Violence and Aggression

The short-term management of violent and physically threatening behaviour in mental health, health and community settings

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1 PREFACE

This guideline has been developed to advise on the management of violent and physically threatening behaviour in mental health, health and community settings in adults, children (aged under 13 years) and young people (aged 13 to 18 years).

This guideline updates *Violence: the Short-term Management of Disturbed/Violent Behaviour in In-Patient Psychiatric Settings and Emergency Departments*, NICE clinical guideline 25, which was developed by the National Collaborating Centre for Nursing and Supportive Care and published in 2005.

Since the publication of the 2005 guideline, there have been some important advances in our knowledge of the management of violence and aggression, including service users' views on the use of physical intervention and seclusion, and the effectiveness, acceptability and safety of drugs and their dosages for rapid tranquillisation. The previous guideline was restricted to people aged 16 and over in adult psychiatric settings and emergency departments; this update has been expanded to include some of the previously excluded populations and settings. All areas of NICE clinical guideline 25 have been updated and this guideline will replace it in full.

The guideline recommendations have been developed by a multidisciplinary team of healthcare professionals, people with mental health problems who have personally experienced management of violent or aggressive behaviour, their carers and guideline methodologists after careful consideration of the best available evidence. It is intended that the guideline will be useful to clinicians and service commissioners in providing and planning high-quality care for the management of violence and aggression, while also emphasising the importance of the experience of these service users' care and the experience of their carers (see Appendix 1 for more details on the scope of the guideline).

Although the evidence base is rapidly expanding, there are a number of major gaps. The guideline makes a number of research recommendations specifically to address gaps in the evidence base. In the meantime, it is hoped that the guideline will assist clinicians, service users and carers, by identifying the merits of particular treatment approaches where the evidence from research and clinical experience exists.

1.1 NATIONAL CLINICAL GUIDELINES

1.1.1 What are clinical guidelines?

Clinical guidelines are 'systematically developed statements that assist clinicians and service users in making decisions about appropriate treatment for specific conditions' (Mann & Executive, 1996). They are derived from the best available research evidence, using predetermined and systematic methods to identify and evaluate the evidence relating to the specific condition in question. Where evidence

is lacking, the guidelines include statements and recommendations based upon the consensus statements developed by the Guideline Development Group (GDG).

Clinical guidelines are intended to improve the process and outcomes of healthcare in a number of different ways. They can:

- provide up-to-date evidence-based recommendations for the management of conditions and disorders by healthcare professionals
- be used as the basis to set standards to assess the practice of healthcare professionals
- form the basis for education and training of healthcare professionals
- assist service users and their carers in making informed decisions about their treatment and care
- improve communication between healthcare professionals, service users and their carers
- help identify priority areas for further research.

1.1.2 Uses and limitations of clinical guidelines

Guidelines are not a substitute for professional knowledge and clinical judgement. They can be limited in their usefulness and applicability by a number of different factors: the availability of high-quality research evidence, the quality of the methodology used in the development of the guideline, the generalisability of research findings and the uniqueness of individuals.

Although the quality of research in this field is variable, the methodology used here reflects current international understanding on the appropriate practice for guideline development (AGREE Collaboration 2003)(Appraisal of Guidelines for Research and Evaluation Instrument [AGREE]; www.agreetrust.org; AGREE Collaboration, 2003), ensuring the collection and selection of the best research evidence available and the systematic generation of treatment recommendations applicable to the majority of people with mental health problems who are violent or aggressive. However, there will always be some people and situations where clinical guideline recommendations are not readily applicable. This guideline does not, therefore, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual, in consultation with the service user or their carer.

In addition to the clinical evidence, cost effectiveness information, where available, is taken into account in the generation of statements and recommendations in clinical guidelines. While national guidelines are concerned with clinical and cost effectiveness, issues of affordability and implementation costs are to be determined by the National Health Service (NHS).

In using guidelines, it is important to remember that the absence of empirical evidence for the effectiveness of a particular intervention is not the same as evidence for ineffectiveness. In addition, and of particular relevance in mental health,

evidence-based treatments are often delivered within the context of an overall treatment programme including a range of activities, the purpose of which may be to help engage the person and provide an appropriate context for the delivery of specific interventions. It is important to maintain and enhance the service context in which these interventions are delivered, otherwise the specific benefits of effective interventions will be lost. Indeed, the importance of organising care in order to support and encourage a good therapeutic relationship is at times as important as the specific treatments offered.

1.1.3 Why develop national guidelines?

The National Institute for Health and Care Excellence (NICE) was established as a Special Health Authority for England and Wales in 1999, with a remit to provide a single source of authoritative and reliable guidance for service users, professionals and the public. NICE guidance aims to improve standards of care, diminish unacceptable variations in the provision and quality of care across the NHS, and ensure that the health service is person-centred. All guidance is developed in a transparent and collaborative manner, using the best available evidence and involving all relevant stakeholders.

NICE generates guidance in a number of different ways, three of which are relevant here. First, national guidance is produced by the Technology Appraisal Committee to give robust advice about a particular treatment, intervention, procedure or other health technology. Second, NICE commissions public health intervention guidance focused on types of activity (interventions) that help to reduce people's risk of developing a disease or condition, or help to promote or maintain a healthy lifestyle. Third, NICE commissions the production of national clinical guidelines focused upon the overall treatment and management of a specific condition. To enable this latter development, NICE has established four National Collaborating Centres in conjunction with a range of professional organisations involved in healthcare.

1.1.4 From national clinical guidelines to local protocols

Once a national guideline has been published and disseminated, local healthcare groups will be expected to produce a plan and identify resources for implementation, along with appropriate timetables. Subsequently, a multidisciplinary group involving commissioners of healthcare, primary care and specialist mental health professionals, service users and carers should undertake the translation of the implementation plan into local protocols, taking into account both the recommendations set out in this guideline and the priorities in the National Service Framework for Mental Health (Department of Health, 1999) and related documentation. The nature and pace of the local plan will reflect local healthcare needs and the nature of existing services; full implementation may take a considerable time, especially where substantial training needs are identified.

1.1.5 Auditing the implementation of clinical guidelines

This guideline identifies key areas of clinical practice and service delivery for local and national audit. Although the generation of audit standards is an important and necessary step in the implementation of this guidance, a more broadly-based implementation strategy will be developed. Nevertheless, it should be noted that the Care Quality Commission in England, and the Healthcare Inspectorate Wales, will monitor the extent to which commissioners and providers of health and social care and Health Authorities have implemented these guidelines.

1.2 THE NATIONAL VIOLENCE AND AGGRESSION GUIDELINE

1.2.1 Who has developed this guideline?

This guideline has been commissioned by NICE and developed within the National Collaborating Centre for Mental Health (NCCMH). The NCCMH is a collaboration of the professional organisations involved in the field of mental health, national service user and carer organisations, a number of academic institutions and NICE. The NCCMH is funded by NICE and is led by a partnership between the Royal College of Psychiatrists and the British Psychological Society's Centre for Outcomes Research and Effectiveness, based at University College London.

The GDG was convened by the NCCMH and supported by funding from NICE. The GDG included people with mental health problems who have personally experienced management of violence or aggression, carers, and professionals from psychiatry, clinical psychology, general practice, nursing, forensic mental health, psychiatric pharmacy, the police force, social care and the private and voluntary sectors.

Staff from the NCCMH provided leadership and support throughout the process of guideline development, undertaking systematic searches, information retrieval, appraisal and systematic review of the evidence. Members of the GDG received training in the process of guideline development from NCCMH staff, and the service users and carers received training and support from the NICE Public Involvement Programme. The NICE Guidelines Technical Adviser provided advice and assistance regarding aspects of the guideline development process.

All GDG members made formal declarations of interest at the outset, which were updated at every GDG meeting. The GDG met a total of 13 times throughout the process of guideline development. The GDG was supported by the NCCMH technical team, with additional expert advice from special advisers where needed. The group oversaw the production and synthesis of research evidence before presentation. All statements and recommendations in this guideline have been generated and agreed by the whole GDG.

1.2.2 For whom is this guideline intended?

This guideline will be relevant for adults, children and young people who have a mental health problems and who are violent or aggressive within health, mental health and community settings. The guideline covers the care provided by primary, community, secondary, tertiary and other healthcare professionals who have direct contact with, and make decisions concerning the care of adults, children and young people who are violent or aggressive.

The guideline will also be relevant to the work, but will not cover the practice, of those in:

- occupational health services
- social services
- the independent sector.

1.2.3 Specific aims of this guideline

The guideline makes recommendations for the management of violence and aggression. It aims to:

- improve access and engagement with treatment and services for people with a mental health problem who are violent or aggressive
- evaluate the role of specific psychological, psychosocial and pharmacological interventions in the treatment of violence and aggression
- evaluate the role of psychological and psychosocial interventions in combination with pharmacological interventions in the treatment of violence and aggression
- evaluate the role of specific service-level interventions for people with mental health problems who are violent or aggressive
- integrate the above to provide best-practice advice on the care of individuals throughout the course of their treatment
- promote the implementation of best clinical practice through the development of recommendations tailored to the requirements of the NHS in England and Wales.

1.2.4 The structure of this guideline

The guideline is divided into chapters, each covering a set of related topics. The first three chapters provide a general introduction to guidelines, an introduction to the topic of violence and aggression and to the methods used to develop them. Chapter 4 to Chapter 6 provide the evidence that underpins the recommendations about the short-term management of violence and aggression in people with mental health problems. Chapter 7 provides the evidence regarding special considerations for children and young people.

Each evidence chapter begins with a general introduction to the topic that sets the recommendations in context. This is followed by information about the review

protocols for the reviews conducted for the topic of each chapter. This is followed by subsections for each topic/setting. Within subsections, there is an introduction, information about studies considered for the review, and the clinical and health economic evidence presented to the GDG. Each chapter ends with a section linking the evidence to the recommendations, and a section for the relevant recommendations. Full details about the included studies can be found in Appendix 12 and Appendix 13. Where meta-analyses were conducted, the data are presented using forest plots in Appendices 15a and 15b. Related GRADE tables can be found in Appendix 14. Health economic evidence tables and GRADE profiles are presented in Appendix 18 and Appendix 19 respectively.

In the event that amendments or minor updates need to be made to the guideline, please check the NCCMH website (nccmh.org.uk) where these will be listed and a corrected PDF file available to download.

2 INTRODUCTION

2.1 THE NEED FOR A VIOLENCE AND AGGRESSION GUIDELINE

The need for a guideline focused on the short-term management of violence and aggression in mental health, health and community settings arises because violence and aggression are relatively common and have serious consequences in such settings (Bourn et al., 2003; Flood et al., 2008) and their prevention and management are complex tasks, because their manifestation will depend on a mix of intrinsic and extrinsic factors as well as the setting and context in which it occurs.

The intrinsic factors are a combination of personality characteristics, current intense mental distress, and problems in dealing with anger. The extrinsic factors are more varied, including the physical and social settings where violence and aggression occur, the attitudes of those who are violent and aggressive, characteristics of the victims, the experience and training of health and social professionals and the perceived risk of danger to others. Understanding how such variable contextual factors interact with historical behaviour in the aetiology of violence and aggression is important in informing evidence-based approaches to the prevention of violence and aggression that would otherwise emerge and also in the management of violence and aggression that has already occurred or is still in progress (Dack et al., 2013). In preparing this guideline, the guideline development group was also aware of a number of preconceptions regarding the perceived relative and absolute dangerousness of certain groups of service users, particularly those with severe mental illness, such as psychotic disorders (Walsh et al., 2002) . It is therefore particularly important to distinguish from the outset between the 'problem' of violence and aggression, and the care of those often distressed individuals who may exhibit violent or aggressive behaviour.

In the NHS there are currently several general policies that are difficult to integrate because of variability in the contexts within which violence and aggression may emerge. While the management of violence and aggression is a core component of criminal justice systems, it has not generally been at the heart of systems for health and social care, which have instead tended to emphasise 'zero tolerance' approaches (Bourn et al., 2003). This approach is anomalous because the impact of violence and aggression in mental health, health and community settings is significant and diverse, adversely affecting the health and safety of service users, carers and staff (NICE, 2005). Critically, the management of violence and aggression may itself be hazardous to those exhibiting violent or aggressive behaviour and accentuate risks to their health and safety (Nissen et al., 2013).

The consequences of violence and aggression in mental health, health and community settings are not confined to the immediate environment but have an impact on the wider health and social care economy (for example, costs of secure care for service users), and the economy in general (for example, sickness absence for

staff; Flood et al., 2008). Incidences of violence and aggression may also affect the perception by staff of services and service users in a manner that has a strong negative impact on the overall experience of care (De Benedictis et al., 2011).

If imminent violence is anticipated its overt manifestations maybe avoided and non-restrictive interventions suffice. But complete avoidance of violence is impossible and so a graded set of preferably evidence-based interventions is needed to prevent minor violence from escalating into major violence. For recommendations about interventions, NICE guidelines rely primarily on the results of randomised controlled trials (RCTs) in providing the underpinning evidence. However, because of the risks associated with severe violence it is often not possible to carry out RCTs, and although there have been significant developments in this field since the previous guideline was published in 2005, it is likely that many recommendations will be based on expert opinion of the GDG.

2.2 DEFINITIONS OF VIOLENCE AND AGGRESSION

There have been almost as many definitions of violence and aggression as authors who have written on the subject. Definitions of violence and aggression usually include some combination of the following elements: an expression of energy which may be goal directed; an immoral, repulsive and inappropriate behaviour; the intention to harm, damage or hurt another person physically or psychologically; the intention to dominate others; the experience and expression of anger; defensive and protective behaviour; verbal abuse, derogatory talk, threats or nonverbal gestures expressing the same; the instrumental use of such threats to acquire some desired goal; damage to objects or the environment from vandalism through to smashing of windows, furniture and so on; attempting to or successfully physically injuring or killing another person with or without the use of weapons, or forcing another to capitulate to or acquiesce in undesirable actions or situations through the use of force; and inappropriate, unwanted or rejected sexual display or contact.

So great are the number of definitions in circulation that they have been combined into a rating scale to measure the Perception of Aggression (Jansen et al 1997) as held by different people. Factor analysis of this scale, based on 32 definitions of aggression, shows that the concept comprises two fundamental elements, a positive perception emphasising healthy, normal protective aggression, and a negative perception of aggression as undesirable and dysfunctional.

Another way to approach the definition is to inspect the contents of the most well-used research instruments and scales that have been used to measure these behaviours. The Overt Aggression Scale (OAS) (Yudofsky et al., 1986) and its derivatives (Sorgi et al., 1991) are used to record aggressive incidents and include: verbal aggression ranging from angry loud shouts and noises through to clear threats; physical aggression against objects ranging from door slamming and making a mess through to fire setting and throwing objects dangerously; and physical aggression against other people from threatening gestures through to attacking another person causing severe physical injury. Perhaps more controversially the

OAS and many other such scales include self-harm and suicide attempts as aggressive behaviours against the self. The Social Dysfunction and Aggression Scale (Wistedt et al., 1990) is used to assess the total level of aggression retrospectively, and while including verbal aggression, aggression towards objects and others, it also incorporates irritability, lack of cooperation, discontentment, provocative behaviour, and self-harm. Because there is a separate guideline on self-harm, this is excluded from the definition of violence and aggression used in this guideline.

For the purposes of this guideline, violence and aggression refer to a range of behaviours or actions that can result in harm, hurt or injury to another person, regardless of whether the violence or aggression is behaviourally or verbally expressed, physical harm is sustained or the intention is clear.

2.3 INCIDENCE AND PREVALENCE OF VIOLENCE AND AGGRESSION IN DIFFERENT SETTINGS

Violence and aggression present a serious problem within the NHS to both service users and staff. Exposure to aggression in the healthcare workplace is reportedly common, constituting 25% of all workplace violence (Di Martino, 2003; Iennaco et al., 2013).

More than 60,000 physical assaults were annually reported against NHS staff across the UK (NHS Protect, 2013), with the absolute rate steadily increasing since 2011-2012 (59,744) and 2010-2011 (57,830). Of these assaults, 43,699 were in mental health or learning disability settings; 1,628 involved primary care staff and 16,475 were targeted at acute hospital staff. More than 25% occurred in hospitals managed by acute trusts, including emergency departments (NHS Protect 2013).

While some figures are collected and national audits conducted across different settings, the main focus has tended to be upon inpatient mental health settings and emergency departments. Information from primary care settings, for example, is relatively scarce; one review found only 14 of 113 studies referred to violence in community settings.

In terms of inpatient literature, one review (Bowers et al., 2011b) of 424 international studies reported that the overall incidence of violence by service users in inpatient psychiatric hospitals was 32.4%. Violent incidents across forensic settings were found to be consistently higher. The review team concluded that forensic inpatients were responsible for a higher proportion of violent incidents; but given that acute wards admit a far higher number of people over time, on balance the risk of violence is actually greater in acute environments.

With regard to forensic settings, 2,137 incidents involving 56.4% of service users were reported by a recent survey of a large independent secure care facility. This rate was greater in medium- as opposed to low-secure services (Dickens et al., 2013). In a high-secure setting, Uppal and McMurran (2009) reported 3,565 violent

incidents over a 16-month period in just under 400 service users. In both surveys, staff and service users were equally as likely to be the victim of these assaults.

Emergency department staff were also reported to have a high exposure to aggression, particularly verbal aggression (Gates et al., 2006; Winstanley & Whittington, 2004). In long-term and older people's settings the figures for aggression were also found to be higher than general medical and surgical wards (Chapman et al., 2009).

Stathopoulou (2007) suggests that workplace violence affects every country and every healthcare setting. According to international data, nearly 4% of the total employee population has reported that they have experienced physical violence. The possibility of nurses being exposed to violence is three times higher than that of any other professional group (International Labor Office, 2002). This was reflected in a National Audit of Violence in the UK, which reported that 44% of clinical staff overall and 72% of nursing staff had been, or experienced feeling, unsafe at work (Royal College of Psychiatrists, 2007). The rates of psychiatrists being or feeling unsafe are reportedly lower than for nurses (Bowers et al., 2011c).

In light of these figures it is important to identify the causative factors that may contribute to these including care failures. This guideline aims to reduce such figures by suggesting best practice and preventative measures.

2.4 THE RELATIONSHIP BETWEEN MENTAL HEALTH PROBLEMS AND VIOLENCE AND AGGRESSION

Despite public perception that mental health problems, in particular severe mental illness (such as bipolar disorder and schizophrenia), and violence are associated (see Section 2.5), the research evidence to support such a relationship is mixed and most people with a mental health problem are never violent, and are more likely to be victims of crime than perpetrators (Pettit et al., 203). However, a small proportion are and consensus has emerged among researchers that there is a consistent, albeit modest, positive association between mental health problems and violence. The extent to which mental health problems contribute to violent behaviour and the relative importance of psychiatric morbidity compared with other risk factors and service-related failings remain areas of controversial ongoing research.

In order to address the question as to whether there is a link between mental health problems and violence, different research designs have been employed, including cross-sectional studies investigating the prevalence of violence in those with mental health problems and, conversely, rates of mental health problems in those who have committed acts of violence, for example, offenders. While such studies have described a link between mental health problems and violence (Shaw et al., 2006), they are prone to selection bias as they tend to sample individuals detained in criminal justice or psychiatric settings. Some studies have been flawed by their lack of attention to potential confounding factors, such as psychosocial factors, comorbidity, substance misuse and so on. Prospective epidemiological studies of

community samples following individuals for extended periods of time to identify those who will become violent and/or develop a mental health problem avoid some of these issues. However, other challenges in the interpretation of findings remain, for example the use of different methods to assess rates of violence, such as self-report, official criminal records and so on, each posing risks of misrepresenting the true prevalence of violence.

Until the 1980s there was a general view that mental health problems and violence were unrelated, that is that those with a mental health problem are no more likely to be violent than healthy individuals, and that the criminogenic factors relevant to violence risk are the same in people with a mental health problem as in healthy individuals (Häfner & Böker, 1973). Several large-scale studies in the 1980s and 1990s have resulted in a reappraisal and modification of this view.

The Epidemiological Catchment Area (ECA) study (Swanson, 1994) comprised a community sample of over 17,000 participants in five large US cities though only about 7,000 subjects contributed to the data on violence. Individuals were asked to report any acts of violence they had committed within the previous year and in their lifetime. The study found a lifetime prevalence of violence in the non-psychiatric population of 7.3%. In those with schizophrenia or major affective disorders this rate was more than doubled at 16.1% but in those with substance-use disorders it rose further to 35% and those with a substance-use disorder and comorbid mental health problem had a lifetime prevalence of violence of 43.6%. Several early Scandinavian birth cohort studies (Hodgins, 1992) have identified a higher likelihood of having committed a violent crime in those with severe mental illness compared with those with no such diagnosis. A recent longitudinal Swedish study linking national registers of hospital admissions and criminal convictions over 33 years found that individuals with schizophrenia and bipolar disorder were more likely to commit violent acts than matched controls. In the period 1973–2006, 8.5% of individuals with schizophrenia without a substance-use disorder and 5.1% of the matched control group were convicted of at least one violent crime; for bipolar disorder these figures were 4.9% and 3.4% respectively. However, those with dual diagnoses showed rates of 27.6% and 21.3% of violent offending for people with schizophrenia and bipolar disorder, respectively.

One of the most influential studies to disentangle some of the complex relationships between mental health problems and other risk factors for violence, in particular substance misuse, has been the MacArthur Violence Risk Assessment Study (Steadman et al., 1998). This follow-up study of over 1000 people discharged from psychiatric care used self-report triangulated with information from carers and criminal records to assess violence rates. The study found no significant difference between the prevalence of violence in patients and others living in the same neighbourhood when only taking those with no substance misuse into account. Substance misuse raised the rates of violence in people with mental health problems as well as healthy individuals but disproportionately so in the patient group. Elbogen and Johnson (2009) also argued that a mental health problem on its own

does not increase violence risk. They evaluated data on about 35,000 individuals who were part of the US National Epidemiological Survey on Alcohol and Related Conditions. Participants were interviewed in two waves in 2001-2003 and 2004-2005 to identify factors that predicted violence in the time between interviews. The researchers found that the incidence of violence was slightly higher in those with a mental health problem but significant only in those with a comorbid substance-use disorder. The researchers concluded that historical, dispositional and contextual factors were more important in determining the risk of future violence than a mental health problem. However, a later re-analysis of these data (Van Dorn et al., 2012), using different statistical methods and diagnostic categories found that those with severe mental illness were significantly more likely to be violent than those with no illness, regardless of substance misuse.

More recently a number of meta-analyses have been conducted in an attempt to systematically re-assess the evidence and explore the reasons for variations in findings (Douglas et al., 2009; Fazel et al., 2009; Fazel et al., 2010). These studies, drawing on a large number of primary studies (20 and 204 for schizophrenia, nine for bipolar disorder), concluded that schizophrenia, other psychoses and bipolar disorder are associated with violence. However, large variations were identified with odds ratios between 1 and 7 for schizophrenia in males and between 4 and 27 for females. For bipolar disorder, odds ratio estimates ranged from 2 to 9. However, for both disorders a comorbid substance-use disorder increased odds ratios up to three-fold. For bipolar disorder the significant relationship with violence disappeared when controlling for substance misuse. For schizophrenia the relationship weakened but remained, although in those with a history of substance misuse, schizophrenia did not contribute any additional risk compared with substance misuse alone.

Determining which symptoms of mental health problems drive the increased risk of violence requires further exploration. In the early 1990s researchers first identified a set of symptoms, called threat/control-override (TCO) symptoms, which seemed to be linked to this risk (Link & Stueve, 1994). TCO symptoms are delusional symptoms that cause the person to feel severely threatened and believe that external forces override their self-control. Further studies of the relationship between TCO symptoms and violence revealed conflicted findings with some but not all studies confirming a relationship. In an attempt to disentangle this issue further, Stompe et al. (2006) examined a sample of 119 offenders with schizophrenia found to be not guilty by reason of insanity and a matched sample of non-offending service users with schizophrenia (n = 105). While they found no significant difference in the prevalence of TCO symptoms between the two groups overall, when only taking into account severe violence, TCO symptoms were associated with this form of violence. It seems therefore that the relationship between TCO symptoms and violence is not a straightforward one and more research is needed to explore this concept further. In the meantime clinicians would be well advised to conduct a comprehensive mental state examination as part of their risk assessment, including TCO symptoms.

In summary, a mental health problem on its own appears to be only a modest predictive factor for violence while other factors, most significantly substance misuse, are more relevant in predicting risk. Because of the low base rates of mental health problems, its actual contribution to violence in the general population is small and the vast majority of violence is carried out by those without a mental health problem.

2.5 SOCIAL ATTITUDES TOWARDS VIOLENCE AND AGGRESSION

There has long been an association in the mind of the public between mental health problems and violence (Monahan, 1992), often bound up with moral and judgmental attitudes, whereby people who have a mental health problem are viewed as being irrational, unpredictable and dangerous and presenting with an increased risk of violence (Blumenthal & Lavender, 2000; Butler & Drakeford, 2003; Petch, 2001).

While there may be certain characteristics of some people with a mental health problem that may increase the risk of violence or indeed self-harm, as Section 2.4 has outlined the association between mental health problems and violent or aggressive behaviour is not established. One key issue for the public debate is whether violence generated by people with a mental health problem is increasing or not. The *Avoidable Deaths* report from the National Confidential inquiry in 2006, for example, having examined 249 cases of homicide by current or recent service users, found no evidence of an increase in homicides perpetrated by people with a mental health problem over previous periods (University of Manchester, 2014).

However, a perceived association between mental health problems and violence is nevertheless often reinforced by images in the media and other cultural representations. As an example, in September 2013 the Asda supermarket chain advertised a 'Mental patient' Halloween outfit which had an image of a person in a bloodied suit with a meat cleaver covered with blood. Negative media attention caused Asda to withdraw this item. In commenting on this story, Sue Baker of Time for Change on Radio 4's Today Programme on 26 September 2013 stated that many people with mental health problems feel the stigma they experience is as bad, if not worse, than the mental health problem itself, with public attitudes being experienced by some service users as lacking appreciation of their condition, and the effects of it.

The key point from this example is how such an image could have been brought to mind by those creating and marketing such products in the first place. While there are a number of theories about this, 'labelling' and the 'availability heuristic' (the process whereby people assess the frequency or probability of an event by the ease with which instances or occurrences can be brought to mind (Tversky & Kahneman, 1974)) are two mechanisms that can influence negative attitudes and responses towards people with a mental health problem.

Labelling theory in sociology proposes that labelling occurs when certain members of society interpret certain behaviours as deviant and then attach this label to individuals (Becker, 1963) as a means to identify and control such behaviour. Labelling theory examines who applies what label to whom, why, and what the effects are. The consequences of someone being labelled as having a propensity to violence just because they have a mental health problem can be negative and far-reaching. Labelling results in people having fears engendered by their attributions towards a person, leading them to jump to the conclusion that the person is highly likely to be violent, with no other knowledge of them other than the diagnosis. This in turn will affect their attitudes to, and communications with, people with mental health problems.

Another possible explanation for the negative attitudes towards those with a mental health problem is the 'availability heuristic' (Middleton et al., 1999). This affects our attributions towards a particular idea or group of people; in this case, reporting in the media that draws attention to violence and murders carried out by people with mental health problems, often in a gory and sensationalist way, results in the attribution of violent behaviour to those with a mental health problem. This discourse was played out in the case of Philip Simelane, who murdered a 16 year old female stranger on a bus. The headline in the *Daily Mail* on the 3 October 2013 was: *"Why was schizophrenic who stabbed this girl to death on a bus not having treatment?"* The focus, as here, tends to be on the fact that the person had a mental health problem, implying the murder occurred *because* of the person's mental health problem; other factors that might have been considered if the person had committed the same offence without having a mental health problem do not appear relevant. The more dramatic and easy to visualise the reported event, the more likely it will be contained within such a heuristic, with menacing photographs of 'perpetrators' and 'horror stories' of what they have done. Because of this, for many people, the first thing that often comes to mind about those with a mental health problem is that they are highly likely to be violent. There is much less reporting of other aspects of having a mental health problem, or of people with a mental health problem being more likely to be a victim of violence than a perpetrator, as found by one large-scale study in the USA (Choe et al., 2008).

What is necessary instead is for the reality of the risks to be recognised and taken into account by both the public and professionals in a considered and fair manner, for the sake of all involved.

2.6 PERSONAL CONSEQUENCES OF VIOLENCE AND AGGRESSION FOR THE INDIVIDUAL AND FOR OTHERS

The under-reporting of violence and aggression (Gates et al., 2006; Holmes et al., 2012; National Institute for Social Work, 1999) and the varied effects it may have on those subjected to violence and aggression limits our understanding of the

consequences for the individual. Research into the effects of violence at the individual level has largely been focused on staff. While this is not surprising (because, by and large, staff have conducted the research and published the findings), other areas are less well covered. Other consequences of violence are only spelt out obliquely by research, resulting in limited understanding of the consequences for the individual who is prone to behaving in a violent manner.

The earliest work concerning the effects on staff and others of violence from people with mental health problems was produced by the Department of Health and Social Security (1976) and the Confederation of Health Service Employees (COHSE) (Confederation of Health Service Employees, 1977). The issues raised were in relation to physical violence in inpatient psychiatric units, and the concerns of COHSE were about how their members needed greater recognition for, and protection from, such violence. In social care work in the community, the effects of violence to staff came later in the 1980s (Brown et al., 1986).

Holmes et al. (2012) concluded that the consequences of workplace violence for individuals were far–reaching and included absenteeism related to illness, injury and disability, staff turnover, decreased productivity, decreased satisfaction at work, and decreased staff commitment to work.

Physical injury as a result of assault by a service user can be serious including injuries such as head, back, facial and eye injuries, broken bones, sprains, cuts, grazes and scratches. A review of multiple previous research studies estimated that 26% of violent incidents resulted in mild, 11% in moderate and 6% in serious injuries (Bowers et al., 2011b). A similar review of the psychological impact of violence found by previous research reported that the three most common responses to injury were anger, fear and guilt (self-blame and shame) (Needham et al., 2005). The fear can generalise into avoidance of the service user who has been violent or aggressive (Needham et al., 2005), or all service users, and some victims report persistent ruminations and intrusive thoughts about the incident, with symptoms severe enough to be classified as post-traumatic stress disorder.

Staff in the hospital

On any psychiatric ward a proportion of the staff time is taken up with protecting service users from each other via the identification and protection of the vulnerable, general supervision of the environment, and rapid response to any noise or cry for help, among other strategies. In addition, service users may also become involved in trying to defuse and deal with violence and aggression between service users, and between service users and staff. A proportion of the injuries that occur in staff happen during the breaking up of fights between service users, for example, but staff may also be assaulted unpredictably as service users respond to the symptoms they experience, or as a consequence of confrontations about leaving the ward, medical treatment or other issues (Nicholls et al., 2009). Staff also have to physically intervene to stop service users injuring themselves or trying to leave the ward, sometimes eliciting an aggressive response. Most assaults and aggression against

staff – and by service users on other service users – are thankfully minor, but they can occasionally be severe. Every year several hundred injuries on staff are officially reported to the Health and Safety Executive by psychiatric hospitals as resulting in periods of sickness lasting 5 or more days. As a consequence of physical and/or psychological injuries, staff may leave psychiatry to work elsewhere. Verbal aggression to staff is extremely common and takes the form of abuse, shouting, threats, racism and generalised anger (Stewart & Bowers, 2013). Verbal aggression can have a profound psychological impact (Stone et al., 2010), affect performance and functioning (Uzun, 2003) and is the particular form of aggression that is associated with low staff morale (Bowers et al., 2009; Sprigg et al., 2007).

Staff in the community

Violence and aggression to staff in the community is less well documented and reported. While rates are lower amongst NHS community teams than those experienced by staff in hospital, the consequences are the same when assaults do occur. In England, since the early 1980s, nine social work and social care staff have died as a result of violence from service users. The majority of those killed worked in mental health or child protection. Rates of assault experienced by staff working in supported accommodation run by a range of charities and private companies are unknown.

Personal consequences

Violent behaviour associated with a mental health problem is a criterion for admission to hospital, compulsory admission under the Mental Health Act 1983, transfer or admission into more secure settings such as psychiatric intensive care or forensic services, and the use of severe containment methods such as manual restraint, rapid tranquillisation and seclusion. All things being equal, the violent service user will therefore experience more frequent admissions, more compulsory admissions, to greater security settings, for longer lengths of stay, with more restrictions on their liberty, greater coercion and higher doses of medication. As violent behaviour is a criterion for exclusion from shared accommodation and social activities, the service user who is violent is likely to experience more accommodation instability and change, reduced social networks, social support and be more isolated. Violent service users may have impaired access to mental health services in the community, and for safety reasons home visits may be avoided and all appointments offered at clinics where the backup of other staff is available. Violent behaviour is therefore problematic for the person concerned and may have a negative impact on their quality of life.

Relatives, carers and social networks

Where the risk of violence does exist, it is family members, carers and those in close contact with the individual concerned who are most likely to be injured. Major injuries and deaths are rare, but the number of minor assaults is unknown as they may never be reported to the police or to anyone else. Living with a potentially violent person can lead to the family member or carer becoming severely stressed or developing a mental health problem. Alternatively, if the person concerned is living

independently, relatives may withdraw, cease support or stop visiting if they are regularly faced with abusive and aggressive behaviour.

Other service users

People who share a ward with a potentially violent service user are also at risk of physical and psychological harm. Most aggression is directed at staff that are in positions of power, control access to desirable resources, discharge from the ward and who may impose unwanted treatment. However, living in close proximity with others whose violence is unpredictable coupled with the service user's own psychiatric symptoms does place them at risk. Very occasionally that risk is severe and deaths have been reported. Minor assaults and injuries are regrettably more common, and approximately 20% of violent incidents on psychiatric wards are between service users (Daffern et al., 2006; Foster et al., 2007). The research literature tends to focus on consequences for staff in terms of physical injury and psychological distress, with service user outcomes seldom mentioned or studied. However, the consequences of an assault on people who already have a mental health problem may be considered to be negative, possibly hindering their recovery. It is known that inpatients are at times fearful and frightened of each other, leading to a range of avoidant behaviours to steer clear of other service users considered to have violent propensities (Quirk et al., 2004). Bullying between service users has also been reported (Ireland, 2006) as has sexual aggression. The move to single sex wards in UK psychiatry in recent years has been largely in response to a desire to protect female service users from unwanted or aggressive sexual advances from male service users (Department of Health, 2003). The consequences of unwanted sexual advances, harassment, bullying or assault are considered to impede the treatment and recovery of those service users subjected to it, besides being extremely unpleasant in its own right.

Societal

Violent behaviour by people with a mental health problem is rare and only carried out by a small minority. However, it looms large in the public estimation (Thornicroft et al., 2007), adding to the stigma, fear and exclusion faced by this population. As such the impact of violent behaviours is far bigger than the actual scope of the problem, as it corrodes trust between people and makes it more difficult for the mentally ill to reveal their situation and to seek or obtain social support from others.

Dealing with the consequences

From the above discussion, it can be seen that violence and aggression have consequences for staff, service users, and their families, carers and significant others, and the relationships between these people.

The consequences of violence and aggression cannot be dealt with unless incidents are reported, and those reporting them feel they will benefit from so reporting. Staff working in health and social care may not report incidents because they believe that

they will not be dealt with sympathetically and are worried that they will be viewed negatively by colleagues and managers (Holmes et al., 2012).

Harris and Leather (2011) found in their research with social work and social care staff that as exposure to service user violence increased, so did reporting of stress symptoms, and reduction in job satisfaction. Harris and Leather also found that fear or feeling vulnerable was an important consequence of exposure to violence and aggression; the same consequences of fear and feeling vulnerable can also occur in service users.

Ilkiw-Lavalle and Grenyer (2003), in a study on differences between service user and staff perceptions of aggression in mental health units, found that staff often perceived service users' illness as the cause of aggression, while service users perceived illness, interpersonal and environmental factors as having equal responsibility for their aggression. Such attributions from staff are important in how they will respond to incidents, and this will therefore affect their need for support post incident in order for them to deal effectively and fairly with the consequences for themselves, service users, staff, and others.

Shapland et al. (1985) found that there were special considerations for victims of violence at work. Where staff could depend on supportive work colleagues and managers, and were employed by an organization which proactively offered support, staff were more able to overcome the negative effects of violence at work.

The need for support will depend upon several factors:

- The nature of the emotional and/or physical effects on the individual victim
- The effects on professional and/or personal life for the individual victim (see Holmes et al, 2012)
- How the victim's views about the nature and causes of the violence might affect their approaches to that service users, and possibly other service users
- The individuals' experiences of support in dealing with the consequences
- Service users also have a need for agencies and staff groups to recognise that they too are affected, and take measures to make them be, and feel safe (Holmes et al, 2012).

2.7 THE CURRENT MANAGEMENT OF VIOLENCE AND AGGRESSION IN THE NHS

Given the risks posed by violent behaviour in mental health, health and community settings, all trusts have policies for its prevention and management. These policies can be wide ranging, and are often directed at other primary goals, but also have secondary beneficial impacts on reduction of violent incident rates, reductions in their severity when they do occur, and amelioration of their outcomes. For example, prompt and effective psychiatric treatment resolves acute symptoms, and as symptoms can be linked to violent behaviour, this constitutes one route via which

incidents are reduced. Within forensic settings specific psychotherapies may be available to help people reduce their own capacity to act in a violent way. Buildings and wards are sometimes designed with the possibility of violent behaviour in mind. So, in many areas, and especially in forensic or psychiatric intensive care settings, buildings are made out of stronger materials, doors and furniture may be more robustly constructed, windows are fitted with stronger or safety glass, living areas are designed to maximise observation and supervision so that violent incidents are quickly identified and responded to. Service users are searched for weapons on admission to hospital, and a number of items that could be used as weapons are banned from being brought onto the wards. As an aid to observation CCTV may be fitted in public areas, and a variety of alarm systems may be fitted, from wall mounted buttons to personal alarms for staff that quickly identify where an incident is taking place. These measures are accompanied by policies dictating their use and procedures as to who responds and takes control. In most psychiatric hospitals, if weapons are involved or the situation is beyond the capacity of staff to manage, the police may be called to manage the situation.

Within psychiatric hospitals, the main professional group that manages violent incidents (and who are most likely to be victims) are mental health nurses and health care assistants. The basic training of mental health nurses includes instruction on the causes of aggression, good communication skills and non-confrontational practice. During their training, nurses learn how to quickly establish and strengthen good relationships with service users, and these act as a safeguard against violence to staff, or aid in the de-escalation and management of agitated and violent behaviour. De-escalation or defusion refers to talking with an angry or agitated service user in such a way that violence is averted and the person regains a sense of calm and self-control. Most potential occurrences of violence are averted in this way, especially when there is some warning that they are about to occur, such as raised voices and abusive language. Of course some instances of violent attack occur suddenly and apparently 'out of the blue', and these are more difficult to prevent. All NHS psychiatric services provide additional training to their staff, especially those working in inpatient areas, in the prevention and management of violence. Such training typically (but not always): consists of five days with subsequent annual refresher courses; contains instruction on de-escalation, breakaway techniques and manual restraint; and is provided by an in house training team. Where such training is commissioned from external private providers, a plethora of courses exists with different content. In house courses are often linked to private providers via 'train the trainer' schemes. There are no detailed national guidelines on the content of violence management courses or on the specific physical techniques which are taught, and there are no standards, quality control processes or accreditation procedures for the courses concerned, whether provided in house or by external providers.

If an actively violent service user cannot be verbally calmed and is judged likely to imminently assault another, they will be manually restrained by suitably trained nurses and health care assistants. Such manual restraint is aimed at securely holding the person so that they cannot strike out or hurt others, so that they are not injured

themselves, and so that attempts to verbally engage with them can continue. Such holds can be slowly released when the person is emotionally calmed and can negotiate about their behaviour. If a state of calm cannot be immediately achieved, sedating medication may be offered by mouth or given by injection without the person's consent (rapid tranquillisation). If these efforts fail the service user may be secluded in a specially constructed room, although not all hospitals have these. Additionally or alternatively, as the person becomes calmer, they may be asked to stay away from other service users by remaining in their own bedroom or other area (but without the door being locked), or be placed on some form of special psychiatric observation to facilitate early intervention if the violent behaviour seems likely to recur. Further changes to the person's regular medication regime may occur following a violent incident in an effort to prevent recurrence. Debriefing of the staff team and of the service user involved may also occur in an effort to learn from the incident and plan so as to prevent the chance of a repetition. All these procedures are variously guided by a trust's policies and training provision for staff.

It is important to note that the nature and extent to which violence and aggression is experienced in the NHS varies considerably with the setting. The experience and hence the management of such incidents will differ between community and hospital environments. The interface with non-NHS agencies (such as the police, the courts and social services) has a role to play, and these links are well developed in some settings. Within the NHS hospital setting, there are particular areas which are better developed (by virtue of their philosophy of care, skills mix and clinical experience) to therapeutically manage acute or sustained risk of violence and aggression in the context of mental or physical health problem. These include emergency departments linked to general medical hospitals, psychiatric intensive care units within the acute inpatient mental health care pathway and forensic psychiatric inpatient facilities.

2.8 PREDICTING THE RISK OF VIOLENCE AND AGGRESSION AND THE CULTURE OF THE NHS

The prediction of the risk of violence and aggression by service users in mental health, heath and community settings is challenging in a number of ways. The key challenges include the lack of definition of what is being predicted, over what time-frame and in which context. Intuitively, the clinical tools required to predict imminent or short-term violence and aggression would be different in some degree to those utilised in the prediction of medium to longer-term violence or aggression. Furthermore, the heterogeneity in clinical populations where violence and aggression is exhibited seriously hinders the reliability and validity of specific clinical tools; there is no broad clinical assessment tool which can be applied in all circumstances where violence and aggression needs to be predicted.

Clinicians in the healthcare system have a duty to protect service users (both as potential perpetrators of violence and aggression, and as the victims of such acts), to protect healthcare and other professionals (which includes the attending clinician's personal safety) and to protect the wider public. Such duties are explicit in most

professional codes of practice and are most apparent in the codes which regulate the practice of medical doctors and nursing staff.

In this guidance, the prediction of violence and aggression relates to that which is felt to be imminent or occurring in the very short-term, that is within minutes or up to 72 hours. The old truths would still seem to apply in that the fundamentals of predicting the risk of violence and aggression are driven by the best available psychiatric assessment of the person. Assessment should include a psychiatric history, a mental state examination and an assessment of physical health, leading to clinical and risk formulations. Such an assessment will usually be challenging in the acute clinical scenarios which present with violence and aggression, and much of the clinical and risk information may not be readily available at the outset.

The assessment is an iterative and dynamic process which should lead to responsive changes in the clinical and risk management plan. Particular significance is attached to a past history of violence and aggression, as past behaviour is a guide to future presentation. The impact of mental health problems, physical health problems, personality disorders, substance-use disorders, social impairment and cultural factors, should be considered within the health or social care framework to understand the aetiology of the person's violent or aggressive presentation.

The approach described in the preceding paragraph is essentially that of Unstructured Clinical Assessment. Although it suffers with low reliability, it is operator dependent and one imagines its reliability and validity is improved by more experienced and skilled clinicians, there is some evidence to support the notion that in the case of predicting inpatient aggression in acutely unwell service users, short-term clinical assessment can be useful (McNiel & Binder, 1991; McNiel & Binder, 1995).

There are two other types of violence-related risk assessment: Actuarial Risk Assessments and Structured Clinical Judgements.

Actuarial Risk Assessments use quantifiable predictor variables which are based on empirical research (often derived of an actual patient dataset, which ultimately limits their generalisability); they aim to provide a quantifiable value to the outcome in question. For the purposes of this discussion, the outcome in question would be the probability of violence or aggression occurring in the short-term.

Structured Clinical Judgements are an amalgam of the clinical assessment approach and the actuarial approach. Risk factors derived from a broad literature review are rated by the assessor using multiple sources of clinical information. Although there is no gold standard currently available, it is likely that the Structured Clinical Judgement approach offers the most appropriate paradigm for the development of a practical, reliable and valid assessment tool to predict violence and aggression in the short-term.

A number of violence-related risk assessment tools are currently available and some are in general use in specified clinical settings. In no particular order these include: the Violence Risk Appraisal Guide (VRAG) (Quinsey et al., 2005); Historical Clinical and Risk Management – 20 items (HCR-20) (Douglas et al., 2013); Violence Screening Checklist (VSC) (McNiel & Binder, 1994); Iterative Classification Tree (ICT) (Monahan et al., 2000); Psychopathy Check List – Revised (PCL-R) (Hare, 2003); Overt Aggression Scale (OAS) (Yudofsky et al., 1986); Modified Overt Aggression Scale (MOAS) (Sorgi et al., 1991); Overt Aggression Scale – Modified (OAS-M) (Coccaro et al., 1991); Brøset Violence Checklist (BVC) (Almvik & Woods, 2000); Dynamic Appraisal of Situational Aggression (DASA: Ogloff & Daffern, 2006); Classification of Violence Risk (COVR) (Monahan et al., 2006;); Violence Risk – 10 items (V-RISK-10) (Roaldset et al., 2011; http://forensic-psychiatry.no/volence_risk/index.html); Short-Term Assessment of Risk and Treatability (START) (Nicholls et al., 2006; Webster et al., 2006, 2009); Staff Observation Aggression Rating Scale – Revised (SOAS-R) (Nijman et al., 1999); and the Nurse Observed Illness Intensity Scale (NOIIS) (Bowers et al., 2011).

Current clinical wisdom is that many of the available risk assessment instruments which predict future violence are broadly similar in their somewhat moderate predictive efficacies (Yang et al., 2010). The risk assessment tools listed above cover a wide variety of clinical settings, and most progress has probably been made in the area of forensic psychiatry. The majority of the risk assessment tools focus on medium to long-term risk. A few have some emerging evidence-base for their applicability to the prediction of violence and aggression in the short-term and in non-forensic settings.

Any method which is to predict violence and aggression in the healthcare setting needs to look further than just patient-related factors. Patient-related factors are often well covered in clinical assessments and in violence-related risk assessment tools. Other areas requiring consideration include: staff-related factors (staff experience and training, role clarity); service-related factors (staff-patient ratios; the physical fabric of the ward, the philosophy of care and the 'atmosphere' of the clinical setting, multidisciplinary and multiagency input); and organisational factors (the culture of the organisation shaping the engagement philosophy between service users and staff). These non-patient-related factors are just a few examples, but they serve to illustrate the multitude of factors which can potentially shape the expression of violence and aggression. In terms of prediction, with its aim to better manage and reduce violence and aggression, these areas are probably of equal relevance to the direct patient-related factors.

The background literature is equivocal and the prediction of violence and aggression is an area of ongoing debate and research. It continues to be the case that little progress has been made towards adequately explaining the problem of aggression and violence in any healthcare sector (Winstanley & Whittington, 2004). Good clinical teams will make ongoing clinical and risk assessments (with or without the benefit of a violence-related risk assessment tool), and have quite a low threshold

when considering a service user to be at high risk of violence or aggression. The low threshold usually leads to the use of clinical measures to prevent or manage the behaviour in the least restrictive and most therapeutic manner possible. Therefore, one could argue that good clinical management should lead to false positive predictions of violence and aggression (Steinert , 2006, pp. 118–119). With this in mind, the very purpose of risk assessment can be brought into question. Is the purpose to predict violence or to intervene to prevent violence? The two outcomes would seem to require different instruments; the latter would be based in more of a formulation approach to identify relevant factors which may incite violence in a particular service user, rather than estimate how likely that person is to be violent in the future. Clinicians may be well advised to consider a formulation-based approach which facilitates the prevention and management of aggression and violence, as opposed to an over-reliance on purely predictive methods.

2.9 THE ECONOMIC COSTS OF VIOLENCE AND AGGRESSION TO THE NHS

Due to the complex determinants and broad manifestations of violence and aggression, its full economic impact is difficult to measure and, to date, no formal attempt has been made to quantify this for the UK.

Violence and aggression in the context of mental health issues is associated with a range of negative consequences, which may be broadly grouped into costs to individuals and costs to the UK health service. Incidents of violence and aggression may result in physical pain, stress, loss of confidence and other psychological problems. These personal costs accrue to the individuals at the centre of the episode, to other staff and fellow service users.

The wider health and social care system incurs the costs associated with secure care for service users, staff absence, legal services, extra training costs, NHS trust liabilities, compensation, ill-health retirements, staff replacement costs, counselling and a myriad of retention and recruitment issues.

Combining data from the NHS protect physical assault statistics with health body declarations of staff, NHS protect (NHS Protect, 2009; NHS Protect, 2010; NHS Protect, 2011; NHS Protect, 2012; NHS Protect, 2013) reported that there were an average of 188 assaults per 1000 staff per year in mental health/learning disability trusts. There was a wide variation between the numbers of reported incidents in the different sectors with an average of 36 assaults per 1000 staff reported in the ambulance sector, 19 per 1000 staff reported in the acute sector and 16 per 1000 in the community care sector.

Furthermore, the same report suggested that incidents of assaults across all sectors may be increasing with 44.4 incidents per 1000 staff in 2008/09 rising to 53 incidents per 1000 in 2012/13. This trend has the opposite direction in mental health and learning disabilities trusts with incidents falling from 193.9 per 1000 to 188 per 1000 between the same periods. Apparent trends in this data should be interpreted with

caution as changes in populations, service provision health body amalgamations and reporting culture may all affect published figures.

Another report from the Wales Audit Office (Colman et al., 2005) supports the finding of increased incidents of violence and aggression in mental health services. Between 2003-04, in Wales, most 'generic' incidents of violence took place in mental health settings, with 1,790 such incidents representing 22% of all violent incidents in the country during that period. Incidents of violence and aggression also varied according to service area within mental health services. Adult mental health services were the location of the greatest number of serious incidents reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995. In addition, some of these Welsh trusts qualitatively reported that violence and aggression had an impact on recruitment and retention in mental health areas. However, they were unable to quantify the number of staff who had left due to violence, nor the cost of replacing them.

In order to estimate the health care costs associated with incidents of violence, Flood and colleagues (Flood et al., 2008) collected six months of incident data from a sample of 136 acute psychiatric wards in England and combined these with end-of-shift reports from nurses in 15 wards to estimate the resource use per violent event. The cost calculation only accounted for the payment of identified staff and medication costs and as such does not observe fixed costs such as specialised facilities. The outputs of this analysis are estimates for the mean cost of violent incidents for individual psychiatric wards and for England as a whole. According to these authors, the annual cost in England of physical assaults is £5.3 million (2013/2014 prices), of aggression to objects is £3.7 million and of verbal abuse is £11.5 million. The analysis also estimated the costs associated with various containment strategies. In dealing with incidents, the use of general 'as required' medication was estimated to cost £8.6 million annually, with intramuscular medication in particular costing a further £3.9 million. Furthermore, transferring care to psychiatric intensive care services was estimated to cost £1.1 million and seclusion £2.2 million per year. Intermittent observation was estimated to cost £49.3 million and constant special observation £38.5 million per year. Manual restraint was estimated to cost £6.1 million and time out £1.3 million per year.

In terms of individual psychiatric wards, the work of Flood et al. (2008) estimates that approximately £270,000 of nursing cost per ward per year is associated with the management of violence and aggression. That is, more than one third of the estimated total nursing cost (£736,000) per ward per year is connected with managing violence and aggression.

Although the currently available estimates of the costs of violence and aggression suggest substantial impact, these estimates remain inherently conservative due to the difficulty of measuring system-wide costs associated with incidents of violence and aggression. That the true costs are likely to be larger still emphasises the need to ensure efficient use of health and social care resources to deal with incidents of

violence and aggression in a manner that maximises safety, quality and value for service users, carers and society in general.

3 METHODS USED TO DEVELOP THIS GUIDELINE

3.1 OVERVIEW

The development of this guideline followed *The Guidelines Manual* (NICE, 2012). A team of health and social care professionals, a police representative, lay representatives and technical experts known as the Guideline Development Group (GDG), with support from the NCCMH staff, undertook the development of a person-centred, evidence-based guideline. There are seven basic steps in the process of developing a guideline:

1. Define the scope, which lays out exactly what will be included (and excluded) in the guidance.
2. Define review questions that cover all areas specified in the scope.
3. Develop a review protocol for each systematic review, specifying the search strategy and method of evidence synthesis for each review question.
4. Synthesise data retrieved, guided by the review protocols.
5. Produce evidence profiles and summaries using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.
6. Consider the implications of the research findings for clinical practice and reach consensus decisions on areas where evidence is not found.
7. Answer review questions with evidence-based recommendations for clinical practice.

The clinical practice recommendations made by the GDG are therefore derived from the most up-to-date and robust evidence for the clinical and cost effectiveness of the interventions and services covered in the scope. Where evidence was not found or was inconclusive, the GDG discussed and attempted to reach consensus on what should be recommended, factoring in any relevant issues. In addition, to ensure a service user and carer focus, the concerns of service users and carers regarding health and social care have been highlighted and addressed by recommendations agreed by the whole GDG.

3.2 THE SCOPE

Clinical guideline topics are referred from the Department of Health or the NHS Commissioning Board and the letter of referral defines the remit, which defines the main areas to be covered (see *The Guidelines Manual* [NICE, 2012] for further information). The NCCMH developed a scope for the guideline based on the remit (see Appendix 1). The purpose of the scope is to:

- provide an overview of what the guideline will include and exclude

- identify the key aspects of care that must be included
- set the boundaries of the development work and provide a clear framework to enable work to stay within the priorities agreed by NICE and the National Collaborating Centre, and the remit from the Department of Health/Welsh Assembly Government
- inform the development of the review questions and search strategy
- inform professionals and the public about expected content of the guideline
- keep the guideline to a reasonable size to ensure that its development can be carried out within the allocated period.

An initial draft of the scope was sent to registered stakeholders who had agreed to attend a scoping workshop. The workshop was used to:

- obtain feedback on the selected key clinical issues
- identify which population subgroups should be specified (if any)
- seek views on the composition of the GDG
- encourage applications for GDG membership.

The draft scope was subject to consultation with registered stakeholders over a 4-week period. During the consultation period, the scope was posted on the NICE website (www.nice.org.uk). Comments were invited from stakeholder organisations The NCCMH and NICE reviewed the scope in light of comments received, and the revised scope was signed off by NICE.

3.3 THE GUIDELINE DEVELOPMENT GROUP

During the scope consultation phase, members of the GDG were appointed by an open recruitment process. GDG membership consisted of: professionals in psychiatry, clinical psychology, nursing, social work, general practice and policing; academic experts in psychiatry and psychology; and service users, carers. The guideline development process was supported by staff from the NCCMH, who undertook the clinical and health economic literature searches, reviewed and presented the evidence to the GDG, managed the process, and contributed to drafting the guideline.

3.3.1 Guideline Development Group meetings

13 GDG meetings were held between 22 March 2013 and 20 January 2015. During each day-long GDG meeting, in a plenary session, review questions and clinical and economic evidence were reviewed and assessed, and recommendations formulated. At each meeting, all GDG members declared any potential conflicts of interest (see Appendix 2), and service user and carer concerns were routinely discussed as a standing agenda item.

3.3.2 Service users and carers

Individuals with direct experience of services gave an integral service-user focus to the GDG and the guideline. The GDG included four service users and carers. They

contributed as full GDG members to writing the review questions, providing advice on outcomes most relevant to service users and carers, helping to ensure that the evidence addressed their views and preferences, highlighting sensitive issues and terminology relevant to the guideline, and bringing service user research to the attention of the GDG. In drafting the guideline, they contributed significantly to writing the guideline's introduction and identified recommendations from the service user and carer perspective.

3.3.3 National and international experts

National and international experts in the area under review were identified through the literature search and through the experience of the GDG members. These experts were contacted to identify unpublished or soon-to-be published studies, to ensure that up-to-date evidence was included in the development of the guideline. They informed the GDG about completed trials at the pre-publication stage, systematic reviews in the process of being published, studies relating to the cost effectiveness of treatment and trial data if the GDG could be provided with full access to the complete trial report. Appendix 4 lists researchers who were contacted.

3.4 REVIEW PROTOCOLS

Review questions drafted during the scoping phase were discussed by the GDG at the first few meetings and amended as necessary. The review questions were used as the starting point for developing review protocols for each systematic review (described in more detail below). Where appropriate, the review questions were refined once the evidence had been searched and, where necessary, sub-questions were generated. The final list of review questions can be found in Appendix 5.

For questions about interventions, the PICO (Population, Intervention, Comparison and Outcome) framework was used to structure each question (see Table 1).

Table 1: Features of a well-formulated question on the effectiveness of an intervention – PICO

Population:	Which population of service users are we interested in? How can they be best described? Are there subgroups that need to be considered?
Intervention:	Which intervention, treatment or approach should be used?
Comparison:	What is/are the main alternative/s to compare with the intervention?
Outcome:	What is really important for the service user? Which outcomes should be considered: intermediate or short-term measures; mortality; morbidity and treatment complications; rates of relapse; late morbidity and readmission; return to work, physical and social functioning and other measures such as quality of life; general health status?

Questions relating to diagnosis or case identification do not involve an intervention designed to treat a particular condition, and therefore the PICO framework was not used. Rather, the questions were designed to pick up key issues specifically relevant

to clinical utility, for example their accuracy, reliability, safety and acceptability to the service user.

In some situations, the prognosis of a particular condition is of fundamental importance, over and above its general significance in relation to specific interventions. Areas where this is particularly likely to occur relate to assessment of risk, for example in terms of behaviour modification or screening and early intervention. In addition, review questions related to issues of service delivery are occasionally specified in the remit from the Department of Health/Welsh Assembly Government. In these cases, appropriate review questions were developed to be clear and concise.

Where review questions about service user experience were specified in the scope, the SPICE format was used to structure the questions (Table 2).

Table 2: Features of a well-formulated question about the experience of care (qualitative evidence) – SPICE

Setting	Where? In what context?
Perspective	For who?
Intervention (phenomenon of interest):	Which intervention/interest should be included?
Comparison:	What?
Evaluation:	How well? What result?
Adapted from Booth (2003).	

For each topic, addressed by one or more review questions, a review protocol was drafted by the technical team using a standardised template (based on PROSPERO[1]). After a protocol was finalised by the GDG, registration on the PROSPERO website was performed for those likely to be published in peer-reviewed journals. All protocols are included in Appendix 9.

To help facilitate the literature review, a note was made of the best study design type to answer each question. There are four main types of review question of relevance to NICE guidelines. These are listed in Table 3. For each type of question, the best primary study design varies, where 'best' is interpreted as 'least likely to give misleading answers to the question'. For questions about the effectiveness of interventions, where RCTs were not available, the review of other types of evidence was pursued only if there was reason to believe that it would help the GDG to formulate a recommendation.

However, in all cases, a well-conducted systematic review (of the appropriate type of study) is likely to always yield a better answer than a single study.

[1] http://www.crd.york.ac.uk/prospero/

Table 3: Best study design to answer each type of question

Type of question	Best primary study design
Effectiveness or other impact of an intervention	Randomised controlled trial (RCT); other studies that may be considered in the absence of RCTs are the following: internally/externally controlled before and after trial, interrupted time-series
Accuracy of information (for example, risk factor, test, prediction rule)	Comparing the information against a valid gold standard in an RCT or inception cohort study
Rates (of disease, service user experience, rare side effects)	Prospective cohort, registry, cross-sectional study
Experience of care	Qualitative research (for example, grounded theory, ethnographic research)

3.5 CLINICAL REVIEW METHODS

The aim of the clinical literature review was to systematically identify and synthesise relevant evidence from the literature in order to answer the specific review questions developed by the GDG. Thus, clinical practice recommendations are evidence-based, where possible, and, if evidence is not available, informal consensus methods are used to try and reach general agreement between GDG members (see Section 3.5.6) and the need for future research is specified.

3.5.1 The search process

Scoping searches

A broad preliminary search of clinical guidelines, Health Technology Assessment (HTA) reports, key systematic reviews and RCTs was undertaken in early 2013 to obtain an overview of the issues likely to be covered by the scope, and to help define key areas.

Systematic literature searches

After the scope was finalised, a systematic search strategy was developed to locate as much relevant evidence as possible. The balance between sensitivity (the power to identify all studies on a particular topic) and specificity (the ability to exclude irrelevant studies from the results) was carefully considered, and a decision made to utilise a broad approach to searching to maximise retrieval of evidence to all parts of the guideline. Searches were restricted to certain study designs if specified in the review protocol, and conducted in the following databases:

- Cochrane Database of Abstracts of Reviews of Effects (DARE)
- Cochrane Database of Systematic Reviews (CDSR)
- CENTRAL
- Embase
- HTA database (technology assessments)

- MEDLINE/MEDLINE In-Process
- Psychological Information Database (PsycINFO).

The search strategies were initially developed for MEDLINE before being translated for use in other databases/interfaces. Strategies were built up through a number of trial searches and discussions of the results of the searches with the review team and GDG to ensure that all possible relevant search terms were covered. In order to assure comprehensive coverage, search terms for the guideline topic were kept purposely broad to help counter dissimilarities in database indexing practices and thesaurus terms, and imprecise reporting of study populations by authors in the titles and abstracts of records. Full details of the search strategies and filters used for the systematic review of clinical evidence are provided in Appendix 10.

Reference management

Citations from each search were downloaded into reference management software and duplicates removed. Records were then screened against the eligibility criteria of the reviews before being appraised for methodological quality (see below). The unfiltered search results were saved and retained for future potential re-analysis to help keep the process both replicable and transparent.

Search filters

To aid retrieval of relevant and sound studies, filters were used to limit a number of searches to specific study designs. The search filters for systematic reviews and RCTs are adaptations of filters designed by Health Information Research Unit of McMaster University. The observational and qualitative research filters were developed in-house. Each filter comprises index terms relating to the study type(s) and associated textwords for the methodological description of the design(s).

Date and language

Systematic database searches were initially conducted in May 2013 up to the most recent searchable date. Search updates were generated on a 6-monthly basis, with the final re-runs carried out in August 2014 ahead of the guideline consultation. After this point, studies were only included if they were judged by the GDG to be exceptional (for example, if the evidence was likely to change a recommendation).

Although no language restrictions were applied at the searching stage, foreign language papers were not requested or reviewed, unless they were of particular importance to a review question.

Other search methods

Other search methods involved: (a) scanning the reference lists of all eligible publications (systematic reviews, stakeholder evidence and included studies) for more published reports and citations of unpublished research; (b) asking the GDG; (c) conducting searches in ClinicalTrials.gov for unpublished trial reports; (f) contacting included study authors for unpublished or incomplete datasets.

Study selection and assessment of methodological quality

All primary-level studies included after the first scan of citations were acquired in full and re-evaluated for eligibility at the time they were being entered into the study information database. More specific eligibility criteria were developed for each review question and are described in the relevant clinical evidence chapters. Eligible systematic reviews and primary-level studies were critically appraised for methodological quality (risk of bias) using a checklist (see *The Guidelines Manual* [NICE, 2012] for templates). The eligibility of each study was confirmed by at least one member of the GDG.

Unpublished evidence

The GDG used a number of criteria when deciding whether or not to accept unpublished data. First, the evidence must have been accompanied by a trial report containing sufficient detail to properly assess risk of bias. Second, the evidence must have been submitted with the understanding that data from the study and a summary of the study's characteristics would be published in the full guideline. Therefore, in most circumstances the GDG did not accept evidence submitted 'in confidence'. However, the GDG recognised that unpublished evidence submitted by investigators might later be retracted by those investigators if the inclusion of such data would jeopardise publication of their research.

3.5.2 Data extraction

Quantitative analysis

Study characteristics, aspects of methodological quality, and outcome data were extracted from all eligible studies, using an Excel template.

In most circumstances, for a given outcome (continuous and dichotomous), where more than 50% of the number randomised to any group were missing or incomplete, the study results were excluded from the analysis (except for the outcome 'leaving the study early', in which case, the denominator was the number randomised). Where there were limited data for a particular review, the 50% rule was not applied. In these circumstances the evidence was downgraded (see section 3.5.4).

Where possible, outcome data from an intention-to-treat analysis (ITT) (that is, a 'once-randomised-always-analyse' basis) were used. Where ITT had not been used or there were missing data, the effect size for dichotomous outcomes were recalculated using best-case and worse-case scenarios. Where conclusions varied between scenarios, the evidence was downgraded (see section 3.5.4).

Where some of the studies failed to report standard deviations (for a continuous outcome), and where an estimate of the variance could not be computed from other reported data or obtained from the study author, the following approach was taken.[2] When the number of studies with missing standard deviations was less than one-

[2] Based on the approach suggested by Furukawa and colleagues (2006).

third and when the total number of studies was at least ten, the pooled standard deviation was imputed (calculated from all the other studies in the same meta-analysis that used the same version of the outcome measure). In this case, the appropriateness of the imputation was assessed by comparing the standardised mean differences (SMDs) of those trials that had reported standard deviations against the hypothetical SMDs of the same trials based on the imputed standard deviations. If they converged, the meta-analytical results were considered to be reliable. When the conditions above could not be met, standard deviations were taken from another related systematic review (if available). In this case, the results were considered to be less reliable.

Consultation with another reviewer or members of the GDG was used to overcome difficulties with coding. Data extracted by one reviewer was checked by a second reviewer. Disagreements were resolved through discussion. Where consensus could not be reached, a third reviewer or GDG members resolved the disagreement. Masked assessment (that is, blind to the journal from which the article comes, the authors, the institution and the magnitude of the effect) was not used since it is unclear that doing so reduces bias (Berlin, 1997; Jadad et al., 1996).

3.5.3 Evidence synthesis

The method used to synthesize evidence depended on the review question and availability and type of evidence (see Appendix 6 for full details). Briefly, for questions about test accuracy, bivariate test accuracy meta-analysis was conducted where appropriate. For questions about the effectiveness of interventions, standard meta-analysis was used, otherwise narrative methods were used with clinical advice from the GDG. In the absence of high-quality research, an informal consensus process was used (see 3.5.6).

3.5.4 Grading the quality of evidence

For questions about the effectiveness of interventions, the GRADE approach[3] was used to grade the quality of evidence for each outcome (Guyatt et al., 2011). For questions about the experience of care and risk assessment and prediction, methodology checklists (see section 3.5.1) were used to assess the risk of bias, and this information was taken into account when interpreting the evidence. The technical team drafted GRADE evidence profiles (see below) using GRADEprofiler (GRADEpro) software (Version 3.6), following advice set out in the GRADE handbook (Schünemann et al., 2009).

Evidence profiles

A GRADE evidence profile was used to summarise both the quality of the evidence and the results of the evidence synthesis for each 'critical' and 'important' outcome (see Table 4 for an example of an evidence profile). The GDG made the final decision about the importance of each outcome by informal consensus, and this information was recorded in the review protocol. The GRADE approach is based on a sequential

[3] For further information about GRADE, see www.gradeworkinggroup.org

assessment of the quality of evidence, followed by judgment about the balance between desirable and undesirable effects, and subsequent decision about the strength of a recommendation.

Within the GRADE approach to grading the quality of evidence, the following is used as a starting point:

- RCTs without important limitations provide high quality evidence
- observational studies without special strengths or important limitations provide low quality evidence.

For each outcome, quality may be reduced depending on five factors: limitations, inconsistency, indirectness, imprecision and publication bias. For the purposes of the guideline, each factor was evaluated using criteria provided in Table 5.

For observational studies without any reasons for down-grading, the quality may be up-graded if there is a large effect, all plausible confounding would reduce the demonstrated effect (or increase the effect if no effect was observed), or there is evidence of a dose-response gradient (details would be provided under the 'other' column).

Each evidence profile includes a summary of findings: number of participants included in each group, an estimate of the magnitude of the effect, and the overall quality of the evidence for each outcome. Under the GRADE approach, the overall quality for each outcome is categorised into one of four groups (high, moderate, low, very low).

Table 4: Example of a GRADE evidence profile

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other consider-ations**	**Intervention**	**Control group**	**Relative (95% CI)**	**Absolute**		
Outcome 1 (measured with: any valid method; Better indicated by lower values)												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	47	43	-	SMD 0.20 lower (0.61 lower to 0.21 higher)	MODERATE	CRITICAL
Outcome 2 (measured with: any valid rating scale; Better indicated by lower values)												
4	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[1]	none	109	112	-	SMD 0.42 lower (0.69 to 0.16 lower)	LOW	CRITICAL
Outcome 3 (measured with: any valid rating scale; Better indicated by lower values)												
26	randomised trials	no serious risk of bias	serious[3]	no serious indirectness	no serious imprecision	none	521/5597 (9.3%)	798/3339 (23.9%)	RR 0.43 (0.36 to 0.51)	136 fewer per 1000 (from 117 fewer to 153 fewer)	MODERATE	CRITICAL
Outcome 4 (measured with: any valid rating scale; Better indicated by lower values)												
5	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	503	485	-	SMD 0.34 lower (0.67 to 0.01 lower)	HIGH	CRITICAL

[1] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.
[2] Risk of bias across domains was generally high or unclear.
[3] There is evidence of moderate heterogeneity of study effect sizes.

Table 5: Factors that decrease quality of evidence

Factor	Description	Criteria
Limitations	Methodological quality/ risk of bias.	Serious risks across most studies (that reported a particular outcome). The evaluation of risk of bias was made for each study using NICE methodology checklists (see Section 3.5.1).
Inconsistency	Unexplained heterogeneity of results.	Moderate or greater heterogeneity (see Appendix 6 for further information about how this was evaluated)
Indirectness	How closely the outcome measures, interventions and participants match those of interest.	If the comparison was indirect, or if the question being addressed by the GDG was substantially different from the available evidence regarding the population, intervention, comparator, or an outcome.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of the effect.	If either of the following two situations were met: • the optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) was not achieved • the 95% confidence interval around the pooled or best estimate of effect included both 1) no effect and 2) appreciable benefit or appreciable harm
Publication bias	Systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies.	Evidence of selective publication. This may be detected during the search for evidence, or through statistical analysis of the available evidence.

3.5.5 Presenting evidence to the Guideline Development Group

Study characteristics tables and, where appropriate, forest plots generated with Review Manager Version 5.3 (Cochrane Collaboration, 2014) and GRADE summary of findings tables (see below) were presented to the GDG.

Where meta-analysis was not appropriate and/or possible, the reported results from each primary-level study were reported in the study characteristics table and presented to the GDG. The range of effect estimates were included in the GRADE profile, and where appropriate, described narratively.

Summary of findings tables

Summary of findings tables generated from GRADEpro were used to summarise the evidence for each outcome and the quality of that evidence (Table 6). The tables provide illustrative comparative risks, especially useful when the baseline risk varies for different groups within the population.

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Table 6: Example of a GRADE summary of findings table

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Any control group	Intervention group			
Outcome 1 any valid rating scale		The mean outcome in the intervention group was **0.20 standard deviations lower** (0.61 lower to 0.21 higher)		90 (2 studies)	moderate[1]
Outcome 2 any valid rating scale		The mean outcome in the intervention group was **0.42 standard deviations lower** (0.69 to 0.16 lower)		221 (4 studies)	low[1,2]
Outcome 3 dichotomous data	**239 per 1000**	**103 per 1000** (86 to 122)	**RR 0.43** (0.36 to 0.51)	8936 (26 studies)	moderate[3]
Outcome 4 any valid rating scale		The mean outcome in the intervention group was **0.34 standard deviations lower** (0.67 to 0.01 lower)		988 (5 studies)	high

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

Note. CI = Confidence interval.
[1] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.
[2] Risk of bias across domains was generally high or unclear.
[3] There is evidence of moderate heterogeneity of study effect sizes.

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3.5.6 Method used to answer a review question in the absence of appropriately designed, high-quality research

In the absence of appropriately designed, high-quality research (including indirect evidence where it would be appropriate to use extrapolation), an informal consensus process was adopted.

The process involved a group discussion of what is known about the issues. The views of GDG were synthesised narratively by a member of the review team, and circulated after the meeting. Feedback was used to revise the text, which was then included in the appropriate evidence review chapter and summarised in the 'linking evidence to recommendations' sections.

3.6 HEALTH ECONOMICS METHODS

The aim of the health economics was to contribute to the guideline's development by providing evidence on the cost effectiveness of interventions for violence and aggression covered in the guideline. This was approached using:

- systematic literature review of existing economic evidence
- decision-analytic economic modelling.

Systematic reviews of economic literature were conducted in all areas covered in the guideline. Economic modelling was considered in areas with likely major resource implications, where the current extent of uncertainty over cost effectiveness was significant and economic analysis was expected to reduce this uncertainty, in accordance with the *Guidelines Manual* (NICE, 2012). Prioritisation of areas for economic modelling was a joint decision between the Health Economist and the GDG. The rationale for prioritising review questions for economic modelling was set out in an economic plan agreed between NICE, the GDG, the Health Economist and the other members of the technical team. The cost effectiveness of rapid tranquilisation options was selected as a key issue to be addressed by economic modelling.

The rest of this section describes the methods adopted in the systematic literature review of economic studies. The methods employed in economic modelling are described in the respective sections of the guideline.

3.6.1 Search strategy for economic evidence

Scoping searches

A broad preliminary search of the literature was undertaken in early 2013 to obtain an overview of the issues likely to be covered by the scope, and help define key areas. Searches were restricted to economic studies and health technology assessment reports, and conducted in the following databases:

- EMBASE

- MEDLINE / MEDLINE In-Process
- Health Technology Assessment (HTA) database (technology assessments)
- NHS Economic Evaluation Database (NHS EED)

* Any relevant economic evidence arising from the clinical scoping searches was also made available to the health economist during the same period.

Systematic literature searches

After the scope was finalised, a systematic search strategy was developed to locate all the relevant evidence. The balance between sensitivity (the power to identify all studies on a particular topic) and specificity (the ability to exclude irrelevant studies from the results) was carefully considered, and a decision made to utilise a broad approach to searching to maximise retrieval of evidence to all parts of the guideline. Searches were restricted to economic studies and health technology assessment reports, and conducted in the following databases:

- EMBASE
- MEDLINE / MEDLINE In-Process
- PsycINFO
- Health Technology Assessment (HTA) database (technology assessments)
- NHS Economic Evaluation Database (NHS EED)

* Any relevant economic evidence arising from the clinical searches was also made available to the health economist during the same period.

The search strategies were initially developed for MEDLINE before being translated for use in other databases/interfaces. Strategies were built up through a number of trial searches, and discussions of the results of the searches with the review team and GDG to ensure that all possible relevant search terms were covered. In order to assure comprehensive coverage, search terms for violence and aggression were kept purposely broad to help counter dissimilarities in database indexing practices and thesaurus terms, and imprecise reporting of study populations by authors in the titles and abstracts of records.

For standard mainstream bibliographic databases (EMBASE, MEDLINE and PsycINFO) search terms for violence and aggression combined with a search filter for health economic studies. For searches generated in topic-specific databases (HTA, NHS EED) search terms for violence and aggression were used without a filter. The sensitivity of this approach was aimed at minimising the risk of overlooking relevant publications, due to potential weaknesses resulting from more focused search strategies. The search terms are set out in full in Appendix 16.

Reference Manager

Citations from each search were downloaded into Reference Manager (a software product for managing references and formatting bibliographies) and duplicates removed. Records were then screened against the inclusion criteria of the reviews

before being quality appraised. The unfiltered search results were saved and retained for future potential re-analysis to help keep the process both replicable and transparent.

Search filters

The search filter for health economics is an adaptation of a filter designed by Centre for Reviews and Dissemination (CRD). The filter comprises a combination of controlled vocabulary and free-text retrieval methods.

Date and language restrictions

Systematic database searches were initially conducted in May 2013 up to the most recent searchable date. Search updates were generated on a 6-monthly basis, with the final re-runs carried out in August 2014. After this point, studies were included only if they were judged by the GDG to be exceptional (for example, the evidence was likely to change a recommendation).

Although no language restrictions were applied at the searching stage, foreign language papers were not requested or reviewed, unless they were of particular importance to an area under review. All the searches were restricted to research published from 2002 onwards in order to obtain data relevant to current healthcare settings and costs.

Other search methods

Other search methods involved scanning the reference lists of all eligible publications (systematic reviews, stakeholder evidence and included studies from the economic and clinical reviews) to identify further studies for consideration.

Full details of the search strategies and filter used for the systematic review of health economic evidence are provided in Appendix 16.

3.6.2 Inclusion criteria for economic studies

The following inclusion criteria were applied to select studies identified by the economic searches for further consideration:

- Only studies from Organisation for Economic Co-operation and Development countries were included, as the aim of the review was to identify economic information transferable to the UK context.

- Selection criteria based on types of clinical conditions and patients as well as interventions assessed were identical to the clinical literature review.

- Studies were included provided that sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed, and provided that the study's data and results were extractable. Poster presentations of abstracts were excluded.

- Full economic evaluations that compared two or more relevant options and considered both costs and consequences as well as costing analyses that compared only costs between two or more interventions were included in the review.

- Studies were included only if the examined interventions were clearly described. This involved the dosage and route of administration and the duration of treatment in the case of pharmacological therapies; and the types of health professionals involved as well as the frequency and duration of treatment in the case of psychological interventions.

3.6.3 Applicability and quality criteria for economic studies

All economic papers eligible for inclusion were appraised for their applicability and quality using the methodology checklist for economic evaluations recommended by NICE (NICE, 2009), which is shown in Appendix 17 of this guideline. All studies that fully or partially met the applicability and quality criteria described in the methodology checklist were considered during the guideline development process. The completed methodology checklists for all economic evaluations considered in the guideline are provided in Appendix 17.

3.6.4 Presentation of economic evidence

The economic evidence considered in the guideline is provided in the respective evidence chapters, following presentation of the relevant clinical evidence. The references to included studies and the respective evidence tables with the study characteristics and results are provided in Appendix 18. Characteristics and results of all economic studies considered during the guideline development process are summarised in economic evidence profiles accompanying respective GRADE clinical evidence profiles in Appendix 19.

3.6.5 Results of the systematic search of economic literature

The titles of all studies identified by the systematic search of the literature were screened for their relevance to the topic (that is economic issues and information on health-related quality of life associated with violence and aggression). References that were clearly not relevant were excluded first. The abstracts of all potentially relevant studies (27 references) were then assessed against the inclusion criteria for economic evaluations by the health economist. Full texts of the studies potentially meeting the inclusion criteria (including those for which eligibility was not clear from the abstract) were obtained. Studies that did not meet the inclusion criteria, were duplicates, were secondary publications of one study, or had been updated in more recent publications were subsequently excluded. Economic evaluations eligible for inclusion (four references) were then appraised for their applicability and quality using the methodology checklist for economic evaluations. Finally, one economic study partially met the applicability and quality criteria was considered at formulation of the guideline recommendations.

3.7 LINKING EVIDENCE TO RECOMMENDATIONS

Once the clinical and health economic evidence was summarised, the GDG drafted the recommendations. In making recommendations, the GDG took into account the trade-off between the benefits and harms of the intervention/instrument, as well as other important factors, such as economic considerations, values of the GDG and society, the requirements to prevent discrimination and to promote equality[4], and the GDG's awareness of practical issues (Eccles et al., 1998; NICE, 2012).

Finally, to show clearly how the GDG moved from the evidence to the recommendations, each chapter has a section called 'from evidence to recommendations'. Underpinning this section is the concept of the 'strength' of a recommendation (Schünemann et al., 2003). Some recommendations can be made with more certainty than others. The GDG makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision.

3.7.1 Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

3.7.2 Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer…') when we are confident that an intervention will not be of benefit for most patients.

3.7.3 Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention

[4]See NICE's equality scheme: www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp

at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Where the GDG identified areas in which there are uncertainties or where robust evidence was lacking, they developed research recommendations. Those that were identified as 'high priority' were developed further in the NICE version of the guideline, and presented in Appendix 7.

3.8 STAKEHOLDER CONTRIBUTIONS

Professionals, service users, and companies have contributed to and commented on the guideline at key stages in its development. Stakeholders for this guideline include:

- service user and carer stakeholders: national service user and carer organisations that represent the interests of people whose care will be covered by the guideline
- local service user and carer organisations: but only if there is no relevant national organisation
- professional stakeholders' national organisations: that represent the healthcare professionals who provide the services described in the guideline
- commercial stakeholders: companies that manufacture drugs or devices used in treatment of the condition covered by the guideline and whose interests may be significantly affected by the guideline
- providers and commissioners of health services in England and Wales
- statutory organisations: including the Department of Health, the Welsh Assembly
- Government, NHS Quality Improvement Scotland, the Care Quality Commission and the National Patient Safety Agency
- research organisations: that have carried out nationally recognised research in the area.

NICE clinical guidelines are produced for the NHS in England and Wales, so a 'national' organisation is defined as one that represents England and/or Wales, or has a commercial interest in England and/or Wales.

Stakeholders have been involved in the guideline's development at the following points:

- commenting on the initial scope of the guideline and attending a scoping workshop held by NICE
- contributing possible review questions and lists of evidence to the GDG
- commenting on the draft of the guideline.

3.9 VALIDATION OF THE GUIDELINE

Registered stakeholders had an opportunity to comment on the draft guideline, which was posted on the NICE website during the consultation period. Following the consultation, all comments from stakeholders and experts (see Appendix 3) were responded to, and the guideline updated as appropriate. NICE also reviewed the guideline and checked that stakeholders' comments had been addressed.

Following the consultation period, the GDG finalised the recommendations and the NCCMH produced the final documents. These were then submitted to NICE for a quality assurance check. Any errors were corrected by the NCCMH, then the guideline was formally approved by NICE and issued as guidance to the NHS in England and Wales.

4 RISK FACTORS AND PREDICTION

4.1 INTRODUCTION

The identification and management of risk for future violence has become an increasingly important component of psychiatric practice. The Royal College of Psychiatrists, for example, emphasizes its commitment 'to minimising risk in psychiatric practice' and describes risk management as 'the guiding force behind all recent reports' of the College (Morgan, 2007) whilst also recognising that risk cannot be eliminated. In the UK, it has been estimated that about 60% of general psychiatric and 80% of forensic-psychiatric patients are regularly risk assessed (Higgins et al., 2005).

Despite this widespread implementation of risk assessment, driven largely by public concern, which factors are associated with violence and how to best assess risk remains uncertain. While consensus exists that structured risk assessment is superior to 'unaided clinical judgement' alone, a number of recent reviews (for example, (Fazel et al., 2012; Yang et al., 2010b) on risk assessment instruments have found their predictive validity to be modest at best and have concluded that the current evidence does not support sole reliance on such tools for decision making on detention or release of individuals with mental health problems. To complicate matters further, risk assessment is not just a scientific or clinical endeavour, but carries a significant political dimension – which level of risk is acceptable (even if it can be identified accurately) and how to weigh the consequences of false positive and false negative assessments is ultimately for society as a whole to decide.

4.2 REVIEW PROTOCOL

The review protocol summary, including the review questions and the eligibility criteria used for this chapter, can be found in Table 7 (risk factors) and Table 8 (prediction instruments). A complete list of review questions can be found in Appendix 5; information about the search strategy can be found in Appendix 10; the full review protocols can be found in Appendix 9).

The review of risk factors was restricted to prospective cohort studies that used multivariate models to look for independent risk factors. The review strategy primarily involved a meta-analysis of odds ratios for the risk of violence for each risk factor or antecedent. Additionally, results from studies that examined the correlation between multiple factors and violence (reported as R^2 or Beta) are presented alongside the meta-analysis. Studies only presenting data from univariate analyses (unadjusted results) were excluded from the review.

The review of predictive instruments included prospective or retrospective cross sectional/cohort studies that presented outcomes that could be used to determine sensitivity and specificity. Additionally, sensitivity and specificity were plotted using a summary receiver operator characteristic (ROC) curve.

1
2

Table 7: Clinical review protocol summary for the review of risk factors

Component	Description
Review questions	2.1 What are the risk factors and antecedents (including staff characteristics) for violent and aggressive behaviour by mental health service users in health and community care settings? 2.2 What factors do service users and staff report as increasing the risk of violent and aggressive behaviour by mental health service users in health and community care settings?
Subquestions	2.1.1 Do the identified risk factors have good predictive validity for future violent and aggressive behaviour by mental health service users in health and community care settings? 2.12 Does being subjected to the Mental Health Act 1983 alter the risk of violent and aggressive behaviour by mental health service users in health and community care settings? 2.12.1 If so, is the effect of detention proportional in relation to the factors that led to its implementation?
Population	Adults who are mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	Risk factors and antecedents
Comparison	Not applicable
Context	Health and community care settings
Critical outcomes	Adjusted outcomes for: • Risk of violence (odds ratio for risk of violence/aggression) • Association between risk factor and violence/aggression (R^2 or Beta value)
Study design	Prospective observational studies

3
4
5
6

Table 8: Clinical review protocol summary for the review of prediction

Component	Description
Review questions	2.3 Which instruments most reliably predict violent and aggressive behaviour by mental health service users in health and community care settings in the short-term? 2.4 What is the best the approach for anticipating violent and aggressive behaviour by mental health service users in health and community care settings?
Subquestion	2.3.1 Do the identified instruments have good predictive validity for future violent and aggressive behaviour by mental health service users in health and community care settings?
Population	Adults who are mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	• Prediction instruments • Approaches for anticipating violence and aggression
Comparison	• Violent and aggressive events (recorded by observation)
Context	• Health and community settings
Critical outcomes	Clinical utility (including sensitivity and specificity)
Study design	Any

4.3 RISK FACTORS FOR VIOLENCE AND AGGRESSION

4.3.1 Introduction

Risk, according to the Oxford Dictionary of English, can be defined as 'a situation involving exposure to danger'. It is the probability of an uncertain outcome occurring caused by a combination of factors (risk factors) which – if known – offer a chance to intervene to prevent the outcome from happening. In addition to the likelihood of the negative event occurring, how soon it is likely to occur and the expected severity of the outcome are important considerations.

In the context of this guideline, risk factors are characteristics of service users (or their environment and care) which are associated with an increased likelihood of that individual acting violently and/or aggressively. These risk factors can be divided into static and dynamic factors (Douglas & Skeem, 2005). Static risk factors are historical and do not change, such as family background, childhood abuse or seriousness of offending. Age and gender also fall within this category. Dynamic risk factors, on the other hand, are changeable and hence offer the opportunity for intervention. Examples include current symptoms, use of alcohol or illicit substances and compliance with treatment. Risk assessment involves the identification of risk factors and an estimation of the likelihood and nature of a negative outcome while risk management puts in place strategies to prevent these negative outcomes from occurring or to minimise their impact. Some authors have argued that static factors may be better for long-term predictions while dynamic factors may be more suited for the assessment of violence risk in the short term (Douglas & Skeem, 2005).

A large body of literature exists on risk factors for violence, including in individuals with mental disorders (Bo et al., 2011; Cornaggia et al., 2011; Dack et al., 2013; Papadopoulos et al., 2012; Reagu et al., 2013; Witt et al., 2013). The largest of these (Witt et al., 2013) was a systematic review and meta-analysis of risk factors in people with psychosis, providing data from 110 studies and over 45,000 individuals. The authors found that 146 risk factors had been examined in these studies. In line with findings from other studies, criminal history was found to be the strongest static risk factor. Dynamic factors included hostile behaviour, impulsivity, recent drug or alcohol misuse, 'positive symptoms' of psychosis and non-adherence with therapy (including psychological and medication). Whilst the factors identified by Witt and colleagues are based on a large body of evidence, it is of note that considerable heterogeneity exists in the samples studied with regards to the nature of the violence, the way in which the outcome was measured and the clinical settings involved.

Current practice

Failings in the care provided to mentally ill individuals have been highlighted by a number of high profile cases of mentally ill patients committing serious acts of violence and subsequent inquiries into their care in the 1990s[5]. Since then mental health practise in the UK has seen an increased focus on risk, and guidance has been produced to aid the process of risk assessment and management (for example, (Department of Health, 2007; Royal College of Psychiatrists, 2007) . These documents stipulate that each patient's risk should be routinely assessed and identify a number of best practice recommendations.

The Department of Health best practice guidance outlines as key principles in risk assessment: awareness of the research evidence, positive risk management, collaboration with the service user, recognising their strengths, multi-disciplinary working, record keeping, regular training and organisational support of individual practitioners. It further emphasizes the importance of 'risk formulation', that is, a process which 'identifies and describes predisposing, precipitating, perpetuating and protective factors, and how these interact to produce risk'. This formulation should be discussed with the service user and a plan of action produced as to how to manage the risks identified. Tool-based assessments (as outlined below) should form part of a thorough and systematic overall clinical assessment. It is suggested that given the fluidity of risk, its assessment should not be a one off activity but should be embedded in every day practice and reviewed regularly.

[5] Examples include Christopher Clunis, a service user with a diagnosis of schizophrenia, who stabbed Jonathan Zito to death in a London Underground station in 1992. The subsequent enquiry (Ritchie et al., 1994) identified multiple failures in the care provided to Mr Clunis, including poor communication, lack of continuity and reluctance to provide services to him. Another example is Michael Stone, an individual with psychopathic disorder, who killed a mother and her six year old daughter in Kent in 1996 while the nine year old daughter survived with severe head injuries. This incident significantly contributed to the introduction of services for people with 'dangerous and severe personality disorders' (Völlm & Konappa, 2012).

Definition of risk factors and antecedents for predicting violence

For the purposes of this review, risk factors and antecedents were categorised using the psychosocial and clinical domains described by Witt et al. (2013):
a) demographic and premorbid;
b) criminal history;
c) psychopathological, positive symptoms and negative symptoms;
d) substance misuse;
e) treatment-related; and
f) suicidality.

4.3.2 Studies considered[6]

For the review of risk factors (see Table 7 for the review protocol), thirteen studies (N = 5,380) met the eligibility criteria: Amore 2008 (Amore et al., 2008), Chang 2004 (Chang & Lee, 2004), Cheung 1996 (Cheung et al., 1996), Ehamann 2001 (Ehamann et al., 2001), Hodgins 2011 (Hodgins & Riaz, 2011), Kay 1998 (Kay et al., 1988), Ketelsen 2007 (Ketelsen et al., 2007), Kho 1998 (Kho et al., 1998), Oulis 1996 (Oulis et al., 1996), Palmstierna 1990 (Palmstierna T, 1989; Palmstierna & Wistedt, 1990), UK700 (Thomas et al., 2005) Watts 2003 (Watts et al., 2003) and Yesavage 1984 (Yesavage, 1984). Of these, all 13 were published in peer-reviewed journals between 1984 and 2011. In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

Of the 13 eligible studies, seven (N = 3,903) included sufficient data to be included in the statistical analysis (see Table 9 for a summary of the study characteristics). Of these, five included adult participants in an inpatient setting and two included adult participants in a community setting. Of the six studies not included in the analysis, three (Ehamann 2001, Kay 1988, Kho 1998) reported no usable data, and three (Oulis 1996, Palmstierna 1990, Yesavage 1984) reported statistics that made synthesis with the other studies very difficult. However, the latter three studies used very small samples (ranging from 70 to 136) and therefore the results from these studies are not included here as it was felt they would not be useful for making recommendations.

[6]Here and elsewhere in the guideline, each study considered for review is referred to by a study ID (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

Table 9: Summary of study characteristics for the review of risk factors for violence and aggression in adults

	Inpatient setting	Community setting
Total no. of studies (N)	5 (2,944)	2 (959)
Study ID	(1) Amore 2008 (2) Chang 2004 (3) Cheung 1996 (4) Ketelsen 2007 (5) Watts 2003	(1) Hodgins 2011 (2) UK700[1]
Sample size	(1) 303 (2) 111 (3) 220 (4) 2210 (5) 100	(1) 251 (2) 780
Country	(1) Italy (2) Taiwan (3) Australia (4) Germany (5) UK	(1) Various (Canada, Finland, Germany and Sweden) (2) UK
Year of publication	1996-2008	2005-2011
Diagnosis (range across trials)	24-71% schizophrenia or schizophreniform 0-9% schizoaffective disorder 0-34% bipolar 0-28% personality disorder 0-23% mood disorder 0-51% other disorders	7-81% schizophrenia or schizophreniform 19-38% schizoaffective disorder 0% bipolar 0% personality disorder 0-49% mood disorder 0-6% other disorders
Age (mean)	40 years	38 years
Sex (mean)	64% male	71% male
Ethnicity	(1, 2, 3, 4) Not reported (5) 28% White	(1) Not reported (2) 51% White
Outcome (measure)	(1) Violence (OAS) (2) Violence (OAS) (3) Violence and/or aggression (SOAS) (4) Violence and/or aggression (SOAS) (5) Violence (modified OAS)	(1) Violence (MacArthur Community Violence Interview) (2) Violence (case notes, interviews with patients, and interviews with case managers)

Note. N = Total number of participants; OAS = Overt Aggression Scale; SOAS = Staff Observation Aggression Scale.

[1] A sub-sample of 304 women was reported in a separate paper (mean age = 40 years; 53% White, 31% African-Caribbean; 31% schizophrenia, 54% schizoaffective disorder, 9% bipolar disorder, 6% other psychosis)

4.3.3 Evidence for risk factors in adults

All studies reported below had generally low risk of bias, except for the domain 'loss to follow-up,' which was often unclear due to non-reporting (see Appendix 11 for further information).

Demographic and premorbid factors

As can be seen in Table 10, which shows the demographic and premorbid factors in the multivariate model for each study, only two factors (age and gender) were commonly included.

Table 10: Demographic and premorbid factors included in the multivariate model for each study

	Inpatient setting					Community setting	
	Amore 2008	Chang 2004	Cheung 1996	Ketelsen 2007	Watts 2003	Hodgins 2011	UK700
Age	✓	✓	✓	✓	✓	✓	✓
Gender	✓	✓	✓			✓	✓
Ethnicity					✓		✓
Living in supported housing				✓			✓
History of being victimised							✓
History of homelessness							✓
Marital status		✓					✓
Past special education							✓
Education		✓					
Employment		✓					

Age

In five studies of 2,944 adults in inpatient settings (Amore 2008 ; Chang 2004 ; Cheung 1996 ; Ketelsen 2007 ; Watts 2003), there was evidence that age was unlikely to be associated with the risk of violence and/or aggression on the ward.

In two studies of 1,031 adults in community settings (Hodgins 2011 ; UK700), there was evidence that was inconsistent as to whether age was associated with the risk of violence in the community.

Gender

In both inpatient (Amore 2008; Chang 2004; Cheung 1996) (N = 634) and community (Hodgins 2011; UK700) (N = 1,031) settings, the evidence was inconclusive as to whether male gender was associated with the risk of violence.

Ethnicity

In one study of 100 adults in an inpatient setting (Watts 2003), there was evidence that African ethnicity was associated with a reduced risk of violence, but the

evidence was inconclusive as to whether African-Caribbean ethnicity was associated with a reduced risk.

In one study of 780 adults in community settings (UK700), there was evidence that non-white ethnicity was associated with an increased risk of violence. In a sub-sample of 304 women, there was evidence that African-Caribbean ethnicity was associated with an increased risk of violence in the community.

Living in supported housing

In one study of 2,210 adults in an inpatient setting (Ketelsen 2007), there was evidence that previous residence in supported accommodation was associated with an increased risk of violence and/or aggression on the ward.

In one study of 780 adults in the community (UK700), there was evidence that was inconclusive as to the association between previous residence in supported accommodation and the risk of violence in the community.

Other demographic and premorbid factors

In one study of 780 adults in community settings (UK700), there was evidence that history of being victimised was associated with an increased risk of violence but the association was inconclusive for history of homelessness, marital status, and past special education. In a sub-sample of 304 women, there was evidence that unmet needs and history of being victimised were associated with an increased risk of violence in the community.

Criminal history factors

In the inpatient setting, no criminal history factors were included in more than one study, and in the community setting, only one factor (lifetime history of violence) was included in both studies (Table 11).

Table 11: Criminal history factors included in the multivariate model for each study

	Inpatient setting					Community setting	
	Amore 2008	Chang 2004	Cheung 1996	Ketelsen 2007	Watts 2003	Hodgins 2011	UK700
Behavioural disorder						✓	
Pre-admission (24 hrs) violence					✓		
Recent (past month) violence	✓						
History (lifetime) violence	✓					✓	✓
Recent verbal or against object aggression	✓						
History (lifetime) of verbal or against object aggression	✓						

Conduct disorder

In one study of 251 adults in the community (Hodgins 2011), there was evidence that was inconclusive as to whether the presence of a conduct disorder was associated with an increased risk of violence in the community.

History of aggression

In inpatient settings, in one study of 303 adults (Amore 2008), there was evidence that recent (past month) and lifetime history of physical aggression and recent verbal or against object aggression were associated with an increased risk of violence on the ward. However, the evidence was inconclusive as to whether a history (lifetime) of verbal or against object aggression was associated with the risk of violence. In one study of 100 inpatients (Watts 2003), there was evidence that violence in the 24 hours prior to admission was unlikely to be associated with violence on the ward.

In one study of 780 adults in community settings (UK700), there was evidence that a history of physical aggression was associated with increased risk of violence, and in the subsample of 304 women, there was evidence that a conviction for non-violent offense was associated with an increased risk of violence in the community.

Psychopathological, positive symptom and negative symptom factors

In the inpatient setting, only two factors (diagnosis of a mood disorder and hostility-suspiciousness) were included in more than one study, and in the community setting, only one factor (number of threat/control-override delusions) were included in both studies (Table 12).

Table 12: Psychopathological, positive symptom and negative symptom factors included in the multivariate model for each study

	Inpatient setting					Community setting	
	Amore 2008	Chang 2004	Cheung 1996	Ketelsen 2007	Watts 2003	Hodgins 2011	UK700
Recent onset of a psychotic disorder		✓					
Diagnosis			✓				
Psychiatric diagnosis		✓					
Diagnosis of schizophrenia				✓		✓	
Threat/control-override delusions						✓	✓
Severity of psychopathology		✓					
Number of positive symptoms						✓	
Organic brain syndrome					✓		
Personality disorder							✓
Symptoms of depression						✓	
Diagnosis of a mood disorder	✓				✓		
Diagnosis of anxiety						✓	
Hostility-suspiciousness (cluster)	✓				✓		
Withdrawl-retardation (cluster)					✓		
Thought disturbance	✓						
Tension	✓						
Excitement	✓						
Lethargy	✓						
Family history of psychiatric disorder		✓					

Onset of psychotic disorder

In one study of 111 adults in inpatient wards (Chang 2004), there was evidence that later onset of a psychotic disorder was associated with an increased risk of violence on the ward.

Diagnosis

In one study of 2,210 adults in inpatient wards (Ketelsen 2007), there was evidence that presence of schizophrenia was associated with an increased risk of violence and/or aggression on the ward.

In one study of 303 adult inpatients (Amore 2008), there was evidence that was inconclusive as to whether a mood disorder (anxiety or depression) was associated with an increased risk of violence on the ward.

In one study of 251 adults in community settings (Hodgins 2011), there was evidence that was inconclusive as to whether the presence of anxiety was associated with an increased risk of violence in the community.

Other symptoms

In two studies of 403 adults in inpatient settings (Amore 2008; Watts 2003), one study was inconclusive, but the other found evidence that hostility-suspiciousness was associated with an increased risk of violence on the ward. In one study of 303 adults in inpatient wards (Amore 2008), there was evidence that was inconclusive as to whether a thought disturbance, the presence of tension or excitement or lethargy were associated with an increased risk of violence.

In one study of 780 adults in the community (UK700), there was evidence that presence of a personality disorder was associated with an increased risk of violence, and in two studies of 1,031 adults in the community (Hodgins 2011; UK700) there was evidence that the presence of threat/control-override delusions was associated with an increased risk of violence.

Treatment-related factors

In the inpatient setting, only two factors (duration of hospitalisation and number of previous admissions) were included in more than one study, and in the community setting, no factors were included in both studies (Table 13).

Table 13: Treatment-related factors included in the multivariate model for each study

	Inpatient setting					Community setting	
	Amore 2008	Chang 2004	Cheung 1996	Ketelsen 2007	Watts 2003	Hodgins 2011	UK700
Duration of hospitalisation		✓	✓				✓
Referral by a crisis intervention team				✓			
Referral by home staff (for service users who live in supported housing)				✓			
Referral by the doctor with regular responsibility				✓			
Involuntary admission				✓			
Number of previous admissions		✓		✓			
Age at first admission				✓			

Duration of hospitalisation

In two studies of 331 adult inpatients (Chang 2004; Cheung 1996), there was evidence that duration of hospitalisation was not associated with an increased risk of violence on the ward.

In one study of 780 adults in the community (UK700), there was evidence that was inconclusive as to whether longer duration of hospitalisation was associated with an increased risk of violence in the community.

Referral route and admission

In one study of 2,210 adult inpatients (Ketelsen 2007), there was evidence that referral by a crisis intervention team, home staff (for service users who live in supported housing), and involuntary admission were associated with an increased risk of violence and/or aggression. In addition, higher number of previous admissions and younger age at first admission were associated with a very small increased risk of violence and/or aggression. In contrast, referral by the doctor with regular responsibility for the service user was associated with a reduced risk.

Substance misuse factors

In the inpatient setting, no substance misuse factors were included, and in the community setting, recent drug use was the only factor and this was included in both studies (Table 14).

Table 14: Substance misuse factors included in the multivariate model for each study

	Inpatient setting					Community setting	
	Amore 2008	Chang 2004	Cheung 1996	Ketelsen 2007	Watts 2003	Hodgins 2011	UK700
Recent (past 6 or 12 months) drug use						✓	✓

Previous drug use

In two studies of 1,031 adults in community settings (Hodgins 2011; UK700), there was evidence that indicated an association between recent (past 6 or 12 months) drug use and the risk of violence in the community.

Suicidality factors

In the inpatient setting, no suicidality factors were included, and in the community setting, previous attempted suicide was the only factor and this was included in only one study (Table 15).

Table 15: Suicidality factors included in the multivariate model for each study

	Inpatient setting					Community setting	
	Amore 2008	Chang 2004	Cheung 1996	Ketelsen 2007	Watts 2003	Hodgins 2011	UK700
Previous attempted suicide							✓

Previous attempted suicide

One study of 780 adults in the community (UK700) examined previous attempted suicide as a potential risk factor for violence, but the evidence was inconclusive.

4.3.4 Health economics evidence

Identification of risk factors for violent and aggressive behaviour by mental health service users in health and community care settings may lead to better prediction of incidents of violence and aggression and has therefore potentially important resource implications. However, this review question is not relevant for economic analysis.

4.4 PREDICTION AND ANTICIPATION OF VIOLENCE

4.4.1 Introduction

Prediction is the cornerstone of the assessment, mitigation and management of violence and aggression. The prediction of violence and aggression is challenging due to the diversity of clinical presentation and it is unlikely that one broad predictive (assessment) tool could be valid and reliable in all circumstances where violence and aggression needs to be predicted. This is not surprising given that the prevalence of violence and aggression varies considerably in different clinical settings; the prevalence would vary markedly between the community, an inpatient psychiatric ward and a forensic setting. Furthermore, the baseline prevalence of what one is trying to predict is important when considering the utility of the prediction tool.

Fundamentally, the process of prediction requires two separate assessments. The application of the prediction tool constitutes the first assessment, and categorises the patient into a lower or higher risk of exhibiting the future behaviour one is interested in predicting. Further down the line, the second assessment concludes whether the patient did or did not exhibit the behaviour of interest. As an instrument, the prediction tool's statistical properties are relevant in assessing its clinical utility. False positives (when the prediction tool identifies that violence and aggression will occur, but it does not) are especially troublesome in this respect, as they can lead to unnecessarily restrictive clinical interventions for the patient. False negatives (when the prediction tool identifies that violence and aggression will not occur, but it does) can have serious consequences for the patient, clinicians and potential victims of the violence or aggression. In reality there is a balance between true and false predictions, which needs to be equated with the consequences thereof.

Translating this process into the clinical or research setting is difficult. The majority of violence and aggression risk assessment tools (prediction tools) are not designed to be completed in minutes to allow for rapid screening, and if they are designed to be completed expeditiously, they often incorporate a phase of retrospective monitoring of behaviour. The behaviour of interest is violence and aggression, and there is a complex and often unclear relationship between the variables in risk assessment tools, the process of conducting a risk assessment, and the occurrence further down the line, of violence and aggression. An interesting example in this area is the idea that the mere process of conducting a risk assessment may change

the probability of future violence and aggression, by either better structuring the ongoing clinical care of the patient or by changing their clinical pathway (for example, to a more secure clinical setting)(Abderhalden et al., 2004).

With such obstacles to prediction of violence and aggression, one is left wondering whether accurate prediction is even possible. Yet in mental health and criminal justice settings, and increasingly in the wider health and social care setting, there is anecdotal evidence that violence and aggression is a major factor inhibiting the delivery of effective modern day services. Currently there is a genuine drive to achieve parity between mental and physical health care for patients in the health and social care system. Given that violence and aggression is often associated with a clinical psychiatric emergency, one way to raise the profile of the management of violence and aggression may be to consider it to be on a par with more classical medical and surgical emergencies which clinicians encounter in the general hospital setting.

In the inpatient psychiatric setting, the early detection and then intervention with individuals at risk of behaving aggressively, is crucial, as once the aggression escalates, the nurses are left with fewer and more coercive interventions such as sedation, restraint and seclusion (Abderhalden et al., 2004; Gaskin et al., 2007; Rippon 2000; Griffith 2013). In this sense, early detection has implications for a more therapeutic and safer patient and staff experience.

Clinical experience and research has led to a plethora of identified violence and aggression risk variables (static, dynamic, patient-related, environmental), which provide the predictive input for risk assessment tools. The utility of predictive risk assessment tools can only be as good as the robustness of the violence and aggression risk variables. In this guideline, the focus is on the evaluation of predictive risk assessment tools and their utility in the prediction of imminent violence and aggression.

Definition and aim of intervention

Prediction instruments (actuarial and structured clinical judgement) can be used to assign service users to two groups: those predicted to become violent or aggressive in the short-term and those predicted not to become violent or aggressive in the short-term. In this context, an actuarial assessment is a formal method to make this prediction based on an equation, a formula, a graph, or an actuarial table. Structured professional/ clinical judgement involves the rating of specified risk factors that are well operationalized so their applicability can be coded reliably based on interview or other records. Based on this, clinical judgement is used to come to a decision about risk, rather than using an established algorithm (Heilbrun et al., 2010). In addition, the risk factors included in a prediction instrument can be static or dynamic (changeable), and it is the latter that are thought to be important in predicting violence in the short-term (Chu et al., 2013).

There is a long history of research demonstrating that unaided clinical prediction is not as accurate as structured or actuarial assessment (Heilbrun et al., 2010), therefore unstructured clinical judgement is not included in this review.

For the purposes of the guideline, prediction instruments were defined as checklists of service user characteristics and/or clinical history used by members of staff to predict imminent violent or aggressive behaviour (commonly in the next 24 hours).

The behaviour being predicted could range from verbal threats to acts of aggression directed at objects or property to physical violence against other service users or staff.

Methodological approach

When evaluating prediction instruments, the following criteria were used to decide whether an instrument was eligible for inclusion in the review.

Primary aim of the instrument: the prediction of imminent violence and aggression.

Clinical utility: the criterion required the primary use of the prediction instrument to be feasible and implementable in a routine clinical care. The instrument should contribute to the identification of further assessment needs and therefore be potentially useful for care planning.

Tool characteristics and administrative properties: the prediction instrument should have validated cut-offs in the population of interest. Furthermore, and dependent on the practitioner skill set and the setting, instruments were evaluated for the time needed to administer and score them as well as the nature of the training (if any) required for administration or scoring. An instrument should be easy to administer and score and be able to be interpreted without extensive and specialist training.

Population: the population being assessed reflects the scope of this guideline. The instrument should have been validated in adults and/or children and young people and preferably be applicable to the UK, for example by being validated in a UK population or a population that is similar to UK demographics.

Psychometric data: the instrument should have established reliability and validity. In addition, it should have been tested against a gold standard assessment of violence and aggression (direct observation and recording of events), for which sensitivity and specificity is reported or able to be calculated. The sensitivity of an instrument refers to the probability that it will produce a true positive result when given to a population with the target disorder (as compared to a reference or "gold standard"). The specificity of an instrument refers to the probability that a test will produce a true negative result when given to a population without the target disorder (as determined by a reference or "gold standard"). When evaluating the sensitivity and specificity of the different instruments, the GDG examined both in

tandem and used the following definitions as a general rule-of-thumb: values above 0.9 were defined as 'excellent', 0.8 to 0.9 as 'good', 0.5 to 0.7 as 'moderate', 0.3 to 0.4 as 'low', and less than 0.3 as 'poor'.

The qualities of a particular tool can be summarised in a receiver operator characteristic (ROC) curve, which plots sensitivity (expressed as a proportion) against (1-specificity). Finally, positive (LR+) and negative (LR-) likelihood ratios are thought not to be dependent on prevalence. LR+ is calculated by sensitivity/(1-specificity) and LR- is (1-sensitivity)/specificity. A value of LR+ >5 and LR- <0.3 suggests the test is relatively accurate (Fischer *et al*., 2003).

See Chapter 3 for further information about the methodology used for this review.

4.4.2 Studies considered[7]

For the review of prediction instruments (see Table 8 for the review protocol), 10 studies (N = 1,659) met the eligibility criteria: Abderhalden 2004 (Abderhalden et al., 2004), Abderhalden 2006 (Abderhalden et al., 2006), Almvik 2000 (Almvik et al., 2000) Barry-Walsh 2009 (Barry-Walsh et al., 2009), Chu 2013a (Chu et al., 2013), Griffith 2013 (Griffith et al., 2013), McNiel 2000 (McNiel et al., 2000), Ogloff 2006 (Ogloff & Daffern, 2006),Vojt 2010 (Vojt et al., 2010), Yao 2014 (Yao et al., 2014). All were published in peer-reviewed journals between 2000 and 2014. In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

Of the 10 eligible studies, six (Abderhalden 2004, Abderhalden 2006, Almvik 2000, Chu 2013a, McNeil 2000, Yao 2014) included sufficient data to be included as evidence. As the reference standard, three studies (Abderhalden 2004, Abderhalden 2006, Almvik 2000) used the Staff Observation of Aggression Scale Revised (SOAS-R) or a modification of this to record all violent and aggressive incidents in the shift following the index test. Two studies (Chu 2013a, McNeil 2000) used the Overt Aggression Scale (OAS), and violence data and preventive measures were concurrently collected from nursing records and case reports by one study (Yao 2014).

4.4.3 Prediction instruments included in the review

Data were available for two actuarial prediction instruments: the Brøset-Violence-Checklist (BVC; (Almvik & Woods, 1998)), the Dynamic Appraisal of Situational Aggression – Inpatient Version (DASA-IV) (Ogloff & Daffern, 2002). In addition, the Clinical Scale from the Historical, Clinical, and Risk Management (HCR-20) (Webster et al., 1997) structured clinical judgment instrument was assessed in one study. See Table 16 for further information about each instrument.

[7]Here and elsewhere in the guideline, each study considered for review is referred to by a study ID (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

Table 16: Summary of characteristics for each included prediction instrument

Instrument	Instrument information	Time to administer	Published reliability
Brøset-Violence-Checklist (BVC)	Scale: 6 items Score: 0-6 Cut-off: ≥ 2 or 3 Format: pen and paper Behaviour measured: confusion, irritability, boisterous, verbal threats, physical threats, and attacks towards objects	< 5 min	Inter-rater reliability: Kappa = 0.44[1]
Dynamic Appraisal of Situational Aggression – Inpatient Version (DASA-IV)	Scale: 7 items Score: 0-7 Cut-off: ≥ 2 or 3 Format: pen and paper Behaviour measured: negative attitudes and impulsivity (from the HCR-20), irritability and verbal threats (from the BVC), and sensitive to perceived provocation, easily angered when requests are denied and unwillingness to follow directions	< 5 min	Inter-rater reliability: ICC = 0.91[2]
The Historical, Clinical, and Risk Management (HCR-20) – Clinical scale (C-5)	Scale: 5 items Score: Cut-off: ≥ 2 or 3 Format: pen and paper Behaviour measured: lack of insight, negative attitudes, active symptoms of major mental illness, impulsivity, unresponsiveness to treatment	< 5 min	Inter-rater reliability: ICC = 0.65[3]
Note. SU = service user. [1]Almvik et al. (2000) [2]Chu et al. (2012) [3]Claix et al. (2002)			

4.4.4 Evidence for prediction instruments

All studies reported below had generally a low risk of bias, except for the domain covering the reference standard, which was assessed by staff who also completed the instrument being investigated (see Appendix 11 for further information).

In four studies of 679 adults in an inpatient or forensic setting, the BVC using a cut-off of ≥ 2 had a pooled sensitivity of 0.71 (95% CI, 0.61 to 0.80) and specificity of 0.89 (95% CI, 0.87 to 0.91) and AUC = 0.93; Pooled LR+ = 7.71 (95% CI, 6.20 to 9.59), I^2 = 0%; Pooled LR- = 0.32 (95% CI, 0.24 to 0.44), I^2 = 0%.

In four studies of 870 adults in an inpatient or forensic setting, the BVC using a cut-off of ≥ 3 had a pooled sensitivity of 0.60 (95% CI, 0.52 to 0.67) and specificity of 0.93 (95% CI, 0.92 to 0.94) and AUC = 0.85; Pooled LR+ = 8.74 (95% CI, 7.25 to 10.53), I^2 = 0%; Pooled LR- = 0.44 (95% CI, 0.37 to 0.53), I^2 = 0%.

In one study of 300 adults in an inpatient setting, the BVC combined with a visual analogue scale using a cut-off of ≥ 7 had a sensitivity of 0.68 (95% CI, 0.59 to 0.76) and specificity of 0.95 (95% CI, 0.94 to 0.96).

In one study of 300 adults in an inpatient setting, the DASA using a cut-off of ≥ 2 had a sensitivity of 0.88 (95% CI, 0.62 to 0.98) and specificity of 0.59 (95% CI, 0.45 to 0.72) and LR+ = 2.15; LR- = 0.21.

In one study of 300 adults in an inpatient setting, the DASA using a cut-off of ≥ 3 had a sensitivity of 0.81 (95% CI, 0.54 to 0.96) and specificity of 0.69 (95% CI, 0.54 to 0.80) and LR+ = 2.58; LR- = 0.27.

In one study of 70 adults in a forensic setting, the HCR-20 Clinical Scale using a cut-off of ≥ 3 had a sensitivity of 0.88 (95% CI, 0.62 to 0.98) and specificity of 0.41 (95% CI, 0.28 to 0.55) and LR+ = 1.48; LR- = 0.31.

In one study of 70 adults in a forensic setting, the HCR-20 Clinical Scale using a cut-off of ≥ 4 had a sensitivity of 0.81 (95% CI, 0.54 to 0.96) and specificity of 0.52 (95% CI, 0.38 to 0.66) and LR+ = 1.69; LR- = 0.36.

For comparison, one study of 470 adults in an inpatient setting that evaluated unstructured clinical judgement is included here. When doctors and nurses independently agreed about the risk, the sensitivity was 0.17 (95% CI, 0.09 to 0.29) and specificity was 0.99 (95% CI, 0.97 to 0.99), and LR+ = 11.86; LR- = 0.84. When doctors and nurses did not agree, the sensitivity was 0.31 (95% CI, 0.20 to 0.44) and specificity was 0.93 (95% CI, 0.90 to 0.95), and LR+ = 4.62; LR- = 0.74.

Figure 1: Forest plot of sensitivity and specificity for instruments used to predict violence in the short-term

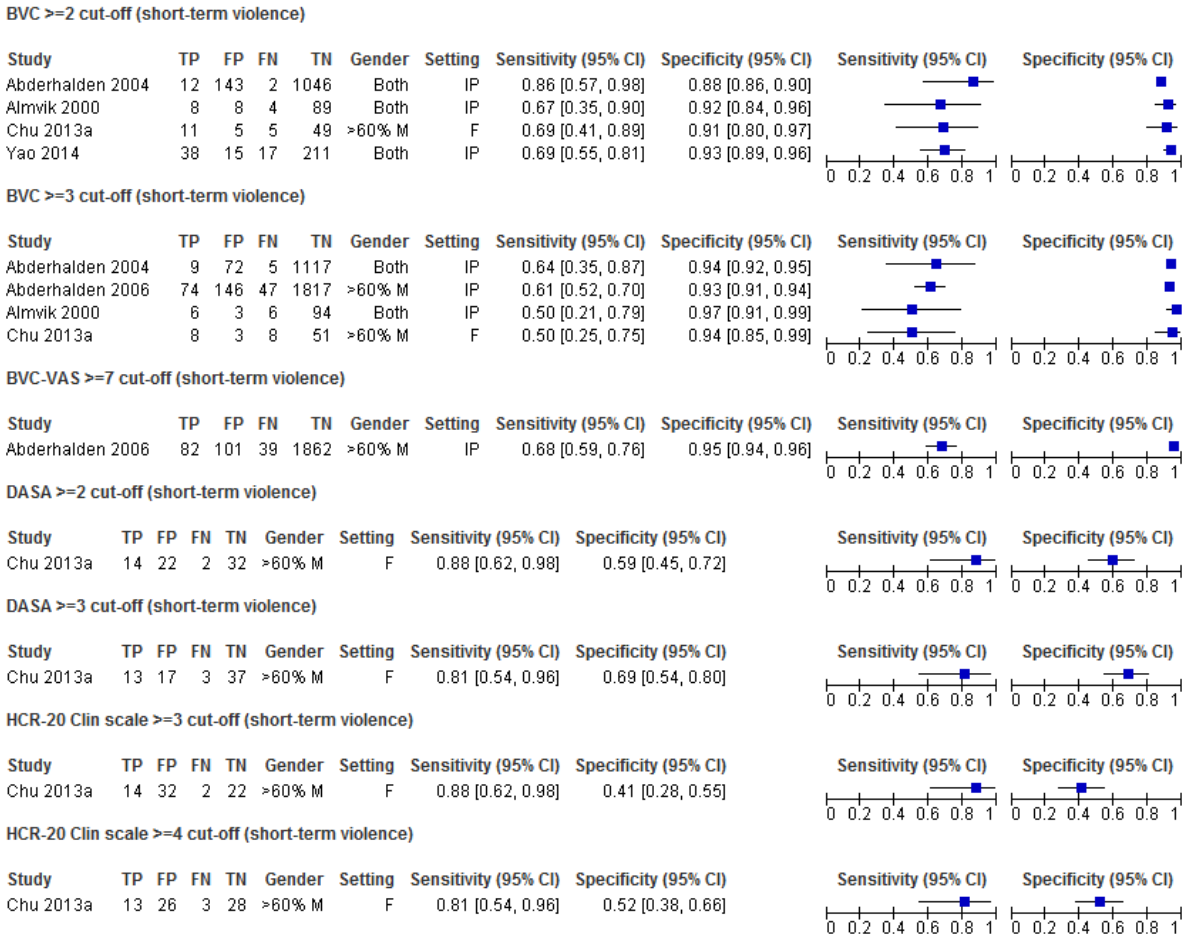


Figure 2: Summary receiver operator characteristic (ROC) curve for the prediction of violence in the short-term

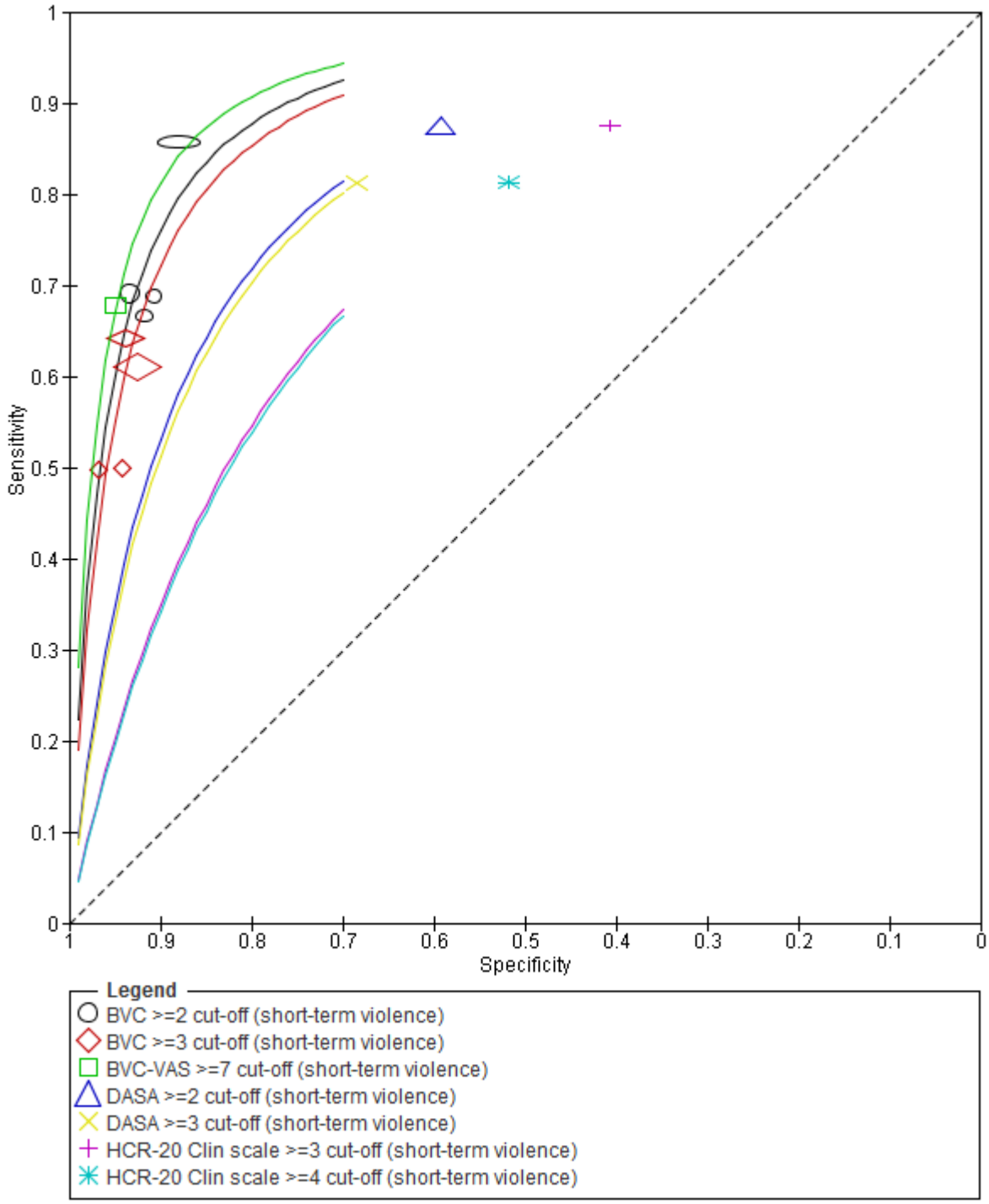
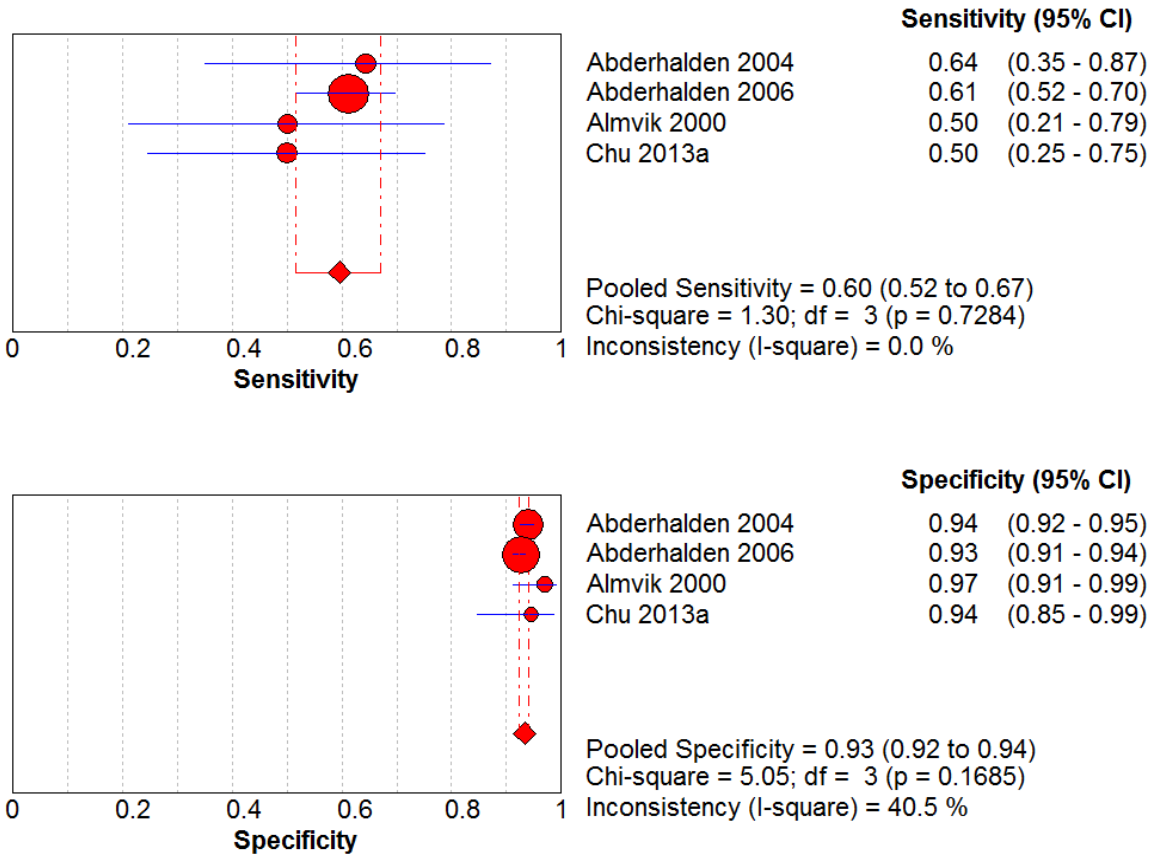


Figure 3: Forest plots of pooled sensitivity and specificity for the BVC used to predict violence in the short-term (cut-off ≥ 2)

Figure 4: Forest plots of pooled sensitivity and specificity for the BVC used to predict violence in the short-term (cut-off ≥ 3)



4.4.5 Health economics evidence

No studies assessing the cost effectiveness of prediction instruments for violent and aggressive behaviour by mental health service users in health and community care settings were identified by the systematic search of the economic literature. Details on the methods used for the systematic review of the economic literature are described in Chapter 3.

A case identification model that would model the health and cost consequences of risk prediction of violent and aggressive incidents by mental health service users was considered to be useful; nevertheless, the available clinical and cost data were not of sufficient quality to populate an informative model.

Economic evidence statement

No relevant economic evaluations were identified. Moreover, no economic modelling was possible to undertake in this area.

4.5 LINKING EVIDENCE TO RECOMMENDATIONS

4.5.1 Risk factors and prediction of violence and aggression

Relative value placed on the outcomes considered

For the review of risk factors, the association between a risk factor and the occurrence of violence/aggression (controlling for other factors) was the outcome of interest. Therefore, only studies that used a multivariate model to determine factors that were independently associated with violence were included. For the review of prediction instruments, sensitivity and specificity of each instrument was primarily used to assess test accuracy. In addition, the AUC and negative and positive likelihood ratios were examined.

Trade-off between clinical benefits and harms

For the review of risk factors, seven studies (out of 13) with a total of just under 4,000 participants were included in the analysis. Of these, five included adult participants in an inpatient setting, and two included adult participants in a community setting. All but one study, which was conducted in Taiwan, were conducted in Westernised countries. Most participants were diagnosed with schizophrenia or bipolar disorder and, on average, two-thirds were male.

In inpatient settings for adults, the most notable finding was the paucity of evidence from studies that used multivariate models to establish which factors were independently associated with violence and aggression. With regard to demographic and premorbid factors only age and gender were included in more than one study, and no conclusion could be reached based on the evidence. Regarding criminal history factors, no individual factors were included in more than one study. Nevertheless, the evidence did support previous reviews, suggesting that recent and lifetime history of violence is an independent risk factor. With regard to psychopathological risk factors, again, few factors were included in more than one study, but diagnosis of schizophrenia and later onset of a psychotic disorder were associated with increased risk. With regard to treatment-related factors, two studies suggested duration of hospitalisation was unlikely to be a risk factor, and the largest study reported referral by a crisis intervention team, referral by home staff (for those living in supported housing), and involuntary admission were independent risk factors. In community settings for adults, the only factors demonstrated to be risk factors in both studies were history of being victimised and recent drug use. Other risk factors demonstrated in one study were history of violence – for women only - and conviction for a non-violent offence. In women, African-Caribbean ethnicity was also an independent risk factor for violence. Based on this evidence and the GDG's expert opinion, several recommendations were made about assessing and managing the risk of violence and aggression (see discussion below under *other considerations* for further rationale).

For the review of prediction instruments, the evidence suggested that the BVC using a cut-off of 2 or more has the best trade-off between sensitivity and specificity.

Pooled likelihood ratios indicate that the test is relatively accurate. The BVC combined with a visual analogue scale (cut-off ≥ 7) has similar sensitivity and specificity. The DASA has poorer accuracy than the BVC, but still has good sensitivity and moderate specificity. The HCR-20 Clinical Scale has good sensitivity but only low specificity. These findings need to be contrasted with unstructured clinical judgement, which was shown to have poor sensitivity even when both a doctor and nurse agreed about each service user's risk of short-term violence. The GDG agreed that prediction instruments should not be used to grade risk (for example, as low, medium, high), but rather as part of an approach to monitor and reduce incidents of violence and aggression and to help develop a risk management plan in inpatient settings. Recommendations were then drafted in light of the knowledge that incorrectly assessing a service user as high risk could harm the therapeutic relationship.

Trade-off between net health benefits and resource use

As the costs and consequences of violent events are substantial, there are clear resource and quality of life implications associated with prediction instruments that allow prevention and containment.

From the clinical review, the use of prediction instruments based on risk factors does appear to offer utility over clinical opinion alone. Given the potentially serious clinical and cost consequences of violent and aggressive incidents, any improvement in the management of an event due to prescience is considered likely to be cost effective.

Quality of the evidence

For the review of risk factors, across the inpatient studies and across the community studies, the samples do appear to represent the population of interest and therefore the risk of bias associated with this factor was judged to be low. However, all but one inpatient and one community study were conducted outside the UK. With regard to loss to follow-up, poor reporting made it difficult to judge whether any loss was unrelated to key characteristics of the sample. With regard to measurement of risk factors and violence and aggression, the potential for bias was judged to be low because of the methods used. With regard to confounders and statistical analysis, only studies using an appropriate multivariate analysis were included in the evidence, and therefore the risk of bias was judged to be low.

For the review of prediction instruments, for all studies included in the statistical analysis the risk of bias was generally low. However, in all studies the reference standard was assessed by staff who also completed the instrument being investigated. This issue is well discussed in the literature and potentially leads to a false positive test rate that is exaggerated because the observed behaviour itself will usually lead to staff taking action to prevent violent behaviour.

Other considerations

Taking into account the evidence presented in this chapter, the GDG also reviewed the recommendations from the previous guideline and judged, based on their expert opinion, that several recommendations were still relevant and of value but would need redrafting in the light of the current context, a widening of the scope, and latest NICE style for recommendations.

Following this approach, the GDG agreed, using consensus methods described in Chapter 3, a framework for anticipating violence and aggression in inpatient wards. It was also agreed that it was good practice that risk assessment and risk management should be undertaken using a multidisciplinary approach, and that staff undertaking assessments of the risk of violence and aggression should be culturally aware. The GDG also saw the benefit or recommending that risk assessments and management plans should be regularly reviewed in the event that the nature of the risk had changed. Finally, following discussion about modifications to recommendations about risk assessment for community and primary care settings, the GDG wished to emphasise that staff working in these settings should share information from risk assessment with other services, partner agencies such as the police and probation services, and with the person's carer if there are risks to them.

4.6 RECOMMENDATIONS

4.6.1 Risk factors and prediction

A framework for anticipating and reducing violence and aggression on inpatient wards

4.6.1.1 Use the following framework to anticipate violence and aggression in inpatient wards, exploring each domain to identify ways to reduce violence and aggression and the use of restrictive interventions.

- Ensure that the staff work as a therapeutic team by using a positive and encouraging approach, maintaining staff emotional regulation and self-management (see recommendation 5.7.1.36) and encouraging good leadership).
- Ensure that service users are offered appropriate psychological therapies, physical activities, and leisure pursuits such as film clubs and reading or writing groups.
- Recognise possible teasing, bullying, unwanted physical contact or miscommunication between service users.
- Recognise how each service user's mental health problem might affect their behaviour (for example, their diagnosis, severity of illness, current symptoms and past history of violence or aggression).
- Anticipate the impact of the regulatory process on each service user (for example, being formally detained, having leave refused,

having a failed detention appeal or being in a very restricted environment such as a low-, medium- or high-secure hospital).

- Improve or optimise the physical environment (for example, use unlocked doors whenever possible, enhance the décor, simplify the ward layout and ensure easy access to outside spaces and privacy).
- Anticipate that restricting a service user's liberty and freedom of movement (for example, not allowing service users to smoke or to leave the building) can be a trigger for violence and aggression.
- Anticipate and manage any personal factors occurring outside the hospital (for example, family disputes or financial difficulties) that may affect a service user's behaviour.

Assessing and managing the risk of violence and aggression

4.6.1.2 Use a multidisciplinary approach to risk assessment and risk management that reflects the care setting.

4.6.1.3 Before assessing the risk of violence or aggression:

- Take into account previous violent or aggressive episodes because these are associated with an increased risk of future violence and aggression.
- Do not make negative assumptions based on culture, religion or ethnicity.
- Recognise that unfamiliar cultural practices and customs could be misinterpreted as being aggressive.
- Ensure that the risk assessment will be objective and take into account the degree to which the perceived risk can be verified.

4.6.1.4 Carry out the risk assessment in an interview with the service user and, if they agree, their carer. If there is a risk that the service user could become violent or aggressive, set out approaches that address service user-related domains in the framework (see recommendation 4.6.1.1) and:

- the contexts in which violence and aggression tend to occur
- usual manifestations and factors likely to be associated with the development of violence and aggression
- primary prevention strategies that focus on improving quality of life and meeting the service user's needs
- symptoms or feelings that may lead to violence and aggression, such as anxiety, agitation, disappointment, jealousy and anger, and secondary prevention strategies focusing on these symptoms or feelings
- de-escalation techniques that have worked effectively in the past
- restrictive interventions that have worked effectively in the past, when they are most likely to be necessary and how potential harm or discomfort can be minimised.

4.6.1.5 Consider using an actuarial prediction instrument such as the BVC (Brøset Violence Checklist) or the DASA-IV (Dynamic Appraisal of Situational Aggression – Inpatient Version), rather than unstructured clinical judgement alone, to monitor and reduce incidents of violence and aggression and to help develop a risk management plan in inpatient settings.

4.6.1.6 Regularly review risk assessments and risk management plans, addressing the service user and environmental domains listed in recommendation 4.6.1.1 and following recommendations 4.6.1.3 and 4.6.1.4. The regularity of the review should depend on the assessment of the level of risk. Base care plans on accurate and thorough risk assessments.

4.6.1.7 If service users are transferring to another agency or care setting, or being discharged, share the content of the risk assessment with staff in the relevant agencies or care settings, and with carers.

Managing violence and aggression

4.6.1.8 After a risk assessment has been carried out, staff working in community and primary care settings should:

- share the risk assessment with other health and social care services and partner agencies (including the police and probation service) who may be involved in the person's care and treatment, and with carers if there are risks to them
- be aware of professional responsibilities in relation to limits of confidentiality and the need to share information about risks.

4.7 RESEARCH RECOMMENDATIONS

4.7.1.1 What is the effect of detention under the Mental Health Act on rates of incidence of violence and aggression in inpatient psychiatric wards?

4.7.1.2 Are Safewards and/or short term risk assessment effective ways to reduce rates of inpatient aggression?

5 PRE- AND IMMEDIATELY PRE-EVENT

5.1 INTRODUCTION

The occurrence of a violent incident is generally portrayed as the culmination of a gradually escalating behaviour pattern, starting with restlessness, moving through agitation and irritability, through verbal aggression, gestures, threats, damage to objects in the surrounding area and culminating in an assault. When such a gradually developing behaviour pattern is seen, it allows most scope for prevention, diversion and de-escalation. Several short term frequent risk assessment and prevention methods are based on this 'escalation cycle', which has some clear validity.

Initial triggers of these assaults may be internal to the service user, based on their perception of the environment potentially shaped by delusions, hallucinations, confusion, disorientation, and misperception. Or they may be responding to irritating behaviour from others around them. Common triggers from staff interventions are denial of a request, or a demand to do or cease some activity. The symptomatic behaviours of other patients can also trigger violence as they may be intrusive or hard to tolerate. A service user's ability to handle frustration may be severely weakened by their mental disorder or current symptoms, making an aggressive response more likely than if they were well.

However, far from all incidents arise so slowly and signalled so clearly so as to allow time for diversion or de-escalation. Some occur suddenly and without warning, perhaps during close personal care. Other attacks apparently occur out of the blue without any clear provocation, and any escalation might be both fast and brief. Where there is a clear and gradual pattern of escalation, staff have the opportunity to implement actions previously agreed with the service user as most likely to help them relax, de-escalate and reach a calmer state of mind. Where there is no warning and violent behaviour has to be immediately managed, staff can, if feasible, use those management methods previously agreed with the service user as being most acceptable. These previous agreements are generally known as 'advance directives'.

Thankfully the vast majority of incidents are of low severity. Nevertheless, some assaults on staff or between patients are serious and severe. Very rarely it is clear that such an attack has been planned in advance by the service user or is deliberately targeted on one individual, weapons may have been fashioned in advance or plans for distractions put in place. Occasionally long term injury is caused, and deaths are not completely unknown.

5.1.1 Training programmes

Specific training courses on the prevention and management of aggression, initially called Control and Restraint or C&R, first emerged in the inpatient psychiatric care

setting in the 1980s, being at first derived from so called 'Home Office approved' training courses in the UK prison system. These courses were first taken up by staff working in the High Security Psychiatric Hospitals and then passed on to generic district mental health services. Prior to these courses, manual restraint was carried out in an unskilled, ad hoc manner by assembling large numbers of nurses who surrounded the patient and who, on a signal of the person in charge, seized hold of the patient and overpowered them. C&R courses brought standardisation and skilled practice to this situation, and were within a matter of ten years being universally provided in the form of five day courses and annual one day updates to all staff (nurses and health care assistants) working in inpatient areas. These courses quickly spread from the UK to other European countries, while other similar courses were arising in North America.

The content of such courses included legal aspects, ethics, prevention strategies, and management (breakaway and manual restraint). All components have varied over time and between providers and countries, making any overall evaluation of 'training' impossible. As many courses in the UK and elsewhere are commercially provided, it is not even possible to accurately describe what is taught, as there is no publication of curricula, no common manual of taught techniques, no quality control, no national reporting systems for injuries related to techniques, and no way to say how or how well it is taught, and to what standards it is assessed.

Potential criteria for the outcome of training are also varied, from use of restraint only in legal and ethical circumstances (never evaluated or reported), through reductions in violent incident rates following investments in training (frequently reported) or frequency of use of manual restraint (never reported), to reductions in staff and patient injuries (seldom reported). The most frequently reported outcome of training is confidence in handling violent situations, and while this clearly increases it is not known how this relates to any of the more important outcomes such as the frequency of violent incidents or the use of restraint. What is known is that retention of the taught skills by trainees is far from perfect (Dickens et al., 2006). There are no published randomised controlled trials evaluating such training packages, but their provision remains a practical necessity for staff to handle extremely disturbed patients in an organised and planned way.

5.1.2 Management strategies

Superimposed on the type of training provision described above are a number of management strategies designed to reduce the frequency of use of seclusion and mechanical/manual restraint, and/or to reduce the frequency of violent incidents on inpatient wards. All of these contain some element of training, to a greater or lesser degree. Most notable amongst these are the use of short term risk assessment tools (considered elsewhere in the guideline); Six Core Strategies; Safewards; and positive behavioural support. Each of these initiatives has multiple components and there exists varying degrees of overlap between them.

The Six Core Strategies for Reducing Seclusion and Restraint Use© were authored by Kevin Ann Huckshorne in the US (National Technical Assistance Center of the National Association of State Mental Health Program Directors). At their point of first codification, there had been on-going efforts for some years in the US to reduce the use of seclusion and mechanical restraint. Such methods had come to be seen as aversive, traumatising and being used excessively. The Six Core Strategies attempted to describe the common features of successful seclusion and restraint reduction programmes, so that hospitals attempting to do the same in future could do so more reliably and successfully. Given the nature of its origin, Six Core Strategies was not based around a single idea or theory, but represented a collection of what was best validated by experience at the time of its definition. The six strategies are: senior management commitment to change, auditing local practice to inform change, workforce development including extensive training, the use of seclusion and restraint reduction tools, increased consumer involvement, and debriefing techniques.

Safewards was defined in the UK by Len Bowers (Bowers, 2014; Bowers et al., 2014) and arose out of a lengthy research programme on conflict (behaviours likely to cause harm to the patient or others: aggression, self-harm, suicide, drug/alcohol use, absconding, rule breaking and medication refusal) and containment (actions by the staff to prevent or minimise harm: p.r.n. medication, special observation, coerced IM medication, seclusion, manual restraint, show of force and time out) in inpatient care. The Safewards Model was defined from the findings of this research program and a thorough review of all previous literature. From the Safewards Model a subset of ten small interventions (out of many possibilities) were subject to a randomised controlled trial, and are now being implemented in many hospitals in the UK. Safewards implementation requires minimal training.

Positive behavioural Support (PBS) is the only one of the models originating in the Learning Disability field (Johnston et al., 2006). It seems to have emerged in the US in the late 1990s, but is composed of many previous common elements and strands in Learning Disability care, particularly the management of 'challenging behaviour' and the use of skills training and interventions based on functional analysis. It includes environmental adjustment, skills training for patients, enriching patients' quality of life as well as various behavioural strategies. It is only now being suggested as applicable to inpatient psychiatry via guidance from the English Department of Health (2014a).

5.2 REVIEW PROTOCOL

The review protocol summary, including the review questions and the eligibility criteria used for this section of the guideline, can be found in Table 17 (prevention strategies), Table 18 (advance directives), Table 19 (substance misuse). A complete list of review questions can be found in Appendix 5; further information about the search strategy can be found in Appendix 10; the full review protocols can be found in Appendix 9.

Table 17: Clinical review protocol summary for the review of prevention strategies

Component	Description
Review questions	Pre-event: 2.5 Do observation techniques, used to pre-empt or prevent violent and aggressive behaviour by mental health service users in an inpatient setting, produce benefits that outweigh possible harms when compared to an alternative approach? 2.6 Do modifications to the environment (physical and social) of health and community care settings, used to reduce the risks of violent and aggressive behaviour by mental health service users, produce benefits that outweigh possible harms when compared to an alternative approach? 2.7 Do management strategies (including staffing levels and IT systems), used to reduce the risks of violent and aggressive behaviour by mental health service users, produce benefits that outweigh possible harms when compared to an alternative approach? 2.8 Do training programmes for the use of interventions designed to prevent and manage violent and aggressive behaviour by mental health service users in health and community care settings, for staff, and for staff and service users combined, produce benefits that outweigh possible harms when compared to an alternative management strategy? Immediately pre-event: 3.2 Do observation techniques used to pre-empt or prevent imminent violent and aggressive behaviour by mental health service users in an inpatient setting produce benefits that outweigh possible harms when compared to an alternative management strategy? 3.3 Do personal and institutional alarms, CCTV and communication devices used to alert staff to imminent violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? 3.4 What principles of practice are necessary to ensure the effectiveness of personal and institutional alarms, CCTV and communication devices in reducing violent and aggressive behaviour by mental health service users in health and community care settings when compared to an alternative management strategy? 3.5 Do de-escalation methods used to prevent imminent violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? 3.6 Does p.r.n. (pro re nata) medication used to prevent imminent violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy?
Population	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	• Observation techniques • Modifcations to the environment • Management strategies • Personal and institutional alarms • De-escalation methods • p.r.n. medication
Comparison	Usual care or other alternative management strategies

Context	Health and community care settings (RQ2.5 & 3.2: Inpatient settings only).
Critical outcomes	Any reported measures of safety, effectiveness and experience relevant to the prevention of violence and aggression
Study design	Any
Note. RQ = review question.	

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Table 18: Clinical review protocol summary for the review of advance decisions and statements

Component	Description
Review question(s)	Pre-event: 2.9 What role should advance decisions and statements play in the prevention of violence and aggression by mental health service users in health and community care settings? Immediately pre-event: 3.1 What role should advance decisions and statements play in the management of imminent violence and aggression by mental health service users in health and community care settings?
Population	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention	Advance decisions and statements
Comparison	Usual care or other alternative management strategies
Context	Health and community care settings
Critical outcomes	Any reported measures of safety, effectiveness and experience relevant to the prevention of violence and aggression
Study design	Any

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Table 19: Clinical review protocol summary for the review of substance misuse

Component	Description
Review question(s)	2.11 What is the most appropriate method of recognition and management of substance misuse in mental health service users with violent and aggressive behaviour in health and community care settings?
Population	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention	Recognition and management of substance misuse
Comparison	Any relevant
Context	Health and community care settings
Critical outcomes	Any reported measures of safety, effectiveness and experience relevant to the recognition and management of substance misuse
Study design	Any

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5.3 INPATIENT SETTINGS

5.3.1 Introduction

Violent incidents are more likely to occur in inpatient settings, in particular acute admission wards and some other speciality areas. This is because patients are more acutely ill, therefore more likely to misinterpret what is going on around them as well as being less able to control their impulses. It is also because these highly ill patients are in an environment in close proximity with each other, and because that environment is highly regulated. Finally, as many inpatients are admitted because they are known to be a risk to others when ill, and are detained against their will under the Mental Health Act 1983, they are already angry and frustrated. In combination these factors can produce a tense atmosphere that provides many potential triggers to aggression. It is a tribute to staff that actual physical aggression to others is as rare as it currently is.

Whilst violence is a higher risk in inpatient areas, it is also the location with the most skilled staff in the highest numbers. These staff can act in ways that avert aggression from occurring through the avoidance of flashpoints, distraction, skilled communication and patient management. Speedy and efficacious medical treatment can also reduce symptoms and therefore risk of aggression. However, should aggression be imminent or actually occur, staff require the necessary skills to manage the patients so as to prevent harm to the aggressor, other patients and the staff themselves, whilst maintaining the aggressor's dignity and respect and minimising any coercion applied.

5.3.2 Studies considered[8]

For the review of prevention strategies in inpatient settings (see Table 17 for the review protocol), in addition to the review conducted for the previous guideline, six systematic reviews were judged to be eligible: Bowers 2011 (Bowers et al., 2011b); Johnson 2010 (Johnson, 2010); Livingston 2010 (Livingston et al., 2010); Manna 2010 (Manna, 2010); Stewart 2010a (Stewart et al., 2010); van der Merwe 2009 (Van Der Merwe et al., 2009). In addition, a Cochrane review, Sailas 2012 (Sailas & Fenton, 2012), which examined RCT evidence for seclusion and restraint (including the use of management strategies) identified only two trials that were awaiting classification. Hence, Sailas 2012 is not considered further. Eleven additional primary studies also met eligibility criteria: Ashcraft 2008 (Ashcraft & Anthony, 2008); Bjorkdahl 2013 (Bjorkdahl et al., 2013); Bowers (Bowers et al.); Feeney 2007 (Feeney et al., 2007); Laker 2010 (Laker et al., 2010); Lee 2012 (Lee et al., 2012); Putkonen 2013 (Putkonen et al., 2013); Steinert 2008 (Steinert et al., 2008); Sutton 2013 (Sutton et al., 2013); Vaaler 2005 (Vaaler et al., 2005); van der Schaaf 2013 (Van Der Schaaf et al., 2013).

[8] Here and elsewhere in the guideline, each study considered for review is referred to by a study ID (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

No studies were identified that reviewed the use of advance decisions and statements or substance misuse within an inpatient setting. In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

Prevention strategies

Observation techniques

With regard to observation, in the previous guideline review, 11 studies were included (N~400). Of these, two studies provided sufficient evidence to evaluate effectiveness. A further three studies provided limited evidence about experience (staff and service user). In the update search, two reviews met the inclusion criteria; the first examined the efficacy of formal observation as a risk prevention tool (Manna, 2010); the second considered the outcomes and experiences associated with special observation (Stewart et al., 2010) (see Table 20).

Table 20: Study information table for systematic reviews evaluating observation techniques (inpatient setting)

	CG25	Manna 2010	Stewart 2010a
Review question/ Aim	Are psychosocial techniques, such as observation, effective and appropriate in terms of pre-empting and preventing disturbed/violent and potentially violent situations?	To determine the efficacy of formal observation as a strategy to prevent potential harm.	To examine the incidence, duration, antecedents, outcomes and temporal ecology of special observation.
Method used to synthesise evidence	Narrative synthesis	Narrative synthesis	Narrative synthesis
Design of included studies	Expert opinion, non-analytic studies (case reports, case series).	Observational studies	Observational studies
Dates searched	Inception to 2002/3	1996 to 2009	1960 to 2009
Electronic databases	MEDLINE , EMBASE, PsycINFO, CINAHL	PubMed, CINAHL, Cochrane Database of Systematic Reviews and PsycINFO.	PsycINFO, Cochrane, MEDLINE, EMBASE Psychiatry, CINAHL, British Nursing Index
No. of included studies	5[1]	10	63
Participant characteristics	Adult psychiatric service users > 16 years	Psychiatric inpatients	'At risk' adult psychiatric inpatients
Intervention	Observation: a two-way relationship which forms the basis of risk assessment and violence management (catergorised as: general, intermittent, within eyesight and within arms length]	'Formal Observation': routine or general observation; 30 to 15 minute checks; constant and continuous.	'Special observation:' observation above the minimum general level of care required for inpatients.
Comparison	Usual care or alternative management strategies	Usual care where applicable	Usual care or alternative managament strategy
Outcome	• Rates of violence and aggression • Experience (service user and staff)	• Rates of violence and aggression • Experience (staff)	• Rates of observation • Rates of violence and aggression • Experience (staff)

Note.
[1] Of the included studies, five studies were judged to address the current review question.

Modifications to the environment

With regard to the previous guideline, five observational studies (N≈ 390) provided limited evidence about the impact and believed impact (staff and service user) of

environmental factors on rates of violence and aggression. In addition, # studies were excluded from this review.

In the update search, four observational studies were identified (N≈15,145, see Table 21). The first study compared violence and aggression rates and experience of care between refurbished and 'traditional' seclusion rooms using a controlled before and after design (Vaaler 2005). The second was a qualitative study that examined staff and service user's attitudes towards the introduction of a pilot sensory modulation room (Sutton 2008). The remaining studies explored the impact of wider hospital features on rates of violence and aggression (Feeney 2007) and rates and duration of seclusion (van der Schaaf 2013).

Table 21: Study information table for primary studies evaluating modifications to the environment (inpatient settings)

Modifications to the environment	
Total no. of studies	4 observational studies
Study ID (N[1])	(1) Feeney 2007 (N = 195) (2) Sutton 2013 (N = 60) (3) Vaaler 2005 (N = 56) (4) van der Schaaf 2013 (N = 14,834)
Consent gained?	(1, 3) Not applicable (2, 4) Not reported
Country	(1) Iran (2) New Zealand (3) Norway (4) Netherlands
Setting	(1-4) Inpatient
Diagnosis	(1) Not explicitly stated (2) Schizophrenia and bipolar disorder (3) Mental illness (4) Schizophrenia, schizotypal and delusional disorders; mood disorders; personality disorders and disorders due to the use of psychoactive substances.
Age (mean)	(1) 45 (2) 39.6 (3) 37.1 (4) 46.6
Sex (% Female)	(1) 43 (2) 90 (3) 50 (4) 46
Ethnicity (% White)	(1, 2, 3, 4) Not reported
Intervention(s)	(1) Specialised treatment wards (2) Sensory modulation room (3) Ward refubishment: 'home-like' seclusion rooms (4) Ward design features
Comparison	(1) 'Stand alone' psychiatric hospital (2) Not applicable (3) TAU: traditional seclusion rooms (4) Not applicable
Funding	(1, 2) Not reported (3) Norweigan University of Science and Technology (4) Dutch Ministry of Health, Welfare and Sport
Outcomes	(1) Rates of violence and aggression (Modified Overt Aggression Scale) (2) Experience of modification (staff and patient) (3) Rates of violence and aggressive behaviour (PANSS, BCV); rates of seclusion; experience of seclusion (patient) (4) Rates and duration of seclusion (Argus Scale)
Note. N = total number of participants.	

Management strategies/training programmes

Three reviews were included which considered the impact of management strategies/training programmes on violent and aggressive behaviour in inpatient

settings (Bowers 2011; Johnson 2010; Livingston 2010) (see Table 22). Of these, two reviews (Johnson 2010; Livingston 2010) considered the use of integrated training packages. The first (Johnson 2010) considered the role of combined educational programmes on incidences of aggression and the use of restraint and seclusion. Livingston (2010) explored similar outcomes when considering the use of specific and broad training programmes. The final review (Bowers 2011) examined the interaction of containment variables (such as staff factors, including training) and rates of conflict (behaviour likely to harm the individual or others).

With regard to the primary studies, two RCTs were included that assessed specific intervention packages: 'Safewards' (Bowers) and an approach based on 'Six Core Strategies for Reducing Seclusion and Restraint Use'© (Putkonen 2013). In addition, five observational studies were included that examined: a) whether an approach based on the Six Core Strategies could fully eliminate restraint and seclusion use in two crisis centres (Ashcraft 2008), b) the impact of good staff-patient training relationships (Bergen model) on patient and staff attitudes (Bjorkdahl 2013), c) de-escalation and physical training interventions compared to Control and Restraint (general services) (Laker 2010), d) 'Strategies in Crisis Intervention and Prevention' (Lee 2012), and c) a new specialised crisis intervention ward for individuals with personality disorders and adjustment disorders (Steinert 2008) (see Table 23).

Table 22: Study information table for systematic reviews evaluating management strategies/training programmes (inpatient settings)

	Bowers 2011	Livingston 2010	Johnson 2010
Review question/ Aim	To consider the impact of staff factors on seclusion and restraint	To provide a synthesis and critical analysis of the literature relating to aggression management training	To examine research and quality improvement projects that aimed to reduce restraint and seclusion
Method used to synthesise evidence	Narrative synthesis	Narrative synthesis	Narrative synthesis
Design of included studies	Not reported	RCTs through to interrupted time series studies	Interrupted time series design, pre-post design with a comparison group
Dates searched	1960 to 2009	Jan 1990 to April 2007	Inception to May 2009
Electronic databases	MEDLINE, PsycINFO, Cochrane Clinical Trials, EMBASE Psychiatry, CINAHL, DARE	NCBI PubMED, ISI Web of Science, Ovid, Campbell collaboration	CINAHL, PsycINFO, MEDLINE
No. of included studies	Total number not reported	29	46
Participant characteristics	Adult psychiatric inpatient populations	Adult psychiatric inpatient staff and patients	Psychiatric units, staff and service users
Intervention	Aggression management training program or a staff training program with an aggression management component	Aggression management training programmes or staff training programmes with an aggression management component	Seclusion and restraint
Comparison	Standard care or other alternative intervention	Standard care or other alternative intervention	Standard care or other alternative intervention
Outcome	• Aggressive incidents • Staff injuries • Restraint and seclusion rates • Staff confidence, knowledge and perceptions	• Rates of aggressive incidents • Rates of restrictive interventions • Experience (staff) • Adverse effects	• Violent and aggressive incidents • Rates of restrictive interventions • Experience (staff) • Adverse events

Note. RCT = Randomised controlled trial.
[1] Research not conducted within the UK, methodological issues.
[2] One small scale interrupted time series design conducted outside the UK.
[3] Most studies were small scale, uncontrolled with limited statistical analysis – difficult to identify mechanism of change in multi-faceted approaches adopted.

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Table 23: Study information table for primary studies evaluating management strategies/training programmes (inpatient settings)

	Management/training programmes
Total no. of studies	2 RCTs and 5 observational studies
Study ID (N)	(1) Ashcraft 2008 (N = 458) (2) Bjorkdahl 2013 (41 wards) (3) Bowers (N = 1,800 annually; 31 wards) – cluster RCT (4) Laker 2010 (N = 195) (5) Lee 2012 (N = 315) (6) Putkonen 2013 (13 wards/88 beds) – cluster RCT (7) Steinert 2008 (N = 588)
Consent gained?	(2) Yes (4, 5, 7) Not applicable (1, 3, 6) Unclear
Country	(1) United States (2) Sweden (3, 4, 5) United Kingdom (6) Finland (7) Germany
Setting	(1, 2, 3, 7) Inpatient (4, 5) PICU (6) Forensic inpatient
Diagnosis	(1, 2, 3, 5) Not explicitly stated (4) Schizophrenia and bipolar (6) Psychosis (7) Personality and adjustment disorders
Age (mean)	(1, 2, 5) Not reported (4) 35.4 (6) 39.42 (7) 35.5
Sex (% Female)	(2) 46 (4) 25 (1, 3, 5) Not reported (6) 3 (7) 64
Ethnicity (% White)	(1, 2, 3, 5, 6, 7) Not reported (4) 22
Intervention(s)	(1, 6) Approach based on Six Core Strategies for Reducing Seclusion and Restraint Use©: training (risks, primary and secondary prevention; trauma informed care), the role of leadership, post-event analysis and service user involvement. (2) Bergen model: training in positive appreciation of patients, self-regulation of emotional responses and effective structures of rules and routines. (3) Safewards: a complex intervention involving 10 'safewards' interventions, which include training (de-escalation model, tools), agreed staff behaviour protocols such as saying something positive at shift handover, positive messages and regular meetings for service users. (4) Training in de-escalation and restraint (5) Strategies in Crisis Intervention and Prevention: training in early intervention and restraint (7) Specialised crisis intervention programme, including patient choice of three "modules" of treatment: crisis, therapy or discharge.

Comparison	(1, 2) Not applicable (3) Package of interventions directed at improving staff physical health (4) Unclear (5) Control and restraint (general services) trained wards (6) Control ward (7) General acute ward
Funding	(1) National Institute on Disability and Rehabilitation Research (Department of Education and the Center for Mental Health Services) (2) AFA Insurance (non-profit organisation) (3, 4, 7) Not reported (5) United Kingdom Central Council for Nurses, Midwives and Health Visiting (6) National Institutes of Health and Welfare
Outcomes	(1) Rates of seclusion and restraint (months until a whole month without use), rates of adverse events (staff injuries) (2) Experience: staff-patient interaction [E13] (3) Rates of containment and rates of violent and aggressive behaviour (conflict) (4) Rates and severity of coercive intervention (RT/ HO) (5) Rates of violent and aggressive behaviour (6) Rates and duration of seclusion, restraint and room observation and rates of violent and aggressive behaviour.
Note. N = total number of participants.	

5.3.3 Clinical evidence for prevention strategies (inpatient settings)

Observation techniques

Effectiveness of observation

In the previous guideline and two more recent reviews with several thousand participants[9] (CG25; Manna 2010; Stewart 2010a), there was low quality evidence that was inconclusive as to the effectiveness of observation in pre-empting and preventing violence and aggression. Furthermore, the practice of observation was complex and involved the simultaneous accommodation of benefits, such as increased opportunities for one-to-one nursing, with harms, such as increased pressure on nursing hours.

In one review of several hundred participants (Stewart 2010a), there was low quality evidence suggesting that potential reductions in observation could occur without an increase in violence and aggression.

Service user and staff experience of observation

In the previous guideline review with several thousand participants, there was low quality evidence suggesting that service users prefer to be observed by a nurse that they know and that most staff find observation a stressful procedure.

[9] An estimate value is given where number of participants was not directly available for all studies; here the number has been approximated from available data, such as numbers of beds.

Modifications to the environment

Effectiveness of modifications to the environment

In two observational studies with 251 participants (Feeney 2007; Vaaler 2005), there was very low quality evidence that was inconclusive with regard to the impact of environmental modifications on rates of violence and aggression.

In one observational study with 14,834 participants (Van der Schaaf 2013), there was low quality evidence suggesting that specific design features were associated with likelihood of seclusion. Features reported to increase the rate of seclusion included presence of outdoor space and the availability of 'special safety measures'. Features that decrease rates of seclusion included having private space, a higher level of comfort and visibility on wards.

Service user and staff experience of modifications to the environment

In two observational studies with 116 participants (Sutton 2013; Vaaler 2005), there was very low quality evidence suggesting that environmental modifications were associated with positive service user experience.

Management strategies/training programmes

Effectiveness of management strategies/training programmes

Low quality evidence from two reviews that included 46 studies of management strategies (Johnson 2010) and 29 studies of training programmes (Livingston 2010) highlighted the difficulty of reaching conclusions based on this evidence. Reasons given by Johnson 2010 were 'the small sample sizes, the fact that many of these projects were conducted in one institution, the lack of statistical analyses, and the lack of comparison groups reduce the confidence one ascribes to the findings and the generalizability of the findings to other settings.' (Johnson 2010, p. 186) Reasons given by Livingston 2010 include the fact that the included research evaluated '…different types of aggression management programs, which contain a variety of approaches. The focus, curriculum, and duration of the training vary substantially from one program to another.' (Livingston 2010, p. 24)

Moderate quality evidence from two RCTs involving 44 wards (Bowers; Putkonen 2013), suggested that a management strategy/training programme can reduce the use of restrictive interventions without increasing the rate of violence and aggression. In the trial of Safewards, Bowers demonstrated that the intervention reduced both 'containment events' and 'conflict events' when compared to the control. In the trial of Six Core Strategies, Putkonen 2013 demonstrated that the intervention when compared to the control reduced 'restraint-seclusion and observation days' with no difference between groups in terms of violence. An earlier observational study with 458 inpatients (Ashcraft 2008) found that it was possible to

reduce seclusion and restraint to near zero using an approach based on the Six Core Strategies (low quality evidence).

Low quality evidence from one observational study with 588 people with personality disorders and adjustment disorders (Steinert 2008) supported the findings from the RCTs described above, demonstrating that a specialised crisis intervention programme reduced violent behaviour and the use of restrictive interventions. However, low quality evidence from an observational study with 195 service users admitted to a PICU (Laker 2010), failed to show de-escalation and restraint training to be effective.

Another observational study (Lee 2012) compared training in early intervention and de-escalation techniques (Strategies in Crisis Intervention and Prevention) with training in a non-pain variant of restraint (Control and Restraint – general services). The authors reported low quality evidence in favour of restraint training, but also noted that the findings cannot be generalised to other inpatient settings.

In two reviews (Johnson 2010; Livingston 2010) and one observational study (Ashcraft 2008), with several hundred participants, there was low quality evidence, which was inconclusive in terms of the impact of staff training on adverse effects, including staff injuries.

Service user and staff experience of management strategies/training programmes

There was low quality evidence from three reviews (Bowers 2011; Johnson 2010; Livingston 2010) and one observational study (Bjorkdahl 2013), with several hundred participants, suggesting partial support that staff training had a positive impact on staff confidence, knowledge and attitudes.

5.3.4 Health economics evidence

From the range of interventions considered in this section, one economic study was found which referred to a modification to the environment in an inpatient setting (Nanda et al., 2011). Details on the methods used for the systematic review of the economic literature are described in Chapter 3; full references and evidence tables for all economic evaluations included in the systematic literature review are provided in Appendix 18. Completed methodology checklists of the studies are provided in Appendix 17.

In the modification to the environment study identified (Nanda et al., 2011), modification took the form of visual art. This study compared four different art conditions: an abstract image by Pollock, an abstract-representational scene by Van Gogh, a realistic nature stock photography image and no art. The study was carried out in an acute care psychiatric unit in the US. Each art condition was displayed on the main wall of the patient lounge for between 16 and 19 days with the control condition of no art being displayed for 21 days. A hospital perspective was taken, with data collected on the number of events requiring p.r.n medication and staff costs during the period the art was displayed. Local cost sources were used to

calculate costs. Using the data collected during the study period, the number of events was projected to estimate the costs over a one year time horizon. Qualitative interviews with unit nurses were also carried out to investigate the mechanisms of the treatment.

According to the results, there were fewer events requiring p.r.n medication in the realistic nature art condition than in the purely abstract or control conditions. The costs per event of p.r.n provision were calculated as $60.30, which when projected over a year implied hospital cost savings of $4,748, $1,297 and $719 for realistic nature, abstract representational and abstract when respectively compared with the control condition of no art (cost year: 2011). The intervention artwork was donated and its cost was not incorporated. Though an incremental analysis was not carried out, the realistic condition resulted in the greatest cost savings and fewest events and so may be considered the dominant option in this analysis.

This study has a number of limitations, these are: short observation time (16 to 19 days for treatment conditions), no quality of life measure and an observational estimate of treatment effect. Fluctuations in service user populations may fully explain the results in absence of statistical or experimental controls. In addition the study was carried out over 6 weeks at one US location. For these reasons the study was considered to be only partly applicable and to have very serious limitations and was not considered in decision making.

Economic evidence statement

One economic study was identified which suggested that displaying realistic nature scenes may reduce need for p.r.n. medication. This analysis was considered to be partially applicable with very serious limitations and therefore was not considered in making recommendations.

5.4 EMERGENCY DEPARTMENT SETTINGS

5.4.1 Introduction

The previous guideline focused on inpatient psychiatric settings and emergency departments, but since this was published in 2005, much has changed economically, politically and socially concerning the NHS in general, and emergency departments in particular.

The Mental Health Crisis Care Concordat published in February 2014 states that 'The Government has put mental health at the centre of its programme of health reform.' It has therefore included a specific objective for the NHS, in the Mandate from the Government to NHS England (Department of Health, 2013).

Conversely, in April 2013 the Health Secretary Jeremy Hunt spoke of pressure on accident and emergency departments as the 'biggest operational challenge facing the NHS' (Hunt, 2013). The Labour party similarly described a crisis in this area with the

Shadow Health Secretary Andy Burnham saying that the number of people waiting longer than four hours in emergency departments had risen from 340,000 in 2009/10 to 888,000…' in 2012 (Burnham, 2012).

On 10th November 2011, the Design Council published a report on 'Reducing Violence and Aggression in A&E: Through a better experience' (The Design Council, 2011). The report states:

> 'Violence and aggression towards frontline hospital staff is estimated to cost the NHS at least £69 million a year in staff absence, loss of productivity and additional security. As many as 59,000 physical assaults occur in English NHS hospitals each year, a figure which continues to rise. With over 21 million patients attending A&E departments each year, increasing pressure on A&E departments can lead to negative experiences for both patients and staff. In the complex, high pressure environment of A&E escalating frustrations can be particularly difficult to manage and diffuse.'

The report identified six profile types, which may contribute to the development of violence and aggression, accepting that many patients exhibit the traits of more than one profile. This, as the report suggests, clearly makes the management of service users who are violent and aggressive more complex and difficult. The profiles identified are those who are clinically confused, frustrated, intoxicated, anti-social/angry, distressed/frightened and socially isolated. Significantly the report states 'Intoxication, in particular alcohol consumption, is believed by staff to be one of the most significant contributors to violence and aggression in A&E departments'. The report also refers to …'environmental factors playing their part, including waiting times, lack of information and boredom to name but a few'.

For the purposes of this guideline, it is recognised that violence and aggression in emergency settings can come from a number of sources outside of patients experiencing mental health crisis. There are, however, key indicators so it is important to identify at the earliest opportunity those patients potentially more disposed to violent and aggression, gathering within reason all available information, to help inform staff when making decisions to firstly try and prevent an episode, and if not possible the management of any violence and aggression (James et al., 2006).

5.4.2 Studies considered

One review and one primary study, which examined management strategies/training programmes for the prevention of violence and aggression within the context of emergency departments (see Table 17 for the review protocol), met eligibility criteria: Anderson 2010 (Anderson et al., 2010); Gerdtz 2013 (Gerdtz et al., 2013). No studies met the eligibility criteria for the remaining review questions. In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

Prevention strategies

Management strategies/ training programmes

One review (Anderson 2010) examined the impact of management strategies/training programmes on the levels of violent and aggressive behaviour directed towards emergency department nurses (Table 24). The reviewed interventions included: modifications to practices and policies and educational programmes targeting individual and collective skills sets. One primary study was also included which used a mixed methods design to measure the impact of a staff training programme on attitude change (Gerdtz 2013) (Table 25).

Table 24: Study information table for systematic reviews evaluating management strategies/training programmes (emergency department)

	Anderson 2010
Review question/ Aim	To review interventions intended to minimise workplace violence directed against emergency department nurses.
Method used to synthesise evidence	Narrative synthesis
Design of included studies	Reviews and primary study equivalent to 'expert opinion'
Dates searched	May & September 2007
Electronic databases	Cochrane, CINAHL, MEDLINE, JBI, ISI Current Contents, First Search, Digital Dissertations.
No. of included studies	14
Participant characteristics	Nurses and emergency department clientele
Intervention	Environment modifications, practice and policy interventions, individual and collective skill set interventions
Comparison	Standard care or other alternative intervention
Outcome	Skills acquisition, attitudes, weapon confiscation, changes in workplace practice

Table 25: Study information table for primary studies evaluating management strategies/training programmes (emergency department)

	Training programmes
Total no. of studies	1 observational study
Study ID (N)	Gerdtz 2013 (471)
Consent gained?	Yes
Country	Australia
Setting	Emergency department
Diagnosis	Not reported
Age (mean)	Not reported
Sex (% Female)	Service user: Not reported Staff: 81
Ethnicity (% White)	Not reported
Intervention(s)	45 minute staff in-service training programme
Comparison	Not applicable
Funding	Victorian Department of Health Nurse Policy Branch Occupational Violence Prevention Fund
Outcomes	Experience: staff attitudes to management

5.4.3 Clinical evidence for prevention strategies (emergency department settings)

Management strategies/training programmes

Effectiveness of management strategies/training programmes

In one review (Anderson 2010), with several hundred participants, there was low quality evidence that was inconclusive as to whether management strategies/training programmes reduced the rates of violence and aggression in emergency departments.

Service user and staff experience of management strategies/training programmes

In one observational study with 471 participants (Gerdtz 2013), there was low quality evidence suggesting partial support for staff training having a positive impact on staff attitudes.

5.4.4 Health economics evidence

No studies assessing the cost effectiveness of interventions in emergency department settings were identified by the systematic search of the economic literature. Details on the methods of the systematic search of economic literature are provided in Chapter 3.

5.5 COMMUNITY SETTINGS

5.5.1 Introduction

The previous guideline was focused solely upon inpatient care. While a number of features are the same, there are also a number of different issues for community settings.

Community settings do not provide the same controlled environments as inpatient settings. Community settings include GP surgeries, home visits, residential units (one of the highest incidences of aggression to care staff is in residential units for older people with dementia), public places, Community Mental Health Teams, assertive outreach teams, and paramedic services. In contrast to inpatient settings, where the more controlled environment means that access to information on any previous incidents tends to be more readily available and more easily shared, in community settings there may be more dispersed and fragmented knowledge about the patient/client; and frequently there is more isolation from the support of other staff. Furthermore, community settings generally lack features of infrastructure that may be used in the management of violence and aggression in inpatient settings.

Violence and aggression in community health and social care settings is not uncommon. A survey of over 2000 care workers found that one of the greatest difficulties reported was clients' challenging behaviours, as experienced by nearly 1 in 10 workers (Skills for Care, 2007). Care workers had often suffered verbal or physical abuse from service users or their families at some stage in their careers - 49% reported verbal abuse and 35% reported physical abuse. In 2010/11, there were 2,348 injuries to workers in non-residential social care (Health and Safety Executive, 2012).

Social care workers in the field of mental health and residential work are more likely to be assaulted than those working in other areas. Research suggests that violence is under-reported in both health and social care settings (O'Beirne & Gabe, 2005; Pahl, 1999). Whilst fatal assaults on social care professionals are rare, when these have occurred there has often been a shared characteristic of professionals working in relative isolation in the community.

How information about how violent incidents is collated, by whom, how, and then shared with other agencies, is key to risk assessment and management in this area. In particular, the sharing of information across inpatient and community settings, and health and social care organisations is crucial. Employers have a responsibility to ensure that risk assessments are appropriately carried out and shared, and have been prosecuted under health and safety legislation where this has not been the case.

The scale and seriousness of violence and aggression in community settings means that we need better knowledge and understanding of its triggers and consequent responses. This is crucial for the safety of staff and service users, and is essentially a

joint enterprise to find more socially acceptable ways to deal with conflict and stress in day-to-day interactions.

This means that we need to find better ways to gain knowledge of and understand the evidence about, and triggers for and best responses to, aggression and violence in community settings when working with clients with mental health problems. This is not only for the staff themselves, but also to help service users engage as a problem for themselves and others, and if needs be to learn ways which are more socially acceptable to deal with conflict, stress and upset in contact with mental health staff in the community.

5.5.2 Studies considered

For the review of prevention strategies within community settings (see Table 17 for the review protocol), seven studies met eligibility criteria for community settings: Thornicroft 2013 (Barrett et al., 2013; Thornicroft et al., 2013); Campbell 2009 (Campbell & Kisely, 2009); Papageorgiou 2004 (Papageorgiou et al., 2004); Ruchlewska 2014 (Ruchlewska et al., 2014); Srebnik 2005 (Srebnik et al., 2005); Swanson 2006 (Swanson et al., 2006) and Swanson 2008 (Swanson et al., 2008). All addressed the role of advance decisions and/or statements in the prevention and management of violent and aggressive behaviour. No literature addressing the remaining review questions was eligible. In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

Advance decisions and statements

One review (2 RCTs) was included which considered the use of 'advance treatment directives' (defined as a document specifying a person's preferences for treatment, should he or she lose capacity to make such decisions in the future) as a strategy to prevent violent and aggressive behaviour (Campbell 2009). As part of a larger review, the authors examined the impact of directives on the reduction of violence as defined by rates of compulsory admission at 18 months (see Table 26).

With regard to primary studies, three RCTs were included which examined the impact of advance decisions and statements on long-term rates of compulsory admission (Thornicroft 2013; Ruchlewska 2014) and coercive crisis interventions (Swanson 2006). Three observational studies (Papageorgiou 2004; Srebnik 2005; Swanson 2008) were also included which examined clinician and service future preferences recorded in the statements (Table 27).

Table 26: Study information table for systematic reviews evaluating advance decisions and statements (community setting)

	Campbell 2012
Review question/ Aim	To examine the effects of 'advance treatment directives' for people with severe mental illness.
Method used to synthesise evidence	Meta-analysis
Design of included studies	RCTs
Dates searched	1872 to February 2008
Electronic databases	Cochrane Library, BIOSIS, CINAHL, EMBASE, MEDLINE, SCISEARCH, Google
No. of included studies	2
Participant characteristics	Psychotic illness or non-psychotic bipolar disorder
Intervention	Joint Crisis Planning
Comparison	Standard Care or alternative interventions
Outcome	• Rates of psychiatric admissions within 15 months • Adverse effects: death at 15 months
Note. RCT = randomised controlled trial.	

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Table 27: Study information table for primary studies evaluating advance decisions and statements (community setting)

Total no. of studies (N)	3 RCTs and 3 observational studies (1,674)
Study ID (N)	(1) Thornicroft 2013 (569)* (2) Papageorgiou 2004 (79) (3) Ruchlewska 2014 (212)* (4) Srebnik 2005 (106) (5) Swanson 2006 (469) * (6) Swanson 2008 (239)
Consent gained?	(1, 2, 3, 4, 5, 6) Yes
Country	(1, 2) United Kingdom (3) Netherlands (4, 5, 6) United States
Setting	(1, 2, 3, 4, 5, 6) Community mental health service
Diagnosis	(1) Schizophrenia spectrum disorder and affective disorders (2) Psychosis (63%), depression/ bipolar disorder (28%) and other (9%) (3) Schizophrenia and bipolar disorder II (4) Schizophrenia spectrum (44%), bipolar disorder (27%), major depression (22%) and other (7%) (5, 6) Schizophrenia, schizoaffective disorder; other psychotic disorder or major mood disorder with psychotic features.
Age (mean)	36-42
Sex (% Female)	(1) 5 (2) 39 (3) 31 (4 - 6) 55 - 60
Ethnicity (% White)	(1) 62 (2,3) Not reported (4) 75 (5, 6) 38
Intervention(s)	(1) Joint crisis planning and treatment as usual (2) Preference for care booklet (3) Patient advocate crisis plan/ clinican facilitated crisis plan (4) Computer facilitated prefence statements (AD-Maker) (5, 6) Structured facilitation of psychiatric advance directives
Comparison	(1) Treatment as usual only – the care programme approach (2, 4) Not applicable (3) Standard practice (crisis plan may be created if requested) (5, 6) 'Non-completers' who chose/ did not complete psychiatric advance directives
Funding	(1) UK Medical Research Council and the National Institute for Health Research (2) National Health Service (3) NIMH and Independent Research Scientist Career Award (4) NIMH and John D. and Katherine T. MacArthur Foundation (5, 6) NIMH, MacArthur Foundation Research Network on Mandated Community Treatment
Outcomes	(1, 3) Rates of psychiatric admission within 18 months (1) Experience: working alliance, service engagement and percieved coercion (2, 4) Experience: service user and/ or clinician preference (5) Experience: working alliance

	(6) Rates of coercive Crisis Interventions: (i) being picked up by the police and transported to an emergency room or other facilitiy for psychiatric treatment (ii) being placed in handcuffs; (iii) being involuntarily committed to hospital (iv) being placed in seclusion (v) being placed in physical restraint (v) receiving forced medication.
Note. N = total number of participants; NIMH = National Institute of Mental Health. * Randomised controlled trial.	

5.5.3 Clinical evidence for prevention strategies (community settings)

Advance decisions and statements

Effectiveness of advance decisions and statements

In one review that included two RCTs (Campbell 2012) and two new RCTs (Thornicroft 2013, Ruchlewska 2014), with a total of 1,359 participants, there was very low quality evidence that was inconclusive as to whether advance decisions and statements reduced voluntary and involuntary psychiatric admissions or duration of hospitalisation, within 18 months. However, Campbell 2012 reported that based on the RCT with 160 participants, there was evidence that the risk of violence was lower in the group that used 'advance treatment directives'.

In one observational study with 239 participants (Swanson 2008), there was very low quality evidence which provided partial support that the use of 'psychiatric advance directives' reduced the odds of future use of coercive crisis interventions by 24 months.

In one RCT with 469 participants (Swanson 2006), there was very low quality evidence which found partial support for the short-term (1 month) improvement in working alliance between service users and clinicians following the use of an intervention that facilitated the use of 'psychiatric advance directives'. Based on low quality evidence, no long-term (18 months) effect was found by a trial of joint crisis plans that included 569 participants (Thornicroft 2013).

In two observational studies with 185 participants (Papageorgiou 2004; Srebnik 2005), there was low quality evidence suggesting that advance decisions and statements could be used by service users even with more severe mental health problems. However, Papageorgiou 2004 highlighted the difficulty of using advance decisions and statements, and the need to integrate them into service users care plan.

5.5.4 Health economics evidence

No studies assessing the cost effectiveness of interventions in the community setting were identified in the systematic economic literature search. Details on the methods of the systematic search of economic literature are provided in Chapter 3.

5.6 LINKING EVIDENCE TO RECOMMENDATIONS

5.6.1 All settings

Relative value placed on the outcomes considered

The GDG agreed that any reported outcomes relevant to the safety, effectiveness and experience of the management of short-term violence and aggression should be considered. In practice, the outcomes most often reported were rates of violence and aggression, use of restrictive interventions, and experience based on both quantitative and qualitative evidence.

Trade-off between clinical benefits and harms

For inpatient settings, based on evidence from studies of observation techniques used to pre-empt or prevent violent and aggressive behaviour, there is currently insufficient evidence to reach a conclusion about the impact that observation techniques have directly on violence and aggression. However, there was some evidence that levels of observation could in some circumstances be reduced without an increase in violence and aggression. Regarding service user and staff experience, it is perhaps not surprising that service users preferred to be observed by a nurse that they knew and that most staff found observation a stressful procedure.

For all settings, based on evidence from studies of modifications to the environment in the inpatient setting, there is currently insufficient evidence to reach a conclusion about the impact that modifications have directly on violence and aggression. However, environmental features do likely impact on the need for seclusion and can have a positive impact on service user experience.

For all settings, based on evidence from studies of management strategies/training programmes in inpatient and emergency department settings, there is currently insufficient evidence to reach a conclusion about the impact that they have directly on violence and aggression. Nevertheless, such strategies may reduce the rates and duration of restrictive interventions without increasing the rate of violence and aggression. In addition, staff training is likely to improve staff confidence, knowledge and attitudes. The GDG agreed that although specific strategies and training programmes could not be recommended, a variety of principles would help improve practice by reducing the use of restrictive interventions. In addition, it was also felt that although there was a paucity of evidence, good practice necessitated recommendations about using medication, including p.r.n. medication, and de-escalation, and recommendations were developed by consensus. The GDG agreed that recommendations should make it clear that any pharmacological strategy used to calm, relax, tranquillise or sedate service users in inpatient settings should be individualised and reviewed at least once a week or more often if necessary. Specific recommendations were also developed about the use of p.r.n. medication because the GDG was concerned about possible risk of harm associated with use of p.r.n., for example, the maximum daily dose (including the standard dose, p.r.n. dose and dose used for rapid tranquillisation) being exceeded.

For all settings, based on evidence from studies of advance decisions (formerly called 'advance directives') and advance statements in community settings, there is currently insufficient evidence to reach a conclusion about the impact that advance decisions and statements have on violence and aggression directly. Despite this, the GDG agreed that it was good practice to involve service users in all decisions about their care, and advance decisions or statements about the use of restrictive interventions should be encouraged.

No relevant evidence examining the benefits and harms associated with the use of personal and institutional alarms, CCTV and communication devices met eligibility criteria, and therefore the GDG chose not to make recommendations concerning their use. In addition, there was no evidence that specifically addressed the question about the recognition and management of substance misuse in mental health service users with violent and aggressive behaviour in health and community care settings.

More generally, the GDG agreed that across all settings there were principles for managing violence and aggression that could be used to improve service user experience, participation in decision-making, and reduce discrimination. This includes respecting human rights and compliance with existing legislation. In particular, the GDG felt that barriers to a service user exercising their rights should be identified and reduced, and if this is not possible, the reason should be recorded in their notes. It was also agreed that carers should also be involved in decision-making wherever possible, if the service user agrees. In addition, prevention of violence and aggression would be assisted by health and social care provider organisations having policies around searching service users, carers and visitors.

In the inpatient setting, the GDG felt it important to make recommendations relevant to prevention based on good practice. It was felt that all staff working in inpatient settings should be trained and understand the risks involved in using restrictive interventions. With regard to observation, it was agreed that health and social care provider organisations should have a policy on observation and positive engagement that adheres to definitions set out in this guideline. Based on expert opinion, the GDG agreed that when observation above the general level continues for 1 week or more, a multidisciplinary review should be conducted. In addition, to avoid any potential misunderstanding about the levels of observation, the GDG used what they considered to be commonly accepted definitions of general, intermittent, continuous and multiprofessional continuous observation, based on a review of the definitions in the previous guideline and their expert opinion. Recommendations about the use of other restrictive interventions during an event are covered in Chapter 6.

In emergency department settings, the GDG agreed that healthcare provider organisations had an obligation to train staff in techniques to reduce the risk of violence and aggression, and in mental health triage and this should be used alongside physical health triage. In addition, it was important to ensure there were

sufficient numbers of staff on duty who have had this training. Also regarding staffing, the GDG agreed that every emergency department should have a psychiatric liaison service that can provide immediate access to a psychiatric nurse or doctor.

In community settings, the GDG agreed it was good practice for healthcare provider organisations, including ambulance trusts, to ensure they have up-to-date policies for managing violence and aggression. These policies should cover lone working in community and primary care settings. As with other settings, the GDG agreed that it was important to make recommendations about staff training and management of violence and aggression, including risk assessment. In particular, based on GDG expert opinion, a recommendation was made about sharing risk assessments.

Trade-off between net health benefits and resource use

The use of observation will draw staff time away from other duties and this opportunity cost must be compared with the alternative methods of managing comparable episodes of violence and aggression. Clinical evidence evaluating observation techniques was unclear but generally supportive of their use, however, it provided little support for particular methods. Difficulties defining observation and its relevant alternatives are barriers to developing economic guidance in this area. The recommendations made here primarily refer to principles of observation which point to benefits such as safety, positive engagement and dignity given that observation will be practiced. These benefits represent principles of the NHS and as such rigid trade-offs in terms of resources and observable benefit may be less appropriate.

The clinical evidence on modifications to the environment was also inconclusive with sparse evidence and difficulties in defining the intervention as separate from multi-component programmes. Recommendations for all settings were based on general principles and local appropriateness with sensible modifications likely to produce important improvements in patient experience and reduce management costs of violent and aggressive incidents.

Though the evidence on the effect of training, management strategies and advance decisions and statements is inconclusive across settings, the GDG considered that the area remains worthy of investment due to savings from improved management of violent events.

In addition to reduced costs there are wider goals which staff training, a reduced focus on restrictive interventions and advance decisions and statements may promote, such as improved relationships and an increased understanding of the causes of violence in mental health settings.

Quality of the evidence

The evidence for the management of violence and aggression pre- and immediately pre-event was generally low to very low quality. For the review of modification to

the environment, the evidence was from observational studies with serious risk of bias across multiple domains, and imprecision due to small sample sizes. For the review of staff training, the evidence was from RCTs, but risk of bias across multiple domains and/or imprecision due to small sample sizes.

Other considerations

Taking into account the evidence presented in this chapter, the GDG also reviewed the recommendations from the previous guideline and judged, based on their expert opinion, that several recommendations were still relevant and of value but would need redrafting in the light of the current context, a widening of the scope, and latest NICE style for recommendations.

Following this approach, the GDG agreed, using consensus methods described in Chapter 3, to recommend that safety and dignity of service users (and the safety of staff) are to the fore when anticipating violence and aggression and that staff understand the legal framework in the context of managing violence and aggression. The recommendations on a policy for searching, and how to carry out searches, were also based on the previous guideline, updated in line with the current context. Recommendations about de-escalation principles and techniques were also formulated using this method.

The GDG also reviewed the guideline, *Service User Experience in Adult Mental Health*, and agreed that a cross-reference to this guideline would be beneficial because that guideline covers detention under the Mental Health Act and other areas that are relevant to people with a mental health problem who exhibit violent or aggressive behaviour.

5.7 RECOMMENDATIONS

5.7.1 All settings

Principles for managing violence and aggression

Improving service user experience

5.7.1.1 Use this guideline in conjunction with NICE's guideline on service user experience in adult mental health and:

- work in partnership with service users and their carers
- adopt approaches to care that respect service users' independence, choice and human rights
- increase social inclusion by decreasing exclusionary practices, such as the use of seclusion and the Mental Health Act 1983.

5.7.1.2 Ensure that the safety and dignity of service users and the safety of staff are priorities when anticipating or managing violence and aggression.

5.7.1.3 Use of restrictive interventions must be undertaken in a manner that complies with the Human Rights Act 1998 and the relevant rights in the European Convention on Human Rights.

5.7.1.4 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.

Staff training

5.7.1.5 In any setting in which restrictive interventions could be used, health and social care provider organisations should train staff to understand and apply the Human Rights Act 1998, the Mental Capacity Act 2005 and the Mental Health Act 1983.

Involving service users in decision-making

5.7.1.6 Involve service users in all decisions about their care, and develop care and risk management plans jointly with them. If a service user is unable or unwilling to participate, offer them the opportunity to review and revise the plans as soon as they are able or willing and, if they agree, involve their carer.

5.7.1.7 Check whether service users have made advance decisions or advance statements about the use of restrictive interventions, and whether a decision-maker has been appointed for them, as soon as possible (for example, during admission to an inpatient unit) and take this information into account when making decisions about care.

5.7.1.8 If a service user has not made any advance decisions or statements about the use of restrictive interventions, encourage them to do so as soon as possible (for example, during admission to an inpatient unit). Ensure that service users understand the side-effect profiles of the medications recommended in this guideline for rapid tranquillisation (see recommendation 6.6.1.22) so that they can make an informed choice.

5.7.1.9 Ensure that service users understand that during any restrictive intervention their human rights will be respected and the least restrictive intervention will be used to enable them to exercise their rights (for example, their right to follow religious or cultural practices during restrictive interventions) as much as possible. Identify and reduce any barriers to a service user exercising their rights and, if this is not possible, record the reasons in their notes.

5.7.1.10 Ensure that carers are involved in decision-making whenever possible, if the service user agrees, and that carers are involved in decision-making for all service users who lack mental capacity, in accordance with the Mental Capacity Act 2005.

Preventing violations of service users' rights

5.7.1.11 Evaluate, together with the service user, whether adjustments to services are needed to ensure that their rights and those of their carers (including rights related to protected characteristics as defined by the Equality Act 2010) are respected, and make any adjustments that are needed. Adjustments might include providing a particular type of support, modifying the way services are delivered or the approach to interaction with the service user, or making changes to facilities. Record this in the service user's care plan.

5.7.1.12 Health and social care provider organisations should train staff in cultural awareness and in the organisation's duties under the Equality Act 2010.

Anticipating and reducing the risk of violence and aggression

Reducing the use of restrictive interventions

Staff training

5.7.1.13 Health and social care provider organisations should train staff who work in services in which restrictive interventions may be used in psychosocial methods to avoid or minimise restrictive interventions. This training should enable staff to develop:

- a person-centred, values-based approach to care, in which personal relationships, continuity of care and a positive approach to promoting health underpin the therapeutic relationship
- an understanding of the relationship between mental health problems and the risk of violence and aggression
- skills to assess why behaviour is likely to become violent or aggressive, including personal, constitutional, mental, physical, environmental, social, communicational, functional and behavioural factors
- skills, methods and techniques to reduce or avert imminent violence and defuse aggression when it arises
- skills, methods and techniques to undertake restrictive interventions safely when these are required

- skills to undertake a post-incident review in collaboration with experienced service users who are not currently using the service.

Restrictive intervention reduction programme

5.7.1.14 Health and social care provider organisations should ensure that all services that use restrictive interventions have a restrictive intervention reduction programme (see recommendation 5.7.1.15) to reduce the incidence of violence and aggression and the use of restrictive interventions.

5.7.1.15 Restrictive intervention reduction programmes should:

- ensure effective service leadership
- address environmental factors likely to increase or decrease the need for restrictive interventions (see recommendation 4.6.1.1)
- involve and empower service users and their carers
- include leisure activities and physical exercise for service users
- use clear and simple care pathways
- use de-escalation
- use crisis and risk management plans and strategies to reduce the need for restrictive interventions
- include post-incident reviews (see recommendations 6.6.2.6–6.6.2.12)
- explore the current and potential use of technology in reporting, monitoring and improving the use of restrictive interventions
- have routine outcome monitoring, including quality of life and service user experience
- be based on outcome measures (safety, effectiveness and service user experience) to support quality improvement programmes.

An individualised pharmacological strategy to reduce the risk of violence and aggression

5.7.1.16 A multidisciplinary team that includes a psychiatrist and a specialist pharmacist should develop and document an individualised pharmacological strategy for using routine and p.r.n. medication to calm, relax, tranquillise or sedate service users who are at risk of violence and aggression as soon as possible after admission to an inpatient unit.

5.7.1.17 The multidisciplinary team should review the pharmacological strategy and the use of medication at least once a week and more frequently if events are escalating and restrictive interventions are being planned or used. The review should be recorded and include:

- clarification of target symptoms
- the likely timescale for response to medication
- the total daily dose of medication, prescribed and administered, including p.r.n. medication
- the number of and reason for any missed doses
- therapeutic response

- the emergence of unwanted effects.

A senior doctor should review medication used for rapid tranquillisation at least once a day.

Preventing violence and aggression

Searching

Developing a policy on searching

5.7.1.18 Health and social care provider organisations should have an operational policy on the searching of service users, their belongings and the environment in which they are accommodated, and the searching of carers and visitors. The policy should address:

- the reasons for carrying out a search, ensuring that the decision to search is proportionate to the risks
- the searching of service users detained under the Mental Health Act 1983 who lack mental capacity
- the rationale for repeated searching of service users, carers or visitors, for example those who misuse drugs or alcohol
- the legal grounds for, and the methods used when, undertaking a search without consent, including when the person physically resists searching
- which staff members are allowed to undertake searching and in which contexts
- who and what can be searched, including persons, clothing, possessions and environments
- the storage, return and disposal of drugs or alcohol
- how to manage any firearms or other weapons carried by service users, including when to call the police
- links to other related policies such as those on drugs and alcohol, and on police liaison.

5.7.1.19 Develop and share a clear and easily understandable summary of the policy on searching for use across the organisation for all service users, carers or visitors who may be searched.

Carrying out searches

5.7.1.20 Health and social care provider organisations should ensure that searches are undertaken by staff who are the same sex as the person being searched.

5.7.1.21 When a decision has been made to undertake a search:

- provide the person who is to be searched with the summary of the organisation's policy on searching
- seek consent to undertake the search
- explain what is being done and why throughout the search
- ensure the person's dignity and privacy are respected during the search
- record what was searched, why and how it was searched, and the disposal of any items found.

5.7.1.22 If a service user refuses to be searched, carry out a multidisciplinary review of the need to perform a search using physical force and explore any consequences in advance. Use physical force only as a last resort.

5.7.1.23 If consent for a search has not been given, a multidisciplinary review has been conducted and physical force has been used, conduct a post-incident review with the service user that includes a visit from an advocacy service or hospital manager.

5.7.1.24 If a service user is carrying a weapon, ask them to place it in a neutral location rather than handing it over.

5.7.1.25 If a service user who is at risk of becoming violent or aggressive is in a room or area where there are objects that could be used as weapons, remove the objects or relocate the service user.

5.7.1.26 Audit the exercise of powers of search and report the outcomes to the trust board or equivalent governing body at least twice a year.

Using p.r.n. medication

5.7.1.27 When prescribing p.r.n. medication to prevent violence and aggression:

- do not prescribe p.r.n. medication routinely or automatically on admission
- tailor p.r.n. medication to individual need and include discussion with the service user
- ensure there is clarity about the rationale and circumstances in which p.r.n. medication may be used and that these are included in the care plan

- ensure that the maximum daily dose is specified and does not inadvertently exceed the maximum daily dose stated in the British national formulary (BNF) when combined with the person's standard dose or their dose for rapid tranquillisation
- only exceed the BNF maximum daily dose (including p.r.n. dose, the standard dose and dose for rapid tranquillisation) if this is planned to achieve an agreed therapeutic goal, documented and carried out under the direction of a senior doctor
- ensure that the interval between p.r.n. doses is specified.

5.7.1.28 The multidisciplinary team should review p.r.n. medication at least once a week and, if p.r.n. medication is to be continued, the rationale for its continuation should be included in the review. If p.r.n. medication has not been used since the last review, consider stopping it.

De-escalation

Staff training

5.7.1.29 Health and social care provider organisations should give staff training in de-escalation that enables them to:

- recognise the early signs of agitation, irritation, anger and aggression
- understand the likely causes of aggression or violence, both generally and for each service user
- use techniques for distraction and calming, and ways to encourage relaxation
- recognise the importance of personal space
- respond to a service user's anger in an appropriate, measured and reasonable way and avoid provocation.

General principles

5.7.1.30 Establish a close working relationship with service users at the earliest opportunity and sensitively monitor changes in their mood or composure that may lead to aggression or violence.

5.7.1.31 Separate agitated service users from others (using quiet areas of the ward, bedrooms, comfort rooms, gardens or other available spaces) to aid de-escalation, ensuring that staff do not become isolated.

5.7.1.32 Use a wide range of verbal and non-verbal skills and interactional techniques to avoid or manage known 'flashpoint' situations (such as refusing a service user's request, asking them to stop doing something they wish to do or asking that they do something they don't wish to do) without provoking aggression.

5.7.1.33 Encourage service users to recognise the triggers and early warning signs of violence and aggression and other vulnerabilities, and to discuss and negotiate their wishes should they become agitated. Include this information in care plans and advance statements and give a copy to the service user.

5.7.1.34 Communicate respect for and empathy with the service user at all stages of de-escalation.

De-escalation techniques

5.7.1.35 If a service user becomes agitated or angry, 1 staff member should take the primary role in communicating with them. That staff member should assess the situation for safety, seek clarification with the service user and negotiate to resolve the situation in a non-confrontational manner.

5.7.1.36 Use emotional regulation and self-management techniques to control or suppress verbal and non-verbal expressions of anxiety or frustration (including body posture and eye contact) when carrying out de-escalation.

5.7.1.37 Use a designated area or room to reduce emotional arousal or agitation and calm the service user. In services where seclusion is practised, do not routinely use the seclusion room for this purpose.

Using restrictive interventions in inpatient settings

Staff training

5.7.1.38 Health and social care provider organisations should train staff working in inpatient settings to undertake restrictive interventions and understand the risks involved in their use, including the side-effect profiles of the medication recommended for rapid tranquillisation in this guideline, and to communicate these risks to service users.

Observation

General principles

5.7.1.39 Staff should be aware of the location of all service users for whom they are responsible, but not all service users need to be kept within sight.

5.7.1.40 At least once during each shift a nurse should set aside dedicated time to assess the mental state of, and engage positively with, the service user. As part of the assessment, the nurse should evaluate the impact of the service user's mental state on the risk of violence and aggression, and record any risk in the notes.

Developing a policy on observation

5.7.1.41 Health and social care provider organisations should have a policy on observation and positive engagement that includes:

- definitions of levels of observation in line with recommendation 5.7.1.42

- who can instigate, increase, decrease and review observation
- when an observer should be male or female
- how often reviews should take place
- how service users' experience of observation will be taken into account
- how to ensure that observation is underpinned by continuous attempts to engage therapeutically
- the levels of observation necessary during the use of other restrictive interventions (for example, seclusion)
- the need for multidisciplinary review when observation above the general level continues for 1 week or more.

Levels of observation

5.7.1.42 Staff in inpatient wards (including general adult wards, older adult wards, psychiatric intensive care units and forensic wards) should use the following definitions for levels of observation, unless a locally agreed policy states otherwise.

- General observation: the baseline level of observation in a specified psychiatric setting. The frequency of observation is once every 30–60 minutes.
- Intermittent observation: usually used if a service user is at risk of becoming violent or aggressive but does not represent an immediate risk. The frequency of observation is once every 15–30 minutes.
- Continuous observation: usually used when a service user presents an immediate threat and needs to be kept within eyesight or at arm's length of a designated one-to-one nurse.
- Multiprofessional continuous observation: usually used when a service user is at the highest risk of harming themselves or others and needs to be kept within eyesight of 2 or 3 staff members and at arm's length of at least 1 staff member.

Using observation

5.7.1.43 Use observation only after positive engagement with the service user has failed to dissipate the risk of violence and aggression.

5.7.1.44 Recognise that service users sometimes find observation provocative, and that it can lead to feelings of isolation and dehumanisation.

5.7.1.45 Use the least intrusive level of observation necessary, balancing the service user's safety, dignity and privacy with the need to maintain the safety of those around them.

5.7.1.46 Give the service user information about why they are under observation, the aims of observation, how long it is likely to last and what needs to be achieved for it to be stopped. If the service user agrees, tell their carer about the aims and level of observation.

5.7.1.47 Record decisions about observation levels in the service user's notes and clearly specify the reasons for the observation.

5.7.1.48 When deciding on levels of observation take into account:

- the service user's current mental state
- any prescribed and non-prescribed medications and their effects
- the current assessment of risk
- the views of the service user, as far as possible.

5.7.1.49 Record clearly the names and titles of the staff responsible for carrying out a review of observation levels (see recommendation 5.7.1.42) and when the review should take place.

5.7.1.50 Staff undertaking observation should:

- take an active role in engaging positively with the service user
- be appropriately briefed about the service user's history, background, specific risk factors and particular needs
- be familiar with the ward, the ward policy for emergency procedures and potential risks in the environment
- be approachable, listen to the service user, know when to use self-disclosure and therapeutic silence, and be able to convey to the service user that they are valued.

5.7.1.51 Ensure that an individual staff member does not undertake a continuous period of observation above the general level for longer than 2 hours. If observation is needed for longer than 2 hours, ensure the staff member has regular breaks.

5.7.1.52 When handing over to another staff member during a period of observation, include the service user in any discussions during the handover if possible.

5.7.1.53 Tell the service user's psychiatrist or on-call doctor as soon as possible if observation above the general level is carried out (see recommendation 5.7.1.42).

5.7.2 Emergency department settings

Staff training

5.7.2.1 Healthcare provider organisations should train staff in emergency departments in methods and techniques to reduce the risk of violence and aggression, including anticipation, prevention and de-escalation.

5.7.2.2 Healthcare provider organisations should train staff in emergency departments in mental health triage.

Staffing

5.7.2.3 Healthcare provider organisations should ensure that, at all times, there are sufficient numbers of staff on duty in emergency departments who have training in the management of violence and aggression in line with this guideline.

5.7.2.4 Healthcare provider organisations and commissioners should ensure that every emergency department has a psychiatric liaison service that can provide immediate access to a psychiatric nurse or doctor.

Preventing violence and aggression

5.7.2.5 Undertake mental health triage for all service users on entry to emergency departments, alongside physical health triage.

5.7.3 Community and primary care settings

Developing policies

5.7.3.1 Healthcare provider organisations, including ambulance trusts, should ensure that they have up-to-date policies on the management of violence and aggression in people with mental health problems, and on lone working, in community and primary care settings, in line with this guideline.

Staff training

5.7.3.2 Healthcare provider organisations, including ambulance trusts, should train staff working in community and primary care settings in methods of avoiding violence, including anticipation, prevention, de-escalation and breakaway techniques.

5.7.3.3 Healthcare provider organisations, including ambulance trusts, should ensure that staff working in community and primary care settings are able to undertake a risk assessment for violence and aggression in service users known to be at risk. The risk assessment should be available for case supervision and in community teams it should be subject to multidisciplinary review.

Managing violence and aggression

5.7.3.4 In community settings, carry out Mental Health Act 1983 assessments in pairs, for example a doctor and a social worker.

5.8 RESEARCH RECOMMENDATIONS

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

5.8.1.2 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?

5.8.1.3 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?

5.8.1.4 How effective are restraint and seclusion minimisation models in reducing the use of restraint, seclusion and/or restrictive interventions in UK inpatient mental health settings?

6 DURING AND POST-EVENT

6.1 INTRODUCTION

Once a violent event has occurred the time scale for action changes dramatically. Within a very short time interventions have to be given that are 'restrictive', in that they curtail, control and avoid further violence. These interventions include pharmacological treatment, restraint, seclusion, and environmental changes to prevent damage to property or harm to others. The method chosen depends greatly on the nature of the violence and the setting in which it occurs. Where weapons are involved and the level of threat is greater, the police may have to be called to render assistance and disarm the person before subsequent management by the staff. Once any capacity for continuing the attack is neutralised, the focus moves to resolving the situation with the service user, verbally, via medical treatment, or via the setting, rather than longer-term forms of containment.

6.2 REVIEW PROTOCOL

The review protocol summaries, including the review questions and the eligibility criteria used for this Chapter of the guideline, can be found in Table 28 (experience – during and post-event), Table 29(non-pharmacological management strategies – during an event), Table 30 (rapid tranquillisation – during an event), Table 31 (management strategies involving the police – during an event), and Table 32 (post-incident management). A complete list of review questions can be found in Appendix 5; further information about the search strategy can be found in Appendix 10; the full review protocols can be found in Appendix 9).

Table 28: Clinical review protocol summary for the review of the experience of the management of violence and aggression (during and post-event)

Component	Description
Review questions	Mental health service users 1.1 Does race/ethnicity of a service user or staff member make a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings? 1.2 Do service users perceive that the race/ethnicity of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings? 1.3 Does gender of a service user or staff member make a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings? 1.4 Do service users perceive that the gender of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings? 1.5 What are the service users' perspectives of the considerations needed for the short-term management of violent and aggressive behaviour in health and community care settings where the service user has physical disabilities? Carers of mental health service users 1.6 Do carers perceive that the race/ethnicity of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings? 1.7 Do carers perceive that the gender of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings? 1.8 What are the carers of mental health service users perspectives of the considerations needed for the short-term management of violent and aggressive behaviour in health and community care settings where the service user has physical disabilities? Staff 1.9 Do staff perceive that the race/ethnicity of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings? 1.10 Do staff perceive that the gender of a service user or staff member makes a difference to how they are treated when they are involved in a violent and aggressive behaviour incident in health and community care settings? 1.11 What are the staff perspectives of the considerations needed for the short-term management of violent and aggressive behaviour in health and community care settings where the service user has physical disabilities?
Population	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	Not applicable
Comparison	Not applicable
Context	Short-term (72 hours) management in health and community care settings
Critical outcomes	Service user/carer/staff views

Study design	Systematic reviews and qualitative research

Table 29: Clinical review protocol summary for the review of non-pharmacological management strategies (during an event)

Component	Description
Review questions	4.1 Do modifications to the environment (both physical and social) of health and community care settings used to reduce the level of violent and aggressive behaviour by service users with mental health problems produce benefits that outweigh possible harms when compared to an alternative management strategy? 4.2 Does the use of personal and institutional alarms, CCTV and communication devices for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? 4.3 Does seclusion used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? 4.4 Do de-escalation methods used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? 4.5 Do physical restraint techniques (including, manual and mechanical restraint) used by staff for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? 4.9 What factors should influence the decision to transfer a mental health service user with violent and aggressive behaviour to a more secure environment?
Subquestion	4.6 If physical restraint techniques (including, manual and mechanical restraint) are used by staff for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings, how should use be modified if, for example, the service user is: • undergoing withdrawal • intoxicated • a heavy drinker • seriously medically ill • has physical disabilities or injuries or is physically frail • pregnant • obese.
Population	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	- Modifications to the environment - Personal and institutional alarms - Seclusion - De-escalation methods - Physical restraint
Comparison	Usual care or other alternative management strategies
Context	Short-term (72 hours) management in health and community care settings
Critical outcomes	• Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views
Study design	RCTs, observational studies and systematic reviews

Note.

1
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Table 30: Clinical review protocol summary for the review of rapid tranquillisation (during an event)

Component	Description
Review question(s)	4.7 Does rapid tranquillisation used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy?
Subquestion	4.8 If rapid tranquillisation is used in the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings, how should use be modified if, for example, the service user is: • undergoing withdrawal • intoxicated • a heavy drinker • seriously medically ill • has physical disabilities or injuries or is physically frail • pregnant • obese.
Population	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	Rapid tranquillisation or urgent sedation (the use of medication to calm/lightly sedate the service user, reduce the risk to self and/or others and achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place, and allowing comprehension and response to spoken messages throughout the intervention. Although not the overt intention, it is recognised that in attempting to calm/lightly sedate the service user, rapid tranquillisation may lead to deep sedation/anaesthesia): • Antipsychotic drugs (aripiprazole, chlorpromazine, haloperidol, loxapine, olanzapine, quetiapine, risperidone) • Benzodiazepines • Antihistamines
Comparison	• Placebo • Another intervention
Context	Short-term (72 hours) management in health and community care settings
Critical outcomes	• Rates of violence and aggression* • Tranquillisation (feeling of calmness and/or calm, non-sedated behaviour)* • Sedation/somnolence* • Adverse effects* • Service user/carer/staff views * • Economic outcomes* * Adapted from the previous guideline.
Study design	RCTs
Note.	

3
4

Table 31: Clinical review protocol summary for the review of management strategies involving the police (during an event)

Component	Description
Review question(s)	4.10 What is the best management strategy for the transfer of mental health service users to or between places of safety? 4.11 What is the best management strategy when the police are called to support mental health staff manage violent and aggressive behaviour by mental health service users in health and community care settings? 4.12 What is the best management strategy when mental health staff are required to call the police to take someone into custody because of violent and aggressive behaviour in health and community care settings?
Population	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	Management strategies involving the police
Comparison	Usual care or other alternative management strategies
Context	Short-term (72 hours) management in health and community care settings
Critical outcomes	• Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views
Study design	Any
Note.	

Table 32: Clinical review protocol summary for the review of post-incident management (post-event)

Component	Description
Review question(s)	5.1 After violent and aggressive behaviour by mental health service users in health and community care settings, what post-incident management should occur for the service user(s) involved? 5.2 After violent and aggressive behaviour by mental health service users in health and community care settings, what post-incident management should occur for the staff involved? 5.3 After violent and aggressive behaviour by mental health service users in health and community care settings, what post-incident management should occur for any witnesses involved?
Population	Mental health service users (excluding people with dementia, learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	Post-incident management strategies
Comparison	Usual care or other alternative management strategies
Context	Short-term (72 hours) management in health and community care settings
Critical outcomes	• Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views
Study design	Any
Note.	

6.3 DURING AN EVENT – ALL SETTINGS

6.3.1 Introduction

Once a violent event has been initiated the response can no longer be just one of prevention. There has to be direct action to prevent the violence from creating more damage to person or property. But the sole aim of interventions to prevent further damage to property is not generally justified because of the increased risk of harm to staff or others. The intervention will depend very much on the setting in which the violence occurs. In primary and community settings where there are dispersed locations, for example on home visits, certain residential and day care units, it is often not possible to have the support from other staff that may be more readily available at inpatient settings, and staff are unlikely to have been trained for restraint; in any event trying to undertake such procedures alone or with just one other colleague or where they have not trained together on this is not a viable or safe option. Equally, it is very unlikely that a professional involved will be qualified and trained to administer rapid tranquillisation, and again, attempting to do so may not be a viable or safe option.

If the individual is in an environment such as a purpose-built seclusion room, where little or no physical damage can be done either to the self, others or physical structures, then the response can be a more measured and gentle one than when a similar episode occurs in a busy and crowded emergency department. Because action has to be taken quickly in settings where others are at risk there is little opportunity to carry out research studies on the best method of managing these episodes when they are not perceived as major in form. As a consequence the number of research studies involving different forms of simple intervention in such settings is very small, and these have been summarised by Taylor and Rew (2011)as inadequate to provide a framework for evidence-based practice. In particular, the randomised controlled trial, the best measure of comparing any intervention, may be perfectly possible to carry out over a long time scale in studies of the prevention of violence (for example,(Abderhalden et al., 2008) but is more difficult to undertake once violence has been instigated unless the intervention can be carried out very quickly. The most common actions involve some form of restraint or what is commonly known as rapid tranquillisation and this is the area where many of the interventions have been compared. The term 'rapid tranquillisation' has been used to describe the administration of medication by any route. Whilst it is generally accepted that the oral route should always be considered as a first option, the majority of clinical trial evidence relates to rapid tranquillisation when medication is administered by the parenteral route. The time scale of the evaluation of these interventions has to be a relatively short one, but it also needs to be appreciated that there may be long-term sequelae to many of these interventions, both psychological in terms of stress, and physical in terms of physical harm and adverse effects of, mainly pharmacological, interventions.

This section is therefore concerned with practical steps and recommendations in each of the settings where violence takes place, most of which constitutes consensual

recommendation, and rapid tranquillisation, where the violence requires urgent pharmacological action and when drug treatment through the oral route is not practical or appropriate – or has been found to be ineffective.

Intervention involves three components:

- Direct action to reduce or end the violence
- The protection of those being attacked and others in the vicinity
- Care to ensure that whatever measures are used to reduce the violence they create as little psychological and physical harm to the person as possible.

Because the setting in which violence occurs is so important it is impossible to set down unequivocal recommendations on the basis of evidence. Desirable methods of intervening may not be available in the very short time between the violence and intervention and yet practitioners always need to be aware that any intervention they make has to be proportionate and safe. That which is proportionate and safe in the community setting may differ to the setting of an acute inpatient psychiatric ward (for example, a psychiatric intensive care unit). The nature of the acute disturbed clinical state leading to the violence and the range of available clinical interventions in the setting will often drive the choice of intervention.

6.3.2 Studies considered[10]

For the review of non-pharmacological management strategies (see Table 29 for the review protocol), in addition to the review conducted for the previous guideline, CG25 (published as Nelstrop 2006 (Nelstrop et al., 2006), four more recent existing reviews met eligibility criteria: Happell 2010 (Happell & Harrow, 2010), Stewart 2009a (Stewart et al., 2009)) and van der Merwe 2009 (Van Der Merwe et al., 2009). In addition, a Cochrane review (Sailas 2012 (Sailas & Fenton, 2012) examined RCT evidence for seclusion and restraint, but found only two trials that were still awaiting classification (that is, were not yet included in the review). These trials were also identified in the guideline search and were judged to be eligible: Bergk 2011 (Bergk et al., 2011) and Huf 2012 (Huf et al., 2012). For this reason, Sailas 2012 is not considered further. Two additional observational studies: Georgieva 2012 (Georgieva et al., 2012; Whitecross et al., 2013) and Whitecross 2013 met eligibility criteria. No studies were identified that addressed the review questions concerning personal and institutional alarms, de-escalation or transfer.

For the review of rapid tranquillisation (see Table 30 for the review protocol), a series of Cochrane reviews (Belgamwar & Fenton, 2005; Gillies et al., 2013; Huf et al., 2009; Powney et al., 2012) were utilised with permission from the publishers, John Wiley and Sons, and with assistance from the Cochrane Schizophrenia Group (Clive Adams, email communication, July 2013). Relevant data from these reviews were

[10]Here and elsewhere in the guideline, each study considered for review is referred to by a study ID (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

combined into one review and analysed according to the strategy set out in the guideline review protocol. Fifty-four RCTs met eligibility criteria: Alexander 2004 (Alexander et al., 2004), Allen 2011b (Allen et al., 2011), Baldacara 2011 (Baldacara et al., 2011), Battaglia 1997 (Battaglia et al., 1997), Battaglia 2002 (Battaglia et al., 2002), Bieniek 1998 (Bieniek et al., 1998), Breier 2001 (Breier et al., 2002), Bristol Myers 2004 (Bristol-Myers, 2004), Bristol-Myers 2004f (Andrezina et al., 2006), Bristol-Myers 2005b (Bristol-Myers, 2005), Brook 1998a (Brook et al., 1998), Chan 2013 (Chan et al., 2013), Chouinard 1993 (Chouinard et al., 1993), Dorevitch 1999 (Dorevitch et al., 1999), Eli 2004 (Eli, 2004), Fitzgerald 1969 (Fitzgerald, 1969), Foster 1997 (Foster S et al., 1997), Fruensgaard 1977 (Fruensgaard et al., 1977), Garza-Trevino 1989 (Garza-Trevino ES et al., 1989), Guo 2007 (Guo, 2007), Han 2005 (Han et al., 2005), Higashima 2004 (Higashima et al., 2004), Hsu 2010 (Hsu et al., 2010), Huf 2007 (Huf et al., 2007), Hwang 2012 (Hwang et al., 2012), Katagiri 2013 (Katagiri et al., 2013), Kelwala 1984 (Kelwala et al., 1984), Kwentus 2012 (Kwentus et al., 2012), Lerner 1979 (Lerner et al., 1979), Lesem 2011 (Lesem et al., 2011), Li 2006 (Li et al., 2006), Man 1973 (Man & Chen, 1973), Meehan 2001 (Meehan K et al., 2001), NCT00316238 (Eli, 2007), NCT00640510 (Eli, 2009), Nobay 2004 (Nobay et al., 2004), Paprocki 1977 (Paprocki & Versiani, 1977), Qu 1999 (Qu et al., 1999), Raveendran 2007 (Raveendran et al., 2007), Reschke 1974 (Reschke, 1974), Resnick 1984 (Resnick & Burton, 1984), Ritter 1972 (Ritter et al., 1972), Salzman 1991 (Salzman et al., 1991), Shu 2010 (Shu et al., 2010), Simeon 1975 (Simeon et al., 1975), Stotsky 1977 (Stotsky, 1977), Subramaney 1998 (Subramaney et al., 1998), Taymeeyapradit 2002 (Taymeeyapradit & Kuasirikul, 2002), TREC 2003 (TREC, 2003), Tuason 1986 (Tuason, 1986), Wang 2004 (Wang et al., 2004), Wright 2001 (Wright et al., 2001), Yang 2003 (Yang et al., 2003), Zimbroff 2007(Zimbroff et al., 2007).

During the review it became known that the manufacturer of IM olanzapine had discontinued the product in the UK and so the GDG would not be able to make recommendations for its use. For this reason evidence relating to IM olanzapine is not presented in this section, but can be found in the full GRADE evidence profiles and associated forest plots, which provide all critical outcomes (see Appendix 14 and Appendix 15b, respectively).

No studies were identified that specifically addressed the review questions that covered experience (see Table 28) or management strategies involving the police (see Table 31). In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

Non-pharmacological management strategies

Seclusion and restraint

The first review, in order of publication date (Nelstrop 2006), was a published version of the previous guideline review, which examined the effectiveness and safety of restraint and seclusion in adult psychiatric inpatient settings and emergency departments (see Table 33). The second review (Stewart 2009a) examined

the prevalence, duration, antecedents and outcomes of manual restraint in adult psychiatric inpatient settings (see Table 34). The third review (van der Merwe 2009) examined empirical studies on seclusion conducted in adult psychiatric inpatient settings (see Table 34). The fourth review (Happell 2010) examined nurses' attitudes towards and the factors governing the implementation of seclusion (see Table 33).

The search for primary studies identified two RCTs (Bergk 2011, Huf 2012) that met eligibility criteria. Both trials compared mechanical restraint with seclusion in a general inpatient or emergency department setting (see Table 35). Two observational studies were also included (Georgieva 2012, Whitecross 2013) which examined service user experience; the former considered future preference for coercive measures and medication, and the latter seclusion-related trauma (see Table 36).

Table 33: Study information table for systematic reviews evaluating restraint and/or seclusion

	Happell 2010	Nelstrop 2006
Review question/ Aim	To explore nurses' attitudes towards the use of seclusion.	To assess whether restraint and seclusion are safe and effective interventions for the short-term management of disturbed/ violent behaviour.
Method used to synthesise evidence	Narrative synthesis	Narrative synthesis
Design of included studies	Unclear	Systematic reviews, cohort studies, descriptive studies, qualitative studies and case studies/ case series.
Dates searched	January 1995 to January 2009	1985 to 2002
Electronic databases	SCOPUS, CINAHL	MEDLINE, CINAHL, PsycINFO, sIGLE, HMIC, SETOC, AMED, BIOME, BNI, BIOLOGICAL ABSTRACTS, COCHRANE LIBRARY, NHS Centre for Reviews and Dissemination, HTA, ReFeR, COIN, POINT, ECONLIT, NATIONAL RESEARCH REGISTER, CURRENT CONTROLLED TRIALS, WEB OF SCIENCE, HEALTHSTAR, BEST EVIDENCE TRIP
No. of included studies	28	35
Participant characteristics	Mental health professionals: nurses	Adult inpatient mental health setting
Intervention	Seclusion	Seclusion and physical restraint
Comparison	Not applicable	Standard care or other alternative intervention
Outcome	• Experience (staff)	• Effectiveness and safety of restrictive interventions • Adverse events
Note.		

Table 34: Study information table for systematic reviews evaluating restraint and/or seclusion

	Stewart 2009a	van der Merwe 2009
Review question/ Aim	To examine the prevalence, duration, antecedents and outcomes of manual restraint in adult psychiatric inpatient settings.	To conduct a comprehensive review on seclusion conducted in psychiatric inpatient settings.
Method used to synthesise evidence	Narrative synthesis.	Narrative synthesis
Design of included studies	Retrospective analyses of charts, observational, qualitative.	Retrospective analyses of records, questionnaires, case-control, before-after, observational and qualitative.
Dates searched	Inception to 2009 (NR publish date)	Inception to November 2006.
Electronic databases	PsycInfo; Cochrane, MEDLINE, EMBASE Psychiatry, CINAHL, British Nursing Index.	PsychInfo, Cochrane, MEDLINE, EMBASE psychiatry, CINAHL and the British Nursing Index.
No. of included studies	45	115
Participant characteristics	Adult psychiatric inpatients	Psychiatric inpatients
Intervention	Manual restraint	Seclusion
Comparison	Standard care or other alternative intervention	Standard care or other alternative intervention.
Outcome	• Experience (service user and staff) • Adverse events	• Experience (service user and staff)
Note.		

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2

Table 35: Summary of study characteristics for trials comparing restraint versus seclusion

	Restraint versus seclusion
Total no. of studies (N)	2 RCTs (131)
Study ID	(1) Bergk 2011[1] (2) Huf 2012
Consent gained?	(1, 2) No
Country	(1) Germany (2) Brazil
Setting	(1) Inpatient (2) Emergency department
Diagnosis	(1) Schizophrenia, affective disorder or personality disorder (2) Serious mental illness[2]
Age (mean)	(1) 39 (2) 40
Sex (% Female)	(1) 27 (2) 66
Ethnicity (% White)	(1, 2) Not reported
Intervention(s)	(1) Mechanical restraint (described as "five-point restraints in a bed (both arms, both legs, and a hip belt)…According to internal hospital guidelines, patients had to be constantly monitored face-to-face during mechanical restraint. If this was not possible, patients had to be monitored at least for 15 minutes of each hour of restraint and by sight check every ten to 15 minutes for the remainder of each hour.") (2) Mechanical restraint (described as "strong cotton bands to both arms and both legs and attached to the bedside to allow some restricted movement in the prone position.")[3]
Comparison	(1) Seclusion (described as "involuntary confinement of a person in a room from which the person is physically prevented from leaving…During seclusion patients were observed every ten to 15 minutes through a window in the door.") (2) Seclusion (described as "sparsely furnished with just bed and toilet, but are airy, and well lit by daylight and an unglazed barred window opening to the nursing station. Seclusion was a restricted experience but not isolated.")
Funding	(1) Not reported (2) Public funding
Outcomes	(1) Coercion Experience Scale (1) PANSS Aggression score (2) Need to change intervention early – within 1 hour (2) Still restricted by 4 hours (2) Change – because of improvement (2) Chance – because of deterioration (2) Compliance – need to call doctor (in first 24 hours) (2) Compliance – did not accept oral medication (2) Compliance – needed extra tranquillising drugs (in first 24 hours) (2) Not discharged by 14 days (2) Satisfaction with conduct of episode (2) Adverse events

Note. N = Total number of participants; RCT = randomised controlled trial.
[1] The trial was stopped early because the regulatory body (Ministry of Social Welfare) advised that patients in mechanical restraint must be continuously monitored. Doing so would have changed the study conditions, therefore the study was stopped with half the planned number recruited.
[2] Inclusion criteria were 'anyone thought to have a serious mental illness admitted to the hospital who: (a) had a degree or risk of aggression or violent behaviour that endangered themselves or others; and (b) was thought by medical and nursing staff to need some form of physical restriction; and (c) for whom the medical and nursing staff had doubt as to whether one form of restriction (restraints) would be better than the other (seclusion room).'
[3] 'Both procedures were also combined with the standard levels of observations (nursing observations every 30 min, medical observations every hour) and use of medications as prescribed within routine care.'

Table 36: Study information table for primary studies evaluating non-pharmacological management strategies

	Management strategies
Total no. of studies (N)	2 observational study (192)
Study ID	(1) Georgieva 2012 (2) Whitecross 2013
Consent gained?	(1) Unclear (2) Yes
Country	(1) Netherlands (2) Australia
Setting	(1, 2) Inpatient
Diagnosis	(1) Psychotic disorder; mood disorder; personality disorder; addiction; PTSD. (2) Schizophrenia or other psychotic illness (52%), schizoaffective disorder (32%), other psychiatric disorder (16%)
Age (mean)	(1) 39.25 (2) 36.89
Sex (% Female)	(1) 54 (2) 26
Ethnicity (% White)	(1,2) Not reported
Intervention(s)	(1) Forced medication and/ or seclusion (2) Post-seclusion counselling/ training
Comparison	(1) No experience of coercion (2) Treatment as usual
Funding	(1) Dutch Ministry of Health and Mental Health Centre Western North-Brabant. (2) Alfred Research Trust
Outcomes	(1) Experience – preference of containment method in a future emergency. (2) Experience – Seclusion-related trauma (Impact of Event Scale – Revised [IES-R]); number of seclusion episodes and number of hours in seclusion.
Note. N = Total number of participants.	

Rapid tranquillisation

Of the 54 trials, there were: two trials of a IM benzodiazepine versus placebo, nine trials of a IM benzodiazepine versus IM antipsychotic, four trials of a comparison of IM haloperidol versus placebo, 16 trials of IM haloperidol versus another IM antipsychotic, two of IM benzodiazepine versus IM antipsychotic plus antihistamine,

three trials of an IM benzodiazepine plus IM antipsychotic versus the same IM benzodiazepine, three trials of an IM benzodiazepine plus IM antipsychotic versus the same IM antipsychotic, three trials of an IM benzodiazepine plus IM antipsychotic versus a different IM antipsychotic, and 1 trial of an IM benzodiazepine plus IM antipsychotic versus IM antipsychotic plus IM antipsychotic. For a summary of the number of studies by individual drug, see Table 37 and Table 38. For a summary of study characteristics, see Table 39, Table 40, Table 41, Table 42, and Table 43.

In addition, there was one trial (Learner 1979) of IV benzodiazepine versus IV haloperidol, and one trial (Chan 2013) of IV antipsychotic (olanzapine or droperidol) plus IV benzodiazepine versus placebo (see Appendix 13 for study details).

There were three trials of inhaled loxapine versus placebo (N = 787). See Table 44 for a summary of study characteristics.

Table 37: Number of studies for each IM benzodiazepine or IM antipsychotic comparison

		IM benzodiazepine				IM antipsychotic
		Clonazepam	**Flunitrazepam**	**Lorazepam**	**Midazolam**	**HAL**
Placebo				2		4
IM antipsychotic	**ARI**			1		2
	CPZ					3
	DRO					1
	HAL	2	1	4		
	LOX					3
	OLZ			1		3
	PER					1
	THI					2
	ZUC					1
IM antipsychotic + antihistamine	**HAL + promethazine**			1	1	

Note. ARI = aripiprazole; CPZ = chlorpromazine; DRO = droperidol; HAL = haloperidol; LOX = loaxapine; OLZ = olanzapine; PER = perphenazine; THI = thiothixene; ZUC = zuclopenthixol acetate.

Table 38: Number of studies for each IM benzodiazepine plus IM antipsychotic comparison

		IM benzodiazepine + IM antipsychotic		
		Lorazepam + HAL	**Midazolam + HAL**	**Clonazepam + RIS**
IM benzodiazepine	**Lorazepam**	2		
IM antipsychotic	**CLZ**			2
	HAL	2	1	
	OLZ		1	
	ZIP		1	
	HAL + CLOTH	1		
IM antipsychotic + antihistamine	**HAL + promethazine**		1	

Note. CLOTH = clothiapine; CLZ = clozapine; HAL = haloperidol; OLZ = olanzapine; RIS = risperidone; ZIP = ziprasidone.

1

Table 39: Summary of study characteristics for trials comparing IM benzodiazepines with placebo or an IM antipsychotic drug

	IM benzodiazepine versus placebo	**IM benzodiazepine versus IM antipsychotic**
Total no. of studies (N)	2 RCTs (243)	9 RCTs (703)
Study ID	(1) Meehan 2001 (2) Zimbroff 2007	(1) Chouinard 1993 (2) Qu 1999 (3) Dorevitch 1999 (4) Garza-Trevino 1989 (5) Salzman 1991 (6) Battaglia 1997 (7) Foster 1997 (8) Meehan 2001 (9) Zimbroff 2007
Consent gained?	(1, 2) Yes	(1, 6, 8, 9) Yes (3, 5, 7) No (2, 4) Unclear
Country	(1) Romania & United States (2) United States	(1) Canada (2) China (3) Israel (8) Romania & United States (4 – 7, 9) United States
Setting	(1) General hospital (2) Not reported	(2 – 4) Acute general psychiatric inpatient (5) PICU (6) General emergency department (1, 7) Psychiatric emergency service (8) General hospital (9) Not reported
Diagnosis	(1, 2) Bipolar disorder	(3, 5 – 8) Psychosis (2, 4) Mental illness (1, 8, 9) Bipolar disorder
Age (mean)	40 to 40.8	32 to 40.8 (3, 6) Not reported

Sex (% Female)	47 to 48	26 to 54 (4) Not reported
Ethnicity (% White)	73 to 72	57 to 73 (1 – 6) Not reported
Intervention(s)	(1) IM lorazepam (2-5 mg) (2) IM lorazepam (2 mg per injection, mean = 1.4 injections)	(1, 2) IM clonazepam (1-2 mg)[1] (3) IM flunitrazepam (1 mg) (7) Oral or IM lorazepam (2 mg) (4 – 6, 8, 9) IM lorazepam (2-5 mg)
Comparison	(1, 2) Placebo	(1 – 6) IM haloperidol (5-10 mg)[2] (7) Oral or IM haloperidol (5 mg) (8) IM olanzapine (10-25 mg) (9) IM aripiprazole (9.75 or 15 mg)
Funding	(1, 2) Pharmaceutical industry	(5, 6, 8) Pharmaceutical industry (7) Nonprofit organisation (1 – 4) Not reported
Outcomes	(1) Global impression – no improvement (1) Global impression – need for additional medication (1, 2) Global impression – sedation (1) Behaviour – ABS (1, 2) Adverse effects – EPS	(1, 3, 5, 6, 8) Global impression – no improvement (6, 8) Global impression – need for additional medication (1, 3, 4, 5, 6, 7, 8, 9) Global impression – sedation (6, 8) Behaviour – ABS (1, 2, 3, 5, 6, 7, 8 , 9) Adverse effects – EPS
Note. IM = Intramuscular injection; N = Total number of participants; PICU = Psychiatric Intensive Care Unit. [1] One trial (Chouinard 1993) administered an anticholinergic (procyclidine) to the haloperidol group and placebo procyclidine to the clonazepam group.		

1
2

Table 40: Summary of study characteristics for trials comparing IM benzodiazepine plus IM antipsychotic with the same benzodiazepine or same antipsychotic drug

	IM benzodiazepine plus IM antipsychotic versus same IM benzodiazepine	**IM benzodiazepine plus IM antipsychotic versus same IM antipsychotic**
Total no. of studies (N)	3 RCTs (130)	3 RCTs (172)
Study ID	(1) Battaglia 1997 (2) Bieniek 1998 (3) Garza-Trevino 1989	(1) Baldacara 2011 (2) Battaglia 1997 (3) Garza-Trevino 1989
Consent gained?	(1) Yes (2) No (3) Unclear	(1, 2) Yes (3) Unclear
Country	United States	(1) Brazil (2, 3) United States
Setting	(1) General emergency department (2) Psychiatric emergency service (3) Acute general psychiatric inpatient	(1) Psychiatric emergency service (2) General emergency department (3) Acute general psychiatric inpatient
Diagnosis	(1) Psychosis	(1, 3) Mental illness

	(2) Severe/acute agitation (3) Mental illness	(2) Psychosis
Age (mean)	34 to 36 (1) Not reported	32 to 34 (3) Not reported
Sex (% Female)	26 to 40	26 to 40
Ethnicity (% White)	Not reported	Not reported
Intervention(s)	(1, 2) IM lorazepam (2 mg) + IM haloperidol (5 mg) (3) IM lorazepam (4 mg) + IM haloperidol (5 mg)	(1) IM midazolam (15 mg) + IM haloperidol (5 mg) (2) IM lorazepam (2 mg) + IM haloperidol (5 mg) (3) IM lorazepam (4 mg) + IM haloperidol (5 mg)
Comparison	IM lorazepam (2 mg)	IM haloperidol (5 mg)
Funding	(1) Pharmaceutical industry (2, 3) Not reported	(2) Pharmaceutical industry (1, 3) Not reported
Outcomes	(2) Global impression – no improvement (1, 2) Global impression – need for additional medication (1, 2, 3) Global impression – sedation (1) Behaviour – ABS (1, 2) Adverse effects – EPS (1) Adverse effects – specific	(1, 2) Global impression – no improvement (2) Global impression – need for additional medication (1, 2, 3) Global impression – sedation (2) Behaviour – ABS (1) Behaviour – OAS (1, 2) Adverse effects – EPS (1, 2) Adverse effects – specific
Note. IM = Intramuscular injection; N = Total number of participants.		

1
2

Table 41: Summary of study characteristics for trials comparing IM benzodiazepine plus IM antipsychotic with different IM antipsychotic drug

	IM benzodiazepine plus IM antipsychotic versus different IM antipsychotic	**IM benzodiazepine plus IM antipsychotic versus IM antipsychotic plus IM antipsychotic**
Total no. of studies (N)	3 RCTs (404)	1 RCT (60)
Study ID	(1) Yang 2003 (2) Han 2005 (3) Baldacara 2011	Subramaney 1998
Consent gained?	(3) Yes (1, 2) Unclear	Yes
Country	(1, 2) China (3) Brazil	South Africa
Setting	(1, 2) Acute general psychiatric inpatient (3) Psychiatric emergency service	Acute general psychiatric inpatient
Diagnosis	(1, 2) Schizophrenia (3) Mental illness	Not explicitly stated, but all had aggressive and disorganised behaviour
Age (mean)	(3) 32.1 (1, 2) Not reported	Not reported
Sex (% Female)	39 to 60	23
Ethnicity (% White)	(1, 2, 3) Not reported	Not reported
Intervention(s)	(1, 2) IM clonazepam (2-6 mg) + IM	IM lorazepam (4 or 10 mg) + IM

	risperidone (2-6 mg) (3) IM midazolam (15 mg) + IM haloperidol (5 mg)	haloperidol (10 mg)
Comparison	(1, 2) IM clozapine (25-200 mg) (3) IM olanzapine (10 mg) or IM ziprasidone (20 mg)	IM clothiapine (40 mg) + IM haloperidol (10 mg)
Funding	Not reported	Not reported
Outcomes	(3) Global impression – no improvement (3) Global impression – sedation (3) Behaviour – OAS (2) Behaviour – PANSS-EC (1, 2) Adverse effects – side effects (2, 3) Adverse effects – EPS	Behaviour – OAS
Note. EPS = extrapyramidal symptoms; IM = Intramuscular injection; N = Total number of participants.		

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Table 42: Summary of study characteristics for trials comparing IM benzodiazepine with IM antipsychotic and/or antihistamine

	IM benzodiazepine versus IM antipsychotic plus antihistamine	**IM benzodiazepine plus IM antipsychotic versus IM antipsychotic plus antihistamine**
Total no. of studies (N)	2 RCTs (501)	1 RCT (60)
Study ID	(1) Alexander 2004 (2) TREC 2003	Baldacara 2011
Consent gained?	(1) Yes (2) No	Yes
Country	(1) India (2) Brazil	Brazil
Setting	(1, 2) Acute general psychiatric inpatient	Psychiatric emergency service
Diagnosis	(1, 2) N/R	Severe Mental illness
Age (mean)	(1) 32 (2) 38	32
Sex (% Female)	(1) 41 (2) 51	39
Ethnicity (% White)	(1, 2) Not reported	Not reported
Intervention(s)	(1) IM lorazepam (4 mg) (2) IM midazolam (15 mg)	IM midazolam (15 mg) + IM haloperidol (5 mg)
Comparison	(1) IM haloperidol (10 mg) + IM promethazine (25/50 mg) (2) IM haloperidol (15 mg) + IM promethazine (50 mg)	IM haloperidol (5 mg) + IM promethazine (50 mg)
Funding	(1, 2) Non-industry	Not reported
Outcomes	(1) Global impression – no improvement (1) Global impression – need for additional medication (1, 2) Global impression – sedation (1, 2) Adverse effects – specific	Global impression – no improvement Global impression – sedation Behaviour – OAS Adverse effects – specific, EPS
Note. EPS = extrapyramidal symptoms; IM = Intramuscular injection; N = Total number of participants.		

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Table 43: Summary of study characteristics for trials comparing IM haloperidol with placebo or IM another antipsychotic

	IM haloperidol versus placebo	IM haloperidol versus another IM antipsychotic
Total no. of studies (N)	4 RCTs (1386)	16 RCTs (1899)
Study ID	(1) Battaglia 2002 (2) Breier 2001 (3) Bristol-Myers 2004f (4) Bristol-Myers 2005b (5) Reschke 1974	(1) Battaglia 2002 (2) Breier 2001 (3) Bristol-Myers 2004f (4) Bristol-Myers 2005b (5) Eli 2004 (6) Fitzgerald 1969 (7) Fruensgaard 1977 (8) Kewala 1984 (9) Man 1973 (10) Paprocki 1977 (11) Reschke 1974 (12) Resnick 1984 (13) Ritter 1972 (14) Stotsky 1977 (15) Taymeeyapradit 2002 (16) Tuason 1986
Consent gained?	(1-5) Unclear	(1-16) Unclear
Country	(1-4) Multiple (11) Not reported	(1-4) Multiple (5) Taiwan (6, 8, 10, 12, 14, 16) United States (7) Denmark (9) China (15) Thailand (11, 13) Not reported
Setting	(1-4) Not reported (5) General emergency and urgent care services	(7, 8, 15, 16) Acute general psychiatric inpatient (10, 12, 14) Psychiatric emergency service (11) General emergency and urgent care services (1-6, 9, 13) Not reported
Diagnosis	(1-4) Not explicitly stated (5) Schizophrenia	(5, 11) Schizophrenia (6, 7, 9, 10, 16) Psychosis (12) Severe/acute agitation (1-4, 8, 13-15) Not explicitly stated
Age (mean)	36 to 38 (2-4) Not reported	33 to 38.6 (2-5, 7, 8, 10, 12, 14, 15) Not reported
Sex (% Female)	34 to 96 (3) Not reported	0 to 100 (3, 12, 15) Not reported
Ethnicity (% White)	(1-5) Not reported	(1-16) Not reported
Intervention(s)	(1, 2, 4) IM haloperidol (7.5 mg) (3) IM haloperidol (6.5 mg) (5) IM haloperidol (1-5 mg)	(1, 2, 4, 5) IM haloperidol (7.5 mg) (3) IM haloperidol (6.5 mg) (6, 9, 12, 13) IM haloperidol (5 mg) (7, 10) IM haloperidol (2.5-5 mg) (8) IM haloperidol (2.5-10 mg)

		(11) IM haloperidol (1-5 mg) (14) IM haloperidol (4-8 mg) (15) IM haloperidol (5-10 mg) (16) IM haloperidol (2.5-5 mg)
Comparison	(1-4) Placebo	(1, 5) IM olanzapine (10 mg) (2) IM olanzapine (2.5-10 mg) (3) IM aripiprazole (10 mg) (4) IM aripiprazole (1-15 mg) (6) IM perphenazine (5 mg) (7, 10) IM loxapine (25-50 mg) (8) IM thiothixene (2.5-10 mg) (9, 13) IM chlorpromazine (50 mg) (11) IM chlorpromazine (25 mg) (12) IM droperidol (4 mg) (14) IM thiothixene (4-8 mg) (15) IM zuclopenthixol acetate (50-100 mg) (16) IM loxapine (12.5-25)
Funding	(2) Pharmaceutical industry (1, 3, 4) Not reported	(2, 5, 8, 14) Pharmaceutical industry (6) No clear interested funding (1, 3, 4, 7, 9-13, 15, 16) Not reported
Outcomes	(5) Global impression – no improvement (1-4) Global impression – need for additional medication (2-4) Behaviour – ABS (2, 3) Behaviour – PANSS-EC (3, 4) Adverse effects – General (4) Adverse effects – Serious (3, 4) Adverse effects – Specific (2, 3, 5) Adverse effects – EPS	Global impression – no improvement Global impression – need for additional medication Global impression – sedation Behaviour – ABS Adverse effects – EPS
Note. EPS = extrapyramidal symptoms; IM = Intramuscular injection; N = Total number of participants.		

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Table 44: Summary of study characteristics for trials comparing inhaled loxapine with placebo

	Inhaled loxapine versus placebo
Total no. of studies (N)	3 RCTs (787)
Study ID	(1) Allen 2011b (2) Kwentus 2012 (3) Lesem 2011
Consent gained?	(1, 2) Yes (3) Unclear
Country	(1 - 3) United States
Setting	(1 - 3) Psychiatric research facilities
Diagnosis	(1) Psychosis (2) Bipolar disorder (3) Schizophrenia
Age (mean)	40 – 43
Sex (% Female)	(1) 19 (2) 50 (3) 26
Ethnicity (% White)	(1) 43 (2) 44 (3) 34
Intervention(s)	Inhaled loxapine (5 or 10 mg) (via inhalation using the Staccato® system)
Comparison	Placebo (via inhalation using the Staccato® system)
Funding	(1 – 3) Pharmaceutical industry
Outcomes	(1 – 3) Global impression – no improvement (1) Global impression – need for additional medication (2) Global impression – mild to marked agitation (2) Global impression – deep sleep/unarousable (1 – 3) Adverse effects – any
Note. IM = Intramuscular injection; N = Total number of participants.	

6.3.3 Clinical evidence for non-pharmacological management strategies (during an event)

Seclusion and restraint

In a review of 21 observational studies in adult psychiatric inpatient settings (Nelstrop 2006), the authors concluded that there was insufficient evidence to determine whether 'seclusion and restraint are safe and/or effective interventions for the short-term management of disturbed/violent behaviour'. In the emergency department, one RCT of 105 adults (Huf 2012), reported low quality evidence that in terms of effectiveness, a least restrictive care pathway (seclusion) could be as effective as a more restrictive pathway (mechanical restraint) with the majority fully managed. Furthermore, for the minority who could not be managed, transition was not found to significantly increase the overall time of the restraint compared to time in seclusion.

With regard to preference, one RCT of 26 inpatients (Bergk 2011) reported low quality evidence suggesting there was little difference in terms of service user's perceived level of coercion between mechanical restraint and seclusion.

Restrictive interventions

One survey of 161 inpatients (Georgieva 2012) reported low quality evidence that service user preference for restrictive interventions during an emergency was influenced by previous experience. The evidence suggested that in those individuals who had not experienced a restrictive intervention and in those who had experienced both seclusion and forced medication, the majority expressed a preference for forced medication in the future. However, in those who had only experienced seclusion, the majority would prefer seclusion in the future.

One review including 45 studies of manual restraint (Stewart 2009a) and one review including 115 studies of seclusion (Van der Merwe 2009) found low quality evidence that service users had predominately negative attitudes towards the use of restrictive interventions, including fear, pain and anger. Furthermore, one cohort study of 31 participants (Whitecross 2013) suggested low quality evidence of notable service user trauma following recent seclusion episodes; with 'probable PTSD' reported in 47% of cases.

One review including 45 studies of manual restraint (Stewart 2009a), one review including 115 studies of seclusion (Van der Merwe 2009) and one review including 28 studies of seclusion (Happell 2010) found that whilst staff generally viewed restrictive interventions as necessary, this benefit was also accompanied by negative feelings including: staff regret, trauma and concerns with regard to the therapeutic relationship.

6.3.4 Clinical evidence for rapid tranquillisation (during an event)

Because there were a large number of specific adverse effects reported in the trials, but event rates were low, only the total numbers of adverse events or those considered serious are presented here (see the full GRADE evidence profiles and associated forest plots for all adverse effects).

For each comparison, summary of findings tables are reported in Table 45, Table 46, Table 47, Table 48, Table 49, Table 50, Table 51, Table 52, Table 53, Table 54. All evidence statements are then grouped at the end of this subsection.

Table 45: Summary of findings table for intramuscular (IM) benzodiazepine compared to placebo

Outcomes	Illustrative comparative risks (95% CI) Assumed risk PLB	Corresponding risk IM BZD	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
Global impression: 1. no improvement - short term Follow-up: 15-60 min	**725 per 1000**	**646 per 1000** (501 to 842)	**RR 0.89** (0.69 to 1.16)	102 (1 study)	**low**[1,2]
Global impression: 1. no improvement - medium term Follow-up: 1-24 hrs	**569 per 1000**	**353 per 1000** (227 to 552)	**RR 0.62** (0.4 to 0.97)	102 (1 study)	**low**[1,2]
Global impression: 2. need for additional medication - medium term Follow-up: mean 1-24 hours	**529 per 1000**	**529 per 1000** (365 to 762)	**RR 1** (0.69 to 1.44)	102 (1 study)	**low**[1,2]
Global impression: 3. sedation - medium term Follow-up: mean 1-24 hours	**65 per 1000**	**139 per 1000** (68 to 264)	**RR 2.16** (1.06 to 4.09)	243 (2 studies)	**low**[2]
Behaviour: 1. average change score (ABS) - medium term Follow-up: mean 1-24 hours		The mean score in the intervention group was **0.60 standard deviations lower** (1 to 0.21 lower)		101 (1 study)	**low**[1,2]
Adverse effects/events: 3. specific - sedation - medium term Follow-up: mean 1-24 hours	**14 per 1000**	**116 per 1000** (15 to 903)	**RR 8.35** (1.07 to 65.01)	141 (1 study)	**low**[1,2]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Generally unclear risk of bias and funded by manufacturer.
[2] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.
[3] One study shows a positive effect and one study shows a negative effect and I^2 value is significant.

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Table 46: Summary of findings table for intramuscular (IM) benzodiazepine compared to IM antipsychotic

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk IM AP	Corresponding risk IM BZD			
Global impression: 1. no improvement; vs haloperidol - medium term Follow-up: 1-24 hrs	**561 per 1000**	**488 per 1000** (314 to 763)	**RR 0.87** (0.56 to 1.36)	158 (4 studies)	**low**[1,2]
Global impression: 2. need for additional medication; vs haloperidol - medium term Follow-up: mean 1-24 hours	**886 per 1000**	**771 per 1000** (620 to 965)	**RR 0.87** (0.7 to 1.09)	66 (1 study)	**low**[1,2]
Global impression: 3. sedation; vs haloperidol - short term Follow-up: mean 15-60 minutes	**333 per 1000**	**390 per 1000** (177 to 863)	**RR 1.17** (0.53 to 2.59)	44 (1 study)	**low**[1,2]
Global impression: 3. sedation; vs haloperidol - medium term Follow-up: 1-24 hours	**203 per 1000**	**270 per 1000** (191 to 379)	**RR 1.33** (0.94 to 1.87)	394 (7 studies)	**low**[1,2]
Global impression: 3. sedation; vs aripiprazole - medium term Follow-up: 1-24 hours	**120 per 1000**	**191 per 1000** (100 to 367)	**RR 1.59** (0.83 to 3.06)	218 (1 study)	**low**[1,2]
Behaviour: 2. average change/endpoint score (ABS); vs haloperidol - medium term Follow-up: 1-24 hours		The mean score in the intervention groups was **0.20 standard deviations higher** (0.28 lower to 0.69 higher)		66 (1 study)	**low**[1,2]
Behaviour: 4. average change score (OAS); vs haloperidol - medium term Follow-up: 1-24 hours		The mean change score was **0.15 standard deviations higher**		46 (1 study)	**low**[2,3]

		(0.43 lower to 0.73 higher)			
Adverse effects: 3. specific; vs aripiprazole - sedation - medium term Follow-up: 1-24 hours	**53 per 1000**	**116 per 1000** (45 to 296)	**RR 2.17** (0.85 to 5.55)	219 (1 study)	**low**[1,2]
Adverse effects: 1. extrapyramidal symptoms - vs haloperidol - medium term Follow-up: 1-24 hours	**186 per 1000**	**24 per 1000** (7 to 80)	**RR 0.13** (0.04 to 0.43)	233 (6 studies)	**low**[1,2]
Adverse effects: 1. extrapyramidal symptoms - vs aripiprazole - medium term Follow-up: 1-24 hours	**53 per 1000**	**7 per 1000** (1 to 116)	**RR 0.13** (0.01 to 2.17)	219 (1 study)	**low**[1,2]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Generally unclear risk of bias and funded by manufacturer.
[2] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.
[3] Generally unclear RoB and funding not reported.

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Table 47: Summary of findings table for intramuscular (IM) benzodiazepine plus IM antipsychotic versus same IM benzodiazepine

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk **Same BZD**	Corresponding risk **IM BZD + AP**			
Global impression: 1. no improvement; + haloperidol - short term (15-60min) Follow-up: 15-60 minutes	**455 per 1000**	**50 per 1000** (5 to 791)	**RR 0.11** (0.01 to 1.74)	20 (1 study)	**very low**[1,2]
Global impression: 1. no improvement; + haloperidol - medium term (1-24hrs) Follow-up: 1-24 hour	**683 per 1000**	**656 per 1000** (478 to 888)	**RR 0.96** (0.7 to 1.3)	83 (2 studies)	**low**[1,3]
Global impression: 2. need for additional medication; + haloperidol - medium term Follow-up: 1-24 hours	**619 per 1000**	**576 per 1000**	**RR 0.93** (0.34 to 2.55)	83 (2 studies)	**low**[1,3]
Global impression: 3. sedation; + haloperidol - short term Follow-up: 15-60 minutes	**391 per 1000**	**751 per 1000** (430 to 1000)	**RR 1.92** (1.1 to 3.35)	47 (1 study)	**low**[3,4]
Global impression: 3. sedation; + haloperidol - medium term Follow-up: 1-24 hours	**556 per 1000**	**472 per 1000** (294 to 750)	**RR 0.85** (0.53 to 1.35)	110 (2 studies)	**low**[1,3]
Behaviour: 1. average endpoint score (ABS); + haloperidol - medium term Follow-up: 1-24 hours		The mean score in the intervention group was **0.18 standard deviations lower** (0.67 lower to 0.32 higher)		63 (1 study)	**low**[1,3]
Adverse effects: 1. extrapyramidal symptoms - +haloperidol - medium term Follow-up: 1-24 hours	**24 per 1000**	**46 per 1000** (4 to 483)	RR 1.94 (0.18 to 20.3)	83 (2 studies)	**low**[1,3]
Adverse effects: 2. use of medication for EPS - +haloperidol - medium term Follow-up: 1-24 hours	**129 per 1000**	**94 per 1000** (23 to 386)	RR 0.73 (0.18 to 2.99)	63 (1 study)	**low**[1,3]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Generally unclear risk of bias and funded by manufacturer.
[2] Very small sample with wide CIs crossing the line of no effect
[3] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.
[4] Generally unclear RoB and funding not reported.

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Table 48: Summary of findings table for intramuscular (IM) benzodiazepine plus IM antipsychotic compared to same antipsychotic

Outcomes	Illustrative comparative risks (95% CI) Assumed risk **SAME AP**	Corresponding risk **IM BZD + IM AP**	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
Global impression: 1. no improvement; +/vs haloperidol - medium term (1-24hrs) Follow-up: 1-24 hours	**385 per 1000**	**1000 per 1000** (50 to 1000)	**RR 3** (0.13 to 67.48)	127 (2 studies)	**low**[1,2]
Global impression: 2. need for additional medication; +/vs haloperidol - medium term Follow-up: 1-24 hours	**886 per 1000**	**841 per 1000** (700 to 1000)	**RR 0.95** (0.79 to 1.15)	67 (1 study)	**low**[2,3]
Global impression: 4. sedation; +/vs haloperidol - short term Follow-up: 15-60 minutes	**333 per 1000**	**750 per 1000** (393 to 1000)	**RR 2.25** (1.18 to 4.3)	45 (1 study)	**low**[2,4]
Global impression: 4. sedation; +/vs haloperidol - medium term Follow-up: 1-24 hours	**256 per 1000**	**427 per 1000** (171 to 1000)	**RR 1.67** (0.67 to 4.12)	172 (3 studies)	**very low**[1,2,3]
Behaviour: 1. average endpoint score (ABS); +/vs haloperidol - medium term Follow-up: 1-24 hours		The mean score in the intervention groups was **0.02 standard deviations higher** (0.46 lower to 0.5 higher)		67 (1 study)	**low**[2,3]
Behaviour: 2. average endpoint score (OAS); +/vs haloperidol - short		The mean score in the intervention groups was **0.48 standard**		60 (1 study)	**low**[2,5]

term Follow-up: 15-60 minutes		**deviations higher** (0.03 lower to 1 higher)			
Behaviour: 2. average endpoint score (OAS); +/vs haloperidol - medium term Follow-up: 1-24 hours		The mean score in the intervention groups was **0.66 standard deviations higher** (0.14 to 1.18 higher)		60 (1 study)	**low**[2,5]
Adverse effects: 1. extrapyramidal symptoms - +/vs haloperidol - medium term Follow-up: 1-24 hours	**185 per 1000**	**83 per 1000** (31 to 225)	RR 0.45 (0.17 to 1.22)	127 (2 studies)	**low**[2,3]
Adverse effects: 2. use of medication for EPS - +/vs haloperidol - medium term Follow-up: 1-24 hours	**257 per 1000**	**126 per 1000** (44 to 368)	RR 0.49 (0.17 to 1.43)	67 (1 study)	**low**[2,3]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Studies found contrasting results. High, significant I squared value.
[2] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.
[3] Generally unclear risk of bias and funded by manufacturer.
[4] Generally unclear or high RoB and funding not reported.
[5] Generally unclear RoB and funding not reported.

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Table 49: Summary of findings table for intramuscular (IM) benzodiazepine plus IM antipsychotic compared to different IM antipsychotic

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk **Different IM AP**	Corresponding risk **IM BZD + AP**			
Global impression: 1. no improvement; + haloperidol vs ziprasidone - medium term (1-24hrs) Follow-up: 1-24 hours	**100 per 1000**	**400 per 1000** (125 to 1000)	**RR 4** (1.25 to 12.75)	60 (1 study)	**low**[1,2]
Global impression: 3. sedation; + haloperidol vs ziprasidone -	**100 per 1000**	**400 per 1000** (125 to 1000)	**RR 4** (1.25 to 12.75)	60 (1 study)	**low**[1,2]

medium term Follow-up: 1-24 hours					
Behaviour: 1. average change score (OAS); + haloperidol vs ziprasidone - short term Follow-up: 15-60 minutes		The mean score in the intervention groups was **0.55 standard deviations higher** (0.03 to 1.06 higher)		60 (1 study)	**low**[1,2]
Behaviour: 1. average change score (OAS); + haloperidol vs ziprasidone - medium term Follow-up: 1-24 hours		The mean score in the intervention groups was **0.96 standard deviations higher** (0.43 to 1.5 higher)		60 (1 study)	**low**[1,2]
Adverse effects: 2. extrapyramidal symptoms - +haloperidol vs ziprasidone - medium term Follow-up: 1-24 hours	Zero events	Not estimable	RR 7 (0.38 to 129.93)	60 (1 study)	low[1,2]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Generally unclear risk of bias and funding not reported
[2] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

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Table 50: Summary of findings table for intramuscular (IM) benzodiazepine plus IM antipsychotic compared to IM antipsychotic plus another IM antipsychotic

Outcomes	**Illustrative comparative risks (95% CI)**		**Relative effect (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**
	Assumed risk **IM AP + IM AP**	Corresponding risk **IM BZD + AP**			
Behaviour: 3. average endpoint score (OAS) + haloperidol vs clothiapine + haloperidol - medium term (1-24hrs) Follow-up: 1-24 hours		The mean score in the intervention groups was **0.13 standard deviations lower** (0.64 lower to 0.37 higher)		60 (1 study)	**low**[1,2]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Generally unclear risk of bias and funding not reported
[2] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

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Table 51: Summary of findings table for intramuscular (IM) benzodiazepine versus IM antipsychotic plus antihistamine

Outcomes	Illustrative comparative risks (95% CI) Assumed risk IM AP + antihistamines	Corresponding risk IM BZD	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
Global impression: 1. no improvement; vs haloperidol + promethazine - immediate term Follow-up: 0-15 minutes	**390 per 1000**	**698 per 1000** (530 to 924)	**RR 1.79** (1.36 to 2.37)	200 (1 study)	**low**[1,2]
Global impression: 1. no improvement; vs haloperidol + promethazine - short term Follow-up: 15-60 minutes	**170 per 1000**	**420 per 1000** (257 to 685)	**RR 2.47** (1.51 to 4.03)	200 (1 study)	**low**[1,2]
Global impression: 1. no improvement; vs haloperidol + promethazine - medium term Follow-up: 1-24 hours	**120 per 1000**	**260 per 1000** (139 to 486)	**RR 2.17** (1.16 to 4.05)	200 (1 study)	**low**[1,2]
Global impression: 2. need for additional medication; vs haloperidol + promethazine - immediate term Follow-up: 0-15 minutes	Zero events	Not estimable	No events in either group	200 (1 study)	-
Global impression: 2. need for additional medication; vs haloperidol + promethazine - short term Follow-up: 15-60 minutes	Zero events	Not estimable	**RR 3** (0.12 to 72.77)	200 (1 study)	**low**[1,2]
Global impression: 2. need for additional medication; vs haloperidol + promethazine - medium term Follow-up: 1-24 hours	**30 per 1000**	**40 per 1000** (9 to 174)	**RR 1.33** (0.31 to 5.81)	200 (1 study)	**low**[1,2]
Global impression: 3. sedation (tranquil or asleep); vs haloperidol + promethazine - immediate term (lorazepam) Follow-up: 0-15 minutes	**890 per 1000**	**783 per 1000** (685 to 881)	**RR 0.88** (0.77 to 0.99)	200 (1 study)	**low**[1,2]

Global impression: 3. sedation (tranquil or asleep); vs haloperidol + promethazine - short term (lorazepam) Follow-up: 15-60 minutes	**950 per 1000**	**808 per 1000** (731 to 902)	**RR 0.85** (0.77 to 0.95)	200 (1 study)	**low**[1,2]
Global impression: 3. sedation (tranquil or asleep); vs haloperidol + promethazine - medium term (lorazepam) Follow-up: 1-24 hours	**970 per 1000**	**883 per 1000** (815 to 951)	**RR 0.91** (0.84 to 0.98)	200 (1 study)	**low**[1,2]
Global impression: 3. sedation (tranquil or asleep); vs haloperidol + promethazine - short term (midazolam) Follow-up: 15-60 minutes	**673 per 1000**	**889 per 1000** (781 to 1000)	**RR 1.32** (1.16 to 1.49)	301 (1 study)	**low**[1,2]
Global impression: 3. sedation (tranquil or asleep); vs haloperidol + promethazine - medium term (midazolam) Follow-up: 1-24 hours	**827 per 1000**	**934 per 1000** (860 to 1000)	**RR 1.13** (1.04 to 1.23)	301 (1 study)	**low**[1,2]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Participants and outcome assessors were non-blinded.
[2] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

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Table 52: Summary of findings table for intramuscular (IM) benzodiazepine plus IM antipsychotic versus IM antipsychotic plus antihistamine

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk **IM AP + antihistamine**	Corresponding risk **IM BZD + AP**			
Global impression: 1. no improvement; + haloperidol vs haloperidol + promethazine - medium term (1-24hrs) Follow-up: 1-24 hours	**0 per 1000**	**0 per 1000** (0 to 0)	**RR 25** (1.55 to 403.99)	60 (1 study)	**low**[1,2]

Global impression: 3. sedation - + haloperidol vs haloperidol + promethazine - medium term Follow-up: 1-24 hours	**33 per 1000**	**400 per 1000** (55 to 1000)	**RR 12** (1.66 to 86.59)	60 (1 study)	**low**[1,2]
Behaviour: 1. average endpoint score (OAS) + haloperidol vs haloperidol + promethazine - short term Follow-up: 15-60 minutes		The mean score in the intervention groups was **0.85 standard deviations lower** (1.38 to 0.32 lower)		60 (1 study)	**low**[1,2]
Behaviour: 1. average endpoint score (OAS) + haloperidol vs haloperidol + promethazine - medium term Follow-up: 1-24 hours		The mean score in the intervention groups was **0.48 standard deviations higher** (0.03 lower to 1 higher)		60 (1 study)	**low**[1,2]
Adverse effects/events: 1. extrapyramidal symptoms - +haloperidol vs haloperidol+promethazine - medium term Follow-up: 1-24 hours	**167 per 1000**	**100 per 1000** (27 to 382)	**RR 0.6** (0.16 to 2.29)	60 (1 study)	**low**[1,2]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Participants and outcome assessors were non-blinded.
[2] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

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Table 53: Summary of findings table for intramuscular (IM) haloperidol versus placebo

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk **PLB**	Corresponding risk **IM HAL**			
Repeated need for tranquillisation - needing additional injection during 24 hours (agitation only)	**582 per 1000**	**303 per 1000** (245 to 379)	**RR 0.52** (0.42 to 0.65)	660 (4 studies)	**low**[1,2]

Global outcome: 1. Not improved - not marked improvement	**1000 per 1000**	**610 per 1000** (440 to 840)	**RR 0.61** (0.44 to 0.84)	40 (1 study)	**low**[1,2]
Global outcome: 1. Not improved - not any improvement	**364 per 1000**	**102 per 1000** (29 to 389)	**RR 0.28** (0.08 to 1.07)	40 (1 study)	**low**[1,2]
Global outcome: 2. Need for benzodiazepine during 24 hours - need for benzodiazepine during 24 hours	**269 per 1000**	**135 per 1000** (81 to 218)	**RR 0.5** (0.3 to 0.81)	660 (4 studies)	**low**[1,2]
Specific behaviour - agitation: 2a. Average score - by about 2 hours - change score - ABS (high = worse)		The mean score in the intervention groups was **0.65 standard deviations lower** (0.95 to 0.35 lower)		474 (3 studies)	**moderate**[1]
Specific behaviour - agitation: 2a. Average score - by about 2 hours - change score - PANSS-EC (high = worse)		The mean score in the intervention groups was **0.59 standard deviations lower** (1.04 to 0.14 lower)		357 (2 studies)	**low**[1,2]
Specific behaviour - agitation: 2b. Average score - by about 24 hours - change score - ABS (high = worse)		The mean score in the intervention groups was **0.59 standard deviations lower** (1.02 to 0.15 lower)		85 (1 study)	**low**[2,3]
Specific behaviour - agitation: 2b. Average score - by about 24 hours - change score - PANSS-EC (high = worse)		The mean score in the intervention groups was **0.38 standard deviations lower** (0.81 lower to 0.05 higher)		85 (1 study)	**low**[2,3]
Adverse effects: 1. General - one or more drug related adverse effects during 24 hours	**280 per 1000**	**459 per 1000** (342 to 616)	**RR 1.64** (1.22 to 2.2)	395 (2 studies)	**moderate**[1,2]
Adverse effects: 1. General - increased severity of	**136 per 1000**	**443 per 1000** (256 to 768)	**RR 3.25** (1.88 to 5.63)	273 (1 study)	**low**[1,2]

adverse effects after 2nd injection					
Adverse effects: 1. General - overall adverse events during 72 hours	**273 per 1000**	**485 per 1000** (335 to 706)	**RR 1.78** (1.23 to 2.59)	273 (1 study)	**low**[1,2]
Adverse effects: 2. General - Serious - death	Zero events	Not estimable	Zero events in either group	273 (1 study)	–
Adverse effects: 2. General - Serious - rated as serious	**16 per 1000**	**5 per 1000** (0 to 134)	**RR 0.34** (0.01 to 8.29)	122 (1 study)	**low**[1,2]
Adverse effects: 2. General - Serious - tonic clonic seizure	Zero events	Not estimable	Zero events in either group	117 (1 study)	–
Adverse effects: 3. Specific - arousal level - "over" sedated	**51 per 1000**	**154 per 1000** (64 to 367)	**RR 3.04** (1.27 to 7.26)	313 (2 studies)	**low**[1,2]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] RoB generally unclear and funding not reported
[2] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.
[3] RoB generally unclear and trial funded by manufacturer.

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Table 54: Summary of findings table for intramuscular (IM) haloperidol versus another IM antipsychotic

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk **OTHER IM AP**	Corresponding risk **IM HAL**			
Repeated need for rapid tranquillisation: needing additional injection	**338 per 1000**	**351 per 1000** (294 to 422)	**RR 1.04** (0.87 to 1.25)	1418 (9 studies)	**low**[1,2]
Repeated need for rapid tranquillisation: needing additional injection - vs aripiprazole	**411 per 1000**	**325 per 1000** (255 to 411)	**RR 0.79** (0.62 to 1)	473 (2 studies)	**low**[3,4]
Repeated need for rapid tranquillisation: needing additional injection - vs chlorpromazine	**933 per 1000**	**999 per 1000** (831 to 1000)	**RR 1.07** (0.89 to 1.28)	30 (1 study)	**very low**[3,5]
Repeated need for rapid tranquillisation: needing	**364 per 1000**	**811 per 1000** (360 to 1000)	**RR 2.23** (0.99 to 5.06)	27 (1 study)	**low**[3,4]

additional injection - vs droperidol					
Repeated need for rapid tranquillisation: needing additional injection - vs zuclopenthixol acetate	**184 per 1000**	**468 per 1000** (219 to 1000)	**RR 2.54** (1.19 to 5.46)	70 (1 study)	**low**[3,4]
Repeated need for rapid tranquillisation: needing additional injection - vs thiothixene	**933 per 1000**	**999 per 1000** (831 to 1000)	**RR 1.07** (0.89 to 1.28)	30 (1 study)	**low**[1,4]
Global outcome: Not improved	**258 per 1000**	**188 per 1000** (119 to 304)	**RR 0.73** (0.46 to 1.18)	840 (10 studies)	**low**[3,4]
Global outcome: Not improved - vs chlorpromazine	**286 per 1000**	**46 per 1000** (14 to 137)	**RR 0.16** (0.05 to 0.48)	89 (2 studies)	**low**[3,4]
Global outcome: Not improved - vs loxapine	**254 per 1000**	**208 per 1000** (107 to 412)	**RR 0.82** (0.42 to 1.62)	121 (3 studies)	**low**[3,4]
Global outcome: Not improved - vs perphenazine	**95 per 1000**	**44 per 1000** (4 to 446)	**RR 0.46** (0.04 to 4.68)	44 (1 study)	**low**[3,4]
Global outcome: Not improved - vs thiothixene	**0 per 1000**	**0 per 1000** (0 to 0)	**RR 4.2** (0.21 to 82.72)	44 (1 study)	**low**[1,4]
Adverse effects: 1a. General (aripiprazole) - one or more drug related adverse effects during 24 hours	**384 per 1000**	**453 per 1000** (364 to 560)	**RR 1.18** (0.95 to 1.46)	477 (2 studies)	**low**[3,4]
Adverse effects: 1a. General (aripiprazole) - increased severity of adverse effects after 2nd injection	**331 per 1000**	**444 per 1000** (341 to 577)	**RR 1.34** (1.03 to 1.74)	360 (1 study)	**low**[3,4]
Adverse effects: 1a. General (aripiprazole) - overall adverse events during 72 hours	**366 per 1000**	**486 per 1000** (380 to 622)	**RR 1.33** (1.04 to 1.7)	360 (1 study)	**low**[3,4]
Adverse effects: 1b. 'Serious' (aripiprazole) – any	**30 per 1000**	**17 per 1000** (3 to 95)	**RR 0.55** (0.1 to 3.16)	477 (2 studies)	
Adverse effects: 1b. 'Serious' (aripiprazole) - tonic clonic seizure	**18 per 1000**	**6 per 1000** (0 to 134)	**RR 0.32** (0.01 to 7.62)	117 (1 study)	**low**[3,4]
Adverse effects: 1b. 'Serious' (aripiprazole) – death	Zero events	Not estimable	Zero events in either group	360 (1 study)	–
Adverse effects: any serious or specific AEs (chlorpromazine) - arousal - drowsy but asleep	**600 per 1000**	**36 per 1000** (6 to 252)	**RR 0.06** (0.01 to 0.42)	39 (1 study)	**low**[3,4]

Adverse effects: 1. General (perphenazine) - one or more adverse effect	**333 per 1000**	**433 per 1000** (203 to 933)	**RR 1.3** (0.61 to 2.8)	44 (1 study)	**low**[3,4]
Adverse effects: 1. General (ziprasidone) - one or more drug related adverse effects - by 72 hours	**317 per 1000**	**536 per 1000** (390 to 739)	**RR 1.69** (1.23 to 2.33)	739 (3 studies)	**very low**[1,2,4]
Adverse effects: 1. General (ziprasidone) - severe adverse effect - by 72 hours	Zero events	Not estimable	Zero events in either group	376 (1 study)	–
Adverse effects: 1. General (loxapine) - one or more drug related adverse effect	**667 per 1000**	**533 per 1000** (293 to 967)	**RR 0.8** (0.44 to 1.45)	30 (1 study)	**low**[3,4]
Adverse effects: 1. General - one or more adverse effects (thiothixene)	**400 per 1000**	**568 per 1000** (388 to 836)	**RR 1.42** (0.97 to 2.09)	74 (2 studies)	**low**[1,4]

Note. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] RoB generally unclear and funded by manufacturer
[2] High and significant I squared value
[3] RoB generally unclear and funding not reported
[4] Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.
[5] Very small sample with wide CIs crossing the line of no effect.

Given the large number of comparisons, summary forest plots were used to aid interpretation as can be seen in Figure 5 (global effect – no improvement), Figure 6 (behaviour – agitation), Figure 7 (global effect – excessive sedation), and Figure 8 (adverse effect – extrapyramidal symptoms).

Figure 5: Rapid tranquillisation summary forest plot for the global effect – no improvement

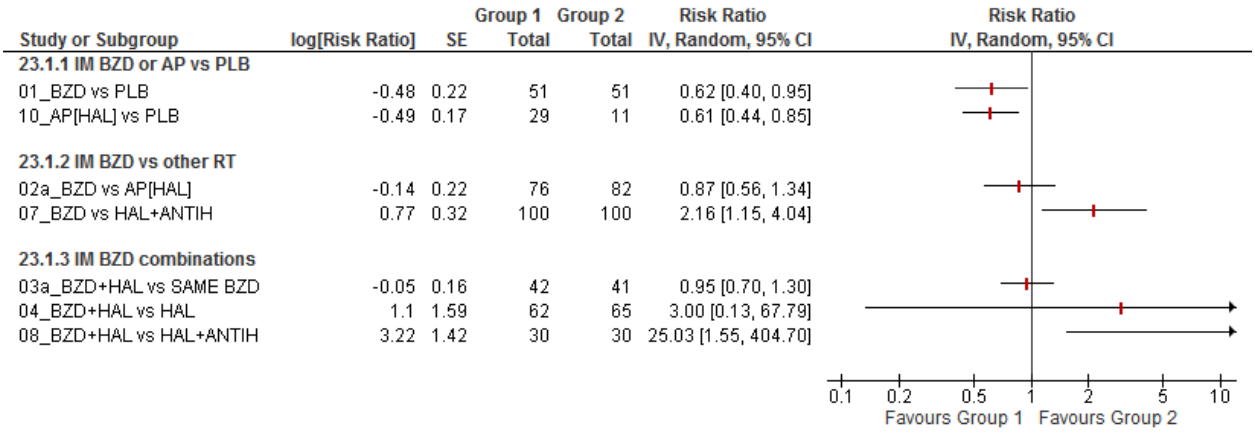


Figure 6: Rapid tranquillisation summary forest plot for agitation

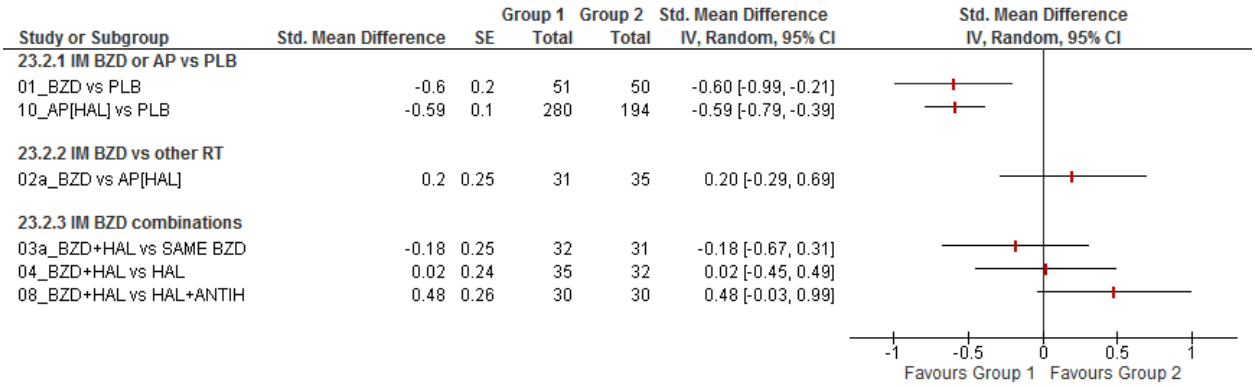


Figure 7: Rapid tranquillisation summary forest plot for the global effect – excessive sedation

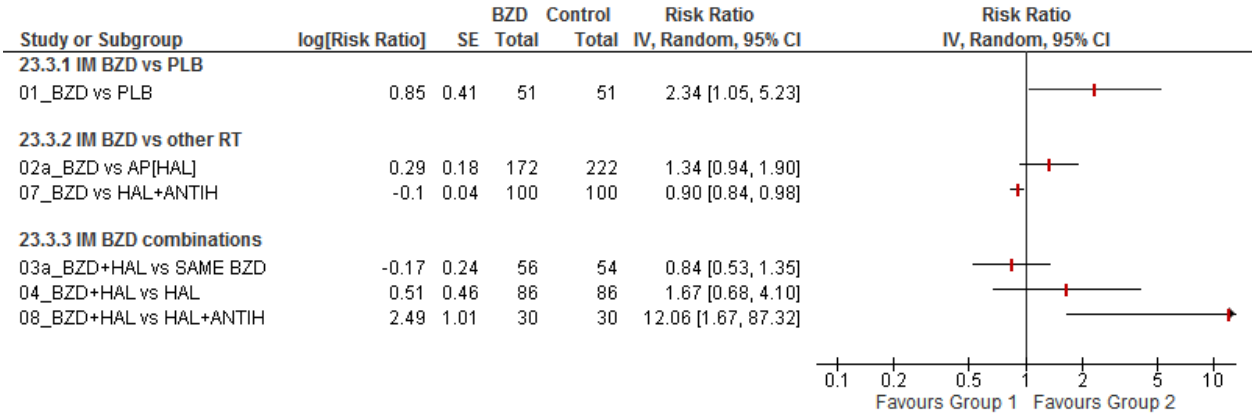
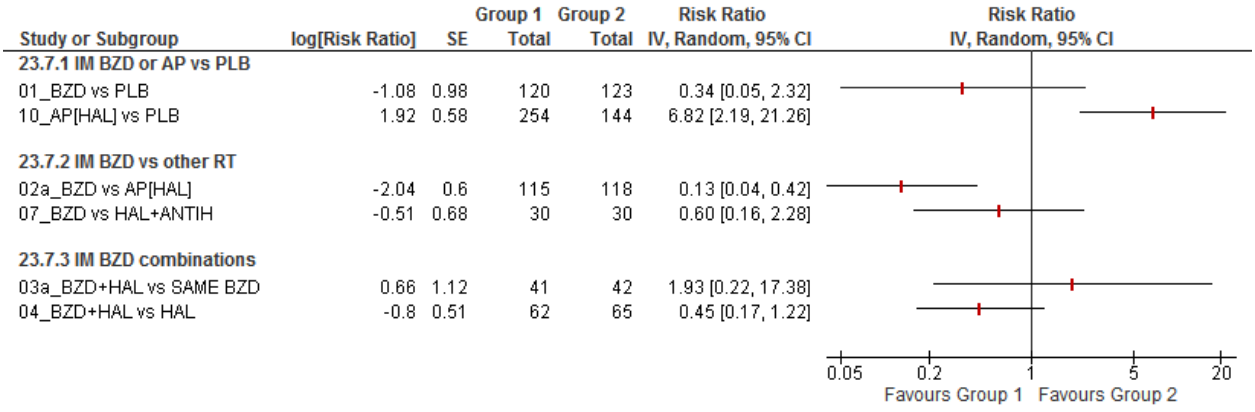


Figure 8: Rapid tranquillisation summary forest plot for the adverse effect – extrapyramidal symptoms



Evidence statements

Low quality evidence from one to two RCTs with up to 243 participants showed that an IM benzodiazepine was more effective than placebo, but increased the risk of excessive sedation (Table 45).

Low quality evidence from between one and seven RCTs with up to 394 participants showed no clear evidence that an IM benzodiazepine was more or less effective than an IM antipsychotic, but the latter increased the risk of extrapyramidal side effects (Table 46).

Low to very low quality evidence from between one and three RCTs with up to 110 participants showed no clear evidence that an IM benzodiazepine plus an IM antipsychotic was more or less effective or harmful than the same IM benzodiazepine used alone (Table 47).

Low to very low quality evidence from between one and three RCTs with up to 172 participants showed no clear evidence that an IM benzodiazepine plus an IM antipsychotic (haloperidol) was more or less effective or harmful than the same IM antipsychotic used alone (Table 48).

Low quality evidence from one RCT with 60 participants showed that an IM benzodiazepine (midazolam) plus an IM antipsychotic (haloperidol) was less effective than a different IM antipsychotic (ziprasidone) used alone (Table 49).

Low quality evidence from one RCT with 60 participants showed that an IM benzodiazepine plus an IM antipsychotic was similar to an IM antipsychotic plus another IM antipsychotic with regard to the effect on aggressive behaviour (Table 50).

Low quality evidence from one RCT with 200 participants showed that an IM benzodiazepine was less effective than an IM antipsychotic plus an IM antihistamine (Table 51), but there was insufficient evidence to establish if there was a difference in the risk of harm.

Low quality evidence from one RCT with 60 participants showed that an IM benzodiazepine plus an IM antipsychotic (haloperidol) was less effective and no less harmful than an IM antipsychotic plus an IM antihistamine (Table 52).

Low to moderate quality evidence from one to four RCTs with up to 660 participants showed that an IM antipsychotic (haloperidol) was more effective than placebo, but had higher risk of adverse effects (Table 53).

Very low to low quality evidence from between one and 10 RCTs with up to 840 participants showed that an IM antipsychotic (haloperidol) was not clearly more effective than other antipsychotics, but had higher risk of some adverse effects (Table 54).

6.3.5 Health economics evidence

Systematic literature review

No studies assessing the cost effectiveness of non-pharmacological management strategies during an event were identified by the systematic search of the economic literature.

One study that assessed the cost effectiveness of interventions for rapid tranquillisation (Freeman et al., 2009) was identified by the systematic search of the economic literature and one model was identified from the previous guideline (NICE, 2005) investigating resuscitation training to support restrictive interventions.

Details on the methods used for the systematic review of the economic literature are described in Chapter 3; full references and evidence tables for all economic evaluations included in the systematic literature review are provided in Appendix 18. Completed methodology checklists of the studies are provided in Appendix 17.

Freeman and colleagues (2009) compared IM haloperidol with IM olanzapine in a population of people with violent or aggressive episodes in a state psychiatric hospital in the US. Although IM olanzapine is not available in the UK (as described above in Section 6.3.2), the study by Freeman and colleagues is included here because of the comparison with haloperidol.

Data was collected retrospectively by investigating the hospital notes for service users who had received haloperidol or olanzapine in response to a violent or aggressive incident. A hospital perspective was taken with data was collected on: subjective effectiveness, percentage of people with violent and aggressive incidents requiring seclusion and/or physical restraint, percentage of people requiring repeat doses, and mean number of people requiring repeat doses. The data was only coded if the event fell within the 24 hours after the administration of olanzapine or haloperidol. Records were also searched for documentation of extrapyramidal side effects and for clinically significant changes in blood pressure though no data was found. Prices were taken from national sources for the year 2009.

The results of the analysis showed that haloperidol was less expensive than olanzapine with a cost per event of $4.06 versus $27.84 (cost year 2009). Additionally, haloperidol appeared more effective across outcomes. According to the nurse's subjective assessment, haloperidol was considered effective in 62% of cases, whereas olanzapine was effective in 49% of cases. Haloperidol was considered not effective in 13% of instances versus 30% for olanzapine. Significantly fewer patients required repeat doses when given haloperidol (41%) compared with olanzapine (69%). No significant differences were noted between percentages of service users requiring seclusion and/or restraint.

As acknowledged by the authors the study had many limitations the most important of these being the non-randomised retrospective study design, poorly defined

efficacy criteria, lack of quality of life data and unclear dose equivalence. Given the limitations of the study design, as olanzapine injection has been discontinued in the UK and not generally available, this study was excluded from further consideration.

Cost considerations

The development of an economic model assessing the cost effectiveness of alternative options for rapid tranquillisation was considered of high priority by the GDG, due to important resource implications associated with the choice of pharmacological options. Nevertheless, an economic model was not possible to develop due to poor quality clinical studies reporting heterogeneous outcomes. Therefore, simple costings of each rapid tranquillisation option were presented to the GDG, as an indication of the opportunity costs involved with each treatment option. Typical doses were informed by GDG opinion and the total drug acquisition cost was applied using the national electronic drug tariff (Drug Tariff, 2014), electronic market information tool (eMIT, 2013) and British national formulary (British National Formulary, 2014) in that order of preference. These sources provide a measure of opportunity cost to the NHS. The drug tariff details payments to NHS contractors and is compiled on behalf of the department of health by the NHS business services authority, eMIT prices are based on average price paid for a product over last for months and prices in the BNF are based on information provided by the NHS prescription services. Only options available on the NHS were eligible for costing.

The output of this process is displayed in Table 55. It needs to be noted that the full economic cost associated with each pharmacological treatment option used for rapid tranquillisation is greater than the prices quoted due to costs of staff involved in administering the drug (which, however, should be similar across treatment options), and treatment costs associated with side effects such as extrapyramidal symptoms and weight gain. Costs associated with the management of side effects were not considered in the analysis because of variation in outcomes reported in the RCTs that provided the clinical data and treatment pathways.

Table 55: Cost data for typical doses of rapid tranquillisation

IM medication (dose)	Cost source	Cost
Lorazepam (4 mg)	BNF	£0.35
Aripiprazole (20 mg)	BNF	£3.43
Haloperidol (10 mg)	Drug tariff	£0.73
Lorazepam (2 mg) and haloperidol (10 mg)	BNF and drug tariff	£1.08
Haloperidol (10 mg) and Promethazine (25 mg)	BNF and drug tariff	£1.40
Note. BNF = British National Formulary; IM = intramuscular.		

In order to aid decision making some basic modelling was carried out as part of the previous guideline on violence and aggression (NICE, 2005).A model was produced to investigate the cost effectiveness of immediate life support training over basic life support training in improving survival using automatic external defibrillators.

This question was modelled using a non-statistically significant difference in discharge rate following cardiac arrest with ventricular fibrillation or pulseless ventricular tachycardia from a nurse defibrillation trial (Coady, 1999). The maximum treatment effect attributable to advanced life support was estimated as 6 percent from a UK observational study (Gwinnutt et al., 2000). This study was also used alongside data reported in a review article (Woollard, 2001) to estimate the proportion of cardiac arrests with ventricular fibrillation.

Due to the lack of data for the population of interest, values had to be assumed for incidence of cardiac events, proportion of service users surviving with brain damage, and proportion of people with cardiac arrest preceded by respiratory arrest. The model assumed a survival improvement with immediate life support over basic life support and used this to estimate cost effectiveness. An NHS and personal social services perspective was taken for the analysis. No formal utility data was employed with a utility score of zero assigned to death or brain damage and full health assumed for all other states. The source of unit costs was not reported.

The results indicate a cost per QALY of £23,800 for immediate versus basic life support training with sensitivity analysis illustrating a QALY for under £20,000 if survival rates of the intervention are higher, incidence rates of cardiac events are higher or training costs are lower than in the base case.

The perspective taken in the model is directly applicable to the current decision context after updating costs, however the lack of data informing the clinical parameters of this model inserts great uncertainty into any conclusions that may be drawn from this analysis. For this reason the analysis was deemed to suffer from very serious methodological limitations and was therefore not considered when making recommendations.

Economic evidence statement

One economic study was identified which suggested that IM haloperidol is more cost effective than IM olanzapine. This analysis was considered to be partially applicable with very serious limitations and therefore was not considered in making recommendations.

Cost analysis indicated that there are not large cost differences between drugs under consideration.

One economic study was identified which suggested that immediate life support training may be cost effective under certain assumptions. This analysis was considered to be directly applicable but with very serious limitations and therefore was not considered in making recommendations.

6.4 POST-EVENT – ALL SETTINGS

6.4.1 Introduction

During an event the priority is to manage the situation in order to minimise injury to the service user, the victim and others in the vicinity. This may involve the use of force if necessary by adequate numbers of staff who are capable of overwhelming an individual in a way that is safe for all concerned. A great deal happens in a short time span and it is not always possible to provide the ideal intervention unless the violence is anticipated. Much can be gained from a review of the event, both in the short and medium term, both in terms of managing repeated episodes of violence from the same individual, and general lessons for future management of others. In primary and community settings where the staff involved is likely to be in different teams, agencies and locations, they are not so readily available to undertake joint discussions in order to review incidents and make plans to make matters safer for the service user, staff and others involved.

6.4.2 Studies considered

For the review of post-incident management (see Table 32 for the review protocol), one review Lim 2010a (Lim, 2010) and one primary study Whitecross 2013 (Whitecross et al., 2013) met eligibility criteria. No studies were identified which considered post-incident management for witnesses, or addressed the review questions that covered experience (see Table 28). In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

The review (Lim 2010) aimed to identify evidence-based practices for managing the aftermath of patient's aggression towards nurses (see Table 56). The primary study (Whitecross 2013) examined the effectiveness of post-seclusion counselling (see Table 57). In addition, the authors measured service users' experience of seclusion (see Section 6.3.3).

Table 56: Study information table for systematic reviews for post-incident management

	Lim 2010
Review question/ Aim	To identify evidence-based practices for managing the aftermath of patient's aggression towards nurses.
Method used to synthesise evidence	Narrative synthesis
Design of included studies	Non-controlled interrupted time series studies, expert opinion pieces
Dates searched	Search conducted 21/02/10
Electronic databases	Academic Research Library, APA PsycArticles, BMJ Journals, Cochrane Library, CINAHL, ERIC, MEDLINE, PsycINFO
No. of included studies	10
Participant characteristics	Staff (nurses) with a previous experience of aggression
Intervention	Post-incident management strategies
Comparison	Standard care or other alternative intervention
Outcome	• Experience (staff)
Note.	

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Table 57: Study information table for primary studies for post-incident management

	Post-incident management
Total no. of studies (N)	1 observational study (31)
Study ID	Whitecross 2013
Consent gained?	Yes
Country	Australia
Setting	Inpatient
Diagnosis	Schizophrenia or other psychotic illness (52%), schizoaffective disorder (32%), other psychiatric disorder (16%)
Age (mean)	36.89
Sex (% Female)	26
Ethnicity (% White)	Not reported
Intervention(s)	Post seclusion counselling conducted 3-7 days after the incident; included: counselling, ventilation, support and reassurance; screening for physical adverse effects and psychoeducation.
Comparison	Ad hoc informal debriefing
Funding	Alfred Research Trust
Outcomes	• Rates of restrictive intervention (seclusion) • Hours in seclusion during current admission • Experience (service user)
Note. N = Total number of participants.	

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6.4.3 Clinical evidence for post-incident management

Low quality evidence from one review of 10 studies (Lim 2010) and one observational study with 31 participants (Whitecross 2013) was inconclusive regarding the use of post-incident management strategies for service users and staff. Nevertheless, it was clear that violent incidents and the management of these can be traumatic for both service users and staff, and good practice dictates support and training should be used to post-incident management.

6.4.4 Health economics evidence

No studies assessing the cost effectiveness of post event management strategies were identified by the systematic search of the economic literature. Details on the methods used for the systematic review of the economic literature are described in Chapter 3.

Economic evidence statement

No relevant economic evaluations were identified.

6.5 LINKING EVIDENCE TO RECOMMENDATIONS

6.5.1 During event

Most episodes of violence take place over a very short time span, and so action to correct it and protect others has to be made very quickly. Because of the potential dangers associated with violence the standard method of evaluating a new treatment, an RCT comparing active intervention and a placebo equivalent, is rarely possible. Large RCTs are also very rare. There is also uncertainty about the best outcomes to measure when treating violence. Most of the outcomes are short-term, but it is also necessary to take into account any long-term consequences of treatment given, and studies with a longer timescale are not common in this population. Because of the need to measure short-term outcomes, and the general use of tranquillising medication to reduce violence, most of the studies that have incorporated randomisation have been included collectively under the title of 'rapid tranquillisation'. Indeed, in the previous guideline on violence and aggression it was concluded that 'all medication given in the short term management of disturbed/violent behaviour should be considered as part of rapid tranquillisation (including p.r.n. medication)' (NICE, 2005; p.100). Although the term 'rapid tranquillisation' has now become part of general use in psychiatry it is somewhat confusing. If a small dose of a drug is given orally very early in the manifestation of a violent episode, and given in the hope of stopping it, it is part of the same procedure as rapid tranquillisation, but is not identical to it. The same applies to p.r.n. medication given earlier than normally because nursing staff have detected signs of impending violence. Under these circumstances the aim is not to give rapid tranquillisation, but to assist other measures that are essentially preventive.

Relative value placed on the outcomes considered

The outcomes of interventions for violence can be separated into the early and long-term outcomes to (a), the violent individual, (b) the staff involved in trying to reduce

violence, and (c) other effects of violence on others. For rapid tranquillisation, the most common measured outcome is a level of sedation that causes the violence to cease. Whilst many service users welcome a degree of sedation as a consequence of rapid tranquillisation, in the main excessive sedation is an undesirable outcome. It can be distressing to patients and may compromise the ability of staff to safely monitor the outcome of the intervention. There can also be short and long-term consequences of sedation, particularly with regard to adverse effects, that influence the choice of treatment. One of the major problems in choosing a form of treatment to reduce violence is the lack of time to obtain information from patients about their preferred form of violence reduction. Although advance decisions and statements are now becoming increasingly used in mental health they either do not exist, or are rarely available, to those involved in the acute management of violent episodes.

One of the major problems in assessing the relative benefit and harm of an intervention in aggression is that the short-term effects are usually the main focus of interest, even though the long-term effects may be negative and highly damaging. However, it should be noted that in the context of this guideline, it was not possible to review long-term effects.

Trade-off between clinical benefits and harms

There is a paucity of evidence with which to judge the effectiveness and safety of seclusion and restraint, and other restrictive interventions. What little evidence there is, suggests seclusion can be as effective as mechanical restraint, but service users dislike both. The GDG therefore based their decisions and recommendations on expert opinion after considering documents published by the DH (Department of Health, 2014b) and the Royal College of Nursing (Royal College of Nursing, 2005), and the recommendations in the previous guideline. Recommendations were drafted specifically for the inpatient setting around the safe and ethical use of restrictive interventions, observation, manual and mechanical restraint, and seclusion.

In the emergency department, the GDG agreed that, based on their expert opinion, it was important not to remove service users who become aggressive or violent. Rather, violence and aggression should be managed in line with recommendations for using restrictive interventions in inpatient settings, and referred to mental health services urgently for a psychiatric assessment within 1 hour. However, they felt it was good practice not to use seclusion in the emergency department.

In community settings, unlike in other settings, the GDG felt that in the event that manual restraint is needed, the police should be called rather than being carried out by community mental health teams due to the risks involved.

Based on the review of rapid tranquillisation, the evidence suggested that two management strategies may have benefits that outweigh the risks of harm: an IM benzodiazepine (lorazepam) used alone and the combination of IM haloperidol plus an IM antihistamine (promethazine). When IM haloperidol is combined with IM promethazine there is some suggestion that risk of movement-related side effects

may be reduced. In contrast, the combination of an IM benzodiazepine plus IM haloperidol does not appear to be more effective than an IM benzodiazepine used alone. While IM haloperidol used alone is more effective than placebo, it clearly carries greater risk of extrapyramidal and other side effects when compared with placebo or an IM benzodiazepine. There was insufficient evidence to make a judgement about the use of other antipsychotic drugs including inhaled loxapine.

Prescribing the initial medication as a single dose enables prescribers to individualise the medication regime used for rapid tranquillisation. This will reduce the risks of repeated doses of medication being administered without adequate review and reduce the risks of unintentional high dose prescribing (Paton et al., 2008).

On a case by case basis, previous response to medication can provide a sound basis for prescribing medication for use as rapid tranquillisation. This should be considered alongside any concerns that the service user may have about their personal experience of medicines that have been used as rapid tranquillisation.

Despite a lack of high-quality evidence, the use of IM lorazepam as a first choice option is supported because of its favourable benefit/harm profile. The use of IM haloperidol in combination with IM promethazine is moderated to a certain extent by practicalities of administering a combination of medication during an episode of violence.

Rapid tranquillisation is potentially a high risk intervention and the GDG developed their recommendations in order to support staff to ensure best use of medication when used as rapid tranquillisation and reduce the risks of medicine-related harm.

With regard to management strategies involving the police, because no evidence was identified, the GDG used their expert opinion after considering several policy documents (HM Government, 2014; Royal College of Psychiatrists, 2013), and the previous guideline recommendations. It was agreed that it is the responsibility of health and social care provider organisations to work with the police (and local service user groups if possible) to develop policies for joint working and locally agreed operating protocols.

As in the previous guideline, no evidence was identified that examined the benefits and harms associated with the use of personal and institutional alarms, CCTV and communication devices.

Trade-off between net health benefits and resource use

No comparative economic evidence was found on the use of non-pharmacological management strategies such as physical restraint or seclusion. The recommendations made were largely driven by patient safety, positive engagement and dignity given that some level of restraint and seclusion will be practiced. These benefits represent

principles of the NHS and as such rigid trade-offs in terms of resources and observable benefit may be less appropriate.

In choosing between seclusion, restraint and pharmacological interventions both qualitative review and the GDG opinion indicate that complex preferences exist for these interventions and that quality of life depends on interactions between intervention, service user characteristics and the service user's mental associations with the intervention. For this reason along with the paucity of clinical evidence, economic modelling was considered inappropriate.

Though complex service user preferences still feature, there are more tangible economic concerns involved in choosing the most appropriate pharmacological option in rapid tranquillisation. The occurrence of extrapyramidal symptoms or other distressing side effects entails important consequences in terms of resource use and quality of life.

Drug acquisition costs were presented to the GDG to provide some notion of opportunity cost though the relative rates of side effects and associated treatment costs were not possible to estimate from the available clinical data. Overall these costs suggest that the cost difference between drug options are not large and that the most cost effective strategy is likely to be one which tailors treatment to each individual, taking into account preferences, current medication and drug history.

It was the view of the GDG that as the use of restrictive interventions increases the risk of a cardiac event, their safe and responsible usage implies a capacity to respond with competent resuscitation making their provision a necessity.

In the absence of evidence around involvement of the police, recommendations were driven by respect for human rights and compliance with existing legislation. Similarly, in the post-incident management of service-users and witnesses, recommendations were driven largely by general principals and respect for dignity.

Quality of the evidence

For the review of non-pharmacological management strategies, evidence from both randomised and non-randomised studies was low to very low quality, primarily due to small sample sizes and risk of bias.

For the review of rapid tranquillisation, although the evidence came from RCTs, it was generally graded down to low quality because of risk of bias, funding by the manufacturer, and small sample sizes.

Other considerations

Taking into account the evidence presented in this chapter, the GDG also reviewed the recommendations from the previous guideline and judged, based on their expert opinion, that several recommendations were still relevant and of value but would

need redrafting in the light of the current context, a widening of the scope, and latest NICE style for recommendations.

Following this approach, the GDG agreed, using consensus methods described in Chapter 3, to recommend that health and social care provider organisations should define the numbers of staff needed to undertake restrictive interventions and that resuscitation equipment and a doctor trained to use it are immediately available. During the use of restrictive interventions, the GDG wished to reiterate that these interventions should not be users to inflict pain, or as a means of punishment, and that the methods used should be proportionate to the risk and potential seriousness of harm and be the least restrictive option to meet that particular need.

Regarding manual restraint, in the absence of evidence, the GDG based their recommendations on the advice in the previous guideline about what was termed 'physical intervention' but wished to specify the preferred body position for this form of restraint. The GDG discussed this at length and agreed that taking a service user to the floor should be avoided if possible, but if it became necessary then the supine position was preferred over the prone position. The GDG also wished to make it clear that manual restraint should not be used for more than 15 minutes at a time, and that one staff member should take the lead throughout its use. In addition, the GDG considered the use of manual restraint in community settings and judged that it should not be used in this context and that it would be safer for the staff involved to contact the police.

Regarding mechanical restraint, as in the previous guideline, the GDG saw the need to restrict its use as far as possible. The GDG agreed that its use should be reserved for high-secure settings only and should only be used for managing extreme violence or self-injurious behaviour of extremely high frequency or intensity. The GDG also saw that mechanical restraint might have a place when transferring service users at risk of violence between healthcare settings or during periods of leave. In all cases, the GDG agreed that the use of mechanical restraint should be planned in advance and reported to the trust board.

The GDG also drew on the recommendations about seclusion in the previous guideline, reiterating that the use of seclusion should be undertaken in accordance with the Mental Health Act 1983 and the Mental Health Act 1983 Code of Practice, used for the shortest time possible, that any cultural or religious practices should be respected, and that the service user should keep their own clothing. The GDG also saw the benefit of carrying over the recommendation on the use of rapid tranquillisation and seclusion, but modified it to make it clear that these combined interventions should be used with caution. In addition, the GDG discussed the room used for seclusion and agreed how it should be equipped.

6.5.2 Post-event

Relative value placed on the outcomes considered

The GDG agreed that any reported outcomes relevant to the safety, effectiveness and experience of the management of short-term violence and aggression should be considered. In practice, the outcomes reported included use of restrictive interventions, and the experience of care.

Trade-off between clinical benefits and harms

Based on studies of post-incident management strategies, there is currently insufficient evidence to reach a conclusion about the effectiveness and experience of specific strategies. Nevertheless, the GDG agreed, having reviewed the previous guideline, that it was good practice to conduct post-incident reviews and regular reports should be received by trust boards or equivalent governing bodies. In addition, the GDG agreed that, based on their expert opinion, a service user experience monitoring unit (or equivalent service user group) should be set up and should undertake an external post-incident review as soon as possible and no later than 72 hours after each incident. The GDG considered that the health and social care provider organisations responsible for undertaking internal reviews would need to share this information with the teams and services involved and the trust board or equivalent organisational governing body, and involve service users in the process, taking account of relevant information sharing protocols.

Trade-off between net health benefits and resource use

No economic evidence was found on post incident management strategies. Clear costs are incurred when considering the staff time required to provide comprehensive post-incident reviews. These costs may be recouped by the potential for improved relationships and better understanding of events, allowing safer and more adaptive practice in the future.

Quality of the evidence

The evidence for post-incident management strategies was generally low quality from observational designs.

6.6 RECOMMENDATIONS

6.6.1 During event

Principles for managing violence and aggression

Working with the police

6.6.1.1 Health and social care provider organisations should work with the police, and local service user groups if possible, to develop policies for joint working and locally agreed operating protocols that cover:

- when and how police enter health or social care settings (including psychiatric and forensic inpatients, emergency departments, general health inpatients, GP surgeries, social care and community settings and 136 place-of-safety suites)
- when and how health and social care professionals enter police cells
- transferring service users between settings.

Review the operating protocols regularly to ensure compliance with the policies and update the policies in light of operational experience.

Using restrictive interventions in inpatient settings

Staffing and equipment

6.6.1.2 Health and social care provider organisations should:

- define staff:patient ratios for each inpatient ward and the numbers of staff required to undertake restrictive interventions
- ensure that restrictive interventions are used only if there are sufficient numbers of trained staff available.

6.6.1.3 Health and social care provider organisations should ensure that resuscitation equipment is immediately available if restrictive interventions might be used and:

- include an automatic external defibrillator, a bag valve mask, oxygen, cannulas, intravenous fluids, suction and first-line resuscitation medications
- maintain equipment and check it every week.

6.6.1.4 A doctor trained to use emergency equipment should be immediately available to attend an emergency if restrictive interventions might be used.

Using restrictive interventions

6.6.1.5 Use a restrictive intervention only if de-escalation and other preventive strategies, including p.r.n. medication, have failed and there is potential for harm to the service user or other people if no action is taken. Continue to attempt de-escalation throughout a restrictive intervention.

6.6.1.6 Do not use restrictive interventions to punish, inflict pain, suffering or humiliation, or establish dominance.

6.6.1.7 Ensure that the techniques and methods used to restrict a service user:

- are proportionate to the risk and potential seriousness of harm
- are the least restrictive option to meet the need
- are used for no longer than necessary
- take account of the service user's preferences, if known and it is possible to do so.

Manual restraint

6.6.1.8 Health and social care provider organisations should ensure that manual restraint is undertaken by staff who work closely together as a team, understand each other's roles and have a clearly defined lead.

6.6.1.9 When using manual restraint, avoid taking the service user to the floor, but if this becomes necessary:

- use the supine position if possible **or**
- if the prone position is necessary, use it for as short a time as possible.

6.6.1.10 Do not use manual restraint in a way that interferes with the service user's airway, breathing or circulation, for example by applying pressure to the rib cage, neck or abdomen, or obstructing the mouth or nose.

6.6.1.11 Do not use manual restraint in a way that interferes with the service user's ability to communicate, for example by obstructing the eyes, ears or mouth.

6.6.1.12 Undertake manual restraint with extra care if the service user is physically unwell or disabled.

6.6.1.13 Aim to preserve the service user's dignity and safety as far as possible during manual restraint.

6.6.1.14 Do not routinely use manual restraint for more than 15 minutes.

6.6.1.15 Consider rapid tranquillisation or seclusion as alternatives to prolonged manual restraint (longer than 15 minutes).

6.6.1.16 Ensure that the level of force applied during manual restraint is justifiable, appropriate, reasonable, proportionate to the situation and applied for the shortest time possible.

6.6.1.17 One staff member should lead throughout the use of manual restraint. This person should ensure that other staff members are:

- able to protect and support the service user's head and neck, if needed
- able to check that the service user's airway and breathing are not compromised
- able to monitor vital signs
- supported throughout the process.

6.6.1.18 Monitor the service user's physical and psychological health for as long as clinically necessary after using manual restraint.

Mechanical restraint

6.6.1.19 Health and social care provider organisations should ensure that mechanical restraint is used only in high-secure settings (except when transferring service users between medium- and high-secure settings as in recommendation 6.6.1.21), planned in advance and reported to the trust board.

6.6.1.20 Use mechanical restraint only for the purpose of:

- managing extreme violence directed at other people **or**
- limiting self-injurious behaviour of extremely high frequency or intensity.

6.6.1.21 Consider mechanical restraint, such as handcuffs, when transferring service users who are at high risk of violence and aggression between medium- and high-secure settings. In this context, restraint should be clearly planned as part of overall risk management.

Rapid tranquillisation

Rapid tranquilisation in this guideline refers to the use of medication by the parenteral route (usually intramuscular or, exceptionally, intravenous) if oral pharmacotherapy is not possible or appropriate and urgent sedation with medication is needed.

6.6.1.22 Use either intramuscular lorazepam on its own or intramuscular haloperidol together with intramuscular promethazine for rapid tranquillisation. When deciding which medication to use, take into account:

- the service user's preferences or advance statements and decisions
- pre-existing physical health problems
- previous response to these medications, including adverse effects
- potential for interactions with other medications
- the total daily dose of medications prescribed and administered.

6.6.1.23 If there is insufficient information to guide the choice of medication for rapid tranquillisation, or the service user has not taken antipsychotic medication before, use intramuscular lorazepam.

6.6.1.24 If there is evidence of cardiovascular disease, including a prolonged QT interval, or no electrocardiogram has been carried out, avoid intramuscular haloperidol together with intramuscular promethazine and use intramuscular lorazepam.

6.6.1.25 If there is a partial response to intramuscular lorazepam, consider a further dose.

6.6.1.26 If there is no response to intramuscular lorazepam, consider intramuscular haloperidol together with intramuscular promethazine.

6.6.1.27 If there is a partial response to intramuscular haloperidol together with intramuscular promethazine, consider a further dose.

6.6.1.28 If there is no response to intramuscular haloperidol together with intramuscular promethazine, consider intramuscular lorazepam if this hasn't been used already during this episode.

6.6.1.29 When prescribing medication for use in rapid tranquillisation, write the initial prescription as a single dose, and do not repeat it until the effect of the initial dose has been reviewed.

6.6.1.30 After rapid tranquillisation, monitor side effects and the service user's pulse, blood pressure, respiratory rate, temperature, level of hydration and level of consciousness at least every hour until there are no longer any concerns. Monitor every 15 minutes if the BNF maximum dose has been exceeded or the service user:

- appears to be asleep or sedated
- has taken illicit drugs or alcohol
- has a pre-existing physical health problem
- has experienced any harm as a result of any restrictive intervention.

Seclusion

6.6.1.31 Use seclusion only if the service user is detained in accordance with the Mental Health Act 1983, except in an emergency.

6.6.1.32 Services that use seclusion should have a designated seclusion room that:

- allows staff to clearly observe the service user
- is well insulated and ventilated, with temperature controls outside the room
- has access to toilet and washing facilities
- has furniture, windows and doors that can withstand damage.

Carrying out seclusion

6.6.1.33 Record the use of seclusion in accordance with the Mental Health Act 1983 Code of Practice.

6.6.1.34 Ensure that seclusion lasts for the shortest time possible. Review the need for seclusion at least every 2 hours and tell the service user that these reviews will take place.

6.6.1.35 Set out an observation schedule for service users in seclusion. Allocate a nurse to carry out the observation, which should be within eyesight as a minimum.

6.6.1.36 Ensure that a service user in seclusion keeps their clothing and, if they wish, any personal items, including those of personal, religious or cultural significance, unless doing so compromises their safety or the safety of others.

Rapid tranquillisation together with seclusion

6.6.1.37 If rapid tranquillisation is needed while a service user is secluded, undertake with caution and:

- be aware of and prepared to address any complications associated with rapid tranquillisation
- ensure the service user is observed within eyesight by a trained staff member
- end the seclusion when rapid tranquillisation has taken effect.

Managing violence and aggression in emergency departments

6.6.1.38 If a service user with a mental health problem becomes aggressive or violent, do not remove them from the emergency department. Manage the violence or aggression in line with recommendations 5.7.1.38–5.7.1.53 and recommendations 6.6.1.2–6.6.1.30 and do not use seclusion. Refer the service user to mental health services urgently for a psychiatric assessment within 1 hour.

Managing violence and aggression in community and primary care settings

6.6.1.39 Community mental health teams should not use manual restraint in community settings. If manual restraint is needed, staff should remove themselves from the situation and contact the police.

6.6.2 Post-event

Anticipating and reducing the risk of violence and aggression

Reducing the use of restrictive interventions

Restrictive intervention reduction programme

6.6.2.1 Health and social care provider organisations should collate, analyse and synthesise all data about violent events and the use of restrictive interventions, share this information with the teams and services involved and the trust board or equivalent organisational governing body, and involve service users in the process. They should link the information to the standards set in safeguarding procedures.

6.6.2.2 Health and social care provider organisations should develop a service user experience monitoring unit, or equivalent service user group, led by service users and including staff, to report and analyse data on violence and aggression and the use of restrictive interventions.

6.6.2.3 Health and social care provider organisations should publish board reports on their public websites that include data about incidents of violence and aggression and use of restrictive interventions within each team, ward and service, and include reasons for the similarities and differences between services.

Post-incident reviews

6.6.2.4 Health and social care provider organisations should ensure that wards have sufficient staff with a mix of skills and seniority levels that enable them to:

- conduct immediate post-incident reviews
- monitor and respond to ongoing risks (see recommendation 6.6.2.6)
- contribute to external post-incident reviews (see recommendation 6.6.2.13).

6.6.2.5 The trust board or equivalent governing body should ensure that it receives regular reports from each ward about violent incidents, the use of restrictive interventions, service users' experience of those interventions and the learning gained.

Immediate post-incident review

6.6.2.6 After using a restrictive intervention, and when the risks of harm have been contained, conduct an immediate post-incident review, including a nurse and a doctor, to identify and address physical harm to service users or staff, ongoing risks and the emotional impact on service users and staff, including witnesses.

6.6.2.7 Use the framework outlined in recommendation 4.6.1.1 to determine the factors that contributed to an incident that led to a restrictive intervention, identify any factors that can be addressed quickly to reduce the likelihood of a further incident and amend risk and care plans accordingly.

6.6.2.8 Record the findings of the post-incident review and advise the service user experience monitoring unit, or equivalent service user group, to start an external post-incident review.

6.6.2.9 Ensure that the service user involved has the opportunity to discuss the incident in a supportive environment with a member of staff or an advocate or carer. Offer the service user the opportunity to write their perspective of the event in the notes.

6.6.2.10 Ensure that any other service users who may have seen or heard the incident are given the opportunity to discuss it so that they can understand what has happened.

6.6.2.11 Ensure that all staff involved in the incident have the opportunity to discuss their experience with staff who were not involved.

6.6.2.12 Discuss the incident with service users, witnesses and staff involved only after they have recovered their composure and aim to:

- acknowledge the emotional responses to the incident and assess whether there is a need for emotional support for any trauma experienced
- promote relaxation and feelings of safety
- support a return to normal patterns of activity
- ensure that everyone involved in the service user's care, including their carers, has been informed of the event, if the service user agrees.

Ensure that the necessary documentation has been completed.

External post-incident review

6.6.2.13 The service user experience monitoring unit or equivalent service user group should undertake an external post-incident review as soon as possible and no later than 72 hours after the incident. The unit or group should ensure that the external post-incident review:

- is led by a service user and includes staff from outside the ward where the incident took place, all of whom are trained to undertake

investigations that aim to help staff learn and improve rather than assign blame
- uses the information recorded in the immediate post-incident review and the service user's notes
- includes interviews with staff, the service user involved and any witnesses if further information is needed
- uses the framework in recommendation 4.6.1.1 to:
  - evaluate the physical and emotional impact on everyone involved, including witnesses
  - help service users and staff to identify what led to the incident and what could have been done differently
  - determine whether alternatives, including less restrictive interventions, were discussed
  - determine whether service barriers or constraints make it difficult to avoid the same course of actions in future
  - recommend changes to the service's philosophy, policies, care environment, treatment approaches, staff education and training, if appropriate
  - avoid a similar incident happening in future, if possible.

6.6.2.14 The service user experience monitoring unit or equivalent service user group should give a report to the ward that is based on the external post-incident review.

6.7 RESEARCH RECOMMENDATIONS

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

6.7.1.2 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?

6.7.1.3 Is there any evidence that aids to managing violence by mechanical restraint such as emergency response belts (ERB's) that allow patients to be bound without creating pain, or cutting off the blood supply to any limb (the Pinel system) are effective?

7 SPECIAL CONSIDERATIONS FOR CHILDREN AND YOUNG PEOPLE

7.1 INTRODUCTION

Violence and aggression can be relatively common and serious occurrences in settings that manage children (aged 12 years or under) and young people (aged between 13 and 17 years) with mental health problems. Aggressive behaviours are common in young children and peak between 2 and 4 years of age, most children being socialised out of these behaviours by the time they start school (Tremblay et al., 2004). A minority maintain a high level of aggression during childhood, but most aggressive children exhibit decreasing aggression between 6 and 15 years.

Although continuing and high levels of aggression towards others is a feature of the conduct disorders of childhood and adolescence, acute aggression and violence requiring immediate management – in order to preserve the child or young person's safety and that of others – may be seen in the context of other psychiatric disorders. In fact, overt aggressive behaviours incorporating verbal abuse or physical aggression are some of the most common reasons for referral to mental health services and psychiatric hospitalisation in children and adolescents. Accordingly acute aggressive episodes are common during inpatient admission, where they are associated with disruptive behaviour disorders, but also with autistic spectrum and psychotic disorders, and in the context of intellectual disability (Barzman et al., 2011; Sukhodolsky et al., 2005).

The management of aggression and violence in young children is primarily a matter for parents, but it can also be an issue for teachers. Aggressive behaviours are a focus of treatment in evidence-based parenting programmes of children with conduct and disruptive disorders. Aggression and violence can become an acute management issue for healthcare staff working with children and young people with mental health problems in ambulatory health settings, but most prominently in day or inpatient units in emergency and paediatric inpatient settings.

As in adults, the manifestation of acute aggression and violence towards others is likely to be a consequence of a mixture of intrinsic and extrinsic factors, involving current intense mental distress and problems dealing with anger, but the physical and social setting where violence occurs and the attitudes and experience of health professional staff are also relevant. Reviews of both prospective and retrospective research suggest that victimisation and loss at an early age have consequences for future violent acts. A combination of personal (gender, substance misuse) and environmental hazards (history of child abuse, stressful and traumatic events, rates of unemployment) have been found to predict almost a third of the variance in adolescent violent behaviour in some longitudinal studies (Bailey, 2002; Stiffman et al., 1996). Consequently, in the evaluation of interventions to prevent and treat violence, both intrinsic and extrinsic factors need being taken into account.

As with adults, the management of violence in young people may occur in the context of restrictions that limit subjective freedom, including detention of young people under the Mental Health Act 1983, but in younger children this context may be determined by the Children Act (The Children Act HMSO, 2004).

The incidence of aggression and violence by children and young people with mental health problems in health settings has not been widely documented. Where it has, the focus has tended to be on inpatient mental health settings and emergency departments; assaultive threats and attempts against other service users and staff members have been reported in one-third to nearly two-thirds of child and adolescent inpatients (Sukhodolsky et al., 2005; Barzman et al., 2011). Common behaviours include head banging, throwing oneself on the floor, and hitting, pushing and kicking others; these tend to be linked to noncompliant behaviour. Balzman and colleagues (2011) reported aggressive acts in 29% of children and adolescents admitted to psychiatric units; in 21%, the aggressive acts were towards others and there was an inverse relationship with age. In a survey of younger children admitted to a psychiatric inpatient unit, 28% of aggression episodes consisted of striking, kicking, pushing and pulling hair without injury, 12% of attacks involved mild to moderate injury (such as bruises and welts) and 2% severe injury (involving broken bones and lacerations) (Sukhodolsky et al., 2005). Levels of aggression among psychiatrically hospitalised children may be related to general deficits in affect regulation, executive functioning and social skills deficits related to psychopathology.

Aggressive behaviours and violence in children and young people with mental health problems can manifest in educational and social services institutions and especially in forensic settings (Kelsall et al., 1995). Rarely but dramatically do they result in episodes of mass shootings in schools. Within psychiatric hospitals the main professional group that manages violent incidents and who are most likely to be victims, are mental health nurses and healthcare assistants. Exposure of nurses to aggressive acts is common and often distressing, with negative emotional and professional sequelae (Dean et al., 2010).

Violence-related risk assessment tools have been developed for children and young people, and include the Modified Overt Aggression Scale (Kay et al., 1988) and the Brief Rating of Aggression by Children and Adolescents (Barzman et al., 2011). They have been complemented with non-compliance scales such as the Disruptive Behaviour Rating Scale (Sukhodolsky et al., 2005), which assesses oppositional defiant behaviours, tempers, touchiness, anger and resentment.

As far as we are aware, there is no recommended training in the restraint of children and young people in the UK. A number of private companies provide this to inpatient child and adolescent psychiatric units, but there is no national accreditation of trainers, no standardisation of techniques and no audit or inspection standards.

Generally the teaching follows the framework of the laws and acts that cover restraint, and it is understood that any form of restraint must be the very last resort and fully justified within the law. It is widely accepted that the use of force needs to be appropriate to the situation, reasonable, proportionate and necessary, used for the shortest period possible, and that during the restraint vital observations are taken and recorded. The legal framework for Adolescent Units includes the Mental Health Act 1983 (The Mental Health Act HMSO, 2007), the Human Rights Act (1998), The Health and Safety at Work Act HMSO (1974)the Health & Safety Act, Mental Capacity Act HMSO (2005) and NICE Guideline 25 (NICE, 2005).

7.2 REVIEW PROTOCOL

Due to the lack of evidence for children and young people, only review questions for which there is evidence is presented here. The review protocol summary, including the review questions and the eligibility criteria used for this chapter of the guideline, can be found in Table 7 (risk factors), Table 8 (prediction), Table 29 (non-pharmacological management strategies) and Table 61 (rapid tranquillisation). A complete list of review questions can be found in Appendix 5, information about the search strategy is in Appendix 10 and the full review protocols are in Appendix 9).

The review of risk factors was restricted to prospective cohort studies that used multivariate models to look for independent risk factors. The review strategy primarily involved a narrative synthesis of odds ratios for the risk of violence for each risk factor or antecedent. Results from studies that examined the correlation between multiple factors and violence (reported as R^2 or Beta) were also used. Studies only presenting unadjusted results were excluded from the review.

The review of prediction instruments included prospective or retrospective cross sectional/cohort studies that presented outcomes that could be used to determine sensitivity and specificity.

Table 58: Clinical review protocol summary for the review of risk factors (children and young people)

Component	Description
Review questions (RQs)	RQ2.1 What are the risk factors and antecedents (including staff characteristics) for violent and aggressive behaviour by mental health service users in health and community care settings? RQ2.2 What factors do service users and staff report as increasing the risk of violent and aggressive behaviour by mental health service users in health and community care settings?
Subquestions	2.1.1 Do the identified risk factors have good predictive validity for future violent and aggressive behaviour by mental health service users in health and community care settings?
Population	Children and young people who are mental health service users (excluding people with learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	Risk factors and antecedents
Comparison	Not applicable
Context	Health and community care settings
Critical outcomes	Adjusted outcomes for: • Risk of violence (odds ratio for risk of violence/aggression) • Association between risk factor and violence/aggression (R^2 or Beta value)
Study design	Prospective observational studies

1
2

Table 59: Clinical review protocol summary for the review of prediction (children and young people)

Component	Description
Review questions	RQ2.3 Which instruments most reliably predict violent and aggressive behaviour by mental health service users in health and community care settings in the short-term?
Subquestion	2.3.1 Do the identified instruments have good predictive validity for future violent and aggressive behaviour by mental health service users in health and community care settings?
Population	Children and young people who are mental health service users (excluding people with learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	• Prediction instruments • Approaches for anticipating violence and aggression
Comparison	Gold standard approach to prediction and anticipation
Context	Short-term (72 hours) management in health and community care settings
Critical outcomes	Clinical utility (including sensitivity and specificity)
Study design	Any

3

Table 60: Clinical review protocol summary for the review of non-pharmacological management strategies (children and young people)

Component	Description
Review questions	RQ2.7 Do management strategies (including staffing levels and IT systems), used to reduce the risks of violent and aggressive behaviour by mental health service users, produce benefits that outweigh possible harms when compared to an alternative approach? RQ2.8 Do training programmes for the use of interventions designed to prevent and manage violent and aggressive behaviour by mental health service users in health and community care settings, for staff, and for staff and service users combined, produce benefits that outweigh possible harms when compared to an alternative management strategy? RQ4.3 Does seclusion used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? RQ4.4 Do de-escalation methods used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? RQ4.5 Do physical restraint techniques (including, manual and mechanical restraint) used by staff for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy?
Subquestion	RQ4.6 If physical restraint techniques (including, manual and mechanical restraint) are used by staff for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings, how should use be modified if, for example, the service user is: • undergoing withdrawal • intoxicated • a heavy drinker • seriously medically ill • has physical disabilities or injuries or is physically frail • pregnant • obese.
Population	Children and young people who are mental health service users (excluding people with learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	• Modifications to the environment • Personal and institutional alarms • Seclusion • De-escalation methods • Physical restraint
Comparison	Usual care or other alternative management strategies
Context	Short-term (72 hours) management in health and community care settings
Critical outcomes	• Any reported measures of safety and effectiveness relevant to the short-term management of aggressive/violent behaviour • Service user/carer/staff views
Study design	RCTs, observational studies and systematic reviews

1

Table 61: Clinical review protocol summary for the review of pharmacological interventions (children and young people)

Component	Description
Review question(s)	RQ3.6 Does p.r.n. (pro re nata) medication used to prevent imminent violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy? RQ4.7 Does rapid tranquillisation used for the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings produce benefits that outweigh possible harms when compared to an alternative management strategy?
Subquestion	RQ4.8 If rapid tranquillisation is used in the short-term management of violent and aggressive behaviour by mental health service users in health and community care settings, how should use be modified if, for example, the service user is: • undergoing withdrawal • intoxicated • a heavy drinker • seriously medically ill • has physical disabilities or injuries or is physically frail • pregnant • obese.
Population	Children and young people who are mental health service users (excluding people with learning disabilities, and women with mental health disorders during pregnancy and the postnatal period; these are covered by existing or guidelines in development)
Intervention(s)	Rapid tranquillisation or urgent sedation (the use of medication to calm/lightly sedate the service user, reduce the risk to self and/or others and achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place, and allowing comprehension and response to spoken messages throughout the intervention. Although not the overt intention, it is recognised that in attempting to calm/lightly sedate the service user, rapid tranquillisation may lead to deep sedation/anaesthesia). • Antipsychotic drugs (aripiprazole, chlorpromazine, haloperidol, loxapine, olanzapine, quetiapine, risperidone) • Benzodiazepines • Antihistamines.
Comparison	• Placebo • Another intervention
Context	• Short-term (72 hours) management in health and community care settings
Critical outcomes	• Rates of violence and aggression* • Tranquillisation (feeling of calmness and/or calm, non-sedated behaviour)* • Sedation/somnolence* • Adverse effects* • Service user/carer/staff views * • Economic outcomes* * Adapted from the previous guideline.
Study design	RCTs

1

2

7.3 RISK FACTORS

7.3.1 Introduction

For a general introduction to risk factors for violence and aggression, please see Chapter 4 (section 4.3.1).

Definition of risk factors and antecedents for predicting violence

For the purposes of this review, risk factors and antecedents were categorised using the psychosocial and clinical domains described by Witt and colleagues (2013): (a) demographic and premorbid, (b) criminal history, (c) psychopathological, positive symptom and negative symptom, (d) substance misuse, (e) treatment-related and (f) suicidality.

7.3.2 Studies considered[11]

For the review of risk factors in children and young people (see Table 58 for the review protocol), three studies (N = 355) met the eligibility criteria: Dean 2008 (Dean et al., 2008); Stafford 2003 (Stafford & Cornell, 2003); Tompsett 2011 (Tompsett et al., 2011). In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

For the three included studies, a summary of the study characteristics can be found in Table 62.

[11] Here and elsewhere in the guideline, each study considered for review is referred to by a study ID (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

Table 62: Summary of study characteristics for the review of risk factors for violence and aggression (children and young people)

	Inpatient setting
Total no. of studies (N)	3 prospective observational studies (355)
Study ID (N)	(1) Dean 2008 (134) (2) Stafford 2003 (72) (3) Tompsett 2011 (149)
Country	(1) Australia (2–3) US
Year of publication	2003-2011
Diagnosis	46% mood/anxiety/depressive disorders 25% bipolar disorder 19% ADHD/disruptive behaviour/conduct disorder/oppositional defiant disorder 7% pervasive developmental disorder 3% adjustment disorder
Age (mean)	13.94
Sex (% female)	40
Ethnicity	73% Caucasion 26% African American, Native American, Asian American, and Hispanic American or other 1% Torres Straight Islanders

7.3.3 Evidence for risk factors of violence and aggression in children and young people

Because of differences in the type of violence and aggression measured in each study (see Table 63), meta-analysis could not be used to pool the findings from the three studies of children and/or young people (Dean 2008; Stafford 2003; Tompsett 2011).

All three studies had generally unclear risk of bias (see Appendix 11 for further information).

Table 63: Type of violence and aggression measured and risk factors included in the multivariate model for each study

	Inpatient setting		
	Dean 2008	**Stafford 2003**	**Tompsett 2011**
Type of violence and aggression			
Persistent physical aggression	✓		
Total aggression		✓	
Restraint because of imminent danger of harm			✓
Risk factor			
ADHD/disruptive behaviour disorder	✓		
Age	✓	✓	✓
Gender	✓	✓	✓
History of aggression (any)	✓		
History of aggression (property damage)			✓
History of aggression (self-harm)	✓		✓
History of aggression (towards adults)			✓
History of aggression (towards peers)			✓
Duration of hospitalisation		✓	
Mood disorder/suicide ideation	✓		
Pervasive developmental disorder	✓		
Psychopathy		✓	
Psychotropic medication at admission	✓		
Socio-economic status		✓	

Nevertheless, there was consistent evidence from two studies with 283 children and young people (Dean 2008; Tompsett 2011) that history of aggression was associated with violence. The other study (Stafford 2003) found age, duration of hospitalisation and psychopathy to be associated with any aggression. In addition, psychotropic medication at admission was found to be related to violence in one study (Dean 2008).

Other factors with no clear evidence of an association with violence or aggression included gender, pervasive developmental disorder, ADHD/disruptive behaviour disorder, mood disorder/suicide ideation, self-harm and socioeconomic status.

7.3.4 Health economics evidence

Identification of risk factors for violent and aggressive behaviour in children and young people with mental health problems in health and community care settings may lead to better prediction of incidents of violence and aggression and has therefore potentially important resource implications. However, this review question is not relevant for economic analysis.

7.4 PREDICTION

7.4.1 Introduction

For a general introduction to prediction of violence and aggression, please see Chapter 4 (Section 4.4.1)

7.4.2 Studies considered

For the review of prediction instruments (see Table 59 for the review protocol), one study (N = 418) met the eligibility criteria: Barzman 2011 (Barzman et al., 2011). In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both included and excluded studies can be found in Appendix 13.

7.4.3 Prediction instruments included in the review

Data were available for the Brief Rating of Aggression by Children and Adolescents–Preliminary Version (BRACHA 0.8). See Table 16 for further information about the instrument.

Table 64: Summary of characteristics for each included prediction instrument

Instrument	Instrument information	Time to administer; Time to score	Published reliability
Brief Rating of Aggression by Children and Adolescents–Preliminary Version (BRACHA 0.8)	Scale: 16 items Score: 1-32 Cut-off: ≥ 13 (aggression) or ≥ 14 (interpersonal violence) Format: pen and paper	Not reported	Inter-rater reliability: ICC = 0.91 (0.9 version, with 14-items)[1]
Note. [1]Barzman et al. (2012)			

The BRACHA 0.9 is a 16-item instrument with 14 historical and behavioural items and two clinical observations. In the most recent 0.9 version, two items about physical and sexual abuse were dropped. It is completed by '…emergency room staff members using information that is consistently available, even during short, high-pressure evaluations.' (Barzman et al., 2012) Interviewers generally obtain answers to the questions from the child or young person's parents or guardians, although collateral sources or the child/young person can provide additional information. Scoring uses an algorithm that includes age to generate a total score.

7.4.4 Evidence for prediction instruments

In one study of 418 children and young people in an emergency department setting, the base rate for violence was 15% and for any form of aggression it was 29%. Aggression was defined as any threatening verbal or physical behaviour toward self, other people, or objects that would generate a score of 1 or higher on any subscale of the Overt Aggression Scale (OAS). Violence was defined as actions that would

generate a score of 1 or above on the 'physical aggression toward other people' subscale of the OAS. The BRACHA 0.8, using a cut-off of ≥ 14 for predicting violence, had a sensitivity of 0.85 (95% CI, 0.74 to 0.93) and specificity of 0.68 (95% CI, 0.62 to 0.72); LR+ = 2.64; LR- = 0.22. For predicting aggression, using a cut-off of ≥ 13, the BRACHA 0.8 had a sensitivity of 0.80 (95% CI, 0.72 to 0.87) and specificity of 0.57 (95% CI, 0.51 to 0.63); LR+ = 1.86; LR- = 0.35. Figure 1 displays the sensitivity and specificity, and Figure 10 displays the ROC curve.

Figure 9: Forest plot of sensitivity and specificity for instruments used to predict violence and aggression in the short-term

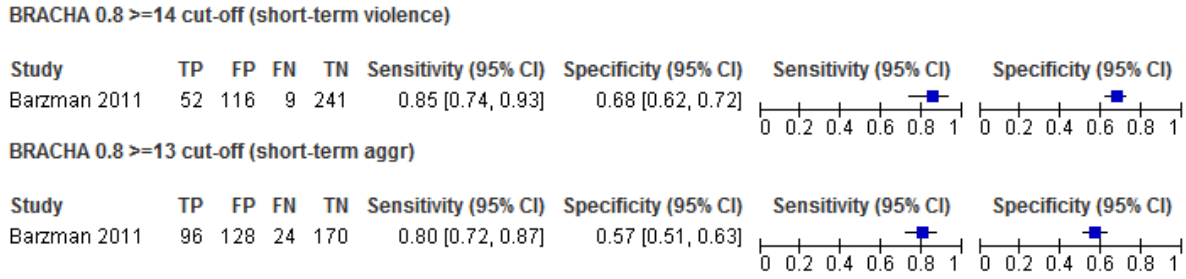
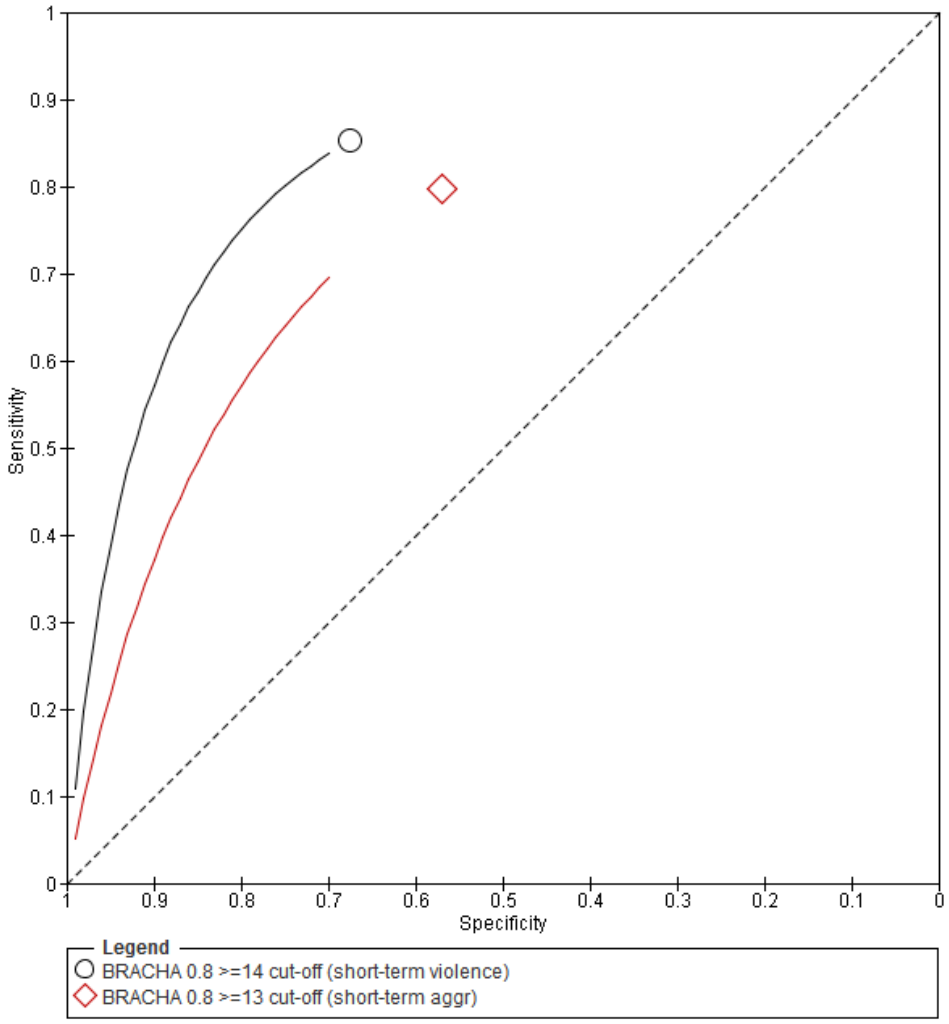


Figure 10: Summary receiver operator characteristic (ROC) curve for the prediction of violence and aggression in the short-term



7.4.5 Health economics evidence

No studies assessing the cost effectiveness of prediction instruments for violent and aggressive behaviour by children and young people with mental health problems in health and community care settings were identified by the systematic search of the economic literature. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.5 NON-PHARMACOLOGICAL MANAGEMENT STRATEGIES - ALL SETTINGS AND PHASES

7.5.1 Introduction

Because of the ubiquity of aggressive behaviours amongst a number of children and young people seen by mental health services, their management is often part of treatment programmes. These aim to help children and young people take responsibility for attempting to control their own aggressive behaviour and use stress reduction techniques, and to provide guidance for parents in dealing appropriately with aggressive behaviour and violence. To manage actual angry outbursts and violence that represent an immediate risk to the child and young person and/or to others, parents and teachers, in addition to preventive measures, will have developed distraction and de-escalation techniques, followed sometimes by physical restraint procedures, the latter being more commonly used in the younger more physically immature children.

Restraint is rarely used by community CAMHS staff, and seclusion is impractical to implement in community CAMHS settings. Most aggressive and violent episodes are seen in psychiatric day or inpatient units. Many community and most inpatient child and adolescent mental health units therefore will be expected to develop guidance or protocols to manage aggression and violence - especially in forensic adolescent units where these behaviours are more likely to occur - and to set up training sessions for staff where different restraint and seclusion techniques are explored that take into account the level of physical and psychological maturity in the child. Discussion with children and young people, but also with parents and carers of the use of seclusion and restraint procedures would be regarded as good clinical practice.

7.5.2 Studies considered

For the review of non-pharmacological management strategies (see Table 60 for the review protocol), two studies met eligibility criteria: De Hert 2011 (De Hert et al., 2011) and Azeem 2011 (Azeem et al., 2011). In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about both the included and excluded studies can be found in Appendix 13.

Non-pharmacological management strategies

One existing systematic review was included which considered the impact of management strategies and training on seclusion and restraint rates in children and

young people (DeHert 2011, see Table 65). The following programmes were included: a new model of care, environmental modifications, collaborative problem solving and a behavioural therapy approach. One primary study was also included which examined the impact of the Six Core Strategies programme on seclusion and restraint rates in a child and adolescent inpatient service (Azeem 2011, see Table 66).

1

Table 65: Study information table for systematic reviews evaluating non-pharmacological management strategies (children and young people)

	De Hert 2011
Review question/ Aim	To examine the prevalence and determinants of restraint and seclusion use in children and young people.
Method used to synthesise evidence	Narrative synthesis
Design of included studies	Interrupted time series study, observational studies
Dates searched	2000 – 2010
Electronic databases	PubMed, PsycINFO, CINAHL
No. of included studies	4[1]
Participant characteristics	Pediatric psychiatric populations (6-21 years)
Intervention	Seclusion and restraint
Comparison	Standard care or other alternative intervention
Outcome	Prevalence of seclusion and restraint use: proportion of patients restrained/ secluded and number of restraints/seclusions per number of patient days.
Note. [1] Out of 7 included studies, 4 studies were judged relevant to the review questions.	

2

3

Table 66: Study information table for primary studies evaluating non-pharmacological management strategies (children and young people)

	Management strategies
Total no. of studies (N)	1 observational study (458)
Study ID	Azeem 2011
Consent gained?	Unclear
Country	United States
Setting	Children and adolescent* mental health service
Diagnosis	Not explicitly stated
Age (mean)	14.4 years
Sex (% Female)	60
Ethnicity (% White)	30.63
Intervention(s)	Approach based on Six Core Strategies for Reducing Seclusion and Restraint Use©: training (risks, primary and secondary prevention; trauma informed care), the role of leadership, post-event analysis and service user involvement.
Comparison	Not applicable
Funding	Not reported
Outcomes	Rates of seclusion and restraint
Note. * Child = < 12 years; adolescent = 13-17 years.	

4

7.5.3 Clinical evidence for non-pharmacological management strategies

In one review that included 4 relevant observational studies (De Hert 2011), and one new observational study with 458 children and young people (Azeem 2011), there was low quality evidence that supported the use of management strategies for reducing the number of episodes and duration of seclusion and restraint in an inpatient setting.

7.5.4 Health economics evidence

From the range of interventions considered in this section, one economic study was found which referred to a non-pharmacological management strategy of children and young people.

LeBel and Goldstein (2005) examined the effect of a management initiative to reduce or eliminate the use of restraint. Details on the methods used for the systematic review of the economic literature are described in Chapter 3; full references and evidence tables for all economic evaluations included in the systematic literature review are provided in Appendix 18. Completed methodology checklists of the studies are provided in Appendix 17. Economic evidence profiles of studies considered during guideline development (that is studies that fully or partly met the applicability and quality criteria) are presented in Appendix 19.

This was a before-after study which was carried out in a privately run, 30-bedded, mixed inpatient unit for youths aged 13 to 18, located in the US. Data were collected on staff time and medication for evaluation of the initiative. Aggregate costs were calculated from these data and years 2000 and 2003 were compared. The costs included were from a hospital perspective and were composed of staff time and medication use. The main outcome measure was the number of restraint episodes. The time horizon was 12 months.

The results of the analysis indicated a decrease in costs associated with the intervention from $1,446,740 to $177,036 associated with a decrease in episodes of restraint from 3,991 to 373 at the ward level. Discounting was not reported and so it is unclear if this was carried out, if not, then these figures represent the cost years 2000 and 2003 respectively. The paper also reported reduced recidivism, rehospitalisation and restraint related injuries.

There were a number of limitations of this study, these were: the lack of any formal statistical analysis, quality of life was not measured, cost of implementation was not measured, discounting was unclear and the intervention was poorly defined. The most important limitation, however, is its before-after design. As stated by the authors, the results could be due to extraneous variables or secular trends, when considered alongside the other methodological issues this study has potentially serious limitations. As the study was carried out in a single US centre and the

intervention itself is difficult to define and reproduce, the generalisability of the results to an NHS context is limited; the study is therefore only partially applicable to the UK setting.

Economic evidence statement

One economic study was identified which suggested restraint reduction initiatives may result in a reduction in restraint episodes and cost-savings. This analysis was considered to be partially applicable with potentially serious limitations and therefore was of limited use in making recommendations.

7.6 PHARMACOLOGICAL INTERVENTIONS - ALL SETTINGS AND PHASES

7.6.1 Introduction

In outpatient settings pharmacological interventions are very rarely used as a means of controlling aggressive and violent behaviour in children and young people with mental health problems. Even if still uncommonly, these interventions are most likely to be used in acute paediatric services for children with joint medico/psychiatric or severe and acute psychiatric disorders, and in psychiatric inpatient units, usually after other management techniques have been tried unsuccessfully, and with ongoing nursing supervision. Medication delivered p.r.n. tends to be used in psychiatric inpatient units for young people with rare and severe psychiatric disorders such as psychotic states. It is recommended that parents are involved in decisions about rapid tranquillisation and the different units tend to develop their own rapid tranquillisation protocols, normally using antipsychotics and benzodiazepines, and sometimes and when practicable advanced decisions and statements. Rapid tranquillisation drugs are used with care because of the unpleasant acute dystonic reactions that have been reported with drugs such as haloperidol, and the apparent paradoxical agitating effects of benzodiazepines on some children.

7.6.2 Studies considered

No studies were identified which met eligibility criteria for the review questions addressing the role of pharmacological interventions in the short-term management of violent and aggressive behaviour in children and young people (see Table 61 for the review protocol). In addition, 528 studies failed to meet eligibility criteria for the guideline. Further information about excluded studies can be found in Appendix 13.

7.6.1 Health economics evidence

No studies assessing the cost effectiveness of p.r.n. medication used to prevent imminent violent and aggressive behaviour by children and young people with mental health problems in health and community care settings were identified by the systematic search of the economic literature. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.7 LINKING EVIDENCE TO RECOMMENDATIONS

7.7.1 Risk factors

Relative value placed on the outcomes considered

The GDG agreed that the association between a risk factor and violence/aggression was the outcome of interest. Studies that found independent factors by using a multivariate model were preferred.

Summary of evidence

Only three studies (with a total of 355 participants) were found that met eligibility criteria. Of these, all included children and/or young people in an inpatient setting and were conducted in the USA or Australia, with the majority of participants having a mood disorder. Nearly two-thirds were male and nearly three-quarters were white.

The GDG agreed that the evidence supported history of aggression as an independent risk factor for violence in an inpatient setting. Based on their expert opinion, they also suggested that experience of abuse or trauma, previous response to the management of violence or aggression, and cognitive, language and cultural factors are important and should be assessed. To reduce the risk of violence, the GDG agreed that health and social care professionals working with children and young people could consider offering those with a history of violence help developing greater self-control and techniques for self-soothing. In addition, parents of children and young people who are violent or aggressive should be offered a parent training programme and support to help prevent future problems.

Quality of the evidence

In general all evidence was downgraded to very low quality because it was from observational studies with high or unclear risk of bias.

7.7.2 Prediction

Relative value placed on the outcomes considered

Sensitivity and specificity of each instrument was primarily used to assess test accuracy. In addition, the AUC and negative and positive likelihood ratios were examined.

Trade-off between clinical benefits and harms

The GDG agreed that the evidence suggested that the BRACHA 0.8 had excellent sensitivity and good specificity for predicting both violence (aggression towards others) and any form of aggression. However, the positive likelihood ratio did not reach an accepted level of accuracy for predicting either violence or aggression, and therefore further evidence would need to be available before a specific recommendation for use of the BRACHA could be made.

Trade-off between net health benefits and resource use

As with adults the consequences of poorly handled violent events can be substantial, there are clear resource and quality of life implications associated with prediction tools.

No applicable evidence was identified in the economic searches. From the clinical review, the use of prediction tools based on risk factors may offer utility over clinical

opinion alone and given the potentially serious consequences, any improvement in the management of an event due to prescience is likely to be cost effective.

Quality of the evidence

Risk of bias was generally low, although raters of actual violence and aggression were not blind to how items of the prediction instrument were scored.

7.7.3 Non-pharmacological management strategies

Relative value placed on the outcomes considered

The GDG agreed that any reported outcomes relevant to the safety, effectiveness and experience of the management of short-term violence and aggression should be considered. In practice, the outcomes reported included use of restrictive interventions.

Trade-off between clinical benefits and harms

The GDG agreed that management strategies could be used to reduce the use of restrictive interventions without increasing the risk of harm. Use of restrictive interventions should be limited to instances where other attempts to defuse the situation had failed and should not be used as a punishment. As part of this reduction, the GDG wished to highlight the role of staff training and stress that training programmes should include the use of psychosocial methods to avoid or minimise restrictive interventions whenever possible. During these discussions, the GDG also decided that there were a number of general principles covering: training, policy, safeguarding, shared decision making with the child or young person, collaboration with those with parental responsibility and use of recommendations for adults.

Based on expert opinion and the limited evidence, the GDG agreed a number of recommendations covering de-escalation and the use of restrictive interventions, such as manual and mechanical restraint, and seclusion. In summary, de-escalation techniques recommended for adults could also be used in children and young people, but with some modifications. With regard to restrictive interventions, it was decided that manual restraint, based on the methods recommended for adults could also be used. However, it was emphasised that staff should be trained in the use of these interventions in these age groups and should be able to adjust the techniques according to the child or young person's height, weight and physical strength. The GDG also considered that it would be preferable for a staff member who is the same sex as the child to carry out manual restraint. As part of this, the GDG debated extensively whether or not to proscribe prone restraint in children. It was agreed that there was insufficient evidence or consensus between GDG members to make a 'do not use recommendation.' Reasons discussed included that it is problematic to set an arbitrary distinction between children and young people, when considering manual restraint, given variation in size and weight. The GDG agreed that mechanical restraint should not be used in children, and only used in young people in high-secure settings and when transferring young people between secure settings. The

GDG also considered that seclusion could be used, but that the ultimate decision should rest with the multidisciplinary team; that all uses of seclusion should be reported to the trust board for monitoring purposes, and that locked rooms should not be used. The GDG additionally highlighted that throughout the use of a restrictive intervention the child or young person should be monitored throughout.

Finally, given the paucity of evidence, the GDG decided to include a new research recommendation to encourage further research into the use of manual restraint techniques in the management of violence and aggression in children and young people.

Trade-off between net health benefits and resource use

The general principles and objectives influencing decision making in adults play a similar role in the management of violence and aggression in children. These concerns include a focus on service user safety, positive engagement and dignity. From the review there is some limited evidence suggesting that reductions in restraint can be cost saving.

Quality of the evidence

The evidence was from observational studies and therefore graded as low quality (with no reason for upgrading).

7.7.4 Pharmacological interventions

Relative value placed on the outcomes considered

The GDG agreed that any reported outcomes relevant to the safety, effectiveness and experience of the management of short-term violence and aggression should be considered.

Trade-off between clinical benefits and harms

No evidence that met eligibility criteria was available for assessing the benefits and harms of pharmacological interventions. Based on expert opinion, the GDG agreed that in some circumstances the use of an IM benzodiazepine (lorazepam) for rapid tranquillisation could be justified, but dose would need to be adjusted according to age and weight, and the child or young person monitored continuously.

Trade-off between net health benefits and resource use

As with adults the trade-offs involved in the pharmacological management of violence and aggression are complex. No economic studies were found which were applicable to the decision context.

Drug acquisition costs were presented to the GDG and provide some notion of opportunity cost though the relative rates of side effects and associated treatment costs were not possible to estimate from the available clinical data. These costs

suggest small difference in acquisition across alternatives which allows considerable flexibility in choosing options to individualise treatment based on a service user.

Quality of the evidence

No research evidence was eligible.

Other considerations

The GDG considered the settings in which violence and aggression in children and young people are managed and developed some general principles based on consensus. They considered that CAMHS should have a policy about managing antisocial behaviour and ensure that staff are trained in managing that behaviour using psychosocial and behavioural techniques.

The GDG also developed other general principles around working with parents and carers, safeguarding and joint decision making.

Finally, the GDG wished to ensure that any underlying mental health problems, such as antisocial behaviour and conduct disorders, ADHD and autism were assessed and treated according to the relevant NICE guideline.

7.8 RECOMMENDATIONS

7.8.1 Clinical practice recommendations

Staff training

7.8.1.1 Child and adolescent mental health services (CAMHS) should ensure that staff are trained in the management of violence and aggression using a training programme designed specifically for staff working with children and young people. Training programmes should include the use of psychosocial methods to avoid or minimise restrictive interventions whenever possible. Staff who might undertake restrictive interventions should be trained:

- in the use of these interventions in these age groups
- to adapt the manual restraint techniques for adults in recommendations 6.6.1.11–6.6.1.21, adjusting them according to the child or young person's height, weight and physical strength.

7.8.1.2 CAMHS should have a clear and consistently enforced policy about managing antisocial behaviour and ensure that staff are trained in psychosocial and behavioural techniques for managing the behaviour.

7.8.1.3 CAMHS staff should be familiar with the Children Act 1989 and 2004 as well as the Mental Capacity Act 2005 and the Human Rights Act 1998. They should also be aware of the United Nations Convention on the Rights of the Child.

Managing violence and aggression

7.8.1.4 Manage violence and aggression in children and young people in line with the recommendations for adults in sections 4.6, 5.7 and 6.6, taking into account:

- the child or young person's level of physical, intellectual, emotional and psychological maturity
- the recommendations for children and young people in this section.
- that the Mental Capacity Act 2005 applies to young people aged 16 and over.

7.8.1.5 Collaborate with those people who have parental responsibility when managing violence and aggression in children and young people.

7.8.1.6 Use safeguarding procedures to ensure the child or young person's safety.

7.8.1.7 Involve the child or young person in making decisions about their care whenever possible.

Assessment and initial management

7.8.1.8 Assess and treat any underlying mental health problems in line with relevant NICE guidelines, including those on antisocial behaviour and conduct disorders in children and young people, attention deficit hyperactivity disorder, psychosis and schizophrenia in children and young people, autism diagnosis in children and young people and autism.

7.8.1.9 Identify any history of aggression or aggression trigger factors, including experience of abuse or trauma and previous response to management of violence or aggression.

7.8.1.10 Identify cognitive, language and cultural factors that may increase the risk of violence or aggression in a child or young person.

7.8.1.11 Consider offering children and young people with a history of violence or aggression help to develop greater self-control and techniques for self-soothing.

7.8.1.12 Offer a parent training programme and support to parents of children and young people who are violent or aggressive.

De-escalation

7.8.1.13 Use de-escalation in line with recommendations 5.7.1.29–5.7.1.37 for adults, modified for children and young people, and:

- use calming techniques and distraction
- offer the child or young person the opportunity to move away from the situation in which the violence or aggression is occurring, for example to a quiet room or area
- aim to build emotional bridges and maintain a therapeutic relationship.

Restrictive interventions

7.8.1.14 Use restrictive interventions only if all attempts to defuse the situation have failed and the child or young person becomes aggressive or violent.

7.8.1.15 When restrictive interventions are used, monitor the child or young person's wellbeing closely and continuously, and ensure their physical and emotional comfort.

7.8.1.16 Do not use punishments, such as removing contact with parents or carers or access to social interaction, withholding nutrition or fluids, or corporal punishment, to force compliance.

Manual restraint

7.8.1.17 If possible, allocate a staff member who is the same sex as the child or young person to carry out manual restraint.

Mechanical restraint

7.8.1.18 Do not use mechanical restraint in children.

7.8.1.19 CAMHS should ensure that mechanical restraint in young people is used only in high-secure settings (except when transferring young people between medium- and high-secure settings as in recommendation 7.8.1.20), in accordance with the Mental Health Act 1983 and with support and agreement from a multidisciplinary team that includes a consultant psychiatrist in CAMHS.

7.8.1.20 Consider using mechanical restraint, such as handcuffs, when transferring young people who are at high risk of violence or aggression between medium- and high-secure settings, and remove the restraint at the earliest opportunity.

Rapid tranquillisation

7.8.1.21 Use intramuscular lorazepam for rapid tranquillisation in a child or young person and adjust the dose according to their age and weight[12].

7.8.1.22 If there is only a partial response to intramuscular lorazepam, check the dose again according to the child or young person's age and weight and consider a further dose.

7.8.1.23 Monitor physical health and emotional impact continuously when undertaking rapid tranquillisation in a child or young person.

Seclusion

7.8.1.24 Decisions about whether to seclude a child or young person should only be made by a multidisciplinary team.

7.8.1.25 Report all uses of seclusion to the trust board or equivalent governing body.

7.8.1.26 Do not seclude a child or a young person in a locked room, including their own bedroom.

7.9 RESEARCH RECOMMENDATIONS

7.9.1.1 What is the most appropriate physical restraint technique to use should it become necessary for the short-term management of violent and aggressive behaviour in children and young people?

[12] At the time of consultation (November 2014), lorazepam did not have a UK marketing authorisation for use in children and young people for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

8 APPENDICES

Please note that the appendices are in separate files.

Appendix 1: Scope for the development of the clinical guideline

Appendix 2: Declarations of interests by Guideline Development Group members

Appendix 3: Stakeholders and experts who submitted comments in response to the consultation draft of the guideline

Appendix 4: Researchers contacted to request information about unpublished or soon-to-be published studies

Appendix 5: Review questions

Appendix 6: Method for evidence synthesis

Appendix 7: Research recommendations

Appendix 8: Medication for rapid tranquillisation

Appendix 9: Clinical evidence – review protocols

Appendix 10: Clinical evidence – search strategies

Appendix 11: Clinical evidence – methodology checklists

Appendix 12: Clinical evidence – study characteristics (original guideline)

Appendix 13: Clinical evidence – study characteristics (update)

Appendix 14: Clinical evidence – GRADE profiles

Appendix 15a: Clinical evidence – risk factors forest plots

Appendix 15b: Clinical evidence – rapid tranquillisation forest plots

Appendix 16: Health economic - search strategies

Appendix 17: Health economic evidence – methodological checklists

Appendix 18: Health economic evidence – evidence tables

Appendix 19: Health economic evidence – GRADE profiles

Appendix 20: YoungMinds focus groups report

See separate files.

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