Better research, better palliative care for people with disabling breathlessness

"This is a research unit. This is what we do"

Winston Churchill Memorial Trust Fellow 2015

Miriam Johnson

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Educating doctors, improving care.

CONTENTS

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- Alex Clinch, Consultant Palliative Physician
- Gillian McCarthy, Research Nurse
- Marion Lieschke, clinical oncology trials nurse manager
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- Peter Hudson, Professor and Director of the Centre for Palliative Care
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- Wendy Muircroft, Consultant Palliative Physician
- Belinda Fazekas, National Project Officer for PaCCSC

2.0 GLOSSARY OF TERMS

COPD	chronic obstructive pulmonary disease
GP	general practitioner
HF	heart failure
HYMS	Hull York Medical School
MDT	Multi-disciplinary team
PaCCSC	Palliative Care Clinical Studies Collaborative
PCT	Palliative Care Team
PhD	Doctor of Philosophy
RCT	randomised controlled trials
RMH	Royal Melbourne Hospital
SAPS	South Adelaide Palliative Care Service
SEDA	Supportive care, Early Diagnosis and Advanced disease
SWSLHD	South West Sydney Local Health District

3. PERSONAL PROFILE

I am a Professor of Palliative Medicine at the Hull York Medical School. I direct the Wolfson Palliative Care Research Centre and am a Co-Director of the Supportive care, Early Diagnosis and Advanced disease (SEDA) Research group at the University of Hull. http://research.hyms.ac.uk/researchcentres/chaps/research/seda

My clinical and research interests include the causes of and management of breathlessness and how to reduce the inequalities in palliative care service provision. This last area mainly relates to the poor access to palliative care experienced by people with non-cancer conditions such as heart failure and respiratory disease. As many of these conditions cause breathlessness, the two areas clearly overlap. Unfortunately, it is still the case that most patients who receive hospice care have cancer even though people with other conditions experience as many difficulties.

I also work clinically, based at St Catherine's Hospice in Scarborough, providing a Palliative Care outpatient clinic in the Scarborough General Hospital, and an advisory service for inpatients in the hospital. https://www.stcatherineshospice-nyorks.org/.

In my clinical service, I set up one of the UK's first integrated palliative care services for people with heart failure in 2000, and I still run the palliative/cardiology MDT in the hospital. St. Catherine's Hospice is a research active service with experience of recruitment to several studies.

My research projects use a wide range of research methodologies: clinical trials of drug or complex interventions, qualitative studies (interviews and focus groups), observational, secondary data analysis, data linkage studies. I have collaborative partners across different disciplines and countries, but the collaboration with Prof David Currow, who runs the world's most successful clinical trials collaboration in palliative care, led to this Winston Churchill Fellowship. One of the big challenges in clinical trial work is recruitment of enough participants to be able to answer the question that the trial is aiming to answer. Therefore the opportunity to visit David in Australia was too good to miss.

4.0 EXECUTIVE SUMMARY

Successful recruitment to multi-centre clinical trials required commitment from the institution, the site principal investigator, research nurse and the clinical team. Study specific considerations were important. Multi-centre research was fostered by a formal collaborative between interested research active clinicians and benefited from a central infrastructure. Findings are directly applicable to the UK.

4.1 Institutional support and vision

- There must be an understanding that clinical service, education and research are inextricably entwined to prevent perpetuation of outdated practices and to ensure best patient outcomes.
- The time and resources required for research should be made legitimate and non-income generating collaborative projects supported as part of commitment to best practice.
- Palliative care services and research must be credible and responsive and earn the respect of the institution.

4.2 The principal investigator

- The most important factor in successful recruitment is an engaged PI, committed to the trial, with a good relationship with the research nurse and who runs a functional clinical team.
- The PI needs to be an inspirational, uncompromising and resilient leader who will confront and change the environment; prepared to oversee “the long game”.
- They need to model personally the necessary commitment
- Support for the PI must be available appropriate for the level of experience

4.3 The research nurse:

- is the indispensable bedrock of the team, (“no research nurse, no recruitment”)
- alleviates the clinical team of much of the work of data collection and supports the participant through the study procedures.
- needs both clinical and research skills; seen as integrated with the clinical team
- have support from other research nurses in palliative care or allied disciplines
- should be located in or close to the clinical unit if possible for ease of referral
- needs to have multiple contact points with the clinical team to ensure trials have a high prominence

4.4 The clinical team

- An understanding by the whole team that patient outcomes are best in a unit which is research active whether or not the patient is participating in a trial
- The clinical director must be committed to research, "This is a research unit....this is what we do".
- A clinical culture of evidence-based practice should be fostered with initiatives such as journal clubs and guideline groups
- Culture and attitudes may take time to change, and perseverance and consistency is needed
- Senior clinician recognition and support of the time and resources for research

- Research should be in clinicians' job descriptions
- The team should be resourced well enough so they can respond flexibly to enable swift recruitment of interested patients
- Regular review regarding service demands and configuration is needed to ensure research remains a central part of the service
- There must be an explicit expectation about participation in research, and obstructive and undermining behaviour challenged
- Minimise the additional research related work required of the clinical team
- Regular feedback of research trials and results is important to develop pride in being part of a research unit
- Exposure to research and research opportunities for specialist trainee doctors encouraged thus helping to develop a generation of consultants open to research

4.5 The study

- The choice and timing of study, making sure resources to conduct the study are in place.
- Assessing whether the unit has good access to eligible patients for the study
- Try to run several trials at once; patients may then go from one trial to the next, and the unit will maintain skills and keep research as a priority in the minds of the clinical team, keeping them motivated

Breathlessness studies

- Be able to respond quickly to get interested patients on to the trial
- Offer as many assessments as possible by phone or with a home visit
- Keep the follow up time as short as possible
- Keep study assessments to the absolute minimum
- Foster collaboration with relevant disciplines e.g. respiratory medicine

4.6 The role of PaCCSC

- PaCCSC provides a research community with peer review, advice and mentorship which encourages an increase in palliative care research capacity.
- Palliative care clinicians wanting to be involved in research are able to be part of and contribute to trials even if they do not feel able to be independent researchers themselves.
- The annual conference is a focus which helps to build this community and support network and is a forum where research ideas can be presented in a safe environment.
- The central PaCCSC office provides support with knowledge, standardised procedures and processes.
- There is a palpable sense of being part of something big, and of contributing to something important – especially when trial results come out with real answers to important clinical questions; "we helped find that out…", "we are part of changing practice round the world..".
- Multi-centre research is acknowledged as the only way to conduct large clinical trials which lead to relevant and generalisation results which directly inform everyday clinical practice.

5.0 INTRODUCTION

a. Breathlessness research in context

Millions of people in the UK and world-wide live lives which are severely limited by the symptoms of chronic, progressive medical conditions which will also cause their untimely death. Conditions such as cancer, chronic obstructive pulmonary disease (COPD) and heart failure (HF) cause breathlessness and other symptoms which affect work, family and social life. These are often experienced over months and years by patients and family caregivers and impact on health services. As the disease progresses, burdens may persist despite best management of the underlying medical condition. The number and proportion of people with these conditions is increasing.[1]

Traditional disease-directed health care models address breathlessness and its widespread affects poorly. In contrast, palliative care focusses on active care for people with advanced, progressive illnesses where the main goal is relief from the symptoms and stress of the disease. Needs-driven palliative care services should be available irrespective of diagnosis *alongside* treatment directed at the disease to allow patients and their family caregivers to be supported systematically as the disease progresses.[2-5]

Despite its importance, the evidence base in palliative care has lagged behind other fields of clinical care. Patients living with serious illness constitute a frail population at greater risk of side effects from a range of the very treatments which are intended to help.[6] [7] More international palliative care research is needed in order to develop, test and deliver effective and cost-effective interventions and services. The paucity of high quality expert researchers in this field in the UK has been highlighted; “Anecdotally, there are fewer professors of palliative medicine in the whole of the United Kingdom than there are professors of oncology at the Royal Marsden Hospital in London.”[8]

Breathlessness is a common and distressing manifestation of common chronic medical conditions. As the condition progresses, breathlessness becomes persistent at rest or on minimal exertion despite best treatment of the underlying disorder(s). If the breathlessness experienced by patients is not assessed systematically, it is often “invisible” to researchers, clinicians and even family caregivers; not “noticed” until it is bad enough to be easily seen and the patient comes to accept that nothing more can be done.

Breathlessness is a particularly frightening and serious condition. When it is bad people may fear they are dying. There are few palliative treatments to help breathlessness; we need better research to find better solutions.

b. Palliative care clinical trials studying breathlessness at the University of Hull

Our HYMS research group is a leader in breathlessness palliative care research, but we need large collaborative projects to help us get answers. I lead the Palliative Care Research Programme which is based at the University of Hull where we have

over 30 researchers working on palliative care studies. We have a developing track record of clinical and applied health research which includes randomised controlled trials (RCTs) of effectiveness for drug *and* non-drug interventions. Our work in this field has been recently recognised by an award from the Wolfson Foundation to allow the formation of the Wolfson Palliative Care Research Centre at the University of Hull. It is of note that my Winston Churchill Travelling Fellowship award was recognised as an indication of esteem in the application to the Wolfson Foundation.

Clinical studies of breathlessness

I have led, or contributed to the following clinical studies

1. Breathing training intervention in people with breathlessness due to lung cancer (phase 2 [initial testing trials] and phase 3 [definitive trials] RCTs).[9, 10] We showed that one session of breathing training was as cost-effective as three. Our service can now help three times the number of patients within the same resource.
2. The use of low dose oral morphine for breathlessness in heart failure and other conditions.[11-18] We showed that only low doses are need for benefit, that people with worse breathlessness are more likely to benefit.
3. The use of the hand-held battery operated fan for breathlessness.[19, 20] We have conducted trials with in-depth interviews to show that a simple, inexpensive and safe fan can improve the lives of people living with chronic breathlessness. One of these studies was conducted in collaboration with the support of the Palliative Care Clinical Studies Collaborative (PaCCSC).[20] One of my PhD students, Flavia Swan is currently writing up her thesis on this subject.
4. The role of breathlessness in attendance at the emergency department. One of my PhD students, Ann Hutchinson is currently writing up her thesis on this subject.

We are currently recruiting to, or preparing the following studies:

1. A trial of low dose morphine versus placebo for breathlessness in people with heart failure, funded by the British Heart Foundation
2. A trial of mirtazapine versus placebo for breathlessness due to a variety of conditions, led by Prof Irene Higginson at King's College London, funded by Marie Curie and building directly on the PaCCSC studies.

These studies represent enormous effort from the participants, clinical and research teams and I am therefore very keen to learn from other successful units how to improve completion and the study experience for the patients.

c. Recruitment challenges in palliative care research

Palliative care research is hard, and many studies in this area are small. Research including people with advanced disease is difficult and there are many examples of abandoned studies due to poor recruitment.[21] This is always a poor outcome; for the evidence base, and given the time and effort given, for the patients who did participate. The presence of breathlessness increases this challenge as it makes it

more difficult for patients to attend hospital or a research centre, or to complete exercise tasks, or even to fill out questionnaires.

However, the areas where careful attention is required have been described: effect of the workload of the clinical team; relationship with and culture of the clinical team; study design (simple, short, with minimal assessments).[22-27] Palliative care trials also have problems with missing data due to participants withdrawing from the trial (due to deterioration or death) or being unable to complete all the assessments. Recent work from our team has shown that shorter trials with shorter and fewer questionnaires are associated with less missing data.[28]

Further, although research is challenging for many reasons in a palliative care unit environment, the case for the importance of hospice involvement is well made by a recent Hospice UK commissioned report. ["Research in palliative care: can hospices afford not to be involved?" Professor Sheila Payne, Dr Nancy Preston, Dr Mary Turner, Dr Liz Rolls. October 2013. Available from: https://www.hospiceuk.org/what-we-offer/commission-into-the-future-of-hospice-care/commission-resources]

The trials conducted by PaCCSC are examples of good recruitment, where they have addressed many of these issues.

d. Palliative Care Clinical Studies Collaborative (PaCCSC)

PaCCSC is a national, multi-centre research network to support clinical studies in palliative care, funded by the Australian Government Department of Health, co-ordinated through the National Palliative Care Program at Flinders University. PaCCSC was started because of the poor evidence base for the medications used in palliative care due to the unique challenges of the frailty of this population and the challenge of how to measure both benefits and burdens of any intervention. PaCCSC randomised its first phase III (large enough to detect a different if one exists) trial patient in 2008 and to date they have recruited > 1700 participants to nine phase III clinical trials from 20 recruiting sites around Australia. This is the world's largest phase III study group in palliative care. Key completed studies include placebo controlled RCTs of ketamine for pain, octreotide for bowel obstruction, dexamethasone or megestrol acetate for appetite and morphine for breathlessness. Further trials in breathlessness are ongoing: the use of morphine in addition to pulmonary rehabilitation, and sertraline (an antidepressant) for breathlessness.

The Chief Investigator of PaCCSC, Professor David Currow, and I have collaborated in the field of breathlessness since 2008, firstly as members of an international breathlessness research group, and since 2010 as a growing research partnership. I had visited PaCCSC briefly in 2012, but only to meet the central PaCCSC co-ordinating team in Flinders University. Thus the opportunity to spend time visiting a selection of PaCCSC recruiting sites afforded by this WCMT fellowship was one not to be missed.

6. AIMS AND OBJECTIVES

I therefore went to visit PaCCSC to learn and bring back the successful components of their programme, e.g. recruitment and implementation strategies, to the UK where completed palliative care clinical trials of medication are still rare, and deepen UK led collaborator projects.

I aimed to learn in general and with regard to the breathlessness research stream:

- How PaCCSC sites embed research successfully into clinical practice at their centre;
- The views of research team members about the factors which contribute to consistently successful recruitment;
- How PaCCSC supports, funds and trains recruiting site clinical teams and how the structure, staffing and organisation facilitates this;
- How research results are disseminated and implemented; what challenges have been met and which approaches have been successful;
- The impact of their breathlessness research on patient clinical services

I spent four weeks visiting several recruiting sites to see if research is seen as part of daily clinical practice or a burdensome “add on”, ending up with time in the co-ordinating centre in Adelaide. At each site I met with the site principal investigator (consultant palliative physician), their research nurse(s), study co-ordinators, clinicians, and, where possible, the Directors of research at the institution.

I also spent time with Prof Currow to explore his experience of running a large multi-centre palliative care clinical trials initiative. As palliative care nursing is such a keystone in palliative care, I also visited Professor Jane Phillips, (Palliative Care Nursing professor and Chair of the PaCCSC Trials Management Committee), to understand how palliative care nurses have engaged with research.

After each site visit, I summarised the strategies discussed in each site, completed an analysis of key elements and sent them to the relevant people to confirm and for their own use and prior to including in this report.

7.0 PEOPLE AND PLACES

7.1. Sydney

Day 1

PaCCSC 7th Annual Research Forum
Program – Thursday 3rd March 2016
Dreamliner Room, Rooftop
Rydges Hotel, Sydney International Airport

Time	Presentation	Chair
9.30	*WELCOME TO THE 2016 PaCCSC ANNUAL RESEARCH FORUM:* *Professor David Currow*	
9.45	*INVITED SPEAKER:* *Name: Professor Miriam Johnson* *Hull York Medical School* Title: My trials experiences - the good, the bad and the ugly!	
10.30	MORNING TEA	

My aim during this Fellowship was to draw alongside the recruiting teams in several clinical sites recruiting to PaCCSC trials and hear about the good, the bad and the ugly of getting patients into trials, and keeping them there until it's finished.

My first fellowship day coincided with the PaCCSC 7th annual national conference where trial proposals are presented for feedback, and preliminary results of completed trials are presented. Each year the conference starts with an invited international presenter who will talk about their trials experience. This year it was me – hence in at the deep end. My title? "My clinical trials experience, the good, the bad and the ugly". I was pleased to find that my offerings were received with warmth and empathy as the delegates recognised similar experiences. It was a great way to introduce myself to many of the people I would be travelling around Australia to meet over the following few weeks, many of whom took the trouble to come and introduce themselves. The rest of the day was an inspiration, hearing about repeatedly successful trials completing, each bringing new knowledge to help inform clinicians treat patients at a very vulnerable time of life, when it is vitally important that we do not do more harm than good."

One particularly useful presentation was by the PaCCSC central office who presented an overall screen to consent ratio for all the PaCCSC trials to date – about five patients are screened for every patient consented. I was pleasantly surprised as that is in the same ball park, if not a bit more, for the trials I have run (depending on the trial). So maybe we're not doing so badly in the UK.

I was struck by the great team spirit, and leadership provided by David and other principal investigators such as Prof Meera Agar, and Prof Katy Clark. It was also impressive to see what they had achieved with the government funding for the clinical trials team. However, as the funding for PaCCSC infrastructure is short term only, every few years they have to reapply to continue. Much effort and time goes into this process which is starting up again as the funding for this world first unit runs out in 2017. Whilst it is important to require teams to be accountable and confirm value for money rather than an automatic, non-performance related manner, the effort required to maintain funding should not be underestimated.

7.2 Melbourne

Days 3 – 9

The choice of Melbourne as the first site to visit, was made for me by the invitation to give a plenary lecture to the 10th annual conference Australasian Cardiovascular Nursing College while I was in Australia.

My title was "The integration of palliative care into routine heart failure practice". As always, it was stimulating to talk with clinicians trying to incorporate excellent palliative care into their daily practice even though they are not palliative care specialists.

For the rest of the week, I had a full programme organised by Dr Brian Le, consultant palliative physician at the Royal Melbourne Hospital (RMH) palliative care

department. Since 2006 he has built a clinical palliative care advisory team in the RMH growing from a small team of two (himself and a clinical nurse specialist, Marian Allison), to the current vibrant service with four clinical nurse specialists, three consultants and their own in-patient unit.

Alexandra Clinch. Marian Allison. Brian Le. MJ. Amv Noble.

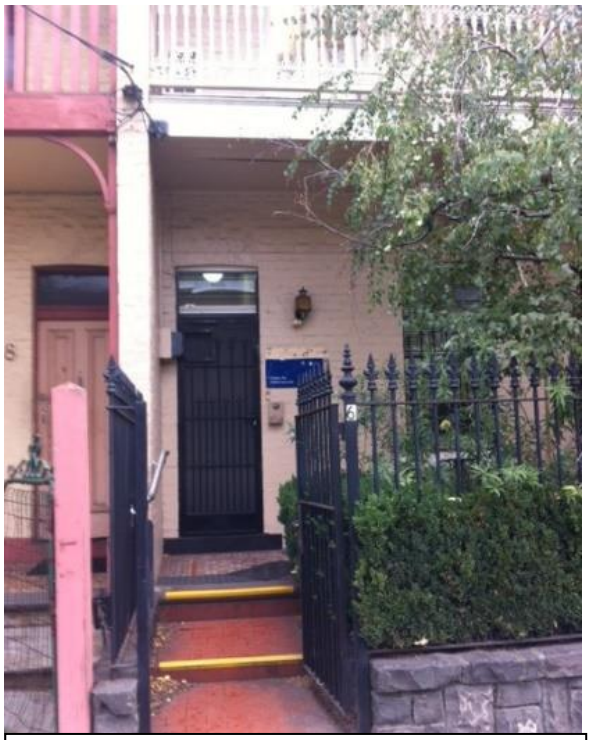
In addition they have become a training practice for doctors training to be specialists in palliative care, and taking part in the medical student teaching. Finally, they have become research active and have recruited successfully to PaCCSC trials (the delirium study, and morphine/oxycodone/placebo study for breathlessness). Brian is now principal investigator for a PaCCSC -supported feasibility trial to investigate dexamethasone for the treatment of pain.

Research capacity for palliative care trials has clearly grown over this time. Three strands have contributed to this: i) access to a very supportive oncology clinical trials infrastructure and a mentor in Mark Rosenthal, Director Medical Oncology, and Director Parkville Cancer Clinical Trials Unit - Royal Melbourne Hospital, ii) successful application for funding for, and recruitment of a palliative care research nurse (Gillian McCarthy) and iii) the PaCCSC. I had the opportunity to speak to Mark and ask him why he felt the palliative care research capacity had grown, and how this fitted into the trials context at the RMH. I then spoke with Marion Lieschke, clinical oncology trials nurse manager, who has had responsibility for Gillian.

The whole day's discussion was in the context of uncertainty. The new oncology centre is about to open accompanied by reorganisation of services, relocation of offices to new sites "over the road". In the new configuration, the palliative care research group will not be in the oncology trials unit although advice will be available. Gillian will no longer sit under Marion's line management, but be within Brian's, although access to ongoing professional development will still be possible as needed. Later on in the week I also spent time with Gillian. It was remarkable how her comments independently concurred with many I had already heard.

Whilst in Melbourne I also met with the St Vincent's (public and private hospitals) Palliative Care Team and spent time discussing development of research capacity in palliative care with Assoc/Prof Jenny Philip and Prof Peter Hudson, (Director) of the Centre for Palliative Care, (St Vincent's Hospital and Collaborative Centre of The University of Melbourne) and their two research nurses Lucy Barrack and Sally Kidd. It was good to hear another story of how the team have increased research capacity, with imaginative and committed ways to address the common issues of funding

shortfalls that result from participation in collaborative clinical trials. In this unit, the interested clinicians presented the case for the importance of research to the management, and suggested that funding shortfall for research nurses and other expenses was made up from the funds generated by private consultations at the private St Vincent's hospital. They are also a large training centre for doctors training to be palliative medicine specialists, and have been able to identify funds for a year's research fellowship at the end of their specialty training. Some of these doctors have gone on to do PhDs, and the team obviously take pleasure from seeing them develop their research interest and skills.



St Vincent's PCT Office

Research had arisen because of the research interests of Jenny and Peter. As they have research nurses in post, they are able to recruit to PaCCSC trials where a fee per recruited patient is paid rather than research nurse salaries. Although the PaCCSC trials do not directly impinge on Peter's work, he felt that the PaCCSC clinical trials had helped raise the profile of palliative care research and embed it in the clinical service which could see the benefit of taking part in trials. Having collaborative trials to contribute to as well as conducting their own pilot studies, had helped to nurture a culture of pride in being a research centre. The research nurses clearly enjoyed being part of the PaCCSC network of research nurses around the country working on the same studies and that attendance at the PaCCSC conference was valued.

7.3 Newcastle

Days 12 - 14

Professor Katy Clark heads up the palliative care team at the Calvary Mater Hospital in Newcastle which has a 20 bed in-patient unit, hospital in-reach teams and a community service covering a large geographical area. Since 2010, Katy has been conducting research in both the delivery of palliative care and the optimal approach to managing physical symptoms experienced by palliative care patients in the department. Her main interests are improving very end of life care and the assessment and management of gastrointestinal symptoms, especially constipation.

There are two research nurses at the Calvary Mater team: Naomi (trials co-ordinator and senior research nurse) and Abby (seconded from the palliative care clinical unit). Naomi joined the unit in 2009 when the clinical team at that time was not involved in research. Although challenges remain, this has changed considerably over time and there is a good relationship with the clinical unit housed on the floor below. They have a consistent recruitment rate to trials of on average of one patient

each month, which has been helped recently by the adoption of routine invitation to all new patients to be contacted by the research team. The importance of the PaCCSC community to the research nurses was again commented upon, with value of meeting face to face at the annual conference. Capacity building initiatives include a seed grant opportunity for interested clinicians to apply for backfill money for one day per week to free them to do a project supported by Katy. Palliative medicine doctors in specialist training are encouraged to participate in projects. The profile of research is also raised by taking up every possible teaching opportunity about trials in the community, going to GPs etc. Katy saw PaCCSC as pivotal in growing her as a principal investigator for multisite trials. It has provided infrastructure, peer review, support network for trial conduct and enabled her to gain an international and national profile. PaCCSC has led to strong relationships with colleagues who have also become friends. By recruiting to PaCCSC trials and taking part in the RAPID pharmacovigilance studies, she has been able to demonstrate compliance with the Australian Commission on Safety and Quality in Health Care, which in turn helps her institution see that involvement in research is good for the institution. Furthermore, the palliative care team has become a sought after place to work and train and its noticeable that they have had no trouble in recruiting consultants or filling their trainee places. This is unusual across the region. Katy feels that being a research and teaching unit helps raise standards and the profile of the unit.

MJ, Naomi Byfieldt and Katy Clark

7.4 Back in Sydney

Days 15 – 24

7.4.1 Westmead Hospital.

I was invited by Dr Tracy Smith to spend a morning with the respiratory team at Westmead Hospital, a major 975 bed tertiary hospital in Sydney. Tracy has dual training in respiratory and palliative medicine with an interest in breathlessness management and was aware of my work in the field. She has also just started a breathlessness service within the department along the lines of breathlessness services in some areas of the UK.

First, I presented the departmental lecture to a room full of respiratory doctors, nurses, physiologists and physiotherapists: “Chronic breathlessness: clinical practice

to research and back again". I then met with the breathlessness clinical staff before spending time with Sharon Lee, the Respiratory Medicine Research Manager. Sharon leads a team of research nurses who recruit to a variety of trials in respiratory medicine. Although they are not palliative care specialists, and the palliative care clinical team are not involved in research at present, Sharon's team are successfully recruiting to a PaCCSC trial comparing pulmonary rehabilitation and morphine with pulmonary rehabilitation and placebo, on breathlessness. This illustrated the potential for collaborating across disciplines where the research question was pertinent. A recurring theme across all sites visited so far was the importance of working with other specialties as many eligible patients were under the care of other teams. Whilst at Westmead, Tracy and I met with one of the palliative care consultants at the hospital who was thinking about getting involved in research, but felt he lacked knowledge and support. It was good to see him and Tracy talking about ways he could access the support of the established respiratory trials unit, illustrating how palliative care research can learn from other disciplines in the same hospital.

7.4.2 Liverpool Hospital, the Ingham Research Institute and Braeside Hospital

Clinical trials team, Ingham institute

Liverpool Hospital is located in the south-western suburbs of Liverpool, New South Wales. With 855 beds, it is one of the largest hospitals in New South Wales and one of the leading trauma centres in Australia. I spent two days visiting Professor Meera Agar and her team. Meera manages to juggle many roles: Director of Palliative Care, Braeside Hospital, Clinical trials unit, South West Sydney Palliative Care Service, the Clinical trials director at the Ingham Institute of Applied Medical Research as well as her recent appointment as Professor at the University of Technology, Sydney. Meera completed her PhD at Flinders University supervised by Professor David Currow and has become one of the world's most experienced clinical triallist in the challenging field of delirium in palliative care. She was chief investigator for the PaCCSC trial comparing two common drug treatments for delirium with placebo.

Until recently, Meera had had more clinical input at Braeside and it was clear that research was totally embedded there into clinical practice. The research nurses had an office immediately above the clinical area which made it easy for clinicians to inform them of potential participants. However, this is now changing due to service reconfiguration by the service providers. A recurring phrase during many of my visits was particularly pronounced at Braeside; "Research is just what we do". In the hospital, there was more of a challenge, where willingness wasn't as translated into second nature as yet. However, palliative care research clearly was a significant part

of the research of the hospital, helped by Meera's role as clinical trials director which had brought her respect from senior management and other clinical and research teams.

South West Sydney Local Health District (SWSLHD) (with Liverpool being its largest tertiary hospital) has made a large investment (governance structures, key profiled positions such as a trials director and manager and clinical trials pharmacist, enhancements for academic units) to support research in this area. This is a key strategy to improve health for its rapidly growing population, which is culturally and linguistically diverse, with areas of socioeconomic disadvantage, high prevalence of disease and health challenges. Commitment to ensuring that local people have the opportunity to participate in research, and "buy-in" to better outcomes for patients attending research active units even if not directly in a study.

On the first day, Meera had asked me to present the Ingham Seminar, which was the monthly research seminar, attended by a variety of clinicians and academics. My title was "Breathlessness research - state of the art". Following this I had the opportunity to talk with the Chief Operating Officer of the Ingham Institute, Associate Professor Greg Kaplan, and Associate Professor Norbert Kienzle, Manager and Strategic Development Executive for translational cancer research at the Ingham Institute for Applied Medical Research, and Professor Delaney, Director of Cancer Services for the SWSLHD and Director of Liverpool Cancer Centre. This helped me see how Meera had been able to position palliative care research securely in such a major cancer clinical and research facility.

7.4.3. Sacred Heart Hospice, St. Vincent's

Starting as a palliative care cottage for the terminally ill in 1890, the Sacred Heart Hospice, St Vincent's, has grown to one of the largest services in Australia, with a 39 bed inpatient unit, a 24 hour community and outpatient consultative service in Eastern Sydney, a day centre, community and respite programmes. Care of the dying, bereavement to rehabilitation and research are all aspects of the service and seen as equally important. A consultation service is provided to St Vincent's Hospital Sydney which is situated next door. The team is led by Assoc/Prof Richard Chye, who is also the principal research investigator although he describes himself more as a "research facilitator" rather than a researcher. He was not always involved in research, but became convinced over time that research is vital to provide answers to clinical questions and to continue to challenge accepted practice. He felt that PaCCSC provides the opportunity to be part of and contribute to trials even if you do not generate the protocol yourself. It provides a research community with peer review, annual conference and a support network particularly for research nurses.

There are two research nurses at Sacred Heart, Frances Bellemore and Penny West, who were under Prof Jane Phillips' management until she took up a position recently in the University of Technology, Sydney. Jane's commitment also encouraged an increase in the engagement of the clinical team in research, especially by facilitating an evidence based approach in nursing care. Frances and Penny are now managed by the clinical nurse team which helps to embed them further into routine practice as that baseline commitment to research is now there. It was a particular pleasure to meet up with Frances and Penny, as, I had jointly run a

trial of the hand-held fan for breathlessness with Jane and David the previous year recruiting between Australia and England. Sacred Heart Hospice and St Vincent's Hospital was one of the recruiting sites, and so it was great to have the opportunity to thank the nurses in person for their hard work in helping recruit to that study. We were able to discuss the particular challenges of recruiting to that study – which was hard as the breathless patients were often too unwell to tolerate many study measures.

St Vincent's attracts a significant amount of donations which, as palliative care services are 100% state/territory funded in Australia (unlike the UK), are not put towards clinical services. Richard has found a use for them in ensuring that the research nurses are employed even if the per patient recruitment fee from PaCCSC studies does not cover the wages or other institutional costs. However, in order to drive home the key role of the research nurse, Richard reminds his clinical staff regularly that it is important to identify a regular flow of study participants, to maintain the nurses' funding. A repeated comment from various principal investigators was that the research nurses were crucial, and that without them, clinicians would not have time to participate in research. The nurses were valued by the team, who took pride in being a research unit, but sometimes the clinicians "forgot" that they still had a vital role to play, and it couldn't be left to the research team alone.

7.4.4. University of Technology, Sydney (UTS)

So, having already started collaborative work with Prof Jane Phillips, it was a great opportunity to meet with her following her recent appointment as Director of Centre for Cardiovascular and Chronic Care at UTS. Jane is developing an impressive team of researchers and clinical academics at UTS and has recently appointed Meera as Professor. I was able to spend time talking with her about her experience of changing the culture at Sacred Heart to be research active. In addition, she has taken up the Chair of the PaCCSC Trials Management Committee, and so has a unique insight into the overall role and function of PaCCSC in terms of fostering excellent multi-centre palliative care research, and the factors which can be a barrier or facilitate research at recruiting sites. I also met one of her post-doctoral researchers, Dr Tim Luckett, who is conducting qualitative research to investigate the experience of patients living with chronic breathlessness but who have developed self-management strategies which seem to be effective in preventing emergency department visits. I have been involved in developing the protocol for this study, and in other work we are building across our respective research centres, as there is so much overlap in the work we are conducting at the Wolfson Centre. Face to face meetings are always a good way to strengthen developing collaboration between units. One of the privileges of my

work is to meet people around the world who recognise the same research priorities that I do, and with whom it is exciting and stimulating to work.

7.5. Adelaide

Days 29 - 30

And so, the last few days of my Fellowship… what more fitting place than the South Adelaide Palliative Care Service (SAPS) and the central offices of PaCCSC. SAPS is Australia's highest performing research team within PaCCSC, sometimes recruiting as many as five patients per week to a variety of trials. SAPS provides a full range of specialist palliative care clinical services across a wide area with a 15 bedded inpatient unit (Daw House) on the Repatriation General Hospital site. Medical outpatient clinics and advisory inreach services are provided in the "Repat", Flinders Medical Centre, and Noarlunga Health Services (rather confusing "NHS" acronym for this Brit). Community nurse specialists support patients at home and work closely with the SAPS base, with offices alongside the inpatient unit. Ms Kate Swetenham, Service Director of SAPS explained how research was inextricably integrated into their service. She described the three strands of clinical, education and research, described initially by Dame Cicely Saunders, as mutually dependent elements required to provide an excellent clinical service and the best outcomes for patients. Without active involvement in research, education and clinical practice becomes outdated very quickly. With research, the necessary systematic approach to documentation and practice becomes incorporated into care whether or not the patient is on a trial, and fosters an ability to constantly evaluate practice. The recognition that patient outcomes were better if they were cared for by a research active unit, something confirmed in published literature, was clearly a message which had been taken to heart by many of the sites I visited.

The SAPS research co-ordinator, Mrs Aine Greene, had laid on a full programme including the suggestion that I present at the hospital Grand Round to a group of clinicians and academics. I was happy to give something in return and ended up not only presenting at the Grand Round "Breathlessness research: what's new?", but also presenting to the Aged Care team on "Integrated palliative care for people with heart failure", and doing a recorded

Daw House Hospice Foundation Tree Project

interview on “chronic breathlessness” with one of the Lecturers in Palliative Care at Flinders University. This video is now being used as part of their course, and I have brought back a copy to use in our own junior doctor induction at St Catherine’s Hospice, Scarborough.

I was able to spend time with the clinical team and spoke with five of the consultant palliative physicians about their experience of working in a research active unit. They provided a, by now, familiar account of “research is just something we do”, and that working closely with the research nurses, but also with other medical disciplines (two consultants practised in sleep medicine, and geriatric care respectively, which gave access to more potentially eligible patients). They gave much credit to the team of research nurses, Vera Margitanovic and Urska Cosic, and Aine, saying that they took much of the workload, and that systems were in place to streamline the process of patient identification. At SAPS, every new patient is asked if they would be happy to sign consent for one of the research team to contact them about the studies ongoing at SAPS. This means that the research team are able to directly contact patients who could be eligible for trials, rather than depending on clinicians to remember to ask during busy clinics. This has the effect that patients are routinely offered the opportunity to participate rather than have this decision, either made for them in a paternalistic fashion by staff, or simply overlooked. It is notable that the vast majority (in the region of 80%) of patients agree to be contacted about trials confirming recent awareness that patients want to make this decision themselves.

Aine was clearly pivotal to recruitment success, being a constant, experienced and authoritative presence; raising awareness of ongoing trials. Like Richard in Sacred Heart, she reminded the clinicians regularly that a certain number of recruits per week was required in order to generate sufficient per patient recruitment funds to support the research nurses. She has been a key member of SAPS since it became a research site, and her crucial role has been recognised in the light of her planned retirement – succession planning is important. The need for constant review, and the risk of resting on the laurels of historical success, was highlighted in the context of a major service re-configuration occurring as a result of a new hospital build in Adelaide. When I visited, the clinical service was not sure where its physical base would be, and this was a cause of much uncertainty and speculation about the running of the clinical service and how this would impact upon their research.

Two other factors were highlighted as key factors in their success; the physical proximity to the central PaCCSC team of trial co-ordinators and data managers (in the same building), and the driving force of David as the Chief Investigator and instigator of PaCCSC, although he no longer has a clinical role in SAPS.

Belinda Fazekas

So, in the light of my travels round a variety of PaCCSC sites, I was keen to talk with Belinda Fazekas, the National Project Officer for PaCCSC. She was able to give me a potted history of the development of research at SAPS. She sees the appointment of David Currow to Flinders University and SAPS in 2000 as the watershed. Although there had been some research prior to this

time, the main academic focus had been on education. Therefore, the arrival of a clinical academic who set up a clinical trials collaborative, having secured a large infrastructure grant from the Australian Government through the Department of Health, was the catalyst for a totally radical change of direction.

Belinda emphasised that this could only be done by an inspirational, uncompromising, credible leader who was not afraid to confront and challenge the *status quo*. David introduced research as an underpinning feature of good clinical care and the expectation that research was to be incorporated into the unit was made very clear. Very soon after appointment, a placebo controlled trial was started which had the effect of the unit making a systematic change very quickly. Belinda said, "this was not changing the temperature of the water so much as changing the water"; hitherto, evidence based practice was not high on the agenda. As a result, people either stepped up, or chose to move on and replacements were keen to take part in the venture. Over time the culture has continued to change so that research is now completely embedded in the clinical service and is looked on with pride by the team. Although David's physical presence on site reduced in 2006 due to additional appointments elsewhere, the systems and culture change meant that SAPS has continued to function as the highest recruiting site in PaCCSC.

From her position as National Project Officer she was able to offer her insights as to what made a good recruiting site, and what ensured cause for concern. She reiterated the need for multiple recruiting sites in order to complete the clinical trials in this patient population, and recognised the challenges inherent in that. Initial relationships made with face to face contact in addition to the annual conference were valuable, but as infrastructure money in PaCCSC is less than at the start, despite regular extension grants, these have to be limited to triggered site monitoring visits where there are concerns which changes the context. However, she felt that the annual conference was a great forum to celebrate the incredible work contributed by sites, and gave a chance to foster a sense of joint purpose.

I talked with the Chief Investigator of PaCCSC, David about how to increase capacity for research in palliative care and how to successfully embed research into clinical practice. He paid credit to the Australian Government's commitment to improving the evidence base and hence clinical care despite the challenges within current legislative and regulatory frameworks for prescribing in palliative care. He also commented on the dedication and commitment of the many clinicians around the country who contribute to the success of PaCCSC despite having to address shortfall in institutional costs themselves and working hard on top of busy clinical schedules. He also recognised the tremendous contribution by the patients, and often their caregivers as well, at the centre of it all; without the people who were prepared to contribute to a clinical trial at a difficult time of life, there would be no progress in our understanding of best

MJ, David Currow

treatment. He paid tribute to the PaCCSC national coordinating team that ensured processes were excellent and delivered high quality data.

We discussed the importance of training the next generation of researchers in palliative care, and it is of note that he supervised Meera for her PhD, and has also been very instrumental in Katy and Jane's development as a researcher. When asked specifically about how to complete a trial as quickly as possible, he emphasised the need to open a lot of recruiting sites, each of which needed a committed principal investigator and effective research nurses who minimised the impact on the clinicians' workload. Breathlessness trials afforded particular problems as clinicians often didn't "see" the problem of breathlessness until the patient was very unwell and there was a narrow window of opportunity to enter the patient on a trial if they wished. Therefore the recruiting team had to be very responsive, and be able to contact the patient on receipt of notice by the clinical team – an appointment at the end of the following week was not good enough.

8.0 FINDINGS

"Don't give up, or lose sight of the bigger picture. Be resilient and pick yourself up again and again." (Principal investigator)

8.1 Institutional support and vision

It was important that the service viewed research as a core function with a top down commitment to research; "This is a research unit....this is what we do". The "three strand" approach to service provision was a clear feature in sites that were recruiting well. A determined understanding from Senior Management at the Institutional, Departmental, and clinical team levels that clinical service, education and research should be inextricably entwined was considered to be paramount. In successful sites there was a clear appreciation that in order to provide cutting edge, continually improving clinical care, then ongoing education (both provided as outreach, and within the clinical team) was crucial. There was an understanding at this top level that this should be underpinned by research to make sure that outdated practices were not perpetuated. An evidence-based approach with excellent documentation and systematic use of patient reported outcomes as well as activity measures formed the bedrock for the best results for patients irrespective of whether an individual was participating in a trial. This attitude was put into practice by legitimising time and resources spent on research.

Support from the Institution was seen by site teams as very important whether this was a big hospital, or smaller hospice unit. The teams where recruitment was consistent tended to be those where palliative care research had become embedded, not only in the palliative care clinical service, but also seen as a legitimate research stream in units set in larger hospitals despite the lower rate of income from commercially sponsored trials. This latter point meant that the institution needed to determine that they would support the shortfall in costs provided by collaborative studies such as PaCCSC trials. Institutions found a variety of ways to do this; allowing oncology commercial trial income to underwrite losses, using private fees or charitable donations, grant applications.

In bigger hospitals, palliative care trials could be considered in competition with others in the same situation. In sites such as the Royal Melbourne Hospital, or Liverpool Hospital, it was apparent that the palliative care principal investigators were held in high esteem by those who made these decisions at an institutional level. At the RMH, initially it was perceived that palliative care was a small specialty in terms of research and needed to be part of a bigger whole. The Director of the Parkville Cancer Clinical Trials Unit could see that palliative care research had grown with such support, largely due to Brian's ability to learn and grow and attract external funding for his research nurse, and was now at the stage where an independent palliative care trials unit could be set up. At Liverpool, Meera, in her role as clinical trials director had raised the kudos and credibility of palliative care research by being useful to other research groups - solving problems and demonstrating useful skills – as well as by conducting excellent trials herself. A track record helped foster credibility and to be taken seriously in the institution.

8.2 The principal investigator

In order for palliative care research to become embedded in clinical practice, there must be an inspirational and uncompromising leader who will confront and change the environment. This is most often the medical consultant, but nurse leadership is also important, as seen by the leadership afforded by Jane in Sydney and Kate Swetenham and Aine in Adelaide. They need to be able to grow a team sense of pride in being a part of a research unit. Willingness to model personally the commitment and importance of clinical trial work by going over and above was often necessary. They also need to be seen as clinically effective and relevant; respected by other clinicians.

Some principal investigators reported that perseverance was needed over years and although some previously less engaged clinical staff became more open to the importance of research in palliative care, others remained less convinced, concerned about the time pressures and relevance of any research in the discipline. In other units, where the principal investigator was in a position of directing the team and being responsible for appointments, the expectation to participate in research was made clear; those who did not wish to be involved in research then tended to leave as a result of the changing environment. Replacements were with clinicians who were attracted by being part of a research unit. This approach takes a resilient leader who is prepared to oversee “the long game”.

The clear message was that the most important factor in successful recruitment is an engaged principal investigator, committed to the trial, and who runs a functional clinical team. The research nurse, no matter how good she/he is, cannot successfully recruit to a trial where the principal investigator is nowhere to be seen, or if there is not a good relationship between the two. The ability to take advice, and to have access to support, e.g. from more experienced principal investigators in oncology trials units, or other principal investigators in PaCCSC, was seen as important.

8.3 The research nurse

The research nurse was seen as the indispensable bedrock of the team, (“no research nurse, no recruitment”) alleviating the clinical team of much of the work of data collection and supporting the patient through the study procedures. Ideally, the research nurse should have relevant clinical experience as well as a genuine commitment to research, although research expertise should be given preference when appointing a research nurse over their clinical background if a choice had to be made.

In sites where research nurses had a background in palliative care, or oncology or other advanced conditions, they felt this helped the clinical nurses have confidence in them particularly with regard to communication skills and the ability to support the patient and recognise clinical problems. There was a perception that this helped overcome clinical nurse gatekeeping and helped the research nurse to be perceived as part of the team. Where the research nurse did not have a clinical background

perceived by the clinical team as relevant, the nurse had to work harder to win the respect and confidence of the palliative care nurses. Nurses with a relevant background felt that if they were a generic research nurse appointed to work on a particular study by an external body rather than being embedded in the palliative care clinical team, then it would be a very time-consuming and difficult task to get to that stage of relationship.

Goodwill in the clinical team was also fostered if the research nurse would help with clinical duties on occasion, although this must be seen as “over and above” rather than an expectation. Nurses felt that they had a particular role in fostering acceptance of research in the clinical team, working with clinicians over time. The development of exemplary supportive relationships with patient participants not only gave the patients a good experience of the trial, but this was noticed by the clinical team – members are then more likely to refer patients to the trial. They also considered that if a particular clinician persisted in not helping with research, then they would find a way to work round them whilst respecting their views. The ability to “choose your battles” and be nuanced in interactions with the clinical team was important.

Some research nurses were line managed by the clinical nurse team. Where research was already embedded in the clinical team, this was felt to be helpful, but not if there was a lack of understanding or antagonism with regard to the role. In larger units, the palliative care research nurses might be managed by a research nurse manager, e.g. in the oncology trials team along with many other research nurses, or have a palliative care research manager such as Aine. This was felt to be very useful, prevented isolation and provided support for ongoing professional development and training. It also allowed cross cover for holidays thereby preventing a hiatus in recruitment, or data collection. It was important to seek out and access structures already in place for research nurses in the institution, even if in another discipline, if possible. However, many units were small, and particularly in these circumstances, the PaCCSC research nurse network was considered invaluable, and the monthly phone conferences for trials arranged by PaCCSC was commented on as helpful.

Geographical location of the research nurse office was very important. Where this was located in or close to the clinical unit, this enabled the trials to have a high prominence and acted as a reminder to the clinical team to look out for potential recruits daily. Also, if the office was close to the ward, then the doctors tended to “pop in” on their way past to tell the nurses about a potential recruit. In turn this helped the nurses to respond very quickly which was considered very important by all the nurses, given the unstable clinical situation of many potential patient participants – again, especially those with breathlessness. One team was aware they needed to put in effort to overcome the fact that their offices are "over the road" and not directly in the clinical unit by maintaining a high visible profile in the clinical team – e.g. going to clinical MDT meetings even if 90% might not be directly relevant.

8.4 The clinical team

The first response about how to embed research into the clinical team was always about the need to have top down commitment to research from the clinical director - "This is a research unit....this is what we do". Sometimes there was such resistance to research that change could only happen with persistence and over time as “antagonists” retiring or moving elsewhere were replaced with newer doctors. One principal investigator told me that with successive appointments, the use of the discriminatory question "what do you think about the importance of research?", over time had replaced clinicians who struggled with the idea of research with those who are keen.

There were stories of direct undermining of recruitment to trials by medical staff in particular; of patients given the drug off label in the knowledge that the patient had consented to the trial; of patients being “talked out of the trial” (in contrast to the ethical imperative of non-coercion that accompanied their consent). Another site principal investigator described how such “bad behaviour” would not be tolerated; if there was an ongoing trial of an off label drug, then that drug could only be prescribed *off*-trial if the patient was ineligible, or did not consent to the trial when invited. Other management strategies were also used, e.g. ensure all doctors had contribution to research in their job description. In high recruiting sites, the expectation about participation in research was made explicit to medical staff, and a reminder given that *per* patient recruitment fees contributed to research nurse wages.

The newer doctors often had at least some experience of research either from having worked at a PaCCSC site as a specialist trainee. Such exposure to research meant that the new consultants were more open and committed to research. Some had also taken advantage of some of the research capacity building initiatives offered by some PaCCSC sites such as clinical fellowships for palliative medicine specialist trainees at the end of their training for a year to give experience of research. These fellowships were funded by the PIs in the recruiting sites in a variety of ways, e.g. private fees (St Vincent’s, Melbourne) or donations (Sacred Heart). There was a good track record of these research fellows going on to be involved in further research e.g. Meera. Even if the trainee specialists did not take a whole year for research, several were interested in doing a small project during their time with the PaCCSC site and often found valued help from the research nurse. This again raised goodwill for when the research team were looking to the clinicians to help find recruits.

Although there was an expectation of at least some experience of research during medical training, this was not the case for palliative care nurses. Therefore, it was also important to foster an evidence based approach amongst the clinical nurses, to help them see the relevance of research in providing the best care for their patients. Journal clubs, clinical guideline groups, link nurses for particular topics, were ways used to do this. This required the support of the nurse manager in order for nurses to be encouraged to go to these sessions. The research teams made great efforts to have multiple contact points with the clinical team and to work with the education sessions for nurses by having one meeting where the research team updated the staff on ongoing trials (usually with tea and cake, quizzes and prizes), both in recruitment but also to feedback results. This helped to develop a sense of pride

amongst the clinical nurses for being part of a research unit, and seeing at first-hand how patients often enjoy and benefit from the additional support that being in a trial often brings. Sites reported that the clinical nurses now actively identified patients for trials with much more confidence and enthusiasm. Thus, there was a repeated story of culture and attitude change amongst both medical and nursing staff from one of suspicion about research to one of great team pride in being a research clinical unit; “it’s just what we do".

Alongside the need for culture and attitude change was the recognition that the time taken to be involved in research must not be underestimated. Thus, initiatives to minimise the work the clinical team had to do, such as the research permission form in Adelaide, and the research leaflet in Newcastle allowed patients to be directly contacted by the research team. The relationship with the research nurse is key as noted above. Again, the importance of legitimising the time for research was emphasised in one unit, where the next available medical clinic was used for patient consent visits. This ensured that there was a responsive medical team available for medical reviews and consents where needed, and flexibility to accommodate patients so the window of opportunity to recruit was not missed.

There was a need for constant vigilance as staff changes and service configuration changes could both impinge on the success of recruitment, and the need for succession planning was commented on. Several services were facing imminent service change, and Braeside in particular could face a change in patient profile which could mean that many patients were not those eligible for PaCCSC trials.

8.5 The study

Choice of PaCCSC study and timing of study was important, making sure resources to conduct the study were in place and the time it takes to recruit to that particular trial properly was not underestimated. Some units had good access to eligible patients for some trials but not others, e.g. the RMH team chose the delirium study, and Morphine or Placebo study so they wouldn’t compete with other oncology trials, could recruit from medical wards and the respiratory unit with whom they were developing good relationships, and who did not have their own active research studies. This showed the RMH trials director that they could successfully recruit to trials, and were not affecting recruitment to other ongoing trials; this helped secure ongoing support from the Director.

Most units also tried to run several trials. Many PaCCSC trials have similar eligibility criteria, which helps patients to go from one trial to the next, and also allows the unit to maintain skills and keep research as a priority in the minds of the clinical team. It also helps to keep the research nurses motivated and busy. Careful consideration of the eligibility for each trial was made before deciding to run the trial at any particular site, as the site teams had a good idea as to whether they saw enough patients with that particular issue.

Breathlessness studies

I came with the particular remit to look at recruitment to breathlessness trials. Much of what I saw were generic considerations about recruitment to palliative care trials which were relevant to breathlessness trials, however, there were some issues that were seen as specific to recruiting to breathlessness studies.

Links with respiratory (including pulmonary rehabilitation) and sleep medicine clinicians (which often cared for people with respiratory disease) and oncology were important to be able to invite appropriate patients to participate. This allowed patients who were perhaps a little earlier in their disease trajectory and thus more stable to participate to be invited. Despite this, by the time patients and their clinicians noted troublesome breathlessness, the patients were often limited in what they could do and an intervention was urgently needed. It was also noted that patients with lung cancer now received successive lines of chemotherapy, and by the time they were breathlessness, they were very sick and often not well enough to participate, or deteriorated very quickly on trial. There were other groups which were also difficult to get on trial or to keep on trial such as those undergoing thoracic surgery, or transplants although they were undoubtedly symptomatic.
The breathlessness itself meant that it was important to ensure close parking facilities to the unit, or transport that included a wheelchair, so the journey was not an ordeal if the patient chose to come to clinic. Also, the ambient weather could have an impact as patients often suffered more in hot, humid temperatures; thus the hand-held fan study I was involved in recruited less well in Adelaide in summer when the weather was oppressively hot. Likewise, if the weather was very windy it made it hard for the patient to venture out – hence the need for flexibility about using telephone and home visit assessments to ensure as complete data collection as possible.

In general the following were considered important: i) having a quick response to getting interested patients on to the trial; ii) offering as many assessments by phone or with a home visit; iii) keeping the follow up time as short as possible; iv) keeping study assessments to the absolute minimum.

8.6 The role of PaCCSC

PaCCSC provided a research community with peer review, advice and mentorship which encourages an increase in palliative care research capacity. Palliative care clinicians wanting to be involved in research were able to be part of and contribute to trials even if they did not feel able to be independent researchers themselves. The annual conference was a focus which helped build this community of practice and support network and was a forum where research ideas could be presented in a safe environment, even for very junior researchers. The network was particularly for research nurses who could be in an isolated unit with little support from other research nurses. The central support from the PaCCSC office was invaluable, with their knowledge, standardised procedures and processes. The standard operating procedures and team operating procedures have been crucial for success, allowing PaCCSC sites to grown in number. This would not have been possible without the generous sharing by the Trans Tasmin Radiation Oncology Group. There was a palpable sense of being part of something big, and of contributing to something important – especially when trial results came out with real answers to important

clinical questions; “we helped find that out…”, “we are part of changing practice round the world..”.

Although collaborative trials were seen by institutions as “money losers”, the PaCCSC trials were accepted as a good way of getting palliative care research embedded in clinical practice to build evidence-based treatments.

Multi-centre research was acknowledged as the only way to conduct clinical trials which led to relevant and generalisation results which directly informed everyday clinical practice. The team spirit and cohesion seen in the sites who were participating in the collaborative takes years to develop, and although this can happen on a trial by trial basis, PaCCSC has the efficiency of multiple trials tapping into established relationships and experience.

9.0 CONCLUSIONS

I went to Australia to observe the characteristics of successful recruitment sites to palliative care studies. I found that researchers faced the same challenges that we did in the UK and therefore many findings are directly applicable to my own practice.

Successful recruitment to palliative care multisite trials is possible. However, this requires persistence and a firm belief and commitment from senior management of the recruiting institution through to the clinicians on the ground that research is integrally important and a core part of what they do to ensure excellent clinical service and education. Time and resources needed for research should be recognised and legitimised.

Research active units co-ordinated by a funded central office form a supportive network, allowing less experienced researchers to participate and “grow”.

To succeed, in addition to institutional support, an engaged principal investigator and a research nurse who work together well are crucial.

The choice of study and study design need to be considered carefully. Breathlessness trials are particularly challenging and need to be designed to ensure that participant burden is minimised. The trial team need to be able to respond to a referral quickly to allow an interested patient to participate while they are able.

Embedding research into clinical practice requires a culture change in many palliative care units, however, PaCCSC has shown that this can be done. The result is a series of clinical trials which have addressed everyday clinical problems about regularly used medications. The patients cared for by palliative care teams are at the most risk of unwanted side-effects from the very medications intended to help them. In order to make sure that patients receive treatments that do good rather than harm, we must continue the quest to conduct high quality research to identify effective and tolerated treatments; as David wrote in his call to arms,

“The evidence is that such research is feasible and an ethical imperative in continuing to improve the quality of the care we offer.”[6]

10.0 RECOMMENDATIONS FOR THE UK

Institutional

1. Foster a commitment to service provision based on Cicely Saunders' original vision of the "three stranded" approach; clinical service, education, research.
2. Consider the research strategy for the institution, recognise the resources required, and make them legitimate e.g. by including in job descriptions.

Principal Investigator

1. Identify a clinician committed to research who will lead and stimulate change, if needed, in the clinical culture and work well with the research nurse.
2. Access support and training, relevant to experience, from academic centres, collaboratives, NHS Research & Development support and the Research Design Service.

Research nurse

1. A research nurse is key to minimise workload on the clinical team.
2. Ensure multiple points of access to the clinical team
3. The research nurse should have relevant clinical skills, but above all, be committed to research.
4. Access support from other researchers, or networks such as the CRN nurses.

Clinical Team

1. Foster a culture of evidence based practice e.g. with regular evidence based education in journal clubs and use of clinical guidelines. This should be an aim for all palliative care units.
2. For those units where the decision has been taken to be involved in research, have a clear expectation that participation in research is "what we do"; part of the service provided to ensure patients have the opportunity to participate in studies.
3. Make sure the research team, especially the research team is visible and that the contribution from the clinical team is kept at a minimum for the specific study.
4. Foster a pride in being a research unit with regular feedback on studies, excellent care of study participants, and demonstrating good clinical outcomes for patients and carers.

Studies

1. Choose the study to fit the patient population and resources of the institution
2. Ensure a continuous flow of studies so skills are not lost and the culture of research does not ebb

Collaboration

1. Where possible contribute to multi-site research as part of the institution's contribution to the overall evidence base e.g. contact the CRN and local palliative care academic centres to ask about studies.

11.0 PRELIMINARY DISSEMINATION AND OTHER OUTCOMES

I have seen benefits from the Fellowship in addition to the skills I learnt with regard to study recruitment to breathlessness and other trials. Not only has this Fellowship fulfilled its promise with the aims and objectives with which I went, but the resulting collaborations and working together has outstripped them.

Disseminating findings

- On May11th, I participated in a Hospice UK national workshop on research in hospices. I was able to present a summary of my WCMT findings, and Hospice UK have requested a copy of my report. Hospice UK are "the national voice of hospice care in the UK, working closely with our members to support their work and to advocate and raise awareness of hospice care."
- I have been requested to share the report by my Trust Research & Development Department, who manage the research nurse across our two hospital sites.
- I am due to report to our hospice senior management team about my fellowship findings, and review the hospice's research readiness.
- On June 7th, I will be presenting the SEDA Seminar, University of Hull, reporting on my findings.

I will also send an executive summary of my report to:

- Manager of our Clinical Research Network for the Yorkshire & Humber.
- The National Council for Palliative Care
- CRN Palliative Care Specialty Groups in the UK
- The Supportive and Palliative Care Clinical Studies Group of the National Cancer Research Institute
- The National Director and Chief Investigator of PaCCSC as requested to submit with their forthcoming continuation funding application.

New connections

- Dr Nikki McCaffrey (health economist with the PaCCSC group at Flinders) has been introduced to our Centre for Health Economics at the University of York. She has now included a few days to visits our unit in Hull and York in her Australian Bicentennial Fellowship application. If successful, this will strengthen links between our institutions.
- Associate Professor Deborah Parker, has been put in touch with St Catherine's Care Home team in Scarborough. She will meet with one of the team when she visits the UK for a care home conference later in the year.
- A new collaboration with Meera Agar, Jane Phillips, myself and colleagues at HYMS at the University of York has started to develop a project to look at prevention and management of delirium in hospices.
- In Melbourne, I presented to a group of advanced palliative care trainee doctors. As a result of that, one has arranged to come and spend a 6 month research fellowship based with me in Hull, but also visiting my colleague Dr

Hogg in Glasgow. She will learn about palliative care in heart failure – of course, management of breathlessness will be a significant part of that.

Resources

- A copy of the recorded interview on “chronic breathlessness” with one of the Lecturers in Palliative Care at Flinders University is now being used in St Catherine’s hospice as part of the doctor and nurse induction.

Publications

- The chapter for the European Respiratory Society Monograph, “Management of breathlessness”, has been completed and accepted for publication. David Currow and I have also written parts of the chapter. This is a landmark publication by the ERS, recognising the importance of the provision of palliative care and management of serious symptoms for people with respiratory disease. It will be launched at the 2016 ERS Congress in September in London.

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APPENDIX A

Presentations

1. Sydney. PaCCSC 7th annual national conference: “My clinical trials experience, the good, the bad and the ugly”
2. Melbourne. 10th annual conference Australasian Cardiovascular Nursing College: “The integration of palliative care into routine heart failure practice”
3. Melbourne. Palliative care advanced trainees’ teaching: “The integration of palliative care into routine heart failure practice”
4. Sydney. Westmead Hospital Respiratory Departmental Presentation: “Chronic breathlessness: clinical practice to research and back again”.
5. Sydney. Ingham Seminar, Ingham Institute. “Breathlessness research - state of the art”
6. Adelaide. Daw Park Repatriation Hospital Grand Rounds: “Chronic breathlessness: clinical practice to research and back again”
7. Adelaide. Daw Park Repatriation Hospital Aged Care meeting: “The integration of palliative care into routine heart failure practice”