

Supplementary file 1: Definitions

An **adverse event** is (1) an unintended injury (physical and/or mental) which results in (2) temporary or permanent disability, death or prolonged hospital stay and (3) that is caused by health care management rather than by the patient's underlying cardiac disease.

Unintended injury refers to any disadvantage for the patient that leads to prolonged or strengthened treatment, temporary or permanent (physical and/or mental) impairment or death.

Disability refers to temporary or permanent impairment of physical or mental function attributable to the adverse event (including prolonged or strengthened treatment, prolonged hospital stay, readmission, subsequent hospitalisation, extra outpatient department consultations or death).

Causation refers to injury caused by health care management including acts of omission (inactions) i.e. failure to diagnose or treat, and acts of commission (affirmative actions) i.e. incorrect diagnosis or treatment, or poor performance.

Health care management includes the action of individual hospital staff as well as the broader systems and care processes. Health care management is any care related activity that involves the delivery of care or monitoring of health which is provided by individuals or a team of professionals.

Preventable adverse event is an adverse event resulting from an error in management due to failure to follow accepted practice at an individual or system level. Accepted practice was taken to be 'the current level of expected performance for the average practitioner or system that manages the condition in question'.

Process deviation was defined as every operation or treatment that differentiated from the MISSION! Protocol.

Supplementary file 2: Causation score

Preceding questions:

1. Does the timing of events suggest that the injury is related to the treatment or to the lack of treatment? (Likely/Possibly/Unlikely/Not applicable)
2. Is there a note in the medical record indicating that a health care professional or health care management caused the injury? (No/Yes/Not applicable)
3. Is there a note in the medical record suggesting the possibility of an unintended injury from the patient's disease? (No/Yes/Not applicable)
4. Are there other reasonable explanations for the cause of the unintended injury? (No/Yes/Possibly/Not applicable)
5. Is the lack of treatment or delayed treatment a recognized cause of this injury? (Widely recognized/Recognized by other specialists/No/Not applicable)
6. Is the lack of diagnosis or delayed diagnosis a recognised cause of this injury? (Widely recognized/Recognized by other specialists/No/Not applicable)
7. Is this injury a recognized complication of the patient's underlying index disease? (Widely recognized/Recognized by other specialists/No/Not applicable)

A score on *causation* was given on a 6 point Likert scale:

1. (Virtually) no evidence for health care management causation.
2. Slight to modest evidence of health care management causation.
3. Health care management causation not likely (less than 50/50, but 'close call').
4. Health care management causation more likely (more than 50/50, but 'close call').
5. Moderate to strong evidence of health care management causation.
6. (Virtually) certain evidence of health care management causation.

Counted as caused by healthcare if the score was 4 to 6.

Supplementary file 3: Preventability score

Preceding questions:

1. How complex was this case? (Very complex/Moderately complex/Somewhat complex/Not complex/Unable to determine)
2. What was the co-morbidity of the patient? (Significant co-morbidity/Moderate co-morbidity/Mild co-morbidity/No co-morbidity)
3. What was the degree of deviation of management of the primary illness (not the adverse event) from the accepted norm? (Severe/Moderate/Little/None)
4. What potential benefit was associated with the management of the illness which led to the Adverse Event? (Life saving/Curing/Life prolonging/Symptom relief/Palliation//No potential benefit)
5. What was the degree of emergency in management of the primary illness (not the adverse event) prior to the occurrence of adverse event? (Very urgent/Moderately urgent/Not urgent)
6. Did the patient have any follow-up as a result of this Adverse Event?
(No/Counselling/Psychiatric/Rehabilitation/Routine clinical/Other/UTD)

Preparatory questions, added to the protocol:

7. Was the management of the primary illness (not the adverse event) appropriate?
(Definitely appropriate/Possibly appropriate/Probably appropriate/Definitely not appropriate)
8. What was the risk of an adverse event related to the management ?
(High/Moderate/Low/Not applicable)

A score on **preventability** was given on a 6 point-Likert scale:

1. (Virtually) no evidence for preventability.
2. Slight to modest evidence of preventability.
3. Preventability not quite likely (less than 50/50, but 'close call').
4. Preventability more than likely (more than 50/50, but 'close call').
5. Strong evidence of preventability.
6. (Virtually) certain evidence of preventability.

Counted as preventable if the score was 4 to 6.

Supplementary file 4: Comparison of inter-rater variability in other adverse events studies.

Author	Year	Country	Causality		Preventability	
			<i>Kappa statistics (95%CI)</i>	<i>Agreement</i>	<i>Kappa statistics (95% CI)</i>	<i>Agreement</i>
Brennan	1991	United States of America	0.61	89%		
Wilson	1995	Australia	0.42		0.33	
Thomas	2000	United States of America	0.40 (0.3 – 0.5)	76%		
Baker	2004	Canada	0.45 (0.33 – 0.57)		0.69 (0.55 – 0.83)	
Michel	2007	France	0.83 (0.67 – 0.99)	92%	0.31 (0.05 – 0.57)	68%
Sari	2007	United Kingdom	0.64	86%	0.33	83%
Soop	2009	Sweden	0.80	91%	0.76	91%
Zegers	2009	The Netherlands	0.25 (0.05 – 0.45)	76%	0.40 (0.7 – 0.73)	70%
Hogan	2012	United Kingdom	0.54 (0.37 – 0.71)			
Baines	2013	The Netherlands	0.47 (0.33 – 0.61)	83%	0.49	74%
Merten	2015	The Netherlands (focus hip fractures)	0.52	85%	too small (4 cases)	