NICE National Institute for Health and Care Excellence

## Surveillance proposal consultation document

# 2019 surveillance of Violence and aggression: short-term management in mental health, health and community settings (NICE guideline NG10)

## Surveillance proposal

We will not update the guideline on Violence and aggression: short-term management in mental health, health and community settings.

However, it is proposed that the Person-Centered Care section of the guideline is refreshed to incorporate other guidelines that are relevant to recommendations in NG10. It is also proposed that the terms used in this guideline section is refreshed to clarify the use of the term "debrief". And it is proposed that recommendation 1.4 is refreshed to reference relevant legislation and other guidelines in order to ensure it reflects current equality considerations.

## Reasons for the proposal

Topic expert feedback, stakeholder input and several studies highlighted areas where there had been amendments to national policies and where new legislation had and new evidence had been published. The main areas included:

- restraint positions
- post-incident debriefs
- liberty protection safeguards
- pharmacological methods for rapid tranquilisation

Overall, the new evidence is either not directly relevant to the guideline population of service users in mental health settings or was insufficient in volume or quality to impact on the recommendations.

For further details and a summary of all evidence identified in surveillance, see the summary of evidence from surveillance.

## Overview of 2019 surveillance methods

NICE's surveillance team checked whether recommendations in Violence and aggression: short-term management in mental health, health and community settings (NICE guideline NG10) remain up to date.

The surveillance process consisted of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews and national policy.
- Examining related NICE guidance and quality standards and NIHR signals.
- A search for ongoing research.
- Examining the NICE event tracker for relevant ongoing and published events.
- Focused literature searches to identify relevant evidence.
- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the proposal with stakeholders, except if we propose to update and replace the whole guideline (this document).

For further details about the process and the possible update proposals that are available, see the chapter ensuring that published guidelines are current and accurate in Developing NICE guidelines: the manual.

# Evidence considered in surveillance

## Search and selection strategy

We found 19 studies in a search for evidence on debriefing, physical restraint and pharmacological management published between 4th August 2014 and 28th May 2019.

We also included:

- 9 relevant studies from a total of 11 identified by topic experts

From all sources, we considered 28 studies to be relevant to the guideline.

See the summary of evidence from surveillance for details of all evidence considered, and references.

### Selecting relevant studies

Studies involving debriefing were eligible if they were set in psychiatric settings.

All studies involving physical restraint were included.

Studies involving pharmacological management were eligible if they involved psychiatric patients. Studies involving pharmacological management that were not randomised controlled trails, systematic reviews or meta-analyses were not included.

## Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, 3 studies were assessed as having the potential to change recommendations. Therefore, we plan to regularly check whether these studies have published results and evaluate the impact of the results on current recommendations as quickly as possible. These studies are:

- ‘Integrated violence prevention’ – an intervention aimed at preventing violence and threats against employees in psychiatric units and the Prison and Probation Service in Denmark
- De-escalating conflict in adult inpatient mental health settings: development of evidence-based trainingIntelligence gathered during surveillance
- Reduction of coercion and aggression in psychiatry - the aggression, coercion reduction study

### Views of topic experts

We considered the views of topic experts who were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty. For this surveillance

review, topic experts completed a questionnaire about developments in evidence, policy and services related to the guideline.

We sent questionnaires to 17 topic experts and received 7 responses.

Areas raised in topic expert feedback included:

- The Human Rights Framework for Restraint has been published which considers new equalities issues around the age of service users. The guideline will be refreshed to incorporate these recommendations.
- The publication of the Use of Force Act. This Act states that a policy must be published regarding the use of force by staff who work in mental health settings and the guideline will be refreshed to incorporate legislation.
- Strengthening the guideline on pharmacological management, however areas of concern were not specified and a literature search was conducted during the surveillance process.
- The new scheme of Liberty Protection Safeguards which will replace current Deprivation of Liberty legislation. This is due to publish in 2020 and NICE will track this legislation and the content will be assessed for impact on publication.

## Other sources of information

We considered all other correspondence received since the guideline was published. Two areas were highlighted by stakeholders.

1) The guideline recommendation for supine restraint compared with the prone restraint position was queried and evidence was submitted indicating that both approaches appear safe and effective. However, the evidence provided was not conducted in mental health settings and the studies were conducted with small numbers of healthy volunteers. Due to a lack of directly relevant high-quality evidence it is proposed that there is no impact on the recommendations in the guideline at this time.

2) The use of post-incident debriefs was queried as the NICE Guideline NG116 on Post Traumatic Stress Disorder specifically recommends not using psychologically focused debriefing techniques. Therefore, it is proposed that the term debriefing after incidents of violence and aggression is clarified in the terms used in this guideline section.

## Equalities

An equality issue was identified during the surveillance process. To meet the recommendations of the Human Rights Framework for Restraint, relevant recommendations will be refreshed to ensure that the age of the service user is considered along with other factors when undertaking manual restraint.

## Editorial amendments

During surveillance of the guideline, we identified the following points in the guideline that should be amended. This included:

- Person-centred care: It is suggested that the following wording should be added to enhance NICE's recommendations around anticipating and reducing violence and aggression; to encourage improvement of communication between mental health settings and criminal justice settings and to consider those service users with coexisting substance misuse or withdrawal and mental health conditions (new text has been written in *italics*):

  NICE has also produced guidance on the components of good service user experience *and recommendations for improving services for those who have coexisting substance misuse or withdrawal and mental health conditions.* All healthcare professionals should follow the recommendations in service user experience in adult mental health *and coexisting severe mental illness and substance misuse.*

  *The Department for Health and Public Health England have produced evidence-based guidance for commissioners and service providers on safeguarding service user's rights, ensuring compliance with law and providing effective care. All healthcare professionals should follow the recommendations in the Mental Health Act*

*1983: Code of Practice and Better care for people with co-occurring mental health and alcohol/drug use conditions.'*

- Recommendation 1.1.1: It is suggested that this recommendation should link through to other guidelines that can be used in conjunction with NG10. These guidelines cover evidence-based interventions that improve and prevent violence and aggression in service users, for example care plans, care coordinators and intervention reduction programmes. The proposed amendment would read as follows (new text has been written in *italics*):

  'Use this guideline in conjunction with NICE's guidelines on service user experience in adult mental health *and coexisting severe mental illness (psychosis) and substance misuse: assessment and management in healthcare settings; and other relevant NICE guidelines regarding mental health and behavioural conditions.'*

- 1.4 Using restrictive interventions in inpatient psychiatric settings: It is recommended that the first paragraph of this section should be amended to ensure that restrictive interventions are used in accordance with the Use of Force Act 2018. The proposed amendment would read as follows (new text has been written in *italics*):

'Restrictive interventions are most likely to be used in inpatient psychiatric settings, but may be used in emergency departments, outpatient services and child and adolescent mental health services (CAMHS). *Restrictive interventions should be used in accordance with the Use of Force Act 2018.'*

- Recommendation 1.4.27: It is suggested that this wording is amended to ensure that age is considered when undertaking manual restraint in line with equalities issues as specified in the Human Rights Framework for Restraint. The proposed amendment would read as follows (new text has been written in *italics*):

  'Undertake manual restraint with extra care if the service user is physically unwell, disabled, pregnant or obese *and consider age.'*

- Recommendation 1.4.37: It is suggested that this wording is amended to ensure that age is considered when undertaking chemical restraint in line with equalities issues as specified in the Human Rights Framework for Restraint. It is also suggested that this wording is amended to ensure that rapid tranquilisation is used with extra care with women who are pregnant. The proposed amendment would read as follows (new text has been written in *italics*):

  'When deciding which medication to use, take into account: pre-existing physical health problems, *age* or pregnancy *(use in conjunction with CG192 Antenatal and postnatal mental health: clinical management and service guidance Recommendation 1.8.23).'*

- Terms used in this guideline: It is suggested that the term "debrief" should be incorporated into this list to ensure that it is fully understood and never misused within this vulnerable population. The proposed amendment would read as follows:

'*Debrief – A discussion involving the staff team and service user involved with the aim of learning from the incident and initiating planning to prevent the chance of incident repetition. This should not be considered a psychologically-focused debrief. If a psychologically-focused debrief is considered to be necessary, use in conjunction with NICE's guideline NG116 Post-traumatic stress disorder.'*

See the summary of evidence from surveillance for full details.

## Overall proposal

After considering all evidence and other intelligence and the impact on current recommendations, we decided that no update is necessary.

# Appendix A Summary of Evidence from Surveillance.

# 2019 surveillance of Violence and aggression: short-term management in mental health, health and community settings (2015) NICE guideline NG10

## Overview

Studies identified in searches are summarised from the information presented in their abstracts.

Feedback from topic experts who advised us on the approach to this surveillance review, was considered alongside the evidence to reach a view on the need to update each section of the guideline.

## Person-centred care

### Surveillance proposal

This section of the guideline describes expectations of care for service users and does not comprise specific recommendations around violence and aggression. However, information from the surveillance review suggested that this section should be refreshed, as noted below.

### Editorial amendments

It is recommended that this section should be refreshed to support and complement the recommendations in this guideline; to encourage improvement of communication between mental health settings and criminal justice settings and to consider those service users with coexisting substance misuse or withdrawal and mental health conditions. The proposed amendment would be as follows (new text has been written in *italics*):

NICE has also produced guidance on the components of good service user experience *and recommendations for improving services for those who have coexisting substance misuse or withdrawal and mental health conditions*. All healthcare professionals should follow the recommendations in service user experience in adult mental health *and coexisting severe mental illness and substance misuse*.

*The Department for Health and Public Health England have produced evidence-based guidance for commissioners and service providers on safeguarding service user's rights, ensuring compliance with law and providing effective care. All healthcare professionals should follow the*

*recommendations in the Mental Health Act 1983: Code of Practice and Better care for people with co-occurring mental health and alcohol/drug use conditions.'*

## 1.1 Principles for managing violence and aggression

### Surveillance proposal

The section of the guideline should not be updated.

### 2019 surveillance summary

No published evidence was found, however an ongoing study is looking at methods to prevent violence in psychiatric hospitals and to develop tools for mapping the violence prevention practice. This study is expected to complete in December 2019. However, the protocol indicates that the study will be evaluating interventions for long term management plans and it is unknown whether the results will provide useful interventions for short term management of violence and aggression. This study will be tracked by NICE and the results will be assessed for impact on publication.

### Intelligence gathering

One topic expert noted that in domestic homicide reviews, the person who was killed was sometimes related to or in a relationship with the perpetrator but was not formally their carer and was therefore not involved in decision making around their care. This reflects the NG10 glossary which defines "carer" as "a person who provides unpaid support to a partner, family member, friend or neighbour who is ill, struggling or disabled", however the topic expert suggested that the term carer should be more broadly expressed within the NICE guideline.

One topic expert noted that The Mental Capacity Amendment Bill has recently been published and the NICE guideline should refer to this. This document amends the Mental Capacity Act 2005 in relation to procedures in accordance with which a person may be deprived of liberty where the person lacks capacity to consent. It repeals the Deprivation of Liberty Safeguards and replaces them with the Liberty Protection Safeguards and legislation for this will publish in Spring 2020. NG10 currently recommends that "unless a service user is detained under the Mental Health Act 1983 or subject to a deprivation of liberty authorisation or order under the Mental Capacity Act 2005, health and social care provider organisations must ensure that the use of restrictive interventions does not impose restrictions that amount to a deprivation of liberty".

NICE Guideline CG120 Coexisting severe mental illness (psychosis) and substance misuse: assessment and management in healthcare settings is relevant to NG10. There are no recommendations in NG10 regarding the care of this specific population even though the scope for NG10 states that specific consideration will be given to adults, children and young people with mental health conditions who are currently service users within healthcare, including mental healthcare, social care and community settings who have coexisting substance misuse (both hazardous use and dependence) or withdrawal. CG120 aims to help

healthcare professionals guide people with psychosis with coexisting substance misuse to stabilise, reduce or stop their substance misuse, to improve treatment adherence and outcomes, and to enhance their lives. It could offer further information to be used alongside NG10 that would be beneficial to the recommendations.

Public Health England suggest in their reports on this population that if service users are receiving the right care for their needs then they have better outcomes. CG120 covers useful information such as the use of care coordinators and the Care Programme Approach, that is also mentioned in other evidence-based reports such as Public Health England's Better care for people with co-occurring mental health and alcohol/drug use conditions and the Department of Health's Mental Health Act 1983: Code of Practice (2015) and is not noted in NG10. Public Health England's Better care for people with co-occurring mental health and alcohol/drug use conditions notes that "The Care Programme Approach (CPA) is a system for co-ordinating the care of people who have been diagnosed as having a serious mental illness. Its aim is to ensure that people with serious mental illness have a full assessment of need and a named care coordinator to ensure that needs are being met via the delivery of appropriate, regularly reviewed care based on collaboration between health and social services". This document could also offer further information to be used alongside NG10 that would be beneficial to the recommendations.

One topic expert noted that the use of technologies such as CCTV could be considered within the guideline.

## Impact statement

New intelligence was identified that highlighted the lack of information in NG10 regarding service users with coexisting substance misuse or withdrawal issues, and also the lack of reference to the Care Programme Approach. Both of these areas are covered by NICE guideline CG120 Coexisting severe mental illness (psychosis) and substance misuse: assessment and management in healthcare settings. The population of service users with substance misuse issues is highlighted for special consideration within the NG10 scope. Therefore it is proposed that NG10 cross refers to CG120 and other relevant NICE guidelines on mental health and behavioural conditions to ensure that clinicians are aware of specific ways to help this population and to ensure the best care is given to service users both before and after violent or aggressive incidents.

NG10 makes recommendations for carers or advocates. One expert commented on the term carer and whether it should also encompass close family and friends in decision making. No evidence was found regarding the use of involving others who are not considered to be "carers" in this population's care. NICE guideline CG120 recommends that decisions and statements can also be shared with any person the service user considers to be important to them. It is proposed that NG10 cross refers to CG120 to ensure that, as long as the service user approves, people other than formal carers can be informed about the care of the service user.

It was noted that The Mental Capacity Amendment Bill (2019) has been published with the resulting legislation publishing in Spring 2020. Until the new regulations have been drafted this document does not have any impact on the current recommendations within the guideline and therefore it is proposed there is no update at this time. NICE will track this legislation and the content will be assessed for impact on publication.

A suggestion was made that NICE should consider the use of technologies, such as CCTV in mental health, health and community settings. During the development of NG10, no relevant evidence examining the benefits and harms associated with the use of personal institutional alarms, CCTV and communication devices (including IT systems) met eligibility criteria, therefore the Guideline Development Group chose not to make recommendations concerning their use. During this surveillance review there wasn't a strong indication to examine this further and therefore it is proposed that no impact on the guideline is expected.

### Editorial amendments

- Recommendation 1.1.1: It is suggested that this recommendation should link through to other guidelines that can be used in conjunction with NG10. These guidelines cover evidence-based interventions that improve and prevent violence and aggression in service users, for example care plans, care coordinators and intervention reduction programmes. The proposed amendment would be as follows (new text has been written in *italics*):

'Use this guideline in conjunction with NICE's guidelines on service user experience in adult mental health *and coexisting severe mental illness (psychosis) and substance misuse: assessment and management in healthcare settings; and other relevant NICE guidelines regarding* mental health and behavioural conditions.'

## 1.2 Anticipating and reducing the risk of violence and aggression

### Surveillance proposal

This section of the guideline should not be updated.

### 2019 surveillance summary

No evidence from published studies was found, however an ongoing study is developing and testing a new training package that aims to provide staff in UK psychiatric inpatient wards with de-escalation skills to help to reduce anger and distress which can lead to physical restraint. This study is expected to complete in June 2020 and may provide useful information around specific training packages that may reduce levels of restraint in inpatient wards. This study will be tracked by NICE and the results will be assessed for impact on publication.

Another ongoing study is looking at testing the Safewards intervention in Swiss psychiatric wards in order to encourage intervention much earlier in the process of escalation. This

study was due to complete in January 2019 however no results have been published yet. As it is mainly focused on the implementation of interventions in Swiss psychiatric wards it is not known whether the results will be directly relevant to the UK. This study will be tracked by NICE and the results will be assessed for impact on publication.

### Intelligence gathering

The Mental Health Act 1983: Code of Practice (2015) discusses factors that may contribute to behaviour disturbance and which should be considered within assessments, and discusses primary, secondary and tertiary strategies to enhance a service user's quality of life and meet their unique needs; recognising early signs of impending behavioural disturbance and how to respond thereby reducing the likelihood of behaviour disturbances. NG10 currently recommends training to enable staff to develop skills "to assess why behaviour is likely to become violent or aggressive, including personal, constitutional, mental, physical, environmental, social, communicational, functional and behavioural factors" and "to reduce or avert imminent violence and defuse aggression when it arises (for example, verbal de-escalation)".

One topic expert suggested that NICE look into incident reporting practices in mental health, health and community settings.

### Impact statement

NG10 does not suggest specific factors that could contribute to behavioural disturbance or suggest specific strategies that may reduce the likelihood of behaviour disturbance. New intelligence was identified that could help recognition of early signs of behaviour disturbance and effective ways of responding. The Mental Health Act 1983: Code of Practice (2015) contains useful information about these measures. It is therefore proposed that this document is added the list of documents that should be considered by healthcare professionals within the person-centred care section of the guideline.

Although a suggestion was made that NICE should consider incident reporting practices, NG10 already mentions reporting and analysing data on: violent incidents; the use of restrictive interventions; service users' experience of those interventions; and the learning gained.

## 1.3 Preventing violence and aggression

### Surveillance proposal

This section of the guideline should not be updated.

### 2019 surveillance summary

No new evidence was identified at the surveillance review.

### Intelligence gathering

One topic expert suggested that the recommendation regarding searching should be broadened to state that additional vigilance is needed in cases where the person detained under the Mental Health Act was being detained because they had killed someone. The topic expert also noted that there is a lack of communication between the criminal justice system and the mental health system when managing people who have a mental health issue and who commit homicide. Public Health England's Better care for people with co-occurring mental health and alcohol/drug use conditions recommends joint commissioning across mental health and alcohol/drugs (including primary care, criminal justice settings and specialise/acute care) and is intended to be used alongside and in support of implementation of NICE and other clinical guidance. Public Health England believe that joint commissioning across mental health and the criminal justice settings is important for safety and efficacy purposes and could potentially flag individuals who may carry a higher risk of conducting violent or aggressive acts.

### Impact statement

NG10 makes recommendations around developing a policy on searching and carrying out searches. No evidence or further intelligence was found to suggest that services needed to conduct searches with extra vigilance in extreme cases, therefore it is proposed that there will be no impact on the guideline at this time.

No evidence was found regarding improving the contact between mental health and criminal justice services, however Better care for people with co-occurring mental health and alcohol/drug use conditions recommends this communication. NG10 does not contain any recommendations on this area. It is therefore proposed that this document is added to the list of documents that should be considered by healthcare professionals within the person-centred care section of the guideline.

## 1.4 Using restrictive interventions in inpatient psychiatric settings

### Surveillance proposal

No new information from evidence or intelligence was identified in this surveillance review regarding: staff training; staffing and equipment; using restrictive interventions; observation; mechanical restraint or seclusion. Evidence and intelligence was identified in this surveillance review regarding: manual restraint; rapid tranquilisation and post-incident debrief and formal review and this information is detailed below.

This section of the guideline should not be updated.

### Editorial amendments

It is recommended that the first paragraph of this section should be amended to ensure that restrictive interventions are used in accordance with the Use of Force Act 2018. The proposed amendment would be as follows (new text has been written in *italics*):

‘Restrictive interventions are most likely to be used in inpatient psychiatric settings, but may be used in emergency departments, outpatient services and child and adolescent mental health services (CAMHS). *Restrictive interventions should be used in accordance with the Use of Force Act 2018*.’

## Manual restraint

### 2019 surveillance summary

In 1 qualitative study (Barnett, Stirling, Hall, Davies, & Orme, 2016) 20 healthy participants were held in either the supported prone restraint position or the unsupported prone restraint position. The results showed that perceptions of comfort were greater and perceptions around anxiety and breathing limitation were less in the supported prone position. An unsupported prone restraint position was associated with feeling trapped, vulnerable and included a heightened concern over heart rate.

One retrospective study (Michaud, 2016) considered data on restraint related deaths (RRD) in excited delirium syndrome in Ontario over the period of 2004-2011. There were 14 RRDs during this period. Four of the people who died had been restrained in the prone position and had immediate cardiorespiratory arrests. It was noted that delayed cardiorespiratory arrest also occurred in the non-prone position however data on this is not given.

A topic expert highlighted 9 studies on restraint approaches. These studies were conducted in healthy adult volunteers but the original recommendation was developed using committee consensus with limited evidence and, as risks of restraint were raised by a topic expert as an area of concern in the surveillance review, we reviewed these studies in order to consider as much relevant evidence as possible.

- Adults restricted with weight on their back experienced a statistically significant 70% reduction in lung function compared with those restrained in a seated position (Michalewicz, 2007).
- Face down positions flexed and with weight resulted in a significant reduction in lung function compared with standing control. There were no significant clinical changes when flat on the floor prone and supine positions were compared with the control (Parkes J.T, 2008).
- Three different prone restraint positions, all significantly reduced lung function compared with an upright seated position (Barnett, 2013).
- One study (Vilke, 2011) found no significant physiological differences between the restraint chair and the sitting position.
- One study (Parkes J. T., 2011) found significant reductions in lung function when participants were leant forward in a seated position, compared with upright seated positions.
- One study noted that inferior vena cava diameter significantly decreased in size when the restraint positions were changed from standing through to prone with weight applied (Ho, 2011).
- No difference in psychological and physiological impact of 4 different head-hold techniques was noted compared with a standing control (Parkes J, 2015).

- For "hobble" restraint, there were no significant physiological changes in participants who were restrained in the upright position compared with control but there were significant differences when restraining in prone position compared with control (Roeggla, 1997). There was a significant decline in lung function between sitting and "hobble" restraint positions but no differences in other vital signs (Chan, 1997).

## Intelligence gathering

One topic expert noted that Deprivation of Liberty Safeguards will be changing to a scheme known as Liberty Protection Safeguards in 2020 and that this may influence some of the recommendations on the use of restraint and medication. New safeguards may be put in place once deprivations of liberty have been authorised and regular reviews by a responsible body may need to be conducted.

The topic expert also noted that The Equality and Human Rights Commission for Great Britain published a Human Rights Framework for Restraint in 2019. Within this it lists the reasons why services would need to use restraint. It has 2 recommendations which state "Any anticipated use of restraint must be planned and regularly reviewed. This must include active consideration of the risks to the person's physical and mental well-being, taking into account matters such as disability and age". It states that public bodies should collect and analyse data on their use of restraint in order to identify if restraint is being used disproportionately against people with particular protected characteristics.

Another topic expert highlighted the Use of Force Act 2018 that states that the responsible person for each mental health unit must publish a policy regarding the use of force by staff who work in that unit. This aligns with the recommendation in the Human Rights Framework for Restraint. The policy must set out what steps will be taken to reduce the use of force in the mental health unit by staff who work in that unit. The responsible person for each mental health unit must keep a record of any use of force by staff who work in that unit in accordance with this section.

One topic expert requested that NICE reconsider the recommendation on the preferred use of the supine position rather than the prone position for manual restraint. The topic expert provided evidence suggesting that certain prone positions were safe and effective and should be considered for manual restraint. Although the studies did not meet the usual inclusion criteria for a surveillance review, it was thought that they might inform this sensitive issue and a brief summary is included in the 2019 surveillance summary above.

It was noted that the Modernising the Mental Health Act (2018) states that prone restraint can be traumatising and can lead to significant trauma for those restrained as well as for the people that see it happen. The Act does not suggest other forms of restraint that may still be traumatising. It does not mention supine restraint.

## Impact statement

The Human Rights Framework for Restraint recommends that services admitting restraint take into account matters such as disability and age. Although NG10 recommends services take extra care if the service user is physically unwell, disabled, pregnant or obese it does not

consider age. It is proposed that this recommendation is amended to state "undertake manual restraint with extra care if the service user is physically unwell, disabled, pregnant or obese and consider age".

The Use of Force Act 2018 states that services should publish a policy regarding use of force and this should be kept under review. NG10 does not specifically recommend a policy around the use of force. Therefore, it is proposed that this recommendation be refreshed to ensure that the guideline is used in accordance with the Use of Force Act.

One topic expert requested that we consider restraint positions in NG10 as the current recommendation preferring the supine position is based on committee consensus and not based on evidence. The expert suggested NICE consider 9 studies around the different positions used for restraint. The studies were all conducted in volunteers, 2 considered the supine position and 7 the prone position. There was little difference between supine and prone positions in terms of safety and 6 suggested that prone restraint positions were safe and effective if used without weight, without hobble restraint and not flexed. The 2 studies that considered the supine position noted that it was safe when not combined with the hobble restraint.

The evidence did not find any difference in harms between supine and prone restraint positions however evidence from 1 study and information from 1 government review suggested that prone positions can be physiologically and psychologically traumatising. As the original committee believed that supine positions would be the safest practice and. with a lack of directly relevant high-quality evidence it is proposed that the recommendations are not updated at this time.

One topic expert noted that the new Liberty Protection Safeguards will influence restraint recommendations. This legislation is yet to become a code of practice and will publish in Spring 2020. We will monitor this and once it is published we will consider the output and how it may affect this recommendation.

## Editorial amendments

- Recommendation 1.4.27 It is suggested that this wording is amended to ensure that age is considered when undertaking manual restraint in line with equalities issues as specified in the Human Rights Framework for Restraint. The proposed amendment would be as follows (new text has been written in *italics*):

Undertake manual restraint with extra care if the service user is physically unwell, disabled, pregnant or obese *and consider age*.

## Rapid tranquillisation

## 2019 surveillance summary

New evidence relating to drugs used for rapid tranquilisation purposes is summarised below.

**Droperidol vs Haloperidol**

A randomised controlled trial (RCT) (Calver, Drinkwater, Gupta, Page, & Isbister, 2015) (n=228) patients in a psychiatric intensive care unit received either haloperidol (10 mg) or droperidol (10 mg) intramuscularly after an acute behaviour disturbance. Sedation occurred in 92% of the patients within 2 hours with no significant differences between the 2 groups. There was a difference in additional sedation needed, 13% with haloperidol compared with only 5% for droperidol, but it was not statistically significant. There were fewer adverse effects with haloperidol but this was also non-significant.

**Droperidol vs Haloperidol and Midazolam**

A Cochrane review (Khokhar & Rathbone, 2016) looked at 6 RCTs comparing droperidol to any other treatment or placebo in agitated or violent patients experiencing acute psychotic illnesses. The routes these drugs were administered by was not clarified within the abstract. Droperidol was significantly more effective in achieving tranquilisation after 30 minutes compared with placebo. There was a significant reduction in the need for additional medication after 60 minutes when comparing droperidol with haloperidol. There were no increased adverse effects with the use of droperidol when compared with placebo and haloperidol. These results were non-significant, however the authors considered droperidol to be safe. Midazolam was more effective compared with droperidol for achieving tranquilisation, but it was not statistically significant and 4% of the patients in the midazolam group needed airway management compared with none in the droperidol group (no statistical values were given).

**Haloperidol and promethazine, risperidone, droperidol, lorazepam and aripiprazole**

A systematic review and meta-analysis (Bak et al., 2019) of 53 RCTs considered pharmacological interventions for acute agitation in patients within a psychiatric setting. The routes these drugs were administered by was not clarified within the abstract. Haloperidol plus promethazine, olanzapine, risperidone, droperidol and aripiprazole were most effective for reducing agitation after 2 hours compared with other pharmaceutical interventions which were not clarified within the abstract. There were more adverse effects (the detail of which were not clarified) with haloperidol and haloperidol plus lorazepam compared with other drugs. Statistical values were not given in this abstract.

**Haloperidol plus promethazine vs haloperidol alone, ziprasidone and haloperidol plus midazolam**

A Cochrane review (Huf, Alexander, Gandhi, & Allen, 2016) looked at 6 RCTs (n=1367) comparing haloperidol plus promethazine with other treatments for psychosis-induced aggression. The routes these drugs were administered by was not clarified within the abstract. Haloperidol plus promethazine was significantly more effective for sedation at 30 minutes compared with haloperidol alone. Ten incidences of adverse effects occurred with

haloperidol alone compared with none in the combination group (significance unknown). There was no significant difference in effectiveness for haloperidol plus promethazine compared with intramuscular ziprasidone or intramuscular olanzapine. Haloperidol plus midazolam was more significantly sedating than haloperidol plus promethazine but had a statistically significant increased risk of excessive and prolonged sedation. Haloperidol plus promethazine was significantly more effective at causing sedation at 30 minutes compared with lorazepam. Haloperidol plus promethazine was significantly slower at tranquilising an aggressive situation compared with midazolam alone, and there were no significant differences in adverse effects between the 2 treatment groups.

**Haloperidol vs placebo, aripiprazole and lorazepam**

A Cochrane review (Ostinelli, Brooke-Powney, Li, & Adams, 2017) of 41 RCTs compared intramuscular haloperidol alone with placebo, aripiprazole and lorazepam for controlling aggression or agitation in people with psychosis. Haloperidol was significantly more effective compared with placebo for sedation within 2 hours and haloperidol required significantly fewer injections compared with aripiprazole. There were significantly more cases of dystonia with haloperidol when compared to aripiprazole. For haloperidol compared with lorazepam, there were no significant differences for sedation within 1 hour.

**Haloperidol vs Sodium valproate**

A small randomised, double-blind, parallel-group trial (n=80 patients in emergency psychiatry) (Asadollahi et al., 2015) compared intravenous sodium valproate (20 mg) with intramuscular haloperidol (5 mg) in decreasing agitation levels. The mean postintervention Agitation-Calmness Evaluation Scale from baseline to 30-minute post injection was 4.73 (SD=1.93) for valproate and 5.45 (SD=2.09) for haloperidol. This was statistically significant. There were significantly more occurrences of intense sedation and extrapyramidal symptoms with haloperidol compared with sodium valproate.

**Haloperidol vs risperidone**

A small naturalistic RCT (Walther et al., 2014) compared the efficacy of oral haloperidol (15 mg) with oral risperidone (2 to 6 mg over 5 days) and oral olanzapine (20 mg) in reducing agitation in patients (n=43) with psychotic conditions. There were no significant differences between the groups with both being effective within 2 hours.

**Haloperidol vs levosulpiride**

A small randomised, double-blind, parallel-group (n=60) study (Lavania, Praharaj, Bains, Sinha, & Kumar, 2016) compared intramuscular haloperidol (10-20 mg) with intramuscular levosulpiride (25-50 mg) in controlling agitation and aggression in acute psychosis over 5 days. The time to effect was significantly faster in the haloperidol group. Haloperidol was also associated with a greater reduction in agitation scores compared with levosulpiride, but the difference was not statistically significant. There were more frequent adverse effects with haloperidol compared with levosulpiride (significance unknown).

**Haloperidol vs aripiprazole, risperidone and lorazepam**

A systematic review and meta-analysis (Dundar, Greenhalgh, Richardson, & Dwan, 2016) of 17 RCTs (n=3841) compared haloperidol, olanzapine, aripiprazole, risperidone, loxapine, olanzapine and lorazepam for the treatment of agitation in patients with schizophrenia or bipolar disorder. The route the treatment was administered by is not given in the abstract. After 60 minutes, no treatment was significantly more effective than any other.

**Lorazepam vs Midazolam**

A systematic review (Kousgaard, Licht, & Nielsen, 2017) examined 16 RCTs (n=906) comparing intramuscular lorazepam (2-4 mg) and intramuscular midazolam (5-15 mg) in patients within a psychiatric setting to treat acute agitation and found no significant differences in effectiveness between the 2 groups.

**Risperidone vs haloperidol and quetiapine**

A Cochrane review (Ostinelli, Hussein, et al., 2018) of 9 RCTs (n=582) compared oral risperidone with haloperidol, olanzapine and quetiapine in patients with psychosis with the outcome of controlling aggressive, agitated or violent behaviour. After 24 hours, there were no significant differences in efficacy between risperidone and haloperidol, risperidone and quetiapine nor risperidone and olanzapine and no significant differences in adverse effects between any of the groups.

**Aripiprazole vs placebo and haloperidol**

A Cochrane review (Ostinelli, Jajawi, Spyridi, Sayal, & Jayaram, 2018) of 3 RCTs (n=707) compared intramuscular aripiprazole with placebo, intramuscular haloperidol and intramuscular olanzapine in patients with psychosis. There were no significant differences in outcome or adverse effects when aripiprazole was compared with haloperidol, although aripiprazole required more injections. When compared with placebo aripiprazole was significantly more effective at improving agitation after 2 hours and required significantly less injections. When compared with olanzapine, aripiprazole was significantly less effective at reducing agitation.

**Benzodiazepines vs haloperidol**

A Cochrane review (Zaman et al., 2017) of 20 RCTs (n=695) compared benzodiazepines or benzodiazepines plus an antipsychotic with placebo and haloperidol in patients with psychotic illnesses (route of administration was not stated in the abstract and neither was the type of benzodiazepine). There was no significant difference in controlling agitated or violent behaviour for benzodiazepines compared with placebo or haloperidol in the short term, however in the medium-term benzodiazepines were significantly more effective than placebo. There were more extrapyramidal effects in the haloperidol group when compared with benzodiazepines. There was no significant difference in effectiveness for benzodiazepine plus haloperidol compared with benzodiazepines alone or haloperidol alone in the short term but in the medium-term sedation was significantly more likely in the benzodiazepine plus haloperidol group when compared with haloperidol alone. Olanzapine was significantly more effective than benzodiazepines at improving agitation. When lorazepam was compared with haloperidol plus promethazine there was a significantly lower

risk of sedation in the benzodiazepine group. When midazolam was compared with haloperidol plus promethazine there was a significantly higher risk of sedation on the benzodiazepine group.

## Intelligence gathering

NICE Guideline CG192 Antenatal and postnatal mental health: clinical management and service guidance recommendation 1.8.23 gives detailed information on the rapid tranquilisation of pregnant women; at present, NG10 does not refer to the information in this guideline.

The Human Rights Framework for Restraint 2019 states that age should be considered when undertaking chemical restraint. NG10 currently does not consider age when recommending rapid tranquilisation. It was also noted that NICE Guideline CG185 Bipolar disorder: assessment and management recommends considering the impact that psychotropic medication can have on older people.

One topic expert suggested that NICE should strengthen the recommendations on pharmacological management but did not specify areas of concern.

**Lorazepam**

One topic expert expressed concerns around possible disruptions in the supply of injectable lorazepam in the UK.

**Loxapine**

NICE Technology appraisal guidance TA286 states that NICE is unable to recommend the use in the NHS of loxapine inhalation for treating acute agitation and disturbed behaviours associated with schizophrenia and bipolar disorder because no evidence submission was received from the manufacturer of the technology.

**Olanzapine**

During development of NG10, the manufacturer of intramuscular (IM) olanzapine discontinued the product in the UK and so the Guideline Development Group was not able to make recommendations for its use. This product is not routinely available for use in the UK.

**Risperidone**

Risperidone is licensed for oral administration in the UK for short-term symptomatic treatment (up to 6 weeks) of persistent aggression in certain populations, but the injection is usually used for maintenance treatment and not in the acute phase.

## Impact statement

NICE Guideline CG192 Antenatal and postnatal mental health: clinical management and service gives further recommendations on how to care for pregnant women who require rapid tranquilisation. NG10 currently does not have recommendations which suggest considering areas such as what sort of agent to choose for rapid tranquilisation, not secluding

after rapid tranquilisation and adapting restraint procedures for pregnant women. Therefore, it is proposed that NG10 cross refers to CG192 to ensure awareness of these concerns if pregnant women need chemical restraint.

Intelligence from NICE Guideline CG185 Bipolar disorder: assessment and management and the Human Rights Framework for Restraint 2019 suggest that age should be a considered factor when administering psychotropic medication. NG10 makes separate recommendations for children and young people however does not consider the elderly. Therefore, it is proposed that NG10 is amended to say "when deciding which medication to use, take into account pre-existing physical health problems, age or pregnancy" to ensure that service users' age is considered when using rapid tranquilisation.

New evidence was identified around pharmacological management for rapid tranquilisation. NG10 currently recommends using either intramuscular lorazepam on its own or intramuscular haloperidol combined with intramuscular promethazine for rapid tranquilisation in adults.

**Lorazepam**

New evidence suggested that haloperidol plus promethazine was more effective at sedation at 30 minutes than lorazepam. There were no significant differences in efficacy between lorazepam when compared with haloperidol alone and midazolam. New evidence found did not highlight any concerns with the safety of lorazepam. New evidence does not conflict with the current recommendations around lorazepam and therefore has no impact the guideline.

NICE believes the issue around UK supply problems of injectable lorazepam has been resolved.

**Haloperidol plus promethazine**

One Cochrane review indicated that haloperidol plus promethazine is more effective than haloperidol alone or haloperidol plus lorazepam or lorazepam, with fewer side effects. Midazolam was more effective than haloperidol plus promethazine at tranquilising, however midazolam was associated with adverse effects. There were no significant differences when comparing haloperidol plus promethazine with ziprasidone. There is no new evidence to challenge the safety and efficacy of haloperidol plus promethazine when used in exceptional circumstances and therefore it is proposed that no impact on the guideline is expected.

**Droperidol**

NG10 does not contain recommendations for the use of droperidol. New evidence did not suggest that droperidol is better tolerated or more effective than haloperidol plus promethazine or lorazepam, therefore it is proposed that no impact on the guideline is expected.

**Haloperidol**

NG10 does not contain recommendations for the use of haloperidol alone. New evidence suggested that haloperidol alone was less effective than haloperidol plus promethazine and there was no significant difference when comparing haloperidol with risperidone, aripiprazole, droperidol and benzodiazepines. Haloperidol was associated with more adverse effects when compared with lorazepam, aripiprazole, sodium valproate and droperidol. Therefore, it is proposed that no impact on the guideline is expected.

**Midazolam**

NG10 does not contain recommendations for the use of midazolam. New evidence suggested that there was no significant difference between the safety and efficacy of midazolam compared with lorazepam. Midazolam alone or in combination with haloperidol was more effective than haloperidol plus promethazine. However, the use of midazolam was associated with more adverse effects such as excessive and prolonged sedation and increased saturation. Therefore, it is proposed that no impact on the guideline is expected.

**Olanzapine**

NG10 does not contain recommendations for the use of olanzapine. Olanzapine is not available for routine use in the UK and therefore it is proposed that no impact on the guideline is expected.

**Ziprasidone**

NG10 does not contain recommendations for the use of ziprasidone and little new evidence was identified in this surveillance review, therefore it is proposed that no impact on the guideline is expected.

**Aripiprazole**

NG10 does not contain recommendations for the use of aripiprazole. New evidence did not suggest that aripiprazole is safer or more effective than haloperidol plus promethazine or lorazepam, therefore it is proposed that no impact on the guideline is expected.

**Levosulpiride**

NG10 does not contain recommendations for the use of levosulpiride and the injection is not licensed for use in the UK. Little new evidence was identified in this surveillance review, therefore it is proposed that no impact on the guideline is expected.

**Risperidone**

NG10 does not contain recommendations for the use of risperidone. New evidence did not suggest that risperidone is safer or more effective than haloperidol plus promethazine or lorazepam, therefore it is proposed that no impact on the guideline is expected.

**Quetiapine**

NG10 does not contain recommendations for the use of quetiapine. New evidence showed quetiapine is more effective than risperidone at reducing agitation but did not suggest that

quetiapine is safer or more effective than haloperidol plus promethazine or lorazepam, therefore it is proposed that no impact on the guideline is expected.

**Sodium valproate**

NG10 does not contain recommendations for the use of sodium valproate. New evidence did not suggest that sodium valproate is safer or more effective than haloperidol plus promethazine or lorazepam, therefore it is proposed that no impact on the guideline is expected.

## Editorial amendments

- Recommendation 1.4.37 It is suggested that this wording is amended to ensure that age is considered when undertaking chemical restraint in line with equalities issues as specified in the Human Rights Framework for Restraint. It is also suggested that this wording is amended to ensure that rapid tranquilisation is used with extra care with women who are pregnant. The proposed amendment would be as follows (new text has been written in *italics*):

'When deciding which medication to use, take into account: pre-existing physical health problems, *age* or pregnancy (*use in conjunction with CG192 Antenatal and postnatal mental health: clinical management and service guidance Recommendation 1.8.23*).'

# Post-incident debrief and formal review

## 2019 surveillance summary

A systematic review of 34 studies (Aguilera-Serrano, Guzman-Parra, Garcia-Sanchez, Moreno-Kustner, & Mayoral-Cleries, 2018) (n=1869 psychiatric patients) considered patients' experiences of an episode of mechanical restraint, seclusion or forced administration. It was noted that debriefing is an important procedure/technique to use to effectively help reduce the emotional impact that these measures can take.

A qualitative study (Lanthen, Rask, & Sunnqvist, 2015) considered psychiatric patients' experience of mechanical restraint and was conducted in the form of interviews. The results suggested that debriefing must be conducted after an incident, however details around how this was concluded were not given.

A qualitative study (Ling, Cleverley, & Perivolaris, 2015) considered forms that were filled in by mental health service users during a debriefing session where they discussed their experiences before, during and after a restraint event (n=55). A thematic analysis showed that debriefing, when guided by a form, is a useful and effective experience and can be used to re-establish therapeutic relationships and can inform plans of care.

A qualitative study (Stevenson, Jack, O'Mara, & LeGris, 2015) considered nurses' experiences of violence (n=12 with 33 exposures to violence) in an acute care inpatient psychiatric setting using thematic analysis and comparison techniques. It was noted that the nurses endorsed the need for debriefing following incidences.

## Intelligence gathering

One topic expert requested that NICE reconsider the recommendations in NG10 for undertaking immediate post-incident debriefing (recommendations 1.4.55 to 1.4.61). The expert was concerned around the negative impact a debrief may have on service users suffering from post-traumatic stress disorder. This is reflected in NICE Guideline NG116 Post-traumatic stress disorder (PTSD) which recommends not offering psychologically-focused debriefing for the prevention or treatment of PTSD. The full guideline for NG116 states that "Evidence on psychologically-focused debriefing, either individually or in groups, showed no benefit for children or adults, and some suggestion of worse outcomes than having no treatment. The committee agreed that psychologically-focused debriefing should not be offered. Providing an ineffective intervention can be regarded as harmful because it means that people are being denied access to another intervention with greater evidence of benefits." The guideline also states that "the evidence does not support the use of single-session debriefing for children of any age".

The World Health Organisation's guideline on Psychological debriefing in people exposed to a recent traumatic event recommends that "psychological debriefing should not be used for people exposed recently to a traumatic event as an intervention to reduce the risk of post-traumatic stress, anxiety or depressive symptoms".

The Modernising the Mental Health Act (2018) suggests that imposition of unwanted treatment can be considered as traumatic, frightening and confusing for service users. The Act cited a service user who claimed that "being sectioned was one of the most traumatic experiences of my life. Sadly, as a result of being sectioned I developed PTSD as the direct result of the way I was treated". The report noted that actions such as prone restraint can be particularly traumatising and can lead to significant trauma for those restrained.

The full NG10 guideline details the rationale behind the debrief recommendation being evidence from The Six Core Strategies for Reducing Seclusion and Restraint Use which list debriefing techniques as 1 of the strategies. The committee who created the guideline believed there was insufficient evidence to reach a conclusion about the effectiveness and experience of these strategies however, and after reviewing other NICE guidelines, they agreed that it was good practice to conduct a post-incident debrief and review, and that regular reports should be sent to trust boards.

NICE Guideline CG178 Psychosis and schizophrenia in adults: prevention and management recommends assessing "for post-traumatic stress disorder and other reactions to trauma because people with psychosis or schizophrenia are likely to have experienced previous adverse events or trauma associated with the development of the psychosis or as a result of the psychosis itself".

NICE Guidelines CG178 and CG155 Psychosis and schizophrenia in children and young people: recognition and management support the idea of debriefing by recommending that “after rapid tranquilisation, (clinician’s should) offer the (service user) the opportunity to discuss their experiences”. The rationale supporting these recommendations was not discussed in the full guidelines.

## Impact statement

NG10 recommends conducting an immediate post-incident debrief after violent or aggressive events when a restrictive intervention has been used. This recommendation was developed through committee consensus as little evidence was available.

One topic expert challenged this recommendation, however new qualitative evidence from small numbered study groups was identified which recommends debriefing techniques and was directly relevant for service users and staff in mental health settings. There was no indication that post-incident debriefing was harmful to service users or staff in mental health settings.

NICE Guideline NG116 Post-traumatic stress disorder recommends never using psychologically-focused debriefing techniques, but this guideline is addressing a different situation and population from NG10. However, there is relevant evidence from other guidelines and from Mental Health Acts which suggests that the population in NG10 may be suffering from PTSD symptoms. NICE Guideline NG116 refers to psychologically-focused debriefing and NG10 is focused on post-incident debriefing. Therefore, it is proposed that the term debriefing after incidents of violence and aggression is clarified further in the terms used in this guideline section. If there is a chance that service users may be suffering from PTSD it may be beneficial to their health and safety to assess them first alongside the recommendation in CG178 prior to conducting debriefs after incidents of violence and aggression and to treat them according to the recommendations in NG116. It is noted that this proposed amendment will require glossary links to the word “debrief” in many other areas of the guideline found in the following sections: 1.2, 1.3, 1.5 and 1.6.

## Editorial amendments

- Terms used in this guideline It is suggested that the term “debrief” should be incorporated into this list to ensure that it is fully understood and never misused within this vulnerable population. The proposed amendment would be as follows:

‘*Debrief – A discussion involving the staff team and service user involved with the aim of learning from the incident and initiating planning to prevent the chance of incident repetition. This should not be considered a psychologically-focused debrief. If a psychologically-focused debrief is considered to be necessary, use in conjunction with NICE’s guideline NG116 Post-traumatic stress disorder.* ‘

# 1.5 Managing violence and aggression in emergency departments

### Surveillance proposal

No new information from evidence or intelligence was identified at the surveillance review

This section of the guideline should not be updated.

## 1.6 Managing violence and aggression in community and primary care settings

### Surveillance proposal

This section of the guideline should not be updated.

### 2019 surveillance summary

No new evidence was identified at the surveillance review.

### Intelligence gathering

One topic expert noted that there is very little in the guideline around violence in community mental health settings.

### Impact statement

New intelligence was identified that noted there is little in the guideline around community mental health settings. Recommendation 1.6 is dedicated to managing violence and aggression in community and primary care settings and offers advice regarding developing policies, staff training and managing violence and aggression. No new evidence was found regarding violence and aggression in community mental health settings during the surveillance review and therefore no impact on the guideline is expected.

## 1.7 Managing violence and aggression in children and young people

### Surveillance proposal

This section of the guideline should not be updated.

### 2019 surveillance summary

New evidence was identified around pharmacological management for rapid tranquilisation and debriefing however it was not clear whether any of the evidence found involved children and young people. See recommendation section 1.4 for the summaries.

### Intelligence gathering

It is noted that lorazepam does not have a UK marketing authorisation for use in children and young people under 12 years for this indication. NICE Guideline CG155 Psychosis and schizophrenia in children and young people recommends being cautious when considering

high-potency antipsychotic medication in children and young people, especially those who have not taken antipsychotic medication before, because of the increased risk of acute dystonic reactions in that age group.

### Impact statement

It is proposed that there is not enough directly relevant evidence to update the guideline at this time. The guideline will be amended in line with recommendation section 1.4 above to say that age should be considered when chemical restraint is used.

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## Research recommendations

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

### Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

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

### Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

**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?**

### Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

**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?**

## Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

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

## Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

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