APPENDIX 9: CLINICAL EVIDENCE – REVIEW PROTOCOLS

Note. In April 2014, the protocol regarding smoking was removed because this review question was no longer being addressed in this guideline.

Abbreviations

CCTV	closed-circuit television
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IQ	intelligence quotient
IT	information technology
n	number of participants
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
p.r.n.	pro re nata, as required
PICU	psychiatric intensive care units
RCT	randomised controlled trial
RQ	review question
SD	standard deviation
SE	standard error

TOPIC: EXPERIENCE OF THE MANAGEMENT OF VIOLENCE AND AGGRESSION

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	Not registered
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 6
3.	Objective of review	To review issues related to ethnicity/gender/physical disabilities and the experience of the short-term management of mental health service users with violent and aggressive behaviour in health and community care settings (including the experience of the staff involved).
	Review title and timescale	
4.	Review title [1]	Issues related to ethnicity/gender/physical disabilities and the experience of the short-term management of mental health service users with violent and aggressive behaviour in health and community care settings (including the experience of the staff involved).
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	**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 staff 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?
8.	Sub-question(s)	
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression: • The terms 'violence' and 'aggression' in this guideline 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.
11.	Participants/ population [19] **[Perspective]**	Mental health service users, carers, staff and witnesses (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
12.	Intervention(s), exposure(s) [20] **[Phenomenon of interest]**	Not applicable
13.	Comparator(s)/ control [21] **[Comparison]**	Not applicable
14.	Types of study to be included initially [22]	Systematic reviews and qualitative research
15.	Context [23] **[Setting]**	Health and community care settings.
16.	Primary outcome/ evaluation [24] **[Evaluation]**	• Experience of care • Satisfaction • Views about interventions.
17.	Secondary/ important, but not critical outcomes [25]	• Not applicable

18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. **Data to be extracted:** Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment [number of groups, randomisation, n cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias [sequence generation, allocation concealment, blinding, missing outcome data, selective outcome reporting]) Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration) Outcomes (outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, mean, SD, n, events]).
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
20.	Strategy for data synthesis [28]	A narrative synthesis or qualitative methods will be used. If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will update the review as necessary.
21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services • Assertive community teams • Community mental health teams • Primary care • Social care.

		The review will examine evidence from studies of adults and children/ young people separately.
	General information	
22.	Type of review [30]	Not applicable
23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website. The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	Although this review updates the original NICE guideline on Violence (CG25), the original review was conducted by different authors.
25.	Review status [38]	Complete

TOPIC: RISK FACTORS AND PREDICTION

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	Not registered
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 4
3.	Objective of review	To review the evidence relating to risk factors and prediction (including involuntary admission) of violent and aggressive behaviour by mental health service users in health and community care settings.
	Review title and timescale	
4.	Review title [1]	Risk factors and prediction of violent and aggressive behaviour by mental health service users in health and community care settings.
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	**Pre-event:** 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? 2.2 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? 2.4 What is the best the approach for anticipating violent and aggressive behaviour by mental health service users in health and community care settings?
8.	Sub-question(s)	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? 2.3.1 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? 2.12 Does being subjected 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?
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression: • The terms 'violence' and 'aggression' in this guideline 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.

11.	Participants/ population [19]	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
12.	Intervention(s), exposure(s) [20]	• **Risk factors and antecedents for violent and aggressive behaviour:** – Risk factor = a variable associated with an increased risk of disease/disorder – Antecedent = anything that precedes another thing, especially the cause of the second thing. • **Instruments for predicting violent and aggressive behaviour:** for example, Staff Observation Aggression Scale, Routine Assessment of Patient Progress, Nurse's Observation Scale for Inpatient Evaluation, Modified Overt Aggression Scale, Brøset violence checklist, Aggression Risk Profile. • **Approach for anticipating violent and aggressive behaviour:** Risk assessment approach or prediction instrument. • **Mental Health Act:** Compulsory or involuntary admission to hospital.
13.	Comparator(s)/ control [21]	• **Instruments for predicting violent and aggressive behaviour:** • Diagnostic accuracy studies: Instruments compared with a reference standard of violent or aggressive behaviour during follow-up. Comparative studies, where another instrument is also compared with the reference standard, will also be included • RCTs: instruments compared with no instrument use or another instrument • **Approach for anticipating violent and aggressive behaviour:** Alternative management strategy
14.	Types of study to be included initially [22]	• **Risk factors and antecedents**: Prospective observational studies (including prognostic course studies, prognostic factor [explanatory] studies, outcome prediction [risk group] studies) • **Factors reported by service users and staff:** Qualitative studies and surveys • **Instruments:** Diagnostic accuracy studies or • **Approach for anticipating violent and aggressive behaviour:** RCTs
15.	Context [23]	Health and community care settings.
16.	Primary/Critical outcomes [24]	• **Risk factors and antecedents**: • Risk of violence (odds ratio for risk of violence/ aggression) • Association between risk factor and violence/ aggression (R2 or Beta value) • **Factors reported by service users and staff:** Experience of service users and staff

		• **Instruments:** Clinical utility (including sensitivity and specificity) (accuracy studies) • **Approach for anticipating violent and aggressive behaviour:** Rates of violence and aggression
17.	Secondary/ important, but not critical outcomes [25]	• Not applicable
18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. Data to be extracted (as appropriate for each RQ): Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment [number of groups, randomisation, n cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias) Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration) Outcomes (outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, hazard ratio and SE]) Prognostic factors and potential confounders (applies to a prognostic factor study, or an outcome prediction study) (n, n with factor, n with outcome. Where not available, odds ratio or risk ratio) Diagnostic accuracy outcomes (where available: true positives, true negatives, false positives, false negatives. Otherwise: sensitivity and specificity or area under the curve) Factors reported by service users and staff.
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.

20.	Strategy for data synthesis [28]	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will update the review as necessary.
21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services • Assertive community teams • Community mental health teams • Primary care • Social care. The review will examine evidence from studies of adults and children/young people separately. 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.
	General information	
22.	Type of review [30]	• **Risk factors and antecedents**: Prognostic • **Factors reported by service users and staff:** Qualitative • **Instruments:** Diagnostic • **Approach for anticipating violent and aggressive behaviour:** Intervention
23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website. The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	Although this review updates the original NICE guideline on Violence (CG25), the original review was conducted by different authors.
25.	Review status [38]	Complete

TOPIC: PREVENTION STRATEGIES (PRE-EVENT)

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	Not registered
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 5
3.	Objective of review	To review the evidence for the use of interventions to prevent violent and aggressive behaviour by mental health service users in health and community care settings, and training programmes for staff.
	Review title and timescale	
4.	Review title [1]	Interventions and training programmes for the prevention of violent and aggressive behaviour by mental health service users in health and community care settings.
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	**Pre-event:** 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? 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? **Immediately pre-event:** 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?
8.	Sub-question(s)	-
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression: • The terms 'violence' and 'aggression' in this guideline 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.
11.	Participants/ population [19]	Mental health service users
12.	Intervention(s), exposure(s) [20]	• **Observation techniques**: known by 'various terms such as special/close/maximum/continuous/constant observation/attention/ supervision; suicide watch or precaution, 15-minute checks, behavioural checklists, "specialling" and one-to-one nursing.' UK practice guidelines) suggest three levels of special observation: 'intermittent, where the patient's location must be checked at specified intervals; within eyesight, where the patient should be kept within sight at all times; and within arm's length, where patients must be observed in close proximity at all times.'(Stewart 2010) • **Changes to the physical and social environment**: The physical and therapeutic external conditions or surroundings. Examples of modifications include locked wards, how pleasant the environment is, use of art, en suite, architecture, ward atmosphere, change in setting (such as, moving people). • **Management strategies:** including staffing levels, IT systems, searching of service users and visitors in psychiatric inpatient settings

		• **Personal and institutional alarms, CCTV and communication devices:** Personal alarms include the simple 'shriek' type or may form part of more complex systems that are linked to fixed detection systems by infra-red or radio systems. Institutional alarms and CCTV include panic buttons and surveillance cameras that are hardwired systems strategically placed in high risk areas. • **De-escalation methods**: 1. Verbal communication techniques; 2. Use of body language; 3. Prevention and recognition strategies (risk assessment tools); 4. Staff attitudes, knowledge and skills; 5. Setting of limits for patients to follow; 6. Environmental controls (for example minimising light, noise and conversations) used for the management of aggression; 7. Time-out; 8. Extra-care area. • **p.r.n (pro re nata) medication:** 1. Any regimen of medication administered for the short-term relief of behavioural disturbance, or psychotic symptoms, to be given at the discretion of ward staff ('as required', 'p.r.n.'). Any drug, dose, route or interval of administration was considered, including studies using rapid tranquillisation techniques; 2. Fixed non-discretionary patterns of drug administration of the same drug for the short-term relief of behavioural disturbance, or psychotic symptoms. These interventions could be given alone, or in addition to any medication prescribed for the long-term treatment of schizophrenia or schizophrenia-like illnesses. Chakrabarti 2012b. • **Staff training programmes**
13.	Comparator(s)/ control [21]	• Usual care • Another management strategy
14.	Types of study to be included initially [22]	Systematic reviews and RCTs
15.	Context [23]	• Health and community care settings (RQ2.5 & 3.2: Inpatient settings only).
16.	Primary/Critical outcomes [24]	**Observation techniques**: • The effectiveness of observation techniques at decreasing the number of violent episodes or potentially violent episodes, without the use of other interventions. • Service user/carer/staff views **Modifications to the physical and service environment** • Any reported measures of the safety and effectiveness of seclusion for the short-term management of aggressive/violent behaviour • Service user/carer/staff views **Management strategies:**

		• Any reported measures of the safety and effectiveness of management strategies for the short-term management of aggressive/violent behaviour • Service user/carer/staff views **Personal and institutional alarms, CCTV and communication devices:** • Any reported measures of change to the occurrences of aggressive/violent behaviour or, how incidences are managed, as a result of alarms and devices • Service user/carer/staff views **Seclusion:** • Any reported measures of the safety and effectiveness of seclusion for the short-term management of aggressive/violent behaviour • Service user/carer/staff views **De-escalation methods:** • Any reported measures of the safety and effectiveness of de-escalation techniques for the short-term management of aggressive/violent behaviour • Service user/carer/staff views **p.r.n. (pro re nata) medication:** • Any reported measures of the safety and effectiveness of p.r.n. medication for the short-term management of aggressive/violent behaviour • Service user/carer/staff views
17.	Secondary/ important, but not critical outcomes [25]	• Not applicable
18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. **Data to be extracted:** Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment [number of groups, randomisation, n

		cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias [sequence generation, allocation concealment, blinding, missing outcome data, selective outcome reporting]). Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration). Outcomes (outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, mean, SD, n, events]).
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
20.	Strategy for data synthesis [28]	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations.
21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services • Assertive community teams • Community mental health teams • Primary care • Social care. The review will examine evidence from studies of adults and children/young people separately. 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.
	General information	
22.	Type of review [30]	Prevention

23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website. The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	Although this review updates the original NICE guideline on Violence (CG25), the original review was conducted by different authors.
25.	Review status [38]	Complete

TOPIC: SUBSTANCE MISUSE

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	Not registered
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 5
3.	Objective of review	To review the evidence for the recognition and management of substance misuse in mental health service users with violent and aggressive behaviour in health and community care settings.
	Review title and timescale	
4.	Review title [1]	Recognition and management of substance misuse in mental health service users with violent and aggressive behaviour in health and community care settings.
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	**Pre-event:** 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?
8.	Sub-question(s)	
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression: • The terms 'violence' and 'aggression' in this guideline 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.
11.	Participants/ population [19]	Mental health service users
12.	Intervention(s), exposure(s) [20]	• Identification of substance misuse (including both drugs and alcohol) • Management of substance misuse (including both drugs and alcohol).
13.	Comparator(s)/ control [21]	• Usual care • Another intervention.
14.	Types of study to be included initially [22]	Systematic reviews, RCTs, and observational studies
15.	Context [23]	• Health and community care settings.
16.	Primary/Critical outcomes [24]	• Clinical utility (including test accuracy) • To be confirmed.
17.	Secondary/ important, but not critical outcomes [25]	• Not applicable

18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. **Data to be extracted:** Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment [number of groups, randomisation, n cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias [sequence generation, allocation concealment, blinding, missing outcome data, selective outcome reporting]). Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration). Outcomes (outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, mean, SD, n, events]).
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
20.	Strategy for data synthesis [28]	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations.

21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services • Assertive community teams • Community mental health teams • Primary care • Social care. The review will examine evidence from studies of adults and children/young people separately. 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.
	General information	
22.	Type of review [30]	• Diagnostic • Treatment.
23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website. The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	None
25.	Review status [38]	Complete

TOPIC: ADVANCE TREATMENT DIRECTIVES

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	Not registered
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 5
3.	Objective of review	To review the evidence for the role of advance treatment directives in the management of violent and aggressive behaviour by mental health service users in health and community care settings.
	Review title and timescale	
4.	Review title [1]	The role of advance treatment directives in the management of violent and aggressive behaviour by mental health service users in health and community care settings.
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	**Pre-event:** 2.9 What role should advance treatment directives play in the prevention of violence and aggression by mental health service users in health and community care settings? **Immediately pre-event:** 3.1 What role should advance treatment directives play in the management of imminent violence and aggression by mental health service users in health and community care settings?
8.	Sub-question(s)	
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression: • The terms 'violence' and 'aggression' in this guideline 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.
11.	Participants/ population [19]	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
12.	Intervention(s), exposure(s) [20]	• Advance treatment directives: 'Instructional mental health advance directives communicate instructions for treatment providers in the event of a mental health crisis, should the patient become incompetent and unable to do so themselves. They may contain decisions regarding hospitalisation, methods for handling emergencies (such as use of restraint, seclusion, or sedation), medication (including types of medications to be used, dosages, methods and timing of

		administration), treatment approaches (such as electroconvulsive therapy or psychotherapy), persons to be notified in the event of hospitalisation, persons responsible for childcare, personal, and financial matters, and medical care issues… …Proxy directives are health care power of attorney documents, which allow the patient to designate someone else to make decisions on his or her behalf should the patient become incompetent.' (Campbell 2012). Also known as: • Advance statements of wishes and feelings • Advance directive • Joint crisis planning • Advance crisis planning • Anticipatory psychiatric planning • Ulysses directive
13.	Comparator(s)/ control [21]	Usual care or other alternative management strategies
14.	Types of study to be included initially [22]	Systematic reviews, RCTs, and observational studies
15.	Context [23]	• Health and community care settings.
16.	Primary/Critical outcomes [24]	• Any reported
17.	Secondary/ important, but not critical outcomes [25]	• Not applicable
18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. **Data to be extracted:** Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment [number of groups, randomisation, n cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias [sequence generation, allocation concealment, blinding, missing outcome data, selective outcome reporting]). Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration).

		Outcomes (Outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, mean, SD, n, events]).
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
20.	Strategy for data synthesis [28]	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will update the review as necessary.
21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services • Assertive community teams • Community mental health teams • Primary care • Social care. The review will examine evidence from studies of adults and children/young people separately. 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.
	General information	
22.	Type of review [30]	• Intervention.
23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website. The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	Although this review updates the original NICE guideline on Violence (CG25), the original review was conducted by different authors.
25.	Review status [38]	Complete

TOPIC: NON-PHARMACOLOGICAL MANAGEMENT STRATEGIES (DURING EVENT)

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	CRD42013006450
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 6
3.	Objective of review	To review the evidence for non-pharmacological management strategies for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings.
	Review title and timescale	
4.	Review title [1]	Non-pharmacological management strategies for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings.
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	**During event:** 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? 4.9 What factors should influence the decision to transfer a mental health service user with violent and aggressive behaviour to a more secure environment?

8.	Sub-question(s)	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.
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression: • The terms 'violence' and 'aggression' in this guideline 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.
11.	Participants/ population [19]	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
12.	Intervention(s), exposure(s) [20]	• **Modifications to the physical and service environment**: The physical and therapeutic external conditions or surroundings. Examples of modifications include locked wards, how pleasant the environment is, use of art, en suite, architecture, ward atmosphere, change in setting (such as, moving people). • **Personal and institutional alarms, CCTV and communication devices for staff:** Personal alarms include the simple 'shriek' type or may form part of more complex systems that are linked to fixed detection systems by infra-red or radio systems. Institutional alarms and CCTV include panic buttons and surveillance cameras that are hardwired systems strategically placed in high risk areas. • **Seclusion:** Seclusion is the supervised confinement of a patient in a room, which may be locked to protect others from significant harm. Its sole aim is to contain severely disturbed behaviour, which is likely to cause harm to others. Seclusion should be

		used as a last resort; for the shortest possible time. Seclusion should not be used as a punishment or threat; as part of a treatment programme; because of shortage of staff; where there is ~~any~~ risk of suicide or self-harm. Seclusion of an informal patient should be taken as an indicator of the need to consider formal detention. – Seclusion must be differentiated from asking a service user to go to a designated room for the purpose of calming down. The latter is a de-escalation technique and the seclusion room should not routinely be used for this purpose ([CG25, based on the Mental Health Act 1983 Code of Practice). • **De-escalation methods:** 1. Verbal communication techniques; 2. Use of body language; 3. Prevention and recognition strategies (risk assessment tools); 4. Staff attitudes, knowledge and skills; 5. Setting of limits for patients to follow; 6. Environmental controls (for example minimising light, noise and conversations) used for the management of aggression; 7. Time-out; 8. Extra-care area. • **Physical restraint techniques:** 1. Manual restraint (physically holding the patient to prevent or restrict movement), 2. Mechanical restraint (which includes devices designed for the purpose of restricting the patient's ability to move). – Definition: skilled hands-on techniques involving restraint by trained designated staff to prevent individuals from harming themselves, endangering others or seriously compromising the therapeutic environment. Its purpose is to safely immobilise the individual concerned. – Mental Health Act 1983 Code of Practice states that pphysical restraint should be a last resort, only being used in an emergency where there appears to be a real possibility of significant harm if withheld. It must be of the minimum degree necessary to prevent harm and be reasonable in the circumstances. [18.10-18.11]
13.	Comparator(s)/ control [21]	• Usual care • Another intervention.
14.	Types of study to be included initially [22]	Systematic reviews and RCTs (if none, observational studies will be searched for)
15.	Context [23]	Short-term (72 hours) management in health and community care settings.
16.	Primary/Critical outcomes [24]	**Modifications to the physical and service environment**

		• Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views **Personal and institutional alarms, CCTV and communication devices for staff:** • Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views **Seclusion:** • Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views **De-escalation methods:** • Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views **Physical restraint techniques:** • Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views
17.	Secondary/ important, but not critical outcomes [25]	• Not applicable
18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. **Data to be extracted:** Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment

		[number of groups, randomisation, n cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias [sequence generation, allocation concealment, blinding, missing outcome data, selective outcome reporting]). Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration). Outcomes (outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, mean, SD, n, events]).
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
20.	Strategy for data synthesis [28]	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will update the review as necessary.
21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services • Assertive community teams • Community mental health teams • Primary care • Social care. The review will examine evidence from studies of adults and children/young people separately. 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.
	General information	
22.	Type of review [30]	Intervention
23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website.

		The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	Although this review updates the original NICE guideline on Violence (CG25), the original review was conducted by different authors.
25.	Review status [38]	Complete

TOPIC: PHARMACOLOGICAL MANAGEMENT STRATEGIES (DURING EVENT)

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	Not registered
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 6
3.	Objective of review	To review the evidence for brief or fast acting pharmacological interventions for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings.
	Review title and timescale	
4.	Review title [1]	Brief or fast acting pharmacological interventions for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings.
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	**During event:** 4.7 Does rapid tranquillisation 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?
8.	Sub-question(s)	4.8 If rapid tranquillisation is 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.
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression • The terms 'violence' and 'aggression' in this guideline 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.

		The Cochrane reviews covering RT include psychosis-induced agitation (agitation is characterised by restlessness, excitability and irritability, and for some people, this can result in verbal and physical aggressive behaviour)[1]
11.	Participants/ population [19]	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
12.	Intervention(s), exposure(s) [20]	• **Rapid tranquillisation** or urgent sedation (the use of medication to calm/lightly sedate the service user, reduce the risk to self and/or others and achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place, and allowing comprehension and response to spoken messages throughout the intervention. Although not the overt intention, it is recognised that in attempting to calm/lightly sedate the service user, rapid tranquillisation may lead to deep sedation/anaesthesia). – **Antipsychotic drugs** (aripiprazole, chlorpromazine, haloperidol, loxapine, olanzapine, quetiapine, risperidone) – **Benzodiazepines** – **Antihistamines**
13.	Comparator(s)/ control [21]	• Another intervention • Placebo.
14.	Types of study to be included initially [22]	Systematic reviews and RCTs (if none, observational studies will be searched for)
15.	Context [23]	Short-term (72 hours) management in health and community care settings.
16.	Primary/Critical outcomes [24]	• **Rapid tranquillisation:** – Rates of violence and aggression [lower = good] – Tranquillisation (feeling of calmness and/or calm, non-sedated behaviour) [higher = good] – Sedation/somnolence [lower = good] – Adverse effects [lower = good] – Service user/carer/staff views – Economic outcomes Adapted from the original guideline.
17.	Secondary/ important, but not critical outcomes [25]	– Perception of staff – Agitated behaviour (any scale) – Duration of intervention use – Total sedative medication dose used – Length of hospital stay
18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be

[1] Mohr P, Pecenak J, Svestka J, Swingler D, Treuer T. Treatment of acute agitation in psychotic disorders. Neuro Endocrinology Letters 2005;26(4):327–35. [PUBMED: 16136016]

		screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. **Data to be extracted:** Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment [number of groups, randomisation, n cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias [sequence generation, allocation concealment, blinding, missing outcome data, selective outcome reporting]). Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration). Outcomes (outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, mean, SD, n, events]).
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
20.	Strategy for data synthesis [28]	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will update the review as necessary.
21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services

		• Assertive community teams • Community mental health teams • Primary care • Social care. The review will examine evidence from studies of adults and children/young people separately. 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.
	General information	
22.	Type of review [30]	Intervention
23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website. The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	Although this review updates the original NICE guideline on Violence (CG25), the original review was conducted by different authors.
25.	Review status [38]	Complete

TOPIC: MANAGEMENT STRATEGIES INVOLVING THE POLICE (DURING AN EVENT)

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	Not registered
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 6
3.	Objective of review	To review the interface between mental health services and the police during the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings.
	Review title and timescale	
4.	Review title [1]	The interface between mental health services and the police during the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings.
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	**During event:** 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?
8.	Sub-question(s)	
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression: • The terms 'violence' and 'aggression' in this guideline 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.
11.	Participants/ population [19]	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
12.	Intervention(s), exposure(s) [20]	• Management strategies when the police are involved.

13.	Comparator(s)/ control [21]	• Usual care • Another intervention.
14.	Types of study to be included initially [22]	Systematic reviews, RCTs and observational studies.
15.	Context [23]	Short-term (72 hours) management in health and community care settings.
16.	Primary/Critical outcomes [24]	• Any reported outcomes, including: • Service user/carer/staff views
17.	Secondary/ important, but not critical outcomes [25]	• Not applicable
18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. **Data to be extracted:** Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment [number of groups, randomisation, n cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias [sequence generation, allocation concealment, blinding, missing outcome data, selective outcome reporting]). Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration). Outcomes (outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, mean, SD, n, events]).
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
20.	Strategy for data synthesis [28]	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used.

		If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations.
21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services • Assertive community teams • Community mental health teams • Primary care • Social care. The review will examine evidence from studies of adults and children/young people separately. 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.
	General information	
22.	Type of review [30]	Treatment
23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website. The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	Although this review updates the original NICE guideline on Violence (CG25), the original review was conducted by different authors.
25.	Review status [38]	Complete

TOPIC: POST-INCIDENT MANAGEMENT

Item no.	Item [PROSPERO field no.]	Details
	PROSPERO: Reg. no.	Not registered
	Guideline details	
1.	Guideline	Violence and aggression
2.	Guideline chapter	Chapter 6
3.	Objective of review	To review post-incident management strategies after violent and aggressive behaviour by mental health service users in health and community care settings.
	Review title and timescale	
4.	Review title [1]	Post-incident management strategies after violent and aggressive behaviour by mental health service users in health and community care settings.
5.	Anticipated or actual start date [3]	01/02/2013
6.	Anticipated completion date [4]	
	Review methods	
7.	Review question(s) [15]	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?
8.	Sub-question(s)	
9.	Searches [16]	See Appendix 6
10.	Condition or domain being studied [18]	Violence and aggression: • The terms 'violence' and 'aggression' in this guideline 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.
11.	Participants/ population [19]	Mental health service users, staff and witnesses (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
12.	Intervention(s), exposure(s) [20]	• Post-incident management strategies – also described as post-incident review or debriefing; managing the aftermath effects of patient's aggression and violence.
13.	Comparator(s)/ control [21]	• Usual care • Another management strategy.

14.	Types of study to be included initially [22]	Systematic reviews, RCTs and observational studies.
15.	Context [23]	Short-term (72 hours) management in health and community care settings.
16.	Primary/Critical outcomes [24]	• Any reported outcomes, including: – Service user/carer/staff views – Experience of other service users when witnessing a violent and/or aggressive event
17.	Secondary/ important, but not critical outcomes [25]	• Not applicable
18.	Data extraction (selection and coding) [26]	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. **Data to be extracted:** Study characteristics (study ID, year, intervention/comparison, context or setting, recruitment [recruitment location, approached n, completed screening n, randomised n, exclusion rate, screening format, screening admin, diagnostic system, diagnostic method], run in/ washout, inclusion/exclusion criteria, group assignment [number of groups, randomisation, n cluster], demographics [age, sex, race, IQ, and so on], funding, publication type, references, risk of bias [sequence generation, allocation concealment, blinding, missing outcome data, selective outcome reporting]). Comparisons (n, n post-treatment, n follow up, intervention, target group, dose type, dose, frequency, duration). Outcomes (outcome type, outcome name, data type, rater, weeks post-randomisation, time point – phase, outcome data [for example, mean, SD, n, events]).
19.	Risk of bias (quality) assessment [27]	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
20.	Strategy for data synthesis [28]	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used.

		If existing reviews are found, the review team with advice from the GDG will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will update the review as necessary.
21.	Analysis of subgroups or subsets [29]	The review will address how care may need to be modified in specific settings, including: • Inpatient settings (including forensic psychiatry inpatient units, psychiatric intensive care units [PICUs], acute general psychiatric hospitals and NHS general hospitals) • Emergency and urgent care services • Assertive community teams • Community mental health teams • Primary care • Social care. The review will examine evidence from studies of adults and children/young people separately. 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.
	General information	
22.	Type of review [30]	Intervention
23.	Dissemination plans [35]	This review is being conducted for the NICE guideline on violence and aggression (update). Further information about the guideline and plans for implementation can be found on the NICE website. The review findings will be included in the full guideline developed by the National Collaborating Centre for Mental Health.
24.	Details of any existing review of the same topic by the same authors [37]	Although this review updates the original NICE guideline on Violence (CG25), the original review was conducted by different authors.
25.	Review status [38]	Complete