

Appendix 3

Data extraction form adapted from Hayden and colleagues Framework

Abbreviation

| | |
|-----|--------------------------------|
| MUS | Medically Unexplained Symptoms |
| SSD | Somatic Symptoms Disorder |
| IBS | Irritable Bowel Syndrome |
| GP | General Practitioner |
| BDS | Bodily Distress Syndrome |
| EX | Excluded |
| NR | Not Reported |

Eligibility criteria for the title and abstract screening phase

| Study design | Assessment | Comment |
|--|----------------------|---------|
| Is it: [1] A cohort study (prospective or retrospective) [2] A case-control or nested case-control [3] A cross-sectional study | Yes No Unclear | |
| Population [1] Were patients high users of healthcare [2] Accrue high healthcare costs Including: high cost patients, high users, distressed high users, utilisers of care, frequent attenders in primary care, frequent attenders at an emergency department. Please answer yes if high users or high cost patients included as a sub-group. [3] Were patients with MUS included in the study defined by a recognised measure including: a standardised research interview (e.g. the Structured Clinical Interview for Mental Disorders) to generate a diagnosis of a somatoform disorder according to: DSM-III; DSM-IV-R; DSM V; ICD-9; ICD-10; or other relevant diagnostic system; a clinical assessment leading to a clinical diagnosis of a somatoform disorder according to any of the above diagnostic systems; a validated scale for the assessment of MUS, such as the Screening for Somatoform Disorders, the Bradford Somatic Inventory, or component subscales of validated standardised instruments for the assessment of general psychopathology or general health status, such as the Patient Health Questionnaire-15 (PHQ-15); or an assessment which generated a recognised symptom grouping of MUS developed for research purposes (e.g. abridged somatisation disorder, multi-somatoform disorder, bodily distress disorder, and complex somatic symptom disorder . NB: Please answer YES if MUS is diagnosed as a sub group | Yes No Unclear | |
| Are patients aged (18 years or above) NB: Please answer Yes if mixed age population | Yes No Unclear | |
| Outcomes | | |

| | | |
|--|-------------------------------|--|
| Did the study report any of the following outcomes: [1] Prevalence of MUS [2] Patient characteristics and context associated with high service usage/costs among patients with MUS [3] Magnitude or risk of cost or use of healthcare associated with the presence of MUS | | |
| Follow-up | | |
| Were the patients followed up and adequate measures taken NB: Please answer Yes if adequate measure were taken and key characteristics described | Yes No Unclear | |
| Final decision (please tick) | Include Exclude Unclear | |

Exclusion criteria

| Reasons for exclusion of study from review (please circle where appropriate) | |
|---|---|
| Methods | [1] Not a cohort/case-control or cross-sectional study [2] Qualitative study |
| Patients | Age: <18 Physical illness/psychiatric condition: [1] Paediatric patients [2] Palliative care [3] Obstetrics [4] Patients in acute mental health settings |
| Intervention | [1] Testing of any intervention [2] Screening |
| Outcomes | No relevant outcomes assessed No data for relevant subgroup extractable |
| Follows-up period | No follow-up |
| Other | Duplicate publication Other |

Inclusion criteria

| Specific inclusion criteria (please include if answer is Yes to all question below) | |
|--|----------------------|
| Eligibility criteria | |
| Satisfaction of eligibility criteria | Yes No Unclear |
| Effect sizes | |
| Is there sufficient reporting of statistics or data to calculate effect sizes | Yes No Unclear |

Organisation

| Organisational aspect | Exclude | Include |
|-----------------------|--------------------|---------|
| Reviewer/date: | Checked by: | |
| Author/Year | | |
| Journal/Source | | |
| Country of origin | | |

| | |
|------------------|---|
| Publication type | Full text/Abstract/Book chapter/progress report/ Other – please specify |
| Fate | Decision: pending/Checked reference/Use for discussion/EX without listing/EX with listing Other – please specify |
| Notes | |

Study characteristics

| | |
|---|---|
| General study characteristics (please circle where appropriate) | |
| Location of study | |
| Study aims | Reported/NR |
| Date of recruitment | From _____ to _____ Median (range):# Mean:# |
| Length of follow-up of outcome of interest + length of follow-up of study | From _____ to _____ Median (range):# Mean:# |
| Outcome assessed | Did the study report any of the following outcome: [1] Prevalence of MUS [2] Patients characteristics and context associated with high service usage/costs among patients with MUS [3] Magnitude of cost or use of healthcare associated with the presence of MUS Other (<i>please specify</i>) |
| Outcome definition | |
| Relationship between outcome and relevant factor | Is the relationship statistically significant? Yes/No OR/mean difference:# If No, is it due to: Low powered or inconclusive study/A true negative study |
| Power calculation | Yes/No/Not reported Calculated sample size:# Sample size achieved: Yes/No |
| Funding | Unclear NR Please state where reported |
| Conflict of interest statement | Yes/No/NR |

| Baseline characteristics of patients (please circle where appropriate) | | | |
|--|------------------|------------------|--|
| | Exposure | Control | Notes: Any relationship with outcomes? Yes/No/NR If Yes Please state if statistically significant and OR/mean changes in continuous values |
| Overall comment: Significant/Insignificant | | | |
| Number of patients | | | |
| Age range (if reported) Mean | | | |
| Ethnicity No% | | | |
| Gender No% | Male: Female: | Male: Female: | |
| No of patients screened for MUS | | | |
| No of patients recruited | | | |
| No of patients allocated | | | |
| No of patients evaluated | | | |
| No of dropouts | | | |
| Reasons for dropouts | | | |
| | | | |
| Number of protocol violations | | | |
| | | | |
| Definition of MUS [1] Clinical interview [2] Standardised questionnaire Please circle all that applies and list all | | | |
| Status of patient at recruitment Any treatment for any comorbidities If treated: Please state What treatment Duration | | | |
| Adverse event? Yes/No <i>If Yes please state</i> | | | |

| Observational study characteristics (please circle where appropriate) | |
|---|---|
| Sample size | |
| Number of excluded patients | |
| Recruitment method | |
| Type of observational study | Cohort studies (prospective/retrospective) Case-control studies/nested case-control Cross-sectional studies |
| Are group comparable | Yes/No If No, please specify |
| Any confounders? | Yes/No If No, please specify |
| Analysis | |
| Drop outs stated | Yes/No If Yes:# in each group |

Outcome details

The following table have been copied for every relevant outcome assessed (please fill out fields only where applicable)

| Outcome assessed (please state where relevant) | |
|--|--|
| Definition of each outcome | |
| Time of assessment of each outcome (post MUS) | |
| Timing of assessment | |
| Length of follow up for each outcome | |
| Method of measurement | |
| No of patients evaluated for each outcome, as stated above | |

| Methodological quality summary for observational studies | | | | | |
|--|------------------|--------|-----------------------|--------|-------------------|
| Reviewer/Date: | | | Checked by: | | |
| Contents (please refer to tables below for guidance) | Yes | Partly | No | Unsure | Comments |
| Study participation | | | | | |
| Study attrition | | | | | |
| Measurement of prognostic factors | | | | | |
| Measurement and controlling for confounding variables | | | | | |
| Measurement of outcomes | | | | | |
| Analysis approach | | | | | |
| Summarised validity | Low risk of bias | | Moderate risk of bias | | High risk of bias |
| Remarks: | | | | | |