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# Adverse Events in Hospice and Palliative Care: A Pilot Study to Determine Feasibility of Collection and Baseline Rates

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## Abstract

**Background:** Continuous quality improvement is fundamental in all health care, including hospice and palliative care. Identifying and systematically reducing symptomatic adverse events is limited in hospice and palliative care because these events are mostly attributed to disease progression.

**Objectives:** The aim of this study was to assess the feasibility of symptomatic adverse events in hospice and palliative care and assessing their incidence.

**Methods:** A retrospective, consecutive cohort of notes from a specialist palliative care inpatient service was surveyed by a clinical nurse consultant for symptomatic adverse events: falls, confusion, decreased consciousness, hypo- and hyperglycaemia, urinary retention, and hypotension. Demographic and clinical factors were explored for people at higher risk.

**Results:** Data were available on the most recent admissions of 65 people, generating >900 inpatient days. Fifty people (78%) had events precipitating admission, of whom 31 (62%) had at least one further event during admission. Eleven of 15 people who were admitted without an event experienced at least one during their admissions. Only 4 did not have an adverse event. During their stay, there were 0.13 (standard deviation [SD]=0.19) events per patient per day. No drug-drug or drug-host events were noted. No clinical or demographic factors predicted groups at higher risk.

**Conclusions:** This pilot highlights the feasibility of collecting, and ubiquity of, symptomatic adverse events, and forms a baseline against which future interventions to decrease the frequency or intensity can be measured. Given the frailty of hospice and palliative patients, any adverse event is likely to accelerate irreversibly their systemic decline.

## Introduction

MINIMIZING SUFFERING is a key role espoused by hospice and palliative care services. Some suffering will be iatrogenic. Avoiding harm is a critical concern given that any deterioration is likely to cause at least some degree of irreversible deterioration in this population given people's frailty. On average in inpatient care, there is more than one medication error per patient per day.<sup>1</sup> Inpatient and community hospice and palliative care services are unlikely to have rates that are lower given that medications for symptom control are often simply added to medications for long-term comorbid

diseases,<sup>2</sup> leading at times to futile or inappropriate prescribing.<sup>3,4</sup> A previous report from this setting documented an average of five medications per person in hospice and palliative care for symptom control and comorbid disease management, peaking at more than seven regular medications in the days before death.<sup>2</sup> Given this number of medications, it would be expected that drug-drug and drug-host interactions<sup>5</sup> are frequently seen in the hospice and palliative care populations—a key, predictable cause of symptomatic adverse events. This may be magnified by the widespread “off-livence” prescribing in hospice and palliative care.<sup>6</sup> Individual therapies that may cause harm include medications that may

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cause prolonged QT interval or gastrointestinal bleeding, or parenteral fluids that may cause pulmonary edema. Estimates suggest that medication-related events are under-reported in hospice and palliative care, but occur frequently.<sup>7-9</sup>

A focus for quality improvement in health care is the identification and prevention of adverse events,<sup>10</sup> yet such documentation is not as frequent in hospice and palliative care as in other clinical settings. Progressive frailty, organ dysfunction, weight loss altering drug distribution, and polypharmacy puts the hospice and palliative population at higher risk of symptomatic adverse events. The rates of symptomatic adverse events, their impact on symptom control and overall patient function, and whether they could be more systematically avoided are unknown. Actively monitoring for such events becomes important if their likelihood is high, their consequences cause irreversible deterioration, or both, as in hospice and palliative care.

The need for a definition of symptomatic adverse events tailored to palliative care may make reporting easier and allow a composite measure to assess and monitor them. An adverse event in health is defined as an undesirable or unintended occurrence subsequent to a clinical intervention, and may indicate that a person has received poor-quality health care.<sup>11</sup> Such events, many of which are avoidable, do or could cause morbidity or premature death.<sup>10,12,13</sup> The Joint Commission on Accreditation of Healthcare Organizations' view is that these events should also be discussed explicitly with patients and their families.<sup>14</sup> In the hospice and palliative setting, the authors suggest that defining an adverse event should include that the occurrence renders symptoms, distress, or irreversible deterioration for the patient. This distinguishes *symptomatic adverse events* from disease progression of advancing disease. Using this definition, iatrogenic renal dysfunction would not be coded from laboratory results unless it also caused directly attributable symptoms.

There have been frameworks proposed to codify the preventive strategies being employed in managing active comorbid illnesses by incorporating: other associated risk factors that should influence the decision making, the prognosis of the person concerned, and the likely onset of consequences by reducing or ceasing medications.<sup>15-17</sup> Ceasing or reducing therapy for active comorbidities too early or too late may have dire consequences for the patient. For example, if someone has poorly controlled hypertension despite an aggressive antihypertensive regime on a background of two previous cerebrovascular accidents (tertiary prevention), ceasing this person's antihypertensives would risk a further cerebrovascular event thus increasing the likelihood that such medications should be continued into the terminal phase.<sup>17</sup> By contrast, for secondary prevention, if an antihypertensive medication is continued unmonitored while the person loses weight from disseminated cancer, this may lead to hypotension thus increasing the risks of falls with potential consequences including fractures or a subdural hematoma. Systems to identify rates and subsequent impacts of symptomatic adverse events (which may easily be attributed to disease progression) in hospice and palliative care are needed, as in all health care. Finding ways of monitoring and understanding contributing factors, and reducing the risk of iatrogenic events, is an urgent priority in hospice and palliative care.

The aim of this retrospective, consecutive, cohort, pilot study is to assess the feasibility of collecting patient-defined, symptomatic adverse events and to quantify the frequency with which people experience these at the end of life. This baseline rate would allow assessment of interventions to reduce the number or severity of events, or both.

## Methods

### Study setting

Australian health care provides universal insurance that can be supplemented by private insurance and patient co-payments. Southern Adelaide Palliative Services is a specialist metropolitan palliative care program that provides inpatient care, community and outpatient visits, nursing home and hospital consultations, complementary care, and bereavement services. It serves a population of 350,000 people over an area of more than 750 km<sup>2</sup> in public and private sectors. The service receives more than 1100 referrals per year. The inpatient unit provides direct specialist care and has approximately 330 admissions of 280 patients annually.

### Study design and participants

A consecutive cohort of case notes for the most recent admission for 70 people was audited. The inclusion criterion was every inpatient under the direct care of the service in a 4 month period at the end of 2008.

### Data collection

Case notes including medication charts and mandatory hospital-wide incident-reporting documents were surveyed. A subset of symptomatic events frequently encountered in hospice and palliative care were sought including: urinary retention or incontinence; constipation, diarrhea or fecal impaction; acute confusion, poor concentration, or unexpected decrease in level of consciousness; hypo- or hyperglycemia; symptomatic renal or hepatic failure; symptomatic hypo- or hypertension; and decrease mobility or falls (Table 1). These were chosen on the grounds that they were symptomatic for the patient and a fraction of them may be directly related to clinical management including polypharmacy (over- or under-treatment of comorbid diseases) or total anticholinergic load.<sup>18</sup> A composite measure for a crude event rate was created by looking at the sum of all events divided by the total number of inpatient days for all of the admissions. Only symptomatic adverse events were included, with the exception of acute confusion or unexpected deterioration in level of consciousness where the observations of others were accepted. An experienced clinical nurse consultant reviewed each file for coding.

### Data analysis

Descriptive data are presented. Using  $\chi^2$  (or Fisher's exact test as appropriate) dichotomous relationships were explored between demographic and clinical factors (including age, diagnosis, gender, and vital status at end of admission) and symptomatic adverse events. Data were analysed in PWAS (SPSS Corp. Inc., Chicago, IL). Means were compared using *t* tests having established that equal variances could be assumed by using Levene's test for equality of variances.

TABLE 1. ADVERSE EVENTS ON AND DURING ADMISSION OF A CONSECUTIVE COHORT OF PEOPLE ADMITTED TO A SPECIALIST PALLIATIVE CARE UNIT (N=65)

		<i>Prevalent (only on admission/caused the admission)</i>	<i>Incident (only noted during the admission)</i>	<i>Both (prevalent and incident)</i>	
<i>Symptomatic adverse events</i>	Drug effects	Drug -drug interactions	0	0	0
		Adverse drug reactions	7 <sup>a</sup>	19 <sup>a</sup>	4 <sup>b</sup>
		Worsening of preexisting comorbid condition	2	3	1
		Worsening symptom control	33	20	2 <sup>d</sup>
	Micturition	Urinary retention	1	10	1
		Urinary incontinence	5	21	6
	Lower GIT	Constipation	2	7	1
		Diarrhea	3	8	0
		Fecal impaction	2	4	1
	CNS	Acute confusional state	6	22	6
		Poor concentration	0	1	0
		Decreased level of consciousness	3	20	0
	Metabolic	Hypoglycemia	0	1	0
		Hyperglycaemia	2	1	1
		Renal failure	2	4	1
		Hepatic failure	8	1	1
	Circulatory	Hypotension	0	1	1
		Hypertension	1	0	0
		Decreased mobility	10 <sup>e</sup>	12	6
		Falls	7 <sup>f</sup>	8 <sup>c</sup>	0

<sup>a</sup>Only 4 due to medications for comorbid conditions including atenolol causing severe symptomatic hypotension, digoxin toxicity, frusemide causing severe hyperkalemia, and a cutaneous medication reaction to vancomycin. All other adverse events were due to medications for symptom control (predominantly opioids ( $n=13$ ; 5 on admission, 8 during admission) and dexamethasone ( $n=6$ ; 3 on admission and 3 during admission)).

<sup>b</sup>Four people with adverse events at the time of this admission went on to have adverse events with other classes of medications during the admission.

<sup>c</sup>Four people had multiple falls documented.

<sup>d</sup>For the same symptom on both occasions.

<sup>e</sup>Two people have had spinal cord compression—a suggested “sentinel event.”

<sup>f</sup>One person had multiple falls documented.

CNS, central nervous system; GIT, gastro-intestinal.

## Results

Of the 70 consecutive, most recent admissions requested for review, one was inadvertently a duplicate, and the physical medical records of another 4 people were not available, leaving 65 evaluable patients. There were 41 males (63%) and 59 people had cancer (91%). The age of people was a mean of 69.4 years (standard deviation [SD] 14.2; range 23–93; median 70). Forty-three people (66%) died during this admission. Average length of stay was 14.3 days (SD 15.2; median 7; range 0–65).

From the defined events (Table 1), 50 patients (78%) had symptomatic events precipitating admission, and of these, 31 of 50 (62%) went on to have further symptomatic adverse events arising during the admission, none of which was reported through the hospital's incident reporting process (Table 2; Fig. 1). For the 15 patients (23%) without symptomatic adverse events on admission, 11 of 15 (73%) had symptomatic events during the admission. Only 4 people (6%) had no symptomatic adverse events on or during the admission (Table 3).

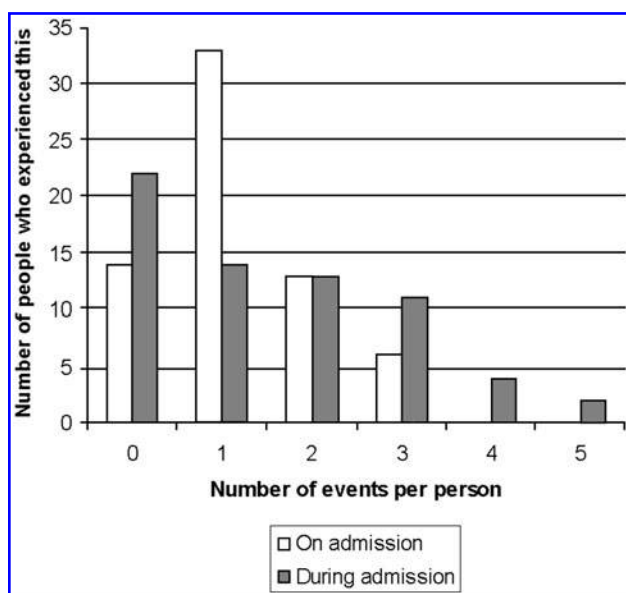
The mean number of symptomatic adverse events noted per person on admission was 1.14 (SD 0.88; median 1.0; range 0–3). During admission, the mean number of events per person was 1.50 (SD 1.42; median 1.0; range 0–5).

Length of inpatient stay was then calculated and the crude event rate (number of events per patient per day) was calculated. There was a mean of 0.13 events per day (SD 0.19; median 0.06; range 0–0.51) across this cohort, not including events noted at the time of admission. This equates to an average of one such event per person every 7.7 days of inpatient care.

There were no significant differences between any demographic or clinical factors and the number of events at the time of admission or subsequently during the admission (Table 4).

TABLE 2 NUMBER OF PATIENTS WITH FREQUENCY OF EVENTS NOTED (PERCENTAGE IN BRACKETS)

<i>Number of events</i>	<i>Events on presentation</i>	<i>Events during admission</i>
0	15 (23)	22 (34)
1	32 (49)	14 (22)
2	12 (19)	13 (20)
3	6 (9)	11 (17)
4	–	4 (6)
5	–	1 (1)



**FIG 1.** Cumulative number of sentinel events that may be related to prescribing ( $n = 70$ ).

## Discussion

Only 4 patients in this study did not have a symptomatic adverse event (an undesirable and unintended occurrence), underscoring the importance of monitoring and evaluating such events in this population for preventable harm. Given the reduced physiological reserve of the hospice and palliative care population, any insult (a fall, an episode of severe hypoglycaemia) has the potential to irreversibly limit independence, especially if function is already compromised.<sup>19,20</sup> A recent, large, cohort confirmed that a sudden drop in performance status led to the person's prognosis most closely reflecting the performance status after the drop. Although symptomatic adverse events are often the reason for presentation, 65% of patients developed events during admission, with 45% having more than one subsequent event.

Events that impact on people's mobility, confidence (patient and caregiver), or independence appear from this study to be ubiquitous in the hospice and palliative care population, with 94% of people having such an event leading to or in their most recent admission. This study has not demonstrated a particular group defined by age, gender, or diagnosis as having increased events, suggesting that every hospice and palliative care inpatient is at risk and should be a focus for reducing the frequency and severity of such events. By creating a crude event rate similar to the Institutes of Medicine

medication error rate, it is possible to plan prospective studies that could evaluate interventions specifically designed to reduce such events.<sup>1</sup>

A proportion of these events may be iatrogenic especially due to the unnecessary continuation or early cessation of medications for comorbid illnesses at the end of life or medications for symptom control.<sup>21</sup> Although it is not possible to attribute many such events to one factor, prescribing for comorbid illnesses is a modifiable factor that can reduce such risks. Therefore, it would be possible to compare an intervention group that had a careful medication review with a control group offered current practice.<sup>22,23</sup> Using patient-defined event rates as a surrogate for improved prescribing would allow empiric testing of a structured model of rationalizing medications for comorbid diseases at the end of life in a structured way and would define whether this translates into improved patient outcomes.<sup>4</sup>

Given the prescribing patterns in hospice and palliative care, it is of note that no drug-drug interactions were documented in this cohort. Likewise, no medication errors were documented despite an aggregate measure (similar to the crude event rate used in this article) estimating one event per patient per inpatient day.<sup>1</sup> Factors contributing to this may include under-recognition, lack of documentation, or misattribution of the event to disease progression. Statistically, it would be almost impossible for the more than 900 consecutive patient days of inpatient care reported here to have had no such events.<sup>1,24,25</sup>

A specific subgroup of adverse events are sentinel events (Table 1). These are defined as "an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof."<sup>11</sup> In hospice and palliative care, sentinel events to consider include spinal cord compression (especially if there are preceding symptoms or signs that were missed or not acted on), significant proximal myopathy as a result of long-term glucocorticoids, and falls that result in serious injury or death. Palliative care and hospice services need to have systems in place to systematically record sentinel events and analyse contributing factors that are modifiable rather than attribute these events uncritically to progressive underlying disease, given their recently reported frequency.<sup>20</sup>

## Limitations

This is a retrospective case note review and therefore only captures events and their symptom complexes that were documented in the clinical notes; hence the estimates may be under-reporting actual events, especially given the propensity to attribute changes in clinical condition in hospice and palliative care to disease progression. The threshold for the severity of events to be documented and reported is unlikely to be standardized across the whole group of practitioners. Falls for example are more likely to be noticed and reported than hypoactive delirium. The list of "events" was arbitrary, but aimed to cover most of the frequently encountered issues that may have an iatrogenic component or contribute to functional decline.

The severity of events or reversibility was not graded in the data collection. Future work can help to estimate the severity and the proportion that was avoidable or reversible without loss of function. Association of adverse clinical outcomes that may appear much later after such an event (a subsequent deep

**TABLE 3.** NUMBER OF PATIENTS WITH EVENTS ON ADMISSION MATCHED TO EVENTS DURING ADMISSION (PERCENTAGE OF TOTAL [ $N = 65$ ] IN BRACKETS)

		Events during admission	
		Yes	No
Events noted at the time of admission	Yes	31 (48)	19 (29)
	No	11 (17)	4 (6)

TABLE 4. VARIANCE BETWEEN GROUPS FOR EVENTS PER DAY OF ADMISSION<sup>a</sup> (N=65)

	(Number in group in brackets)	Mean	Standard Deviation (SD)	P value
Age	Age ≤ 70 (33)	0.14	0.18	0.638
	Age > 70 (32)	0.12	0.20	
Gender	Male (41)	0.13	0.17	0.866
	Female (24)	0.14	0.21	
Diagnosis	Cancer (59)	0.14	0.19	0.444
	Noncancer (6)	0.08	0.11	
Event(s) noted on admission	Yes (50)	0.12	0.19	0.466
	No (15)	0.16	0.15	
Vital status at discharge	Dead (43)	0.18	0.03	0.313
	Alive (22)	0.20	0.04	

<sup>a</sup>Compared using independent sample *t* test (2 tailed), with Levene's test for equality of variances (all of which had  $p > 0.05$ ).

vein thrombosis after a much earlier fall causing a fractured neck of femur; cessation of long-term anticoagulation for atrial fibrillation and subsequent cerebrovascular accident) was not possible. The timing of each symptomatic adverse event in relation to the date of admission was not tabulated, but could strengthen future work.

### Generalizability

This study is from one inpatient unit. The rates quoted may vary between services with differing length of inpatient stays, demographics of patients referred (especially average age given the relationship to increasing comorbid illness with age), time from referral to death, and the diagnoses of those referred to a service.

### Implications for research

Comparing and contrasting these event rates prospectively with a community cohort will help to understand the frequency and severity of such events across the whole hospice and palliative care population. The severity of events needs to be systematically graded in the future. The clinical response (speed of recognition, response to reversible causes) to each event also needs to be codified in prospective data collection as well as when each incident event occurs in relation to date of inpatient admission.

A key challenge is, having had an event, what has been done to prevent a recurrence? It is understandable that, despite optimal management, patients will have symptomatic adverse events, but how can they be minimized? One episode of hypoglycemia *may* be acceptable, but repeated episodes rapidly call into question the clinical management offered to this person.

The frequency of events noted in this study suggests an urgent need to evaluate systematic methods for guiding clinical decision making in prescribing for primary and secondary prevention in inactive comorbid disease. Ultimately, as one strategy, could iatrogenic morbidity and mortality be minimized by adopting a systematic approach to the evaluation of each comorbid illness for each dying person?

### Implications for practice

These data present a high baseline event rate of symptomatic adverse events in a hospice and palliative care population. It is certain that almost all such events in hospice

and palliative care practice are multifactorial and attribution is difficult. The first step in dealing with symptomatic adverse events is to obtain consensus on their definition, attribution, and importance in hospice and palliative care and monitor their impact on functional status prospectively in the way that Downing and colleagues have recently described.<sup>20</sup>

Can the number of events be decreased or lessened in severity? Contributing factors that are not directly modifiable include the global deterioration associated with late-stage life-limiting illnesses. How many symptomatic adverse events are iatrogenic either from less than optimal management of comorbid conditions as functional and metabolic status worsens, or from symptom control initiatives that, at times, are having a net detriment on the patient?<sup>26</sup>

These data suggest that no specific patient profile allows us to target people *a priori*. These events are ubiquitous given the frail and progressively worsening function of the population, but rates may be modified.

At the very least, the checklist may form a baseline for regular hospice and palliative care morbidity meetings. Also included should be hospice and palliative care-specific sentinel events including spinal cord compression, steroid induced myopathy, or sudden death in the setting of a high functional status *ante mortem*.

### Conclusions

These data demonstrate that it is feasible to identify symptomatic adverse events in the hospice and palliative care population and, given the frequency with which they occur, that every effort should be made to measure them routinely and systematically. These data provide a baseline against which future work can be compared and the definition and metric of symptomatic adverse events in hospice and palliative care can be developed and refined. As clinicians, if we regard these events as simply another inevitable outcome of worsening disease, we will continue to preclude the possibility of systematically reducing the risks of such events, some of which are likely to be iatrogenic. Such reduction in rates is likely to be able to be achieved without worsening symptom control.

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