

A.1 Review protocol for review questions 1-5 (Factors and indicators)

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| Review questions 1-5 | <p>What service user and other outcomes are associated with safe staffing for nursing in inpatient mental health settings?</p> <p>What service user, environmental, staffing and organisational factors affect nursing staff requirements in inpatient mental health settings?</p> | This review question was extended to cover all outcomes during the development of the guideline. |
| Context and objectives | <ul style="list-style-type: none"> • Is there evidence of a relationship between nursing staff levels or skill mix and increased risk of harm? • Do nursing staff levels or staff to service user ratios impact on outcomes? • Which outcomes should be used as indicators of safe staffing? • Identify whether any of the following factors affect nursing staff requirements and outcomes; <ul style="list-style-type: none"> ○ Service user factors (such as case mix and volume, acuity (how ill the patient is), comorbid conditions, medication use, risk of crisis, turnover, availability of support [family, carers, relatives] and level of dependency on nursing care) ○ Environmental factors (such as ward size and physical layout, ease of access to key specialties and the existence of other teams [such as crisis teams and acute day units] and how near they are to the ward) ○ Staffing factors (such as the division and balance of tasks between registered nurses and healthcare assistants, experience, skill mix and specialisms, proportion of temporary staff, staff turnover, availability of and care and services provided by other multidisciplinary team members, management and administrative factors, staff and student teaching and supervision) arrangements) ○ Organisational factors at a departmental level (such as organisational management structures and approaches, organisational culture, organisational policies and procedures, including staff training, policies and procedures for preventing self-harm and 'blanket rules' [these are rules whether written or matters of custom or practice that are applied to everyone at the service and are generally inflexible; an example of this may be the use of mobile phones]). | |

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| | <ul style="list-style-type: none"> Identify how important each factor is in determining safe staffing requirements | |
| Searches | <p>Sources to be searched: British Nursing Index (ProQuest), CINAHL (Ebsco), Cochrane Library (Wiley): CDSR, Central, DARE, HTA, NHS EED, Embase (Ovid), Health Management Information Consortium (HMIC) (Ovid), HEED (Wiley), Medline (Ovid), Medline-in-Process (Ovid), PsychINFO (Ovid) and Social Policy & Practice (Ovid).</p> <p>Supplementary search techniques: web searching for grey literature</p> <p>If any relevant systematic reviews are identified during the sifting process these will be used to identify any additional, relevant primary research by carrying out (backwards) citation searching using Web of Science</p> <p>Limits: date restriction of 1998 onwards (this is because practice and standards used within healthcare settings before 1998 differ compared with recent practice, making these studies of limited relevance) This specific cut-off date was selected based on topic specialist input</p> <p>The following publication types will be filtered out at the searching stage: news articles; commentaries; editorials; letters; “notes”; animal studies. Non-English language publications will also be excluded.</p> <p>Database results will be downloaded and de-duplicated in Reference Manager (version 12).</p> | |
| Types of study to be included | <p>Comparative studies (e.g. RCTs, before and after trials, cohort studies, cross sectional, case-control and simulation studies), economic evaluations (e.g. cost-utility analyses, cost-effectiveness studies, cost benefit studies, cost-consequences studies) and qualitative studies (interviews, surveys, focus groups, if associated with staffing). NB: Included studies within systematic reviews will also be included</p> | |
| Setting | <ul style="list-style-type: none"> Inpatient mental health settings for adults and older adults. This includes: <ul style="list-style-type: none"> psychiatric intensive care units (PICUs) acute wards designated section 136 units or places of safety that are staffed by the nursing establishment of inpatient mental health settings rehabilitation units low and medium secure units | |

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| | <ul style="list-style-type: none">• Tier 4 child and adolescent mental health services (CAMHS) inpatient settings. | |

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| Patient group of interest | Adults, children and young people | |
| Staffing group of interest | Nursing staff who are part of the nursing staff establishment in inpatient mental health settings. This includes: <ul style="list-style-type: none"> • Registered nurses • Non registered nursing staff such as healthcare assistants or assistant practitioners | |
| Exposures(s) | This may be staffing levels of registered nurses, healthcare assistants and assistant practitioners (this measurement will include the denominator of activity which accounts for the size of the ward and the number of patients. For example this may be staff to patient ratio or staff per patient) | |
| Comparator(s) | This may be different staffing levels (e.g. this may be different staff to service user ratios compared against each other) | |
| Potential confounders or effect modifiers | Factors that potentially confound or modify the association between staffing levels and outcomes including; <ul style="list-style-type: none"> ○ Service user factors ○ Environmental factors ○ Staffing factors ○ Organisational factors at a departmental level | |
| Outcome(s) | <ul style="list-style-type: none"> • Serious incidents, delivery of nursing care, reported feedback or other (see scope for examples of each category) • Economic outcomes (such as incremental costs, or incremental outcome/effects, and ICERS) • Cost and resource use | |

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| Inclusion criteria | <ul style="list-style-type: none"> • Studies with comparative analysis (e.g. RCTs, before and after trials, cohort studies, cross sectional or case-control and simulation studies) examining the association between staffing levels and outcomes or staffing levels and factors (service user, environmental, staffing or organisational) • Economic evaluations (e.g. cost-utility analyses, cost-effectiveness studies, cost benefit studies, cost-consequences studies) examining staffing levels or skill mix. • Qualitative studies (interviews, surveys, focus groups, if associated with staffing) | |
| Exclusion criteria | <ul style="list-style-type: none"> • Staff requirements for other member of the wider multidisciplinary team (except as a confounder and/or modifier) • Measurement of staff levels that does not include an appropriate patient denominator • Conference abstracts and theses • Non-primary study publication (e.g. editorials) • Non-comparative studies • Non-English studies and studies carried out in non-OECD countries • Studies comparing effectiveness of different models of care • Studies carried out before 1998 (this includes data collection which is limited to before 1998) • No outcomes of interest reported • Any studies that do not relate to staffing (e.g. examining the association between factors and outcomes without considering staffing) | |
| Data extraction and quality assessment | <p>Data extraction: Study information (including reference, study quality, study type, number of characteristics of participants, length of follow-up, data collection methods, staffing measurement, statistical methods used, outcome measures including definitions, results, author's conclusions and additional comments)) will be extracted into evidence tables. Data on serious incidents, delivery of nursing care, reported feedback or other will be extracted as outcomes of interest. Modified GRADE tables may be used to present the results.</p> <p>Quality assessment: A quality appraisal checklist appropriate for the study design will be used from the developing NICE guidelines manual. For economic evaluations: the economic evaluation checklist in the NICE guideline – the manual Appendix H, will be</p> | |

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| | used to assess study quality. Deviations from unified manual: None identified | |
| Strategy for data synthesis | If multiple studies are included, results from all included studies may be reported using modified GRADE tables. | |
| Analysis of subgroups | The following patient subgroups may need to be considered; <ul style="list-style-type: none"> • People under section • Children and young people • Older adults • People involved with the criminal justice system In addition, results may be reported separately for registered nurses, healthcare assistants and assistant practitioners | |
| Other information | None | |

A.2 Review protocol for review question 6 (Nursing care activities)

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| Review question 6 | What core nursing care activities should be considered when determining nursing staff requirements in inpatient mental health settings? | |
| Context and objectives | <ul style="list-style-type: none"> • What key activities are currently carried out by nursing staff? • Do the activities carried out by registered nurses, healthcare assistants and assistant practitioners differ? • How much time is needed for each activity? • Are activities that are carried out by nursing staff associated with service user outcomes? | |
| Searches | <p>Sources to be searched: British Nursing Index (ProQuest), CINAHL (Ebsco), Cochrane Library (Wiley): CDSR, Central, DARE, HTA, NHS EED, Embase (Ovid), Health Management Information Consortium (HMIC) (Ovid), HEED (Wiley), Medline (Ovid), Medline-in-Process (Ovid), PsychINFO (Ovid) and Social Policy & Practice (Ovid).</p> <p>Supplementary search techniques: web searching for grey literature</p> <p>If any relevant systematic reviews are identified during the sifting process these will be used to identify any additional, relevant primary research by carrying out (backwards) citation searching using Web of Science</p> <p>Limits: date restriction of 1998 onwards (this is because practice and standards used within healthcare settings before 1998 differ compared with recent practice, making these studies of limited relevance) This specific cut-off date was selected based on topic specialist input</p> <p>The following publication types will be filtered out at the searching stage: news articles; commentaries; editorials; letters; "notes"; animal studies. Non-English language publications will also be excluded.</p> <p>Database results will be downloaded and de-duplicated in Reference Manager (version 12).</p> | |
| Types of study to be included | Qualitative studies (e.g. cross-sectional surveys, interviews, focus groups, questionnaires) and studies reporting comparative analyses (e.g. RCTs, before and after trials, cohort studies, cross sectional, case-control) will be included | |

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| Setting | <ul style="list-style-type: none"> • Inpatient mental health settings for adults and older adults. This includes: <ul style="list-style-type: none"> ○ psychiatric intensive care units (PICUs) ○ acute wards ○ designated section 136 units or places of safety that are staffed by the nursing establishment of inpatient mental health settings ○ rehabilitation units ○ low and medium secure units • Tier 4 child and adolescent mental health services (CAMHS) inpatient settings. | |
| Patient group of interest | Adults, children and young people | |
| Staffing group of interest | <ul style="list-style-type: none"> • Registered nurses working in inpatient mental health settings who are part of the nursing establishment (this is the number of registered nurse, healthcare assistant and assistant practitioner posts funded to work in a particular ward, department or hospital). This includes mental health nurses (including paediatric mental health nurses) • Healthcare assistants and assistant practitioners working in inpatient mental health settings | |
| Exposures(s) | For comparative studies this may be activities carried out by registered nurse (this could also relate to different levels of registered nurses) | |
| Comparator(s) | For comparative studies this may be activities carried out by healthcare assistant or assistant practitioner | |
| Potential confounders or effect modifiers | These may include factors that may impact on staffing requirements or the ability to carry out activities (e.g. ward size, acuity, staff sickness) | |
| Outcome(s) | <ul style="list-style-type: none"> • Activities and tasks carried out by registered nurses and healthcare assistants working on acute wards in mental health inpatient settings • Time taken to carry out key activities and tasks • Serious incidents, delivery of nursing care, reported feedback or other (see scope for examples of each category) | |

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| Inclusion criteria | <ul style="list-style-type: none"> Qualitative (e.g. cross-sectional surveys, interviews, focus groups, questionnaires) or comparative studies focusing on key activities and tasks carried out by registered nurses and healthcare assistants which were carried out the UK in 2005 or after (this is because the aim of the review question is to examine current practice and it is assumed that practice and standards used within healthcare settings over 10 years ago differ compared with recent practice making these studies of limited relevance). The inclusion criteria will also be restricted to UK only as this review question aims to identify current practice within NHS settings. | |
| Exclusion criteria | <ul style="list-style-type: none"> Opinions on what activities should be carried out by registered nurses, healthcare assistants or assistant practitioners Conference abstracts and theses Non-primary study publication (e.g. editorials) Study design not of interest Studies that are not reported in English Studies carried out before 2005 (this includes data collection which is limited to before 2005) Studies that were carried out outside of the UK No outcomes reported | |
| Data extraction and quality assessment | <p>Data extraction: Study information (including reference, study quality, research question, theoretical approach, data collection methods, methods of analysis, sample details, results and author's conclusions) will be extracted into evidence tables. Data on activities and tasks and time taken to carry these out will be extracted as outcomes of interest. For comparative studies serious incidents, delivery of nursing care, reported feedback or other outcomes will be extracted. Applicability will not be assessed as only studies carried out in the UK will be included.</p> <p>Quality assessment: CASP will be used to assess study quality</p> <p>Deviations from unified manual: None identified</p> | |
| Strategy for data synthesis | If multiple studies are included, results from all included studies will be reported in table format with study details, study quality and results for nursing and healthcare assistant activities. No further analysis will be carried out. | |
| Analysis of subgroups | Papers may report results for registered nurses, healthcare assistants and assistant practitioners separately. Where results have been reported for subgroups of the population, these will be extracted. | |

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| Other information | References found: Bee et al (2006). Mapping nursing activity in acute inpatient mental healthcare settings. Journal of mental health 15 (2); 217-226 | |

A.3 Review protocol for review question 7 (Approaches and toolkits)

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| Review question 7 | What approaches for identifying safe staffing for nursing and/or skill mix, including toolkits, are effective in inpatient mental health settings and how frequently should they be used? | |
| Context and objectives | <ul style="list-style-type: none"> To assess whether a systematic approach to calculate staffing requirements and skill mix is associated with better outcomes compared with alternative approaches (e.g. professional judgement) What evidence is available on the reliability and/or validity of any identified toolkits? To assess how often they should be used | |
| Searches | <p>Sources to be searched: British Nursing Index (ProQuest), CINAHL (Ebsco), Cochrane Library (Wiley): CDSR, Central, DARE, HTA, NHS EED, Embase (Ovid), Health Management Information Consortium (HMIC) (Ovid), HEED (Wiley), Medline (Ovid), Medline-in-Process (Ovid), PsychINFO (Ovid) and Social Policy & Practice (Ovid).</p> <p>Supplementary search techniques: web searching for grey literature</p> <p>If any relevant systematic reviews are identified during the sifting process these will be used to identify any additional, relevant primary research by carrying out (backwards) citation searching using Web of Science</p> <p>Limits: date restriction of 1998 onwards (this is because practice and standards used within healthcare settings before 1998 differ compared with recent practice, making these studies of limited relevance) This specific cut-off date was selected based on topic specialist input</p> <p>The following publication types will be filtered out at the searching stage: news articles; commentaries; editorials; letters; “notes”; animal studies. Non-English language publications will also be excluded.</p> <p>Database results will be downloaded and de-duplicated in Reference Manager (version 12).</p> | |
| Types of study to be included | Studies with comparative analysis (e.g. RCTs, before and after trials, cohort studies, cross sectional, or case-control and simulation studies), economic evaluations (e.g. cost-utility analyses, cost-effectiveness studies, cost benefit studies, cost-consequences studies) and qualitative studies (interviews, surveys, focus groups, if associated with staffing levels). NB: Included studies within systematic reviews will also be included | |

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| Setting | <ul style="list-style-type: none"> Inpatient mental health settings for adults and older adults. This includes: <ul style="list-style-type: none"> psychiatric intensive care units (PICUs) acute wards designated section 136 units or places of safety that are staffed by the nursing establishment of inpatient mental health settings rehabilitation units low and medium secure units Tier 4 child and adolescent mental health services (CAMHS) inpatient settings. | |
| Patient group of interest | Adults, children and young people | |
| Staffing group of interest | <ul style="list-style-type: none"> Registered nurses working in inpatient mental health settings who are part of the nursing establishment (this is the number of registered nurse, healthcare assistant and assistant practitioner posts funded to work in a particular ward, department or hospital). This includes mental health nurses (including paediatric mental health nurses) Healthcare assistants and assistant practitioners working in inpatient mental health settings | |
| Intervention(s) | Any approach/method/process/toolkit for identifying registered nurse and healthcare assistant staffing requirements such as professional judgement, the MHLA workload tool and nursing hours per patient day | |
| Comparator(s) | <ul style="list-style-type: none"> Professional judgement Any approach/method/toolkit used for determining staffing requirement | |
| Potential confounders or effect modifiers | N/A | |
| Outcome(s) | <ul style="list-style-type: none"> Serious incidents, delivery of nursing care, reported feedback or other (see scope for examples of each category) Economic outcomes (such as incremental costs, or incremental outcome/effects, and ICERS) Cost and resource use | |

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| Inclusion criteria | <ul style="list-style-type: none"> • Studies with comparative analysis (e.g. RCTs, before and after trials, cohort studies, cross sectional or case-control and simulation studies) examining the association between toolkits/approaches/processes/methods to determine staffing levels and outcomes • Economic evaluations (e.g. cost-utility analyses, cost-effectiveness studies, cost benefit studies, cost-consequences studies) examining toolkits/approaches/processes/methods to determine staffing levels and outcomes • Qualitative studies (interviews, surveys, focus groups, if associated with staffing) | |
| Exclusion criteria | <ul style="list-style-type: none"> • Studies that look solely at the reliability and validity of tools to assess factors and do not link the tool to staffing decisions (e.g. patient dependency tools) • Conference abstracts and theses • Non-primary study publication (e.g. editorials) • Studies that do not report comparative analysis • Non-English studies and those carried out in non-OECD countries • Studies comparing effectiveness of different models of care • Studies carried out before 1998 (this includes data collection which is limited to before 1998) • No outcomes reported • Toolkits or processes evaluated in non-mental health inpatient settings | |
| Data extraction and quality assessment | <p>Data extraction: Study information (including reference details, study type, quality, description of intervention, comparator, methods, setting, participants, follow-up, analysis, results and quality) will be extracted into evidence tables. Data on the outcomes listed will be extracted. Applicability will be assessed using GRADE.</p> <p>Quality assessment: A quality appraisal checklist appropriate for the study design will be used from the developing NICE guidelines manual. For economic evaluations: the economic evaluation checklist in the NICE guideline – the manual Appendix H, will be used to assess study quality.</p> <p>Deviations from unified manual: None identified</p> | |
| Strategy for data synthesis | <p>If multiple studies are included, results from all included studies may be reported using modified GRADE tables.</p> | |

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| Analysis of subgroups | <p>The following patient subgroups may need to be considered;</p> <ul style="list-style-type: none"> • People under section • Children and young people • Older adults <p>In addition, results may be reported separately for registered nurses, healthcare assistants and assistant practitioners</p> | |
| Other information | None | |