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A randomised control trial for Advanced care planning and symptom management: (plan EARLY study)

## A randomised control trial for Advanced care planning and symptom management: plan EARLY

Advance care planning is a process “whereby a patient, in consultation with health care providers, family members and important others, makes decisions about his or her future health care, should he or she become incapable of participating in medical treatment decisions.”

Singer PA, Robertson G, Roy DJ: CMAJ 1996;155:1689-92.

## A randomised control trial for Advanced care planning and symptom management: plan EARLY

Bottom Line...

3 months recruitment c. 850 patients screened  
2 patients consented

Many institutional staff and patient related barriers, but focus on methodological issues.

## What was successful

- Relationship building
- Engagement of ED staff – not sufficient for recruitment but areas of success
  - Endorsement of electronic record “alert” for ACPs
  - Co-ordination with chronic care initiatives
- Community engagement residential aged care facility training

ISSUE	IDEAL	CHALLENGES	ANSWERS
Primary outcome measure	Single validated measure	?Which PRO validated in this context	
Treatment of control arm	Standardised	<ul style="list-style-type: none"> <li>• SAS and POS 6 weekly</li> <li>• Is an intervention</li> <li>• What to do if symptoms or distress in control group</li> <li>• Usual care or ACP lite</li> <li>• Referral to SPC</li> </ul>	
Identification of population	Validated tool	<ul style="list-style-type: none"> <li>• Tool vs inclusion criteria</li> <li>• Disease based eg SPICT or more general</li> </ul>	

## Plan EARLY: What is the experience?

*Resuscitation bay 2, 92yo, CCF, RF, BIBA with increasing SOB, Sats 86% on RA, RR 32/min. All ED team members present.  
TI- 01:32:01*

Nurse: '[Patient's name] is in VF. Defib?'

[pause 4.9s]

Nurse: 'CPR?'

[pause 5.1s]

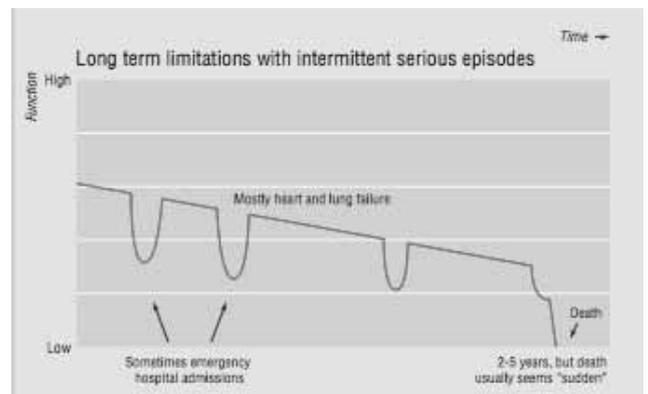
[Monitor now shows asystole]

JMO: 'CPR?'

[Monitor now shows reperfusion rhythm]

Consultant: [checking the MR] 'I'll talk to the daughter, see if they've discussed palliation'

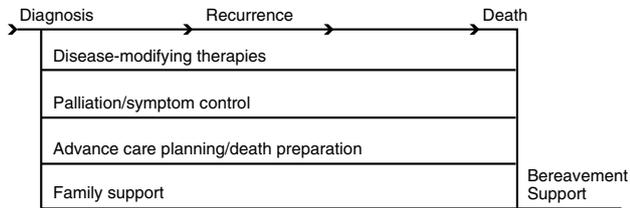
Slide courtesy of W. Varnell POWH ED UTS 2013 unpublished



Murray, S. (2005) BMJ (Clinical Research Ed), 330(7498), 1007–1011.

## Advance Care Planning needs based approach

### C. Mixed Management of Various Eventually Fatal Illnesses

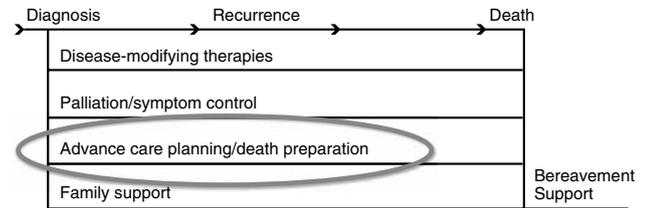


Cassell et al 1997 Committee on care at the end of life  
Institute of Medicine Washington DC



## Advance Care Planning needs based approach

### C. Mixed Management of Various Eventually Fatal Illnesses

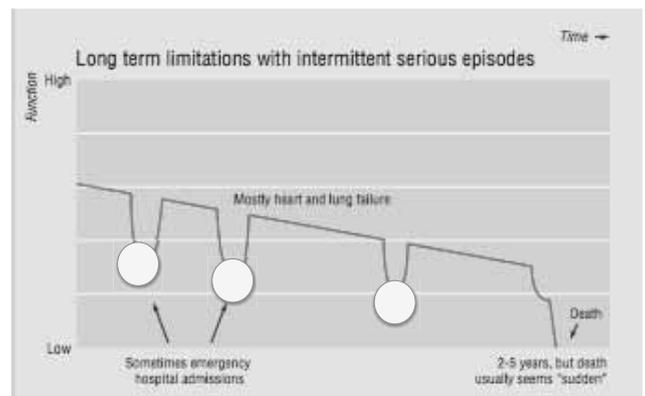


Cassell et al 1997 Committee on care at the end of life  
Institute of Medicine Washington DC

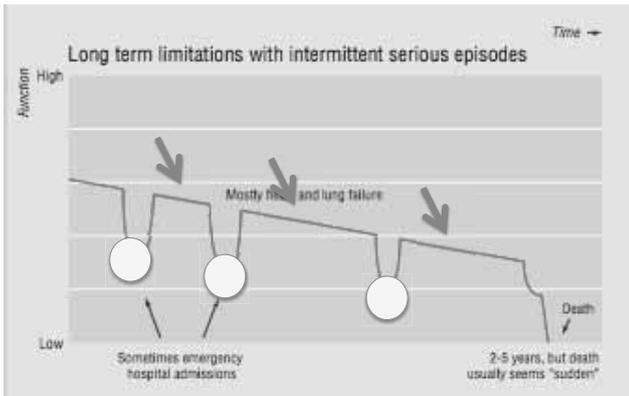


- 83% of patient deaths in our state registered an ED presentation in the last year of life .

O'Connell DL, Goldsbury DE, Davidson P, et al BMJ Open 2014;4:e004455.



## Plan EARLY



- A Randomised Control Trial for Advanced Care Planning(ACP) and Symptom Management
- 3 components in the same group of patients
  1. Patient intervention: ACP process – locally developed over 10yrs
  2. System intervention: Training to enable confident palliative approach (education, support, incl. last 72hrs)
  3. System intervention: Documentation/communication/ electronic resources (GP, med specialist, ED, Ambulance)

## Research Question

- Is the Plan EARLY intervention superior to usual care in terms of patient and carer outcomes and healthcare utilisation?

## Timeline

- July 2013 Human Research and Ethics Committee Approval
- July to November 2013 approval staff recruitment (institutional barriers)
- November 2013 to February 2014 development of project plan
- February 2014 to May 2014 pilot recruitment phase
- June 2014 suspension of recruitment
- June 2014 evaluation – ongoing

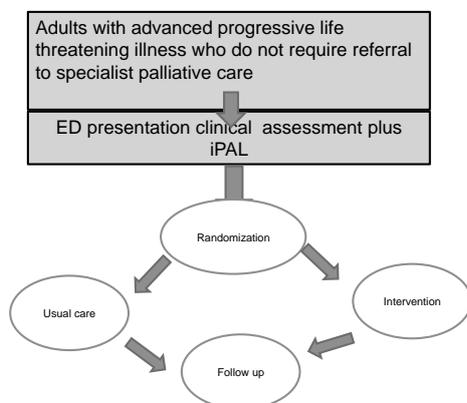
## STUDY DESIGN AND METHODOLOGY: Site and population

- Single site, unblinded, randomized control trial

## STUDY DESIGN AND METHODOLOGY: Inclusion and exclusion criteria

- Inclusion criteria: English speaking, competent, adult patients who present to POWHED with advanced progressive life threatening illnesses also meeting criteria identified by the iPAL-EM
- Exclusion Criteria: Pregnant women, prisoners, individuals with psychotic illness or severe mood disorders

## Plan EARLY study schema



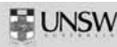
## STUDY DESIGN AND METHODOLOGY: Outcome measures

Primary endpoint is: Intervention Outcome Index (IOI) composed of

1. Symptom Management Score (SAS)
2. Palliative Outcome Score Patient (POS patient)
3. Palliative Outcome Score Carer (POS carer)

## STUDY DESIGN AND METHODOLOGY: Statistical considerations

- Given evidence for survival advantage with ACP we wished to power the study to detect clinically significant change in survival
- An overall sample size of 500 patients was required to detect of a 12% or larger change in survival,
- The study was powered for equivalence.
- The primary outcome measure requires a smaller sample size.



## FUTURE DIRECTION

- Review
- Redesign
  - Could simplify primary outcome measure to one item in patient or carer POS Q5
  - Setting admitted and clinic setting (ED v hard)
  - Population identification
  - Staff training
- Feasibility
  - Participant recruitment
  - Physician engagement and endorsement



### Plan EARLY Project Team

Christie Norris, RN  
Bobby Antoniou, RN  
Nichole Carter, RN  
Elizabeth Rogalski, JD  
Dr Meg Sands

#### POWH

- Dr Michael Golding
- A/Prof Gideon Caplan
- A/Prof Richard Chye
- A/Prof Patrick Bolton
- Dr Sue Hertzberg
- Anne Meller, RN
- UNSW Simpson Centre for Health Services Research
- Dr Roberto Forero
- Dr Blanca Gallano Luxan
- Dr Scott Walker



ISSUE	IDEAL	BARRIERS/ QUESTIONS	ANSWERS
Study design		RCT v pre & post	
Primary outcome measure	Single validated measure	PRO validated in this context	
Treatment of control arm	Standardised	<ul style="list-style-type: none"> <li>• SAS and POS 6 weekly</li> <li>• Is an intervention</li> <li>• What to do if symptoms or distress in control group</li> <li>• Usual care or ACP lite</li> <li>• Referral to SPC</li> </ul>	
Identification of population	Validated tool	<ul style="list-style-type: none"> <li>• Tool vs inclusion criteria</li> <li>• Disease based eg SPICt or more</li> </ul>	

## STUDY DESIGN AND METHODOLOGY: Outcome measures

### Secondary endpoints are:

- Survival from randomisation (no worse)
- Australian Modified Karnofsky Performance Status (AKPS) (no worse)
- Number of ED presentations
- Length of stay in the ED (hours)
- Number of hospital admissions
- Hospital admission length of stay
- Total case weight (NWAU)
- ICU admissions
- PACE call/TIER 2 ALS
- Number of ACP documented
- Progress along ACP continuum
- Concordance with desired place of death
- Utilisation of Terminal Care Plan
- Number of days that a Not for CPR order, NSW Ambulance Plan or NSW Health Resuscitation Plan was documented
- General Practitioner visits
- Referrals to specialist palliative care



## Primary Outcome Measure

### Q5. Over the past 3 days, how much information have you and your family or friends been given?

- 00 Full information or as much as wanted – always feel free to ask
- 01 Information given but hard to understand
- 02 Information given on request but would have liked more
- 03 Very little given and some questions were avoided
- 04 None at all – when we wanted information

### I. Patients with a Serious, Life-Threatening Illness\*\* and One or More of the Following<sup>1</sup>:

NOT SURPRISED

You would not be surprised if the patient died in the next 12 months, or if pediatric patient, will not survive to adulthood<sup>2,3</sup>

BOUNCE-BACKS

More than one ED visit or hospital admission for the same condition within several months<sup>4</sup>

UNCONTROLLED SYMPTOMS

ED visit prompted by difficult-to-control physical or psychological symptoms<sup>5</sup>

FUNCTIONAL DECLINE

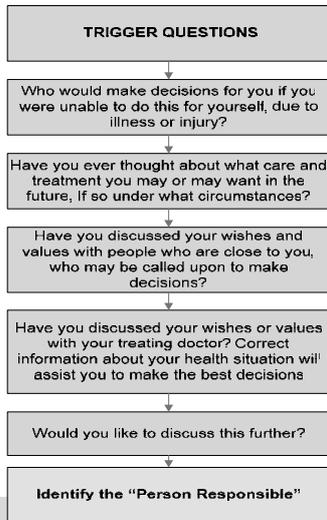
Decline in function, feeding intolerance, unintentional weight loss or caregiver distress<sup>6</sup>

INCREASINGLY COMPLICATED

Complex long-term care needs requiring more support<sup>7</sup>

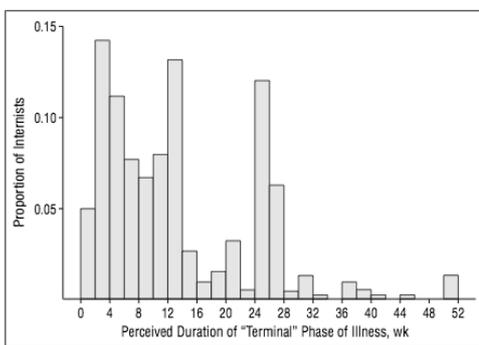
© 2011 The IPAL-EM Project, Center to Advance Palliative Care



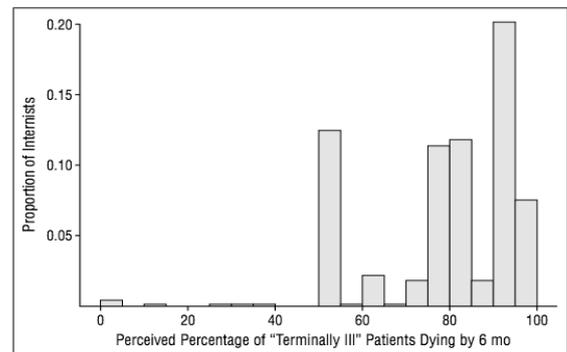


## Plan EARLY

- 3 components in the same group of patients
  1. Participant intervention: ACP process – locally developed over 10yrs
  2. Systems intervention: Training to enable confident palliative approach (education, support, incl. last 72hrs)
  3. Systems intervention: Documentation/communication/ electronic resources (GP, med specialist, ED, Ambulance)
- Versus "usual care"



**Figure 1.** Definition of terminal in terms of weeks left to live in a national sample of internists.



**Figure 2.** Definition of terminal in terms of percentage who had died by 6 months in a national sample of internists.

Christakis, N. A., & Iwashyna, T. J. (1998). Archives of Internal Medicine.

Christakis, N. A., & Iwashyna, T. J. (1998). Archives of Internal Medicine.

## When should these conversations begin?

- 43.7% US internists preferred to wait until asked to give prognostic information
- Patients believe physicians should bring up the topic

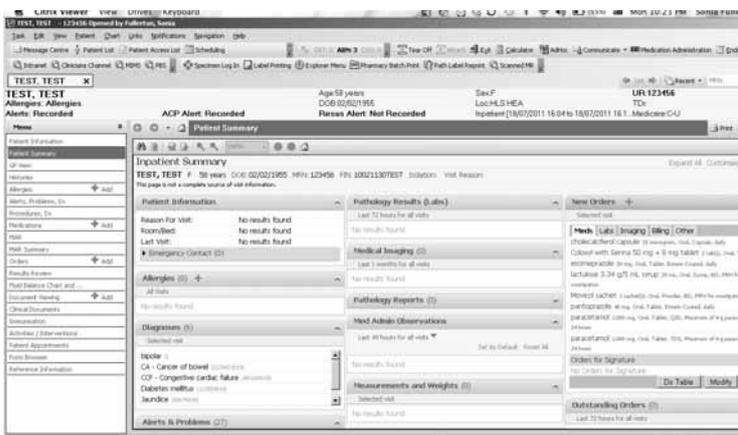
Lamont, E. B., & Christakis, N. A. (2001). *Annals of Internal Medicine*  
Steinhauser, K. E., (2001)



## When should these conversations begin?

- 43.7% US internists preferred to wait until asked to give prognostic information
- Patients believe physicians should bring up the topic
- Physicians tend not to communicate the formulated prognosis which tends to overestimate anyway
  - 26 days actual/75 formulated/90 day communicated survival

Lamont, E. B., & Christakis, N. A. (2001). *Annals of Internal Medicine*  
Steinhauser, K. E., (2001)



## ACP: What is the evidence? Staged discussion of future medical care

### Original Contributions

Around 50%

- of patients preferred to avoid CPR but their treating clinician was not aware of this preference
- The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT)

The SUPPORT Principal Investigators

**Objectives.**—To improve end-of-life decision making and reduce the frequency of a mechanically supported, painful, and prolonged process of dying.

**Design.**—A 2-year prospective observational study (phase I) with 4301 patients followed by a 2-year controlled clinical trial (phase II) with 4804 patients and their physicians randomized by specialty group to the intervention group (n=2652) or control group (n=2152).

**Setting.**—Five teaching hospitals in the United States.

**PUBLIC HEALTH** and clinical medicine during this century have given Americans the opportunity to live longer and more productive lives, despite progressive illness. For some patients, however, this progress has resulted in prolonged dying, accompanied by substantial emotional and financial expense.<sup>1</sup>

The importance of relationship building; documentation not enough

## A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients

The Study to Improve End-of-Life Care for Seriously Ill Hospitalized Patients (SUPPORT) Principal Investigators

**Objectives.**—To improve end-of-life decision making and reduce the frequency of a mechanically supported, painful, and prolonged process of dying.  
**Design.**—A 2-year prospective observational study (phase I) with 4301 patients followed by a 2-year controlled clinical trial (phase II) with 4804 patients and their physicians randomized by specialty group to the intervention group (n=2652) or control group (n=2152).  
**Setting.**—Five teaching hospitals in the United States.  
**Patients.**—A total of 9106 adults hospitalized with one or more of nine

PUBLIC HEALTH and clinical medicine during this century have given Americans the opportunity to live longer and more productive lives, despite progressive illness. For some patients, however, this progress has resulted in prolonged dying, accompanied by substantial emotional and financial expense.<sup>1</sup>



### ORIGINAL INVESTIGATION

## Death and End-of-Life Planning in One Midwestern Community

Bernard J. Hammes, PhD; Brenda L. Rooney, PhD, MPH

95% population in this county

**Background:** The major health care organizations in a geographically defined area implemented an extensive, collaborative advance directive education program approximately 2 years prior to this study.

**Objectives:** To determine for a geographically defined population the prevalence and type of end-of-life planning and the relationship between end-of-life plans and decisions in all local health care organizations, including hospitals, medical clinics, long-term care facilities, home health agencies, hospices, and the county health department.

**Methods:** For more than 11 months, end-of-life planning and decisions were retrospectively studied for all adult decedents residing in areas within 5 ZIP codes. These decedents were mentally capable in the 10 years prior to death and died while under the care of the participating health care organizations. Data were collected from medical records and death certificates. Treating physicians and decedent proxies were also contacted for interviews.

**Results:** A total of 540 decedents were included in this study. The prevalence of written advance directives was 85%. Almost all these documents (95%) were in the decedent's medical record. The median time between advance directive documentation and death was 1.2 years. Almost all advance directive documents requested that treatment be forgone as death neared. Treatment was forgone in 98% of the deaths. Treatment preferences expressed in advance directives seemed to be consistently followed while making end-of-life decisions.

**Conclusions:** This study provides a more complete picture of death, end-of-life planning, and decision making in a geographic area where an extensive advance directive education program exists. It indicates that advance planning can be prevalent and can effectively guide end-of-life decisions.

Arch Intern Med. 1998;158:383-390

BMJ

RESEARCH

### The impact of advance care planning on end of life care in elderly patients: randomised controlled trial

Karen M Detering, respiratory physician and clinical leader,<sup>1</sup> Andrew D Hancock, project officer,<sup>1</sup> Michael C Reade, physician,<sup>2</sup> William Silvester, intensive care physician and director<sup>3</sup>

<sup>1</sup>Resolving Patient Choices Program, Austin Health, PO Box 555, Heidelberg, Victoria, Australia 3086  
<sup>2</sup>Intensive Care Unit, Austin Health  
Correspondence to: K M Detering, Karen.detering@austin.org.au  
© 1999, BMJ 2003;368:1345-1350

**ABSTRACT**  
**Objective** To investigate the impact of advance care planning on end of life care in elderly patients.  
**Design** Prospective randomised controlled trial.  
**Setting** Single centre study in a university hospital in Melbourne, Australia.  
**Participants** 309 legally competent medical inpatients aged 80 or more and followed for six months or until death.  
**Interventions** Participants were randomised to receive usual care or usual care plus facilitated advance care planning. Advance care planning aimed to assist patients to reflect on their goals, values, and beliefs; to consider future medical treatment preferences; to appoint a surrogate; and to document their wishes.  
**Main outcome measures** The primary outcome was whether a patient's end of life wishes were known and respected. Other outcomes included patient and family satisfaction with hospital stay and levels of stress, anxiety, and depression in relatives of patients who died.  
**Results** 154 of the 309 patients were randomised to advance care planning, 125 (81%) received advance care

decisions,<sup>1,2</sup> resulting in patients being cared for in a way they would not have chosen.<sup>3</sup> This has continued to the present day.<sup>4</sup> Apart from progress in palliative care, the main focus to deal with these needs has been the development of advance care planning. Advance care planning is a process "whereby a patient, in consultation with health care providers, family members and important others, makes decisions about his or her future health care, should he or she become incapable of participating in medical treatment decisions."<sup>5</sup> The process of advance care planning informs and empowers patients to have a say about their current and future treatment. Advance care planning and the importance of improving end of life care are both supported by legislation in Australia,<sup>6</sup> the United Kingdom,<sup>7</sup> and the United States,<sup>8</sup> and are endorsed by professional bodies, including the Australian,<sup>9</sup> British,<sup>10</sup> and American<sup>11</sup> medical associations.  
Elements of advance care planning include clarifying a patient's understanding of their illness and treatment options; understanding their values, beliefs, and goals of care; and identifying their wishes. If required a

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BMJ

RESEARCH

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wishes followed 86% intervention versus 30% non-intervention

Less family stress, anxiety, depression in intervention group at 3mths bereavement

**Main outcome measures** The primary outcome was whether a patient's end of life wishes were known and respected. Other outcomes included patient and family satisfaction with hospital stay and levels of stress, anxiety, and depression in relatives of patients who died.  
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## Advance care planning and hospital in the nursing home

GIDEON A. CAPLAN<sup>1,2</sup>, ANNE MELLER<sup>1</sup>, BARBARA SQUIRES<sup>3</sup>, STELLA CHAN<sup>4</sup>, WENDY WILLETT<sup>5</sup>

<sup>1</sup>Prince of Wales Hospital, Post Acute Care Services, Sydney, NSW, Australia  
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Email: gcaplan@unsw.edu.au

### Abstract

**Background:** the number of nursing home residents (NHRs) in hospital is increasing although hospital admission may be deleterious to their health.

**Objective:** to evaluate a system of educating residents, their families, staff and general practitioners about outcomes of dementia, advance care planning (ACP) and hospital in the home.

**Methods:** we employed one clinical nurse consultant, who utilised the 'Let Me Decide' Advance Care Directive. The intervention area consisted of two hospitals and the 21 nursing homes (NHs) around them compared with another, geographically separate, hospital and the 13 homes around it. We conducted a controlled evaluation monitoring emergency admissions to hospital.

**Results:** emergency calls to the ambulance service from intervention NHs decreased (intervention versus control, -1 versus +21%;  $P = 0.0019$ ). The risk of a resident being in an intervention hospital bed for a day compared with in a control hospital bed, per NH bed, fell by a quarter from being initially similar [Relative Risk (RR) = 1.01; 95% confidence interval (CI) 0.98-1.04;  $P = 0.442$ ] to being lower (RR = 0.74; 95% CI 0.72-0.77;  $P < 0.0001$ ). There was no significant change in mortality in the intervention homes, but in the control homes mortality rose in the third year to be 11.2 per 100 beds higher than in the intervention area ( $P < 0.05$ ).

**Conclusion:** ACP and hospital in the home can result in decreased hospital admission and mortality of NHRs.

**Keywords:** nursing homes, advance care planning, living with advance care directive, dementia, hospitalisation, home care services—beneficial, based on evidence.

## Advance care planning and hospital in the nursing home

GIDEON A. CAPLAN<sup>1,2</sup>, ANNE MELLER<sup>1</sup>, BARBARA SQUIRES<sup>3</sup>, STELLA CHAN<sup>4</sup>, WENDY WILLETT<sup>5</sup>

<sup>1</sup>Prince of Wales Hospital, Post Acute Care Services, Sydney, NSW, Australia

### Mortality increased in control RACF by 11.2%

RR of hospital fell from 1.01 to 0.74 in intervention CI 0.72-0.77

### Abstract

**Background:** the number of nursing home residents (NHRs) in hospital is increasing although hospital admission may be deleterious to their health.

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## Aging, health expenditure, proximity to death, and income in Finland

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Proximity to death not age predicts health care expenditure

**Abstract:** This study revisits the debate on the 'red herring', i.e. the claim that population aging will not have a significant impact on health care expenditure (HCE), using a Finnish data set. We decompose HCE into several components and include both survivors and deceased individuals into the analyses. We also compare the predictions of health expenditure based on a model that takes into account the proximity to death with the predictions of a naive model, which includes only age and gender and their interactions. We extend our analysis to include income as an explanatory variable. According to our results, total expenditure on health care and care of elderly people increases with age but the relationship is not as clear as is usually assumed when a naive model is used in health expenditure projections. Among individuals not in long-term care, we found a clear positive relationship between expenditure and age only for health

Hakkinen 2008 also Zweifel et al 1999 Seshamani and Gray 2004 Stearns and Norton 2004 emphasize that even in the future, health care expenditure might be driven more