Seclusion and psychiatric intensive care evaluation study

Aims and objectives

Evaluate the innovations of no seclusion and restricted access to Psychiatric Intensive Care Units (PICUs) by:
1. Assessing the outcomes of
(a) PICU transfer versus continued acute inpatient care among patients admitted to general adult wards, and of
(b) seclusion versus no seclusion among PICU patients,
in terms of:
(i) repeated physical violence to others, injury to staff or patients, absconding and length of stay; (ii) costs and cost-effectiveness.

2. Under innovative vs. traditional organisational systems (differing access to PICU and seclusion): (i) describing how the same patient high risk behaviours are managed; (ii) exploring and identifying differing thresholds for the commencement of severe containment methods (manual restraint, rapid tranquillisation, seclusion, PICU transfer)

Background

One of the main purposes of acute inpatient psychiatry is the management and reduction of risks to patients and others, through self-harm, self-neglect and violence to others (1). It is often increases in risk that prompt admission, and continued presence of risk that prolongs admissions, *ceteris paribus*. Within the psychiatric hospital, the risks posed by patients are managed through the deployment of effective psychiatric treatment for the risk provoking psychiatric disorder. While this takes effect and the correct treatment is found, risks are managed through 24 hour supervision, a range of security policies (e.g. personal searches, contraband items, restrictions on patient behaviour, controlled egress from the ward) and in cases of imminent and actual risk of harm, containment methods (e.g. special observation, manual restraint, coerced intramuscular medication, seclusion, etc.).

Where risks are higher than the norm for an acute psychiatric ward, patients can be transferred to a psychiatric intensive care unit (PICU). PICUs are small wards, with higher levels of nursing and other staff, built on an open plan design to ease observation, and often (but not always) locked, and sometimes (but not always) with facilities for seclusion. A recent literature review (2) identified that typical PICU patients are: male; younger; single; unemployed; suffering from schizophrenia or mania; from a black Caribbean or African background; legally detained; with a forensic history. The most common reason for admission is for aggression management, and most patients stay a week or less. Only two studies provide any data on cost, and of these, only one is from the UK. This gives a cost per patient per annum of £103,501 based mainly on staffing costs in the mid 1990s (3). The other study, from Canada, gives a cost of $365 per patient per day compared to $235 for an acute unit (4) (i.e. a difference of 55%). Information is lacking on costs and cost-

effectiveness of PICU care relative to acute care have never been identified or described. The same literature review (1) concludes that PICUs have been very poorly evaluated for their efficacy, with only two small scale studies carried out on single units reporting decreases in aggression. Given the expenditure on PICU care, it is anomalous that no systematic evaluation has ever taken place.

Analysis of data from the SDO funded City-128 cross sectional multivariate study of acute psychiatric wards (5) of differences in access to PICU care, has raised questions about outcomes (Bowers et al, Journal of Psychiatric Intensive Care, in press). Controlling for other factors, wards with greater ease of PICU access did not have lower rates of adverse incidents. PICU transfers were associated with seclusion, manual restraint and other severe containment measures, and were triggered by aggression, drug use and absconding. The findings suggest that transferring patients to a PICU may not be an effective means of reducing the frequency of adverse incidents on acute wards. Further longitudinal research using individual patient level data is required to assess whether this conclusion is valid.

Seclusion is the isolation of a disturbed psychiatric patient in a robust locked room. A recent literature review (6) found that 12-48% of patients were secluded at least once during their admission to acute wards. Secluded patients were younger than non-secluded patients, more likely to be formally detained and less likely to suffer from depression. Gender, ethnicity and socio-economic status had no influence on seclusion rates. Seclusion made patients feel angry, lonely, sad, hopeless, punished and vulnerable. The efficacy of seclusion in reducing aggression and injuries to staff and patients has not been evaluated. The City-128 study (5) found that seclusion use was associated with increased rather than reduced aggression, and that seclusion usage and provision was associated in complex ways with the proximity of a PICU and the use of locked doors on acute wards. However, these analyses were based on data aggregated at ward level at each timepoint, so were unable to estimate the effect of seclusion at individual level. A more recent study (7) found that the outcome of seclusion (judged as the repetition of physical violence to others) was no better than that for time out (a request for the patient to stay in their own room for a period, without the door being locked), although the sample size was modest and this analysis did not control for differences in patient characteristics.

The past few years have seen several innovations and changes to PICU provision. In some cases, a significant number of PICU beds have been allocated to the treatment of transfers of acutely mentally ill people from the prison system, leading to reduced availability of PICU for transfers of difficult and high risk patients from acute psychiatric wards. At the same time, the increasing practice of keeping acute psychiatric wards locked is likely to have led to reduced transfers of patients to PICUs in order to prevent risk consequent upon the patient absconding (8, 9). Finally, some new psychiatric units have opened with no PICU provision at all, or PICU provision has been limited to a single site within a much larger multi-hospital NHS Trust. The consequences and efficacy of these differing systems to managing high risk patients has neither been compared or evaluated on a wide scale.

The main UK innovation to seclusion in the past ten years has been its abolition in some hospitals. About 25% - 50% of hospitals do not seclude patients at all and do not have seclusion rooms for acute psychiatric patients, whereas in some hospitals up

to a quarter of admissions are secluded once or more during the first two weeks of their admission (5, 7). While many countries are running large scale programmes to reduce seclusion use (e.g. the USA, Australia, the Netherlands), with varying success, it is not known how some of our UK hospitals are achieving seclusion free care, or whether the outcomes in terms of aggression rates and injuries are better or worse. We do know that access to seclusion rooms in UK hospitals is linked to the age the unit concerned was built, with more modern units less likely to have one (5). Presumably as new units have been built to replace older ones, seclusion has been eradicated with the move. However it is not known whether this been accomplished by *substitution* (greater use of alternative forms of containment), *early intervention* (faster progression to manual restraint during crises leading to easier resolution), *therapeutic intensity* (behavioural or psychotherapeutic interventions to avert crises before they occur) or *non-standard transfers* (to other hospitals or services). The use of manual restraint is clearly critically important as this is a gateway measure to other coercive interventions (seclusion, PICU, rapid tranquillisation) or a replacement for them if utilised continuously for long durations.

The use of coercive containment methods is an area of primary concern to service users. A recent report by MIND on acute inpatient care (10) calls for the elimination of seclusion and manual restraint as soon as possible, and their replacement with a system based on cooperation, negotiation and mutual respect. Previous research has shown that patients rate seclusion as less acceptable than nearly every other form of containment, and PICU care as less acceptable than several other forms of containment such as special observation (11). It is salutary that staff rate these interventions as much more acceptable than do the service users. Their priority for the patient experience of good quality care indicates the need for research that may enable reductions in their use.

PICU care is a potentially very expensive intervention. The provision of a special ward with high staffing levels could not be anything other. However this cost may be acceptable if outcomes are improved or savings occur due to reduced length of stay or reduced use of other services. Even the provision of a PICU may itself be cost neutral to some degree if it enables lower nurse staffing levels on the acute wards to which it provides a service. The question of cost and outcome therefore has a clear bearing on the choices service managers must make in this area. However currently there is no research evidence upon which they can draw, underscoring the need for the projects proposed here.

This proposal addresses the fourth topic area of the call: innovations arising from new approaches to managing risk and the threshold for intervention. The abolition of seclusion use in some hospitals and the reduction or elimination of access to PICU care, are both new trends in the management of risk. These changes may actually increase risks and costs, the reverse, or they may simply trigger compensatory increases in other forms of containment, such as manual restraint and rapid tranquillisation. These other forms of containment also have potential risks. For example there are a (small) number of deaths during restraint, and the struggle to gain control can itself lead to injuries of staff and patients (12). Reductions in PICU or seclusion access may also lead to increases in patient violence through inadequate containment, causing injuries. At present there is little evidence having a bearing on these questions, hence our proposal.

Most psychiatric services in the UK do use seclusion, yet there is a widespread aspiration to minimise the use of such interventions, which are unpalatable to nurses (13) and patients (10). A key practical question for managers is "what are the services not using seclusion actually doing to manage disturbed behaviour in a safe and successful manner". This is not a straightforward question, and simply asking professionals does not generate an adequate answer. If you ask nurses at a hospital that does not use seclusion to explain how they do it, they will struggle to find an answer. They simply do not use it and don't feel the need for it. Yet those in hospitals with seclusion struggle to understand how others do without it, and speculate that sedating drugs are given more often and in higher doses, or that patients are held in manual restraint for long periods. The importance of this proposed research is that it will provide some answers to these questions, which are critical for psychiatric service managers faced with demands to reduce reliance on coercive methods, and make inpatient care more efficient. Absence of answers to these questions holds back many who might otherwise abolish seclusion use by simply decommissioning seclusion rooms, or reducing the numbers of PICU beds.

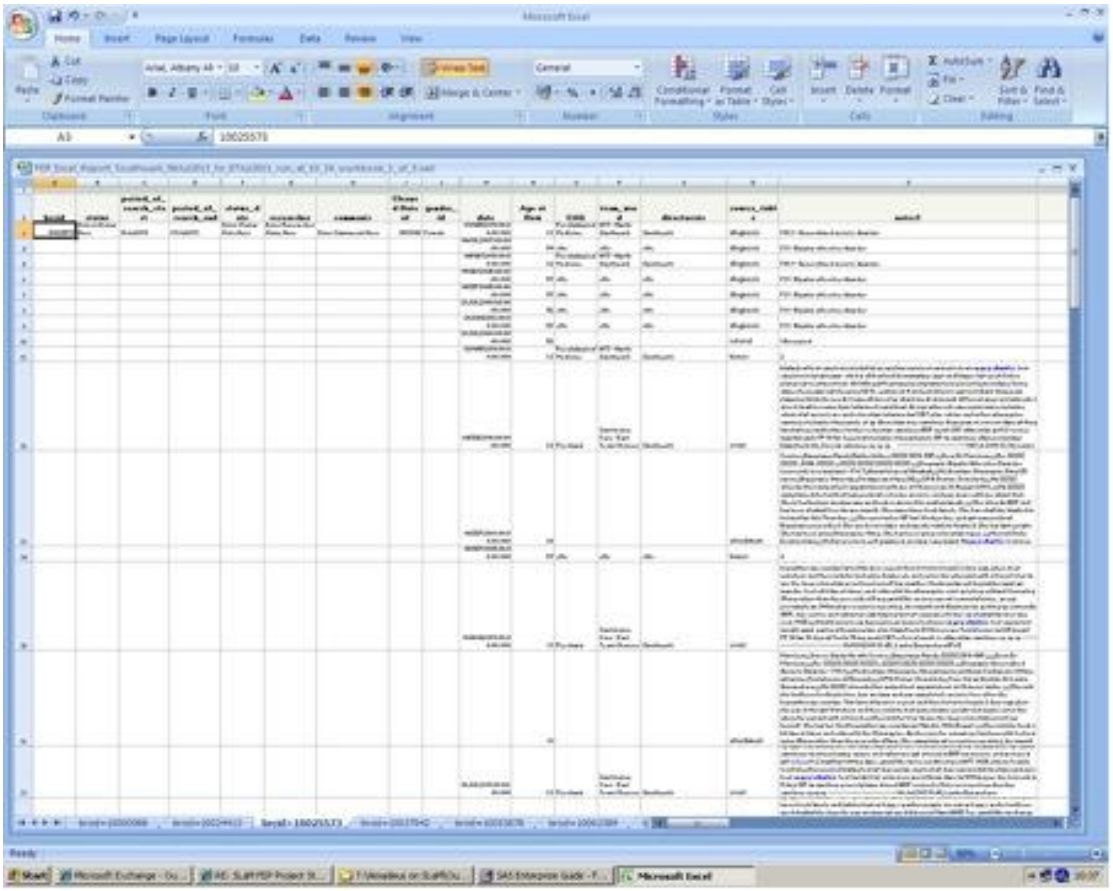
In the South London and Maudsley NHS Foundation Trust—one of the partner Trusts for the present proposal—seclusion rooms are available in all four Trust PICUs and a small number of wards providing specialised care for forensic patients and patients with developmental disabilities. Seclusion of patients admitted to general wards is, however, highly unusual in the Trust, and is nearly always achieved through transfer to the wards with seclusion rooms, with subsequent full transfer of clinical responsibility: preliminary analyses based on data from the Case Register maintained by the NIHR South London and Maudsley / Institute of Psychiatry Specialist Biomedical Research Centre for Mental Health (the BRC Case Register – see below) detected only around 50 periods of seclusion since 2006 which did not immediately lead into PICU admission (~0.25% of admissions – a negligible number).

The BRC Case Register

South London and Maudsley NHS Foundation Trust (SLaM) has used a comprehensive electronic patient record—Patient Journey System (PJS)—for all clinical activity since 2006. In 2007, SLaM and the Institute of Psychiatry, King's College London successfully applied to NIHR to become the UK's only specialist Biomedical Research Centre for Mental Health. A key part of the offer to NIHR was to set up a system for the use of anonymised electronic patient records for health research—the BRC Case Register, now operational since 2009 (14). The Case Register contains all of the electronic patient records maintained by SLaM since 2006, but anonymised and optimised for data retrieval (querying). Studies now completed and either published or in press include studies of mortality (15) and life expectancy (16) among service users with serious mental illness, of mortality among service users with substance misuse diagnoses (17), of residential mobility (18) and homelessness (19) among acute psychiatric inpatients, and of khat use among Somali mental health service users (20). BRC funding was recently renewed until 2017, and in recognition of the progress made in informatics, our BRC has assumed a national leading role for informatics in the BRC programme. A team of IoP / BRC researchers were recently awarded £490K by the SDO programme to use the BRC Case Register as part of an evaluation of a management restructuring within South London and Maudsley NHS Foundation Trust (11/1015/20).

PJS contains a variety of structured data (numbers, dates or short standardised text) and unstructured data (free text), which together are equivalent to all of the data that would have been held across a computerised Patient Administration System and paper casenotes. Structured data include personal details, demographic details and details of clinical activity such as appointments, dates of periods of service by clinical teams and details associated with free text records—for example, the date on which a particular item of correspondence was created and added to the case notes. Free text data comprise mainly the aforementioned free text progress notes, and also correspondence. Anonymisation has two stages. In the first, patient identifiable information is stripped from the structured data in the database. Therefore, dates of birth are truncated to month and year of birth, ethnicity is grouped into broad categories, addresses are converted to the corresponding Office of National Statistics Output Area, and names of the service user and contacts are removed. A pseudonymous identifier (the BRC ID) is created, replacing trust and NHS IDs. In a second stage, free text data are cleaned of names: wherever names or recorded aliases for the user or his/her relatives are encountered in the free-text, they are replaced with ZZZZZ or similar. Once cleaned, data are organised into around 100 data tables ranging from the small (some tables containing infrequently used test scores) to the extremely large (the "Event" table containing free-text progress notes, which has over 10 million rows). The security procedures in place at the BRC have been reviewed by Oxfordshire REC and the BRC is treated for ethics purposes as an anonymised database: that is, access is granted after review of applications by a oversight committee, but formal ethics approval is not required. For the present application, the Case Register will be accessed as an SQL database using SAS 9.2.

We have developed a number of strategies for generating numeric data from the free-text data held in the Case Register. Firstly, we are able to retrieve records only meeting specified criteria, for example those containing particular words or those which meet some criteria in other linked fields (for example, records made during a time interval defined separately for each of a sample of individuals). This can achieve important economy of effort. For example, in studies of homelessness and residential mobility during 4485 inpatient admissions (18, 19), coding of homelessness required the review of only those records associated with these admissions and containing the terms "homeless", "NFA" or "no fixed abode" (only 2000 progress notes out of a total of 10 million). Coding of these progress notes was eased by using SAS to insert "tags" that change font colour and weight for the target words when the data were outputted as an Excel table. The entire process of data extraction and coding then took no more than a day. Where it is necessary simultaneously to view multiple items of information for one participant or treatment episode in order to perform coding, SAS can also be used to place output into multisheet Excel workbooks, an approach followed by a current project to detect new episodes of psychosis in the Trust (see screenshot below):



Note: image deliberately blurred to protect confidentiality

STUDY 1

OBJECTIVE

To assess the outcomes of (a) PICU transfer versus continued acute inpatient care among patients admitted to general adult wards, and of (b) seclusion versus no seclusion among PICU patients, in terms of: (i) repeated physical violence to others, injury to staff or patients, absconding and length of stay; (ii) costs and cost-effectiveness.

DESIGN

Well-developed propensity scores are able to achieve covariate balance between treated and untreated cases equivalent to that achieved through randomisation, and are therefore among the best approaches to deriving effect estimates from observational data. In particular, through the use of matching, they can provide a means of ensuring that those treated with a particular intervention are only compared with others with very similar characteristics. Although this can restrict the number of suitable controls, it avoids problems of extrapolation created by the use of regression techniques on subjects who were not in any meaningful sense at risk of the treatment under investigation (this is likely to be an important consideration in this area, as those

treated in PICU or secluded are likely to be quite different from most of those patients who are not.)

We will use the BRC Case Register – which is an anonymised version of the electronic patient record used by South London and Maudsley NHS Foundation Trust (14) – to develop models for the hazard of transfer to PICU during an admission to a general adult ward and the hazard of seclusion during a PICU admission, and to derive propensity score-based estimates of the effectiveness and cost-effectiveness of PICU care and seclusion.

For propensity scores to have value, and to minimise bias in estimates derived using them, it is essential that they are calculated using as many potential determinants of the occurrence of the treatment of interest are included as are available. The existing literature and clinical experience dictate that the timing and characteristics of behavioural disturbance are key determinants of transfer to PICU and of the use of seclusion: we will be able to code such events using the free-text progress notes held in electronic form in the Case Register. Please see notes above regarding processes for coding free-text data in the Case Register.

PROCEDURE: DATA EXTRACTION, CODING AND ANALYSIS

Step 1:
Using Structured Query Language (SQL), extract test dataset of dates of 200 transfers onto PICU. Based on principle that events close to these dates should contain events relevant to transfer, iteratively develop SQL-based method to automatically select free-text records containing events potentially relevant to transfer, so that these can be manually coded. Develop coding scheme for events of interest based on Overt Aggression Scale (21). Apply to new test dataset of free-text progress notes selected as above to contain events potentially relevant to transfer, but irrespective of whether transfer occurs. Measure inter-rater reliability. Iterate until acceptable value of kappa achieved. Repeat step 1 for seclusion, using standardised format of seclusion review documentation to extract periods of seclusion.

Step 2:
Extract two study datasets: (1) general adult admissions +/- transfer to PICU; (2) PICU admissions +/- use of seclusion. Using SQL, join these to free-text records possibly referring to relevant behaviours (pre- and post- transfer) where such records exist, also to other structured data required effectiveness / cost-effectiveness analyses, whether as exposure or outcome. Such variables will include: age, sex, ethnicity, marital status, previous service use (number of admissions, length of admissions, whether admitted to PICU previously, previous history of detention under Mental Health Act), Health of the Nation Outcome Scale scores, principal diagnosis, lifetime drug and alcohol diagnosis, service use in 12 months post transfer (or equivalent period for controls) – number of general ward days, number of PICU days, face-to-face contacts.

Code free-text events of interest, creating fully numerical dataset. Where no relevant free-text record exists for a particular admission—indicating, given the validation exercise above, that the relevant behaviour did not occur—then generate appropriate zero values for the variables representing relevant behaviours. Multiple imputation as

required in order to accommodate missing structured data (for example, 5% of structured values for diagnosis may be missing based on previous experience).

Step 3:
Separate multivariable analyses for each study dataset, leading to calculation of propensity scores for PICU transfer and for seclusion on PICU. Propensity scores will be calculated separately for successive time intervals per individual patient, allowing them to accommodate variation in behavioural disturbance over time. Test for zone of common support, test for balancing property of propensity scores. Use missingness pattern indicators to support use of multiply imputed data to create propensity scores (22). Select matched controls using propensity scores.

Step 4:
Effectiveness analyses, studying effects of PICU and of seclusion on
(1) count of subsequent violent incidents using Poisson regression
(2) subsequent length of stay using Cox regression
(3) odds of absconding using logistic regression.

The study will be powered to detect an effect of PICU transfer on violence. If we assume (conservatively) that transfer to PICU is common only among those at high propensity to be transferred, it follows that selected controls should also have high propensity to be transferred. Therefore, the required sample size will be a sample of high-propensity admissions, and the total pool of admissions that would be needed to create such a group must be calculated based on an assumption of what proportion of total admissions are at high propensity to be transferred to PICU. So, assuming that:

(a) PICU transfer leads to a relative risk of violence of 0.8
(b) 50% of high propensity cases are transferred
(c) $\alpha = 0.05$
(d) $(1- \beta) = 0.8$
(e) R2 for other covariates of 0.20

a power calculation produced using G-Power gives a required sample size of treated cases and matched controls of N = 1392.

Review of the frequency of violence terms such as ‘punch’, ‘kick’ and ‘hit’ in free text notes suggests that around 10% of inpatients may commit an assault during a general hospital admission. If these patients are assumed to be the group at high propensity of transfer, then around 1700 high propensity cases must be available based on current data (ca. 17,000 general hospital admissions since 2007 – see flowchart). This total of 1700 high propensity cases is greater than the 1392 estimated to be necessary.

Step 5:
The datasets above will include service use from the time of the assault until 12 months later, including time spent on inpatient wards (including the PICU) and, where applicable, subsequent contacts with mental health professionals in community settings. Costs will be calculated by combining these data with unit costs derived from hospital management accounts and, where necessary, from published sources (e.g. NHS Reference Costs, University of Kent). PICU unit costs will reflect greater staff

levels per bed. Cost comparisons will be made between the groups using bootstrap methods if data are skewed. Cost predictors will be identified using regression models, with independent variables reflecting clinical and demographic characteristics of patients. Cost-effectiveness will be assessed by combining the cost data with information on further assaults. If one intervention has lower costs and reduced rates of assault then it will be 'dominant'. Better outcomes at a higher cost will lead to the calculation of incremental cost-effectiveness ratios (ICERs) to indicate the extra cost incurred to produce one fewer assault over the follow-up period. Uncertainty around the ICERs will be assessed by generating cost-effectiveness planes and cost-effectiveness acceptability curves. The latter require a range of hypothetical societal monetary values to be placed on reductions in assaults. The lower bound of this range will by convention be zero. To inform the positive values in the range we will obtain data on fines and penalties associated with assaults and also official data on the estimated costs of assaults. We are not measuring quality-adjusted life years in this study as the main effect of interest, reduction in assaults, is not directly a patient outcome measure. In theory we could make assumptions about the impact on health-related quality of life of those assaulted (or not) but data are unlikely to be suitable for this.

STUDY 2

OBJECTIVES

To compare the management of disturbed behaviours in four different service configurations: no seclusion and restricted PICU access; no seclusion and full PICU access; seclusion available and restricted PICU access; seclusion available and full PICU access.

By seclusion available we mean there is a defined seclusion room available to acute wards and which is on the same hospital site as the acute ward. By restricted PICU access we mean that a PICU may be available to the acute wards, but is on another site, and/or in a different organisation and/or privately provided.

Specific hypotheses to be explored

The absence of seclusion and/or restricted access to PICU care are managed through one or more of the following four mechanisms:

1. Substitution: seclusion for PICU (or vice versa), or other alternatives such as medication (regular in higher dose, more intensely sedating medications, and/or routes of faster or more effective absorption, intramuscular/intravenous), and/or long duration manual restraint, time out, open area seclusion (confinement of a disturbed patient in a separate area together with nursing staff) of some form.
2. Early intervention: faster response to escalation, earlier physical intervention, leading to safer management and more benign outcomes, possibly accompanied by temporarily increased nurse staffing levels, or the use of intensive forms of constant special observation (such as two staff to one patient).

3. Therapeutic intensity: deployment of a range of psychotherapeutic and behavioural interventions to manage, ameliorate and reduce the frequency of risky patient behaviours.
4. Non-standard transfer: move of the patient to another ward providing more secure or intensive care in some fashion, perhaps in a private hospital or in a neighbouring Trust, or via a secure rehabilitation ward or a forensic ward of some type.

DESIGN

Comparative qualitative analysis of interviews of nurses working within the four different service configurations on the management of disturbed behaviour, using vignettes to stimulate thinking.

Comparative quantitative analysis of thresholds for the use of manual restraint in the four different service configurations.

INSTRUMENTS

Demographic characteristics

The following data will be collected from all participants. Age, gender, ethnicity, role, nurse training, years of psychiatric experience, training in the prevention and management of violence, most recent update training on prevention and management of violence, whether previously a victim of assault by a patient and the severity of that assault, approximate number of manual restraints participated in, time since most recent restraint experience.

Attitude to Containment Measures Questionnaire (ACMQ v2)

This short scale will be collected from all participants. It provides relative measures of views on the acceptability of 11 different forms of containment for disturbed behaviour, from extra sedating medication given at nurses' discretion through manual restraint and psychiatric intensive care to seclusion and mechanical restraint. Scores for nurse respondents have been shown to relate to past history of participation in their use (11). This scale has been widely translated and used in many countries, with professional, non professional and patient respondents (23-25).

The Moylan Progression of Aggression Tool (MAPAT)

All participants will undertake the MAPAT.

Description: The MAPAT consists of a 300 second video showing interactions between a nurse and a patient who is becoming increasingly agitated and aggressive, culminating in a serious physical attack on the nurse. The research subject watching the video is told that he or she is the nurse, and that just off camera are a team of other nurses waiting to assist. The subject is asked to push a button or switch when he or she considers that, were this a real situation occurring in the service context in which

they work, restraint should be initiated. The picture below shows a series of stills from the video and provides some flavour as to what it is like. Completing the MAPAT requires a PC/laptop with DVD drive and a quiet room. It takes about 10 minutes, a couple to explain the test, 5 minutes to complete, and a few minutes debriefing afterwards.

Development: The MAPAT was developed by Professor Lois Moylan of Molloy College in New York. Drawing on the psychiatric nursing literature, clinical and empirical on escalation to violence, she identified a large number of indicators or increasing agitation. Submitting these to a panel of expert nurses, an agreed order of signs of increasing agitation and escalation were produced. These were then used to devise the script for the MAPAT video (26).

Psychometric data: The MAPAT has shown good test-retest validity ($r = 0.88$), and has shown associations with past experience of violent assault by a patient causing injury (27). The mean MAPAT score was 252 seconds with a standard deviation of 26.9 seconds. Means scores between institutions (hospitals) varied by up to 15 seconds, although sample sizes were too small to be powerful enough to detect differences in previous studies.

UK applicability: In preparation for this application, the MAPAT was tested with twelve staff (5 experienced nurse clinicians, 4 researchers and 3 trainers in the prevention and management of violence). All unanimously endorsed the MAPAT as credible and applicable to UK psychiatry, usable without any changes. Mean MAPAT scores in this group were 268 seconds (sd 13.7 seconds).

Interview based on vignettes (threshold interviews)

Of those completing the ACMQ and MAPAT, a smaller sub sample within each service context will be invited to participate in a longer interview. Four short vignettes of newly admitted patients will be devised, loosely based on cases from a previous study by the research team of patients who were subject to high levels of containment. The vignette technique essentially involves presenting respondents with believable

scenarios and then asking them how they would respond when confronted with the circumstances in that scenario (28-30). The four scenarios in this study will comprise patients who are: aggressive and very psychotic; aggressive, psychotic and personality disordered; self-harming and very psychotic; self-harming, psychotic and personality disordered. Following some opening general questions about the management of disturbed patient behaviour, these vignettes will be presented in turn to the research participant, who will be asked to describe how they would advise on the management and treatment of the patient in the short and longer term. For each vignette, once the participant has given as much information as they can, the interviewer will ask 'and what if the violence/self-harm was more severe, frequent or continuous?' The interviewer will present a card with a range of possible behaviours for the respondent to choose from and expand upon. For example the initial vignette might present a patient being aggressive by turning over chairs and kicking doors. Once the participant has given their ideas on how the situation should be managed, they will be asked how that management plan might differ if the patient did this several times during a single shift, or if they actually broke the furniture by hammering it against a wall, or made threatening gestures to others with it; then if they actually assaulted a fellow patient or nurse; then if that person was mildly (bruising) or even severely injured to the point of broken bones. The aim of the interview is to gradually increase the intensity of disturbed behaviour in the imagined scenario, taking the participant to the extremes of patient behaviour, in order to elicit normative judgements about how extremely challenging behaviour within the service context in which they work should be managed. Each of the four short vignettes will be presented to participants in this way, accompanied by a ratchet of intensity of disturbed behaviour on the part of the patient. The order of presentation of the four vignettes will be randomly generated for each interview, to remove any bias from this source. Interviews will be structured, tape recorded and transcribed for subsequent analysis.

The vignette technique requires that the scenarios are believable, so considerable effort will go into constructing credible situations. Initial drafts of the vignettes will be drawn from cases identified during the HICON study, supplemented by the team's 15 year experience of qualitative and quantitative research in this area, including several studies of officially reported adverse incidents and data from the NPSA. The HICON study identified all patients subject to high levels of containment in one Mental health NHS Trust. The key nurses and consultants of each patient were interviewed in order to accurately describe the problem behaviours of patients and the endeavours of staff to manage them or treat underlying causes. We will also draw upon our literature reviews of inpatient violence, self-harm and suicide, as well as our copious previous research in this area as represented by more than a hundred peer reviewed publications. Once formulated, the vignettes will be submitted to two expert groups:

1. The service user and carer group (SUGAR), consisting of 15-20 members, many of whom have recent experience of inpatient care as consumers of services, and who have been receiving training in research methods for the past three years.
2. A group of expert clinicians called together specifically for this purpose, consisting of trainers in the prevention and management of violence, clinical nurses from acute psychiatric wards and psychiatric intensive care units with at least three years experience, lead nurses and modern matrons with direct managerial responsibility for such units, and a consultant nurse.

The vignettes will be amended based on the feedback received, and will then be piloted, following which further refinements will be made. The interviews will last approximately 45-60 minutes (for those completing all ACMQ, MAPAT and threshold components). Interviewers will be trained by senior members of the research team, who will attend each interviewer's first interview, to provide support and offer detailed feedback.

SAMPLE AND SAMPLE SIZE

Eight hospitals providing inpatient acute psychiatric care will be identified in a purposeful sample, two in each of the following categories: no seclusion and restricted PICU access; no seclusion and full PICU access; seclusion available and restricted PICU access; seclusion available and full PICU access. In order to ensure a less London-centric sample and greater national representativeness, half of the sample will be drawn from hospitals in the North West, and half from hospitals in and around London. All NHS mental health hospitals in these areas will be identified, and one hospital in each category will be randomly selected for inclusion (with replacement for any refusals. Thus in the NW, four randomly selected hospitals, one in each category will be included in the study; and the same for London. The necessary mapping exercise to generate the sample pool has already largely been completed through previous studies or in preparation for this application.

Each hospital will have at least four wards providing a potential sample pool of approximately 80 nurses and healthcare assistants (31). From the sample pool at each category of hospital, a random sample of 54 nurses and health care assistants will be drawn and asked to complete demographic information sheets, the ACMQ and the MAPAT. This sample size is based on the mean and standard deviation for the MAPAT from five hospitals in a previous study (26, 27, 32). When the sample size in each of the 4 groups is 54, a one-way analysis of variance will have 80% power to detect at the 0.050 level a difference in means characterized by a Variance of means, $V=\Sigma(\mu_i-\mu)^2 / G$ of 37.581, assuming that the common standard deviation is 26.918 (33).

A random subsample of 30 qualified nurses at each category of hospital will be drawn to participate in the threshold interview. This figure is a compromise between achieving a degree of representativeness of the nursing workforce at each hospital, and thus being able to accurately describe their patient management systems and techniques, and being able to comprehensively manage data analysis of a large volume of interviews centrally. While previous research has shown that the use of containment by nurses is strongly influenced by local tradition, there is still likely to be variation in approaches and decision making by individual nurses. Thus a significant number of nurses need to be interviewed in order to obtain a general picture of 'how things are done and handled' at each of the study hospitals. A sample of 10-20 at each site could be too few to reliably identify the nature of local custom and practice, whereas a sample of 50 is likely to introduce redundancy through later interviews repeating what has already been described by previous participants.

The research team does have experience of managing such a high volume of qualitative data previously (34). In addition, the research interviews are not seeking an

in-depth understanding of participants views, perceptions or tacit theoretical frameworks, Instead the interviews seek to make manifest the local custom and practice regarding the nursing management of disturbed patient behaviour of various severities. As such, they will be quite concrete and relatively brief in comparison to other types of qualitative interviews such as those conducted during phenomenological research. This both allows and requires a larger than normal qualitative sample size.

ANALYSIS

Using the hospital with both PICU and seclusion access as a reference category, evidence will be sought in the data for substitution of other containment methods, early intervention using manual restraint, therapeutic intensity, and/or non-standard transfer. The analysis will focus on identifying participants' normative judgements about how disturbed behaviours should be managed, and thus how staff behaviour is moulded by the service context in which they work

ACMQ and MAPAT data will be entered on computer, assessed for their relationship to the demographic data. Models will then be computed for differences between hospitals, using analysis of variance.

Interviews will be professionally transcribed, imported into NVivo 9 qualitative data analysis software. They will be thematically analysed (35) for intervention themes (the treatment and management methods described by respondents) and thresholds (the point of severity at which these are recommended by respondents to be deployed). Not every intervention will be linkable to a threshold, but there will be enough for a general framework to be described for each hospital site, together with a background of other available treatments and management methods. These frameworks and their backgrounds will be summarised for each site using network diagrams and flow charts (36). These summaries will then be compared across hospital sites to identify both differences and commonalities.

Greater frequency or duration of non seclusion or PICU containment methods, and initiation at lower thresholds (from interviews), more positive ratings of non seclusion or PICU containment methods on the ACMQ, at those hospitals without access to one or both seclusion and PICU, will all be taken as evidence for substitution. Lower scores on the MAPAT, lower thresholds for initiation of manual restraint in the interviews, and higher ratings of manual restraint on the ACMQ, at those hospitals without access to one or both seclusion and PICU, will all be taken as evidence for early intervention. A greater number of interventions deployed, more psychotherapeutic, behavioural and multi-professional interventions described in the interviews, at those hospitals without access to one or both seclusion and PICU, will all be taken as evidence for therapeutic intensity. Any unanticipated potential explanations that emerge from the data will also be described.

PROCEDURE

Ethics: NRES no longer wishes to review studies involving data collection from staff alone. Study 2 will therefore be submitted to the Kings College Ethics Committee.

The study raises no special ethical issues, other than the usual necessity for confidentiality and for informed consent. The NHS R&D approval framework will still be used for each Trust where the study takes place. Directors of Nursing in participating Trusts will be asked to act as local collaborators, and arrangement that has worked well in our studies in the past.

Mental Health Research Network: It is proposed that data for study 2 will be collected by a project research assistant supported by Clinical Scientific Officers from the MHRN. These personnel will be brought to a central location for training in conducting the interviews, including an opportunity to conduct practice interviews with local staff. Interviews will be digitally recorded and collated centrally, where professional transcription will be managed. Completion of the study is dependent on MHRN support. Early discussion with a member of the 3A's committee of the MHRN suggests that in principle this will be forthcoming, and adequate time has been allowed in the project plan for a formal request to be made and processed.

CONTRIBUTION TO COLLECTIVE RESEARCH EFFORT AND RESEARCH UTILISATION

Psychiatric Intensive Care is a grossly under researched area in psychiatry, despite the resources invested in it. As far as the authors are aware, there has never been any funded research in PICU care or its outcomes. Much good work has been completed by the National Association of Psychiatric Intensive Care Units (NAPICU), but this has largely been surveys or small scale pilot studies completed through the dedication and commitment of individual members. NAPICU has initiated an academic journal, the Journal of Psychiatric Intensive Care, and although this is peer reviewed it does not yet have an impact factor. The PI has good relationships with NAPICU, and has presented at their conferences on many occasions, and a member of the NAPICU board is a collaborator on this study. We would hope to present the results of this study there, and/or at some of the international conferences they now sponsor as NAPICU builds links with other countries. We will seek to publish the main results of the study in a high profile and high impact journal, and incorporate results into the many conference plenary presentations the PI does every year. It is anticipated that a major funded project into PICU care will raise the profile of the topic and kick start further funded research in the area.

Seclusion practice varies considerably in the UK. While about a quarter of hospitals do not have seclusion rooms and do not seclude patients, some others seclude up to a quarter of admissions during the first two weeks. The PI is already working with the DH and the Forum of Mental Health Nurse Directors with a view to having seclusion rates monitored and compared as nurse sensitive outcome measures. Seclusion practice is under researched in the UK. Investment in reduction and research in other countries has led to a large group of international researchers with an interest in the field, and many high profile publications, often in English language journals based in the UK. However a review of seclusion reduction intervention studies demonstrated that only two out of 36 were conducted in the UK. Australia, the Netherlands and the USA are making major research advances on seclusion use. The UK, with its low overall rate of seclusion coupled with successful seclusion elimination in some hospitals, has a distinctive and powerful contribution to make, should this study be

supported. The PI has good links with most of the international researchers on seclusion, providing consultancy and mentoring to some, speaking at national meetings in Australia, and being a member of a the national advisory group on seclusion reduction in the Netherlands. Should this study be funded, the results will be well disseminated across these international networks, potentially affecting and contributing to nursing practice in many different countries in addition to the UK.

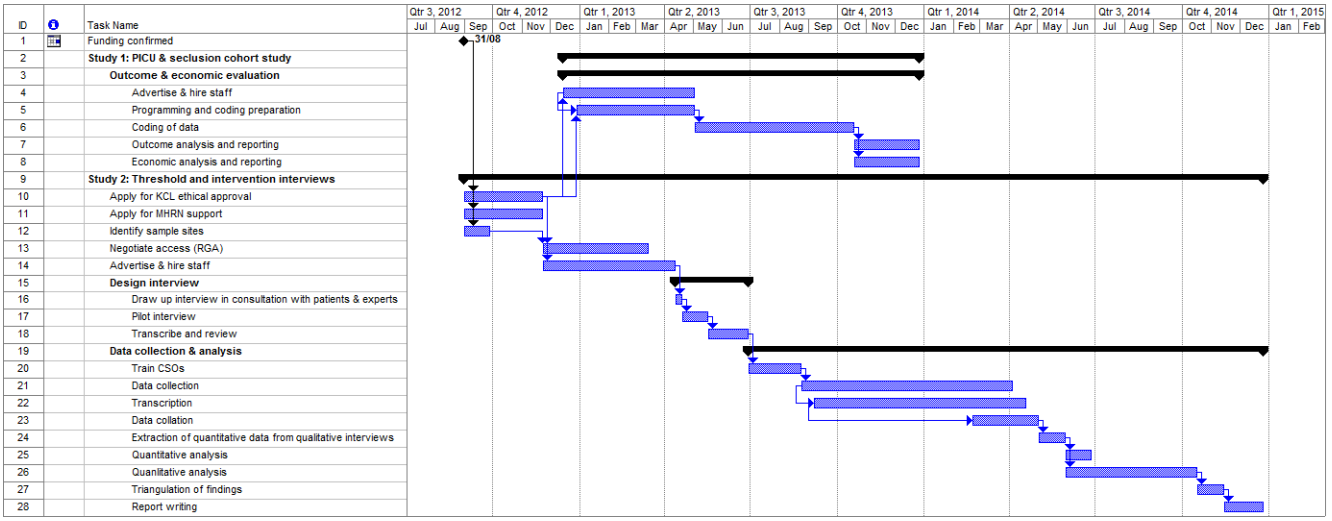
Towards the close of the project a national collaborative learning event will be held in conjunction with experts from the National Association of Psychiatric Intensive Care Units (NAPICU) including expert managers, consultant psychiatrists, psychologists, pharmacists and occupational therapists. Presentation of results will be followed by group discussion and small group work on implications and ramifications. We have added suitable costs for this exercise.

On completion of the research, in addition to the full report a 'research summary' specifically designed for NHS service managers will be written. This summary will give a background to the research, and outline the key findings for managers. These will take the form of separate evaluations of PICU care and seclusion, bringing together the findings from study 1 and 2 to set out plainly the pros and cons of these containment methods (with respect to patient safety, staff safety other risks and economic costs), plus the likely impacts of provision versus more restricted use. This summary will be distributed to all Directors of Nursing in UK MH Trusts, enabling them to take local decisions about these containment strategies.

The PI works with an established group of service users and carers called SUGAR. This group has been running for over two years with a committed membership, and is funded as part of an NIHR Programme Grant. The members meet regularly to consider research projects, review results, and receive education in research methods. They have been consulted about this proposal, will be consulted again in more detail should a full proposal be requested, will review data collection tools and assist with the interpretation of results should the project go ahead. Should the project go ahead, the research team will open channels of communication the MIND, the service user organisation that has declared an interest in the area of seclusion and restraint reduction, so that they can have early knowledge of the results and be involved in dissemination activities.

Through the NIHR Specialist Biomedical Centre for Mental Health (BRC-MH), IoP and SLaM (South London and the Maudsley MH NHS Trust) are at the forefront of health research using electronic patient records. This initiative was recently cited and praised by the Prime Minister in a speech on the Government's Life Sciences Strategy (5/12/11). We have recently been awarded increased funding, and now lead health informatics research on behalf of the entire BRC programme. This project will demonstrate the value of the data extraction tools available, and contribute to establishing the need to spread the capacity for this form of research by extending data collection to other NHS mental health Trusts.

PLAN OF INVESTIGATION AND TIMETABLE



PROJECT MANAGEMENT

The PI (Bowers) will hold overall responsibility for the management of the project within timescale and budget. Study 1 will be led by Tulloch. The economic evaluation will be nested within Study 1 and will be led by McCrone. Each will meet with other staff responsible to them and working on elements of Study 1 at weekly intervals during active task completion to monitor progress to targets. Study 2 will be led by the PI, who will similarly meet with staff responsible to him at weekly intervals for the same purposes.

The core project group, consisting of Bowers, Tulloch and McCrone, will meet monthly during preparation and data collection/extraction. These meetings will consist of reviews of progress to targets, and planning to overcome any hurdles or delays that arise. During data analysis this group will meet less frequently, but will be joined by other members of the collaboration to assist with analytic and interpretative work. Early results will also be taken and presented to meetings of the service user and carer group (SUGAR) for feedback on interpretation. All members of the collaboration will receive an email update on project progress following meetings of the core group. Ad hoc email, telephone and skype meetings will be convened as required.

A Project Advisory Group will also be formulated, including representatives from SUGAR, clinical experts and representatives of NAPICU (Sethi, Rumble), a service manager (Canning). A representative from MIND will also be invited to join. This group will meet three times, once prior to finalisation of data collection/extraction to offer input, once mid way through data analysis to consider early results and offer thoughts and perspectives on interpretation, and once to consider a draft of the final report and offer support and advice about dissemination and implementation of any conclusions.

PUBLIC USERS/PUBLIC INVOLVEMENT

The PI works with an established group of service users and carers called SUGAR. This group has been running for over two years with a committed membership, and is funded as part of an NIHR Programme Grant. The members meet regularly to consider research projects, review results, and receive education in research methods. They have been consulted about this proposal, have provided input into the design of study 2 (interview content) and have viewed the MAPAT for applicability, affirming its face validity. They will further review data collection tools and assist with the interpretation of results should the project go ahead. Two members of SUGAR will also formally join the Project Advisory Group for more intense input to the study and its outputs.

Should the project go ahead, the research team will open channels of communication the MIND, the service user organisation that has declared an interest in the area of seclusion and restraint reduction, so that they can have early knowledge of the results and be involved in dissemination activities. MIND will also be invited to send a representative to the Project Advisory Group.

EXPERTISE AND JUSTIFICATION OF SUPPORT REQUIRED

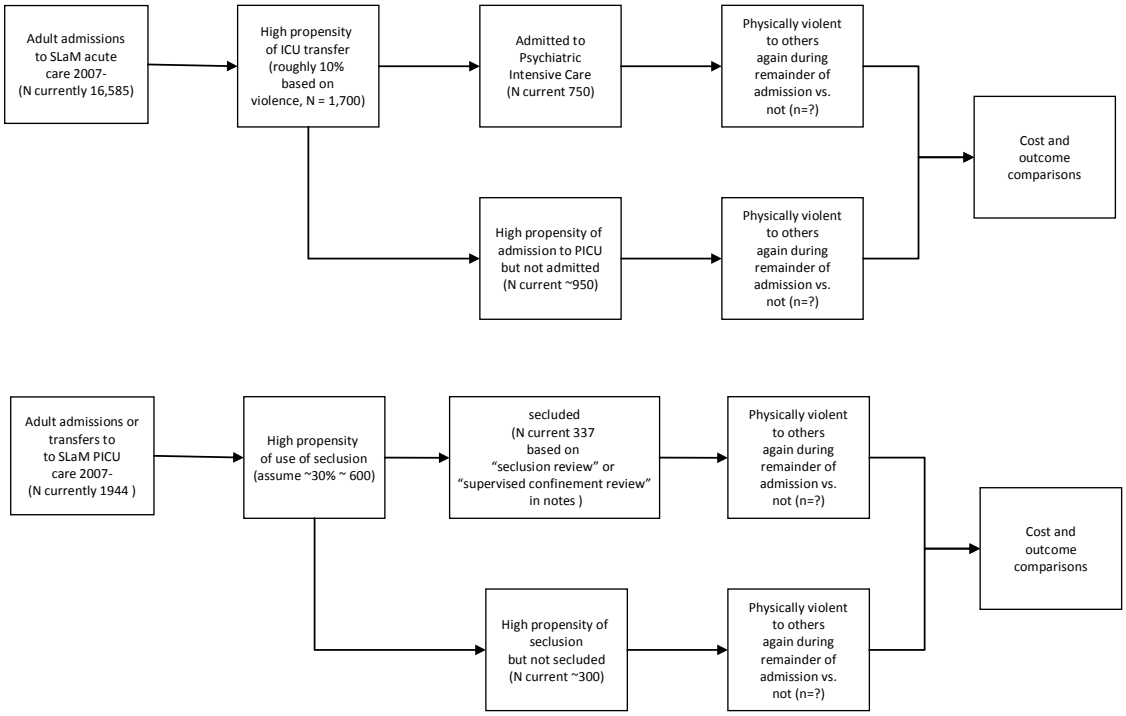
Baker has extensive clinical and research experience within acute inpatient settings, and in use of a variety of methods including, surveys, vignettes, qualitative and mixed methods. He has work on a portfolio of NIHR funded (and other i.e. Health Foundation) studies. His work on PRN medication as a containment intervention is internationally known.
Bowers is an internationally leading researcher in the area of safety and acute psychiatric inpatient care, having published more than a hundred peer reviewed papers, and successfully conducting many innovative research projects that already influence policy. He is a psychiatric nurse by background, and has lead many large scale studies, some of which included the use of large numbers of interviews and mixed method designs. He will lead on study three, supervising the researcher for this element of the work, and will have overall responsibility for the two studies, chairing meetings, supervising or liasing with key staff, and ensuring progress to deadlines.
Canning is shortly to become service manager of the Psychosis Clinical Academic Group at SLaM, and will thus be responsible for many acute wards and several PICUs. She will advise on the interpretations of findings, implications for practice, and dissemination.
Khondoker is a Lecturer in Biostatistics at the Institute of Psychiatry and NIHR Biomedical Research Centre at SLaM with expertise in survival analysis and applied statistics in mental health research. Dr. Khondoker will advise on data coding scheme consistent with various statistical models proposed and supervise Statistical analysis and interpretation of results from the statistcal analysis of the data.
McCrone is a health economist who has worked on numerous mental health care evaluations. He will be responsible for the conduct of the cost-effectiveness analysis. Time is required from McCrone to supervise the researcher conducting the economic analyses and for input to project management.

Moylan (consultancy) will advise on the construction of the restraint related video, the conduct of the interviews and testing, and the interpretation of results, and will form a link to the seclusion and restraint reduction initiatives in the USA.
Quirk is a sociologist who has extensive qualitative research experience in psychiatric settings, and has published widely on aspects of acute inpatient care. He will supervise the thematic analysis of qualitative data.
Rumble is Head of Nursing for the Psychosis Clinical Academic Group in SLaM/Kings Health Partners Academic Health Sciences Centre. She has responsibility for nursing care in acute wards and PICUs, and will advise on the interpretations of findings, implications for practice, and dissemination.
Sethi is a Consultant Psychiatrist responsible for services on a PICU within SLaM, and is also on the board of NAPICU. He will form a bridge to that organisation, as well as advise on the interpretations of findings, implications for practice, and dissemination.
Stewart has a long track record of involvement in successful health service outcome research in various settings. He has specialist knowledge on special observation, manual restraint and interventions to reduce seclusion use. He will be involved in the training of MHRN CSOs and co-ordination of interview data collection. He will also contribute to the analysis and reporting stages of the project.
Tulloch is a psychiatrist and health services researcher at the IoP. He is expert in the use of the BRC-MH case register, will lead on information governance, will supervise programming and data coding, and will contribute to statistical analysis.

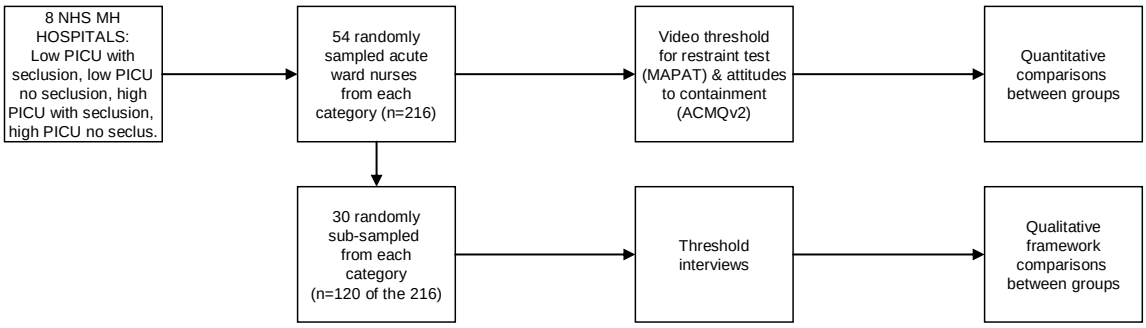
The costs for study are in line with experience of the time taken to construct relatively complex datasets, along with time taken to teach and supervise one RA in data coding, another in data collection, and yet another in economic analysis, along with general project management time for the lead researchers. The cost of study 2 is significantly reduced through the aid of the MHRN, although equipment will be needed for the Clinical Studies Officers to record interviews and collect data using the MAPAT. Transcription costs for interviews have been included, as have costs for open access publication and conference dissemination. Service user advisor fees have been included, the remainder of the costs represent travel and accommodation.

FLOW DIAGRAM

Study 1



Study 2



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