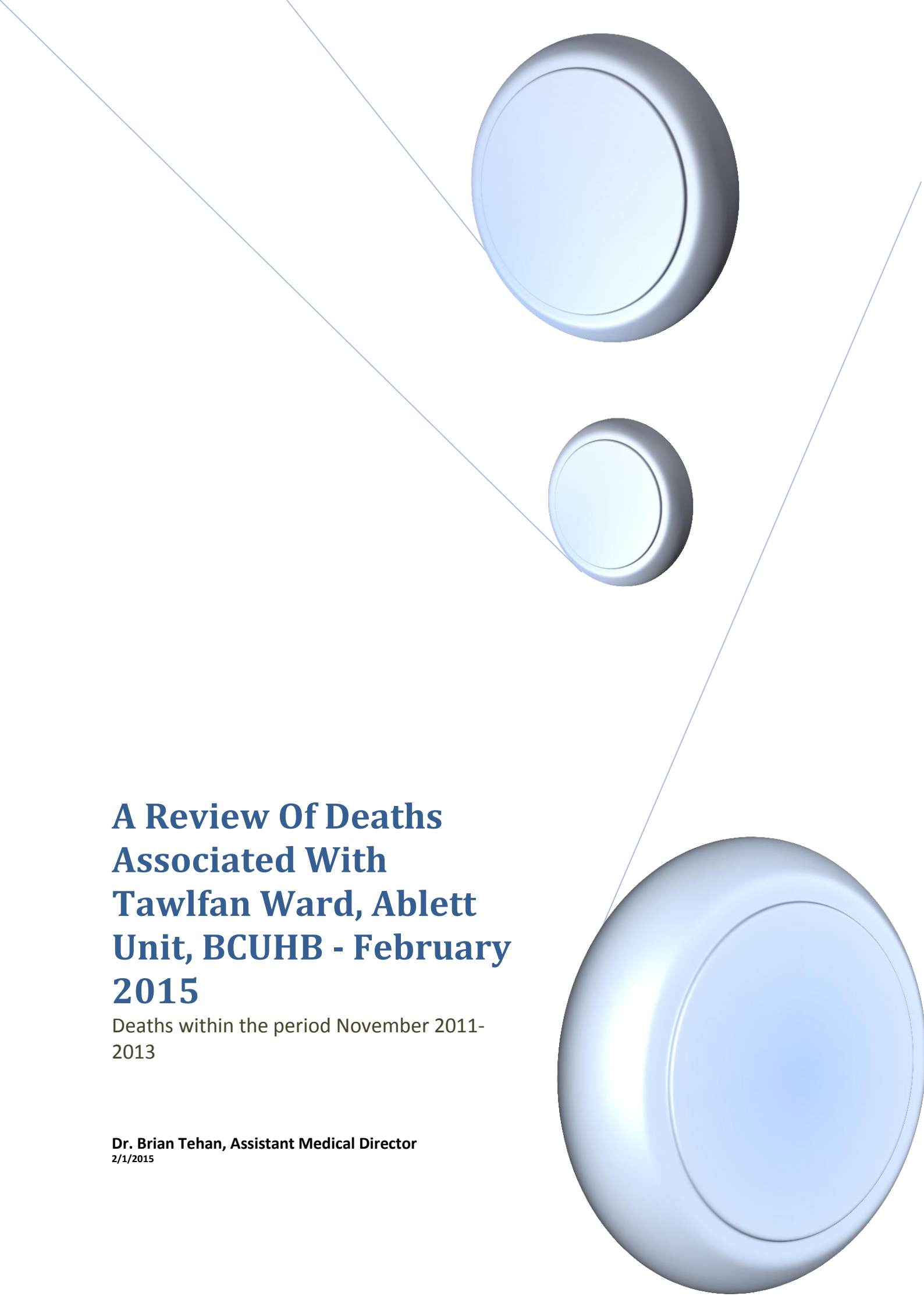

A Review Of Deaths Associated With Tawlfan Ward, Ablett Unit, BCUHB - February 2015

Deaths within the period November 2011-2013

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2/1/2015

Contents

Acknowledgements

A complex and thorough review, the Author acknowledges with great gratitude the helpfulness and work of the following, without whom this would not have been possible

a. [redacted]
b. [redacted] for an extensive review of the available literature and provision of papers to advise the review
c. Reviewers- [redacted]
d. Supplementary reviewers for their agreement to support, even though they were not ultimately required- [redacted]
e. Clinical Informatics Support- [redacted]
f. Clinical Audit- [redacted]
g. Coding- [redacted] and Team
h. Cardiff University- [redacted]

Introduction

Alerted by Staff and Families to serious concerns, regarding patient care at Tawel Fan Ward, Ablett Unit, Glan Clywd Hospital, in December 2013 the Board closed the ward and commenced an investigation. As part of that investigation a review was requested and this was completed using the established mortality review process. Reporting in September 2014 (Appendix 1) this reviewed 23 patients who had died either on, or within 30 days of discharge from Tawel Fan Ward for the two year period to the end of November 2014.

While this review identified certain themes, some weaknesses were recognised and a more robust further review recommended. Seeking to apply a peer reviewed validated process, and in the absence of clear guidance on how to conduct such a review in the context of mental health, advise was sought from [redacted], Senior Lecturer in Healthcare Improvement, and [redacted], Senior Project Manager both from the Institute of Primary Care & Public Health, Cardiff University. These were consulted on account of their experience with research into the development of a global trigger tool, and provenance in supporting the 1000 Lives Plus Mortality Review work stream.

The literature

Retrospective studies of hospital case records have been used since the 1970's as a means to identify adverse events. These are defined as unintended injuries caused by medical management rather than the disease process. The Harvard Medical Practice study (HMPS) carried out in New York and published in 1991(Brennan et al., 1991) reported an incidence of 3.7% of admissions, with 14% considered to have contributed to death.

This methodology has subsequently been applied in Australia, the U.K, New Zealand and Canada, and "become the benchmark method for research on adverse events in hospitals and for assessing the status of patient safety in hospitals around the world" (Zegers et al., 2007). The Quality in Australian Healthcare Study (Wilson et al., 1995) identified adverse events in 16.6% of admissions.

In 2001, Vincent et al (Vincent, Neale, & Woloshynowych, 2001) reported the first UK feasibility study, which using similar methodology found in the region of 11% had experienced an adverse event and recommended a much larger study. Duly completed this was reported in 2012 (Hogan et al., 2012). At that time the Chief Medical Officer estimated that between 60,000- 255,000 NHS patients suffer death or serious disability associated with healthcare, this paper sought to determine the proportion that might be preventable. As with HMPS, retrospective case record review (RCRR) was the approach used considering it "the most sensitive approach in determining the proportion of hospital deaths that are preventable".

In this study, reviewers were asked to judge whether there had been a problem in care that had contributed to the patient's death. Further to this, they were asked to make a judgement on preventability using a 6-Point Likert scale. Recognising the difficulty in committing to 'Yes' or 'No" answers use of the Likert scale gave them a tool whereby they could make a probalistic statement of their confidence of their opinion on preventability. Death was acknowledged as preventable if the score allocated was 4-6, or likelihood greater than 50%. Recruiting a population of 1000 adult patients dying in acute hospitals in England, this determined 5.2% of those deaths were preventable.

A number of well-publicised investigations such as that at Bristol Royal Infirmary and the Mid Staffordshire inquiry have given hospital death rates a prominence, best backed up with the use of RCRR. Drawing on work from the US Institute for Healthcare Improvement (IHI) this has been further endorsed by the Modernisation Agency and subsequently the NHS institute for innovation and improvement. However, while their use has become accepted, some appreciation of the nuances in approaches is required.

To start, RCRR can be "exlicit" (criterion based) or "implicit" (holistic). In an "Explicit" type review healthcare professionals assess the quality of processes of healthcare using a set of predetermined criteria. In contrast, in an "implicit" (holistic) review they are allowed to make judgements using their knowledge and experience. An "explicit" review, for example, might be structured as a form which limits the parts of the case notes to be reviewed as well as using more 'closed' types of questions. "Explicit" reviews are less constraining, giving the reviewer discretion to review and describe what He / She considers significant.

The strength of "explicit" reviews is limiting the answers they can provide, data is easier to collate and interpret. Moreover, in comparison to unstructured holistic reviews, there is less inter-observer variability (Lilford et al., 2007) and they can be "under-taken by staff from different backgrounds" (Hutchinson, Coster, Cooper, McIntosh, Walters, Bath, Pearson, Rantell, et al., 2010). This has been the predominant approach adopted for clinical audit in the UK. But having such strengths, this is off-set by a rigidity in that constraining reviewers to explicit questions, it has been criticised for insensitivity and inability to identify unexpected factors influencing outcomes of care (Hutchinson, Coster, Cooper, McIntosh, Walters, Bath, Pearson, Rantell, et al., 2010).

"Implicit" reviews, on the other hand, are considered (Hutchinson et al., 2013) "more effective for identifying and recording the detail and nuance of care (both unsatisfactory and good), and …….. probably more appropriate for detailed exploration of the care for people who die in hospital". As noted earlier, this approach is potentially highly idiosyncratic and reviewer dependent (Hutchinson, Coster, Cooper, McIntosh, Walters, Bath, Pearson, Young, et al., 2010) and associated with lower levels of inter-rater reliability. Even with attempts to reduce levels of subjectivity by providing extensive training for physician reviewers, concerns remain about review methods based principally on professional judgement (Hutchinson, Coster, Cooper, McIntosh, Walters, Bath, Pearson, Rantell, et al., 2010).

It is for these reasons, a mixed strategy is recommended (Hutchinson et al., 2013), as exemplified by the methodology of the 2006 PRISM Study (Preventable Incidents, Survival and Mortality) (Hogan et al., 2012) . Unstructured implicit review formats have been criticised for low inter-rater reliability and potential reviewer bias, whereas the approach taken their as a structured alternative limits the variability and provides structured frameworks so that reviewers are able to make, justify and organise statements on care (Hutchinson et al., 2013).

A further difference is in their use of reviewers. In general, Nurses have been used to screen populations on the basis of certain criteria, passing the positives to medical reviewers for more detailed analysis. Some use single reviewers, while others use 2 or more and look for consensus. Using an implicit approach, "Nurses and physician reviewers often came to substantially different conclusions" (Hutchinson, Coster, Cooper, McIntosh, Walters, Bath, Pearson, Rantell, et al., 2010). As such, there is little agreement between different staff types when used to rate the quality of care for the same clinical record. Hutchinson attributes this to each exploring different aspects of care

(Hutchinson, Coster, Cooper, McIntosh, Walters, Bath, Pearson, Young, et al., 2010). Doctors tend to focus more on the technical aspects, and make more explicit judgements on quality of care (ibid). While "nurses sought data on the routines of care ….. Doctors looked for a wider picture and …. neither group considered both dimensions" (Weingart et al. quoted in Hutchinson, Coster, Cooper, McIntosh, Walters, Bath, Pearson, Rantell, et al., 2010).

Unfortunately, while the studies described show an efficacy to this process, these have excluded mental health facilities. Given the reported concerns, key to which is the question whether poor care can be evidenced and considered to have contributed to death, the proposition, with the agreement of the Executive Team, is to apply RCRR using the latest version of the PRISM 2 methodology as supplied by Dr. Helen Hogan. Acknowledging the difficulties where more than one individual is commissioned to review each case record, it is further proposed the risks of their disagreeing are off-set by the richness of the wider perspective this provides. Consistent with the literature, both a Nurse and Physician have been engaged for this purpose. Furthermore, given the findings from "Trusted to Care" (Andrews & Butler, 2014) the third, a pharmacist was recruited to complete the team.

PRISM 2 does not specifically address medication issues, and case notes reviews have been shown to be "largely ineffective for detecting mistakes in drug administration and drug related adverse clinical events (ADEs)"(Rozich, Haraden, & Resar, 2003). Seeking to address this deficit trigger tools (IHI.org) have been developed, described in this context as "specific events—including the ordering of certain drugs, orders for antidotes, certain abnormal laboratory values, and abrupt stop orders—serve as sentinels or "triggers" to initiate a more detailed concurrent chart audit" (Rozich et al., 2003). A specific tool has been developed for mental health settings (Appendix 2), and this has been used by the Pharmacist as an added check to the PRISM 2 (Appendix 3 & 4) process.

Methods

Prior to commencing the review the following were agreed as Terms of Reference:-

- Focussing on the period November 2011- November 2013, to determine whether the standard of care received was reasonable.
- Outlining instances where care falls below those standards, to make a judgement whether the patient has suffered as a consequence.
- To address the specific question whether sub-standard care has contributed to or been causative of death

The methodology agreed comprised

A. Patients to be reviewed

While the initial review considered all patients who had died on Tawel Fan or within 30 days of discharge, in the 2 year period up to November 2013, a further 33 have been identified as requiring review. These were documented as having stayed on Tawel Fan during the index period, and having died out with the 30 day period specified for the original review. Seeing Mortality RCRR as a means to provide, using a sensitive cohort sample, an indication of care and harms on the ward, assuming increase in the sample size helpful, it was agreed to review this new total of 56 patients.

B. The Review Process

- Review of mental health and general hospital case notes using the PRISM 2 Review Form Template (Appendix 3).
- This defines a problem in healthcare as 'any point where the patient's healthcare fell below an acceptable standard and led to harm'.
- To limit the focus to time on Tawel Fan ward and subsequent in-patient care, at whatever location, up to time of death.

- This to be supplemented with a further review by the Pharmacist reviewer using the IHI Trigger Tool for Measuring Adverse Drug Events in a Mental Health setting- Version 2.0 November 2008 (Appendix 2)

C. Personnel

To meet the specifications, the following were recruited, [redacted], and [redacted].

All are respected senior professionals with a wide experience of healthcare in the context of the NHS, including that in North Wales. [redacted], all were commissioned full time for the required period, estimated as 4-6 weeks.

Physician- [redacted]. Highly respected and experienced as a clinician, [redacted] has accumulated extensive experience of RCRR, having worked with[redacted] and [redacted].

Nurse- [redacted], a[redacted], with extensive experience rising to Matron, and leading on professional and practice development.

Pharmacist- [redacted]. [redacted]

Confirmed in good standing with their respective regulators, all were contracted for the period of the review on a Consultancy basis, and provided Letters of Access to conduct the review.

At the outset the intention was for each to review the case notes as primary reviewers, and where they have concerns which they feel merits further specialist advice, if this could not be accommodated within this group, they had the option to seek that advice through the author as lead. The potential such advice might be required is anticipated in the design of the PRISM 2 form.

As no reviewer had specialist knowledge or experience of Old Age Psychiatry, in anticipation, on advice [redacted] and [redacted] were approached and agreed to help should this be required to assist the reviewers. However, neither has as yet been approached

D. Training

Consistency is of course important, and the tool, while it's comprehensive, is estimated to take up to an hour to complete. Prior to starting, each received training from [redacted].

E. Administration

- Having identified the 56 cases for review, where available, pertinent elements of the case record for each were accumulated and stored in the office of the Author. In view of the sensitivity additional security was provided through the use of a dual lock, and limiting control of access to I and [redacted].
- All case notes and progress monitored and managed by [redacted] using a master excel spreadsheet. Through this assured each reviewer reviewed all notes and clear knowledge of location of notes at all times.
- Prior to commencing the review, noting an earlier finding of deficiencies in coding of mental health records, all were coded by the DGH coding department and initial elements of the PRISM 2 form completed.
- In collaboration with Clinical Audit, the PRISM 2 form was formatted for scanning into the FORMIC database. This enabled ready collation of the extensive data collected, both criterion based and narrative, with reporting as an excel spread sheet with pivot table analysis.

F. Progress

Reviews commenced on 17th November and completed on 19th December 2014 (i.e 5 weeks).

Findings

Demographic Information

Unable to secure all 56, the review has considered the case notes for 52 Patients, comprising 29 Males and 23 females. Ages ranged from 18 - 94 years of age. All were subjected to independent review by each of the three reviewers.

As can be seen in Appendix 5, the following are observed-

- This population was elderly with more than 90% over 60 years of age, and 61.6% over 80 years.
- The majority were admitted with a fairly even split between own home and nursing or residential care home
- Most were as emergency admissions (69.2%), but only 23.1% were admitted through A&E. (Appendix 6).
- Moreover, for 71.2% the first admitting specialty was documented as “Other specify”, to be taken as admission under mental health (Appendix 6)
- Presentations to hospital services were unusual after 22:00, and admissions to the ward only on weekdays (Monday to Friday) (Appendix 5)
- Lengths of Stay for the majority were prolonged, with <20% staying less than 2 weeks, and 13.5% staying more than 90 days (Appendix 5)
- As a consequence the time required for review each case record was prolonged. This meant on average the time required per case notes was 310 minutes, taking this three independent reviewer approach.

	Average Minutes	Max	Minimum
[redacted]	77.2	140	40
[redacted]	121.3	480	40
[redacted]	111.6	240	55
All	102.9	480	40

Looking to risk factors, in Appendix 6-

- Tawel Fan was regarded as a specialist ward, hence it is no surprise 84.6% evidenced confusion / memory problems, with the majority of this (71.2%) attributed to dementia alone.
- Significant mental illness was present in a relative minority(c 30%), and there were no indications learning disability was an issue
- Co-morbidities were common, with the top 5 determined as, Cerebrovascular disease, Other, Myocardial Infarction, Diabetes (with and without end organ damage) and Chronic lung disease.
- Immediately prior to the deterioration that led to admission, few (13.5%) were independent, with 82.7% showing some degree of dependency. This for the greater majority included personal care.
- As far as could be determined (53.5%) the review considered care on this ward as "definitely" or "probably" appropriate for their condition (Table 11)

General Harm

In the second section of the PRISM 2 Form reviewers were asked to identify whether there had been problems with healthcare, and, if so, judge had that problem not occurred might the death have been avoidable.

- For 5, there was consensus there had not been problems with healthcare and death was unavoidable [redacted]
- For 1 [redacted], two agreed, but one did not.
- For 44 (85%), 2 or more reviewers judged there were problems in healthcare.
- For 8 patients [redacted], at least 2 reviewers agreed, had the problems in healthcare been avoided death might not have occurred.
- The corollary of this is for 36 (82% of all patients) while problems in healthcare could be identified, death was considered unavoidable.

From a hand search by the author (Appendix 7) a number of key themes emerge.

1. **Falls –**

   Documented as the most common problem, in 12 patients the reviewers determined there an association with problems in healthcare.

Falls Documented	
Case Number	Reviewers Observations
[redacted]	Here deficiencies in care were not thought to have contributed to death and falls despite acceptable standards of prevention, nevertheless, it took 12 hours following a fall for a medical review. Moreover, a similar tardy response is noted when the patient was found to be hypotensive.
[redacted]	While falls prevention adequate no consideration given to assessing drugs and hypotension as possible aetiologies
[redacted]	Ankle Fracture. This occurred despite adequate preventative measures
[redacted]	Despite adequate prevention. No evidence presence of [redacted] had been considered assessing risk of falls. Also [redacted] present but similarly does not appear to have been considered as possible contributor and investigated
[redacted]	Fracture[redacted], from fall despite adequate prevention
[redacted]	Fall [redacted]. [redacted]l. One reviewer questioned the adequacy of preventative manoeuvres, whilst another felt they were adequate
[redacted]	[redacted], after ? Unwitnessed fall. Most falls un-witnessed leading reviewers to question the adequacy of supervision

[redacted]	Falls In Tawelfan lead to review of medications associated with [redacted], but not [redacted]. Discharged alive to Nursing Home. [redacted]. Reviewers question why arranged package of 1:1 supervised care had been withdrawn in the Nursing Home.
[redacted]	Persistently [redacted] was noted, yet this was not considered as potential aetiology. Problem with monitoring
[redacted]	[redacted]. Falls prevention considered adequate Not thought to have contributed to death. Death some months after discharge
[redacted]	Falls but Not On Tawel Fan
[redacted]	[redacted], not adequately investigated. When fell, Inadequate consideration of possible causes. Specifically [redacted] not excluded.

From this, there is an impression falls preventative measures could be considered adequate, but there has been a lack of consideration of potential aetiologies, in particular hypotension.

In addition where falls have occurred where a patient has been under 1:1 supervision, the reviewers have questioned its adequacy.

[redacted] observes- *"Many were at risk of falling out of bed; high/low beds were in use with mattresses on the floor at the bedside to support the patient, should they fall."*

[redacted] adds-*"Falls are a major problem; causes multifactorial and probably to be expected in this group of patients even with increased staff/patient ratios. The only way to prevent falls would be to immobilise the patient either by physical restraint or using the "liquid cosh" of pharmacology. There*

is no evidence of this. I suspect that even with more attention paid to the causes of falls ,they would still happen".

2. **Medications Omitted / Refused**

While few, [redacted], omissions would appear predominantly to relate to non-psychiatric medications. Antibiotics emerge as a particular concern with reviewers questioning timeliness of prescription, antibiotic indication and choice, duration of use and consistency in dosing.

It is evident refusals a particular challenge with this group of patients, yet reviewers observe the covert administration policy appeared to be poorly utilised. Where staff have resorted to covert administration, again this has prioritised mood stabilising medicines to the exclusion of those for physical conditions. Significant number of instances when medicines for physical conditions not administered, e.g. antihypertensives, inhalers, diabetes2 drugs, antibiotics

[redacted] comments- "*Management of medicines for physical conditions was more varied. Much empiric prescribing of antibiotics, with antibiotic choice on the whole appropriate. However there were instances of recurrent infections being inadequately treated. Some patients would probably have benefited from earlier intervention with IV antibiotics."*

"Where there was significant patient refusal of medicines there was rarely a review of prescription chart by medical staff. Consideration should have been given to discontinuing medication at least on a temporary basis rather than leaving the situation of prescription charts being liberally annotated with '4' in the administration section, which leaves nursing staff in a difficult position".

[redacted] adds- *"Drugs by and large were used appropriately, though there was a tendency to use antibiotics empirically (in common with the rest of the hospital)-no evidence of resultant C.Difficile. Drugs often omitted because of patient refusal:"*

In contrast with [redacted] felt- the *"Trust policy on covert administration of drugs recognised and followed".*

3**. Lack of Clinical Review / Inadequate Clinical Assessment / Missed Diagnosis / Delays in Medical Review / Inadequate medical treatment**

Concerns have been highlighted with respect to standards of medical care. Though lengths of stay were, in comparison to an acute DGH, relatively long, the quality of assessment on admission ("clerking") is called into question. Failures to conduct an adequate physical examination were noted on admission, and similarly following deteriorations or falls. There are several instances (7) where delay was noted in obtaining a medical review, and from time of admission on the ward to first medical assessment.

More broadly, there is a flavour that physical issues would have been treated with a lesser expertise than mental health issues. Where patients suffered falls, or deteriorated there is little evidence to indicate this has lead to a holistic review of the patient (e.g. [redacted]) and their medications. Moreover, in a significant few, where hypotension is noted (Low BP- 10), this has not consistently lead to a review of all medications with the potential to contribute to the problem, and there are instances where despite continuing hypotension, clinical staff have continued with the prescription for, and administration of, anti-hypertensive medication (e.g. [redacted]).

Where investigations have been requested this review has identified 7 instances where findings have failed to elicit appropriate action. One is documented under the care of the Orthopaedic Team, as failure to respond to the diagnosis of pneumonia [redacted] on a Chest X-[redacted]. Another, on Tawel Fan is a failure to respond to hypernatremia.

Summarising his impressions [redacted] comments- *"I think that there are deficiencies in the medical assessments of these patients - either because of lack of medical support or poor cooperation in the process by the patient; full examination is often impossible because of aggressive behaviour, there is little evidence to suggest that medical examination is attempted at a later date when the patient's behaviour is more controlled. This is important if trying to establish delirium as a cause for deterioration. Repeat medical examination was usually in response to new problems- often occasioned by a fall, and often delayed. There was some evidence that quite long delays happened from the time that investigations were performed until results were reviewed and acted upon. Investigations were probably under used when compared with general wards - patient's behaviour, need to transfer to main hospital for X-ray, access to ECG etc."*

4. **Assaults-**

Though not specifically highlighted as problems in care, in the free text reviewers have noted the patients reviewed have either assaulted, or been assaulted by another patient (6 & 6). It would appear staff too have been the subjects of such assaults. Bruising, skin breaks and cuts are of similar frequency, though no linkages are made by this review to either falls or assaults.

5. Fractures-

Seeing fractures as serious injury, these merit specific comment. The review identifies 5 patients with fractures.

[redacted]

[redacted]

[redacted]

Nevertheless, there was consensus care had been good and falls had occurred despite apparently acceptable standard of falls prevention. [redacted] died many months after discharge, and there was no evidence deficits in care on Tawel Fan had contributed to death.

[redacted] death was considered potentially avoidable, this will be covered in a later section.

Patients where problems in healthcare identified

Having identified patients where the reviewer considered there had been a problem in healthcare, they were then asked to judge whether, had those problems not occurred, death might have been avoided. As described earlier, to help the reviewers, statements were framed using a 5 level scale ranging from 2, Slight evidence for avoidability, through to 6, the death was definitely avoidable (See Appendices 3 & 4). Patients, the level of agreement and considered avoidability are

outlined in the table in Appendix 8. For 7 patients there was consensus death was avoidable, with evidence strongest for [redacted]

[redacted] was alone in considering [redacted] at level 4, probably avoidable, while [redacted] felt with a confidence level less that 50:50 death was avoidable for [redacted] and [redacted].

Evidence of avoidability Strong - 5 (at least 2 reviewers given a score of 5+)

A. [redacted]

Conclusion inadequately treated chest infection

B. [redacted] Patient died from sepsis [redacted]. [redacted]Not all records available to the reviewers. Unclear [redacted] and gaps in available medication history. Judged slow medical response to initial injury lead ultimately to demise.

C. [redacted] Death therefore considered avoidable.

Moderate evidence of avoidability (i.e where 2 or more reviewers have given a score of 4)

A. 52 [redacted] Questionable prescription of this psychotropic agent (prior to admission to Tawel Fan) in context of documented ECG findings. [redacted]

B. [redacted] Early attention to ensuring adequate fluid intake and stopping medications would have prevented this. Acknowledging the difficulties presented in managing confused aggressive patients, reviewers did not feel there was adequate consideration of the various modalities available. [redacted] suggests charting may not have helped in tracking fluid intake. [redacted]

Low (Average score 3 or less, or only one reviewer flagging as a concern)

A. [redacted] Dieticians appear not to have been involved, and as such further options for nutrition not fully explored. During this stay antibiotics were prescribed orally, leading the reviewers to question whether parenteral might have been more appropriate. Care rated by 2 reviewers as "Adequate".

B. [redacted] Only one reviewer considered death avoidable. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]This not being the case, this death, in Tawel Fan terms, becomes unavoidable.

C. [redacted]- Consensus death may have been avoidable. [redacted]

[redacted]

Though clearly difficult to assess ("aggressively resistant"), [redacted]critical of the lack of a thorough physical examination, and the performance of "certain essential investigations". There had not been a physical assessment for a week prior to discharge [redacted]

[redacted]

[redacted]

[redacted]Criticism that dieticians might have been involved at an earlier point and refusal of medications might have been addressed using the covert medications policy.

Care was rated over-all as "adequate" by 2 reviewers, and "poor" by [redacted]

D. [redacted]

[redacted]

[redacted]

Overall care was rated as Good by two of the reviewers. [redacted],acknowledging the difficulties in assessing a patient who is uncooperative, rated it as adequate on the grounds of monitoring of blood pressure,.

E. [redacted]- Considered as an unavoidable death by [redacted], both other reviewers disagreed, albeit at the lowest level of likelihood. Nevertheless, over all care was rated as “adequate”.

[redacted] The key concerns [redacted]with

respect to Tawel Fan were that falls occurred despite apparently acceptable standards of fall prevention; there was slow progress in arranging transfer to a non-hospital setting (EMI Nursing Home) attributed to difficulties securing the agreement of [redacted] and the lack of availability on the unit of an ECG machine when this was required.

F. [redacted] While all agreed there were problems in healthcare, only [redacted] felt this death was avoidable, at a confidence level of 4. Stays on Tawel Fan ward were limited, [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Overall care was rated by the reviewers as adequate and good. [redacted]

[redacted]

Medications Issues

Using the IHI Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting (Version2 November 2008 available The Institute for Healthcare Improvement at ihi.org), the following is the incidence of triggers-

Key	Count
16- Over sedation, lethargy, Falls	31
18- Abrupt cessation of medication	26
25- Laxatives	14
15- Rising serum creatinine	9
19- Abrupt reduction of dose of medication	7
20-Transfer to a higher level of care	6
21- Unexpected death	5
30- Drug combination not normally recommended	5
1- Anti-Histamines	4
17- Rash	3
24- serum Sodium less than 135 mmol/l	2
26- Antimuscarinic Drugs	2
28- Insertion of a urinary catheter for retention	2

4- Anti-emetics	1

Triggers are sentinel events which suggest there may be links to harm. For example use of laxatives can be taken as possibly indicating a side effect form use of opioids. Through this vehicle the most common triggers were 16 and 18. Elaborated in the comments below, one can see this refers mainly to Falls, which in the majority of incidents do not appear to have been associated with sedation. Indeed, as observed earlier in the paper, where this has been associated with an Adverse Drug Event (ADE), predominately this has been considered associated with a fall in blood pressure.

The frequency of Trigger 18, is consistent with the observations made earlier in this paper on the frequency of drug refusals or omissions. Seven of the ADE are documented as associated with this trigger with omission of prophylaxis for thrombosis (DVT) considered as contributory to the death of [redacted].

Triggers have lead to the following Adverse Drug Events

I: Patient Death	2
E: Temporary harm to the patient which required intervention	8
F: Temporary Harm to the patient and required initial or prolonged hospitalisation	4
Unclassified by Reviewer	3

Further details are provided in Appendix 9, but in all cases PRISM 2 documents concerns with healthcare. Also consistent has been the finding of falls associated with hypotension

Patient death, is recorded as the outcome for [redacted] and [redacted] Both have been identified using PRISM 2 as linking to death with a moderate to high confidence.

Further summarising the findings

Total of Patients with Trigger	50
Number of Triggers	113
Rate per 100	226
Number of ADE	24
ADE rate as %	48%

The rate of ADE is high, but needs to be qualified. The numbers of patients in this review are small and the focus on those who have died. This tool is not intended as a means to bench-marked, but as a measurement for improvement. These findings point to where Tawel Fan might focus improvement efforts.

Having completed both PRISM 2 and the Trigger tool, [redacted] gives [redacted] impressions as follows-

1. "Management of mental health medicines generally appropriate and titrated according to response. Little evidence of excessive drowsiness and no evidence of use of antipsychotics as chemical cosh for chaotic behaviour".

2. "Management of medicines for physical conditions was more varied. Much empiric prescribing of antibiotics, with antibiotic choice on the whole appropriate. However there were instances of recurrent infections being inadequately treated. Some patients would probably have benefited from earlier intervention with IV antibiotics".

3. "Significant number of instances when medicines for physical conditions not administered, e.g. antihypertensives, inhalers, diabetes2 drugs, antibiotics".

4."Use of covert administration policy appeared to be poorly utilised. Sometimes when it was in place it was only to cover mood stabilising medicines and not the medicines for physical conditions".

5. "When there was significant patient refusal of medicines there was rarely a review of prescription chart by medical staff. Consideration should have been given to discontinuing medication at least on a temporary basis rather than leaving the situation of prescription charts being liberally annotated with '4' in the administration section, which leaves nursing staff in a difficult position".

6. "There were several instances when the palliative care team were appropriately involved and the Integrated Care Pathway used. However the prescription on the ICP was not generally transferred to the inpatient chart which may it difficult for myself to review the full medication history and I would have thought it would have increased the risk of confusion and error, at the time, for nursing staff not very familiar with palliative care. In general it is good practice for all drugs administered to inpatients to be prescribed on the inpatient chart".

Over-All Standards of Care

Over-all care was considered “Good” or “Excellent” in almost 61% of patients reviewed.

Over-All Standard of Care %	
a) Excellent	5.3
b) Good	55.3
c) Adequate	26.0
d) Poor	4.0
Blank	9.3

Comparing reviewers [redacted] found no evidence of “Poor” care, and only 5 considered “Adequate”. Others are more critical. [redacted] regarded care as “Adequate” in 15, and Poor in 3, while for [redacted] the balance was 19 and 3.

Care was considered “Poor” by agreement of 2 for [redacted] and [redacted] And by [redacted] for [redacted] and [redacted] for [redacted] The reasons are outlined in the table as below

Patient ID Number	Reviewer	Q20 - How would you rate overall quality of healthcare	Q20 - Comments
[redacted]		d) Poor	
[redacted]		d) Poor	Lack of clear responsibility for care. Poor interdepartmental /inter hospital communication
[redacted]		d) Poor	Admission of patients for investigation of increased confusion [redacted] should seek to establish remediable causes. [redacted]
[redacted]		d) Poor	Medicine management related to psychotropic medications was adequate however it was poor relating to this patient's [redacted]
[redacted]		d) Poor	Within hospital transfers add to problem of confusion. No clear responsibility taken for (???) EMI problems
[redacted]		d) Poor	Poor medication reconciliation. Lack of recognition of potential seriousness of infection

Case Records

Inevitably in RCRR one must comment on the case record. Expressed as % of forms reviewed these were found to be

a) Adequate to make a reasonable judgement	40.7
b) Some deficiencies in the records	28.7
c) Major deficiencies	6.0
Blanks	24.7

WG comments - *"The notes themselves were chaotic, in poor physical condition partly because they had been copied and reassembled in loose leaf and partly because of the enormous volumes engendered by the various unified assessments. Many of the nursing assessments were completed according to a proforma, on line.*

When printed, there is no patient ID, date or signature on each page. It becomes increasingly important as notes become thicker and inevitably more likely to disintegrate that all pages are labelled with patient ID,dated (with day,month and year and time if possible) and authors are identifiable.This is a general problem with hospital notes and not peculiar to this unit. I noted that a formal discharge letter to the patient's G.P was not universal , surely essential communication as often the patient was transferred to a NH distant from original place of residence with a different GP attending.

A failing in the notes is that they are written continuously in a "stream" making it very difficult to identify when the patient was admitted after OP follow up or as an emergency,the ward admitted to and transfers inter and intra department are difficult to identify. This is a general problem and the Trust should insist that this information is made a Standard to be followed for all admissions."

From the extensive comments made, the following is a summary -

General Issues:

- Thick case notes make for difficulty in following patients journey.
- Significant events need to be highlighted e.g. admission/discharge.
- Chaotic case notes occasional pages not adequately labeled with patient identifiers. Filing of drug charts; observation charts no logical sequencing. Chaotic order to notes, making it very difficult to arrange in sequence.
- Missing elements- Drugs Charts, Observations charts, Parts of case record

Documentation:

- Hand written notes illegible
- "All Wales Food chart does not separate Food & fluids, making tracking of fluid intake difficult".
- Transfers between locations with reasons not specified- "no clear note of transfer"
    - Admission and discharge dates not specified –
    - "Difficult to follow patient journey" with admission + discharge dates.
    - "No record of patients death in notes"
    - "Not clear which ward admitted to".

- “As Ward not specified, at times difficult to identify location”
- Health care plans filled on computer; when printed the sheets have no date, which makes statements e.g. 'today patient....' irrelevant.

Identification of staff-

- Specialty of medial staff reviewing patient unclear
- Not clear which staff present on ward rounds - full names not given
- Difficult to identify authors of combined notes
- Consultant input difficult to identify

Process of Clinical Care-

- Lack of documentation of physical examination- “poor initial clerking; poor examination; no record of drugs on admission; no systems review
- Apparent lack of systematic records for medical problems.”

- Method of recording progress in Ablett unit. Problem list; individual pages: difficult to follow "journey".

- Nursing notes very chaotic. Some have taken a problem approach while others write in combined nursing/medical notes. This has made it difficult to review the whole patient journey

Prescription charts-

- Missing charts
- Prescription charts were in several volumes of notes and so difficult to locate them all

- Difficult to identify authors of notes and rank of authors
- Reasons for changes in medication not always clear
- Palliative care drugs were not prescribed on the inpatient chart but only on the Integrated Care Pathway documentation. “This made it difficult to locate these records. It would be good practice if the inpatient prescription chart was used.”

Reviewers Impressions

Having completed such an extensive review, consuming many hours, by way of summary each reviewer was asked to provide an outline of their impressions of the care on Tawel Fan Ward. While previous sections have incorporated comments as relevant to those sections, accepting the cost of repetition, I believe it of benefit to present them in their entirety. Unedited, the views expressed are their impressions and opinions. Removed from the constraints of the PRISM 2 form, sharing with me an impression the process has focussed on the negatives, this has allowed a frankness of opinion and an opportunity to recognise the good. The purpose of this review of deaths associated with Tawel Fan Ward has been to form an impression of the quality of care and circumstances on that ward. Those who have died are recognised as rich cohort if one is looking to identify harms.

[redacted]- Medical

“The cohort of patients reviewed were predominantly elderly with an established diagnosis of dementia, generally ascribed to Alzheimer's type or cerebrovascular disease. There were small numbers with a diagnosis of depression and these tended to be the younger patients [redacted].

There was a syndrome for the patients with dementia: typically, the diagnosis had been established and they were under varying degrees of supervision by the EMI team in the community. There then followed a deterioration in their behaviour, either as a consequence of disease progression or inter current illness causing delirium. Behaviour deteriorated dramatically to the extent that the patient became unmanageable in his/her normal place of residence (usually a residential or nursing home not specifically registered to care for patients with EMI needs).An emergency admission resulted either by arrangement with the team or via Section 2 of the Mental Health Act. (The requirements of the Act were observed to the letter), then followed a period of assessment, prolonged in many cases with the aim of stabilising chaotic, disturbed, often aggressive behaviour by the use of drugs approved for this purpose. Long delays were experienced trying to find suitable EMI registered accommodation, because of a shortage of such and bureaucratic difficulties with the interaction of Health and Social Services. The majority of patients who died did so after discharge to an EMI Nursing Home, smaller numbers died in the ward or after transfer to the main hospital for medical treatment.

This is a particularly difficult group of patients: their behaviour is so disruptive that nursing on a general ward is nigh on impossible, their need for close supervision compromises the care of other patients and the generalist reaction (myself included) would be to sedate these patients for the benefit of the majority. I saw no evidence that excessive sedation was used in Tawel Fan ward or Glan Traeth unit when the patient had been transferred. I'm not convinced that the drugs available are particularly effective; they are certainly not curative, simply taking "the edge" off the more extreme behaviour perhaps.

It is sobering to think that younger, depressed patients were admitted to the same ward because of reduced assessment beds elsewhere in the Ablett Unit, I cannot imagine that being

exposed constantly to elderly patients with dementia and extreme behavioural problems was conducive to the highest standard of treatment.

It must be remembered that because of their age and other associated medical conditions these are patients with a poor prognosis (recognised by Hippocrates, confusion and weight loss in the elderly-article in recent BMJ). I think that there are deficiencies in the medical assessments of these patients - either because of lack of medical support or poor cooperation in the process by the patient; full examination is often impossible because of aggressive behaviour, there is little evidence to suggest that medical examination is attempted at a later date when the patient's behaviour is more controlled. This is important if trying to establish delirium as a cause for deterioration. Repeat medical examination was usually in response to new problems- often occasioned by a fall, and often delayed. There was some evidence that quite long delays happened from the time that investigations were performed until results were reviewed and acted upon. Investigations were probably under used when compared with general wards - patient's behaviour, need to transfer to main hospital for X-ray, access to ECG etc.

Nutrition is a problem in these patients, swallowing can be affected by cerebrovascular disease, behavioural problems, a lack of perception of hunger, other medical problems, drugs etc. Weight loss is a feature.
Nutritional support is patchy, there is access to the Nutritional Support Team, Dieticians and Speech and Language team but often delayed or missed.

Falls are a major problem, causes multifactorial and probably to be expected in this group of patients even with increased staff/patient ratios. The only way to prevent falls would be to immobilise the patient either by physical restraint or using the "liquid cosh" of pharmacology. There

is no evidence of this. I suspect that even with more attention paid to the causes of falls, they would still happen.

Drugs by and large were used appropriately, though there was a tendency to use antibiotics empirically (in common with the rest of the hospital)-no evidence of resultant C.Difficile. Drugs often omitted because of patient refusal: note that Trust policy on covert administration of drugs recognised and followed.

The notes themselves were chaotic, in poor physical condition partly because they had been copied and reassembled in loose leaf and partly because of the enormous volumes engendered by the various unified assessments. Many of the nursing assessments were completed according to a proforma, on line. When printed, there is no patient ID, date or signature on each page. It becomes increasingly important as notes become thicker and inevitably more likely to disintegrate that all pages are labelled with patient ID, dated (with day, month and year and time if possible) and authors are identifiable. This is a general problem with hospital notes and not peculiar to this unit. I noted that a formal discharge letter to the patient's G.P was not universal, surely essential communication as often the patient was transferred to a NH distant from original place of residence with a different GP attending.

A failing in the notes is that they are written continuously in a "stream" making it very difficult to identify when the patient was admitted after OP follow up or as an emergency, the ward admitted to and transfers inter and intra department are difficult to identify. This is a general problem and the Trust should insist that this information is made a Standard to be followed for all admissions.

The PRISM 2 is useful as a start in reviews, it could be expanded to accommodate the department being reviewed e.g. the section on medication could include analgesia, drug interactions

recognised? Side effects, drug doses correct?, drugs for neurological, respiratory ,gastroenterological diseases etc.,etc.

Having said all this I don't know how staff could elect to work with such difficult patients, putting up with abusive, aggressive, chaotic behaviour without the pleasure and satisfaction most of us were privileged to enjoy when our patients improved with our treatment and said "thank you". They deserve all the support that the Trust can offer.

[redacted] Nurse

My overall impression is of nursing staff trying hard to offer care to patients with very complex physical and mental health needs.

Having spent 5-6 weeks reading through the case notes of patients within the date range for the mortality review I have gained an impression of the complex needs of these patients, both physical and mental health needs. I concentrated mainly on the nursing notes, medical notes, observation charts and laboratory reports for my feedback. I restricted my comments on prescription charts to the occasions when medications had not been given or when commenced and discontinued.

The nursing notes discussed the difficulties in supporting the nutritional needs of patients, in particular those who could not or would not swallow. All those who had difficulties in eating were supported and encouraged to eat and drink, with nursing staff offering small frequent amounts to tempt people to eat. All were weighed on a regular basis and those who were causing concern had their nutritional intake recorded on the all Wales Food Chart.

There appears to have been supervision by nursing staff at mealtimes to support, entice and encourage people to eat and drink.

On one occasion [redacted] patient was seen to be coughing and choking at meal time. The nurse present took quick action and when banging [redacted] on the back failed to relieve the choke she resorted to doing the Heimlich manoeuvre twice, resulting in a piece of food being dislodged from [redacted] throat. She probably saved this [redacted] life.

Efforts were made to maintain individualised care with support given to enable patients to do as they wished within the confines of the mental health ward. Many patients had disturbed sleep pattern and would wander at night, sometimes they would be encouraged to return to bed, other times they would be supported to settle in the lounge, and if they fell asleep in the chair or the lounge, nursing staff would ensure they were warm and left to sleep.

Many were at risk of falling out of bed, high/low beds were in use with mattresses on the floor at the bedside to support the patient, should they fall.

Regular checks were undertaken on all patients day and night with regular toileting and repositioning if necessary. Checks were undertaken at varying intervals, depending on the patient's mental health and physical needs. Different levels of observation were in force with some people receiving one to one observation and support

One of the most regular things cited within the nursing notes was the involvement of relatives. Relatives were encouraged to be involved in the care, in the care planning and discharge arrangements and also supported to take patients out for periods (when appropriate. They were encouraged to bring in suitable clothing [redacted]

Relatives were telephoned to inform them if there had been any changes in condition, any incidents or injuries and frequently if there were any changes to medication. Relatives were often present during ward rounds and at MDT meetings.

Relatives would take clothing home to wash and when adequate clothing was not returned to the ward, patients would be dressed in clothing from the communal store. Nursing staff have commented on this and the need for relatives to bring in adequate clothing.

These appear to have been some of the most difficult patients to care for with most of them requiring help with basic hygiene needs and with dressing. Many had short-term memory problems and staff spent a great deal of time and patience trying to reassure patients when they were distressed and to repeat instructions and information on regular basis. The agitated and violent patients required skilled intervention with many nursing notes describing the way they spoke to patients, the way they explained things and reassured them. Nursing staff seamed to tread a fine line when dealing with very agitated and often extremely violent patients. They needed every ounce of patience and a toolkit of problem solving and intervention techniques to avoid running the risk of escalating situations if dealt with the wrong way.

Nursing staff did seek advice from other professionals such as the Diabetic Nurse Specialist, Tissue Viability team, Speech and Language Team and Infection Control, but sometimes there was a delay in the specialist team being able to visit the ward, with comments in the notes re *chase up xyz etc*

There were a few occasions when patients were transferred to A&E in the middle of the night. Perhaps consideration could be given to utilising the Advanced Nurse Practitioner or Critical Care Outreach for an initial assessment, rather than transfer a very disturbed and confused patient in the middle of the night.

The follow-up after discharge was always well documented by the CPN, with a full description given of the assessment and condition of the patient. For those who were transferred back into the community with community support, this support was given and telephone calls were regular and fully documented.

There have been some references to activities such as *Pets as Therapy*, music, art and discussion sessions. These notes do not give detail only a reference to the patients' attendance and whether they enjoyed them or not. Birthdays and Christmas were celebrated on the ward with special attention given to the individual.

Comments within the notes were often personalised e.g. about how the patient felt today, how they looked, whether they were pleased with celebrating a birthday, having their nails done and enjoying being pampered etc.

[redacted] Pharmacist

1. Management of mental health medicines generally appropriate and titrated according to response. Little evidence of excessive drowsiness and no evidence of use of antipsychotics as chemical cosh for chaotic behaviour.

2. Management of medicines for physical conditions was more varied. Much empiric prescribing of antibiotics, with antibiotic choice on the whole appropriate. However there were instances of recurrent infections being inadequately treated. Some patients would probably have benefited from earlier intervention with IV antibiotics.

3. Significant number of instances when medicines for physical conditions not administered, e.g. antihypertensives, inhalers, diabetes2 drugs, antibiotics.

4.Use of covert administration policy appeared to be poorly utilised. Sometimes when it was in place it was only to cover mood stabilising medicines and not the medicines for physical conditions.

5. When there was significant patient refusal of medicines there was rarely a review of prescription chart by medical staff. Consideration should have been given to discontinuing medication at least on a temporary basis rather than leaving the situation of prescription charts being liberally annotated with '4' in the administration section, which leaves nursing staff in a difficult position.

6. There were several instances when the palliative care team were appropriately involved and the Integrated Care Pathway used. However the prescription on the ICP was not generally transferred to the inpatient chart which may it difficult for myself to review the full medication history and I would have thought it would have increased the risk of confusion and error, at the time, for nursing staff not very familiar with palliative care. In general it is good practice for all drugs administered to inpatients to be prescribed on the inpatient chart.

7. Comments on methodology & documentation:

Difficult to confine review just to Tawel Fan, e.g. Glan Traeth episodes

Form tends to lead to negative comments- through listing problems rather than being balanced with positives

ADE mental health trigger tool was not well utilised as most issues were related to non mental health drugs In addition because lab results often could not be found it was not possible to complete some triggers based on these results.

Discussion

In conducting this review, the intention has been, using a validated more thorough tool to provide for BCU greater insight into care on Tawel Fan ward. At first review, reporting in September 2014 (Appendix 1), we have used our standard mortality review, "stage 2" form, but realising we had no previous experience of its use in the context of mental health, and in use finding it ill suited for that environment and the prolonged lengths of stay, we sought something better. While it has been encouraging to see similar themes have emerged, there are slight differences in emphasis. Our standard review process, recognised as more "explicit" points reviewers to question whether there have been failures in detection of, and response to the deteriorating patient on the ward, hence, hints this maybe an issue in the PRISM 2 review, see this aspect understated in comparison with its earlier comparator.

However, the themes being comparable, the real strength in the PRISM 2 approach has been in the detailing of problems and their impact for individual patients, and pressing reviewers – accepting its subjectivity- to commit to a view on the overall quality of care and linkages between problems in care and death.

That said, the cost in terms of time and personnel has been most extensive. In our standard weekly review, using a mix of individual reviewers each reviewing a single case record, the expectation is to spend no more than 20 -30 minutes for each. Testing this process for mental health notes has demonstrated unmodified, this extend to 2- 3 hours, but even this compares favourably with the average approximately 5 hours required here. While the volume of data from PRISM 2 is unquestionably valuable, and aspects may provide useful additions it is difficult to see this applicable on a large scale as a routine mechanism of hospital governance. Its rigour and validation should give greater assurance, and having demonstrated it can effectively extend to include mental health, this author would suggest this be considered the tool for targeted reviews, such as that exemplified by use in this context.

The absence of a tool for mental health, and reviewers with little familiarity of old age psychiatry might be considered a weakness. In design, we have mitigated this by securing the support of [redacted] and [redacted]. Surprisingly the issues of concern have been those of physical care, and reviewers have not felt the need to seek further advice.

While PRISM 2 is generic, the IHI Trigger tool form mental health has been designed for use in this context. Despite this, further endorsing the impressions above, describes a limited usefulness pointing to more problems with physical health drugs than the psychiatric agents expected. Furthermore, it has been interesting to experience the use of a trigger tool. Of little apparent value to the reviewers, collating the data and seeing comparisons with PRISM 2, reveals its true potential as it draws the reviewer to notice harms a speedier and less thorough review might miss. Learning from this, and seeing a resonance to its findings, this would suggest further consideration should be given to incorporating this as a future development of the routine mortality review process.

Falls

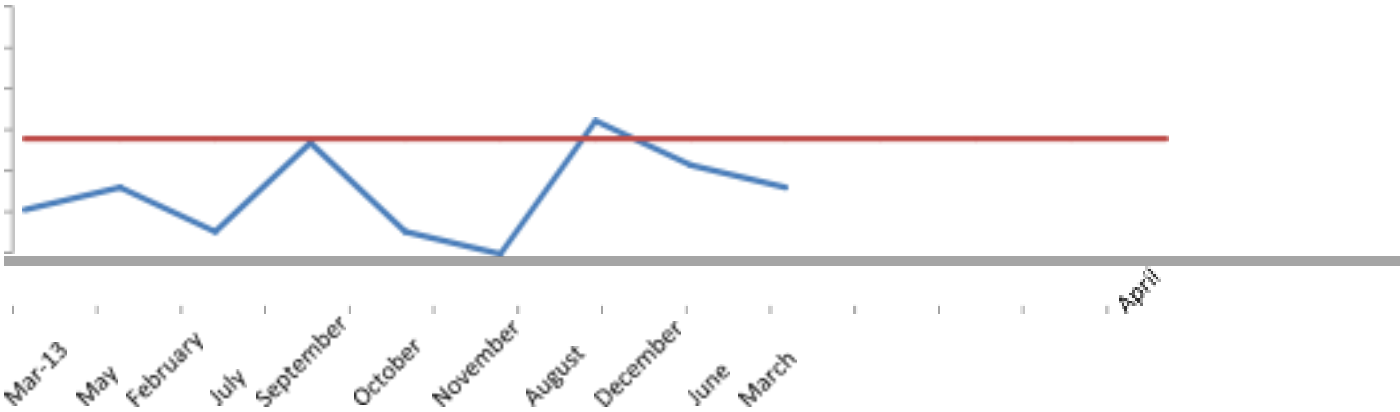
Falls stand out as a key issue. At the request of [redacted] has drafted a review dates April 2014 which has been presented to the BCUHB Quality & Safety Committee {Appendix 10). This is helpful in outlining the context and making comparison between wards across the CPG.

Taking a mean expected monthly fall rate from data provided by the Cochrane collaborative (Cameron et al., 2012), this found "Tawel Fan ward crossed the threshold once in September 2013 with an excess fall rate of +0.8. By the time of its closure in December 2013 the excess fall rate was -2.2." and concluded -"Overall the fall rates for OPMH (Older Persons Mental Health) would appear to be satisfactory".

Adding more specifics to the context, he adds-

- Falls are common events and their incidence increases with the age of the participant.
- The incidence of falls amongst hospital in-patients is 2 to 3 times greater than for older people in the community.

- Falls occurring in in-patient psycho geriatric wards are in the region of 6.2 falls per patient per year.
- Furthermore people with dementia have up to a threefold risk of falls.
- The debate regarding possible preventative interventions is well rehearsed in the literature but the evidence for effectiveness is either inadequate or conflicting.
- The mean annual average for all Older Persons Mental Health Wards, despite these accumulative risk factors, remains less than the Cochrane reported thresholds. Specifically that for Tawel Fan is determined as 3.77
- Across the thirteen month period of retrospective measurement and when the mean individual annual fall rate is used, no ward crossed the threshold. This indicates no excess falls occurred during the year as a whole.
- Tawel Fan



Limitations & Cautions

Before drawing this report to conclusions, it is appropriate to consider the limitations of the approach taken. Prompted by expressions of concern from staff and families, it is inevitable readers will expect some those concerns reflected in some of the findings from this review. However, seeing these as different perspectives on the 'truth' of what has happened on Tawel Fan, there is a need to state what some might consider the obvious. RCRR focuses solely on events documented, by staff, in the case record, at their discretion, from their perspective.

In this reviewers have been asked to make judgements about the quality of care; contribution to death and the causality of individual problems in healthcare. But noting the age profile of the

patients reviewed, and the numbers of co-morbidities one needs to be cautious in making such interpretations. Describing the HMP study Brennan (Brennan et al., 1991) states "Many patients who died after an adverse event had very serious underlying disease, and several surely had shortened life expectancies independent of their iatrogenic injury". To paraphrase, not wishing to excuse the adverse event, one must be careful in the context of a patient who "might have lived only a few more hours or days had the adverse event not occurred" to judge the death as having resulted from the medical injury.

Finally there is the question whether the findings from this review are unique to Tawel Fan, or indicative of wider issues. Physical medical care forms the basis to the majority of the concerns this review has exposed. Given the context of an Older Persons Psychiatric ward, deficiencies have been identified in the care delivered. While less palatable, seeing deficits in this care extending to other wards where these patients have been managed, this would suggest rather than consider with the closure of Tawel Fan the problem resolved, the findings should be taken as a prompt to asking how we might assure better medical assessment and care of these patients more widely. Personally reviewing cases in earlier case notes reviews, I observed physical issues and assessments appeared to be delegated to more junior members of the medical team. This prompts one to question whether this may exemplify a deficit in knowledge and skills as a consequence to medical specialisation. In another context, Orthopaedic Surgeons recognising the complexities of caring for elderly patients have campaigned for greater involvement of Geriatricians or Ortho-geriatricians. Learning form this review, prompts me to ask should Old Age Psychiatry now start to explore similar models of joint care.

Conclusions

A. Terms of Reference:-

1. Focussing on the period November 2011- November 2013, to determine whether the standard of care received was reasonable.
    a. In terms of Over-all standards, care was considered "Good" or "Excellent" in almost 61% of patients reviewed.
    b. However in 85%, 2 or more reviewers judged there were problems in healthcare
    c. Care was considered "poor" by consensus of at least 2 reviewers, in 2 and by individual reviewers for 2 patients
    d. While this was the case, for 82% of that number, death would not have been avoidable were that problem not to have occurred.
    e. Where care has been criticised, it has in the main been issues of medical physical, rather than Nursing or Psychiatric

2. Outlining instances where care falls below those standards, to make a judgement whether the patient has suffered as a consequence.

    As might be expected with such an incisive review tool, a range of problems were identified, with the following the most common

    a. Falls
    b. Omitted / Refused medications, especially non-psychiatric
    c. Deficiencies in medical assessment, investigation, diagnosis and treatment
    d. Assaults to Patients and Staff

Elaborating on these I conclude

a. Falls-

    i. While a number of Fractures have been documented, and in the context of so many falls and histories of assault, require further review, 2 predated arrival on Tawel Fan, and the 3 which can be attributed to the ward occurred despite “apparently acceptable standards of falls prevention”.

    ii. Over-all, while under-reporting has not specifically been excluded, Page’s (Appendix 10) review of Falls and the weight of comments suggest “apparently acceptable standards of falls prevention” have applied on the ward

    iii. Though the numbers stand out as problems in healthcare, it would appear the incidence is consistent with the wards case mix

b. Omitted / Refused medications, especially non-psychiatric

    i. Refusals and omissions stand out as common events. While refusals may reflect on the mental state of the patients treated, the number of omissions invites challenge, especially where documentation makes limited reference BCU covert medicines policy. This points to a need for review of practice tightening up of refusals / omissions management

    ii. Where medications were administered, a preference is demonstrated toward psychiatric medications leaving physical medications omitted.

    iii. Team knowledge of physical medicines and their side –effects is called into question, especially management of those for high blood pressure

c. Deficiencies in medical assessment, investigation, diagnosis and treatment-

    i. In the quality and timeliness of medical assessment and review

ii. In knowledge of current standards of treatment for physical disorders, especially those likely to be manifest in the elderly population served
iii. Specifically the appropriate assessment of, and care of patients presenting with increasing delirium and falls
iv. In ensuring appropriate investigations are requested, and results received, reviewed and acted on, in a timely manner
v. Documentation of, and ensuring safe and adequate handover
vi. Omissions and Refusals have not been taken as prompts for formal review by the medical team and pharmacist of medicines prescribed and required
vii. There are indications these issues are not unique to practice on Tawel Fan ward and there are suggestions this may extend more widely in mental health

d. Assaults to Patients and Staff

While these have been noted, and questions asked in earlier reviews whether adequate supervisory mechanisms have been in place to protect patients and staff, this review has not found any associated problems in care.

With Brennan's caution (Brennan et al., 1990) a-c are cited as contributory at varying levels of probability in a number of patients described.

Further to "Trusted to Care" (Andrews & Butler, 2014), this review found no evidence, even in patients with falls, sedative agents had been used excessively.

3. To address the specific question whether sub-standard care has contributed to or been causative of death

   Causation has not been explored or identified. However, the probability of avoidability was judged strong for 3 and moderate for 2, on the weight of consensus of reviewers. For two patients, death has been an outcome from one or more Adverse Drug Events (ADE)

Straying beyond the terms of reference, two further conclusions I feel should be documented

a. In common with other reviews the many critical observations concerning documentation, to include its physical state and the discipline and organisation of its content.
b. The positive experience of the use of this new tool, and the lessons it provides to developing routine mortality review processes

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Appendices

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A review of Deaths associated with Tawlfan Ward, Ablett Unit, BCUHB- Preliminary Findings

Deaths within the period November 2011-2013

Dr. Brian Tehan, Assistant Medical Director
9/15/2014

Introduction

Further to the on-going investigation we have been requested to review a number of deaths which have occurred in relation to patient stays on Tawelfan Ward, Ablett Unit, Glan Clwyd Hospital. Initially 4, identified to Mrs. Donna Ockenden through interviews with relatives conducted as part of her inquiries, this number increased as this progressed. A search of secondary care data systems have identified a total of 23 deaths in the 2 year period to November 2013 when Tawelfan was closed. These deaths, which include those flagged by Mrs. Ockenden, and include those on Tawelfan, or closely related to a stay on that ward.

Methods

Consistent with national practice, BCUHB have an established system for mortality reviews. Using a standard template approach (see Appendix 1), the reviewer is guided to answer a number of questions covering key areas of harm. While this provides consistency, and facilitates the collation of findings, additional observations can be entered as free text allowing for unanticipated harms to be identified.

As far as practicable, case notes from both mental health and the District General Hospital (YGC) were reviewed. The majority of reviewers had prior experience of this process, and those new to the process were supported by colleagues at the same table.

Prior to this, review of DGH deaths had not included (small numbers) those from mental health. At the outset it became evident the standard format,- though the key harms of concern were similar-, could not be readily applied to mental health case records. In the absence of a similar tool for mental health, we have opted to use the form, supplementing this with collation of free text comments.

The notes being quite extensive (lengths of stay typically in weeks to months), starting with the date of death, the reviews have focussed on the time immediately prior to that death to include any stay in the DGH (typically Glan Clwyd), and related time on Tawalfan Ward, Ablett Unit.

For clarity, this review though it has taken many hours per case, should not be considered forensic, and our findings are limited to what could be determined from entries made in those notes alone. Moreover, all but 2 of the reviewers have come from outside mental health. While bringing an experience of physical care and mortality reviews, there is a need to highlight a lack of familiarity with the patient group described, may have a bearing (potentially misunderstood) on conclusions drawn concerning acceptable practice.

Summary of Findings

- **Falls and Trauma**
  - Though a documented high risk group, risk assessments inconsistently used
  - Similar for protective measures
  - Concerns at the documentation of injuries as a consequence and medical review for same
- **Management of violent patients**
  - Limited / No evidence of risk assessment
  - Inconsistency in the application of 1:1 supervision (i.e. several instances where despite several documented instances of violence to staff or other patients, 1:1 still not applied, nor assessment for such)
  - Instances where even with documented 1:1, other patients injured, which calls into question the quality of this….. ???? a formal system for reviewing such events. This not evident from the case notes
- **Recognition and Response to deterioration in physical condition**
  - Lack of routine ward observations
  - Infrequent when done (e.g. Hypotension, yet once daily review)
  - Alarm signs such as low Blood Pressures ignored
  - Use of Old style observation charts, with no reference to NEWS / EWS
  - Poor fluid balance monitoring and documentation
- **No evidence of DVT risk assessment or use of prophylaxis**
- **Medical review and management of physical illness**
  - The quality of review
  - Left to relatively junior staff, apparently attending when called rather than as the normal medical staff caring for these patients
  - Delays apparent (on occasion days) from admission to medical clerking
  - Inadequate review of medications (e.g. Very low blood pressure, yet continues prescription and administration of anti-hypertensive drugs)
  - Observation that physical examination an inconsistent element of admission
  - Though clear evidence of systematic ward rounding, any problems flagged up, tend only to be addressed by an on-call Doctor (e.g. injuries sustained in falls).
  - Difficulties identifying identity of those Doctors
  - Similarly, at times difficult to be clear who is the admitting Consultant
  - Linkages to Consultant review tenuous
  - In stays lasting many weeks to months, difficult to see medical plans for care. Impression care is reactive rather than with specific goals beyond finding appropriate Nursing Homes for ultimate discharge in the longer term
  - Investigations requested (e.g. X-Rays and Bloods)- variation in the time to request, and subsequently to review findings
- **SALT assessment**
  - Are these requested?
  - When requested, time for these to be completed
  - Even where patients noted to choked on food, continued to feed as normal rather than assess

- **Physiotherapy support**
  - Lack of evidence services requested for those developing chest infections
  - Delays in the provision of this service (similar noted while in patients in YGC)
- **Dietetics support**
  - ? These asked to review
  - Difficulties noted obtaining input
- **Diabetes Care**
  - Failure to respond to issues of poor diabetic control
  - Failure to consider and address potential causes of poor diabetic control
  - Long delays in review by Diabetes Team
  - Infrequent review of control of known diabetics
- **Documentation**
  - Difficulties determining identity of authors and grade. Illegible signatures. No use of GMC nor NMC numbers
  - Separation of mental health and physical notes
  - While case note entries on a day to day basis are easy to follow, linkages to items such as risk assessments , investigations, drugs charts, observations charts… etc. difficult
  - Several instances where transfer to Tawelfan from Tegid ward associated with a falloff in nursing documentation
  - Lack of risk assessments
  - While weight loss is associated with progressive dementia, difficult in determining MUST completed from admission

- **Medication Review**
  - No evidence from the case notes of pharmacy involvement in advising care, and potential interactions

Appendix 1

BCU HB Mortality Review stage 2 (October 2013)

Site: YG ☐ YGC ☐ WMH ☐ **Type of review: Generic ☐ Speciality based ☐**

_____

Specialty:	**Place of death:**	**Transfers?** **1 ☐ 2 ☐ 3 ☐ >3 ☐**
NHS number /CRN:	**Date of admission:**	**Date of death:**

Admission	
Admitted from: (circle)	NH / RH / OH / Community Hospital / Other Acute BCU / Other Acute Non-BCU
Via:	ED / GP / Transfer
Diagnosis on Admission:	

Certified Cause of death	
Was a certificate of death present?	Yes ☐ No ☐
If the case was ***discussed*** with the Coroner, is there clear documentation of the communication?	Yes ☐ No ☐ NA ☐
What was the primary documented cause of death?	

Initial Assessment	
Was a senior review carried out within 12hrs of admission? (consultant or registrar)	Yes ☐ No ☐ Unclear ☐
Is there a documented management plan by a senior clinician (consultant or registrar)?	Yes ☐ No ☐ Unclear ☐

	Yes/No/NA	**Comment**
1. Are you surprised this patient died?		
2. Was the patient placed on the 'end of life care pathway'?		If Y - Date commenced:
3. Was a DNAR instigated, or already in place?		If Y - Date commenced:
If Yes, was the DNAR order form present,		
If Yes, Was it appropriately completed as per policy?		

On reviewing the whole case, in your opinion was there evidence of	**Yes/No**	**Comments**
1. Any delays in – diagnosis, investigations, delivery of care, treatment		
2. Poor communication/handovers		

3. Was there documented evidence of communication with the patient/family/carers		
4. Is there any indication of concerns from relatives about this person's care?		

Triggers of potential harm - Please tick if the patient experienced any of the below:	
Inpatient fall ☐ Pressure Ulcer O/A ☐ Hospital Acquired ☐ Hospital Acquired Infection ☐ Medication Errors ☐	Readmission within 30 days ☐ DVT/PE ☐ Outlier ☐
Please comment on any other adverse event identified whilst reviewing the case note:	

Rapid Response to the Acutely Ill	**Yes/No/NA**	**NO / NA answers must be supported by a comment**
Did the patient have a NEWS score documented for every set of observations?		
Was a response documented when a NEWS score of **> 3 or a concern** was triggered?		
Do you feel there is evidence of a failure to take appropriate action on alerts e.g. early warning scores i.e. escalation protocol not followed		

Coding inaccuracies	**Yes/No**	**Comment**
Does the coding for this episode of stay capture the main condition treated, all relevant associated co morbidities and diagnostic / therapeutic procedures undertaken?		
Quality of notes	**Yes/No**	**Comment**
As the reviewer, did you find any issues in respect of notes condition, documentation and filing		

Case notes identified for further review.	
Do you feel these case notes require further review?	Yes ☐ No ☐

If 'yes', please document your reasons:	
Learning points/issues Describe any areas of good practice / learning opportunities, which are evident of review of this case	
NAME OF REVIEWER	**Date_____/_____/_____**

Please send case notes AND this completed proforma to CODING 2

Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting

Institute for Healthcare Improvement
November 2008
Version 2

Cambridge, MA
www.IHI.org

The use of "triggers," or "clues," to identify adverse drug events (ADEs) is an effective method for measuring the overall level of harm from medications in a health care setting. The Trigger Tool methodology provides instructions for conducting a retrospective review of patient records using triggers to identify possible ADEs. This tool, a customization for psychiatry of the IHI Trigger Tool for Measuring Adverse Drug Events (2004),[1] was developed for use with mental health inpatients and includes a list of known ADE triggers in mental health settings, as well as instructions for collecting the data you need to measure the percentage of admissions with an ADE and the number of ADEs per 1,000 doses.

This tool contains:

- Background Information
- List of ADE Triggers
- General Instructions for Identifying and Measuring ADEs
- Two Case Scenarios
- ADE Patient Record Review Sheet
- ADE Monthly Summary Sheet

Note: You can use this tool in conjunction with the Interactive Trigger Tool for Measuring ADEs in the Workspace area on the Institute for Healthcare Improvement website (http://www.ihi.org/ihi/workspace/tools/). Enter your detailed data from all of your ADE Patient Record Review Sheets into the interactive Trigger Tool for Measuring ADEs. The interactive tool will automatically calculate and graph two measures: Percent of Admissions with an ADE and ADEs per 1,000 Doses.

[1] Institute for Healthcare Improvement. Trigger Tool for Measuring Adverse Drug Events. Available at: http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/Trigger+Tool+for+Measuring+Adverse+Drug+Events+%28IHI+Tool%29.htm

Background

Adverse drug events (ADEs) represent the single greatest risk of harm to patients in hospitals, including psychiatric hospitals.

The World Health Organization (WHO) Collaborating Centers for International Drug Monitoring defines an adverse drug event (ADE) as:

> "Noxious and unintended and occurs at doses used in man for prophylaxis, diagnosis, therapy, or modification of physiologic functions."
>
> WHO Publication DEM/NC/84.153(E), June 1984

The WHO definition includes ADEs caused by medication errors. Medication errors can occur at any stage in the medication system—from ordering through administration to the patient. Some of these medication errors are harmless, some cause injury, and some are "near misses" (fail to cause injury either by chance or because they are intercepted before the medication is administrated to the patient).

The Institute for Healthcare Improvement (IHI) formed the Idealized Design of the Medication System (IDMS) Design Group in May 2000. A group of 25 physicians, pharmacists, nurses, and statisticians established an aim to design a medication system that is safer by a factor of 10, and more cost effective than that currently in use.

Trigger Tool Methodology

Traditional efforts to detect ADEs have focused on voluntary reporting and tracking of errors. However public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients in order to select and test changes to reduce harm. This tool provides an easy-to-use method for accurately identifying ADEs and measuring the rate of ADEs over time. Tracking ADEs over time is a useful way to tell if changes the team is making are improving the safety of the medication system.

This tool is a customization for psychiatry of the IHI Trigger Tool for Measuring Adverse Drug Events (2004) and was developed for use with mental health inpatients. All of the triggers from the original IHI Trigger Tool for Measuring ADEs have been retained deliberately as it is common for mental health patients, especially older patients, to be taking cardiac drugs, anticoagulants, insulin, and other medications. Thus this tool is applicable to any group of mental health patients and can also be useful in general medical wards when looking at reducing harm from all drugs, as general wards are often not good at managing lithium, antipsychotics, and other mental health medications.

As with the other IHI Trigger Tools, this tool adapts the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Errors. NCC MERP brings together leading health care organizations to meet, collaborate, and cooperate to address the interdisciplinary causes of errors and to promote the safe use of medications.

This Trigger Tool counts only ADEs—that is, harm to the patient from medications, *whether or not* the result of an error. Harm is defined as "temporary or permanent impairment of physical or psychological body function or structure." Accordingly, the tool excludes the following categories in the NCC MERP Index because these categories describe medication errors that *do not* cause harm:

Category A: Circumstances or events that have the capacity to cause error

Category B: An error occurred but the error did not reach the patient

Category C: An error occurred that reached the patient but did not cause patient harm

Category D: An error occurred that reached the patient and required monitoring or intervention to confirm that it resulted in no harm to the patient

The tool includes categories E, F, G, H, and I of the NCC MERP Index, because these categories describe medication errors that *do* cause harm. (Note that NCC MERP's "An error that contributed to or resulted in…" has been deleted because this tool is designed to find harm, whether or not it was the result of an error.)

Category E: Temporary harm to the patient and required intervention

Category F: Temporary harm to the patient and required initial or prolonged hospitalization

Category G: Permanent patient harm

Category H: Intervention required to sustain life

Category I: Patient death

List of ADE Triggers

Before you conduct the review of patient records to identify adverse drug events, your team needs to agree on a list of triggers—clues that an ADE may have occurred, such as certain drugs or laboratory tests/results. The following is a list of triggers that organizations have found to be the most useful clues that an ADE has occurred, plus modifications or additions relevant to psychiatry.

Your organization may add some triggers to the list and delete others based on your needs—internal consistency is important when using the Trigger Tool.

T1 Antihistamines (e.g., Chlorpheniramine, Promethazine (Phenergan), Diphenhydramine)
Antihistamines are frequently used for allergic reactions to drugs but can also be ordered as a sleep aid, as a preoperative or preprocedure medication, or for seasonal allergies. If an antihistamine has been administered, review the record to determine if it was ordered for symptoms of an allergic reaction to a drug administered either during the hospitalization or prior to admission.

T2 Vitamin K
Determine whether Vitamin K was used as a response to a prolonged prothrombin time or elevated International Normalized Ratio (INR). If either lab value is high, review the record for evidence of bleeding. Look in the lab reports for a drop in hematocrit or for positive fecal occult bloods. Check the progress notes for evidence of excessive bruising or a gastrointestinal (GI) bleed. Less likely, a hemorrhagic stroke or other internal bleeding might have occurred. If any of these is found, it is likely that an ADE has occurred. Bleeding disorders have been reported with selective serotonin reuptake inhibitors (SSRIs).

T3 Flumazenil
This drug reverses benzodiazepine drugs. Determine why the drug was used. If hypotension or marked, prolonged sedation occurred following benzodiazepine administration, an ADE may have occurred.

T4 Anti-Emetics (**e.g., Ondanestron, Promethazine, Prochloperazine, Metoclopramide)**
Nausea and vomiting can be the result of drug toxicity or overdose, particularly in patients with impaired renal function. Drugs such as lithium and theophylline preparations frequently cause nausea and vomiting when levels get high. SSRIs can cause nausea and vomiting and these symptoms can also be part of an antidepressant withdrawal syndrome. Drugs for dementia commonly cause nausea and sometimes vomiting. Anti-emetics are also commonly administered to patients post-anesthetic or those receiving chemotherapy. Professional judgment must be used in these situations to determine if an ADE has occurred.

T5 Naloxone (Narcan)
This is a powerful narcotic antagonist. If it has been used, overdosage of narcotics is a frequent finding. If Narcan was used and the patient's condition changed, excessive narcotic administration, which is an ADE, probably has occurred.

T6 Antidiarrheals
Look for antibiotic-caused *Clostridium difficile* infections. If the *C. difficile* was not ordered and significant diarrhea occurred in a patient receiving multiple antibiotics, it is likely that an ADE occurred.

T7 Sodium Polystyrene Sulfonate (SPS)
Used in the treatment of hyperkalemia and aids in the removal of excess potassium from the body. Look for the reason for hyperkalemia and whether the patient had been receiving potassium. Administration of SPS may be in response to an overdose of potassium, which would be an ADE. Drugs which can cause hyperkalemia include potassium-sparing diuretics, NSAIDs, and ACE inhibitors.

T8 Serum Glucose < 50
Low serum glucose does not necessarily mean an ADE occurred. Look for evidence of symptoms and administration of glucose (orally or IV). Not all patients will be symptomatic. In addition, look for signs or symptoms in the nursing notes about lethargy, shakiness, etc., to help determine if an ADE has occurred.

T9 *Clostridium difficile* Positive Stool
If a patient is on multiple antibiotics, this is a likely complication and an indication of an ADE.

T10 Partial Thromboplastin Time (PTT) > 100 seconds
This is not an infrequent occurrence when patients are on heparin. As with Vitamin K, look for evidence of bleeding to determine if an ADE has occurred. Use professional judgment for patients with high PTTs receiving heparin during a surgical procedure.

T11 International Normalized Ratio (INR) > 6
Again, not an infrequent occurrence when patients are on warfarin. Look for evidence of bleeding to determine if an ADE has occurred.

T12 White Blood Cell Count (WBC) < 3,000
In some cases, this will occur in response to drug administration. Follow the WBC counts throughout the admission and see what has happened. If leukopenia is related to drugs such as antipsychotics (especially Clozapine) or Indomethacin, a drop in WBCs should be evident. Don't include patients currently receiving chemotherapy. If a drop in WBC occurs in the absence of medications that may cause this, an ADE has not occurred.

T13 Platelet Count < 50,000
Certain medications, including antipsychotics (especially Clozapine), can cause the platelet count to drop, placing patients at greater risk for bleeding. Look for adverse events related to bleeding such as strokes, hematomas, and hemorrhage requiring blood transfusions. Look for information about why the platelet count decreased to see if it was as a result of a medication (i.e., an ADE).

T14 Digoxin Level > 2mg/ml
This cardiac medication provides benefits within a continuous therapeutic range depending on the patient and the condition. When the level exceeds this range, some patients get benefits, but

in others, toxicity may occur. The toxicity frequently manifests as arrhythmias or bradycardia, but may also include nausea, vomiting, anorexia, and vision changes even without cardiac symptoms. If the level is greater than the therapeutic range, look for evidence that the patient had complications related to this drug or required other interventions as signs that an ADE may have occurred.

T15 Rising Serum Creatinine
Certain medications, especially lithium, aminoglycosides, diuretics, and anti-hypertensive medications, can cause renal toxicity, which may become evident when serum creatinine levels start rising. Look at several sequential results to see if levels rose. If they did, check to see if the patient received medications that are known to be nephrotoxic. If interventions were required to correct renal problems, an ADE may have occurred.

T16 Over-sedation, Lethargy, Falls
Look in the physician progress notes, nursing or multidisciplinary notes for evidence of oversedation, lethargy, and falls. If found, look for a relationship between the event and administration of a sedative (hypnotics and anxiolytics, antipsychotics, sedative antidepressants, antihistamines, etc.), analgesic, or muscle relaxant. If over-sedation, lethargy, or falls occurred as a result of administration of a sedative, analgesic, or muscle relaxant, an ADE has occurred. Include falls related to an ADE and resulting in the admission. Do not include intentional overdose by the patient resulting in sedation.

T17 Rash
There are many causes for a rash. To determine if an ADE has occurred, look for evidence that the rash is related to drug administration. For example, a yeast infection may indicate overuse of antibiotics.

T18 Abrupt Cessation of Medication
In the medication administration record, whenever "hold" or "stop" medication orders appear, look for the reason. Frequently such abrupt cessation indicates that an ADE has occurred (e.g., discontinuation of penicillin after an allergic reaction, or discontinuation of an antipsychotic due to the development of neuroleptic malignant syndrome).

T19 Abrupt Reduction of Dose of Medication
May indicate that an ADE has occurred but professional judgment is required.

T20 Transfer to a Higher Level of Care
This includes either within the ward (e.g., to special observation), to another ward (e.g., PICU or a medical-surgical ward) from your ward, or to your ward from another. Transfer of a patient to a higher level of care is only a trigger, a clue that an ADE may have occurred. A higher level of care is indicated when a patient's clinical condition (mental or physical) deteriorates or becomes more serious and this can happen for many reasons. However, in some cases an ADE is the cause of the change in condition. When reviewing this trigger, look for the reasons for the transfer and the change in condition; if the latter is linked to any medications, this may be an indication that an ADE has occurred. For example, transfer following management of respiratory arrest is not an ADE if the respiratory arrest was a complication of an acute asthma attack, but would be an ADE

if the respiratory arrest was caused by administration of intravenous diazepam. If a patient becomes aggressive following commencement of benzodiazepines this could be an ADE as benzodiazepines can cause a paradoxical increase in hostility and aggression. Rapid deterioration in mental state following dose reduction or drug cessation is an ADE, as is a drug withdrawal syndrome.

T21 Unexpected Death
Clearly professional judgment will be required but consider the possibility of an ADE, especially if the patient is on antipsychotic medication.

T22 Serum Lithium > 1.0 mmol/liter
Lithium salts have a narrow therapeutic/toxic ratio and doses are adjusted to achieve a serum lithium concentration of 0.4 to 1.0mmol/liter (lower end of the range for maintenance therapy and elderly patients) on samples taken 12 hours after the preceding dose. Common side effects include fine hand tremor, increased thirst, and increased frequency of urination. When the level exceeds the therapeutic range toxicity may occur, and symptoms indicating that harm may have occurred include tremor, ataxia, slurred speech, nystagmus, renal impairment, and convulsions. If the level is greater than the therapeutic range, look for evidence that the patient had complications related to this drug or required other interventions as signs that an ADE may have occurred.

T23 Slow Sodium
Used in the treatment of significant hyponatremia. Look for the reason for the hyponatremia (may or may not be drug related) and, in particular check. if the patient is on antidepressants. Hyponatremia (usually in the elderly and possibly due to the secretion of antidiuretic hormone) has been associated with all types of antidepressants, especially with SSRIs.

T24 Serum Sodium < 135 mmol/liter
Does not necessarily mean an ADE occurred. If patient is on antidepressants look for evidence of harm (drowsiness, confusion, convulsions) which would indicate that an ADE has occurred.

T25 Laxatives
There are many causes of constipation necessitating the prescription of laxatives. To determine if an ADE is likely to have occurred, look for evidence that the prescription of laxatives is related to drug administration (e.g., tricyclic antidepressants, antipsychotics (especially clozapine), antimuscarinic drugs). Professional judgment will be necessary.

T26 Antimuscarinic Drugs (Benzatropine)
Prescribed for the relief of Parkinsonian symptoms induced by antipsychotic drugs, but there is no justification for giving these drugs routinely in the absence of Parkinsonian side effects. Tardive dyskinesia is not improved by antimuscarinic drugs and may be made worse, which would be considered an ADE. Benztropine may be given parenterally as emergency treatment for acute drug-induced dystonic reactions which may be severe.

T27 Tetrabenazine
Prescription of this drug does not necessarily mean that an ADE has occurred as it is used for movement disorders such as Huntington's Chorea and other neurological conditions. Look for evidence that the patient has tardive dyskinesia which indicates harm from antipsychotic medication and is an ADE.

T28 Insertion of a Urinary Catheter for Urinary Retention
There are many causes of urinary retention, but if it followed commencement/increase in dose of an antimuscarinic drug or a drug with antimuscarinic side effects (e.g., tricyclic antidepressants, antipsychotic drugs) an ADE has occurred.

T29 Significant Weight Gain
Look for entries in the record that indicate that prescribed medication is thought to have caused significant weight gain which can occur with, for example, some antipsychotics and lithium. Professional judgment will be required to determine if an ADE has occurred.

T30 Drug Combinations Not Normally Recommended (e.g., combination of two antidepressants; more than one antipsychotic at the same time; lithium plus a thiazide diuretic; etc.)
Does not mean that harm has occurred but makes an ADE more likely.

Identifying and Measuring ADEs in Your Organization

Once your team has decided on the list of triggers, the next step is to review a sample of patient records. Recruit a multidisciplinary team to conduct the ADE patient record review. Ideally, the team should include at a minimum one doctor, one nurse, and one pharmacist. All members of the team should review the Trigger Tool so they understand how to conduct the patient record review.

Edit the list of triggers at the top of the ADE Patient Record Review Sheet per your team's decision. Distribute the ADE Patient Record Review Sheet to all team members, either electronically or on paper. Each patient record in the review requires its own copy of the form, whether or not the record turns out to contain triggers and ADEs.

The patient record review has two major components. First, review in a systematic way the portions of the record where the triggers are most likely to be found. For example, a high serum lithium level would be found in the Laboratory Values portion of the record. *The important point is not to read through the entire patient record, but to read very selectively;* this is how the Trigger Tool review differs from a standard patient record review. If a trigger is found, then go to whatever portion of the record that will reveal the occurrence of an ADE. If a harmful event is found, determine the level of harm using the NCC MERP Index Categories E through I (those that cause harm). *Be sure to include every ADE found, even if not identified by a trigger.*

Measuring ADEs: A Sampling Plan

Measuring the number of ADEs in your organization over time tells you whether or not the changes you are making result in improvement. Instead of reviewing all patient records to detect triggers and investigate them to determine if an ADE has occurred, we suggest using the following sampling plan:

1. Get the list of discharges for the month (minimum two-day hospital stay).

2. Select a *random* sample of 20 patient records (each record has an equal chance of being selected).

3. Obtain those 20 patient records from the Medical Records Department.

4. Review each patient record, paying particular attention to the following sections:
   - Discharge summary: Look for ADEs or hints at ADEs
   - Laboratory reports: Look for trigger lab results
   - Medication Administration Record: Look for trigger medications
   - Physician orders (prescribed medications)

   Note: Generally allow only 20 minutes for a patient record review by an experienced person (allow a little more time for someone just learning the process). Any time left after the review should then be devoted to the notes, in the following order:
   - Nursing care plan: Look for skin rash, altered level of consciousness, etc.
   - Nursing/Multidisciplinary progress notes: Look for over-sedation, lethargy, falls, rash, nausea/vomiting, retention of urine, or other adverse events
   - Medical progress notes

5. List all triggers found on the ADE Patient Record Review Sheet.

6. For each trigger found, read through the appropriate parts of the patient record to determine if an ADE has occurred. Sometimes professional judgment will be required to make this determination. Some ADEs can be identified by more than one trigger; use your best judgment in determining the number of ADEs that occurred in this situation.

7. If an ADE occurred, assign a category of harm (E through I) and provide a brief description of the ADE. Include every ADE found even if not identified by a trigger.

NOTE: You can use the Interactive Trigger Tool for Measuring ADEs on IHI's website to complete the next three steps. Available at: http://www.ihi.org/ihi/workspace/tools/trigger/.

8. After you have completed the ADE Patient Record Review Sheet for the random sample of 20 patient records, summarize your findings in the ADE Monthly Summary Sheet. For each patient record reviewed, document the following:
   - Whether an ADE occurred;
   - The number of ADEs; and

- The total number of medication doses received (if you collected data on doses).

9. Use the data in the ADE Monthly Summary Sheet to calculate one or both of these important measures:
    - Percent of Admissions with an ADE: The total number of patients identified as having experienced any ADEs from a sample of patient records, divided by the total number of records in the sample, and multiplied by 100 to express as a percentage.
    - ADEs per 1,000 doses: The total number of ADEs identified in a sample of patient records, divided by the total number of medication doses administered to those patients. Multiply the result by 1,000.

10. Track the measures (Percent of Admissions with an ADE, ADEs per 1,000 Doses) over time in a run chart, to see if changes you are testing are making the medication system safer. You can use the Interactive Trigger Tool for Measuring ADEs on IHI.org to automatically track and graph these measures over time.

Case Studies: Using the Trigger Tool to Identify ADEs

The two scenarios described below provide examples of how a reviewer might use the Trigger Tool to identify ADEs in the patient record. Following the instructions in the Trigger Tool for Measuring ADEs, the reviewer completed these steps:

1) Reviewed the physician's orders to look for any of the identified triggers, especially the medication triggers.
2) For each trigger found, reviewed progress notes, nursing notes, and multidisciplinary notes for evidence of an ADE. If an ADE was found, then determined the harm category (E through I).
3) Reviewed laboratory findings for any of the lab triggers. If triggers were found, reviewed progress notes, nursing notes, and multidisciplinary notes for evidence of an ADE. If an ADE was found, then determined the harm category (E through I).
4) Obtained financial data (if available) that provides a count of medications doses administered.

Scenario 1

On review of the patient's record, there is an order to discontinue benzylpenicillin. The patient had only received two doses of IV benzylpenicillin. This is the first trigger that is identified (T18 – Abrupt Cessation of Medication). Further in the record, on the same day, is an order for "chlorpheniramine 10-20 mg IV now." This is the second trigger that is identified (T1 – Antihistamines). The physician progress notes are reviewed for information about a potential ADE; the physician's notes indicate that the patient developed a rash to the benzylpenicillin. This is another trigger (T17 – Rash). Also, in the nursing notes, there is documentation about the development of a red, itchy rash. Documentation indicates that the physician was notified and the antibiotic stopped. Nursing notes from later on the same day document that the rash was still present and the patient was complaining of itching. The physician was notified and an order for chlorpheniramine was received.

The remainder of the patient record is reviewed, including lab results, and no other ADEs are identified.

Overall, one ADE is identified (reaction to the benzylpenicillin) with a harm category of E, because the patient did require discontinuation of therapy and treatment with another drug.

Scenario 2

On review of the patient record, no triggers were identified from the physician orders. In the laboratory values, a blood glucose level of 33 from a finger stick is noted (T8 – Serum Glucose <50). The physician progress notes do not include documentation of low glucose levels or any changes in insulin orders. The nursing notes include documentation of the patient being very shaky, lethargic, and slightly confused with blood glucose via finger stick of 33. Physician was notified and orange drink with sugar was prescribed, with follow-up blood sugar measurement. Later that day, there was a physician order to change the sliding scale insulin.

The medication administration record (MAR) documentation shows that regular insulin on a sliding scale had been given approximately 90 minutes prior to the low glucose level.

No other triggers were identified.

Overall, one ADE was identified (symptomatic hypoglycemia after insulin) and a harm category of E was assigned due to the increased monitoring, treatment with orange drink and sugar, and the change of the medication.

ADE Patient Record Review Sheet

Admission date_____ Patient's ID No_____ Patient's Age_____

Discharge Date _____ Reviewer_____
(Two days minimum hospital stay required)

Trigger:	Trigger Found in Review?		ADE Found? If yes, indicate harm category* and describe ADE.	
	Yes	No	Yes	No
T_1 Antihistamines				
T_2 Vitamin K				
T_3 Flumazenil				
T_4 Anti-Emetics				
T_5 Naloxone (Narcan)				
T_6 Antidiarrheals				
T_7 Sodium Polystyrene Sulfonate (SPS)				
T_8 Serum glucose < 50				
T_9 *C. difficile* Positive Stool				
T_{10} PTT > 100 seconds				
T_{11} INR > 6				
T_{12} WBC < 3,000				
T_{13} Platelet Count < 50,000				
T_{14} Digoxin Level > 2mg/ml				
T_{15} Rising Serum Creatinine				
T_{16} Over-sedation/Lethargy/Falls				
T_{17} Rash				
T_{18} Abrupt Cessation of Medication				
T_{19} Abrupt Reduction of Dose of Medication				
T_{20} Transfer to a Higher Level of Care				
T_{21} Unexpected Death				
T_{22} Serum Lithium >1.0 mmol/liter				
T_{23} Slow Sodium				
T_{24} Serum Sodium<135 mmol/liter				
T_{25} Laxatives				
T_{26} Antimuscarinic Drugs				
T_{27} Tetrabenazine				
T_{28} Urinary Catheter				
T_{29} Significant Weight Gain				
T_{30} Drug Combinations				

Total ADEs for this patient:_____

*NCC MERP Index Harm Categories:

- E: Temporary harm to the patient and required intervention
- F: Temporary harm to the patient and required initial or prolonged hospitalization
- G: Permanent patient harm
- H: Intervention required to sustain life
- I: Patient death

NOTE: You can use the Interactive Trigger Tool for Measuring ADEs to complete the ADE Monthly Summary Sheet and automatically calculate and graph Percent of Admissions with an ADE and ADEs per 1,000 Doses. Available at: http://www.ihi.org/ihi/workspace/tools/trigger/.

ADE Monthly Summary Sheet

Date: _____

Patient	ADE Found? (Yes/No)	Total number of ADEs for this patient	Total no of doses of medications for this patient (if available)
Pt #1			
Pt #2			
Pt #3			
Pt #4			
Pt #5			
Pt #6			
Pt #7			
Pt #8			
Pt #9			
Pt #10			
Pt #11			
Pt #12			
Pt #13			
Pt #14			
Pt #15			
Pt #16			
Pt #17			
Pt #18			
Pt #19			
Pt #20			
	Total:	Total:	Total:

Percent of Admissions with an ADE: _____

The total number of patients identified as having experienced any ADE from a sample of patient records (Column 1 Total), divided by the total number of records in the sample; multiplied by 100 to express as a percentage.

ADEs per 1,000 Doses: _____

The total number of ADEs identified in the sample of patient records (Column 2 Total), divided by the total number of medication doses administered to those patients (Column 3 Total); multiply the result by 1,000.

PRISM 2 Review Form

A. Date of the review:

B. Reviewer Name (please print):

C. Patient unique study number:

'Confidential patient information'

With grateful acknowledgement to Graham Neale, Maria Woloshynowych, Charles Vincent and Frances Healey whose iterations of the format over several research studies formed the basis of this document

ADMINISTRATIVE INFORMATION TO COMPLETE FOR ALL REVIEWED DEATHS

1. Age at death (years) ☐
2. Sex M/F ☐
3. Length of admission (no of days) ☐
4. Month of admission ☐
5. Day of admission (Monday to Sunday) ☐
6. Time of patient's first arrival at hospital (A&E or elsewhere). Please circle.
    a. Day (08:00-16:59)
    b. Evening (17:00-21:59)
    c. Night (22:00-07:59)

7. How many inpatient wards/units was the patient on during this admission? ☐

8. Where was the patient admitted from? Please circle.
    a. His or her own home
    b. A nursing or residential care home
    c. A hospital in another NHS trust
    d. Other (specify)

    ☐

9. Type of admission. Please circle
    a. Emergency
    b. Planned/elective
    c. Other (specify)

    ☐

PART A: Risk Factors

We ask for the following information on all patients who have died. This allows analysis of whether some groups of patients, or some types of wards and units, are disproportionately affected by potentially avoidable deaths, so improvement efforts can be focused there.

1. Did the patient have confusion/memory problems at any point in their hospital stay? Please circle.
    a. No
    b. Yes
2. If yes, was a diagnosis of the confusion/memory problems established? Please circle.
    a. No diagnosis of type of confusion/memory problems apparent
    b. Dementia alone
    c. Delirium alone
    d. Delirium superimposed on dementia
    e. Other type of confusion/memory problems please specify

    ☐

3. Did the patient have a significant mental illness (other than confusion/memory problems options above)? Please circle.

a. No indications of a significant mental illness
b. Clear indications of a significant mental illness
c. Some indications of a significant mental illness but records unclear

4. Did the patient have a learning disability? Please circle.

a. No indications of a learning disability
b. Clear indications of a learning disability
c. Some indications of a learning disability but records unclear

5. Did the patient have any of the following comorbidities? This list is based on the Charlson Index of Comorbidity. Other comorbidities can be entered in the last box.

Comorbidity	**Yes**	**No**
Myocardial infarct		
Congestive heart failure		
Peripheral vascular disease		
Cerebrovascular disease		
Hemiplegia		
Chronic lung disease		
Connective tissue disease		
Diabetes without end organ damage		
Diabetes with end organ damage		
Ulcer		
Chronic liver disease		
Moderate or severe liver disease		
Moderate or severe kidney disease		
Lymphoma		
Leukemia		
Non-malignant tumor		
Malignant tumor		
Metastasis		
AIDS		
Other		

6. Patient condition immediately prior to the illness that led to this admission. Please circle.

a. Fully independent
b. Independent in personal care, but needing help with other activities of daily living
c. Dependant on others for personal care (washing, dressing, eating, etc.)
d. Unable to determine; no relevant information in notes (direct or implied)

7. Was the patient initially assessed in A&E and/or any other short term emergency admission assessment unit? (e.g. Clinical Decision Unit, Medical or Surgical Assessment Unit, etc.). Please circle.

a. Yes
b. No
c. Unable to determine

8. Speciality at time of first ward admission (the first ward/unit where the intention was for them to stay at least one night). Please circle.

a. Older people's Medicine
b. Rehabilitation
c. General medicine (including medical assessment/short stay)
d. Medical sub-specialities. Specify if can be determined:

e. General Surgery (including surgical assessment/short stay)
f. Surgical sub-specialities including gynaecology & orthopaedics. Specify if can be determined.

g. Other. Specify

9. Was this an appropriate type of ward for their condition? Please circle.

a. Yes, definitely appropriate
b. Probably appropriate
c. No
d. Unable to determine

10. Speciality at time of death. Please circle.

a. Older people's Medicine
b. Rehabilitation
c. General medicine (including medical assessment/short stay)
d. Medical sub-specialities. Specify if can be determined:

e. General Surgery (including surgical assessment/short stay)
f. Surgical sub-specialities including gynaecology & orthopaedics. Specify if can be determined.

g. Other. Specify

11. Was this an appropriate type of ward for their condition? Please circle.

a. Yes, definitely appropriate
b. Probably appropriate
c. No
d. Unable to determine

12. Apparent main diagnosis on admission:

Note you should record the patient's **apparent main diagnosis at the point their initial medical assessment/clerking was completed** (you will have an opportunity later in the form to note if you consider this diagnosis was incorrect). Please circle.

1. Trauma-related diagnoses
a. Fractured hip
b. Any other falls-related diagnosis
c. Trauma from other cause (not fall)
2. Cardiovascular diagnoses
a. Stroke
b. Acute coronary syndrome/STEMI/angina
c. Heart failure
d. Arrhythmia
e. DVT/PE
g. Any other cardiovascular condition
3. Infection (with or without sepsis)
a. Chest infection/pneumonia
b. Urinary tract infection
c. Bloodstream infection
d. Gastroenteritis
e. Any other diagnosis of infection
4. Cancer-related diagnosis
5. Acute abdomen
6. Gastrointestinal haemorrhage
7. Exacerbation of Chronic Obstructive Pulmonary Disease
8. Any other diagnosis please specify……..

We recognise the list above is not comprehensive, but it represents the diagnoses most commonly seen in patients who died in hospital in the PRISM 1 study, and will be built on in future phases.

PART B: DECISION TO PROCEED TO DETAILED REVIEW Clinical reviewer completes for all reviewed deaths

Before answering the following questions, ensure you have reviewed all available documentation related to the admission in which the patient died, including:

- all inpatient documentation related to the admission in which the patient died, including medical, nursing and therapy records
- any GP referral letters, ambulance summary, A&E summary, etc. related to the admission in which the patient died

Determination of problem in healthcare

13. A problem in healthcare is defined as 'any point where the patient's healthcare fell below an acceptable standard and led to harm'. Considering all that you know about this patient's admission, were there any problems in healthcare (including any problems before admission)? Please circle.

a. No evidence of any problems in healthcare ⇨ please go straight to Part D

b. Some evidence of problem/s in healthcare ⇨ please complete the next question

14. In your judgement, is there some evidence that the patient's death was avoidable if the problem/s in healthcare had not occurred? Please circle.

a. No , death was definitely not avoidable ⇨ please go straight to Part D

b. At least slight evidence the death may have been avoidable ⇨ please complete Part C and then Part D

PART C: DETAILED REVIEW OF PROBLEMS IN HEALTHCARE

Clinical reviewers complete this section ONLY if you have answered Question 14 as "At least slight evidence the death may have been avoidable."

Please summarise in chronological order the background, admission, procedures, and events leading up to the patient's death and cause of death, including any points where there were problems in healthcare. You will have an opportunity to be more specific about these problems in healthcare and justify your judgements later in the review form.

15. Please complete the following table using the laminated category list that accompanies this review form.

- **A problem in healthcare is defined as 'any point where the patient's healthcare fell below an acceptable standard and led to harm'.** To identify the **problems in healthcare,** consider what an acceptable standard of healthcare would be for this patient, and articulate how the healthcare they received fell below this acceptable standard (whether through omission, delay or incorrect actions). Include any problems in healthcare that occurred before the patient's final admission but were identified during it. **Only one problem should be entered per row.**
- It can be difficult to identify **contributory factors** (i.e. the underlying reasons ***why*** the problem in healthcare occurred) from case notes alone. If you can clearly identify any factors that contributed to each problem in healthcare please do so, but avoid making assumptions. **Contributory factor should refer to the problem described in the same row.**

Describe each problem in care in your own words. Please articulate what should have happened AND what did happen.	**Where did the problem occur?**	**Sub-type of problem** ***(select one)***	**Contributory factors** ***(option to select none, one or multiple)***
Example: "First dose of IV penicillin should have been given immediately but was not given until three hours after prescribed"	*D*	*B6*	*c g*

Describe each problem in care in your own words. Please articulate what should have happened AND what did happen.	**Where did the problem occur?**	**Sub-type of problem** ***(select one)***	**Contributory factors** ***(option to select none, one or multiple)***

16. Earlier in the case note review, you made a judgement that there was at least slight evidence that death may have been avoidable if the problem/s in healthcare had not occurred. Considering the problems in healthcare you have described above, please rate on the Likert scale the strength of evidence for the avoidability of the death:

2 Slight evidence for avoidability
3 Possibly avoidable but not very likely, less than 50-50 but close call
4 Probably avoidable, more than 50-50 but close call
5 Strong evidence for avoidability
6 Definitely avoidable

Please record reasons justifying the judgement you have made

17. Earlier in the case note review, you made a judgement that there was at least slight evidence that death may have been avoidable if the problem/s in healthcare had not occurred. Considering the problems in healthcare you have described above, please mark on this continuous scale the strength of evidence for the avoidability of the death. <u>Mark with a single line through the scale.</u>

We appreciate this is an even more difficult judgement call than the decision you made above on Likert Scale (slight/possible/probable/strong evidence for avoidability), but providing your judgement on a continuous scale allows additional analysis.

Death definitely not avoidable

Death definitely avoidable

18. If death was considered avoidable had the problem/s in healthcare had not occurred, by how many days/months/years do you estimate the patient's life was shortened? Please circle.

a. By one week or less
b. By more than a week but less than a month
c. By more than a month but less than three months
d. By more than three months but less than a year
e. By …….years

We appreciate this is difficult judgement call, but even estimates are helpful in prioritising future improvement efforts. In arriving at an estimate, you may wish to consider expected prognosis for a patient presenting with this condition and comorbidities who received an acceptable standard of healthcare, and/or average life expectancy alongside consideration of whether the patient had better or worse general health and capacity to recover than average.

19. If death was considered avoidable had the problem/s in healthcare not occurred, please indicate when you believe the BEST opportunity of avoiding the death occurred:

a. Outside hospital care (primary care, ambulance, etc.)
b. In a prior admission/attendance (this trust)
c. In a prior admission/attendance (another secondary healthcare provider)
d. In an initial assessment unit (e.g. A&E department, or any other short term emergency assessment unit such as a Clinical Decision Unit, Medical Assessment Unit, Surgical Assessment Unit, etc.)
e. During an invasive procedure (including surgery and anaesthesia)
f. During post-operative care or post-procedure care (except HDU/ITU)

g. During High Dependency or ITU care (not including decision to refer to HDU/ITU)
h. During inpatient care on a ward/unit designated as:
    i. Older people's Medicine
    ii. Rehabilitation
    iii. General medicine
    iv. Medical sub-specialities
    v. General Surgery
    vi. Surgical sub-specialities including gynaecology & orthopaedics
    vii. Other (specify)

20. Avoiding future deaths

Although case note review in isolation cannot be a substitute for a full root cause analysis investigation, please indicate any specific improvements you believe might decrease the likelihood of similar deaths occurring in future. Areas you might consider are better design of equipment or procedures, interventions to limit human error or organisational changes.

PART D: GENERAL QUALITY OF CARE AND END OF LIFE CARE
Compete for ALL reviewed deaths

Overall Quality of Care

21. Considering all that you know about this patient's admission, how would you rate the OVERALL quality of healthcare received by the patient from this trust? This question recognises that a problem in care causing patient harm can occur against a backdrop of overall good quality care, and the converse, a patient may experience poor overall quality of care without obvious harm. For this question, do not consider healthcare prior to the admission that ended in the patient's death or give detail of a specific problem in care causing harm, which were entered in Part C.

a. Excellent
b. Good
c. Adequate
d. Poor
e. Very poor

Please add any detail on overall quality of healthcare that can be used for learning (positive or negative):

End of Life Care

Questions 22 and 23 focus on care EITHER from the point where the patient was recognised at high risk of dying (whether this was days or hours before death) OR, for patients who were not recognised as at high risk of dying, the last 48 hours of their life

22. Was the patient subject to any intrusive or invasive procedures that were **not** in their best interests at the end of life (including inappropriate attempts at CPR)?

a. Yes
b. No
c. Unable to determine

23. Was there evidence of discussion of end of life care with family/friends? Please circle.

a. Yes, evidence of discussion
b. No, discussion appeared appropriate and feasible, but no evidence it took place
c. Not appropriate/not feasible to discuss with family/friends

Please add any detail on overall quality of end of life healthcare that can be used for learning (positive or negative) including pain and symptom control:

PART E: REVIEW PROCESS INFORMATION
Complete for ALL reviewed deaths

24. Were your judgements limited or hampered by lack of subspecialty knowledge?

a. No
b. Yes

25. If so was a second specialist opinion sought?

a. No
b. Yes

26. What was your question/s for the specialist?

27. What was the answer/s from the specialist?

28. Did the answer/s change your opinion and how?

29. How adequate were the records in providing information to enable judgements of problems in care? Please circle.

a. Medical records were adequate to make a reasonable judgement
b. Some deficiencies in the records (specify)
c. Major deficiencies (specify)
d. Severe deficiencies, impossible to make judgements about problems in care

Please use this space to specify any deficiencies in the medical record

30. Total time taken to complete review (minutes)? [ ]

Preventable Incidents, Survival and Mortality Study 2 (PRISM)

Medical Record Review Manual

Dr Helen Hogan, Jan 2014

Introduction

Public and policy interest in hospital death rates has risen sharply, particularly following the recent investigations into the Mid Staffordshire NHS Trust and 14 other acute Trusts around the country. For the last decade the Department of Health (DH) has advocated the use of hospital wide measures of mortality such as HSMR and SHMI to provide an early warning system of quality and safety problems within hospitals and to compare performance across hospitals. However, intense debate surrounds whether the "excess deaths" detected by these measures are a valid indicator of the safety of a hospital. Many factors beyond patient safety impact on HSMR/SHMI including coding standards and depth, or the local provision of services for the dying that divert patients from hospitals. Such factors can lead to higher scores for some hospitals which have nothing to do with quality and safety of healthcare provision

Only four published studies, all in N America, have looked at the association between HSMR and avoidable deaths determined by case record review. Three of the studies either found no correlation,[1, 2] or a negative correlation.[3] Only one study found a significant positive association with deaths in a single disease group (pneumonia).[4]This was also the smallest study. (Two additional unpublished studies have found no association). In 2009, we undertook the PRISM 1 to obtain a national estimate of hospital avoidable deaths using case note review of a 1000 deaths across 10 acute hospital sites. By extending the sample size of our previous study from 10 hospitals (1000 deaths) to 34 hospitals (3400 deaths (2400 new reviews across another 24 Trusts)) we will achieve sufficient statistical power to determine the degree of correlation between avoidable death rates at hospital level and HSMR/SHMI.

The PRISM 2 correlation study will inform policy makers' decisions on approaches to tracking hospital quality and safety. It will also provide a national baseline for avoidable deaths against which NHS England will compare future estimates derived from a new national measure of avoidable deaths due to be introduced in 2014/15.

Aims and Objectives of the Study

Aim

To ascertain the relationship between hospital avoidable deaths identified by retrospective case record review and HSMR/ SHMI

Objectives

To determine the proportion of patients dying in hospital who experience a problem in healthcare including acts of omission (inactions) or acts of commission (affirmative actions) and the proportion of such deaths that are avoidable

To determine the strength of correlation between the proportion of avoidable deaths at hospital level and HSMR/ SHMI

To inform policy makers whether "excess deaths" identified by HSMR/SHMI are correlated with avoidable deaths determined by retrospective case record review

Study Design

The methodology for retrospective case record review (RCRR) was first developed in California in the mid-seventies and used to identify the burden of healthcare-related harm as part of an investigation into the costs of a no-fault insurance scheme for hospitals.[5] The method and review forms were further developed in the two largest RCRR studies of adverse events to date: the Harvard Medical Practice Study[6] and the Quality in Australian Healthcare Study.[7] The design of PRISM 2 also draws on the first British RCRR study, conducted by Vincent et al, which examined the incidence of adverse events in 1014 admissions to two London hospitals in 1999.[8] The design has also been influenced by the methodology used by Hayward et al[9] in a US study focused on preventable deaths and a Dutch RCRR [10] which sampled 2000 deaths.

In PRISM 2, case record reviews will be conducted in 24 English acute hospital Trusts. One hundred randomly selected admissions of adult medical and surgical patients who have died during hospitalisation in the financial year 2012/2013 will be reviewed at each site. Obstetric, psychiatric and paediatric patients are excluded. The exclusion of these patient populations, which account for less than 5% of all hospital deaths in England and Wales, is in line with previous studies and will aid comparison with death rates found in such studies.[11]

Admission Selection and Record Collection

The study sample will be drawn from each Trust's Patient Administration System. The Chief Investigator (CI) will develop a joint protocol with each site which covers sampling, location, tracing and retrieval of medical records. The Trusts will be instructed to check that any records which are not traceable do not vary substantially from the rest of the sample in terms of age, sex, specialty, medico-legal investigation or coroners' case. Each Trust will be asked to ensure that any selected medical records subject to medico-legal issues are made available for review.

The reviews will take place at each study hospital. Trusts will be asked to facilitate access to case records, to provide reviewers with desk space to undertake the reviews and help reviewers to access missing lab or imaging information via the Trust computer system. They will also be asked to help orientate reviewers to Trust organisation including names and types of wards and consultant lists. Reviewers will not be expected to be on site at the same times but can coordinate their reviews with others if there is adequate space available. Ten per cent of all records will be double reviewed.

The Review Process

For each case the reviewer will complete a Key Code document which links the patient's hospital number to a unique study number and indicates the date the review. This code remains at the Trust on completion of the reviews, normally within the Clinical Governance Department. Unique study numbers and reviewer ID numbers will be allocated before reviews commence at a site. Reviewers should maintain oversight of the security of both case records and the medical review forms whilst undertaking reviews.

Once reviews are complete the reviewers will contact their nominated lead reviewer to agree a time to discuss any avoidable deaths found (usually by phone). Following these conversations completed forms will be transported back to the London School of Hygiene and Tropical Medicine (LSHTM) by secure courier or by hand (with prior arrangement).

Confidentiality

The PRISM 2 study is required to comply with guidance set out in the NHS Code of Confidentiality and the GMC's Good Research Practice Guidance. The Research Passport

and “Letter of Access” binds each reviewer to a code of confidentiality, both for the selected Trusts and the patients reviewed. Care should be taken to ensure that no patient identifiable information is retained on the Review Forms. Care should also be taken that no Trust, doctor or patient identifiable information is disclosed when using email to discuss cases with other reviewers (as in the case of asking a speciality specific question of a colleague). In the case of a breach of confidentiality, a reviewer will immediately be asked to leave the project and the General Medical Council will be informed.

The Key Code document links a patient’s unique study number to their hospital number. This code will stored in the Trusts’ Clinical Governance Department after the study finishes. The code will only be broken if there are serious concerns of negligence in relation to the care of a patient which need to be fed back to the Trust. If a reviewer uncovers such an issue they should report it to the key Trust contact who will be nominated prior to the start of the reviews. The Trust will then be expected to deal with the issue according to their own internal policies and procedures. .

Contacts

For questions arising during the review period please contact:

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Operational Definitions

To identify avoidable deaths it is important to initially establish whether there were problems in the way healthcare was delivered to the patient (the processes of care). If a patient is harmed by healthcare but the care was delivered to an acceptable standard, this harm is known as a complication. A death following a complication, such as intracerebral bleeding after appropriate administration of thrombolysis would not be regarded as avoidable.

PRISM 2 defines a problem in healthcare as **‘any point where the patient’s healthcare fell below an acceptable standard and led to harm’.** Problems include:

- An omission or inaction such as failure to diagnose and treat
- An act of commission or affirmative actions related to the delivery of care such as incorrect treatment or management

We have chosen to use the term “problems in healthcare” rather than the more traditional term “adverse event” because this latter term tends to be associated with discrete incidents and is more likely to identify acts of commission than omission. The term “problem/s in healthcare” allows a reviewer to broaden their perspective and assess the impact of multiple small events (usually omissions) across the patient journey.

It may be difficult to identify one clear cut problem or even identify the point at which things went wrong. Avoidable deaths are more likely to result from a combination of problems in healthcare, such as in the example below:

*An 82 year old female on regular warfarin developed an infected finger and was prescribed two antibiotics (flucloxacillin and sodium fusidate) (**problem 1/drugs and fluids**) by her GP, leading to an increase in the coagulant effect of warfarin. On admission the patient was commenced on intravenous antibiotic treatment for osteomyelitis. Two days passed without an assessment of clotting status (**problem 2/clinical monitoring**) whist warfarin was continued at her standard dose. On day three the patient developed gastrointestinal bleeding and her level of anticoagulation was found to be well above the therapeutic range. The preferred treatment to reverse the effect of warfarin was not available on the ward overnight (**problem 3/drugs & fluids**) and the patient was given a second line alternative. Despite treatment including transfusion of blood she continued to bleed and died.*

The Review Form provides space to capture these complex scenarios in Section C.

Instructions on how to undertake the review

Before the review commences reviewers should check that the record is complete, the death occurred at some point in the financial year 2012/13 and that the patient was not admitted for Obstetric, Psychiatric or Paediatric care. If a post mortem report is found in the medical records this **should not** be read until the end of the review. The review will be primarily focused on the admission in which the patient's death occurred. The focus of the review will be on those problems in healthcare that were associated or contributed to the death rather than any that are more minor.

Ensure you review all documentation related to that admission, including GP referral letter, ambulance summary, A&E summary, etc. and including death certification and any post mortem reports. All healthcare records should be reviewed, not solely records completed by medical staff.

To avoid hindsight bias i.e. judging the care provided to be deficient because the outcome is poor (death), reviewers should follow the patient journey from the beginning, examining how healthcare was delivered at each stage. Imagining "walking in the shoes" of the clinical team as the story unfolds can be a helpful technique.

A systematic approach to the review would include:

1. A review of the initial presentation with special attention to the GPs referral letter, recent outpatient care, the need for admission, timeliness of initial assessment, diagnostic evaluation and management plan.
2. Review of the rest of the doctors' record to determine if appropriate and timely care was given and to evaluate the reasons for continued hospitalisation, testing and treatment. If there are any causes for concern, these can be marked with sticky notes during the initial read through and returned to for more detailed assessment later.
3. Review of the laboratory and radiology records to determine if important abnormalities were reported and acted on and whether appropriate/ inappropriate testing was performed.
4. Review of the nursing notes and monitoring charts to determine if the management plan was adhered to and that new patient signs and symptoms were dealt with appropriately.
5. Review of the medication record to determine if appropriate/ inappropriate medicines were given

6. Completion of the Review Form making sure that each one is labelled with Reviewer ID and the patient's unique study number.

The timing of the problem/s in healthcare

We are interested in problems in healthcare as a consequence of health care management prior to the index hospitalisation and discovered during the index hospitalisation e.g. a person taking a prescribed drug at home who develops side effects that cause death, and; those that occur during the index hospitalisation and are discovered during the index hospitalisation. We accept only a minority of problems in healthcare occurring outside hospital will be detected in this way, and that without access to previous admission notes from other hospitals/primary care records detail may be unclear, but want to learn from any issues that can be identified.

Reviewers should note that if the problem in healthcare occurred prior to the index hospitalisation there is no time limit on its inclusion in the study. The problem does however need to be related to the patient's death. If there have been multiple admissions as a consequence of a problem in healthcare, the problem is counted only once.

Determination of a problem in healthcare

Some useful approaches:

a. Change analysis: Think about how care should have been for this patient and compare it to how care was

b. Consider what would have been an acceptable standard of care for this patient and consider how the healthcare received fell below this standard

c. Did something happen that could have been averted by different management?

d. Would this have happened under your watch?

e. Would you be happy if a relative of yours received this standard of care?

The Review Form includes a section for a narrative account of the problems in healthcare the patient experienced, which allows the reviewer to tell the story of the admission and what went wrong. This is followed by a section where problems in healthcare are listed and categorised and contributory factors (underlying reasons why the problem occurred) are noted (if they can be determined from the records- which is not always the case) in a table. To complete the table, the reviewer needs to refer to the separate problem category list provided.

Determination of avoidability

The following questions can be useful in helping to identify avoidable deaths:

- Was the death expected or unexpected at the outset?
- Was the death related to a healthcare intervention rather than the natural progression of the patient's disease?
- Did any avoidable events cause harm to the patient
- Was there a deviation from the accepted norms of practice?
- Were there extenuating factors that reduce preventability (co-morbidity, nature of acute illness, urgency of situation)
- Were there mitigating factors which decrease preventability (appropriate use of pressure relieving mattress in case of pressure ulcer, evidence of falls prevention strategies)
- Consider if better care had a reasonable chance of preventing the patient's death
- Is there enough evidence to justify your decision

It is important to gather enough evidence to justify the judgement of avoidability. Don't second guess when it comes to judging the acceptability of care. If enough detail is not found in the record then a judgement cannot be made. This situation is more common when determining whether there was a problem in care prior to the index admission as in the case below:

A patient is admitted with acute myocardial infarction and dies. The history mentions that the patient visited his GP twice in the two weeks before admission complaining of upper gastrointestinal pain.

The reviewer has no knowledge as to whether appropriate examination and tests were undertaken by a GP prior to the admission. If a reviewer's judgement is hampered by lack of evidence this should be recorded in Part E.

Avoidability Ratings

Two scales are provided for making ratings of avoidability. The 1 to 6 Likert scale is the standard approach, but the continuous linear scale will allow for additional analysis. Each scale should be completed independently. Outlined below are some examples of cases rated at different levels of avoidability.

Low avoidability

[redacted]year old with[redacted] unable to walk and requiring full time care. Admitted with fever and drowsy. [redacted] CT suggested abscess. Taken to theatre by SpR who drained [redacted] abscess and undertook [redacted]. Over next few days patient became increasingly acidotic and febrile. [redacted] by another SpR revealed a[redacted] [redacted]which was dealt with. In the post op period the patient remained in a poor condition with [redacted]. Active treatment discontinued after 2 weeks.

Mid

[redacted]year old admitted following fall resulting in [redacted] Initially thought patient may have had[redacted] but signs changed over days. In addition there were problems [redacted]. [redacted] commenced but

stopped after [redacted] days. Operated on day [redacted]. Sudden collapse after 24 hours, presumed [redacted].

High avoidability

[redacted] year old [redacted] admitted for [redacted]. Haemoglobin immediately post op was [redacted] g/dl. Developed [redacted] 12 hours later and haemoglobin found to be [redacted] g/dl. [redacted]. No bleeding site was identified over 10 post-operative days and patient died with a haemoglobin of [redacted] g/dl. Post mortem showed a [redacted]. Patient was known to take aspirin prior to surgery and was given [redacted] on ward following development of cardiac problems. Record of low haemoglobin was found in record two months before operation but this was not followed up.

Estimation of impact of avoidable death on length of life

Reviewers are asked to provide a quantitative estimate of the degree to which a patient's life was shortened by their avoidable death. We accept that this subjective judgement may be difficult, but the findings from this question will be useful in helping to estimate the total number of years of life lost as a result of avoidable deaths. Life tables and other prognostication tools are difficult to apply in the acutely ill elderly with multiple co-morbidities that are likely to form a large proportion of the cases reviewed. You may wish to consider expected prognosis for a patient presenting with this condition and co-morbidities who received an acceptable standard of healthcare, and/or average life expectancy alongside consideration of whether the patient had better or worse general health and capacity to recover than average

Avoiding future deaths

Suggestions for specific improvements that might avoid future deaths might come from any of the following categories:

a. Through improved equipment or procedures e.g. via better design or ensuring correct use.

b. Through improved organisation and management e.g. improved transfer of knowledge or information, the quality and availability of protocols, addressing other management issues such as staffing levels or addressing organisational cultural issues impacting on safety.

c. Through steps to limit human error e.g. through ensuring staff who conduct a task have suitable qualifications, training or supervision, improved task planning, coordination or execution.

Seeking further opinions

Each review should initially be conducted independently. If, after full review, a reviewer is uncertain as to whether a death was caused by a problem in healthcare, then a conversation with your lead reviewer can take place. If judgement is hampered by a specialty-specific question, contact can be made with another PRISM 2 reviewer who is a specialist in that area. Dr Hogan will facilitate this contact.

More space

If more space is needed to complete the free text elements of the review form, please attach additional sheets securely to the Review Form. These sheets should be labelled with:

- Patient Unique Identifier
- Reviewer Identifier
- Number of question

References

1. Best, W.R. and D.C. Cowper, *The ratio of observed-to-expected mortality as a quality of care indicator in non-surgical VA patients.* Med Care, 1994. **32**(4): p. 390-400.
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4. Dubois, R.W., W.H. Rogers, J.H. Moxley, 3rd, et al., *Hospital inpatient mortality. Is it a predictor of quality?* N Engl J Med, 1987. **317**(26): p. 1674-80.
5. Mills, D., *Medical insurance feasibility study. A technical study.* West J Med, 1978. **128**: p. 360-5.
6. Brennan, T., R. Localio, L. Leape, et al., *Identification of adverse events occuring during hospitalisation. A cross sectional study of litigation, quality assurance and medical records at two teaching hospitals* Ann Intern Med 1990. **112**(3): p. 221-6.
7. Wilson, R., W. Runciman, R. Gibberd, et al., *Quality in Australian Health Care Study.* Med J Aust, 1995. **163**(9): p. 472-5.
8. Vincent, C., G. Neale, and M. Woloshynowych, *Adverse events in British hospitals: preliminary retrospective record review.* BMJ, 2001. **322**: p. 517-9.
9. Hayward, R. and T. Hofer, *Estimating Hospital Deaths Due to Medical Error-Preventability is in the eye of the reviewer.* JAMA, 2001. **286**(4): p. 415-20.
10. Zegers, M., C. de Bruijne, C. Wagner, et al., *Design of a retrospective patient record study on the occurrence of adverse events among patients in Dutch hospitals.* BMC Health Serv Res, 2007. **7**: p. 27.
11. *Office of National Statistics. Mortality Statistics. Review of the Registrar General on deaths by cause, sex and age in England and Wales 2005*. 2006, HMSO: London.

Appendix 5-
Administrative Information

1) Age at death		
<40 years	1	1.9%
40-49 years	1	1.9%
50-59 years	0	0.0%
60-69 years	5	9.6%
70-79 years	12	23.1%
80-89 years	25	48.1%
90 + years	7	13.5%
Not stated	1	1.9%
	52	

2) Sex		
Male	29	55.8%
Female	23	44.2%
Not stated	0	0.0%
	52	

3) Length of admission (days)		
<30 days	20	38.5%
30-59 days	8	15.4%
60-89 days	12	23.1%
90-119 days	[redacted]	5.8%
120 + days	[redacted]	7.7%
Not stated	5	9.6%
	52	

4) Month of admission		
Jan	3	5.8%
Feb	3	5.8%
Mar	7	13.5%
Apr	3	5.8%
May	2	3.8%
Jun	7	13.5%
Jul	4	7.7%
Aug	3	5.8%
Sep	4	7.7%
Oct	4	7.7%
Nov	4	7.7%
Dec	7	13.5%
Not stated	1	1.9%
	52	

5) Day of admission (Monday to Sunday)		
Monday	4	7.7%
Tuesday	4	7.7%
Wednesday	2	3.8%
Thursday	1	1.9%
Friday	1	1.9%
Saturday	0	0.0%
Sunday	0	0.0%
Not stated	40	76.9%
	52	

6) Time of patients first arrival at hospital (A&E or elsewhere)		
a) Day (08:00-16:59)	18	34.6%
b) Evening (17:00-21:59)	6	11.5%
c) Night (22:00-07:59)	3	5.8%
Not stated	25	48.1%
	52	

7) How many inpatient wards units was patient on during admission		
1	12	23.1%
2	8	15.4%
3	8	15.4%
4	6	11.5%
5+	4	7.7%
Not stated	14	26.9%
	52	

8) Where was the patient admitted from?		
a) His or her own home	20	38.5%
b) A nursing or residential care home	23	44.2%
c) A hospital in another NHS trust	0	0.0%
d) Other specify	4	7.7%
Not stated	5	9.6%
	52	

9) Type of admission		
a) Emergency	36	69.2%
b) Planned/Elective	9	17.3%
c) Other specify	2	3.8%
Not stated	5	9.6%
	52	

Appendix 6
Risk Factors

1) Did the patient have confusion/memory problems at any point in their hospital stay?		
a) Yes	44	84.6%
b) No	5	9.6%
Not stated	3	5.8%
	52	

2) If yes, was a diagnosis of the confusion/memory problems established?		
a) No diagnosis of type of confusion/memory problems apparent	[redacted]	3.8%
b) Dementia alone	37	71.2%
c) Delirium alone	0	0.0%
d) Delirium superimposed on dementia	[redacted]	3.8%
e) Other type of confusion/memory problems	5	9.6%
Not stated	6	11.5%
	52	

3) Did the patient have a significant mental illness other than confusion/memory problems options above?		
a) No indications of a significant mental illness	36	69.2%
b) Clear indications of a significant mental illness	14	26.9%
c) Some indications of a significant mental illness but records unclear	2	3.8%
Not stated	0	0.0%
	52	

4) Did the patient have a learning disability?		
a) No indications of a learning disability	47	90.4%
b) Clear indications of a learning disability	0	0.0%
c) Some indications of a learning disability but records unclear	0	0.0%
Not stated	5	9.6%
	52	

5) Did the patient have any of the following comorbidities

	Yes	
Myocardial infarct	13	25.0%
Congestive heart failure	[redacted]	7.7%
Peripheral vascular disease	[redacted]	5.8%
Cerebrovascular disease	25	48.1%
Hemiplegia	[redacted]	5.8%
Chronic lung disease	11	21.2%
Connective tissue disease	[redacted]	3.8%
Diabetes without end organ damage	10	19.2%
Diabetes with end organ damage	[redacted]	3.8%
Ulcer	[redacted]	3.8%
Chronic liver disease	[redacted]	1.9%
Moderate or severe liver disease	0	0.0%
Moderate or severe kidney disease	[redacted]	7.7%
Lymphoma	[redacted]	1.9%
Leukemia	0	0.0%
Nonmalignant tumor	0	0.0%
Malignant tumor	7	13.5%
Metastasis	[redacted]	3.8%
AIDS	0	0.0%
Other	19	36.5%

6) Patient condition immediately prior to the illness that led to this admission		
a) Fully independent	7	13.5%
b) Independent in personal care, but needing help with other activities of daily living	12	23.1%
c) Dependant on others for personal care (washing, dressing, eating, etc.)	31	59.6%
d) Unable to determine; no relevant information in notes (direct or implied)	0	0.0%
Not stated	2	3.8%
	52	

7) Was the patient initially assessed in A&E and/or any other short-term emergency admission assessment unit?		
a) Yes	12	23.1%
b) No	33	63.5%
c) Unable to determine	0	0.0%
Not stated	7	13.5%
	52	

8) Speciality at time of first ward admission (the first ward/unit where the intention was for them to stay at least one night)		
a) Older peoples Medicine	7	13.5%
b) Rehabilitation	0	0.0%
c) General medicine including medical assessment/short stay	[redacted]	1.9%
d) Medical sub-specialities	0	0.0%
e) General Surgery including surgical assessment/short stay	[redacted]	1.9%
f) Surgical sub-specialities including gynaecology & orthopaedics	0	0.0%
g) Other specify	37	71.2%
Not stated	6	11.5%
	52	

9) Was this an appropriate type of ward for their condition?		
a) Yes, definitely appropriate	48	92.3%
b) Probably appropriate	0	0.0%
c) No	0	0.0%
d) Unable to determine	2	3.8%
Not specified	2	3.8%
	52	

10) Speciality at time of death		
a) Older peoples Medicine	7	13.5%
b) Rehabilitation	0	0.0%
c) General medicine including medical assessment/short stay	0	0.0%
d) Medical sub-specialities	4	7.7%
e) General Surgery including surgical assessment/short stay	[redacted]	[redacted]
f) Surgical sub-specialities including gynaecology & orthopaedics	[redacted]	[redacted]
g) Other specify	29	55.8%
Not stated	10	19.2%
	52	

11) Was this an appropriate type of ward for their condition?		
a) Yes, definitely appropriate	22	42.3%
b) Probably appropriate	11	21.2%
c) No	1	1.9%
d) Unable to determine	12	23.1%
Not specified	6	11.5%
	52	

12) Apparent main diagnosis on admission		
1 - Trauma-related diagnoses - a Fractured hip		
a) Fractured hip	[redacted]	
b) Any other falls-related diagnosis	0	0.0%
c) Trauma from other cause (not fall)	0	0.0%
2 - Cardiovascular diagnoses		
a) Stroke	[redacted]	
b) Acute coronary syndrome/STEMI/angina	0	0.0%
c) Heart failure	0	0.0%
d) Arrhythmia	[redacted]	
e) DVT/PE	0	0.0%
f) Any other cardiovascular condition	0	0.0%
3 - Infection with or without sepsis		
a) Chest infection/pneumonia	[redacted]	
b) Urinary tract infection	0	0.0%
c) Bloodstream infection	[redacted]	
d) Gastroenteritis	0	0.0%
e) Any other diagnosis of infection	[redacted]	
4 - Cancer-related diagnosis	[redacted]	
5 - Acute abdomen	[redacted]	
6 - Gastrointestinal haemorrhage	0	0.0%
7 - Exacerbation of Chronic Obstructive Pulmonary Disease	0	0.0%
8 - Any other diagnosis please specify	10	19.2%

Appendix 7 Problems in Healthcare- Hand Search

Fall- in hospital	27	[redacted] raised issues with care	5	[redacted]	[redacted]
Medication omitted	16	bruised arms	5	Lack of nurse intervention for infusions	[redacted]
Medication refused	13	bruised legs	5	OOH GP- wrong diagnosis	[redacted]
Lack of Clinical Review	13	Cuts- head	5	HAT- PE	[redacted]
Inadequate identification in parts or all of case notes	13	Medication error	5	Ward transfers- more than [redacted]	[redacted]
Hospital Acquired Infection- respiratory	11	Coughing, choking, swallowing issues	5	Staffing issues	1
Low BP	10	Missing Observations	4	Avoidable death	[redacted]
Missing parts to case notes	10	#NOF / Lower Limb	3	Over-sedated- community	[redacted]
Inadequate clinical assessment	9	Problems with observations	3	Over-sedated[redacted]	[redacted]
Bruising- facial	7	[redacted]		Self harm[redacted]	[redacted]
Cuts- facial	7	Unclear which ward	3	Norovirus	[redacted]
Missed diagnosis	7	[redacted]		Readmission	[redacted]
Lack of documentation in notes- time, date, ward etc	7	[redacted]		Misinterpretation of X-Ray	[redacted]

	7	[redacted]	[redacted]	No evident discharge arrangements	1
Delays in Medical Review	7	[redacted]	[redacted]	Restraint recorded	[redacted]
Assaulted by another patient	6	[redacted]	[redacted]	[redacted]	[redacted]
Assaulted staff or patients	6	[redacted]	[redacted]	OT Referral Issue	[redacted]
Skin break-hospital acquired	6	Failure to investigate	2	DM Team review issues	1
Inadequate handover	6	Failure to engage Physiotherapy	2		
Inadequate Medical Treatment	6	Delayed SALT assessment	2		

Appendix 8- Patients where Deficiencies in Healthcare considered potentially to have contributed to death

Patient ID Number	Reviewer Initials	Q16 - Please rate the strength of evidence for the avoidability of the death:
[redacted]	[redacted]	3 - Possibly avoidable but not very likely, less than 50/50 but close call
	[redacted]	2 - Slight evidence for avoidability
	[redacted]	2 - Slight evidence for avoidability
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	2 - Slight evidence for avoidability
	[redacted]	3 - Possibly avoidable but not very likely, less than 50/50 but close call
	[redacted]	2 - Slight evidence for avoidability
[redacted]	[redacted]	5 - Strong evidence for avoidability

	[redacted]	2 - Slight evidence for avoidability
	[redacted]	4 - Probably avoidable, more than 50/50 but close call
[redacted]	[redacted]	5 - Strong evidence for avoidability
	[redacted]	4 - Probably avoidable, more than 50/50 but close call
	[redacted]	5 - Strong evidence for avoidability
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	4 - Probably avoidable, more than 50/50 but close call
	[redacted]	4 - Probably avoidable, more than 50/50 but close call
	[redacted]	3 - Possibly avoidable but not very likely, less than 50/50 but close call
[redacted]	[redacted]	2 - Slight evidence for avoidability
	[redacted]	

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	5 - Strong evidence for avoidability
	[redacted]	5 - Strong evidence for avoidability
	[redacted]	5 - Strong evidence for avoidability
[redacted]	[redacted]	5 - Strong evidence for avoidability
	[redacted]	5 - Strong evidence for avoidability
	[redacted]	5 - Strong evidence for avoidability

Appendix 9- Adverse Drug Events and Linkages to PRISM 2

Question	ADE count of events	Event	Harm Category	Q13 - Were there any problems in healthcare (including any problems before admission)?	Q14 - In your judgement is there some evidence that the patients death was avoidable if the problems in healthcare had not occurred
[redacted]	2	[redacted]	I: Patient Death	b) Some evidence of problem(s) in healthcare > please complete the next question	b) At least slight evidence the death may have been avoidable
[redacted]	1	[redacted]	I: Patient Death	b) Some evidence of problem(s) in healthcare > please complete the next question	b) At least slight evidence the death may have been avoidable
[redacted]	2	[redacted]	E: Temporary harm to the patient which required intervention	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	1	[redacted]	E: Temporary harm to the patient which required intervention	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	1	[redacted]	E: Temporary harm to the patient which required intervention	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	1	[redacted]	E: Temporary harm to the patient which required intervention	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable

[redacted]	1	[redacted]	E: Temporary harm to the patient which required intervention	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	1	[redacted]	E: Temporary harm to the patient which required intervention	b) Some evidence of problem(s) in healthcare > please complete the next question	
[redacted]	1	[redacted]	E: Temporary harm to the patient which required intervention	b) Some evidence of problem(s) in healthcare > please complete the next question	b) At least slight evidence the death may have been avoidable
[redacted]	1	[redacted]	E: Temporary harm to the patient which required intervention	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	3	[redacted]	F: Temporary Harm to the patient and required initial or prolonged hospitalisation	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	2	[redacted]	F: Temporary Harm to the patient and required initial or prolonged hospitalisation	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	2	[redacted]	F: Temporary Harm to the patient and required initial or prolonged hospitalisation	b) Some evidence of problem(s) in healthcare > please complete the next question	b) At least slight evidence the death may have been avoidable
[redacted]	2	[redacted]	F: Temporary Harm to the patient and required initial or prolonged hospitalisation	b) Some evidence of problem(s) in healthcare > please complete the next question	b) At least slight evidence the death may have been avoidable

[redacted]	1	[redacted]	Unclassified by Reviewer	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	1	[redacted]	Unclassified by Reviewer	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable
[redacted]	1	[redacted]	Unclassified by Reviewer	b) Some evidence of problem(s) in healthcare > please complete the next question	a) No, death was definitely not avoidable

[redacted]

17th April 2014

An analysis of in-patient falls within OPMH wards

March 2013 to March 2014

1: Background

On the 3rd December [redacted] requested a review of falls prevention planning and nursing management on Gwanwyn and Hydref wards in the Heddfan Unit. Both wards are part of the older people's mental health services. The request followed concerns that in the period from 5th October 2013 to 2nd December 2013 four patients had experienced falls.

Ensuring patient safety and preventing falls are key priority areas for BCUHB and hence the review was regarded as urgent. That review culminated in a full root cause analysis which found that the nursing response to each fall had been timely and correct.

[redacted] has subsequently requested a comparison of fall rates over a period of twelve months to establish whether there is a need for a more detailed review. This paper provides comparisons of each ward within OPMH services and uses data from the Cochrane collaborative to identify the mean expected monthly fall rate for such wards.

2: Executive Summary

Over a thirteen month period five of the seven wards included crossed the Cochrane threshold. Two of those (Gwanwyn and Hydref) have already been subject to extensive review and analysis.

Tawel Fan ward crossed the threshold once in September 2013 with an excess fall rate of +0.8. By the time of its closure in December 2013 the excess fall rate was -2.2.

Cemlyn A remained well below the threshold until March 2014 when it has reported an excess fall rate of +2.8.

Bryn Hesketh ward crossed the threshold twice. In July 2013 the excess fall rate was +3.8 and in November 2013 it was +1.8.

Overall the fall rates for OPMH would appear to be satisfactory.

Some further analysis is currently indicated for Bryn Hesketh ward to identify factors that may have been involved and could add to our learning around prevention.

Cemlyn A should be monitored and advice around prevention considered.

3: The Context and Evidence

The consensus definition of a fall is 'an unexpected event in which the participant comes to rest on the ground, floor or at a lower level' (World Health Organisation, 2012). Falls are common events and their incidence increases with the age of the participant. The Cochrane collaborative (Udell et al, 2011) identify that a third of community dwelling people over 65 years fall each year and emergency intervention is frequently indicated. In a twelve month period 650,000 falls, involving people over 60 years occurred that led to A&E attendance. Of these, 200,000 were subsequently admitted to hospital and of those 76% were aged over 75 years.

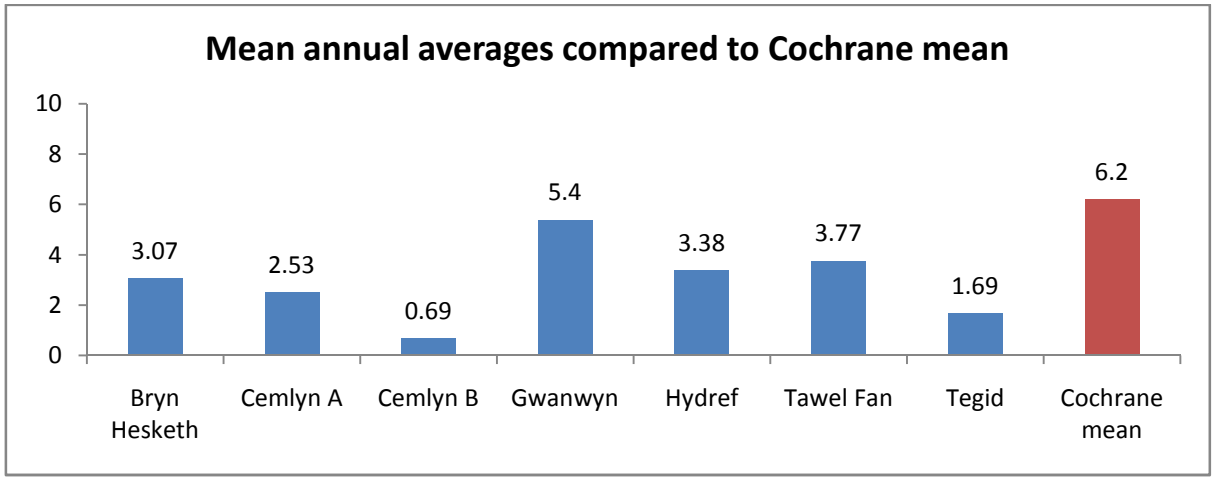
The Cochrane Collaborative (Cameron et al, 2012) states that the incidence of falls amongst hospital in-patients is 2 to 3 times greater than for older people in the community. In the twelve month period 2005-06 some 200,000 in-hospital falls were reported to the National Patient Safety Agency. Falls occurring in in-patient psycho geriatric wards are in the region of 6.2 falls per patient per year. Men fall more commonly than women. Furthermore people with dementia have up to a threefold risk of falls.

Systematic reviews identify probable causes but evidence is often weak or conflicting. Suggested causes of falls on in-patient wards for older people with dementia include: gait instability, agitated behaviour, urinary incontinence, previous history of falls and psychotropic medication.

The debate regarding possible preventative interventions is well rehearsed in the literature but the evidence for effectiveness is either inadequate or conflicting. Of the suggested single preventative interventions (exercise, medication review, vitamin D supplement, environmental or assistive technology, social model of care and education) only vitamin D supplementation was seen to reduce the risk of falls. When interventions are combined (such as, exercise + education + hip protectors) there is slightly more evidence.

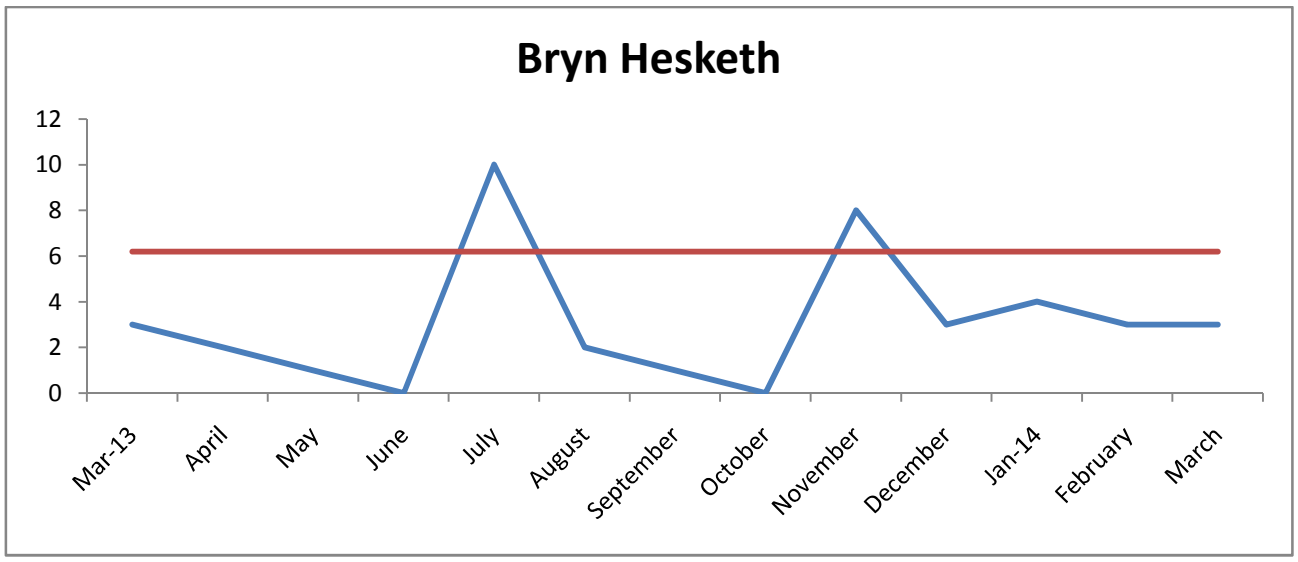
However, the Cochrane Collaboration guidance states mostly that further evidence is indicated.

4: OPMH data



Across the thirteen month period of retrospective measurement and when the mean individual annual fall rate is used, no ward crossed the threshold. This indicates no excess falls occurred during the year as a whole.

An analysis for each ward is now presented.

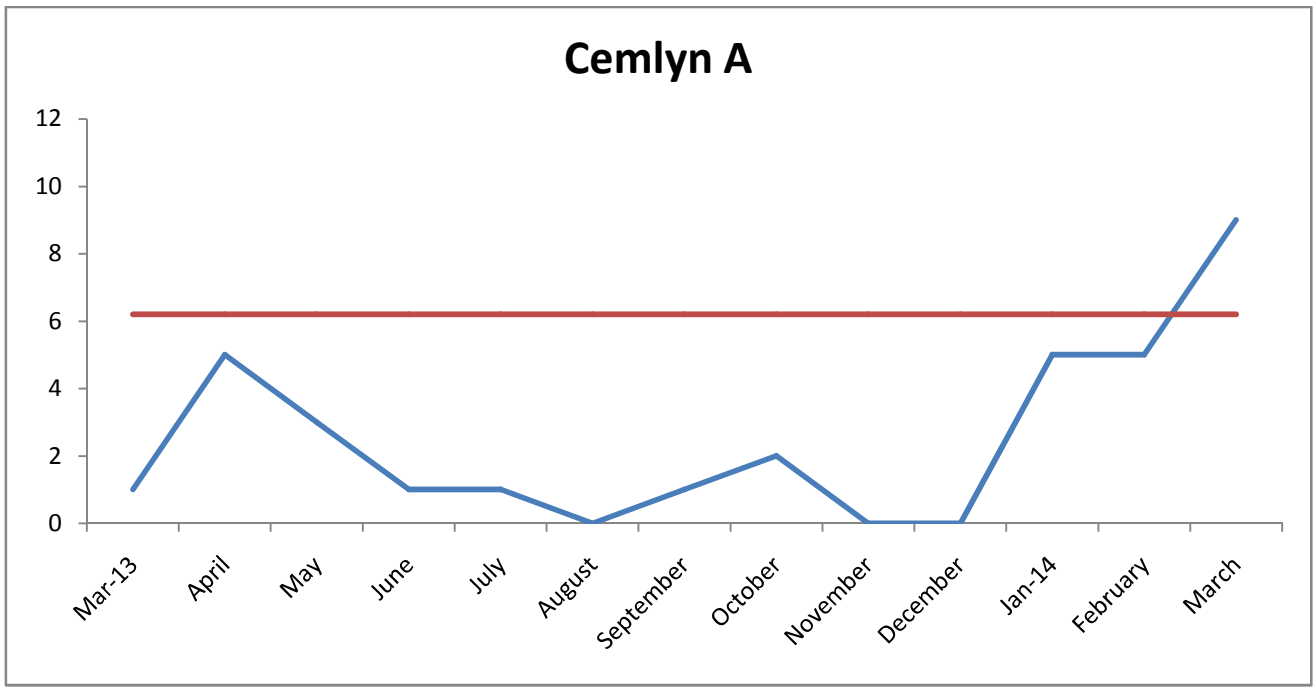


The narrative behind these two periods of excess falls should be explored by the responsible matron and reported back to the Dementia Operational Forum through [redacted] OPMH Programme Manager.

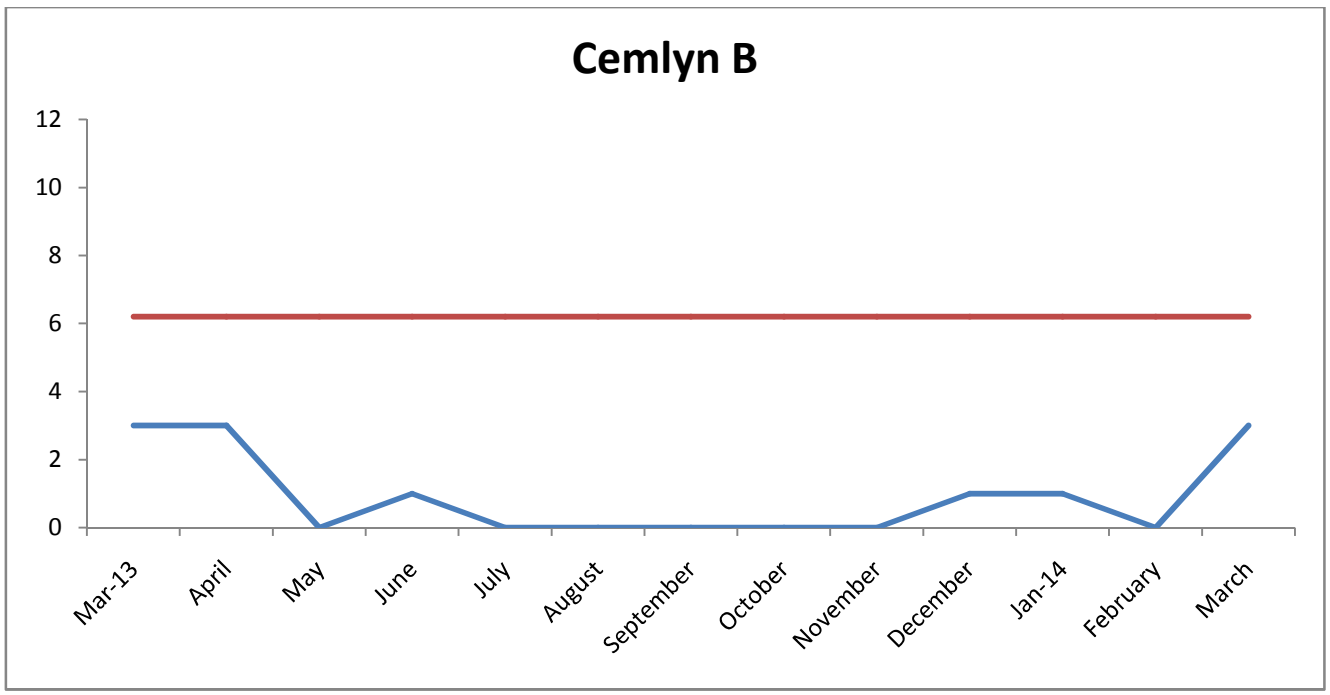
Analysis of Falls within OPMH wards March 2013 to March 2014

[redacted]

17th April 2014



The rate has been increasing since December 2013. Again the narrative should be obtained and reported through [redacted].

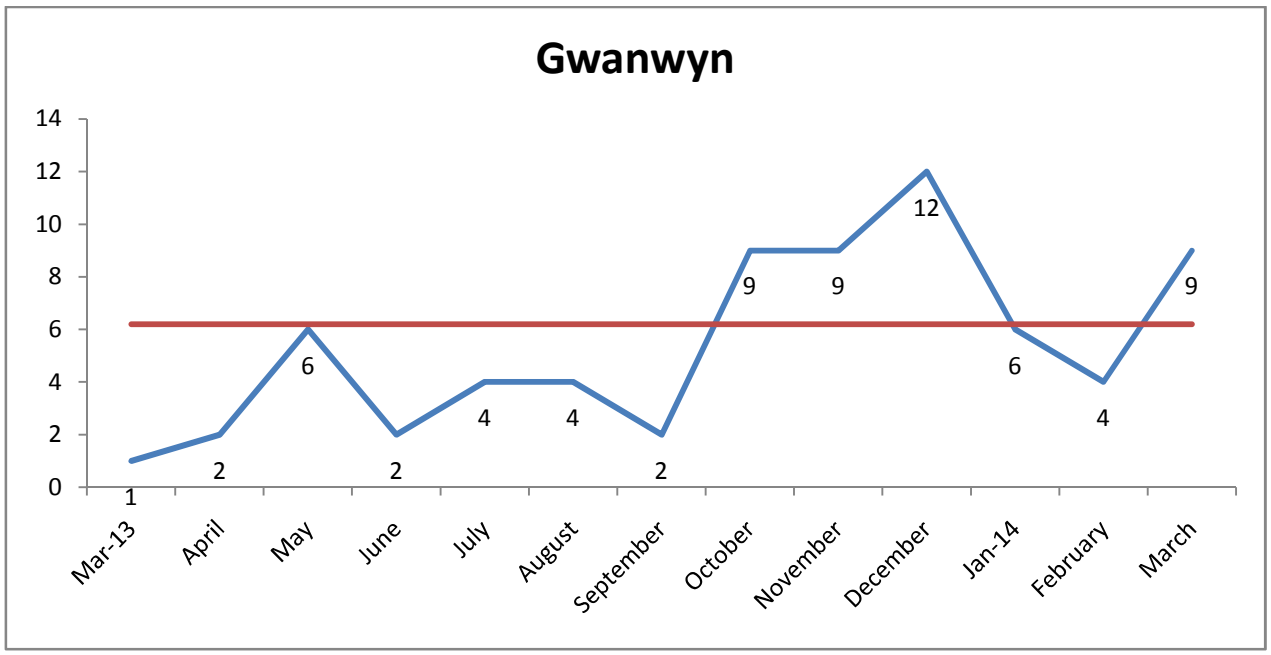


This is a very satisfactory result.

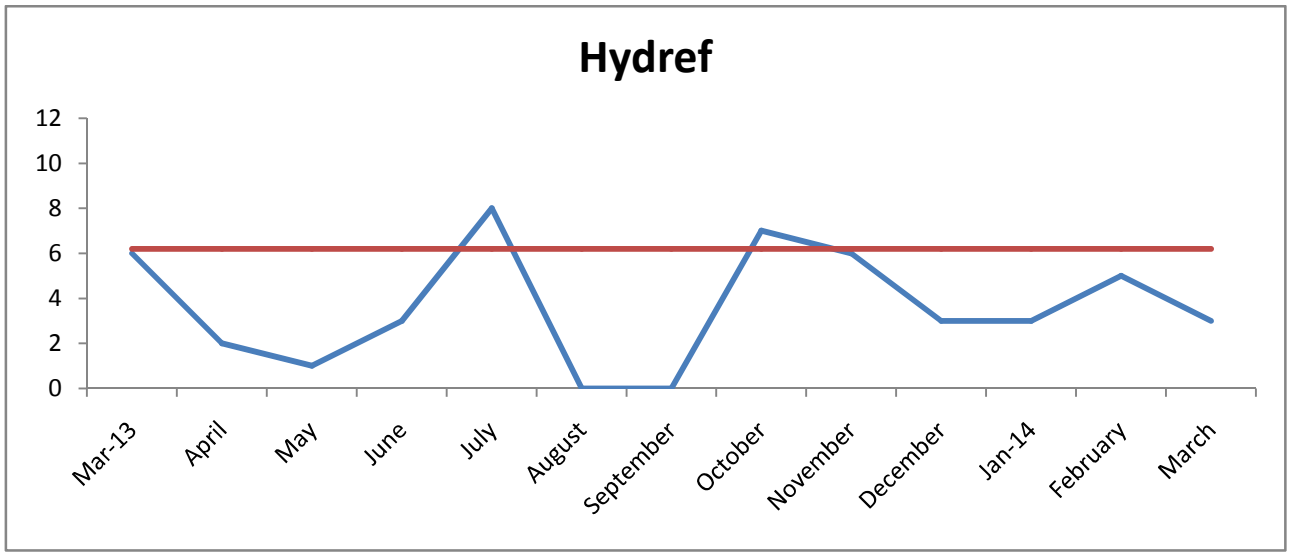
Analysis of Falls within OPMH wards March 2013 to March 2014

[redacted]

17th April 2014



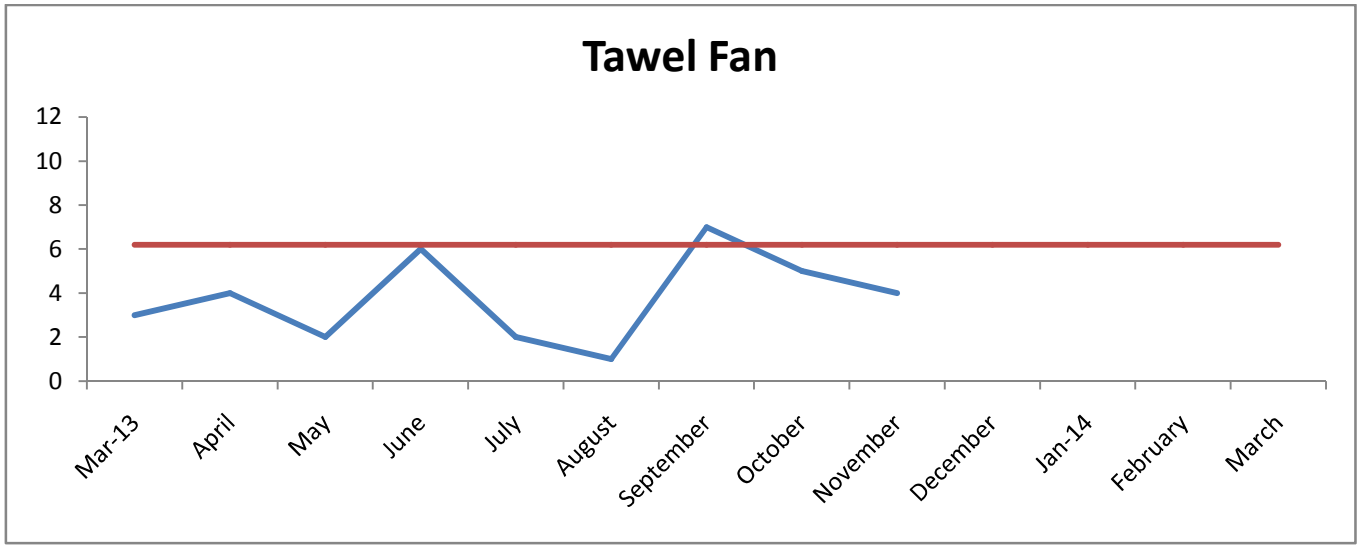
Both Gwanwyn and Hydref have had their excess fall rates extensively reviewed. It is of note that following that review both have seen significant reductions in falls.



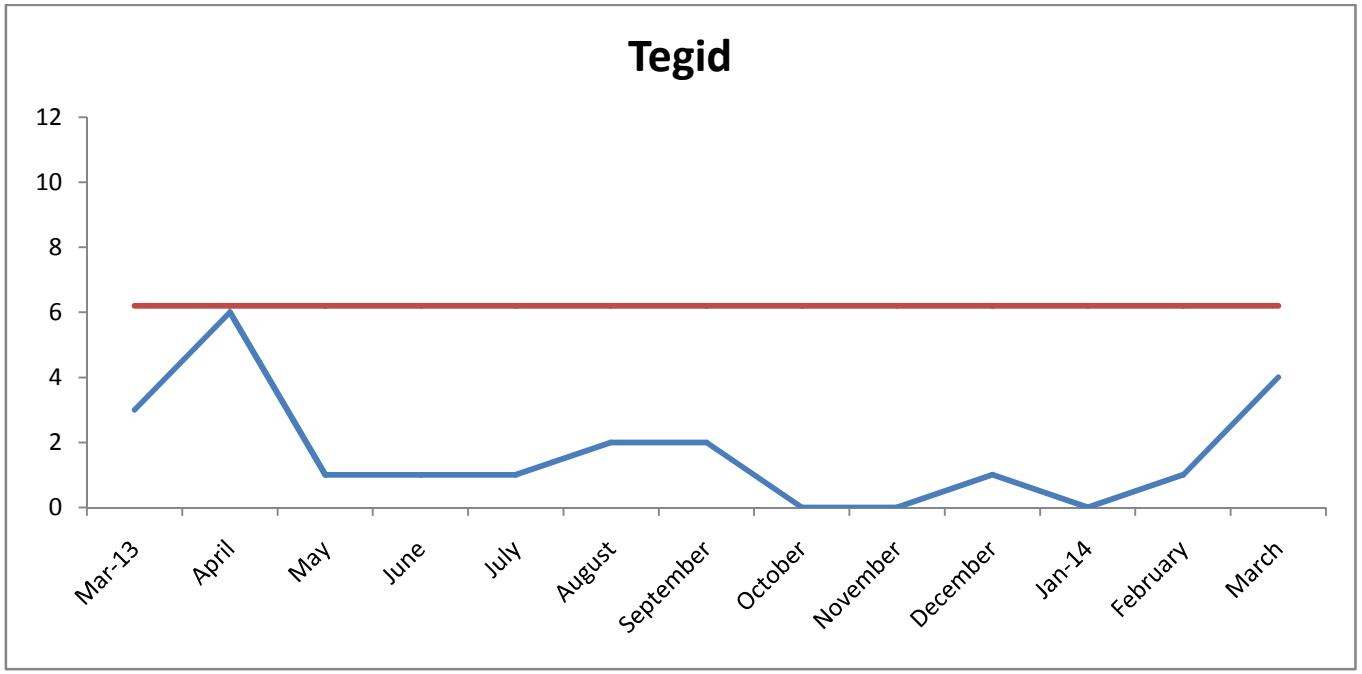
Analysis of Falls within OPMH wards March 2013 to March 2014

[redacted]

17th April 2014



Tawel Fan is now closed and subject to thorough external review.



The fall rate for Tegid whilst not crossing the threshold is increasing and should be closely monitored by the responsible matron.