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**Doctoral Thesis**

The Relationship between Insight and Violence in Psychosis: A Systematic Review

&

The Predictive Validity of the HCR20v3 within Scottish Forensic Inpatient Facilities: A Closer  
Look at Key Dynamic Variables

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*Doctorate in Clinical Psychology, The University of Edinburgh. 2017.*

### **D. Clin. Psychol. Declaration of own work**

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## **Acknowledgments**

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## **Dedication**

I would like to dedicate my doctoral thesis to my family especially my mum, dad, brother and soon to be husband, Paul. Thank you mum and dad for teaching me to be curious about the world, its people and their differences. Thank you for bringing me up with compassion for others and for the difficulties they might experience and for encouraging me to explore my curiosities through my work. Thank you for believing in me in all that I have endeavoured to do in quite a busy life! Most importantly thank you for a lifetime of support, both practically and emotionally. Thank you mum for providing my own safe base for me throughout my life. Thank you for picking me up late at night, making sure I ate properly (!), driving me cross-country for job interviews and for being the most productive, reliable role model. Thank you dad for all of your quiet belief in me and all the humour you have provided to make those late 'study' nights a bit easier. I could never have completed this thesis without you both and I hope you know how much I appreciate you.

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## 1. Abstract

**Introduction:** Poor insight is included as a risk factor for violence in risk assessment tools such as the Historical Clinical Risk-Management-20 version 3 (HCR-20v3) yet there is a lack of consensus around the relationship between poor insight and violence in individuals with psychosis. A systematic literature review was therefore carried out to clarify this relationship. Relatedly, a research project aimed to outline the predictive validity of the HCR-20v3 total and sub-scale scores to violence in forensic inpatients. A secondary aim was to understand the predictive ability of 2 dynamic risk factors within the HCR-20v3 clinical sub-scale; insight and positive symptoms, alongside age and history of violence in relation to violence in psychosis.

**Method:** A systematic search of studies investigating insight and violence in patients with psychosis, published between 1980 and 2016 was carried out on relevant databases. 17 articles from combined search results of 5694, met the inclusion criteria. These were selected for full-text review and quality grading which was subject to inter-rater reliability. In the research project, the predictive validity of the HCR-20v3 to violence was assessed in N=167 forensic inpatients. A sub-sample of N=135 was then used to investigate insight, positive symptoms, age and history of violence in relation to violence. Data was extracted from case files, with the exception of violence data which was collected prospectively from date of HCR-20v3 publication via DATIX.

**Results:** The systematic review found 8 studies in support of a positive relationship between poor insight and violence, whilst 9 studies did not support this relationship. The majority of better quality studies measured the clinical insight dimension which tended to demonstrate a positive relationship between poor insight and violence. Methodological limitations were apparent across studies. The research project found HCR-20v3 total and clinical and risk-management sub-scale scores to predict violence. The clinical sub-scale was the strongest predictor of violence and physical violence specifically. Sub-sample analysis found positive symptoms and history of violence to significantly predict violence generally whilst only positive symptoms demonstrated prediction of physical violence. Insight and age were not significantly associated with either violence type.

**Discussion:** The systematic review found partial support for a positive relationship between poor insight and violence in psychosis. Future good quality research is required to develop a fuller understanding of this issue. Research project results support the use of the HCR-20v3 in the risk assessment and management of forensic inpatients. They reinforce the usefulness of dynamic risk factors within the clinical sub-scale in particular. In line with the majority of studies within the systematic review however, a relationship between insight and violence in a

sub-sample of patients with psychosis was not found. Recommendations are made for the regular re-assessment of dynamic risk factors within the HCR-20v3 clinical sub-scale in order to support patients to reduce their level of risk, with the caveat that future research is still required to support a relationship between insight and violence in this patient group.



## **2. Systematic Literature Review: The Relationship between Insight and Violence in Individuals with Psychosis**

### **2.1 Abstract**

**Objectives:** Poor insight is included as a risk factor for violence within well-established risk-assessment tools, yet its relationship to violence in populations with psychosis is unclear. We therefore sought to systematically review studies investigating the relationship between poor insight and violence in psychosis to provide clarity around this issue.

**Methods:** A systematic search of studies published between 1980 and 2016 was carried out using Pubmed, Embase, Medline, PsychInfo and CINAHL databases. From combined search results of 5694 articles, 17 observational studies met the inclusion criteria and were selected for full-text review and quality grading.

**Results:** 8 studies demonstrated a positive relationship between poor insight and violence whilst 9 failed to find this relationship. Significant methodological limitations were found across studies, with studies which measured the clinical insight dimension specifically and reliably, most able to demonstrate a positive relationship with violence. Choice of measurement tool and co-variables such as psychopathy were shown to influence the relationship.

**Discussion:** There is partial evidence in support of a relationship between poor insight and violence in psychosis. Better quality research accounting for relevant co-variables and using appropriate measurement tools to target the clinical insight dimension is required in order to gain a fuller understanding of this relationship.

**Keywords:** Psychosis, Insight, Violence, Schizophrenia, Aggression

**Word Count:** 10,782

## **2.2 Introduction**

### **2.2.1 Psychosis**

Psychosis is a broad term used to describe abnormalities in thinking, perception, emotions, language, sense of self or behaviour. Psychotic experiences can occur within a number of 'psychiatric disorders', most notably schizophrenia. Indeed, the Diagnostic Statistical Manual-5 (APA, 2013) continues to classify experience of psychosis within diagnostic categories. However, in line with growing research (Brandon, et al, 2009), the DSM-V chapter 'Schizophrenia Spectrum and Other Psychotic Disorders' begins to position psychosis on a continuum with typical mental states. It gives less prominence to schizophrenia with enhanced focus on the five psychopathological domains associated with experience of psychosis generally; hallucinations, delusions, disorganised thought, abnormal motor behaviour and negative symptoms (Heckers et al, 2013).

Alongside the significant challenges psychotic experience can bring to daily functioning (Bowie, et al, 2006), psychosis is associated with negative outcomes such as; poor physical health (Moreno, et al, 2013); early mortality (Fazel et al, 2014), and in a minority of individuals, violence (O'Shea et al, 2014). Due in particular to the latter, persons with psychosis often experience stigma and inequalities. Clarification of this relationship may support the reduction of stigma surrounding psychosis yet existing research has produced contrasting findings. For example, the MacArthur violence study (Monahan et al, 2001) followed up N=1136 patients discharged from psychiatric hospitals for a year, finding a diagnosis of schizophrenia to be associated with a lower rate of violence than personality disorders, depression and bi-polar disorder. Additionally, they found no significant relationship between schizophrenia diagnosis and violent behaviour. Studies focussing only on schizophrenia diagnosis may however inadvertently discount concepts related to violence present within psychosis. Bearing this issue in mind, we suggest there may be greater advantage in studying specific dynamic and clinical variables relevant to psychosis in relation to violence, as opposed to diagnosis led research.

Patient insight into their mental health difficulties is one such clinical variable (Dam, 2006) which may provide further clarity on why a minority of individuals with psychosis behave violently, whilst the majority do not. As a key variable measured within gold standard risk assessment tools such as the HCR-20v3 (Douglas et al, 2013) poor insight is positioned as a factor predictive of violence. To date however, no systematic review or meta-analysis has clarified the extent of this relationship.

### **2.2.2 Insight in Psychosis: Definitions and Assessment**

Poor insight in psychosis has been observed since 1886 when Kraepelin noted that individuals experiencing dementia praecox were generally unaware of the severity of their condition. Today, insight remains largely defined in this way, termed within the psychological literature as ‘clinical insight’ (Amador & David, 1998), it refers to an individuals’ awareness and understanding of their mental health difficulties. Insight is however unlikely to be a unitary concept (Amador et al, 1993), with a number of dimensions found to contribute towards its disposition (Capdevielle et al, 2013). Cognitive insight (Beck et al, 2004) has been proposed as one further dimension. It refers to the ability to recognise mistakes in ones thinking and to consider alternative explanations for the same. Considering both clinical and cognitive insight dimensions, an individual may hold a reasonable level of clinical insight by being aware that they are experiencing psychosis, yet have poor cognitive insight as they are unable to consider alternative explanations for their delusional beliefs. This example highlights the complex multi-dimensional nature of insight and alludes to the difficulties in its assessment.

Although not associated exclusively with psychosis, poor insight is a core feature of psychotic experience, with around 50% of patients with schizophrenia failing to believe they have mental health difficulties (Arango & Amador, 2011). Poor insight has been associated with adverse outcomes including medication non-adherence (Higashi et al, 2013) and violence and aggression (Ekinici & Ekinici, 2013), making reliable assessment all the more essential. Arguably however, due to its multi-dimensionality, assessment tools are often limited in their attempts to measure insight (McCormack et al, 2013). As such, the literature is currently dominated by studies which select one measurement scale and apply it to the whole concept, often without defining the insight domain they aimed to measure, potentially failing to identify significant associations (e.g. Slijepcevic et al, 2014). Additionally, different insight dimensions appear to be associated with different variables. For example, poor clinical insight has consistently been associated with medication non-compliance (Day et al, 2005; Jonsdottir et al, 2013), whilst evidence is lacking with regards to the relationship between cognitive insight and compliance. Misleading findings may then be produced should researchers select measurement scales which do not correspond with intended insight dimensions. These conceptual and methodological difficulties highlight how regardless of its centrality to the condition, insight continues to be an elusive feature of psychosis, not yet fully understood.

### **2.2.3 Violence and Insight in Psychosis**

The propensity for a minority of individuals with psychosis to behave violently is a debated and sensitive issue. A meta-analysis by Fazel et al, (2009) found experience of schizophrenia and other psychoses to be associated with an elevated risk of violence. Although most of the excess risk associated with violence in these studies was mediated by substance abuse co-morbidity, risk of homicide was increased in individuals with psychosis both with and without substance abuse compared to general population controls. Swanson et al (2006) investigated more closely the clinical phenomena inherent within psychosis, as opposed to diagnosis only, in N=1410 community patients. A positive relationship between psychosis and violence was identified, with experience of positive symptoms of psychosis found to significantly increase both minor and serious violence whilst negative symptoms reduced serious violence. Witt et al's (2013) meta-regression analysis of 110 studies provided support for Swanson et al's (2006) findings. They found higher positive symptom scores to be significantly associated with violence in psychosis whilst violence was not significantly associated with negative symptomatology. Thus, it is unlikely to be psychosis in its entirety which is related to violence, rather, it may be specific clinical variables inherent within psychosis such as positive symptoms and poor insight which hold greater relevance to our understanding of violence.

Indeed, multi-dimensional insight comprising insight into; mental disorder; violence risk and need for treatment, is included as a violence risk factor in the HCR-20v3 (Douglas et al, 2013). It is included despite there being only a small number of studies investigating the relationship between insight and violence in psychosis, which have produced inconsistent findings. In a sample of outpatients with psychosis without co-morbid substance abuse, Ekinci & Ekinci (2013) compared patients with a history of violence to a non-violent control group. The non-violent group were found to have significantly higher clinical insight than the violent group, with lower clinical insight found to predict violence. Although this relationship is also demonstrated within other studies (e.g. Arango et al, 1999; Goodman et al, 2005) methodological quality varies greatly. For example, Lincoln & Hodgins (2008) found poor insight to be associated with violence in uni-variate analysis, however when positive symptoms and psychopathy were controlled for, insight did not contribute to the prediction of violent behaviour. Failure to control for key variables may then create differing results between studies. Other methodological limitations such as small sample sizes (Carroll et al, 2004), retrospective designs (Soyka et al, 2007) and the use of inappropriate measurement tools (Slijepcevic et al, 2014) limit our ability to understand the relevance of poor insight to violent

behaviour in individuals with psychosis. Moreover, no amalgamation of existing research has been produced so far and therefore the relationship remains vague.

## **2.2.4 Aims of this Systematic Review**

Given the use of poor insight as a violence risk factor in tools such as the HCR-20v3 and taking account of the lack of consensus around insight's relationship with violence in psychosis, it now seems essential to undertake a systematic literature review of this relationship. This review will seek to understand the relationship between insight and violence in psychosis in an effort to clarify the extent to which a positive relationship between poor insight and violence exists.

## **2.3 Methods**

### **2.3.1 Inclusion Criteria**

All observational studies published between 1980 and October 2016, which investigated the relationship between insight and violence in individuals with psychosis were included. The review sampled participants over the age of 16 who experienced psychosis within recognised schizophrenia spectrum and other psychotic disorders according to DSM-V criteria (APA, 2013). Patients with bi-polar disorder were included only when they were present within mixed samples and only when the study clarified that they experienced psychosis. A broad range of patient samples were included, from community civil-psychiatric patients to patients within forensic mental health hospitals.

### ***Exclusion Criteria***

Non-English language, intervention, single case and qualitative studies were excluded. Studies which considered violence only in the form of self-harm/suicide were excluded as were studies which included patients under the age of 16 and those sampling patients with intellectual disabilities. Studies which sampled patients with a diagnosis of bi-polar disorder only were excluded as were studies which did not clarify the psychotic experience of participants with bi-polar disorder when they were included within mixed diagnostic samples. Studies which measured insight via only clinician/researcher opinion and without the use of a validated insight measurement tool were also excluded. This included studies which may have used HCR-20 item 'C1' 'lack of insight' as their only insight measurement, as reliability/validity of this single item has not been demonstrated<sup>1</sup>.

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<sup>1</sup> This is likely due to individual item ratings rarely being reported within HCR-20 studies due to their existence within sub-scales.

### ***2.3.2 Literature Search Strategy***

Literature searches were carried out on the following electronic databases, producing articles published within stated date ranges: PubMed (1980-25<sup>th</sup> July 2016), Embase (1980- 25<sup>th</sup> July 2016), MedLine (1980-25<sup>th</sup> July 2016), PsychInfo (1987-25<sup>th</sup> July 2016) and CINAHL (1980-19<sup>th</sup> October 2016). A preliminary search of these databases was carried out to ensure there were no existing systematic reviews on the topic, Cochrane and Prospero databases were also searched for this purpose. The following search terms were then input into each database; (INSIGHT) OR (AWARENESS) OR (UNDERSTANDING) OR (COMPREHENSION) AND (PSYCHOSIS) OR (PSYCHOTIC) OR (SCHIZOPHRENIA) OR (SCHIZO-AFFECTIVE) OR (MENTAL ILLNESS) AND (VIOLENCE) OR (AGGRESSION) OR (CHALLENGING BEHAVIOUR) OR (HOSTILITY).

Grey literature was included by searching reference lists of studies which met the inclusion criteria and by retrieving studies which cited included articles. Citation searches were carried out using Scopus and authors eminent in the field were contacted to query whether they had unpublished articles suitable for inclusion. The review was then registered on the University of York's database for systematic reviews and met-analyses.

### ***Search and Selection Strategy***

As per Figure 1. all articles produced by searches were screened for removal of duplicates. Titles and abstracts of remaining articles were then screened for relevance to the review question and those deemed not relevant were excluded. Remaining articles and those acquired from grey literature were then retrieved in full-text. Each article was read in full and subjected to inclusion/exclusion criteria. Studies which fulfilled the inclusion criteria were selected for full review and those which did not were excluded.

### ***2.3.3 Risk of Bias and Methodological Quality Assessment***

The risk of bias and methodological quality of studies was assessed using the 'Quality Appraisal Checklist for Quantitative Studies Reporting Correlations and Associations' (NICE, 2012). This tool facilitates appraisal of the internal and external validity of studies which report on correlations and associations. The tool was adapted slightly for use in this review to better reflect the properties of included studies. For example, all studies were observational in nature and therefore items relating to intervention studies were omitted. To promote clarity and

consistency of ratings amongst raters, all items were also fully operationalised, thereby expanding upon the original descriptions of items provided by NICE<sup>2</sup>. There is evidence that comparison of studies by a total numerical score lacks objectivity due to unequal item weightings (Whiting, et al, 2005). The NICE checklist scoring system therefore provides grades in symbol terms. For a general overview of study quality, each study is also awarded quality grades for internal and external validity.

All studies were subjected to quality assessment by the researcher. To reduce the potential bias that may exist within this process, a suitably qualified 2<sup>nd</sup> independent reviewer graded 6 of the 17 studies (35%). Agreement between reviewers on methodological quality was found to be excellent with an intra-class coefficient (ICC) of .877 (Cicchetti, 1984). Minor disagreements on grades were resolved through discussion between reviewers and any changes made were applied consistently across all studies.

### ***Data Extraction***

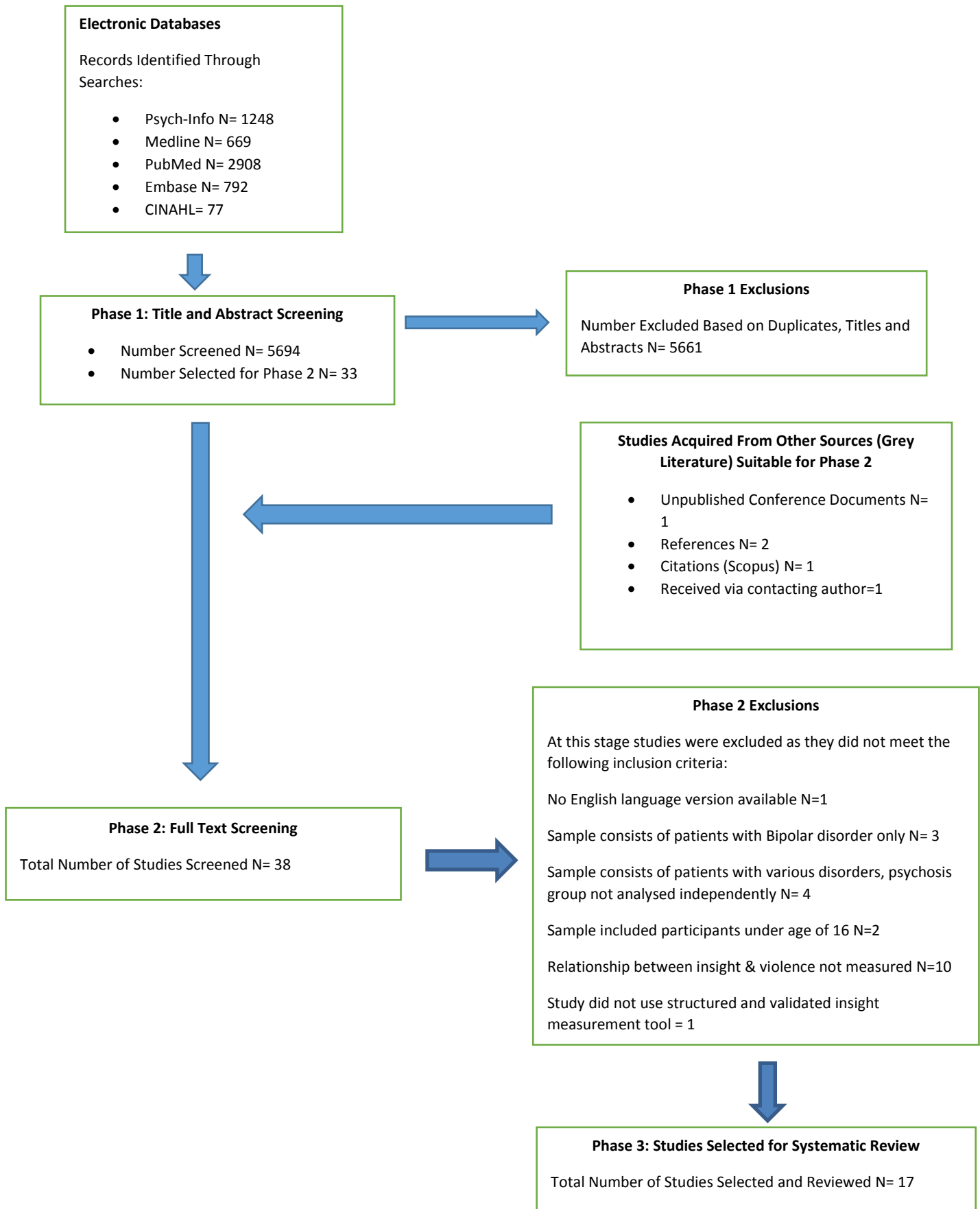
A data extraction table<sup>3</sup> was created to summarise all studies included in the review. This incorporated various components of the ‘Quality Appraisal Checklist...’ (NICE, 2012) and also more specific study information.

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<sup>2</sup> For comparison of the NICE quality appraisal tool and this study’s fully operationalised version please see appendices 3 & 4

<sup>3</sup> See Table 1

**Figure 1. Study Selection Flow Chart**





## **2.4 Results**

### **2.4.1 Participants**

6127 patients were included in this review across 17 studies. Studies were carried out in various countries with 3 conducted in the USA; 2 in Turkey; 2 multi-site across the USA and several European countries; 2 in Ireland, 2 in Spain and 1 in Mexico, China, Croatia, Australia, Israel and Germany respectively. All patients experienced psychosis within various diagnoses, the most common being schizophrenia. Diagnostic samples showed good variation including first episode psychosis and mixed schizophrenia spectrum disorder samples. The mean age of patients was 36.41 and the vast majority were male.

All studies used opportunity sampling, with five sampling consecutively admitted patients to a service. Calatayud et al, (2012) did not provide any information on sampling strategy whilst only Carroll et al, (2004) commented on how many patients were invited to participate in their study in comparison to how many actually did. Patient samples included forensic inpatients (Alia-Klein et al, 2007; Goodman et al, 2005; Carroll et al, 2006; Slijepcevic et al, 2014), forensic outpatients (Lincoln & Hodgins, 2008), outpatients attending community mental health centres (Swanson et al, 2006; Foley et al, 2005), outpatients attending hospital services (Fresan et al, 2005; Ekinici & Ekinici, 2013; Yen et al, 2002; Volavka et al, 2016), discharges from a university psychiatry service (Soyka et al, 2007) county jail and court psychiatric clinic attendees (Buckley et al, 2004) and civil psychiatric inpatients (Arango et al, 1999; Foley et al, 2007; Kosger et al, 2015), creating good generalizability for this review.

**Table 1. Characteristics of Included Studies**

Study No	Author Year, Country & Study Design	Source Population	Diagnoses incl. in sample and diagnostic method	Sample Size Mean Age %Male	Insight Measurement Violence Measurement	Method by which Violence data Collected	Other explanatory / confounding variables considered in analysis	F/Up Length of F/Up	Key Finding	Results as Reported in Article	Effect Size
1	Arango et al (1999) Spain Prospective Cohort	Civil Psychiatric Patients	Schizophrenia & Schizoaffective Disorder by DSM-IV criteria	N=63 Mean =35.2 73%	4 SUMD items OAS	Nursing staff trained in the OAS, blind to the hypotheses of the study scored violent incidents using the OAS.  Researchers then collated this information.	Age, gender, marital status, employment status, parents social class, years in education, age of SZ onset, duration of SZ, No of past hospitalisations and duration, no of suicide attempts, days in hospital, days off ward, involuntary admission, EEG status, PANSS subscale and total scores, violence in week prior to admission and SUMD.  Did not include substance misuse and psychopathy.	3 days to 5 months f/up	Violent patients had significantly poorer insight than non-violent patients.  Poor insight into psychotic symptoms was the best single predictor of violence.	SUMD Items: Awareness of mental disorder: z=-2.26, p<0.05*  Awareness of need for treatment: z=-2.66, p<0.01**  Awareness of social consequences of mental disorder: z=2.62, p<0.01**  Awareness of signs and symptoms of mental disorder: t=4.18(df=61), p<0.001***  X <sup>2</sup> =11.46, p=0.001***(model fit)	d=0.69 (medium)  d=0.82 (large)  d=0.74 (medium)  d=1.073 (large)
2	Buckley et al (2004) USA	County jail, court psychiatrist	Schizophrenia & schizoaffective	N=226 Mean=39.2	PANSS G12 (insight) and 4 SUMD items.	Interview with participant by qualified research personnel.	Gender, age, race, duration of illness, all PANSS subscales, MMSE rating, Trail making test A&B, QOL scale score.	No	The violent group had significantly more prominent lack of	PANSS Insight item: F=45.8(df=1,219),p=0.001*	d=0.913 (large)

	Case-Control	ic clinic, community mental health centre patients	disorder by DSM IV criteria	82% of violent cohort / 76% of non-violent cohort	No specific violence measure used. Violence categorised by assault type.		Did not include substance misuse, psychopathy, medication compliance/use not studied. Only measured assault for which P was in custody for, previous violence history not measured.		insight than a non-violent control group on all insight measures.	SUMD items: Awareness of Mental Disorder: F=14.9 (df=1,219), p=0.001***  Awareness of effects of medication: F= 21.4 (df=1,219), p=0.001***  Awareness of social consequences of mental disorder: F=53.7(df=1,219), p=0.001***  Awareness of poor control of aggressive impulses (Not Reported)	d=0.547 (medium)  d=0.634 (medium)  d=0.987 (large)
3	Calatayud et al (2012) Spain  Cross-Sectional	No information provided	Schizophrenia, Bipolar, Delusional disorder, Schizoaffective by DSM-IV criteria	N=168 Mean=40.6  66.7%	PANSS G12.  Violence measured by PANSS P7 (hostility) and G14 (poor impulse control)	Not clearly stated. However violence was rated by PANSS.	Only diagnosis, hostility and poor impulse control.  Multitude of confounding factors not considered e.g. substance misuse, psychopathy, patient status, positive symptoms.	No	Patients diagnosed with schizophrenia were found to have significantly worse insight than those diagnosed with bipolar disorder.	SZ Insight M=2.71 BPD Insight M=2.02 P=0.008*	Relevant data not available for ES calculation.
4	Carroll et al (2004) Australia	Forensic inpatients and outpatients	Schizophrenia by treating consultant psychiatrist.	N=28 Mean=38.2  89%	SAI total score  No specific measure used for violence.	Via file review and interview with participants by the Principal researcher.	Only diagnosis, previous violence, hopelessness and PANSS scale.	No	In patients with schizophrenia, insight scores did not differ between the group with prior convictions	F=2.81 (df=27), p=0.11	No effect

	Cross-Sectional						Multitude of confounding factors not considered including substance misuse, medication compliance, and psychopathy.		before their violent index offence and the group without prior convictions to their index offence.		
5	Ekinci & Ekinci (2013) Turkey  Retrospective Cohort	Psychiatric Outpatients	Schizophrenia by DSM-IV criteria	N=133  Mean=36.4  66.2%	Clinical insight measured by SUMD total score.  Cognitive insight measured by BCIS self-certainty and self-reflectiveness dimensions  OAS	Violent behaviours in the week prior to clinical assessment collected via interviews with patients, caregivers and mental health professionals and by examining clinical data.	Age, gender, marital status, employment status, socio-eco level, age at illness onset, duration of illness, education in years, family history of psychiatric disease, history of suicide attempts, history of violence, scales for assessment of positive/negative symptoms, Calgary depression scale, Yale-Brown Obsessional and Compulsion scale, Barratt impulsivity scale total.  Did not include: Patients with history of substance misuse, psychopathy and medication compliance.	No	Violent patients demonstrated significantly poorer clinical and cognitive insight (in terms of the self-reflectiveness item only) than non-violent patients.  SUMD total score and BCIS self-reflectiveness score were significant predictors of violence.	SUMD total score (clinical insight): EXP(B)= 1.787, p=0.000* CI=1.341-2.382  BCIS self-reflectiveness item (cognitive insight): EXP(B)=0.681, p=0.000* CI=0.549-0.844	OR=1.78 7 (large)  OR=0.68 1 (small)
6	Goodman et al (2005) Israel  Cross-Sectional	Forensic inpatients	Chronic Schizophrenia by DSM IV criteria	N=35  Mean=38.0  100%	4 SUMD items  No specific violence measurement used	Aggressive/violent incidents during patient's most recent hospital stay were extracted from records by a rater blind to all other testing results.	Age, duration and amount of hospitalisation, education, marital status, medication compliance, SANS/SAPS, Simpson-angus scale for extrapyramidal side effects and abnormal involuntary movement scale, Calgary depression scale.  Wide range of neuro-psych tests also carried out.  Did not include: substance misuse and psychopathy.	No	Patients with higher awareness of their mental disorder had significantly fewer violent events during hospitalization than patients with lower awareness of their mental disorder.	SUMD Awareness of mental disorder item: F(1,33)=6.11, p=0.019**  No significant differences reported in other SUMD insight domains.	d=0.861 (large)

7	Foley et al (2005) Ireland Pseudo-Prospective Cohort	Psychiatric inpatients and outpatients	First episode psychosis by DSM IV criteria.	N=157 Mean=28.2 55%	PANSS G12 MOAS	Single researcher reviewed nursing and incident reports to extract violent incidents which occurred in the week prior to and the week following patient's presentation to the service.	With theoretical basis; diagnosis, gender, alcohol misuse, drug misuse, employment status, admission status, PANSS activation and general psychopathology scores.  Did not include: Psychopathy, medication compliance.	1 week retrospective and 1 week prospective follow up from time of presentation to service.	Lack of insight predicted physical violence post contact with service for the sample as a whole but not specifically for the schizophrenia only group.	OR=2.97, p=0.05* CI=1.03-8.56	OR=2.97 0 (small)
8	Kosger et al (2015) Turkey Cross-Sectional	Psychiatric inpatients	Schizophrenia by DSM IV criteria.	N=68 Mean=42.2 Male=73.3% in violent group 52.6% in non-violent group	SAI total score BPAQ	No new violence data collected in this study – Researchers collected only historical violence data via BPAQ.	Gender, marital and employment status, age, education, duration of illness, age of illness onset, hospitalisation, anti-psychotic medication adherence, substance abuse, suicide attempts, PANSS scales. Psychopathy not included.	No	There was no difference in insight between patients with a history of violent behaviour and those without.	SAI Violent Group Mean/SD=9.23/4.42 SAI Non-Violent Group Mean/SD=10.95/3.40 Mann Whitney U test Z=1.379, p=0.168	No effect
9	Lincoln & Hodgins (2008) Canada Germany Finland Sweden	Forensic and civil psychiatric Outpatients	Schizophrenia via DSM-IV criteria 21.5% of sample also fulfilled criteria for anti-social PD.	N=216 Mean=38.4 96%	PANSS G12 and C1 insight item from hcr20v2  The McArthur Community	Via interview with each participant and an identified collateral witness.  Not stated who conducted interviews.	Positive symptoms (via PANSS) psychopathy (via PCL-R), psycho-social functioning.  Did not include substance abuse or medication compliance or demographic variables generally.	2 years post discharge from hospital	Poor insight did not contribute to the prediction of aggressive behaviour when positive symptoms and psychopathy were	No relevant values related to insight provided.	No effect

	Prospective Cohort				Violence Instrument.				included in a prediction model.		
10	Slijepcevic et al (2014) Croatia  Case-Control	Forensic and civil psychiatric inpatients	Schizophrenia by DSM IV criteria	N=206  Mean=39.3  100%	BCIS total score  OAS	Violence not collected within the study per se instead was based on violence histories.  Data collected by researchers and psychiatrists trained in the purposes of the study. Isn't clear how violence data was actually collected.	Education, marital status, somatic co-morbidity or history, head injury, urbanicity, divorced parents, problems with law, monthly income, psychiatric family history, age, duration of untreated psychosis, alcohol consumption, suicidal ideation, psychopathy, personality factors.  Did not include medication compliance	No	No significant difference was found between the violent and non-violent group in terms of insight into illness.  Insight did not predict violent behaviour.	Mann-Whitney U test P=0.218  OR=0.97, p=0.669 CI=0.85-1.11	No effect
11	Yen et al, (2002) Taiwan  Prospective Cohort	Civil psychiatric outpatients	Schizophrenia spectrum disorders by DSM-IV criteria	N=74  32.9  55.4%	All SAI domains and SAI-E total score  VASA	Interview of patient by researcher blind to results of initial assessment and also via interviews with family members, clinical staff and file reviews.	PANSS positive, negative and general subscales, social functioning, duration of illness, no of hospitalisations, level of education, age.  Did not include psychopathy and patients with substance abuse disorder were excluded restricting generalizability.	Violence data was collected 1 year following insight assessment	No significant difference was found in the 3 SAI insight domains or SAI-E total score between those exhibiting violent behaviour and those not exhibiting violent behaviour.	SAI domains: Treatment compliance: Z=-0.291, p=0.771  Awareness of illness: Z=1.266, p=0.205 Re-labelling of psychotic symptoms: Z=0.024, p=0.981  SAI-E total score: Z=-0.440, p=0.660	No effect
12	Soyka et al (2007) Germany  Retrospective Cohort	Discharged former hospital inpatients	Schizophrenia by ICD 9 criteria	N= 1662  Mean=39.05  41.2%	AMDP Hostility Syndrome lack of insight item  No violence measure used.	By reviewing medical records and the German National Crime register for non-violent and violent crimes.	Wide range of clinical variables from AMDP included. Also, gender, age, age at admission, marital status, education level, substance use, delinquency prior to index offence, violent crimes prior to index offence.	From discharge (1992-1995)	Patients with later violent crimes showed 'lack of insight' significantly more often at hospital discharge than patients	Chi Square, no value provided, p=0.002**	d=0.114 (small)

					Violence categorised as non-violent crime or violent crime	Only convictions measured – charges and other violence not included.	Did not include: psychopathy, medication compliance, positive symptoms.	to 2002.  Minimum 7 years and maximum 12 years follow-up.	without later criminal convictions.		
13	Volavka et al (2016) USA and 13 European Countries Cross-Sectional	Civil Psychiatric Outpatients	Schizophrenia and schizophrenia spectrum disorders. Criteria for diagnosis not specified	N=1154  Mean=37.2  69.6% male	PANSS G12  PANSS P7	By PANSS P7 at 6 months post baseline assessment via clinical interview by research team.	Substance misuse, medication adherence, akathisia, parkinsonism, dyskinesia, positive symptoms, age, and male gender.  Psychopathy not included.  Also possible confounding variable of patients having been randomly assigned to receive different anti-psychotic medications within wider study not controlled for.	No	A significant relationship between insight and hostility was found in cross-sectional analysis however statistical significance was lost after correction for multiple comparisons.	OR=0.972, p=n.s, CI=0.897-1.054	No effect
14	Alia-Klein et al (2007) USA Retrospective Cohort	Detained forensic inpatients	Psychotic disorders or major affective disorder with psychotic features by DSM IV criteria	N=60  Mean=30.8 5  100%	4 SUMD-R items  VAS	Face to face semi-structured interview which was subjected to inter-rater, review of hospital records and interview with an informant identified by the participant, all carried out by the research team.	Diagnosis, threat control over-ride symptoms, substance abuse, previous hospitalisation, childhood abuse, medication adherence, traumatic brain injury.  Did not include psychopathy and other positive symptoms.	No	Severity of community violence was associated with all dimensions of poor insight into illness.	SUMD-R Items:  Awareness of mental disorder: rs=0.38**  Awareness of perception of others: rs=0.37**  Affective concern to having mental illness (externally judged): rs=0.46**	r=0.38 (medium)  r=0.37 (medium)  r=0.46 (medium)

										Affective concern to having mental illness (self-report): rs=0.44**	r=0.44 (medium)
15	Foley et al (2007) Ireland Retrospective Cohort	Civil psychiatric inpatients and outpatients	First episode psychosis by DSM 3-R criteria	N=157 Mean=27 87 of 157 male	PANSS G12. MOAS	For inpatients: MOAS applied retrospectively to case notes, nursing and incident reports by one researcher for the week prior to and week following first contact with service. Outpatients: MOAS applied retrospectively to outpatient notes at second visit for violent behaviour in the week following first contact.	Gender, age at presentation, marital status, employment status, admission status, inpatient, history of alcohol/drug abuse, PANSS subscales, insight.  Did not include psychopathy or medication adherence.	No	Insight was not a significant predictor of violence in a sample of patients with first episode schizophrenia.	Beta=-0.32, SE=0.67, p=0.63	No effect
16	Swanson et al (2006) USA Retrospective Cohort	Civil psychiatric outpatients	Schizophrenia by DSM-IV criteria.	N=1410 Mean=40.5 74.3%	ITAQ total score  The McArthur Violence Interview	Violence data collected during 1 structured interview by trained clinical interviewer. All violence data was self-reported by participant in this interview and family collateral reports. However family collateral reports	A wide range including positive symptoms, substance misuse, age, gender, race, education level, household income, childhood risk factors, depression, years in treatment, recent victimisation, quality of life, total hospitalisations, life satisfaction, and recent criminality.  Did not include psychopathy or medication compliance.	No	Level of insight was not associated with either minor or serious violence in this sample of outpatients with schizophrenia.	Minor violence OR=0.89, p=n.s CI=0.66-1.19  Serious violence OR=1.16, p=n.s CI=0.70-1.91	No effect  No effect



						only available for N=617 of sample.					
17	Fresan et al, (2005)  Mexico  Retrospective Cohort	Civil psychiatric  Inpatient and  Outpatients	Schizophrenia spectrum disorders by DSM IV criteria.	N=100  Mean=29  65%	PANSS G12  OAS	The article does not state how violence data is collected, stating only “all violent behaviours in the week prior to the clinical assessment were included”.	Socio-demographics; gender, inpatient or outpatient, type of schizophrenia, age, and full PANSS scale.  Did not include psychopathy, substance misuse, medication compliance and participants with any co-morbidities included substance misuse were excluded.	No.	Lack of insight and judgement was not significantly associated with violence.	R=0.17, p=0.08	No effect

Key: ITAQ; The Insight and Treatment Attitudes Questionnaire, SUMD; Scale for Assessment of Unawareness of Mental Disorder, SUMD-R; Scale for Assessment of Unawareness of Mental Disorder-Revised; OAS; Overt Aggression Scale, MOAS; Modified Overt Aggression Scale, (SAI; Schedule for Assessment of Insight, PANSS; Positive and Negative Syndrome Scale, VAS; Violence Assessment Scale, AMDP; Association for Methodology and Documentation in Psychiatry, VASA; Violence and Suicide Assessment Scale, BCIS; Beck Cognitive Insight Scale, BPAQ; Bus-Perry Aggression Questionnaire.

M=Mean, SD=Standard Deviation, OR=odds ratio, d=Cohen’s d (standardised mean difference effect size) r=correlation coefficient effect size, CI=confidence intervals.

\*=significant at the 0.05 level

\*\*=significant at the 0.01 level

\*\*\*=significant at the 0.001 level

Effect size interpretations are in line with those suggested by Cohen (1988).

### **2.4.2 Study Designs**

All studies were observational in nature. The majority employed retrospective cohort or cross-sectional designs meaning that insight and violence were measured in the past with their data subsequently collected for the purposes of research. Despite their wide use, these designs are liable to a high level of bias. Whilst Goodman et al, (2004) did well to minimise this bias by using an independent rater blind to study objectives and Foley et al, (2005) minimised bias by making use of multiple information sources for violence data collection, other studies were essentially flawed in their research design. In particular, Carroll et al (2006) measured insight at time of study yet collected violent convictions from several years earlier. It is very likely that insight levels would have changed during the intervening period, particularly as patients began to receive treatment, highlighting the unreliable nature of this research design relative to the aims of the study.

Two studies used retrospective case-control designs, comparing insight in violent individuals to insight in non-violent individuals. Only four studies were designed prospectively, where insight is measured at baseline with patients then followed up for a period of time during which violence may or may not occur. The limited use of prospective designs in this area is unfortunate as these offer fewer potential sources of bias than retrospective and cross-sectional designs and are a more than adequate fit for observational research (Mann, 2003).

In some studies (e.g. Swanson et al, 2006; Goodman et al, 2005) the main focus was not insight and violence, with insight measured only as one of multiple variables. This meant that less detail was provided on the measurement and collection of insight and violence data and that research designs were not necessarily tailored to a rigorous exploration of these variables' relationship.

### **2.4.3 Insight Conceptualisation and Insight Measurements Tool**

There was wide variation in efforts to define insight and it was rarely clarified which insight dimension studies aimed to measure. Many studies did not provide any insight definition (Swanson et al, 2006; Slijepcevic et al, 2014; Volavka et al, 2016; Lincoln & Hodgins, 2008; Fresan et al, 2005; Soyka et al, 2007; Alia-Klein et al, 2008). Whilst the definition of insight assumed by studies could in some cases be derived by considering the insight assessment used, without a clear theoretical basis, insight measurement could be misguided. For example, Slijepcevic et al (2014) did not define the insight dimension they intended to measure and

without providing a rationale, used the BCIS, a cognitive insight measure, despite all other measured variables in their study being clinical in nature. Choosing a measure of clinical insight may have been more in line with study objectives and may have derived significant findings. Without a clear theoretical rationale for the insight dimension they intended to measure however, their investigation was limited.

Other studies such as Ekinici & Ekinici (2013) did provide a clear definition of insight in terms of both clinical and cognitive dimensions. They subsequently applied the SUMD, a clinical insight measure, and the BCIS. This provided clarity on both study objectives and results, enhancing reliability and generalizability. Notably, providing an insight definition and using measures in line with definitions was more common in studies which found a positive relationship between poor insight and violence than in those which did not.

#### ***2.4.4 The Use of Valid Measurement Tools for Insight and Violence***

Beyond issues relating to insight dimensions and corresponding measurement scales, there was variability in studies' choice of insight measurement more generally. Only 11 studies used an insight measurement which was validated and reliable for use with individuals with psychosis. The majority of these; the SUMD (Amador et al, 1993), the SUMD-R (Amador et al, 1999) the SAI (David, 1990) and the ITAQ (McEvoy et al, 1981) measured clinical insight. The BCIS was applied to measure cognitive insight by Ekinici & Ekinici (2013) and Slijepcevic et al (2014). Buckley et al (2004) also measured forensic insight by use of the Eisner Scale (Eisner, 1989).

The use of the PANSS (Kay et al, 1987) 'G12' 'impaired judgement and insight' item was also common, with six studies using this alone as an insight measurement. G12 is a single item intended to assess patients' understanding of their psychiatric condition and life situation via a trained rater's clinical judgement. Although acceptable inter-rater agreement has been found for G12, albeit within a small sample (Bell et al, 1992), the item was not designed to offer a comprehensive measure of insight per se, rather a contribution of the concept to the wider spectrum of psychotic symptoms measured by the PANSS. It is therefore unlikely to be capable of reliably measuring the complexity of insight. Interestingly, G12 was used in four studies which did not find a relationship between poor insight and violence compared to in only two studies which demonstrated this relationship.

In terms of violence measurement, the OAS (Yodofsky et al, 1986) is a widely used and well validated measure of violence as carried out by individuals with psychosis (O'Shea et al, 2014), yet only 7 studies applied the OAS or its modified version (MOAS). Swanson, et al, (2006) and Lincoln & Hodgins (2008) used the McArthur Violence Instrument (Steadman et al, 1998) which although not validated specifically in individuals with psychosis showed good reliability in a wider group of patients with mental health problems (Steadman et al, 1998). Similarly, Alia-Klein et al (2000), Kosger et al (2015) and Yen et al (2002) used more general yet sufficiently reliable violence measurement tools. Of the remaining studies, Volavka et al, (2016) measured violence only through PANSS (P7) hostility rating whilst Calatyud et al (2012) measured violence via PANSS (P7) hostility and PANSS (G14) poor impulse control ratings. These appear to be limited violence measurements, especially as within both studies, ratings were made by the research teams who do not appear to have been blinded to insight ratings, which were also measured by the PANSS.

Carroll et al, (2004) and Soyka et al, (2007) failed to use any specific violence measurement tool, measuring violence only in terms of whether a participant had a violent conviction or not. This simplified measurement method increases risk of bias as it excludes violence which may have occurred out-with convictions. The use of a structured scale such as the OAS would have limited the potential for bias as it encourages consideration of a wide range of violent behaviours. Results of these studies are then unlikely to be reliable as there may have been violent outcomes not captured due to the measurement method.

#### ***2.4.5 Reliable Collection of Violence Data***

Violence data was collected in a number of ways and as previously discussed, was often influenced by study design. Studies which used prospective designs (Arango et al, 1999; Foley et al, 2005; Lincoln & Hodgins, 2008; Yen et al, 2002) appeared to implement the most reliable violence data collection methods. Arango et al, (1999) ensured nursing staff blinded to study objectives, used the OAS to score violent incidents at the end of every shift during the follow-up period. Researchers then collated these ratings, minimising the chance of researcher bias. Some studies which did not utilise independent raters such as Yen et al, (2002), reduced the risk of bias by using a single researcher blind to other study assessments to collate violence data and by accessing multiple data sources.

Violence data collection methods were less reliable within studies conducted with community samples, likely due to the additional complexities encountered when conducting research of this nature out-with controlled, inpatient environments. For example, Swanson et al (2006) based their violence data collection on self-report interviews with patients. Although they endeavoured to reduce risk of bias by gaining a collateral report for each patient, these were available for less than half of the sample. This forced the study to be heavily reliant on self-report alone which is liable to under-reporting of violence.

Slijepcevic et al (2014) and Fresan et al (2005) did not outline their violence data collection method, whilst others were brief in their descriptions. Lincoln & Hodgins (2008) carried out violence data collection via participant and collateral interviews, however, did not clarify who conducted these interviews. Less experienced researchers or researchers un-blinded to other study assessments, may gain different findings than experienced, independent researchers when conducting interviews, which is likely to influence results.

#### ***2.4.6 Methodological Quality of Studies***

Quality grades for all 17 studies are displayed in Table 2. It should be noted that quality rating is not an exact science. For example a criteria could be deemed not applicable to a study whilst not reducing that study's overall quality. Subsequently, this review has not provided individual studies with a 'total' quality score. Taking this caveat into account, quality grades indicate that Arango et al (1999) carried out the strongest study methodically, with Calatayud et al, (2012) being of poorest overall quality.

**Table 2. Study Quality Grades**

STUDY Reference	Quality Criteria Number	1.0	1.1	1.2	1.3	2.0	3.0	3.1	3.2	3.3	3.4	3.5	4.0	4.1	4.2	4.3	5.0	5.1
Arango et al (1999)		++	++	+	++	N/A	++	++	++	+	++	++	++	-	+	+	+	+
Buckley et al (2004)		++	++	-	++	++	-	++	-	-	-	N/A	+	+	-	+	-	+
Calatayud et al (2012)		-	-	+	++	N/A	+	+	-	++	+	N/A	+	+	-	-	-	-
Carroll et al (2004)		++	++	++	++	N/A	++	-	-	-	-	N/A	+	-	-	+	-	+
Ekinci & Ekinci (2013)		+	+	++	+	N/A	++	++	+	+	+	N/A	++	+	+	++	+	+
Goodman et al (2005)		+	-	-	-	N/A	++	-	++	+	+	N/A	+	-	+	+	+	-
Foley et al (2005)		++	++	-	++	N/A	+	++	++	++	++	+	++	-	+	++	+	+
Kosger et al (2015)		+	++	+	+	++	++	++	+	++	+	N/A	++	-	+	++	+	+
Lincoln & Hodgins (2008)		++	+	+	++	N/A	+	+	+	++	++	+	++	+	+	+	+	++
Slijepcevic et al (2014)		++	+	++	++	+	++	++	N/R	-	-	N/A	++	-	++	++	+	+
Yen et al (2002)		++	-	-	++	N/A	++	++	++	+	++	++	+	-	+	+	+	-
Soyka et al (2007)		+	-	+	++	N/A	+	-	-	-	+	+	++	+	+	+	-	+
Volavka et al (2016)		++	+	+	++	N/A	+	+	-	++	+	N/A	++	+	+	++	-	+
Alia-Klein et al (2007)		++	++	+	++	N/A	++	++	++	++	-	N/A	++	-	+	+	+	+
Foley et al (2007)		++	+	+	++	N/A	+	++	-	+	+	+	++	-	+	+	+	+
Swanson et al (2006)		++	++	++	++	N/A	++	+	-	++	+	N/A	++	+	++	++	+	+
Fresan et al (2005)		++	++	+	+	N/A	+	++	N/R	++	+	N/R	+	+	-	+	-	+

**Table 2 Key:**

**Quality Criteria**

- 1.0 The source area and the source population are well described
- 1.1 The recruitment of the eligible population is clear and generalisable
- 1.2 The selected participants represent the eligible population
- 1.3 The characteristics of study participants are clearly stated and are representative of a population of individuals with psychosis
- 2.0 Selection bias was minimised when determining exposure and control groups
- 3.0 Insight is measured in a standard, valid and reliable way within a population of individuals with psychosis
- 3.1 Violence is measured in a standard, valid and reliable way within a population of individuals with psychosis
- 3.2 The collection of violence data is carried out in a standard, valid and reliable way
- 3.3 All important violence outcomes are assessed
- 3.4 The choice of study design is suitable for assessing relationships between insight and violent outcomes
- 3.5 Follow-up time was meaningful
- 4.0 The choice of data analysis is appropriate to the study design and outcome measures.
- 4.1 The study is sufficiently powered to detect an association/regression effect
- 4.2 Confounding variables are identified and considered in analyses
- 4.3 The precision of association was given and is meaningful
- 5.0 The study results are internally valid
- 5.1 The findings are externally valid

**Quality Grades for items 1.0-4.3**

- ++ = for the particular aspect of study design, the study has been conducted in such a way to minimise risk of bias
- + = either the answer to the checklist criteria question is not clear from the way the study is reported or the study may not have addressed all potential sources of bias for that particular aspect of study design
- = should be reserved for those aspects of the study design in which significant sources of bias may persist.

NR = should be reserved for those aspects in which the study under review fails to report how they have been considered

NA = should be reserved for those study design aspects that are not applicable given the study design under review.

#### **Quality Grades for items 5.0 and 5.1**

++ = all or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.

+ = some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.

- = few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

### ***2.4.7 The Case for a Relationship between Insight and Violence in Psychosis***

Overall, 8 of the 17 studies demonstrated a positive relationship between poor insight and violence in psychosis with the majority of effect sizes ranging between small and medium, however several large effects were also found. 9 studies did not find a relationship, highlighting a lack of clarity in the field around this issue. Generally, the group which found a positive relationship, had greater variety of study designs and implemented more valid violence data collection methods. The two groups were equal in terms of their diagnostic sample diversity. Power was reported by only one study in this review, and adequate power appeared to be achieved by only 4 studies which found a positive relationship and by 4 studies which did not find this relationship.

#### ***Positive Associations between Insight and Violence in Psychosis***

Three studies which demonstrated a positive relationship between insight and violence did so by means of correlation analysis. Buckley et al's, (2004) study compared a group of participants in custody for violent offences to a non-violent control group, finding violence to be significantly associated with poorer insight. However, important confounding variables, primarily psychopathy and substance misuse, which may contribute to the insight – violence relationship, were not measured or controlled for. Indeed, across all reviewed studies, only Lincoln & Hodgins (2008) and Slipjecevic et al, (2014) controlled for psychopathy. Similarly, Catalayud et al, (2012) found a positive correlation between poor insight and hostility. However, both of these variables were measured only via their respective PANSS items, with few confounding variables included in analysis and within an overall poor quality study. In Goodman et al's, (2005) study, understanding the insight and violence relationship was a secondary focus, thus little detail was provided on the same. They used a very small (N=35) and specific sample of forensic inpatients which although restricted generalizability, allowed for a rigorous approach to violence data collection, albeit this was limited by failure to use a standardised violence measurement tool.

### ***Insight as a Predictor of Violence in Psychosis***

The remaining studies which supported a positive relationship between poor insight and violence demonstrated this by use of regression models. Ekinici & Ekinici (2013) found poor clinical and cognitive insight to predict violence in patients with schizophrenia. Although their sample (N=133) was small for regression, the study was strengthened by reliable insight and violence measurement and their chosen data collection methods. Furthermore, although violence data was gathered retrospectively to insight measurement, only violent incidents occurring one week prior to insight measurement were collected, reducing the chance of clinically significant change in insight over this time. Arango et al's, (1999) study was of similar high quality, strengthened more so by a prospective design and once again reliable data collection and measurement methods. They found poor clinical insight to significantly contribute to a model which correctly classified 84.3% of participants as violent or non-violent. A small sample size (N=63) limited the study although the patient sample was generalisable with mixed schizophrenia/schizoaffective disorder diagnoses. A number of confounding variables were also controlled for yet medication compliance, substance misuse and psychopathy were not included.

Soyka et al, (2008) benefitted from a large sample size and robust power for the use of logistic regression. However, they measured insight at hospital discharge only and collected violent conviction data up to 12 years afterwards. As insight is a dynamic concept, level of insight at time of violence conviction cannot be assumed to be of the same level as it was several years earlier. Additionally, measuring violence in terms of convictions only may have underestimated true violence rates. Both of these issues cast significant doubt over Soyka et al's, (2008) findings. Similar issues were apparent within Alia-Klein et al's, (2008) findings in their use of a 'lifetime assessment of insight' as opposed to insight assessment before or at the time of violent incidents.

#### ***2.4.8 No Case for a Relationship between Poor Insight and Violence in Psychosis***

9 studies did not find a relationship between poor insight and violence in psychosis. Lincoln & Hodgins (2008) is a pivotal study to consider within this argument as their study was one of only two in this review which measured and controlled for psychopathy. Their analysis showed that although poor insight was associated with aggressive behaviour univariately, when positive symptoms and psychopathy, as measured by the PCL-R (Hare, 1991) were entered into the model, insight no longer contributed to the prediction of aggressive behaviour. This is



an important finding as it suggests that insight may not contribute additional variance when psychopathy and positive symptoms are measured in psychosis. It also opens up the possibility that had these variables been controlled for in other studies, positive relationships between poor insight and violence may not have been found. Although of good overall quality, Lincoln & Hodgins (2008) used only PANSS G12 and HCR20v2 C1 (insight) items for insight assessment. They also had a high drop-out rate with only 86 of the 216 participants followed up until 2 years post discharge. Reasons for drop-out were cited as refused, too ill or admitted to hospital, suggesting it was the most well patients who were fully followed up and thus those potentially judged to have higher levels of insight.

Swanson et al, (2006) retrospectively assessed violence in the six months prior to insight assessment in outpatients with schizophrenia. They did not find level of clinical insight to be related to either minor or serious violence. However, the violence data collection method was limited by self-report, with collateral reports available for less than half of the sample. First episode psychosis and treatment resistant patients were also excluded which may have altered violence rates and increased insight levels. On the contrary, Foley et al's, (2007) study was carried out with first episode psychosis patients specifically and also failed to find a relationship between insight and violence. Their insight measurement was however limited to PANSS G12.

Kosger et al, (2005) compared a group of patients with a history of violence to a non-violent group. They found no difference in level of insight between groups and no relationship between poor insight and violence. However, only historical violence was measured, whilst insight was measured at the time of study. Slijepcevic et al, (2014) carried out a similar study to Kosger et al, (2005) methodologically, comparing a violent and non-violent group in terms of violent history only. The same difficulties with this approach were subsequently evident. Yet this study included a wide range of confounding variables including positive symptoms, alcohol use and psychopathy which strengthen its findings. Yen et al's, (2002) study also failed to find a relationship between poor insight and violence. Although the sample size (N=74) was small, a prospective design and various information sources for collection of violence data, accessed by a blinded researcher, increased reliability of findings.

In Foley et al's, (2005) study, poor clinical insight was found to predict physical violence post-contact with a first episode psychosis service. This relationship however was not found pre-

contact with the service. This suggests that the retrospective data collection method employed was potentially unreliable or that inpatient environments may confound this relationship. Similarly, Volavka et al, (2016) found a uni-variate relationship between insight and hostility that failed to retain significance after correction for multiple comparisons. Insight and violence were however only measured by use of respective PANSS items.

Fresan et al, (2005) and Carroll et al, (2004) also failed to find a relationship, albeit both studies were of low quality and therefore less reliable in their findings. In particular, Carroll et al, (2004) assessed insight at time of study yet collected violent incidents from several years earlier. If insight was measured closer to the time of violent incidents occurring, the two variables may have correlated more closely. Finally, the study's sample of only 28 forensic patients with schizophrenia renders it not only low on internal reliability but also on generalizability.

## **2.5 Discussion**

Violent behaviour by a minority of individuals with psychosis is a poorly understood and much debated phenomenon which contributes to experience of stigma (González-Torres et al, 2007). A number of variables appear to be associated with the perpetration of violence by individuals with psychosis (Witt et al, 2013) and one variable widely believed to do so was poor insight into mental health difficulties. As such, insight is included as a risk factor for violence within tools such as the HCR-20v3. However, to date there existed no systematic review or meta-analysis evidencing a relationship between poor insight and violence in psychosis. It was therefore timely to conduct a systematic literature review to clarify the relationship between these concepts.

Only 17 studies exploring this relationship were identified, highlighting a low level of research in the area. 8 of these articles produced an argument for a positive relationship between poor insight and violence whilst 9 did not demonstrate this relationship. These findings continue to make clarification of this issue challenging especially as studies on both sides suffered from significant methodological limitations. The most common limitations were; poorly designed studies, small and un-generalisable samples and biased data collection methods, all of which reduced the reliability of findings. Both sides of the argument were however roughly equal in their included studies' methodological quality.

The issue relating to the importance of clear insight definition and choice of corresponding measurement tool is of relevance to this review's findings. It is notable that all studies which aimed to measure clinical insight and used the SUMD to do so, found a positive relationship between poor insight and violence. In some studies (e.g. Arango et al, 1999; Buckley et al, 2004; Goodman et al, 2005) effect sizes were large. In contrast, cognitive insight as measured by the BCIS does not appear to be a reliable predictor of violence with Slijepcevic et al, (2016) finding no relationship and Ekinici & Ekinici (2013) finding only a small effect, with a large effect found for clinical insight as measured by the SUMD by Ekinici & Ekinici (2013). The SUMD appears to be a sound measure of clinical insight. In particular, the SUMD item 'awareness of mental disorder' was measured by all studies which applied the tool and was consistently associated with violence across these studies. Indeed, 'awareness of mental disorder' is the essence of clinical insight (Amador et al, 1999) and thus reinforces the relationship between clinical insight and violence in particular, as oppose to alternative insight dimensions. This reviews findings may then have been more consistent should all studies have defined and measured clinical insight by use of the SUMD.

A further issue which should be taken into account when interpreting findings is medication adherence. Poor clinical insight has been found to be associated with non-adherence (Jonsdottir et al, 2013) which could potentially mediate the relationship between insight and violence. Yet, only 2 reviewed studies included adherence in their analyses and these produced opposing findings. Whilst Volavka et al, (2016) found a significant relationship between poor insight and violence to be lost after correcting for multiple comparisons, a significant positive relationship between poor medication adherence and violence remained. Insight was however only measured via PANSS G12 which may not have accurately measured clinical insight in this sample. Alternatively, although Alia-Klein et al, (2007) also found poor adherence to be associated with violence, a strong positive relationship between poor insight and violence continued to exist. Additionally, no relationship was found between poor insight and medication adherence when clinical insight was measured with the SUMD-R. These findings contribute to the consensus developed by this systematic review that inadequate measurement of clinical insight such as through PANSS G12, may render the concept less robust in analysis, allowing alternative variables to account for its variance. In contrast, when insight is measured accurately with reliable measurement tools such as the SUMD-R, it appears to be able to contribute its own variance to violence despite the presence of other important variables, such as medication non-adherence.

A compelling argument against a positive relationship between poor insight and violence comes from studies in this review which controlled for psychopathy. Lincoln & Hodgins (2008) used a mixed forensic/civil psychiatric outpatient sample whilst Slijepcevic et al's, (2014) sample was mixed forensic/civil psychiatric inpatients. Both measured and included psychopathy in their analysis, failing to find relationships between poor insight and violence. Psychopathy rates were however likely to have been higher within these studies due to the inclusion of forensic patients, where the construct is relatively more common (Hare, 2003). Furthermore, it should be noted that Slijepcevic et al, (2014) measured cognitive insight as oppose to clinical insight, which may also have influenced findings. It is a limitation of both studies that sub-group analysis was not carried out as it would have been useful to understand if poor insight remained non-significant when psychopathy was included within civil-psychiatric samples only, where psychopathy rates are likely to have been lower (Skeem & Mulvey, 2001). As psychopathy is a strong predictor of violence in individuals with psychosis (van Dongen et al, 2016) and indeed in persons without psychosis (Hart, 1998), it may be that within forensic populations where psychopathy is more prevalent, that psychopathy as a robust concept, reduces any variance insight would previously have provided.

In contrast, only a very small minority of patients with schizophrenia and civil-psychiatric patients in particular, present with psychopathy (Nolan et al, 1999). Relatedly, four of the studies that demonstrated a positive relationship between poor insight and violence used civil-psychiatric samples, highlighting the apparent usefulness of poor insight as a predictor of violence within this population. Had psychopathy been measured and included in analysis within these studies, it may have been less significantly associated with insight. Poor insight then does appear to be less important in the prediction of violence in patients who experience higher levels of psychopathy, such as those within the forensic mental health system. In samples where psychopathy is not as prevalent, such as in civil-psychiatric patients, poor insight would appear to be a more robust predictor of violence. Future research is however required to further understand the complex interactions between poor insight, psychopathy and violence in psychosis.

### **2.5.1 Future Research**

An increase in good quality research is required to provide a fuller understanding of the reviewed issue. Research in this area may however continue to be limited by the complexities

that occur when attempting to recruit samples experiencing psychosis. Many individuals with psychosis are inpatients engaged in rigorous care and treatment programmes which health-care professionals may be averse to disturbing with research (Hickson, 2013). Yet, there are manageable ways around this issue, such as by making use of routinely collected data. This method poses no disruption to patient's routine care and treatment and reduces opportunity for researcher bias as assessments are carried out by clinical teams. It is recognised that conducting this kind of research with civil-psychiatric outpatients remains a challenge, particularly in terms of violence data collection. However, use of multiple violence data sources and collateral informants can contribute towards good quality research with this population.

Future research should take account of the methodological weaknesses within studies outlined in this review and attempt to minimise these in future work. Primarily, more emphasis should be placed on designing studies to suit their objectives. Prospective designs are the only designs that allow true predictive validity to be investigated whilst reducing the bias that occurs collecting data retrospectively, yet these are rarely implemented. Variables that are known to co-vary and confound the insight – violence relationship such as medication adherence should also be clearly identified and included in the analyses of future research. Further exploration of the influence of psychopathy to the insight – violence relationship is very much warranted, particularly within civil-psychiatric outpatient samples where psychopathy appears less likely to account for poor insight.

### ***2.5.2 Implications for Clinical Practice***

Clinically, this review supports the widely held view that insight is a multi-dimensional concept (Capdevielle et al, 2013). Therefore, when assessing insight, clinician's should clarify the dimension they aim to measure and ensure they use a corresponding assessment. Use of insight assessment without consideration of this issue may lead to measurement of unintended dimensions and misleading results. Clinician's should also be careful not to assume poor insight in psychosis is directly related to violence as this review has shown their relationship to be complex and dynamic, which is essentially in line with the concepts of insight and violence per se.

In terms of risk assessment and management, this review supports the inclusion of poor insight as a risk factor for violence in the HCR-20v3, primarily as the measure implements a multi-dimensional approach to insight which is supported by the current findings. Secondly, 8 of the

studies in this review evidenced a positive relationship between poor insight and violence and this should not be over-looked. HCR-20v3 authors and health-care professionals should however be aware that this relationship is contestable and requires additional research before we can be confident about its extent. Subsequently, professionals should be proportionate in the use of poor insight as a risk factor for violence and continue to reinforce the structured professional judgement approach by placing patient's idiosyncratic characteristics at the forefront of violence risk assessment.

### ***2.5.3 Limitations***

This systematic review contains some limitations that should be taken into account. Firstly, it included articles produced in only English language. However, this was not to the detriment of cultural heterogeneity, with articles included from a wide variety of countries. Samples with patients under the age of 16 were also excluded due to the wide range of variables that can contribute towards both insight and violence in this population, such as impulsivity due to adolescent brain development (Arain et al, 2013). Similarly, studies that included patients with intellectual disabilities were excluded due to a higher level of violence in this population generally (Taylor & Novaco, 2013) which may have skewed findings.

A meta-analysis may also have provided clarity on the overall strength of a relationship between poor insight and violence. However, as this was the first systematic review on the topic, it was felt important to pursue a focus on the vast methodological weaknesses in the area, which indeed are likely to have reduced the reliability of statistical results. The wide range of insight and violence measurement tools used by studies within this review also limited their suitability for inclusion in a meta-analysis.

Lastly, it is acknowledged that there may be data related to insight and violence in psychosis which has not been reported by studies, such as within individual HCR-20 'C1 - lack of insight' item ratings. Should this data have been measured reliably and reported by studies, it may have held implications for the findings of this review. There is therefore an opportunity for future research holding greater resources, to seek out unreported data in relation to insight and violence in psychosis and to conduct a meta-analysis using the same.

### ***2.5.4 Conclusion***

The relationship between insight and violence in psychosis is dynamic and complex and can be influenced by other variables such as psychopathy. This systematic review has subsequently found partial evidence in support of a relationship between poor insight and violence in psychosis. Our findings suggest that poor clinical insight specifically, is a more robust predictor of violence in patient samples with lower levels of psychopathy than in samples where psychopathy rates are higher. Cognitive insight appears to be associated less with violence than clinical insight is, across patient samples. This review also highlighted the multi-dimensionality of insight in psychosis and reinforces the difficulties which can be created by a lack of clarity around the concept and by use of inappropriate measurement tools for the same. Future research focussing on insight in psychosis and its relationship to violence, with the inclusion of relevant co-variables such as medication adherence and psychopathy, is very much required across different patient populations. Additional research may facilitate increased confidence in the use of poor insight as a risk factor for violence in psychosis. It may also improve the knowledge base around psychosis generally in an effort to reduce the stigma and inequalities experienced by individuals with this severe and enduring mental health problem.

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### **3.0 Journal Article:** The Predictive Validity of the HCR20v3 within Scottish Forensic Inpatient Facilities: A Closer Look at Key Dynamic Variables

#### **3.1 Abstract**

**Introduction:** The HCR-20v3 aims to predict and manage violence in patients with mental health difficulties and violent histories, yet its predictive validity has not been demonstrated within a UK sample of forensic inpatients. Two dynamic variables within the HCR-20v3's clinical sub-scale; positive symptoms of psychosis and insight alongside age and history of violence also require clarification in relation to violence in this patient group.

**Methodology:** A pseudo-prospective cohort study of N=167 forensic inpatients was used to assess the predictive validity of HCR-20v3 total and sub-scale scores. A sub-sample of N=135 was then used to assess the predictive abilities of positive symptoms, insight, age and history of violence to inpatient violence. All data was extracted from case files with the exception of violent incidents which were collected prospectively from date of HCR-20v3 publication via DATIX.

**Results:** HCR-20v3 total and clinical and risk management sub-scale scores significantly predicted violence, and physical violence in particular. The clinical sub-scale was the strongest predictor. In the sub-sample, positive symptoms and history of violence significantly predicted violence generally, however only positive symptoms predicted physical violence specifically. Insight and age were not associated with violence.

**Discussion:** The HCR-20v3 is a valid tool for predicting forensic inpatient violence, particularly through its clinical sub-scale. Positive symptoms are useful in violence prediction yet in our sample, insight does not appear to be. Forensic inpatient services should prioritise regular re-assessment of positive symptoms and dynamic HCR-20v3 factors generally, with the caveat that future research is required to support a relationship between insight and violence in this patient group.

**Keywords:** HCR-20v3, violence, risk-assessment, forensic mental health, inpatients

**Word Count:** 10,434

## **3.2 Introduction**

### **3.2.1 Forensic Inpatient Violence**

The perpetration of violence by forensic mental health inpatients remains a challenge to services. In maximum security forensic settings, high rates of violence have been demonstrated, with 56% of 86 patients being found to engage in violence within a Scottish sample (Macpherson & Kevan, 2004). In a further study of N=400 high security patients, Uppal & McMurrin (2009) found 3565 violent incidents to have occurred over 16 months. Despite tailored security within services then, forensic inpatient violence appears to be relatively common, having a negative impact on patient and staff safety (Lam, McNeil & Binder, 2000) and patient recovery (Olsson, Strand, & Kristiansen, 2014). More broadly, inpatient violence is associated with poor therapeutic milieu (McKenzie & Curr, 2005), lower levels of care (Arnetz & Arnetz, 2001) staff psychological distress (Needham et al, 2005) and high absence rates (Lanctot & Guay, 2014).

### **3.2.2 The Structured Professional Judgement Approach**

Evidently, there is potential for progress to be made in the prediction and management of forensic inpatient violence. The Forensic Matrix (Clarke et al, 2011) recommends that all therapeutic process within forensic services be carried out in accordance with risk assessment and risk management. In recent years, the structured professional judgement (SPJ) approach has been advocated as oppose to actuarial methods (RMA, 2011). Whilst actuarial risk assessment relies on statistical calculations to yield probabilities of future violence, SPJ assesses risk at an individual level based on risk factors evidenced in the literature and clinical knowledge of the patient. In turn, this supports patient formulation and the creation of person centred risk management plans, with an overall aim of reducing patient's level of risk.

### **3.2.3 The Historical Clinical Risk Management – 20 (HCR-20) System**

The HCR-20 is a well-established SPJ tool for assessing and managing violence risk amongst forensic mental health patients (Khiroya et al, 2009; Campbell et al, 2009), with HCR-20 version 2 (HCR-20v2; Webster, et al, 1997) used in over 35 countries (Douglas et al, 2013). HCR-20v2 comprised 20 items within 3 sub-scales; the historical scale contained 10 static items related to past behaviour and experiences, the clinical scale contained 5 dynamic risk items and the risk- management scale consisted of 5 items related to risk of future violence. In practice, assessors rated each of the 20 items for presence; not present (0), partially present (1)



and present (2) and created a summary judgement of low, medium or high based on overall impression of violence risk. For research purposes, item presence ratings could be summed and used to assess the predictive abilities of the HCR-20v2 and its sub-scales.

### **Predictive Validity of HCR-20v2**

Meta-analyses have evidenced that the HCR20-v2 demonstrated good predictive validity for violence across a range of patient settings (Campbell et al, 2009; Yang et al, 2010). Whilst for forensic inpatients, the HCR-20v2 appeared to predict violence most strongly via the clinical sub-scale. Macpherson & Kevan (2004) sampled 86 inpatients from a high security hospital, assessing the predictive validity of the HCR20-v2 to violence during the admission-assessment period. HCR-20v2 total and clinical sub-scale scores both predicted violence, however only the clinical sub-scale was able to predict physical violence, albeit with a low area under the curve value (AUC=0.671). Although this study was limited by a small sample size which may have reduced its ability to find greater levels of significance, similar findings have been demonstrated within larger samples. In O'Shea et al's (2014) study of N=505 forensic inpatients, although HCR-20v2 total score predicted both 'any violence' and 'physical violence', the clinical sub-scale was the single strongest predictor of both violence types, suggesting that dynamic risk factors are of increased importance to violence risk in this patient group.

Various other studies (e.g. de Vogel & de Ruiter, 2006; Chu et al, 2011; Arbach-Lucioni, et al, 2011) strengthened the argument for the utility of HCR-20v2's clinical sub-scale in predicting forensic inpatient violence, whilst also highlighting the poor predictive ability of the historical sub-scale for forensic inpatients. Only a minority of studies have shown the historical sub-scale to have significant predictive validity. One such study by Dernevik, et al, (2002) found the historical sub-scale to be the strongest predictor of forensic inpatient violence, yet methodological limitations may have influenced results. Primarily, no standardised scale was used to measure violence, with incidents such as 'handling illicit substances' regarded violent. This is not considered to be violent behaviour within widely used violence measurement tools such as the 'Overt Aggression Scale' (Yodofsky et al, 1986) and as such is not included within alternative studies who applied this tool (e.g. O'Shea et al, 2014). Additionally, 'handling illicit substances' is in-line with item H5 (substance-abuse) and therefore its inclusion as a violent incident may have improved the historical sub-scale's predictive ability.

### **3.2.4 HCR-20v3**

Whilst the HCR-20v2 demonstrated good predicative accuracy for violence, particularly through its clinical sub-scale, the system has recently been updated to HCR-20v3<sup>4</sup> (Douglas, et al, 2013). Although not significantly different from HCR-20v2, the system has undergone some important adjustments<sup>5</sup>. For example, some items present within HCR-20v2 have been adjusted, e.g. ‘psychopathy’ is now encompassed within HCR-20v3 item H7 ‘personality disorder’. New items have been added, with an important addition being item H2 ‘other anti-social behaviour’. Sub-items have also been added to various factors to refine the topic of measurement, and relevance ratings now accompany item presence ratings, enhancing the link to risk management.

### **The Predictive Validity of HCR-20v3**

In light of the aforementioned changes, it is essential that the HCR-20v3 receives empirical validation to support its use with forensic inpatients. However, little research has been conducted so far, with no study investigating the predictive validity of the HCR-20v3 to forensic inpatient violence in a UK sample. Nonetheless, within the limited research, the clinical sub-scale does again appear to be the strongest predictor of violence for forensic patients (Strub et al, 2014; Doyle et al, 2014). For example, in a sample of N=106 forensic and civil-psychiatric patients followed up after community discharge, Strub et al, (2014) found the clinical sub-scale to be the strongest predictor of violence for forensic patients at 6-8 month follow-up. However, no distinction was made between violence types, thus it is unclear if physical violence specifically was most accurately predicted by the clinical sub-scale, as was demonstrated within HCR-20v2 studies (e.g. Macpherson & Kevan, 2004). Risk assessments were also carried out by researchers without the use of inter-rater reliability, thereby reducing ecological validity and increasing risk of bias. In a further study, Doyle et al, (2014) assessed N=387 patients discharged from medium security with the HCR-20v3. Patients were followed up at 6 and 12 months, with the clinical sub-scale showing strongest predictive validity for physical violence at both time points. Yet, again, this study was limited as although researchers defined violence, no standardised measure was applied for categorisation. Furthermore, all HCR-20v3 assessments were carried out only through interviewing staff members. Similarly, violent outcomes were collected via only interview with a care co-ordinator and access to the police computer database. These methods may have resulted in an under-estimation of violence rates within the study.

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<sup>4</sup> See Appendix 9 for a full list of HCR-20v3 scales and items

<sup>5</sup> For a full review of changes see Douglas, et al, (2014)

Recently, Green et al, (2016) retrospectively assessed the HCR-20v3's predictive validity for inpatient violence in N=124 forensic inpatients within a US state hospital. Using logistic regression, a model comprising of all three sub-scales was found to be the strongest predictor of violence, highlighting the strength of HCR-20v3 total score. Although a forensic inpatient sample is a useful addition to the literature, the retrospective design of this study does limit its reliability. Hogan & Olver (2016) conducted a similar retrospective study with a sample of N=99 forensic inpatients in a Canadian hospital. Despite the small sample size, HCR-20v3 total score was found to have good predictive validity for inpatient violence, whilst the clinical sub-scale demonstrated incremental predictive validity when historical items were controlled for.

Although evidence for the predictive validity of HCR-20v3 is growing and appearing to replicate HCR20-v2 in terms of the strength of the clinical sub-scale, methodological difficulties within initial studies limit the reliability of findings. Generalisability to UK forensic inpatients is also low, with no HCR-20v3 predictive validity research conducted within this population. With over 900 individuals held within NHS high secure estates (NHS England, 2013) and higher patient numbers within medium and low secure estates across the UK, it is imperative that the validity of this tool for use with this population is outlined.

### **3.2.5 Dynamic Risk Factors in the Prediction of Forensic Inpatient Violence**

What is evident through HCR-20 research, for forensic patients, is the strength of dynamic risk factors inherent within the clinical sub-scale. Subsequently, it may be useful to develop an enhanced research focus on these risk factors in this patient population. Although in their literature review, Guy et al, (2013) provide rationale for the inclusion of the dynamic risk factors present with the HCR-20v3 clinical sub-scale, for forensic inpatients, evidence for the efficacy of two key dynamic factors; positive symptoms of psychosis and insight is still lacking.

#### **Positive Symptoms as a Predictor of Forensic Inpatient Violence**

In a sample of n=505 forensic inpatients, O'Shea et al, (2014) demonstrated that for male patients with schizophrenia, inpatient violence was predicted best by dynamic factors present within the HCR-20v2 clinical sub-scale. In Scottish forensic inpatient samples where the majority of patients attract a primary diagnosis of a psychotic disorder, dynamic variables are then likely to be all the more important for violence prediction. Relatedly, in N=1410 US community patients with schizophrenia, positive symptoms of psychosis in particular, were found to increase both minor and serious violence, whereas negative symptoms were found to reduce violence (Swanson et al, 2006). Although additional studies (e.g. Arango, et al, 1999)

and meta analyses (e.g. Witt et al, 2013) have also found positive symptoms to be associated with violence in civil-psychiatric samples, there is a dearth of research around this phenomenon for forensic inpatients. Furthermore, in a similar study to Swanson et al (2006), Monahan et al, (2001) followed up N=1136 patients discharged from psychiatric hospitals for 12 months, failing to find any association between positive symptoms and violence. This finding highlights the inconsistency apparent within this field of research which requires not only clarification in the literature generally but clarification in relation to forensic inpatients specifically, whose experience of positive symptoms in relation to violence may differ to that of civil-psychiatric and community samples.

### **Poor Insight as a Predictor of Forensic Inpatient Violence**

A second factor positioned as a dynamic variable within the HCR-20v3 clinical sub-scale, is poor insight into mental health difficulties (clinical insight; Amador & David, 1998). In patients with psychosis, insight as predictor of violence is a debated issue, with various studies (e.g. Alia-Klein et al, 2007; Ekinici & Ekinici, 2013) in support of a positive relationship between poor insight and violence yet with others (e.g. Lincoln & Hodges, 2008; Volavka et al, 2016) failing to find this relationship. On both sides of the argument there is little research evidence relating to forensic inpatients. Within the available research, Goodman et al, (2005) found forensic inpatients experiencing psychosis with higher levels of clinical insight to be significantly less violent than those with lower levels of clinical insight. However, the study's sample size (N=35) was small, reducing reliability of findings. On the contrast, Slijepcevic et al, (2014) found no significant differences between historically violent and non-violent forensic inpatients with psychosis, in terms of insight. However this study measured insight at time of study and assumed this to have been the same as at the time of historical violent behaviour. As insight is a fluctuating concept, this is likely to be an unreliable measurement method. Furthermore, cognitive as oppose to clinical insight was measured which may have influenced results. These studies highlight that evidence pertaining to the relationship between poor insight and violence in psychosis is unclear generally and that there is minimum evidence available to support this relationship in forensic inpatients. It is therefore paramount that further clarification of insight in relation to violence in forensic inpatients with psychosis is gained.

### **Demographic Risk Factors for Forensic Inpatient Violence**

Finally, although dynamic factors appear to be of utmost importance to violence risk assessment in forensic inpatients, the value of some demographic risk factors continues to require clarification. In Steinert's (2002) literature review, he concluded that only history of violence was a robust static-demographic predictor of violence in mental health inpatients. Indeed, history of violence is well established as a strong predictor of future violence generally (Mossman, 1994; Bonta et al, 1998) and the strength of history of violence as a risk factor was demonstrated by Foley et al, (2005) who found inpatient violence to be significantly associated with a history of violence pre-admission in a sample of n=137 non-forensic inpatients with first episode psychosis.

Younger age is a further demographic variable which may remain a risk factor for violence. Dack et al's (2013) meta-analysis found younger age of patients to be a significant predictor of inpatient violence, whilst Caqueo-Urizar et al, (2016) demonstrated this relationship in community patients with psychosis. Unfortunately however, contemporary evidence in support of an argument for a positive relationship between both history of violence and younger age is lacking for forensic inpatients. Thus, it is unclear how these variables relate to violence in this patient group specifically. It would therefore be useful to gain a current understanding of their role in relation to forensic inpatient violence alongside the role of identified dynamic risk factors.

### **3.2.6 The Current Study**

The aim of the current study was to assess the predictive validity of HCR-20v3 total and sub-scale scores in relation to both 'any violence' and 'physical violence' in a UK sample of forensic inpatients. It was hypothesised that HCR-20v3 total and clinical and risk management sub-scale scores would significantly predict both violence types, whilst the historical sub-scale score was hypothesised to be unable to significantly predict either violence type. In line with previous research, the clinical sub-scale was hypothesised to be the strongest predictor of physical violence.

As the clinical sub-scale was hypothesised to be the strongest predictor of physical violence, a secondary aim was to clarify the predictive ability of two dynamic variables inherent within this subscale; positive symptoms of psychosis and insight in a sub-sample<sup>6</sup> of forensic inpatients. We aimed to investigate these variables alongside two demographic variables

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<sup>6</sup> See methodology

requiring further clarification; history of violence and age in relation to both violence types. It was hypothesised that when considered within logistic regression models for ‘any violence’ and ‘physical violence’, high levels of positive symptoms, low levels of patient insight, young age and a greater history of violence would significantly contribute to the prediction of violence.

### **3.3 Methodology**

#### **3.3.1 Design**

A naturalistic pseudo-prospective cohort design (Douglas, et al, 2012) was employed which combines aspects of both retrospective and prospective designs. The retrospective element is retained through collection of HCR-20v3 data which existed prior to access. The prospective element is retained through violent incident data being collected from date of HCR20v3 publication.

The dichotomous dependent variable for all research questions was inpatient violence/non-violence in terms of both ‘any violence’ and ‘physical violence’. The independent variables for the primary research question were HCR20v3 total and subscale scores. Independent variables for the secondary research question were age, history of violence, positive symptom and insight scores.

#### **3.3.2 Setting**

The study sampled data from three NHS Scotland forensic hospitals; The State Hospital, Rowanbank Clinic and Rohallion Clinic. The State Hospital is Scotland’s only high security hospital. It provides care and rehabilitation to patients detained under the Mental Health (Scotland) Act (2003) who have displayed high risk behaviours which have endangered other people. Patients are admitted from Scotland and Northern Ireland, from prisons, courts, lower levels of security and the community. At the time of study, the hospital had capacity for 132 patients.

Rowanbank and Rohallion Clinics are both secure hospitals for forensic inpatients with mental health difficulties, who are assessed to pose a risk of harm to others. Patients are detained by The Mental Health (Scotland) Act (2003) and are admitted from community, prisons, courts, or from conditions of higher and lower security. Rowanbank Clinic serves the West of Scotland and has 74 medium secure beds. Rohallion Clinic has capacity for 67 patients, it serves the

North of Scotland and contains two medium and three low secure wards, all of which were sampled.

### **3.3.3 Participants**

Opportunity sampling was applied whereby data was collected from files of all available patients within identified services at the time of data collection, subject to the following inclusion criteria;

- Male aged 18+
- Diagnosed with or suspected to have a mental disorder in line with DSM V/ICD 10 criteria
- Held an up to date HCR-20v3 in their case file
- Inpatient within the same secure service for a minimum of 2 months after HCR-20v3 completion.

Individuals were excluded from the study if they were subject to any of the following criteria;

- Female
- Diagnosed with an intellectual disability (due to increased rates of violence in this population)
- Discharged from their original service before a minimum follow-up period of 2 months.

### **3.3.4 Measures**

HCR-20v3 (Douglas, et al, 2013).

The HCR-20v3 measured violence risk. The instrument was developed to assess violence risk in persons aged over 18 with a history of violence and mental health problems. HCR-20v3 assesses 20 risk factors, structured within 3 subscales: historical (10 items), clinical (5 items) and risk-management (5 items). In practice, items are rated in terms of presence (not present, partially present or present) and relevance (low, moderate or high). In this study, the focus was on presence ratings which for research purposes, can be rated as 0=not present, 1=partially present and 2=present (Douglas, et al, 2013). HCR-20v3 assessments for all patients were completed by clinical teams with risk factor presence data extracted by the researcher from case-files.

Doyle, et al, (2014) found the HCR20v3 to have good intra-class reliability with coefficients of .92 (total score), .91 (H-scale), .90 (C-scale) and .93 (R-scale). Concurrent validity of HCR20v3 to HCR20v2 showed good correlation at .85 (total score), .87 (H-scale), .76 (C-scale), and .67 (R-scale), whilst inter-rater reliability for presence ratings was found to be excellent. (Douglas & Belfrage, 2014).

### Demographics

Demographic information relating to age, and DSM-V diagnosis (as recorded on CPA documents by consultant psychiatrist) was extracted from patient case files.

### The Violence Rating Scale (VRS; Robertson, et al, 1987).

Previous violence was rated by the researcher using the VRS, based on information available within case files. The VRS produces a rating for index offence ranging from 0 (completely non-violent) to 4 (severe violence wherein the victim died or life was endangered). It also produces a violence history rating ranging from 0 (never being convicted of violence and never getting into fights) to 4 (one or more severely violent episode in which someone's life or health was endangered). Sub-scale scores are summed to create a total previous violence score. The VRS has demonstrated excellent inter-rater reliability in terms of index offence score ( $r=0.95$ ), history of violence score ( $r=0.82$ ) and total score ( $r=0.85$ ) (Wong, et al, 1993).

### The Psychosis Evaluation Tool for Common Use by Caregivers-Revised (PECC-R; DeHert, et al, 1998)

An author approved shortened version of the PECC, PECC-R measured positive symptoms and insight. PECC-R is used in routine nursing assessment within The State Hospital and Rohallion Clinic and was available from these sites only. Patients diagnosed with a psychotic disorder and with PECC-R data available in their case-files subsequently made up the study's sub-sample. The most recent PECC-R data at the time of HCR20v3 data collection was obtained for each patient.

The positive symptom sub-scale assesses 4 symptoms; hallucinations, delusions, grandiosity and thought disorder. After interviewing the patient, each symptom is rated by the assessor on a scale from 1 (absence of symptom) to 7 (symptom present for more than 50% of the time with a severe impact on functioning). Symptom scores are summed to produce a sub-scale total, a higher score indicating greater symptom presence and impairment on functioning.



The insight sub-scale assesses two dimensions of clinical insight; i) awareness of having a mental illness and ii) awareness of symptoms being attributable to a mental illness. The sub-scale uses a 4 point rating scale ranging from 1 (good insight) to 4 (completely absent of insight). A higher score represents lower levels of insight.

Although the PECC-R is approved for use, it is not yet fully validated. However, the positive symptom and insight sub-scales within the PECC-R are retained in full from the original fully validated PECC and were therefore utilised. DeHert, et al, (2002) found the PECC to have good inter-rater reliability across all symptom categories, with agreement never falling below  $r=0.80$ . Concurrent validity of PECC positive and negative symptom sub-scales to the PANSS was also very good ( $r=0.95$ ).

### Inpatient Violence

Inpatient violence was classified in line with Douglas et al's, (2013; pg. 36) definition as "*the actual, attempted or threatened infliction of bodily harm on another person*". Verbal aggression serious enough to warrant a DATIX entry was therefore included as violence. This is in accordance with similar studies (e.g. O'Shea et al, 2014) and aimed to allow optimum data collection despite low violence base rates within secure environments.

#### *i) DATIX*

DATIX electronic reporting system is an industry leading software for the recording of adverse events within healthcare settings. All violent incidents in this study were recorded by staff on DATIX. Each site's risk management departments then reviewed written accounts of incidents to ensure the correct DATIX category coding<sup>7</sup> was used by staff. After the follow-up period, DATIX records were obtained by the researcher who matched each incident to the relevant participant as per study procedures below.

#### *ii) Overt Aggression Scale (OAS; Yudofsky, et al, 1986)*

The OAS was used to standardise DATIX violent incidents to ensure cohesion of violence categorisation. Designed to measure violence in adults and children, the OAS is frequently applied in research to enable standardised categorisation of violence.

The OAS divides violence into 4 categories; verbal aggression, physical aggression against objects, physical aggression to self and physical aggression against others. As this study was interested in interpersonal violence, the 'physical aggression against self' category was not

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<sup>7</sup> See Appendix 12 for DATIX incident categories

utilised. The scale also provides violence severity ratings ranging from 1 – 4 however as the aim was to dichotomise patients as violent or non-violent, severity ratings were not required and violence was therefore coded only by category. O’Shea et al, (2014) found excellent (K=0.91) agreement in OAS violence category ratings between three researchers on a sample of 260 incidents.

For analysis, violence was reduced to 2 categories; ‘any violence’ which included verbal aggression, physical aggression against objects and physical violence towards others and ‘physical violence’ towards others only. Patients were then dichotomised as ‘violent’ or ‘non-violent’ within both of these violence types.

### **3.3.5 Procedure**

#### *Ethical Approval*

Ethical approval was granted by London City & East ethical review board. Scottish national Caldicott approval granted access to NHS patient data without individual consent. This ensured no disruption was caused to the routine care and treatment of patients. Research and development committees of all sites approved the study.

*Data Collection Period 1 (January-December 2016):* Prior to data collection, a field contact was made within each site who assisted the researcher in accessing their site’s data. Field contacts identified cases for sampling on each data collection visit which had completed HCR-20v3s. As HCR-20v3s were completed on an ongoing basis, sites were visited 4 times each in order to collect data when it became available<sup>8</sup>.

The following data was extracted for each case:

- a) HCR20v3 data; historical, clinical and risk-management sub-scale scores and total score.
- b) Demographic data; site, age, diagnosis, previous violence information in terms of index offence and violence history as per VRS.
- c) PECC-R data; positive symptom and insight sub-scale scores.

*Data Collection Period 2 (October-December 2016):* Violence data was collected for 2 - 12 months following date of HCR-20v3 publication. Each case therefore had an individual follow-

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<sup>8</sup> See appendix 10 for data collection visit schedule

up period which was communicated to DATIX administrators. A maximum follow-up of 12 months was applied due to all assessments being updated at least annually by the services sampled. This is also in line with the knowledge that the predictive validity of dynamic measures decreases over time. A general follow-up end date of November 17<sup>th</sup> 2016 was applied and all cases which had not reached 12 month follow-up received this date as a cut-off.

DATIX administrators provided reports of violent incidents in the form of DATIX violence categories<sup>9</sup> together with a narrative of the incident. The OAS was applied to standardise this data, with each incident coded for subsequent analysis by OAS violence category before being classified as ‘any’ or ‘physical’ violence.

### **3.3.6 Power Analysis**

For the primary research question, ‘MedCalc’ calculated minimum sample size for Receiver Operating Characteristic (ROC) analysis. The system requires input in the form of alpha (0.05), power (0.80) and expected ratio of cases in non-violent and violent groups. Studies (e.g. O’Shea et al, 2014) which used ROC with similar populations were referenced to derive violence ratios. For a ratio of 2:1 in favour of non-violence, a minimum of 42 cases were required in the non-violent group and 21 in the violent group.

For the secondary research question, investigated by logistic regression, Peduzzi, et al, (1996) suggest that sample size depends on the number of predictor variables, the number of cases per predictor and the estimated proportion of negative and positive cases in a sample. Sample size was therefore calculated based on the maximum number of predictors and the smallest estimated event proportion of non-violent and violent cases. In line with Macpherson & Kevan’s (2004) study, calculation was based on 30% of cases engaging in ‘physical violence’.

Minimum sample size for the secondary research question based on 4 predictors was 133. A further requirement was that 133 cases were patients diagnosed with a psychotic disorder, with PECC-R data in their case files. These patients would function as a sub-sample for the secondary research question.

## **3.4 Results**

### **3.4.1 Statistical Analysis**

#### **Whole Sample Analysis**

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<sup>9</sup> See appendix 13 for a copy of all available DATIX incident categories

All data was analysed using SPSS version 19. Levene's test was used to verify equality of variance across groups and the Kolmogorov-Smirnov test clarified normality of distribution. As normality was observed, parametric statistics were used (Field, 2014). Prior to whole sample analysis relating to the primary research question, one-way ANOVA's were run to allow identification of any differences in variables between sites. Tukey HSD post-hoc analyses were run when significant differences were found. Sites were then grouped together for subsequent analyses.

ROC and area under the curve (AUC) analyses were used to outline the predictive validity of HCR-20v3 total and sub-scale scores for both violence types. ROC is the recommended statistical method for assessing the predictive validity of violence risk assessment tools as it is not affected by low violence base rates (Mossman, 1994). AUC values range between 0 and 1 with a value of 1 indicating that the tool is able to perfectly classify a patient as violent or non-violent. An AUC of 0 shows that the tool is unable to correctly classify any patient as violent or non-violent. An AUC of 0.5 is considered to be chance level (Park et al, 2004) with AUCs above this value indicating significant predictive ability. AUCs above 0.75 are considered to be large effect sizes (Dolan & Doyle, 2000). Independent samples t-tests were also used to identify differences between violent and non-violent groups in terms of 'any violence' and 'physical violence' on all variables including HCR-20v3 total and sub-scale scores.

### Sub-Sample Analysis

For the sub-sample of patients with a psychotic disorder and with PECC-R data available in their case-files, ROC analyses were again carried out to clarify the predictive validity of the HCR-20v3 total and sub-scale scores for both violence types. Pearson correlations were run to investigate relationships between anticipated predictor variables and violence types. Logistic regression was then conducted using the hierarchal entry procedure to calculate the probability that violence would occur based on variables which significantly correlated with violence in uni-variate analysis. Two logistic regression models were developed, one for 'any violence' and one for 'physical violence' with violence/non-violence dichotomised as the outcome variable in both models.

### 3.4.2 Inter-Rater Reliability

Inter-rater reliability by use of Cohen's Kappa (K) was carried out to reduce the potential for bias in variables which were rated by the researcher using patient case-files and DATIX information. As such, a 2<sup>nd</sup> rater qualified to consultant clinical psychologist level, rated 41

(10%) violent incidents using the OAS and also completed the VRS for 23 (14%) patients. Inter-rater agreement on OAS categories was found to be excellent ( $K=0.953$ ,  $p=0.001$ ). Agreement on VRS index offence ( $K=0.714$ ,  $p=0.001$ ) and previous violence ratings ( $K=0.612$ ,  $p=0.001$ ) were both substantial, with excellent agreement not being reached indicative of the often subjective information content within case-files.

### 3.4.3 Whole Sample Analysis

#### Participant Characteristics

167 patients were included in whole sample analysis. 30 patients were under the care and treatment of Rohallion, 30 Rowanbank and 107 The State Hospital. Mean patient age was 42. Diagnoses as recorded on CPA documents are outlined in Table 1.

Table 1. Diagnoses of Patient Sample Based on DSM-5 Diagnostic Categories

<b>Diagnosis</b>	<b>N</b>	<b>%</b>
Schizophrenia Spectrum and Other Psychotic Disorders	114	68.3
Schizophrenia Spectrum and Other Psychotic Disorders with Co-Morbid Personality Disorder	41	24.6
Bi-Polar and Related Disorders	3	1.8
Personality Disorder Only	2	1.2
Neuro-Developmental Disorder* with Co-Morbid Personality Disorder	2	1.2
Neuro-Developmental Disorder* Only	1	0.6
No Registered Diagnosis	4	2.3
<b>Total</b>	<b>167</b>	<b>100</b>

\*with the exception of intellectual disability within neuro-developmental disorders

#### Previous Violence

Patient's previous violence as measured by the VRS (Robertson et al, 1987) is presented in Table 2. Notably, 56% of the sample had committed an index offence which involved severe violence in that the victim died or their life and/or health was seriously endangered, whilst 32.9% had a significant history of violence involving 3 or more convictions for violent behaviour.

Table 2. Index Offence and History of Violence as Measured by the Violence Rating Scale (VRS; Robertson et al, 1987)

<i>Violence Rating Scale Criteria for N=167 Patients</i>	<b>N</b>	<b>%</b>
<b>Rating for Admission (Index) Offence</b>		
Completely non-violent	2	1.1
Minimal violence (e.g. verbal aggression, shouting or gesturing even if not obviously aimed at others)	5	2.9
Moderate violence (e.g. attack on a person resulting in no serious injury, fighting or property damage)	37	22.1
Moderate to severe violence (e.g. attack on a person which resulted in serious injury but not admission to hospital for more than 24 hours, extensive property damage which could have endangered life)	28	16.7
Severe violence (e.g. victim died or life and health seriously endangered)	95	56.8
<b>Rating for Violence History</b>		
Never been convicted of violence, never gets into fights (prior to violent index offence)	16	9.6
Some evidence of violence and/or occasional fights but no convictions	28	16.8
One or two convictions for minor assaults or property damage	33	21.0
Three or more convictions for violence but none serious in the sense of '4' below	55	32.9
One or more severely violent episode in which a person's life or health was seriously endangered	35	21.0

### Inpatient Violence Rates

The mean length of follow-up was 8.35(SD=3.65) months within a range of 2 to 12 months. 417 incidents of 'any violence' occurred during this follow-up, which included 106 incidents of 'physical violence' towards others. 63 (37.72%) patients carried out 'any violence' during follow-up, of which 33 (19.76%) carried out 'physical violence' specifically.

### Differences in Age, VRS Scores and Inpatient Violence Rates between Sites

One-way ANOVA's found no differences between sites in terms of age and VRS violence history scores. There was however a significant effect of site on VRS index offence score,  $F(2,164)=6.62$ ,  $p=0.002$ . Post-hoc comparisons using Tukey HSD test found mean State Hospital VRS index offence score ( $M=3.43$ ,  $SD=0.89$ ) to be significantly higher than mean Rohallion VRS index offence scores ( $M=2.76$ ,  $SD=0.97$ ),  $p=0.002$ . There was also a significant effect of site on VRS total score,  $F(2,164)=3.86$ ,  $p=0.023$  wherein post-hoc comparisons again found mean State Hospital VRS total score ( $M=5.83$ ,  $SD=1.53$ ) to be significantly higher than mean Rohallion VRS total score ( $M=4.90$ ,  $SD=1.84$ ),  $p=0.018$ .

Site differences were also found for inpatient violence rates. There was a significant effect of site on ‘any violence’,  $F(2,164)=4.60$ ,  $p=0.011$  with post-hoc analysis finding ‘any violence’ means to be significantly higher at Rohallion ( $M=0.53$ ,  $SD=0.50$ ) than at Rowanbank ( $M=0.16$ ,  $SD=0.37$ ),  $p=0.009$ . A significant effect of site was also demonstrated for rates of ‘physical violence’,  $F(2,164)=4.47$ ,  $p=0.013$  with post-hoc comparisons identifying mean ‘physical violence’ scores at Rohallion ( $M=0.33$ ,  $SD=0.47$ ) to be significantly higher than Rowanbank ( $M=0.03$ ,  $SD=0.18$ ),  $p=0.010$ . Following identification of these differences, all sites were grouped together for subsequent analyses.

### Characteristics of Violent and Non-Violent Groups

#### i) Differences in Age and VRS Scores between Violent and Non-Violent Patients

As shown in Table 3, there were no significant differences in age and VRS scores between violent and non-violent patients.

Table 3. Mean Differences in Age and VRS scores between violent and non-violent patients for both violence types

Variable	Overall Mean (SD)	Any Violence Means (SD)					Any Physical Violence Means (SD)				
		Yes	No	t	df	p	Yes	No	t	df	p
Age	42.22(11.39)	43.12(12.31)	41.67(10.81)	-0.798	165	.426	42.66(12.82)	42.11(11.06)	-0.250	165	.803
VRS History of Violence Score	2.38(1.25)	2.60(1.07)	2.25(1.34)	-1.822	153	.070	2.54(1.00)	2.35(1.31)	-0.936	165	.353
VRS Index Offence Score	3.25(0.98)	3.11(0.98)	3.34(0.94)	1.535	165	.127	2.96(1.07)	3.32(0.92)	1.932	165	.055
VRS Total Score	5.64(1.67)	5.69(1.58)	5.61(1.71)	-0.312	165	.755	5.51(1.64)	5.67(1.67)	0.507	165	.613

SD=Standard Deviation, t=t-test of mean difference, p=significance value, df=degrees of freedom

#### ii) Differences in HCR-20v3 Total and Sub-Scale Scores between Violent and Non-Violent Patients<sup>10</sup>

HCR-20v3 total scores were significantly higher for violent than for non-violent patients for ‘any violence’,  $t(165)=-3.87$ ,  $p=0.001$  and ‘physical violence’,  $t(165)=-3.49$ ,  $p=0.001$ . Clinical sub-scale scores were also found to be significantly higher for violent patients for ‘any violence’,  $t(165)=-4.95$ ,  $p=0.001$  and ‘physical violence’,  $t(165)=-4.91$ ,  $p=0.001$ . Risk management sub-scale scores were again significantly higher for violent patients for ‘any violence’,  $t(165)=-3.12$ ,  $p=0.002$  and ‘physical violence’,  $t(165)=-3.23$ ,  $p=0.001$ . There were

<sup>10</sup> See Table 4

no differences between violent and non-violent groups in historical sub-scale scores for either violence type.

Table 4. Mean Differences in HCR-20v3 Total and Sub-Scale Scores between Violent and Non-Violent Patients

HCR-20v3 Scale	Overall Scale Range	Overall Scale Mean (SD)	Any Violence Means (SD)					Any Physical Violence Means (SD)				
			Yes	No	t	df	p	Yes	No	t	df	p
<b>Total</b>	11 - 40	28.40(6.22)	30.65(6.32)	26.95(5.74)	-3.87	165	.001***	31.63(5.86)	27.54(6.05)	-3.49	165	.001***
<b>H Scale</b>	9 - 20	16.34(2.96)	16.47(2.89)	16.25(3.02)	-0.45	165	.649	16.30(3.10)	16.35(2.94)	0.08	165	.934
<b>C scale</b>	0 - 10	6.02(3.04)	7.42(2.85)	5.17(2.84)	-4.95	165	.001***	8.21(2.35)	5.48(2.96)	-4.91	165	.001***
<b>R scale</b>	0 - 10	6.08(2.60)	6.87(2.59)	5.60(2.50)	-3.12	165	.002**	7.36(2.36)	5.76(2.57)	-3.23	165	.001***

SD=Standard Deviation, t=t-test of mean difference, df= degrees of freedom p=significance value, \*=p<0.05, \*\*=p<0.01, \*\*\*=p<0.001

### The Predictive Validity of the HCR-20v3

ROC analysis determined the utility of HCR-20v3 total and sub-scales scores in predicting ‘any violence’ and ‘physical violence’<sup>11</sup>. AUCs ranged between 0.518 and 0.777 with HCR-20v3 total, clinical and risk-management sub-scales all significantly predicting both violence types. The historical sub-scale was not predictive of either violence type. Notably, AUC values overall were larger for the prediction of ‘physical violence’ than for ‘any violence’ and the clinical sub-scale was the strongest predictor of both violence types.

HCR-20v3 total score predicted inpatient violence to a lesser extent than the clinical sub-scale; total score AUC=0.691 vs clinical sub-scale AUC=0.729 for ‘any violence’ and total score AUC=0.703 vs clinical sub-scale AUC=0.777 for ‘physical violence’. Smaller AUC values yet were found for the risk-management sub-scale for both violence types, yet these remained significantly greater than chance.

Table 5. Predictive Validity of HCR-20v3 total and sub-scale scores for Inpatient Violence for Whole Sample (N=167)

HCR-20v3 Scale	Any Violence			Any Physical Violence		
	AUC	p	95% CI	AUC	p	95% CI
<b>Total</b>	0.691	.001***	0.605-0.777	0.703	.001***	0.603-0.804
<b>H Scale</b>	0.518	.704	0.428-0.607	0.501	.986	0.391-0.611
<b>C Scale</b>	0.729	.001***	0.647-0.812	0.777	.001***	0.687-0.866
<b>R Scale</b>	0.643	.002**	0.555-0.731	0.678	.002**	0.578-0.779

AUC=area under the curve, CI=confidence interval, p=significance value, \*=p<0.05, \*\*=p<0.01, \*\*\*=p<0.001

<sup>11</sup> See Table 5



## Post-hoc Analysis

Exploratory post-hoc analysis was carried out to better understand the limitations of HCR-20v3 total score following its under-performance in comparison to the clinical sub-scale in terms of predictive validity. As such the historical sub-scale was removed from analysis with a ROC curve calculated using a ‘revised total’ which included the significant clinical and risk-management sub-scales. Although this increased the total score AUC to 0.710 for ‘any violence’, the improved AUC was still below that of the clinical sub-scale alone for this violence type AUC=0.729. The same pattern was shown for prediction of ‘physical violence’ by the ‘revised total’, which increased to AUC=0.733 however did not reach the clinical sub-scale AUC of 0.777. These results suggest that the clinical sub-scale is better able to predict both types of violence independently than when it is combined with remaining HCR-20v3 sub-scales.

### **3.4.4 Sub-Sample Analysis**

Due to the demonstrated value in the literature of the clinical sub-scale in predicting inpatient violence, two dynamic variables; clinical insight and positive symptoms of psychosis, as measured in a sub-sample of N=135 patients, were investigated in relation to inpatient violence. ROC analysis for the sub-sample<sup>12</sup> again found the clinical sub-scale to produce the highest predictive values for both ‘any violence’, AUC=0.746 and ‘physical violence’, AUC=0.753.

Table 6. Predictive Validity of HCR-20v3 for Inpatient Violence for Sub-Sample (N=135)

HCR-20v3 Scale	Any Violence			Any Physical Violence		
	AUC	p	95% CI	AUC	p	95% CI
<b>Total</b>	0.713	0.001***	0.623-0.803	0.705	0.001***	0.599-0.810
<b>H Scale</b>	0.548	0.339	0.450-0.646	0.545	0.436	0.430-0.660
<b>C Scale</b>	0.746	0.001***	0.659-0.834	0.753	0.001***	0.656-0.850
<b>R Scale</b>	0.647	0.004**	0.552-0.742	0.661	0.005**	0.553-0.770

AUC=area under the curve, CI=confidence interval, p=significance value, \*=p<0.05, \*\*=p<0.01, \*\*\*=p<0.001

## Correlations between Age, History of Violence, Positive Symptoms, Insight and Violence

VRS history of violence score was significantly associated<sup>13</sup> with ‘any violence’  $r=0.181$ ,  $p=0.035$  however was not significantly associated with physical violence. PECC-R positive symptom sub-scale scores were significantly associated with both ‘any violence’  $r=0.276$ ,

<sup>12</sup> See Table 6.

<sup>13</sup> See Table 7.

p=0.001 and ‘physical violence’ r=0.233, p=0.006. There were no significant correlations found between the PECC-R insight sub-scale score or patient age and either violence type.

Table 7. Correlations between variables and violence for sub-sample (N=135)

Measured Variable	Any Violence		Any Physical Violence	
	R	p	R	p
Age	.043	.617	-0.009	.918
VRS History of Violence Score	.181	.035*	.087	.314
PECC-R Positive Symptom Score	.276	.001***	.233	.006**
PECC Insight Score	.029	.737	.053	.538

R=Pearson correlational value, p=significance value, \*=p<0.05, \*\*=p<0.01, \*\*\*=p<0.001

## Logistic Regression Models of Inpatient Violence

### i) ‘Any Violence’

Although it was originally planned to include all variables outlined in Table 7 in a logistic regression model for ‘any violence’, age and insight were not found to significantly correlate with this violence type and were therefore not included in the logistic regression. Positive symptom sub-scale score and VRS history of violence score did significantly correlate with ‘any violence’ uni-vareately and logistic regression was conducted using these variables. The model was created by entering variables a block at a time. As PECC-R positive symptom score held the strongest relationship with ‘any violence’ this variable was entered into block 1. A test of this model against a constant only model was statistically significant  $\chi^2=10.39(df=1)$ , p=0.001. VRS history of violence score was entered into block 2. A test of this model against the model created in block 1 was significant  $\chi^2=11.25(df=1)$ , p=0.001, indicating that history of violence significantly contributed variance to the model.

This logistic regression model, correctly classified 68.9% of violent and non-violent cases and was generally more precise at classifying non-violent (80.5%) than violent (53.4%) cases correctly. The Wald statistic indicated that patients with higher positive symptom scores had a 14.73 fold greater risk of being violent, with positive symptoms making a significant contribution to violence prediction (p=0.001). The Exp(B) value is an odds ratio which indicated that as a positive symptom score increases by 1 unit, the patient is 1.17 times more likely to be violent (CI=1.082-1.276). The Wald statistic for VRS history of violence score also indicated that this predictor made a significant contribution to the model (p=0.002) with patients with higher violence history scores having a 9.75 fold greater risk of violence. The

Exp(B) of 1.71 (CI=1.22-2.39) indicates that as violence history scores increase by 1 unit, the patient is 1.71 times more likely to be violent.

Table 8. Logistic regression for the prediction of ‘any violence’ group membership

Predictor Variables	B	S.E	Wald	df	p	Exp(B)	95% CI for Exp(B)
PECC-R Positive Symptoms	.162	.042	14.73	1	.001***	1.175	1.082-1.276
VRS Previous Violence Score	.537	.172	9.75	1	.002**	1.711	1.221-2.397

B=beta value, Exp(B)=exponential B value (odds ratio), S.E.=standard error, Df=degrees of freedom, CI=confidence interval, p=significance value, \*=p<0.05, \*\*=p<0.01, \*\*\*=p<0.001

## ii) Physical Violence

As PECC-R positive symptom score was the only variable which significantly correlated with ‘physical violence’ in uni-variate analysis, logistic regression was carried out including only this variable. Positive symptom score was therefore added into the first block of the prediction model. A test of this model against a constant only model was statistically significant  $\chi^2=6.96$  (df=1), p=0.008, indicating that positive symptoms are able to reliably distinguish between physically violent and non-violent patients.

This logistic regression model correctly classified 75.6% of violent and non-violent cases, being more precise at classifying non-violent (98.0%) than violent (6.1%) cases correctly. The Wald statistic indicated that patients with higher positive symptom scores had a 6.8 fold greater risk of being violent, with positive symptoms making a significant contribution to violence prediction (p=0.009). The Exp(B) value indicated that as a positive symptom score increases by 1 unit, the patient is 1.10 times more likely to be physically violent (CI=1.026-1.191).

Table 9. Logistic regression for the prediction of ‘physical violence’ group membership

Predictor Variable	B	S.E	Wald	df	p	Exp(B)	95% CI for Exp(B)
PECC-R Positive Symptoms	.100	.038	6.886	1	0.009**	1.105	1.026-1.191

B=beta value, Exp(B)=exponential B value (odds ratio), S.E.=standard error, Df=degrees of freedom, CI=confidence interval, p=significance value, \*=p<0.05, \*\*=p<0.01, \*\*\*=p<0.001

## **3.5 Discussion**

The HCR-20v2 has previously demonstrated predictive accuracy in terms of risk of violence across different cultures, settings and patient populations (Yang et al, 2010). Following an update to the HCR-20 system however, this study is the first to examine the predictive validity of the HCR-20v3 with respect to forensic inpatient violence in a UK sample.

Study results allow for acceptance of hypotheses for the primary research question, with total and clinical and risk management sub-scale scores showing significant predictive validity for

both violence types and the clinical sub-scale showing strongest predictive ability for ‘physical violence’ and also ‘any violence’. As hypothesised, the historical sub-scale did not predict either violence type. Hypotheses for the secondary research question were partially accepted in that history of violence and positive symptoms were found to significantly predict ‘any violence’ whilst only positive symptoms were a significant predictor of ‘physical violence’. Neither insight nor age were significantly associated with either violence type.

### **3.5.1 The Predictive Validity of HCR-20v3**

In terms of predictive validity, the HCR-20v3 clinical sub-scale demonstrated the largest effect sizes for both violence types and was most predictive of ‘physical violence’. Such accurate prediction of physical violence by the clinical sub-scale is encouraging for the HCR-20v3 system considering this is of most concern to NHS services (Renwick et al, 2016). The dominance of the clinical sub-scale supports findings from key HCR-20v2 studies that highlighted its strength in predicting physical violence in forensic inpatients (Macpherson & Kevan, 2004; Wilson et al, 2013; O’Shea et al, 2014).

Our findings also support those of initial HCR-20v3 predictive validity studies conducted with forensic community patients (e.g. Strub et al, 2014; Doyle et al, 2014). Although speculative to compare forensic inpatient violence to community violence, finding the clinical sub-scale to be the strongest predictor of violence across forensic inpatient and community settings seeks to reinforce its utility for forensic patients generally. What is notable within Strub et al, (2014), Doyle et al, (2014) and the current study, is that for forensic samples, clinical sub-scale AUC values are equal to or in the majority of cases, greater than, HCR-20v3 total score AUCs. This suggests that the clinical sub-scale is independently better at predicting both types of violence than when combined with historical and risk-management sub-scales. In post-hoc analysis within the current study this observation was confirmed; the clinical sub-scale demonstrated increased predictive accuracy for both types of violence independently than it did when combined with the still-significant risk-management sub-scale.

The strength of the clinical sub-scale over the total score may be linked to the characteristics of forensic patients. Certainly, Nicholls, et al (2004) demonstrated that the HCR-20v2 clinical sub-scale was not as powerful a predictor for civil-psychiatric inpatient violence as it was for forensic inpatients. Relatedly, various studies have highlighted the poor utility of the HCR-20v2 historical sub-scale for violence in forensic inpatient samples (Macpherson & Kevan, 2004; O’Shea et al, 2014) and this effect appears to have continued within HCR-20v3.

Crucially, forensic inpatients are likely to have experienced the majority of items on the historical sub-scale. As such, they tend to score higher than civil-psychiatric patients (Strub et al, 2014) and highly overall. This results in less variance within the historical sub-scale and thus lower predictive value to contribute towards the total score. Alternatively, there is greater room for variation in patient scores on the clinical sub-scale due to its dynamic nature, thereby facilitating the opportunity for increased variance and greater predictive ability.

Although the risk-management sub-scale was found to be predictive of violence in our study, AUC values were low. Dernevik et al's, (2002) study of the HCR-20v2 with forensic inpatients also showed significant yet low risk-management sub-scale AUC values, whilst the sub-scale did not reach significance within Macpherson & Kevan's (2004) study. Contrastingly, the HCR-20v3 risk-management sub-scale has demonstrated enhanced predictive ability for violence within forensic community samples (Doyle et al, 2014; Strub et al, 2014). This may be due to risk-management items being of more relevance to community patients than to forensic inpatients. Although the mix of security levels within the current study's sample may have allowed for significant AUC values to be found, clinical and risk management sub-scales combined, performed no better than the clinical sub-scale alone in terms of predictive validity. This suggests that risk factors within the risk management sub-scale may not be wholly relevant to forensic inpatients.

The superiority of the clinical scale is in line with a wealth of research outlining the value of dynamic variables within violence risk assessment (Desmaris et al, 2012; Wilson et al, 2013; Johnson et al, 2016). In particular, our findings support those of Hogan & Olver (2016) who found HCR-20v3 dynamic risk factors to be more accurate at predicting forensic inpatient violence when historical sub-scale items were controlled for. Dynamic risk factors within the violence risk scale (VRS) and the short-term assessment of risk and treatability (START) were also found to show enhanced predictive validity in comparison to static risk factors within these tools. This suggests that the dynamic risk factors across risk assessment tools show enhanced prediction of forensic inpatient violence. Relatedly, De Vries- Robbe et al, (2015) found improvements in dynamic risk factors to be associated with lower rates of violence in forensic inpatients, whilst Penney et al, (2016) showed an increase in the same to be associated with higher rates of forensic inpatient violence. These findings offer further support for the importance of dynamic variables in contemporary violence risk assessment and management. Overall, findings provide empirical support for an understanding of violence risk as fluctuating (Douglas & Skeem, 2005) and highlight a requirement for the field to develop enhanced

understanding of the role of specific dynamic risk factors in relation to forensic inpatient violence.

### **3.5.2 Positive Symptoms as a Risk-Factor for Violence**

Empirical research then continues to build evidence for the importance of dynamic risk factors within violence risk assessment. Evidence around the predictive ability of specific dynamic risk factors in relation to forensic inpatient violence however, remains limited (Wilson et al, 2013). Our finding that positive symptoms of psychosis significantly predict ‘any violence’ and ‘physical violence’ provides clarity that a small minority of forensic inpatients with greater positive symptoms may behave violently. Although it is acknowledged that our logistic regression model for ‘physical violence’ in particular was relatively poor at classifying violent patients based on positive symptoms alone, it did clearly outline their significance as a predictor of physical violence. As such, our findings allow for an extension of previous research regarding positive symptoms being a risk factor for violence in civil-psychiatric inpatient (Arango et al, 1999; Nolan et al, 2003), high-risk community (Hodgins et al, 2003; Swanson et al, 2006) and community forensic samples (Lincoln & Hodgins, 2008) to forensic inpatients.

Although Monahan et al, (2000) did not find individual positive symptoms such as delusions, to increase the risk of violence, our study may have found a clearer relationship between positive symptoms and violence as measurement was conducted on a general level by the PECC-R, encompassing 4 key psychotic symptoms; hallucinations, delusions, thought disorder and grandiosity. It may be the experience of positive symptoms holistically that contributes towards violence as oppose to symptoms at an individual level. Indeed, positive symptoms are certainly only one set of a number of variables which contribute towards violence risk in forensic inpatients (Bonta et al, 2014). Identification of their significance is however valuable, as they can be identified within risk assessments, taken account of in risk management plans (Monahan & Skeem, 2016) and improved in psychological therapy (Naeem & Kingdon 2016). These opportunities are in line with forensic mental health policy which seeks to offer patients interventions to reduce their level of risk in order to progress in their recovery and rehabilitation (Clark et al, 2011).

### **3.5.3 The Reduced Value of History of Violence, Insight and Age as Predictors of Violence**

Within this study’s sub-sample, history of violence was found to significantly contribute towards a predictive model of ‘any violence’. This finding replicates a wealth of existing research providing support for a positive relationship between historical and future violence in

psychosis (Witt et al, 2013). It also re-affirms the usefulness of violence history as a static-demographic risk factor within the HCR-20v3. Interestingly, history of violence did not predict 'physical violence' which is in contrast to previous research such as that by Amore et al, (2008) who found a history of aggressive behaviour to be the most significant risk factor for physical violence by inpatients within an acute psychiatric ward. The majority of evidence around risk factors for inpatient violence is however based on non-forensic samples and forensic inpatients may differ in terms of pre-disposing factors to physical violence. Indeed, the importance of dynamic variables to this patient group has already been demonstrated and these appear to prevail in terms of risk of physical violence. It should also be taken into account that base rates of physical violence within the current study were low. This may have reduced the ability of history of violence to reach significant levels of prediction.

Younger age has also received support previously as a risk factor for inpatient violence (Dack et al, 2013) yet predicted neither violence type within the current study. Some studies have shown forensic patients to have an older mean age than their civil-psychiatric peers (Strub et al, 2014) and indeed our sample's mean age of 42 was relatively high. This perhaps reduced the opportunity for violence to be carried out by younger patients and thus lessened the influence of this variable as a predictor. In a sample of N=94 forensic inpatients with a mean age of 38 (SD=9.03), Doyle & Dolan (2006) provide further support for the current findings. They found no significant differences in terms of the age of patients who had been violent compared to those who had not, with age also failing to contribute to a logistic regression model of violence. Doyle & Dolan (2006) and the current study's findings suggest that younger age may not be as relevant to violence in forensic inpatients as it is to other patient groups.

Lastly, insight not emerging as a predictor of violence is not entirely unexpected, primarily as the relationship between poor insight and violence in psychosis remains subject to debate (Ekinci & Ekinci, 2013; Slijepcevic et al, 2014). Our findings should however be considered tentatively, in part due to the complex nature of insight and the difficulties which exist in its measurement (McCormack et al, 2013). Insight is generally understood as a multi-dimensional concept (Amador et al, 1993), with only poor clinical insight so far demonstrating prediction of violent behaviour in forensic inpatients with psychosis (Alia-Klein et al, 2007). Although the PECC-R aims to access the clinical dimension, it does so via only two questions rated by nursing staff. In alternative studies investigating insight and violence in psychosis, those which applied the comprehensive 'scale to assess unawareness of mental disorder' (SUMD; Amador et al, 1993) (e.g. Ekinci & Ekinci, 2013; Goodman et al,

2005; Alia-Klein et al, 2007) found a positive association between poor clinical insight and violence. Studies which utilised briefer scales such as PANSS G12 item (Kay et al, 1987) (e.g. Foley et al, 2007; Fresan et al, 2005) did not demonstrate this relationship. Briefer scales may then be unable to fully capture the complexity of insight in psychosis, with the PECC-R possibly affected by similar measurement limitations, impacting on results. This study then contributes some evidence towards the argument that insight is not a predictor of violence in forensic inpatients with psychosis however does so with the acknowledgement of cited caveats.

### **3.5.4 Implications for Violence Risk Assessment and Management Practice**

Our findings lead to various points of interest for the violence risk assessment and management of forensic inpatients. Firstly, the historical sub-scale of the HCR-20v3 has little predictive value in this group. This is in contrast to the escalating value of the clinic sub-scale and dynamic risk factors such as positive symptoms of psychosis. It is therefore recommended that priority is given to dynamic factors within risk assessment and management in this population. As a minimum, dynamic risk factors present within the clinical sub-scale should be explicitly measured with reliable assessment tools prior to ratings being provided, with care taken in the selection of assessment tools to enable sensitive identification of change over time.

The relationship between positive symptoms of psychosis and forensic inpatient violence perhaps also highlights an area of development for the HCR-20 system. The HCR-20v3 user manual (Douglas et al, 2013) refers to ‘psychotic symptoms’ as a whole within item C3 and does not differentiate positive and negative symptoms, despite the latter continuing to demonstrate a negative relationship with violence (Knezevic et al, 2017). Subject to the replication of our findings, it may be that positive symptoms could be more clearly identified to encourage raters to be mindful of their relevance to violence and to ensure they are re-assessed regularly as part of risk assessment procedures. Overall, in line with current risk management policy (RMA, 2011) our findings imply that dynamic factors and risk assessments generally, should be subject to regular re-assessment and tailored risk management (Monahan & Skeem, 2016). Support is therefore provided for the current care programme approach (CPA) to the management of forensic inpatients within NHS services.

Although our findings outline the usefulness of the HCR-20v3 clinical sub-scale and dynamic over historical risk factors, there remains a place for static risk assessment in forensic settings. Static risk continues to require thorough assessment firstly due to its strong relationship with



longer term violence (Hart et al, 2001). Forensic inpatients also consistently demonstrate high levels of static risk, thus highlighting its continued relevance to this population. Lastly, information contained within the HCR-20v3 historical sub-scale is often richer than that of clinical and risk-management sub-scales and is therefore optimum for developing victim safety planning and violence risk scenarios within risk-management plans. This research then serves not to diminish the role of static risk factors but to provide increased support for the value of the HCR-20v3 clinical sub-scale to this patient group.

### **3.5.5 Limitations**

Some limitations should be taken into account when interpreting this study's findings. Primarily, variables known to co-vary in the psychosis-violence relationship, mainly; substance misuse (van Dorn et al, 2012); and psychopathy (Bo et al, 2011) were not controlled for in subgroup analyses. However, although substance misuse has been found to account for a large proportion of variance in the prediction of community violence by individuals with psychosis (Fazel et al, 2009), its relationship to violence appears to be reduced within inpatient settings (Stewart & Bowers, 2015). Similarly, psychopathy is a strong predictor of violent recidivism in community samples (Vitacco et al, 2014), yet McDermott et al, (2008) found HCR-20v3 clinical and risk-management sub-scale items to be more useful than psychopathy when predicting violence in forensic inpatients. Due to a relatively large sample size and limited resources, it was not possible to assess all patients by use of the PCL-R and it was felt unreliable to derive information on psychopathy from patient case-files without structured assessment.

Our study did not control for psychiatric diagnoses. The vast majority of patients sampled had a primary diagnosis of a psychotic disorder and although a second reasonably sized group had a psychotic disorder diagnosis with co-morbid personality disorder, all other diagnostic groups were too small to justify group comparisons. Additionally, in common with Baumeister et al, (2017) a psychological model of mental health has been advocated throughout this study with psychosis viewed on a continuum as opposed to within discrete diagnostic categories. We therefore did not pursue a focus on diagnosis per se, rather positive symptoms of psychosis which may be experienced within various psychotic disorders.

The method of collecting violent incident data by use of DATIX also has potential limitations. Although DATIX was used across sites, with staff trained in its use, variation may exist on what is recorded and in the quality of incident narratives. To minimise any potential for error however, the accuracy of all DATIX coding was checked against narrative descriptions by risk

management teams. Reliability of this data was then further protected by standardisation of all DATIX incidents by use of the OAS and finally by inter-rater reliability of OAS categorisation which found a high level of agreement between raters.

Finally, as discussed, the PECC-R may not have allowed for the most sensitive measurement of insight. However, it is an ecologically valid tool used regularly by nursing staff which also allowed for maximum sample size due to its availability within case files.

### **3.5.6 Future Research**

As research on the predictive validity of risk assessment tools within this population remains limited, replication of this study would be useful. Further support for the predictive validity of the HCR-20v3 clinical sub-scale in particular would contribute to a growing evidence base around its usefulness for violence prediction in this population. Future research could also develop increased understanding of alternative variables inherent within dynamic risk factors which relate to violence directly, as the current study has demonstrated with positive symptoms. As insight is included multi-dimensionally within the HCR-20v3, yet its relationship to violence in forensic inpatients with psychosis continues to be contestable, each dimension's relationship to inpatient violence could be investigated more closely. In order to increase the reliability of findings, future research should aim to investigate these topics prospectively, with sensitive measurement tools whilst controlling for known co-variables of violence.

### **3.5.7 Conclusions**

To conclude, this study is the first study to investigate the predictive validity of the HCR-20v3 in a UK sample of forensic inpatients. The HCR-20v3 was found to have reasonable predictive accuracy for inpatient violence and physical violence specifically through its total score, with enhanced accuracy demonstrated by the clinical sub-scale independently. For this unique patient group then, current-dynamic risk factors are more valuable to violence risk assessment than historical or future oriented factors. In a sub-sample of patients with psychosis, positive symptoms significantly predicted inpatient violence and physical violence specifically. Patient age and their insight into their mental health difficulties did not predict violence whilst history of violence predicted inpatient violence on only a general level and not physical violence specifically. This highlights that violence risk factors for forensic inpatients may differ from those of other patient populations, with dynamic risk factors such as positive symptoms being of increased importance to this group. It is recommended that health-care professionals

prioritise the HCR-20v3 clinical sub-scale and positive symptoms in particular when assessing violence risk, with the caveat that the use of insight as a risk factor for violence in forensic inpatients with psychosis continues to require further empirical support.

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**Keywords.** A maximum of 5 keywords, relevant to your manuscript, will also be required.



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Appendix 2: Table of Key words Used in Database Searching

<b>Population</b>	<b>Intervention</b>	<b>Comparison</b>	<b>Outcome</b>
Psychosis	Insight	n/a	Violence
psychoses	Awareness	predict*	Aggress*
Schizophrenia	Understanding	associat*	Hostility
Paranoid-	comprehension	relationship	Behaviour
schizophrenia			Challenging
Psychotic			behaviour
Psychotic disorder*			
Schizo-Affective			
Mental Illness			

## Appendix 3: NICE Quality Appraisal Checklist for Quantitative Studies Reporting on Correlations and Associations

## Appendix G Quality appraisal checklist – quantitative studies reporting correlations and associations

A correlates review (see [section 3.3.4](#)) attempts to establish the factors that are associated or correlated with positive or negative health behaviours or outcomes. Evidence for correlate reviews will come both from specifically designed correlation studies and other study designs that also report on correlations.

This checklist<sup>[15]</sup> has been developed for assessing the validity of studies reporting correlations. It is based on the appraisal step of the 'Graphical appraisal tool for epidemiological studies (GATE)', developed by Jackson et al. (2006).

This checklist enables a reviewer to appraise a study's internal and external validity after addressing the following key aspects of study design: characteristics of study participants; definition of independent variables; outcomes assessed and methods of analyses.

Like GATE, this checklist is intended to be used in an electronic (Excel) format that will facilitate both the sharing and storage of data, and through linkage with other documents, the compilation of research reports. Much of the guidance to support the completion of the critical appraisal form that is reproduced below also appears in 'pop-up' windows in the electronic version<sup>[16]</sup>.

There are 5 sections of the revised GATE. Section 1 seeks to assess the key population criteria for determining the study's **external validity** – that is, the extent to which the findings of a study are generalisable beyond the confines of the study to the study's source population.

Sections 2 to 4 assess the key criteria for determining the study's **internal validity** – that is, making sure that the study has been carried out carefully, and that the identified associations are valid and are not due to some other (often unidentified) factor.

Checklist items are worded so that 1 of 5 responses is possible:

++	Indicates that for that particular aspect of study design, the study has been designed or conducted in such a way as to minimise the risk of bias.
+	Indicates that either the answer to the checklist question is not clear from the way the study is reported, or that the study may not have addressed all potential sources of bias for that particular aspect of study design.

-	Should be reserved for those aspects of the study design in which significant sources of bias may persist.
<b>Not reported (NR)</b>	Should be reserved for those aspects in which the study under review fails to report how they have (or might have) been considered.
<b>Not applicable (NA)</b>	Should be reserved for those study design aspects that are not applicable given the study design under review (for example, allocation concealment would not be applicable for case-control studies).

In addition, the reviewer is requested to complete in detail the comments section of the quality appraisal form so that the grade awarded for each study aspect is as transparent as possible.

Each study is then awarded an overall study quality grading for internal validity (IV) and a separate one for external validity (EV):

- ++ All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.
- + Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
- - Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

### Checklist

Study identification: Include full citation details	
Study design: <ul style="list-style-type: none"> <li>• Refer to the glossary of study designs (<a href="#">appendix D</a>) and the algorithm for classifying experimental and observational study designs (<a href="#">appendix E</a>) to best describe the paper's underpinning study design</li> </ul>	
Guidance topic:	
Assessed by:	
Section 1: Population	



<p><b>1.1 Is the source population or source area well described?</b></p> <ul style="list-style-type: none"> <li>• Was the country (e.g. developed or non-developed, type of health care system), setting (primary schools, community centres etc), location (urban, rural), population demographics etc adequately described?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>1.2 Is the eligible population or area representative of the source population or area?</b></p> <ul style="list-style-type: none"> <li>• Was the recruitment of individuals, clusters or areas well defined (e.g. advertisement, birth register)?</li> <li>• Was the eligible population representative of the source? Were important groups underrepresented?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>1.3 Do the selected participants or areas represent the eligible population or area?</b></p> <ul style="list-style-type: none"> <li>• Was the method of selection of participants from the eligible population well described?</li> <li>• What % of selected individuals or clusters agreed to participate? Were there any sources of bias?</li> <li>• Were the inclusion or exclusion criteria explicit and appropriate?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>Section 2: Method of selection of exposure (or comparison) group</b></p>		
<p><b>2.1 Selection of exposure (and comparison) group. How was selection bias minimised?</b></p> <ul style="list-style-type: none"> <li>• How was selection bias minimised?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>2.2 Was the selection of explanatory variables based on a sound theoretical basis?</b></p> <ul style="list-style-type: none"> <li>• How sound was the theoretical basis for selecting the explanatory variables?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>

<p><b>2.3 Was the contamination acceptably low?</b></p> <ul style="list-style-type: none"> <li>• Did any in the comparison group receive the exposure?</li> <li>• If so, was it sufficient to cause important bias?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>2.4 How well were likely confounding factors identified and controlled?</b></p> <ul style="list-style-type: none"> <li>• Were there likely to be other confounding factors not considered or appropriately adjusted for?</li> <li>• Was this sufficient to cause important bias?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>2.5 Is the setting applicable to the UK?</b></p> <ul style="list-style-type: none"> <li>• Did the setting differ significantly from the UK?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>Section 3: Outcomes</b></p>		
<p><b>3.1 Were the outcome measures and procedures reliable?</b></p> <ul style="list-style-type: none"> <li>• Were outcome measures subjective or objective (e.g. biochemically validated nicotine levels ++ vs self-reported smoking -)?</li> <li>• How reliable were outcome measures (e.g. inter- or intra-rater reliability scores)?</li> <li>• Was there any indication that measures had been validated (e.g. validated against a gold standard measure or assessed for content validity)?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>3.2 Were the outcome measurements complete?</b></p> <ul style="list-style-type: none"> <li>• Were all or most of the study participants who met the defined study outcome definitions likely to have been identified?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>

<p><b>3.3 Were all the important outcomes assessed?</b></p> <ul style="list-style-type: none"> <li>• Were all the important benefits and harms assessed?</li> <li>• Was it possible to determine the overall balance of benefits and harms of the intervention versus comparison?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>3.4 Was there a similar follow-up time in exposure and comparison groups?</b></p> <ul style="list-style-type: none"> <li>• If groups are followed for different lengths of time, then more events are likely to occur in the group followed-up for longer distorting the comparison.</li> <li>• Analyses can be adjusted to allow for differences in length of follow-up (e.g. using person-years).</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>3.5 Was follow-up time meaningful?</b></p> <ul style="list-style-type: none"> <li>• Was follow-up long enough to assess long-term benefits and harms?</li> <li>• Was it too long, e.g. participants lost to follow-up?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>Section 4: Analyses</b></p>		
<p><b>4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?</b></p> <ul style="list-style-type: none"> <li>• A power of 0.8 (i.e. it is likely to see an effect of a given size if one exists, 80% of the time) is the conventionally accepted standard.</li> <li>• Is a power calculation presented? If not, what is the expected effect size? Is the sample size adequate?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>4.2 Were multiple explanatory variables considered in the analyses?</b></p> <ul style="list-style-type: none"> <li>• Were there sufficient explanatory variables considered in the analysis?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>

<p><b>4.3 Were the analytical methods appropriate?</b></p> <ul style="list-style-type: none"> <li>• Were important differences in follow-up time and likely confounders adjusted for?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>4.6 Was the precision of association given or calculable? Is association meaningful?</b></p> <ul style="list-style-type: none"> <li>• Were confidence intervals or p values for effect estimates given or possible to calculate?</li> <li>• Were CIs wide or were they sufficiently precise to aid decision-making? If precision is lacking, is this because the study is under-powered?</li> </ul>	<p>++ + - NR NA</p>	<p>Comments:</p>
<p><b>Section 5: Summary</b></p>		
<p><b>5.1 Are the study results internally valid (i.e. unbiased)?</b></p> <ul style="list-style-type: none"> <li>• How well did the study minimise sources of bias (i.e. adjusting for potential confounders)?</li> <li>• Were there significant flaws in the study design?</li> </ul>	<p>++ + -</p>	<p>Comments:</p>
<p><b>5.2 Are the findings generalisable to the source population (i.e. externally valid)?</b></p> <ul style="list-style-type: none"> <li>• Are there sufficient details given about the study to determine if the findings are generalisable to the source population?</li> <li>• Consider: participants, interventions and comparisons, outcomes, resource and policy implications.</li> </ul>	<p>++ + -</p>	<p>Comments:</p>

<sup>[15]</sup> Appraisal form derived from: Jackson R, Ameratunga S, Broad J et al. (2006) The GATE frame: critical appraisal with pictures. Evidence Based Medicine 11: 35–8.

<sup>[16]</sup> Available from CPHE on request.

Appendix 4: Operationalised NICE Checklist for Quantitative Studies Reporting on Correlations and Associations

	<b>Quality Criteria</b>
1	Population
2	Methods of Selection
3	Outcomes
4	Analyses
5	Internal & External Validity

	<b>Quality Gradings for Criteria 1 - 4</b>
++	for the particular aspect of study design, the study has been conducted in such a way to minimise risk of bias
+	either the answer to the checklist criteria question is not clear from the way the study is reported or the study may not have addressed all potential sources of bias for that particular aspect of study design
-	should be reserved for those aspects of the study design in which significant sources of bias may persist.
NR	should be reserved for those aspects in which the study under review fails to report how they have been considered
NA	should be reserved for those study design aspects that are not applicable given the study design under review.

	<b>Internal and External Validity Quality Gradings</b>
++	all or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter
+	some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
-	few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

## **1. Population**

### **1.0 The source area and the source population are well described**

++	Country, setting, and type of source population are all clearly described to sufficient detail to allow for good comparison and generalizability.
+	Most of the information regarding source area and population required for adequate comparison and generalizability are provided
-	Little information is described regarding source area and population to the extent that comparison and generalizability is not possible
Not reported ( - )	
Not applicable ( - )	

### **1.1 The recruitment of the eligible population is clear and generalisable**

++	The recruitment of individuals is well defined e.g. via advertisement, participation offered to consecutive admissions to a hospital, referral by study sites etc.
+	Some details are provided on the recruitment of the eligible population however some important information may be missing
-	Insufficient detail is provided on the recruitment of the eligible population to the extent that it is unclear how they were recruited
Not reported ( - )	
Not applicable ( - )	

### **1.2 The selected participants represent the eligible population**

++	The method of participant selection from the eligible population is well described. Inclusion/exclusion criteria are explicit and appropriate. The study clarifies % of individuals who agreed to participate from eligible population.
+	Some elements of bias may be introduced within the sampling method and the inclusion/exclusion criteria may be deemed inappropriate in parts/may not be clearly described. The study may not clarify the % of individual who agreed to take part from the eligible population.

-	The sampling method is not appropriate. Inclusion/exclusion criteria are absent or misguided to the detriment of the study. Important groups from the source population are not included to the extent the wider source population is not fully represented. The study does not clarify the % of individual who agreed to take part from the eligible population
Not reported ( - )	
Not applicable ( - )	

**1.3 The characteristics of study participants are clearly stated and are representative of a population of individuals with psychosis.**

++	There is a comprehensive description of participant characteristics (gender, age, diagnosis etc.) and these are representative of a population of individuals with psychosis.
+	An adequate amount of relevant characteristics are described which are representative of the majority of a population of individuals with psychosis although some expected characteristics may be missing.
-	Very few or no characteristics are mentioned and/or these are not representative of a population of individuals with psychosis.
Not reported ( - )	
Not applicable ( - )	

**2. Methods of selection**

**2.0 Selection bias was minimised when determining exposure and control groups.**

E.g. in terms of violent and non-violent (control) groups when applicable. (This criteria is unlikely to be applicable to the majority of studies included in the review)

++	Out-with violent behaviour, the violent and non-violent (control) groups are equal in terms of participant characteristics and researchers collecting/rating participant violence data are blind to violent/non-violent group membership.
+	There may be some differences in terms of the participant characteristics between violent and non-violent groups (e.g. more

	outpatients may be in non-violent group) however these are common in violence research and have been identified within the study and/or researchers may not be blind to group membership but reliability checks have been carried out.
-	Significant differences exist in terms of participant characteristics between violent and non-violent groups which are less common in the field of research and which may not be identified by the study and/or researchers are not blind to group membership and reliability checks are not carried out.
Not reported ( - )	
Not applicable ( - )	

### 3. Outcomes

#### 3.0 Insight is measured in a standard, valid and reliable way within a population of individuals with psychosis

++	The measure of insight is objective (e.g. is a published measure), has been validated and is reliable for use with a population of individuals of psychosis.
+	The measure of insight is objective, has been validated in other populations but has not been validated for use within populations of individuals with psychosis or has been measured via psychiatric assessment (clinical judgement) by a senior member of clinical staff separate from the research team or is based on a single item rating e.g. PANSS item G12 only.
-	The measure of insight has not been validated for use in any population or has been measured via psychiatric assessment (clinical judgment) only by a member of the research team.
Not reported ( - )	
Not applicable ( - )	



**3.1 Violence is measured in a standard, valid and reliable way within a population of individuals with psychosis.**

++	The measure of violence is objective (e.g. is a published measure such as the OAS; Yodofsky et al), has been validated and is reliable for use with a population of individuals of psychosis.
+	The measure of violence has been validated in other populations but has not been validated for use within populations of individuals with psychosis or is based on single item ratings e.g. PANSS item P7 only.
-	The measure of violence has not been validated for use in any population.
Not reported ( - )	
Not applicable ( - )	

**3.2 The collection of violence data is carried out in a standard, valid and reliable way**

++	Violence data was collected in an objective manner e.g. prospectively from a start date to a follow-up end date/by use of a hospital incident recording system or reliable clinical notes by researcher's blind to group membership/insight assessment results and/or ratified by data collection from multiple sources.
+	Violence data collection was adequately carried out in that sources of bias which may have been present were adjusted for where possible e.g. by use of collateral informants if violence data was collected via participant self-report interviews/via retrospective violence data collection. Limitations of data collection methods are discussed.
-	Data collection is not carried out in a standard/valid/reliable way, creating substantial bias which is not adjusted for by the study.
Not reported ( - )	
Not applicable ( - )	

**3.3 All important violence outcomes are assessed**

E.g. did study consider full spectrum of violence from verbal threats to homicide or for instance, only recorded violence convictions.

++	The study defined the violent behaviours it aimed to collect and included a full spectrum of violence e.g. from verbal threats to homicide
+	The study defined and collected a more limited range of violent behaviours, perhaps due to setting constraints, however, this remained adequate/definition of violence may not be clear but can be gleaned from other areas of study.
-	No definition was provided for the violent behaviours the study aimed to collect and/or violent behaviour was limited to the extent of significant bias e.g. only collecting violent behaviour in terms of violent convictions.
Not reported ( - )	
Not applicable ( - )	

### 3.4 The choice of study design is suitable for assessing relationships between insight and violent outcomes

++	Prospective longitudinal cohort studies as gold standard where insight has been measured at baseline and participants are followed up for violent behaviour, violent and non-violent groups are then created and compared.
+	Cross-sectional retrospective case-control/cohort studies when insight is measured at the same time as or prior to violent behaviour outcomes.
-	Retrospective research designs where insight is measured and violence data is gathered in months/years prior to this (as insight may have improved since violent behaviour was carried out).
Not reported ( - )	
Not applicable ( - )	

### 3.5 Follow-up time was meaningful

++	Follow-up time was long enough to sufficiently gather violence data yet not too long that many participants were lost to follow-up.
+	Follow-up time was shorter/longer than requirements for optimum data collection and minimum participant loss however this did not have a significantly detrimental effect on the study.
-	Follow-up time did not allow for sufficient violence data to be collected/significant amount of participants lost to follow-up.
Not reported ( - )	
Not applicable ( - )	

#### **4 STATISTICAL ANALYSIS**

##### **4.0 The choice of data analysis is appropriate to the study design and outcome measures.**

++	The analysis is appropriate to the study design.
+	Analysis could have been more complex or expanded
-	Inappropriate analysis is used.
Not reported ( - )	
Not applicable ( - )	

##### **4.1 The study is sufficiently powered to detect an association/regression effect**

++	A power calculation was reported and was sufficient for the study design, outcome measure and statistical analysis used.
+	A power calculation was not reported, but the study appeared to be adequately powered for the analysis undertaken.
-	The study was not adequately powered for the analysis undertaken.
Not reported ( - )	
Not applicable ( - )	

##### **4.2 Confounding variables are identified and considered in analyses**

E.g. if it's a young offender sample and they haven't controlled for ASPD then this could be a weakness, psychopathy and substance abuse should also be considered when measuring violence in forensic samples with psychosis.

++	Variables which through empirical research are known to confound both insight and violence as an outcome measure are identified and controlled for by the study in analysis as far as is reasonably possible
+	Some confounding variables may be identified and controlled for in analysis whereas others may be discussed in terms of study limitations, some may be missing.
-	Many likely confounding variables are neither identified, controlled for in analysis or discussed in terms of study limitations.
Not reported ( - )	
Not applicable ( - )	

#### 4.3 The precision of association was given and is meaningful.

++	confidence intervals and p values have been stated.
+	p values are stated, confidence intervals may not be stated.
-	confidence intervals and p values are not provided.
Not reported ( - )	
Not applicable ( - )	

## 5 Summary

### 5.0 The study results are internally valid

++	All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.
+	Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
-	Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

### 5.1 The findings are generalisable to the source population (i.e. are externally valid)

E.g. sufficient detail is given to determine generalizability, consider all aspects of PICO

++	All or most of the checklist criteria have been fulfilled, where they have not been fulfilled the conclusions are very unlikely to alter.
----	---

+	Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
-	Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

## Appendix 5: PROSPERO International Prospective Register of Systematic Reviews Notice

## PROSPERO International prospective register of systematic reviews

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### The relationship between insight and violence in individuals with psychosis: a systematic review

Kerry Johanna Smith

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#### Citation

Kerry Johanna Smith. The relationship between insight and violence in individuals with psychosis: a systematic review. PROSPERO 2016:CRD42016047044 Available from [http://www.crd.york.ac.uk/PROSPERO\\_REBRANDING/display\\_record.asp?ID=CRD42016047044](http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42016047044)

#### Review question(s)

Are lower levels of insight associated with violence and/or aggression in individuals with psychosis?

#### Searches

We will search the following electronic databases: PsycINFO, MEDLINE, PubMed, EMBASE, The Cochrane Library (Cochrane Database of Systematic Reviews). Citation searches will be carried out via SCOPUS. Grey literature will be searched via University theses databases, through reference searches and by contacting established authors in the field of interest. Hand searching of established journals in the area of interest will also be conducted.

Publication language will be restricted to English. All articles published from 1980 onwards will be considered.

#### Types of study to be included

Quantitative observational designs including cohort, case control, cross-sectional, and correlational of both retrospective and prospective nature.

#### Condition or domain being studied

Psychosis/Schizophrenia spectrum disorders, insight and violent/aggressive behaviour.

#### Participants/ population

Inclusion Criteria:

Adults over the age of 16 diagnosed with Psychosis including schizophrenia, schizophrenia spectrum disorders and major affective disorders with psychotic symptomatology (only when psychosis in addition to the major affective disorder has been clarified by authors of the research study).

All participant settings included e.g. general psychiatry inpatients, community outpatients, patients residing in forensic mental health hospitals.

Participants with psychiatric co-morbidities including substance misuse, personality disorder and affective disorders included.

Exclusion Criteria:

Adolescents under the age of 16 years.

Participants with intellectual disability or traumatic brain injury.

#### Intervention(s), exposure(s)

This review will not include intervention studies. Instead it will review observational studies with the main outcome being violent or aggressive behaviour of participants. Studies included will not impose any change or treatment of any kind on participants and as such exposure to any confounding variables which may influence the participants behavioural outcome are outwith the control of research teams.

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### **Comparator(s)/ control**

Participants who display violent/aggressive behaviour will be compared to non-violent/aggressive control participants.

### **Context**

Participants recruited from a wide range of settings including inpatient psychiatric wards, forensic mental health hospital, academic medical centres, community mental health centres.

Low, middle and high income countries all included.

### **Outcome(s)**

#### **Primary outcomes**

Participant violence and/or aggression as measured by a validated violence measurement scale such as The Overt Aggression Scale (OAS; Yodofsky et, al, 1986).

#### **Secondary outcomes**

None

### **Data extraction, (selection and coding)**

Titles of studies retrieved using the search strategy and those from grey literature will be screened by the author who will identify studies that potentially meet the inclusion criteria. Study titles which are deemed not relevant will be dismissed at this stage. Studies which remain from title screening will then have their abstracts screened by the author which will allow dismissal of further studies from the initial searches. Abstracts will be assessed in accordance with this review's inclusion and exclusion criteria. The full text of the remaining potentially eligible studies will be then be sought and fully assessed for eligibility by the author. At this stage, any studies which are found to meet exclusion criteria will again be rejected.

A standardised data extraction form will be used to extract data from the included studies. This will contribute towards the assessment of study quality and synthesis of information. The extraction form will include information relating to the following areas: study design, setting, participant characteristics, participant selection method, diagnoses included in sample, insight definition and measurement, violence definition and measurement, violence data collection method, confounding variables/co-variates considered, comparison/control group, length of follow-up if applicable, statistical analysis method, P values and key strengths and limitations. Any missing and required data will be requested from study authors.

### **Risk of bias (quality) assessment**

The author will independently review the quality of all included studies. A suitably qualified colleague will also independently review 25% of included studies. Any disagreement between reviews in terms of study quality/risk of bias will be resolved via discussion to reach a unified quality consensus, a third reviewer will be included if necessary.

The National Institute for Health and Care Excellence (NICE) "Quality Appraisal Checklist for Quantitative Studies Reporting Correlations and Associations (NICE; 2012) will be used by reviewers to rate the quality of studies.

### **Strategy for data synthesis**

Primarily, we plan to provide a narrative synthesis of findings from the included studies. This will be especially focussed on the characteristics of the participants included/excluded from studies, the measurement of insight and violence and study considerations of confounding variables/co-variates in the insight - violence relationship in psychosis.

Due to the observational design of the majority of studies included in the review, the correlational nature of the statistical techniques used and the variability in terms of insight and violence measurement tools, there appears to be little opportunity for meta-analysis at the moment.

### **Analysis of subgroups or subsets**



Depending on our findings within the data synthesis, a narrative sub group analysis may be carried out within groups of different participants, for instance it may be useful to carry out a sub group analysis of inpatient who are violent and compare this to a subgroup of outpatients who are violent.

#### **Dissemination plans**

This review will be disseminated firstly via the University of Edinburgh's thesis database and made available to the University of Edinburgh library both electronically and manually. The review will also be submitted to the Scottish Forensic Network for publication.

The review will also be submitted to a high impact journal in the field of schizophrenia research such as "Schizophrenia Research".

#### **Contact details for further information**

Ms Smith

Doorway 6, Medical School, Teviot Place, The University of Edinburgh, Scotland.

kerryjosmith89@hotmail.co.uk

#### **Organisational affiliation of the review**

The University of Edinburgh

www.ed.ac.uk

#### **Review team**

Ms Kerry Johanna Smith, The University of Edinburgh

#### **Collaborators**

Dr Suzanne O'Rourke, The University of Edinburgh

Dr Gary Macpherson, The State Hospital Carstairs

#### **Anticipated or actual start date**

01 August 2016

#### **Anticipated completion date**

01 May 2017

#### **Funding sources/sponsors**

The University of Edinburgh, NHS State Hospital Carstairs.

#### **Conflicts of interest**

None known

#### **Language**

English

#### **Country**

Scotland

#### **Subject index terms status**

Subject indexing assigned by CRD

#### **Subject index terms**

Humans; Problem Solving; Psychotic Disorders; Violence

**Stage of review**  
Ongoing

**Date of registration in PROSPERO**  
06 September 2016

**Date of publication of this revision**  
06 September 2016

<b>Stage of review at time of this submission</b>	<b>Started</b>	<b>Completed</b>
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

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**PROSPERO**

**International prospective register of systematic reviews**

The information in this record has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

---

19 October 2015

Miss Kerry Johanna Smith  
38 Moss Road  
Cambusnethan  
Wishaw  
ML2 8PU

Dear Miss Smith

**Study title:** **The Predictive Validity of the HCR20v3 within Scottish Forensic Inpatient Facilities: A Closer Look at Key Demographic and Clinical Variables.**  
**REC reference:** **15/LO/1874**  
**IRAS project ID:** **187594**

The Proportionate Review Sub-committee of the London - City & East Research Ethics Committee reviewed the above application on 15 October 2015.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mr Rajat Khullar, [nrescommittee.london-cityandeast@nhs.net](mailto:nrescommittee.london-cityandeast@nhs.net). Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

#### **Ethical opinion**

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

#### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.*

*Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

#### Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact [hra.studyregistration@nhs.net](mailto:hra.studyregistration@nhs.net). The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

#### **Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion”).

#### **Summary of discussion at the meeting**

*The Committee agreed that the application does not present any material ethical issues.*

## Approved documents

The documents reviewed and approved were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
IRAS Checklist XML [Checklist_09102015]		09 October 2015
IRAS Checklist XML [Checklist_13102015]		13 October 2015
Letter from sponsor [Letter from Sponsor Confirming State Hospital Approval for Research]	1	05 October 2015
Letter from statistician [Statistical and Academic Review Comments by The University of Edinburgh]	1	04 October 2015
Letter from statistician [Statistical and Academic Review Comments by The University of Edinburgh]	1	29 July 2015
Other [Timetable of Planned Project Activities]	1	15 September 2015
Other [Patient Initial and Corresponding UIDN form]	1	15 September 2015
Other [Data Collection Recording Forms]	2	16 September 2015
REC Application Form [REC_Form_13102015]		13 October 2015
Referee's report or other scientific critique report [Clinical and Academic Supervisor's Support of Research and Comments]	1	04 October 2015
Referee's report or other scientific critique report [Clinical and Academic Supervisor's Support of Research and Comments]	1	13 July 2015
Research protocol or project proposal [Research Proposal in Full]	1	04 October 2015
Summary CV for Chief Investigator (CI) [Summary CV for Chief Investigator]	2	05 October 2015
Summary CV for supervisor (student research) [S O'Rourke Academic Supervisor CV]	1	08 October 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Data Extraction Protocol]	1	31 August 2015

## Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

There were no declarations of interest

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

## After ethical review

### Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

#### **User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

#### **HRA Training**

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

**15/LO/1874**

**Please quote this number on all correspondence**

Yours sincerely



**p Dr John Keen  
Chair**

Email: [nrescommittee.london-cityandeast@nhs.net](mailto:nrescommittee.london-cityandeast@nhs.net)

*Enclosures: List of names and professions of members who took part in the review*

*"After ethical review – guidance for researchers"*

*Copy to: Mr Jamie Pitcairn, The State Hospital*



## Appendix 7: National Caldicott Approval

### Public Benefit and Privacy Panel for Health and Social Care

[nss.PBPP@nhs.net](mailto:nss.PBPP@nhs.net)

[www.informationgovernance.scot.nhs.uk](http://www.informationgovernance.scot.nhs.uk)



Kerry Johanna Smith,  
Trainee Clinical Psychologist,  
Department of Clinical Psychology,  
The State Hospital,  
Lampits Road,  
Carstairs,  
ML11 8RP

Date: 17<sup>th</sup> November 2015

Your Ref:

Our Ref: 1516-0347 Smith

Dear Miss Smith,

**Re: PBPP application – 1516-0347 Smith - The Predictive Validity of the HCR20v3 to Inpatient Violence in Secure Forensic Mental Health Facilities: A Closer Look at the Relationships between Demographic Variables in the Sample as a Whole and Clinical Variables in Patients with Schizophrenia.**

Thank you for your application for consideration by the Public Benefit and Privacy Panel for Health and Social Care. Your application has undergone proportionate governance review and has been approved.

This approval is given to process data as specified in the approved application form, and is limited to this. Approval is valid for the period specified in your application. You are required to notify the Panel Manager of any proposed change to any aspect of your proposal, including purpose or method of processing, data or data variables being processed, study cohorts, individuals accessing and processing data, timescales, technology/infrastructure, or any other relevant change.

I would take this opportunity to remind you of the declaration you have made in your application form committing you to undertakings in respect of information governance, confidentiality and data protection. In particular you should be aware that once personal data (irrespective of de-identification or other controls applied) has been extracted from NHSS Board(s) and transferred to you, that you will then become the Data Controller as defined by the Data Protection Act (1998).

Please note that summary information about your application and its approval, including the title and nature of your proposal, will be published on the panel website ([www.informationgovernance.scot.nhs.uk](http://www.informationgovernance.scot.nhs.uk)).

I hope that your proposal progresses well,

Yours Sincerely

Nicola Starkey  
(Interim) Panel Manager  
NHS Scotland Public Benefit and Privacy Panel for Health and Social Care  
Email: [nss.PBPP@nhs.net](mailto:nss.PBPP@nhs.net)

Appendix 8: State Hospital Research Committee and Management Approvals

*It should be noted that these approvals cover research and development approvals for all sites included in the study in line with the Forensic Network's research & development procedures.*

Kerry Johanna Smith

Trainee Clinical Psychologist

The State Hospital

Monday the 5<sup>th</sup> of October 2015

Dear Kerry Jo,

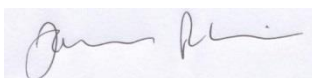
**Re: The Predictive Validity of the HCR20v3 within Scottish Forensic Inpatient Facilities: A Closer Look at Key Demographic and Clinical Variables**

Many thanks for your amended research proposal for the above named study that has been revised in line with the feedback from the TSH Research Committee review on Thursday the 25<sup>th</sup> of September 2015. The committee found the proposal to be rigorous and well written, and outlining an interesting piece of work, and are now happy to approve the study. This letter will be copied to the Associate Medical Director along with evidence of your ethical approval, and will subsequently provide final management approval for the study to take place within TSH. The letter will also be copied to leads of each of the FN regional research groups for information given the multicentre nature of the study.

One condition of the research committees' approval is that you provide the committee with regular 6-monthly progress reports. This is an important mechanism by which the committee track progress, and is also a key component of our research governance processes. We would be grateful if you would be able to provide a study progress report for the committee meeting in March 2016.

If you require any further assistance, or have any feedback on the Research approval process then please do not hesitate to contact me.

Yours sincerely



**JAMIE PITCAIRN, Research & Development Manager, The State Hospital.**



Kerry Johanna Smith  
Trainee Clinical Psychologist  
The State Hospital

Date 20 October 2015  
Our Ref DA/ag  
Your Ref  
Enquiries to Ann Gallacher  
Ext No 2221

Dear Ms Smith

**Re: The Predictive Validity of the HCR20v3 within Scottish Forensic Inpatient Facilities: A Closer Look at Key Demographic and Clinical Variables**

Having considered the views of the Research Committee and noted that you have obtained Ethical Approval from London – City & East Research Ethics Committee, I write to give you Managerial Approval to proceed with your project. This is subject to you fulfilling the requirements of the Ethics Committee and of the State Hospital Research Committee.

May I take this opportunity to wish you every success in your endeavour.

Yours sincerely



**Dr Duncan Alcock**  
Associate Medical Director

cc. Jamie Pitcairn, Research and Development Manager.  
Professor Lindsay Thomson, Medical Director.

Appendix 9: HCR-20v3 Scale Items

<b>Historical (A History of Problems With)</b>	<b>Clinical (Recent Problems With)</b>	<b>Risk Management (Future Problems With)</b>
<b>H1: Violence</b> a) As a Child Aged 12 Years and Under b) As an Adolescent Aged 13 to 17 years c) As an Adult Aged 18 Years and Over	<b>C1: Insight</b> a) Mental Disorder b) Violence Risk c) Need for Treatment	<b>R1: Professional Services and Plans</b>
<b>H2: Other Anti-Social Behaviour</b> a) As a Child Aged 12 Years and Under b) As an Adolescent Aged 13 to 17 Years c) As an Adult Aged 18 Years and Over	<b>C2: Violent Ideation or Intent</b>	<b>R2: Living Situation</b>
<b>H3: Relationships</b> a) Intimate b) Non-Intimate	<b>C3: Symptoms of Major Mental Disorder</b> a) Psychotic Disorder b) Major Mood Disorder c) Other Major Mental Disorder	<b>R3: Personal Support</b>
<b>H4: Employment</b>	<b>C4: Instability</b> a) Affective b) Behavioural c) Cognitive	<b>R4: Treatment or Supervision Response</b> a) Compliance b) Responsiveness
<b>H5: Substance Abuse</b>	<b>C5: Treatment or Supervision Response</b> a) Compliance b) Responsiveness	<b>R5: Stress or Coping</b>
<b>H6: Major Mental Disorder</b> a) Psychotic Disorder		

- 
- b) Major Mood Disorder
  - c) Other Major Mental Disorder
- 

**H7: Personality Disorder**

- a) Anti-Social, Psychopathic, Dissocial
  - b) Other Personality Disorder
- 

**H8: Traumatic Experiences**

- a) Victimization/Trauma
  - b) Adverse Child Rearing Experiences
- 

**H9: Violent Attitudes**

**H10: Treatment or Supervision Response**

---

Appendix 10: Schedule of Data Collection Visits to Sites

<p><b>January 2016</b></p> <p>Rohallion 1<sup>st</sup> Visit of Data Collection (Stage 1)</p>	<p><b>February 2016</b></p> <p>Rowanbank 1<sup>st</sup> Visit of Data Collection (Stage 1)</p>	<p><b>March 2016</b></p> <p>The State Hospital 1<sup>st</sup> Visit of Data Collection (Stage 1)</p>
<p><b>April 2016</b></p> <p>Rohallion 2<sup>nd</sup> Visit of Data Collection (Stage 1)</p>	<p><b>May 2016</b></p> <p>Rowanbank 2<sup>nd</sup> Visit of Data Collection (Stage 1)</p>	<p><b>June 2016</b></p> <p>The State Hospital 2<sup>nd</sup> Visit of Data Collection (Stage 1)</p>
<p><b>July 2016</b></p> <p>Rohallion 3<sup>rd</sup> Visit of Data Collection (Stage 1)</p> <p>Rowanbank 3<sup>rd</sup> Visit of Data Collection (Stage 1)</p> <p>The State Hospital 3<sup>rd</sup> Visit of Data Collection (Stage 1)</p>	<p><b>August 2016</b></p> <p>No Data Collection Visits</p>	<p><b>September 2016</b></p> <p>Rohallion 4<sup>th</sup> Visit of Data Collection (Stage 1)</p> <p>Rowanbank 4<sup>th</sup> Visit of Data Collection (Stage 1)</p> <p>The State Hospital 4<sup>th</sup> Visit of Data Collection</p>
<p><b>October 2016</b></p> <p>No Data Collection Visits</p>	<p><b>November 2016</b></p> <p>Follow-up violence data requested from all sites by 24<sup>th</sup> November.</p>	<p><b>December 2016</b></p> <p>All follow-up violence data received from sites by 21<sup>st</sup> of December.</p>

- 1) Please provide a brief critical review of relevant literature, which should clearly demonstrate the rationale and scientific justification for the research.**

### **Risk Assessment and Inpatient Violence**

Hart (1998; pg. 122) defined violence risk assessment as *'the process of evaluating individuals to characterise the likelihood that they will commit acts of violence and, to develop interventions to manage that likelihood'*. This definition is in line with the structured professional judgement (SPJ) approach taken towards risk assessment within Scottish forensic inpatient services. Recommended by the risk management authority (RMA, 2011), SPJ considers risk at an individual level based on factors systematically derived from literature alongside clinical knowledge and judgement of the patient. In turn, this enables creation of person centred risk-management plans with the aim of violence reduction.

The 'Forensic Matrix' (Clarke, Darjee, Gilchrist, et al, 2011) recommends that all therapeutic process be carried out in accordance with risk assessment and management. This recommendation is important due to the association of inpatient violence with factors such as staff psychological distress (Needham, Abderhalden, Halfens, Fischer & Dassen, 2005), patient and staff injury (Lam, McNeil & Binder, 2000) poor therapeutic milieu (McKenzie & Curr, 2005) and low levels of care (Arnetz & Arnetz, 2001). A literature review by Bowers et al, (2011) found 48% of inpatients within 36 UK forensic samples had engaged in violence, whilst studies with similar methodologies to the proposed found inpatient violence rates of 56% (Macpherson & Kevan, 2004) and 61% (O'Shea, Picchioni, Mason & Sugarman, 2014). Forensic inpatient violence therefore appears common, suggesting that there is progress to be made in its prediction and management.

### **HCR20v2**

One SPJ tool which received extensive research interest and implementation was the Historical Clinical Risk-Management-20 version 2 (HCR20v2; Webster, Douglas, Eaves & Hart, 1997). HCR20v2 was designed to predict violence in adults with a mental disorder and history of violence within inpatient and community settings. The tool contained 20 items within 3 subscales; the Historical (H) scale contained 10 static items, strongly associated with violence, the Clinical (C) scale contained 5 dynamic items whereas the Risk (R) scale had 5 items related to risk of future violence. In research, HCR20v2 was rated to produce sub-scale and total scores. In practice, a summary judgement of low, medium or high was made based on overall impression of violence risk.

HCR20v2 established support in terms of predictive validity for forensic inpatient violence. Macpherson & Kevan (2004) sampled 86 inpatients from a maximum security hospital. They assessed the predictive validity of HCR20v2 to violence during the admission period, finding the total score (AUC=0.642) and C scale (AUC=.0715) to predict 'any violence'. However, only the C scale predicted 'physical' violence (AUC=0.671). Similarly, in a sample of 505 forensic inpatients, O'Shea, et al, (2014) found the C scale to be the strongest predictor of any violence (AUC=0.760) and also predictive of physical violence (AUC=0.698). Both studies are in line with de Vogel & de Ruiter, (2006), Chu, Thomas, Ogloff & Daffern, (2011) and Arbach-Lucioni, Andrew-Pueyo, Pomarol-Clotet & Gomar-Sones, (2011) all of which found the C scale to be the strongest predictor of inpatient violence generally and to predict physical violence specifically.

Results did vary with regards to predictive validity of HCR20v2 with Dernevik, Grann & Johansson, (2002) finding the H scale to be the strongest predictor of forensic inpatient violence. However, this study did not use a standardised scale to measure violence. It therefore considered incidents such as handling illicit substances violent which is not often considered violent and in-line with item H5 (substance-abuse) and thus likely to show stronger prediction. Studies such as Arbach-Lucioni et al, (2011) used a standardised scale to measure violence and were more conservative in categorisation. This methodological difference is likely to have contributed towards alternative findings and is a common limitation of research within this field.

### HCR20v3

HCR20v2 (v2) generally showed good predictive accuracy for inpatient violence, particularly through the C scale. However, it is important that HCR20v3 (v3) (Douglas, Hart, Webster & Belfrage, 2013) is validated in similar ways. Although not significantly different from v2 and still made up of 20 items within H, C, and R sub-scales, v3 has had various adjustments. For a full review of changes see Douglas, Hart, Webster, Belfrage, Guy & Wilson (2014). For reference, HCR20v3 is displayed within Appendix 1.

Although few studies have investigated the predictive validity of v3 and none have sampled forensic inpatients, of interest thus far is the continued strength of the C scale. Doyle, Power, Coid, Kallis, Ullrich & Shaw (2014) assessed 387 patients discharged from medium security in England and Wales. Patients were followed up for community physical violence at 6 and 12 months with the C scale showing strongest predictive validity with AUCs of .747 and .707 respectively. A limitation of this study is that although researchers defined violence, no standardised measure was applied for categorisation. Furthermore, all v3 assessments in this study were completed by researchers, increasing risk of bias.

Additionally, Strub, Douglas & Nicholls (2014) sampled 56 forensic patients and 50 civil-psychiatric patients, who were followed up after community discharge. For forensic patients, the C scale was the strongest predictor of violence (AUC=.79) at 6-8 month follow-up. However, alongside no distinction between any violence and physical violence, v3 assessments were created by researchers without inter-rater reliability, leaving findings vulnerable to doubt. Lastly, both studies measured violence in community patients who are likely to differ from forensic inpatients in terms of violence risk. Subsequently, there is a gap in the literature regarding the predictive validity of HCR20v3 for forensic inpatient violence.

### **Demographic Predictors of Inpatient Violence**

In addition to HCR20's contribution to violence prediction, a range of demographic factors have more generally been found to predict inpatient violence. Younger age (Hoptman, Yates, Patalinjung, Wack & Convit, 1999), male gender (Amore et al, 2008), previous violence (Steinert, 2002), and diagnoses of schizophrenia (Dack, Ross, Papadopoulus, Stewart & Bowers, 2013) and personality disorder (Langton, Hogue, Daffern, Mannion & Howells, 2009) have all shown predictive abilities. However, evidence also exists to contradict these relationships and due to a research focus on the utility of clinical variables in violence prediction, the role of demographic factors is currently unclear. Indeed, Steinert's (2002) literature review suggests that with the exception of previous violence, identified demographic variables are of small importance to inpatient violence prediction, albeit this review was not statistical. Furthermore, there is little research available on the relationship between demographic variables and forensic inpatient violence specifically, with the majority of studies conducted with civil-psychiatric populations.

### **Predictors of Violence in Inpatients with Schizophrenia**

Recently, O'Shea et al, (2014) tested the predictive validity of HCR20v2 as a function of gender, diagnosis, age and ethnicity, finding 'active symptoms of mental illness' to strongly predict any violence in patients with schizophrenia. Active symptoms in patients with schizophrenia have also been found by additional studies (e.g. Swanson, Borum & Swartz, 1996; Van Dorn, Volavka & Johnson, 2012; Keers, Ullrich, DeStavola & Coid, 2014) and meta-analyses (Fazel, Gulati, Linsell, Geddes & Grann, 2009; Dack, et al, 2013) to be associated with an elevated risk of violence.

This area of literature can however be inconsistent. The MacArthur violence study (Monahan, Steadman, Silver et al, 2001) followed up 1136 patients discharged from psychiatric hospitals for a year, finding schizophrenia to be associated with a lower rate of violence than personality or adjustment disorders. Furthermore, positive symptoms (such as hallucinations and delusions) were found to have no association with violence. Although the study sampled community patients whose

symptoms are likely to be improved to forensic inpatients, findings nonetheless contrast with the structure of HCR20v3 which retains 'symptoms of major mental disorder' as a clinical item with a sub-item specifically serving psychotic disorder.

Alternatively, Swanson and colleagues (2006) followed up 1410 community patients with schizophrenia, finding positive symptoms to increase minor and serious violence whilst negative symptoms reduced serious violence. This is an important finding as it suggests that positive and negative symptoms may relate differently to violence and is concerning given that psychotic symptoms are considered as a complete phenomenon within HCR20v3. Furthermore, although other studies (e.g. Arango, Calcedo-Barba, Gonzalez-Salvador & Calcedo-Ordo, 1999; Steinert, 2002, Amore et al, 2008) have found positive symptoms to be associated with violence within civil-psychiatric settings, again, a lack of research exists around this relationship for forensic inpatients.

Research (Arango, et al, 1999; Buckley, Hrouda, Friedman, Noffsinger, Resnick & Camlin-Shingler, 2004) has also found poor insight to be associated with violence in patients with schizophrenia. Ekinci & Ekinci (2013) looked at 133 out-patients with schizophrenia, 47 of whom were violent and 86 non-violent. They found the non-violent group to have significantly higher insight than the violent group, with lower insight found to predict violence. Other studies (Yen, Yeh, Chen & Chung, 2002; Lincoln & Hodgins, 2008) failed to find this association prompting an incoherent argument for this relationship. As insight exists as item C1 in HCR20v3 it would be useful to gain further clarification of its relationship to violence in forensic inpatients with schizophrenia to whom the tool is regularly applied.

### **Summary**

The predictive validity of HCR20v2 was well established and showed acceptable predictive qualities with forensic inpatients, particularly through the C scale. HCR20v3 is yet to be validated in this population although is receiving support within community samples. This study hopes to contribute towards a missing evidence base for the application of HCR20v3 with forensic inpatients. Additionally, it remains useful to understand relationships between demographic variables and inpatient violence. However at present, these are unclear, with current research lending support to clinical variables. More specifically, in inpatients with schizophrenia, there is limited knowledge around relationships between positive symptoms, insight and violence. Of the studies that do exist, findings are varied which is problematic as clinicians consider these factors within HCR20v3. Therefore, this study also hopes to both understand the relevance of demographic variables in the prediction of forensic inpatient violence and to clarify the predictive abilities of positive symptoms and insight towards violence in forensic inpatients with schizophrenia.

## ***2) What is the principal research question?***



- i) Do HCR20v3 total and sub-scale scores predict inpatient violence?

*Hypothesis:* HCR20v3 total and clinical sub-scale scores will predict 'any violence'.

*Hypothesis:* HCR20v3 clinical sub-scale score will predict 'physical violence'.

**3) What are the secondary research questions?**

- ii) Do demographic variables of age, gender, previous violence, schizophrenia diagnosis and personality disorder diagnosis predict violence?

*Hypothesis:* Identified demographic variables will be associated with violence

*Hypothesis:* When considered within a logistic regression model, the identified variables will predict violence better than chance.

- iii) In a sub-sample of patients with schizophrenia do positive symptoms and insight predict violence?

*Hypothesis:* High levels of positive symptoms will be associated with violence.

*Hypothesis:* Lower levels of patient insight will be associated with violence

*Hypothesis:* When considered within a logistic regression model, higher levels of positive symptoms and lower levels of patient insight will predict violence better than chance.

**4) Please give a full summary of your design and methodology. It should be clear exactly what will happen at each stage of the project.**

**Methodology**

**Design**

This study will use a pseudo-prospective cohort design (Douglas, Otto, Desmarais & Borum, 2012) to investigate the predictive validity of HCR20v3 total and sub-scale scores in relation to violence in a sample of forensic inpatients. This design allows measures to be completed independently by patients' clinical teams who have no stake in the research, as per routine practice.

A pseudo-prospective design will also be used to investigate relationships between variables and violence within research question 2 (RQ2) and research question 3 (RQ3). For RQ3, a sub-sample of patients will be created by separating those with a diagnosis of schizophrenia from the sample as a whole.

The dichotomous dependent variable (DV) for all research questions is inpatient violence/non-violence.

Independent variables (IV) for RQ2: (1)Age (2)Gender (3)Previous Violence (4)Schizophrenia Disorder Diagnosis (5)Personality Disorder Diagnosis

IVs for RQ3: (1)Positive Symptoms (2)Insight

**5) Please list the principal inclusion and exclusion criteria**

Sample

Participants will be sampled from forensic inpatient facilities. Opportunistic sampling will be used whereby all patients managed within services at time of data collection will be included subject to the following criteria.

Inclusion:

- Male or Female aged 18+
- Diagnosed with or suspected to have a mental disorder in line with DSM V/ICD 10 criteria
- Has a completed HCR20v3<sup>14</sup> at time of data collection
- Inpatient within the same service for a minimum of 3 months after measure completion.

Exclusion:

- Any patient without a completed HCR20v3
- Any patient discharged from original service before follow-up of 3 months is complete.
- Any patient diagnosed with a learning disability

Setting

The study aims to sample from the following NHS environments;

- a) The State Hospital: A maximum security forensic hospital providing care and rehabilitation to patients with a mental disorder who have displayed violent or criminal high risk behaviours. All patients are detained under The Mental Health (Scotland) Act (2003). Patients are admitted from Scotland and Northern Ireland, from prisons, courts, lower levels of security and the community. The hospital currently has capacity for 132 patients.
- b) Rowanbank, Rohallion and Orchard Clinics: All are medium secure facilities for inpatients with mental health problems, who may have criminal histories and who are assessed to pose a risk of harm. Patients are detained by The Mental Health (Scotland) Act (2003) and admitted from community, prisons, courts, or from conditions of higher and lower security.

Each clinic serves a different region of Scotland; Rowanbank serves the West of Scotland and has 74 beds. Orchard serves the South and East of Scotland and has 50 beds. Rohallion serves the North of Scotland and has 67 beds. Rohallion contains two medium and three low secure wards, all of which will be sampled.

## **6) How will data be collected?**

### **Measures**

Similar to existing studies in the field, all data will be obtained from case files. As such, measures are carried out as per routine clinical practice or applied by the researcher based on file information.

HCR-20v3 (Douglas, Hart, Webster & Belfrage 2013).

HCR20v3 will be used to assess risk of violence. The instrument was developed to measure inpatient and community violence risk in persons over 18 with a history of violence and mental disorder. HCR20v3 is used for patients across all sites. The most recent HCR20v3 data for each patient will be used with follow-up commencing from the day after completion.

The tool assesses 20 violence risk factors derived from empirical research. As with v2, items are structured within 3 subscales: historical (10 items), clinical (5 items) and risk-management (5 items), for clarity, some items include sub-items. In clinical practice, items are rated in terms of presence (not present, partially present or present) and relevance (low, moderate or high). A summary judgement of low, medium or high overall risk is also made. In this study, the focus will solely be on presence ratings which for research purposes, are rated as 0=not present, 1=partially present and 2=present.

Doyle, et al, (2014) found v3 to have good intra-class reliability with coefficients of .92 (total score), .91 (H), .90 (C) and .93 (R). Concurrent validity of v3 to v2 showed good correlation at .85 (total score), .87 (H), .76 (C), and .67 (R), whilst inter-rater reliability for presence ratings was found to be excellent. (Douglas & Belfrage, 2014).

### **Demographics**

For every patient, demographic information relating to age, gender and diagnosis (as recorded by patients' consultant psychiatrist) will be collected from case files.

The Violence Rating Scale (VRS; Robertson, Taylor & Gunn, 1987).

Previous violence will be rated for all patients by the researcher using the VRS, based on file information. The VRS firstly produces a rating for index offence ranging from 0 (completely non-violent) to 4 (severe violence wherein the victim died or life was endangered). Secondly, it produces a

violence record rating ranging from 0 (never being convicted of violence and never getting into fights) to 4 (one or more severely violent episodes in which someone's life or health has been endangered). Lastly, sub-scale scores are summed to create a total previous violence score.

The VRS has highly significant inter-rater reliability,  $R_s=.095$  (index offence),  $.82$  (previous violence record) and  $.85$  (total score) (Wong, Lumsden, Fenton & Fenwick, 1993).

*The Psychosis Evaluation Tool for Common Use by Caregivers-Revised* (PECC-R; DeHert, Bussels, Lindstrom et al, 1998)

An approved shortened version of the PECC, PECC-R will be used to measure positive symptoms. PECC-R is used as per routine nursing assessment within The State Hospital and Rohallion and will only be available for patients within these sites. The most recent PECC-R data for each patient will be used. The measure provides a brief impression of mental state in patients with psychosis, measuring four positive symptoms, one negative and three depressive symptoms alongside ratings on suicidal ideation and insight. This study will utilise only the positive symptom scale which PECC-R retains in full from the original PECC.

The positive symptom scale assesses 4 symptoms; hallucinations, delusions, grandiosity and thought disorder. After interviewing the patient, each symptom is rated by the assessor on a scale from 1 (absence of symptom) to 7 (symptom present for more than 50% of the time with a severe impact on functioning). Symptom scores are summed to produce a positive symptom sub-scale score, a higher score indicating greater symptom presence and impairment on functioning.

DeHert, et al, (2002) found good inter-rater reliability of the PECC across all symptom categories with agreement never falling below  $r=0.80$ . Concurrent validity of PECC positive and negative symptom scales was also tested against the PANSS with a pairwise correlation of  $r=0.95$  found between total scores.

*The Behavioural Status Index (BEST-INDEX; Woods, Reed & Robinson, 1999)*

The BEST-INDEX will be used to measure insight in patients with schizophrenia. The scale is used as part of routine nursing assessment within The State Hospital and Rohallion and will only be available for patients within these sites. The most recent BEST-Index data available for each patient will be used. BEST-Index measures 'social risk' of dangerous and violent behaviours through three subscales:

- risk and probability (20 items)
- insight (20 items)

- communication and social skills (30 items)

After engaging patients in at least a 30 minute conversation about their difficulties, items are rated from 1 (worst case) to 5 (best case). A higher sub-scale score indicates a more socially adaptive performance. Sub-scales can be combined to produce a total score or considered independently. This study will only utilise data from the insight sub-scale.

The insight sub-scale has good reliability with all items correlating highly  $p < 0.001$  and  $R_s = 0.843$  for test re-test. Inter-rater reliability of the subscale with  $N = 37$  was acceptable at  $p = 0.82$  (Wood & Reed, 1998)

### Inpatient Violence

Violence will be considered with respect to Douglas et al's, (2013; pg. 36) definition as "*the actual, attempted or threatened infliction of bodily harm on another person*". This study will therefore include verbal aggression serious enough to warrant a DATIX entry as violence. Including verbal aggression is in accordance with similar studies (e.g. O'Shea et al, 2014) and aims to allow optimum data collection with the knowledge of difficulties that may arise with violence base rates within secure environments.

#### iii) DATIX

Violent incidents will be recorded by nursing staff on DATIX electronic system which is used across sites. DATIX is an industry leading software for the recording of adverse events within healthcare settings.

#### iv) Overt Aggression Scale (OAS; Yudofsky, Silver, Jackson, Endicott & Williams, 1986)

The OAS will be used to code violent incidents extracted from DATIX. Designed to measure violence in adults and children, the OAS is frequently applied within violence research to enable standardised coding. The OAS divides violence into 4 categories; verbal aggression, physical aggression against objects, physical aggression against self and physical aggression against others. As this study is interested in interpersonal violence, the 'physical aggression against self' category will not be utilised. Violence will therefore be coded and rated on severity from 1 (least severe) to 4 (most severe) as follows:

- Verbal Aggression: 1= angry shouting, 4= making clear threats of violence towards others
- Physical Aggression Against Objects: 1= slamming doors, 4= fire setting.
- Physical Aggression Against Others: 1=swings for others and clothing grabs, 4=attack resulting in severe physical injury

O'Shea et al, (2014) found excellent agreement in OAS ratings between three researchers on a sample of 260 incidents with  $K = .91$  (aggression category) and  $K = .90$  (aggression severity).

For analysis, violence will be reduced to 2 categories;

- 'Any violence' including verbal aggression, physical aggression against objects and physical aggression towards others
- 'Physical violence towards others'.

Patients will then be dichotomised as 'violent' or 'non-violent' within these categories.

### **Procedure**

*Period 1:* With the aid of research contacts within each site, available cases will be identified by the researcher and accessed through files or electronic databases. A confidential enquiry approach will be taken to data collection meaning that to ensure minimum disruption to care, the researcher will have no direct contact with patients.

All cases will be screened to ensure inclusion criteria is met and reviewed to collect the following:

- d) HCR20v3 data
- e) Demographic data; age, gender, diagnoses, previous violence.
- f) PECC-R and BEST-Index scores.

*Period 2:* Violent incidents will be collected by accessing sites' DATIX systems. Violence data will be collected within a minimum of 3 and a maximum of 12 months following date of HCR20v3/PECC-R/BEST-Index completion. A maximum follow-up of 12 months will be applied due to these assessments being updated at least annually by services sampled. This is also in line with the knowledge that predictive validity of dynamic measures decreases over time (Doyle et al, 2014).

### **Ethical Considerations**

This study is under development in accordance with the British Psychological Society's 'Code of Human Research Ethics' (2010) and the researcher intends to gain NHS multi-site ethical and R&D approval. Approval from the public benefit and privacy panel for health and social care (previously known as national caldicott) will also be sought to access patient files across health-boards. Preliminary discussions suggest that individual patient consent is unlikely to be required.

Due to the fact the researcher does not require direct patient contact, the risk of harm posed towards them appears minimal. Alternatively, the researcher may be at increased risk of harm due to exposure to a high volume of information relating to violence. The researcher will however be appropriately trained in HCR20v3 assessment and intends to utilise supervision throughout the study to ensure well-being.

### **Management of Patient Data**

Record sheets<sup>15</sup> will be used to aid data collection, each will contain unique identification numbers (UIDNs) relevant to patients whose data the records hold. A second form will contain patient initials and corresponding UIDNs. Pairs of initials and UIDNs are required to match patients with follow-up violence data and for identification of patients for inter-rater reliability. When not in use, the form containing UIDNs and initials will be stored within a locked filing cabinet within the researcher's base, separate from study materials. This form will be destroyed when inter-rater reliability samples are identified and violence follow-up data matched.

Record sheets will be stored securely within a different filing cabinet in the researcher's base. No descriptive evidence will be noted, with information existing on sheets in code incomprehensible to lay persons. The only exception to coding will be age however, this will change over the course of study. For analysis, information from record sheets will be transferred onto SPSS where cases will be marked only by UIDNs. SPSS will be password protected and stored on a secure network drive only accessible to the researcher. Record sheets will be destroyed when statistical analysis is complete.

Findings will be reported anonymously, at group level. Broad categories will be applied when reporting demographic information and findings of low frequency will be amalgamated.

***7) Please describe the methods of analysis by which the data will be evaluated to meet the study objectives.***

All statistical analysis will be conducted using SPSS for Windows

Inter-Rater Reliability of Researcher Ratings: VRS ratings and violence categorisation using the OAS will be assessed using Cohen's Kappa (Cohen, 1960). To allow for this, a sample of cases rated by the researcher will be rated independently by a forensic-clinical psychologist. This sample will be selected through random number tables (Coolican, 1999).

Reliability of DATIX: To assess the reliability of violent incidents extracted from DATIX, the researcher and forensic-clinical psychologist will compare a sample of incidents from DATIX with nursing records of the same incidents. Where disagreement exists between records and DATIX output, this will be discussed between researchers to reach a consensus regarding OAS categorisation.

One way ANOVAs: will be used to identify differences between patients across sites in terms of rates of violence and clinical/demographic characteristics. This will be carried out to provide justification for combining patients from all sites for subsequent analyses.

RQ 1 Analysis: Receiver operating characteristics (ROC) using area under the curve (AUC) scores will be used to determine the predictive validity of HCR20v3 total and sub-scale scores with regards to both 'any violence' and 'physical violence'. ROC is recommended for use within violence research as it does not rely on base rates to the same extent as alternative models (Mossman, 1994). As violence base rates may be lower within secure settings due to risk management, this analysis is most suitable.

Differences between violent and non-violent groups in terms of HCR20v3 scale means and demographic variables for both violence types will be obtained through independent samples t-tests for continuous variables and chi-squares for categorical variables.

RQ2 Analysis: Pearson's Chi-squares for categorical variables and point-biserial correlations for continuous variables, will be used to determine relationships between IVs and the dichotomous DV of violence/non-violence for both violence types.

Logistic regression will be used to estimate the likelihood that a patient will be correctly categorised as violent or non-violent given the inclusion of identified demographic IVs. Through the forced entry method, the model will include IVs which correlations found to be significantly associated with violence. Logistic regression models will be created for both types of violence.

RQ3 Analysis: Point-biserial correlations will be used to identify relationships between positive symptoms and insight with violence/non-violence for both violence types, for the identified sub-sample of patients.

Logistic regression will be used to estimate the likelihood that a patient will be correctly categorised as violent or non-violent given the inclusion of positive symptoms and insight. Assuming significant relationships exist, this will be carried out through the forced entry method with models created for both types of violence.

***8) What sample size is needed for the research and how did you determine this?***

Sample size was calculated based on recommendations of power set at 0.80, alpha of 0.05 and medium effect sizes (Field, 2014).

ROC Analyses: MedCalc was used for ROC sample size calculation. The system requires input in the form of alpha, power and expected ratio of cases in non-violent and violent groups. Studies which used ROC with populations similar to the proposed were referenced to derive violence ratios. As studies varied between equally sized groups and larger samples of non-violent patients, sample size calculation for both possibilities was undertaken.



For equally sized groups, 27 cases in each is needed. For a ratio of 2:1 in favour of non-violence, 42 cases are required in the non-violent group with 21 needed in the violent group. 63 is therefore a minimum sample size for RQ1.

Correlation Analyses: Sample size estimation for chi-squares was derived from guidelines which suggest that frequencies for each variable must be greater than 5 (Field, 2014). G\*Power was used to estimate required sample size for point-biserial correlations which was 82.

Logistic Regression: Work by Peduzzi, Concato, Kemper, Holford & Feinstein (1996) suggests that sample size in logistic regression depends on number of predictor variables, number of cases per predictor and estimated proportion of negative and positive cases in the sample. As correlations are not yet known, sample size has been calculated using Peduzzi et al, (1996) formula based on the maximum number of predictors and the smallest estimated event proportion of non-violent and violent cases. In line with previous research, calculation is based on an estimate of 30% of cases engaging in 'physical violence'. Sample size calculation for the 'any violence' model is not required as event proportions for this are expected to be higher thus requiring a smaller sample.

Minimum sample size for RQ2 based on 5 predictors is 166. Minimum sample size for RQ3 based on 2 predictors is 66, however, taking Long's (1997) recommendations into account this is increased to 100.

***9) Outline reasons for your confidence in being able to achieve a sample of at least this size.***

**Available Sample**

Available sample is estimated in accordance with information received from research contacts with the acknowledgement that sites are unlikely to be at full capacity during the study. Whilst taking account of exclusion criteria, it is estimated currently, that The State Hospital has 120 patients available and suitable for inclusion, Rowanbank has 60, Orchard has 40 and Rohallion has 45, giving a current estimate of 265.

Specifically, RQ1 requires a minimum of 63 patients to have an HCR20v3. Although HCR20v3 is currently in use across all sites, as this is a new tool, the changeover from v2 is still taking place. It should therefore be taken into account that a minority of patients may not have v3 by time of data collection. The researcher is however confident that well above the minimum sample will be achieved based on the following:

- All sites are currently implementing v3 as a replacement to v2 in clinical practice.
- Rowanbank, Rohallion and Orchard Clinics began using v3 in 2014. The State Hospital transferred to v3 in July 2015.

- HCR20 updates take place at least annually for all patients across sites
- Data collection will begin in November 2015, allowing time for additional v3s to be completed.
- The duration of data collection (12 months) allows for additional v3 completion and collection.

RQ2 requires a minimum sample of 166 which can be achieved from the available 265 cases.

RQ3 requires a minimum sub-sample of 100 patients with schizophrenia and PECC-R/BEST-Index scales. Both The State Hospital and Rohallion estimate that around 70% of their population have this diagnosis and confirmed that all of these patients are assessed by PECC-R/BEST-Index as per routine nursing practice, with data available to the researcher. Therefore, around 120 cases between The State Hospital and Rohallion are available of which the minimum sample of 100 can be gained.

**10) Outline a timetable for completion of key stages of the project.**

Activity	Start	End	Time Frame in Months	Information
Complete Proposal	August 2015	October 2015	2	Carry out required changes.
Ethics, Research & Development	July 2015	October 2015	3	Complete paperwork for multi-site IRAS, national Cauldicott and R&D approval. Attend relevant meetings.
Systematic Review	October 2015	March 2016	5	Submit drafts for review, prepare for publication.
Data Collection	November 2015	November 2016	12	Visit sites on study days.
Data Analysis	December 2016	February 2017	2	Carry-out analyses, interpret and write up
Write Up	July 2016	April 2017	9	Provide drafts to supervisor. Have article ready to add results and discussion in February '17.
Hand-In	-	May 2017	-	-

**11) Please summarise the main potential risks to your study, the perceived likelihood of occurrence of these risks and any steps you will or have taken to reduce these risks. Outline how you will respond to identified risks if they should occur.**

1. Whilst the researcher intends to collect HCR20v3 data, there is a risk that this will not be available for all patients, although discussions with research contacts indicate that all patients will have v2 data at least. If HCR20v3's are unavailable to the detriment of sample size, the researcher intends to create v3 ratings based on information available within v2. This seems a reasonable adjustment as not only will the researcher be fully trained in v3 but developers of both tools state that v3 does not differ significantly from v2, "*Indeed, we believe that v3 can be used in much the same way as v2 has come to be used ...*" (Douglas et al, 2014, pg. 95). Moreover, authors of published studies (e.g. Strub et al, 2014) have themselves created HCR20v3 assessments before collating ratings and as such this is an accepted methodology. Inter-rater reliability will be carried-out to ensure agreement on researcher-made ratings and if information is required for v3 and missing from v2 beyond the remits of pro-rating guidelines (Douglas, et al, 2013), the case will be excluded from analysis.
2. There is a low risk that the study will not recruit enough patients to conduct adequately powered logistic regression within the sub-sample required for RQ3. However, provided sample size estimates are conservative. Furthermore, admissions and discharges to The State Hospital are currently stable with 43 discharges and 42 admissions over the 2013/2014 period (TSH, 2015). Whereas as a newly opened site, Rohallion has an increasing population. Lastly, the flexible follow-up period (3-12 months) aims to allow patients to be discharged without data loss and to include data from patients admitted during the data collection process.

**12) How do you intend to report and disseminate the results of the study?**

Dissemination

The study will be submitted to the University of Edinburgh to contribute towards the qualification of Doctorate in Clinical Psychology. Both a systematic review and a journal article will be prepared which the researcher intends to submit to a high quality journal for publication.

A written summary of findings will be disseminated to NHS boards who took part in the research. Boards will also have access to the systematic review and journal article. The researcher intends to present findings at The State Hospital research day aswell as applying to present at the BPS Forensic Psychology Conference. Finally, the study will be submitted to The Scottish Forensic Network for dissemination and forwarded to the authors of HCR20v3 to provide further information on validation.

### ***13) What are the anticipated benefits or implications for services of the project?***

The NHS has a duty of care to protect patients and staff from harm, however inpatient violence remains common within forensic settings. With relevance to the proposed sample, The State Hospital endured 709 aggressive incidents over the 2013/2014 period (TSH, 2015) subsequently, duty of care was frequently challenged. By validating HCR20v3 within forensic inpatient settings and building an evidence base for its application, this study aims to improve violence prediction, reduce risk and thereby strengthen duty of care. A further benefit may be the study's contribution to HCR20v3 evidence base more generally. HCR20v2 was the most frequently used SPJ tool available (Singh, 2013) and for similar success, HCR20v3 requires to be validated within different patient populations and settings.

This study could also be beneficial for psychological research as it investigates behaviour of a population who are difficult to sample and under-researched. Due to the uniqueness of forensic inpatients, it does not seem valid to generalise findings from community and civil-psychiatric samples, however owing to a lack of research, this is frequently done. To improve upon this, this study will demonstrate a methodology by which this population can be adequately researched, using existing data which holds face validity to care and treatment.

Lastly, due to a focus on variables existing within two key HCR20v3 items: symptoms of major mental disorder and insight, findings may hold implications for development of future HCR20 tools. Within 'symptoms of major mental disorder' in particular, the relationship between positive symptoms and inpatient violence is unclear. Should this study find a positive relationship between variables, it could provide an argument for further consideration of positive symptoms within the HCR20. At the moment, lack of clarity regarding variables implicated within HCR20v3 items is concerning given the serious consequences of risk misjudgement. When under-estimated, misjudgement can be dangerous, yet it can also be problematic when over-estimated. The Mental Health (Scotland) Act (2003) states that patients should be managed under least restrictive conditions, however when risk is over-estimated this violates the act and is disadvantageous to recovery. As such, should the null hypothesis be accepted with no relationships found between variables and violence these may also be useful findings for the field to consider.

## Appendix 12: DATIX Categories

Direct Patient Care	Health & Safety	Security	Equipment/Facilities/Property	Infection Control	Communication/Information Governance	Other
<b><u>Medicine Prescribing Incident</u></b>	<b><u>Assault</u></b> pt to pt pt to staff	<b><u>Control of Patients Whereabouts</u></b> Escape	<b><u>Damage</u></b> Deliberate Accidental	<b><u>Clinical Waste</u></b> Other	<b><u>Media Article</u></b> Patient related (general) Organisational issue	<b><u>Adult Support and Protection</u></b>
<b><u>Supply Incident</u></b>	pt to carer/visitor/contractor Carer to carer	Attempted Escape	<b><u>Theft</u></b>	<b><u>Exposure to Bodily Fluids</u></b> Exposure to blood	<b><u>Communication Breakdown</u></b>	<b><u>Child Protection</u></b>
<b><u>Administration Incident</u></b>	Carer/visitor to patient Carer/visitor to staff	Abscond Attempted Abscond	<b><u>Equipment Malfunction</u></b>	Vomit Faeces	Between staff/departments	<b><u>Discrimination</u></b> Sexual orientation
<b><u>Medication Other</u></b>	Staff to patient	Attempt to flee from Staff or locked area	PAA Radio	Urine Spit	Between hospital and carers	Gender Age
<b><u>Failure/Delay/Error</u></b>	<b><u>Behaviour</u></b> Incitement	<b><u>Internal disruption</u></b> Hostage Taking	User Error	<b><u>Needlestick</u></b> Other	Between hospital and external agencies	Race/Ethnicity Religion/Faith Disability
Delayed discharge	Threatening/Intimidating	Attempt to take hostage	<b><u>Lack of adequate equipment/facilities</u></b>	<b><u>Outbreak</u></b> Suspected Outbreak	<b><u>Breach of Patient Confidentiality</u></b>	Marriage/Civil Partnership Pregnancy
Failure to obtain informed consent	Withdrawn	Concerted indiscipline	<b><u>Wrong device/equipment used</u></b>	Actual Outbreak	Email	
Sample Labelling Issue	Destructive	Rooftop Protest	<b><u>Service</u></b>	Other	Mail Printer	<b><u>Mishandling Patient Property</u></b>
Failure/delay in clinician attending	Harassment	Room barricade	Major loss of service	<b><u>Patient suspected contagious illness</u></b> Minor illness	Telephone	<b><u>Radicalisation</u></b>
	Other	High value intentional damage to property	Service disruption	Vomit/Diarrhoea	Other	<b><u>Exploitation</u></b>
<b><u>Self harming behaviour</u></b>	<b><u>Verbal Aggression/Abuse</u></b> pt to pt	<b><u>Keys</u></b> Security key compromise	Other	Other	<b><u>Breach of Staff Confidentiality</u></b>	<b><u>Staff Resource Issues</u></b>
Self harm	pt to staff	Key making	<b><u>Loss/Damage of IT Mobile Device</u></b>	<b><u>Staff suspected contagious illness</u></b>	Email Mail Printer	Loss of Staff Lack of PAA responder
Suspected suicide (actual)	pt to carer/contractor/visitor	Non security key compromise	Smart phone	Minor illness	Telephone	
Suspected suicide (attempted)	Carer to carer	<b><u>Weapons</u></b> Weapon making or discovery	CD's/Disks	Vomit/Diarrhoea	Other	<b><u>Other</u></b>
Threat of self harming behaviour	Carer to patient	<b><u>Breaches</u></b> Security breach	USB Pen	Other	<b><u>Documentation</u></b>	
	Carer to staff		Laptop	<b><u>Other</u></b>	Not provided	
<b><u>Patient death</u></b>	Staff to patient		Other	Other	Incomplete	
<b><u>Patient Physically Unwell</u></b>	<b><u>Sexual</u></b> Inappropriate behaviour/contact		<b><u>Other</u></b>		Lost/missing	
Emergency requiring Resusc. Nurse attendance / ambulance	Inappropriate conversation				Inaccurate	
Non-emergency admission to hospital	Sexual harassment					
Medical advice / NHS 24	Attempted sexual assault					
Collapse / seizure	Sexual assault					
Minor Illness	Other				<b><u>Other</u></b>	

<p>Choking</p> <p><b><u>Suspension of Detention</u></b></p> <p>Cancelled – patient unwell/refused</p> <p>Cancelled – staff unavailable</p> <p>Cancelled – weather</p> <p>Cancelled – other</p> <p>Outing terminated prematurely</p> <p>Unexplained injury</p> <p><b><u>Other</u></b></p>	<p><b><u>Slip, Trip, Fall</u></b></p> <p>On same level</p> <p>Due to spillage</p> <p>Fall from height – bed/chair/</p> <p>Responding to PAA</p> <p>No harm/injury</p> <p>Other</p> <p><b><u>Medical Emergency (Non-Patient)</u></b></p> <p>Emergency requiring Resus Nurse attendance</p> <p>Person unwell/collapse</p> <p>Other</p> <p><b><u>Moving &amp; Handling</u></b></p> <p>Lifting/handling/carrying (pt related)</p> <p>Lifting/handling/carrying (not pt related)</p> <p>Restraint</p> <p>Other</p> <p><b><u>Staff/Patient Injury</u></b></p> <p>Sports</p> <p>Training</p> <p><b><u>Exposure</u></b></p>	<p>Security compromise</p> <p>Loss of Item</p> <p><b><u>Substances</u></b></p> <p>Illicit substances</p> <p><b><u>Threats</u></b></p> <p>Threats</p> <p><b><u>Prohibited or Restricted Items</u></b></p> <p>Any Prohibited or restricted item found within the secure perimeter</p> <p><b><u>Service Disruption</u></b></p> <p>Disruption to service</p> <p><b><u>Other</u></b></p>				
<b><u>Additional Information Menu</u></b>						

	<p>COSHH</p> <p>Exposure to fire/explosion</p> <p>Exposure to radiation</p> <p>Exposure to hot/cold</p> <p><b><u>Contact</u></b></p> <p>Contact with electricity</p> <p>Cut with sharp material object (not sharps)</p> <p>Contact with moving machinery/ equipment</p> <p>Other</p> <p><b><u>Struck</u></b></p> <p>Against something (stationary)</p> <p>By moving, falling object</p> <p>By/in moving vehicle</p> <p>Trapped by something</p> <p>Other</p> <p><b><u>Fire</u></b></p> <p>Fire Requiring Emergency Services</p> <p>False Alarm</p> <p>Other</p> <p><b><u>Injured by animal</u></b></p> <p><b><u>Other</u></b></p>	<p><b><u>BREAKAWAY</u></b></p> <p>Release from bear hug (held from behind)</p> <p>Release from bite</p> <p>Release from clothing/lapel grab</p> <p>Release from hair grab</p> <p>Defence against kicks</p> <p>Not applicable</p> <p>Other please specify in action taken</p> <p>Defence against punches</p> <p>Rail removal</p> <p>Release from sexual assault</p> <p>Release from side head lock</p> <p>release from strangle hold (on ground)</p> <p>release from strangle hold (standing)</p> <p>Release from upper arm grab</p> <p>Defence against wrist grabs</p> <p><b><u>PPE</u></b></p> <p>Bite Proof Gloves</p> <p>Goggles</p> <p>Not applicable</p> <p>PPE not available</p> <p>Protective Suits</p> <p>Shoe Protectors</p> <p>Sleeve Protectors</p> <p><b><u>INFECTION CONTROL</u></b></p> <p>Clinical Waste</p> <p>Exposure to Blood</p> <p>Exposure to Bodily Fluids</p> <p>Faeces</p> <p>Needlestick</p> <p>Not applicable</p> <p>Outbreak</p> <p>Spitting</p>	<p><b><u>SECURE HOLDS</u></b></p> <p>Clothing removal (i.e. strip search)</p> <p>Controlled take down in straight arm hold</p> <p>Controlled take down in full thumb wrist locks</p> <p>Floor restraint (patient held face down)</p> <p>Floor restraint (patient held face up)</p> <p>Full thumb wrist locks</p> <p>Goose neck (i.e. wrist flexion without full thumb wrist locks)</p> <p>In transport – full thumb wrist locks</p> <p>Leg controls applied</p> <p>Mechanical Restraint</p> <p>Not applicable</p> <p>Patient removal/relocation</p> <p>Please specify in action taken</p> <p>Restrained while sitting</p> <p>Straight arm hold (i.e. elbow locked out)</p> <p><b><u>NON-SECURE HOLDS</u></b></p> <p>Not applicable</p> <p>Other please specify in action taken</p> <p>Upper arm holds</p> <p>Used to escort a patient away from an incidents/ area</p> <p>Wrist/lower arm hold (without wrist flexion)</p>
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