APPENDICES 1 TO 8

Please note that the following appendices are in separate files:

Abbreviations

AUC	area under the curve
CI	confidence interval
CCTV	closed-circuit television
GDG	Guideline Development Group
LR+	positive likelihood ratio
LR-	negative likelihood ratio
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
p.r.n.	pro re nata (as required)
PSS	personal social services
QALY	quality of life year
ROC	receiver operator characteristics
ROC	receiver operator characteristic
RR	relative risk/risk ratio

APPENDIX 1: SCOPE FOR THE DEVELOPMENT OF THE CLINICAL GUIDELINE

1 GUIDELINE TITLE

Violence and aggression: the short-term management of violent and physically threatening behaviour in mental health, health and community settings.

Short title

Violence and aggression

2 THE REMIT

This is an update of Violence: the short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments (NICE clinical guideline 25). This update is being undertaken because new evidence has emerged about service users' views on the use of physical intervention and seclusion and the effectiveness, acceptability and safety of available drugs and their dosages for rapid tranquilisation.

3 CLINICAL NEED FOR THE GUIDELINE

The remit has been expanded to include violence and threatening behaviour in all health and social care settings. It is focused on settings rather than individuals because it is recognised that interaction between health and social care professionals and service users may precipitate inadvertent violence and that successful prevention and treatment may necessitate changes in processes across a setting. The terms 'violence' and 'aggression' in this scope describe outwardly aggressive behaviour. They are used in the absence of better ways of describing aggressive behaviour and do not imply deliberate intention. NICE recognises that for people with mental health problems, aggressive behaviour occurs for a number of very complex reasons. The most important of these are often the events and feelings that led up to the behaviour, and precipitating factors will be covered in the guideline.

Epidemiology

On an average psychiatric ward up to 5 episodes per month of manual restraint of patients might be expected, although there is considerable variation. Around 75% of nursing staff experience violent behaviour such as physical assault every year, most commonly in psychiatric settings. Episodes of violence and aggression towards staff are also common in community settings, although many go unreported. Such episodes cause significant morbidity and stress among staff, contributing to sickness absence, low morale and early retirement.

Current practice

The management of violence and aggression towards staff and damage to personal or ward property varies according to setting. In hospital settings the most common response is special observation, followed by manual restraint, seclusion and emergency tranquillisation, usually with antipsychotic drugs. In community settings it is more common for the staff concerned to remove themselves from the scene of violence and ask for police help. Violence is a particular risk when carrying out assessments under the Mental Health Act.

4 THE GUIDELINE

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

Population

Groups that will be covered

a) Adults (aged 18 and over), children and young people with mental health conditions who are currently service users within healthcare, including mental healthcare, social care and community settings.

b) Specific consideration will be given to:

- service users with co-existing substance misuse (both hazardous use and dependence) or withdrawal
- black and minority ethnic groups
- girls and women.

c) Carers of service users with mental health conditions.

Groups that will not be covered

The guideline will also be relevant to, but will not cover, practice regarding:

a) People who do not have a mental health condition and who are not carers of people with a mental health condition.

b) People in whom the primary behaviour is self-harm. Self-harm (NICE clinical guideline 16) focuses specifically on short-term management for this population.

c) People with a primary diagnosis of learning disability. Although the principles of managing threatening behaviour will be relevant to people with learning disability, Challenging behaviour in people with learning disability, a NICE clinical guideline currently in development, will specifically address this population (see section 5, 'Related NICE guidance').

Healthcare setting

a) The guideline will cover the management of violence and aggression by healthcare professionals and how care may need to be modified in specific health and social care settings, including:

- inpatient psychiatric settings (including high-, medium- and low-security psychiatric hospitals and NHS general hospitals)
- emergency and urgent care services
- assertive community teams
- community mental health teams
- primary care.

Clinical management

Key clinical issues that will be covered

Areas from the original guideline that will be updated

a) Identification of potentially violent and aggressive service users and the evaluation of methods and tools for prediction and risk assessment.

b) De-escalation methods and other short-term psychosocial intervention methods.

c) Seclusion.

d) Physical restraint.

e) Pharmacological interventions. (Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.)

f) Training or education requirements for the above-mentioned interventions.

g) Impact of equalities issues on the short-term management of violence and aggression, including ethnicity, gender and physical disability.

Areas not in the original guideline that will be included in the update

a) Anticipation of violence and aggression.

b) Environmental influences and how to modify them.

c) Mechanical restraint.

d) The role of advance directives in the management of violence and aggression.

e) Post-incident management for staff, service users and witnesses.

f) Substance misuse.

g) The interface between mental health services and the police in the immediate management of violence and aggression.

h) Mental Health Act status.

Clinical issues that will not be covered

Condition-specific information will not be covered in this guideline.

Main outcomes

The following outcomes will be considered by the Guideline Development Group:

a) Rates of seclusion.

b) Rates of manual restraint.

c) Use of antipsychotic drugs.

d) Use of rapid tranquillisation methods.

e) Experience of service users and carers.

f) Rates of injury in service users.

g) Rates of injury in staff.

Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is usually the quality-adjusted life year (QALY), but different measures may also be used, including staff outcomes, depending on the availability of appropriate clinical data identified for this guideline. The costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see section 6, 'Further information').

Status

Scope

This is the final scope.

Timing

The development of the guideline recommendations began in March 2013.

5 RELATED NICE GUIDANCE

Published guidance

NICE guidance to be updated

This guideline will update and replace the following NICE guidance:

- Violence. NICE clinical guideline 25 (2005).

Other related NICE guidance

- Patient experience in adult NHS services. NICE clinical guidance 138 (2012).
- Service user experience in adult mental health. NICE clinical guidance 136 (2011).
- Drug misuse – opioid detoxification. NICE clinical guidance 52 (2007).
- Drug misuse – psychosocial interventions. NICE clinical guideline 51 (2007).
- Dementia. NICE clinical guidance 42 (2006).
- Self-harm. NICE clinical guideline 16 (2004).

Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Smoking cessation in secondary care: mental health services. NICE public health guidance. Publication expected November 2013[1].
- Psychosis and schizophrenia in adults. NICE clinical guideline. Publication expected March 2014[2].
- Challenging behaviour in people with learning disability. NICE clinical guideline. Publication expected May 2015[3].

6 FURTHER INFORMATION

Information on the guideline development process is provided in the following documents, available from the NICE website:

- How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS
- The guidelines manual.

Information on the progress of the guideline will also be available from the NICE website.

[1] Since this scope was written, this guidance has been published as Smoking cessation in secondary care: acute, maternity and mental health services (public health guidance 48).
[2] Since this scope was written, this guidance has been published as Psychosis and schizophrenia in adults: treatment and management (clinical guideline 178).
[3] This guidance is still in development as Challenging behaviour and learning disabilities.

APPENDIX 2: DECLARATIONS OF INTERESTS BY GUIDELINE DEVELOPMENT GROUP MEMBERS

With a range of practical experience relevant to violence and aggression in the GDG, members were appointed because of their understanding and expertise in the short-term management of violence and physically threatening behaviour in mental health, health and community settings, including: scientific issues; health research; the delivery and receipt of healthcare, along with the work of the healthcare industry; and the role of professional organisations and organisations for the short-term management of violence and aggression in people with mental health conditions, and their families/carers.

To minimise and manage any potential conflicts of interest, and to avoid any public concern that commercial or other financial interests have affected the work of the GDG and influenced guidance, members of the GDG must declare as a matter of public record any interests held by themselves or their families which fall under specified categories (see below). These categories include any relationships they have with the healthcare industries, professional organisations, and organisations for people with mental health conditions.

Individuals invited to join the GDG were asked to declare their interests before being appointed. To allow the management of any potential conflicts of interest that might arise during the development of the guideline, GDG members were also asked to declare their interests at each GDG meeting throughout the guideline development process. The interests of all the members of the GDG are listed below, including interests declared prior to appointment and during the guideline development process.

Please note that the Violence and Aggression Guideline Development Group was recruited under NICE's 2007 Declaration of Interests Policy.

Categories of interest to be written in third person

Paid employment

Personal pecuniary interest: financial payments or other benefits from either the manufacturer or the owner of the product or service under consideration in this guideline, or the industry or sector from which the product or service comes. This includes holding a directorship or other paid position; carrying out consultancy or fee paid work; having shareholdings or other beneficial interests; receiving expenses and hospitality over and above what would be reasonably expected to attend meetings and conferences.

Personal family interest: financial payments or other benefits from the healthcare industry that were received by a member of your family.

Non-personal pecuniary interest: financial payments or other benefits received by the GDG member's organisation or department, but where the GDG member has not personally received payment, including fellowships and other support provided by the healthcare industry. This includes a grant or fellowship or other payment to sponsor a post, or contribute to the running costs of the department; commissioning of research or other work; contracts with, or grants from, NICE.

Personal non-pecuniary interest: these include, but are not limited to, clear opinions or public statements you have made about the topic of the guideline, holding office in a professional organisation or advocacy group with a direct interest in the topic, and other reputational risks relevant to the topic.

Guideline Development Group – declarations of interest	
Peter Tyrer (Chair)	
Employment	Professor of Community Psychiatry, Centre for Mental Health, Imperial College, London
Personal pecuniary interest	None
Personal family interest	Wife has a pecuniary interest in Anxiety and Worry Service Ltd.
Non-personal pecuniary interest	None
Personal non-pecuniary interest	Director (unpaid) of Anxiety and Worry Service Ltd. Chair of NIDUS-UK (charity for mental health reform)
Non-personal non-pecuniary interest	None
Action taken	None
Tim Kendall (Facilitator)	
Employment	Director, National Collaborating Centre for Mental Health
Personal pecuniary interest	Director and Chief Exectutive Officer of a healthcare organisation provides clinical care. This limited company has no role in the management of violence and aggression nor in providing training.
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Richard Barnett	
Employment	Lecturer, School of Health and Rehabilitation, Keele University
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Len Bowers	
Employment	Professor of Psychiatric Nursing, Institute of Psychiatry, Psychology and Neuroscience, Kings College London
Personal pecuniary interest	Accepted paid speaking engagement for a conference run by Crisis Prevention International, an organisation that provides manual restraint training.
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	As a researcher in the area, there is potential for personal benefit from the review or its content by the acquisition of further research grants. Having conducted research in the area of the review, affiliation to own research findings and theorising about causes that may bias personal interpretation of the evidence. As the author of many systematic reviews in this area, and as the creator of the Safewards model and interventions, and the principal investigator of the Safewards trial, these ideas will have framed my approach to the guideline development.

Non-personal non-pecuniary interest	None
Action taken	None
Lucy Burt	
Employment	Research Assistant, National Collaborating Centre for Mental Health
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Joy Duxbury	
Employment	Professor of Mental Health Nursing, University of Central Lancashire
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Elena Garralda	
Employment	Emeritus Professor of Child and Adolescent Psychiatry, Imperial College London
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
David Glynn	
Employment	Health Economist, National Collaborating Centre for Mental Health
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Mike Hunter	
Employment	Consultant Psychiatrist, Assertive Outreach; Clinical Director, Inpatient Services; Associate Medical Director, Research and Strategy, Sheffield Health and Social Care NHS Foundation Trust
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	[Non-specific]: Local principal investigator for a randomised controlled trial of an investigational medicinal product for schizophrenia sponsored by Amgen Ltd. This study has been adopted in the NHS through the Mental Health Research Network.
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None

Uday Katkar	
Employment	Locum GP; GP with Special Interest in Emergency Medicine, Staffordshire
Personal pecuniary interest	Director of Dr Katkar Limited – the company is related to personal locum work and other works relation to non-pensionable income. Clinical Associate for NICE Guidance Implementation for Stoke Clinical Commissioning Group.
Personal family interest	Wife is Director and Secretary of Dr Katkar Limited.
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Catherine King	
Employment	Service User and Carer Representative
Personal pecuniary interest	Occasional paid reviews for booklets for Mind
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	Member of Mind
Non-personal non-pecuniary interest	None
Brian Littlechild	
Employment	Professor of Social Work, University of Hertfordshire
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Noel McKenna	
Employment	Service User and Carer Representative
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Maryla Moulin	
Employment	Senior Project Manager, National Collaborating Centre for Mental Health
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None

Maeve Murphy	
Employment	Clinical Nurse Specialist, FACTS Team, Greater Manchester West NHS Foundation Mental Health Trust
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Sabrina Naqvi	
Employment	Project Manager, National Collaborating Centre for Mental Health
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None

Tony O'Connell	
Employment	Detective Constable, Criminal Investigations Department, Dorset Police
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Mary Pennant	
Employment	Systematic Reviewer, National Collaborating Centre for Mental Health
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Peter Pratt	
Employment	Chief Pharmacist, Sheffield Health and Social Care NHS Foundation Trust
Personal pecuniary interest	Chaired College of Mental Health Pharmacy session (morning only, on 8 November 2014). Last minute stand-in for presenter who was unable to present. Received a small honorarium payment plus travel expenses
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Belinda Salt	
Employment	Matron, Acute Services, Nottinghamshire Healthcare NHS Trust
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Faisil Sethi	
Employment	Consultant Psychiatrist and Associate Clinical Director, Maudsley Hospital, South London and Maudsley NHS Foundation Trust, London; Psychiatric Intensive Care Unit Lead Consultant, Psychosis Clinical Academic Group, South London and Maudsley NHS Foundation Trust, London; Vice Chair, National Association of Psychiatric Intensive Care and Low Secure Units
Personal pecuniary interest	Sponsorsed by Janssen to attend the American Psychiatric Association Annual Meeting, May 2013. The sponsorship covered reasonable costs for travel, accommodation and registration at the conference; did not conduct any work for Janssen nor receive any speaker fees. Speaker fee and sponsorship by the University Psychiatric Centre of Hvidore in Copenhagen to give Psychiatric

	Intensive Care lecture at their conference, November 2013. The sponsorship covered reasonable costs for travel, accommodation and registration at the conference.
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	Vice Chair and member of the Executive Committee of the National Association of Psychiatric Intensive Care Units. Elected member of the Executive Committee of the General Adult Faculty of the Royal College of Psychiatrists.
Non-personal non-pecuniary interest	None
Action taken	None
Leroy Simpson	
Employment	Service User Representative
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Eric Slade	
Employment	Health Economist, National Collaborating Centre for Mental Health
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Peter Staves	
Employment	Service User and Carer Representative
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Sarah Stockton	
Employment	Senior Information Scientist, National Collaborating Centre for Mental Health
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Clare Taylor	
Employment	Senior Editor, National Collaborating Centre for Mental Health
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None

Action taken	None
Birgit Völlm	
Employment	Clinical Associate Professor and Reader, Head of Section Forensic Mental Health, Division of Psychiatry and Applied Psychology, University of Nottingham and Honorary Consultant Forensic Psychiatrist, Rampton Hospital, Nottinghamshire Healthcare NHS Trust
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None
Craig Whittington	
Employment	Associate Director (Clinical Effectiveness), National Collaborating Centre for Mental Health
Personal pecuniary interest	Member of the scientific steering committee for a US company, Doctor Evidence LLC. Doctor Evidence is a specialty software platform and services company with clients from across the healthcare ecosystem. The role includes a share option (3 year vesting) and a meeting stipend.
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Non-personal non-pecuniary interest	None
Action taken	None

APPENDIX 3A: STAKEHOLDERS AND EXPERTS WHO SUBMITTED COMMENTS IN RESPONSE TO THE CONSULTATION DRAFT OF THE GUIDELINE

Association for Family Therapy and Systemic Practice
Black Country Partnership NHS Foundation Trust
CALM (Crisis, Aggression, Limitation and Management) Training
Cardiff & Vale University Health Board
Central & North West London NHS Foundation Trust
College of Emergency Medicine
College of Mental Health Pharmacy
Cumbria Partnership NHS Foundation Trust
Department of Health
Devon Partnership NHS Trust
East London Foundation Trust
Ferrer Internacional
Hampshire Constabulary
Lancashire Care NHS Foundation Trust
London Metropolitan Police & Association of Chief Police Officers (joint submission)
Mind
National Adolescent Forensic Service
National Association of Psychiatric Intensive Care and Low Secure Units
National Forensic Psychotherapy Development Group
NHS England
NHS Protect
Northamptonshire Healthcare NHS Foundation Trust
Partnerships in Care
Roche Products
Rotherham Doncaster and South Humber NHS Foundation Trust
Royal College of General Practitioners
Royal College of Nursing
Royal College of Paediatrics and Child Health
Royal College of Psychiatrists
Royal College of Speech and Language Therapists
South Central Ambulance Service NHS Trust
South Eastern Health and Social Care Trust
South Staffordshire and Shropshire Healthcare NHS Foundation Trust
South West Yorkshire Partnership NHS Foundation Trust
St John Ambulance
Wales Institute of Forensic Medicine

APPENDIX 3B: SPECIAL ADVISORS TO THE GUIDELINE DEVELOPMENT GROUP

Clive Adams	Coordinating Editor, Cochrane Schizophrenia Group, Faculty of Medicine & Health Sciences
Conor Duggan (retired)	Professor and Head of Section of Forensic Mental Health Institute of Mental Health, University of Nottingham Honorary Consultant Psychiatrist, Arnold Lodge Regional Secure Unit, Leicester
Kevin Gournay	Emeritus Professor, Institute of Psychiatry, King's College, London
Diana Rose	Professor of User-Led Research, Head of Section and Co-director Service User Research Enterprise, Health Services and Population Research Department, Institute of Psychiatry, Psychology & Neuroscience, King's College London Northamptonshire Foundation NHS Trust

APPENDIX 4: RESEARCHERS CONTACTED TO REQUEST INFORMATION ABOUT UNPUBLISHED OR SOON-TO-BE PUBLISHED STUDIES

Clive Adams, Coordinating Editor, Cochrane Schizophrenia Group, Faculty of Medicine & Health Sciences

APPENDIX 5: REVIEW QUESTIONS

Experience of the short-term management of violence and aggression

No.	Review question
	Mental health service users
1.1	Does race/ethnicity of a service user or staff member make a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings?
1.2	Do service users perceive that the race/ethnicity of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings?
1.3	Does gender of a service user or staff member make a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings?
1.4	Do service users perceive that the gender of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings?
1.5	What are the service users' perspectives of the considerations needed for the short-term management of violent and aggressive behaviour in health and community care settings where the service user has physical disabilities?
	Carers of mental health service users
1.6	Do carers perceive that the race/ethnicity of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings?
1.7	Do carers perceive that the gender of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings?
1.8	What are the carers of mental health service users perspectives of the considerations needed for the short-term management of violent and aggressive behaviour in health and community care settings where the service user has physical disabilities?
	Staff
1.9	Do staff perceive that the race/ethnicity of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings?
1.10	Do service users perceive that the gender of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings?
1.11	What are the staff perspectives of the considerations needed for the short-term management of violent and aggressive behaviour in health and community care settings where the service user has physical disabilities?

Pre-event

No.	Review question
	Risk factors and prediction
2.1	What are the risk factors and antecedents (including staff characteristics) for violent and aggressive behaviour by mental health service users in health and community care settings?
2.1.1	Do the identified risk factors have good predictive validity for future violent and aggressive behaviour by mental health service users in health and community care settings?
2.2	What factors do service users and staff report as increasing the risk of violent and aggressive behaviour by mental health service users in health and community care settings?
2.3	Which instruments most reliably predict violent and aggressive behaviour by mental health service users in health and community care settings in the short-term?
2.3.1	Do the identified instruments have good predictive validity for future violent and aggressive behaviour by mental health service users in health and community care settings?
2.4	What is the best the approach for anticipating violent and aggressive behaviour by mental health service users in health and community care settings?
	Prevention interventions
2.5	Do observation techniques, used to pre-empt or prevent violent and aggressive behaviour by mental health service users in an inpatient setting, produce benefits that outweigh possible harms when compared with an alternative approach?
2.6	Do modifications to the environment (physical and social) of health and community care settings, used to reduce the risks of violent and aggressive behaviour by mental health service users, produce benefits that outweigh possible harms when compared with an alternative approach?
2.7	Do management strategies (including staffing levels and IT systems), used to reduce the risks of violent and aggressive behaviour by mental health service users, produce benefits that outweigh possible harms when compared with an alternative approach?
	Training
2.8	Do training programmes for the use of interventions designed to prevent and manage violent and aggressive behaviour by mental health service users in health and community care settings, for staff, and for staff and service users combined, produce benefits that outweigh possible harms when compared with an alternative management strategy?
	Advance directives
2.9	What role should advance directives play in the prevention of violence and aggression by mental health service users in health and community care settings?
	Substance misuse
2.11	What is the most appropriate method of recognition and management of substance misuse in mental health service users with violent and aggressive behaviour in health and community care settings?

	Mental Health Act
2.12	Does being subject to the Mental Health Act alter the risk of violent and aggressive behaviour by mental health service users in health and community care settings?
2.12.1	If so, is the effect of detention proportional in relation to the factors that led to its implementation?

Immediately pre-event

No.	**Review question**
	Advance directives
3.1	What role should advance directives play in the management of imminent violence and aggression by mental health service users in health and community care settings?
	Prevention interventions
3.2	Do observation techniques used to pre-empt or prevent imminent violent and aggressive behaviour by mental health service users in an inpatient setting produce benefits that outweigh possible harms when compared with an alternative management strategy?
3.3	Do personal and institutional alarms, CCTV and communication devices used to alert staff to imminent violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared with an alternative management strategy?
3.4	What principles of practice are necessary to ensure the effectiveness of personal and institutional alarms, CCTV and communication devices in reducing violent and aggressive behaviour by mental health service users in health and community care settings when compared with an alternative management strategy?
3.5	Do de-escalation methods used to prevent imminent violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared with an alternative management strategy?
3.6	Does p.r.n. (*pro re nata*) medication used to prevent imminent violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared with an alternative management strategy?

During event

No.	Review question
	Non-pharmacological management strategies
4.1	Do modifications to the environment (both physical and social) of health and community care settings used to reduce the level of violent and aggressive behaviour by service users with mental health conditions produce benefits that outweigh possible harms when compared with an alternative management strategy?
4.2	Does the use of personal and institutional alarms, CCTV and communication devices for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared with an alternative management strategy?
4.3	Does seclusion used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared with an alternative management strategy?
4.4	Do de-escalation methods used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared with an alternative management strategy?
4.5	Do physical restraint techniques (including, manual and mechanical restraint) used by staff for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared with an alternative management strategy?
4.6	If physical restraint techniques (including, manual and mechanical restraint) are used by staff for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings, how should use be modified if, for example, the service user is: undergoing withdrawal • intoxicated • a heavy drinker • seriously medically ill • has physical disabilities or injuries or is physically frail • pregnant • obese.
4.9	What factors should influence the decision to transfer a mental health service user with violent and aggressive behaviour to a more secure environment?
	Pharmacological management strategies
4.7	Do brief or fast acting pharmacological interventions used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared with an alternative management strategy?
4.8	If brief or fast acting pharmacological interventions are used in the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings, how should use be modified if, for example, the service user is: undergoing withdrawal • intoxicated • a heavy drinker • seriously medically ill

	• has physical disabilities or injuries or is physically frail • pregnant • obese.
	Interface between health and police
4.10	What is the best management strategy for the transfer of mental health service users to or between places of safety?
4.11	What is the best management strategy when the police are called to support mental health staff manage violent and aggressive behaviour by mental health service users in health and community care settings?
4.12	What is the best management strategy when mental health staff are required to call the police to take someone into custody because of violent and aggressive behaviour in health and community care settings?
	a) Training
4.13	What are the most effective and safe training programmes for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings?

Post-event

No.	Review question
	Post-incident management
5.1	After violent and aggressive behaviour by mental health service users in health and community care settings, what post-incident management should occur for the service user(s) involved?
5.2	After violent and aggressive behaviour by mental health service users in health and community care settings, what post-incident management should occur for the staff involved?
5.3	After violent and aggressive behaviour by mental health service users in health and community care settings, what post-incident management should occur for any witnesses involved?

APPENDIX 6: METHOD FOR EVIDENCE SYNTHESIS

Synthesising the evidence from test accuracy studies

Meta-analysis

Review Manager was used to summarise test accuracy data from each study using forest plots and summary receiver operator characteristic (ROC) plots. Where more than two studies reported appropriate data, a bivariate test accuracy meta-analysis was conducted using Meta-DiSc (Zamora et al., 2006) in order to obtain pooled estimates of sensitivity, specificity, and positive and negative likelihood ratios.

Sensitivity and specificity

The sensitivity of an instrument refers to the probability that it will produce a true positive result when given to a population with the target disorder (as compared with a reference or 'gold standard'). An instrument that detects a low percentage of cases will not be very helpful in determining the numbers of service users who should receive further assessment or a known effective intervention, because many individuals who should receive the treatment will not do so. This would lead to an underestimation of the prevalence of the disorder, contribute to inadequate care and make for poor planning and costing of the need for treatment. As the sensitivity of an instrument increases, the number of false negatives it detects will decrease.

The specificity of an instrument refers to the probability that a test will produce a true negative result when given to a population without the target disorder (as determined by a reference or 'gold standard'). This is important so that people without the disorder are not offered further assessment or interventions they do not need. As the specificity of an instrument increases, the number of false positives will decrease.

To illustrate this: from a population in which the point prevalence rate of anxiety is 10% (that is, 10% of the population has anxiety at any one time), 1000 people are given a test that has 90% sensitivity and 85% specificity. It is known that 100 people in this population have anxiety, but the test detects only 90 (true positives), leaving 10 undetected (false negatives). It is also known that 900 people do not have anxiety, and the test correctly identifies 765 of these (true negatives), but classifies 135 incorrectly as having anxiety (false positives). The positive predictive value of the test (the number correctly identified as having anxiety as a proportion of positive tests) is 40% (90/90+135), and the negative predictive value (the number correctly identified as not having anxiety as a proportion of negative tests) is 98% (765/765 +10). Therefore, in this example, a positive test result is correct in only 40% of cases, while a negative result can be relied upon in 98% of cases.

The example above illustrates some of the main differences between positive predictive values and negative predictive values in comparison with sensitivity and specificity. For both positive and negative predictive values, prevalence explicitly

forms part of their calculation (seeAltman & Bland, 1994a). When the prevalence of a disorder is low in a population this is generally associated with a higher negative predictive value and a lower positive predictive value. Therefore although these statistics are concerned with issues probably more directly applicable to clinical practice (for example, the probability that a person with a positive test result actually has anxiety) they are largely dependent on the characteristics of the population sampled and cannot be universally applied (Altman & Bland, 1994a).

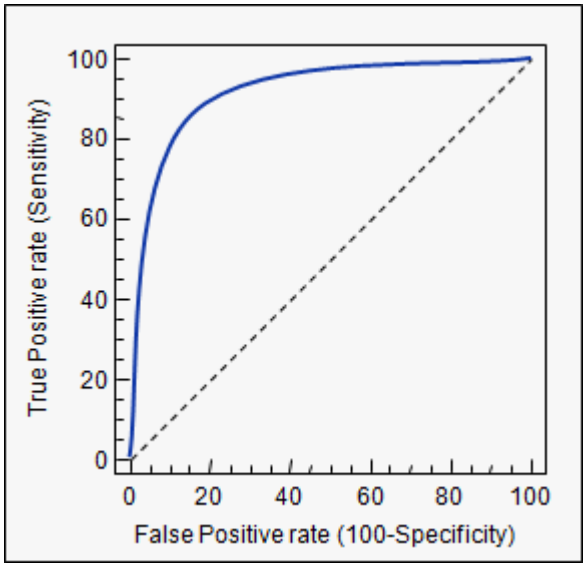
On the other hand, sensitivity and specificity do not necessarily depend on prevalence of anxiety (Altman & Bland, 1994b). For example, sensitivity is concerned with the performance of an identification instrument conditional on a person having anxiety. Therefore the higher false positives often associated with samples of low prevalence will not affect such estimates. The advantage of this approach is that sensitivity and specificity can be applied across populations (Altman & Bland, 1994b). However, the main disadvantage is that clinicians tend to find such estimates more difficult to interpret.

When describing the sensitivity and specificity of the different instruments, the GDG defined values above 0.9 as 'excellent', 0.8 to 0.9 as 'good', 0.5 to 0.7 as 'moderate', 0.3 to 0.4 as 'low', and less than 0.3 as 'poor'.

Receiver operator characteristic curves

The qualities of a particular tool are summarised in a ROC curve, which plots sensitivity (expressed as a per cent) against (100-specificity) (see Figure 1).

Figure 1: Receiver operator characteristic (ROC) curve



A test with perfect discrimination would have an ROC curve that passed through the top left hand corner; that is, it would have 100% specificity and pick up all true positives with no false positives. While this is never achieved in practice, the area under the curve (AUC) measures how close the tool gets to the theoretical ideal. A perfect test would have an AUC of 1, and a test with AUC above 0.5 is better than chance. As discussed above, because these measures are based on sensitivity and 100-specificity, theoretically these estimates are not affected by prevalence.

Negative and positive likelihood ratios

Positive (LR+) and negative (LR-) likelihood ratios are thought not to be dependent on prevalence. LR+ is calculated by sensitivity/(1-specificity) and LR- is (1-sensitivity)/specificity. A value of LR+ >5 and LR- <0.3 suggests the test is relatively accurate (Fischer et al., 2003).

Heterogeneity

Heterogeneity is usually much greater, and is to be expected, in meta-analyses of test accuracy studies compared with meta-analyses of randomised controlled trials (Macaskill et al., 2010). Therefore, a higher threshold for acceptable heterogeneity in such meta-analyses is required. However, when pooling studies resulted in $I^2 > 90\%$, meta-analyses were not conducted.

Synthesising the evidence for the effectiveness of interventions

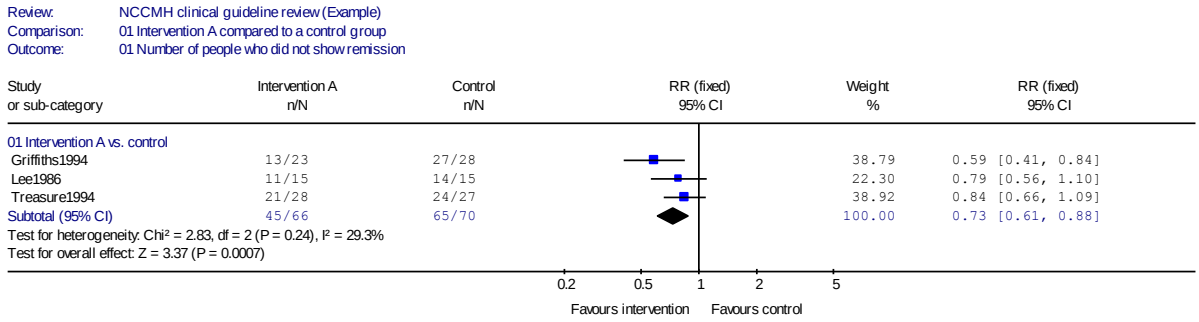
Meta-analysis

Where appropriate, meta-analysis was used to synthesise evidence for the effectiveness of interventions using Review Manager Version 5.3. If necessary, re-analyses of the data or sub-analyses were used to answer review questions not addressed in the original studies or reviews.

Dichotomous outcomes were analysed as relative risks (RR; also called a risk ratio) with the associated 95% confidence interval (CI) (see Figure 2 for an example of a forest plot displaying dichotomous data). An RR is the ratio of the treatment event rate to the control event rate. An RR of 1 indicates no difference between treatment and control. In Figure 2, the overall RR of 0.73 indicates that the event rate (in this case, rate of non-remission) associated with intervention A is about three-quarters of that of the control intervention or, in other words, the reduction in the relative risk is 27%.

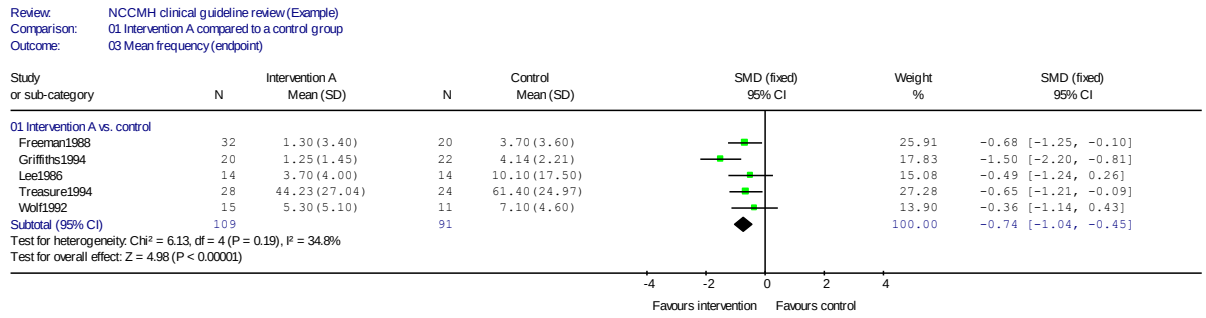
The CI shows a range of values within which it is possible to be 95% confident that the true effect will lie. If the effect size has a CI that does not cross the 'line of no effect', then the effect is commonly interpreted as being statistically significant.

Figure 2: Example of a forest plot displaying dichotomous data



Continuous outcomes were analysed using the mean difference or standardised mean difference when different measures were used in different studies to estimate the same underlying effect (see Figure 3 for an example of a forest plot displaying continuous data). If reported by study authors, intention to treat data, using a valid method for imputation of missing data, were preferred over data only from people who completed the study.

Figure 3: Example of a forest plot displaying continuous data



Where study effects were pooled using the standardised mean difference, the results were back transformed to natural units of the most commonly used outcome scale to facilitate interpretation. The method of doing this depended on availability of data and is reported, where used, in the relevant evidence chapter.

Heterogeneity

To check for consistency of effects among studies, both the I^2 statistic and the chi-squared test of heterogeneity, as well as a visual inspection of the forest plots were used. The I^2 statistic describes the proportion of total variation in study estimates that is due to heterogeneity (Higgins & Thompson, 2002). For meta-analyses of comparative effectiveness studies, the I^2 statistic was interpreted in the following way based on guidelines from the Cochrane Collaboration (Higgins & Green, 2011):

- 0% to 40%: might not be important
- 30% to 60%: may represent moderate heterogeneity
- 50% to 90%: may represent substantial heterogeneity

- 75% to 100%: considerable heterogeneity.

The Cochrane Collaboration advice suggests that overlapping categories are less misleading than simple thresholds since the importance of inconsistency depends on (1) the magnitude and direction of effects, and (2) the strength of evidence for heterogeneity (for example, *p* value from the chi-squared test, or a CI for I^2).

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APPENDIX 7: RESEARCH RECOMMENDATIONS

1. Medication for promoting de-escalation

Which medication is effective in promoting de-escalation in people who are identified as likely to demonstrate significant violence?

Why this is important

Although there are studies that demonstrate the value of medication in the management of violence and aggression, there is little information on management before violence becomes overt. Often p.r.n. medication is given at this point but there is little evidence of efficacy. It is clearly preferable to avoid violence whenever possible.

This question should be addressed by a randomised controlled trial in which people at risk of becoming violent are randomised, with their consent, to 1 or more of the medications commonly used to effect rapid tranquillisation or other medication not normally used for this purpose. Outcomes should include measures of violence, degree of sedation, acceptability of the medication and adverse effects, all recorded over a suitable timescale to match the pharmacokinetic properties of the drugs.

2. Violence related to drug or alcohol misuse

What is the best environment in which to contain violence in people who have misused drugs or alcohol?

Why this is important

There are major problems in managing drug- and alcohol-related violence. The risk of severe violence can last for many hours in people who have misused drugs and alcohol and most settings in which violence takes place (such as emergency departments) do not have the facilities needed to contain people for several hours with an adequate level of supervision. As a consequence many people are taken, often inappropriately, to police cells. It is likely that there are less expensive and more effective environments available for this purpose.

Data about the size of this problem and an epidemiological survey of its frequency and duration, as well as current methods of managing drug and alcohol-related violence, are needed to start answering this question.

3. Advance statements and decisions

What forms of management of violence and aggression do service users prefer and do advance statements and decisions have an important role in management and prevention?

Why this is important

There are widely differing opinions among service users about the best way of managing violence and decisions are often made according to personal preference. Advance statements and decisions are not widely used although they might have an important role in management and prevention.

The question could be answered by randomising people who are at risk of becoming violent, or who have demonstrated repeated violence into 2 groups: a control group with no advance statements and decisions, and a group who make advance statements and decisions indicating the forms of management they prefer and those they do not want. The subsequent frequency of violent episodes and their outcomes could then be compared.

4. Content and nature of effective de-escalation

What is the content and nature of effective de-escalatory actions, interactions and activities used by mental health nurses, including the most effective and efficient means of training nurses to use them in a timely and appropriate way?

Why this is important

Although it is regularly recommended, there has been little research on the nature and efficacy of verbal and non-verbal de-escalation for adults with mental health problems who become agitated. Research is needed to systematically describe current techniques for de-escalation and develop and test these techniques with adults who have cognitive impairment or psychosis. In addition, research should be carried out to develop methods of training staff and test the outcomes of these methods.

There is a similar lack of research on the nature and efficacy of the verbal and non-verbal de-escalation of seriously agitated children and young people with mental health problems. These techniques need to take account of and be adapted to the specific background, developmental/cognitive and psychiatric characteristics of this age group. Additional research should therefore be commissioned on the lines recommended for adults. The research should systematically describe expert practice in adults, develop and test of those techniques in aroused children and young people with mental health problems, and develop and test different methods of training staff working with children and young people with mental health problems.

5. Long duration or very frequent manual restraint

In what circumstances and how often are long duration or repeated manual restraint used, and what alternatives are there which are safer and more effective?

Why this is important

Adults who are agitated and violent sometimes continue to struggle and fight during manual restraint and rapid tranquillisation may fail. This results in long periods of restraint and further doses of medication. These occurrences are used as

justifications for seclusion and, very rarely, for the use of mechanical restraint if repeat episodes occur. Yet there is no information about the frequency of such events or the demography and symptomatology of the adults who are subject to such measures. Exploratory survey work should be commissioned as a matter of urgency to assess the scope of this problem and potential measures for prevention or alternative management that minimise excessive, severe and risky containment methods.

The reasons why children and young people with mental health problems need long duration or very frequent manual restraint may be expected to vary from those in adults but have similarly been little investigated. Exploratory survey work should therefore specifically address the scope of this problem as it affects children and young people and assess potential measures for prevention or alternative management that minimise any existing excessive, severe or risky containment methods.

APPENDIX 8: MEDICATION INCLUDED IN THE REVIEW OF RAPID TRANQUILLISATION

The following information was provided to the GDG during development of the guideline, and is included here for reference purposes only (for most recent licensing information, see the current Summary of Product Characteristics [SPC])[4]

Medication that is recommended in the guideline

Medication	Time to maximum plasma concentra-tion	Approx. plasma half-life	Relevant licensed indications as at January 2014	Common adverse effects/ Notes
Benzodiazepine drugs				
Lorazepam injection	60-90 minutes	12-16 hours	Treatment of acute anxiety states, acute excitement or acute mania.	• Confusion, depression, unmasking of depression • Sedation, drowsiness, ataxia, dizziness • Fatigue, muscle weakness, asthenia. Note. Nervous system adverse effects are dose dependent. Paradoxical reactions may be more likely to occur in children and the elderly. Not recommended in children under 12.
Antipsychotics plus antihistamines				
Haloperidol injection	15–60 minutes	10–36 hours	Adults: Mental or behavioural problems such as aggression, hyperactivity and self-mutilation in the mentally retarded and in patients with organic brain damage. As an adjunct to short term management of moderate to severe psychomotor agitation, excitement, violent or dangerously impulsive behaviour.	• Agitation, insomnia, depression, psychotic disorder • Extrapyramidal disorder, hyperkinesia, headache, tardive dyskinesia, oculogyric crisis, dystonia, dyskinesia, akathisia, bradykinesia, hypokinesia, hypertonia, somnolence, masked facies, tremor, dizziness • Visual disturbance • Orthostatic hypotension, hypotension • Constipation, dry mouth, salivary hypersecretion, nausea, vomiting • Liver function test abnormal • Rash • Urinary retention • Erectile dysfunction • Injection site reaction

[4] http://www.medicines.org.uk/emc/

			Not recommended for parenteral use in children.	
Promethazine injection	2-3 hours	12 hours	Sedation and treatment of insomnia in adults. As a paediatric sedation.	Side effects may be seen in a few patients: drowsiness, dizziness, restlessness, headaches, nightmares, tiredness, and disorientation. Note. Intravenous injection should be performed with extreme care.

Medication included in the review, but not specifically recommended

Medication	Time to maximum plasma concentration	Approx. plasma half-life	Relevant licensed indications as at January 2014	Notes
Antipsychotic drugs				
Aripiprazole injection	1-3 hours	75 hours	• Schizophrenia: rapid control of agitation and disturbed behaviours. • Bipolar I Disorder: treatment of manic episodes when oral therapy is not appropriate.	Should be discontinued as soon as clinically appropriate and the use of oral aripiprazole initiated.
Chlorpromazine injection	6-24 hours	8-35 hours	• Anxiety, psychomotor agitation, excitement, violent or dangerously impulsive behaviour.	Administered by deep intramuscular injection. Parenteral formulation may be used in emergencies.
Droperidol injection	30 minutes	2-4 hours	• Prevention and treatment of postoperative nausea and vomiting.	
Loxapine, inhaled (ADASUVE inhalation powder)	2 minutes	6.8 hours	• Adasuve is indicated for the rapid control of mild-to-moderate agitation in adult patients with schizophrenia or bipolar disorder. Patients should receive regular treatment immediately after control of acute agitation symptoms.	The European Commission granted a marketing authorisation valid throughout the European Union for Adasuve on 20 February 2013[1].
Loxapine injection	1.5-3 hours	19 hours	• Not licensed in the EU	
Olanzapine injection (Zyprexa powder	15-45 minutes	21-54 hours	• Rapid control of agitation and disturbed behaviours in patients with	Intended for short-term use only (maximum 3 days).

for solution)			schizophrenia and manic episode, when oral therapy is not appropriate.	Not recommended for use in children.
Perphenazine injection	1-3 hours	9-12 hours	• Short term management of anxiety, severe psychomotor agitation, excitement, violent or dangerously impulsive behaviour, schizophrenia, treatment of symptoms and prevention of relapse, other psychoses especially paranoid, mania and hypomania, nausea and vomiting.	Not recommended in children under the age of 14 years.
Thiothixene hydrochloride injection	1-3 hours	35-34 hours	• Not licensed in the EU	
Ziprasidone mesylate injection	60 minutes	7 hours	• Not licensed in the EU	
Zuclopenthixol acetate injection	48-72 hours	19 days	• Not licensed in the EU	
Benzodiazepine drugs				
Clonazepam injection	1-4 hours	30-40 hours	• Epilepsy • Myoclonus • Status epilepticus	
Flunitrazepam injection	15-20 minutes	16-35 hours	• Short-term management of insomnia • Premedication in surgery (www.mims.com)	
Midazolam injection	30-60 minutes	1.8-6.4 hours	• Conscious sedation • Anaesthesia • Sedation in intensive care units.	Should be administered by persons specifically trained in the recognition and management of expected adverse events including respiratory and cardiac resuscitation.
[1]http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002400/human_med_001618.jsp&mid=WC0b01ac058001d124				