

Recruitment and consent in the palliative care setting.

Belinda Fazekas¹
Tania Shelby-James¹
David C Currow^{1,2}
Amy P Abernethy^{1,2,3}

¹Southern Adelaide Palliative Services, SA

²Department of Palliative and Supportive Services, Flinders University, SA

³Duke University Medical Center, North Carolina, USA

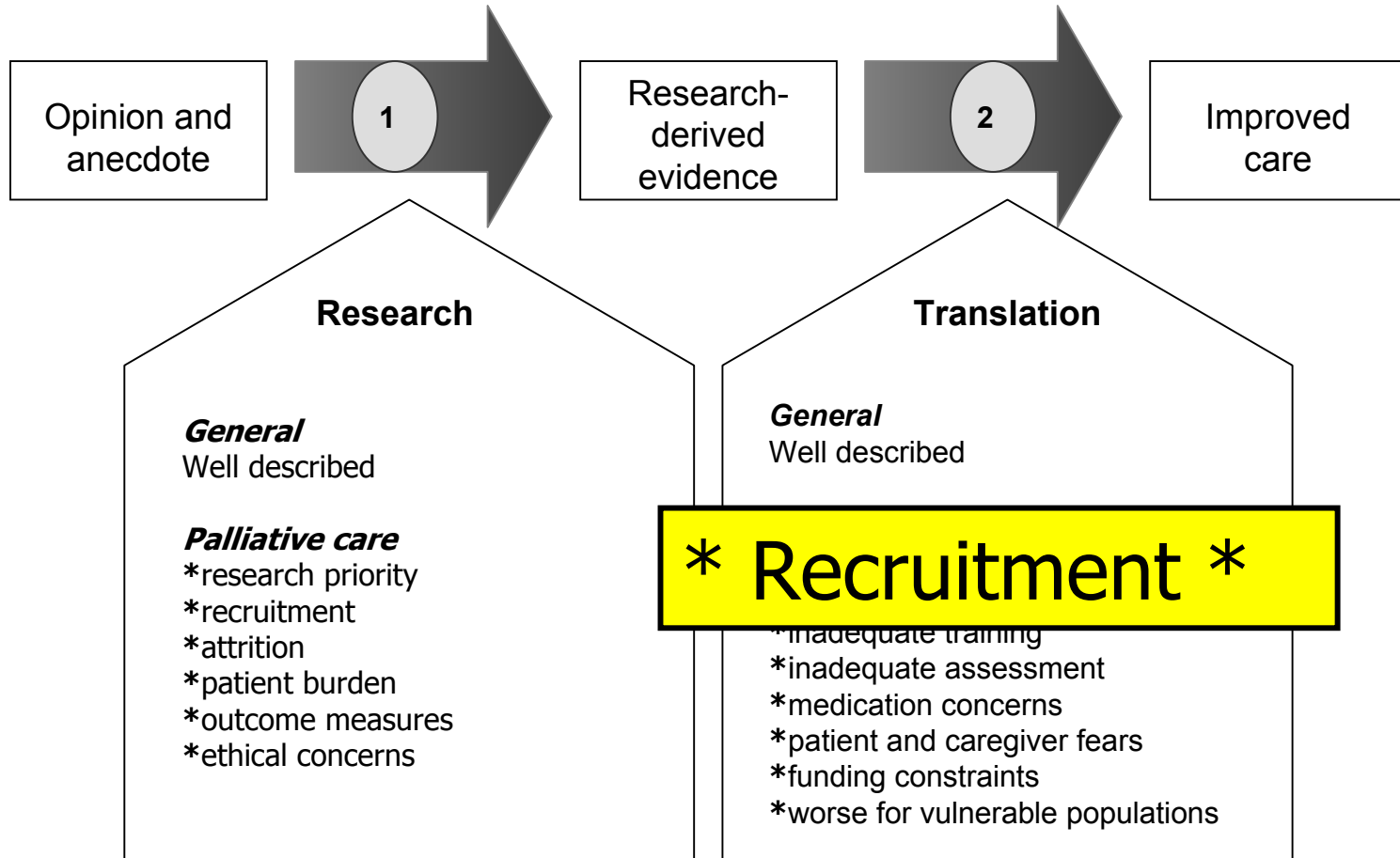


Ethics in Human Research Conference, May 2005



Research in Palliative Care

Barriers to high quality symptom management and palliative care



Barriers to recruitment

- Patient Population
- Formal and informal caregivers
- Ethical concerns

Barriers to recruitment

Patient population

- Frail, ill, nearing death
- Competing demands - doctors/nurses, families/friends
- Participation in research = constant reminder
- May not be able to fulfill requirements and may withdraw
- Questionnaires exhausting
- Die early, before completing follow-up assessments

Barriers to recruitment

Formal and informal caregivers

- Concern research is burdensome and upsetting
- No benefit to participant
- Research perceived as unnecessary intrusion at end-of-life
- Concern of false hope
- Ethical concerns

Gatekeeping

Barriers to recruitment

- Ethical concerns
 - Increased vulnerability
 - Decreased capacity to give informed consent
 - Consent documents can be exhausting and confronting

**Recruitment issues in Palliative care
require special attention!**

Setting

Southern Adelaide Palliative Services (SAPS)

- Large regional interdisciplinary specialised palliative care service with >1,100 referrals per year



Services population of
350,000

Demographically
diverse

85% cancer

Recruitment Strategies

System support

- Research and audit committee
 - Evaluation of new research proposals
 - Mentoring
 - Monitoring burden of proposed and existing research
 - Liaison with HRECs

Recruitment Strategies

System support

- Referral
 - Broad criteria for eligibility referral
 - Permission to contact
 - Eligibility screening by study staff
 - Reduces burden
 - Reduces gatekeeping

Recruitment Strategies

System support

- Marketing
 - Study start-up
 - Presentations
 - Study badging
 - Meetings with stakeholders
 - Ongoing
 - Newsletters
 - Websites
 - Progress letters

Buy in

Recruitment Strategies

System support

- Clinical staff involvement
 - Morning teas
 - Involvement in the study documentation and implementation
 - Inclusion on study groups (investigator, steering, reference)
 - Focus groups

Buy in

Recruitment Strategies

Study strategies

- Pilot studies
 - Test tools
 - Appropriateness
 - Burden
 - Inclusion and exclusion criteria
 - Test recruitment strategies

Recruitment Strategies

Study strategies

- Monitoring of Key Performance Indicators
 - Actual vs Projected recruitment
 - Allows early detection of recruitment problems
 - Can make early changes
 - Maintains momentum and awareness

Recruitment Strategies

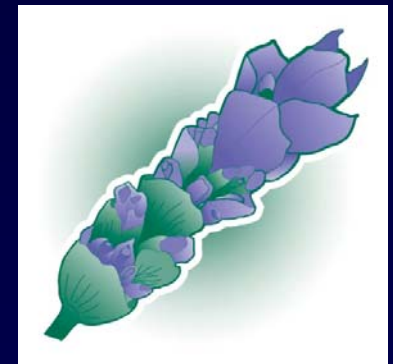
Study strategies

- Individual studies have specific strategies
 - Palliative Care Trial
 - Oxygen vs Air Study
 - Octreotide in terminal secretions

Recruitment Strategies

Study strategies: The Palliative Care Trial

- The best designed study will not be successful if participants are not enrolled and then retained
- PCT had an aggressive agenda and recruitment schedule
- Developed the foundation for system and study strategies based on systematic review of the literature
 - Multiple consent
 - Proxy consent
 - Recruitment nurse
 - Triage and referral
 - Scripting and role play



Recruitment Strategies

Study strategies: The Palliative Care Trial

- Referred to Service - 2,261
- Triaged for Trial - 1,948
- Screened - 614
- Consent - 461

Recruitment Strategies

Study strategies: The Oxygen vs Air study

- International agreement on strategies
- Scripting for
 - Referral
 - Consent
 - Equipment delivery

The logo for the O2 Breathe Study Group features the text "O2 Breathe Study Group" centered within a white rectangular box. The box is decorated with two large, overlapping, curved shapes: a blue one on the right and a pink one on the left, both with a gradient effect.

**O2 Breathe Study
Group**

Recruitment Strategies

Study strategies: The Oxygen vs Air study

- Referred - 84
- Screened - 78
- Eligible - 23
- Consent - 29

Recruitment Strategies

Study strategies: Octreotide in Terminal Secretions

- Consent from patient and carer
- Consent for study intervention when patient not able to withdraw
- Re-consent procedure

Recruitment Strategies

Study strategies: Octreotide in Terminal Secretions

- Referred - 232
- Screened - 232
- Eligible - 64
- Consent - 47

Summary

- Recruitment in large palliative care studies is possible
- Success is based on
 - Planning/piloting
 - Scripting and role playing
 - Buy in of all stakeholders
 - Monitoring of recruitment
 - System mechanisms for support

Key Messages

- Research in palliative care is possible
 - Should be conducted
 - Should be completed
- Patients have the right
 - To be asked
 - To be valued
 - To make own decisions

Proxy Procedure

- HCPOA or legal proxy
- Caregiver could consent on the patient's behalf provided that two letters were supplied to the PCT:
 - (1) a letter from the patient's GP advising that the patient did not have the mental or physical capacity to consent on his or her own behalf and that participation in the PCT was not contrary to the patient's best interests
 - (2) a letter from the caregiver attesting to the fact that he or she ordinarily made health decisions on behalf of the incapacitated patient
- Approved by 11 HRECs and IRBs