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

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 and comments from stakeholders at consultation, were considered alongside the evidence to reach a view on the need to update each section of the guideline.

1.1 Principles for managing violence and aggression

Surveillance proposal

Following comments from stakeholders at consultation this guideline will be fully 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. This study will be tracked by NICE and at publication the results will be assessed for impact and possible inclusion in the future update.

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 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.

Two stakeholders noted at consultation that the guideline did not adequately convey the importance of trauma informed care and support. It was stated that the guideline did not fully consider service users' human rights.

One stakeholder also highlighted the BILD Restraint Reduction Network (RRN) Standards (April 2019) which were commissioned by the NHS and are mandatory for all training with a restrictive intervention component that is delivered to NHS-commissioned services for people with mental health conditions, learning disabilities, autistic people and people living with dementia in the UK. Implementation of these standards will be via commissioning requirement and inspection frameworks from April 2020. This document provides training information on a number of standards including: the use of mechanical restraint; factors that

contribute to risk and elevated risk; post-incident support, review and learning; trauma informed care and support and restraint reduction theory.

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. Following comments from stakeholders at consultation this guideline will be fully updated and 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. Following comments from stakeholders at consultation this guideline will be fully updated and 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. NICE will track this legislation and at publication the content will be assessed for impact.

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 however following comments from stakeholders at consultation this guideline will be fully updated and this area will be considered in scoping.

Training standards that are due to become mandatory in mental health, health and community settings were highlighted during the consultation on this surveillance review. These training standards will cover best practice regarding post-incident reviews and trauma informed care. Therefore it is proposed that these training standards are considered during the full update of this guideline in order to ensure service users receive the best possible

care. The update will also fully consider trauma informed care, support and service users' human rights.

1.2 Anticipating and reducing the risk of violence and aggression

Surveillance proposal

Following comments from stakeholders at consultation this guideline will be fully 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 at publication the results will be assessed for impact on the guideline.

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 at publication the results will be assessed for impact on the guideline.

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.

Two stakeholders noted at consultation that this guideline gave a "reactive" approach to the management of violence and aggression and it was suggested that the guideline did little to reduce incident and failed to reflect preventative approaches. The title of the guideline was also queried, as it currently refers to short-term management and it was believed that NICE

could add value by considering long term interventions. It was requested that the guideline consider positive, proactive and trauma informed care in order to reduce restrictive practices.

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. Following further comments from stakeholders at consultation the guideline will be fully updated and it is proposed that this Code of Practice is considered during development.

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. Following comments from stakeholders at consultation this guideline will be fully updated however, and therefore incident reporting practices will be considered during the update. During the full update trauma informed care will also be considered to ensure that service users receive the best possible care.

Following comments from stakeholders at consultation this guideline will be fully updated however, and therefore incident reporting practices and trauma informed care will also be considered during the scoping of the guideline update.

1.3 Preventing violence and aggression

Surveillance proposal

Following comments from stakeholders at consultation this guideline will be fully 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.

One stakeholder requested that the guideline consider effective proactive interventions in order to manage and prevent violence and aggression more effectively.

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, however following comments from stakeholders at consultation the guideline will be fully updated and this area will be considered during scoping.

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. Following comments from stakeholders at consultation the guideline will be fully updated, and it is proposed that this document is added to the list of documents that should be considered in the guideline update.

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 were identified in this surveillance review regarding: manual restraint; rapid tranquilisation and post-incident debrief and formal review and this information is detailed below.

Following comments from stakeholders at consultation this guideline will be fully updated.

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. This issue was also raised by stakeholders during consultation.

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. Following comments from stakeholders at consultation the guideline will be fully updated, and it is proposed that recommendations regarding manual restraint consider age as well as illness, disability, obesity and pregnancy.

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. Following comments from stakeholders at consultation the guideline will be fully updated, and the Use of Force Act will be considered in the update.

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. There was a lack of directly relevant high-quality evidence in this area, however following comments from stakeholders at consultation this guideline will be fully updated.

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 is anticipated to publish in Spring 2020. Following comments from stakeholders at consultation this guideline will be fully updated and will consider this legislation.

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, 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.

One stakeholder at consultation provided evidence from the British Association for Psychopharmacology Guidelines and requested that NICE consider these recommendation within NG10.

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 and 1 stakeholder expressed concerns around possible disruptions in the supply of injectable lorazepam in the UK. It was also noted that lorazepam IM (Ativan) is licensed for use in young people aged over 12 years.

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. The TA states that the marketing authorisation for loxapine inhalation restricts administration to adults with mild to moderate agitation associated with schizophrenia and bipolar disorder and to the hospital setting. During consultation 1 stakeholder requested that NICE consider the use of loxapine within the guideline.

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. Although olanzapine is listed as an option in the British National Formulary for "control of agitation and disturbed behaviour in schizophrenia or mania", no preparations are licensed in the UK. During consultation 1 stakeholder noted that olanzapine is being used within the NHS for the indication of rapid tranquilisation, h and expressed concern that the NG10does not make any recommendations around for use or non-use.

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 of schizophrenia and not in the acute phase.

Aripiprazole

During consultation 1 stakeholder noted that Aripiprazole is licensed for rapid tranquilisation, however it is not included in NG10. Short-acting intramuscular aripiprazole is licensed for the rapid control of agitation and disturbed behaviours in adult patients with schizophrenia or with manic episodes in Bipolar I Disorder, when oral therapy is not appropriate. It is not licensed for use in children and young people aged 0-17 years.

Diazepam

During consultation 1 stakeholder noted that evidence supports the use of IV diazepam for rapid tranquilisation and that this can be safely used in acute medical settings where rapid access to ventilatory support and reversal agents, as well as the ability to site IV access is readily available. The stakeholder requested that NICE consider different settings when recommending the most safe and effective drug to use for rapid tranquilisation. Some brands of diazepam injection (IM or IV) are licensed for use in severe or disabling anxiety and agitation and to relieve anxiety and provide sedation in severe acute anxiety or agitation but use with violence or aggression is not specified.

Zuclopenthixol acetate

During consultation 1 stakeholder noted that in 11% of UK cases where an intramuscular injection of an antipsychotic drug was used, the drug used was zuclopenthixol acetate (IM).

There are currently no recommendations for the use of this drug within NICE guidelines and evidence found by the stakeholder suggests it is not particularly safe or effective. This drug is licensed for the indication of initial treatment of acute psychoses including mania and exacerbation of chronic psychoses but is not licensed for use in children.

Haloperidol monotherapy

During consultation 1 stakeholder noted that other guidelines actively do not recommend haloperidol monotherapy due to concerns around its safety and efficacy. The stakeholder requested that NICE consider evidence regarding this drug and makes a recommendation regarding its use or non-use for rapid tranquilisation.

Midazolam and buccal

During consultation, 1 stakeholder noted that many drugs were being used within the NHS but are not addressed in NG10. It is noted that buccal midazolam and midazolam are not licensed for the treatment of violence and aggression.

Haloperidol with lorazepam

During consultation, 1 stakeholder noted that haloperidol with lorazepam was the most widely used combination drug for rapid tranquilisation nationally however there were no recommendations from NICE regarding its use.

Promethazine with lorazepam

During consultation 1 stakeholder noted that promethazine with lorazepam is widely used for rapid tranquilisation and NICE should provide information regarding its efficacy and safety.

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. Following consultation with stakeholders this guideline will be fully updated and 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. Following consultation with stakeholders this guideline will be fully updated and it is proposed that recommendations consider age 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 is now licensed for use in young people aged over 12 years and the licensing information will be amended within the guideline during the update to reflect this. Following consultation with stakeholders this guideline will be fully updated and it is proposed that evidence regarding the safety and efficacy of other drugs used within certain settings with the indication for rapid tranquilisation is considered.

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 patients with mental health conditions) 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 patients with mental health conditions' 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.

During consultation 1 stakeholder noted that the British Institute for Learning Disabilities (BILD) Restraint Reduction Network's training standards 2019 gives a useful definition for the act of debriefing without using the term "debrief". These standards offer training content in regard to post-incident reviews. Post-incident reviews should have 2 main components – post-incident support and post-incident reflection and learning.

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. 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. Following consultation on the guideline, 1 stakeholder suggested that debriefing should be defined alongside the BILD Restraint Reduction Network's training standards 2019. This guideline will be fully updated and it is proposed that evidence and intelligence regarding the action of debriefing and the relevant terms that should be used to describe this type of post-incident review, reflection and learning is considered.

1.5 Managing violence and aggression in emergency departments

Surveillance proposal

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

During consultation 1 stakeholder stated that recommendation 1.5.5 uses the term "excited delirium" inappropriately. The stakeholder also noted that delirium was a common cause of violence and aggression and should be considered further within the guideline. Therefore, this guideline will be fully updated and it is proposed that evidence and intelligence regarding delirium and the use of the term "excited delirium" is considered. It is noted that NICE guideline CG103 already covers how to prevent, diagnose and manage delirium and this will be considered during the update.

1.6 Managing violence and aggression in community and primary care settings

Surveillance proposal

Following comments from stakeholders at consultation this guideline will be fully 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. Following comments from stakeholders at consultation on other aspects of this guideline it has been decided that the guideline will be fully updated and it is proposed that evidence and intelligence regarding violence and aggression in community mental health settings is considered.

1.7 Managing violence and aggression in children and young people

Surveillance proposal

Following comments from stakeholders at consultation this guideline will be fully 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.

During consultation 1 stakeholder noted that the guideline has insufficient emphasis on children and young people, and there are no recommendations for those who have learning disabilities. NICE has created a guideline on challenging behaviour and learning disabilities which recommends interventions and support for children, young people and adults with a learning disability and behaviour that challenges however if this behaviour becomes violent or aggressive this guideline refers to NG10. It is noted that NG10 does not contain specific recommendations for those with learning disabilities and therefore there is a gap in NICE guidelines.

Impact statement

Following comments from stakeholders at consultation this guideline will be fully updated in order to focus further on violence and aggression in children and young people. It is suggested that the content of the scope is reconsidered so that evidence regarding children and young people with learning disabilities can also be considered within the recommendations.

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 addressed this research recommendation and the question will be reconsidered during the update of the guideline

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

Summary of findings

No new evidence addressed this research recommendation and the question will be reconsidered during the update of the guideline

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 addressed this research recommendation and the question will be reconsidered during the update of the guideline

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 addressed this research recommendation and the question will be reconsidered during the update of the guideline

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 addressed this research recommendation and the question will be reconsidered during the update of the guideline

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