National Patient Safety Agency

National Reporting and Learning Service

Rapid Response Report: NPSA/2008/RRR011:
Reducing risk of overdose with midazolam injection in adults

9 December 2008

Supporting information

Background

Scope

The recommendations in this Rapid Response Report (RRR) relate to all healthcare sectors and specialties where conscious sedation is undertaken. This might include, amongst others, the conscious sedation of adult patients in acute settings undergoing procedures like endoscopy or minor surgery and, in the community, a range of dental procedures or interventions in community hospitals. In specialties where syringe drivers are used, for example, critical care and palliative care, it is likely to be necessary to retain the use of high strength midazolam i.e. 5mg/ml (2ml and 10ml ampoules) and 2mg/ml (5ml ampoules). In these cases, a risk assessment should be undertaken to ensure that practices ensure safety in use, in particular, if in clinical areas where a range of different strengths of the injection are stored and used.

General guidance on undertaking healthcare risk assessments can be found at:

www.npsa.nhs.uk/patientsafety/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides

The recommendations in this RRR do not apply to paediatric care where the volume and type of incident data did not suggest a similar patient safety problem. Organisations may however wish to take the opportunity to review local arrangements for paediatric use of midazolam injection, taking into account guidelines for the safe sedation of children by the Scottish Intercollegiate Guidelines Network (SIGN) [(1)].

Use of midazolam (and flumazenil)

Midazolam is widely used for conscious sedation in a number of procedures and settings. This might include endoscopic procedures and minor surgery in acute settings and a range of procedures in community dentistry and community hospitals.

Conscious sedation has been defined as 'a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drug and techniques used to provide conscious sedation should carry a margin of safety, wide enough to render loss of consciousness unlikely'[(2)].

However a subsequent document published by the SIGN[(1)] extended the definition (albeit for children) by including that 'no interventions are required to maintain a patent airway, spontaneous ventilation is adequate and cardiovascular function usually maintained.'

For conscious sedation prior to diagnostic or surgical intervention, midazolam is administered intravenously. The dose must be individualised and titrated, and should not be administered by rapid or single bolus injection. The onset of sedation may vary individually depending on the physical status of the patient and the detailed circumstances of dosing (e.g. speed of administration, amount of dose). If necessary, subsequent doses may be administered according to the individual need. The onset of action is about two minutes after the injection. Maximum effect is obtained in about five to10 minutes. Details of dosing for adults is given in Appendix 1.

Flumazenil injection 500micrograms/5ml is licensed in the UK for the complete or partial reversal of the central sedative effects of benzodiazepines. It may be used in anaesthesia and intensive care in the following situations:

- Termination of general anaesthesia induced and/or maintained with benzodiazepines.
- Reversal of benzodiazepine sedation in short diagnostic and therapeutic procedures.
- For the specific reversal of the central effects of benzodiazepines, to allow return to spontaneous respiration and consciousness, in patients in intensive care.

Around 60,000 ampoules of flumazenil are used in the NHS in England annually, of which a proportion (which cannot be identified precisely) are used to reverse clinical overdose. In view of flumazenil's therapeutic indication, for reversal of central sedative effect of benzodiazepines, stocks of flumazenil injection should be available in all areas where midazolam injection is used.

Current problems

The National Patient Safety Agency (NPSA) is alerting all healthcare staff involved in the prescribing, administration or supply of injectable midazolam for use in adult conscious sedation to the risks of overdose or harm where:

- Healthcare staff are participating in procedures requiring conscious sedation techniques, on occasion, without having been trained to an appropriate level of knowledge, skills and competence in both delivering the technique and managing complications.

- The dose is not titrated to individual patient's clinical needs, taking into account age, weight, concurrent medication and/or clinical condition(s) and/or the procedure being undertaken. Problems can arise when drug combinations are used, e.g. when midazolam is used with sedatives and analgesics. Adverse events occur more commonly when drug combinations are used, for example, midazolam with pethidine or other opioid drugs. Such drugs, used in combination, have synergistic effects and as a result, narrower margins of safety. The use of multiple drugs during conscious sedation presents additional training requirements.

- Syringes are prepared with the full contents of high strength product and the incorrect dose is then injected in error, often leading to overdose.

- The use of high strength midazolam preparations often compounds human errors made when syringes are prepared at the same time as other injectable medications, are not labelled and a mis-selection error occurs.

- There is also frequent use and reliance on injectable flumazenil for reversal in patients that have been overdosed.

- The routine reliance on flumazenil for reversal is not considered to be good practice and is not without the potential for side effects. Due to the shorter elimination half life (see Appendix 1) of flumazenil, residual sedation can unexpectedly return. Healthcare staff should be aware of the potential for re-sedation to occur and take steps to minimise risks to patients. An example scenario is when patients are discharged home following short diagnostic and therapeutic procedures.

Review of evidence of harm

Reporting & Learning System (RLS) incident data

The NPSA conducted a search for medication patient safety incident reports received via the Reporting and Learning System (RLS) where the words midazolam or flumazenil (or related terms) were contained in the report. There were 1,529 such reports found in the RLS, at 26 November 2008.*

The majority of incidents (84%) were reported from the acute sector. Approximately a third (498, 33%) involved the prescribing and/or administration of the wrong dose, strength, quantity or frequency.

Interpretation of data from the RLS should be undertaken with caution. As with any voluntary reporting system, the data are subject to bias. A proportion of incidents which occur are not reported, and those which are reported may be incomplete having been reported immediately and before the patient outcome is known.

Data have been produced using a text search for specific word or phrases across the descriptive free text fields in the RLS. Free text fields reported are individual to the reporter, and may contain spelling errors, typing errors or abbreviations which make it difficult to group similar incidents.

Due to the technical challenges inherent in accounting for all the possible variations in describing a given incident, results from this method should be interpreted carefully. In particular, aggregate figures derived using the method above should not be taken as exactly representative of the data on the RLS.

* The RLS was established in October 2003 and all NHS organisations were able to report to the RLS by 1 January 2005. It is important to note the volume of reports received by the RLS has increased since inception, and as the RLS is a voluntary reporting system, the data may not be representative of the rates of incidents across England and Wales. Data are based on the date that incident became available for analysis. All incidents since the inception of the RLS are included (ie from October 2003), but the first reported incident relating to midazolam was received in November 2004.

The following tables provide a breakdown of incidents reported to the RLS[†].

Table 1: Incidents involving midazolam by specialty

Base: All medication incidents involving midazolam or flumazenil in the RLS at 26 November 2008

Specialty – Lvl 1	Number	Percent
Medical specialties	528	35
Surgical specialties	204	13
Primary care/community	141	9
Accident and emergency (A)	104	7
Other specialties	56	4
Anaesthetics	46	3
Diagnostic services	29	2
Mental health	20	1
Learning disabilities	12	1
Obstetrics and gynaecology	10	1
Dentistry - general and community	2	0
PTS (Patient Transport Service)	1	0
Other	354	23
Unknown	14	1
Not applicable	4	0
Missing	4	0
Total	**1,529**	**100**

Note: 'Other specialties' includes nutrition and dietetics; occupational therapy; pharmacy; physiotherapy; and speech and language therapy.

Table 2: Incidents involving midazolam by location

Base: All medication incidents involving midazolam or flumazenil in the RLS at 26 November 2008

Location - Lvl 1	Number	Percent
General/acute hospital	1,291	84
Residence/home	121	8
Community hospital	32	2
Mental health unit/facility	26	2
Primary care setting	25	2
Social care facility	7	0
Public place (specify)	4	0
Ambulance (including call/control centre)	1	0
Other	14	1
Unknown	8	1
Total	**1,529**	**100**

Table 3: Incidents involving midazolam by degree of harm

Base: All medication incidents involving midazolam or flumazenil in the RLS at 26 November 2008

Degree of harm (severity)	Number	Percent
No harm	1,156	76
Low	247	16
Moderate	121	8
Death	3	0
Severe	2	0
Total	**1,529**	**100**

Note: Incidents reported with a degree of harm 'death' or 'severe' were reviewed by a clinical reviewer, recoded where appropriate, and removed if they were not relevant to the search.

[†] The following notation is used in the tables: '0' is used for percentages that are rounded down to zero; '-'is used for a true zero in cell showing percent, i.e. when there are no cases in a category.

Table 4: Incidents involving midazolam by medication process

Base: All medication incidents involving midazolam or flumazenil in the RLS at 26 November 2008

Medication Process	Number	Percent
Administration/supply of a medicine from a clinical area	982	64
Prescribing	164	11
Preparation of medicines in all locations/ dispensing in a pharmacy	124	8
Monitoring/follow-up of medicine use	98	6
Advice	1	0
Other	159	10
Missing	1	0
Total	**1,529**	**100**

Table 5: Incidents involving midazolam by medication error category

Base: All medication incidents involving midazolam or flumazenil in the RLS at 26 November 2008

Medication Error Category	Number	Percent
Wrong/unclear dose or strength, quantity or frequency	498	33
Wrong drug/medicine	164	11
Adverse drug reaction (when used as intended)	73	5
Omitted medicine/ingredient	69	5
Wrong storage	66	4
Wrong/transposed/omitted medicine label	54	4
Wrong method of preparation/supply	43	3
Wrong route	39	3
Contra-indication to the use of the medicine in relation to drugs or conditions	27	2
Patient allergic to treatment	27	2
Wrong/omitted/passed expiry date	20	1
Wrong formulation	17	1
Mismatching between patient and medicine	11	1
Wrong / omitted verbal patient directions	3	0
Other	380	25
Unknown	37	2
Missing	1	0
Total	**1,529**	**100**

Examples of incident types

Incident 1
Wrong dose
Patient prescribed 0.5mg Midazolam intravenously but given 5mg IV by Staff Nurse. Checked by Staff Nurse following administration of Midazolam, patient became unrousable whilst having observations taken. Doctors called and following questioning of staff it became clear that 5mg instead of 0.5mg had been given. Patient given Flumazenil and quarter - hourly neurology observations commenced.

Incident 2
Wrong/high dose
Patient given IV midazolam 7mg and 5mg = 12mg by Dr [Staff name] and during the procedure (gastroscopy and colonoscopy) then was unrousable.
There has been an trend of incidents related to this procedure and Consultants patients over the last few weeks and this matter has been raised with the Unit Manager and Clinical Lead for risk to investigate further.

Incident 3
Wrong dose
Dr [Staff Name] - Dr [Staff Name 2] was sedating pt for reduction of shoulder dislocation in resus room. Inadvertently gave 10mg of Midazolam for bolus. The patient was unrousable for about 30 minutes. Already on O_2 and full Monitoring. No change in RR, HR , O2 SATS (100%) . BP. Patient fully recovered and sent home later in evening.

Incident 4
Possible wrong dose and incomplete reversal
8mg of IV Midazolam given as a bolus to the patient , prior to a supra-pubic catheter procedure (which went uneventfully) , causing reduced consciousness for a prolonged period , which did not completely reverse with flumazenil and naloxone was given .

Incident 5
Wrong drug – unlabelled syringes
The patient had been given 2mg Midazolam IV for the application of traction to a right fractured femur - This syringe was labelled. There was also an unlabelled syringe containing a Normal Saline flush. Staff member had just given the patient 5mg morphine for analgesia and intended to give a further Normal Saline flush for the morphine but accidentally picked up the wrong syringe and gave the remaining 8mg of Midazolam . The error was recognised instantly when the label came into view. The patient remained clinically unchanged and patient was given 300mcg flumazenil IV.

Incident 6
Possible overdose/adverse reaction
Patient administered 10mg IV Midazolam in a single bolus by Locum Registrar. Patient Glasgow Coma Score immediately dropped to 5 / 15. Patient became bradycardic, hypotensive and oxygen saturations dropped.

Incident 7
Possible over-dose/adverse reaction
Patient sedated initially with 5mg midazolam. Further 5mg administered as patient distressed. Patient desaturated by reversal agent, saturation 90%, patient became bradycardic and atropine 0.6mg given, arrested, no pulse, non-shockable rhythm. On auto defib. No further resuscitation attempted. Patient pronounced dead at 16:16. Patient not for DNR.

Incident 8
Incomplete reversal
During IVS procedure pt re-sedated. Flumazenil given at 1420 – flumazenil has a shorter half life than midazolam. Pt woke for about 40minutes then re-sedated. SATS initially normal (brought back from waiting room to surgery). Dentist went for advice from Day Surgery Unit whilst Dental Nurse managed SPO2 drop by managing airway. Pt recovered consciousness shortly afterwards.

Earlier NPSA publication

In December 2006, a Patient Safety Bulletin[3] was disseminated to the NHS and drew attention to 349 incidents reported to the RLS up to September 2005, and involving midazolam or pethidine during conscious sedation. The bulletin endorsed the 2003 dosing recommendations made by the British Society of Gastroenterology[4].

Research evidence

Good quality research studies on the safety of midazolam are very limited and usually focus on clinical efficacy rather than patient safety. A brief summary of published studies involving patient safety issues is provided below:

In a randomised controlled trial to evaluate the effectiveness of four drug regimes in reducing dental treatment anxiety, Dionne et al[5] evaluated midazolam single dose and midazolam with top-up as required together with other drugs. They report adverse effects at 19.7% for the midazolam regimens, including drowsiness and lack of co-ordination, but suggest these were within expected parameters; the authors state that numbers of individual side effects were too low to provide reliable data on adverse effects.

The report of an expert panel convened by the Chief Medical Officer and Chief Dental Officer[6] reviewed the use of general anaesthesia and conscious sedation in primary care dental services; this cites one death due to conscious sedation, and recognizes that although safer than general anaesthetic, conscious sedation carries risks; however few details or research data are presented. The report focuses on recommended good practice (competences, training, consent, patient monitoring, patient-individualised drugs and dosage, antagonist available, reporting of adverse events) to improve patient safety.

In a small (n=34) randomised controlled trial[7], Kankaria et al assessed the psychomotor function of patients given midazolam and diazepam, both reversed with flumazenil. While no resedation effect was noted, there was no control group, drug dosage was based on perceived alertness, and sample size was too small to yield reliable results.

In a small randomised cross-over trial[8] (n=18) of post-operative recovery of benzodiazepine sedation (midazolam reversed with flumazenil and midazolam followed by saline), Girdler (2000) stated that flumazenil had some effect on word recognition and numeric working memory, but not on reaction times; cognitive impairments were still present at 6 hours after taking flumazenil, although staff had assessed the patients as being more alert. Numbers are too small to draw reliable conclusions.

In a further small randomised cross-over trial of healthy volunteers, Coulthard[9] also found that impairment (here, stability) persisted after flumazenil administration, and that staff assessed the participants as more alert than they were according to cognitive tests. Again the study is very small (n=14).

Further studies, including Nagelhout 1999[10], Williams 1999[11], Alarcon 2005[12] focus primarily on amnesia as the required outcome.

In addition, in 2004, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) reported on a review of 1,818 inpatient deaths within 30 days of interventional gastrointestinal endoscopy in hospitals in England, Wales and Northern Ireland[13]. This was an in depth study involving clinical review of patient case notes and other research methods. NCEPOD advisors judged that the sedation given was inappropriate in 14 per cent of these cases, usually because an overdose of benzodiazepine had been administered.

Guidelines and standards

UK Academy of Medical Royal Colleges and their faculties

In 2001, an intercollegiate working group was convened and chaired by the Royal College of Anaesthetists. A report was published which highlighted ongoing shortcomings in the safety of patients receiving sedation and made recommendations for implementing and ensuring safe sedation practice for healthcare procedures in adults[14]. These recommendations centred on the development of national (produced by each relevant professional body) and local organisational guidelines, training requirements and stronger local clinical governance arrangements to ensure that safe standards practices are established and maintained.

British Society of Gastroenterology (BSG)

In 2003, the British Society of Gastroenterology (BSG) drew on the recommendations of the intercollegiate working group and The report of the working party on guidelines for sedation by non-anesthetists, published by The Royal College of Surgeons of England, June 1993 to develop their own recommendations in *Safety and sedation during endoscopic procedures* [4]. This publication gave specific recommendations for the use of midazolam in conscious sedation which included the following:

- The dosage of benzodiazepines and opioids should be kept to a minimum to achieve sedation and should be within the manufacturers guidelines (generally not more than 5mg being required).
- That elderly patients should be given 1-2 mg initially with a sensible pause to observe effect.
- Opioids should, whenever possible, be given before benzodiazepines and their effect observed before proceeding.

In their newsletter in Spring 2008, the BSG went on to say; 'In the view of the Endoscopy Committee and the NPSA the availability of a preparation of midazolam of a strength of 1mg/ml is a significant advance in safety and it is our joint view and advice that all endoscopy units should stock only this single strength of midazolam for all routine diagnostic endoscopy'[15].

Report of an expert group on sedation for dentistry

The confinement of dental general anaesthesia to the hospital setting has seen an increase in conscious sedation for some dental procedures. This change in clinical practice prompted the Department of Health to commission a report on conscious sedation in the provision of dental care[16]. Recognising the need for clarity about the appropriate standards for conscious sedation, the Standing Dental Advisory Committee established an expert group to make recommendations on good practice. This report, published in 2003, gives recommendations for all practitioners providing conscious sedation whether in primary care or in hospitals. The report highlights that safe IV sedation practice involves the use of a single intravenous agent, administered by

experienced practitioners only and supported by a well trained team. Doses of IV sedation should be titrated to the needs of the patient.

National Confidential Enquiry into Patient Outcome and Death (NCEPOD)
As noted in research evidence above, the 2004 NCEPOD report on interventional gastrointestinal endoscopy in hospitals in England, Wales and Northern Ireland[13]. NCEPOD advisors judged that the sedation given was inappropriate in 14 per cent of the 1,818 deaths reviewed, usually because an overdose of benzodiazepine had been administered.

Detailed analysis of the fatalities data showed that patients who had received flumazenil died two days sooner than those who had not received it. NCEPOD made the following recommendations amongst others:

- All those responsible for the administration of sedation should have received formal training and assessment.
- Sedation and monitoring practices within endoscopy units should be audited and reviewed.
- Clear protocols for the administration of sedation should be available and implemented.
- In patients over the age of 70, no more than 2mg of midazolam should be drawn up into any syringe prior to the procedure.
- In patients under the age of 70, no more than 5mg of midazolam should be drawn up into any syringe prior to the procedure.
- The practice of routinely drawing up 10mg of midazolam should cease in all patients.

Conclusions and actions for staff

The National Patient Safety Agency has identified serious problems in the current use of midazolam for conscious sedation in adults. Staff in the NHS have reported three deaths and 263 other incidents where patients received inappropriate doses. Errors occur because of lack of training in the use of midazolam, problems in titration and dosing (including use of part-ampoules and vials of higher strength) for individual patients. The use of flumazenil as an antidote to midazolam overdose is widespread. It is useful to reverse the effects of over-sedation, but bears its own risks.

The Rapid Response Report [NPSA/2008/RRR011] outlines clear actions for the service to minimise risks of overdosing and subsequent harm from midazolam in adults. This has been issued through the Department of Health Central Alert System (CAS) in England and directly to organisations in Wales. It applies to all organisations in the NHS and independent sector where midazolam is used.

The deadline date for actions complete is six months after the date of issue. This implementation period takes into account to the need for manufacturers of low dose midazolam injection to adjust manufacturing processes to ensure maintenance of supply to the NHS of the lower strength injection.

In England, compliance with the recommendations should be entered on the Central Alert System (CAS) by CAS liaison officers. To assist organisations in implementing these actions, a checklist is given in Appendix 2 which can be adapted for local use. These actions should help to ensure the safety of patients undergoing conscious sedation by standardising practice and restricting the use of high strength midazolam.

References

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Appendix 1: Details on use of midazolam (dosing) and flumazenil

Midazolam - dosing in conscious sedation[17]

In adults, the intravenous injection of midazolam should be given slowly at a rate of approximately 1 mg in 30 seconds.

In adults below the age of 60 the initial dose is 2 to 2.5mg given five to 10 minutes before the beginning of the procedure. Further doses of 1mg may be given as necessary. Mean total doses have been found to range from 3.5 to 7.5mg. A total dose greater than 5mg is usually not necessary.

In adults over 60 years of age, debilitated or chronically ill patients, the initial dose must be reduced to 0.5-1.0mg and given five to 10 minutes before the beginning of the procedure. Further doses of 0.5 to 1mg may be given as necessary. Since in these patients the peak effect may be reached less rapidly, additional midazolam should be titrated very slowly and carefully. A total dose greater than 3.5mg is usually not necessary.

Flumazenil - elimination half lives

Manufacturer's information indicates that flumazenil has an elimination half life of 40 to 80 minutes which is largely unaffected by age.

Manufacturer's information indicates that midazolam has an elimination half life of 1.5 to 2.5 hours in adults. In patients over the age of 60 years, this may be prolonged up to 4 times.

Appendix 2: Suggested compliance checklist

Note that actions apply to all organisations where midazolam is used for adult conscious sedation. Primary care trusts and local health boards have responsibilities to ensure that the contents of the Rapid Response Report are communicated to relevant independent contractors, who should be aware of the risks and take the necessary action outlined in this RRR.

No	Recommendation	Action	Compliance Y/N
011/1	The storage and use of high strength midazolam [5mg/ml in 2ml and 10 ml ampoules; or 2mg/ml in 5ml ampoules] should be restricted to anaesthetic use, intensive care sedation, and in clinical areas/situations where its use has been formally risk assessed, for example, where syringe drivers are used.	• Stocks of high strength midazolam injection (5mg/ml as 2ml and 10ml ampoules and 2mg/ml as 5ml ampoules) have been removed from areas except where used for anaesthesia or intensive care sedation. • A risk assessment* has been undertaken in clinical areas/situations where high strength midazolam is used for syringe drivers, to identify and reduce the risks associated with using high strength midazolam in clinical practice. (This is particularly important in clinical areas where different strengths of midazolam are stocked for use in relation to other activities). • Date of actions approved by clinical governance group (or local equivalent).	
011/2	In other clinical areas, storage and use of high strength midazolam, should be replaced with low strength midazolam [1mg/ml in 2ml, 5ml ampoules].	• Stocks in areas other than anaesthesia and intensive care have been reviewed and replaced with 1mg/ml (2ml, 5ml ampoules as appropriate for the intended use).	
011/3	Organisations should review therapeutic protocols to ensure that guidance on use of midazolam is clear and that the risks are minimised particularly in the elderly, frail or at-risk patients.	• Review and update therapeutic protocols. • Date approved by clinical governance group (or local equivalent).	

011/4	Organisations should ensure that all healthcare practitioners involved directly or participating in sedation techniques have the necessary knowledge, skills and competences required.	• Reference to existing guidance on standards agreed by relevant professional bodies has been made and a training plan developed to ensure that all relevant practitioners have the necessary skills and competences required by professional bodies. • The plan is reviewed regularly by the clinical governance group (or local equivalent). • The organisation is able to demonstrate on-going action and improvement in relation to achieving training milestones and maintenance of competence of healthcare practitioners. • Dates plan is reviewed by the clinical governance group (or local equivalent).	
011/5	Organisations should audit and seek to minimise the use of flumazenil in line with licensed indications.	• An assessment of current utilisation and indications for use of flumazenil has been undertaken. • Indications for use of flumazenil are present in therapeutic protocols • The use of flumazenil has been audited against therapeutic protocols. • Date findings reported to clinical governance group (or local equivalent) and record of any proposed subsequent action required.	
011/6	Sedation must be covered by organisational policy and overall responsibility assigned to a senior clinician which, in most cases, will be an anaesthetist.	• Organisational responsibility for conscious sedation has been assigned to a senior clinician. • Local policy has been updated to reflect this. • Date approved by clinical governance group (or local equivalent).	

In addition to the specific actions above, provider organisations should be able to demonstrate the following:

A	Communication to health care staff about the new arrangements for conscious sedation.	• A communication plan has been developed to ensure robust communication of arrangements. • Date approved by clinical governance group (or local equivalent). • Date evidence of dissemination is shared with clinical governance group (or local equivalent).	
B	Evaluation plan – how the organisation will confirm that safer systems for conscious sedation have been implemented. This will involve: • Checking staff and patient awareness. • Audit of procedures in practice ie check of clinical areas and availability of low strength midazolam, where appropriate. • Review of incidents where the safe system has not operated.	• An evaluation plan has been developed. • Date approved by clinical governance group. • Date for evaluation. • Date findings reported to clinical governance group (or local equivalent).	

* Guidance on undertaking healthcare risk assessments can be found at: www.npsa.nhs.uk/patientsafety/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides