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Patient Characteristics related to Length of Stay in a UK Forensic Inpatient Sample: A Systematic Review

&

Examining the Validity of the CORE-OM as a Measure of Distress in a Forensic Population with Severe and Enduring Mental Illness

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Doctorate in Clinical Psychology

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Total Word Count: 19,709 (excluding references and appendices)
1. Thesis Abstract

Introduction
There is concern that individuals may experience prolonged stays in secure inpatient settings, and research highlights little convergence on factors associated with length of stay in the forensic inpatient population. Routine outcome measures are valuable in monitoring patient progress, including patient self-report measures such as the Clinical Outcomes in Routine Monitoring – Outcome Measure (CORE-OM). Research regarding use of the CORE-OM in UK forensic settings is limited. Previous research found CORE-OM scores for this population fell below clinical cut-offs; the reasons for which have not yet been examined. A systematic review was conducted to identify patient factors associated with length of stay in UK medium and high secure settings. An empirical study investigated the validity of the CORE-OM in a high secure setting, examining whether poor insight is associated with low self-report distress, as measured by the CORE-OM, and whether the CORE-OM can adequately capture distress arising from psychotic experience.

Method
A systematic search of studies investigating factors associated with length of stay in UK secure settings, between 2000 and 2020, was conducted. Eight studies from combined search results of 4738 articles, met inclusion criteria. Included studies were subject to full-text review. Quality assessment was subject to two independent ratings. In the empirical study, routinely collected CORE-OM and two measures of insight and symptomatology were retrospectively extracted from case files for 246 males in high secure inpatient care.

Results
The systematic review found a diagnosis of schizophrenia, previous psychiatric and forensic admissions, admission from other secure or prison settings, and Section 37/41 under the Mental Health Act (MHA) were significantly associated with longer stays in secure care. However, significant methodological weaknesses and variability defining ‘long-stay’ were present across studies. The empirical study found symptom subscales significantly predicted CORE-OM all item mean scores. Poor insight
predicted higher self-report distress on CORE-OM all item mean scores and did not mediate the relationship between symptomatology and distress (CORE-OM). Cut-off scores fell below clinical reference samples and revised normative scores are provided for a male high secure population.

**Discussion**

The systematic review found mixed evidence regarding factors associated with length of stay in forensic secure settings, with clinical variables and MHA status providing the most consistent associations with length of stay. Research in high secure settings and with other samples out with England are urgently required to increase generalisability. Future research should focus on standardisation of predictor variables and prospectively designed studies that incorporate factors beyond static variables, including patient self-report measures and dynamic variables. Long-stay definitions should be considered in line with policy changes. The empirical study found the CORE-OM is sensitive to changes in clinician-rated symptomatology. Mean CORE-OM scores were below clinical reference samples in the community and revised normative scores for a high secure forensic sample are provided. Insight did not explain low self-report as poor insight predicted greater distress on CORE-OM scores. Future research considering factors associated with change in CORE-OM scores over time is recommended to investigate the symptoms-insight-distress interactions across the patient journey.

**Total Word Count:** 20,380 *(excluding references and appendices)*
2. Lay Summary

Introduction
Forensic patients stay in secure inpatient services longer than patients in community inpatient services. There are concerns that some forensic patients stay for longer periods of time than they require. There may be particular reasons associated with a longer length of stay for forensic inpatients. Identifying them would help shape what treatments patients receive and how to help them move on to other services, but these reasons are not well known. The first part of this thesis aimed to explore reasons related to long stays for forensic inpatients in the UK. One way that services monitor how patients are progressing is through patients completing questionnaires, looking at different aspects of their mental health. One of the most common measures is the Clinical Outcomes in Routine Monitoring – Outcome Measure (CORE-OM) which is a questionnaire patient’s complete, looking at how distressed they have been in the last week. However, forensic inpatients seem to report very little distress, less than people in the community attending mental health services and similar to people in the community who do not experience any mental health issues. A lot of patients in secure settings have a diagnosis of schizophrenia. Schizophrenia is a mental health condition where people may see, hear, or believe things that are not real. If patients have poor insight this can make it difficult to correctly tell what is reality and what is a symptom of their mental health. This may be one reason why patients report little distress. The CORE-OM was not made specifically for people with a diagnosis of schizophrenia so it may not pick up what they are experiencing. The second part of this thesis aimed to look at whether the CORE-OM is a suitable measure for forensic inpatients given these reasons.

Methods
The first part of this thesis involved identifying all studies that looked at reasons for longer stays in forensic inpatient services in the UK. It also looked at whether these studies were of good quality and conducted well, as this can impact how reliable their findings are. The second part of the thesis collected CORE-OM measures and measures which looked at insight, and symptoms that people with schizophrenia
experience. These measures were already completed by patients in a high secure hospital and were collected for this study.

**Main findings**

The first part of the thesis found that having a diagnosis of schizophrenia, being previously admitted as inpatient in the community or secure settings, being transferred from other secure or prison settings, or being placed under a hospital order with restrictions under the Mental Health Act, were some reasons related to longer stays for forensic inpatients. However, the studies were not of good quality making these results less reliable. The second part of the thesis found that the CORE-OM did pick up on changes in symptoms that people with schizophrenia experience. Instead of finding that poor insight led to low distress, this thesis found poor insight led to higher distress. The patients in this study reported low distress levels on the CORE-OM like studies before.

**Discussion**

The first part of this thesis found mixed evidence for reasons for longer stays in forensic secure settings, although clinical reasons i.e. schizophrenia diagnosis, and section under the mental health act were the most consistent reasons for a longer stay. Research in other UK countries is needed as all studies were conducted in England. Studies also need to pre-agree a definition of ‘long-stay’ and what data to collect to be more consistent, and include more data looking at different aspects of patient's mental health and care. The second part of this thesis found the CORE-OM does pick up on changes in symptoms in schizophrenia. However, forensic inpatients did still report lower distress than would be anticipated and poor insight did not explain this. This study looked at one point in time. Future research should look at how distress on the CORE-OM and insight and symptoms change over time.
3. **Systematic Literature Review**: Patient Characteristics related to Length of Stay in a UK Forensic Inpatient Sample: A Systematic Review

3.1. **Abstract**

**Introduction**: There are concerns regarding excessively long-stays in forensic inpatient settings. This review aimed to identify patient factors associated with length of stay in UK medium and high secure settings.

**Method**: A systematic search of studies was carried out using Embase, Medline, PsycInfo, CINAHL Plus. Papers using sampling timeframes between 2000-2020 were included. From combined search results of 4738 articles, 8 studies met inclusion criteria and underwent full-text review and quality assessment.

**Results**: Diagnosis of schizophrenia, previous psychiatric and forensic admissions, admission from secure or prison settings, and Section 37/41 orders, were significantly associated with longer stays. Studies were limited by weaknesses in study design, definitions of predictor variables, and statistical reporting. There was variability in defining ‘long-stay’. Studies were limited by using pre-existing data collected for alternative purposes.

**Discussion**: There is mixed evidence regarding factors associated with length of stay in a forensic population. Future studies should utilise the definition provided by Völlm et al. (2017) of greater than five years in medium secure, ten years in high secure, or fifteen years in a combination of continuous high and medium secure care to identify long-stay patients. Standardised characteristics associated to length of stay are recommended to reduce variability. Prospectively designed studies of good methodological quality, conducted across the UK, are required to increase our knowledge of the evidence base.

**Keywords**: length of stay (LoS); forensic mental health; systematic review

**Word Count**: 9695

**Word Count**: 7591 (excluding abstract, tables/figures, references, and appendices)
3.2. **Introduction**

3.2.1. **Background**

The aims of forensic services are two-fold: patient care and treatment; and protection of the public by reducing risk of harm from the offender (Völlm, Bartlett, & McDonald, 2016). This is a balancing act, with often incompatible responsibilities towards the patient, public, and wider organisation, through tensions between treatment and security requirements (Holley, Weaver, & Völlm, 2020; McKenna et al., 1999). As the duration of such hospitalisation is not fixed, this has implications for patient’s length of stay (LoS); with concern that forensic patients may risk spending lengthy periods in secure hospital care (Davoren et al., 2015; Paweł et al., 2021). The importance of reducing prolonged stays was first acknowledged in the 1970s in both the Glancy Report and Butler Report (Butler Committee, 1975; Department of Health and Social Security, 1974).

Research suggests LoS is associated with security level, with higher levels of security resulting in longer stays (Sharma et al., 2015). Care was not individualised based on security needs until the Reed report (1993), which prompted the first needs assessment of forensic inpatients in the UK (O’Neill et al., 2003). Previously, inpatients resided in large asylums without appropriately tailored treatment or security (Eastman, 1993). In 1990, Taylor et al. surveyed three high security hospitals, concluding that 59% of patients did not require detention within maximum security. Shaw, Davies, and Morey (2001) found that only 22% of high secure patients were considered appropriately placed. The Reed Report (1993) emphasised the requirement for medium secure units to help bridge the gap between security levels, meet service demands, and reduce delayed movement to more appropriate settings. This paper was considered a landmark document for policy change in secure care (Lart et al., 1999); medium secure units now deliver the most inpatient care in the UK by number of beds (Centre for Mental Health, 2011). ‘Payment by results’ systems were also introduced to decrease LoS using financial incentives in England & Wales. This led to reductions in high secure beds and increased provision within medium and low secure services (Davoren et al., 2015). However, despite such reductions, the overall number of patients detained in secure care and the level of restriction in medium secure
settings has risen (Völlm, 2019); more so for forensic than general psychiatry (Sharma et al., 2015), with the patient population rising by 45% between 1996 and 2006 (Rutherford & Duggan, 2008).

Currently, forensic LoS notably exceeds general psychiatric care (Sharma et al., 2015). LoS has increased across medium and high secure hospitals, with trends for patients to stay for five years or more, and approximately one third deemed as requiring ‘long-term’ care (Melzer et al., 2004; Rutherford & Duggan, 2008). Across several Western countries, LoS varied between four to eight years, however, the range varied from three months in some countries to ten years in others (Sampson et al., 2016). A study by Earnshaw and colleagues (2019) compared lengths of admission in a medium secure unit across three decades. Median LoS increased over time, with an averaging 508±453 days in 2012 compared to 167±299 in 1985. However, fewer medium secure units existed in comparison to the number of units in 2012. Forensic patients present with complex psychopathologies often complicated by trauma, entrenched violence histories, and comorbid psychiatric disorders including substance misuse (Ogloff et al., 2015). They have risk needs and are often subject to additional restriction orders which make moving to lesser security and into the community more difficult (Völlm et al., 2018).

Unfortunately, there is no currently accepted, standard definition of ‘long-stay’ in forensic settings (Völlm, 2019), and there are many ways long-stay is operationalised in research. For example, Earnshaw and colleagues (2019) found fewer patients were being discharged back into the community (13% in 2012). They were instead transferred across secure care, suggesting LoS could be further inflated using a cumulative approach. The classification of patients as ‘long-stay’ has ranged from 2 to 15 years in some studies, although Huband et al. (2018) suggests that the UK has been consistent in selecting a two-year cut-off for medium secure samples. In contrast, Völlm (2019) suggests studies define long-stay as >5 in medium security, >10 years in high security, or >15 years in a combination of both. Reducing LoS is clinically important in terms of quality of life (Senn et al., 2020) assessing recovery (Rees, Pitcairn, & Thomson, 2018), long-term outcomes (Sedgwick et al., 2016), and informing strategies for long-term forensic care (Sampson et al., 2016). LoS also has economic implications as treatment in secure hospitals is expensive for a small
population (Eckert et al., 2017). Research suggested forensic care consumes 10% of the mental health budget in England and Wales at approximately £1.2 billion per annum (Rutherford & Duggan, 2008). Some studies estimate care costs of £152,000 per patient per annum in the UK at low secure services and £273,000 in high secure hospitals (Durcan et al., 2011). In 2009/2010, hospital running costs for an inpatient bed in high secure care in Scotland was £6,365 per week, equating to £330,980 per annum (Public Health Scotland, 2010).

More recently, research has sought to identify clinical characteristics that may underpin LoS to help identify those at risk of long-stay and how to meet their needs when they require longer-term care than others (Sampson et al., 2016). Long-stay patients have been characterised by a high risk of recidivism, non-compliance, and complex comorbidities (Goesk et al., 2020; Schel, Bouman, & Bulten, 2015), which will impact treatment responsiveness and ability to progress through the system. However, research into factors associated with prolonged stay is limited (Völlm, 2019).

Huband and colleagues (2018) acknowledged the lack of evidence surrounding LoS for this group, conducting a rapid review of the literature until December 2016, which summarised characteristics and needs of long-stay forensic inpatients. There were six broad research aims including defining LoS, prevalence of long-stay patients, patients characteristics, predictors, needs, and service provision. Sixty papers, representing fourteen countries, were included. Forty papers focused on patient characteristics, with patient samples collated between 1850 – 2014 across low, medium, and high secure settings (Gibbons et al., 1997; Davoren et al., 2015). Findings showed that an index offence of murder, offence severity, and an index offence involving violence or sexual motivation, were most commonly associated with LoS. Additionally, a history of psychiatric treatment, cognitive deficits, symptom/illness severity, history of violence, substance misuse, and younger age at admission were also associated with increased LoS. A schizophrenia diagnosis was associated with a longer stay in 35% of included studies. However, the forensic systems operating within these countries are heterogeneous, with differences in psychiatric care provision and healthcare structures. Furthermore, systematic or external factors can have as much influence on
LoS as clinical characteristics, with differences becoming more prevalent when evidence is compared internationally (Connell et al., 2019; Salize et al., 2005).

### 3.2.2. Aims of this Systematic Review

Given the international focus of the Huband et al. (2018) review, across all levels of security, and the potential for further papers since the review was published, a further review of the evidence was appropriate. Given the substantial variability surrounding this topic and the potential plethora of factors that may influence LoS in forensic settings, this review focuses specifically on patient characteristics associated with LoS. Low secure settings were excluded as they are often indistinguishable from general inpatient or community care, with blurred distinctions between forensic and non-forensic care (Laing & Buisson, 2006. Cited in Rutherford & Duggan, 2008). To reduce heterogeneity and increase the robustness of findings, this review incorporates UK studies only due to the fundamental differences observed across countries.

Including the older studies that Huband et al. (2018) previously reviewed has limited utility in reflecting on or informing the present situation, given those studies preceded significant changes in UK legislation and service development. Huband et al. (2018) also highlight that forensic services will change over time when drawing conclusions. Whilst it is difficult to determine a natural cut-off, the year 2000 was chosen considering changes in service provision and legislation in the UK nations. Despite recommendations for medium secure units made by the Glancy Report (1974), there was no medium secure provision in place in Scotland until the opening of the first site in 2000 (Lightbody et al., 2010). Further landmark changes impacting UK secure care include the Human Rights Act (1998) which came into force in October 2000, bringing the European Convention of Human Rights into domestic law (Bindman, Maingay, & Szmukler, 2003). This work cemented in law that individuals cannot be held in greater security than they require, meaning patients are more likely to progress through the mental health system quicker. The ‘payment by results’ system, commenced in 2000 (Centre for Mental Health, 2011) influenced discharge rates in England and Wales. This suggests that samples collected primarily after 2000 allow a reasonable timeframe (20 years) whilst accounting for studies that reflect legislative changes and are representative of the current state of forensic services in the UK. The overarching
objective of this review was to provide an overview of quantitative empirical studies examining factors associated with LoS in a UK forensic inpatient population.

3.3. Methodology

3.3.1. Eligibility Criteria

Inclusion Criteria
All observational studies which investigated and measured one or more variables associated with LoS were included. The review sampled adults inpatients in a medium or high secure forensic mental health facility in the UK between 2000 and 2020.

Exclusion Criteria
Non-English language, intervention, single case, and qualitative studies were excluded. Studies that sampled prison wards or any non-forensic inpatient populations were also excluded. This review was specific to the UK, therefore any non-UK-based studies were excluded from the study. Studies where the cohort was sampled pre-year 2000 were excluded for reasons cited in Section 3.2.2.

Inclusion criteria were broad to ensure a representative sample. Female and intellectual disability populations were included.

3.3.2. Search Strategy

PROSPERO & Cochrane databases were searched to identify any existing reviews on this topic and scoping searches were conducted on the below databases for the same purpose. Two systematic reviews were found (Huband et al., 2018; Wilkes, 2012). Methodology and criteria were reviewed and a further systematic review on this topic was warranted considering the geographical focus and potential for new papers to have been published since Huband et al. (2018) review, which included papers until December 2016. Importantly, quality assessment of studies was not conducted in the Huband review.

Literature searches were conducted using the following electronic databases, producing articles published within stated date ranges: EMBASE Classic + EMBASE
To ensure comprehensiveness, the following databases were searched within ProQuest: Criminology Collection (1975-current), which included Criminal Justice Database (1981-December 30, 2020) and National Criminal Justice Reference Service (NCJRS); Abstracts Database (1975-current); Applied Social Sciences Index & Abstracts (ASSIA; 1990 to 2021, January 1); International Bibliography of the Social Sciences (IBSS; 1951-current). Google scholar was searched separately, and the first 150 hits were examined.

Search terms used in the Huband et al. (2018) review were employed and can be found in Appendix 2. These terms were combined using the Boolean operator ‘AND’.

Papers were not restricted by publication year as exclusion criteria related to the sampling time frame instead. Searches were restricted to English language. There were no restrictions based on the document type.

Grey literature was searched through ‘ProQuest Dissertations and Theses Global’. Relevant systematic reviews had reference lists scanned to identify additional relevant studies. Bibliographies of included studies were checked for further references.

### 3.3.3. Search and Selection Strategy

All articles produced by searches were screened for de-duplication. Remaining studies were screened for eligibility by title and abstract, with those deemed not relevant excluded. Remaining studies’ full-texts and those retrieved from additional searches were screened for eligibility as per inclusion/exclusion criteria. Eligibility assessment and 100% of screening of titles, abstracts, and full texts were completed by the primary reviewer (first author) using Covidence Systematic Review Software (see Figure 1).

### 3.3.4. Quality Assessment

Quality assessment was conducted using the National Institute for Health Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies (National
Institutes of Health, 2016) comprising fourteen items designed to evaluate the internal
validity of such studies. This tool was based on quality assessment methods,
concepts, and other tools designed by the Cochrane collection, Scottish Intercollegiate
Guidelines Network, and National Health Service Centre for Reviews and
Dissemination. A detailed guidance document was provided (Appendix 3). Two
questions investigating whether outcomes were assessed more than once and
considering follow-up were not applicable to all studies, due to their observational
study design, and were removed from Table 2.

The primary reviewer quality assessed 100% and a second reviewer assessed 60%
of included studies. All disagreements were resolved through discussion and referring
to the guidance document to clarify applicability of questions depending on study
design, with reviewers reaching 100% agreement. Changes made were applied
across all studies.

3.3.5. Data Extraction

Data extraction was completed by the primary reviewer using Covidence software.
This was extracted using a proforma which considered inclusion criteria to allow for
systematic recording of key findings. Information extracted considered study design,
sample population, key definitions, and data collection methods (see Table 1).

3.3.6. Analysis

Due to the significant heterogeneity of studies and variation in study design, a narrative
synthesis was conducted to explore groups of characteristics and their relationship to
LoS. Finding from papers are included in Table 4. Effect sizes were calculated where
studies had not provided this and where information was sufficient.
Figure 1. Study Selection Flow Chart
3.4. **Results**

An overview of included studies and characteristics is provided, followed by a quality assessment of study methodology and narrative synthesis of findings.

3.4.1. **Overview**

**Participants**

Eight studies, with samples ranging from 30 to 2287 patients across the UK, were included in this review (see Table 1). All papers considered the forensic estate in England. Seven studies comprised medium secure patients (1,2,4,5,6,7,8). One multi-site study incorporated medium and high secure patients, accounting for differences between security levels (3). The majority of the samples were male. One study was based within a women’s medium secure service (6); females were excluded in two studies (2,8). One study focused on patients with intellectual disability (ID; 1) whilst ID diagnosis was excluded from another study (2). Two studies used the same census data (3,5), but examined different characteristics allowing for their inclusion. The researchers (3,5) aimed to be representative of the forensic population, employing oversampling in units including female and ID patients to increase generalisability. While perhaps not representative of the majority of the medium/high secure forensic estate, female and ID patients are key populations specifically catered for within forensic services and often excluded from analysis. Their inclusion suggests good variation in studies representing the forensic inpatient population.

Seven studies employed opportunity sampling (1,2,3,5,6,7,8). One study (5) identified 15 current patients from a 60-bed ward to compare against a discharged sample. It is unclear if additional patients were eligible, leaving the possibility that patients were selected based on lack of progress which could inflate results and possibility of Type I error. In this same study (5), the period from which discharged patients were selected was not specified; groups were from the same site but potentially from two significantly different points in time.
**Study Design**

All studies were observational. Five studies utilised retrospective cohort designs (1,2,6,7,8), with sampling periods between 4-10 years, measuring LoS retrospectively from discharge date. Two studies, using cross-sectional (3,5) designs, utilised census data therefore partial LoS was calculated for the current patient group. Cross-sectional designs are open to a high level of bias as all study factors are measured simultaneously (Jepson et al., 2004). These two studies received their information in an anonymised format and used detailed proformas to aid consistency in data collection (3,5).
<table>
<thead>
<tr>
<th>Study (Year of Publication)</th>
<th>Security Level</th>
<th>Study Design</th>
<th>Sample Type</th>
<th>Study Population</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Sample Period</th>
<th>Sample Size / Age / % male</th>
<th>Sample Groups</th>
<th>Collection Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Alexander et al. (2011)</td>
<td>Norfolk, England – medium</td>
<td>Retrospective cohort</td>
<td>Admission sample</td>
<td>Individuals admitted over a six-year period to a 64-bed inpatient service for offenders with mild intellectual disabilities.</td>
<td>None specified</td>
<td>2003-2009</td>
<td>138</td>
<td>Age (admission; M (SD), median): 30.43 (9.274), 29.5</td>
<td>Discharge sample (n=77) v Not yet discharged (n=25) v Difficult to discharge (n=36)</td>
</tr>
<tr>
<td>2 Brown &amp; Fahy (2009)</td>
<td>South London &amp; Maudsley NHS Trust, England – medium</td>
<td>Retrospective cohort</td>
<td>Discharge sample</td>
<td>Male patients admitted to a MSU within two inner city London boroughs, including NHS &amp; private sector.</td>
<td>Exclusion: female patients; aged over 65; diagnosis of learning disability</td>
<td>2002-2006</td>
<td>157</td>
<td>Restricted Group mean age: 38.9 Civil/Prison Group mean age: 35.1</td>
<td>Restricted group (subject to Section 37/41; n=58) v Civil/Prison Group; n=99</td>
</tr>
<tr>
<td>3 Duke et al. (2018)</td>
<td>England wide – high/medium</td>
<td>Retrospective cross sectional</td>
<td>Census</td>
<td>Patients residing in high/medium secure units at the time of data collection</td>
<td>Exclusion: Individuals who were on trial leave</td>
<td>2013</td>
<td>2287</td>
<td>Age (mean (SD)): Long-stay (high secure): 45.43(9.67) Non-long-stay (high secure): 36.15(9.72)</td>
<td>Long-stay (high secure; n=168) v non-long-stay (high secure; n=547)</td>
</tr>
<tr>
<td>Study</td>
<td>Location</td>
<td>Design</td>
<td>Control Group</td>
<td>Sample Description</td>
<td>Exclusion</td>
<td>Methodology</td>
<td>Year</td>
<td>Sample Size</td>
<td>Gender</td>
</tr>
<tr>
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<tr>
<td>5 Kasmi et al. (2020)</td>
<td>England wide – medium</td>
<td>Retrospective cross sectional</td>
<td>Census</td>
<td>Those admitted to a MSU across 14 NHS/private sector units, stratified by region.</td>
<td>None specified</td>
<td>2013</td>
<td>Age (mean (SD)): 44 (11.79) 83.9% male</td>
<td>NHS patients (n=178) v Private sector patients (n=107)</td>
<td>Routinely collected, anonymised data from case files as part of a wider multi-site study.</td>
</tr>
<tr>
<td>6 Long &amp; Dolley (2012)</td>
<td>Northampton, UK – medium</td>
<td>Retrospective cohort</td>
<td>Admission Sample</td>
<td>First 70 patients admitted to the study’s women’s medium secure service.</td>
<td>None specified</td>
<td>2002-2010</td>
<td>70 (68 in analysis) Whole Sample Age (mean (SD), range): 30.4(7.6), 19-49 0% male</td>
<td>Short stay (n=40) v long-stay (n=28)</td>
<td>Case files</td>
</tr>
<tr>
<td>7 Shah et al. (2011)</td>
<td>East London FMHS – medium</td>
<td>Retrospective cohort</td>
<td>Discharge sample</td>
<td>All patients discharged between 1999-2008</td>
<td>Exclusion: Patients discharged from the specialist dangerous and severe personality disorder service.</td>
<td>1999-2008</td>
<td>Age (mean (SD), median, range): 30.9(8.6), 30, 18-74 90.3% male</td>
<td>Short stay (up to two years; n=172) v Long-stay (2 years+ n=87)</td>
<td>Case files</td>
</tr>
<tr>
<td>8 Wilkes (2012)</td>
<td>West Midlands, England, UK – medium</td>
<td>Retrospective cohort</td>
<td>Discharge sample</td>
<td>Patients discharged from a male medium secure unit in the West Midlands.</td>
<td>Exclusion: if either discharge summary report or HCR-20 not available (186 excluded on this basis).</td>
<td>2001 (assumed) - 2011</td>
<td>Whole sample age (median, range): 33, 17-65 100% male</td>
<td>None specified</td>
<td>Case files</td>
</tr>
</tbody>
</table>

**Note:** FMHS: Forensic Mental Health Service; LoS: Length of Stay; MSU: Medium Secure Unit
3.4.2. Quality Assessment

Methodological Quality of Studies

The summation of individual quality scores and classification of the total score is provided (Table 2) following the assessment guidance document (Appendix 3). Cross-sectional studies scored ‘no’ for questions six and seven as all study factors are measured simultaneously. Scoring guidance in these cases suggests ‘no’ scores do not detrimentally impact overall quality and summary scores. Two items assessed if outcomes were measured more than once and if studies reported those lost to follow-up. LoS was measured at one timepoint i.e. discharge, and follow-up was not applicable therefore both items were removed. Also, some study groups were continuing inpatients so total LoS was unknown.

Taking these caveats into account, studies 3, 7 and 8 carried out the strongest study methodologically. Studies 1, 4, and 6 were the poorest quality studies and their results should be interpreted with extreme caution. The most commonly failed criteria were whether studies controlled for bias, adequately defined predictor variables, or conducted a power analysis. Findings are synthesised with consideration to the methodological quality of studies.
<table>
<thead>
<tr>
<th>Quality Assessment Criteria</th>
<th>Study Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 – Research Question defined</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Y</td>
</tr>
<tr>
<td>Q2 – Defined Study Population</td>
<td>Y</td>
</tr>
<tr>
<td>Q3 – &gt;50% Participation Rate</td>
<td>CD/NR/NA</td>
</tr>
<tr>
<td>Q4 – Same population</td>
<td>Y</td>
</tr>
<tr>
<td>Q5 – Sample Size Justification</td>
<td>N</td>
</tr>
<tr>
<td>Q6 – Exposure prior to outcome</td>
<td>Y</td>
</tr>
<tr>
<td>Q7 – Sufficient timeframe for effect</td>
<td>Y</td>
</tr>
<tr>
<td>Q8 – Levels of exposure of interest</td>
<td>N</td>
</tr>
<tr>
<td>Q9 – exposure measures/assessment</td>
<td>N</td>
</tr>
<tr>
<td>Q11 – outcome measures</td>
<td>N</td>
</tr>
<tr>
<td>Q12 - blinding</td>
<td>N</td>
</tr>
<tr>
<td>Q14 – adjusting for bias/statistical analyses</td>
<td>N</td>
</tr>
</tbody>
</table>

**Summary Score**

<table>
<thead>
<tr>
<th></th>
<th>Poor</th>
<th>Fair</th>
<th>Good</th>
<th>Poor</th>
<th>Fair</th>
<th>Poor</th>
<th>Good</th>
<th>Good</th>
</tr>
</thead>
</table>

**Note:** CD/NR/NA – Could not determine/Not recorded/Not applicable. Q10 and Q12 not applicable to all for reasons described in Section 3.4.2
**Defining LoS**

There were varying efforts to categorise patients based on LoS (Table 3). Two studies (3,5) provided a clear definition of long-stay based on pilot data, which aimed to capture 15-20% of the population, comprising the extreme end of long-stay. However, two studies treated LoS as a continuous variable (2,8) and two studies defined LoS using a median split (1,7). Defining LoS based on a cut-off (e.g. median split) derived from a specific sample limits generalisability to other studies. One study (1) calculated median LoS for the discharged group, defining patients longer than the split as “difficult to discharge”. The median split was 2.8 years, therefore patients considered long-stay according to the Glancy Report (1974), would not be in the “difficult to discharge” group. Furthermore, a third of the “difficult to discharge” group, were discharged to lower security but retained in the analysis. The second study’s median split was 1.8 years, which is below the 2-year threshold (7). Using discharge samples as the basis for this split is problematic when the discharge sample experience positive outcomes (i.e. lesser security). In both studies, 87% (1) and 88% (7) were discharged to lower security. Median splits based on discharge samples also do not account for those who were never discharged. The Glancy Report (1974) recommendation is also problematic and used in two studies to define long-stay (4,7). This cut-off was suggested during the development of medium secure services over forty years ago, therefore it is potentially arbitrary and may lack sensitivity in the current landscape.

**Operationalising Variables**

Predictor variables were collected and analysed in a manner that raises issues about validity and reliability. Studies failed to describe predictor variables in sufficient detail, lacking information about how variables were measured and when i.e. at admission or discharge (1,2,4,6,7,8). Conversely, researchers appeared to use their judgement to infer the presence of a predicted variable from limited file information (4,6,7). No cohort studies indicated using data collection proformas which makes replication and generalisability difficult, whilst reducing the reliability of data collection.
There was no consistent way of categorising or reporting forensic characteristics of samples. This will have been impacted by the purpose of the papers, size, and nature of the samples i.e. manslaughter as a category of its own may be appropriate for high security where there is likely a larger sample. In other settings, for various reasons, there may be few patients with sexual offences so merging categories with other offences would be sensible. However, dichotomising groups into major or minor violence (6) risks losing information relating to individual differences and risks overestimation of effect sizes and statistical significance. Studies that reported sexual offences separately (5) or used a standardised tool to rate violence (7) found no significant effect in a large sample, whilst others found major violence significantly predicted LoS when adopting a ‘broad category of assault’ including sexual offences and manslaughter (6).

Five studies reported on diagnosis (1,5,6,7,8). Only two studies detail using ICD-10 diagnosis (1,7) although one inferred the presence of personality disorder from case notes (7). Others used personality scales (6), or ward type as a proxy for diagnosis (3), which is not always representative of patient diagnoses. Others did not explain what information was used (5,8). All are problematic, liable to bias, and impact the internal reliability of studies. Three studies used outcome measures (6,7,8) although none provided evidence of their reliability. Studies were poor at controlling for confounding variables; one study controlled for substance misuse (7) in a population where multiple diagnoses are commonplace (Timmerman & Emmelkemp, 2001).
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Length of Stay (LoS)</th>
<th>Study Groups</th>
<th>M / Md</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Median length of stay for discharged group. Continuing inpatients whose LoS is in excess of this classification categorised as <em>difficult to discharge</em>.</td>
<td>Discharged group:</td>
<td>Md: 2.80</td>
<td>0 - 17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not yet discharged (including ‘difficult to discharge’):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Number of nights in a medium secure bed irrespective of inter-hospital transfers.</td>
<td>Whole sample:</td>
<td>Md: 1.97</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restricted sample:</td>
<td>Md: 2.72</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Civil/prison sample:</td>
<td>Md: 1.4</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>&gt;5 years in medium secure care, or &gt;10 years in high secure care, or &gt;15 years in continuous secure care in a combination of high and medium secure settings.</td>
<td>Long-stay (high secure):</td>
<td>Md: 11.75</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-long-stay (high secure):</td>
<td>Md: 3.67</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-stay (medium secure):</td>
<td>Md: 4.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-long-stay (medium secure):</td>
<td>Md: 1.17</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Longer stay defined as two or more years.</td>
<td>Undischarged sample:</td>
<td>Md: 2.83</td>
<td>2.17 - 4.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discharged sample:</td>
<td>Md: 1.5</td>
<td>1 - 2</td>
</tr>
<tr>
<td>5</td>
<td>&gt;5 years in medium secure care, or &gt;10 years in high secure care, or &gt;15 years in continuous secure care in a combination of high and medium secure settings.</td>
<td>Current LoS</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Whole sample:</td>
<td>M: 4.43</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NHS sample:</td>
<td>M: 4.67</td>
<td>0.1 – 13.22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PCS sample:</td>
<td>M: 4.05</td>
<td>0.38 - 19.88</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Continuous LoS</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Whole sample:</td>
<td>M: 13.61</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NHS sample:</td>
<td>M: 13.68</td>
<td>5.02 –54.26</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PCS sample:</td>
<td>M: 13.51</td>
<td>5.08 – 52.9</td>
</tr>
<tr>
<td>6</td>
<td>Patients were divided into short and long stay groups on the basis of a median split (21.6 months).</td>
<td>Short-stay:</td>
<td>M: 1.06</td>
<td>0.67 – 1.79</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-stay:</td>
<td>M: 2.49</td>
<td>1.86 – 3.42</td>
</tr>
<tr>
<td>7</td>
<td>Long-stay is exceeding the recommended duration of two years in a medium secure unit.</td>
<td>Whole sample:</td>
<td>Md: 1.17</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>LoS calculated for each case using date of most recent admission to the date of discharge from hospital.</td>
<td>Whole sample:</td>
<td>Md: 1.77</td>
<td>0 – 11.37</td>
</tr>
</tbody>
</table>

* Data has been standardised to years.

**Note:** LoS: Length of Stay; M: Mean; Md: Median; PCS: Private and Charitable Sector
**Data Analysis**

The quality of statistical analysis was substandard limiting the reliability of findings in these primary studies. Justification for sample size was described in two studies (3,5), although no studies provided an *a-priori* power calculation. Four studies made attempts to control for Type I and Type II errors using Bonferroni correction (6,8) or applying fisher's exact tests in place of chi-square tests (1,5). One study conducted post-hoc power analysis (8) and found several analyses to be underpowered. Five studies reported no effect sizes (1,2,4,5,6), which would have aided in interpretation of the clinical significance of study findings in the context of limited statistical power. Effect sizes were calculated where possible (Table 4). Two studies provided odds ratios for linear statistical analysis (3,7), and one study provided effect sizes for categorical comparisons (8).

Three studies used non-parametric tests, namely Mann-Whitney U and chi-square tests (1,2,4). Others used a combination of parametric and non-parametric tests (1,6,7), and one study used logistic regression analysis only (3). Two studies made sufficient reference to having checked assumptions (5,8). Some studies reported only significant results (1,4), or reported *p*>.05 when results were non-significant (2), which gives a biased, less reliable view of findings.
Table 4. Factors associated with LoS in included studies

<table>
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</thead>
<tbody>
<tr>
<td><strong>SOCIODEMOGRAPHIC VARIABLES</strong></td>
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</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td>p&gt;.05 a</td>
<td></td>
<td>OR=3.57,p=.060</td>
<td>OR=0.986,p=.434</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employment History</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>r=.03, p=.658</td>
<td></td>
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<tr>
<td>Employment on admission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>r=.03, p=.669</td>
<td></td>
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</tr>
<tr>
<td>Ethnic Class (White v Black)</td>
<td>OR=0.577, p&gt;.05</td>
<td>OR=0.962,p&gt;.05</td>
<td>r^2 = .03, p=.003 b</td>
<td></td>
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<tr>
<td>Ethnic Class (White v Asian)</td>
<td>OR=1.095,p&gt;.05</td>
<td>OR=1.049,p&gt;.05</td>
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<tr>
<td>Ethnic Class (White v Mixed)</td>
<td>OR=0.517,p&gt;.05</td>
<td>OR=0.814,p&gt;.05</td>
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<tr>
<td>Ethnic Class (White v Other)</td>
<td>OR=0.266,p&gt;.05</td>
<td>OR=0.571,p&gt;.05</td>
<td></td>
<td></td>
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<tr>
<td>Ethnicity Status</td>
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<td>p=.446 a</td>
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</tr>
<tr>
<td>Gender (Male)</td>
<td>OR=1.072,p&gt;.05</td>
<td>OR=0.744,p&gt;.05</td>
<td>p&gt;.05 a</td>
<td></td>
<td>OR=0.75,p=.535</td>
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<tr>
<td><strong>MHA LEGAL STATUS</strong></td>
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<tr>
<td>Civil or Quasi-Civil</td>
<td></td>
<td></td>
<td>r^2 = -.04 p&lt;.001 b</td>
<td></td>
<td>OR=0.90,p=.776</td>
<td>OR=0.587,p=.430</td>
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<tr>
<td>Civil (Section 3) on Admission to current unit</td>
<td></td>
<td></td>
<td>r^2 = -.03 p=.004 b</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Criminal Section</td>
<td></td>
<td></td>
<td>OR=1.513,p=.491</td>
<td></td>
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<tr>
<td>Post-conviction assessment</td>
<td></td>
<td></td>
<td>OR=0.27,p=.084</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Prison transfer</td>
<td></td>
<td></td>
<td>p&gt;.05 a</td>
<td></td>
<td>OR=0.55,p=.106</td>
<td>r=.002,p=.973</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recalled</td>
<td></td>
<td></td>
<td>OR=0.84,p=.807</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remand Section</td>
<td></td>
<td></td>
<td>OR=0.66,p=.178</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Section 37</td>
<td></td>
<td></td>
<td>OR=2.94,p&lt;.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Section 37/41</td>
<td>p&lt;.05 a</td>
<td>p&lt;.05 a</td>
<td>r^2 = .04 p&lt;.001 b</td>
<td></td>
<td>OR=3.62,p&lt;.001</td>
<td>r=.32,p=.004</td>
<td></td>
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</tbody>
</table>
## Section 37/41 v Civil/Quasi Civil
<table>
<thead>
<tr>
<th>OR</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.579</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>0.365</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

## Section 37/41 v Prison Transfer
<table>
<thead>
<tr>
<th>OR</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.328</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>0.347</td>
<td>&lt;.001</td>
</tr>
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</table>

## Transitional Section
<table>
<thead>
<tr>
<th>OR</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.179</td>
<td>.196</td>
</tr>
</tbody>
</table>

## SERVICE LEVEL VARIABLES

**Admission source**
- High secure: OR = 0.518, p > .05
- Low secure: OR = 0.518, p > .05
- Medium secure (NHS): OR = 0.644, p < .001
- Medium secure (Private): OR = 0.533, p > .05
- Prison: OR = 0.02, p = .023

**Admission source (prison v community)**
<table>
<thead>
<tr>
<th>OR</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.379</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>0.518</td>
<td>&gt;.05</td>
</tr>
</tbody>
</table>

**Admission source (prison v high secure)**
<table>
<thead>
<tr>
<th>OR</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.235</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>8.087</td>
<td>&lt;.001</td>
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</tbody>
</table>

**Admission source (prison v low secure)**
<table>
<thead>
<tr>
<th>OR</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.257</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>0.644</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

**Care Provider (NHS v Independent)**
<table>
<thead>
<tr>
<th>OR</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.072</td>
<td>&gt;.05</td>
</tr>
</tbody>
</table>

**Ward pathway category**
- Admission: OR = 0.476, p > .05
- High dependency: OR = 0.755, p > .05
- Slow/rehab: OR = 0.680, p > .05
- Treatment: OR = 0.926, p > .05
- Mental illness: OR = 0.422, p > .05
- Mixed: OR = 0.445, p > .05
- Personality disorder: OR = 0.422, p < .05

**Ward diagnostic category**
- ID v mental illness: OR = 0.422, p > .05
- ID v mixed: OR = 0.445, p > .05
- ID v personality disorder: OR = 0.533, p > .05
### WARD PROGRESSION VARIABLES

<table>
<thead>
<tr>
<th>Variable</th>
<th>$\eta^2$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attaining highest leave status</td>
<td>.22</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Highest security ward status</td>
<td>.17</td>
<td>&lt;.025</td>
</tr>
<tr>
<td>Reductions in leave status</td>
<td>.15</td>
<td>&lt;.025</td>
</tr>
<tr>
<td>Reductions in ward status</td>
<td>.20</td>
<td>&lt;.025</td>
</tr>
</tbody>
</table>

### PSYCHIATRIC VARIABLES

<table>
<thead>
<tr>
<th>Variable</th>
<th>$r^2$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affective disorder</td>
<td>.045</td>
<td></td>
</tr>
<tr>
<td>Age at first contact with services</td>
<td>.03</td>
<td>.197</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>&lt;.05</td>
<td></td>
</tr>
<tr>
<td>BPRS Total Score</td>
<td>.69</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>CANFOR - Psychological Distress</td>
<td>.32</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>CANFOR - Psychotic Symptoms</td>
<td>.13</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>History of self-harm/suicide attempt</td>
<td>&gt;.05</td>
<td></td>
</tr>
<tr>
<td>Intellectual Disability</td>
<td>-.02</td>
<td>&lt;.015</td>
</tr>
<tr>
<td>Mental Illness</td>
<td>.01</td>
<td></td>
</tr>
<tr>
<td>Mental Illness + Personality Disorder</td>
<td>.040</td>
<td></td>
</tr>
<tr>
<td>Organic disorder</td>
<td>&gt;.05</td>
<td></td>
</tr>
<tr>
<td>Personality disorder</td>
<td>&lt;.05</td>
<td></td>
</tr>
<tr>
<td>Personality disorder v Affective disorder</td>
<td>&gt;.05</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Personality (MCMI-III) - Borderline</td>
<td>.002</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Personality (MCMI-III) - Paranoid</td>
<td>.04</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Personality (MCMI-III)-Schizotypal</td>
<td>$r^2 = .09$, $p&lt;.001^{b}$</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td>Previous engagement in psychotherapy</td>
<td>$r^2 = .24$, $p&lt;.01^{b}$</td>
<td></td>
</tr>
<tr>
<td>Previous forensic psychiatric admissions</td>
<td>$p=.045$ $^{a}$</td>
<td></td>
</tr>
</tbody>
</table>
| Previous psychiatric admissions | $r^2 = .008$, $p=.026^{c}$  
OR = 0.992, $p=.833$ |
| Schizophrenia/Schizoaffective disorder/delusional disorder | $r^2 = .20$, $p<.01^{b}$  
OR = 3.13, $p=.009$  
$r = .24$, $p=.001$;  
OR = 3.348, $p=.011$  |
| Schizophrenia v Personality Disorder | $r=.117, p=.117$ |
| Substance Misuse | OR = 0.79, $p=.437$ |
| Therapy Engagement in first 6 months of stay | $r^2 = -.11$, $p<.01^{b}$ |
| Therapy Engagement in last 6 months of stay | $r^2 = -.17$, $p<.01^{b}$ |

**FORENSIC VARIABLES**

| Age at first conviction | $p>.05$ $^{a}$ |
| Age at first violent conviction | $p=.033$ $^{a}$  
$r^2 = .002$,  
$p=.572^{b}$ |
| Discharge Outcome | $\eta^2 = .018$, $p=.171$ |
| HCR-20 Item: Relationship Instability | OR = 1.08, $p=.772$ |
| HCR-20 Item: Lack of personal support | OR = 1.05,  
$p=.862$ |
| HCR-20 Item: Negative Attitudes | $r_s = -.166, p=.019$  
OR = 0.703, $p=.081$  |
<p>| HCR-20: Historical Scale Total | $r_s = -.074, p=.300$ |
| HCR-20: Clinical Scale Total | $r_s = -.009, p=.901$ |
| HCR-20: Risk Scale Total | $r_s = -.037, p=.602$ |
| HCR-20: Total | $r_s = -.058, p=.416$ |
| Hospital order as disposal at first conviction | $p=.009$ $^{a}$ |</p>
<table>
<thead>
<tr>
<th>Hospital order as most severe disposal</th>
<th>p=.003 a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index Offence - Major violence</td>
<td>$r^2 = .18$, p&lt;.01</td>
</tr>
<tr>
<td>Index Offence - Minor Violence</td>
<td>$r^2 = .51$, p&lt;.01</td>
</tr>
<tr>
<td>Manslaughter as first violent conviction</td>
<td>p=.022 a</td>
</tr>
<tr>
<td>Manslaughter as index offence</td>
<td>p=.031 a</td>
</tr>
<tr>
<td>Nature of index offence</td>
<td>$\eta^2 = .022$, p=.346 b</td>
</tr>
<tr>
<td>No convictions</td>
<td>p&gt;.05 a</td>
</tr>
<tr>
<td>Offending history (present v absent)</td>
<td>r =.090, p=.196</td>
</tr>
<tr>
<td>Previous convictions</td>
<td>OR=1.01, p=.972</td>
</tr>
<tr>
<td>Previous violence</td>
<td>OR=3.48, p=.106</td>
</tr>
<tr>
<td>Recorded Incidents</td>
<td>$\eta^2 = .17$, p&lt;.025 b</td>
</tr>
<tr>
<td>Sexual index offence</td>
<td>p&gt;.05 a</td>
</tr>
<tr>
<td>Total number of offences</td>
<td>p&gt;.05 a</td>
</tr>
<tr>
<td>Violent index offence</td>
<td>p=.287 a</td>
</tr>
</tbody>
</table>

**Table 3 Key:**

* a Insufficient information to calculate effect size.
* b Effect sizes calculated by first author.

Abbreviations: BPRS – Brief Psychiatric Rating Scale; CANFOR – Camberwell Assessment of Need Forensic Version; HCR-20 – Historical Clinical Risk 20 (version number not reported); ID – Intellectual Disability; MCMI-III – Millon Multiaxial Clinical Inventory III; MHA – Mental Health Act

Omitted – analysis was conducted but authors concluded results were subject to Type I error and were under powered

**Effect Sizes**

$\eta^2$ – 0.01 (small); 0.06 (medium); 0.14 (large)

OR – odds ratio

r – 0.1 (small); 0.3 (medium); 0.5 (large)

$r_s$ – 0.1 (small); 0.3 (medium); 0.5 (large)

$r^2$ – 0.02 (small); 0.13 (medium); 0.26 (large)
3.4.3. LoS and Associated Factors

Table 4 reports effect sizes and results of statistical tests for variables explored by studies in relation to LoS. Variables that demonstrate a significant association with LoS are highlighted in bold. Variables are grouped under categories which represent the types of variables most frequently investigated and are displayed alphabetically within each category. Due to differences in analysis, there did tend to be overlap between study variables, particularly within the forensic category. These categories will be explored in the following sections.

Sociodemographic Variables and LoS

Four studies, assessed as fair to good quality, examined sociodemographic variables (3,5,7,8). Sociodemographic variables were generally not associated with LoS although all were limited to age, gender, and ethnicity, with one study considering employment (8). One study found white ethnicity was associated with increased LoS (5), although when effect sizes were calculated, this association was considered weak and this study assessment quality was reduced by no power analysis being conducted. Study 3 benefited from a significantly larger sample drawn from the same census data as study 5 and found no association between ethnicity and LoS. Studies are limited by ethnic minorities being significantly under-represented in samples; one study which included a more diverse sample (7) found those of black ethnicity were significantly less likely to have a prolonged stay from categorical comparisons of less than two years or over two years, although black ethnicity was not predictive when LoS was a continuous variable. This was a single-site study, which therefore may lack generalisability and be influenced by site-specific variables. No associations between LoS and age or gender were found.

MHA Status and LoS

Six studies reported on legal status under the Mental Health Act (1,2,3,5,7,8) and all studies found Section 37/41 (Hospital Order with Restrictions) under the Act was significantly associated with prolonged LoS. Three studies compared Section 37/41 to
all other sections, including civil and prison, finding only hospital restrictions were significant predictors of LoS (2,3,8). This relationship was consistently observed even though methods of analysis varied across studies, using non-parametric (1,2,5,8) and logistic regression analysis (3,7). Logistic regression typically requires a large sample size, with research suggesting a minimum of 500 samples for observational studies (Bujang et al., 2018). One study (7) did not meet these criteria and also did not address power which influences the reliability of results and the potential that they were underpowered. Odds ratios for this study (7) were considerably larger than the more robust study (3). This overestimation in odds ratio occurs in studies with small samples, which can lead to inflating of results (Nemes et al., 2009).

Other findings were not as consistent and should be interpreted more cautiously: three studies found detention under prison transfer was not associated with LoS (5,7,8). One study found civil sections were associated with a shorter LoS (5), whilst two studies found no association (7,8). However, the former demonstrated small effect sizes (5) and the latter (7), as previously mentioned, may have been limited by their small sample size.

**Service Level Variables and LoS**

Two studies explored admission source (3,5) and both studies used the same census data. One considered sources of admission to high and medium security (3) and the other considered medium secure only (5). The medium secure only study (5) found only admission from prison was associated with LoS in medium security, consistent with a small effect. The study incorporating high and medium security (3) found, in their medium security sample, that admission from prison was not significant, whilst admissions from other medium secure or high secure units were significant. This study (3) scored higher on quality assessment. Admissions from prison and high security were significant to LoS in the high secure sample (3).

Only one study (4) reported variables associated with ward progression to LoS e.g. being approved leave status, and progressing to less restrictive wards without being transferred back to higher levels following setbacks. They posited that those with prolonged stays would be associated with poor progression through the forensic
system. However, quality assessment considered this study as poor quality, with flaws in all aspects of the methodology beyond defining the population and research aim. Effect sizes for non-parametric tests were calculated by this study author, demonstrating large effects. However, with a small sample size (n=30), no power analysis conducted, and significant flaws within the design, results should be interpreted with extreme caution.

**Psychiatric Variables and LoS**

Five studies explored clinical variables associated with LoS (1,5,6,7,8). There was heterogeneity in how studies defined variables; explanations were poor only two studies provided sufficient detail according to quality assessment criteria (5,7). Three studies found a diagnosis of schizophrenia was significantly associated with longer LoS (6,7,8), using non-parametric analyses (6), logistic regression (7), and a combination of categorical analysis with further analysis using logistic regression (8). Both study 7 and 8 had a small sample for logistic regression (<500), limiting reliability. One study, of good methodological quality (8), found that a diagnosis of schizophrenia, compared to alternative diagnoses, was the only variable retaining significance within the analysis. Categorical analysis also found a significant association with LoS consistent with a small effect (8). Two studies exploration of diagnosis was questionable (3,5). One reduced diagnosis into dichotomous categories of mental illness and personality disorder (5), which fails to account for individual differences and increases the risk of Type I error. Mental illness showed a significant association with LoS, but calculated effect sizes suggest this was a small/weak effect. Other studies (7) which specified types of mental illness found affective disorder was significantly related to a shorter LoS (less than two years). The second study (8) used ward category as a proxy diagnosis which is not always representative, and indeed found no significant associations regarding mental illness (3). Findings highlight the importance of using valid measures i.e. ICD diagnosis, as two studies that found significant findings (6,7) used this method.

Two studies found a diagnosis of personality disorder was inversely related to LoS (1,6), although one study provided no statistical reporting except a p-value (1) and the other (6) did not specify how they defined personality disorder. The latter also utilised
personality outcome measures which were positively associated with LoS on paranoid and schizotypal dimensions (6). It should be noted that both studies scored as ‘poor’ within quality assessment. Two studies found no significant relationship between personality disorder and LoS (5, 7), with one study using ICD-10 criteria to infer the presence of personality disorder from notes as opposed to using diagnosis (7). Variability in how this predictor is defined significantly impacts reliability and validity of findings.

One study found a diagnosis of ID was inversely related to LoS (5). In contrast, two higher quality studies found ID diagnosis predicted longer LoS in comparison to personality disorder as defined by ward type in another study (3), and another found no association (7). Again, ward type is not optimal as a proxy for diagnosis (3). Furthermore, the calculated effect size in the study demonstrating significance is small (5), suggesting a cautious interpretation of this finding. Previous and current engagement in treatment was significant in one study (6), although the terms of engagement were not detailed and current engagement was based on patients attending more than ten sessions a week. ‘Sessions’ were not defined and the cut-off of ten sessions appears arbitrary, with no explanation offered, hence the lower score on quality assessment as ‘poor’.

Previous forensic psychiatric admissions were significant in one study (7), and previous psychiatric admissions showed a significant association to LoS in two studies, consistent with small effect sizes (7, 8). Significance was not retained using logistic regression analysis in one study (8).

**Forensic Variables and LoS**

Five studies investigated forensic variables in relation to LoS (4, 5, 6, 7, 8). Few forensic variables analysed showed significant associations with LoS. Age at first violent conviction was significantly associated with increased LoS in one study (5) but no significance was found in another (7). No significant associations between LoS and age at first conviction, discharge outcome, history of previous convictions or violence, total number of offences, or absence of offending history were found. One study found an index offence of major violence was significantly associated with longer LoS (6), to
which another found this association specifically to manslaughter (5). One study found violent index offence was not associated with LoS (7). One study (6) found a small effect and two (5,7) provided insufficient information for effect sizes to be calculated.

Two studies explored recorded aggressive ward incidents (4,5). One reported a significant association with LoS (4), whilst another, of higher study quality, reported no association (5). The latter (5) created a scale to rate incidents as data was part of a wider study whilst the former (4) did not utilise a standardised rating scale, such as the Overt Aggression Scale (Yudofksy et al., 1986). The authors stated that inclusion as an ‘aggressive’ incident was based on a case-by-case basis without any detailed criteria to ensure consistency, which risks arbitrary values that may overestimate or underestimate how many incidents are included and limits generalisability. This study was rated as poor quality and was the only study that found a significant association with a large effect (4), which does suggest the presence of Type I error. Two, good quality, studies found HCR-20 items were not significant predictors of LoS (7,8). No significant associations were found for HCR-20 historical and clinical variables in one study (8) or two risk factor items (7) in another study.

### 3.5. Discussion

#### 3.5.1. Main Findings

Concerns regarding excessive LoS in secure settings were first raised forty-seven years ago (Glancy Report, 1974). Despite the subsequent provision of medium secure services, excessive LoS remains problematic, and its causes are not well understood (Tomlin et al., 2020). Defining ‘long-stay’ in forensic services is complex; there is no clear consensus and there exists wide variation across countries (Sampson et al., 2016). Two previous reviews that investigated factors associated with LoS focused on UK medium secure services (Wilkes, 2012), and drawing comparisons from international literature (Huband et al., 2018). Given the sampling period and geographical focus for many of the studies included in these reviews, it was considered appropriate to conduct a systematic literature review to identify patient characteristics that influence LoS in samples representative of the current medium and high UK forensic estate, legal context, and mental health legislation. Three
papers, not previously reviewed, were added to this review. Effect sizes for all papers were calculated and studies were subject to and interpreted in consideration of quality checks, which had not been conducted in the previous review.

Only eight studies were identified, highlighting a paucity of research for the reviewed issue in the UK. Findings considering factors associated with LoS suggest that a diagnosis of schizophrenia, a high number of previous psychiatric and forensic admissions, admission from other secure or prison settings, and Section 37/41 legal orders, are significantly associated with long-stay in forensic secure care. Sociodemographic variables were generally not associated with LoS, although exploration was generally limited to age, gender, and ethnicity. Forensic variables were heterogeneous, providing mixed findings, due to variability in how predictors were defined and analysed. HCR-20 historical and clinical variables in one study and two risk factor items in another were not associated with increased LoS. Treatment engagement was predictive of shorter stays.

Huband and colleagues (2018) in their review suggest responsibility for longer stays could, in some instances, be attributable to the legal system. Indeed, a consistent association between Section 37/41 orders and prolonged stays was found in this review. A study by Völlm et al. (2018) found Section 37/41 orders were more prevalent in the most recent admission of long-stay patients compared to their first admission, suggesting an increase in restrictiveness over time. Our decision to limit this review to UK studies meant such issues could be highlighted, with the previous review focusing on sociodemographic, clinical, and forensic variables.

Findings are challenged by the significant methodological limitations of the included studies, an issue which was not addressed in the previous review (Huband et al., 2018), and therefore warranted consideration. Cross-sectional studies were limited by their design, whilst cohort studies were limited by inadequate detail regarding predictor variables. Few studies conducted a power analysis, increasing the likelihood of analyses being underpowered and significant associations with LoS being potentially missed. Conversely, some analyses conducted with an underpowered sample may have produced inflated results. The variation in how studies defined LoS is problematic; the use of a median split limit generalisability to other studies and the
Glancy Report (1974) cut-off is outdated. Studies using discharged patient samples exclude patients who are never discharged, missing the extreme end of long-stay samples from analysis. Variable use of admission, discharge, and census samples limit comparability and reduce the reliability of results. Quality of statistical reporting was variable with few studies reporting effect sizes or providing only significant results. The most common limitation was unclear and insufficient definitions of predictor variables which render studies open to a high level of bias. Cohort studies, in particular, provided basic list descriptions of included variables and poorly controlled for bias during data collection i.e. little use of blinding or dual rating or extraction, which has issues for replicability and internal reliability. The retrospective nature of these studies means that data was previously collected for an alternative purpose and so there may be variance in reporting standards. This is compounded by studies relying on primary case files from patients’ current stay only. Standardisation and detailed proformas may overcome such issues in future research.

In defining long-stay, there appeared to be two main points of reference: the two years suggested for medium secure services in the Glancy Report (1974) and the definition provided by Völlm et al. (2017), used by Duke et al. (2018) and Kasmi et al., (2020), suggesting >5 years for medium secure services, >10 years for high secure, and >15 years of continuous care in a combination of medium and high security. The latter is more than double suggested by the former, which could have implications in skewing the findings of this review. An agreed definition of LoS is the primary recommendation of this study as without one, heterogeneity will continue to challenge all aspects of LoS research. This will also impact clinical practice, with treatments often considered on their impact on discharge. Taylor et al. (1996) argued that when developing medium secure units, emphasis may have been misplaced on the original two-year benchmark made by the Glancy Report (1974), stating that no time limits were specified. As previously stated, Glancy Report (1974) recommendations were made before the opening of medium secure units over forty years prior. Figures suggest that only 34% of secure patients leave facilities after less than two years (Home Office, 2005). More recent research suggests the average LoS across secure services for the UK ranges from 7.4 to 8 years (Tomlin et al., 2020). This suggests that in the current landscape, the Glancy Report (1974) cut-off may not be as sensitive to capturing true long-stay patients. The average LoS should not be “long-stay”, as long-stay should encapsulate
the extreme end of the continuum (Völlm et al., 2017). Völlm et al. (2017) definition also considers "continuous care", which increases the representativeness of long-stay patients, compared to other definitions which include only the current stay, irrespective of previous care. Völlm et al. (2018) found that long-stay patients in their sample had on average 1.43 site changes since original admission, with 18.3% having more than 3 moves. Findings from this review suggest admission from other levels of security is associated with long-stay, and further exploration of this finding in relation to continuous care is suggested. A caveat to Völlm et al. (2017) definition is that it is based on samples in England. Therefore, monitoring this definition is required in the future following changes to legislation or service provision that, according to this review findings, are most likely to impact LoS. It is recommended that future research use Völlm et al. (2017) definition and explore whether this may generalise to other countries outside of England and the UK, with the caveat that this is a time-limited definition as future policy and legislative changes within the forensic estate will likely directly impact LoS.

### 3.5.2. Future Research

The small number of studies included in this review, covering over 20 years, suggests further good quality research is required that considers the methodological weaknesses identified. That there are no papers conducted in the UK outside of England is surprising and limits the generalisability of this review. The inclusion of such papers may highlight differences in outcomes due to geographical variation, legislation and practice between UK countries. For example, dangerous and severe personality disorder units in England have not been implemented in Northern Ireland or Scotland (Thomson, 2010). Despite personality disorders' inclusion specifically in MHA legislation as criteria for admission, Scottish services are led by service development as opposed to legislation on this matter (Darjee & Crichton, 2002) and it is uncommon for patients in Scottish secure units to have a primary diagnosis of personality disorder. Therefore, differences in practice between countries, and inclusion of these samples would give a more representative picture of factors associated with LoS UK-wide.

Research may continue to be limited by reliance on retrospective data. Prospective cohort studies would be optimal yet are extensively time and resource intensive. A
core set of characteristics should be agreed, defined, and collected routinely to allow prospective data collection to inform future service planning and patient care. This will also reduce heterogeneity and improve clarity regarding predictor variables. In defining core characteristics, researchers should consider data that is standardised and validated. For example, routinely collected data and the detailed process all patients undergo upon admission (Davoren et al., 2015). In general, research should continue to make use of routine outcome measures. It is surprising that only one study included such measures, particularly since the Government’s recommended patient-reported outcome measures (PROMs) be embedded into clinical services as part of routine care to measure clinical and recovery outcomes (Thornicroft & Slade, 2014).

Völlm et al. (2018) suggest a whole lifespan view regarding LoS, and it is clear that many factors remain unexplored in this review. However, including more predictor variables must be balanced by a strong rationale that explicitly states variables for inclusion alongside a sufficient explanation of what is being considered and at which point in the patient journey. Study variables tended to incorporate static or historical factors, and within this examined, arguably, a narrow field. No studies attended to neuropsychological factors or the difficult upbringings that this population often faces, which was explored in non-UK studies (Huband et al., 2018). Little attention was placed on dynamic variables which may provide a more telling tale for LoS. For example, patients who may not display physical aggression but present in an impulsive and labile manner. This is due to studies relying on data collected for another purpose, and this will continue to limit the scope of factors associated with LoS to exclude dynamic factors, factors within the individual (i.e. symptoms, engagement), as well as dynamic factors of the organisation and the treatment provided (i.e. discrete interventions). Dynamic variables have shown increased predictive validity in forensic risk assessment (Smith et al., 2020), and their inclusion in predicting LoS could be a promising avenue for future research. Beyond psychopathology, adaptive functioning could be considered. Long-stay patients reside in restrictive settings with reduced responsibility for their daily activities for prolonged periods. It is reasonable to consider whether poor adaptive functioning has bearing on patients remaining in such settings or contributes to difficulty moving to places of lesser restriction.
5.3. Implications for Clinical Practice

Clinically, this review recognises that prolonged LoS is characterised by chronic and complex presentations. However, clinicians should be cautious of assuming that patients with schizophrenia, particularly if considered treatment-resistant, will inevitably face a long-stay in secure care. This association is likely to be complex and there may be particular aspects of such a diagnosis that are likely to be influential and important for further exploration, but are beyond the scope of the current review.

Studies varied in how they collected data regarding personality disorder from medical files, resulting in deductions being made from case notes in the absence of a recorded formal diagnosis. Whilst clinicians may be cautious about recording this diagnosis (Beryl & Völlm, 2018), or perhaps due to diagnostic overshadowing, its presence or absence according to ICD-10 criteria should be clearly stated to avoid such occurrences in future research.

3.5.3. Limitations

There are limitations to this review. Our choice to limit studies to the UK and samples collected in the last twenty years may have influenced the number of papers eligible for inclusion, although this decision was made in consideration of significant legislative change relevant to the forensic estate. While this decision allowed for significant associations regarding legal variables to be identified, all eight studies were conducted in England and only one consider the high secure estate. This significantly limits the generalisability of findings to the rest of the UK and high secure services.

Screening and extraction were completed by the first author. A second rating for this stage of the process would have helped to ensure studies were suitably included or excluded. Two studies included in this paper used data collected from the same census (Duke et al., 2018; Kasmi et al., 2020), and there is likely to be some overlap despite their focus on different outcomes of interest. Given the forensic estate in the UK is relatively small and the focus was on long-stay patients, the potential for overlap would have remained a possibility and limitation, particularly as studies report
retrospectively, either within single sites, groups of services, or through the mechanism of a census.

Quality assessment revealed weaknesses in study design and reporting which cast uncertainty when drawing conclusions. Studies with high levels of bias risk greater potential that the observed differences between and within groups could be due to factors other than the relationship being evaluated, which can result in under or overestimation of the true effect. However, results were presented and conclusions drawn in light of methodological shortcomings. The Quality Assessment tool used provided only yes or no ratings, which can make scoring challenging when studies are including a significant number of variables for analysis and may lead to oversensitivity and overestimation of study quality. Including a ‘partial’ rating would have highlighted studies which had made attempts to define outcome variables in some regards but not others, and further emphasised the discrepancies across studies.

3.6. Conclusions

This review found that clinical and legal variables were the most consistent factors associated with LoS. Sociodemographic and offence variables were generally not predictive of LoS. Long-stay samples are characterised by chronic psychopathology, often including a diagnosis of schizophrenia. Findings from this study are challenged by methodological weakness and importantly, no clear definition for long-stay. The definition provided by Völlm et al. (2017) of >5 years in medium security, or >10 years in high security, or >15 years in a continuous combination of both medium and high security is recommended as a time-limited definition for future research, dependent on future policy and legislation changes. There remains a lack of convergence regarding factors associated with LoS. This may be due to the inclusion of static as opposed to dynamic variables collected for a different purpose as LoS studies remain limited by retrospective designs reliant on pre-existing data. Good quality research is recommended, particularly with UK populations outside of England, which are prospectively designed using rigorous and pre-agreed standardised data collection methods that utilise PROMS. Well defined predictor variables that aim to capture a holistic view of factors associated with LoS in a complex population, with a clear definition of LoS, are essential to avoid stagnation in the evidence base and aid
convergence of patient factors consistently and reliably associated with a true long-stay forensic inpatient population.
3.7. References


4. **Journal Article:** Examining the Validity of the CORE-OM as a Measure of Distress in a Forensic Population with Severe and Enduring Mental Illness

4.1. **Abstract**

**Introduction:** In the few studies which have examined the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) within forensic populations, CORE-OM scores fell between clinical and non-clinical reference samples. One explanation for low self-report is poor insight and whether the CORE-OM can adequately capture distress arising from psychotic experience.

**Method:** In a sample of 246 males in a high secure forensic service, routinely collected CORE-OM and two measures of insight and symptomatology (PANSS, PECC-R) were extracted retrospectively from case files to assess the relationship between CORE-OM, insight, and psychotic symptomatology.

**Results:** Positive, negative, general, and total symptom subscales significantly predicted CORE-OM all item mean scores. The general subscale demonstrated the strongest relationship. Insight significantly predicted CORE-OM all item mean scores, suggesting as insight reduced, self-reported distress increased. Insight did not mediate the relationship between symptomatology and CORE-OM scores. CORE-OM scores were between non-clinical and clinical cut-offs in all domains. Revised normative scores for a male high secure forensic population are provided.

**Discussion:** The CORE-OM is sensitive to changes in clinician-rated symptomatology. However, as reduced insight predicted higher CORE-OM scores, the explanation that low insight is responsible for low self-reported distress is not supported. Future research should explore factors associated with change in CORE-OM scores over time, utilising secondary clinical datasets to overcome the challenges of conducting research in forensic settings.

**Keywords:** CORE-OM, Psychosis, Insight, Severe & Enduring, Forensic, Inpatient

**Word Count:** 9541

**Word Count:** 8482 (excluding abstract, tables/figures, references, and appendices)
4.2. Introduction

4.2.1. Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM)

Routine outcome measures are fundamental in the evaluation and improvement of health care services, with specific measures developed for use in mental health settings to measure therapeutic outcomes (Black, 2013). In 2011, the Scottish Government conducted a national consultation regarding the standardisation of measurement outcomes (Reshaping Care and Mental Health Division, 2011). They recommended that all adult psychological services across NHS Scotland implement a standardised measure to allow comparisons across similar services and consistency at patient, staff, and service level. Due to its robust, well-cited, measurement properties, ease of access, and international use, the CORE-OM (Evans et al., 2000) was recommended. Parallel embedding of the CORE-OM was recommended by strategic working groups, tasked with setting standards of best practice for forensic mental health services (Forensic Matrix Working Group, 2014).

The CORE-OM is a pan-theoretical, self-report measure of global distress and part of a series of measures designed for use in screening, routine monitoring, and measuring outcomes in research and clinical practice in the UK (Evans et al., 2000). Items are designed to explore: subjective wellbeing (e.g. “tension and anxiety have prevented me from doing important things”); commonly experienced symptoms (e.g. “I have thought I am to blame for my problems and difficulties”); life/social functioning (e.g. “I have been happy with the things I’ve done”); and risk to self and others (e.g. “I have threatened or intimidated others”). See Appendix 8. Excellent psychometric properties are reported, with strong discrimination and sensitivity to differences between clinical and non-clinical samples (Evans et al., 2002). Authors recognised research of the CORE-OM in specialist clinical populations was required (Evans et al., 2002), however, such research remains limited. Lack of research may be due to the assumption that once properties are established in one population, they likely generalise to others (MacDonald & Fugard, 2015). Indeed, research establishing psychometrically well-evidenced and sensitive outcome measures for forensic populations are limited (Chambers et al., 2009; Shinkfield & Ogloff, 2014). To date,
four studies have examined psychometric properties of the CORE-OM within forensic settings (McCloskey, 2001; Gilling McIntosh, 2020; O'Connor and Morris, 2019; Perry, 2010).

**4.2.2. CORE-OM in Forensic Populations**

Research, in adults, indicates that those who score higher on the CORE-OM are more likely to experience greater psychological distress and poorer wellbeing (Evans et al., 2000). The CORE-OM has been investigated within primary and secondary care services and despite patient acceptability, it was suggested that those who experience severe and enduring mental health difficulties may underreport their distress (Barkham et al., 2005). This is reflected in forensic samples, with findings that CORE-OM scores are lower than clinical normative samples (Gilling McIntosh, 2020; McCloskey, 2001; Perry, 2010). Perry (2010) examined the feasibility of the CORE-OM in a sample of 34 male, high security patients with schizophrenia. Mean scores fell below clinical cut-offs and no correlations between patient-rated and staff-rated CORE-OM were found on any domains, except for ‘functioning’, which showed a small significant association.

A more recent study was conducted within the State Hospital (TSH), Scotland’s only high secure forensic inpatient service (NHS State Hospitals Board for Scotland, 2020). Using routinely collected data for 188 patients, Gilling McIntosh (2020) explored the internal reliability and test structure of the CORE-OM with TSH patients. CORE-OM scores fell between non-clinical and clinical normative scores in all domains; the risk domain was below non-clinical scores. In total, 68% of TSH patients scored below the clinical cut-offs for a community sample of males established by Evans et al. (2002).

The low levels of distress reported are at odds with the presentation of the population in which they were measured. Clinical normative scores were originally developed from community populations referred to primary and secondary care services (Evans et al., 2000). Forensic populations are involuntary detained, frequently presenting with severe and enduring mental illnesses, predominantly schizophrenia, alongside chronic comorbid psychiatric disorders, histories of trauma, neuropsychological impairments, and significant violence risk (McKenna, Jackson, & Browne, 2019; O’Flynn et al., 2018; Ogloff et al., 2015). Adverse experiences encourage threat-based mentalities
and forensic patients may be mistrustful of authority, have poor insight into their difficulties, and endorse fewer symptoms than their clinicians or comparison patient groups, which creates barriers to engagement (Barnao et al., 2016; Hopko et al., 2002). Perry (2010) found forensic patients feared the consequences of disclosing honest answers, which may have led to a minimising response style that could skew CORE-OM responses. The potential drivers or motivations unique to this population could influence responses to CORE-OM items, suggesting this measure may not adequately capture the difficulties and distress experienced by forensic inpatients.

The reasons for low levels of self-reported distress in this population are not clear. The most prevalent diagnosis within high secure settings is schizophrenia (NHS State Hospitals Board for Scotland, 2020). As the CORE-OM constitutes a global measure of distress, it may not directly capture psychotic experience (Perry, 2010). Importantly, schizophrenia directly impacts an individual’s perception of reality, and studies suggest between 50-80% of patients with schizophrenia are partly lacking in at least one dimension of insight (Dickerson et al., 1997). Impaired insight influences several aspects of clinical outcome, including treatment adherence (Velligan et al., 2009) and symptom severity (Crumlish et al., 2005; Lincoln, Lullman, & Rief, 2007). Research demonstrates a relationship between insight and both positive and negative symptoms (Joseph et al., 2015). Therefore, two intertwined avenues of explanation emerge in relation to low distress scores: the ability of the measure to capture distress arising from psychotic symptomatology and the influence of insight within this. Whilst other potential moderating factors may account for low self-report scores in forensic populations, this study explores insight in depth.

4.2.3. The Role of Insight

Insight is a multi-faceted construct and difficult to define (Amador et al., 1993; Woods, Reed, & Robinson., 1999). Insight considers individuals’ capacity to recognise that they are, or had been, suffering from a mental illness, their ability to re-label unusual mental events as pathological, and their compliance with treatment (David, 1990). The traditional definition, known as clinical insight, refers to an individual’s awareness and comprehension of their mental health difficulties (Amador & David, 1998). Beck and
colleagues (2004) added to the literature with the conception of cognitive insight, which refers to the ability to recognise thinking errors and consider alternative explanations.

Self-report is determined by an individual’s willingness and ability to accurately report their experience. Regarding the latter, patients with poor insight were shown to be less likely to report their experience accurately (Doyle et al., 1999) and experience more difficulty recognising and reporting negative symptoms (Selten et al., 2000). However, Perry (2010) found no correlation between CORE-OM scores and insight in a small forensic sample. Bell and colleagues (2007) examined insight in relation to the patient’s accuracy in self-reporting symptoms of depression and on personality measures. They found patients were able to accurately self-report distress, but that poor insight was associated with less distress. In a sample of high secure patients, patients’ clinical insight was poor regardless of symptom severity, and was associated with an increased likelihood of hasty decision making (e.g. jumping to conclusions) which can lead to impulsive decision making and impact care (Kuokkanen et al., 2016). Patients able to gather more information without such biases reported less distress. With CORE-OM scores below clinical norms in forensic inpatients, this finding may have bearing in this population; in that low CORE-OM scores demonstrate a lack of distress, but due to the presence of poor insight.

4.2.4. Insight & Psychotic Symptoms

Poor insight contributes to the development of psychotic experience and studies have demonstrated relationships between insight and positive and negative symptoms (Joseph et al., 2015). Subotnik et al. (2020) meta-analysed multiple dimensions of insight, finding that positive and negative symptoms were moderately associated with poor insight.

Positive symptoms are defined by the presence of abnormal features, distorted from reality (Beck et al., 2004), and studies have found positive symptoms are frequently associated with impaired insight (Lincoln et al., 2007). Sevvy et al. (2004) found that lack of awareness of illness was correlated only with positive symptoms, and insight correlated strongly with delusions and disorganisation symptoms in another study (Amador et al., 2004). Mintz et al. (2003) meta-analysed 40 studies (n=2838) and
Posited a significant negative association between insight and positive symptomatology, although the relationship was modest, explaining 3-7% of the variance.

Negative symptoms are defined as pathological deficits, characterised by blunted affect, reduced motivation, and general withdrawal from internal experiences and the wider world (Osatuke et al., 2008). This lack of engagement in the world reduces the individuals’ capacity to make sense of their internal experience, which limits their ability to develop insight (Lysaker et al., 2010). Subotnik et al.’s (2020) meta-analysis concluded that insight was most strongly associated with negative symptoms, alongside social cognitive, and disorganisation factors. Again, Mintz et al. (2003) found associations between insight and negative symptoms were modest.

4.2.5. The Insight Paradox

Poor insight has been suggested as a psychological defence and way of coping against negative connotations of psychotic illness (Osatuke et al., 2008), protecting self-esteem and preserving hope (Startup, 1997; Tait et al., 2003). Studies have shown that improved insight is correlated with depression and poor quality of life (Hasson-Ohayon et al., 2006). Where the general ethos is to bolster insight into illness to promote recovery, these findings can cause conflict in goals for treatment (Davis et al., 2020).

The insight ‘paradox’ (Lysaker et al., 2007) in schizophrenia attempts to explain these seemingly contradictory outcomes. They suggest poor insight is associated with reduced depressive symptoms, increased positive symptoms, and higher quality of life. As insight improves, positive symptoms reduce, however, quality of life also reduces, and depressive symptoms become prominent. Improvements in insight have been associated with reduced symptomatology (Saeedi et al., 2007), whilst others failed to find this relationship (Erickson & Lysaker, 2011). Davis et al. (2020) in their meta-analysis exploring this paradox found that the inverse relationship between overall clinical insight and quality of life is more pronounced for those with milder symptoms. With regard to the forensic inpatient population, it is plausible that greater
positive symptom severity and low insight could be a buffer in patients' experience of distress, resulting in reduced distress as evidenced in CORE-OM scores.

4.2.6. The Current Study

In this retrospective cohort study, we extracted CORE-OMs that were routinely administered in all hubs (with the exception of the Intellectual Disability ward) since February 2013. Measures are completed at admission, intermediate, and annual case review (twice-yearly at a minimum). For patients engaged in psychological therapy, measures can be administered more frequently, on a pre-post or session-by-session basis. As the only self-report measure routinely collected, the CORE-OM has a significant role in determining the effectiveness of psychological interventions and assessing a patient's mental state and level of distress, which can inform risk management strategies and clinical practice.

This study builds upon research conducted within forensic settings and aims to investigate whether the CORE-OM is valid for use in forensic mental health settings according to the following research questions:

1. Is the CORE-OM sensitive to symptom severity in psychosis as rated by clinicians?
2. What proportion of variance in the CORE-OM does insight into one's illness (clinical insight) explain?

The study hypothesises that:

- H1: the CORE-OM will be sensitive to clinician-rated measures of symptom severity (as measured by the PECC/PANSS) due to its robust psychometric properties.
- H2: Insight, as measured by the PANSS and PECC, will significantly predict CORE-OM scores in that poor insight will yield lower levels of distress as measured by the CORE-OM.
- H3: Insight will mediate the association between positive symptoms and CORE-OM scores.
To further explore previous observations of low mean scores, CORE-OM mean scores will be compared against established clinical reference samples provided by Evans et al. (2002).

4.3. Methodology

4.3.1. Setting

The study sampled data from The State Hospital (TSH), Scotland’s high secure forensic mental health hospital for patients from Scotland and Northern Ireland. Care and rehabilitation are provided to patients detained under the Mental Health (Care & Treatment) (Scotland) Act (2003/2015). Patients are admitted from prison, court, lower levels of security, and the community. At the time of the study, the hospital had capacity for 144 beds, 12 for the intellectual disability ward and 4 for emergency use (State Hospitals Board for Scotland, 2020). All patients are male; there has been no provision for high security care for female patients in Scotland since 2008 (NHS State Hospital Board for Scotland, 2008).

4.3.2. Sample

Opportunity sampling was applied whereby data was collected from files of all available patients within TSH at the time of data collection. Data was collected over an eight-year period, beginning February 2012 when the CORE-OM was initially implemented on a pilot basis within several wards. A list of all inpatients residing at TSH between February 2012 to the time of request (4th October 2020) was provided by Medical Records, as all patients were eligible. Those admitted and discharged or transferred within the study period were eligible, provided outcome measures were completed as a patient within TSH and were accessible through electronic case files.

Records were subject to the following inclusion criteria:

1. CORE-OM completed on at least one occasion.
2. Clinician rated measure of insight (PANSS/PECC-R) completed on at least one occasion.

Patients with a diagnosis of intellectual disability were excluded from this study.¹

CORE-OM data is collected and monitored by the Psychology Department (administered by assistant/trainee psychologists, specialist nurse therapists, and psychologists). CORE-OMs completed for case review and pre-post psychological intervention (group or individual) were included.

Within the collection period, 377 patients were resident/admitted to TSH. Of those, 131 (34.8%) were excluded for the following reasons: ID diagnosis (n=41,31.3%); deceased (file unavailable; n=5,3.8%); unreliable/incomplete data (n=4,3.1%). For eighty-one patients (61.8%), no CORE-OM was available. Records from 246 patients were retained and included in the study.

4.3.3. Design

The study applied a retrospective cohort design, collecting routine outcome measures completed independently to the study by a member of the patients’ clinical team. Data was extracted electronically (PECC-R) and by hand (Demographic Information, CORE, PANSS), for as many time points as there were available across the patient journey.

Principal component analysis conducted by Gilling McIntosh (2020) found TSH patient’s response patterns did not map onto the four-domain structure established by Evans et al. (2002). Therefore, the dependent variable for all research questions was CORE-OM all item mean score. Independent variables for the primary research question were PANSS total and subscale scores and PECC-R subscales scores.

¹ An ID derivative of the CORE-OM (CORE-LD) was in development by research groups and therefore not available at the time the CORE-OM was introduced in TSH. A tool for use with the LD population had been previously utilised for routine measurement, Dynamic Risk Assessment and Management System (DRAMs; Steptoe, Lindsay, Murphy, & Young, 2008) which continued to be used for the TSH LD population beyond 2011. Two CORE-LD versions later emerged, one from the research group in England of 14-items (Brookes et al., 2013) and a 30-item version developed by the research group in Scotland (Marshall et al., 2013).
Independent variables for the secondary research question were PANSS and PECC-R insight scores. For the third research hypothesis, insight scores were mediating variables.

4.3.4. Measures

Demographics

Demographic information relating to age, ethnicity, index offence, date of admission, and discharge (where applicable) was extracted from patient case files. ICD-10 diagnosis was taken as diagnosis recorded on the last multidisciplinary team review document.

**CORE-OM** *(Evans et al., 2000)*

The CORE-OM is a self-report measure, developed as a transdiagnostic tool for measuring global distress, and has become one of the most widely used outcome measures within the NHS (Barkham, Mellor-Clark, & Stiles, 2015). It comprises 34 items across four domains including subjective wellbeing (4-items), problems i.e. symptomatology (12-items), life functioning (12-items), and risk (to self and others; 6-items). Patients’ answers should be based on the frequency of which they may or may not have had these experiences in the previous week, with item scores ranging from ‘1=not at all’ to ‘4=most or all of the time’. A quarter of items are positively framed and reverse-scored, with a problem-scored method of measurement in that higher scores always indicate greater distress. Dimension scores can be pro-rated in the case of omitted items, up to a maximum of three in total and no more than one in a particular domain. Scores are derived by totalling all items into a clinical score or taking mean item scores within dimensions, for all items minus risk, and all 34 items. The minimum score obtainable is zero and the maximum is 136, therefore all item mean scores can range from 0-4.

Internal consistency ranges from good to excellent at .75-.94 (Evans et al., 2002) One-week test-retest reliabilities are between $r_s= .60-.91$ (good-excellent; Evans et al., 2002) and $r_s=.81$ (very good) at two months respectively (Barkham et al., 2005). The
CORE-OM demonstrated good convergent validity against seven different measures, including self-report measures considering anxiety, depression, interpersonal relationships, and symptomatology. Only clinician-rated measures of risk were included (Evans et al., 2002).

**Positive and Negative Syndrome Scale (PANSS; Kay, Fiszbein, & Opler, 1987)**

The PANSS is a 30-item, clinician/interviewer-rated questionnaire that aims to assess the severity of psychotic symptoms in the preceding 72-hour period. Three subscales measure positive symptoms (7-items), negative items (7-items), and general psychopathology (16-items). Item 12 within the general scale considers ‘lack of insight and judgement’ to which clinicians ascribe a rating according to the thought content expressed during interview. Symptom severity is rated on a 7-point Likert scale, ranging from ‘1=absent’ to ‘7=extreme’, with higher scores reflecting greater severity. For example, an insight score of 1 would suggest the patient has no difficulties in this area and 7 would indicate an extreme lack of insight. The scale scores are derived by totalling ratings across component items. All subscales are calculated to provide an overall total. For positive and negative subscales, scores range from 7-49 and the general subscale ranges from 16-112. Total scores can range from 30-210. Additionally, a composite scale is scored by subtracting the negative score from the positive score. The difference in score reflects the prominence of one syndrome in comparison to the other.

The PANSS is considered one of the most psychometrically robust measures in the assessment of psychotic symptoms (Kay et al., 2000). Positive and negative scales display good interrater reliability, with high internal reliability for the negative scale, and satisfactory internal reliability for the positive and general psychopathology scales (Kay, Fiszbein, & Opler, 1987). Criterion validity of the PANSS was supported in two studies demonstrating a significant inverse relationship between positive and negative items ($r=-0.62$ and $r=-0.55$, $p<.001$, respectively; Kay, Opler, & Lindenmayer, 1989).

The PANSS does not provide clinical cut-off scores which can make interpretation difficult from a clinical perspective. Leucht et al. (2005) compared PANSS total scores with simultaneous ratings from the Clinical Global Impressions (CGI) scale, using
pooled RCT data for 4091 patients with schizophrenia. Being considered “mildly ill” according to the CGI corresponded approximately to a PANSS total score of 58, “moderately ill” to a PANSS of 75, “markedly ill” to a PANSS of 95, and “severely ill” to a PANSS of 116.

Within TSH, the PANSS has been incorporated into review documents for TSH patients diagnosed with a psychotic disorder since 2016.

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

This tool was developed for the longitudinal evaluation and follow-up of psychiatric patients with psychosis, designed for integration into nursing practice and considering various dimensions of psychotic symptomatology (De Hert et al., 1998). At TSH, an approved-for-use, shortened version of the PECC-R is completed routinely by nursing staff for all patients regardless of diagnosis. The shortened scale is not fully validated, however positive symptom and insight subscales within the PECC-R are retained, in full, from the original measure. DeHert et al., (2002) found good inter-rater reliability across all symptom categories, with agreement never falling below r=0.80. The concurrent validity of PECC-R positive and negative symptom subscales to the PANSS was excellent (r=0.95).

The positive symptom sub-scale (4-items) addresses hallucinations, delusions, grandiosity, and thought disorder. Following patient interviews, symptoms are rated by assessors from ‘1=absence of symptoms’ to ‘7=symptom present for more than 50% of the time with severe impact on functioning’. Higher scores indicate greater severity and impairment, and scores can range from 4-28. The insight subscale comprises two items: awareness of having a mental illness and awareness of symptoms associated with a mental illness. Ratings range from ‘1=good insight’ to ‘4=completely lacking in insight’. Higher scores represent poorer levels of insight, with total scores ranging from 2-8.
4.3.5. Procedure

Research Permissions

Ethical approval was granted by the South East Scotland ethical review board. The study was approved by the State Hospital Research and Development Committee, with local Caldicott permission included, to access patient data without individual re-consent.

Data Collection

Data was collected between 4th October 2020 and 14th December 2020 and entered into an electronic spreadsheet.

The following data were extracted for each case:

1. **CORE-OM**: date, occasion i.e. annual review, item scores, subscale totals and means, total score, all item mean score. Dimension scores were pro-rated where appropriate i.e. only one item missing per domain up to three items.
2. **PANSS**: date, item scores, subscale totals, overall total, composite score.
3. **PECC-R**: date, item-by-item scores.

Data Preparation

The study utilised clustered data as each patient completed each measure on more than one occasion. Measures completed by patients needed to be matched to ensure an accurate representation of patients’ distress, symptoms, and insight, within the same timeframe. Measures were time-matched within one month of each other as each measure is completed by a different healthcare professional (psychiatry, psychology, nursing). Once all data had been linked, patients were given a unique identification number and identifiable information was removed. Sample size varied according to the availability of matched data: CORE-PANSS \((n=167)\); CORE-PECC-R \((n=706)\); PANSS-PECC-R \((n=362)\).
4.3.6. Statistical Analysis

All data was analysed using IBM SPSS Version 25. Descriptive statistics are reported for sample characteristics. Exploratory tests of association were conducted using Spearman’s rank-order correlation ($r_s$) due to measures using different scales and violating assumptions of normality. All statistical tests were two-tailed, even where the hypothesised direction of the relationship between variables was pre-specified.

The sample mean dimension scores were compared to the clinical samples provided by Evans et al. (2002) and revised normative cut-off scores were calculated.

To explore H1, a linear mixed model was applied due to the clustered data design. Mixed models are robust methods for data that occurs at different time points across patients, and with different numbers of observations completed per individual. Mixed models are extensions of linear regression models that include fixed linear predictor variables (i.e. PANSS scores) but also include random predictors to account for cluster-related correlations in the data (in this case, where there are several measurement occasions per individual). Data was clustered within the individual (according to subject ID) by observation number. Without accounting for the clustered structure, the risk of inflating estimates for fixed effects is high which could result in a Type I error. However, the full dataset could not be retained without violating the statistical test assumptions of independence of observations, therefore a mixed model was employed.

Separate mixed models were conducted with each PANSS subscale (positive, negative, general, total) as fixed effects. To account for overlapping effects of PANSS subscales, a further mixed regression was conducted in which the three PANSS subscales were included as fixed effects within the same model. CORE-OM all item mean score was the dependent variable in all analyses. Each analysis included a random intercept for individuals to control for within-cluster dependencies.

Linear mixed models were also appropriate to examine whether insight scores (Analysis 1: PANSS insight; Analysis 2: PECC-R insight) significantly predicted CORE-OM all item mean scores (H2).
It is well known that there is no current consensus on how to generalise $R^2$ from mixed models due to difficulty accounting for the random variance within the model (Jaeger et al., 2017). For this reason, SPSS mixed procedure does not produce an $R^2$ (IBM SPSS, 2020). Feingold (2015) suggests that Cohen’s $d$ can be calculated for multilevel models by dividing the unstandardised regression coefficient ($b$) with the pooled within-group standard deviation. Cohen’s $d$ has therefore been used to calculate and report effect size estimates from mixed models.

To answer H3, a multilevel mediation was fitted using the MLMed Macro in SPSS (Rockwood & Hayes, 2017) to test whether level of insight mediates the effect of positive symptoms scores on distress, as measured by the CORE-OM all item mean score. Multilevel mediation extends classic simple mediation models that assume independence (Preacher & Hayes, 2004) accounting for clustered data by using multilevel modelling.

This model assumes two levels of data in the dataset, with level 1 units nested within level 2 units. This includes when level 2 refers to persons and level 1 refers to observations or repeated measurements, which is the structure of this study data (Kenny, Korchmaros, & Bolger, 2003). Data collected at a higher level (e.g. person-level) are called level-2 data (e.g. sex). As all variables of interest were measured at level-1 (i.e. PANSS, CORE, PECC-R item measures), the hypothesis was tested with a 1-1-1 multilevel mediation model. Model parameters were estimated using restricted maximum likelihood estimation (Rockwood, 2017). Monte Carlo confidence intervals tested for the significance of mediating effects.

In the first mediation, the outcome variable was CORE-OM all item mean score and the predictor variable was PANSS positive score. PANSS insight score was the mediating variable. In the second mediation, PECC-R positive score was the predictor variable with PECC-R insight as the mediating variable.
4.3.7. Power Analysis

Power analysis refers to the determination of statistical power to identify fixed effects in the analysis, as modelling will account for clustered data within the random variance. Therefore, to calculate the minimum sample required to find the fixed effects of interest in the following analyses, a power analysis was carried out where there was one observation per individual.

A priori power analysis was conducted using G*Power 3.1 (Faul et al., 2007) concerning the power to reject the null hypothesis, in this case, the power to detect that a single regression coefficient is significantly different from zero. Cohen's (1988) guidelines to determine effect sizes were followed as small (.02), medium (.15), and large (.35). To detect a small or medium effect size for models with a single predictor ($f^2=.02$ and .15 respectively), and an alpha of .05, a sample of 395 patients was required for a small effect and 53 patients were required to detect a medium effect. A power of 80% was assumed. Therefore, analysis with the PECC-R data was sufficient to detect a small effect, and PANSS data to detect a medium effect. In the model with three predictors, a sample of 77 patients was required to detect a medium effect ($f^2=.15$) with an alpha of .05 at 80% power.

According to Fritz & MacKinnon (2007), for a mediation model using a bias-corrected bootstrap to detect a medium effect size (0.39) at 80% power, the estimated sample size required is 71.

In each of the following analyses, a sample of data from more than the minimum required was available. With the retention of additional observations per patient, afforded by adopting a nested data structure, the total N per analysis well exceeded the minimum sample required. Therefore, all analyses were sufficiently powered to detect a medium effect size.
4.4. **Results**

4.4.1. **Checking Assumptions**

The assumptions of mixed-effects models involve the validity of the model, linearity, homogeneity of residuals, and assumptions about the distribution of the residuals and random effects (Schielzeth et al., 2020). Residuals from each mixed model were saved to test assumptions. Uttley (2019) suggests a three-pronged approach to comprehensively assess normality: (1) Visual inspection of graphical data representations; (2) Assessment of descriptive statistics; (3) Statistical tests of deviation from a normal distribution (Shapiro Wilks; W statistic). For each of the mixed models, data appeared to violate the assumption of normality, although this was not consistent between the three indicators i.e. W statistics were close to or above 0.98 which suggests deviations from normality are minor. Furthermore, statistical tests of normality can be oversensitive for larger samples and have been criticised when used for large datasets (Field, 2013). The smallest dataset in this analysis was $n=167$ and the largest was $n=706$.

Therefore, without glaring violations of normality, attempts were made to address non-normality where possible as suggested by Uttley (2019). The ‘Restricted Maximum Likelihood Estimator’ was used in linear mixed model analysis, which is a robust estimate in estimating variance components when faced with skewed distributions (Banks, Mao, & Walter, 1985). It is known that variance components will be biased when models are fitted using ‘Maximum Likelihood’ (Nakagawa & Schielzeth, 2013). To add precision to fixed-effects parameter estimates, Bias-correlated-and-accelerated (BCa) 95% confidence intervals (CI) were reported, using the bootstrapping approach based on 1,000 samples.

4.4.2. **Sample Characteristics**

Demographic, clinical, and offence characteristics of the whole sample are presented in Table 1. This includes all individuals who contributed at least one CORE-OM to this dataset. The mean age was 37.82 years (SD=10.71), ranging from 18-74 years. Mean age was calculated from the age of patients on completion of their first CORE-OM.
due to the long data collection period. The average length of stay was 66 (73.94) months. Median length of stay was 44 months, ranging from 1-439 months.

Table 1. Sample Demographic, Clinical, and Offence Characteristics

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>231</td>
<td>93.9</td>
</tr>
<tr>
<td>White British</td>
<td>216</td>
<td>87.8</td>
</tr>
<tr>
<td>Asian/Asian British</td>
<td>5</td>
<td>2.0</td>
</tr>
<tr>
<td>African/Black British</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>2.0</td>
</tr>
<tr>
<td>Not known</td>
<td>2</td>
<td>0.9</td>
</tr>
<tr>
<td><strong>Primary Diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychotic disorder</td>
<td>208</td>
<td>84.5</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>161</td>
<td>65.4</td>
</tr>
<tr>
<td>Schizoaffective disorder</td>
<td>16</td>
<td>6.5</td>
</tr>
<tr>
<td>Delusional disorder</td>
<td>10</td>
<td>4.1</td>
</tr>
<tr>
<td>Other psychotic disorder e.g. drug induced</td>
<td>21</td>
<td>8.5</td>
</tr>
<tr>
<td>Personality Disorder</td>
<td>15</td>
<td>6.2</td>
</tr>
<tr>
<td>Mood</td>
<td>16</td>
<td>6.5</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>1.6</td>
</tr>
<tr>
<td>No diagnosis made*</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>Secondary Diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substance misuse</td>
<td>138</td>
<td>54.5</td>
</tr>
<tr>
<td>Personality disorder</td>
<td>83</td>
<td>32.8</td>
</tr>
<tr>
<td>Anxiety</td>
<td>9</td>
<td>3.6</td>
</tr>
<tr>
<td>Mood</td>
<td>9</td>
<td>3.6</td>
</tr>
<tr>
<td>Other</td>
<td>14</td>
<td>5.5</td>
</tr>
<tr>
<td><strong>Index Offence Type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homicide</td>
<td>90</td>
<td>33.6</td>
</tr>
<tr>
<td>Attempted murder</td>
<td>50</td>
<td>18.7</td>
</tr>
<tr>
<td>Other violence</td>
<td>74</td>
<td>27.6</td>
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<tr>
<td>Sexual crimes</td>
<td>29</td>
<td>10.8</td>
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<tr>
<td>Fire-raising</td>
<td>5</td>
<td>1.9</td>
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<tr>
<td>No index offence</td>
<td>13</td>
<td>4.9</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>2.5</td>
</tr>
</tbody>
</table>

*CORE-OM was completed ahead of admission case review and a diagnosis had not yet been made.
**Not all patients received a secondary diagnosis. Some patients receive multiple secondary diagnoses.
***Several patients had multiple charges (most serious offence categorised i.e. sexual offences AND homicide=2 entries).

Note: Antisocial personality disorder recorded in n=67
Descriptive statistics are provided for all patients’ first CORE-OM (Table 2). Information published on the CORE-OM in non-clinical and clinical reference samples is provided to facilitate comparisons to mean scores.

**Table 2.** CORE-OM (N=246) mean score comparison for each domain and all item mean score

<table>
<thead>
<tr>
<th>Mean Scores Dimension</th>
<th>Study Sample (N=246) Mean</th>
<th>SD</th>
<th>Non-Clinical (N=471) Mean</th>
<th>SD</th>
<th>Clinical (N=338) Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wellbeing</td>
<td>1.24</td>
<td>0.95</td>
<td>0.68</td>
<td>0.71</td>
<td>2.22</td>
<td>0.98</td>
</tr>
<tr>
<td>Problems</td>
<td>1.23</td>
<td>0.91</td>
<td>0.78</td>
<td>0.64</td>
<td>2.32</td>
<td>0.92</td>
</tr>
<tr>
<td>Functioning</td>
<td>1.21</td>
<td>0.75</td>
<td>0.83</td>
<td>0.62</td>
<td>1.92</td>
<td>0.87</td>
</tr>
<tr>
<td>Risk</td>
<td>0.20</td>
<td>0.40</td>
<td>0.23</td>
<td>0.47</td>
<td>0.69</td>
<td>0.75</td>
</tr>
<tr>
<td>All non-risk items</td>
<td>1.22</td>
<td>0.76</td>
<td>0.79</td>
<td>0.59</td>
<td>2.13</td>
<td>0.84</td>
</tr>
<tr>
<td>All items</td>
<td>1.04</td>
<td>0.67</td>
<td>0.69</td>
<td>0.53</td>
<td>1.88</td>
<td>0.78</td>
</tr>
</tbody>
</table>


The sample mean CORE-OM scores for all dimensions fell below clinical cut-off scores with the addition of the CORE-Risk domain, which fell below non-clinical scores and replicates previous findings (Gilling McIntosh, 2020). Additionally, from visual inspection of scatterplots (see figure 1) and using the score classification (see section 4.3.4) proposed by Leucht et al. (2005), the majority of patients in this sample would be categorised as “mildly ill” according to their PANSS scores.

Cut-offs to assess clinically significant change were derived by Evans et al. (2002) using the Jacobson and Truax (1991) procedure and are shown below (Table 3). Given existing normative scores appear not to capture forensic samples, values that can be used in the determination of whether clinically significant change has occurred for a high secure forensic population were calculated from this sample. Jacobson and Truax (1991) procedure was employed using criterion (c.2) due to unequal variances between groups.
\[ c = \frac{s_0 M_1 + s_1 M_0}{s_0 + s_1}. \]

(c.2).

**Table 3.** Cut-off scores to determine Clinically Significant Change for CORE-OM Domains

<table>
<thead>
<tr>
<th>Domain</th>
<th>Males – clinical sample (Evans et al., 2002)</th>
<th>Males – high secure forensic sample (current study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wellbeing</td>
<td>1.37</td>
<td>0.92</td>
</tr>
<tr>
<td>Problems</td>
<td>1.44</td>
<td>0.97</td>
</tr>
<tr>
<td>Functioning</td>
<td>1.29</td>
<td>1.00</td>
</tr>
<tr>
<td>Risk</td>
<td>0.43</td>
<td>0.21</td>
</tr>
<tr>
<td>All non-risk items</td>
<td>1.36</td>
<td>0.98</td>
</tr>
<tr>
<td>All items</td>
<td>1.19</td>
<td>0.84</td>
</tr>
</tbody>
</table>

**4.4.3. Is the CORE-OM sensitive to symptom severity in psychosis as rated by clinicians?**

*H1: The CORE-OM is sensitive to clinician rated measures of symptom severity*

Spearman's rank order correlations were conducted for the three PANSS subscales to investigate associations between subscales. VIFs were calculated to check for multicollinearity to ensure reliability of the estimates of the model parameters (Field, 2013).

No VIF values were above 10 and no tolerance levels below 0.2 suggesting the assumption of multicollinearity was met. All subscales showed significant positive correlations (Table 4).
The linear mixed model analysis (Table 5) found positive, negative, and general subscales showed significant positive relationships to CORE-OM all item mean scores, demonstrated in Figures 1 and 2. Both PANSS and PECC-R positive symptomatology scores significantly predicted distress. PANSS negative, general, and total symptoms scores were also significant, meaning as clinician-rated symptomatology increased in severity, self-reported distress also increased. Results are consistent with a small effect size and provide support for H1.

Table 5. Estimated Fixed Effects of Predictors (Symptoms) for CORE-OM All Item Mean Score

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate ($\beta$)</th>
<th>SE</th>
<th>df</th>
<th>F</th>
<th>t</th>
<th>$P$</th>
<th>d</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>0.55</td>
<td>0.09</td>
<td>163.15</td>
<td>32.64</td>
<td>5.72</td>
<td>&lt;.001</td>
<td>.347</td>
<td>.347</td>
<td>.791</td>
</tr>
<tr>
<td>PANSS Positive</td>
<td>0.02</td>
<td>0.006</td>
<td>145.42</td>
<td>15.81</td>
<td>3.98</td>
<td>&lt;.001</td>
<td>0.31</td>
<td>0.014</td>
<td>.026</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.62</td>
<td>0.006</td>
<td>164.68</td>
<td>32.66</td>
<td>5.72</td>
<td>&lt;.001</td>
<td>.396</td>
<td>.837</td>
<td></td>
</tr>
<tr>
<td>PANSS Negative</td>
<td>0.02</td>
<td>0.001</td>
<td>133.33</td>
<td>7.01</td>
<td>2.65</td>
<td>.009</td>
<td>0.22</td>
<td>0.004</td>
<td>.027</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.31</td>
<td>0.11</td>
<td>164.25</td>
<td>7.5</td>
<td>2.74</td>
<td>.007</td>
<td>-0.037</td>
<td>.877</td>
<td></td>
</tr>
<tr>
<td>PANSS General</td>
<td>0.02</td>
<td>0.004</td>
<td>143.58</td>
<td>29.34</td>
<td>5.42</td>
<td>&lt;.001</td>
<td>0.35</td>
<td>0.014</td>
<td>.018</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.38</td>
<td>0.12</td>
<td>163.38</td>
<td>10.78</td>
<td>3.28</td>
<td>&lt;.001</td>
<td>.017</td>
<td>.752</td>
<td></td>
</tr>
<tr>
<td>PANSS Total</td>
<td>0.009</td>
<td>0.002</td>
<td>137.85</td>
<td>23.17</td>
<td>4.81</td>
<td>&lt;.001</td>
<td>0.35</td>
<td>0.006</td>
<td>.009</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.52</td>
<td>0.06</td>
<td>434.24</td>
<td>87.68</td>
<td>9.36</td>
<td>&lt;.001</td>
<td>0.436</td>
<td>.555</td>
<td></td>
</tr>
<tr>
<td>PECC-R Positive</td>
<td>0.04</td>
<td>0.005</td>
<td>703.56</td>
<td>69.06</td>
<td>8.31</td>
<td>&lt;.001</td>
<td>0.30</td>
<td>0.028</td>
<td>.058</td>
</tr>
</tbody>
</table>

Note: The estimates indicate differences in average CORE-OM all item mean score between groups.
Figure 1. Scatterplot of observed CORE-OM and PANSS scores, with fixed parameter estimates from mixed model (line)\(^2\)

\(^2\) Higher CORE-OM and PANSS/PECC-R scores reflect higher distress and greater symptom severity, respectively.
To partition out shared variance and increase the precision of analysis a mixed regression model was specified, which included fixed effects of PANSS positive, negative, and general subscales.

Only the general subscale remained significant when all three subscales were entered into the model, $F(1,128.505)=13.302$, $p<.001$, $d=.27$, $\beta=0.024$, 95%BCaCI [0.015,0.024]. This was consistent with a small effect. The positive subscale, $F(1,142.566)=.001$, $p=.970$, $d=.11$, $\beta=-.0004$, 95%BCaCI [-.0195,.0212] and negative subscale were no longer significant, $F(1,154.297)=1.844$, $p=.177$, $d=.10$, $\beta=-.012$, 95%BCaCI [-.042,.028]. Once unique and shared variance is separated out, the result is that the general subscale has an effect on CORE-OM scores over and above the other PANSS subscales.

Overall, the linear mixed model analysis indicates individual differences in the CORE-OM all item mean scores are sensitive to differences in clinician ratings of symptom severity, with the strongest relationship with general symptoms, providing support for H1.
4.4.4. What proportion of variance does in the CORE-OM does insight into one’s illness (clinical insight) account for?

_H2: Insight will significantly predict CORE scores in that reduced insight will yield lower levels of distress as measured by the CORE-OM_

Prior to conducting the mixed model, Spearman’s rank order correlation tested the association between PANSS and PECC-R Insight scales to determine whether they tapped into the same dimension of insight (clinical insight). There was a statistically significant, strong positive correlation between scales, \( r_s(208)=.897, \ p<.001 \), confirming a significant degree of conceptual overlap between measures.

The linear mixed model found significant positive relationships to CORE-OM all item mean scores for both PANSS and PECC-R measures of insight, consistent with a small effect size (Table 6). Results indicate that insight significantly predicts CORE-OM all item mean scores, in that reduced levels of insight, as measured by clinicians, are associated with increased levels of distress, as reported by patients. Due to the positive direction of this relationship (Figure 3), this finding does not provide support for H2.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate (( \beta ))</th>
<th>SE</th>
<th>df</th>
<th>F</th>
<th>t</th>
<th>P</th>
<th>d</th>
<th>95% BCa CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>.668</td>
<td>.090</td>
<td>163.57</td>
<td>54.61</td>
<td>7.39</td>
<td>&lt;.001</td>
<td>.488</td>
<td>.834</td>
</tr>
<tr>
<td>PANSS Insight</td>
<td>.076</td>
<td>.026</td>
<td>124.20</td>
<td>8.44</td>
<td>2.91</td>
<td>.004</td>
<td>0.23</td>
<td>.028 .105</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.52</td>
<td>0.07</td>
<td>520.57</td>
<td>62.36</td>
<td>7.90</td>
<td>&lt;.001</td>
<td>.442</td>
<td>.513</td>
</tr>
<tr>
<td>PECC-R Insight</td>
<td>0.07</td>
<td>0.01</td>
<td>703.89</td>
<td>39.3</td>
<td>6.27</td>
<td>&lt;.001</td>
<td>0.22</td>
<td>.027 .126</td>
</tr>
</tbody>
</table>

**Note:** The estimates indicate differences in average CORE-OM all item mean score between groups.

**Note:** p-values pertain to t-values.
Figure 3. Scatterplot demonstrating mixed model association between PANSS Insight and PECC-R Insight on CORE-OM all item mean score

---

3 High scores on insight are associated with greater impairment. Higher CORE-OM scores signify greater distress.
H3: Insight mediates the association between positive symptoms and CORE-OM scores

A planned multi-level mediation between CORE-OM all item mean scores and PANSS and PECC-R positive scores was conducted (Figures 4-5). Following the results of H1, which found a relationship of similar strength between CORE-OM all item mean scores and the other PANSS scales, two further multi-level mediation analyses were conducted post-hoc (Figures 6-7). Predictor variables were PANSS negative and PANSS general subscales.

In cases where the level 2-unit (between-cluster) is a person, this might explain the coefficients in the level 1 (within-effects) equations. Research has tended to focus on level 2 units which explain the effects between individuals as there may be many variables, beyond those included in this study, which account for intra-individual variation at within-subject level e.g. time (Kenny, Korchmaros, & Bolger, 2003). Between effects results are reported in Figures 4-7.

---

General subscale total score was adjusted to total score minus the PANSS Item G12 Insight which is an item within this scale.
The between-indirect effect of PANSS positive symptom scores on CORE all item mean scores via PANSS insight scores was not significant: IE=.002, 95%CI [-.013,.018]. As Monte Carlo confidence intervals passed through zero, there was no mediating effect.

Figure 4. Multilevel mediation (between-effects) model associations between PANSS Positive Symptoms (X), Insight (M), and CORE-OM all item mean scores (Y).

The between-indirect effect of PECC-R positive symptom scores on CORE-OM all item mean scores via PECC-R insight scores was not significant, IE=-.001; 95%CI [-.011,.009], with Monte Carlo confidence intervals demonstrating no mediating effect.

Figure 5. Multilevel mediation (between-effects) model associations between PECC-R Positive Symptoms (X), Insight (M), and CORE-OM all item mean scores (Y).
The between-indirect effect of PANSS negative symptom scores on CORE-OM all item mean cores, via insight, was not significant, IE=.013; 95%CI [-.001,.028]. Monte Carlo confidence intervals passed through zero, indicating no mediating effect.

**Figure 6. Multilevel mediation (between-effects) model associations between PANSS Negative Symptoms (X), Insight (M), and CORE-OM all item mean scores (Y).**

The between indirect effect of PANSS general symptom scores on CORE-OM all item mean scores via PANSS insight scores was not significant: IE=-.008; 95%CI [-.020,.003]. As Monte Carlo confidence intervals passed through zero, there was no mediating effect.

**Figure 7. Multilevel mediation (between-effects) model associations between PANSS General Symptoms (X), Insight (M), and CORE-OM all item mean scores (Y).**
Output from the mediation analysis was strikingly consistent across predictor variables, with no mediating effect of insight found between symptoms and CORE-OM all item mean scores at the level of the individual. Therefore, H3 is not supported.

4.5. Discussion

4.5.1. Main Findings

This study examined the CORE-OM in a sample of male high security inpatients. Positive, negative, and general symptomatology subscales significantly predicted CORE-OM all item mean scores, demonstrating small effect sizes. That is, as clinician-rated symptom severity increased, self-report distress also increased, suggesting the CORE-OM appears sensitive to changes in symptom severity. On comparison, general symptoms had the strongest relationship to CORE-OM all item mean scores. Intuitively, this would be sensible; the CORE-OM was developed as a transdiagnostic tool and the PANSS subscale, intended to measure general symptoms, is perhaps not as exclusively connected to psychotic experience.

Rather than poor insight significantly predicting lower self-reported distress, the direction of this relationship is positive which suggests as clinical insight reduces, becoming more impaired, distress levels increase on the CORE-OM. Both measures of insight, rated by two independent disciplines, found this relationship. Effect sizes were small. This finding ran counter to the hypothesised relationship and contradicts previous studies (e.g. Perry, 2010) which found no association between insight and distress. Results contradict the ‘insight paradox’, which suggests poor insight protects against negative outcomes due to the presence of positive symptoms, which in turn impair insight. However, visual inspection of scatterplots suggests PANSS symptoms are generally ‘mild’ (Leucht et al., 2005). High secure forensic populations may be relatively stable in their symptomatology, and therefore positive symptoms may not be as prevalent or experienced as acutely. Studies have found that following an acute phase, during periods of remission, positive symptoms may not have as strong associations with insight (Češková et al., 2007). That negative symptoms increase as insight reduces also runs counter to the insight paradox, which suggests negative symptoms increase due to improved insight. Finally, this study found insight did not
mediate the relationship between symptomatology and distress, which contradicts findings for this paradoxical relationship that fluctuates depending on insight.

Lysaker et al. (2007) found that the insight paradox is mediated by self-stigma. Although self-stigma is particularly relevant in schizophrenia and recognised within forensic psychiatry (Margetić et al., 2008), for this sample, perhaps it may not have such bearing. A large proportion of our sample have a diagnosis of personality disorder, of which antisocial personality disorder is most common, and unfortunately, forensic patients can often be alienated from and perceived negatively by wider society (Mezey et al., 2010). Mezey et al. (2016), in a later study, found no increased stigma and discrimination in forensic psychiatric patients compared with non-forensic psychiatric populations. They suggested the nature of the environment may explain the lack of differences. Patients benefit from high multidisciplinary support over significantly longer periods than community samples, working with forensic mental health professionals who are supportive of the patient and their recovery and may play a role in challenging stigma (Livingston et al., 2011). Combined with their view of the world and how they respond to it, patients may be less likely to endorse stigmatising beliefs regarding their illness or may perceive them as less relevant, although this is hypothetical and out with the scope of the present study.

McGlashan et al. (1975) suggest a continuum of recovery styles; one end considers patients eagerly interested in their psychotic experience and gaining perspective, perhaps those most likely to endorse stigmatising beliefs. At the other extreme, they describe a process of “sealing over”, characterised by patients’ denial of their illness existence and poor recall when describing their psychotic experience. The latter, regarding this sample, suggests that lack of insight may be attributable to psychological defences, with denial of stigmatising beliefs protecting against self-stigma. Negative symptoms are characterised by withdrawal from society, and as patients’ symptoms increase, they may “seal over” as their insight challenges their attempts to understand their reality. Lysaker et al. (2007) suggest for some, essentially forgetting past psychotic experiences by denying previous difficulties is adaptive. This is a tentative suggestion, as equally, patients newly admitted into the hospital may experience an opposite effect upon admission i.e. being acutely aware of the stigma of being transferred to the hospital (Gilling McIntosh, 2020). Indeed, our current
sample has an average length of stay of 5.5 years and therefore patients may be reasonably settled in their environment.

This study found positive symptoms increase as insight becomes more impaired. Impaired insight suggests individuals have more difficulty making sense of their reality. Whilst it was previously suggested that this may act as a buffer against distress, within a forensic population this may not be the case. The experience of positive symptoms can be characterised by intense persecutory beliefs and hallucinatory experiences that could be intensely frightening and distressing. This may be particularly true when combined with histories of trauma, negative adverse experiences, and beliefs based upon feeling unsafe and mistrustful. The lack of escape from these experiences may also compound difficulties (Birchwood et al., 2005). Belvederi-Murri et al. (2016) suggest that in subgroups of patients suffering from severe positive or negative symptoms, an association between reduced insight and severe depression may be observed, in this case, opposing the direction of the insight paradox.

The finding that insight does not mediate the relationship between positive symptoms and distress but is independently a significant predictor of distress, as measured by the CORE-OM, suggests insight plays a significant role but not at the level of a mediating effect. Insight is a multifaceted construct and the relationships between concepts are complex. Furthermore, this study used measures of clinical insight concerning unawareness of symptoms and the need for hospitalisation, which are essential for diagnosis and treatment. However, the inclusion of ‘awareness of need for treatment’ when assessing insight is controversial. Instead of indicating self-knowledge, insight becomes entangled with whether an individual complies with the medical understanding of their experience (Curk et al., 2020), which fails to consider that individuals can also accept treatment while maintaining that they are not mentally unwell and vice versa (David, 2018). Beck and colleagues (2004) suggest that even though patients may be genuinely accepting of an explanation and able to relay this explanation when asked, their underlying delusional belief system may remain unchanged. For this sample, having an awareness of their diagnosis and associated symptoms may have no bearing on distress if their internal experience is fraught with misinterpretation based on persisting delusional beliefs. Therefore, the demand from insight instruments for compliance is problematic, both clinically and ethically. On the
PANSS subscale, the difference between extreme to absent insight is non-compliance. Therefore, agreement to treatment is always more insightful than to refuse (Curk et al., 2020). David & Ariyo (2021) considered practitioners’ views, suggesting their account invariably constructed insight as proven by treatment compliance. This risks confusing a compliant patient as an insightful patient, and highlights specific challenges when assessing the forensic population as individuals are held against their will and their progression through the system largely depends on their compliance. Furthermore, determining an individual’s level of insight involves relational negotiation, which requires a good therapeutic relationship so not to place ‘disagreement’ at the core of insight evaluation. Such relationships involve trust, which is a potential area of difficulty for this population (Hopko et al., 2002). Therefore, even if internal conflict is present, individuals may not disclose this to the assessor, which reflects reluctance based on the relationship as opposed to level of insight (Curk et al., 2020). This is in line with the minimising response style evidenced by Perry (2010), which suggest patients may keep their underlying beliefs undisclosed.

Minimising for fear of potential consequences (Perry, 2010) may help in our understanding of the low scores reported for this sample. Using 246 patients’ first CORE-OMs, this study reinforces Gilling McIntosh’s (2020) findings that CORE-OM scores for this sample are below clinical cut-offs and between clinical and non-clinical normative samples in all domains, including all item mean score. This study hypothesised that low scores may be explained by insight, but this is not supported, and so the question remains: what accounts for such low scores?

The population from which CORE-OM normative data was developed were self-presented persons purposely seeking help for mental health difficulties, likely inclined to use their responses on the CORE-OM to signal their difficulties and need for support and/or treatment. In contrast, the current sample has an awareness of the consequences of disclosing problems, particularly regarding risk, in a secure hospital environment where they are compulsorily detained. Given the differences between samples, one potential solution is to consider revised normative data scores, taken from a forensic sample for a forensic population, which previous studies have recommended (McCloskey, 2001; Gilling McIntosh, 2020; Perry et al., 2013). This is not the first study to provide new norms for a specialist population, Barkham et
al. (2005) found older adult samples scored below clinical and non-clinical samples and provided revised norms for those over 65. Given the large amount of data available within this study, a set of male, high secure normative scores were produced which should be considered for further exploration in research and clinical practice.

Despite the general downshift in scores, the finding from this study appears to be that, regardless of insight, high security patients are able to access their internal emotional experience and report their distress, providing support for the CORE-OM as a measure sensitive to distress in a forensic sample with psychosis. Findings also lend evidence of CORE-OMs validity in a forensic population where there is currently none. This study challenges assumptions that the CORE-OM may be unsuitable for this population given concerns regarding self-report and the role of insight in potentially obscuring patients’ emotional experience.

4.5.2. Future Research

Although predictive of CORE-OM all item mean scores, insight did not explain the general dampening of scores observed in this large sample of forensic inpatients. Revised forensic normative data is provided to aid both research and routine monitoring in clinical practice. Future research should seek to replicate the use of these scores in forensic samples, whilst exploring potential mechanisms behind low self-report i.e. self-stigma, minimising response styles, blunted affect. Gilling McIntosh (2020) found a three-component structure underlying CORE-OM items, of which one was relational difficulties. Given the limited interactions patients may have and the previous suggestion that staff interactions can be protective, relational difficulties for this sample may differ from their previous experiences or may not have the opportunity to arise. For example, the consequences for patients responding violently to others within a secure environment differs significantly from non-secure or community environments. Therefore, fewer or altered interpersonal difficulties may lead to reduced distress, particularly as patients settle in their environment. Other factors, such as the presence of comorbid personality disorder may influence how patients conceptualise and report distress, which may have influenced results of this study. Considering the average patient stay was 5.5 years, factors such as length of stay
may be relevant. Symptoms may improve as they settle into their environment, leading to improvements in insight and relatively little distress.

Studies using longitudinal data and considering change over time are required to explore interactions between CORE-OM scores, symptomatology, and insight as patients engage in treatment, relationships, recovery, offending, and identity work, which are all potential determinants of distress. Distress will likely vary as patients undergo these experiences in their forensic recovery journey. The CORE-Risk subscale remains below non-clinical cut-offs in this sample, echoing Gilling McIntosh’s (2020) recommendation. Exploration of this subscale and its predictive validity for risk incidents is warranted. Finally, this study utilised pre-existing data, and measured clinical insight only. Future research should explore whether cognitive insight plays a role in the distress-insight-symptomatology relationship and both patient and clinician-rated measures would be optimal.

4.5.3. Limitations

This study has limitations. First, data was extracted retrospectively from patient electronic files by the primary author. It is possible that before extraction, by the clinical team, or during extraction, by the author, missing data or errors inputting scores occurred. This could have implications for the reliability of the data. However, attempts were made to counteract such errors through accuracy checks, checking for impossible values, electronic extraction of one measure (PECC-R), and having a standardised data collection form. Furthermore, the sample size is considered large enough to mitigate any possible inaccuracies, and recognition is given that this is often unavoidable when relying on previously collected data from case records. Eighty-one patients did not complete a CORE-OM and were excluded from this study. Reasons for non-completion may relate to implementation problems embedding CORE as a routine outcome measure, or patients being too unwell or unwilling to partake, which could skew the sample towards more mentally well patients. Glancy et al. (2021) highlight such barriers to routine monitoring. Measures of insight included the PANSS G12 item and the PECC-R which comprises two questions. The use of brief scales to assess insight is a limitation, particularly considering the complexity of insight and the availability of comprehensive measures designed to measure it e.g. Scale to Assess
Unawareness of Mental Disorder (SUMD; Amador et al., 1993), Birchwood Insight Scale (BIS; Birchwood et al., 2004). However, both measures, in particular the PECC-R, appear to be ecologically valid tools, completed regularly by staff and allowing for the maximum possible sample size.

4.6. Conclusions

In a very large sample of forensic high secure patients with severe and enduring diagnoses, the CORE-OM as a self-report measure of distress demonstrated sensitivity to differences in ratings on two clinician-rated measures of symptomatology. Clinical insight significantly predicted CORE-OM all item mean scores; however, insight does not mediate the relationship between symptoms and distress. As symptoms increase, distress increases, and as insight reduces, distress also increases. This finding contradicts the concept of the ‘insight paradox’ in relation to distress. Results provide additional evidence in support of the validity of the CORE-OM in forensic settings and suggest patients with psychosis are able to make meaning of and self-report their distress. However, CORE-OM scores remain below clinical cut-offs. Normative data, representative of a male high secure forensic population, have been provided as part of this study and should be explored in further research and clinical practice. Longitudinal studies exploring factors associated with changes in self-reported distress over time are important to investigate the distress-insight-symptomatology relationship over the patient journey. This study showed how research can take forward the recommendations from Chambers et al. (2009) and build the evidence base for measurement properties of commonly used outcome measures by leveraging secondary clinical datasets, allowing for significant samples to be obtained in a cohort where conducting research is otherwise challenging.
4.7. **References**


What does the PANSS mean? *Schizophrenia research, 79(2-3), 231-238.*


(Accessed 9th February 2021).


Appendices – Systematic Review

Appendix 1. Journal of Aggression and Violent Behaviour – Author Guidelines

AGGRESSION AND VIOLENT BEHAVIOR

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DESCRIPTION

Aggression and Violent Behavior, A Review Journal is a multidisciplinary journal that publishes substantive and integrative reviews, as well as summary reports of innovative ongoing clinical research programs on a wide range of topics germane to the field of aggression and violent behavior. Papers encompass a large variety of issues, populations, and domains, including homicide (serial, spree, and mass murder: sexual homicide), sexual deviance and assault (rape, serial rape, child molestation, paraphilias), child and youth violence (firesetting, gang violence, juvenile sexual offending), family violence (child physical and sexual abuse, child neglect, incest, spouse and elder abuse), genetic predispositions, and the physiological basis of aggression.

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• Supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); the resolution is too low.
• Supply files that are too low in resolution.
• Submit graphics that are disproportionately large for the content.
**Color artwork**

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**Figure captions**

Ensure that each illustration has a caption. A caption should comprise a brief title (not on the figure itself) and a description of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.

**Tables**

Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

**References**

**Citation in text**

Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

**Web references**

As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

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Reference style
List: references should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.
Examples:
Reference to a journal publication:
Reference to a journal publication with an article number:
Reference to a book:
Reference to a chapter in an edited book:
Reference to a website:
Reference accessed January 6, 2016
Reference to a dataset:
Reference to a conference paper or poster presentation:

Journal abbreviations source
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Appendix 2. Table of Key Words used in Database Searching

Example search strategy including MEDLINE (PubMed)
Search conducted 30/12/2020, 14:00

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Line</th>
<th>Search Term</th>
<th>Records Retrieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>1</td>
<td>((patient$ OR inpatient$ OR detaine$) adj12 (felon$ OR forensic mental OR forensic psychiat$ OR (((low OR medium OR high OR maximum) adj3 secur$))) OR (insanity acquittee$ OR insanity defend$ OR offender patient$) OR ((hosp$ OR ward OR inpatient OR setting$ OR unit OR facility OR institut$) adj5 (forensic psych$ OR forensic mental OR secur$)) OR (((low OR medium OR high OR maximum) adj3 secur$) OR (Broadmoor OR Rampton OR Ashworth OR Carstairs OR forensic institut$))</td>
<td>11243</td>
</tr>
<tr>
<td>Outcome</td>
<td>2</td>
<td>length of stay OR exp &quot;Length of Stay&quot;/</td>
<td>124280</td>
</tr>
<tr>
<td>Outcome</td>
<td>3</td>
<td>((length$ OR duration OR time OR period OR long$) adj3 (stay$ OR treatment OR admission OR detention OR hospitali$ OR confinement)) OR (inpatient duration OR longstay OR long-stay)</td>
<td>356802</td>
</tr>
<tr>
<td>Combined</td>
<td>4</td>
<td>2 OR 3</td>
<td>356802</td>
</tr>
<tr>
<td>Combined</td>
<td>5</td>
<td>1 AND 4</td>
<td>542</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Limit 5 to (English Language, Humans)</td>
<td>384</td>
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</tbody>
</table>


**Appendix 3.** Quality Assessment Tool and Guidance Document

**NOTE:** Questions 10 and 13 were not applicable in all cases and were removed.

**Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies**

**- Study Quality Assessment Tools**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes</th>
<th>No</th>
<th>Other (CD, NR, NA)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the research question or objective in this paper clearly stated?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Was the study population clearly specified and defined?</td>
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<tr>
<td>3. Was the participation rate of eligible persons at least 50%?</td>
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<tr>
<td>4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?</td>
<td></td>
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<tr>
<td>5. Was a sample size justification, power description, or variance and effect estimates provided?</td>
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<td></td>
</tr>
<tr>
<td>Criteria</td>
<td>Yes</td>
<td>No</td>
<td>Other (CD, NR, NA)*</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
<td>---------------------</td>
</tr>
<tr>
<td>6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?</td>
<td></td>
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<tr>
<td>8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?</td>
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<td></td>
</tr>
<tr>
<td>9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?</td>
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<tr>
<td>10. Was the exposure(s) assessed more than once over time?</td>
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<tr>
<td>11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criteria</td>
<td>Yes</td>
<td>No</td>
<td>Other (CD, NR, NA)*</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----</td>
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<td>---------------------</td>
</tr>
<tr>
<td>implemented consistently across all study participants?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Were the outcome assessors blinded to the exposure status of participants?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>13. Was loss to follow-up after baseline 20% or less?</td>
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<tr>
<td>14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*CD, cannot determine; NA, not applicable; NR, not reported

**Guidance for Assessing the Quality of Observational Cohort and Cross-Sectional Studies**

The guidance document below is organized by question number from the tool for quality assessment of observational cohort and cross-sectional studies.

**Question 1. Research question**

Did the authors describe their goal in conducting this research? Is it easy to understand what they were looking to find? This issue is important for any scientific paper of any type. Higher quality scientific research explicitly defines a research question.

**Questions 2 and 3. Study population**
Did the authors describe the group of people from which the study participants were selected or recruited, using demographics, location, and time period? If you were to conduct this study again, would you know who to recruit, from where, and from what time period? Is the cohort population free of the outcomes of interest at the time they were recruited?

An example would be men over 40 years old with type 2 diabetes who began seeking medical care at Phoenix Good Samaritan Hospital between January 1, 1990 and December 31, 1994. In this example, the population is clearly described as: (1) who (men over 40 years old with type 2 diabetes); (2) where (Phoenix Good Samaritan Hospital); and (3) when (between January 1, 1990 and December 31, 1994). Another example is women ages 34 to 59 years of age in 1980 who were in the nursing profession and had no known coronary disease, stroke, cancer, hypercholesterolemia, or diabetes, and were recruited from the 11 most populous States, with contact information obtained from State nursing boards.

In cohort studies, it is crucial that the population at baseline is free of the outcome of interest. For example, the nurses' population above would be an appropriate group in which to study incident coronary disease. This information is usually found either in descriptions of population recruitment, definitions of variables, or inclusion/exclusion criteria.

You may need to look at prior papers on methods in order to make the assessment for this question. Those papers are usually in the reference list.

If fewer than 50% of eligible persons participated in the study, then there is concern that the study population does not adequately represent the target population. This increases the risk of bias.

**Question 4. Groups recruited from the same population and uniform eligibility criteria**

Were the inclusion and exclusion criteria developed prior to recruitment or selection of the study population? Were the same underlying criteria used for all of the subjects involved? This issue is related to the description of the study population, above, and you may find the information for both of these questions in the same section of the paper.

Most cohort studies begin with the selection of the cohort; participants in this cohort are then measured or evaluated to determine their exposure status. However, some cohort studies may recruit or select exposed participants in a different time or place than unexposed participants, especially retrospective cohort studies—which is when data are obtained from the past (retrospectively), but the analysis examines exposures prior to outcomes. For example, one research question could be whether diabetic men with clinical depression are at higher risk for cardiovascular disease than those without clinical depression. So, diabetic men with depression might be selected from a mental health clinic, while diabetic men without depression might be selected from an internal medicine or endocrinology clinic. This study recruits groups from different clinic populations, so this example would get a "no."
However, the women nurses described in the question above were selected based on the same inclusion/exclusion criteria, so that example would get a “yes.”

**Question 5. Sample size justification**

Did the authors present their reasons for selecting or recruiting the number of people included or analyzed? Do they note or discuss the statistical power of the study? This question is about whether or not the study had enough participants to detect an association if one truly existed.

A paragraph in the methods section of the article may explain the sample size needed to detect a hypothesized difference in outcomes. You may also find a discussion of power in the discussion section (such as the study had 85 percent power to detect a 20 percent increase in the rate of an outcome of interest, with a 2-sided alpha of 0.05). Sometimes estimates of variance and/or estimates of effect size are given, instead of sample size calculations. In any of these cases, the answer would be "yes."

However, observational cohort studies often do not report anything about power or sample sizes because the analyses are exploratory in nature. In this case, the answer would be "no." This is not a "fatal flaw." It just may indicate that attention was not paid to whether the study was sufficiently sized to answer a prespecified question—i.e., it may have been an exploratory, hypothesis-generating study.

**Question 6. Exposure assessed prior to outcome measurement**

This question is important because, in order to determine whether an exposure causes an outcome, the exposure must come before the outcome.

For some prospective cohort studies, the investigator enrolls the cohort and then determines the exposure status of various members of the cohort (large epidemiological studies like Framingham used this approach). However, for other cohort studies, the cohort is selected based on its exposure status, as in the example above of depressed diabetic men (the exposure being depression). Other examples include a cohort identified by its exposure to fluoridated drinking water and then compared to a cohort living in an area without fluoridated water, or a cohort of military personnel exposed to combat in the Gulf War compared to a cohort of military personnel not deployed in a combat zone.

With either of these types of cohort studies, the cohort is followed forward in time (i.e., prospectively) to assess the outcomes that occurred in the exposed members compared to nonexposed members of the cohort. Therefore, you begin the study in the present by looking at groups that were exposed (or not) to some biological or behavioral factor, intervention, etc., and then you follow them forward in time to examine outcomes. If a cohort study is conducted properly, the answer to this question should be "yes," since the exposure status of members of the cohort was determined at the beginning of the study before the outcomes occurred.
For retrospective cohort studies, the same principal applies. The difference is that, rather than identifying a cohort in the present and following them forward in time, the investigators go back in time (i.e., retrospectively) and select a cohort based on their exposure status in the past and then follow them forward to assess the outcomes that occurred in the exposed and nonexposed cohort members. Because in retrospective cohort studies the exposure and outcomes may have already occurred (it depends on how long they follow the cohort), it is important to make sure that the exposure preceded the outcome.

Sometimes cross-sectional studies are conducted (or cross-sectional analyses of cohort-study data), where the exposures and outcomes are measured during the same timeframe. As a result, cross-sectional analyses provide weaker evidence than regular cohort studies regarding a potential causal relationship between exposures and outcomes. For cross-sectional analyses, the answer to Question 6 should be "no."

**Question 7. Sufficient timeframe to see an effect**

Did the study allow enough time for a sufficient number of outcomes to occur or be observed, or enough time for an exposure to have a biological effect on an outcome? In the examples given above, if clinical depression has a biological effect on increasing risk for CVD, such an effect may take years. In the other example, if higher dietary sodium increases BP, a short timeframe may be sufficient to assess its association with BP, but a longer timeframe would be needed to examine its association with heart attacks.

The issue of timeframe is important to enable meaningful analysis of the relationships between exposures and outcomes to be conducted. This often requires at least several years, especially when looking at health outcomes, but it depends on the research question and outcomes being examined.

Cross-sectional analyses allow no time to see an effect, since the exposures and outcomes are assessed at the same time, so those would get a "no" response.

**Question 8. Different levels of the exposure of interest**

If the exposure can be defined as a range (examples: drug dosage, amount of physical activity, amount of sodium consumed), were multiple categories of that exposure assessed? (for example, for drugs: not on the medication, on a low dose, medium dose, high dose; for dietary sodium, higher than average U.S. consumption, lower than recommended consumption, between the two). Sometimes discrete categories of exposure are not used, but instead exposures are measured as continuous variables (for example, mg/day of dietary sodium or BP values).

In any case, studying different levels of exposure (where possible) enables investigators to assess trends or dose-response relationships between exposures and outcomes—e.g., the higher the exposure, the greater the rate of the health outcome. The presence of trends or dose-response relationships lends credibility to the hypothesis of causality between exposure and outcome.
For some exposures, however, this question may not be applicable (e.g., the exposure may be a dichotomous variable like living in a rural setting versus an urban setting, or vaccinated/not vaccinated with a one-time vaccine). If there are only two possible exposures (yes/no), then this question should be given an "NA," and it should not count negatively towards the quality rating.

**Question 9. Exposure measures and assessment**

Were the exposure measures defined in detail? Were the tools or methods used to measure exposure accurate and reliable—for example, have they been validated or are they objective? This issue is important as it influences confidence in the reported exposures. When exposures are measured with less accuracy or validity, it is harder to see an association between exposure and outcome even if one exists. Also as important is whether the exposures were assessed in the same manner within groups and between groups; if not, bias may result.

For example, retrospective self-report of dietary salt intake is not as valid and reliable as prospectively using a standardized dietary log plus testing participants' urine for sodium content. Another example is measurement of BP, where there may be quite a difference between usual care, where clinicians measure BP however it is done in their practice setting (which can vary considerably), and use of trained BP assessors using standardized equipment (e.g., the same BP device which has been tested and calibrated) and a standardized protocol (e.g., patient is seated for 5 minutes with feet flat on the floor, BP is taken twice in each arm, and all four measurements are averaged). In each of these cases, the former would get a "no" and the latter a "yes."

Here is a final example that illustrates the point about why it is important to assess exposures consistently across all groups: If people with higher BP (exposed cohort) are seen by their providers more frequently than those without elevated BP (nonexposed group), it also increases the chances of detecting and documenting changes in health outcomes, including CVD-related events. Therefore, it may lead to the conclusion that higher BP leads to more CVD events. This may be true, but it could also be due to the fact that the subjects with higher BP were seen more often; thus, more CVD-related events were detected and documented simply because they had more encounters with the health care system. Thus, it could bias the results and lead to an erroneous conclusion.

**Question 10. Repeated exposure assessment**

Was the exposure for each person measured more than once during the course of the study period? Multiple measurements with the same result increase our confidence that the exposure status was correctly classified. Also, multiple measurements enable investigators to look at changes in exposure over time, for example, people who ate high dietary sodium throughout the followup period, compared to those who started out high then reduced their intake, compared to those who ate low sodium throughout. Once again, this may not be applicable in all cases. In many older studies, exposure was measured only at baseline. However, multiple exposure measurements do result in a stronger study design.
**Question 11. Outcome measures**

Were the outcomes defined in detail? Were the tools or methods for measuring outcomes accurate and reliable—for example, have they been validated or are they objective? This issue is important because it influences confidence in the validity of study results. Also important is whether the outcomes were assessed in the same manner within groups and between groups.

An example of an outcome measure that is objective, accurate, and reliable is death—the outcome measured with more accuracy than any other. But even with a measure as objective as death, there can be differences in the accuracy and reliability of how death was assessed by the investigators. Did they base it on an autopsy report, death certificate, death registry, or report from a family member? Another example is a study of whether dietary fat intake is related to blood cholesterol level (cholesterol level being the outcome), and the cholesterol level is measured from fasting blood samples that are all sent to the same laboratory. These examples would get a "yes." An example of a "no" would be self-report by subjects that they had a heart attack, or self-report of how much they weigh (if body weight is the outcome of interest).

Similar to the example in Question 9, results may be biased if one group (e.g., people with high BP) is seen more frequently than another group (people with normal BP) because more frequent encounters with the health care system increases the chances of outcomes being detected and documented.

**Question 12. Blinding of outcome assessors**

Blinding means that outcome assessors did not know whether the participant was exposed or unexposed. It is also sometimes called "masking." The objective is to look for evidence in the article that the person(s) assessing the outcome(s) for the study (for example, examining medical records to determine the outcomes that occurred in the exposed and comparison groups) is masked to the exposure status of the participant. Sometimes the person measuring the exposure is the same person conducting the outcome assessment. In this case, the outcome assessor would most likely not be blinded to exposure status because they also took measurements of exposures. If so, make a note of that in the comments section.

As you assess this criterion, think about whether it is likely that the person(s) doing the outcome assessment would know (or be able to figure out) the exposure status of the study participants. If the answer is no, then blinding is adequate. An example of adequate blinding of the outcome assessors is to create a separate committee, whose members were not involved in the care of the patient and had no information about the study participants’ exposure status. The committee would then be provided with copies of participants' medical records, which had been stripped of any potential exposure information or personally identifiable information. The committee would then review the records for prespecified outcomes according to the study protocol. If blinding was not possible, which is sometimes the case, mark "NA" and explain the potential for bias.

**Question 13. Followup rate**
Higher overall followup rates are always better than lower followup rates, even though higher rates are expected in shorter studies, whereas lower overall followup rates are often seen in studies of longer duration. Usually, an acceptable overall followup rate is considered 80 percent or more of participants whose exposures were measured at baseline. However, this is just a general guideline. For example, a 6-month cohort study examining the relationship between dietary sodium intake and BP level may have over 90 percent followup, but a 20-year cohort study examining effects of sodium intake on stroke may have only a 65 percent followup rate.

**Question 14. Statistical analyses**

Were key potential confounding variables measured and adjusted for, such as by statistical adjustment for baseline differences? Logistic regression or other regression methods are often used to account for the influence of variables not of interest.

This is a key issue in cohort studies, because statistical analyses need to control for potential confounders, in contrast to an RCT, where the randomization process controls for potential confounders. All key factors that may be associated both with the exposure of interest and the outcome—that are not of interest to the research question—should be controlled for in the analyses.

For example, in a study of the relationship between cardiorespiratory fitness and CVD events (heart attacks and strokes), the study should control for age, BP, blood cholesterol, and body weight, because all of these factors are associated both with low fitness and with CVD events. Well-done cohort studies control for multiple potential confounders.

**Some general guidance for determining the overall quality rating of observational cohort and cross-sectional studies**

The questions on the form are designed to help you focus on the key concepts for evaluating the internal validity of a study. They are not intended to create a list that you simply tally up to arrive at a summary judgment of quality.

Internal validity for cohort studies is the extent to which the results reported in the study can truly be attributed to the exposure being evaluated and not to flaws in the design or conduct of the study—in other words, the ability of the study to draw associative conclusions about the effects of the exposures being studied on outcomes. Any such flaws can increase the risk of bias.

Critical appraisal involves considering the risk of potential for selection bias, information bias, measurement bias, or confounding (the mixture of exposures that one cannot tease out from each other). Examples of confounding include co-interventions, differences at baseline in patient characteristics, and other issues throughout the questions above. High risk of bias translates to a rating of poor quality. Low risk of bias translates to a rating of good quality. (Thus, the greater the risk of bias, the lower the quality rating of the study.)

In addition, the more attention in the study design to issues that can help determine whether there is a causal relationship between the exposure and outcome, the higher quality the study. These include exposures occurring prior
to outcomes, evaluation of a dose-response gradient, accuracy of measurement of both exposure and outcome, sufficient timeframe to see an effect, and appropriate control for confounding—all concepts reflected in the tool.

Generally, when you evaluate a study, you will not see a "fatal flaw," but you will find some risk of bias. By focusing on the concepts underlying the questions in the quality assessment tool, you should ask yourself about the potential for bias in the study you are critically appraising. For any box where you check "no" you should ask, "What is the potential risk of bias resulting from this flaw in study design or execution?" That is, does this factor cause you to doubt the results that are reported in the study or doubt the ability of the study to accurately assess an association between exposure and outcome?

The best approach is to think about the questions in the tool and how each one tells you something about the potential for bias in a study. The more you familiarize yourself with the key concepts, the more comfortable you will be with critical appraisal. Examples of studies rated good, fair, and poor are useful, but each study must be assessed on its own based on the details that are reported and consideration of the concepts for minimizing bias.
Appendices – Journal Article

Appendix 4. Schizophrenia Research – Author Guidelines

SCHIZOPHRENIA RESEARCH
An International Multidisciplinary Journal of the Schizophrenia International Research Society

AUTHOR INFORMATION PACK

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DESCRIPTION

As official journal of the Schizophrenia International Research Society (SIRS) Schizophrenia Research is THE journal of choice for international researchers and clinicians to share their work with the global schizophrenia research community. More than 6000 institutes have online or print (or both) access to this journal - the largest specialist journal in the field, with the largest readership!

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Appendix 5. Ethical Approval

Lothian NHS Board

South East Scotland Research Ethics Committee 01

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

www.nhslothian.scot.nhs.uk

Date: 24 August 2020

Enquiries: [Redacted]
Ext: [Redacted]
Direct Line: 0131 465 5473
Email: Sandra.Wylie@nhslothian.scot.nhs.uk

24 August 2020

Dear [Redacted]

Study title: Examining the Validity of the CORE-OM as a Measure of Distress in a Forensic Population with Severe and Enduring Mental Illness.

REC reference: [Redacted]
Protocol number: [Redacted]
IRAS project ID: [Redacted]

Thank you for your letter of 18 August 2020, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.
Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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 management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that all clinical trials are registered on a publicly accessible database. For this purpose, ‘clinical trials’ are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/).

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

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).

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, including early termination of the study
- Final report
The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

**Ethical review of research sites**

**NHS/HSC sites**

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Non-NHS/HSC sites**

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

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Valuated questionnaire [TSHCore_Scale-PECC]

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.

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 Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities—see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 277188  Please quote this number on all correspondence

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

Yours sincerely

[Signature]

Dr Lucy Kershaw
Chair

Email: [Redacted]@nhlothian.scot.nhs.uk

Enclosures:  “After ethical review – guidance for researchers”

Copy to:  Miss [Redacted]
Appendix 6. The State Hospital Board Research & Development and Management Approvals

XXX

Thursday the 28th November 2019

Dear X,

Re: Examining the Validity of the CORE-OM as a Measure of Distress in a Forensic Population with Severe & Enduring Mental Illness

Many thanks for your revised research proposal that was initially reviewed by the TSH Research Committee in September 2019. I have subsequently reviewed the amended proposal in line with the feedback from the committee to your original submission. I am satisfied that you have attempted to address each aspect of the feedback given within your revised proposal and I am happy to provide approval on behalf of the research committee for your study to commence. You should now address any need for REC Ethical approval, and evidence of this review alongside this letter will be provided to the AMD who will sign off management approval for your to proceed.

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.

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
Dear [Name],

Examining the Validity of the CORE-OM as a Measure of Distress in a Forensic Population with Severe & Enduring Mental Illness

Having considered the views of the Research Committee and noted that ethical approval has been granted by the South East Scotland Research Ethics Committee 01 and that you have completed a DPIA, I write to give you Managerial Approval to proceed with your project. This is subject to you fulfilling the requirements of the State Hospital Research Committee.

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

Yours sincerely,

[Signature]

Dr Duncan Alcock
Associate Medical Director

cc Jamie Pitcairn, Research and Development Manager,
Professor Lindsay Thomson, Medical Director.
Non-CTIMP Study Protocol

The CORE-OM as a Measure of Distress in Forensic Population

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1. INTRODUCTION

1.1. BACKGROUND

Routine outcome measures are fundamental in the evaluation and improvement of health care services, with specific measures developed for use in mental health settings to measure therapeutic outcomes (Black, 2013). In 2011, the Scottish Government carried out a national consultation regarding the standardisation of measurement outcomes for adult psychological therapy services (Reshaping Care and Mental Health Division, 2011). It was recommended that all adult psychological services across NHS Scotland should implement a standardised measure. Due to its robust, well-cited measurement properties and international use (Barkham et al., 2001), The Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM; Evans et al., 2000) system was selected. Implementation across Forensic mental health services in Scotland was encouraged (Forensic Matrix Working Group, 2014).

The CORE-OM is a 34-item, self-report measure of global distress and is part of a range of CORE measures designed for use in screening, routine assessment, and outcome in research and clinical practice (Evans et al., 2000). The CORE-OM is a pan-theoretical, trans-diagnostic measure covering four domains: subjective well-being (4-items), problems/symptoms (12-items), life functioning (12-items), and risk to self and others (6-items) (Evans et al., 2002). Higher total scores indicate higher levels of self-report distress. Excellent psychometric properties are reported for the CORE-OM, with strong discrimination between clinical and non-clinical samples suggesting a measure sensitive to differences between clinical and general samples (Evans et al., 2002). Alpha coefficients range from .75-.95, and test re-test correlations between $r_s = .87$ to $.91$ after one week (Evans et al., 2002), and $r_s = .81$ at two months respectively (Barkham et al., 2007).

Nonetheless, researchers recognise the need for further evidence which fully represents specialised clinical populations (Evans et al., 2002). MacDonald & Fugard (2015) suggest that this delay may be due to the assumption that once properties are established in one population, they are likely to generalise to others. Within forensic mental health, there is a recognised lack of psychometrically well evidenced and sensitive outcome measures (Chambers et al., 2009; McIntosh et al., 2019, in revision). To date, only four studies, the most recent being within The State Hospital (TSH), have examined the psychometric properties of the CORE-OM in forensic settings (McCloskey, 2001; McIntosh et al., 2019, in revision; O’Connor & Morris, 2019; Perry, 2010). As such, the aim of this study is to examine aspects of the validity of the CORE-OM within a forensic mental health population.

Research indicates that those who score higher on the CORE-OM are more likely to experience greater levels of psychological distress and poorer wellbeing (Evans et al., 2000). Greater distress is also associated with increased violence and aggression (Smith, O’Rourke, & MacPherson, 2019). However, a recent study conducted within TSH by McIntosh et al. (2019) found CORE-OM scores fell between non-clinical and clinical reference samples cited by Evans et al. (2002). Sixty-eight percent of TSH patients scored below the clinical cut-offs for males established by Evans et al. (2002), highlighting variability when self-reporting distress in forensic samples. Both McCloskey (2001) and Perry (2010) indicate that forensic
samples report distress scores lower than the clinical norms. Barkham et al. (2005) analysed the suitability of the CORE-OM across primary and secondary care services and although concluded that the CORE-OM was an acceptable measure, they suggested that those who may be more ‘severe and enduring’ in their presentation may underreport their distress. Therefore, the CORE-OM may not fully or adequately capture the difficulties and distress experienced by a ‘severe and enduring’ forensic population, within which the most prevalent diagnosis is psychosis.

Evidence suggests an association between psychological distress and violence, and the effects of forensic inpatient violence are far more likely, far greater, and further reaching, with studies suggesting more than a third of patients behave violently during admission (Smith, O’Rourke, & MacPherson, 2019). Notably, the CORE-OM Risk items were developed using a student counselling sample (Lyne et al., 2006), a population that is not only voluntary, but can be considered higher functioning and of low risk in comparison to those detained in high secure settings. In the only study utilising an inpatient sample and considering the utility of the CORE-OM Risk Domain, Rowsell & Stennett-Cox (2009) found none of the six CORE-Risk items showed predictive validity for aggression or violence. Their participants were 32 inpatients who had been admitted for at least six months. Risk behaviours were gathered from records of all incident reports logged by staff, including ‘all acts of verbal or physical aggression and violence, including self-harm’. The NHS Datix system is a reporting mechanism which contains similar incident reports logged by staff in relation to inpatient violence. Incidents of violence and aggression could be considered as behavioural indicators of distress and are important to consider in relation to CORE-OM scores within that time. Further research is needed to study the validity of the risk items in particular for forensic populations as low scores, equivalent to that of the non-clinical population, contradict other risk assessment measures and their detainment in a high secure setting.

When considering potential mechanisms underlying low levels of self-reported distress within TSH, the clear differentiating factor is that the CORE was developed within self-identifying, voluntary populations; TSH patients are compulsorily detained. Involuntary patients endorse fewer symptoms than either clinicians or a comparison patient group (Hopko et al., 2002). Therefore, there is always the possibility that forensic mental health patients, who are detained against their will, may report scores on outcome measures that are in contrast to clinicians (Taylor, 1998). As such, it is important to include clinician rated measures. The Positive and Negative Syndrome Scale (PANSS Kay, Fiszbein, & Opler, 1987), is a clinician rated measure of symptom severity in patients with psychosis, which is the primary diagnosis within TSH. We would expect some positive correlation between measures over time as the CORE-OM includes a symptom domain, and quantity and severity of symptoms is likely associated with greater overall distress. This also provides scope to consider whether the CORE lacks sensitivity to change within a forensic setting or within a population with psychosis.

From a clinical perspective in relation to psychosis and distress, the concept of insight appears relevant. Over the years, insight has emerged as an important multi-faceted construct (Amador et al., 1993). Woods, Reed, and Robinson (1999) posit that three significant issues have been highlighted from the literature from several attempts by authors to define the concept. Firstly, the individuals’ capacity to recognise that they are suffering or had been suffering from a mental illness. Second to this is their ability to re-label unusual mental events
as pathological, and finally, their compliance with treatment (David, 1990). The traditional
definition, known as clinical insight, refers to an individual’s awareness and comprehension
to the literature with the conception of cognitive insight, which refers to the ability to
recognise thinking errors and consider alternative explanations.

Schizophrenia directly impacts an individual’s perception of reality and is often associated
poor insight (Amador & David, 1998). Studies suggest between 50-80% of patients with
schizophrenia are partly lacking in at least one dimension of insight (Dickerson, Ringel, &
Parente, 1997). Mintz, Dobson, & Romney (2003) meta-analysed 40 studies (N=2838) and
posited a modest negative association between insight and positive symptomatology. Lack of
insight can be associated with poorer outcomes (Lincoln, Lullmann, & Rief, 2007), despite
research from more than twenty years ago suggesting that a greater level of insight is not a
guarantee of behavioural change (Collins & Collins, 1992).

Notably, a lack of insight has been considered in relation to patient self-report measures
(Doyle et al., 1999). Selten et al. (2000) found that those who were severely ill were unable
to accurately report negative symptoms, even if they were aware that they suffered from
psychosis. Indeed, the validity of self-report is determined by the individual’s willingness and
ability to accurately report their experience. As such, there are considerably more factors of
potential influence; a point which is acknowledged but is beyond the scope of this study to
consider. Given that a high percentage of the patients detained within TSH have a primary
diagnosis of schizophrenia, the accuracy of self-report in other domains such as those
involving routine outcome measures, may be impacted by degree of insight, and perhaps
more so when considering the severe and enduring nature of many of the patients difficulties
and their involuntary detainment (State Hospitals Board for Scotland, 2016; Weiler et al.,
2000). As such, it is important to consider whether CORE-OM scores do change over time for
TSH patients and whether there is an associated relationship with insight. Within TSH, there
are two routinely collected measures which measure insight across multiple dimensions: An
Adapted TSH version of The Psychosis Evaluation Tool for Common Use by Caregivers (PECC;
Hert et al., 2002); and the Behavioural Status Index (BEST-Index; Woods, Reed, & Robinson,
1999). Both are routinely collected and completed in conjunction with the other. A growing
literature exists on the vulnerability of self-report instruments to different sources of
distortion, including impression management, malingering, and the effects of acute
symptoms (Bell et al., 2007). However, there is a lack of research examining the role of insight
as a mediator. Bell and colleagues (2007) examined the influence of insight on the accuracy
of self-reporting symptoms of depression and personality measures. They found that patients
were able to self-report their distress, but that poor insight was also associated with less
distress. Considering CORE-OM scores were below clinical norms in TSH patients, this finding
may have bearing in the TSH population; in that low CORE-OM scores demonstrate a lack of
distress, but due to the mediating effect of poor insight. The role of insight as a mediating
factor requires further exploration in relation to how this may affect reporting distress in
relation to the CORE-OM for forensic inpatients.
1.2.  RATIONALE FOR STUDY

The aim of this study is to examine aspects of the validity of the CORE-OM within a forensic mental health population. This project is relevant due to the widespread use of the CORE-OM across all adult psychological services, despite little evidence of its validity within specialist population groups. Initial research by McIntosh et al. (2019, in revision) highlights concerns as to whether the CORE-OM can adequately capture distress experienced by TSH patients. Results from this study will help further determine the validity of the CORE-OM as a routinely collected outcome measure.

At TSH, administration of the CORE-OM was piloted in February 2012. Routine administration of the CORE-OM has been implemented across all hubs since February 2013 (with the exception of those within Iona 2, Intellectual Disability Ward). It is completed at admission, intermediate, and annual case review, and so completed a minimum of twice-yearly. If a patient is engaged in psychological therapy, measures can be administered more frequently, on a pre/post or session-by-session basis. As the only self-report measure routinely collected within the site, the CORE-OM has a significant role in determining the effectiveness of psychological interventions, assessment of patient’s mental state, and level of distress which can inform risk management strategies and clinical practice. With concerns relating to the validity of CORE-risk subscale, self-report indicating lower levels of distress than expected, and the ability the CORE-OM potentially has within TSH to inform practice, there is a clear need to further investigate the validity and sensitivity of this measure for TSH patients. Therefore, this study has implications for TSH continued use of the CORE as a routine outcome measure. This could have a significant impact in routine assessment, through determining if such data is meaningful and if so, for whom, and therefore has the potential to inform patient’s care and treatment.

By including self-report data (CORE-OM), clinician rated data (PECC, BEST, PANSS), and objective behavioural data (DATIX) this study hypothesises that:

H1: Clinician rating and objective behavioural data will co-vary, but that self-report data will not co-vary.

H2: Self-report data will not co-vary with clinician rating and objective behavioural data due to low levels of insight.

2.  STUDY OBJECTIVES

2.1.  OBJECTIVES

2.1.1.  Primary Objective

To determine whether inpatient stay at The State Hospital reduces patients’ self-rated distress, as measured by the CORE-OM, over time.
2.1.2. **Secondary Objectives**

To determine:

Is the CORE-OM sensitive to changes in measures of symptom severity in psychosis as rated by clinicians?

Does self-reported risk of harm to self or others correlate with observed risk incidents within TSH?

What proportion of variance in CORE-OM scores does insight into one’s illness account for?

3. **STUDY DESIGN**

This study will employ a retrospective cohort design. This will allow inclusion of data and information that has been collected independently by the patients' clinical teams, who are not involved in the research, to be used in the study.

Therefore, the researcher will have no contact with patients at any point throughout the study and will collect only existing, routinely collected data from electronic case files.

All longitudinal, quantitative data has been routinely collected at six-month time points from February 2012 to the time of data collection (proposed April 2020). Participants’ case notes will be accessed on Rio as well as the existing CORE-OM database developed and utilised in McIntosh et al. (in revision) TSH study. The CORE-OM measure will be retrospectively extracted from individual case files, alongside measures of insight (PECC, BEST) and symptom-specific measures. All data should be routinely collected at six-month time points in accordance with the site’s review processes. All included measures will be extracted from the first available time point for as many time points as there are completed measures.

Retrospective information relating to violent incidents within the hospital or whilst detained within the hospital i.e. on outings, will be requested from the Risk Management team by the PI. This information will be extracted from the NHS incident reporting system (DATIX) for each of the identified participants. Following extraction, Incidents of aggression (either verbal, physical, or other) for the included individuals and retrospectively coded using the Overt Aggression Scale (Yudofsky et al., 1986) in order to overcome issues related to inconsistent reporting and rating of incidents. Aggression will be divided into four categories: verbal aggression, physical aggression against objects or self or others. Any DATIX data from one week before the CORE-OM was administered to one-week post CORE-OM for each time point will be gathered to determine how these factors affect rates of variation within the CORE-OM.

4. **STUDY POPULATION**

4.1. **NUMBER OF PARTICIPANTS**
This is a single site study conducted entirely from data collected within the State Hospital. The existing CORE-OM database has been utilised in recent research within the site, incorporating data from February 2012 to February 2017 (McIntosh et al., 2019, in revision).

Within this five-year period, 251 people were detained within the site, of whom 188 (75%) had a completed CORE-OM. The database is expected to increase when considering time (three years two months; proposed data collection April 2020), review processes (every six months), and new admissions. With approximately 15-20 new admissions per year to the site, and considering CORE-OM data from admissions only after February 2017, a further 45-60 CORE-OM measures could potentially be completed and included in the database, totalling N= 248 for admission CORE-OM only. However, it is important to note that this is a maximum possible sample estimate.

4.2. INCLUSION CRITERIA

Inclusion criteria includes:

Male adults who have been detained within the State Hospital from February 2012 to the time of data collection (proposed April 2020)

For which a CORE-OM has been completed on at least one occasion

Participants who were admitted and may have been discharged or transferred within this time period are still eligible, provided the outcome measures are completed as part of a case review and are accessible by case file.

4.3. EXCLUSION CRITERIA

Exclusion criteria includes:

Individuals with a diagnosed intellectual disability

5. PARTICIPANT SELECTION AND ENROLMENT

5.1. IDENTIFYING PARTICIPANTS

The population will be identified by requesting from Medical Records a list of all patients under care of TSH (with the exception of patients with a diagnosis of Intellectual Disability which will be noted in the request) since the implementation of the CORE-OM in TSH (February 2012).

5.2. CONSENTING PARTICIPANTS

All data collected for use in this study will be pre-existing and no direct contact will be made with the participants. The researcher hopes to collect data without individual consent from patients whose data is being used which is a recognised ethical issue. Patients are provided
information upon admission which includes details of the possibility that their clinical data may be used anonymously to support research, evaluation, and audit. This approach prevents disruption to patient care, whilst facilitating optimal data collection within a population who present with unique challenges to include in research otherwise. This has been used in support of previous REC applications for studies conducted within the State Hospital. Ethical approval has been granted by the State Hospital R&D Committee following Caldicott principles, with final Caldicott approval being obtained from the on-site guardian following REC approval.

6. DATA COLLECTION

Time points for collection

All included measures will be extracted from the first available time point (beginning February 2012) for as many time points as there are completed measures. All data should be routinely collected at six-month time points in accordance with the site’s review processes. Incidents of aggression (either verbal, physical, or other) for the included individuals will be extracted from the NHS incident reporting system (DATIX) and retrospectively coded using the Overt Aggression Scale (Yudofsky et al., 1986) in order to overcome issues related to inconsistent reporting and rating of incidents. Aggression will be divided into four categories: verbal aggression, physical aggression against objects or self or others. DATIX Data from one week before the CORE-OM was administered to one-week post CORE-OM for each time point will be gathered to determine how these factors affect rates of variation within the CORE-OM.

Who will collect the data

All data is pre-existing with the patients’ electronic case file. The PI will be responsible for sourcing and collating all study data.

Measures

Items to record:
Date of assessment
Assessment occasion (admission/intermediate/annual CPA)
Responses (item-by-item, range)

Outcome Measures

Clinical Outcomes in Routine Evaluation - Outcome Measure (CORE-OM; Evans et al., 2000)

The CORE-OM is a self-report measure used as an index of global distress and has become one of the most widely used outcome measures within the NHS (Barkham, Mellor-Clark, & Stiles, 2015). Specifically, the CORE-OM is the most comprehensive of the CORE system measures, including shortened versions. The CORE-OM consists of 34-items across four domains including subjective well-being (4-items), problems i.e. symptomatology (12-items), life functioning (12-items), and risk (to self and others; 6-items). Twenty-five percent of items
are positively framed and reversed scored, with a problem-scored method of measurement i.e. higher scores indicating higher levels of distress (Evans et al., 2002).

Patient answers should be based on the frequency of which they may or may not have had these experiences in the past week. Scores are derived by totalling all items into a clinical score or taking mean item scores within dimensions, for all items minus risk, or for all 34-items. The CORE-OM is routinely collected and is the primary outcome measure within this study.

Psychosis Evaluation Tool for Common Use by Caregivers (PECC; Hert et al., 2002)

The Psychosis Evaluation tool for Common use by Caregivers was developed for the longitudinal evaluation and follow-up of psychotic patients and designed to be easily integrated into daily nursing practice. Furthermore, the PECC was specifically developed for use in residential as well as outpatient settings (De Hert et al., 1998; De Hert, Bussels, & Peuskens, 1999). Within TSH, an adapted version is used.

The PECC is comprised of functional and symptomatic outcome measures, covering positive, negative symptoms, degree of suicidal ideation and insight into illness. Higher scores indicate higher levels of severity. Positive and negative symptoms are based on a 7-point Likert scale, and 4-point scale for the remaining items. With the exception of four items, the remaining PECC items achieved satisfactory internal reliability above 0.8. Interscale and interrater validity were good, although the latter was based on only two videotaped interviews (De Hert et al., 1998). Within the site, the PECC should be routinely completed by nursing staff for review.

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

The Behavioural Status Index is a behaviourally founded, clinician-rated instrument, originally known as the behavioural recovery index (BRI) and was developed to assess therapeutic impacts during patient transitions, for example, from inpatient to community care. Any member of the patients’ multi-disciplinary team may administer the scale, as completion is dependent on a strong working knowledge of patient i.e. keyworkers.

The Behavioural Status Index aims to generate data to facilitate risk assessment through investigating three areas of cognitive-affective adjustment and skilled performance. These include behaviours usually associated with ‘risk’ in a forensic context, known as risk and probability, degree of insight into cause of their difficulties and current mental health status, and assessment of current communication and social skills.

Inclusion of insight in forensic psychiatric assessment is based on the assumption that level of risk will tend to vary inversely with the level of personal insight gained (Richfield, 1954). The insight subscale consists of 20-items with a concise description and ordinal scale of rating from 1 (worst case) to 5 (best case). As such, lower scores reflect greater lack of insight. All subscales displayed good internal consistency and satisfactory test-retest reliability (insight = 0.89). Interrater reliability for the insight subscale was 82% indicating acceptable agreement.
Within the site, the BEST-Index is a routinely collected measure, completed by a member of nursing staff for review. It is completed in conjunction with the PECC.

**Positive and Negative Syndrome Scale (PANSS; Kay, Fiszbein, & Opler, 1987)**

The Positive and Negative Syndrome Scale is a 30-item, clinician/interviewer-rated questionnaire that aims to assess the severity of psychotic symptoms in the preceding 72-hour period. There are three subscales measuring positive symptoms (7-items), negative items (7-items) and general psychopathology (16-items). Item 12 within the general scale considers ‘lack of insight and judgement’ to which clinicians ascribe a rating according to the thought content expressed during interview. Studies have shown that the whilst individuals can improve following treatment, significant impairments such as insight as measured by PANSS, can persist (Phahladria et al., 2019). Symptom severity is rated on a 7-point Likert scale, ranging from ‘absent’ to ‘extreme’, with higher scores reflecting greater severity. The scores for these scales are derived by totalling ratings across component items. Additionally, a composite scale is scored by subtracting the negative score from the positive score to determine the difference score reflecting the level of prominence one of syndrome in comparison to the other.

The PANSS is considered one of the most psychometrically sound and robustly used measures in relation to the assessment of psychotic symptoms (Martinis et al., 2017). Positive and Negative scales displayed good interrater reliability with high internal reliability for the negative scale, and satisfactory internal reliability for the positive and general psychopathology scales (Kay, Fiszbein, & Opler, 1987). Convergent validity was also satisfactory in comparison with the Scale for the Assessment of Positive Symptoms and Scale for the Assessment of Negative Symptoms (Andreasen, 1981; Andreasen, 1984; Peralta & Cuesta, 1994). Criterion validity of the PANSS was supported in two studies demonstrating significant inverse relationship between positive and negative items \((r= -0.62\) and \(-0.55,\) respectively, \(P<0.01\)) (Kay, Opler, & Lindenmayer, 1988).

Within the site, the PANSS is completed at CPA’s by Junior Doctors and has been utilised in those patients experiencing psychosis within the site. It has been used site-wide since 2016. Nonetheless, a more sporadic pattern of administration is expected specifically in relation to this measure.

**NHS DATIX Incident Report System**

The DATIX system is an electronic, patient-safety software program used across the NHS in which incidents are recorded using a generic entry form provided by their local health board intranet server (Irwin et al., 2011). Such systems are designed to gather information regarding patient safety which can be applied into individual and organisation level development (Stavropoulou, Doherty, & Tosey, 2015). Reporters are asked the nature of the incident, location, outcome, and contributing factors. Severity level is recorded from ‘low’ to ‘severe’. The primary difficulty of using DATIX data is discrepancies in the quality of data reported or variations in coding. Additionally, within the site, DATIX reporting procedure also requires a secondary review of DATIX reports conducted by the Risk Management Department to ensure consistency.
6.1. **SOURCE DATA DOCUMENTATION**

**Electronic Databases**

**Master List.** Each TSH patient will be assigned a unique study identification number for the duration of the study. The electronic spreadsheet (password protected) will be maintained for reference for the duration of the study.

**Pseudo-anonymized data spreadsheet.** All data will be recorded in a pseudo-anonymized electronic spreadsheet. No identifiable information will be included in this spreadsheet.

7. **DATA MANAGEMENT**

7.1. **PERSONAL DATA**

The following personal data will be collected as part of the research through extraction of data from case-notes where appropriate:

Name  
Age  
Gender  
Ethnicity  
Index Offence Category

A list of the participant names will be kept on a separate master list, with a corresponding unique identification number. This master list will remain on site at all times and kept electronically within a secure NHS drive. Only the principal investigator and supervisors will have access to this master list. A separate electronic database will be kept which includes the remaining personal information in relation to the unique identification number. This ensures anonymity of the data.
7.2. DATA INFORMATION FLOW

List from Medical Records for all patients under care of TSH between February 2012 to April 2020 (specifying exclusion criteria).

Accessing identified participants’ electronic case file to obtain CORE-OM data.

Eligible participants identified. Creation of master list and corresponding unique identification numbers.

Input CORE-OM data for each participant (matched by UIDN) into separate database.

Collection of Clinical/Demographic Information/PECC/BEST/PANSS. Match data to participant in database.

Request to Risk Management Team to extract relevant DATIX data. Match data to participant in database.

Once all data collected, replace name with unique identification number. Database anonymised.

Master list kept separate, secure, and on site at all times.

Exclusion criteria: No completed CORE-OM
7.3. TRANSFER OF DATA

Data collected or generated by the study (including personal data) will not be transferred to any external individuals or organisations outside of the Sponsoring organisation(s).

7.4. DATA CONTROLLER

A data controller is an organisation that determines the purposes for which, and the manner in which, any personal data are processed.

The University of Edinburgh and NHS State Hospitals Board for Scotland are joint data controllers along with any other entities involved in delivering the study that may be a data controller in accordance with applicable laws (e.g. the site).

7.5. DATA BREACHES

Any data breaches will be reported to the University of Edinburgh and NHS State Hospitals Board for Scotland Data Protection Officers who will onward report to the relevant authority according to the appropriate timelines if required.

8. STATISTICS AND DATA ANALYSIS

8.1. SAMPLE SIZE CALCULATION

Studies have shown that sample size is problematic to determine in multilevel modelling. Maas & Hox (2005) conducted a simulation study and found samples of 50 or less may lead to some bias in estimates suggesting the need for a large sample size. However, due to multiple sample sizes for different levels and variables in the design, power considerations are problematic and significantly more complex as they differ depending on whether the researcher focuses on a certain parameter or coefficient (Hox, 1998). As this is an opportunistic study with a very specialized population, the largest dataset possible will be extracted based on the population and data that has been previously collected. This is estimated to be a sample size of approximately N=248. To be conservative effect sizes with confidence intervals will be interpreted alongside any null hypothesis statistical testing (p-values). Should the sample size be insufficient, null hypothesis testing will not be conducted and effect sizes and confidence intervals generated. This is a recognised potential limitation of this study.
8.2. PROPOSED ANALYSES

Does inpatient stay at The State Hospital reduce patients’ self-rated distress, as measured by the CORE-OM, over time?

A multilevel longitudinal analysis will be used to answer the first research question. Multilevel models are statistical models of parameters that vary at more than one level (Field, 2017). They are particularly relevant for analysis of data that has a hierarchical or clustered structure, for example, a measure within a patient within a hospital. Where data for participants is organised at more than one level, this is known as nested data (Buxton, 2008). In a recent meta-analysis considering the role of insight in relation to the validity of self-report measures, the use of multi-level modelling was recommended, as part of future research, to allow for an investigation of mediating and moderating factors, and to allow tests for the presence of non-linear associations between constructs (Murri et al., 2015).

Multilevel modelling is appropriate for longitudinal data within which information is nested at different levels within the individual. For example, measures of the CORE-OM at regular time periods will be grouped within the individual subjects. The scores from each individual for each administration of the CORE-OM over time are likely to correlate, this dependency consequently violates the assumption of many statistical tests that observations are independent of one another. This dependency needs to be accounted for within the analysis which multilevel modelling can do. For example, data can be considered as level 1 – each individual CORE-OM and also within level 2 – CORE-OM scores for the individual patient. Therefore, the CORE is nested to the relevant patient on level 2.

Multilevel modelling allows the researcher to view data as a series of repeated measurements nested within individual subjects (Hox, 1998). The advantage of this over other designs is that this method can cope with variances in the times of measurement from subject to subject i.e. when individuals are tested at separate times in accordance with their review process as opposed to being administered CORE-OMs simultaneously in line with an experimental protocol (Boxton, 2008). Multilevel models contain a mix of fixed and random effects, with random variables used to model the variation between groups (Field, 2017). This allows for inclusion of predictors at group level and individual level.

Is the CORE-OM sensitive to changes in measures of symptom severity in psychosis as rated by clinicians?

A correlation analysis, using Pearson’s coefficient, will be used in the first instance to analyse the strength of the relationship between the two measures. Despite measuring different constructs, we would hypothesise that there would be a positive association between elevated levels of distress correlating with increased symptomatology. In the event of a negative or no association, consideration will be given to undertaking a post-hoc exploratory secondary analysis that tests the moderating role of insight between the CORE and the PANSS, such as the use of regression analysis.
**Does self-reported risk of harm to self or others correlate with observed risk incidents within TSH?**

Regression analysis will be used to answer the third research objective. A logistic regression analysis will be used for when CORE scores precede the DATIX incidents and therefore a logistic regression would allow an analysis of whether CORE-OM risk scores predict caseness, with caseness being the presence or absence of a relevant DATIX incident in the next three months following. This analysis will be repeated by category i.e. verbal, physical. For those CORE-Risk items which ask about a risk event that has already happened in the week i.e. I have threatened someone (risk to others), or I have hurt myself (risk to self), a reversed analysis would be appropriate; in this case, a linear regression analysis with CORE-Risk score as the dependent variable and the presence or absence of DATIX incidents as a nominal predictor variable.

There is 85% power to detect medium effect size using logistic regression analysis, where the predictor variable is dichotomous (presence v. absence of DATIX), with a sample size of N=269, which is feasible when considering CORE-OMs completed as part of intermediate and annual case review, as well as upon admission.

**What proportion of variance in CORE-OM scores does insight into one’s illness account for?**

Insight was selected due to the research highlighting the potential influence poor insight can have on self-report measures and general levels of distress over time. Furthermore, from a pragmatic perspective these data are available for the same time points as the CORE-OM as they are all measures completed for the purposes of case review. A cross sectional analysis will be used in respect to the fourth research objective. By using a cross sectional approach, individual differences in CORE scores will be considered in order to analyse what proportion of variance identified predictor variables account for. In this case, multiple regression analyses would be used, where CORE-OM would be the dependent variable and level of insight would be the independent predictor variable.

According to Green (1991), for a medium effect (R² = .07, [beta] = .20), considering the significance of the R² value and beta weights of the predictor variables, sample size to achieve 80% power would be N > 104 + k (where k is each predictor variable). For this analysis, where there are three predictor variables, N > 104 + 3, therefore the sample size required is N=107, which is achievable given the current dataset.

**9. RISKS**

There is no direct contact with patients required, and data has been previously collected by the clinical team as part of routine care. Therefore, the level of risk posed is considered minimal.

**10. OVERSIGHT ARRANGEMENTS**
10.1. INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

11. GOOD CLINICAL PRACTICE

11.1. ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

11.2. INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

11.2.1. Informed Consent
The Investigator will have no contact with patients at any point throughout the study and will collect only existing, routinely collected data from electronic case files. See section 7b.

11.2.2. Study Site Staff
The Investigator must be familiar with the protocol and the study requirements. It is the Investigator’s responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

11.2.3. Data Recording
The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

11.2.4. Investigator Documentation
The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

11.2.5. GCP Training
For non-CTIMP (i.e. non-drug) studies all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. However, this is not a mandatory
requirement unless deemed so by the sponsor. GCP training status for all investigators should be indicated in their respective CVs.

GCP training was completed by PI, Maxine MacDonald, on 09/01/2019.

11.2.6. Confidentiality
All laboratory specimens, evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

11.2.7. Data Protection
All Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) with regard to the collection, storage, processing and disclosure of personal information.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data and be of a form where individuals are not identified and re-identification is not likely to take place.

12. STUDY CONDUCT RESPONSIBILITIES

12.1. PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

12.2. MANAGEMENT OF PROTOCOL NON-COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within
3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

12.3. SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:
(a) the safety or physical or mental integrity of the participants of the trial; or
(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

12.4. STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

12.5. END OF STUDY

The end of study is defined as the last participant’s last visit. The Investigators or the sponsor have the right at any time to terminate the study for clinical or administrative reasons. The end of the study will be reported to the REC, and R+D Office(s) and sponsor within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot. A summary report of the study will be provided to the REC within 1 year of the end of the study.

12.6. INSURANCE AND INDEMNITY

The sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff. The following arrangements are in place to fulfil the co-sponsors’ responsibilities: The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault
compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.

Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.

Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.

Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

**13. REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS**

**13.1. AUTHORSHIP POLICY**

Ownership of the data arising from this study resides with the study team.

**14. REFERENCES**


## Appendix 8. CORE-OM Outcome Measure

### Important - Please read this first

This form has 34 statements about how you have been OVER THE LAST WEEK. Please read each statement and think how often you felt that way last week. Then tick the box which is closest to this.

*Please use a dark pen (not pencil) and tick clearly within the boxes.*

### Over the last week

<table>
<thead>
<tr>
<th>Statement</th>
<th>Not at all</th>
<th>Occasionally</th>
<th>Sometimes</th>
<th>Often</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have felt terribly alone and isolated</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>F</td>
</tr>
<tr>
<td>I have felt tense, anxious or nervous</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>P</td>
</tr>
<tr>
<td>I have felt I have someone to turn to for support when needed</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>F</td>
</tr>
<tr>
<td>I have felt OK about myself</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>W</td>
</tr>
<tr>
<td>I have felt totally lacking in energy and enthusiasm</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>P</td>
</tr>
<tr>
<td>I have been physically violent to others</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>R</td>
</tr>
<tr>
<td>I have felt able to cope when things go wrong</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>F</td>
</tr>
<tr>
<td>I have been troubled by aches, pains or other physical problems</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>P</td>
</tr>
<tr>
<td>I have thought of hurting myself</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>R</td>
</tr>
<tr>
<td>Talking to people has felt too much for me</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>F</td>
</tr>
<tr>
<td>Tension and anxiety have prevented me doing important things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>P</td>
</tr>
<tr>
<td>I have been happy with the things I have done</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>F</td>
</tr>
<tr>
<td>I have been disturbed by unwanted thoughts and feelings</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>P</td>
</tr>
<tr>
<td>I have felt like crying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>W</td>
</tr>
<tr>
<td>Question</td>
<td>Not at all</td>
<td>Only occasionally</td>
<td>Sometimes</td>
<td>Often</td>
<td>Most or all of the time</td>
<td>OFF THE SCALE</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------</td>
<td>------------------</td>
<td>-----------</td>
<td>-------</td>
<td>-------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>15 I have felt panic or terror</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ P</td>
<td></td>
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</tr>
<tr>
<td>16 I made plans to end my life</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 I have felt overwhelmed by my problems</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ W</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 I have had difficulty getting to sleep or staying asleep</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ P</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 I have felt warmth or affection for someone</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ F</td>
<td>☐ 0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 My problems have been impossible to put to one side</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ P</td>
<td></td>
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</tr>
<tr>
<td>21 I have been able to do most things I needed to</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ 0 ☐ F</td>
<td></td>
<td></td>
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<tr>
<td>22 I have threatened or intimidated another person</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 I have felt despairing or hopeless</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ 4 ☐ P</td>
<td></td>
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<tr>
<td>24 I have thought it would be better if I were dead</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ R</td>
<td></td>
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<tr>
<td>25 I have felt criticised by other people</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ F</td>
<td></td>
<td></td>
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<tr>
<td>26 I have thought I have no friends</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ F</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>27 I have felt unhappy</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ P</td>
<td></td>
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<tr>
<td>28 Unwanted images or memories have been distressing me</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ P</td>
<td></td>
<td></td>
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<tr>
<td>29 I have been irritable when with other people</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ F</td>
<td></td>
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<tr>
<td>30 I have thought I am to blame for my problems and difficulties</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ P</td>
<td></td>
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<tr>
<td>31 I have felt optimistic about my future</td>
<td>☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0</td>
<td></td>
<td>☐ W</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>32 I have achieved the things I wanted to</td>
<td>☐ 4 ☐ 3 ☐ 2 ☐ 1 ☐ 0</td>
<td></td>
<td>☐ F</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33 I have felt humiliated or shamed by other people</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ F</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34 I have hurt myself physically or taken dangerous risks with my health</td>
<td>☐ 0</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4</td>
<td>☐ R</td>
<td></td>
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</tr>
</tbody>
</table>

**THANK YOU FOR YOUR TIME IN COMPLETING THIS QUESTIONNAIRE**

**Total Scores**

**Mean Scores**

(Total score for each dimension divided by number of items completed in that dimension)