Dual diagnosis: Review Protocols

Contents

Epidemiology and current practice

	Details
PROSPERO: Reg. No.	CRD#########
Guideline details	
Guideline*	Severe mental illness and substance misuse (dual diagnosis): community health and social care services
Guideline chapter*	Evidence review 1
Objective of review*	• To review the health and social care needs of people in the UK with a severe mental illness who also misuse substances • To review the current configuration of health and social care community services in the UK and describe the care pathway through which people with coexisting severe mental illness and substance misuse are recognised, treated, managed and followed-up
Review title and timescale	
Review title*	The epidemiology, and current configuration of health and social care community services, for people in the UK with a severe mental illness who also misuse substances
Anticipated or actual start date	27th February 2015
Anticipated completion date	15th July 2015
Stage of review at time of registration	**Started** **Completed** Preliminary searches ☐ ☐ Piloting of the study selection process ☐ ☐ Formal screening of search results against eligibility criteria ☐ ☐ Data extraction ☐ ☐

	Risk of bias (quality) assessment ☐ ☐ Data analysis ☐ ☐ Prospective meta-analysis ☐ ☐ Provide any other relevant information about the stage of the review here (e.g. Funded proposal, final protocol not yet finalised).

Review team details	
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Review team members and their organisational affiliations	Dr. Odette Megnin-Viggars NCCMH
Organisational affiliation of the review	National Collaborating Centre for Mental Health
Funding sources/ sponsors	National Institute for Health and Care Excellence
Conflicts of interest	⊙ None known ○ Yes
Review methods	
Review question(s)*	RQ 1.1: What are the health and social care needs of people in the UK with a severe mental illness who also misuse substances? RQ 1.2: What is the current configuration of health and social care community services and the care pathway through which people in the UK with coexisting severe mental illness and substance misuse are recognised, treated, managed and followed-up?
Sub-question(s)	Where possible, consideration will be given to the specific needs of:- • older people • people with a learning disability • teenage parents • people from black and minority ethnic groups

	- travellers - asylum seekers or refugees - women - lesbian, gay, bisexual, transsexual or transgender people - people who are homeless or in insecure accommodation - people from a low-income family or on a low income - people who are socially isolated - ex-offenders - sex workers - people who are, or have a history of being, 'looked after' or adopted - adults who have a history of experiencing, or witnessing or perpetrating violence or abuse - young people who have experienced abuse or witnessed domestic violence and abuse - young people who are excluded from school - young people whose parents have mental health or substance misuse problems
Searches*	**Search approach:** Systematic/exhaustive **Search concepts:** RQ 1.1: (((drug/alcohol misuse and (dual diagnosis or serious mental illness)) or (serious mental illness and (drug/alcohol misuser or dual diagnosis))) and epidemiology and setting) RQ 1.2: (((drug/alcohol misuse and (dual diagnosis or serious mental illness)) or (serious mental illness and (drug/alcohol misuse or dual diagnosis))) and community services) **Limits:** Publication limit 2000-current English-language studies **Databases (RQ 1.1 and RQ 1.2):** - ASSIA - CINAHL - Cochrane Central Register of Controlled Trials (CENTRAL) - Cochrane Database of Reviews of Effect (DARE) - Cochrane Database of Systematic Reviews (CDSR)

- Econlit
- Embase
- EPPI Centre databases - Bibliomap and DOPHer
- HMIC
- IBSS
- Medline and Medline in Process
- PsycEXTRA
- PsycINFO
- Social Care Online
- Social Policy & Practice
- Social Science Citation Index
- Social Service Abstracts
- Sociological Abstracts

Searches for RQ 1.2 will be restricted to mostly (or wholly) management, policy and practice databases, with significantly more time spent searching web pages, the most likely avenue for identification of the study types in question.

Several iterations of the MEDLINE search strategy will be undertaken before agreement is reached on its final computation.

Steps will be taken to ensure that the database searches do not come at the expense of other search methods. Steps will be deployed as part of a proportionate and graduated response to searches that produce unmanageable volumes of information (these follow).
- Excluding non-English studies, animal studies, letters, editorials and other non-relevant publication types from results.
- Searching Embase using only major Emtree headings.
- Increasing the precision of search strategies intended for one or a handful of databases.
- Staggering resources using a tiered model in which databases are searched in probable ascending order of importance, only stopping when the set of results reach a point where more searching is no longer possible (due to insufficient resource) or advantageous (turning in lower than expected returns).

Key steps will include:
- Undertaking the searches in a series of steps, starting with a high specificity construct and using the sifted results from each database to predict the outcome of more comprehensive strategies that take up more screening time.

	- Coding references in EndNote from their point of origin and measuring the effectiveness of each database/search by its incremental input/output ratio – that is, dividing the number of records selected for potential full text review from a given database/search over the total number of references found in the same database/search. Databases with the best returns will be prioritised. References identified from searches conducted in key databases will also be used as a benchmark in determining the course of the strategy and subsequent judgements made. EPPI-Reviewer priority screening - Priority screening in EPPI-Reviewer as a multiple method strategy may also sit alongside the manual screen – a tool that will further inform decision making and help build a compelling case for the inclusion/exclusion/modification of a given database search. The specific processes involved in managing the endeavour will be subject to approval by NICE. **Websites (RQ 1.1 and RQ 1.2):** - British Medical Association - Care Quality Commission - Centre for Mental Health - Department of Health - DrugScope - European Monitoring Centre for Drug & Drug addiction - European Observatory on Healthcare Systems and Policies - Faculty of Public Health - Google (for identification of other web sites of relevance to the topic area) - Guidelines and Audit Implementation Network - Health and Social Care Information Centre - Health Services Management Centre - Healthcare Quality Improvement Partnership - Healthcare Improvement Scotland - Institute for Public Policy Research - Indicators for Quality Improvement - Joseph Rowntree Foundation - Kings Fund - Mental Healthcare - Mind - National Audit Office

- NHS Choices
- NHS England
- NHS Improving Quality
- NICE (guidelines and Evidence Search)
- Office for National Statistics
- Patient UK
- Public Health Wales
- Public Health England (including National Treatment Agency for Substance Misuse)
- Rethink Mental Illness
- Royal College websites
- Scottish Government
- Scottish Public Health Network
- SIGN
- Turning Point
- US National Guidelines Clearninghouse
- Welsh Government
- Who Health Evidence Network
- World Health Organisation

Searches for RQ 1.1 will be restricted to websites which are most likely to identify evidence of epidemiological systematic reviews, surveys and health needs assessments. The search construction may be spread around a broader range of terms depending on the size of the result e.g. community mental health services.

Trial registries (RQ 1.1):
- ClinicalTrials.gov (US National Institutes of Health service)
- International Standard Randomised Controlled Trial Number (ISRCTN) Register

Other resources (RQ 1.1):
- Searching reference lists
- Citation tracking in Scopus and Web of Knowledge (WoK)
- Searching for additional studies by authors of papers identified for inclusion and/or possible inclusion
- Contacting authors of relevant works for 'sibling' studies
- PROSPERO (http://www.crd.york.ac.uk/Prospero/)

Priorities for the above methods will be selected in conjunction with NICE.

	Miscellaneous (RQ 1.1): • Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in full. Unpublished data will only be included where a full study report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study characteristics will be published in the full guideline. The searches will be recorded as required by the NICE manual section 5.9
Condition or domain being studied*	'Dual diagnosis' is defined as a severe mental illness combined with misuse of substances. Severe mental illness includes a clinical diagnosis of: • schizophrenia, schizotypal and delusional disorders • bipolar affective disorder • severe depressive episode(s) with or without psychotic episodes Substance misuse refers to the use of legal or illicit drugs including alcohol and medicine, in a way that causes mental or physical damage (this may include low levels of substance use that would not usually be considered harmful or problematic, but may have a significant effect on the mental health of people with a mental illness such as psychosis)
Participants/ population*	Included: Young people (aged 14 to 25) and adults (over 25) who have been diagnosed as having a severe mental illness and who misuse substances (dual diagnosis) who live in the community. Excluded: • children (aged under 14 years old) • people with a severe mental illness but no evidence of substance misuse (apart from as a control group) • people who misuse substances who have not been diagnosed with a severe mental illness (apart from as a control group) • people with a severe mental illness who smoke or use tobacco but do not misuse any other substances • people who have a severe mental illness and misuse substances, but who are not living in the community
Intervention(s), exposure(s)*	People who have been diagnosed as having a severe mental illness and who misuse substances
Comparator(s)/ control*	RQ 1.1: Included:

	• general UK population • people with a severe mental illness who do not misuse substances • people who misuse substances but do not have a coexisting severe mental illness RQ 1.2: N/A
Types of study to be included initially*	RQ 1.1: Included: Cohort studies, cross-sectional studies, surveys, health needs assessments. Epidemiological data derived from the control arm of randomised clinical trials and case-control studies will be considered if there is evidence of reasonable representativeness of the sample. Systematic reviews will be used as a source for identifying any studies that may not have been picked up in the searches. Excluded: N/A RQ 1.2: Included: Surveys, service reports, protocols and audits Excluded: N/A
Context*	Included: Community settings (including a range of services provided by the NHS, social care and schools, as well as the community and voluntary sectors) in the UK Excluded: • non-UK studies • prisons and other custodial settings • young offenders units • forensic secure mental health settings
Primary/Critical outcomes*	RQ 1.1: • Prevalence and incidence of combined severe mental illness and substance misuse (dual diagnosis) • Prevalence and incidence of dual diagnosis by: mental health diagnosis; substance that is misused; setting; sociodemographic characteristics (for instance, gender, age); geographical region • Prevalence of other coexisting conditions, for instance, physical health problems • Prevalence of social care needs (such as housing, employment rate, financial issues, legal issues)

	RQ 1.2:
	  • Content, configuration and integration of community-based services (including services provided by the NHS, social care and schools, as well as the community and voluntary sectors) to address the health and social care needs of people with a severe mental illness who misuse substances, including:
	     o the structure and organisation of different service components (for example, information sharing and care pathways)
	     o the type of staff involved, for example, availability/location of skills (training, experience, specialist input) and staffing levels
	     o availability of services (for example, out-of-hours availability)
	     o accessibility of services (for example, transfer/referral times, time to assessment and diagnosis, time to treatment, waiting times, physical accessibility of services)
	     o acceptability of services (for instance, service user, carer and family satisfaction with care, met/unmet treatment needs, appropriateness of management plan to diagnostic grouping)
	     o service capacity
	     o service utilisation (for instance, number of missed appointments, treatment adherence)

Secondary/Important, but not critical outcomes*	
Data extraction (selection and coding)*	Citations from each search will be downloaded into EndNote and duplicates removed. Titles and abstracts of identified studies will be screened by two reviewers for inclusion against criteria, until a good inter-rater reliability has been observed (percentage agreement =>90% or Kappa statistics, K>0.60). Initially 10% of references will be double-screened. If inter-rater agreement is good then the remaining references will be screened by one reviewer. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Two researchers will extract data into the study database, comparing a sample of each other's work (10%) for reliability. Discrepancies or difficulties with coding will be resolved through discussion between reviewers or the opinion of a third reviewer will be sought. Data to be extracted: Study characteristics: RQ addressed, study design, geographical region, service setting, N, year/s of data collection, inclusion/exclusion criteria, sampling frame, severe mental illness, diagnostic criteria/status, substance misuse, method of substance misuse assessment, demographics (age, sex, ethnicity), study limitations (as identified by the authors of the paper and by the review team)

	RQ 1.1: Outcomes: Outcome name, outcome measure, outcome rater, outcome data (for instance, prevalence of dual diagnosis, prevalence of coexisting conditions, prevalence of social care needs [housing, employment rate], relationship between severe mental illness and substance misuse [correlation]) RQ 1.2: Outcomes: Outcome name, outcome measure, outcome rater, outcome data (for instance, staffing levels, transfer/referral times, time to assessment and diagnosis, time to treatment, waiting times, met/unmet treatment needs, service capacity, number of missed appointments, treatment adherence), model of current care pathway
Risk of bias (quality) assessment*	The quality of individual studies will be assessed using the relevant checklist recommended in the NICE guidelines manual
Strategy for data synthesis*	Data will be synthesised using narrative synthesis methods. Where possible a 'problem-oriented' conceptual model will also be produced to describe and summarise the current clinical understanding of the relevant characteristics of people with coexisting severe mental illness and substance misuse and describe the baseline configuration of health and social care community services and the current care pathway through which people with coexisting severe mental illness and substance misuse are detected, diagnosed, treated and followed-up.
Analysis of subgroups or subsets (including sensitivity analyses)	In addition to subgroup analyses giving specific consideration to the groups outlined in the sub-question section, where possible subgroup analyses will be considered, including by: • geographical location (rural; urban) • service setting (primary care; secondary mental health care [community mental health teams, early intervention services, crisis resolution teams, assertive outreach teams]; substance misuse services) • assessment method (consensus method [structured diagnostic interview combined with at least one other source]; self-report using formal diagnostic interviews; self-report using screening instrument; staff ratings) • timescales for assessing comorbidity (lifetime; 1 year; 6 months; current) Where substantial heterogeneity exists, sensitivity analyses will be considered, including: • Excluding studies where diagnosis or data collection was carried out pre-2000
General information	
Type of review	Epidemiologic
Dissemination plans	This review is being conducted for the NICE guideline on 'Severe mental illness and substance misuse (dual diagnosis): community health and social care services'. Further information about the guideline and plans for implementation can be found on the NICE website: http://guidance.nice.org.uk
Details of any existing review of the same topic by the same authors*	N/A
Review status	Ongoing

Further information (not needed for Prospero registration)	
Existing reviews utilised in this review:*	
• Updated	
• Not updated	

Experience of care

	Details
PROSPERO: Reg. No.	CRD#########
Guideline details	
Guideline*	Severe mental illness and substance misuse (dual diagnosis): community health and social care services
Guideline chapter*	Evidence review 2
Objective of review*	To review the views and experiences of health and social care community services for people with a severe mental illness who also misuse substances from the perspective of service users, their families or carers, providers and commissioners
Review title and timescale	
Review title*	Service user, family and carer, provider and commissioner views and experiences of health and social care services for people with a severe mental illness who also misuse substances
Anticipated or actual start date	6th April 2015
Anticipated completion date	7th October 2015
Stage of review at time of registration	**Started Completed** Preliminary searches ☐ ☐ Piloting of the study selection process ☐ ☐ Formal screening of search results ☐ ☐ against eligibility criteria Data extraction ☐ ☐ Risk of bias (quality) assessment ☐ ☐ Data analysis ☐ ☐ Prospective meta-analysis ☐ ☐ Provide any other relevant information about the stage of the review here (e.g. Funded proposal, final protocol not yet finalised).
Review methods	
Review question(s)*	RQ 2.1: What are the facilitators and barriers for commissioners or practitioners in their commissioning or delivery of health and social care community services for people with a severe mental illness who also misuse substances?

	RQ 2.2: What are the facilitators and barriers to accessing and using health and social care community services, and to satisfaction with those services, for people with coexisting severe mental illness and substance misuse and their family or carers?
Sub-question(s)	Where possible, consideration will be given to the specific needs of:- • older people • people with a learning disability • teenage parents • people from black and minority ethnic groups • travellers • asylum seekers or refugees • women • lesbian, gay, bisexual, transsexual or transgender people • people who are homeless or in insecure accommodation • people from a low-income family or on a low income • people who are socially isolated • ex-offenders • sex workers • people who are, or have a history of being, 'looked after' or adopted • adults who have a history of experiencing, or witnessing or perpetrating violence or abuse • young people who have experienced abuse or witnessed domestic violence and abuse • young people who are excluded from school • young people whose parents have mental health or substance misuse problems
Searches*	Search approach: Systematic/exhaustive Search concepts: RQ 2.1: Version 1: (((drug/alcohol misuse and (dual diagnosis or serious mental illness)) or (serious mental illness and (drug/alcohol misuse or dual diagnosis))) and (service delivery or commissioning) and ((health and social care services) or setting)) OR Version 2: (((drug/alcohol misuse and (dual diagnosis or serious mental illness)) or (serious mental illness and (drug/alcohol misuse or dual diagnosis))) and (service delivery or commissioning) and ((health and social care services) or setting) and (experience of care or qualitative [incl. autobiographical] or survey or case study))

Choice of search construction will be dependent on the size of the literature. If version '2' is used 'experience of care' will be run as an adjunct to a qualitative filter to maximise returns.

RQ 2.2:
(((drug/alcohol misuse and (dual diagnosis or serious mental illness)) or (serious mental illness and (drug/alcohol misuse or dual diagnosis))) and (health & social care services or setting) and (experience of care or qualitative [incl. autobiographical] or survey or case study))

Terms for 'experience of care' will be used as an adjunct to a qualitative filter in order to maximise returns.

Limits:
Publication limit 2000-current

Search filters:
Qualitative in-house development (partial use only - see search concepts)

Databases (RQ 2.1 and RQ 2.2):

- ASSIA
- CINAHL
- Cochrane Database of Reviews of Effect (DARE)
- Cochrane Database of Systematic Reviews (CDSR)
- Embase
- EPPI Centre databases - Bibliomap and DOPHer
- HMIC
- IBSS
- Medline and Medline in Process
- PsycEXTRA
- PsycINFO
- Social Care Online
- Social Policy & Practice
- Social Science Citation Index
- Social Service Abstracts
- Sociological Abstracts

Several iterations of the MEDLINE search strategy will be undertaken before agreement is reached on its final

computation.

Steps will be taken to ensure that the database searches do not come at the expense of other search methods. Steps will be deployed as part of a proportionate and graduated response to searches that produce unmanageable volumes of information (these follow).

1. Excluding animal studies, letters, editorials and other non-relevant publication types from results.
2. Searching Embase using only major Emtree headings
3. Increasing the precision of search strategies intended for one or a handful of databases.
4. Staggering resources using a tiered model in which databases are searched in probable ascending order of importance, only stopping when the set of results reach a point where more searching is no longer possible (due to insufficient resource) or advantageous (turning in lower than expected returns).

Key steps will include:
- Undertaking the searches a series of steps, starting with a high specificity construct and using the sifted results from each database to predict the outcome of more comprehensive strategies that take up more screening time.
- Coding references in EndNote from their point of origin and measuring the effectiveness of each database/search by its incremental input/output ratio - that is, dividing the number of records selected for potential full text review from a given database/search over the total number of references found in the same database/search. Databases with the best returns will be prioritised. References identified from searches conducted in key databases will also be used as a benchmark in determining the course of the strategy and subsequent judgements made.

EPPI-Reviewer priority screening
- Priority screening in EPPI-Reviewer as a multiple method strategy may also sit alongside the manual screen – a tool that will further inform decision making and help build a compelling case for the inclusion/exclusion/modification of a given database search.

Websites (RQ 2.1 and RQ 2.2):

- Addaction
- Alcohol Concern
- Alcohol Research UK
- Audit Commission
- British Medical Association
- Care Quality Commission
- Centre for Mental Health

	• Changes.org.uk • Department of Health • DrugScope • European Monitoring Centre for Drug & Drug addiction • European Observatory on Healthcare Systems and Policies • Google UK (for identification of case studies and other web sites of relevance to the topic area) • Health and Social Care Information Centre • Health Services Management Centre • Healthcare Improvement Scotland • Healthcare Quality Improvement Partnership • Healthtalkonline • Hearing Voices Network • Institute for Public Policy Research • Joseph Rowntree Foundation • Kings Fund • Mental Health Research UK • Mental Healthcare • MIND • National Audit Office • National Survivor User Network • NHS England • NHS Improving Quality • NICE (guidelines and Evidence Search – including QIPP) • NIHR Health Services & Delivery Research Programme • Nuffield Trust • Office for National Statistics • OpenGrey • Patient UK • Public Health England (including National Treatment Agency for Substance Misuse) • Public Health Observatory • Public Health Wales • Race Equality Foundation • Rethink Mental Illness • Royal College websites • Sane

	- Scottish Government - Scottish Public Health Network - SIGN - South Asian Health Foundation - Turning Point - US National Guidelines Clearninghouse - Welsh Government - World Health Organisation - Youthtalkonline Other resources (RQ 2.1 and RQ 2.2): - Searching reference lists - Citation tracking in Scopus and Web of Knowledge (WoK) - Searching for additional studies by authors of papers identified for inclusion and/or possible inclusion - Contacting authors of relevant works for 'sibling' studies - PROSPERO (http://www.crd.york.ac.uk/Prospero/) Priorities for the above methods will be selected in conjunction with NICE. Miscellaneous (RQ 2.1 and RQ 2.2): - Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in full. Unpublished data will only be included where a full study report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study characteristics will be published in the full guideline. The searches will be recorded as required by the NICE Manual as set out in section 5.9
Condition or domain being studied*	'Dual diagnosis' is defined as a severe mental illness combined with misuse of substances. Severe mental illness includes a clinical diagnosis of: - schizophrenia, schizotypal and delusional disorders - bipolar affective disorder - severe depressive episode(s) with or without psychotic episodes

	Substance misuse refers to the use of legal or illicit drugs including alcohol and medicine, in a way that causes mental or physical damage (this may include low levels of substance use that would not usually be considered harmful or problematic, but may have a significant effect on the mental health of people with a mental illness such as psychosis)
Perspective*	Service users, their family or carers, providers and commissioners **Excluded:** • children (aged under 14 years old) • people with a severe mental illness but no evidence of substance misuse • people who misuse substances who have not been diagnosed with a severe mental illness • people with a severe mental illness who smoke or use tobacco but do not misuse any other substances • people who have a severe mental illness and misuse substances, but who are not living in the community

Phenomenon of interest*	• Factors or attributes (at the individual-, practitioner-, commissioner- or service- level) that can enhance or inhibit access to services
	• Factors or attributes (at the individual-, practitioner-, commissioner- or service- level) that can enhance or inhibit delivery of services
	• Factors or attributes (at the individual-, practitioner-, commissioner- or service- level) that can enhance or inhibit uptake of and engagement with intervention and services
	• Actions by services that could improve or diminish the experience of care for example:-
	  ▪ Form, frequency, and content of interactions with service users, families or carers
	  ▪ Sharing information with and receiving information from service users, families or carers
	  ▪ Planning of care with service users, families or carers
	• Experience of specific recognition or assessment tools, or specific interventions, from the perspective of practitioners, commissioners, service users, family or carers
	
	Excluded:
	• The provision of financial support (for example direct payments) is outside the scope of this guideline and will not be included.

Comparison*	None
Types of study to be included initially*	Primary qualitative research, surveys, case studies, autobiographical accounts Systematic reviews will be used as a source for identifying any studies that may not have been picked up in the searches. **Excluded:**

	Commentaries, editorials, vignettes, books, policy and guidance, and non-empirical research
Setting	Community settings (including a range of services provided by the NHS, social care and schools, as well as the community and voluntary sectors) Studies from any OECD member country will be included. However, applicability to the UK service setting will be considered during data analysis and synthesis. Excluded: • non-OECD studies • prisons and other custodial settings • young offenders units • forensic secure mental health settings
Evaluation	Experience and views of services. This includes experience/views of: • assessment received/delivered/commissioned • care received/delivered/commissioned • access to care • engagement with care • care planning and coordination • content and configuration of services • satisfaction with services • resource needs • awareness, knowledge and use of wider services • a service delivery model change/intervention **Excluded:** • Experiences of coexisting severe mental illness and substance misuse with no explicit implications for management, planning and/or delivery of care
Data extraction (selection and coding)*	Citations from each search will be downloaded into EndNote and duplicates removed. Titles and abstracts of identified studies will be screened by two reviewers for inclusion against criteria, until a good inter-rater reliability has been observed (percentage agreement =>90% or Kappa statistics, K>0.60). Initially 10% of references will be double-screened. If inter-rater agreement is good then the remaining references will be screened by one reviewer. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Two researchers will extract data into the study database. Discrepancies or difficulties with coding will be resolved through discussion between reviewers or the opinion of a third reviewer will be sought.

	Data to be extracted: Study characteristics: RQ addressed, geographical region, N, inclusion/exclusion criteria, severe mental illness (for carer/family/practitioner/commissioner this will be based on service user demographics where applicable), substance misuse (for carer/family/practitioner/commissioner this will be based on service user demographics where applicable), demographics of service user and family/carer/practitioner/commissioner (age, sex, ethnicity, SES, other characteristics), service/setting details, data collection method, data analysis method Data extraction (for thematic meta-synthesis): RQ addressed, population (commissioner, practitioner, service user, family member, carer), point on care pathway, overarching theme from the NICE Service User Experience in Adult Mental Health (NICE, 2011; NCCMH, 2012) matrix (see Appendix), intervention/service, type of experience, emotional valence of experience (positive/negative/mixed/neutral), themes, sub-themes, author quotes to support themes, participant quotes to support themes
Risk of bias (quality) assessment*	The Critical Appraisal Skills Programme CASP (2013) checklist (available from http://www.casp-uk.net/) will be completed for each study
Strategy for data synthesis*	Qualitative data synthesis will be guided by a "best fit" framework synthesis approach (Carroll et al., 2011). The distinguishing characteristic of this type of approach, and the aspect in which it differs from other methods of qualitative synthesis such as meta-ethnography (Campbell et al., 2003) is that it is primarily deductive involving a priori theme identification and framework construction against which data from included studies can be mapped. This review will use the thematic framework identified and developed by the Service User Experience in Adult Mental Health guidance (NICE, 2011; NCCMH, 2012) as a starting point to systematically index and organise all relevant themes and sub-themes within an Excel-based matrix. A secondary thematic analysis will then be used to inductively identify additional themes in cyclical stages (Carroll et al., 2011).
Analysis of subgroups or subsets	N/A
Further information	
Existing reviews utilised in this review:*	
• Updated	
• Not updated	

Service delivery models

	Details
PROSPERO: Reg. No.	CRD#########
Guideline details	
Guideline*	Dual diagnosis
Guideline chapter*	Evidence review 3
Objective of review*	To estimate the effectiveness and efficiency of service delivery models for health, social care and voluntary and community sector organisations at meeting the needs of people with a severe mental illness who also misuse substances
Review title and timescale	
Review title*	The effectiveness and efficiency of service delivery models for health, social care and voluntary and community sector organisations at meeting the needs of people with a severe mental illness who also misuse substances
Anticipated or actual start date	18th May 2015
Anticipated completion date	16th November 2015
Stage of review at time of registration	**Started** **Completed** Preliminary searches ☐ ☐ Piloting of the study selection process ☐ ☐ Formal screening of search results against eligibility criteria ☐ ☐ Data extraction ☐ ☐ Risk of bias (quality) assessment ☐ ☐ Data analysis ☐ ☐ Prospective meta-analysis ☐ ☐ Provide any other relevant information about the stage of the review here (e.g. Funded proposal, final protocol not yet finalised).
Review team details	
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Review team members and their organisational affiliations	Dr. Odette Megnin-Viggars NCCMH
Organisational affiliation of the review	National Collaborating Centre for Mental Health
Funding sources/ sponsors	National Institute for Health and Care Excellence
Conflicts of interest	⊙ None known ○ Yes
Review methods	
Review question(s)*	RQ 3: Which service models for health, social care and voluntary and community sector organisations are effective and efficient at meeting the needs of people with a severe mental illness who also misuse substances?
Sub-question(s)	Where possible, consideration will be given to the specific needs of:- • older people • people with a learning disability • teenage parents • people from black and minority ethnic groups • travellers • asylum seekers or refugees • women • lesbian, gay, bisexual, transsexual or transgender people • people who are homeless or in insecure accommodation • people from a low-income family or on a low income • people who are socially isolated • ex-offenders • sex workers • people who are, or have a history of being, 'looked after' or adopted • adults who have a history of experiencing, or witnessing or perpetrating violence or abuse • young people who have experienced abuse or witnessed domestic violence and abuse • young people who are excluded from school • young people whose parents have mental health or substance misuse problems
Searches*	Search approach: Systematic/exhaustive

Search concepts:
(((drug/alcohol misuse and (dual diagnosis or serious mental illness)) or (serious mental illness and (drug/alcohol misuse or dual diagnosis))) and service delivery models and setting)

Limits:
Publication limit 2000-current

Search filters:
RCT (developed by the McMaster University Hedges team)

Databases:
- ASSIA
- CEA Registry
- CINAHL
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Cochrane Database of Reviews of Effect (DARE)
- Cochrane Database of Systematic Reviews (CDSR)
- Econlit
- EconPapers
- Embase
- EPPI Centre databases - Bibliomap and DOPHer
- HMIC
- IBSS
- Medline and Medline in Process
- NHS Economic Evaluations Database (NHS EED)
- PsycINFO
- Social Care Online
- Social Policy & Practice
- Social Science Citation Index
- Social Service Abstracts
- Sociological Abstracts

Several iterations of the MEDLINE search strategy will be undertaken before agreement is reached on its final computation.

Steps will be deployed as part of a proportionate and graduated response to searches that produce unmanageable volumes of information (these follow).

1. Excluding animal studies, letters, editorials and other non-relevant publication types from results.
2. Searching Embase using only major Emtree headings
3. Increasing the precision of search strategies intended for one or a handful of databases.
4. Staggering resources using a tiered model in which databases are searched in probable ascending order of importance, only stopping when the set of results reach a point where more searching is no longer possible (due to insufficient resource) or advantageous (turning in lower than expected returns).

Key steps will include:
- Undertaking the searches a series of steps, starting with a high specificity construct and using the sifted results from each database to predict the outcome of more comprehensive strategies that take up more screening time.
- Coding references in EndNote from their point of origin and measuring the effectiveness of each database/search by its incremental input/output ratio - that is, dividing the number of records selected for potential full text review from a given database/search over the total number of references found in the same database/search. Databases with the best returns will be prioritised. References identified from searches conducted in key databases will also be used as a benchmark in determining the course of the strategy and subsequent judgements made.

EPPI-Reviewer priority screening
- Priority screening in EPPI-Reviewer as a multiple method strategy may also sit alongside the manual screen – a tool that will further inform decision making and help build a compelling case for the inclusion/exclusion/modification of a given database search.

Websites:
- Campbell Collaboration
- European Observatory on Healthcare Systems and Policies
- Institute for Clinical Systems Improvement
- McMaster University Health Evidence
- NICE (guidelines and Evidence Search)
- NIHR Health Services & Delivery Research Programme
- Public Health England (including National Treatment Agency for Substance Misuse)

	- Public Health Wales - Scottish Government - SIGN - Turning Research into Practice - US National Guidelines Clearninghouse - Welsh Government Trial registries: - ClinicalTrials.gov (US National Institutes of Health service) - International Standard Randomised Controlled Trial Number (ISRCTN) Register Other resources: - Searching reference lists - Citation tracking using Scopus and Web of Knowledge (WoK) - Searching for additional studies by authors of papers identified for inclusion and/or possible inclusion - Contacting authors of relevant works for 'sibling' studies - PROSPERO (http://www.crd.york.ac.uk/Prospero/) Priorities for above search methods will be selected in conjunction with NICE. Miscellaneous: - Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in full. Unpublished data will only be included where a full study report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study characteristics will be published in the full guideline. The searches will be recorded as required by the NICE Manual as set out in section 5.9
Condition or domain being studied*	'Dual diagnosis' is defined as a severe mental illness combined with misuse of substances. Severe mental illness includes a clinical diagnosis of: - schizophrenia, schizotypal and delusional disorders

	• bipolar affective disorder • severe depressive episode(s) with or without psychotic episodes Substance misuse refers to the use of legal or illicit drugs including alcohol and medicine, in a way that causes mental or physical damage (this may include low levels of substance use that would not usually be considered harmful or problematic, but may have a significant effect on the mental health of people with a mental illness such as psychosis)
Participants/ population*	Included: Young people (aged 14 to 25) and adults (over 25) who have been diagnosed as having a severe mental illness and who misuse substances (dual diagnosis) who live in the community. Excluded: • children (aged under 14 years old) • people with a severe mental illness but no evidence of substance misuse • people who misuse substances who have not been diagnosed with a severe mental illness • people with a severe mental illness who smoke or use tobacco but do not misuse any other substances • people who have a severe mental illness and misuse substances, but who are not living in the community

Intervention(s), exposure(s)*	Included:
	• Any service delivery model, including:
	   ○ Integrated models of care: mental health and substance misuse treatments are delivered by the same service, clinician or team of clinicians at the same time (for example, assertive community treatment [ACT], case management, integrated motivational interviewing and cognitive behavioural therapy, mainstreaming)
	   ○ Parallel models of care: separate treatment programmes are delivered in parallel by mental health and substance misuse services
	   ○ Serial models of care: separate treatment programmes are delivered sequentially by mental health and substance misuse services
	• Measures aimed at improving accessibility and availability of services, for example, services available 24 hours a day, 7 days a week
	• Measures aimed at promoting uptake of and engagement with services, for example, practical help (such as reminders to attend) and non-clinical activities (such as 'coffee mornings')
	
	Excluded: N/A

Comparator(s)/ control*	Included: • Treatment as usual • No treatment

	• Waitlist control • Placebo (including attention control) • Any alternative service delivery model Excluded: N/A
Types of study to be included initially*	Included: RCTs (including crossover randomised trials if data from the first phase is available) If there are no RCTs found in the evidence search, or the results from the RCTs are inconclusive, the range of included studies will be expanded to include non-randomised studies. Preference will be given to quasi-randomised controlled trials (for example, allocation by alternation or date of birth), controlled non-randomised studies and large cohort studies. If little evidence meets the above criteria, then before-and-after studies will be considered cautiously. Systematic reviews will be used as a source for identifying any studies that may not have been picked up in the searches.

Context*	Included: Community settings (including a range of services provided by the NHS or other healthcare systems, social care and schools, as well as the community and voluntary sectors).
	
	Studies from any OECD member country will be included. However, applicability to the UK service setting will be considered during data analysis and synthesis.
	
	Excluded:
	    • non-OECD studies
	    • prisons and other custodial settings
	    • young offenders units
	    • forensic secure mental health settings

Primary/Critical outcomes*	• Mental and physical health outcomes (including mortality, recovery and relapse, physical morbidity) • Accessibility of services (for instance, transfer/referral times, waiting times, physical accessibility of services) • Acceptability of services (for instance, service user, carer and family satisfaction with care) • Adaptive functioning outcomes (for instance, employment, housing, quality of life) • Service utilisation (for instance, number of missed appointments, changes in treatment adherence)
Secondary/Important, but not critical outcomes*	

Data extraction (selection and coding)*	Citations from each search will be downloaded into EndNote and duplicates removed. Titles and abstracts of identified studies will be screened by two reviewers for inclusion against criteria, until a good inter-rater reliability has been observed (percentage agreement =>90% or Kappa statistics, K>0.60). Initially 10% of references will be double-screened. If inter-rater agreement is good then the remaining references will be screened by one reviewer. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Two researchers will extract data into the study database, comparing a sample of each other's work (10%) for reliability. Discrepancies or difficulties with coding will be resolved through discussion between reviewers or the opinion of a third reviewer will be sought.
	Data to be extracted:
	Study characteristics: RQ addressed, study design, country, N, inclusion/exclusion criteria, severe mental illness, diagnostic criteria, substance misuse, method of substance misuse assessment, demographics (age, sex, ethnicity), risk of bias (selection bias, performance bias, detection bias, attrition bias, other bias)
	Comparisons: For both experimental and control conditions: Service delivery model or control condition, group size, intensity/dose, frequency, duration, setting
	Outcomes: Outcome name, outcome measure, rater, direction of scale, time point (for instance, weeks post-randomisation), phase, outcome data (for instance, mean, SD, N, events)
Risk of bias (quality) assessment*	The quality of individual studies will be assessed using the relevant checklist recommended in the NICE guidelines manual
Strategy for data synthesis*	If RCTs are included, meta-analysis using a random-effects model will be used to combine results from similar studies. If this is not possible, a narrative synthesis will be used.
	Repeated observations on participants: If studies report results for several periods of follow-up (e.g. 4 weeks, 12 weeks and 26 weeks post treatment) the longest follow-up from each study will be utilised in analyses. If the periods of follow-up are sufficiently distanced by time, we will consider defining several different outcomes, based on different periods of follow-up, and performing separate analyses (e.g. short-term, medium-term and long-term follow-up).
	Method of dealing with missing data:

	Because imputation of missing data in order to perform a full ITT analysis is controversial, only the results for available participants will be analysed in meta-analysis. However, for dichotomous outcomes a sensitivity analyses will be carried out whereby missing data will be imputed according to worst case scenario. Outcomes from the sensitivity analysis will only be presented if the ITT analysis differs significantly from the available case analysis. If possible a 'design-oriented' conceptual model will be produced which will build upon the 'problem-oriented' conceptual model developed for review 1 in order to map how changes to configuration of components impact on outcomes.
Analysis of subgroups or subsets (including sensitivity analyses)	In addition to subgroup analyses giving specific consideration to the groups outlined in the sub-question section, where possible subgroup analyses will be considered, including by: • geographical location (rural; urban) Where substantial heterogeneity exists, sensitivity analyses will be considered, including: • Excluding RCTs with <10 participants per arm
General information	
Type of review	Service delivery
Dissemination plans	This review is being conducted for the NICE guideline on Severe mental illness and substance misuse (dual diagnosis): community health and social care services. Further information about the guideline and plans for implementation can be found on the NICE website: http://guidance.nice.org.uk
Details of any existing review of the same topic by the same authors*	N/A
Review status	Ongoing
Further information (not needed for Prospero registration)	
Existing reviews utilised in this review:*	
• Updated	
• Not updated	

Appendix: Matrix of service user experience

Experience of the disorder		Key points on the pathway of care		Themes that apply to all points on the pathway
The relationship between individual service users and professionals	Involvement in decisions and respect for preferences			
	Clear, comprehensible information and support for self-care			
	Emotional support, empathy and respect			
The way that services and systems work	Fast access to reliable health advice			
	Effective treatment delivered by trusted professionals			
	Attention to physical and environmental needs			
	Involvement of, and support for, family and carers			
	Continuity of care and smooth transitions			