim of adaptability and flexibility to diversity of locations and patient complexity (eg through complex case review and revision of psychosocial care plans and active involvement of clinicians from rural locations in this process).[22]

Outcomes

The primary outcome is a system-wide increase in the proportion of eligible patients receiving care at the study facility who complete a DT and accompanying Problem Checklist (see Data Collection Methods) on at least one occasion and have a psychosocial care plan developed which complies with recommended care pathways. This outcome will be assessed at baseline, then at 12 and 24 months post-baseline (ie following the establishment of the new model of care – refer to Intervention section).

The secondary outcome is an increase in the proportion of eligible patients receiving care at the study facility who report positive experiences of their cancer care at 12 and 24 months post-baseline compared to patients receiving care in this facility at baseline.

The tertiary outcome is an increase in the proportion of health professionals providing care to the eligible patient population at the study facility who report high levels of knowledge and confidence in responding to patients' psychosocial concerns at 24 months post-baseline compared to the health professionals caring for the eligible patient population at baseline.

The resource use and costs of the intervention will also be monitored, by maintaining comprehensive logs of intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and ascribing the associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Table 1: Study design and data collection timeline

Time period	**Intervention delivery**	**Data collection**
0 months		Recruitment of baseline Health Care Professional sample Completion of Health Professional Knowledge and Confidence Survey
	Development and delivery of communication skills training to health professionals	Recruitment of Patient Cross-sectional Sample #1 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients
12 months	PACT intervention delivery On-going monitoring of costs of the intervention (time spent in direct patient contact, on staff training, inter-professional case reviews and other communications required to support rural and regional providers)	Recruitment of Patient Cross-sectional Sample #2 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients
24 months		Recruitment of Patient Cross-sectional Sample #3

		Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients
		Recruitment of post-intervention HCP sample Completion of Health Professional Knowledge and Confidence Survey
		Recruitment and interviews with purposively sampled HCPs regarding acceptability of the PACT intervention
		Retrospective review of Medicare and Pharmaceutical Benefits Scheme (PBS) claims data for use and costs of medical services and pharmaceuticals for the three cross-sectional patient samples (Department of Human Services data extraction)
		Review of hospital's databases Assessment of set-up and on-going costs associated with the PACT intervention

Recruitment

Patients

Three cross-sectional samples of patients will be recruited, at baseline, 12 months and 24 months, to complete a Patient Experience Survey (of their cancer care) and provide consent for access to their hospital and other medical records. Patients will be recruited from inpatient wards and the outpatient clinics associated with the JHH. During the study audit periods at baseline, 12 months and 24 months, the Research Officer (RO) will contact staff of the outpatient clinics and inpatient wards in which care is provided for urological and H&N cancers, on a weekly basis, to identify whether patients meeting the inclusion criteria will be attending those clinics or wards that week. The RO will attend those clinics and/or wards at which potential participants will be present, briefly introduce those patients to the study, answer questions, and provide interested persons with an Information Pack. The Information Pack will contain an Information Letter, a Consent Form for data to be obtained from Hunter New England Local Health District (HNELHD), a Consent Form for data to be obtained from the Department of Human Services, a Request for Summary of Study Results Form, a copy of

the self-administered Patient Experience Survey and a Paperwork Return Checklist. Patients will be asked to take the Information Pack home to consider before completing the survey and consent forms and posting them back to the researchers, using a self-addressed reply paid envelope, within 10 days. Staff at the outpatient clinics and inpatient wards will also be supplied with Information Packs to distribute to eligible patients who attend the clinic when the RO is not in attendance.

Staff

Health Professional Knowledge and Confidence Survey

Two cross-sectional samples of HCPs involved in the care of patients with H&N or urological cancers at the study facility will be recruited during the study audit periods at baseline and at 24 months, to assess the skills development of clinical staff who work at the parent facility. At each time point, the RO will contact the Managers of the inpatient wards and outpatient clinics in which care is provided to patients with urological and H&N cancers. The Managers will be asked to identify the nursing and allied health staff members who routinely provide care to the patients of their respective wards/clinics, as well as each staff member's employment status as either permanent or casual. A list of HCPs eligible to receive an Information Pack will then be generated, and Information Packs sent via internal mail to the department at which each staff member is based. The Information Pack will contain an Information Letter and a copy of the self-administered Knowledge and Confidence Survey for HCPs to complete and post back to the researchers, using a self-addressed reply paid envelope, within 10 days. A second survey will be mailed to HCPs who do not return a completed survey within four to six weeks and a third survey will be sent to non-returnees four to six weeks after that.

Health Professional receptivity and acceptability interviews

At approximately 24 months (nearing study completion), purposively sampled allied health, nursing and medical staff will be interviewed by the RO about the acceptability of the key aspects of the PACT integrated model of psychosocial care (including screening, triage, access to psychosocial services/providers, clinical case reviews), perceived effectiveness of the model at improving care, and perceived impact of the staff training. The RO will send an Information Pack to those staff members who meet the inclusion criteria. The Information Pack will contain an Information Letter, Consent Form and Request for Interview Transcript Form. Consenting staff will participate in a 20-minute telephone interview at a mutually convenient time.

Data collection methods

The primary outcome of system-level change will be assessed through audit of patient medical records, and through Medicare and PBS claims information for follow-up care sought via referral through the new model of care; the secondary outcomes of acceptability of the model and impact on HCP knowledge and confidence will be assessed via patient and HCP surveys and HCP interviews; and the tertiary outcome of cost of the intervention will be assessed from information collected through Medicare and PBS claims information, as well as information logged pertaining to intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Medical records audit and Medicare and Pharmaceutical Benefits Scheme (PBS) claims information

At baseline, 12 months and 24 months, the files of all patients who provide their consent will be reviewed by the RO and an appointed research assistant who is not involved in the intervention delivery, to calculate the proportions of patients a) who have completed a DT and accompanying Problem Checklist at least once, b) who have had a psychosocial care plan developed, and c) whose management, including referrals, complies with recommended care pathways. A checklist will be used to achieve a systematic approach to extraction of these records. The coders (RO and a second research assistant) will initially review one file with the Clinical Psychologist to ensure consistency in understanding of the checklist and 10% of the files will be double-coded by the two coders to calculate inter-rater reliability.

Medicare and PBS claims information will also be extracted by the Department of Human Services for those participants who provide their consent, and will be reviewed by the health economist investigators (MH and RV) to extract information relating to psychosocial care delivered in a hospital or community health setting, by a private provider, or by a general practitioner.

Patient Experience Survey

A 35-item survey will include items assessing patient perceptions of care received, relating to the dimensions of emotional support, information, education and coordination of care. All items are phrased from the first-person perspective (eg *"I had confidence and trust in the staff treating me"*), to be answered using a 5-point Likert-type scale ranging from 1 = 'strongly disagree' to 5 = 'strongly agree'. A patient experience score will be aggregated based on the sum of selected responses.

The survey will also measure key *socio-demographic, disease and medical variables*, including age, residential location, gender, marital status, indigenous identification, languages spoken, country of birth, educational attainment, employment status, private health coverage, income, cancer type, date of diagnosis, treatment received, recurrence status, and number of prior inpatient admissions and outpatient clinic visits.

Health Professional Knowledge and Confidence Survey

A 65-item survey will include items targeting health professionals' knowledge, skills and confidence pertaining to responding to patients' specific psychosocial concerns. The survey contains 12 items from a *Confidence in Communication Skills and Discussing Prognosis and End-of-Life Issues* module used by Clayton, Butow, Waters et al.[23] The survey also contains a case study and associated Care Planning, Monitoring and Review items from the Client-Centred Care – Training Needs Survey;[24] all adapted such that they refer to a patient with urological cancer and explicitly address psychosocial care. A Clinician Belief Scale is contained in the survey; based on the Physician Belief Scale,[25] it contains all 32 items of the Physician Belief Scale, but has been renamed to apply to a broader group of health professionals than doctors, and items will be answered on a 5-point Likert-type scale ranging from 1= 'strongly disagree' to 5= 'strongly agree'. Finally, the survey contains the single-item Clinician Burnout survey, which is the Physician Burnout survey,[26] renamed to apply to a broader group of health professionals than doctors. A knowledge/confidence score will be aggregated based on the sum of selected responses.

The survey will also measure key *socio-demographic, experience and training variables*, including age, residential location, gender, occupational specialty, number of years of experience in a) their current specialty and b) in cancer care, number of hours spent

weekly in direct patient contact, indigenous identification, languages spoken, country of birth, and country of training.

Health Professional receptivity and acceptability interview

An interview will be scheduled with consenting participants to assess the acceptability of the key aspects of the integrated model of psychosocial care (including screening, triage, access to psychosocial services/providers and clinical case reviews), perceived effectiveness of the model in improving care, and the perceived impact of training. It is anticipated that the interview will take 20 minutes, with an audio recording being made for transcription purposes. Examples of questions in the interview guide include: “Have you been aware of there being a more systematic approach to the provision of psychosocial care for people with H&N or urological cancers over the past year or so compared to previously?” and “What’s your impression of patient/family member/caregiver attitudes toward the new model (eg acceptance)?”

Intervention costs

In keeping with the time series design, information about resource use and associated costs will be obtained at baseline, 12 and 24 month time points. Information will be obtained from the hospital’s databases regarding emergency department (ED) attendance, triage category, whether the patient was admitted or discharged from the ED, and their diagnosis. Information about use and costs of medical services and pharmaceuticals will be obtained from Medicare and PBS claims data. Specific set-up and on-going costs associated with staff training, inter-professional case reviews and other communications required to support rural and regional providers, will also be monitored.

Sample size

Patients

Data from twenty-five patient surveys were used to estimate the sample size. The mean patient experience score at baseline was 45 (out of a possible 55). Hence, at least 38 patients will need to be recruited at each time point to achieve a minimum clinically significant improvement of 5 points between baseline and last follow-up (24 months), assuming a standard deviation of 7.58 (derived from current surveys), significance level of 5%, and power of 80%.

Health care professionals

Data from twenty-eight surveys were used to estimate the sample size. The mean score of knowledge/confidence was 61.5 (out of a possible 105). Hence, at least 48 health professionals will need to be recruited at each time point to achieve a minimum clinically significant improvement of 10 points between baseline and follow-up (24 months), assuming a standard deviation of 17.13 (derived from current surveys), significance level of 5%, and power of 80%.

Data management

Data which are collected in paper format (i.e. patient consent forms, surveys and requests for study results, and health care professional surveys, requests for study results and interview transcripts) will be stored in a locked cabinet, accessible only by the RO. Data which are collected in computer file format (i.e. data obtained through the Department of Human Services and Hunter New England Local Health District, and interview audio and transcript files) will remain in computer file format. In addition, computer files will be created for the entry and storage of participant details and survey responses. All of this

electronically stored data will be maintained in separate, password-protected files, which will be stored on a password-protected local area network drive, accessible only by the RO and the chief investigators. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the RO and the chief investigators.

Data in paper format will be stored for seven years, while computer files will be stored for 15 years. All will be shredded by a contracted security waste disposal company at the conclusion of the storage period.

Statistical methods

Analysis of primary and secondary outcomes

In keeping with a focus on evaluating the feasibility of implementing a new service, it is essential to proceed in stages, with initial evaluation of a new model being devoted to performance monitoring and process studies, before moving on to studies that document impact.[27] Therefore, this evaluation will focus on the feasibility and acceptability of the new model of care, with system-level outcomes being of primary interest. Data will be collected at baseline, 12 months and 24 months on the proportion of patients a) who are screened for distress at least once, b) who have a psychosocial care plan developed, and c) whose management complied with recommended care pathways.

Data on points a) to c) above will be collected at the three time points and analysed using Poisson or Negative Binomial regression depending on over-dispersion of the counts of each outcome. The Poisson/Negative binomial models will include a time variable (0, 12 and 24 months), a before and after variable, a term for the interaction of these two variables, and an offset variable which is used to adjust for the total number of patients consented at each time point. The interaction term will be used to estimate any difference between the two

periods, which would indicate a slow improvement in the outcome during the intervention period. The before and after variable will be used to estimate the change in the outcome that may occur immediately after the introduction of the model of care. The models will adjust as appropriate for potential confounding variables such as age, gender, residential location, indigenous status, cancer type, and time since diagnosis.

Patient Experience and Health Professional Knowledge and Confidence

For patient experience surveys, a linear regression will be used to model the patient experience scores over the three time points to determine whether there was a significant improvement during the study period whilst adjusting for potential confounding variables (eg duration of care within the service, other psychosocial support services used, disease and treatment characteristics, age, and gender). Similarly, for the health professional knowledge and confidence surveys, a linear regression be used to determine if there was a difference in the knowledge/confidence scores between the two time points whilst adjusting for potential confounding variables (eg other training in psychosocial care received, duration of employment in this service, prior experience, work role and time allocation, age, and gender).

Economic analysis

Estimates of resource use and costs will take into account the costs of implementation of the new model, but will not include costs of the evaluation/audit. At each time point (baseline, 12 months and 24 months), mean estimates of costs will be used and confidence intervals will be generated by boot-strapping the data. Benefits will be measured via surveys and interviews to ascertain the acceptability of the intervention and how the new model is experienced, as well as changes in clinicians' knowledge and confidence. Costs and outcomes will be reported separately at each time point and trends over time will be evaluated.

Qualitative analysis of HCP interviews

HCP interviews will be audio-recorded, transcribed verbatim, and analysed qualitatively. Inductive thematic analysis will be used to identify, analyse and report themes (or patterns) in the data (MapInfo Professional Version 8, MapInfo Corporation). Transcripts will be initially read and any words, statements, and/or paragraphs related to HCPs' views on the PACT intervention will be extracted by assigning a label or code. Similar excerpts will be identified by using the same code, with clustering of the codes denoting themes in the data. Data analysis will focus on a detailed description of emerging themes, with a focus on identifying the positive and negative aspects of the PACT model and strategies to support its ongoing implementation in the care facility.

DISCUSSION

This research program specifically addresses the objective of improving quality of care of patients with cancer and has been developed to address existing gaps in psychosocial care. The proposed program will provide a mechanism for delivering integrated, high quality, evidence-based cancer care that is embedded in routine practice, and responsive to the needs of individual cancer patients by (1) systematically identifying patients' physical and psychosocial health needs, (2) developing care pathways and plans to address identified needs, (3) linking patients to skilled HCPs and appropriate services, and (4) coordinating on-going psychosocial health care. The project has a focus on translating evidence regarding psychosocial care into an integrated model that promotes the role of 'frontline' clinical staff, including those in rural settings, and will promote improved coordination and continuity of care for patients in rural and remote areas. Improving the psychosocial component of routine care, building distress screening into a model of routine care, and developing a psychosocial care plan for patients will enhance the acceptability and appropriateness of psychosocial care.

Specialist services will be active in providing training, advice and support within an inter-professional team, and providing specialist assessment and treatment as a member of this team when needed. Addressing the process and outcome variables will support investigation of the quality of care provided from patient and clinician perspectives.

The proposed care model has the potential to address several unmet needs identified in key policy documents and surveys. Specifically, it will provide improved emotional support and information for both cancer inpatients and outpatients,[9] expand psycho-oncology services to improve access to specialised care,[17] and provide timely individualised support to the level and detail required for patients.[28] In addition, this research program directly addresses the priority issue of delivering quality cancer care that addresses patients' physical and psychosocial health needs [6, 8] by bringing together the scientific evidence about the management of cancer patients' psychosocial problems into a model of patient-centred cancer care. Furthermore, it focuses on patients with urological or H&N cancers given their lack of research attention compared to their burden on the Australian community.[29]

The translational capacity of this research program is enhanced through three major strengths. First, it is supported by a very strong collaborative team. Enhancing the role of 'frontline' clinical staff, defining pathways of care and promoting integration between major centres and rural clinicians entails a high level of support from clinical staff for objective implementation and evaluation. This project has strong support from the highest level of cancer service governance in our area, senior nursing clinicians and existing on-site psychiatric services. The linkage of the PACT model to Area-level network of psycho-oncology services will promote integration of psychosocial care into routine clinical care, promote continuity of care, and, through its clinician training model, improve the overall quality of care for patients and their families.

Second, the study utilises strong methodology appropriate for health services research. The evaluation framework and methodology ensures that the evaluation is sensitive to the role of general clinical staff, appropriate to the setting, relevant to stakeholders, inclusive and informative. Cost analyses will be undertaken to facilitate comparisons of costs and outcomes and changes in these over time; an important consideration as economics is an often overlooked element of interventional research. The close engagement of clinicians in the planning, implementation and evaluation will ensure maximum relevance of the project to the local context of clinical practice, including rural and remote settings. The built-in capacity for flexibility in the clinical setting (eg documenting and addressing local barriers to integration of psychosocial care) will promote translation to routine care, and potential applicability to other settings.[27]

Third, there is strong support for integration of psychosocial care into routine care, and efficient use of specialist services. This project will provide important evidence for the effective use of existing resources for nurses and allied health professionals working in routine cancer care. If the outcomes of the research are positive, this will provide the basis for a model of implementing psycho-oncology services across other clinical services within this network. While the project includes the use of routine screening, it does so in a manner that builds this into a model of care, so that these tools can support clinical practice within a model of integrated care, defined service pathways and support to distant sites. The work has substantial potential for translation into other cancer services beyond the research collaborators.

Despite the strengths, there are also several challenges for the research and evaluation. The target population is vulnerable and experiencing an acute stressor that may impact on recruitment. As the intervention will continue over a twenty-four month period, changes in health professional staff over that time may be substantial. Hence, some of the health

professionals completing the survey at twenty-four months may have been minimally exposed to the intervention, hence potentially diluting perceptions of impact. Finally, health initiatives introduced more broadly into hospitals in the study location may affect the impact of this intervention, but are beyond the control of the research team.

ETHICS AND DISSEMINATION

Ethics approval

Research ethics approval has been obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of New South Wales. Minor adverse events (eg a participant being tearful and distressed when talking with the RO) will be logged and fed back to the study team by the end of the study. Serious adverse events (eg expressing suicidal thoughts) will be reported immediately to the chief investigators and to the ethics committees. Any protocol amendments will be submitted to the ethics committees before these are implemented, and relevant changes will also be communicated to other relevant organisations (eg trial registry).

Confidentiality

The names of potential patient and health care professional participants will be entered into the study's password-protected administrative database, accessible only by the RO. Upon receipt of completed surveys and/or consent forms from participants, a study ID will be assigned to each participant, and recorded with identifying information only in the study's password-protected administrative database. Thereafter, survey, consent form and request for results data will be linked to participants only via the allocated study ID. There is no foreseeable reason for personal or identifying participant information to be shared throughout the conduct of the trial, except where required for adverse event reporting.

All of the electronically stored personal participant information will be maintained and destroyed in the same manner as all data collected throughout the study. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the RO. These will be stored for fifteen years, then shredded by a contracted security waste disposal company at the conclusion of the storage period.

Competing interests

As a Consultant Psychiatrist for the Consultation Liaison Psychiatry Service of John Hunter Hospital and a chief investigator on this project, BK may experience competing interests with respect to reporting the feasibility, cost and acceptability of the new psychosocial care model. These potentially competing interests will be minimised and managed by having the other chief investigator, AG, primarily responsible for the conduct of the research and result reporting.

Access to data

The study's chief investigators (AG, BK), RO, Biostatistician, and Health Economists will have exclusive access to the final trial dataset.

Dissemination policy

The results will be widely disseminated through peer-reviewed publications as well as relevant health care professional and consumer publications. Oncology health care professionals and administrators within Hunter New England Local Health District will be invited to a face-to-face presentation of the results by the chief investigators. Presentations will be delivered at relevant national oncology and nursing conferences and meetings. The

results will be reported to the funding body and other peak bodies with influence on cancer policy and practice, including Cancer Australia, Clinical Oncology Society of Australia, Cancer Council Australia, and Cancer Voices Australia. In addition, all research participants who request a summary of the study's key findings will be mailed one on completion of the project.

AUTHORS' CONTRIBUTIONS

BK and AG conceived of the study and are the grant holders. AB assisted in the initial study design and AP and DB provided organisational guidance on service model and implementation. BK and AG, along with the newly appointed clinical staff, developed the communication skills training, and HC will oversee the day-to-day study implementation according to the protocol. MH and RV provided guidance on data requirements for the economic analysis and will undertake these analyses. JD provided guidance on sample size requirements and will be conducting the primary statistical analyses. All authors contributed to refinement of the study protocol and approved the final manuscript.

ACKNOWLEDGEMENTS

The study detailed in this protocol is endorsed by the Psycho-oncology Co-operative Research Group (PoCoG), The University of Sydney, Australia. The study protocol and relevant documents have been reviewed by the PoCoG Scientific Advisory Committee and the Joint Community Advisory Group. Debbie O'Brien and Gai Shylan will play a central role in facilitating recruitment and implementation of the intervention, and Catherine Adams and Deanna Sue in the communication skills training of health professionals involved in the delivery of the PACT model of care.

FUNDING

This work is funded by the Cancer Institute New South Wales (NSW), grant number 10/THS/2-08. This body had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

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

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	☑
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	☑
	2b	All items from the World Health Organization Trial Registration Data Set	☑
Protocol version	3	Date and version identifier	☑
Funding	4	Sources and types of financial, material, and other support	☑
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	☑
	5b	Name and contact information for the trial sponsor	☑
	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	☑
	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)	☑
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	☑
	6b	Explanation for choice of comparators	N/A

Objectives	7	Specific objectives or hypotheses	☑
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)	☑
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	☑
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)	☑
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	☑
	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)	N/A
	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	☑
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)	☑ Table 1

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	☑
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	☑
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	☑

	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	☑
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	☑
	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	☑
	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	☑
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	☑
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	☑
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)	☑
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	☑
	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	☑
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	☑
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	☑
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	N/A
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	☑
	31b	Authorship eligibility guidelines and any intended use of professional writers	☑
	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	☑

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

The PACT Study Protocol: A time series study investigating the impact, acceptability and cost of an integrated model for psychosocial screening, care and treatment of patients with urological and head and neck cancers.

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The PACT Study Protocol: A time series study investigating the impact, acceptability and cost of an integrated model for psychosocial screening, care and treatment of patients with urological and head and neck cancers

Professor Afaf Girgis, PhD (corresponding author)
Translational Cancer Research Unit, Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales
Liverpool NSW 2170 Australia
afaf.girgis@unsw.edu.au

Professor Brian Kelly, PhD
Priority Research Centre for Translational Neuroscience and Mental Health
School of Medicine and Public Health, The University of Newcastle
Callaghan NSW 2308 Australia
Consultation Liaison Psychiatry Service
Hunter New England Local Health District
John Hunter Hospital (JHH), Lookout Road
New Lambton NSW 2305 Australia
brian.kelly@newcastle.edu.au

Dr Allison Boyes, PhD
Priority Research Centre for Health Behaviour & Hunter Medical Research Institute
The University of Newcastle, Callaghan NSW 2308 Australia
allison.boyes@newcastle.edu.au

Professor Marion Haas
Centre for Health Economics Research & Evaluation
University of Technology Sydney, Ultimo NSW 2007 Australia
marion.haas@chere.uts.edu.au

Professor Rosalie Viney
Centre for Health Economics Research & Evaluation
University of Technology Sydney, Ultimo NSW 2007 Australia
rosalie.viney@chere.uts.edu.au

Dr Joseph Descallar
Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales, Liverpool NSW 2170 Australia
joseph.descallar@sswahs.nsw.gov.au

Ms Hayley Candler
Translational Cancer Research Unit, Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales
Calvary Mater Newcastle, Edith Street
Waratah NSW 2298 Australia

hayley.candler@unsw.edu.au

Mr Douglas Bellamy
Hunter New England Cancer Network Directorate
Hunter New England Local Health District
JHH, Lookout Road
New Lambton NSW 2305 Australia
douglas.bellamy@hnehealth.nsw.gov.au

Associate Professor Anthony Proietto
Hunter New England Cancer Services
Hunter New England Local Health District
JHH, Lookout Road
New Lambton NSW 2305 Australia
anthony.proietto@hnehealth.nsw.gov.au

The PACT Study team also includes Catherine Adams, Debbie O'Brien, Gai Shylan, Ben Britton, Sandy Grant, Vicky Parker, Chris Wratten, Deanna Sue.

Contact Information
Professor Afaf Girgis, Translational Cancer Research Unit, Ingham Institute for Applied Medical Research, South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales
Liverpool Hospital, Locked Bag 7103, LIVERPOOL BC NSW 1871
T: +61 (4) 12 142 841
F: +61 (2) 9602 3221
E: afaf.girgis@unsw.edu.au

Keywords: Stress, Psychological; Psychotherapy; Intervention Studies; Urologic Neoplasms; Head and Neck Neoplasms.

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ABSTRACT

Introduction: Whilst there is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve distress experienced by people affected by cancer, much of this psychosocial morbidity is undetected and untreated, with consequent exacerbated suffering, decreased satisfaction with care, impaired adherence to treatment regimens and poorer morbidity and mortality outcomes. The objective of this study is to develop, implement and assess the impact, acceptability and cost of an integrated, patient-centred Psychosocial Assessment, Care and Treatment (PACT) model of care for patients with urological and head and neck cancers.

Methods and analysis: A time series research design will be used to test the PACT model of care, newly introduced in an Australian tertiary hospital. The primary outcome is system-level impact, assessed through audit of patients' medical records and Medicare claims for follow-up care. The secondary outcomes are impact of the model on patient experience and health care professionals' (HCPs) knowledge and confidence, assessed via patient and HCP surveys at baseline and at follow-up. Acceptability of the intervention will be assessed through HCP interviews at follow-up, and cost will be assessed from Medicare and Pharmaceutical Benefits Scheme claims information and information logged pertaining to intervention activities (eg time spent by the newly appointed psycho-oncology staff in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg salaries, training materials, videoconferencing).

Ethics and dissemination: Ethics approval was obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of NSW. Results will be widely disseminated to the funding body and through peer-reviewed publications, HCP and consumer publications, oncology conferences and meetings.

Trial registration: The study is registered with the Australian New Zealand Clinical Trials Registry with registration number ACTRN12613000916741.

STRENGTHS AND LIMITATIONS

Strengths of the study:

- It has been developed specifically to address existing gaps in psychosocial care, and proposes a model of care which will be integrated, high quality, evidence-based, embedded in routine practice, and responsive to individual patients' needs.
- It promotes an active role for frontline staff, as well as improved coordination and continuity of care; particularly for patients in rural and remote areas.
- The lack of research attention on patients with urological or H&N cancers, despite their burden on the Australian community, is addressed.
- The translational capacity of the program is enhanced through the support of a very strong collaborative team, a strong methodology for health services research (including cost analyses, which are often overlooked in interventional research), and strong support for the integration of psychosocial care into routine care. Importantly, this work has substantial potential for translation into other cancer services, beyond the current study.

Limitations of the study:

- The target population is vulnerable and experiencing an acute stressor that may impact on recruitment.
- As the intervention will continue over a twenty-four month period, changes in health professional staff over that time may be substantial. Consequently, some of the health professionals who complete a survey at twenty-four months may be only minimally exposed to the intervention and have diluted perceptions of impact.
- Other health initiatives may be introduced into hospitals in the study area, which could affect the impact of this intervention.

Emotional distress, pain and fatigue are commonly experienced by the majority of cancer patients, while other issues are unique to specific cancer types. Individuals diagnosed with urological cancers (bladder, kidney, prostate, testicles, penis) typically experience urinary and bowel dysfunction, and sexual problems.[1] Those diagnosed with head and neck (H&N) cancers (mouth, jaw, throat, larynx, salivary glands, skin of head and neck including melanoma, thyroid) often experience profound disfigurement and functional disability, changed body image, speech difficulties, nutritional problems, and have higher suicide rates than other people with cancer.[2] Both urological and H&N cancer patients often report negative changes in their intimate and social relationships.[1, 3] Some cancers, including urological and H&N cancers, are more prevalent in rural areas,[4] where people experience major difficulties accessing cancer services, including psychosocial care.[5] There is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve the distress experienced by cancer patients.[6] Nevertheless it is well established that much psychosocial morbidity experienced by cancer patients is undetected and untreated.[7] Failure to address these problems can exacerbate suffering and lead to decreased patient satisfaction with care, impaired adherence to treatment regimens, and poorer morbidity and mortality outcomes.[8]

Recent cancer patient satisfaction surveys in Australia, the United Kingdom and Canada have highlighted problems in coordination of services and limitations in psychosocial care.[9-11] Skills, confidence and beliefs of clinical staff regarding psychosocial aspects of care are important contributing factors.[12] Many health care professionals are not aware of effective evidence-based strategies to address patients' concerns, or underestimate the benefits of attending to psychosocial needs or referring to psychosocial personnel or services. There are few formalised mechanisms for communication between health care providers and systems of care may contribute to patients receiving fragmented and poorly coordinated care;

especially those who reside in rural areas.[8] With well supported stepped care models, the needs of the majority of cancer patients can be met without referral to specialist psychosocial services.[13] Models of care that provide basic psychosocial care delivered by frontline health care providers (eg oncology nurses), with appropriate training and mentorship by psycho-oncology specialists, have demonstrated efficacy and cost effectiveness in terms of the increase in quality-adjusted life-years achieved.[14]

The Institute of Medicine [8] has recommended a model for integrated psychosocial cancer care that comprises: 1) identifying patients' health needs through screening and assessment; 2) linking patients to health services via structured referral, case management and clinical integration of services; 3) supporting patients in illness self-management; 4) coordinating psychosocial and biomedical health care through care coordinators, multidisciplinary team meetings, multidisciplinary care plans and electronic health records; and 5) following up on care delivery by telephone calls or web-based technology to re-evaluate and adjust the patient's care plan.[8] Achieving such a model of care in most specialist oncology services and evaluating its effectiveness represent major challenges.[15-16] These challenges are accentuated in settings where cancer care is integrated into general medical or surgical care, with the absence of dedicated on-site cancer teams. This means that staff may not identify themselves as cancer clinicians and service models are generic to cater for a diverse range of illness groups. Nevertheless this represents the setting in which a significant proportion of cancer patients experience at least part of their treatment. Within this type of care delivery setting, how can effective models of integrated psycho-oncology care be developed, implemented and evaluated? This is one of the key questions this project aims to investigate.

Objective

The objective of this study is to develop, implement and assess the impact, acceptability and cost of, an integrated, patient-centred model for psychosocial screening, care and treatment of patients with urological and H&N cancers at a large tertiary referral hospital.

Study Design

A time series research design will be utilised to test the Psychosocial Assessment, Care and Treatment (PACT) model of care (detailed below). While the RCT is often used as the gold standard for assessing the effectiveness of health interventions, it is not always practical in health services research. A time series design will be used, as it is regarded as the strongest quasi-experimental design for evaluating longitudinal effects of interventions [17] and is an acceptable design for inclusion in Cochrane reviews.[18] Time series designs attempt to detect whether an intervention has an effect significantly greater than the underlying secular trend,[18] and are useful in quality improvement research for evaluating the effects of interventions when it is difficult to randomise patients. The study will focus on system-level outcomes as being of primary interest. We will monitor the process, outcomes and costs of establishing the specialised psycho-oncology service, including the development of evidence-based management protocols and referral pathways specifying defined roles for different health professionals within the cancer care setting.

METHODS

Study Setting

The setting for this study is John Hunter Hospital (JHH)/Royal Newcastle Centre; the largest tertiary referral teaching hospital in the Hunter New England Local Health District of

NSW, Australia. It provides the main services for a large sector of the state of NSW, comprising a population of over 850,000 people, including a major metropolitan centre and several large regional centres, as well as many smaller rural centres and remote communities. This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000 inpatient separations per year for cancer related conditions.[19] It is the main teaching hospital of the University of Newcastle.

The current model of cancer care at the John Hunter Hospital (JHH), the site for this study, includes investigation, diagnosis, surgery and follow-up surveillance. Patients needing radiation or chemotherapy are referred to a nearby specialist cancer service and generally return to the JHH or a regional hospital facility for follow-up and monitoring. In 2012, 124 urology and 69 H&N patients received inpatient cancer care at the JHH. The JHH urology service comprises five senior urologists and four dedicated outpatient nursing staff, and the H&N unit comprises four senior surgeons, one dedicated outpatient nurse and four ward-based nurses. Each inpatient unit comprises 20 nursing staff caring for patients with a range of cancer and non-cancer conditions. For both tumour groups, multidisciplinary team meetings provide a forum to discuss individuals with complex cancers. Although each unit is supported by dedicated allied health clinicians, the JHH has no dedicated psycho-oncology services. Patients requiring psycho-oncology assessment are either referred to generic Liaison Psychiatry, which provides a limited role including advice, inpatient consultation and a restricted level of outpatient assessment, or to the Psycho-oncology service at the nearby cancer hospital, which is a separate service with no shared records and located at a different site to patients' routine outpatient care at the JHH.

Eligibility criteria

Patients

Inclusion criteria are: a) aged 18 years or over, b) diagnosed with a urological cancer or a H&N cancer, and c) receiving inpatient and/or outpatient care at JHH. Patients from metropolitan and all rural areas served by this hospital are included in the study.

Staff

Staff will be eligible to complete the Knowledge and Confidence Survey if they: a) are a nursing or allied health staff member, and b) provide care for patients who are receiving inpatient or outpatient urological or H&N cancer services at this site. Staff will be eligible to participate in interviews to assess the acceptability of the PACT care model if they meet the following inclusion criteria: they a) are a medical, nursing or allied health staff member, b) provide care for patients who are receiving inpatient or outpatient urological or H&N cancer services, and c) have been involved in the PACT care pathway of one or more patients, either on-site at JHH, or through provision of follow-up care, following discharge from JHH.

Intervention

It is important to note that this study focuses on a system-level intervention aimed at modifying provision of service to all patients attending these units, rather than recruiting a sample of patients for the provision of a specific psychosocial intervention. While data are collected periodically from patients attending this hospital and from staff, this is chiefly with the intention of examining the impact of the service changes. The PACT (**P**sychosocial **A**ssessment, **C**are and **T**reatment) model focuses on a system of care for patients with H&N or urological cancers. This model aims to systematise the approach to screening for distress and responding to that distress in a coordinated manner, including facilitating continuity of care for patients who reside some distance from the acute care setting where they were

treated for cancer. In order to address the needs of those patients in rural regions, a specific component of the innovation introduced to the system of care is extended to this population. The development of this care model includes the following key components:

1) The implementation for inpatients and outpatients of the two surgical units of routine screening for distress, and associated psychosocial care plans.
2) The identification of intervention options for all levels of need, and pathways to specialist psycho-oncology care if required.
3) The addition of dedicated psycho-oncology clinical services (including psychologist, psychiatrist and mental health nurse).
4) The provision of staff development and support to implement such a model (including training in skilled communication to identify and respond to emotional distress), and structured case review for complex or challenging cases. The latter strategies will incorporate oncology clinical staff and others working with cancer patients within urban, regional and remote communities.
5) Videoconferencing to facilitate case review meetings between clinicians at the hospital base site and those at rural sites who are engaged in the on-going post-discharge care of patients initially treated at the hospital.

In order to achieve these intervention goals, the following are intrinsic to the service model:

a) A dedicated Clinical Nurse Consultant (CNC), with experience in psycho-oncology and adult education, will coordinate the establishment and delivery of the model, with a special focus on development and implementation of a systematic and structured approach to routine screening, triage and management of cancer patients' individual physical, psychological and social concerns during active treatment and at follow-up.

b) The CNC, a newly appointed Clinical Psychologist, and two of the investigators with experience in communication skills training (AG, BK) will develop and deliver a communication skills-based training program to support frontline clinical staff (mostly nursing and allied health care professionals) in implementing the psycho-oncology care model and facilitating within-team communication to enhance continuity of patient care. This training program will be run on numerous occasions to reach as many frontline staff as possible during the intervention period and is based on an evidence-based consultation skills training program previously developed and evaluated by our team. [20-21]

c) The CNC and Clinical Psychologist will facilitate the delivery of the care model through the training of frontline staff, provision of clinical assessment and specialised evidence-based care for patients who are referred to the psycho-oncology service, monitoring of progress on psychosocial care plans including with rural clinicians through case reviews, and providing advice as required to rural clinicians to support linking patients to local rural specialised services. Where specialised services are not available, the Clinical Psychologist will collaborate with the local clinician (eg rural clinical nurse) to provide outreach specialist assessment by videoconference. The lead psychiatrist (BK) will provide clinical oversight of the program, participate in staff training, and direct clinical evaluation and treatment of patients with the highest level of distress or complexity.

Clinical practice guidelines recommend routine distress screening of cancer patients (with feedback to health care providers) at periods of increased vulnerability to ensure that those at risk are identified promptly and offered appropriate treatment.[22] As part of the newly developed model of care, all inpatient and outpatient urology and H&N cancer patients will be screened at their first diagnostic or treatment visit and at each subsequent follow-up visit, using the Distress Thermometer (DT) and accompanying Problem Checklist,[13] which will inform the development of a care plan to address the issues identified through the

screening and second-line inquiry. The care plan will facilitate provision of care tailored to the specific needs of patients and promote continuity of care across care settings and providers, including with health care professionals (HCPs) in the rural and regional areas.

The screening and problem checklist will act as a trigger for frontline staff to inquire about, and discuss the cause/s of, distress with patients whose distress levels are above the recommended cut-off of 4 or more out of 10.[23] Training for frontline staff will focus on discussing the cause/s of the distress, developing a psychosocial care plan to address identified concerns providing information and/or basic counselling, or referring patients with significant or persistent distress to the psycho-oncology service, and facilitating continuity of care, including linking patients with hospital and community services as required. Staff will also assist patients with access to self-management information on tablets which will be available during their hospital visit. Long-term sustainability of these service changes will be promoted through organisational leadership and management support, engagement of cancer clinician leaders in each unit in the design and evaluation of the service model, and development of a model with the aim of adaptability and flexibility to diversity of locations and patient complexity (eg through complex case review and revision of psychosocial care plans and active involvement of clinicians from rural locations in this process).[24]

Outcomes

The primary outcome is a system-wide increase in the proportion of eligible patients receiving care at the study facility who complete a DT and accompanying Problem Checklist (see Data Collection Methods) on at least one occasion and have a psychosocial care plan developed which complies with recommended care pathways. This outcome will be assessed at baseline, then at 12 and 24 months post-baseline (ie following the establishment of the new model of care – refer to Intervention section).

The secondary outcomes are: a) an increase in the proportion of eligible patients receiving care at the study facility who report positive experiences of their cancer care at 12 and 24 months post-baseline compared to patients receiving care in this facility at baseline, and b) an increase in the proportion of health professionals providing care to the eligible patient population at the study facility who report high levels of knowledge and confidence in responding to patients' psychosocial concerns at 24 months post-baseline compared to the health professionals caring for the eligible patient population at baseline. HCP satisfaction with the PACT intervention will also be assessed via interviews at follow-up, and the resource use and costs of the intervention will be monitored by maintaining comprehensive logs of intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and ascribing the associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Table 1: Study design and data collection timeline

Time period	Data collection	Intervention delivery
Commencing at 0 months (March 2013)	Recruitment of baseline Health Care Professional sample Completion of Health Professional Knowledge and Confidence Survey	
	Recruitment of Patient Cross-sectional Sample #1 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	Development and delivery of communication skills training to health professionals PACT intervention delivery throughout the study period On-going monitoring of costs of the intervention (time spent in direct patient contact, on staff training, inter-professional case reviews and other communications required to support rural and regional providers)
Commencing at 12 months	Recruitment of Patient Cross-sectional Sample #2 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	
Commencing	Recruitment of Patient Cross-sectional	

at 24 months	Sample #3 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	
	Recruitment of post-intervention HCP sample Completion of Health Professional Knowledge and Confidence Survey	
	Recruitment and interviews with purposively sampled HCPs regarding acceptability of the PACT intervention	
	Retrospective review of Medicare and Pharmaceutical Benefits Scheme (PBS) claims data for use and costs of medical services and pharmaceuticals for the three cross-sectional patient samples (Department of Human Services data extraction)	
	Review of hospital's databases Assessment of set-up and on-going costs associated with the PACT intervention	

Recruitment

Patients

Three cross-sectional samples of current inpatients and outpatients will be recruited, at baseline, 12 months and 24 months, to complete a Patient Experience Survey (of their cancer care) and provide consent for access to their hospital and other medical records. The main purpose of these data collection phases is the evaluation of the impact of system-level changes, rather than recruiting patients who will undertake the intervention. During the study audit periods at baseline, 12 months and 24 months, the Research Officer will contact staff of the outpatient clinics and inpatient wards in which care is provided for urological and H&N cancers, on a weekly basis, to identify whether patients meeting the inclusion criteria will be attending those clinics or wards that week. The Research Officer will attend those clinics and/or wards at which potential participants will be present, briefly introduce those patients to the study, answer questions, and provide interested persons with an Information Pack. The Information Pack will contain an Information Letter, a Consent Form for data to be obtained

from Hunter New England Local Health District (HNELHD), a Consent Form for data to be obtained from the Department of Human Services, a Request for Summary of Study Results Form, a copy of the self-administered Patient Experience Survey and a Paperwork Return Checklist. Patients will be asked to take the Information Pack home to consider before completing the survey and consent forms and posting them back to the researchers, using a self-addressed reply paid envelope, within 10 days. Staff at the outpatient clinics and inpatient wards will also be supplied with Information Packs to distribute to eligible patients who attend the clinic when the Research Officer is not in attendance.

Staff

Health Professional Knowledge and Confidence Survey

Two cross-sectional samples of HCPs involved in the care of patients with H&N or urological cancers at the study facility will be recruited during the study audit periods at baseline and at 24 months, to assess the skills development of clinical staff who work at the parent facility. At each time point, the Research Officer will contact the Managers of the inpatient wards and outpatient clinics in which care is provided to patients with urological and H&N cancers. The Managers will be asked to identify the nursing and allied health staff members who routinely provide care to the patients of their respective wards/clinics, as well as each staff member's employment status as either permanent or casual. A list of HCPs eligible to receive an Information Pack will then be generated, and Information Packs sent via internal mail to the department at which each staff member is based. The Information Pack will contain an Information Letter and a copy of the self-administered Knowledge and Confidence Survey for HCPs to complete and post back to the researchers, using a self-addressed reply paid envelope, within 10 days. A second survey will be mailed to HCPs who

do not return a completed survey within four to six weeks and a third survey will be sent to non-returnees four to six weeks after that.

Health Professional receptivity and acceptability interviews

At approximately 24 months (nearing study completion), purposively sampled allied health, nursing and medical staff will be interviewed by the Research Officer about the acceptability of the key aspects of the PACT integrated model of psychosocial care (including screening, triage, access to psychosocial services/providers, clinical case reviews), perceived effectiveness of the model at improving care, and perceived impact of the staff training. The Research Officer will send an Information Pack to those staff members who meet the inclusion criteria. The Information Pack will contain an Information Letter, Consent Form and Request for Interview Transcript Form. Consenting staff will participate in a 20-minute telephone interview at a mutually convenient time.

Data collection methods

The primary outcome of system-level change will be assessed through audit of patient medical records, and through Medicare and PBS claims information for follow-up care sought via referral through the new model of care; the secondary outcomes of impact of the model on patient experiences and on HCP knowledge and confidence will be assessed via patient and HCP surveys. Acceptability of the intervention will be assessed via HCP interviews, and cost of the intervention will be assessed from information collected through Medicare and PBS claims information, as well as information logged pertaining to intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg

CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Medical records audit and Medicare and Pharmaceutical Benefits Scheme (PBS) claims information

At baseline, 12 months and 24 months, the files of all patients who provide their consent will be reviewed by the Research Officer and an appointed research assistant who is not involved in the intervention delivery, to calculate the proportions of patients a) who have completed a DT and accompanying Problem Checklist at least once, b) who have had a psychosocial care plan developed, and c) whose management, including referrals, complies with recommended care pathways. A checklist will be used to achieve a systematic approach to extraction of these records. The coders (Research Officer and a second research assistant) will initially review one file with the Clinical Psychologist to ensure consistency in understanding of the checklist and 10% of the files will be double-coded by the two coders to calculate inter-rater reliability.

Medicare and PBS claims information will also be extracted by the Department of Human Services for those participants who provide their consent, and will be reviewed by the health economist investigators (MH and RV) to extract information relating to psychosocial care delivered in a hospital or community health setting, by a private provider, or by a general practitioner.

Patient Experience Survey

A 35-item survey will include items assessing patient perceptions of care received, relating to the dimensions of emotional support, information, education and coordination of care. All items are phrased from the first-person perspective (eg *"I had confidence and trust in the staff treating me"*), to be answered using a 5-point Likert-type scale ranging from 1 =

'strongly disagree' to 5 = 'strongly agree'. A patient experience score will be aggregated based on the sum of selected responses. The survey contains 3 items from the Cancer Care Survey, [25] and 8 items from the Hospital Care – Overnight Patient Survey; [26] all adapted such that they could be answered from the first-person perspective. The survey also contains 10 items from the Critical Cancer Care Events Scale; [27] some of which required adaptation so that they referred to a broader group of health professionals than doctors, and all of which were adapted to be answered on a 5-point Likert-type scale (as described above).

The survey will also measure key *socio-demographic, disease and medical variables*, including age, residential location, gender, marital status, indigenous identification, languages spoken, country of birth, educational attainment, employment status, private health coverage, income, cancer type, date of diagnosis, treatment received, recurrence status, and number of prior inpatient admissions and outpatient clinic visits.

Health Professional Knowledge and Confidence Survey

A 65-item survey will include items targeting health professionals' knowledge, skills and confidence pertaining to responding to patients' specific psychosocial concerns. The survey contains 12 items from a *Confidence in Communication Skills and Discussing Prognosis and End-of-Life Issues* module used by Clayton, Butow, Waters et al.[28] The survey also contains a case study and associated Care Planning, Monitoring and Review items from the Client-Centred Care – Training Needs Survey;[29] all adapted such that they refer to a patient with urological cancer and explicitly address psychosocial care. A Clinician Belief Scale is contained in the survey; based on the Physician Belief Scale,[30] it contains all 32 items of the Physician Belief Scale, but has been renamed to apply to a broader group of health professionals than doctors, and items will be answered on a 5-point Likert-type scale ranging from 1= 'strongly disagree' to 5= 'strongly agree'. Finally, the survey contains

the single-item Clinician Burnout survey, which is the Physician Burnout survey,[31] renamed to apply to a broader group of health professionals than doctors. A knowledge/confidence score will be aggregated based on the sum of selected responses.

The survey will also measure key *socio-demographic, experience and training variables*, including age, residential location, gender, occupational specialty, number of years of experience in a) their current specialty and b) in cancer care, number of hours spent weekly in direct patient contact, indigenous identification, languages spoken, country of birth, and country of training.

Health Professional receptivity and acceptability interview

An interview will be scheduled with consenting participants to assess the acceptability of the key aspects of the integrated model of psychosocial care (including screening, triage, access to psychosocial services/providers and clinical case reviews), perceived effectiveness of the model in improving care, and the perceived impact of training. It is anticipated that the interview will take 20 minutes, with an audio recording being made for transcription purposes. An interview schedule previously developed by our team has been adapted for use in the present study, and examples of questions in the interview guide include: “Have you been aware of there being a more systematic approach to the provision of psychosocial care for people with H&N or urological cancers over the past year or so compared to previously?” and “What’s your impression of patient/family member/caregiver attitudes toward the new model (eg acceptance)?”

Intervention costs

In keeping with the time series design, information about resource use and associated costs will be obtained at baseline, 12 and 24 month time points. Information will be obtained

from the hospital's databases regarding emergency department (ED) attendance, triage category, whether the patient was admitted or discharged from the ED, and their diagnosis. Information about use and costs of medical services and pharmaceuticals will be obtained from Medicare and PBS claims data. Specific set-up and on-going costs associated with staff training, inter-professional case reviews and other communications required to support rural and regional providers, will also be monitored.

Sample size

Patients

Data from the initial twenty-five patient surveys completed were used to estimate the required patient sample size. The mean patient experience score at baseline was rated highly at 45 out of a possible 55. Hence, the research team determined that a 5-point improvement between baseline and the last follow-up (24 months) would be a meaningful change, assuming a standard deviation of 7.58 (derived from current surveys), significance level of 5%, and power of 80%, with at least 38 patients needing to be recruited at each time point to detect this change over time.

Health care professionals

Data from the first 28 surveys completed were used to estimate the required sample size. The mean score of knowledge/confidence was moderate at 61.5 out of a possible 105. Hence, it was determined that at least 48 health professionals were required to be recruited at each time point to achieve a significant improvement of 10 points between baseline and follow-up (24 months), assuming a standard deviation of 17.13 (derived from current surveys), significance level of 5%, and power of 80%.

Data management

Data which are collected in paper format (i.e. patient consent forms, surveys and requests for study results, and health care professional surveys, requests for study results and interview transcripts) will be stored in a locked cabinet, accessible only by the Research Officer. Data which are collected in computer file format (i.e. data obtained through the Department of Human Services and Hunter New England Local Health District, and interview audio and transcript files) will remain in computer file format. In addition, computer files will be created for the entry and storage of participant details and survey responses. All of this electronically stored data will be maintained in separate, password-protected files, which will be stored on a password-protected local area network drive, accessible only by the Research Officer and the chief investigators. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the Research Officer and the chief investigators.

Data in paper format will be stored for seven years, while computer files will be stored for 15 years. All will be shredded by a contracted security waste disposal company at the conclusion of the storage period.

Statistical methods

Analysis of primary and secondary outcomes

This evaluation will focus on the impact and acceptability of the new model of care, with system-level outcomes being of primary interest. Cross-sectional data will be collected at baseline, 12 months and 24 months on the proportion of patients a) who are screened for distress at least once and b) who have a psychosocial care plan developed.

Data will be collected at the three time points and analysed using Poisson or Negative Binomial regression depending on over-dispersion of the counts of each outcome. The Poisson/Negative binomial models will include a time variable (0, 12 and 24 months), a before and after variable, a term for the interaction of these two variables, and an offset variable which is used to adjust for the total number of patients consented at each time point. The interaction term will be used to estimate any difference between the two periods, which would indicate a slow improvement in the outcome during the intervention period. The before and after variable will be used to estimate the change in the outcome that may occur immediately after the introduction of the model of care. The models will adjust as appropriate for potential confounding variables such as age, gender, residential location, indigenous status, cancer type, and time since diagnosis.

Patient Experience and Health Professional Knowledge and Confidence

For patient experience surveys, a linear regression will be used to model the patient experience scores over the three time points to determine whether there was a significant improvement during the study period whilst adjusting for potential confounding variables (eg duration of care within the service, other psychosocial support services used, disease and treatment characteristics, age, and gender). Similarly, for the health professional knowledge and confidence surveys, a linear regression will be used to determine if there was a difference in the knowledge/confidence scores between the two time points whilst adjusting for potential confounding variables (eg other training in psychosocial care received, duration of employment in this service, prior experience, work role and time allocation, age, and gender).

Economic analysis

Estimates of resource use and costs will take into account the costs of implementation of the new model, but will not include costs of the evaluation/audit. At each time point (baseline, 12 months and 24 months), mean estimates of costs will be used and confidence intervals will be generated by boot-strapping the data. Benefits will be measured via surveys and interviews to ascertain the acceptability of the intervention and how the new model is experienced, as well as changes in clinicians' knowledge and confidence. Costs and outcomes will be reported separately at each time point and trends over time will be evaluated.

Qualitative analysis of HCP interviews

HCP interviews will be audio-recorded, transcribed verbatim, and analysed qualitatively. Inductive thematic analysis will be used to identify, analyse and report themes (or patterns) in the data (MapInfo Professional Version 8, MapInfo Corporation). Transcripts will be initially read and any words, statements, and/or paragraphs related to HCPs' views on the PACT intervention will be extracted by assigning a label or code. Similar excerpts will be identified by using the same code, with clustering of the codes denoting themes in the data. Data analysis will focus on a detailed description of emerging themes, with a focus on identifying the positive and negative aspects of the PACT model and strategies to support its ongoing implementation in the care facility.

DISCUSSION

This research program specifically addresses the objective of improving quality of care of patients with cancer and has been developed to address existing gaps in psychosocial care. The proposed program will provide a mechanism for delivering integrated, high quality, evidence-based cancer care that is embedded in routine practice, and responsive to the needs

of individual cancer patients by (1) systematically identifying patients' physical and psychosocial health needs, (2) developing care pathways and plans to address identified needs, (3) linking patients to skilled HCPs and appropriate services, and (4) coordinating on-going psychosocial health care. The project has a focus on translating evidence regarding psychosocial care into an integrated model that promotes the role of 'frontline' clinical staff, including those in rural settings, and will promote improved coordination and continuity of care for patients in rural and remote areas. Improving the psychosocial component of routine care, building distress screening into a model of routine care, and developing a psychosocial care plan for patients will enhance the acceptability and appropriateness of psychosocial care. Specialist services will be active in providing training, advice and support within an inter-professional team, and providing specialist assessment and treatment as a member of this team when needed. Addressing the process and outcome variables will support investigation of the quality of care provided from patient and clinician perspectives.

The proposed care model has the potential to address several unmet needs identified in key policy documents and surveys. Specifically, it will provide improved emotional support and information for both cancer inpatients and outpatients,[9] expand psycho-oncology services to improve access to specialised care,[19] and provide timely individualised support to the level and detail required for patients.[32] In addition, this research program directly addresses the priority issue of delivering quality cancer care that addresses patients' physical and psychosocial health needs [6, 8] by bringing together the scientific evidence about the management of cancer patients' psychosocial problems into a model of patient-centred cancer care. Furthermore, it focuses on patients with urological or H&N cancers given their lack of research attention compared to their burden on the Australian community.[33]

The translational capacity of this research program is enhanced through three major strengths. First, it is supported by a very strong collaborative team. Enhancing the role of

'frontline' clinical staff, defining pathways of care and promoting integration between major centres and rural clinicians entails a high level of support from clinical staff for objective implementation and evaluation. This project has strong support from the highest level of cancer service governance in our area, senior nursing clinicians and existing on-site psychiatric services. The linkage of the PACT model to Area-level network of psycho-oncology services will promote integration of psychosocial care into routine clinical care, promote continuity of care, and, through its clinician training model, improve the overall quality of care for patients and their families.

Second, the study utilises strong methodology appropriate for health services research. The evaluation framework and methodology ensures that the evaluation is sensitive to the role of general clinical staff, appropriate to the setting, relevant to stakeholders, inclusive and informative. Cost analyses will be undertaken to facilitate comparisons of costs and outcomes and changes in these over time; an important consideration as economics is an often overlooked element of interventional research. The close engagement of clinicians in the planning, implementation and evaluation will ensure maximum relevance of the project to the local context of clinical practice, including rural and remote settings. The built-in capacity for flexibility in the clinical setting (eg documenting and addressing local barriers to integration of psychosocial care) will promote translation to routine care, and potential applicability to other settings.[34]

Third, there is strong support for integration of psychosocial care into routine care, and efficient use of specialist services. This project will provide important evidence for the effective use of existing resources for nurses and allied health professionals working in routine cancer care. If the outcomes of the research are positive, this will provide the basis for a model of implementing psycho-oncology services across other clinical services within this network. While the project includes the use of routine screening, it does so in a manner that

builds this into a model of care, so that these tools can support clinical practice within a model of integrated care, defined service pathways and support to distant sites. The work has substantial potential for translation into other cancer services beyond the research collaborators.

Despite the strengths, there are also several challenges for the research and evaluation. The target population is vulnerable and experiencing an acute stressor that may impact on recruitment. As the intervention will continue over a twenty-four month period, changes in health professional staff over that time may be substantial. Hence, some of the health professionals completing the survey at twenty-four months may have been minimally exposed to the intervention, hence potentially diluting perceptions of impact. Finally, health initiatives introduced more broadly into hospitals in the study location may affect the impact of this intervention, but are beyond the control of the research team.

ETHICS AND DISSEMINATION

Ethics approval

Research ethics approval has been obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of New South Wales. Minor adverse events (eg a participant being tearful and distressed when talking with the Research Officer) will be logged and fed back to the study team by the end of the study. Serious adverse events (eg expressing suicidal thoughts) will be reported immediately to the chief investigators and to the ethics committees. Any protocol amendments will be submitted to the ethics committees before these are implemented, and relevant changes will also be communicated to other relevant organisations (eg trial registry).

Confidentiality

The names of potential patient and health care professional participants will be entered into the study's password-protected administrative database, accessible only by the Research Officer. Upon receipt of completed surveys and/or consent forms from participants, a study ID will be assigned to each participant, and recorded with identifying information only in the study's password-protected administrative database. Thereafter, survey, consent form and request for results data will be linked to participants only via the allocated study ID. There is no foreseeable reason for personal or identifying participant information to be shared throughout the conduct of the trial, except where required for adverse event reporting.

All of the electronically stored personal participant information will be maintained and destroyed in the same manner as all data collected throughout the study. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the Research Officer. These will be stored for fifteen years, then shredded by a contracted security waste disposal company at the conclusion of the storage period.

Competing interests

As a Consultant Psychiatrist for the Consultation Liaison Psychiatry Service of John Hunter Hospital and a chief investigator on this project, BK may experience competing interests with respect to reporting the impact, cost and acceptability of the new psychosocial care model. These potentially competing interests will be minimised and managed by having the other chief investigator, AG, primarily responsible for the conduct of the research and result reporting.

Access to data

The study's chief investigators (AG, BK), Research Officer, Biostatistician, and Health Economists will have exclusive access to the final trial dataset.

Dissemination policy

The results will be widely disseminated through peer-reviewed publications as well as relevant health care professional and consumer publications. Oncology health care professionals and administrators within Hunter New England Local Health District will be invited to a face-to-face presentation of the results by the chief investigators. Presentations will be delivered at relevant national oncology and nursing conferences and meetings. The results will be reported to the funding body and other peak bodies with influence on cancer policy and practice, including Cancer Australia, Clinical Oncology Society of Australia, Cancer Council Australia, and Cancer Voices Australia. In addition, all research participants who request a summary of the study's key findings will be mailed one on completion of the project.

AUTHORS' CONTRIBUTIONS

BK and AG conceived of the study and are the grant holders. AB assisted in the initial study design and AP and DB provided organisational guidance on service model and implementation. BK and AG, along with the newly appointed clinical staff, developed the communication skills training, and HC will oversee the day-to-day study implementation according to the protocol. MH and RV provided guidance on data requirements for the economic analysis and will undertake these analyses. JD provided guidance on sample size requirements and will be conducting the primary statistical analyses. All authors contributed to refinement of the study protocol and approved the final manuscript.

ACKNOWLEDGEMENTS

The study detailed in this protocol is endorsed by the Psycho-oncology Co-operative Research Group (PoCoG), The University of Sydney, Australia. The study protocol and relevant documents have been reviewed by the PoCoG Scientific Advisory Committee and the Joint Community Advisory Group. Debbie O'Brien and Gai Shylan will play a central role in facilitating recruitment and implementation of the intervention, and Catherine Adams and Deanna Sue in the communication skills training of health professionals involved in the delivery of the PACT model of care.

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The PACT Study Protocol: A time series study investigating the ~~feasibility~~ impact, ~~and~~ acceptability and cost of an integrated~~,~~ ~~patient-centred~~ model for psychosocial ~~assessment~~screening, care and treatment of patients with urological and head and neck cancers

Professor Afaf Girgis, PhD (corresponding author)
Translational Cancer Research Unit, Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales
Liverpool NSW 2170 Australia
afaf.girgis@unsw.edu.au

Professor Brian Kelly, PhD
Priority Research Centre for Translational Neuroscience and Mental Health
School of Medicine and Public Health, The University of Newcastle
Callaghan NSW 2308 Australia
Consultation Liaison Psychiatry Service
Hunter New England Local Health District
John Hunter Hospital (JHH), Lookout Road
New Lambton NSW 2305 Australia
brian.kelly@newcastle.edu.au

Dr Allison Boyes, PhD
Priority Research Centre for Health Behaviour & Hunter Medical Research Institute
The University of Newcastle, Callaghan NSW 2308 Australia
allison.boyes@newcastle.edu.au

Professor Marion Haas
Centre for Health Economics Research & Evaluation
University of Technology Sydney, Ultimo NSW 2007 Australia
marion.haas@chere.uts.edu.au

Professor Rosalie Viney
Centre for Health Economics Research & Evaluation
University of Technology Sydney, Ultimo NSW 2007 Australia
rosalie.viney@chere.uts.edu.au

Dr Joseph Descallar
Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales, Liverpool NSW 2170 Australia
joseph.descallar@sswahs.nsw.gov.au

Ms Hayley Candler
Translational Cancer Research Unit, Ingham Institute for Applied Medical Research
South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales

Calvary Mater Newcastle, Edith Street
Waratah NSW 2298 Australia
hayley.candler@unsw.edu.au

Mr Douglas Bellamy
Hunter New England Cancer Network Directorate
Hunter New England Local Health District
JHH, Lookout Road
New Lambton NSW 2305 Australia
douglas.bellamy@hnehealth.nsw.gov.au

Associate Professor Anthony Proietto
Hunter New England Cancer Services
Hunter New England Local Health District
JHH, Lookout Road
New Lambton NSW 2305 Australia
anthony.proietto@hnehealth.nsw.gov.au

The PACT Study team also includes Catherine Adams, Debbie O'Brien, Gai Shylan, Ben Britton, Sandy Grant, Vicky Parker, Chris Wratten, Deanna Sue.

Contact Information
Professor Afaf Girgis, Translational Cancer Research Unit, Ingham Institute for Applied Medical Research, South Western Sydney Clinical School, UNSW Medicine
The University of New South Wales
Liverpool Hospital, Locked Bag 7103, LIVERPOOL BC NSW 1871
T: +61 (4) 12 142 841
F: +61 (2) 9602 3221
E: afaf.girgis@unsw.edu.au

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ABSTRACT

Introduction: Whilst there is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve distress experienced by people affected by cancer, much of this psychosocial morbidity is undetected and untreated, with consequent exacerbated suffering, decreased satisfaction with care, impaired adherence to treatment regimens and poorer morbidity and mortality outcomes. The objective of this study is to develop, implement and assess the ~~feasibility~~impact, acceptability and cost of an integrated, patient-centred Psychosocial Assessment, Care and Treatment (PACT) model of care for patients with urological and head and neck cancers.

Methods and analysis: A time series research design will be used to test ~~the feasibility, acceptability and cost of~~ the PACT model of care, newly introduced in an Australian tertiary hospital. The primary outcome is system-level impact~~change~~, assessed through audit of patients' medical records and Medicare claims for follow-up care. The secondary outcomes are ~~acceptability~~ impact of the model ~~to~~ on patient experience~~s~~ and health care professionals' (HCPs) ~~and impact on the~~ knowledge and confidence ~~of HCPs~~, assessed via patient and HCP surveys at baseline and at follow-up. ~~and~~ Acceptability of the intervention will be assessed through HCP interviews at follow-up~~;~~, and ~~. The intervention~~ cost ~~(tertiary outcome)~~ will be assessed from Medicare and Pharmaceutical Benefits Scheme claims information and information logged pertaining to intervention activities (eg time spent by the newly appointed psycho-oncology staff in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg salaries, training materials, videoconferencing).

Ethics and dissemination: Ethics approval was obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of NSW. Results will be widely disseminated to the funding body and through peer-reviewed publications, HCP and consumer publications, oncology conferences and meetings.

Trial registration: The study is registered with the Australian New Zealand Clinical Trials Registry with registration number ACTRN12613000916741.

STRENGTHS AND LIMITATIONS

Strengths of the study:

- It has been developed specifically to address existing gaps in psychosocial care, and proposes a model of care which will be integrated, high quality, evidence-based, embedded in routine practice, and responsive to individual patients' needs.
- It promotes an active role for frontline staff, as well as improved coordination and continuity of care; particularly for patients in rural and remote areas.
- The lack of research attention on patients with urological or H&N cancers, despite their burden on the Australian community, is addressed.
- The translational capacity of the program is enhanced through the support of a very strong collaborative team, a strong methodology for health services research (including cost analyses, which are often overlooked in interventional research), and strong support for the integration of psychosocial care into routine care. Importantly,

this work has substantial potential for translation into other cancer services, beyond the current study.

Limitations of the study:

- The target population is vulnerable and experiencing an acute stressor that may impact on recruitment.
- As the intervention will continue over a twenty-four month period, changes in health professional staff over that time may be substantial. Consequently, some of the health professionals who complete a survey at twenty-four months may be only minimally exposed to the intervention and have diluted perceptions of impact.
- Other health initiatives may be introduced into hospitals in the study area, which could affect the impact of this intervention.

Emotional distress, pain and fatigue are commonly experienced by the majority of cancer patients, while other issues are unique to specific cancer types. Individuals diagnosed with urological cancers (bladder, kidney, prostate, testicles, penis) typically experience urinary and bowel dysfunction, and sexual problems.[1] Those diagnosed with head and neck (H&N) cancers (mouth, jaw, throat, larynx, salivary glands, skin of head and neck including melanoma, thyroid) often experience profound disfigurement and functional disability, changed body image, speech difficulties, nutritional problems, and have higher suicide rates than other people with cancer.[2] Both urological and H&N cancer patients often report negative changes in their intimate and social relationships.[1, 3] Some cancers, including urological and H&N cancers, are more prevalent in rural areas,[4] where people experience major difficulties accessing cancer services, including psychosocial care.[5] There is good evidence of the effectiveness of a variety of interventions and services to prevent and/or relieve the distress experienced by cancer patients.[6] Nevertheless it is well established that much psychosocial morbidity experienced by cancer patients is undetected and untreated.[7] Failure to address these problems can exacerbate suffering and lead to decreased patient satisfaction with care, impaired adherence to treatment regimens, and poorer morbidity and mortality outcomes.[8]

Recent cancer patient satisfaction surveys in Australia, the United Kingdom and Canada have highlighted problems in coordination of services and limitations in psychosocial care.[9-11] Skills, confidence and beliefs of clinical staff regarding psychosocial aspects of care are important contributing factors.[12] Many health care professionals are not aware of effective evidence-based strategies to address patients' concerns, or underestimate the benefits of attending to psychosocial needs or referring to psychosocial personnel or services. There are few formalised mechanisms for communication between health care providers and systems of care may contribute to patients receiving fragmented and poorly coordinated care;

especially those who reside in rural areas.[8] With well supported stepped care models, the needs of the majority of cancer patients can be met without referral to specialist psychosocial services.[13] Models of care that provide basic psychosocial care delivered by frontline health care providers (eg oncology nurses), with appropriate training and mentorship by psycho-oncology specialists, have demonstrated efficacy and cost effectiveness in terms of the increase in quality-adjusted life-years achieved.[14]

The Institute of Medicine [8] has recommended a model for integrated psychosocial cancer care that comprises: 1) identifying patients' health needs through screening and assessment; 2) linking patients to health services via structured referral, case management and clinical integration of services; 3) supporting patients in illness self-management; 4) coordinating psychosocial and biomedical health care through care coordinators, multidisciplinary team meetings, multidisciplinary care plans and electronic health records; and 5) following up on care delivery by telephone calls or web-based technology to re-evaluate and adjust the patient's care plan.[8] Achieving such a model of care in most specialist oncology services and evaluating its effectiveness represent major challenges.[15-16] These challenges are accentuated in settings where cancer care is integrated into general medical or surgical care, with the absence of dedicated on-site cancer teams. This means that staff may not identify themselves as cancer clinicians and service models are generic to cater for a diverse range of illness groups. Nevertheless this represents the setting in which a significant proportion of cancer patients experience at least part of their treatment. Within this type of care delivery setting, how can effective models of integrated psycho-oncology care be developed, implemented and evaluated? This is one of the key questions this project aims to investigate.

~~The Hunter New England Local Health District of New South Wales, Australia, includes three tertiary referral hospitals and a total of over 2500 hospital beds servicing a~~

major metropolitan centre and several large regional centres, as well as many smaller rural centres and remote communities. This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000 inpatient separations per year for cancer related conditions.[17]

The current model of cancer care at the John Hunter Hospital (JHH), the site for this study, includes investigation, diagnosis, surgery and follow-up surveillance. Patients needing radiation or chemotherapy are referred to a nearby specialist cancer service and generally return to the JHH or a regional hospital facility for follow-up and monitoring. In 2012, 124 urology and 69 H&N patients received inpatient cancer care at the JHH. The JHH urology service comprises five senior urologists and four dedicated outpatient nursing staff, and the H&N unit comprises four senior surgeons, one dedicated outpatient nurse and four ward-based nurses. Each inpatient unit comprises 20 nursing staff caring for patients with a range of cancer and non-cancer conditions. For both tumour groups, multidisciplinary team meetings provide a forum to discuss individuals with complex cancers.

Screening for psychosocial needs is not routine and when it is conducted (using pen-and-paper Distress Thermometer and Problem Checklist),[18] the Cancer Care Coordinator discusses the issues with the patient and referrals may be made to allied health care professionals or other agencies, albeit not based on a specific care pathway. Although each unit is supported by dedicated allied health clinicians, the JHH has no dedicated psycho-oncology services; patients requiring psycho-oncology assessment are either referred to generic Liaison Psychiatry, which provides a limited role including advice, inpatient consultation and a restricted level of outpatient assessment, or to the Psycho-oncology service at the nearby cancer hospital, which is a separate service with no shared records and located at a different site to patients' routine outpatient care at the JHH.

Objective

The objective of this study is to develop, implement and assess the ~~feasibility~~impact, acceptability and cost of, an integrated, patient-centred model for psychosocial ~~assessment~~screening, care and treatment of patients with urological and H&N cancers at a large tertiary referral hospital.

Study Design

A time series research design will be ~~used~~ utilised to test the ~~feasibility and acceptability of the~~ Psychosocial Assessment, Care and Treatment (PACT) model of care (detailed below). While the RCT is often used as the gold standard for assessing the effectiveness of health interventions, it is not always practical in health services research. A time series design will be used, as it is regarded as the strongest quasi-experimental design for evaluating longitudinal effects of interventions [1~~9~~7] and is an acceptable design for inclusion in Cochrane reviews.[~~20~~18] Time series designs attempt to detect whether an intervention has an effect significantly greater than the underlying secular trend,[~~20~~18] and are useful in quality improvement research for evaluating the effects of interventions when it is difficult to randomise patients. The study will focus on system-level outcomes as being of primary interest. We will monitor the process, outcomes and costs of establishing the specialised psycho-oncology service, including the development of evidence-based management protocols and referral pathways specifying defined roles for different health professionals within the cancer care setting.

METHODS

Study Setting

The setting for this study is John Hunter Hospital (JHH)/Royal Newcastle Centre; the largest tertiary referral teaching hospital in the Hunter New England Local Health District of NSW, Australia. It provides the main services for a large sector of the state of NSW, comprising a population of over 850,000 people, including a ~~–~~major metropolitan centre and several large regional centres, as well as many smaller rural centres and remote communities. This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000 inpatient separations per year for cancer related conditions.[197] It is the main teaching hospital of the University of Newcastle. ~~The Hunter New England Local Health District of New South Wales, Australia, includes three tertiary referral hospitals and a total of over 2500 hospital beds servicing a major metropolitan centre and several large regional centres, as well as many smaller rural centres and remote communities. This area has an average of 4,171 new cases of cancer diagnosed per annum, with over 9,000 inpatient separations per year for cancer related conditions.[17]~~

The current model of cancer care at the John Hunter Hospital (JHH), the site for this study, includes investigation, diagnosis, surgery and follow-up surveillance. Patients needing radiation or chemotherapy are referred to a nearby specialist cancer service and generally return to the JHH or a regional hospital facility for follow-up and monitoring. In 2012, 124 urology and 69 H&N patients received inpatient cancer care at the JHH. The JHH urology service comprises five senior urologists and four dedicated outpatient nursing staff, and the H&N unit comprises four senior surgeons, one dedicated outpatient nurse and four ward-based nurses. Each inpatient unit comprises 20 nursing staff caring for patients with a range of cancer and non-cancer conditions. For both tumour groups, multidisciplinary team meetings provide a forum to discuss individuals with complex cancers. Although each unit is supported by dedicated allied health clinicians, the JHH has no dedicated psycho-oncology

services. Patients requiring psycho-oncology assessment are either referred to generic Liaison Psychiatry, which provides a limited role including advice, inpatient consultation and a restricted level of outpatient assessment, or to the Psycho-oncology service at the nearby cancer hospital, which is a separate service with no shared records and located at a different site to patients' routine outpatient care at the JHH.

Eligibility criteria

Patients

Inclusion criteria are: a) aged 18 years or over, b) diagnosed with a urological cancer or a H&N cancer, and c) receiving inpatient and/or outpatient care at JHH. Patients from metropolitan and all rural areas served by this hospital are included in the study.

Staff

Staff ~~who are employed through the JHH~~ will be eligible to complete the Knowledge and Confidence Survey if they: a) are a nursing or allied health staff member, and b) provide care for patients who are receiving inpatient or outpatient urological or H&N cancer services at this site. Staff will be eligible to participate in interviews to assess the acceptability of the PACT care model if they meet the following inclusion criteria: they a) are a medical, nursing or allied health staff member, b) provide care for patients who are receiving inpatient or outpatient urological or H&N cancer services, and c) have been involved in the PACT care pathway of one or more patients, either on-site at JHH, or through provision of follow-up care, following discharge from JHH.

Intervention

It is important to note that this study focuses on a ~~system level~~system-level intervention aimed at modifying provision of service to all patients attending these units,

rather than recruiting a sample of patients for the provision of a specific psychosocial intervention. -While data are collected periodically from patients attending this hospital and from staff, this is chiefly with the intention of examining the impact of the service changes.

The PACT (**P**sychosocial **A**ssessment, **C**are and **T**reatment) model focuses on a system of care for , ~~targeting~~ patients with H&N or urological cancers~~, will be developed as part of this study~~. This model aims to systematise the approach to screening for distress and responding to that distress in a coordinated manner, including facilitating continuity of care for patients who reside some distance from the acute care setting where they were treated for cancer. In order to address the needs of those patients in rural regions, a specific component of the innovation introduced to the system of care is extended to this population. The development of this care model includes the following key components:

1) The implementation for inpatients and outpatients of the two surgical units of routine screening for distress, and associated psychosocial care plans.
2) The identification of intervention options for all levels of need, and pathways to specialist psycho-oncology care if required.
3) The addition of dedicated psycho-oncology clinical services (including psychologist, psychiatrist and mental health nurse).
4) The provision of staff development and support to implement such a model (including training in skilled communication to identify and respond to emotional distress), and structured case review for complex or challenging cases. The latter strategies will incorporate oncology clinical staff and others working with cancer patients within urban, regional and remote communities.
5) Videoconferencing to facilitate case review meetings between clinicians at the hospital base site and those at ~~urban and~~ rural sites who are engaged in the on-going post-discharge care of patients initially treated at the hospital.

In order to achieve these intervention goals, the following are intrinsic to the service model:

a) A dedicated Clinical Nurse Consultant (CNC), with experience in psycho-oncology and adult education, will coordinate the establishment and delivery of the model, with a special focus on development and implementation of a systematic and structured approach to routine ~~assessment~~screening, triage and management of cancer patients' individual physical, psychological and social concerns during active treatment and at follow-up.

b) The CNC, a newly appointed Clinical Psychologist, and two of the investigators with experience in communication skills training (AG, BK) will develop and deliver a communication skills-based training program to support frontline clinical staff (mostly nursing and allied health care professionals) in implementing the psycho-oncology care model and facilitating within-team communication to enhance continuity of patient care. This training program will be run on numerous occasions to reach as many frontline staff as possible during the intervention period and is based on an evidence-based consultation skills training program previously developed and evaluated by our team. [20-21]

c) The CNC and Clinical Psychologist will facilitate the delivery of the care model through the training of frontline staff, provision of clinical assessment and specialised evidence-based care for patients who are referred to the psycho-oncology service, monitoring of progress on psychosocial care plans including with rural clinicians through case reviews, and providing advice as required to rural clinicians to support linking patients to local rural specialised services. Where specialised services are not available, the Clinical Psychologist will collaborate with the local clinician (eg rural clinical nurse) to provide outreach specialist assessment by videoconference. The lead psychiatrist (BK) will provide clinical oversight of the program, participate in staff training, and direct clinical evaluation and treatment of patients with the highest level of distress or complexity.

Clinical practice guidelines recommend routine distress screening of cancer patients (with feedback to health care providers) at periods of increased vulnerability to ensure that those at risk are identified promptly and offered appropriate treatment.[~~18~~22] As part of the newly developed model of care, all inpatient and outpatient urology and H&N cancer patients will be screened at their first diagnostic or treatment visit and at each subsequent follow-up visit, using the Distress Thermometer (DT) and accompanying Problem Checklist,[13] which will inform the development of a care plan to address the issues identified through the screening and second-line inquiry. The care plan will facilitate provision of care tailored to the specific needs of patients and promote continuity of care across care settings and providers, including with health care professionals (HCPs) in the rural and regional areas.

The screening and problem checklist will act as a trigger for frontline staff to inquire about, and discuss the cause/s of, distress with patients whose distress levels are above the recommended cut-off of 4 or more out of 10.[23~~1~~] Training for frontline staff will focus on discussing the cause/s of the distress, developing a ~~an evidence based~~ psychosocial care plan to address identified concerns~~,~~ providing information and/or basic counselling, or referring patients with significant or persistent distress to the psycho-oncology service, and facilitating continuity of care, including linking patients with hospital and community services as required. St~~st~~aff will also assist patients with access to self-management information on tablets which will be available during their hospital visit. Long-term sustainability of these service changes will be promoted through organisational leadership and management support, engagement of cancer clinician leaders in each unit in the design and evaluation of the service model, and development of a model with the aim of adaptability and flexibility to diversity of locations and patient complexity (eg through complex case review and revision of psychosocial care plans and active involvement of clinicians from rural locations in this process).[2~~2~~4]

Outcomes

The primary outcome is a system-wide increase in the proportion of eligible patients receiving care at the study facility who complete a DT and accompanying Problem Checklist (see Data Collection Methods) on at least one occasion and have a psychosocial care plan developed which complies with recommended care pathways. This outcome will be assessed at baseline, then at 12 and 24 months post-baseline (ie following the establishment of the new model of care – refer to Intervention section).

The secondary outcomes are: ~~is~~ a) an increase in the proportion of eligible patients receiving care at the study facility who report positive experiences of their cancer care at 12 and 24 months post-baseline compared to patients receiving care in this facility at baseline, and b) ~~.~~

~~The tertiary outcome is~~ an increase in the proportion of health professionals providing care to the eligible patient population at the study facility who report high levels of knowledge and confidence in responding to patients' psychosocial concerns at 24 months post-baseline compared to the health professionals caring for the eligible patient population at baseline. HCP satisfaction with the PACT intervention will also be assessed via interviews at follow-up, and

~~T~~the resource use and costs of the intervention will ~~also~~ be monitored~~,~~ by maintaining comprehensive logs of intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and ascribing the associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Table 1: Study design and data collection timeline

Time period	Data collection	Intervention delivery
Commencing at 0 months (March 2013)	Recruitment of baseline Health Care Professional sample Completion of Health Professional Knowledge and Confidence Survey	
	Recruitment of Patient Cross-sectional Sample #1 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	Development and delivery of communication skills training to health professionals PACT intervention delivery throughout the study period On-going monitoring of costs of the intervention (time spent in direct patient contact, on staff training, inter-professional case reviews and other communications required to support rural and regional providers)
Commencing at 12 months	Recruitment of Patient Cross-sectional Sample #2 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	
Commencing at 24 months	Recruitment of Patient Cross-sectional Sample #3 Completion of Patient Experience Survey Retrospective audit of medical and hospital records for consenting patients	
	Recruitment of post-intervention HCP sample Completion of Health Professional Knowledge and Confidence Survey	
	Recruitment and interviews with purposively sampled HCPs regarding acceptability of the PACT intervention	
	Retrospective review of Medicare and Pharmaceutical Benefits Scheme (PBS) claims data for use and costs of medical services and pharmaceuticals for the three cross-sectional patient samples (Department of Human Services data extraction)	
	Review of hospital's databases Assessment of set-up and on-going costs associated with the PACT intervention	

Recruitment

Patients

Three cross-sectional samples of current inpatients and outpatients will be recruited, at baseline, 12 months and 24 months, to complete a Patient Experience Survey (of their cancer care) and provide consent for access to their hospital and other medical records. The main purpose of these data collection phases is the evaluation of the impact of ~~system level~~system-level changes, rather than recruiting patients who will undertake the intervention.~~Patients will be recruited from inpatient wards and the outpatient clinics associated with the JHH.~~ During the study audit periods at baseline, 12 months and 24 months, the Research Officer ~~(RO)~~ will contact staff of the outpatient clinics and inpatient wards in which care is provided for urological and H&N cancers, on a weekly basis, to identify whether patients meeting the inclusion criteria will be attending those clinics or wards that week. The ~~RO~~Research Officer will attend those clinics and/or wards at which potential participants will be present, briefly introduce those patients to the study, answer questions, and provide interested persons with an Information Pack. The Information Pack will contain an Information Letter, a Consent Form for data to be obtained from Hunter New England Local Health District (HNELHD), a Consent Form for data to be obtained from the Department of Human Services, a Request for Summary of Study Results Form, a copy of the self-administered Patient Experience Survey and a Paperwork Return Checklist. Patients will be asked to take the Information Pack home to consider before completing the survey and consent forms and posting them back to the researchers, using a self-addressed reply paid envelope, within 10 days. Staff at the outpatient clinics and inpatient wards will also be supplied with Information Packs to distribute to eligible patients who attend the clinic when the ~~RO~~Research Officer is not in attendance.

Staff

Health Professional Knowledge and Confidence Survey

Two cross-sectional samples of HCPs involved in the care of patients with H&N or urological cancers at the study facility will be recruited during the study audit periods at baseline and at 24 months, to assess the skills development of clinical staff who work at the parent facility. At each time point, the ~~RO~~Research Officer will contact the Managers of the inpatient wards and outpatient clinics in which care is provided to patients with urological and H&N cancers. The Managers will be asked to identify the nursing and allied health staff members who routinely provide care to the patients of their respective wards/clinics, as well as each staff member's employment status as either permanent or casual. A list of HCPs eligible to receive an Information Pack will then be generated, and Information Packs sent via internal mail to the department at which each staff member is based. The Information Pack will contain an Information Letter and a copy of the self-administered Knowledge and Confidence Survey for HCPs to complete and post back to the researchers, using a self-addressed reply paid envelope, within 10 days. A second survey will be mailed to HCPs who do not return a completed survey within four to six weeks and a third survey will be sent to non-returnees four to six weeks after that.

Health Professional receptivity and acceptability interviews

At approximately 24 months (nearing study completion), purposively sampled allied health, nursing and medical staff will be interviewed by the ~~RO~~Research Officer about the acceptability of the key aspects of the PACT integrated model of psychosocial care (including screening, triage, access to psychosocial services/providers, clinical case reviews), perceived effectiveness of the model at improving care, and perceived impact of the staff training. The ~~RO~~Research Officer will send an Information Pack to those staff members who

meet the inclusion criteria. The Information Pack will contain an Information Letter, Consent Form and Request for Interview Transcript Form. Consenting staff will participate in a 20-minute telephone interview at a mutually convenient time.

Data collection methods

The primary outcome of system-level change will be assessed through audit of patient medical records, and through Medicare and PBS claims information for follow-up care sought via referral through the new model of care; the secondary outcomes of ~~acceptability of the model and~~ impact of the model on patient experiences and on HCP knowledge and confidence will be assessed via patient and HCP surveys. Acceptability of the intervention will be assessed via ~~and~~ HCP interviews; and ~~the tertiary outcome of~~ cost of the intervention will be assessed from information collected through Medicare and PBS claims information, as well as information logged pertaining to intervention activities (eg time spent by the CNC and Clinical Psychologist in direct patient contact, providing training sessions, engaging in case review) and their associated costs (eg CNC and Clinical Psychologist salaries and on-costs, materials used in training sessions, videoconferencing costs).

Medical records audit and Medicare and Pharmaceutical Benefits Scheme (PBS) claims information

At baseline, 12 months and 24 months, the files of all patients who provide their consent will be reviewed by the ~~RO~~Research Officer and an appointed research assistant who is not involved in the intervention delivery, to calculate the proportions of patients a) who have completed a DT and accompanying Problem Checklist at least once, b) who have had a psychosocial care plan developed, and c) whose management, including referrals, complies with recommended care pathways. A checklist will be used to achieve a systematic approach to extraction of these records. The coders (~~RO~~Research Officer and a second research

assistant) will initially review one file with the Clinical Psychologist to ensure consistency in understanding of the checklist and 10% of the files will be double-coded by the two coders to calculate inter-rater reliability.

Medicare and PBS claims information will also be extracted by the Department of Human Services for those participants who provide their consent, and will be reviewed by the health economist investigators (MH and RV) to extract information relating to psychosocial care delivered in a hospital or community health setting, by a private provider, or by a general practitioner.

Patient Experience Survey

A 35-item survey will include items assessing patient perceptions of care received, relating to the dimensions of emotional support, information, education and coordination of care. All items are phrased from the first-person perspective (eg *"I had confidence and trust in the staff treating me"*), to be answered using a 5-point Likert-type scale ranging from 1 = 'strongly disagree' to 5 = 'strongly agree'. A patient experience score will be aggregated based on the sum of selected responses. The survey contains 3 items from the Cancer Care Survey, [25] and 8 items from the Hospital Care – Overnight Patient Survey; [26] all adapted such that they could be answered from the first-person perspective. The survey also contains 10 items from the Critical Cancer Care Events Scale; [27] some of which required adaptation so that they referred to a broader group of health professionals than doctors, and all of which were adapted to be answered on a 5-point Likert-type scale (as described above).

The survey will also measure key *socio-demographic, disease and medical variables*, including age, residential location, gender, marital status, indigenous identification, languages spoken, country of birth, educational attainment, employment status, private health coverage,

income, cancer type, date of diagnosis, treatment received, recurrence status, and number of prior inpatient admissions and outpatient clinic visits.

Health Professional Knowledge and Confidence Survey

A 65-item survey will include items targeting health professionals' knowledge, skills and confidence pertaining to responding to patients' specific psychosocial concerns. The survey contains 12 items from a *Confidence in Communication Skills and Discussing Prognosis and End-of-Life Issues* module used by Clayton, Butow, Waters et al.[283] The survey also contains a case study and associated Care Planning, Monitoring and Review items from the Client-Centred Care – Training Needs Survey;[294] all adapted such that they refer to a patient with urological cancer and explicitly address psychosocial care. A Clinician Belief Scale is contained in the survey; based on the Physician Belief Scale,[3025] it contains all 32 items of the Physician Belief Scale, but has been renamed to apply to a broader group of health professionals than doctors, and items will be answered on a 5-point Likert-type scale ranging from 1= 'strongly disagree' to 5= 'strongly agree'. Finally, the survey contains the single-item Clinician Burnout survey, which is the Physician Burnout survey,[3126] renamed to apply to a broader group of health professionals than doctors. A knowledge/confidence score will be aggregated based on the sum of selected responses.

The survey will also measure key *socio-demographic, experience and training variables*, including age, residential location, gender, occupational specialty, number of years of experience in a) their current specialty and b) in cancer care, number of hours spent weekly in direct patient contact, indigenous identification, languages spoken, country of birth, and country of training.

Health Professional receptivity and acceptability interview

An interview will be scheduled with consenting participants to assess the acceptability of the key aspects of the integrated model of psychosocial care (including screening, triage, access to psychosocial services/providers and clinical case reviews), perceived effectiveness of the model in improving care, and the perceived impact of training. It is anticipated that the interview will take 20 minutes, with an audio recording being made for transcription purposes. An interview schedule previously developed by our team has been adapted for use in the present study, and ~~E~~examples of questions in the interview guide include: "Have you been aware of there being a more systematic approach to the provision of psychosocial care for people with H&N or urological cancers over the past year or so compared to previously?" and "What's your impression of patient/family member/caregiver attitudes toward the new model (eg acceptance)?"

Intervention costs

In keeping with the time series design, information about resource use and associated costs will be obtained at baseline, 12 and 24 month time points. Information will be obtained from the hospital's databases regarding emergency department (ED) attendance, triage category, whether the patient was admitted or discharged from the ED, and their diagnosis. Information about use and costs of medical services and pharmaceuticals will be obtained from Medicare and PBS claims data. Specific set-up and on-going costs associated with staff training, inter-professional case reviews and other communications required to support rural and regional providers, will also be monitored.

Sample size

Patients

Data from the initial twenty-five patient surveys completed were used to estimate the required patient sample size. The mean patient experience score at baseline was rated highly at 45 ~~(~~out of a possible 55~~)~~. Hence, the research team determined that a 5-point improvement between baseline and the last follow-up (24 months) would be a meaningful change~~Hence, at least 38 patients will need to be recruited at each time point to achieve a minimum clinically significant improvement of 5 points between baseline and last follow-up (24 months)~~, assuming a standard deviation of 7.58 (derived from current surveys), significance level of 5%, and power of 80%, with ~~at least 38 patients needing to be recruited at each time point to detect this change over time.

Health care professionals

Data from the first ~~twenty-eight~~ 28 surveys completed were used to estimate the required sample size. The mean score of knowledge/confidence was moderate at 61.5 ~~(~~out of a possible 105~~)~~. Hence, it was determined that at least 48 health professionals were required ~~will need~~ to be recruited at each time point to achieve a ~~minimum clinically~~ significant improvement of 10 points between baseline and follow-up (24 months), assuming a standard deviation of 17.13 (derived from current surveys), significance level of 5%, and power of 80%.

Data management

Data which are collected in paper format (i.e. patient consent forms, surveys and requests for study results, and health care professional surveys, requests for study results and interview transcripts) will be stored in a locked cabinet, accessible only by the ~~RO~~Research

Officer. Data which are collected in computer file format (i.e. data obtained through the Department of Human Services and Hunter New England Local Health District, and interview audio and transcript files) will remain in computer file format. In addition, computer files will be created for the entry and storage of participant details and survey responses. All of this electronically stored data will be maintained in separate, password-protected files, which will be stored on a password-protected local area network drive, accessible only by the ~~RO~~Research Officer and the chief investigators. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the ~~RO~~Research Officer and the chief investigators.

Data in paper format will be stored for seven years, while computer files will be stored for 15 years. All will be shredded by a contracted security waste disposal company at the conclusion of the storage period.

Statistical methods

Analysis of primary and secondary outcomes

~~In keeping with a focus on evaluating the feasibility of implementing a new service, it is essential to proceed in stages, with initial evaluation of a new model being devoted to performance monitoring and process studies, before moving on to studies that document impact.[27] Therefore, t~~This evaluation will focus on the impact ~~feasibility~~ and acceptability of the new model of care, with system-level outcomes being of primary interest. Cross-sectional ~~D~~data will be collected at baseline, 12 months and 24 months on the proportion of patients a) who are screened for distress at least once and~~,~~ b) who have a psychosocial care plan developed~~, and c) whose management complied with recommended care pathways~~.

Data ~~on points a) to c) above~~ will be collected at the three time points and analysed using Poisson or Negative Binomial regression depending on over-dispersion of the counts of each outcome. The Poisson/Negative binomial models will include a time variable (0, 12 and 24 months), a before and after variable, a term for the interaction of these two variables, and an offset variable which is used to adjust for the total number of patients consented at each time point. The interaction term will be used to estimate any difference between the two periods, which would indicate a slow improvement in the outcome during the intervention period. The before and after variable will be used to estimate the change in the outcome that may occur immediately after the introduction of the model of care. The models will adjust as appropriate for potential confounding variables such as age, gender, residential location, indigenous status, cancer type, and time since diagnosis.

Patient Experience and Health Professional Knowledge and Confidence

For patient experience surveys, a linear regression will be used to model the patient experience scores over the three time points to determine whether there was a significant improvement during the study period whilst adjusting for potential confounding variables (eg duration of care within the service, other psychosocial support services used, disease and treatment characteristics, age, and gender). Similarly, for the health professional knowledge and confidence surveys, a linear regression will be used to determine if there was a difference in the knowledge/confidence scores between the two time points whilst adjusting for potential confounding variables (eg other training in psychosocial care received, duration of employment in this service, prior experience, work role and time allocation, age, and gender).

Economic analysis

Estimates of resource use and costs will take into account the costs of implementation of the new model, but will not include costs of the evaluation/audit. At each time point (baseline, 12 months and 24 months), mean estimates of costs will be used and confidence intervals will be generated by boot-strapping the data. Benefits will be measured via surveys and interviews to ascertain the acceptability of the intervention and how the new model is experienced, as well as changes in clinicians' knowledge and confidence. Costs and outcomes will be reported separately at each time point and trends over time will be evaluated.

Qualitative analysis of HCP interviews

HCP interviews will be audio-recorded, transcribed verbatim, and analysed qualitatively. Inductive thematic analysis will be used to identify, analyse and report themes (or patterns) in the data (MapInfo Professional Version 8, MapInfo Corporation). Transcripts will be initially read and any words, statements, and/or paragraphs related to HCPs' views on the PACT intervention will be extracted by assigning a label or code. Similar excerpts will be identified by using the same code, with clustering of the codes denoting themes in the data. Data analysis will focus on a detailed description of emerging themes, with a focus on identifying the positive and negative aspects of the PACT model and strategies to support its ongoing implementation in the care facility.

DISCUSSION

This research program specifically addresses the objective of improving quality of care of patients with cancer and has been developed to address existing gaps in psychosocial care. The proposed program will provide a mechanism for delivering integrated, high quality, evidence-based cancer care that is embedded in routine practice, and responsive to the needs

of individual cancer patients by (1) systematically identifying patients' physical and psychosocial health needs, (2) developing care pathways and plans to address identified needs, (3) linking patients to skilled HCPs and appropriate services, and (4) coordinating on-going psychosocial health care. The project has a focus on translating evidence regarding psychosocial care into an integrated model that promotes the role of 'frontline' clinical staff, including those in rural settings, and will promote improved coordination and continuity of care for patients in rural and remote areas. Improving the psychosocial component of routine care, building distress screening into a model of routine care, and developing a psychosocial care plan for patients will enhance the acceptability and appropriateness of psychosocial care. Specialist services will be active in providing training, advice and support within an inter-professional team, and providing specialist assessment and treatment as a member of this team when needed. Addressing the process and outcome variables will support investigation of the quality of care provided from patient and clinician perspectives.

The proposed care model has the potential to address several unmet needs identified in key policy documents and surveys. Specifically, it will provide improved emotional support and information for both cancer inpatients and outpatients,[9] expand psycho-oncology services to improve access to specialised care,[197] and provide timely individualised support to the level and detail required for patients.[3228] In addition, this research program directly addresses the priority issue of delivering quality cancer care that addresses patients' physical and psychosocial health needs [6, 8] by bringing together the scientific evidence about the management of cancer patients' psychosocial problems into a model of patient-centred cancer care. Furthermore, it focuses on patients with urological or H&N cancers given their lack of research attention compared to their burden on the Australian community.[3329]

The translational capacity of this research program is enhanced through three major strengths. First, it is supported by a very strong collaborative team. Enhancing the role of

'frontline' clinical staff, defining pathways of care and promoting integration between major centres and rural clinicians entails a high level of support from clinical staff for objective implementation and evaluation. This project has strong support from the highest level of cancer service governance in our area, senior nursing clinicians and existing on-site psychiatric services. The linkage of the PACT model to Area-level network of psycho-oncology services will promote integration of psychosocial care into routine clinical care, promote continuity of care, and, through its clinician training model, improve the overall quality of care for patients and their families.

Second, the study utilises strong methodology appropriate for health services research. The evaluation framework and methodology ensures that the evaluation is sensitive to the role of general clinical staff, appropriate to the setting, relevant to stakeholders, inclusive and informative. Cost analyses will be undertaken to facilitate comparisons of costs and outcomes and changes in these over time; an important consideration as economics is an often overlooked element of interventional research. The close engagement of clinicians in the planning, implementation and evaluation will ensure maximum relevance of the project to the local context of clinical practice, including rural and remote settings. The built-in capacity for flexibility in the clinical setting (eg documenting and addressing local barriers to integration of psychosocial care) will promote translation to routine care, and potential applicability to other settings.[34~~27~~]

Third, there is strong support for integration of psychosocial care into routine care, and efficient use of specialist services. This project will provide important evidence for the effective use of existing resources for nurses and allied health professionals working in routine cancer care. If the outcomes of the research are positive, this will provide the basis for a model of implementing psycho-oncology services across other clinical services within this network. While the project includes the use of routine screening, it does so in a manner that

builds this into a model of care, so that these tools can support clinical practice within a model of integrated care, defined service pathways and support to distant sites. The work has substantial potential for translation into other cancer services beyond the research collaborators.

Despite the strengths, there are also several challenges for the research and evaluation. The target population is vulnerable and experiencing an acute stressor that may impact on recruitment. As the intervention will continue over a twenty-four month period, changes in health professional staff over that time may be substantial. Hence, some of the health professionals completing the survey at twenty-four months may have been minimally exposed to the intervention, hence potentially diluting perceptions of impact. Finally, health initiatives introduced more broadly into hospitals in the study location may affect the impact of this intervention, but are beyond the control of the research team.

ETHICS AND DISSEMINATION

Ethics approval

Research ethics approval has been obtained from the Human Research Ethics Committees of Hunter New England Local Health District and the University of New South Wales. Minor adverse events (eg a participant being tearful and distressed when talking with the ~~RO~~Research Officer) will be logged and fed back to the study team by the end of the study. Serious adverse events (eg expressing suicidal thoughts) will be reported immediately to the chief investigators and to the ethics committees. Any protocol amendments will be submitted to the ethics committees before these are implemented, and relevant changes will also be communicated to other relevant organisations (eg trial registry).

Confidentiality

The names of potential patient and health care professional participants will be entered into the study's password-protected administrative database, accessible only by the ~~RO~~Research Officer. Upon receipt of completed surveys and/or consent forms from participants, a study ID will be assigned to each participant, and recorded with identifying information only in the study's password-protected administrative database. Thereafter, survey, consent form and request for results data will be linked to participants only via the allocated study ID. There is no foreseeable reason for personal or identifying participant information to be shared throughout the conduct of the trial, except where required for adverse event reporting.

All of the electronically stored personal participant information will be maintained and destroyed in the same manner as all data collected throughout the study. On completion of data analysis and report writing, computer files will be transferred to CD-ROM, which will then be stored in a locked cabinet, accessible only by the ~~RO~~Research Officer. These will be stored for fifteen years, then shredded by a contracted security waste disposal company at the conclusion of the storage period.

Competing interests

As a Consultant Psychiatrist for the Consultation Liaison Psychiatry Service of John Hunter Hospital and a chief investigator on this project, BK may experience competing interests with respect to reporting the ~~feasibility~~impact, cost and acceptability of the new psychosocial care model. These potentially competing interests will be minimised and managed by having the other chief investigator, AG, primarily responsible for the conduct of the research and result reporting.

Access to data

The study's chief investigators (AG, BK), ~~RO~~Research Officer, Biostatistician, and Health Economists will have exclusive access to the final trial dataset.

Dissemination policy

The results will be widely disseminated through peer-reviewed publications as well as relevant health care professional and consumer publications. Oncology health care professionals and administrators within Hunter New England Local Health District will be invited to a face-to-face presentation of the results by the chief investigators. Presentations will be delivered at relevant national oncology and nursing conferences and meetings. The results will be reported to the funding body and other peak bodies with influence on cancer policy and practice, including Cancer Australia, Clinical Oncology Society of Australia, Cancer Council Australia, and Cancer Voices Australia. In addition, all research participants who request a summary of the study's key findings will be mailed one on completion of the project.

AUTHORS' CONTRIBUTIONS

BK and AG conceived of the study and are the grant holders. AB assisted in the initial study design and AP and DB provided organisational guidance on service model and implementation. BK and AG, along with the newly appointed clinical staff, developed the communication skills training, and HC will oversee the day-to-day study implementation according to the protocol. MH and RV provided guidance on data requirements for the economic analysis and will undertake these analyses. JD provided guidance on sample size requirements and will be conducting the primary statistical analyses. All authors contributed to refinement of the study protocol and approved the final manuscript.

ACKNOWLEDGEMENTS

The study detailed in this protocol is endorsed by the Psycho-oncology Co-operative Research Group (PoCoG), The University of Sydney, Australia. The study protocol and relevant documents have been reviewed by the PoCoG Scientific Advisory Committee and the Joint Community Advisory Group. Debbie O'Brien and Gai Shylan will play a central role in facilitating recruitment and implementation of the intervention, and Catherine Adams and Deanna Sue in the communication skills training of health professionals involved in the delivery of the PACT model of care.

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This work is funded by the Cancer Institute New South Wales (NSW), grant number 10/THS/2-08. This body had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

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

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	☑
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	☑
	2b	All items from the World Health Organization Trial Registration Data Set	☑
Protocol version	3	Date and version identifier	☑
Funding	4	Sources and types of financial, material, and other support	☑
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	☑
	5b	Name and contact information for the trial sponsor	☑
	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	☑
	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)	☑
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	☑
	6b	Explanation for choice of comparators	N/A

Objectives	7	Specific objectives or hypotheses	☑
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)	☑
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	☑
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)	☑
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	☑
	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)	N/A
	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	☑
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)	☑ Table 1

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	☑
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	☑
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	☑

	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	☑
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	☑
	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	☑
	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	☑
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	☑
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	☑
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)	☑
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	☑
	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	☑
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	☑
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	☑
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	N/A
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	☑
	31b	Authorship eligibility guidelines and any intended use of professional writers	☑
	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	☑

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