National Guideline Centre

Consultation version

Physical health of people in prison

Physical health of people in prison: assessment, diagnosis and management of physical health problems of people in prison

NICE guideline

Methods, evidence and recommendations

16 May 2016

Draft for consultation

Commissioned by the National Institute for Health and Care Excellence

Royal College of Physicians

The Royal College of Surgeons of England

Royal College of General Practitioners

Royal College of Nursing

NICE accredited

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Healthcare professionals are expected to take NICE guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and, where appropriate, their guardian or carer.

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- Saskia Cheyne
- Yasmina Hedhli
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- The Mental health of adults in contact with the criminal justice system technical team
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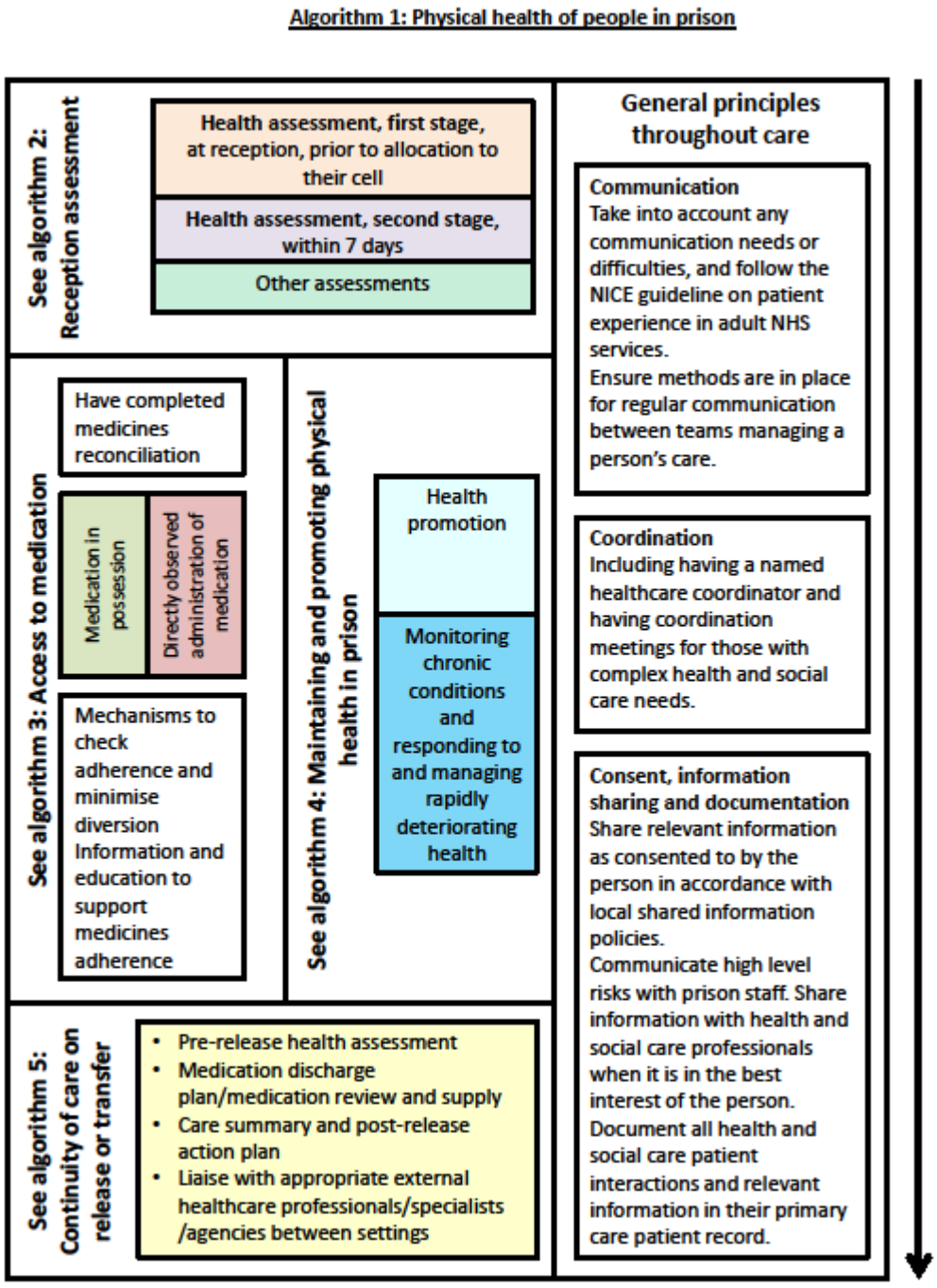
1 Guideline summary

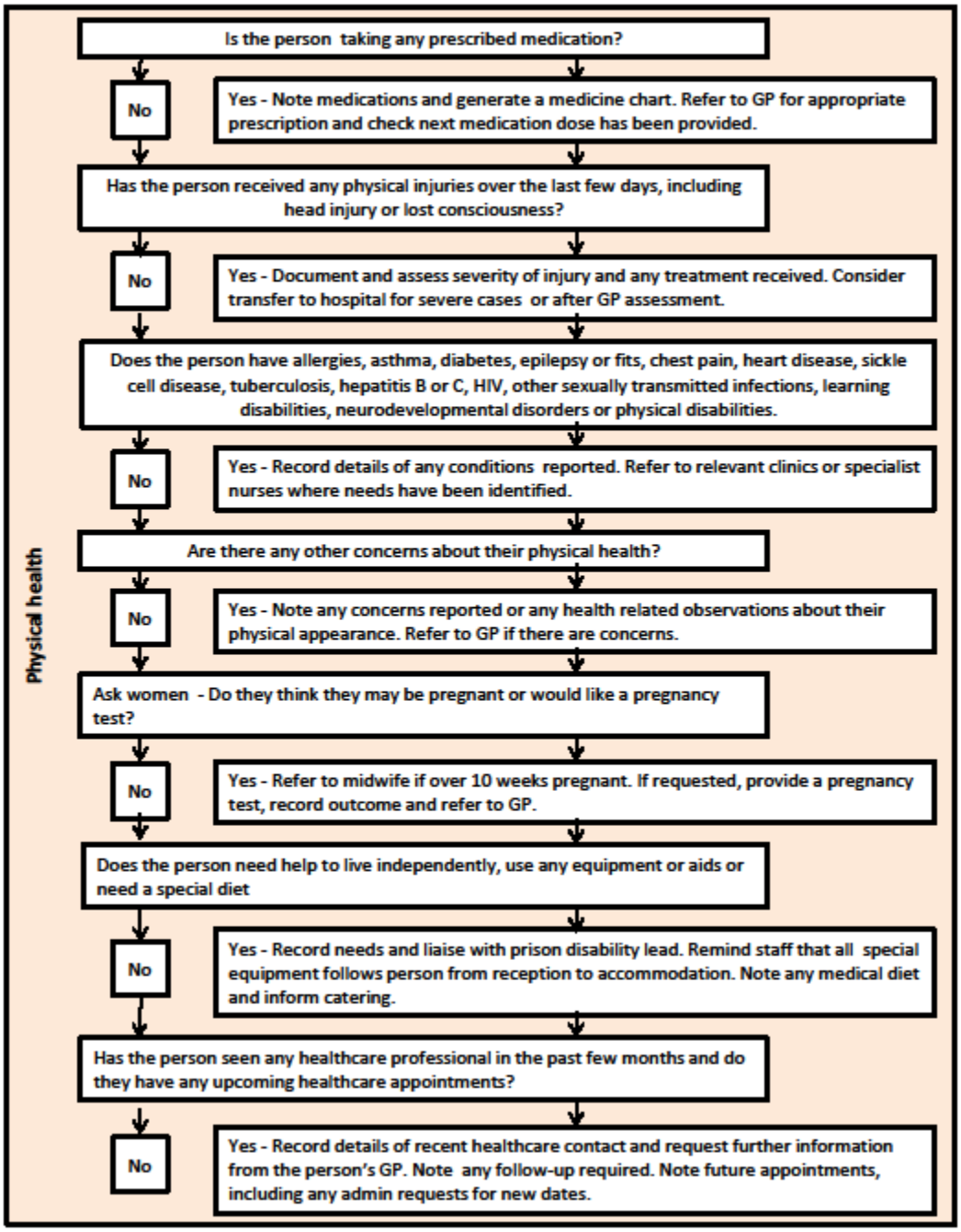
Please note: this guideline includes recommendations on mental health assessment at a person's reception into prison, but not on their ongoing mental health care. These are covered by the accompanying guideline Mental health of adults in contact with the criminal justice system. The mental health guideline is currently in development and will be available for stakeholder comment in September 2016. Further information about this guideline is available from the NICE website.

1.1 Algorithms



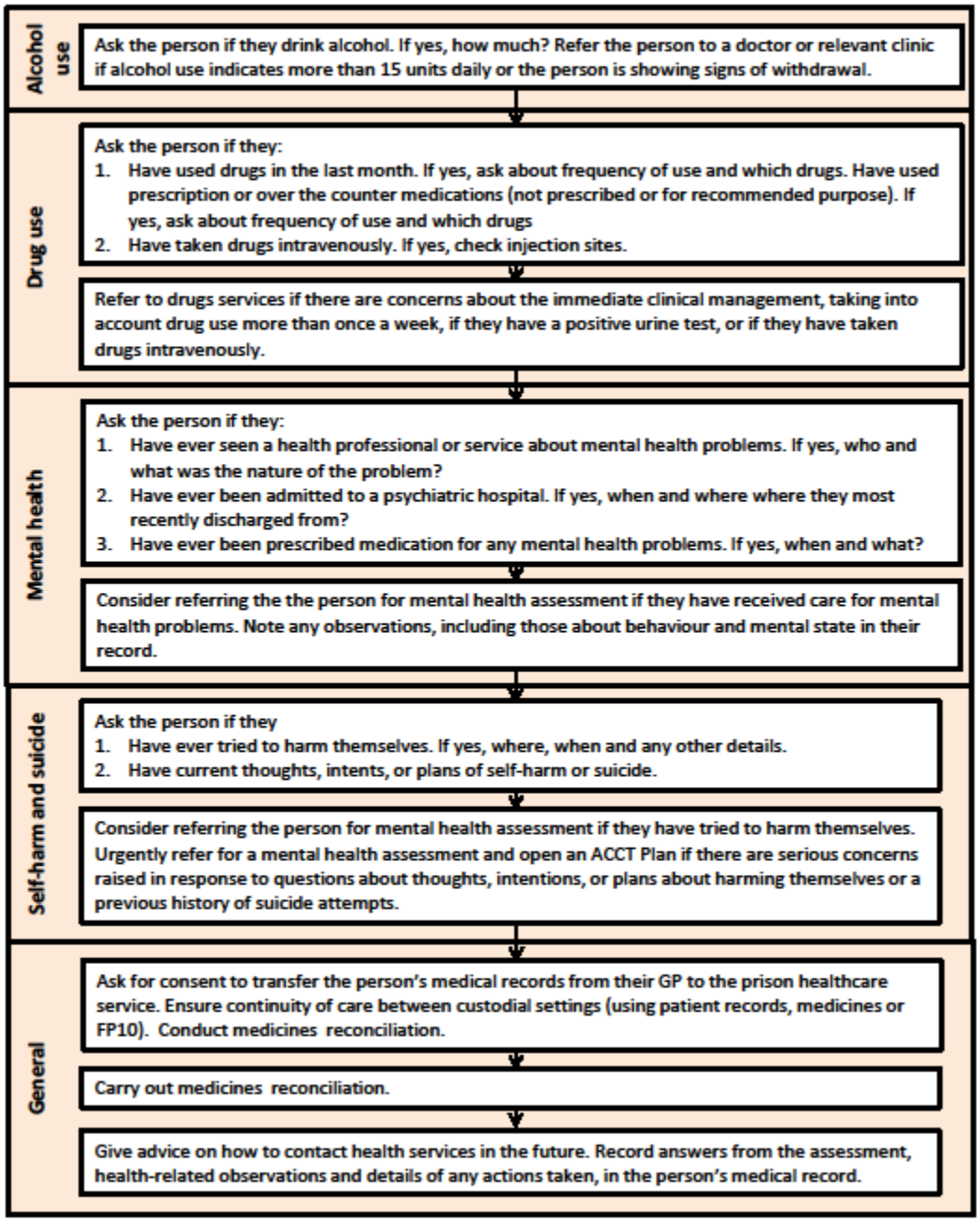
Algorithm 2: Reception assessment

Reception assessment part one, prior to allocation to their cell.



Algorithm 2: Reception assessment

Reception assessment part one, prior to allocation to their cell (continued).



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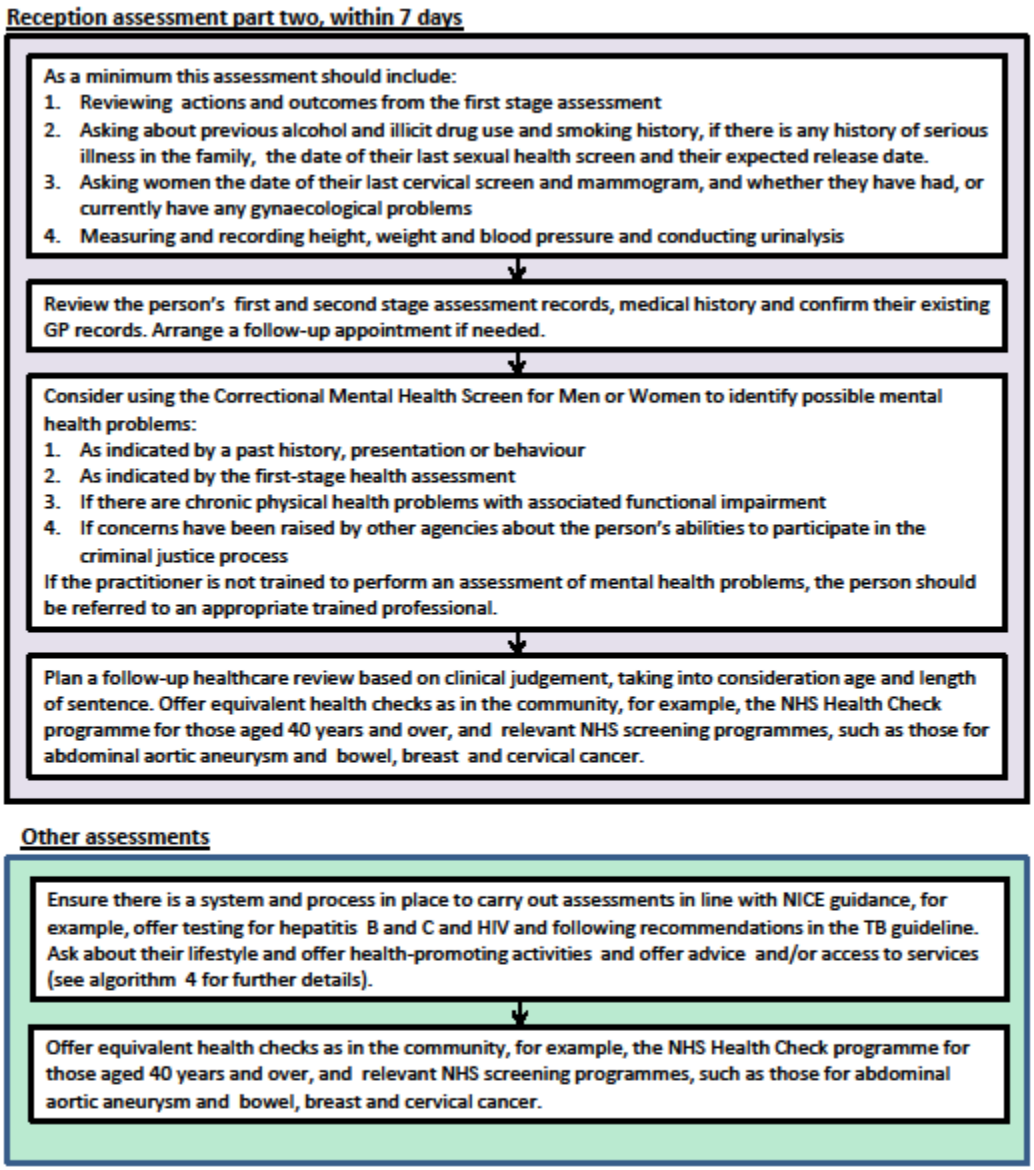
Algorithm 2 continued : Reception assessment



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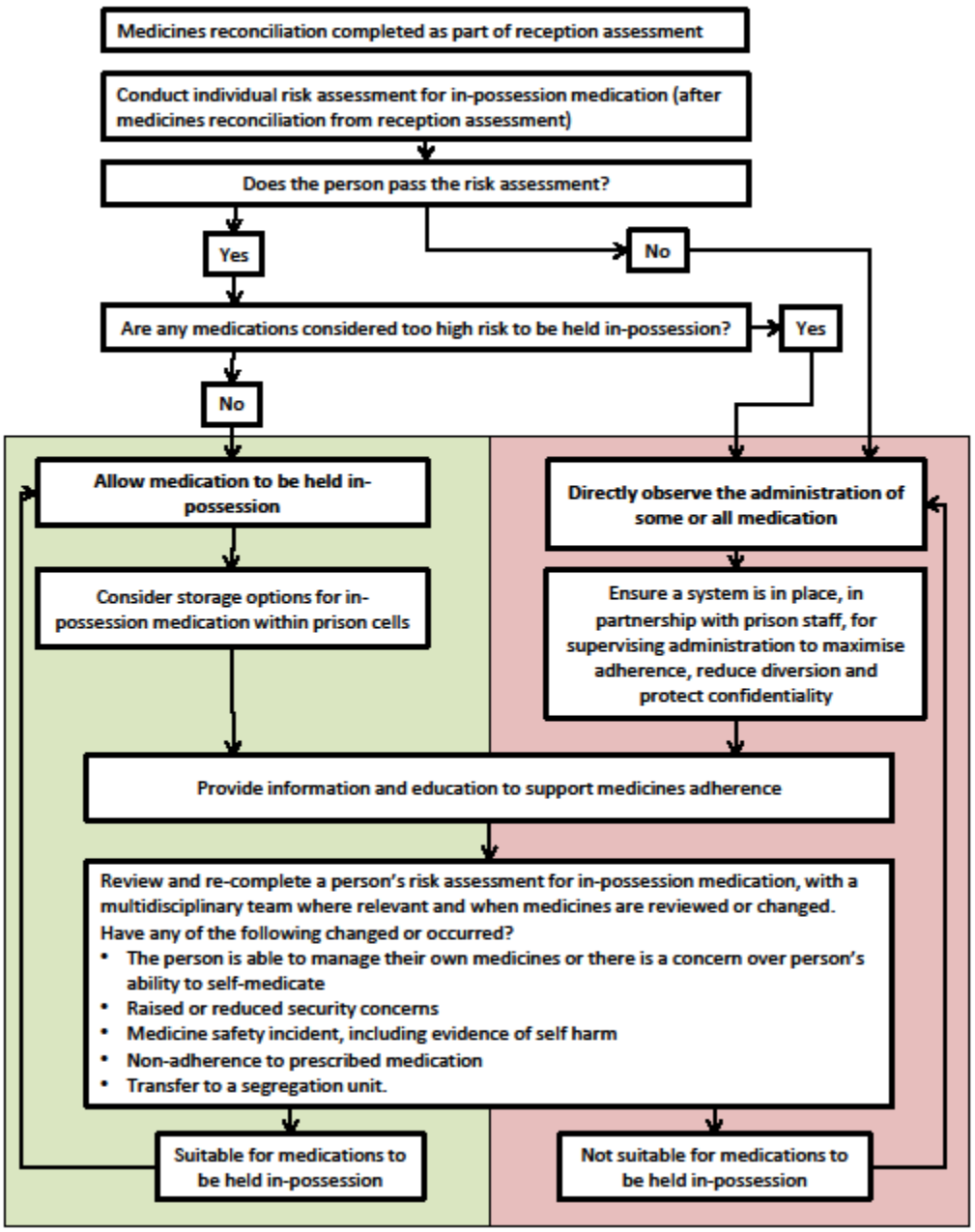
Algorithm 3: Access to medication



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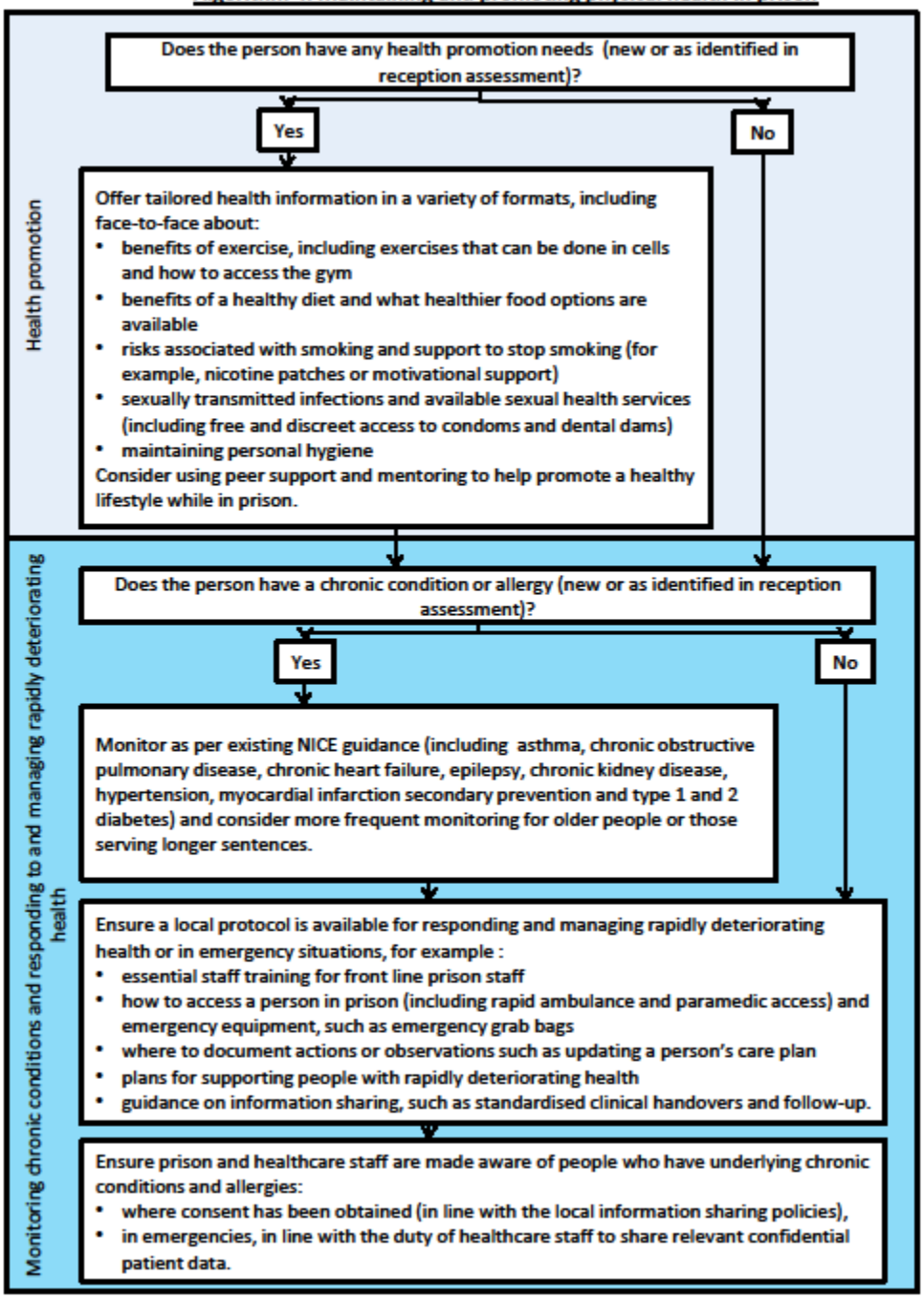
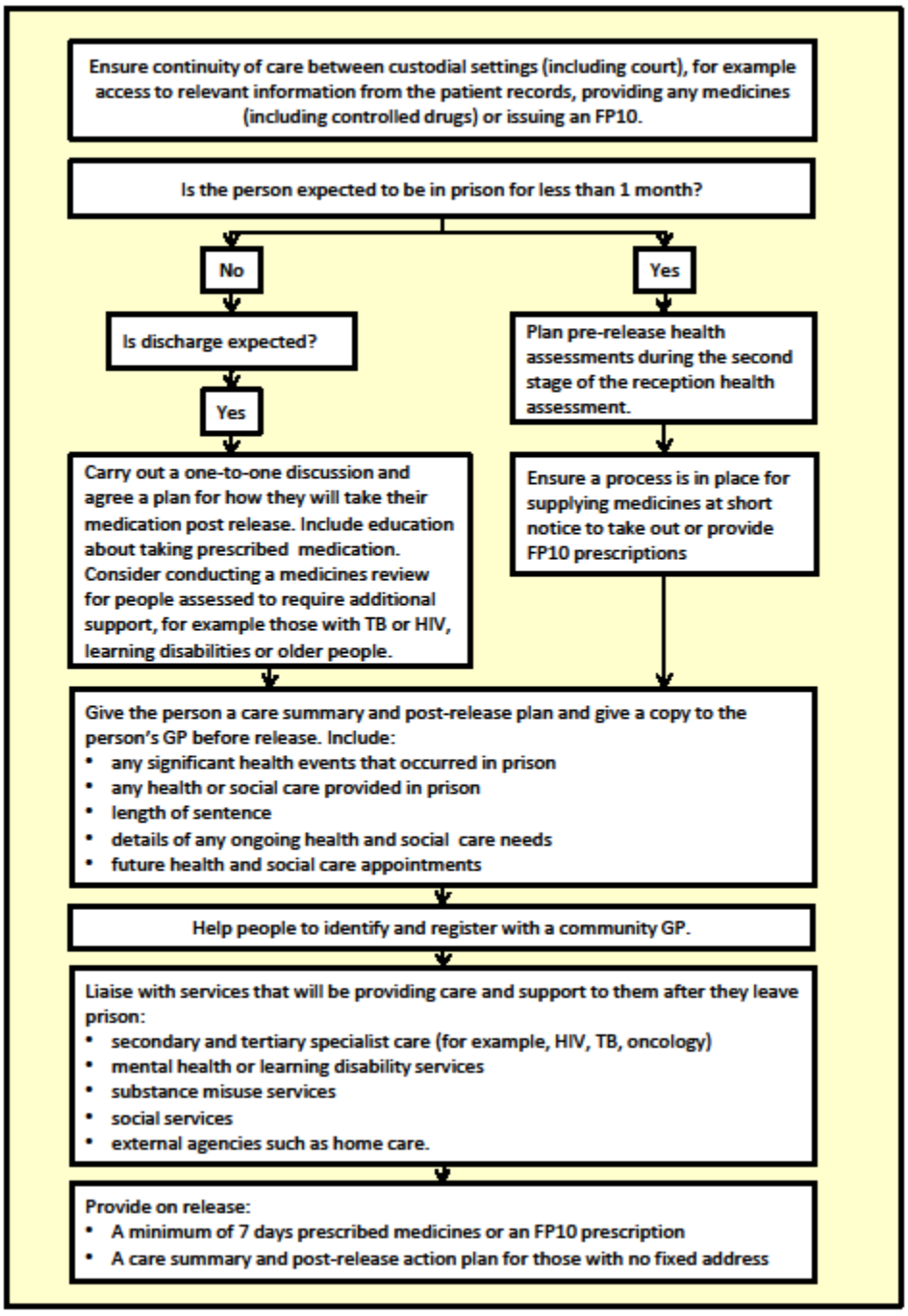
Algorithm 4: Maintaining and promoting physical health in prison



Algorithm 5: Continuity of care on release or transfer



1.2 Full list of recommendations

Assessing health

First stage health assessment at reception into prison

1. A healthcare professional (or trained healthcare assistant under the supervision of a registered nurse) should carry out a health assessment for every person on their first reception into prison. This should be done before the person is allocated to their cell. It should include identifying:
   - any issues that may affect the person's immediate health and safety before the second-stage health assessment
   - priority health needs to be addressed at the next clinical opportunity.
2. The first-stage health assessment should include the questions and actions in Table 44. It should cover:
   - physical health
   - alcohol use
   - drug use
   - mental health
   - self-harm and suicide.
3. Take into account any communication needs or difficulties the person has, and follow the principles in NICE's guideline on patient experience in adult NHS services.

   Please see Table 44 for the questions for the first-stage health assessment.

Following the first-stage health assessment

4. Give the person advice about how to contact prison health services and book GP appointments in the future.
5. Ask the person for consent to transfer their medical records from their GP to the prison healthcare service (see recommendations 64 - 65 for more information about transfer of medical records).
6. Enter in the person's medical record:
   - all answers to the reception health assessment questions
   - health-related observations, including those about behaviour and mental state (including eye contact, body language, rapid, slow or strange speech, poor hygiene, strange thoughts)
   - details of any action taken.
7. Carry out a medicines reconciliation (in line with NICE's guideline on medicines optimisation) before the second-stage health assessment. See also recommendations 46 and 53 for recommendations on risk assessments for in-possession medicines and ensuring continuity of medicine.

Second stage health assessment

8. A health professional (for example a registered general nurse) should carry out a second-stage health assessment for every person in prison. This should be done within 7 days of the first-stage health assessment. It should include as a minimum:

- reviewing the actions and outcomes from the first-stage health assessment
- asking the person about:
- measuring and recording the person's height, weight and blood pressure, and carryng out a urinalysis.

9. Review the person's first- and second-stage health assessment records, medical history and GP records and:
   - refer the person to the GP or a relevant clinic if further assessment is needed. See for example NICE's guidelines on cardiovascular disease (recommendations on identifying people for full formal risk assessment) or type 2 diabetes (the recommendation on risk assessment)
   - arrange a follow-up appointment if needed.
10. Offer people tailored health advice based on their responses to the assessment questions. This should be in a variety of formats (including face-to-face). It should include advice on:
    - alcohol (see NICE's guideline on alcohol use disorders)
    - substance misuse (see NICE's guideline on drug misuse).
    - exercise (see recommendations 38 and 39)
    - diet (see recommendation 40)
    - stopping smoking (see recommendation 43)
    - sexual health (see recommendations 41 and 42).
11. Ask the person if they want to attend any health-promoting activities, for example exercise or going to the gym, help with stopping smoking or other courses.
12. Offer the person advice on:
    - how to contact prison health services and book GP appointments
    - where to find health information that is accessible and understandable
    - how to attend any health-promoting activities in the future (see recommendations 38-45).
    - medicines adherence (see recommendation 52).
13. Enter in the person's medical record:
    - all answers to the second-stage health assessment questions
    - health-related observations
    - details of any action taken.
14. Plan a follow-up healthcare review at a suitable time based on clinical judgement, taking into account the age of the person and length of their sentence.

Mental health first-stage assessment

Please see Table 44 for the questions for the first-stage health assessment; these include: alcohol and drug use, mental health,self-harm and suicide.

Mental health second-stage assessment

15. Consider using the Correctional Mental Health Screen for Men (CMHS-M) or Women (CMHS-W) to identify possible mental health problems if:

- the person's history, presentation or behaviour suggests they may have a mental health problem
- the person's responses to the first-stage health assessment suggest they may have a mental health problem
- the person has a chronic physical health problem with associated functional impairment
- concerns have been raised by other agencies about the person's abilities to participate in the criminal justice process.

16. If a man scores 6 or more on the CMHS-M, or a woman scores 4 or more on the CMHS-W, or there is other evidence supporting the likelihood of mental health problems:

- a practitioner who is trained to perform an assessment of mental health problems should conduct further assessment, or

  a practitioner who is not trained to perform an assessment of mental health problems should refer the person to an appropriately trained professional for further assessment.

Other health assessments

Ensure that there is a system and processes in place to carry out other assessments in line with recommendations in NICE guidelines.

17.

18. Prison healthcare services (coordinated with, and supported by, the NHS lead for hepatitis) should ensure that:

- all prisoners are offered a hepatitis B vaccination when entering prison (for the vaccination schedule, refer to the Green Book)
- all prisoners are offered access to confidential testing for hepatitis B and C when entering prison and during their detention
- prisoners who test for hepatitis B or C receive the results of the test, regardless of their location when the test results become available
- results from hepatitis B and C testing are provided to the prisoner's community-based GP, if consent is given.

HIV testing: increasing uptake in men who have sex with men

19. Primary care providers should ensure annual HIV testing is part of the integrated healthcare offered to men who are known to have sex with men.

20. Provide information on HIV testing and discuss why it is recommended (including to those who indicate that they may wish to decline the test).

21. Conduct post-test discussions, including giving positive test results and delivering post-test and general health promotion interventions.

22. Recognise illnesses that may signify primary HIV infection and clinical indicator diseases that often coexist with HIV.

Identify individuals at high risk of STIs using their sexual history. Opportunities for risk assessment may arise during consultations on

contraception, pregnancy or abortion, and when carrying out a cervical smear test or offering an STI test.

23. Risk assessment could also be carried out during routine care or when a new patient registers.

24. Have one-to-one structured discussions with people at high risk of STIs (if trained in sexual health), or arrange for these discussions to take place with a trained practitioner.

tuberculosis

25. Healthcare professionals in prisons should ensure all prisoners are screened for TB within 48 hours of arrival.

26. Prisons with Department of Health-funded static digital X-ray facilities for TB screening should X-ray all prisoners (including people being transferred from other establishments) if they have not had a chest X-ray in the past 6 months. This should take place within 48 hours of arrival.

27. Prison staff should report all suspected and confirmed TB cases to the local multidisciplinary TB team within 1 working day.

28. Multidisciplinary TB staff should visit every confirmed TB case in a prison in their locality within 5 working days.

29. If a case of active TB is identified, the local Public Health England unit, in conjunction with the multidisciplinary TB team, should plan a contact investigations exercise. They should also consider using mobile X-ray to check for further cases.

30. Prison health services should have contingency, liaison and handover arrangements to ensure continuity of care before any prisoner on TB treatment is transferred between prisons or released. In addition, other agencies working with prisoners should also be involved in this planning.

Heath checks and screening programmes

31. Offer people equivalent health checks to those offered in the community, for example:

- the NHS health check programme for people aged 40 and over
- relevant NHS screening programmes, such as those for abdominal aortic aneurysm and bowel, breast and cervical cancer.

Communication and coordination

32. Ensure that every person in prison has a named healthcare coordinator who is responsible for managing their care. Ensure that the person and all healthcare and prison staff know who this is.

33. Ensure that the different teams that manage a person's care in prison communicate with one another to coordinate care.

34. Share relevant information about people with complex needs with prison staff using prison record systems in line with legislation and national guidance. This should include information about any high-level risks, such as:

- risk of self-harm
- risk to others
- communicable diseases
- epilepsy

- diabetes
- allergies
- deteriorating health conditions
- learning disabilities.

35. Review people in prison with complex health and social care needs. Ensure that if a person is supported by a multidisciplinary team the team meets regularly to plan and coordinate ongoing management. These meetings should be facilitated by primary care.

36. Document all health and social care patient interactions and any information related to health and social care in the person's primary care patient record.

37. Share information with other health and social care staff who are involved in the person's care in prison if it is in the person's best interests.

Promoting health and wellbeing

Exercise

38. Encourage people to be physically active. Offer them information about:

- the benefits of exercise
- what exercise facilities are provided, where they are and how they can use them, for example:

39. Offer people information and advice in line with recommendations in the NICE guidelines on:

- physical activity: brief advice for adults in primary care
- physical activity: exercise referral schemes
- preventing excess weight gain
- obesity: identification, assessment and management (see the section on physical activity).

Diet

40. Offer people information about:

- the benefits of a healthy diet
- healthier food options available in the prison.

See the section on diet in NICE's guideline on obesity: identification, assessment and management

Sexual health

41. Offer people in prison information about sexually transmitted infections and available sexual health services.

42. Ensure that people in prison have discreet access to condoms, dental dams and water-based lubricants without the need to ask for them.

Stopping smoking

43. Offer people in prison information about:

- the risks of smoking
- support available to stop (for example nicotine patches or motivational support)

See the NICE pathway on smoking.

General health advice

44. Consider using peer support and mentoring to help promote a healthy lifestyle while in prison.

45. Offer people in prison tailored health information in a variety of formats, including face-to-face. Include advice about:

- exercise
- diet
- stopping smoking
- sexual health
- personal hygiene.

Managing medicines

Access to medicines

46. Carry out an individual risk assessment to determine if the person can hold their medicines in-possession. Allow people in prison to hold all medicine in-possession unless the person does not pass the risk assessment.

47. Directly observe the administration of all schedule 2 and 3 medicines (see NICE's guideline on controlled drugs) and medicines for tuberculosis (see NICE's guideline on tuberculosis).

48. Directly observe the administration of any medicine that is not in-possession.

49. Work with prison staff to ensure a system is in place to:

- supervise the administering of medicines not held in-possession to maximise adherence
- reduce diversion (passing medicines on to other people)
- protect confidentiality.

See the section on supporting adherence in NICE's guideline on medicines adherence.

50. Review and (if necessary) repeat a person's risk assessment for in-possession medicine if the person's circumstances change. Involve a multidisciplinary team if needed, including prison staff. Examples of when the risk assessment should be repeated include:

- when carrying out a medicines review
- if a person is considered able to manage their own medicines after a period of having medicines not in-possession
- if there is a medicine safety incident, including evidence of self-harm
- if someone has raised security concerns (for example, about bullying, diversion or hoarding)
- if the person has not been taking their prescribed medicines
- if there is concern about the person's ability to self-medicate
- following the Assessment Care in Custody and Teamwork care planning approach

- if the person is transferred to a segregation unit.

51. Consider providing storage for in-possession medicine in prison cells, for example, a lockable cupboard.

52. Give people in prison information and education about medicines adherence (see the section on patient involvement in decisions about medicines in NICE's guideline on medicines adherence).

Continuity of medicine

53. Ensure the person can keep taking their medicines after coming into prison. Use the examples of critical medicines in Table 107 in conjunction with clinical judgement and any safety alerts.

54. Hold a one-to-one discussion with the person to agree a plan for how they will take their medicine after their release from prison. This should include education about taking prescribed medicines.

55. Consider carrying out a medicines review for people who are assessed as needing extra support to manage their medicines on release or transfer from prison. For example:

- people with tuberculosis, HIV, diabetes, substance misuse or mental health problems
- people with neurodevelopmental disorders or learning disabilities
- people receiving end of life care
- older people
- people serving long-term sentences.

56. When a person is discharged or transferred from prison give them a minimum of 7 days' prescribed medicines or an FP10 prescription.

57. Set up a process to ensure that people being discharged or transferred at short notice from prison are given a supply of their medicines or are given an FP10 prescription.

58. For recommendations on care for people moving from one care setting to another see the section on medicines-related communication systems in NICE's guideline on medicines optimisation.

Monitoring chronic conditions

59. Monitor people with chronic conditions in accordance with the following NICE guidelines (see appendix Q in the supporting evidence for this guideline for specific recommendations):

- chronic heart failure
- chronic kidney disease
- chronic obstructive pulmonary disease
- epilepsies
- hypertension
- myocardial infarction
- type 1 diabetes and type 2 diabetes

See also the NICE quality standard on asthma.

60. Monitor people with chronic conditions that need specialist management in line with relevant NICE guidelines (for example on hepatitis B).

61. Consider more frequent monitoring for older people and people with chronic conditions (such as diabetes) who are serving longer prison sentences.

Managing deteriorating health and health emergencies

62. Ensure a local protocol is available for responding to and managing situations in which a person's health quickly deteriorates, or in a health emergency. This could include, for example:

- essential training for front-line prison staff, including the first person likely to be on the scene in an emergency
- processes to enable healthcare staff to reach a person in prison quickly, such as how to gain access to their cell
- processes to ensure a person can be quickly seen by a healthcare professional if their health deteriorates quickly
- availability of emergency equipment, such as emergency 'grab bags'
- recording the actions and observations taken by prison and healthcare staff when assessing people with rapidly deteriorating health or in an emergency situation, such as:
- a clear care plan for supporting people with rapidly deteriorating health
- guidance on sharing information between prison staff and healthcare staff, such as details on standardised clinical handovers and follow-up.

63. Ensure prison and healthcare staff are made aware of people who have underlying chronic conditions and allergies:

- if the person agrees (in line with the local information-sharing policies)
- in emergencies, in line with the duty of healthcare staff to share relevant confidential patient data.

Continuity of healthcare

On entry into prison

64. Arrange for the person's medical records to be transferred from primary and secondary care to the prison healthcare team on the person's entry to prison (see recommendation 5).

65. Primary and secondary care services should provide information from the person's medical records to the prison healthcare team that is:

- relevant
- in the person's best interests.

Transit between custodial settings

66. Ensure continuity of care between custodial settings including court, the receiving prison or during escort periods by, for example:

- providing access to relevant information from the patient record
- providing any medicines (including controlled drugs) – see also recommendations 53-58 on continuity of medicines
- issuing an FP10 prescription.

Before release from prison

67. Carry out a pre-release health assessment. This should be led by primary healthcare and involve multidisciplinary team members and the person. It should take place at least 1 month before the date the person is expected to be released.

68. For people who may be in prison for less than 1 month, plan pre-release health assessments during the second-stage health assessment (see recommendation 30 for details of this assessment).

69. Include the following in the person's care summary and post-release action plan:

- any significant health events that affected the person while they were in prison, for example:
- any health or social care provided in prison
- details of any ongoing health and social care needs, including:
- future health and social care appointments, including appointments with:

70. Give the person a copy of the care summary and post-release plan and also send a copy to the person's GP (if they are registered with one).

71. Help people who are being released from prison to find and register with a community GP if they are not already registered with one.

72. Before the person is released, liaise with services that will be providing care and support to them after they leave prison. This should include (as needed):

- secondary and tertiary specialist services (for example HIV, TB, oncology)
- mental health or learning disability services
- substance misuse services
- social services
- external agencies such as home care.

1.3 Key research recommendations

1. What is the prevalence of disease in the UK prison population?
2. When should subsequent health assessments be carried out in prison for people serving long-term sentences?
3. What are the most effective tools to determine the health promotion needs of people in prison?
4. What is most effective method for delivering health promotion activities and who should lead them (peers or professionals)?
5. Does the use of directly observed supply of named high-risk medicines (that is, not supplying medicines to prisoners to hold 'in possession') reduce diversion, abuse and non-adherence?

2 Introduction

In April 2013 NHS England became responsible for commissioning all health services for people in prison in England. Healthcare in prison has a very important role in identifying significant health needs, maintaining health and detecting chronic conditions. This guideline supports equivalence of healthcare in prisons, a principle whereby health services for people in prisons are provided to the same standard, quality and to the same specification as for patients in the wider NHS. Providing equivalence of care will aim to address health need, reduce health inequalities, prevent deterioration, reduce deaths due to natural causes and subsequently assist rehabilitation and reduce re offending. This approach takes into account the differences in client groups to support improved take up of services and contribute to health improvement of people in prison.

- For women, these include women-specific services and national screening programmes being available. For those women who are pregnant, maternity and social care services are provided in line with the wider community.
- For young people aged 18-21 in young offender institutions, services are geared to take into account age appropriateness and the opportunity to have access to catch-up services (for example, vaccinations) that they may have missed in mainstream services during childhood.
- For males, this includes a range of services to support healthier lives and better understanding of health issues as well as access to adult male screening programmes available to the wider population.

The prison population comprises of highly vulnerable groups; those with a learning disability who find it difficult to understand the prison regime and what is happening to them; older prisoners and those serving longer sentences whose physical health often deteriorates or is exacerbated by previous lifestyle choices during imprisonment; those who have or acquire a physical disability; and prisoners who have short sentences and chaotic lifestyles, making it difficult for prison healthcare to achieve any sustainable change in their health.

Since 2006 there have been considerable changes in prison health services. However, there continue to be barriers to service delivery within custodial settings, which make providing healthcare equivalent to that provided in the community a significant challenge. There are many recognised areas of pressure that both the prison system and healthcare need to address to manage the overall safety of prisoners, which are considered by this guideline such as:

- Ensuring that both the initial reception assessment and subsequent general health assessment are completed to provide a full health history. This includes liaison and communication with external health organisations for the benefit of individuals' care, whilst in prison or hospital, between establishments and on release;
- Providing continuity of healthcare for those moving around the prison estate, including continuity of medication, multidisciplinary working between prison health, and visiting health services and prison staff;
- Ensuring effective communication between teams, in particular when dealing with complex needs and sharing information to support individual's care in the wider prison;
- Managing emergency situations, including high levels of complex needs within the prison population, the staff skills required to work with this client group and the large numbers of people in prison moving across the prison estate.
- Providing responsive and flexible methods to support prisoners on transit between custodial settings or on release to the community.

Whilst committed to equivalence, it is noted that prison health care is delivered in a complex environment that includes primary care, preventative care, emergency care, secondary care and tertiary care. It should be highlighted that the prison environment cannot be compared to a primary care facility in the community, as it provides more enhanced services. The prison population is

generally more complex and potentially more vulnerable than the population that a local GP practice would experience; therefore, staff skills, qualifications and experience and the range of services provided need to reflect these differences to ensure that improvements are achieved within the prison population. In addition, health service provision across the prison estate differs due to the purpose and function of each prison, such as prisons with high security and those taking new prisoners from the courts, training prisons where the population is more stable, and open prisons where people are preparing to move back into the community. The provision of health services and staffing will range from 24 hours 7 days a week to 9am-5pm services.

Being in prison provides a unique setting to offer services and support that is unlikely to be available or taken up in the community due to the nature and vulnerabilities of individuals remanded and sentenced to prison; often these individuals have a history of poor access or poor uptake of existing community health services, often using emergency services and adding pressure to already overburdened services. This makes prison a good setting to provide services that will benefit the NHS and communities in the long term, improving health, aiding rehabilitation and reducing system costs for a vulnerable and high-need population.

This guidance should be read in tandem with the Mental health of adults in contact with the criminal justice system guideline, taking a holistic approach as the two pathways are interwoven. Prisoners as patients can often have a mix of physical and mental health issues as they progress along the pathway; therefore, health professionals working in prisons must be multi-skilled in dealing with the assessment, diagnosis and management of physical health, mental health and addiction problems, as well as underlying complex social and behavioural issues.

3 Development of the guideline

3.1 What is a NICE guideline?

NICE guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances within the NHS – from prevention and self-care through primary and secondary care to more specialised services. These may also include elements of social care or public health measures. We base our guidelines on the best available research evidence, with the aim of improving the quality of healthcare. We use predetermined and systematic methods to identify and evaluate the evidence relating to specific review questions.

NICE guidelines can:

- provide recommendations for the treatment and care of people by health professionals
- be used to develop standards to assess the clinical practice of individual health professionals
- be used in the education and training of health professionals
- help patients to make informed decisions
- improve communication between patient and health professional.

While guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills.

We produce our guidelines using the following steps:

- A guideline topic is referred to NICE from NHS England.
- Stakeholders register an interest in the guideline and are consulted throughout the development process.
- The scope is prepared by the National Clinical Guideline Centre (NCGC).
- The NCGC establishes a Guideline Development Group.
- A draft guideline is produced after the group assesses the available evidence and makes recommendations.
- There is a consultation on the draft guideline.
- The final guideline is produced.

The NCGC and NICE produce a number of versions of this guideline:

- The 'full guideline' contains all the recommendations, plus details of the methods used and the underpinning evidence.
- The 'NICE guideline' lists the recommendations.
- 'Information for the public' is written using suitable language for people without specialist medical knowledge.
- NICE Pathways brings together all connected NICE guidance.

This version is the full version. The other versions can be downloaded from NICE at www.nice.org.uk.

3.2 Remit

NICE received the remit for this guideline from NHS England. NICE commissioned the NCGC to produce the guideline.

The remit for this guideline is:

to develop a clinical guideline on the Assessment, diagnosis and management of physical health problems of people in prison.

3.3 Who developed this guideline?

A multidisciplinary Guideline Development Group (GDG) comprising health professionals and researchers as well as lay members developed this guideline (see the list of Guideline Development Group members and the acknowledgements).

The National Institute for Health and Care Excellence (NICE) funds the National Clinical Guideline Centre (NCGC) and thus supported the development of this guideline. The GDG was convened by the NCGC and chaired by Richard Bradshaw in accordance with guidance from NICE.

The group met approximately every 4 weeks during the development of the guideline. At the start of the guideline development process all GDG members declared interests including consultancies, fee-paid work, shareholdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared arising conflicts of interest.

Members were either required to withdraw completely or for part of the discussion if their declared interest made it appropriate. The details of declared interests and the actions taken are shown in Appendix B.

Staff from the NCGC provided methodological support and guidance for the development process. The team working on the guideline included a project manager, systematic reviewers (research fellows), health economists and information scientists. They undertook systematic searches of the literature, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate and drafted the guideline in collaboration with the GDG.

3.3.1 What this guideline covers

This guideline covers health assessment, coordination and communication between health care staff, health promotion, use of medication, urgent and emergency management including management of deteriorating conditions and continuity of healthcare. For further details please refer to the scope in Appendix A and the review questions in Section 4.1.

3.3.2 What this guideline does not cover

The guideline does not provide recommendations for children or young people under the age of 18, babies of mothers in prison, people in Immigration Removal Centres or police custody. The guideline does not cover the management of mental health of prisoners, NHS care outside the prison service, end of life care, dental management or the cultural and spiritual needs of prisoners or their families and carers.

3.3.3 Relationships between the guideline and other NICE guidance

Related NICE guidelines:

- Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence. NICE guideline CG115 (2011)
- Anaemia management in people with chronic kidney disease (update). NICE guideline NG8 (2015).
- Antenatal care. NICE guideline CG62 (2008)
- Antenatal and postnatal mental health. NICE guideline CG45 (2007)
- Behaviour change: individual approaches. NICE guideline PH49 (2014)
- Behaviour change: the principles for effective interventions. NICE guidance PH6 (2007)

- Brief interventions and referral for smoking cessation. NICE guidance PH1 (2006)
- Cardiovascular disease: risk assessment and reduction, including lipid modification. NICE guideline CG181 (2014)
- Chest pain of recent onset. NICE guideline CG95 (2010)
- Chronic obstructive pulmonary disease: Management of chronic obstructive pulmonary disease in adults in primary and secondary care (partial update). NICE guideline CG101 (2010)
- Chronic heart failure: Management of chronic heart failure in adults in primary and secondary care. NICE guideline CG108 (2010).
- Chronic kidney disease: early identification and management of chronic kidney disease in adults in primary and secondary care. NICE guideline CG182 (2014).
- Diabetes in pregnancy. NICE guideline CG63 (2008)
- Drug misuse in over 16s: psychosocial interventions. NICE guideline CG51 (2011)
- Drug misuse – opioid detoxification. NICE guideline CG52 (2007)
- Epilepsies: diagnosis and management. NICE guideline CG137 (2012)
- Falls in older people: assessing risk and prevention. NICE guideline CG161 (2013)
- Hepatitis B (chronic): Diagnosis and management of chronic hepatitis B in children, young people and adults. NICE guideline CG165 (2013).
- Hepatitis B and C testing: people at risk of infection. NICE guideline PH43 (2015).
- HIV testing: increasing uptake in men who have sex with men. NICE guideline PH34 (2011).
- Hypertension: Clinical management of primary hypertension in adults. NICE guideline CG127 (2011).
- Hypertension in pregnancy NICE guideline CG107 (2010)
- Identifying and managing tuberculosis among hard-to-reach groups. NICE guidance PH37 (2012)
- Increasing the uptake of HIV testing among black Africans in England NICE guideline PH33 (2011)
- Interventions to reduce substance misuse among vulnerable young people. NICE guidance PH4 (2007)
- Intrapartum care. NICE guideline CG55 (2007)
- Management of stable angina. NICE guideline CG126 (2011)
- Maternal and child nutrition NICE guidance PH11 (2008)
- Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence. NICE guideline CG76 (2009)
- Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes. NICE guideline NG5 (2015)
- Myocardial infarction: cardiac rehabilitation and prevention of further MI. NICE guideline CG172 (2013).
- Obesity: identification, assessment and management. NICE guideline CG189 (2014)
- Patient experience in adult NHS services. NICE guideline CG138 (2012)
- Physical activity: brief advice for adults in primary care. NICE guideline PH44 (2013)
- Physical activity: exercise referral schemes. NICE guideline PH54 (2014)
- Postnatal care. NICE guideline CG37 (2006)
- Pregnancy and complex social factors NICE guideline CG110 (2010)
- Preventing excess weight gain. NICE guideline NG7 (2015)
- Preventing the uptake of smoking by children and young people. NICE guidance PH14 (2008)

- Preventing type 2 diabetes: population and community-level interventions. NICE guideline PH35 (2011)
- Quitting smoking in pregnancy and following childbirth. NICE guidance PH26 (2010)
- Rheumatoid arthritis in adults: management. NICE guideline CG79 (2009)
- Sexually transmitted infections and under-18 conceptions: prevention. NICE guideline PH3 (2007).
- Stroke and transient ischaemic attack. NICE guideline CG68 (2008)
- The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care. NICE guideline CG137 (2012)
- The safe use and management of controlled drugs. NICE guideline NG26. (2016)
- Tobacco: harm-reduction approaches to smoking. NICE guideline PH45 (2013)
- Tuberculosis. NICE guideline NG33 (2016)
- Type 1 diabetes: diagnosis and management. NICE guideline NG17 (2015)
- Type 2 diabetes in adults: management. NICE guideline NG28 (2015)
- Type 2 diabetes: prevention in people at high risk. NICE guideline PH38 (2012)
- Unstable angina and non-ST-segment-elevation myocardial infarction. NICE guideline CG94 (2010)
- Weight management before, during and after pregnancy. NICE guidance PH27 (2010)
-

Related NICE guidance currently in development:

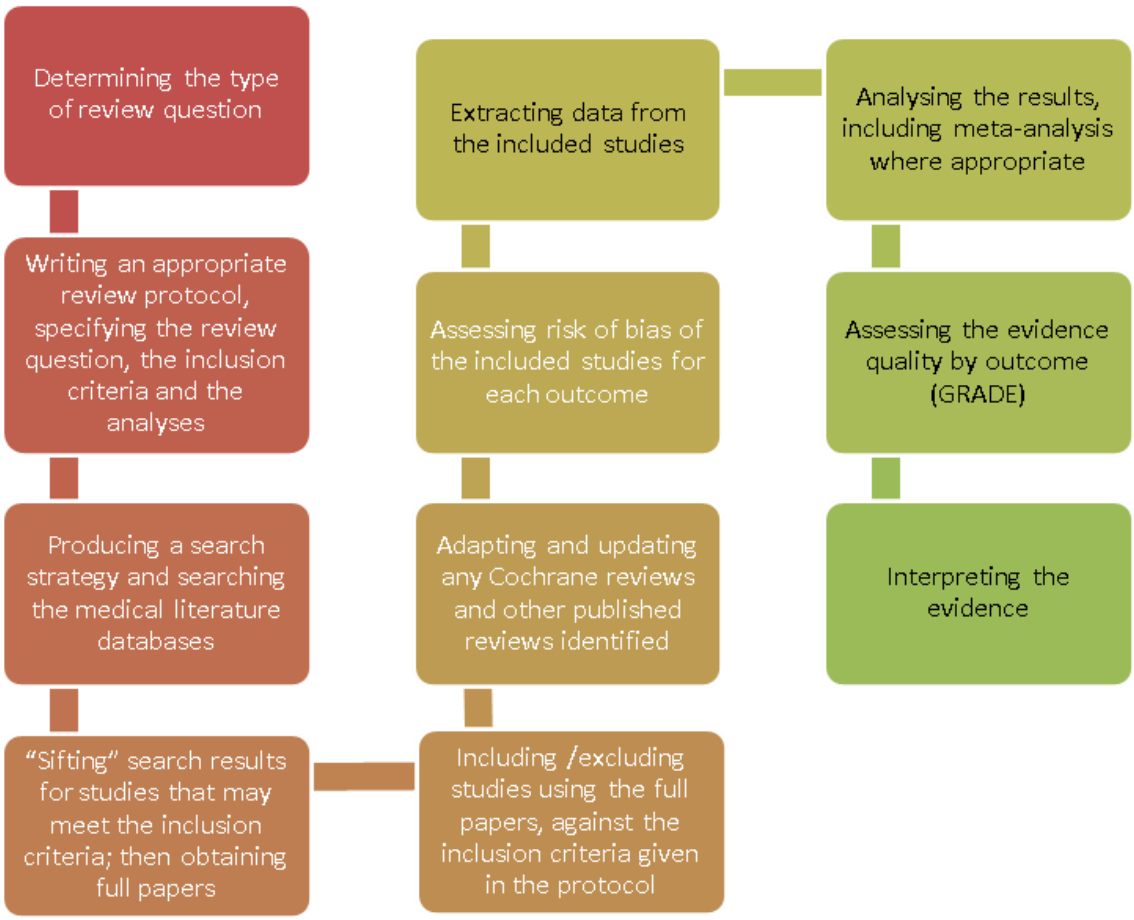
- Asthma - diagnosis and monitoring. NICE guideline CG. Publication delayed.
- Mental health of adults in contact with the criminal justice system. NICE guideline CG. Publication expected November 2016.
- Smoking cessation interventions and services. NICE guideline PH. Publication expected October 2017

4 Methods

This chapter sets out in detail the methods used to review the evidence and to develop the recommendations that are presented in subsequent chapters of this guideline. This guidance was developed in accordance with the methods outlined in the NICE guidelines manual, 2012 and 2014 versions.[92,108]

Sections 4.1 to 4.3 describe the process used to identify and review clinical evidence (summarised in Figure 1), Sections 4.2 and 4.4 describe the process used to identify and review the health economic evidence, and Section 4.4 describes the process used to develop recommendations.

Figure 1: Step-by-step process of review of evidence in the guideline



4.1 Developing the review questions and outcomes

Review questions were developed using a PICO framework (patient, intervention, comparison and outcome) for intervention reviews; using a framework of population, index tests, reference standard and target condition for reviews of diagnostic test accuracy; and using population, presence or absence of factors under investigation (for example prognostic factors) and outcomes for prognostic reviews.

This use of a framework guided the literature searching process, critical appraisal and synthesis of evidence, and facilitated the development of recommendations by the GDG. The review questions were drafted by the NCGC technical team and refined and validated by the GDG. The questions were based on the key clinical areas identified in the scope (Appendix A).

A total of 17 review questions were identified.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified review questions.

Table 1: Review questions

Chapter	Type of review	Review questions	Outcomes
5.2	Intervention, diagnostic in absence of evidence	What health assessment needs to be done at reception into prison?	Critical outcomes: • Morbidity • Mortality until second screen (7 days) Important outcomes: • Health-related quality of life • Patient safety incidents • Reduced self-harm • Reduced hospital admission • Delayed and omitted medicine • Reduced infectious disease transmission • Risk factors • Referrals • Self-reported satisfaction Diagnostic review: Diagnostic accuracy data
5.5	Intervention, diagnostic in absence of evidence	What subsequent health assessment(s) are clinically and cost-effective in prisons?	Critical outcomes: • Morbidity Important outcomes: • Health-related quality of life • Patient safety incidents • Reduced self-harm • Reduced hospital admission • Delayed and omitted medicine • Reduced infectious disease transmission • Risk factors • Referrals • Self-reported satisfaction • New diagnoses Diagnostic review: Diagnostic accuracy data
5.6	Intervention	When should subsequent health assessments be done in prisons?	Critical outcomes: • Morbidity Important outcomes: • Health-related quality of life • Patient safety incidents

Chapter	Type of review	Review questions	Outcomes
			• Reduced self-harm • Reduced hospital admission • Delayed and omitted medicine • Reduced infectious disease transmission • Risk factors • Referrals • Self-reported satisfaction • New diagnoses
5.7	Intervention	What are the most effective and cost-effective assessment tools to determine the health promotion needs of prisoners?	Critical outcomes: • Nutrition – healthy BMI • Personal hygiene/self care/oral health – patient-reported satisfaction • Physical activity – healthy BMI, 30 minutes a day • Sexual health – decrease in STD diagnosis from in-prison, accessing barrier methods and sexual health clinics • Smoking cessation – quit for at least 4 weeks Important outcomes: • Uptake of screening programmes. • Morbidity. • Mortality. • Health-related quality of life
6.2	Qualitative	What are barriers and facilitators to coordination, case management and communication between healthcare professionals involved in primary care, mental healthcare, substance misuse care and secondary care?	Thematic analysis
7.2	Intervention	What are the most clinically and cost-effective interventions that can be implemented to promote health and wellbeing in prisons?	Critical outcomes: • Nutrition – healthy BMI • Personal hygiene/self care/oral health – patient-reported satisfaction • Physical activity – healthy BMI, 30 minutes a day • Sexual health – decrease in STD diagnosis from in-prison, accessing barrier methods and sexual health clinics • Smoking cessation – quit for at least 4 weeks Important outcomes: • Uptake of screening programmes.

Chapter	Type of review	Review questions	Outcomes
			• Morbidity. • Mortality. • Health-related quality of life
7.3	Intervention	What are the most clinically and cost-effective methods of delivering health promotion activities in prison?	Critical outcomes: • Nutrition – healthy BMI • Personal hygiene/self care/oral health – patient-reported satisfaction • Physical activity – healthy BMI, 30 minutes a day • Sexual health – decrease in STD diagnosis from in-prison, accessing barrier methods and sexual health clinics • Smoking cessation – quit for at least 4 weeks Important outcomes: • Uptake of screening programmes. • Morbidity. • Mortality. • Health-related quality of life
7.4	Intervention	Who should deliver health promotion activities in prison?	Critical outcomes: • Nutrition – healthy BMI • Personal hygiene/self care/oral health – patient-reported satisfaction • Physical activity – healthy BMI, 30 minutes a day • Sexual health – decrease in STD diagnosis from in-prison, accessing barrier methods and sexual health clinics • Smoking cessation – quit for at least 4 weeks Important outcomes: • Uptake of screening programmes. • Morbidity. • Mortality. • Health-related quality of life
7.5	Qualitative	What are the barriers and facilitators to information provision, support and mentoring for prisoners to promote health and wellbeing?	Thematic analysis
8.2	Intervention	What are the most clinically and cost-effective methods for people to access medicines in prisons to maximise adherence and good health outcomes and reduce	Critical outcomes: • Drug adherence • Morbidity Important outcomes:

Chapter	Type of review	Review questions	Outcomes
		inappropriate use?	• Measures of drug diversion/trading (either from being bullied or selling medication) • Overdose • Mortality. • Health-related quality of life • Drug diversion
8.3	Intervention	What are the most clinically and cost-effective methods for continuity of care for people to access medicines to maximise adherence and good health outcomes and reduce inappropriate use when: • coming into prison? • being transferred between prisons? • discharged from prison?	<u>Critical outcomes</u> • Drug adherence • Morbidity <u>Important outcomes</u> • Measures of drug diversion/trading (either from being bullied or selling medication) • Overdose • Mortality. • Health-related quality of life • Unplanned admissions
8.4	Qualitative	What are the barriers and facilitators to ensuring access to medicines to maximise adherence and good health outcomes and reduce inappropriate use when: • coming into prison? • in prison? • being transferred between prisons? • discharged from prison?	Thematic analysis
9.2	Review of NICE guidance	How should chronic conditions be monitored in prison?	Outcomes as reported in published NICE guidance
10.2	Qualitative	What are the barriers and facilitators to prison staff, healthcare workers and prisoners for recognising deteriorating health?	Thematic analysis
10.3	Qualitative	What are the barriers and facilitators for prison staff, healthcare workers and prisoners in managing emergency situations including first person on the scene?	Thematic analysis
11.2	Qualitative	What are the barriers and facilitators to ensuring continuity of healthcare, including management of patient records, of people moving from: • community to prison? • prison to prison? • prison to court? • court to prison? • prison to hospital? • hospital to prison?	Thematic analysis

Chapter	Type of review	Review questions	Outcomes
		• prison to community? • transport to or from other detention centres?	
11.3	Intervention	What are the most clinically and cost-effective systems to manage patient records, to ensure continuity of healthcare of people moving from one prison to another, or between prison and the community or hospital?	Critical outcomes Omitted and delayed medication. Cancelled hospital appointments Medication errors Adverse events Patient safety incidents

4.2 Searching for evidence

4.2.1 Clinical literature search

Systematic literature searches were undertaken to identify all published clinical evidence relevant to the review questions. Searches were undertaken according to the parameters stipulated within the NICE guidelines manual 2012.[108] Databases were searched using relevant medical subject headings, free-text terms and study-type filters where appropriate. Where possible, searches were restricted to papers published in English. Studies published in languages other than English were not reviewed. All searches were conducted in Medline, Embase, The Cochrane Library PsycINFO, CINAHL and Social Policy & Practice. All searches were updated on 14 January 2016. A search was run in PubMed on 21 January 2016 to look for epub ahead of print papers not yet indexed in the other databases. No papers published after this date were considered.

Search strategies were quality assured by cross-checking reference lists of highly relevant papers, analysing search strategies in other systematic reviews, and asking GDG members to highlight any additional studies. Searches were quality assured by a second information scientist before being run. The questions, the study types applied, the databases searched and the years covered can be found in Appendix G.

The titles and abstracts of records retrieved by the searches were sifted for relevance, with potentially significant publications obtained in full text. These were assessed against the inclusion criteria.

During the scoping stage, a search was conducted for guidelines and reports on the websites listed below from organisations relevant to the topic.

- Guidelines International Network database (www.g-i-n.net)
- National Guideline Clearing House (www.guideline.gov)
- National Institute for Health and Care Excellence (NICE) (www.nice.org.uk)
- National Institutes of Health Consensus Development Program (consensus.nih.gov)
- NHS Evidence Search (www.evidence.nhs.uk).

All references sent by stakeholders were considered. Searching for unpublished literature was not undertaken. The NCGC and NICE do not have access to drug manufacturers' unpublished clinical trial results, so the clinical evidence considered by the GDG for pharmaceutical interventions may be different from that considered by the MHRA and European Medicines Agency for the purposes of licensing and safety regulation.

4.2.1.1 Call for evidence

The GDG decided to initiate a 'call for evidence' for all areas identified in the scope as the GDG believed that important evidence existed that would not be identified by the standard searches. The NCGC contacted all registered stakeholders and asked them to submit any relevant published or unpublished evidence. See appendix T for further details on evidence submitted during the call for evidence.

4.2.2 Health economic literature search

Systematic literature searches were also undertaken to identify health economic evidence within published literature relevant to the review questions. The evidence was identified by conducting a broad search relating to prisons in the: NHS Economic Evaluation Database (NHS EED), the Health Technology Assessment database (HTA) and the Health Economic Evaluations Database (HEED) with no date restrictions (NHS EED ceased to be updated after March 2015; HEED was used for searches up to 5 December 2014 but subsequently ceased to be available). Additionally, the search was run on Medline and Embase using a health economic filter, from January 2014, to ensure recent publications that had not yet been indexed by the economic databases were identified. Where possible, searches were restricted to papers published in English. Studies published in languages other than English were not reviewed.

The health economic search strategies are included in Appendix G. All searches were updated on 14 January 2016. No papers published after this date were considered.

4.2.2.1 Call for evidence

The GDG decided to initiate a 'call for evidence' for all areas identified in the scope as the GDG believed that important evidence existed that would not be identified by the standard searches. The NCGC contacted all registered stakeholders and asked them to submit any relevant published or unpublished evidence. See appendix T for further details on evidence submitted during the call for evidence.

4.3 Identifying and analysing evidence of effectiveness

Research fellows conducted the tasks listed below, which are described in further detail in the rest of this section:

- Identified potentially relevant studies for each review question from the relevant search results by reviewing titles and abstracts. Full papers were then obtained.
- Reviewed full papers against prespecified inclusion and exclusion criteria to identify studies that addressed the review question in the appropriate population, and reported on outcomes of interest (review protocols are included in Appendix C).
- Critically appraised relevant studies using the appropriate study design checklist as specified in the NICE guidelines manual.[92]
- Extracted key information about interventional study methods and results using 'Evibase', NCGC's purpose-built software. Evibase produces summary evidence tables, including critical appraisal ratings. Key information about non-interventional study methods and results was manually extracted onto standard evidence tables and critically appraised separately (evidence tables are included in Appendix H).
- Generated summaries of the evidence by outcome. Outcome data were combined, analysed and reported according to study design:
    - Randomised data were meta-analysed where appropriate and reported in GRADE profile tables.

- Observational data were presented as a range of values in GRADE profile tables or meta-analysed if appropriate.
- Diagnostic data studies were meta-analysed where appropriate or presented as a range of values in adapted GRADE profile tables
- Qualitative data were summarised across studies where appropriate and reported by themes.

- A sample of a minimum of 10% of the abstract lists were double-sifted by a senior research fellow and any discrepancies were rectified. All of the evidence reviews were quality assured by a senior research fellow. This included checking:
  - papers were included or excluded appropriately
  - a sample of the data extractions
  - correct methods were used to synthesise data
  - a sample of the risk of bias assessments.

4.3.1 Inclusion and exclusion criteria

The inclusion and exclusion of studies was based on the criteria defined in the review protocols, which can be found in Appendix C. Excluded studies by review question (with the reasons for their exclusion) are listed in Appendix L. The GDG was consulted about any uncertainty regarding inclusion or exclusion.

The key population inclusion criterion was: adults (18 and older) in prisons or young offender institutions.

Conference abstracts were not automatically excluded from any review. The abstracts were initially assessed against the inclusion criteria for the review question and further processed when a full publication was not available for that review question. If the abstracts were included the authors were contacted for further information. No relevant conference abstracts were identified for this guideline. Literature reviews, posters, letters, editorials, comment articles, unpublished studies and studies not in English were excluded.

4.3.2 Type of studies

Randomised trials, non-randomised trials, and observational studies (including diagnostic or prognostic studies) were included in the evidence reviews as appropriate.

For most intervention reviews in this guideline, parallel randomised controlled trials (RCTs) were included because they are considered the most robust type of study design that can produce an unbiased estimate of the intervention effects. If non-randomised studies were appropriate for inclusion (for example, non-drug trials with no randomised evidence) the GDG stated a priori in the protocol that either certain identified variables must be equivalent at baseline or else the analysis had to adjust for any baseline differences. If the study did not fulfil either criterion it was excluded. Please refer to the review protocols in Appendix C for full details on the study design of studies selected for each review question.

For diagnostic review questions, test-and-treat RCTs, cross-sectional studies and retrospective studies were included. For prognostic review questions, prospective and retrospective cohort studies were included. Case–control studies were not included.

Where data from observational studies were included, the results for each outcome were presented separately for each study and meta-analysis was not conducted.

4.3.3 Methods of combining clinical studies

4.3.3.1 Data synthesis for intervention reviews

Where possible, meta-analyses were conducted using Cochrane Review Manager (RevMan5)[135] software to combine the data given in all studies for each of the outcomes of interest for the review question.

All analyses were stratified for gender (male and female), which meant that different studies reporting males and females were not combined and analysed together.

4.3.3.1.1 Analysis of different types of data

Dichotomous outcomes

Fixed-effects (Mantel-Haenszel) techniques (using an inverse variance method for pooling) were used to calculate risk ratios (relative risk, RR) for the binary outcomes, which included:

- morbidity
- mortality
- adverse events.

The absolute risk difference was also calculated using GRADEpro[34] software, using the median event rate in the control arm of the pooled results.

For binary variables where there were zero events in either arm or a less than 1% event rate, Peto odds ratios, rather than risk ratios, were calculated. Peto odds ratios are more appropriate for data with a low number of events.

Continuous outcomes

Continuous outcomes were analysed using an inverse variance method for pooling weighted mean differences. These outcomes included:

- heath-related quality of life (HRQoL)
- symptom scales body mass index (BMI)

Where the studies within a single meta-analysis had different scales of measurement, standardised mean differences were used (providing all studies reported either change from baseline or final values rather than a mixture of both); each different measure in each study was 'normalised' to the standard deviation value pooled between the intervention and comparator groups in that same study.

The means and standard deviations of continuous outcomes are required for meta-analysis. However, in cases where standard deviations were not reported, the standard error was calculated if the p values or 95% confidence intervals (95% CI) were reported, and meta-analysis was undertaken with the mean and standard error using the generic inverse variance method in Cochrane Review Manager (RevMan5[135] software. Where p values were reported as 'less than', a conservative approach was undertaken. For example, if a p value was reported as 'p≤0.001', the calculations for standard deviations were based on a p value of 0.001. If these statistical measures were not available then the methods described in Section 16.1.3 of the Cochrane Handbook (version 5.1.0, updated March 2011) were applied.

4.3.3.1.2 Generic inverse variance

If a study reported only the summary statistic and 95% CI the generic-inverse variance method was used to enter data into RevMan5.[135] If the control event rate was reported this was used to generate the absolute risk difference in GRADEpro.[34GRADE Working Group, 2011 GRADE2011 /id] If multivariate analysis was used to derive the summary statistic but no adjusted control event rate was reported no absolute risk difference was calculated.

4.3.3.1.3 Heterogeneity

Statistical heterogeneity was assessed for each meta-analysis estimate by considering the chi-squared test for significance at $p<0.1$ or an I-squared (I^2) inconsistency statistic (with an I-squared value of more than 50% indicating significant heterogeneity) as well as the distribution of effects. Where significant heterogeneity was present, predefined subgrouping of studies was carried out for either:

- Age (people <50 or > 50 years)
- Length of stay in prison (<12 months, 12 months to 4 years or >4 years)
- People with or without a disabilities (including physical disabilities, learning disabilities and borderline learning disabilities)
- People with or without a history of substance misuse
- Women, especially pregnant women and the mothers of babies in prison.

If the subgroup analysis resolved heterogeneity within all of the derived subgroups, then each of the derived subgroups were adopted as separate outcomes (providing at least 1 study remained in each subgroup. Assessments of potential differences in effect between subgroups were based on the chi-squared tests for heterogeneity statistics between subgroups. Any subgroup differences were interpreted with caution as separating the groups breaks the study randomisation and as such is subject to uncontrolled confounding.

If all predefined strategies of subgrouping were unable to explain statistical heterogeneity within each derived subgroup, then a random effects (DerSimonian and Laird) model was employed to the entire group of studies in the meta-analysis. A random-effects model assumes a distribution of populations, rather than a single population. This leads to a widening of the confidence interval around the overall estimate, thus providing a more realistic interpretation of the true distribution of effects across more than 1 population. If, however, the GDG considered the heterogeneity was so large that meta-analysis was inappropriate, then the results were described narratively.

4.3.3.2 Data synthesis for diagnostic test accuracy reviews

The protocol was produced to reflect the 2 different diagnostic study designs.

Test-and-treat RCTsTest-and-treat RCTs(sometimes referred to as diagnostic RCTs) are a randomised comparison of 2 diagnostic tests, with study outcomes being clinically important consequences of the diagnosis (patient-related outcome measures similar to those in intervention trials, such as mortality). Patients are randomised to receive test A or test B, followed by identical therapeutic interventions based on the results of the test (so someone with a positive result would receive the same treatment regardless of whether they were diagnosed by test A or test B). Downstream patient outcomes are then compared between the 2 groups. As treatment is the same in both arms of the trial, any differences in patient outcomes will reflect the accuracy of the tests in correctly establishing who does and does not have the condition. Data were synthesised using the same methods for intervention reviews (see Section 4.3.3.1.1 above).

4.3.3.2.1 Diagnostic accuracy studies

Diagnostic test accuracy measures used in the analysis were: sensitivity and specificity for different thresholds (if appropriate). The threshold of a diagnostic test is defined as the value at which the test can best differentiate between those with and without the target condition. In practice this varies amongst studies. If a test has a high sensitivity then very few people with the condition will be missed (few false negatives). For example, a test with a sensitivity of 97% will only miss 3% of people with the condition. Conversely, if a test has a high specificity then few people without the condition would be incorrectly diagnosed (few false positives). For example, a test with a specificity of 97% will only incorrectly diagnose 3% of people who do not have the condition as positive. For this guideline, sensitivity was considered more important than specificity due to the consequences of a missed condition (false negative result).Coupled forest plots of sensitivity and specificity with their 95% CIs across studies (at various thresholds) were produced for each test, using RevMan5[135]. In order to do this, 2×2 tables (the number of true positives, false positives, true negatives and false negatives) were directly taken from the study if given, or else were derived from raw data or calculated from the set of test accuracy statistics.

Heterogeneity or inconsistency amongst studies was visually inspected.

4.3.3.3 Data synthesis for qualitative study reviews

For each included paper themes were identified and, where possible a meta-synthesis was conducted to combine qualitative study results. Broader generic themes were identified and subthemes were linked to these. In some cases, subthemes related to more than 1 generic theme. A summary evidence table of generic themes and underpinning subthemes was then produced; this included information on how many studies had contributed to an identified overarching theme, alongside the quality of the evidence. The themes and subthemes were them placed into a thematic map presenting the relationship between themes and subthemes. The included and excluded studies identified from the literature search and mapping of themes were drafted by 1 reviewer and quality assured by a senior research fellow.

4.3.4 Appraising the quality of evidence by outcomes

4.3.4.1 Intervention reviews

The evidence for outcomes from the included RCTs and, where appropriate, observational studies were evaluated and presented using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group (http://www.gradeworkinggroup.org/). The software (GRADEpro[34GRADE Working Group, 2011 GRADE2011 /id]) developed by the GRADE working group was used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results.

Each outcome was first examined for each of the quality elements listed and defined in Table 2.

Table 2: Description of quality elements in GRADE for intervention studies

Quality element	Description
Risk of bias	Limitations in the study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect. Examples of such limitations are selection bias (often due to poor allocation concealment), performance and detection bias (often due to a lack of blinding of the patient, healthcare professional or assessor) and attrition bias (due to missing data causing systematic bias in the analysis).
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the review question.

Quality element	Description
Inconsistency	Inconsistency refers to an unexplained heterogeneity of effect estimates between studies in the same meta-analysis.
Imprecision	Results are imprecise when studies include relatively few patients and few events (or highly variable measures) and thus have wide confidence intervals around the estimate of the effect relative to clinically important thresholds. 95% confidence intervals denote the possible range of locations of the true population effect at a 95% probability, and so wide confidence intervals may denote a result that is consistent with conflicting interpretations (for example a result may be consistent with both clinical benefit AND clinical harm) and thus be imprecise.
Publication bias	Publication bias is a systematic underestimate or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies. A closely related phenomenon is where some papers fail to report an outcome that is inconclusive, thus leading to an overestimate of the effectiveness of that outcome.
Other issues	Sometimes randomisation may not adequately lead to group equivalence of confounders, and if so this may lead to bias, which should be taken into account. Potential conflicts of interest, often caused by excessive pharmaceutical company involvement in the publication of a study, should also be noted.

Details of how the 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) were appraised for each outcome are given below. Publication or other bias was only taken into consideration in the quality assessment if it was apparent.

4.3.4.1.1 Risk of bias

The main domains of bias for RCTs are listed in Table 3. Each outcome had its risk of bias assessed within each study first. For each study, if there were no risks of bias in any domain, the risk of bias was given a rating of 0. If there was risk of bias in just 1 domain, the risk of bias was given a 'serious' rating of −1, but if there was risk of bias in 2 or more domains the risk of bias was given a 'very serious' rating of −2. A weighted average score was then calculated across all studies contributing to the outcome, by taking into account the weighting of studies according to study precision. For example if the most precise studies tended to each have a score of −1 for that outcome, the overall score for that outcome would tend towards −1.

Table 3: Principle domains of bias in randomised controlled trials

Limitation	Explanation
Selection bias (sequence generation and allocation concealment)	If those enrolling patients are aware of the group to which the next enrolled patient will be allocated, either because of a non-random sequence that is predictable, or because a truly random sequence was not concealed from the researcher, this may translate into systematic selection bias. This may occur if the researcher chooses not to recruit a participant into that specific group because of: • knowledge of that participant's likely prognostic characteristics, and • a desire for one group to do better than the other.
Performance and detection bias (lack of blinding of patients and healthcare professionals)	Patients, caregivers, those adjudicating or recording outcomes, and data analysts should not be aware of the arm to which patients are allocated. Knowledge of the group can influence: • the experience of the placebo effect • performance in outcome measures • the level of care and attention received, and • the methods of measurement or analysis all of which can contribute to systematic bias.
Attrition bias	Attrition bias results from an unaccounted for loss of data beyond a certain level (a differential of 10% between groups). Loss of data can occur when participants are

Limitation	Explanation
	compulsorily withdrawn from a group by the researchers (for example, when a per-protocol approach is used) or when participants do not attend assessment sessions. If the missing data are likely to be different from the data of those remaining in the groups, and there is a differential rate of such missing data from groups, systematic attrition bias may result.
Selective outcome reporting	Reporting of some outcomes and not others on the basis of the results can also lead to bias, as this may distort the overall impression of efficacy.
Other limitations	For example: • Stopping early for benefit observed in randomised trials, in particular in the absence of adequate stopping rules. • Use of unvalidated patient-reported outcome measures. • Lack of washout periods to avoid carry-over effects in crossover trials. • Recruitment bias in cluster-randomised trials.

4.3.4.1.2 Indirectness

Indirectness refers to the extent to which the populations, interventions, comparisons and outcome measures are dissimilar to those defined in the inclusion criteria for the reviews. Indirectness is important when these differences are expected to contribute to a difference in effect size, or may affect the balance of harms and benefits considered for an intervention. As for the risk of bias, each outcome had its indirectness assessed within each study first. For each study, if there were no sources of indirectness, indirectness was given a rating of 0. If there was indirectness in just 1 source (for example in terms of population), indirectness was given a 'serious' rating of −1, but if there was indirectness in 2 or more sources (for example, in terms of population and treatment) the indirectness was given a 'very serious' rating of −2. A weighted average score was then calculated across all studies contributing to the outcome by taking into account study precision. For example, if the most precise studies tended to have an indirectness score of −1 each for that outcome, the overall score for that outcome would tend towards −1.

4.3.4.1.3 Inconsistency

Inconsistency refers to an unexplained heterogeneity of results for an outcome across different studies. When estimates of the treatment effect across studies differ widely, this suggests true differences in the underlying treatment effect, which may be due to differences in populations, settings or doses. When heterogeneity existed within an outcome (chi-squared $p<0.1$, or $I^2>50\%$), but no plausible explanation could be found, the quality of evidence for that outcome was downgraded. Inconsistency for that outcome was given a 'serious' score of −1 if the I^2 was 50–74%, and a 'very serious' score of −2 if the I^2 was 75% or more.

If inconsistency could be explained based on prespecified subgroup analysis (that is, each subgroup had an $I^2<50\%$), the GDG took this into account and considered whether to make separate recommendations on new outcomes based on the subgroups defined by the assumed explanatory factors. In such a situation the quality of evidence was not downgraded for those emergent outcomes.

Since the inconsistency score was based on the meta-analysis results, the score represented the whole outcome and so weighted averaging across studies was not necessary.

4.3.4.1.4 Imprecision

The criteria applied for imprecision were based on the 95% CIs for the pooled estimate of effect, and the minimal important differences (MID) for the outcome. The MIDs are the threshold for appreciable benefits and harms, separated by a zone either side of the line of no effect where there

is assumed to be no clinically important effect. If either end of the 95% CI of the overall estimate of effect crossed 1 of the MID lines, imprecision was regarded as serious and a 'serious' score of −1 was given. This was because the overall result, as represented by the span of the confidence interval, was consistent with 2 interpretations as defined by the MID (for example, both no clinically important effect and clinical benefit were possible interpretations). If both MID lines were crossed by either or both ends of the 95% CI then imprecision was regarded as very serious and a 'very serious' score of −2 was given. This was because the overall result was consistent with all 3 interpretations defined by the MID (no clinically important effect, clinical benefit and clinical harm). This is illustrated in Figure 2. As for inconsistency, since the imprecision score was based on the meta-analysis results, the score represented the whole outcome and so weighted averaging across studies was not necessary.

The position of the MID lines is ideally determined by values reported in the literature. 'Anchor-based' methods aim to establish clinically meaningful changes in a continuous outcome variable by relating or 'anchoring' them to patient-centred measures of clinical effectiveness that could be regarded as gold standards with a high level of face validity. For example, a MID for an outcome could be defined by the minimum amount of change in that outcome necessary to make patients feel their quality of life had 'significantly improved'. MIDs in the literature may also be based on expert clinician or consensus opinion concerning the minimum amount of change in a variable deemed to affect quality of life or health. For binary variables, any MIDs reported in the literature will inevitably be based on expert consensus, as such MIDs relate to all-or-nothing population effects rather than measurable effects on an individual, and so are not amenable to patient-centred 'anchor' methods.

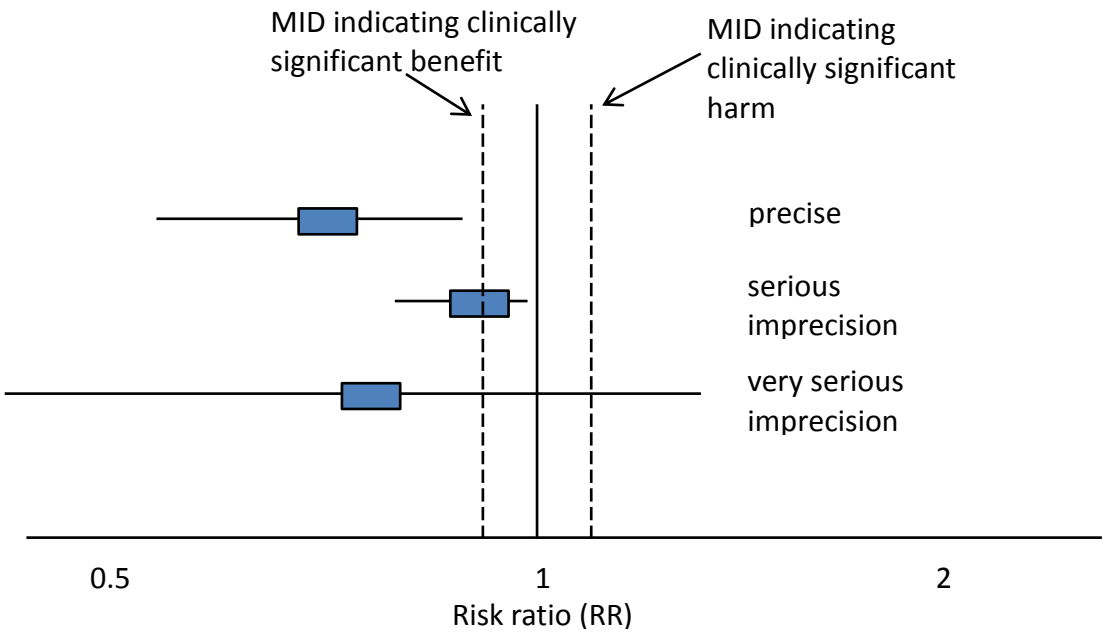
As no MIDs were identified in the literature for the review questions in this guideline, the 'default' method was adopted, as follows:

- For categorical outcomes the MIDs were taken to be RRs of 0.75 and 1.25. For 'positive' outcomes such as 'patient satisfaction', the RR of 0.75 is taken as the line denoting the boundary between no clinically important effect and a clinically significant harm, whilst the RR of 1.25 is taken as the line denoting the boundary between no clinically important effect and a clinically significant benefit. For 'negative' outcomes such as 'bleeding', the opposite occurs, so the RR of 0.75 is taken as the line denoting the boundary between no clinically important effect and a clinically significant benefit, whilst the RR of 1.25 is taken as the line denoting the boundary between no clinically important effect and a clinically significant harm.
- For mortality any change was considered to be clinically important and the imprecision was assessed on the basis of the whether the confidence intervals crossed the line of no effect, that is, whether the result was consistent with both benefit and harm.
- For continuous outcome variables the MID was taken as half the median baseline standard deviation of that variable, across all studies in the meta-analysis. Hence the MID denoting the minimum clinically significant benefit was positive for a 'positive' outcome (for example, a quality of life measure where a higher score denotes better health), and negative for a 'negative' outcome (for example, a visual analogue scale [VAS] pain score). Clinically significant harms will be the converse of these. If baseline values are unavailable, then half the median comparator group standard deviation of that variable will be taken as the MID.
- If standardised mean differences have been used, then the MID will be set at the absolute value of +0.5. This follows because standardised mean differences are mean differences normalised to the pooled standard deviation of the 2 groups, and are thus effectively expressed in units of 'numbers of standard deviations'. The 0.5 MID value in this context therefore indicates half a standard deviation, the same definition of MID as used for non-standardised mean differences.

The default MID value was subject to amendment after discussion with the GDG. If the GDG decided that the MID level should be altered, after consideration of absolute as well as relative effects, this was allowed, provided that any such decision was not influenced by any bias towards making stronger or weaker recommendations for specific outcomes.

For this guideline, no appropriate MIDs for continuous or dichotomous outcomes were found in the literature, and so the default method was adopted.

Figure 2: Illustration of precise and imprecise outcomes based on the 95% CI of dichotomous outcomes in a forest plot (Note that all 3 results would be pooled estimates, and would not, in practice, be placed on the same forest plot)



4.3.4.1.5 Overall grading of the quality of clinical evidence

Once an outcome had been appraised for the main quality elements, as above, an overall quality grade was calculated for that outcome. The scores (0, −1 or −2) from each of the main quality elements were summed to give a score that could be anything from 0 (the best possible) to −8 (the worst possible). However scores were capped at −3. This final score was then applied to the starting grade that had originally been applied to the outcome by default, based on study design. All RCTs started as High and the overall quality became Moderate, Low or Very Low if the overall score was −1, −2 or −3 points respectively. The significance of these overall ratings is explained in Table 4. The reasons for downgrading in each case were specified in the footnotes of the GRADE tables.

Observational interventional studies started at Low, and so a score of −1 would be enough to take the grade to the lowest level of Very Low. Observational studies could, however, be upgraded if there were all of: a large magnitude of effect, a dose-response gradient, and if all plausible confounding would reduce the demonstrated effect.

Table 4: Overall quality of outcome evidence in GRADE

Level	Description
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

13.4.2 Diagnostic studies

Risk of bias and indirectness of evidence for diagnostic data were evaluated by study using the Quality Assessment of Diagnostic Accuracy Studies version 2 (QUADAS-2) checklists (see Appendix H in the NICE guidelines manual 2014[92NICE2014]). Risk of bias and applicability in primary diagnostic accuracy studies in QUADAS-2 consists of 4 domains (see Table 5):

- patient selection
- index test
- reference standard
- flow and timing.

Table 5: Summary of QUADAS-2 with list of signalling, risk of bias and applicability questions

Domain	Patient selection	Index test	Reference standard	Flow and timing
Description	Describe methods of patient selection. Describe included patients (prior testing, presentation, intended use of index test and setting)	Describe the index test and how it was conducted and interpreted	Describe the reference standard and how it was conducted and interpreted	Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2×2 table (refer to flow diagram). Describe the time interval and any interventions between index test(s) and reference standard
Signalling questions (yes/no/ unclear)	Was a consecutive or random sample of patients enrolled?	Were the index test results interpreted without knowledge of the results of the reference standard?	Is the reference standard likely to correctly classify the target condition?	Was there an appropriate interval between index test(s) and reference standard?
	Did the study avoid inappropriate exclusions?	If a threshold was used, was it pre-specified?	Were the reference standard results interpreted without knowledge of the results of the index test?	Did all patients receive a reference standard?
				Did all patients receive the same reference standard?
				Were all patients included in the analysis?
Risk of bias; (high/low/ unclear)	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct or its interpretation have introduced bias?	Could the patient flow have introduced bias?
Concerns regarding applicability (high/low/ unclear)	Are there concerns that the included patients do not match the review question?	Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Are there concerns that the target condition as defined by the reference standard does not match the review question?	

4.3.4.2.1 Inconsistency

Inconsistency refers to an unexplained heterogeneity of results for an outcome across different studies. Inconsistency was assessed by inspection of the sensitivity value (based on the primary measure) using the point estimates and 95% CIs of the individual studies on the forest plots. Particular attention was placed on values above or below 50% (diagnosis based on chance alone) and the threshold set by the GDG (the threshold above which it would be acceptable to recommend a test). For example, the GDG might have set a threshold of 90% as an acceptable level to recommend a test. The evidence was downgraded by 1 increment if the individual studies varied across 2 areas (for example, 50–90% and 90–100%) and by 2 increments if the individual studies varied across 3 areas (for example, 0–50%, 50–90% and 90–100%).

4.3.4.2.2 Imprecision

Diagnostic meta-analysis was not conducted in this guideline. Imprecision was assessed according to the range of point estimates or, if only one study contributed to the evidence, the 95% CI around the single study. As a general rule (after discussion with the GDG) a variation of 0–20% was considered precise, 20–40% serious imprecision, and >40% very serious imprecision. Imprecision was assessed on sensitivity values (the primary outcome measure for decision-making).

4.3.4.2.3 Overall grading

Quality rating started at high for prospective and retrospective single-gate studies, and each major limitation (risk of bias, indirectness, inconsistency and imprecision) brought the rating down by 1 increment to a minimum grade of very low, as explained for intervention reviews.

4.3.4.3 Qualitative reviews

Table 6 summarises the factors that were assessed to inform the quality rating for each subtheme. The overall quality rating for each subtheme was a subjective judgement that took into consideration these factors. The overall quality rating for each subtheme is reported in a summary table in the evidence report.

Table 6: Summary of factors assessed in qualitative reviews

Quality element	
Limitations of evidence	• Were qualitative studies or surveys an appropriate approach? • Were the studies approved by an ethics committee? • Were the studies clear in what they seek to do? • Is the context clearly described? • Is the role of the researcher clearly described? • How rigorous was the research design and research methods? • Was the data collection rigorous? • Was the data analysis rigorous? • Are the data rich (for qualitative study and open ended survey questions)? • Are the findings relevant to the aims of the study? • Are the findings and conclusions convincing?
Coherence of findings	• Do the subthemes identified complement, reinforce or contradict each other?
Applicability of evidence	• Are the findings of the study applicable to the evidence review? (For example, are the population and setting relevant?)
Theme saturation	• Was theme saturation was achieved (that is, no further citations or observations would provide more insight or suggest a different

Quality element	
	interpretation of this theme)? • Was the depth of data and quotes or observations were provided sufficient to underpin the findings?

4.3.5 Assessing clinical importance

The GDG assessed the evidence by outcome in order to determine if there was, or potentially was, a clinically important benefit, a clinically important harm or no clinically important difference between interventions. To facilitate this, binary outcomes were converted into absolute risk differences (ARDs) using GRADEpro[34] software: the median control group risk across studies was used to calculate the ARD and its 95% CI from the pooled risk ratio.

The assessment of clinical benefit, harm, or no benefit or harm was based on the point estimate of absolute effect for intervention studies, which was standardised across the reviews. The GDG considered for most of the outcomes in the intervention reviews that if at least 100 more participants per 1000 (10%) achieved the outcome of interest in the intervention group compared to the comparison group for a positive outcome then this intervention was considered beneficial. The same point estimate but in the opposite direction applied for a negative outcome. For the critical outcome of mortality any reduction represented a clinical benefit. For adverse events 50 events or more per 1000 (5%) represented clinical harm. For continuous outcomes if the mean difference was greater than the minimally important difference (MID) then this resented a clinical benefit or harm. For outcomes such as mortality any reduction or increase was considered to be clinically important.

This assessment was carried out by the GDG for each critical outcome, and an evidence summary table was produced to compile the GDG's assessments of clinical importance per outcome, alongside the evidence quality and the uncertainty in the effect estimate (imprecision).

4.3.6 Clinical evidence statements

Clinical evidence statements are summary statements that are included in each review chapter, and which summarise the key features of the clinical effectiveness evidence presented. The wording of the evidence statements reflects the certainty or uncertainty in the estimate of effect. The evidence statements are presented by outcome and encompass the following key features of the evidence:

- The number of studies and the number of participants for a particular outcome.
- An indication of the direction of clinical importance (if one treatment is beneficial or harmful compared to the other, or whether there is no difference between the 2 tested treatments).
- A description of the overall quality of the evidence (GRADE overall quality).

4.4 Identifying and analysing evidence of cost-effectiveness

The GDG is required to make decisions based on the best available evidence of both clinical effectiveness and cost-effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected health benefits (that is, their 'cost-effectiveness') rather than the total implementation cost. [92] Thus, if the evidence suggests that a strategy provides significant health benefits at an acceptable cost per patient treated, it should be recommended even if it would be expensive to implement across the whole population.

Health economic evidence was sought relating to the key clinical issues being addressed in the guideline. Health economists:

- Undertook a systematic review of the published economic literature.
- Undertook new cost-effectiveness analysis in priority areas.

4.4.1 Literature review

The health economists:

- Identified potentially relevant studies for each review question from the health economic search results by reviewing titles and abstracts. Full papers were then obtained.
- Reviewed full papers against prespecified inclusion and exclusion criteria to identify relevant studies (see below for details).
- Critically appraised relevant studies using economic evaluations checklists as specified in the NICE guidelines manual.[108]
- Extracted key information about the studies' methods and results into health economic evidence tables (included in Appendix I).
- Generated summaries of the evidence in NICE health economic evidence profile tables (included in the relevant chapter for each review question) – see below for details.

4.4.1.1 Inclusion and exclusion criteria

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost-utility, cost-effectiveness, cost-benefit and cost-consequences analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially includable as health economic evidence.

Studies that only reported cost per hospital (not per patient), or only reported average cost-effectiveness without disaggregated costs and effects were excluded. Literature reviews, abstracts, posters, letters, editorials, comment articles, unpublished studies and studies not in English were excluded. Studies published before 1999 and studies from non-OECD countries or the USA were also excluded, on the basis that the applicability of such studies to the present UK NHS context is likely to be too low for them to be helpful for decision-making.

Remaining health economic studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high quality, directly applicable UK analysis was available, then other less relevant studies may not have been included. However, in this guideline, no economic studies were excluded on the basis that more applicable evidence was available.

For more details about the assessment of applicability and methodological quality see Table 7 below and the economic evaluation checklist (Appendix G of the 2012 NICE guidelines manual[108]) and the health economics review protocol in Appendix D.

When no relevant health economic studies were found from the economic literature review, relevant UK NHS unit costs related to the compared interventions were presented to the GDG to inform the possible economic implications of the recommendations.

4.4.1.2 NICE health economic evidence profiles

NICE health economic evidence profile tables were used to summarise cost and cost-effectiveness estimates for the included health economic studies in each review chapter. The health economic evidence profile shows an assessment of applicability and methodological quality for each economic study, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from the NICE guidelines manual.[108] It also shows the incremental costs, incremental effects (for example, quality-adjusted life years [QALYs]) and incremental cost-effectiveness ratio (ICER) for the base case analysis in the study, as well as information about the assessment of uncertainty in the analysis. See Table 7 for more details.

When a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity.[123]

Table 7: Content of NICE health economic evidence profile

Item	Description
Study	Surname of first author, date of study publication and country perspective with a reference to full information on the study.
Applicability	An assessment of applicability of the study to this guideline, the current NHS situation and NICE decision-making:[(a)] • Directly applicable – the study meets all applicability criteria, or fails to meet 1 or more applicability criteria but this is unlikely to change the conclusions about cost-effectiveness. • Partially applicable – the study fails to meet 1 or more applicability criteria, and this could change the conclusions about cost-effectiveness. • Not applicable – the study fails to meet 1 or more of the applicability criteria, and this is likely to change the conclusions about cost-effectiveness. Such studies would usually be excluded from the review.
Limitations	An assessment of methodological quality of the study:[(a)] • Minor limitations – the study meets all quality criteria, or fails to meet 1 or more quality criteria, but this is unlikely to change the conclusions about cost-effectiveness. • Potentially serious limitations – the study fails to meet 1 or more quality criteria, and this could change the conclusions about cost-effectiveness. • Very serious limitations – the study fails to meet 1 or more quality criteria, and this is highly likely to change the conclusions about cost-effectiveness. Such studies would usually be excluded from the review.
Other comments	Information about the design of the study and particular issues that should be considered when interpreting it.
Incremental cost	The mean cost associated with one strategy minus the mean cost of a comparator strategy.
Incremental effects	The mean QALYs (or other selected measure of health outcome) associated with one strategy minus the mean QALYs of a comparator strategy.
Cost-effectiveness	Incremental cost-effectiveness ratio (ICER): the incremental cost divided by the incremental effects (usually in £ per QALY gained).
Uncertainty	A summary of the extent of uncertainty about the ICER reflecting the results of deterministic or probabilistic sensitivity analyses, or stochastic analyses of trial data, as appropriate.

(a) Applicability and limitations were assessed using the economic evaluation checklist in Appendix G of the 2012 NICE guidelines manual[108]

4.4.2 Undertaking new health economic analysis

As well as reviewing the published health economic literature for each review question, as described above, new health economic analysis was undertaken by the health economist in selected areas. Priority areas for new analysis were agreed by the GDG after formation of the review questions and consideration of the existing health economic evidence.

The GDG identified the question of who should be conducting the health assessment at reception into prison as the highest priority area for original health economic modelling. This was due to the extra benefits and potentially costs associated with a health assessment conducted by a nurse (instead of a healthcare assistant). The GDG also highlighted the significant economic impact of this decision especially when considering the number of people that annually go through the reception

process (estimated around 75,000). A cost and threshold analysis was therefore undertaken to inform relevant recommendations.

The following general principles were adhered to in developing the cost-effectiveness analysis:

- Methods were consistent with the NICE reference case for interventions with health outcomes in NHS settings.[92,112]
- The GDG was involved in the design of the model, selection of inputs and interpretation of the results.
- Model inputs were based on the systematic review of the clinical literature supplemented with other published data sources where possible.
- When published data were not available GDG expert opinion was used to populate the model.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.
- The model was peer-reviewed by another health economist at the NCGC.

Full methods for the cost threshold analysis are described in Appendix N.

4.4.3 Cost-effectiveness criteria

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money.[105] In general, an intervention was considered to be cost-effective (given that the estimate was considered plausible) if either of the following criteria applied:

- the intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
- the intervention cost less than £20,000 per QALY gained compared with the next best strategy.

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'Recommendations and link to evidence' section of the relevant chapter, with reference to issues regarding the plausibility of the estimate or to the factors set out in 'Social value judgements: principles for the development of NICE guidance'.[105]

When QALYs or life years gained are not used in the analysis, results are difficult to interpret unless one strategy dominates the others with respect to every relevant health outcome and cost.

4.4.4 In the absence of health economic evidence

When no relevant published health economic studies were found, and a new analysis was not prioritised, the GDG made a qualitative judgement about cost-effectiveness by considering expected differences in resource use between options and relevant UK NHS unit costs, alongside the results of the review of clinical effectiveness evidence.

The UK NHS costs reported in the guideline are those that were presented to the GDG and were correct at the time recommendations were drafted. They may have changed subsequently before the time of publication. However, we have no reason to believe they have changed substantially.

4.5 Developing recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and health economic evidence reviewed from the literature. All evidence tables are in Appendices H and I.
- Summaries of clinical and health economic evidence and quality (as presented in Chapters 5-11).
- Forest plots (Appendix K).
- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (Appendix N).

Recommendations were drafted on the basis of the GDG's interpretation of the available evidence, taking into account the balance of benefits, harms and costs between different courses of action. This was either done formally in an economic model, or informally. Firstly, the net clinical benefit over harm (clinical effectiveness) was considered, focusing on the critical outcomes. When this was done informally, the GDG took into account the clinical benefits and harms when one intervention was compared with another. The assessment of net clinical benefit was moderated by the importance placed on the outcomes (the GDG's values and preferences), and the confidence the GDG had in the evidence (evidence quality). Secondly, the GDG assessed whether the net clinical benefit justified any differences in costs between the alternative interventions.

When clinical and health economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on its expert opinion. The considerations for making consensus-based recommendations include the balance between potential harms and benefits, the economic costs compared to the economic benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were agreed through discussions in the GDG. The GDG also considered whether the uncertainty was sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation (see Section 4.5.2 below).

The GDG considered the appropriate 'strength' of each recommendation. This takes into account the quality of the evidence but is conceptually different. Some recommendations are 'strong' in that the GDG believes that the vast majority of healthcare and other professionals and patients would choose a particular intervention if they considered the evidence in the same way that the GDG has. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost-effective. However, there is often a closer balance between benefits and harms, and some patients would not choose an intervention whereas others would. This may happen, for example, if some patients are particularly averse to some side effect and others are not. In these circumstances the recommendation is generally weaker, although it may be possible to make stronger recommendations about specific groups of patients.

The GDG focused on the following factors in agreeing the wording of the recommendations:

- The actions health professionals need to take.
- The information readers need to know.
- The strength of the recommendation (for example the word 'offer' was used for strong recommendations and 'consider' for weaker recommendations).
- The involvement of patients (and their carers if needed) in decisions on treatment and care.
- Consistency with NICE's standard advice on recommendations about drugs, waiting times and ineffective interventions (see Section 9.2 in the 2014 NICE guidelines manual[92]).

The main considerations specific to each recommendation are outlined in the 'Recommendations and link to evidence' sections within each chapter.

4.5.1 Cross referring to existing NICE guidance

The GDG considered other published related NICE guidance to be relevant to a prison population and individual guidelines were reviewed for applicability and relevance, taking into consideration equity of care for people in prison. The GDG chose to cross-refer to the recommendation(s) in other published NICE guidance in accordance with the NICE guidelines manual.[92] Cross reference to recommendations was as a result of two different approaches in reviewing the clinical evidence review :

- Monitoring chronic conditions (see chapter 9). This review question set out to specifically look at existing NICE recommendations, as detailed in the review protocol. This approach was taken because there is existing NICE recommendations on monitoring people who have the conditions specified within the protocol. The GDG were presented with details about the evidence underpinning the recommendations within tables in the full guideline. This included assessing the evidence presented in the published NICE guideline, including evidence statements and full details of study design and quality.
- Other intervention reviews, for example within the health promotion interventions reviews (see chapter 5). Systematic reviews were conducted following the standard NICE methodology to identify evidence in a prison population and presented to the GDG. Little or no evidence was found for many of the reviews, however, the GDG highlighted that there was already NICE guidance issued on several of these topics, some of which were included a prison setting. Any related NICE guidance not specific to a prison population was assessed for applicability and relevance by the GDG and documented in sections labelled 'related NICE guidance', that include summary tables (a brief description of the underpinning evidence and recommendations from other related published NICE guidelines).

In both situations the GDG formally determined and documented that:

- the review question in the guideline in development is similar to the question addressed in the published guideline
- the evidence review underpinning any recommendations is not likely to have changed significantly since the publication of the related guideline
- the evidence review for the review question in the published guideline is relevant and appropriate to the question in the guideline in development.

Published NICE guidelines that make direct recommendations for a prison population, and specifically include prisoners in their scope, were checked for applicability and relevance and cross referred to where relevant. Further discussion, including areas of agreement and difference, are detailed in the linking evidence to recommendation sections of the relevant recommendations.

4.5.2 Research recommendations

When areas were identified for which good evidence was lacking, the GDG considered making recommendations for future research. Decisions about the inclusion of a research recommendation were based on factors such as:

- the importance to patients or the population
- national priorities
- potential impact on the NHS and future NICE guidance
- ethical and technical feasibility.

4.5.3 Validation process

This guidance is subject to a 6-week public consultation and feedback as part of the quality assurance and peer review of the document. All comments received from registered stakeholders are responded to in turn and posted on the NICE website.

5.3.1 Focus groups

Prison organisations are registered as stakeholders and invited to comment on the guideline during the consultation phase of development. Serving prisoners however, were identified as a group who would not have an opportunity to comment directly on the draft guideline. User organisations as identified by the NICE Patient and Public Involvement Programme and the Guideline Development Group were invited to submit a proposal to conduct focus groups on behalf of the Guideline Development Group to obtain feedback on the draft recommendations from people currently serving a prison sentence. User Voice were selected to conduct this work.

The remit for the focus groups was to include people with disabilities (including physical and learning disabilities), women, older prisoners, long and short term prisoners, and those with a history of substance misuse. These groups had been identified for special consideration within the guideline Scope. The focus groups would also include participants from different category prisons in a range of different geographical areas. Prisoners views will be gathered though facilitated group discussion and summarised into a report to be considered by the Guideline Development Group (GDG) along with other comments received though the stakeholder consultation process.

4.5.4 Updating the guideline

Following publication, and in accordance with the NICE guidelines manual, NICE will undertake a review of whether the evidence base has progressed significantly to alter the guideline recommendations and warrant an update.

4.5.5 Disclaimer

Healthcare providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources.

The National Clinical Guideline Centre disclaims any responsibility for damages arising out of the use or non-use of this guideline and the literature used in support of this guideline.

4.5.6 Funding

The National Clinical Guideline Centre was commissioned by the National Institute for Health and Care Excellence to undertake the work on this guideline.

5 Health assessment

5.1 Introduction

On reception all people entering prison (either on remand or after being sentenced) are assessed by healthcare professionals prior to being located within the prison. The health assessment undertaken in reception on entry into prison is for a health professional to explore the person's health to ensure physical and mental health issues are identified, and to ensure continuity of care (for example, continuity of medication).

Undertaking an assessment at reception is important; this could be the only opportunity for a healthcare professional to engage with each person, as they may not wish to access healthcare during their stay in prison. The health assessment enables long-term conditions, sexual health, vaccinations, substance misuse, mental health and many more health needs to be identified. It also gives the opportunity for patients to be offered health promotion advice. Some people have never been in prison before and/or they may be detoxing from a substance, which could make them more vulnerable. It is the role of the health professional at this point to address this issue as self-harm and suicides whilst in prison are at a higher rate than in the community.

In current practice the Grubin health assessment, or a variation of it, is used.[36] The Grubin health assessment has two parts. The initial assessment is a triage that takes place on reception that identifies immediate health needs to ensure mental and physical safety on the first night(s), and provides information on health services that are available and how to access these. The second health assessment is conducted within 5 days of reception to prison by a qualified nurse. This is a more comprehensive assessment that is similar to the assessment that takes place in primary care. Based on these assessments primary care staff refer people to relevant healthcare professionals and clinics (for example mental health nurse, HIV coordinator, substance misuse services). The initial assessment on reception to prison was mandated and is therefore conducted for all new receptions in prisons in the UK.[45]

5.2 Review question: What physical health assessment needs to be done at reception into prison?

For full details see review protocol in Appendix C.

Table 8: Characteristics of review question

Population	Adults (18 and over) in prisons or young offender institutions (YOIs) Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low-medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Intervention	Validated (physical) health assessment tools, triage, policies, screening protocol at reception into prison Mental health interventions will be excluded
Comparison	Other validated health assessment tools, triage, policies, screening protocol

Outcomes	Morbidity Mortality until further assessment Health-related quality of life Diagnostic accuracy data
Setting	Prisons or YOIs
Study design	Randomised controlled trials Non-randomised controlled trials If no intervention studies are included, diagnostic cohort studies (prospective and retrospective) will be considered Systematic reviews and meta-analyses of the above

5.2.1 Clinical evidence

Two studies[16,36,61] were included in the review and are summarised in Table 9. One study[36] was directly relevant. The aim of this study was to assess the accuracy of the Grubin (2002) reception screen (to be referred to as the Grubin reception assessment from here on, to avoid confusion with national population screening programmes) in identifying the physical health conditions of adults in remand prisons. The second study[16] was indirectly relevant. The aim of this study was to assess the accuracy of the comprehensive health assessment tool (CHAT) in identifying the physical health conditions of young males in YOIs (aged 15–18 years). Evidence from these studies is summarised in the clinical evidence profile below (Table 10). See also the study selection flow chart in Appendix E, study evidence tables in Appendix H and exclusion list in Appendix L.

Table 9: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Grubin 2002[36]	Intervention: Grubin reception assessment Comparison: Structured interviews, conducted 1–8 days after reception into prison, including questions on clinical history. Blood pressure, pulse, respiratory flow rate and general physical observations were also recorded.	n=150 Aged 16 years or over Male/female ratio 8:2 New on remand 6 adult male remand prisons , 2 female remand prisons, 2 YOIs England	• Sensitivity • Specificity • Positive predictive value (PPV) • Negative predictive value (NPV)	Indirect population: aged 16 years or over
Chitsabensan 2014[16]	Intervention: comprehensive health assessment tool (CHAT) completed by nurse Comparison: Routine clinical history and physical health exam by	n=127 Aged 15-18 Male/female ratio 1:0 New on remand or	• Sensitivity • Specificity • PPV • NPV	Indirect population: aged 15-18

Study	Intervention and comparison	Population	Outcomes	Comments
	GP	sentenced 1 YOI England		

Table 10: Clinical evidence profile: accuracy of tools for health assessment at reception

Index Test	No of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity %	Specificity %	Quality
Grubin reception assessment	1	150	Serious risk of bias[a]	No inconsistency	Serious indirectness [b]	Not applicable	95% (CI not reported)	73% (CI not reported)	VERY LOW
CHAT	1	127	Serious risk of bias[a]	No inconsistency	Serious indirectness [b]	Not applicable	64% (CI not reported)	59% (CI not reported)	VERY LOW

(a) Risk of bias was assessed using the QUADAS-2 checklist.
(b) Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.

5.2.2 Economic evidence

5.2.2.1 Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

5.2.2.2 Original economic analysis

Original analysis was undertaken to consider the cost-effectiveness of the reception assessment being conducted by a specified member of healthcare staff (a registered nurse compared to a healthcare assistant). The ultimate aim was to determine whether the extra benefit of having the assessment conducted by a member of staff who was more experienced and trained to a higher level, in terms of better health outcomes for people in prisons, is large enough to justify the extra cost of a nurse's time.

The analysis included 3 physical health conditions (asthma, ischemic heart disease, epilepsy) and, under GDG request, one major mental health event (suicides). Due to a lack in available evidence, numerous assumptions had to be made over some input variables. Specifically for suicides, 3 scenarios were tested on a range of preventable suicide figures. The full analysis can be found in Appendix N.

5.2.2.2.1 Summary of results

Reception appointments with nurses were not cost-effective at a £20,000 threshold when only one condition/event was considered. In these scenarios, ICERs were ranging between £22,207 and £1,208,116 per QALY gained, with the 30% preventable suicides scenario delivering the lowest figure.

When all 4 conditions/events were taken into account, ICERs ranged from £13,846 to £31,108 depending on the assumed suicide scenario. Out of the 3 scenarios only the "30% preventable suicides" assumption delivered an ICER under the pre-specified £20,000 per QALY gained threshold.

Table 11: Total QALY gain (for 4 conditions/events) and ICER per preventable suicides scenario

	Total QALY gain	ICER (£)
Scenario 1 – 30% preventable suicides	0.000,793	13,846
Scenario 2 – 20% preventable suicides	0.000,518	21,198
Scenario 3 – 10% preventable suicides	0.000,353	31,108

In addition, a threshold scenario sub-analysis which was also conducted specified that only under extreme parameter values a nurse appointment was considered cost-effective at the £20,000 per QALY gained threshold.

Complementary sensitivity analysis for suicides using a lower QoL figure increased the overall ICER (including the 4 conditions/events) from £13,846 to £18,738.

5.2.3 Evidence statements

Clinical

- One very low quality prospective diagnostic cohort study with 150 adults showed that the Grubin reception assessment has a sensitivity of 95% and a specificity of 73%.
- One very low quality prospective diagnostic cohort study with 127 young males showed that the Comprehensive Health Assessment Tool (CHAT) has a sensitivity of 64% and a specificity of 59%.

Economic

- One original economic analysis that compared nurses to healthcare assistants when conducting a first-stage health assessment at reception to prison found that at a cost-effectiveness threshold of £20,000 per QALY gained:
  - The choice of a nurse to conduct the assessment was not cost-effective compared to a HCA when asthma, angina, epilepsy and suicides were each considered individually.
  - The choice of a nurse to conduct the assessment was not cost-effective compared to a HCA when the effect of the 4 health conditions was combined, when the proportion of suicides prevented was up to 20%.
  - The choice of a nurse to conduct the assessment could be cost-effective compared to a HCA when the effect of the 4 health conditions were combined, when the proportion of suicides prevented was 30%, given other assumptions.

  This analysis was assessed as directly applicable with potentially serious limitations.

5.2.4 Recommendations and link to evidence

See section 5.8 below.

<Questions completed by the mental health of adults in contact with the criminal justice system guideline>

5.3 Review question: What are the most appropriate tools for the recognition of mental health problems, or what modifications are needed to recognition tools recommended in existing NICE guidance, for adults:

- **in contact with the police?**
- **in police custody?**
- **for the court process?**
- **at reception into prison?**
- **at subsequent time points in prison?**
- **in the community (serving a community sentence, released from prison on licence or released from prison and in contact with a community rehabilitation company [CRC] or the probation service)?**

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 12 . A complete list of review questions and full review protocols can be found in Appendix R; further information about the search strategy can be found in Appendix R.

Table 12: Clinical review protocol summary for the review of the most appropriate tools for the recognition of mental health problems

Component	Description
Review question	RQ 2.1: What are the most appropriate tools for the recognition of mental health problems, or what modifications are needed to recognition tools recommended in existing NICE guidance, for adults: in contact with the police? in police custody? for the court process? at reception into prison? at subsequent time points in prison? in the community (serving a community sentence, released from prison on licence or released from prison and in contact with a community rehabilitation company [CRC] or the probation service)?
Population	Adults (aged 18 and over) with, or at risk of developing, a mental health problem who are in contact with the criminal justice system
Intervention(s)	Any formal recognition and assessment tools considered appropriate and suitable for use
Comparison	Diagnosis Statistical Manual (DSM) or International Classification of Diseases (ICD) diagnosis
Critical outcomes	Sensitivity: the proportion of true positives of all cases diagnosed with the target condition in the population Specificity: the proportion of true negatives of all cases not-diagnosed with the target condition in the population

Component	Description
	Reliability (for instance, inter-rater or test-retest reliability or internal consistency) Validity (for instance, criterion or construct validity)
Study design	Systematic reviews of diagnostic test accuracy studies, diagnostic cross-sectional studies (including cohort studies, case-control studies and nested case-control studies)

15.3.1 Clinical evidence

Scanning titles or abstracts identified 954 articles potentially relevant to the above review questions.

The GDG agreed that for a tool to be considered appropriate and suitable for use for recognition it should: 1) have ≤28 items, 2) take ≤5 minutes to administer, 3) be able to be completed by a non-expert, and 4) be free to use where possible. Further, the decision was made to only review tools targeting disorders covered by existing NICE guidance if there was a substantial evidence base for tools for such disorders in the criminal justice system or when assessed by criminal justice specific tools that intend to assess multiple mental health issues. This decision was made for two reasons: 1) referring into existing guidance for specific disorders would provide a stronger evidence base than the limited number of studies for a given disorder in the criminal justice system, and 2) it was considered more practical to recommend a tool that was applicable to multiple mental health problems than recommending the use of multiple tools that are disorder specific.

After further inspection of the full articles, 926 studies did not meet one or more eligibility criteria outlined above. An additional seven studies forwarded by stakeholders, three studies identified by handsearching, and one study identified by another literature search for this guideline also did not meet the inclusion criteria. The most common reasons for exclusion were that: there was no appropriate gold standard, the population was not relevant (individuals cared for in hospital, not in contact with the criminal justice system, or aged under 18 years), or sensitivity and specificity were not presented (or sufficient information to allow for their calculation). This resulted in 10 articles representing 11 studies that were included for this review question, one study that was included for review question 5.4.

There were two additional studies [59,60] forwarded by stakeholder met the inclusion criteria resulting in a total of 12 articles, representing 13 studies, that provided sufficient data to be included in the evidence synthesis for this review question: [5,29,30,39,54,59,60,141,142,150,151,153].

All studies were published in peer-reviewed journals between 1989 and 2015. Of these eligible studies, five reported on the Brief Jail Mental Health Screen BJMHS; [151] or the revised version of the BJMHS BJMHS-R; [150], four reported on the Referral Decision Scale RDS; [153] or its subscales, two reported on the Co-occurring Disorders Screening Instrument for Mental Disorders CODSI-MD; [141], two reported on the Co-occurring Disorders Screening Instrument for Severe Mental Disorders CODSI-SMD; [141], two reported on the Correctional Mental Health Screens for Men CMHS-M; [29] and Women CMHS-W; [29], two reported on the HELP-PC [59] and two reported on the Custody Risk Assessment Form [5]. Characteristics of these recognition tools can be found in Table 13.

Further information about both included and excluded studies can be found in Appendix R. A summary of the methodological quality of the studies is presented in Table 14 and the full methodological checklists can be found in Appendix R. If data was presented in sufficient detail for analysis, the data are presented using forest plots and summary ROC curves in Appendix R.

Table 13: Characteristics of tools included in the review of the most appropriate tools for the recognition of mental health problems

Tool	Target disorder	Intended population/setting	Scale information	Recommended cut-off	Format	Administration & qualifications	Cost/restrictions
BJMHS/ BJMHS-R	Serious mental illness	Prison	BJMHS: 8 items BJMHS-R: 12 items	≥2 from section 1 or ≥1 from section 2	Questionnaire administered by staff	Administration time: 2-3 minutes Administered by criminal justice service professionals following training.	Freely available from: http://www.prainc.com/wp-content/uploads/2015/10/bjmhsform.pdf
CODSI-MD/ CODSI-SMD	CODSI-MD: general mental health CODSI-SMD: serious mental illness	Prison substance abuse treatment programs	CODSI-MD: 6 items CODSI-SMD: 3 items	CODSI-MD: ≥3 CODSI-SMD: ≥2	Questionnaire administered by staff	Administration time: Unclear as they have only been administered as part of a test battery No specialist training required	Freely available from: http://www.ndri.org/manuals-and-instruments.html
CMHS-M	General mental health	Prison	12 items	≥6	Questionnaire administered by staff	Administration time: 3-5 minutes Administered by criminal justice or healthcare staff	Freely available from: http://www.asca.net
CMHS-W	General mental health	Prison	8 items	≥5	Questionnaire administered by staff	Administration time: 3-5 minutes Administered by criminal justice or healthcare staff	Freely available from: http://www.asca.net
Custody Risk Assessment	Risk	Police custody	Total number of items NR	≥1	Completed by police officer	Administration time: unclear	Unclear. Appears to be a local form used by

Tool	Target disorder	Intended population/setting	Scale information	Recommended cut-off	Format	Administration & qualifications	Cost/restrictions
Form			Depressed/ suicidal: 1 item Mental illness: 1 item				one police station.
HELP-PC	General mental health and learning disabilities	Police custody	Embedded in wider assessment Mental health subscale: number of items not reported Learning disabilities subscale: 4 items (3 questions and 1 observation)	≥1	Interview and observation	Administration time: Median time by end of pilot 7.75 minutes Administered by custody officers. Details of training not reported.	Does not appear to be available outside of the London MET Police
RDS	Serious mental illness (Depression, bipolar, schizophrenia)	Prison	Total: 14 items[a] Bipolar subscale: 5 items Depression subscale: 5 items	≥2 on depression or schizophrenia subscales, or ≥3 on bipolar subscale	Questionnaire administered by staff	Administration time: 5 minutes Training: may be used by laypersons but reliability/validity are only assured if users receive extensive training	Unclear

Tool	Target disorder	Intended population/setting	Scale information	Recommended cut-off	Format	Administration & qualifications	Cost/restrictions
			Schizophrenia subscale: 5 items				

Note.
a One item contributes to both the depression and bipolar subscales.

1

1 **Table 14: Quality assessment of studies included in the review of the most appropriate tools for the recognition of mental health problems**

Study ID	Index test	Risk of bias				Applicability concerns		
		Participant selection	Index test	Reference standard	Flow and timing	Participant selection	Index test	Reference standard
Baksheev 2012	BJMHS/BJMHS-R, Custody Risk Assessment Form	Unclear	Higha Unclear[b]	Higha Unclear[b]	Low	Low	Low	Low
Ford 2007	BJMHS/BJMHS-R, CMHS-M, CMHS-W, RDS	Low	Unclear	Low	High	Low	Low	Low
Ford 2009	CMHS-M, CMHS-W	High	Unclear	Low	High	Low	Low	Low
Harrison 2007	RDS	High	Unclear	Low	Low	Low	Low	Low
Louden 2013	BJMHS/BJMHS-R	Unclear	Low	Unclear	High	Low	Low	Low
McKinnon 2014	HELP-PC	Low	Unclear	Unclear	High	Low	Low	Low
McKinnon 2015	HELP-PC	Unclear	Unclear	Unclear	Unclear	Low	Low	Low
Sacks 2007a	CODSI	Unclear	Unclear	Low	High	Low	Unclear	Low
Sacks 2007b	CODSI	Unclear	Low	Low	High	Low	Unclear	Low
Steadman 2005	BJMHS/BJMHS-R	Unclear	Unclear	Low	High	Low	Low	Low
Steadman 2007	BJMHS/BJMHS-R	Unclear	Unclear	Low	High	Low	Low	Low
Teplin 1989a	RDS	Low	High	Unclear	Unclear	Low	Unclear	Low
Teplin 1989b	RDS	Unclear	Unclear	Unclear	Unclear	Low	Unclear	Low
Grubin 2002								
Evans 2010								

Note.
a BJMHS/BJMHS-R; b Custody Risk Assessment Form

2

5.3.1.1 Tools without acceptable sensitivity and specificity

Due to the number of identified tools and reported cut-off points, the GC agreed to only review tools and cut-off points with acceptable sensitivity and specificity, which was determine by a relatively conservative threshold of ≥0.70 for both values.

Therefore, evidence relating to the following tools was not considered by the GC: Brief Jail Mental Health Screen (BJMHS)/Brief Jail Mental Health Screen - Revised (BJMHS-R), Co-occurring Disorders Screening Instruments (CODSI) and Custody Risk Assessment Form. An overview of the studies examining these tools can be found in Table 15.

Table 15: Study information table for the review of the most appropriate tools for the recognition of mental health problems – studies not presented to the GC

	BJMHS/BJMHS-R	CODSI	Custody Risk Assessment Form
Total no. of studies (N)	5 (1422)	2 (280)	1 (150)
Study ID	(1) Baksheev 2012 (2) Ford 2007 (3) Louden 2013 (4) Steadman 2005 (5) Steadman 2007	(1) Sacks 2007a (2) Sacks 2007b	(1) Baksheev 2012
Country	(1) Australia (2 – 5) USA	(1, 2) USA	(1) Australia
Target Condition(s)	(1, 4, 5) Serious mental illness (1, 3) Axis-I disorder (Exc. Substance misuse) (2) Affective disorder, (2) Anxiety disorder (2) Axis-I disorder (2) Axis-I or Axis-II disorder	(1, 2) General mental health (1, 2) Serious mental illness	(1) Serious mental illness (1) Axis-I disorder (Exc. Substance misuse)
Reference Standard(s)	(1 – 5) DSM-IV	(1, 2) DSM-IV	(1) DSM-IV
Setting	(1) Police custody (2, 4, 5) Reception into prison (3) Community	(1, 2) Subsequent time points in prison	(1) Police custody
Age (mean)	(1) 30 (2, 5) Not reported (3) 34 (4) 32	(1) Not reported (2) 35	(1) 30
Sex (% female)	(1) 9 (2, 3) 33 (4) 41 (5) 56	(1) 25 (2) 41	(1) 9
Ethnicity (% Caucasian)	(1) 81 (2) 43 (3) 39 (4, 5) Not reported	(1) Not reported (2) 52	(1) 81

	BJMHS/BJMHS-R	CODSI	Custody Risk Assessment Form
Note. N = total number of participants			

1

5.311.1.1 Depression

Three studies examined the sensitivity and specificity of recognition tools for depression (N = 1249) [39,59,153]. An overview of the trials included in this review can be found in Table 16. Summary of findings can be found in **Error! Reference source not found.**.

Table 16: Study information table for the review of the most appropriate tools for the recognition of mental health problems – depression

	HELP-PC	RDS: Depression subscale
Total no. of studies (N)	1 (323)	2 (926)
Study ID	(1) McKinnon 2014	(1) Harrison 2007 (2) Teplin 1989a
Country	(1) UK	(1, 2) USA
Reference Standard(s)	(1) Unclear	(1) DSM-IV (2) DSM-III
Setting	(1) Police custody	(1) Subsequent time points in prison (2) Reception into prison
Age (mean)	(1) 32	(1) 34 (2) 25
Sex (% female)	(1) 10	(1, 2) 0
Ethnicity (% Caucasian)	(1) 57	(1) Not reported (2) 12
Note. N = total number of participants		

Table 17: Clinical evidence profile: RDS and HELP-PC Depression subscale compared with DSM IV/III criteria – Depression

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test									
HELP-PC (not reported)	1	323	Serious[a]	No inconsistency	Serious[b]	Not applicable	75% (55-89)	80% (75-84)	LOW
RDS: Depression subscale at 2	2	828	Serious[a]	Serious inconsistency	Serious[b]	Very Serious	86% (34-99)[c]	77% (2-100)[c]	VERY LOW

a) *Risk of bias was assessed using the QUADAS-2 checklist.*
b) *Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.*
c) *Compared with DSM-III criteria, the sensitivity and specificity were 92% (95%CI: 78-98) and 98% (95%CI: 97-99) whereas compared with DSM-IV criteria, the sensitivity and specificity were 85%(95%CI: 55-98) and 49% (95%CI: 39-60).*

5.311.1.2 Bipolar disorder

One study examined the sensitivity and specificity of recognition tools for bipolar disorder (N = 728) [153].

An overview of this trial can be found in Table 18. Summary of findings can be found in **Error! Reference source not found.**.

Table 18: Study information table for the review of the most appropriate tools for the recognition of mental health problems – bipolar disorder

	RDS: Bipolar subscale
Total no. of studies (N)	1 (728)
Study ID	(1) Teplin 1989a
Country	(1) USA
Reference Standard(s)	(1) DSM-III
Setting	(1) Reception into prison
Age (mean)	(1) 25
Sex (% female)	(1) 0
Ethnicity (% Caucasian)	(1)12
Note. N = total number of participants	

Table 19: Clinical evidence profile: RDS-Bipolar subscale compared with DSM III criteria – Bipolar disorder

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test									
RDS: Bipolar subscale (1)	1	728	Serious[a]	No inconsistency	Serious[b]	Not applicable	100% (86-100)	87% (84-89)	LOW
RDS: Bipolar subscale (2)	1	728	Serious[a]	No inconsistency	Serious[b]	Not applicable	92% (73-99)	98% (97-99)	LOW
RDS: Bipolar subscale (3)	1	728	Serious[a]	No inconsistency	Serious[b]	Not applicable	83% (63-95)	100% (99-100)	LOW

a) *Risk of bias was assessed using the QUADAS-2 checklist.*
b) *Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.*

5.3.1.3 Affective disorder

One study examined the sensitivity and specificity of recognition tools for affective disorder (N = 302)[29].

An overview of this trial can be found in Table 20. Summary of findings can be found in **Error! Reference source not found.**.

Table 20: Study information table for the review of the most appropriate tools for the recognition of mental health problems – affective disorder

	CMHS-M	CMHS-W
Total no. of studies (N)	1 (302)	1 (302)
Study ID	(1) Ford 2007	(1) Ford 2007
Country	(1) USA	(1) USA
Reference Standard(s)	(1) DSM-IV	(1) DSM-IV
Setting	(1) Reception into prison	(1) Reception into prison
Age (mean)	(1) Not reported	(1) Not reported
Sex (% female)	(1) 33	(1) 33
Ethnicity (% Caucasian)	(1) 43	(1) 43
Note. N = total number of participants		

Table 21: Clinical evidence profile: CMHS compared with DSM-IV criteria for affective disorder

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test									
CMHS-M(All men) at 7	1	201	Serious[a]	No inconsistency	Serious[b]	Not applicable	83% (63-95)	73% (66-79)	LOW
CMHS-M(Caucasian men) at 7	1	98	Serious[a]	No inconsistency	Serious[b]	Not applicable	94% (73-100)	78% (67-86)	LOW

CMHS-M (Black men) at 7	1	69	Serious[a]	No inconsistency	Serious[b]	Not applicable	100% (29-100)	70% (57-80)	LOW
CMHS-W at 5	1	100	Serious[a]	No inconsistency	Serious[b]	Not applicable	73% (54-87)	70% (58-81)	LOW

a) Risk of bias was assessed using the QUADAS-2 checklist.
b) Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.

5.3.1.4 Learning disabilities

One study examined the sensitivity and specificity of recognition tools for learning disabilities (N = 351): [60].

An overview of this trial can be found in Table 22. Summary of findings can be found in **Error! Reference source not found.**.

Table 22: Table 11: Study information table for the review of the most appropriate tools for the recognition of mental health problems – learning disabilities

	HELP-PC
Total no. of studies (N)	1 (351)
Study ID	(1) McKinnon 2015
Country	(1) UK
Reference Standard(s)	(1) Unclear
Setting	(1) Police custody
Age (mean)	(1) Not reported
Sex (% female)	(1) Not reported
Ethnicity (% Caucasian)	(1) Not reported
Note. N = total number of participants	

Table 23: Clinical evidence profile: HELP-PC scale (unclear reference standard) for learning disabilities

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test									
HELP-PC	1	351	Serious[a]	No inconsistency	Serious[b]	Not applicable	83% (36-100)	88% (84-91)	LOW

a) *Risk of bias was assessed using the QUADAS-2 checklist.*
b) *Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.*

5.3.61.1.5 Schizophrenia

One study examined the sensitivity and specificity of recognition tools for schizophrenia (N = 728) [153].

An overview of this trial can be found in Table 24. Summary of findings can be found in **Error! Reference source not found.**.

Table 24: Study information table for the review of the most appropriate tools for the recognition of mental health problems – schizophrenia

	RDS: Schizophrenia subscale
Total no. of studies (N)	1 (728)
Study ID	(1) Teplin 1989a
Country	(1) USA
Reference Standard(s)	(1) DSM-III
Setting	(1) Reception into prison
Age (mean)	(1) 25
Sex (% female)	(1) 0
Ethnicity (% Caucasian)	(1)12
Note. N = total number of participants	

Table 25: Clinical evidence profile: RDS-Schizophrenia subscale compared with DSM-III criteria for Schizophrenia

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test									
RDS: Schizophrenia subscale at 1	1	728	Serious[a]	No inconsistency	Serious[b]	Not applicable	88% (68-97)	96% (94-97)	LOW

a) *Risk of bias was assessed using the QUADAS-2 checklist.*
b) *Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.*

5.311.1.6 Psychosis

One study examined the sensitivity and specificity of recognition tools for psychosis (N = 323)[59].

An overview of this trial can be found in Table 26. Summary of findings can be found in

Table 27: Clinical evidence profile: HELP-PC (unclear reference standard) for Psychosis

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test									
HELP-PC (not reported)	1	323	Serious[a]	No inconsistency	Serious[b]	Not applicable	93% (76-99)	81% (76-86)	LOW

a) Risk of bias was assessed using the QUADAS-2 checklist.
b) Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.

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Table 26: Table 15: Study information table for the review of the most appropriate tools for the recognition of mental health problems – psychosis

	HELP-PC
Total no. of studies (N)	1 (323)
Study ID	(1) McKinnon 2014
Country	(1) UK
Reference Standard(s)	(1) Unclear
Setting	(1) Police custody
Age (mean)	(1) 32
Sex (% female)	(1) 10
Ethnicity (% Caucasian)	(1) 57
Note. N = total number of participants	

Table 27: Clinical evidence profile: HELP-PC (unclear reference standard) for Psychosis

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test									
HELP-PC (not reported)	1	323	Serious[a]	No inconsistency	Serious[b]	Not applicable	93% (76-99)	81% (76-86)	LOW

c) Risk of bias was assessed using the QUADAS-2 checklist.
d) Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.

5.3.1.7 Axis-I or Axis-II disorder

Two studies examined the sensitivity and specificity of recognition tools for Axis-I or Axis-II disorder (N = 508)[29,30].

An overview of this trial can be found in Table 28. Summary of findings can be found in Table 29.

Table 28: Study information table for the review of the most appropriate tools for the recognition of mental health problems – Axis-I or Axis-II disorder

	CMHS-M	CMHS-W	RDS
Total no. of studies (N)	2 (508)	1 (206)	1 (302)
Study ID	(1) Ford 2007 (2) Ford 2009	(1) Ford 2009	(1) Ford 2007
Country	(1, 2) USA	(1) USA	(1) USA
Reference Standard(s)	(1, 2) DSM-IV	(1) DSM-IV	(1) DSM-IV
Setting	(1, 2) Reception into prison	(1) Reception into prison	(1) Reception into prison
Age (mean)	(1, 2) Not reported	(1) Not reported	(1) Not reported
Sex (% female)	(1) 33 (2) 49	(1) 49	(1) 33
Ethnicity (% Caucasian)	(1) 43 (2) Not reported	(1) Not reported	(1) 43
Note. N = total number of participants			

Table 29: Clinical evidence profile: CMHS or RDS compared with DSM-IV criteria for Axis-I or Axis-II disorder

a) Risk of bias was assessed using the QUADAS-2 checklist.
b) Indirectness was assessed using the QUADAS-2 checklist items referring to applicability

Index test (Threshold)	Disease condition	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test										
CMHS-M(All men) at 5	Axis-I or Axis-II disorder, excluding ASPD	1	106	Serious[a]	No inconsistency	Serious[b]	Not applicable	80% (66-91)	78% (66-88)	LOW
CMHS-M(All men) at 6	Axis-I or Axis-II disorder, excluding ASPD	2	307	Serious[a]	Serious	Serious[b]	Serious	69% (17-96)	76% (26-98)	VERY LOW
CMHS-M(Caucasian men) at 6	Axis-I or Axis-II disorder, excluding ASPD	1	97	Serious[a]	No inconsistency	Serious[b]	Not applicable	82% (65-93)	78% (66-87)	LOW
CMHS-M (Black men) at 6	Axis-I or Axis-II disorder, excluding ASPD	1	69	Serious[a]	No inconsistency	Serious[b]	Not applicable	80% (56-94)	71% (57-83)	LOW
CMHS-W at 4	Axis-I or Axis-II disorder	1	100	Serious[a]	No inconsistency	Serious[b]	Not applicable	75% (63-85)	84% (67-95)	LOW
CMHS-W at 4	Axis-I or Axis-II disorder, excluding ASPD	1	100	Serious[a]	No inconsistency	Serious[b]	Not applicable	74% (61-84)	72% (55-85)	LOW
RDS at 3	Axis-I or Axis-II disorder, excluding ASPD	1	27	Serious[a]	No inconsistency	Serious[b]	Not applicable	73% (45-92)	83% (52-98)	LOW

5.3.1.1.8 Serious Mental Illness

One study examined the sensitivity and specificity of recognition tools for Serious Mental Illness (N = 1149)[59].

An overview of this trial can be found in Table 30. Summary of findings can be found in

Table 27: Clinical evidence profile: HELP-PC (unclear reference standard) for Psychosis

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality
Index test									
HELP-PC (not reported)	1	323	Serious[a]	No inconsistency	Serious[b]	Not applicable	93% (76-99)	81% (76-86)	LOW

e) Risk of bias was assessed using the QUADAS-2 checklist.
f) Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.

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Table 30 Study information table for the review of the most appropriate tools for the recognition of mental health problems – severe mental illness

	RDS
Total no. of studies (N)	1 (1149)
Study ID	(1) Teplin 1989b
Country	(1) US
Reference Standard(s)	(1) DSM III
Setting	(1) Prison
Age (mean)	(1) 27.2
Sex (% female)	(1) NR
Ethnicity (% Caucasian)	(1) 45
Note. N = total number of participants	

Table 31 Clinical Evidence profile: RDS compared with DSM III criteria for severe mental illness

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality of the evidence (GRADE)

Index test									
RDS at (schizophrenia subscale at 2) (Depression subscale at 2) (Bipolar subscale at 3)	1	1149	Serious[a]	No inconsistency	Serious[b]	Not applicable	79%[c]	99%[c]	LOW

a) *Risk of bias was assessed using the QUADAS-2 checklist.*
b) *Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.*
c) *There was insufficient presentation of results.*

5.3.2 Current prison reception health assessment

There were no studies that met our inclusion criteria that examined the prison reception health assessment developed by Grubin et al.[36] As this tool has been widely adopted in UK prisons, the GC decided that it was important to review evidence regarding its sensitivity and specificity to provide some context in which to interpret the performance of the included recognition tools.

Therefore, two studies identified by the search strategy described above, but that did not meet our inclusion criteria, were presented to the GC (N = 1442). [26,36] These studies were both excluded because they did not use an appropriate reference standard; further, [26] weighted sensitivity and specificity and therefore the results could not be included in the analysis.

An overview of these trials can be found in Table 32. Clinical evidence profile can be found in **Error! Reference source not found.**.

Table 32: Study information table for the review of the most appropriate tools for the recognition of mental health problems – current prison reception health assessment

	Prison reception health assessment
Total no. of studies (N)	2 (1442)
Study ID	(1) Evans 2010 (2) Grubin 2002
Country	(1) New Zealand (2) UK
Reference Standard(s)	(1) MINI (2) SADS-L
Setting	(1, 2) Reception into prison
Age (mean)	(1, 2) Not reported
Sex (% female)	(1) 0 (2) 20
Ethnicity (% Caucasian)	(1, 2) Not reported
Note. N = total number of participants	

Table 33: Clinical evidence profile: Prison reception health screen compared with MINI or SADS-L for mental health disorders

Index test (Threshold)	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (95% CI)	Specificity % (95% CI)	Quality of the evidence (GRADE)
Index test									
Prison reception health screen at 1	2	680	Serious[a]	Serious	Serious[b]	Serious	42-97%	75-83%	LOW

a) Risk of bias was assessed using the QUADAS-2 checklist.
b) Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.

5.3.3 Economic evidence

Published literature

No economic evidence on the tools for the recognition of mental health problems for adults who are in contact with the criminal justice system was identified by the systematic search of the economic literature undertaken for this guideline.

5.3.4 Evidence statements

Clinical

Depression

- There was very low quality evidence from two studies (n=828) that the RDS: Depression Subscale with a cut-off of 2 has sensitivity of 86(95%CI: 34-99) %and specificity of 77(95%CI: 2-100)% for the recognition of depression.
- There was low quality evidence from one study (n=323) that the HELP-PC (cut-off not reported) has sensitivity of 75(95%CI 55-89)% and specificity of 80(95%CI: 75-84)% for the recognition of depression.

Bipolar disorder

- There was low quality evidence from one study (n=728) that the RDS: Bipolar Subscale with a cut-off of 1 has sensitivity of 100(95%CI: 86-100) %and specificity of 87(95%CI: 84-89)%for the recognition of bipolar disorder.
- There was low quality evidence from one study (n=728) that the RDS: Bipolar Subscale with a cut-off of 2 has sensitivity of 92(95%CI: 73-99) %and specificity of 98(95%CI: 97-99)%for the recognition of bipolar disorder.

- There was low quality evidence from one study (n=728) that the RDS: Bipolar Subscale with a cut-off of 3 has sensitivity of 83 (95%CI: 63-95) %and specificity of 100(95%CI: 99-100)%for the recognition of bipolar disorder.

Affective disorder

- There was low quality evidence from one study (n=201) that the CMHS-M with a cut-off of 7 has sensitivity of 83 (95%CI: 63-95) %and specificity of 73(95%CI: 66-79)% for the recognition of affective disorders. The subgroup analyses indicated that the tool can detect affective disorders among Caucasian men with sensitivity of 94(95%CI: 73-100)% and specificity of 78(95%CI: 67-86)% whereas among Black men with sensitivity of 100(95%CI 29-100)% and specificity of 70 (95% CI: 57-80)%.
- There was low quality evidence from one study (n=100) that the CMHS-W with a cut-off of 5 has sensitivity of 73 (95%CI: 54-87) % and specificity of 70 (95%CI: 58-81) % for the recognition of affective disorders.

Learning disabilities

- There was low quality evidence from one study (n=351) that the HELP-PC with a cut-off of 1 has sensitivity of 83(95%CI: 36-100) % and specificity of 88(95%CI: 84-91) % for the recognition of learning disabilities.

Schizophrenia

- There was low quality evidence from one study (n=728) that the RDS: Schizophrenia Subscale with a cut off of 1 has sensitivity of 88(95%CI: 68-97) % and specificity of 96(95%CI: 94-97)% for the recognition of schizophrenia.

Psychosis

- There was low quality evidence from one study (n=323) that the HELP-PC (cut-off not reported) has sensitivity of 93(95%CI: 76-99) % and specificity of 81(95%CI: 76-86)% for the recognition of psychosis.

Axis-I or Axis-II disorder

- There was low quality evidence from one study (n=100) that the CMHS-W with a cut-off of 4 has sensitivity of 74(95%CI: 61-84)% and specificity of 84(95%CI: 67-95)% for the recognition of Axis-I or Axis-II disorders.
- There was very low quality evidence from two studies (n=307) that the CMHS-M with a cut-off of 6 has sensitivity of 69(95%CI: 17-96)% and specificity of 76(95%CI: 26-98)% for the recognition of Axis-I or Axis-II disorders, excluding Anti-Social Personality Disorder (ASPD). The subgroup analyses indicated that the tool can detect the disorders among Caucasian men with sensitivity of 82(95%CI: 65-93)% and specificity of 78(95%CI: 66-87)% whereas among Black men with sensitivity of 80(95%CI 56-94)% and specificity of 71 (95% CI: 57-83)%.
- There was low quality evidence from one study (n=100) that the CMHS-W with a cut-off of 4 has sensitivity of 74(95%CI: 61-84)% and specificity of 72(95%CI: 55-85)% for the recognition of Axis-I or Axis-II disorders, excluding ASPD.
- There was low quality evidence from one study (n=27) that the RDS with a cut off of 3 has sensitivity of 73(95%CI: 45-92)% and specificity of 83(95%CI: 52-98)% for the recognition of Axis-I or Axis-II disorders, excluding ASPD.

Serious mental illness

- There was low quality evidence from one study (n=1149) that the RDS with a cut-off of 2 on the schizophrenia subscale, 2 on the depression subscale, or 3 on the bipolar subscale has sensitivity of 79% and specificity of 99% for the recognition of serious mental illness.

- There was low quality evidence from two studies (n=680) that the current prison reception health screen with a cut-off of 1 has sensitivity of 42-97% and specificity of 75-83% for the recognition of mental health disorders.

Economic

- No economic evidence on tools for the recognition of mental health problems for adults who are in contact with the criminal justice system is available.

5.3.5 Recommendations and link to evidence

Please see section 5.8 below.

5.4 Review question: What are the most appropriate tools to support or assist in the assessment of mental health problems, or what modifications are needed to assessment tools recommended in existing NICE guidance, for adults:

- **in contact with the police?**
- **in police custody?**
- **for the court process?**
- **at reception into prison?**
- **at subsequent time points in prison?**
- **in the community (serving a community sentence, released from prison on licence or released from prison and in contact with a community rehabilitation company [CRC] or the probation service)?**

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 34. A complete list of review questions and full review protocols can be found in Appendix R; further information about the search strategy can be found in Appendix R.

Table 34: Clinical review protocol summary for the review of the most appropriate tools for the assessment of mental health problems

Component	Description
Review question	RQ 2.2: What are the most appropriate tools to support or assist in the assessment of mental health problems, or what modifications are needed to assessment tools recommended in existing NICE guidance, for adults: in contact with the police? in police custody? for the court process? at reception into prison? at subsequent time points in prison?

Component	Description
	in the community (serving a community sentence, released from prison on licence or released from prison and in contact with a community rehabilitation company [CRC] or the probation service)?
Population	Adults (aged 18 and over) with, or at risk of developing, a mental health problem who are in contact with the criminal justice system
Intervention(s)	Any formal recognition and assessment tools considered appropriate and suitable for use
Comparison	Diagnosis Statistical Manual (DSM) or International Classification of Diseases (ICD) diagnosis
Critical outcomes	Sensitivity: the proportion of true positives of all cases diagnosed with the target condition in the population Specificity: the proportion of true negatives of all cases not-diagnosed with the target condition in the population Reliability (for instance, inter-rater or test-retest reliability or internal consistency) Validity (for instance, criterion or construct validity)
Study design	Systematic reviews of diagnostic test accuracy studies, diagnostic cross-sectional studies (including cohort studies, case-control studies and nested case-control studies)

5.4.1 Clinical evidence

There was only one study that that provided sufficient data to be included in the evidence synthesis for this review question .[67]

The study was published in a peer-reviewed journal and reported on the Severe Sexual Sadism Scale (SSSS; [122]). Characteristics of this tool can be found in Table 35 and a summary of the study's methodological quality in Table 36.

The SSSS did not have acceptable sensitivity and specificity; therefore, the above study was not considered by the GC. An overview of this study can be found in Table 37.

Table 35: Characteristics of the tools included in the review of the most appropriate tools for the assessment of mental health problems

Tool	Target disorder	Intended population/setting	Scale information	Recommended cut-off	Format	Administration & qualifications	Cost/restrictions
SSSS	Sexual sadism	Prison & inpatient	11 items	≥4 but ≥3 of these should be from 'core criteria'	File-based assessment	Coding completed by forensic psychologist in development and validation studies	Unclear

Table 36: Quality assessment of studies included in the review of the most appropriate tools for the assessment of mental health problems

		Risk of bias				Applicability concerns		
Study ID	Index test	Participant selection	Index test	Reference standard	Flow and timing	Participant selection	Index test	Reference standard
Mokros 2012	SSSS	Low	Unclear	Unclear	Unclear	Low	Low	Low

Table 37: Study information table for the review of the most appropriate tools for the assessment of mental health problems

	SSSS
Total no. of studies (N)	1 (105)
Study ID	(1) Mokros 2012
Country	(1) Austria
Target Condition(s)	(1) Sexual Sadism
Reference Standard(s)	(1) DSM-IV-TR
Setting	(1) Prison
Age (mean)	(1) 33
Sex (% female)	(1) 0
Ethnicity (% Caucasian)	(1) Not reported
Note. N = total number of participants	

5.4.23 Economic evidence

No economic evidence on the tools for the assessment of mental health problems for adults who are in contact with the criminal justice system was identified by the systematic search of the economic literature undertaken for this guideline.

5.4.37 Evidence statements

Clinical

- There was no clinical evidence considered by the GC for this review question as the only study that met the inclusion criteria did not report any evidence for a tool with acceptable sensitivity and specificity.

Economic

- No economic evidence on the tools for the assessment of mental health problems for adults who are in contact with the criminal justice system is available.

5.4.45 Recommendations and link to evidence

See section 5.8 below.

5.5 Review question: What subsequent health assessment(s) are clinically and cost-effective in prisons?

For full details see review protocol in Appendix C.

Table 38: Characteristics of review question

Population	Adults (18 and over) in prisons or young offender institutions (YOIs). Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low-medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Intervention	Validated health assessment tools, triage, policies, screening protocols Self-reporting, tick boxes Patient history Secondary screen Second health check Transfer screen Clinical health assessment Comprehensive clinical assessment Primary healthcare screen Induction Annual health check for those not qualifying for national requirement
Comparison	Each other
Outcomes	**Critical**: Mortality. **Important**: Health-related quality of life (related to continuity of treatment/symptom management) Patient safety incidents Reduced self-harm Reduced hospital admission Delayed and omitted medicine Reduced infectious disease transmission Risk factors Referrals Self-reported satisfaction New diagnoses Diagnostic accuracy data
Study design	Randomised controlled trials Non-randomised controlled trials If no intervention reviews, diagnostic cohort studies (prospective and retrospective) will be considered

	Systematic reviews and meta-analyses of the above

5.5.11 Clinical evidence

One study was included in the review[4] and is summarised below (**Table 39**). Evidence from this study is summarised in the clinical evidence profile below (**Table 40**). See also the study selection flow chart in Appendix E, study evidence tables in Appendix H and exclusion list in Appendix L.

Table 39: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Bai 2014[4]	Intervention: Structured questionnaire administrated by trained research assistant, including questions on clinical history (undertaken at least 6 months after reception into prison) Comparison: Medical records	n=679 Aged 16 years or older, mean age 37 Male/female ratio 45:55 2 maximum security prisons (1 male and 1 female) Been in prison for at least 6 months USA	Sensitivity Specificity k coefficient	Prospective diagnostic cohort study

Table 40: Clinical evidence profile: subsequent health assessment

Index test	Number of studies	n	Risk of bias	Inconsistency	Indirectness	Imprecision	Sensitivity % (range)	Specificity % (range)	Quality
Bai structured questionnaire	1	679	Serious risk of bias[a]	No inconsistency	Serious indirectness[b]	Not applicable	50 – 86%[c] (CI not reported)	95.9 - 99.5%[c] (CI not reported)	VERY LOW

(a) Risk of selection bias. Risk of bias was assessed using the QUADAS-2 checklist.
(b) Indirect population (aged 16 or older); Indirect comparison (medical records rather than other validated health assessment tool. Indirectness was assessed using the QUADAS-2 checklist items referring to applicability.
(c) Range of sensitivity and specificity across the following conditions: HIV, diabetes, asthma, hepatitis C, hypertension, renal/kidney disease.

Related NICE guidance

The evidence identified for health assessment at reception into prison is limited, however the GDG considered other published related NICE guidance to be relevant to a prison population. 7 related NICE guidelines were identified by hand searching the NICE website and considered by the group. These look at a broad population, and as such were discussed by the GDG for applicability and relevance, taking into consideration equity of care for people in prison.

The following guidelines were identified and detailed in **Table 41**:

- CG181 Cardiovascular disease; risk assessment and reduction, including lipid modification [70]
- PH3 Sexually transmitted infections and under-18 conceptions: prevention [PH3][79]
- PH34 HIV testing: increasing uptake in men who have sex with men[85]
- PH38 Type 2 diabetes: prevention in people at high risk[110]

NG33 Tuberculosis,[100] published in January 2016, contains a section (1.6.2. NICE version) on opportunistic case finding. This section includes a specific heading of “People in prisons or immigration removal centres” and makes several recommendations including that all prisoners should be screened for TB on entry.

PH43 Hepatitis B and C testing: people at risk of infection 2012.[109] See recommendation 5 in the NICE version: Recommendation 5 Testing for hepatitis B and C in prisons and immigration removal centres. This includes recommendations on testing such as offering all prisoners access to confidential testing for hepatitis B and C when entering prison.

Table 41: Related NICE guidance: Health assessment at reception

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
CG181	Yes. Chapter 6 of the full guideline details cardiovascular disease risk assessment tools.	No. Published 2008, guideline updated 2014.	24 studies included in the review all diagnostic cohorts. Evidence ranges from low to high risk of bias. QRISK2 is derived in the UK from a large database of GP records. QRISK 2 has been externally validated in another UK population cohort Population included in studies are also representative of a prison population.	CG181 recommends using the QRISK2 risk assessment tool to assess cardiovascular disease (CVD) risk for the primary prevention of CVD in people up to and including age 84 years. The GDG considered this appropriate to use in a prison population. CG181 recommends that people older than 40 should have their estimate of cardiovascular disease risk reviewed on an ongoing basis. The GDG agreed that this recommendation was appropriate for a prison population and that, on the basis of equivalence, the same health checks for cardiovascular disease in the community should happen in prison.
PH3	No. Identify individuals at high risk of STIs using their sexual history (recommendation 1 of NICE guideline). Review question in evidence review 2 of the full guideline covers opportunistic screening for chlamydia in women and men under 25 years of age.	No. Published 2007.	Population of the guideline was men who have sex with men and people who have come from or who have visited areas of high HIV prevalence. Evidence is from 3 RCTs and 1 non randomised study (USA, Denmark, Canada) and supports the use of proactive chlamydia testing. Population is only in those under 25, but still applicable to a prison population.	PH3 makes recommendations aim to identify individuals at high risk of STIs using their sexual history. Opportunities for risk assessment may arise during consultations on contraception, pregnancy or abortion, and when carrying out a cervical smear test. Risk assessment could also be carried out during routine care or when a new patient registers. Recommendations 5 and 6 in the NICE version target those under 18 so are not applicable.
PH34	Yes. Focused on the clinical effectiveness and cost-	No. Published 2011.	Population of the guideline was men who have sex with men.	PH34 recommends that primary care providers should offer and recommend HIV testing to all

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
	effectiveness of HIV testing in men who have sex with men, see review question 1 of the full guideline.		The recommendations for HIV testing were based on 3 before and after studies (moderate to low quality). None of the studies were conducted in the UK (The Netherlands and Australia), but were considered applicable. Evidence also came from an expert report and from inference derived from the evidence. The GDG considered the population is representative of a prison population.	men who have not previously been diagnosed HIV positive and who: register with a practice in an area with a large community of men who have sex with men, or register with a practice in an area with a high HIV prevalence (high prevalence means more than two diagnosed cases per 1000 people), or disclose that they have sex with other men, or are known to have sex with men and have not had a HIV test in the previous year, or are known to have sex with men and disclose that they have changed sexual partner or disclose high risk sexual practices, or have symptoms that may indicate HIV or HIV is part of the differential diagnosis, or are diagnosed with, or request screening for, a sexually transmitted infection, or live in a high prevalence area and are undergoing blood tests for another reason. The GDG discussed the recommendations in PH34 and agreed that they were appropriate for a prison population as this population may contain men who have sex with men and the prison population can have a high HIV prevalence and may engage in high risk sexual practices.
PH38	Yes. See review 1 in the full guideline on Identification and Risk Assessment of adults with pre-diabetes. This is focused on the identification and risk assessment of adults with	No. Published 2012.	Total of 29 included papers. The quality of papers was reasonable, with 2 papers rated as very good (++), 24 as good (+) and 3 as poor (-).The GDG considered the population is representative of a prison population. Evidence states that the single risk factor	PH38 recommends healthcare professionals should assess the risk of all adults aged 40 and above and people aged 25–39 of South Asian, Chinese, African-Caribbean, black African and other high-risk black and minority ethnic groups, except pregnant women for Type 2 diabetes. The GDG agreed that this recommendation was

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
	pre-diabetes.		that identified most people (71.5%) as being at high risk for undiagnosed diabetes was age ≥ 55 years, and another 24.2% were identified because they were age 45–54 years with one of the following: BMI≥ 30 kg/m2, hypertension, or family history of diabetes.	appropriate for a prison population and that, on the basis of equivalence, the same risk assessments for type 2 diabetes in the community should be undertaken in prison.

1

5.5.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

Unit costs

See Table 58 in Appendix O.

5.5.3 Evidence statements

Clinical

- One very low quality prospective diagnostic cohort study with 679 adults showed that the Bai structured questionnaire has a sensitivity ranging from 50 to 86% and a specificity ranging from 95.9 to 99.5% for a number of specific physical health conditions.

Economic

- No relevant economic evaluations were identified.

5.5.4 Recommendations and link to evidence

See section 5.8 below.

5.6 Review question: When should subsequent health assessments be done in prisons?

For full details see review protocol in Appendix C.

Table 42: PICO characteristics of review question

Population	Adults (18 and over) in prisons or young offender institutions. Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low-medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Interventions	Validated health assessment tools/triage/policies/screening protocols Self-reporting/tick boxes Patient history Secondary screen Second health check Transfer screen Clinical health assessment Comprehensive clinical assessment Primary healthcare screen Induction Annual health check for those not qualifying for national requirement
Comparison	Usual care
Outcomes	**Critical**: Mortality **Important**: Health-related quality of life (related to continuity of treatment/symptom management) Patient safety incidents Reduced self-harm Reduced hospital admission Delayed and omitted medicine Reduced infectious disease transmission Risk factors Referrals Self-reported satisfaction New diagnoses
Study design	Randomised controlled trials Diagnostic cohort studies (prospective and retrospective) Systematic reviews and meta-analyses of the above

5.6.1 Clinical evidence

No relevant clinical studies that conducted a health assessment at a specific time point were identified.

5.6.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

Unit costs

See Table 58 in Appendix O.

5.6.3 Evidence statements

Clinical

- No relevant clinical evidence was identified.

Economic

- No relevant economic evaluations were identified.

5.6.4 Recommendations and link to evidence

See section 5.8 below.

5.7 Review question: what are the most effective and cost-effective assessment tools to determine the health promotion needs of prisoners?

For full details see review protocol in Appendix C.

Table 43: PICO characteristics of review question

Population	Adults (18 and over) in prisons or young offender institutions. Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low-medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Interventions	Validated health assessment tools/triage/policies/protocols Self-reporting/tick boxes Patient history Secondary screen Second health check Transfer screen Clinical health assessment Comprehensive clinical assessment Primary healthcare screen Focus groups/prisoner consultation meetings/user group meetings Opportunistic PER form (prisoner escort record) Don Grubin reception screen CHADS screening in young offenders/CHAT1/2 Medicines reconciliation/medication history taking/medicines confirming SystmOne Induction Wellbeing clinic (Wellmen and Wellwomen) Mental health interventions will be excluded
Comparisons	Usual care or each other
Outcomes	<u>Critical</u> Adoption of health-promoting behaviours: • Nutrition – healthy BMI • Smoking cessation – quit for at least 4 weeks • Personal hygiene/self-care/oral health – patient-reported satisfaction • Physical activity – healthy BMI, 30 minutes a day • Sexual health – decrease in STD diagnosis from in-prison, access to barrier methods <u>Important</u> Uptake of screening programmes Morbidity Mortality Health-related quality of life

Study design	Randomised controlled trials Non-randomised controlled trials Diagnostic cohort studies (prospective and retrospective) Systematic reviews and meta-analyses of the above

5.7.1 Clinical evidence

No relevant clinical studies were identified that used assessment tools to determine the health promotion needs of prisoners.

5.7.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

5.7.3 Evidence statements

Clinical

- No relevant clinical evidence was identified.

Economic

- No relevant economic evaluations were identified.

5.7.4 Recommendations and link to evidence

See section 5.8 below.

5.8 Recommendations and link to evidence

5.8.1 First-stage reception health assessment (see section 5.2)

Recommendations	**<u>Assessing health</u>** **<u>First stage health assessment at reception into prison</u>** **1. A healthcare professional (or trained healthcare assistant under the supervision of a registered nurse) should carry out a health assessment for every person on their first reception into prison. This should be done before the person is allocated to their cell. It should include identifying:** • **any issues that may affect the person's immediate health and safety before the second-stage health assessment** • **priority health needs to be addressed at the next clinical opportunity.** **2. The first-stage health assessment should include the questions and actions in Table 44. It should cover:**

	• **physical health** • **alcohol use** • **drug use** • **mental health** • **self-harm and suicide.** 3. **Take into account any communication needs or difficulties the person has, and follow the principles in NICE's guideline on patient experience in adult NHS services.** **Please see Table 44 for the questions for the first-stage health assessment.** **Following the first-stage health assessment** 4. **Give the person advice about how to contact prison health services and book GP appointments in the future.** 5. **Ask the person for consent to transfer their medical records from their GP to the prison healthcare service (see recommendations 64 - 65 for more information about transfer of medical records).** 6. **Enter in the person's medical record:** • **all answers to the reception health assessment questions** • **health-related observations, including those about behaviour and mental state (including eye contact, body language, rapid, slow or strange speech, poor hygiene, strange thoughts)** • **details of any action taken.** 7. **Carry out a medicines reconciliation (in line with NICE's guideline on medicines optimisation) before the second-stage health assessment. See also recommendations 46 and 53 for recommendations on risk assessments for in-possession medicines and ensuring continuity of medicine.**
Research recommendation	**1. What is the prevalence of disease in the UK prison population?**
Relative values of different diagnostic measures and outcomes	For this review question the GDG considered the following as critical outcomes: morbidity, mortality until further assessment and health-related quality of life. As no intervention reviews were identified in the review, diagnostic cohort studies were included. The GDG considered that, of the diagnostic accuracy outcomes, sensitivity was the most important outcome measure because the reception assessment should identify people with suspected condition(s) for follow-up. The objective of the reception assessment is to ensure that the person is safe for entry into prison and that any immediate health needs will be met until the second stage health assessment (see section 0). The consequences of missing a person with a health condition could result in a serious event or even death. Specificity was considered less important than sensitivity as any individual with a suspected condition(s) would be followed-up and be correctly classified as having the condition or not.

	False positives would be identified in the follow-up health assessment(s) and would not lead to serious consequences. False negatives are likely to lead to serious consequences, as many prisoners will not come into contact with the prison health service again.
Trade-off between clinical benefits and harms	The GDG considered the trade-off between high sensitivity of assessment and time taken for staff to conduct assessment at reception. In relation to this, the GDG also considered the number of staff members that would be necessary to conduct health assessments at reception at during different times, for example evenings. One very low quality prospective diagnostic cohort study with 150 adults showed that the Grubin (2002) reception assessment has a sensitivity of 95% and a specificity of 73%. A very low quality prospective diagnostic cohort study with 127 young males showed that the Comprehensive Health Assessment Tool (CHAT) has a sensitivity of 64% and a specificity of 59%. The GDG noted that the Grubin (2002) assessment took less time to undertake than CHAT. The GDG discussed the potential harms of missing a condition at this stage of assessment, such as a person with diabetes or a serious heart condition, and noted the importance of this assessment in correctly identifying and referring people quickly. However, it was noted that the second part of the reception assessment would pick up any missed conditions within 7 days. The group noted that the Grubin assessment had both a higher sensitivity and specificity than CHAT, and therefore based their recommendation on the Grubin assessment. Some additional assessment questions were added (as discussed in other considerations below) as although the sensitivity is high, it is still 95%, indicating that 5% of people who should have been referred where not.
Trade-off between net clinical effects and costs	No relevant published economic evidence was identified for this review. The GDG discussed the potential cost-effectiveness of a reception health assessment based on its diagnostic accuracy and the costs involved with conducting the assessment and resulting from downstream effects. The GDG noted that not doing any health assessment at reception is not an option – this is currently mandated in prison and healthcare procedures, and not doing so would lead to people with serious conditions or who were on medication before admission being left without necessary care until the second stage assessment. This review is therefore looking at the cost-effectiveness of different designs of assessment. The GDG agreed that an effective brief assessment in the form of a checklist that addresses the immediate health needs of prisoners would identify conditions that would lead to significant ill health, and associated significant costs, later if not identified early thus enabling appropriate treatment. Set against this is a small initial cost per person in respect of the time of the person conducting the assessment. The GDG noted that assessment at reception in line with the recommendations of Grubin 2002 is currently standard practice within prisons, and so the recommendation to use a similar checklist is not expected to significantly change the resource currently required for this purpose. A small number of additional questions have been added to cover questions, such as identification of any disabilities, which were missing from the Grubin checklist (see 'Other considerations' below). The GDG considered that these questions were necessary as they sought information that is required for the first few days in prison, but that the overall effect would in any case be only a very short extension in the length of the assessment. The GDG did not believe that it would be appropriate to recommend a more lengthy or detailed form of assessment at the reception stage. There is more time for more detailed questions at the second stage assessment (see Section 0), whereas adding extra questions to the reception assessment about conditions that are not likely to need addressing in the first week in prison would not be expected to be cost-

	effective, as there would be little benefit from identifying them at the first rather than the second assessment stage.Original cost-effectiveness analysis was conducted to consider the cost-effectiveness of the reception assessment being conducted by a specified member of healthcare staff (a nurse compared to a healthcare assistant). This looked at whether the additional benefit of having the assessment conducted by a more highly trained member of staff (nurse) could be large enough to justify the extra cost of paying for the nurse's time instead of the healthcare assistant's time. This analysis found that a reception assessment conducted by a nurse would only be cost-effective at a £20,000 per QALY gained threshold compared to an assessment conducted by a healthcare assistant in the most extreme scenarios examined. The ICERs for this comparison varied between £13,863 and £31,145 per QALY gained, with only 1 of the 3 base case scenarios giving an ICER of under £20,000 per QALY gained. This analysis required nurses to identify a very high proportion of health conditions correctly, and healthcare assistants to identify a very low proportion of health conditions correctly for the result to be cost-effective. The GDG acknowledged that there was great uncertainty in the cost-effectiveness results that, resulting from the number of assumptions under each analysis scenario. Considering this, alongside the issues related to the complexities of organising the mix of staffing provision in prison healthcare services (see 'Other considerations' below), the GDG agreed not to specify which members of healthcare staff should conduct the assessment, so long as they are trained and competent to do so, but to leave this decision to the healthcare service in each prison. Each service should consider the costs and benefits of deploying staff members for reception health assessment, compared to the other tasks they could be undertaking, bearing in mind the specific healthcare needs of the population that that prison is receiving.
Quality of evidence	The protocol specified RCTs as the preferred study design, with the following critical outcomes: morbidity; mortality until second assessment (undertaken with 7 days); health-related quality of life. As no RCTs were found, diagnostic cohort studies, which reported diagnostic accuracy data were included. The quality of the evidence for the Grubin (2002) reception assessment was very low due to serious risk of bias and serious indirectness. The identified risk of bias was due to the following: a risk of selection bias (unclear which method of randomisation used; unclear if study made inappropriate exclusions), risk of measurement bias: (unclear if participants received same reference standard) and risk of incomplete outcome data bias (unclear if all participants included in the analysis). Additionally the evidence was indirect due to the inclusion of an indirect population (aged 16 years or older). The quality of the evidence for CHAT was very low due to serious risk of bias and serious indirectness. The identified risk of bias was due to the following: a risk of selection bias (unclear which method of randomisation used; unclear if study made inappropriate exclusions), risk of measurement bias: (unclear if participants received same reference standard) and risk of incomplete outcome data bias (unclear if all participants included in the analysis). Additionally the evidence was indirect due to the inclusion of an indirect population (aged 15–18 years).
Other considerations	Reception assessment questions and associated actions are detailed in Table 44 and include questions relating to physical health, alcohol use, drug use, mental health and self-harm and suicide. The elements relating to physical health are predominantly based on the Grubin 2002 reception assessment. The mental health of adults in contact with the criminal justice system guideline[103] included a review question on the recognition and assessment of mental health problems in adults, including the diagnostic accuracy of available mental health assessment tools and the key components of what should be included in a comprehensive assessment. Key reception assessment questions about drug or alcohol use, risk of self-harm and any previous mental health care received were considered by the mental health guideline group[103] and have been incorporated in

order to provide a comprehensive first-stage health assessment at reception into prison (see 5.8.3).

The GDG noted that health assessments on entry into prison provided a unique opportunity to identify conditions in a population that typically does not readily access healthcare services. The GDG considered whether the aim of the reception assessment was just to identify immediate harms or whether a more comprehensive assessment should be undertaken. The GDG agreed that the main purpose of the reception assessment was to ensure the safety of people during their first few days in prison by identifying immediate potential harms. For example, to identify medicines that must be continued if there is a risk of severe adverse events or mortality when they are missed. The GDG noted that both the first and second stage assessments are for all new arrivals into prison. Those going to court and returning will just get a short "status/situational change" check on return and relevant support and advice given. The first stage assessment will not be repeated, this only happens once during an individuals prison stay.

The GDG agreed that the reception assessment should be brief and only include questions that identify immediate harms. The GDG suggested that conditions that pose less immediate harms could be identified by a second stage of the health assessment, which would be conducted within 7 days after reception (see section 0. Significantly lengthening the reception stage of the health assessment could also pose practical problems, as people often arrive at prison in the evening, and undergo other reception processes before the health assessment, so it can be late by the time the health assessment starts and there may be many people needing to be assessed at the same time.

The GDG noted that conducting a health assessment on reception into prison is mandatory and that use of the Grubin (2002) reception assessment is standard practice to identify immediate physical and mental health problems, and problems with substance misuse. PSO 0500 on reception[44] gives instructions on reception procedures and states: For a prisoner's first reception into custody, an initial assessment of the healthcare needs of all newly received prisoners is undertaken within 24 hours of first reception by an appropriately trained member of the healthcare team to identify any existing problems and to plan any subsequent care. A health screen, using the Revised F2169 [paperwork that makes up the first night reception screen (Grubin)], takes place before the prisoner's first night to primarily detect: immediate physical health problems, immediate mental health problems, significant drug or alcohol abuse, risk of suicide and/or self-harm. The GDG discussed PSO 3050 on continuity of healthcare for prisoners,[45] which details mandatory actions relating to first reception.

Table 44 details questions for the first-stage assessment and gives associated actions, which are based on the Grubin (2002) assessment tool. Examples of actions include noting current medicines and generating a medicines chart following questions on prescribed medication. All actions are written to be undertaken by a healthcare professional (or trained healthcare assistant under the supervision of a registered nurse), unless otherwise stated. Examples of actions under the physical injuries section include GP assessment for severe cases, and liaising with prison staff if a transfer to a hospital is required.

Actions in the past or future medical appointments section include arranging a contact letter to to obtain further information from the person's doctor. This might be a community mental health nurse that specific information is requested from, or a secondary care clinic, such as urology. Future appointment dates should be noted and healthcare administrative staff should manage these appointments or arrange new dates. Healthcare admin manage all hospital appointment requests and liaise with security and transport. The group noted that prisoners are not allowed to know when external hospital appointments are, if they are aware of these dates they will be changed (due to security issues) when entering prison. Security will decide if any original dates can be kept or if healthcare admin staff will re-arrange.

The GDG noted that the Grubin (2002) assessment tool does have gaps in some areas, notably:

- Help to live independently. This includes any physical disabilities The actions described in the associated table include liaising with the prison disability lead regarding cell location and any further disability assessments required. The prison will lead on this as part of thier allocation responsibilities, and may require specialist advice from healthcare.
- Learning disabilities; which will influence how the assessor will be able to communicate with the person and tailor information provision appropriately.
- Use of equipment or aids (for example, walking stick, hearing aid); the GDG noted that if these are not identified early there can be a long delay in receiving them, having a negative impact on the person and highlighted the current inequality in providing adequate care for some populations with particular needs.
- Dietary requirements; as clinically indicated, such as those with coeliac disease.

The GDG also noted that it is important who undertakes the reception assessment and that staff members receive training on how to conduct the assessment and identify problems. The GDG discussed whether a registered nurse or healthcare assistant should undertake the first stage of the assessment. The GDG noted that responsibility for making clinical decisions at the first stage of the assessment rests with registered nurses, and that healthcare assistants may need to report to a registered nurse if uncertain about decision-making

Currently the staff mix and staff allocation of every healthcare prison team varies considerably depending on the size and nature of the prison. The GDG specifically highlighted the example of a nurse or pharmacist being required to assess the in-possession medication of people arriving at reception. For that reason in some prisons it is preferred for all assessments to be conducted by a nurse who can validate medication required at the same time, rather than requiring an additional interview with a nurse to check medication after the reception assessment is carried out by a healthcare assistant. However, the GDG noted that in other prisons it would be limiting for healthcare prisons teams to allocate valuable nurse time for reception assessments when other activities would be of higher priority.

Taking note of the economic considerations, the GDG agreed that healthcare professionals conducting the assessment should have the competencies required to carry out the assessment and may require training in conducting the assessmentThe GDG noted that people who enter prison are often disorientated, fearful or suspicious and may not disclose all current known health conditions. The GDG agreed that this concern could be addressed in the second stage of the reception health assessment.

The GDG also made recommendations on how to contact health services in the future, which is supported by the health assessment qualitative review findings in the continuity of care chapter (see Chapter 11), under the theme of contact with healthcare professionals on entry to prison.

The group also discussed the importance of recording information in the person's medical record to ensure continuity of care. In addition the group recommended requesting consent to transfer medical records from the community GP to the health service to again ensure continuity and also to carry out medicine reconciliation (as detailed in the NICE Medicines Optimisation guideline[98] and detail in the continuity of medications section (see section 8.3). Confirmation of the prescription is required from the community GP before the medication is re-prescribed and given to the patient. The GDG chose to cross-refer to the NICE guideline on Medicines optimisation, in particular the section on medicines reconciliation, as the

	recommendations made here are applicable to a prison population. The GDG noted that the current prevalences of a wide range of health conditions in people in prison in the UK are largely unknown compared to the general population. The GDG noted evidence of the prevalence of health conditions in the UK prison population would be useful to inform recommendations for people in prison in the future, therefore the GDG decided to make a research recommendation in this area (for more details please see Appendix P). **Research recommendation** Currently it is estimated that there are around 85,000 people in prison in the UK. To date, we have little clear evidence of the disease burden of this population as a whole and have therefore had to rely upon anecdotal experience. This was highlighted by our reviews on chronic conditions, in which there was an absence of disease prevalence data, and when searching for prevalence data for the health economic model. Systems are now in place that will allow the relevant data to be gathered and inform a longitudinal study revealing this information and provide a useful foundation for better understanding how to shape the healthcare services provided to prisoners, both in terms of meeting the needs of the prison population and providing commissioners with priority areas for health service delivery and development.

1 **Table 44: Questions for first-stage health assessment**

Topic questions	Actions
1. Has the person been charged with murder or manslaughter?	Yes: refer for urgent mental health assessment by the prison mental health in-reach team. Ensure that the person is seen by the GP while they are in reception. No: record no action required.
2. Physical health	
2.1 Prescribed medicines	
Is the person taking any prescribed medicines, including preparations such as creams or drops, and if so: • what are they? • what are they for? • how do they take them?	Yes: make a note of any current medicines being taken and generate a medicine chart. Refer the person to the GP for appropriate medicines to be prescribed and continued. If medicines are being taken check that the next dose has been provided (see recommendation 53). No: record no action required.
2.2. Physical injuries	
Has the person received any physical injuries over the past few days, and if so: • what were they? • how were they treated?	Yes: assess severity of injury, any treatment received and record any head, abdominal injuries or fractures. Refer the person to the GP at reception. In very severe cases, or after GP assessment, the person may need to be transferred to an external hospital. Liaise with prison staff to transfer the person to the hospital emergency department by ambulance. Document any bruises or lacerations observed. If the person has made any allegations of assault, record negative observations as well (for example, no physical evidence of injury). No: record no action required.
2.3. Head injuries or loss of consciousness	

Topic questions	Actions
Has the person ever suffered a head injury or lost consciousness, and if so: • how many times has this happened? • have they ever been unconscious for more than 20 minutes? • do they have any problems with their memory or concentration?	Yes: refer the person to the GP at reception. No: record no action required.
2.4. Other physical health conditions	
Does the person have any of the following: • allergies, asthma, diabetes, epilepsy or fits • chest pain, heart disease • tuberculosis, sickle cell disease • hepatitis B or C virus, HIV, other sexually transmitted infections • learning disabilities • neurodevelopmental disorders • physical disabilities?	Ask about each illness listed. Yes: make short notes on any details of the person's condition or management. For example, "Asthma – on Ventolin one puff daily". Make appointments with relevant clinics or specialist nurses if specific needs have been identified. No: record no action required.
2.5 Are there any other physical health problems the person is aware of, that have not been reported?	Yes: record the details and check with the person that no other physical health complaint has been overlooked. No: record no action required.
2.6 Are there any other concerns about the person's physical health?	Make a note of any other concerns about physical health. This should include any health-related observations about the person's physical appearance (for example, weight, pallor, jaundice, gait). As with recent injuries, both negative and positive signs are relevant. Yes: refer the person to the GP at reception. No: note "Nil".
2.7 Additional questions for women	
Ask the woman if she has reason to think she is pregnant.	Yes: refer the person to the GP at reception and to a midwife. No: record response.
Ask if she would like a pregnancy test.	Yes: if requested, provide a pregnancy test. Record the outcome and if positive make an appointment for the person to see the GP. No: record response.
2.8 Independent living and diet	
Ask the person if they need help to live independently.	Yes: note any needs. Liaise with the prison disability lead in reception about: • the location of the person's cell • further disability assessments the prison may need to carry out.

Topic questions	Actions
	No: record response.
Ask if they use any equipment or aids (for example, walking stick, hearing aid, glasses).	Yes: remind prison staff that all special equipment and aids the person uses should follow them from reception to their cell. No: record response.
Ask if they need a special medical diet.	Yes: note the medical diet the person needs and send a request to catering. No: record response.
2.9 Past or future medical appointments	
Ask the person if they have seen a doctor or other healthcare professional in the past few months, and if so what this was for.	Yes: note details of any recent medical contact. Arrange a contact letter to get further information from the person's doctor. Note any ongoing treatment the person needs and make appointments with relevant clinics, specialist nurses, GP or other healthcare staff. No: record no action required.
Ask if they have any outstanding medical appointments, who they are with, and the dates.	Yes: note future appointment dates.Ask healthcare administrative staff to manage these appointments or arrange for new dates and referral letters to be sent if the person's current hospital is out of the local area. No: record no action required.
3. Alcohol and drug use	
3.1 Ask the person if they drink alcohol, and If so: • how much they normally drink • how much they drank in the week before coming into custody.	Urgently refer the person to the GP at reception or the drug services team if: • they drink more than 15 units of alcohol daily or • they are showing signs of withdrawal. No: record response
3.2 Type and frequency of drug use	
Ask the person if they have used drugs in the last month. If yes, ask about frequency of use, and last use of, for example: • heroin • methadone • benzodiazepines • amphetamine • cocaine or crack • novel psychoactive substances.	Ask about use of different drugs including those listed. Yes: Refer the person to drug services if there are concerns about their immediate clinical management and they need immediate support. Take into account whether: • they have taken drugs intravenously • they have a positive urine test for drugs • their answers suggest that they use drugs more than once a week. Refer the person to theGP at reception if any physical health concerns. No: record response.
3.3 Intravenous drugs	
Ask the person whether they have taken any drugs intravenously.	Yes: check injection sites. Refer the person to drug services if there are concerns about their immediate clinical management and they need immediate support. Refer the person to theGP at reception for any physical health concerns. No: record response.

Topic questions	Actions
3.4 Prescription drugs	
Ask the person whether they have used prescription or over-the-counter medicines in the past month that: • were not prescribed or recommended for them, or • for purposes or at doses that were not prescribed. If yes, ask what this medicine was and how they used it (frequency and dose).	Yes: Refer the person to drug services if there are concerns about their immediate clinical management and they need immediate support. Refer the person to the GP at reception if there are any physical health concerns. No: record response.
4. Mental health	
4.1 Previous contact with mental health services	
Ask the person if they have ever seen a health professional or service about a mental health problem (including a psychiatrist, GP, psychologist, counsellor, community mental health team or learning disability team). If yes, ask: • who they saw • what was the nature of the problem.	Yes: consider referring the person for mental health assessment by the prison mental health in-reach team if they have received care for mental health problems. Refer the person to the GP at reception. If the person has been in contact with learning disability services refer them to the GP at reception. No: record response.
Ask the person if they have ever been admitted to a psychiatric hospital. If yes, ask them: • the date of their most recent discharge • the name of the hospital • the name of their consultant.	Yes: refer the person for mental health assessment by the prison mental health in-reach team if they have received inpatient care for mental health problems. Refer the person to the GP at reception No: record response.
4.2 Medicine for mental health problems	
Ask the person if they have ever been prescribed medicine for any mental health problems. If yes, ask: • what the medicine was • when they received it • what the current dose is (if they are still taking it).	Yes: consider referring the person for mental health assessment if they have received medicine for mental health problems. Refer the person to the GP at reception No: record response.
5. Self-harm and suicide	
5.1 History of self-harm or suicide attempts	
Ask the person whether they have ever tried to harm themselves. If yes: • whether this was inside or outside prison • what the most recent incident was • what the most serious incident was.	Yes: consider referring the person for a mental health assessment if they have ever tried to harm themselves. No: record response
Ask the person if they: • have a history of previous suicide attempts • are currently thinking about or planning to harm themselves or attempt suicide.	Yes: refer the person for an urgent mental health assessment. Open an Assessment, Care in Custody and Teamwork (ACCT) plan if there are: • serious concerns raised in response to questions about self-harm, including thoughts, intentions, or plans • a history of previous suicide attempts. Refer the person to the GP at reception. No: record response.

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15.8.2 Second-stage health assessment (see section 5.2)

Recommendations	**Second stage health assessment**
	
	8. A health professional (for example a registered general nurse) should carry out a second-stage health assessment for every person in prison. This should be done within 7 days of the first-stage health assessment. It should include as a minimum:
	• **reviewing the actions and outcomes from the first-stage health assessment**
	• **asking the person about:**
	  ○ **any previous use of alcohol and illicit drugs**
	  ○ **smoking history**
	  ○ **the date of their last sexual health screen**
	  ○ **any history of serious illness in their family (for example, heart disease, diabetes, epilepsy, cancer or chronic conditions)**
	  ○ **their expected release date**
	  ○ **(for women) whether they have ever had a cervical screening test or mammogram**
	  ○ **(for women) whether they have, or have had, any gynaecological problems.**
	• **measuring and recording the person's height, weight and blood pressure, and carryng out a urinalysis.**
	
	9. Review the person's first- and second-stage health assessment records, medical history and GP records and:
	• **refer the person to the GP or a relevant clinic if further assessment is needed. See for example NICE's guidelines on cardiovascular disease (recommendations on identifying people for full formal risk assessment) or type 2 diabetes (the recommendation on risk assessment)**
	• **arrange a follow-up appointment if needed.**
	
	10. Offer people tailored health advice based on their responses to the assessment questions. This should be in a variety of formats (including face-to-face). It should include advice on:
	• **alcohol (see NICE's guideline on alcohol use disorders)**
	• **substance misuse (see NICE's guideline on drug misuse).**
	• **exercise (see recommendations 38 and 39)**
	• **diet (see recommendation 40)**
	• **stopping smoking (see recommendation 43)**
	• **sexual health (see recommendations 41 and 42).**
	
	11. Ask the person if they want to attend any health-promoting activities, for example exercise or going to the gym, help with stopping smoking or other courses.

	12. Offer the person advice on: • **how to contact prison health services and book GP appointments** • **where to find health information that is accessible and understandable** • **how to attend any health-promoting activities in the future (see recommendations 38-45).** • **medicines adherence (see recommendation 52).** **13. Enter in the person's medical record:** • **all answers to the second-stage health assessment questions** • **health-related observations** • **details of any action taken.** **14. Plan a follow-up healthcare review at a suitable time based on clinical judgement, taking into account the age of the person and length of their sentence.**
Relative values of different diagnostic measures and outcomes	For this review question the GDG considered mortality as a critical outcome. The following outcomes were considered important: health-related quality of life (related to continuity of treatment/symptom management), patient safety incidents, reduced self-harm, reduced hospital admission, delayed and omitted medicines, reduced infectious disease transmission, risk factors, referrals, self-reported satisfaction and new diagnoses. As no intervention reviews were identified in the review, diagnostic cohort studies were included. The GDG considered that, of the diagnostic accuracy outcomes, sensitivity was considered the most important measure by the GDG for this review question because the reception health assessment (first and second stages) should identify individuals with suspected condition(s) for follow-up. The consequences of missing a person with a health condition could result in a serious event or even death. Specificity was considered less important than sensitivity as any individual with a suspected condition(s) will be followed-up and would later be correctly classified as having the condition or not. False positives will be identified as such in the follow-up health assessment(s) and will not lead to serious consequences. False negatives are likely to lead to serious consequences, as many prisoners will not systematically come into contact with the prison health service again.
Trade-off between clinical benefits and harms	The GDG considered the trade-off between identifying suspected health conditions and the length of time to conduct the assessment. The GDG noted that this assessment has similarities to the process of registering with a new GP practice, at which point it is normal to collect standardised information on current and previous health and personal information, and to check on management plans for any ongoing conditions. In prisons it may be appropriate to ask some additional questions due to higher rates of some conditions in the prison population. A face-to-face interview is recommended instead of only requiring a form to be filled in, due to higher rates of health conditions in prisoners (meaning that many will need to be referred to a GP) and higher rates of illiteracy.
Trade-off between net clinical effects and costs	In the absence of relevant published economic evidence, the GDG discussed the potential cost-effectiveness of a second-stage health assessment based on its expected form and clinical effectiveness.

	It was noted that this will require upfront resource use since it will involve the equivalent of an extended primary care appointment for each person entering prison. The GDG judges that this may take 30 to 40 minutes per person – mostly with a nurse, though routine measurements and urine testing, for example, could be delegated to a more junior healthcare staff member. However, the GDG highlighted that these initial appointments would be expected to lead to a reduction in later expenditure, in addition to an improvement in later health. A significant proportion of people entering prison will have at least 1 existing health condition. Not giving a second-stage health assessment to such a person would not save time or cost to the health service as they would present with their condition later during their time in prison and so they will ultimately be seen by health staff and an equivalent appointment to assess their condition and put a management plan into place would still be needed. However, making the prison healthcare services aware of their pre-existing condition at an early stage, or identifying the condition for the first time if previously unknown to the person, will allow appropriate management and treatment of the condition to be planned for the duration of their time in prison at the most appropriate time. Good management of the condition from the start, as well as leading to better long-term health for the person, is expected to decrease the number of people presenting late or at an emergency stage, when more expensive treatments would typically be required. For people without any medical conditions, the appointment would be shorter and thus less costly, and would provide a measure of reassurance, which may lead to a small improvement in quality of life. Currently second-stage health assessments are recommended and are implemented in approximately 85% of prisons, but not universally, so the resource impact would be asmall to moderate increase in appointments from an existing base. Assuming current appointments have an average duration of 15-20 minutes and the expected future duration (after excluding components recommended in other NICE guidelines) is around 25 minutes, the approximate resource impact for the total annual number of admissions would be £680,000. The GDG noted that this estimate is not including the possible downstream cost savings related to the extended assessment. Therefore, the GDG concluded that a health assessment during the first 7 days after reception into prison is expected to be cost-effective since it is necessary for correct management of the healthcare needs of prisoners, and this will improve health and reduce the potentially very high costs of later emergency health interventions. In addition, a one-to-one consultation with each person entering prison also affords an opportunity to give each person an introduction to the healthcare system in prison and health promotion programmes available (see Chapter 7). If used successfully this could lead to more appropriate utilisation of the healthcare system in future (more necessary contacts but fewer unnecessary contacts) and increase the number of people subsequently engaging with health promotion programmes. This would be an efficient use of this time and would increase the cost-effectiveness of the health promotion programmes. The GDG also considered the second stage assessment as appropriate to recommend on the principles of equality, since a similar (possibly briefer) assessment would be relevant when a member of the general public is registered with a GP practice. More detailed justification can also be found in section 7.6.1 (Trade-off between net clinical effects and costs).
Quality of evidence	No quantitative evidence was identified in this area. Evidence identified in the continuity of care review (see chapter 11) suggested that medical records were not always transferred on reception into prison and that when transferred some records were not complete. Therefore the GDG noted that a system should be in place on reception to obtain a person's medical records and to review these during the second stage of the reception health assessment.

	Evidence identified in the qualitative review in health promotion (see section 7.5) suggested that there was often a lack of health promotion information available for people in prison and that where available health promotion information was in a form inaccessible to certain people (for example written information being inaccessible to people who cannot read). The evidence also showed that often people found it difficult to access health promotion information from staff due to time restrictions. The GDG noted that on this basis health promotion advice should be given and information provided in an accessible form to prisoners during the second stage of the reception health assessment. The GDG noted the second stage Grubin assessment, which is currently used to varying degrees across the prison estate, contains many highly applicable questions which were the basis of many of the recommendations here. In addition, the GDG noted the existence of community GP registration assessments and what the components of these are and felt that the recommendations made were equivalent.
Other considerations	The GDG noted that the Grubin (2002) reception assessment has 2 parts: the first part is to be undertaken at reception into prison and the second part is a full primary care assessment undertaken that is meant to be undertaken within 7 days after reception into prison. The GDG noted that only the first part of the Grubin (2002) reception assessment was mandatory to be undertaken at reception into prison in the UK. However, a more comprehensive assessment conducted after reception into prison was not mandated and so in practice the completion of the general health assessments varies greatly across establishments. This may have led to missed opportunities for care and a number of deaths within prison.[129] The GDG was aware that the second part of the Grubin (2002) assessment could not be included in this review as no clinical studies have been published in this area. However, the GDG decided that this additional stage of assessment should be provided due to high 'did not attend' (DNA) rates of prisoners with healthcare appointments. The GDG commented that DNAs are often due to conflicts with the general prison induction, and therefore the GDG suggested incorporating the further stage of health assessment into the general prison induction. The GDG noted that high DNAs, difficulties in accessing appointments and a reluctance among some prisoners to engage with healthcare can be a problem throughout a person's time in prison. Scheduling 1 initial appointment for each person shortly after reception to allow them to discuss their health with a nurse would ensure that everyone is given an opportunity to report and seek help for any existing health issues or concerns they have without them having to initiate and organise this contact at a later stage. It could also help to promote a culture of engagement with prison healthcare from the beginning of a person's prison experience, which could be a positive factor when new health issues arise later on. The GDG agreed that as the main function of the first stage of the reception health assessment was to identify immediate harms, the second stage of the reception health assessment should function to identify any other current health conditions, complex cases, or other concerns. The GDG noted that as a consequence of this, this additional assessment would be comprehensive and take a longer time to undertake. The GDG agreed that the second stage of the health assessment should be completed within 7 days, including weekends and bank holidays. The second assessment should not duplicate any of the first reception assessment, but seek to review any notable outcomes and ensure any actions recorded have been followed up. The GDG considered whether the following elements should be added to the second stage of the reception health assessment: BP; urinalysis; weight; height; smoking; communicable disease; STIs; cholesterol (for those aged 40 or older in accordance with NICE guidance); dietary requirements; learning disabilities; physical disabilities; language barriers; and exercise. The GDG also agreed that the second stage of the reception assessment should

include asking about health-related lifestyle choices and offering advice and information on health promotion and health promoting activities. This recommendation was based on the clinical evidence on found in the health promotion in prison reviews (see chapter 7).

The group noted that sexual health was not covered under the first assessment and felt it was an important area to cover due to the high prevalence of sexually transmitted diseases in the prison population. Therefore, the question of asking the date of their last sexual health screen was was added. In addition there is existing NICE guidance on Hepatitis B and C[109] and HIV,[104,107] see section 5.8.4 on other health assessments.

The GDG also discussed other factors to be explored during the assessment such as length of sentence and where the prisoner has been transferred from.An additional recommendation was made to pull together the first and second stage health assessments and also any relevant information from the medical history and GP records, to identify anything missed or any red flags that may need to be referred onwards. The recommendation cross refers to other assessments detailed in related NICE guidance, such as cardiovascular disease or type 2 diabetes. The NICE guidance on cardiovascular disease (CG181),[70] states that people older than 40 should have their estimate of cardiovascular disease risk reviewed on an ongoing basis through the NHS health check programme. The NICEguidance on diabetes (PH38),[110] which states that a validated computer-based risk-assessment tool should be used to identify people who may be at high risk of type 2 diabetes and a validated self-assessment questionnaire should be offered to adults aged 40 and over, people of South Asian and Chinese descent aged 25–39, and adults with conditions that increase the risk of type 2 diabetes, other than pregnant women. For further details on monitoring of chronic conditions, see Chapter 9.

The GDG agreed that the reception health assessment (first and second stage) should also include questions on alcohol and illicit drugs, as addressed by the corresponding mental health in prisons guideline..[103] Mental health problems, any neurodevelopmental disorders or learning disabilities are explored in the first reception assessment and therefore not duplicated here.

The GDG also considered the NICE guideline CG51 Drug misuse in the over 16's,[76] published in 2007, to be relevant to a prison population and noted that this makes directly applicable recommendations for the prison population: see section 1.5.2 Criminal justice system.

The cancer guideline on Suspected cancer: recognition and referral (NG12)[74] was also discussed. This guideline covers the recognition and selection for referral or investigation in primary care of people of all ages, including children and young people, who may have cancer. The guideline aims to help people understand what to expect if they have symptoms that may suggest cancer. It should also help those in secondary care to understand which services should be provided for people with suspected cancer.

<Linking evidence to recommendation completed by the mental health of adults in contact with the criminal justice system guideline>

5.8.3 Mental health assessment (see sections 5.3 and 5.4)

Recommendations	**Mental health first-stage assessment** **Please see Table 44 for the questions for the first-stage health assessment; these include: alcohol and drug use, mental health, self-harm and suicide.** **Mental health second-stage assessment** **15. Consider using the Correctional Mental Health Screen for Men (CMHS-M) or Women (CMHS-W) to identify possible mental health problems if:** • **the person's history, presentation or behaviour suggests they may have a mental health problem** • **the person's responses to the first-stage health assessment suggest they may have a mental health problem** • **the person has a chronic physical health problem with associated functional impairment** • **concerns have been raised by other agencies about the person's abilities to participate in the criminal justice process.** **16. If a man scores 6 or more on the CMHS-M, or a woman scores 4 or more on the CMHS-W, or there is other evidence supporting the likelihood of mental health problems:** • **a practitioner who is trained to perform an assessment of mental health problems should conduct further assessment, or** • **a practitioner who is not trained to perform an assessment of mental health problems should refer the person to an appropriately trained professional for further assessment.**
Relative values of different outcomes	When assessing tools for recognition and assessment of mental health problems the GDG agreed that preference should be given to tools that could identify a range of mental health problems, as opposed to recommending the use of multiple specific tools. Sensitivity and specificity were selected as the primary outcomes as the GDG were concerned with how accurately tools could identify the presence of mental health problems.
Trade-off between clinical benefits and harms	When considering whether or not to recommend a case identification tool, the GDG were mindful of the benefits associated with the identification of mental health problems in the prison population (which are known to be significantly higher than in the general population) but also considered the potential harm or inappropriate use of resources that may arise from false positives. For this reason, the GDG were careful to evaluate both the

	sensitivity and specificity of the measures reviewed.
Trade-off between net clinical effects and costs	First stage assessment: The GDG considered screening all individuals upon reception into prison is very resource intensive. In order to minimise the impact on resources, the GDG agreed that the purpose of this screen should be to keep the service user safe (In other words, identify anything that is so urgent that it needs immediate attention/referral) and that other issues could be addressed in subsequent assessments. Second stage assessment: The GDG agreed that the use of a recognition tool (such as the CMHS-M/CMHS-W) which could be administered by a non-expert in five minutes or less would be the most effective way to limit the impact of this assessment on resources. The CMHS-M/W has considerably improved sensitivity when compared with standard care. This would result in a significant reduction in the rate of false negatives. According to the GDG, false negative findings could potentially result in an unnecessary and severe exacerbation of a mental illness, crisis, or even in a suicide; aggression and violence, and disruptive behaviour; and also increased risk for reoffending. Assuming similar specificity rates between CMHS-M/W and standard care, there is a clear cost advantage of using this tool given that it takes only 5 minutes to administer and reduces the number of false negatives by approximately 200 per 1,000 prisoners screened. The group was aware of a wide range of alternative methods used in the prison system and considered that the addition of this measure will impose no additional burden on the system, and given the clinical evidence may, very likely, produce better outcomes
Quality of evidence	The quality of the evidence ranged from moderate to low. The most common reasons that studies were marked down in terms of quality were that the flow and timing of the study, the conduct or interpretation of the index test and/or the participant selection introduced possible bias. Due to the quality of the evidence and the small number of studies that examined any combination of recognition tools and target conditions, the GDG agreed that there was insufficient evidence to either dissuade use of, or recommend an alternative to, the current prison reception health screen. The GDG agreed that using an adapted version of this assessment for the reception screen would be preferred and that the RDS should be added to the second stage of prison health screening.
Other considerations	First stage assessment: The GDG decided through informal consensus drawing on their knowledge and expertise that amendments to the current prison reception health screen were needed in the following areas: drugs and alcohol, contact with previous mental health services, self-harm and suicide, learning disabilities, assessor's impression of the service user. Amendments were made via informal consensus from the GDG after consideration of various versions of the screen currently being used in UK prisons. Further, the GDG decided that the current threshold of 20 units per day for urgent referral regarding alcohol withdrawal was too high; therefore, this was lowered to 15 units in line with NICE CG 115. Second stage assessment: The RDS and the CMHS-M/CMHS-W were the recognition tools preferred by

	the GDG as they had similar sensitivity and specificity and were applicable to a range of mental health problems. The author of the RDS was contacted who advised that the tool was outdated as it was based on the current Diagnostic Interview Schedule at the time of development. Further, none of the reviewed evidence used this tool in this way. Therefore, the decision was made to recommend the CMHS-M/CMHS-W as part of the second stage assessment.

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15.8.4 Other health assessments (see section 5.5)

Recommendations	Other health assessments

17. Ensure that there is a system and processes in place to carry out other assessments in line with recommendations in NICE guidelines[a].

18. Prison healthcare services (coordinated with, and supported by, the NHS lead for hepatitis) should ensure that:

- **all prisoners are offered a hepatitis B vaccination when entering prison (for the vaccination schedule, refer to the Green Book)**
- **all prisoners are offered access to confidential testing for hepatitis B and C when entering prison and during their detention**
- **prisoners who test for hepatitis B or C receive the results of the test, regardless of their location when the test results become available**
- **results from hepatitis B and C testing are provided to the prisoner's community-based GP, if consent is given.**

HIV testing: increasing uptake in men who have sex with men[b]

19. Primary care providers should ensure annual HIV testing is part of the integrated healthcare offered to men who are known to have sex with men.

20. Provide information on HIV testing and discuss why it is recommended (including to those who indicate that they may wish to decline the test).

21. Conduct post-test discussions, including giving positive test results and delivering post-test and general health promotion interventions.

22. Recognise illnesses that may signify primary HIV infection and clinical indicator diseases that often coexist with HIV.

sexually transmitted infections and under-18 conceptions: prevention[c]

23. Identify individuals at high risk of STIs using their sexual history. Opportunities for risk assessment may arise during consultations on contraception, pregnancy or abortion, and when carrying out a cervical smear test or offering an STI test. Risk assessment could also be carried out during routine care or when a new patient registers.

[a] The recommendations in this section are from the following NICE guidelines: hepatitis B and C testing: people at risk of infection; HIV testing: increasing uptake in men who have sex with men; sexually transmitted infections and under-18 conceptions: prevention and tuberculosis.

[b] Please note that the following recommendations (in yellow) are taken from other guidelines and therefore are not part of the consultation.

[c] Please note that the following recommendations (in yellow) are taken from other guidelines and therefore are not part of the consultation.

	24. Have one-to-one structured discussions with people at high risk of STIs (if trained in sexual health), or arrange for these discussions to take place with a trained practitioner. **tuberculosis[d]** **25. Healthcare professionals in prisons should ensure all prisoners are screened for TB within 48 hours of arrival.** **26. Prisons with Department of Health-funded static digital X-ray facilities for TB screening should X-ray all prisoners (including people being transferred from other establishments) if they have not had a chest X-ray in the past 6 months. This should take place within 48 hours of arrival.** **27. Prison staff should report all suspected and confirmed TB cases to the local multidisciplinary TB team within 1 working day.** **28. Multidisciplinary TB staff should visit every confirmed TB case in a prison in their locality within 5 working days.** **29. If a case of active TB is identified, the local Public Health England unit, in conjunction with the multidisciplinary TB team, should plan a contact investigations exercise. They should also consider using mobile X-ray to check for further cases.** **30. Prison health services should have contingency, liaison and handover arrangements to ensure continuity of care before any prisoner on TB treatment is transferred between prisons or released. In addition, other agencies working with prisoners should also be involved in this planning.** **Heath checks and screening programmes** **31. Offer people equivalent health checks to those offered in the community, for example:** • **the NHS health check programme for people aged 40 and over** • **relevant NHS screening programmes, such as those for abdominal aortic aneurysm and bowel, breast and cervical cancer.**
Research recommendation	**2. When should subsequent health assessments be carried out in prison for people serving long-term sentences?** **3. What are the most effective tools to determine the health promotion needs of people in prison?**

[d] Please note that the highlighted recommendation is taken from NICE's tuberculosis guideline and is therefore not part of the consultation.

Relative values of different diagnostic measures and outcomes	Sensitivity was considered the most important measure by the GDG for this review question because subsequent health assessments should identify individuals with suspected condition(s) for follow-up. The consequences of missing a person with a health condition could result in a serious event or even death. Specificity was considered less important than sensitivity as any individual with a suspected condition(s) will be followed-up and would later be correctly classified as having the condition or not. False positives will be identified as such in the follow-up health assessment(s) and will not lead to serious consequences. False negatives are likely to lead to serious consequences, as many prisoners will not systematically come into contact with the prison health service again.
Trade-off between clinical benefits and harms	The GDG considered the trade-off between the sensitivity and specificity of the subsequent assessment and the length of the subsequent assessment. One very low quality prospective diagnostic cohort study with 679 adults showed that the Bai structured questionnaire has a sensitivity ranging from 50% to 86% and a specificity ranging from 95.9% to 99.5% for specific physical health conditions. Overall the specificity of the questionnaire in identifying physical health conditions was good, so then few people without the condition(s) would be incorrectly diagnosed (few false positives). However there was a wide range in specificity values for different health conditions from poor to good. So, the questionnaire was good at identifying some conditions (few false negatives) but poor at identifying other conditions (many false positives). This questionnaire was undertaken at least 6 months after reception into prison. Due to the limited evidence identified the GDG were unable to recommend a specific time point for any subsequent assessment other than cross referring to national screening programmes and existing NICE guidance.
Trade-off between net clinical effects and costs	In the absence of relevant published economic evidence, the GDG discussed the potential cost-effectiveness of subsequent health assessments based on their possible form and clinical effectiveness. The GDG considered the existing NHS health checks and screening programmes for the general public as relevant for a prisons population although their cost-effectiveness may vary in a prisons context. This is also supported on the principles of equality and obligations under the Equalities Act 2010. Relevant justification can also be found in section 7.6.1 (Trade-off between net clinical effects and costs). The GDG agreed that healthcare reviews (for those without ongoing chronic conditions) should be targeted at people who would benefit from subsequent contact with a healthcare professional. This will depend particularly on their age and the length of their sentence. For a young person serving a short sentence, it will not usually be necessary to schedule a subsequent healthcare review once the second-stage health assessment has been completed. However, an older patient in prison for a period of years would have a significant risk of developing a new condition which may not be picked unless the person is proactively monitored. The GDG highlighted that although such monitoring would require an upfront resource use in the form of a primary care appointment, it could lead to the early identification of a serious chronic condition, such as cardiovascular disease or diabetes, which if undiagnosed could lead to an acute event causing severe ill health and requiring an emergency response. Therefore periodic checks for older, long-term prisoners would be likely to be a good investment of resources, but should be determined on a case by case basis. The GDG also noted that national screening programmes and the NHS health check programme have already been determined to be cost-effective for the general population and are standard practice in the community. There is therefore no reason

	why these should not also be conducted within prisons for the relevant age groups.
Quality of evidence	The protocol specified RCTs as the preferred study design, with the following critical outcomes: morbidity; mortality until second assessment (undertaken within 7 days); health-related quality of life. As RCTs were not found, diagnostic cohort studies were included. The main outcomes of diagnostic cohort studies are sensitivity and specificity. The quality of the evidence was very low. The evidence was at serious risk of bias; a risk of selection bias was identified within the study, which was due to the consecutive recruitment of participants on reception to prison. The evidence was seriously indirect as the study had an indirect population (aged 16 or older) and an indirect comparison (medical records rather than other validated health assessment tool).
Other considerations	Recommendations in this linking evidence section contains other assessments which should take place alongside those conducted within the first 7 days of entry to prison, or atsubsequent assessments, that is those conducted after the first and second stage reception assessments. No quantitative evidence was identified for other assessments, but the GDG highlighted that there was already NICE guidance issued on several relevant topics that included further assessments, some of which included a prison setting. The GDG formally determined and documented that the evidence for the review questions in the published guideline were relevant and appropriate to the prison setting. Published NICE guidelines that make direct recommendations for a prison population, and specifically include prisoners in their scope, were checked for applicability and relevance and cross referred to where appropriate. As discussed below several NICE guidelines include recommendations on assessment therefore it is recommended that there is a system and processes in place to carry out other assessments in line with these adopted recommendations. Please note that recommendations in the Hepatitis B and C testing guideline[109] and the TB guideline,[100] refer to both prisons and immigration removal centres/detainees. As immigration centres are excluded from the scope of this guideline these recommendations have been adapted to remove this setting. This change does not affect the meaning or applicability of the recommendations to a prison setting. The GDG noted the current NICE guidance on Hepatitis B and C testing (PH43).[109] Recommendation 5 is specifically aimed at prisons and recommends testing such as offering all prisoners access to confidential testing for hepatitis B and C when entering prison and has been adopted by this guideline. This section also includes a recommendation that all prisoners should be offered a hepatitis B vaccination on reception to prison. The GDG discussed the recommendations in PH34[85] (HIV testing: increasing uptake in men who have sex with men). Recommendations state that people should be routinely offered and recommended HIV testing in high risk populations (PH3, PH33),[104,107] in particular when having a blood test (regardless of reason). The group agreed that these recommendations were appropriate for a prison population as the prison population can have a high HIV prevalence and may engage in high risk sexual practices. It was noted that the population of the guideline was only in those under 25 year old men, however this is still applicable to a prison population. PH3 Sexually transmitted infections and under-18 conceptions: prevention,[79] was also discussed and recommendations included as it contains relevant recommendations on assessment. PH3 makes recommendations aiming to identify individuals at high risk of STIs using their sexual history and focuses on opportunities for risk assessment, including during routine care or when a new patient registers. The recommendation on opportunities to identify people at risk of STIs included when providing travel immunisation and the GDG agreed this was not a relevant example in a prson setting and therefore the recommendation was adpated to remove this example.

The GDG also included recommendations from the current NICE guidance on TB (NG33),[100] which states that prisoners should be asked on reception if they are taking TB medication and should be tested for TB on entry to each prison system by a health questionnaire. This is highly applicable as it makes direct recommendations for the prison population. This includes a recommendation for Prisons with Department of Health-funded static digital X-ray facilities for TB screening that should X-ray all new prisoners and detainees (if they have not had a chest X-ray in the past 6 months. Examples of prisons with these facilities include London prisons (Belmarsh, Brixton, Pentonville, Wandsworth and Wormwood Scrubs).

The GDG discussed subsequent health assessments that could be conducted after the first and second stage reception health assessments, for example annual healthcare reviews. The GDG considered the importance of the prisoner choosing when to seek healthcare, as would happen in the community, against actively identifying conditions that may not be diagnosed until a more serious stage or not at all, and the duty of care towards prisoners. The GDG considered whether to specify a time point for when a healthcare review should be undertaken. The GDG agreed that a healthcare review should be considered in relation to the persons' needs, for example older people or people serving longer sentences may require more regular health checks than younger people due to poorer or deteriorating health. The GDG did not think that there was sufficient evidence to recommend a healthcare review at predetermined regular intervals but agreed that at the second stage of the health assessment the healthcare professional should use their clinical judgement to determine when a healthcare review should take place. However, the GDG noted that subsequent health assessments may be of benefit to prisoners, in particular to those serving longer sentences, therefore the GDG decided to make a research recommendation in this area (see below).

Additionally the GDG noted that some health assessments are undertaken at certain time points in the community, such as the NHS health check programme. National screening programmes, such as NHS abdominal aortic aneurysm (AAA) programme, NHS bowel cancer screening programme, NHS breast screening programme and NHS cervical screening programme were also recommended by the group for equivalence with the community and they noted that are not always offered in prison. The group also discussed current NICE guidance for certain populations (for example assessment of diabetes in people aged 40 or older). The GDG noted that, as care in prisons should be equivalent to the community, people in prison should be offered such assessments.

Research recommendations

The GDG agreed further research was needed, and in particular to determine when further health assessments should be provided for older and long-term prisoners who may require more frequent health check-ups. (for more details see Appendix P). Within prison there are growing numbers of people who are serving long-term sentences. There is emerging anecdotal evidence that long-term incarceration exacerbates chronic ill health and causes early onset of conditions associated with old age. Currently, once a person has undertaken the reception assessment no further comprehensive health assessments are undertaken. No evidence was identified for this question and evidence in this area would help inform future recommendation on when additional health checks may be required to prevent potential health deterioration and quickly identify any new health-related conditions.

The GDG noted the potential benefit of assessing the health promotion needs of people in prison in order for appropriate health promotion interventions to be offered. Therefore, the GDG decided to make a research recommendation on which tools could be used to identify health promotion needs of people in prison (for more details see Appendix P).

	Health promotion in prison can vary and may not be the priority for healthcare staff. However, people in prison are entitled to an equivalent standard of healthcare as they would receive in the community. Whilst in prison there is an ideal opportunity to assist people who perhaps have not previously attended health services. The prison population is known to have a high prevalence of smoking, often a poor diet and difficulties in accessing exercise programmes or information on sexual health, all of which may lead to poor health or infection or exacerbate existing health conditions. Health promotion services are delivered in many ways in prison, however an effective, valid assessment tool would ensure care is commensurate with accurately identified need. No evidence was identified for health promotion needs assessment and a study would inform future recommendations in this area. A validated assessment tool may identify specific healthcare needs more quickly, leading to appropriate education to enable self-care whilst in prison and on release from prison into the community.

6 Coordination and communication

6.1 Introduction

Communication and coordination between staff in the prison setting is more complex compared with the community, as healthcare providers not only have to coordinate and communicate with other healthcare providers and social services for multiple related or unrelated health conditions, but also with security and other prison staff. Effective multidisciplinary working between prison staff and health professionals is essential to ensure that appropriate information is shared in a timely manner between teams.

Good communication and coordination is an imperative tool to ensure effective non-fragmented healthcare provision for patients requiring high levels of care and who often have complex needs. Good communication and coordination should continue through the entire journey through the prison estate: entry, transfers between prisons, referrals to external hospitals and release back into the community.

Coordination of services between the different healthcare teams in prisons is often poor, with the consequence that people with dual or multiple diagnoses are often not provided with an integrated physical and mental health service. Delivering coordinated services in prisons by focusing on intra-agency communication is an important area to improve health outcomes for prisoners and ensuring efficient access to the health care system and other needed supports.

6.2 Review question: What are the barriers and facilitators to coordination, case management and communication between healthcare professionals involved in primary care, mental healthcare, substance misuse and secondary care?

For full details see review protocol in Appendix C.

Table 45: Characteristics of review question

Objective	Identification of the barriers and facilitators to coordination, case management and communication between multiple individuals and teams involves in assessing, managing and delivering healthcare, to enable the GDG to identify the necessary features for an effective coordinated healthcare service for prisoners.
Population and setting	Adults (18 and over) in prisons or young offender institutions Health professionals and other staff working in prisons or young offender institutions Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low or medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres
Review strategy	Study designs to be considered: Qualitative studies (for example, structured interviews, focus groups, observations). A thematic analysis of the data will be conducted and findings presented in the studies will be reported

6.3 Clinical evidence

6.3.1 Methods

Studies were searched for exploring the barriers and facilitators to coordination, case management and communication between prison staff and healthcare professionals involved in primary care, mental healthcare, substance misuse care and secondary care. Five qualitative studies were included in the review[24,48,127,139,166] these are summarised in Table 101. The majority of evidence is from staff who work in prisons, with only 1 study gathering evidence from former prisoners. Key findings from these studies are summarised in the evidence summary (Table 47). See also the study selection flow chart in Appendix E, study evidence tables in Appendix H and excluded studies list in Appendix L.

6.3.2 Summary of included studies

Table 46: Summary of studies included in the review

Study	Design	Population	Research aim	Comments
Dyer 2013[24]	Semi-structured interviews and focus groups	n=17 Prison staff members including GPs, nurses, nursing assistants and healthcare support workers, members of the Mental Health In-Reach Teams, pharmacy and CARATs (Counselling, Assessment, Referral, Advice and Throughcare) staff. UK	To explore prison health discharge planning in 4 prisons in North East England	
Joanna 2008[48]	Semi-structured interviews and focus groups	n= 70 (45 former prisoners; 25 professionals in prisons and community services, including: psychiatric nurses, GPs, substance misuse workers and staff from non-statutory agencies - generic resettlement assistance, employment advice, assistance with housing needs) Former prisoners: Mainly adults (aged 17 years or older) Male/female ratio 18:27 UK	To explore the continuity of care experienced by prisoners before and after release	Includes n=1 young offender
Powell 2010[127]	Semi-structured interviews and focus groups	n=80 (67 nurses working in prison healthcare centres including nurse managers, community psychiatric nurses/mental health nurses,	To explore views and experiences of nurses and other prison healthcare staff	

Study	Design	Population	Research aim	Comments
		substance misuse nurses and in-patient nurses; 13 healthcare assistants/healthcare workers/nursing auxiliaries) Age: not stated Gender: not stated UK	about their roles and the nursing care they provide to prisoners	
Ricketts 2007[139]	Semi-structured interviews and focus groups	n=62 (6 in-reach team manager, 20 in-reach team member, 15 healthcare staff, 2 prison governor, 19 discipline staff) UK	To explore the impact of prison mental health in-reach teams	
Wright 2014[166]	Semi-structured interviews	n=23 (1 admin staff, 1 clinical psychologist, 1 dual trained nurse, 1 GP, 2 psychiatrist, 8 RGN, 7 RMN, 2 service manager) UK	To explore the links between social and structural aspects of the penal setting, the provision of mental healthcare in prisons, and mental health work in this environment	

16.3.3 Evidence synthesis

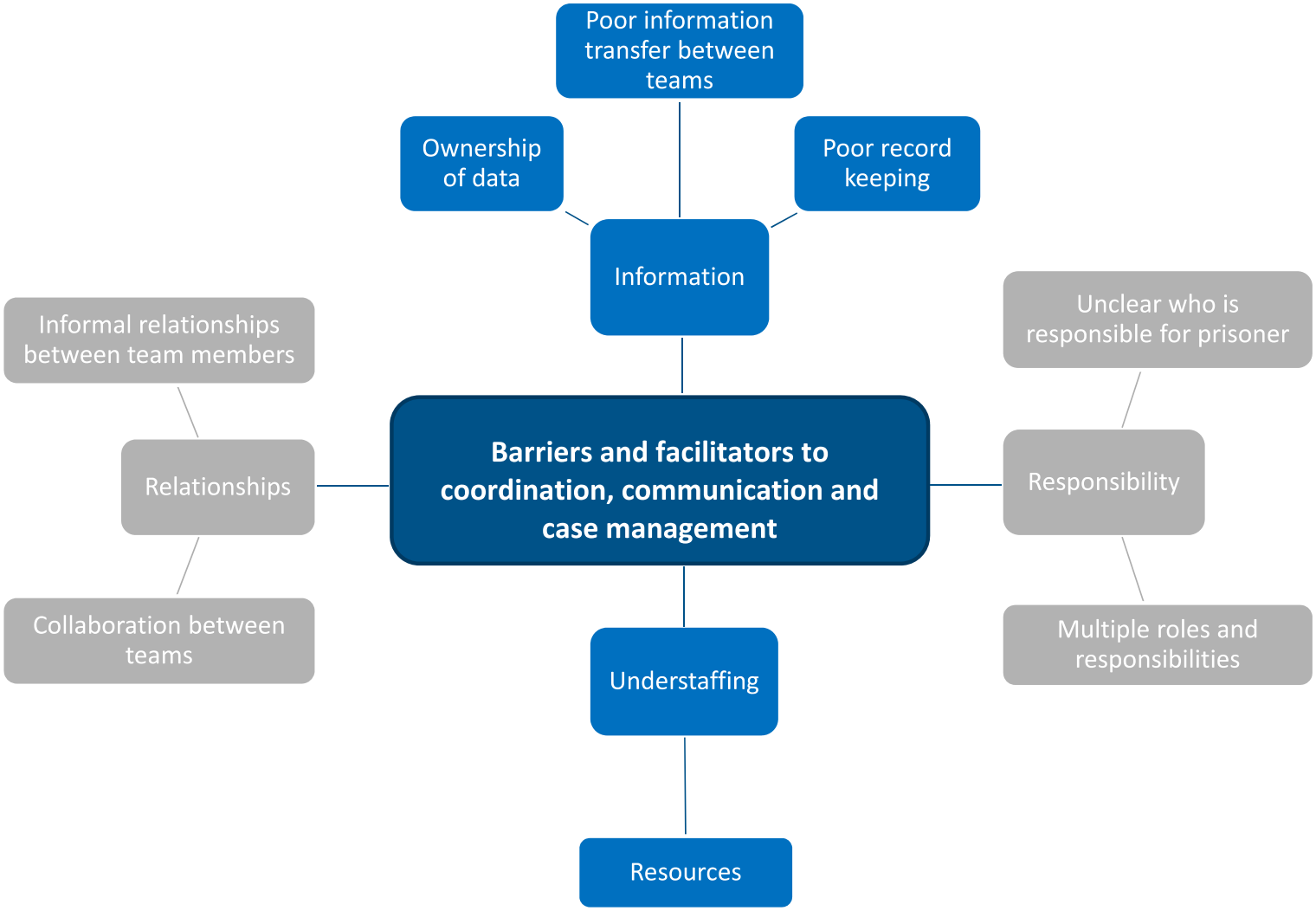
623.3.1 Themes and sub-themes derived from the evidence

3 **Table 47: Themes and sub-themes**

Main theme	Sub-themes
Information	Poor information transfer between teams Poor record keeping Ownership of data
Responsibility	Unclear who is responsible for prisoner Multiple roles and responsibilities
Relationships	Informal relationships between team members Collaboration between teams
Resources	Understaffing

4

Figure 3: Themes and sub-themes



6.3.3.2 1 Evidence summary

2 **Table 48: Summary of evidence: Theme 1: Information**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Poor information transfer between teams					
2	1 semi-structured interviews 1 semi-structured interviews and focus groups UK	For example: patient status, which services patient has been referred to "if someone's going from the mental health wing to the general wing they don't pass information over'" (Resettlement agency, England) "To find out that he'd been referred to counselling, and he'd been seeing the counselling woman for three or four weeks … and it was only by accident that I found out, because I went over to see him and she was in with him" (UK)	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Poor record keeping					
1	1 semi-structured interviews UK	Healthcare staff described a process where only the minimum information required was documented, due to concerns about confidentiality of patient information in the future	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 3: Ownership of data					
1	1 semi-structured interviews UK	Some healthcare staff reported a hierarchal inter- and intra-professional desire to not share data and retain ownership of it; whilst at the same time expecting other professional disciplines in the prison to communicate with them.	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	

Table 49: Summary of evidence: Theme 2: Responsibility

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Unclear who is responsible for prisoner					
1	1 semi-structured interviews UK	Participants reported that prison staff were often unsure who to refer people to. Healthcare staff were also reported to be unclear where the boundaries of responsibility were.	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Multiple roles and responsibilities					
3	1 semi-structured interviews 2 semi-structured interviews and focus groups UK	Participants reported that staff often play multiple roles in prison and would benefit from extra training in these roles. E.g. non-specialised staff assessing mental health needs on reception, prison officers playing a role in identifying and referring prisoners with suspected mental health issues "[GPs] just refer them straight to the mental health team…we need to stop this… a lot of the neurotic illnesses don't really need a psychiatrist's input." (Healthcare Manager, category B prison, England) "Education for officers regarding mental health issues is inconsistently provided" (UK)	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	

Table 50: Summary of evidence: Theme 3: Relationships

Study design and sample	Descriptors of themes	Quality assessment

No of studies	Design		Criteria	Rating	Overall
Sub-theme 1: Informal relationships between team members					
1	1 semi-structured interviews and focus groups UK	Participants reported that communication of information between team members often depends on informal relationships rather than formal databases.	Limitations of evidence	No limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Collaboration between teams					
2	2 semi-structured interviews and focus groups UK	Participants noted the importance that teams within the prison and agencies work together. "there's been an awful lot of resistance and barriers… so one of the greatest challenges has been networking but the one of the greatest accomplishments has been establishing a place within both prisons we work in and being able to work effectively with a lot of our colleagues" (in-reach team member social worker, UK)	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	

1

2 **Table 51: Summary of evidence: Theme 4: Resources**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Understaffing					
2	2 semi-structured interviews and focus groups UK	Understaffing was reported as a barrier to coordination between teams, through reducing the time available, and to taking prisoner to a centralised clinic. For example, lack of prison officers to escort patients to appointments, nurses undertaking security duties	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	

3

6.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

6.5 Evidence statements

Clinical

- Information was identified as a theme by 2 qualitative studies (n=93) of interviews and focus groups with former prisoners, healthcare professionals and prison staff in the UK. Subthemes included: poor information transfer between teams, poor record keeping and ownership of data. The evidence was of very low quality due to having minor limitations and no theme saturation.
- Three qualitative studies (n=120) used interviews and focus groups with healthcare professionals and prison staff in the UK to identify responsibility as a theme. Subthemes included: staff being unclear who is responsible for prisoner; staff having multiple roles and responsibilities. The evidence was of very low quality due to having minor limitations and no theme saturation.
- Relationships was identified as a theme by 2 low to very low quality qualitative studies (n=133) of interviews and focus groups with former prisoners, healthcare professionals and prison staff in the UK. Subthemes included: informal relationships between team members and the collaboration between teams. The collaboration subtheme had minor limitations. Both subthemes showed no theme saturation.
- Two qualitative studies (n=150) of interviews and focus groups with former prisoners, healthcare professionals and prison staff in the UK, identified resources as theme. The evidence was of very low quality due to having minor limitations and no theme saturation. This theme centred on understaffing as a barrier to coordination between teams.

Economic

- No relevant economic evaluations were identified.

6.6 Recommendations and link to evidence

Recommendations	**<u>Communication and coordination</u>** **32. Ensure that every person in prison has a named healthcare coordinator who is responsible for managing their care. Ensure that the person and all healthcare and prison staff know who this is.** **33. Ensure that the different teams that manage a person's care in prison communicate with one another to coordinate care.** **34. Share relevant information about people with complex needs with prison staff using prison record systems in line with legislation and national guidance. This should include information about any high-level risks, such as:** • **risk of self-harm**

	• **risk to others** • **communicable diseases** • **epilepsy** • **diabetes** • **allergies** • **deteriorating health conditions** • **learning disabilities.** **35. Review people in prison with complex health and social care needs. Ensure that if a person is supported by a multidisciplinary team the team meets regularly to plan and coordinate ongoing management. These meetings should be facilitated by primary care.** **36. Document all health and social care patient interactions and any information related to health and social care in the person's primary care patient record.** **37. Share information with other health and social care staff who are involved in the person's care in prison if it is in the person's best interests.**
Barriers and facilitators	The GDG agreed with the themes identified in the qualitative review on barriers and facilitators to coordination, case management and communication between prison staff and healthcare professionals in prison. The following barriers were identified: poor information transfer between teams; poor record keeping; desire to not share data and retain ownership of it; obscurity around who is responsible for prisoner; staff having multiple roles and responsibilities; and understaffing (resources). The following facilitators were identified: informal relationships between team members; collaboration between teams.
Trade-off between net clinical effects and costs	No published economic evaluations were identified. The GDG highlighted the clinical benefits of smoother, less fragmented coordination of care in prisons. The GDG noted that there are no major resource implications from these recommendations since these are associated with the current methods of multidisciplinary working for existing staff and do not require additional resources. Specifically, the GDG highlighted that documenting and sharing patient information within prisons should lead to the avoidance of unnecessary, duplicated healthcare-related activities. Therefore the GDG concluded that better coordination of care within prisons would be likely to be cost saving for the NHS.
Quality of evidence	The overall quality of the evidence was low to very low. The limitations of the evidence ranged from no limitations to minor limitations. All of the findings were coherent. All of the studies were very applicable as they were all conducted in the UK. None of the themes were saturated as the themes were only identified in a few studies and the data was not rich.
Other considerations	The GDG noted that the evidence suggests that healthcare staff in prison are unsure of where their boundaries of responsibility lie. The GDG agreed that everyone in prison should have a named care coordinator and both healthcare and prison staff should know who this is. The GDG also mentioned the 'National Partnership Agreement', 2015[117] between the National Offender Management Service, NHS

England and Public Health England, which outlines who is responsible for which services in prison. The GDG noted the possible benefits of having a named care coordinator (for example GP) who would be responsible for managing a person's healthcare in prison, liaising with other healthcare staff involved in the person's care (for example ensuring follow-up on diagnostic tests) and making sure relevant information is shared between primary and secondary care teams.

The GDG recommended that methods of working should be in place to enable regular communication and coordination between different teams in prison, for example this may be structured handovers of care or informal ways of increasing communication. Collaboration between teams was identified in the review as a facilitator to aid effective team working. Furthermore, for complex cases, a system should be in place to enable regular coordination between different teams in prison (for example weekly meetings) to identify new complex cases and review identified complex cases. The group discussed an example of complex case review including multi-disciplinary team meetings potentially involving primary care, secondary care, social care and custodial staff where relevant.

The GDG noted that prison staff do not have access to people's computerised medical records so information about high level risks (for example risk of self-harm, risk to others, deteriorating condition) should be shared with prison staff using their electronic record system, as supported by the evidence review key theme on information. The GDG noted the General Medical Council 2009[33] guidance on when to disclose information about serious communicable diseases, which states that with consent "you should make sure information is readily available to patients explaining that personal information about them will be shared within the healthcare team, including administrative and other staff who support the provision of care" and "if a patient refuses to allow you to inform someone outside the healthcare team of their infection status, you must respect their wishes unless you consider that failure to disclose the information will put healthcare workers or other patients at risk of infection".

The GDG emphasised the importance of documenting all health and social care information in the person's medical record. The GDG recognised the finding in the evidence that suggested that not all relevant information was being recorded in the patients computerised record of care, despite all healthcare professionals involved in care being required to do so, including healthcare teams in prison and in-reach services.

The GDG also noted that it may be helpful to assist custodial staff by entering a summary of important information in the wing record to aid coordination and communication.

The GDG agreed with the evidence which suggested that information was not be documented due to concerns about confidentiality and privacy. The GDG felt that healthcare professionals were often unsure about which information could be shared and when, and so were worried about being criticised for sharing information. The GDG agreed that it was important to support both healthcare and prison staff in understanding what information they are entitled to share with other professionals involved in their care, where appropriate consent[32] has been obtained or that is in the person's best interests in accordance with the Caldicott 2013[14] principles.

Coordination and communication were seen as crucial elements of care by the GDG and were discussed at many points during guideline development. The group noted the links between this and all stages in the care pathway for people in prison, notably in the monitoring chronic conditions and deteriorating health reviews see chapters 9 and 10 and also for ensuring continuity of care in chapter 11.

7 Promoting health and wellbeing

7.1 Introduction

The prison population, although younger than the general population, has overall poorer health. Many come from a background of social deprivation and economic disadvantage and, as a result, have significant health needs. Many of these needs are related to unhealthy lifestyles; the majority of people in prison smoke and over half are dependent on alcohol and/or drugs, and previous engagement with health services has usually been minimal.

Promoting and maintaining a healthy lifestyle in this vulnerable population is therefore a key challenge for prison staff, prison healthcare staff and visiting healthcare professionals. Supporting interventions in a prison environment is complex, due to the limitations of the regime and facilities. Across the prison estate health promotion activities and interventions are variable, joint working is required to weave health promotion opportunities in activities within the prison. This is part of the prison and NHS partnership working to promote a whole prison approach to health promotion; they focus on 5 key areas: healthy eating and nutrition, smoking, healthy lifestyles, including sex and relationships and active living, mental health promotion and wellbeing and drug and other substance misuse.[63]

Healthcare staff routinely provides information about what health services are available and how to access these. Health promotion information is available on wing notice boards and staff can provide information for specific illnesses/conditions. Health promotion activity is generally carried out by healthcare staff; physical education instructors can support this activity in the gym setting, but generally the focus sits with healthcare where physical health issues are identified. These health promotion activities need to be tailored to the educational abilities of prisoners to improve outcomes and support lifestyle changes.

Prisons offer a unique opportunity to educate and encourage prisoners to better understand their own health; stopping smoking, nutrition, exercise and how to use health services are all activities that take place in the wider prison. A wide range of tools can be used to support prisoners, including peer support and the questions asked in this chapter intend to identify the most effective interventions and how to deliver them.

7.2 Review question: What are the most clinically and cost-effective interventions that can be implemented to promote health and wellbeing in prisons?

For full details see review protocol in Appendix C.

Table 52: PICO characteristics of review question

Population	Adults (18 years and over) in prisons or young offender institutions (YOIs)
Interventions	Nutrition (food served, access to canteen, snack food) Personal hygiene, self-care, oral health Physical activity (including time in open air, mobilisation) Sexual health (advice, access to barrier methods) Smoking cessation (validated measures of cessation)
Comparisons	Usual care or alternative interventions appropriate within prioritised areas.
Outcomes	**Critical** Nutrition:

	• healthy BMI Personal hygiene, self-care, oral health: • patient-reported satisfaction Physical activity: • healthy BMI Sexual health: • decrease in sexually transmitted disease (STD) diagnosis from in-prison, accessing barrier methods and sexual health clinics Smoking cessation: • quit for at least 4 weeks **Important** • Uptake of screening programmes • Morbidity • Mortality • Health-related quality of life
Study design	Randomised controlled trials Non-randomised controlled trials Systematic reviews and meta-analyses of the above Observational studies if no RCTs are identified

7.2.1 Clinical evidence

RCTs were searched for comparing the effectiveness of interventions for health promotion compared to usual care or alternative interventions. Non-randomised and observational studies were searched for in the absence of RCT evidence. Five areas of health promotion were prioritised by the GDG; nutrition, hygiene, physical activity, sexual health and smoking cessation.

7.2.1.1 Nutrition

One non randomised controlled study was identified comparing a healthy diet plus education intervention in women with diabetes compared to control. See the study selection flow chart in Appendix E and excluded studies list in Appendix L.

Table 53: Summary of studies included in the review for the intervention: nutrition health promotion

Study	Intervention and comparison	Population	Outcomes	Comments
Firth 2015[28] Non randomised controlled trial	Reduced calorie menu and small classes and training opportunities related to nutrition and gardening. n = 63	Female prisoners with a diagnosis of diabetes USA (Oregon) - minimum security (intervention) medium security (control) Follow-up at 1 year	BMI Glycaemic control Cholesterol	Non randomised

1 **Table 54: Clinical evidence summary: healthy diet plus education versus control**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Nutrition (95% CI)
BMI	63 (1 study) 1 years	⊕⊖⊖⊖ VERY LOW[a] due to imprecision		The mean BMI in the control groups was 34.5	The mean BMI in the intervention groups was 3.2 lower (6.17 to 0.23 lower)

[a] Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs.

2

Related NICE guidance: Nutrition

The evidence identified for nutrition in the prison population is limited, however the GDG considered other published related NICE guidance to be relevant to a prison population. 2 related NICE guidelines were identified by hand searching the NICE website and considered by the group. These look at a broad population, and as such were discussed by the GDG for applicability and relevance, taking into consideration equity of care for people in prison.

The following guidelines were identified and detailed in Table 55:

- NG7 Preventing excess weight gain[99]
- CG189 Obesity: identification, assessment and management[94]

1 **Table 55: Related NICE guidance: Nutrition**

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
NG7	Yes. See review 1 in the full guideline of NG7, which includes a broad literature search covering interventions based on different types of food and drinks (consumption of sugary drinks, whole grains, fruit and vegetables etc.), total energy and nutrients (e.g. total fat, protein or energy consumption).	No. Published 2015	Moderate to high quality evidence – applicable to UK. Population was adults and children, but all reported separately. Population is representative of a prison population. Although the studies do not include people in prison.	Our review only identified one low quality study with imprecise outcome and therefore the GDG did not have enough information to make a recommendation. The recommendations made in NG7 were deemed applicable to the prison population who do have access to additional sugary drinks and high fat snacks via the canteen and often have choice of meals labelled as healthy options at meal times. The evidence identified in NG7 supports an increase in drinking water, eating more fruit and vegetables and whole grains, and a reduction in total fat and sugary drink consumption. The section in NG7 on takeaway food is not applicable to a prison population.
CG189	Yes Focussed review on diet, looking specifically on health information in section 7.4 of the full guideline CG189. Also looks at combined diet and nutrition interventions,	No. Published 2014. The review on physical activity was conducted in 2006, but not updated.	Evidence from RCT and before and after studies (moderate to high quality). All conducted in the UK. Population was adults and children, but all reported separately. Population included in studies are also representative of a prison population. All adults, range of ages and some other co-morbidities such as diabetes or pre-existing chronic conditions.	CG189 identified that consumption of high-fat foods decreased in the health information intervention group but remained stable in the control group. The recommendations made in CG189 were discussed by the GDG and thought to be appropriate for a prison population as they focus on a balanced diet and avoid the use of very restricted calorie control diets.

7.2.1.2 Hygiene

One observational study was included in the review,[20] which is summarised in Table 56. Evidence from this study is summarised in the clinical evidence summary (Table 57). See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, GRADE tables in Appendix J and excluded studies list in Appendix L.

Table 56: Summary of studies included in the review for the intervention: hygiene health promotion

Study	Intervention and comparison	Population	Outcomes	Comments
Cutler 1979[20] Before and after study	3 educational workshops (n=52) 1 hour per week for 3 weeks plus a dental kit (brush, floss, disclosing tablets and mirror) Participants were measured pre-education (n=52)	Female prisoners, self-selected convenience sample from a total prison population of roughly 200. 92 prisoners completed initial questionnaire and Implication in article that 40 prisoners either stopped participation or were excluded. USA (Nashville) Follow-up at 2 months	Russell's Oral Hygiene Index and Green's and Vermillion's Periodontal Index	Literature search indicates that the names of the 2 indexes used in this study were transposed. No standard deviations were reported. Age not reported

Related NICE guidance: Sexual health

No related NICE guidance was identified as applicable to cross refer to for hygiene.

1 **Table 57: Clinical evidence summary: hygiene health promotion versus no care**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with no care	Risk difference with hygiene health promotion (95% CI)
Oral Hygiene Index Russell's Oral Hygiene Index.[c] Scale from: 0 to 6.	87 (1 study) 2 months	⊕⊖⊖⊖ VERY LOW[a,b] due to risk of bias		The mean oral hygiene index with usual care was 1.11 points	The mean oral hygiene index in the health promotion group was 0.1 lower
Periodontal Index Vermillion's Periodontal Index.[c] Scale from: 0 to 8.	87 (1 study) 2 months	⊕⊖⊖⊖ VERY LOW[a,b] due to risk of bias		The mean periodontal index with usual care was 0.52 points	The mean periodontal index in the health promotion group was 0.33 higher

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[b] Imprecision was undetectable as standard deviations were unreported
[c] Literature search indicates that the names of the two indexes used in this study were transposed.

2

7.2.1.3 Physical activity

Two RCTs[6,15] and 1 observational before and after study[58] were included in this review, these are summarised in Table 58. Observational studies were included as the RCT evidence identified was in men only. Evidence from these studies is summarised in the clinical evidence summary below (Table 59 to Table 62). See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, forest plots in Appendix K, GRADE tables in Appendix J and excluded studies list in Appendix L.

The population in each study are quite different, as noted in the table below, with two studies including men only[6,15] and 1 with women only.[58]

Table 58: Summary of studies included in the review for intervention: physical activity

Study	Intervention and comparison	Population	Outcomes	Comments
Battaglia 2013[6] RCT	Cardiovascular plus resistance training (CRT) High intensity strength training (HIST) Usual care n=75	Men with more than 1 year detention and age ≤50 years (to allow for random assignment to high intensity protocol). Italy Follow up 9 months	Body mass index (BMI), blood pressure, Coronary heart disease (CHD) risk (calculated from ratio of total cholesterol/high density lipoprotein).	17 subjects dropped out due to voluntary decision (n = 10) or were moved to another prison (n = 7). Note that change scores have not been used and that there is some variation in baseline outcomes.
Cashin 2008[15] RCT	Structured exercise (cardiorespiratory endurance, strength and flexibility training). The programme was group based, although each individual participant received a tailored fitness plan. Usual care n=13	Male inmates who had a chronic illness, 2 or more risk factors for developing a chronic illness or who were over the age of 40 years. Australia Follow up 12 weeks	BMI, blood pressure, heart rate.	
Martin 2013[58] Observational (before and after)	Exercise and nutrition program versus usual care n=32	Incarcerated women aged over 18. All participants were assessed for their safety to participate in personal fitness component. Canada Follow up 6 weeks	BMI	Note study design: observational study (before and after).

1 **Table 59: Clinical evidence summary: cardiovascular plus resistance training (CRT) versus usual care**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with physical activity (95% CI)
Body mass index (BMI) kg/m^2	39 (1 study) 9 months	⊕⊕⊕⊖ MODERATE[a] due to risk of bias		Mean 28.3 (SD 2.7) in control pre test	The mean BMI in the intervention groups was 0.7 lower (2.65 lower to 1.25 higher)
Systolic blood pressure mmHg	39 (1 study) 9 months	⊕⊕⊖⊖ LOW[b] due to risk of bias, imprecision		Mean 119.2 (SD 6.4) in control pre test	The mean systolic blood pressure in the intervention groups was 7.8 lower (17 lower to 1.4 higher)
Diastolic blood pressure mmHg	39 (1 study) 9 months	⊕⊕⊕⊖ MODERATE[a] due to risk of bias		Mean 68.5 (SD 9.0) in control pre test	The mean diastolic blood pressure in the intervention groups was 4.6 lower (9.18 to 0.02 lower)
Coronary heart disease (CHD) risk ratio of total cholesterol/high density lipoprotein	39 (1 study) 9 months	⊕⊕⊕⊖ MODERATE[a] due to risk of bias		Mean 4.7 (SD 1.9) in control pre test	The mean CHD risk in the intervention groups was 0.6 lower (1.56 lower to 0.36 higher)

[a] Downgraded by 1 increment for selection bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

[b] Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs.

2

1 **Table 60: Clinical evidence summary: high intensity strength training (HIST) versus usual care**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with physical activity (95% CI)
High intensity strength training (HIST) - Body mass index (BMI) kg/m^2	37 (1 study) 9 months	⊕⊕⊕⊖ MODERATE[a] due to risk of bias		Mean 28.3 (SD 2.7) in control pre test	The mean BMI in the intervention groups was 1.2 lower (2.91 lower to 0.51 higher)
HIST - Systolic blood pressure mmHg	37 (1 study) 9 months	⊕⊕⊖⊖ LOW[a, b] due to risk of bias, imprecision		Mean 119.2 (SD 6.4) in control pre test	The mean systolic blood pressure in the intervention groups was 1.5 lower (10.63 lower to 7.63 higher)
HIST - Diastolic blood pressure mmHg	37 (1 study) 9 months	⊕⊕⊕⊖ MODERATE[a] due to risk of bias		Mean 68.5 (SD 9.0) in control pre test	The mean diastolic blood pressure in the intervention groups was 1.9 lower (5.82 lower to 2.02 higher)
HIST - Coronary heart disease risk ratio of total cholesterol/high density lipoprotein	37 (1 study) 9 months	⊕⊕⊕⊖ MODERATE[a] due to risk of bias		Mean 4.7 (SD 1.9) in control pre test	The mean coronary heart disease risk in the intervention groups was 0.6 higher (0.83 lower to 2.03 higher)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

[b] Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs.

2

1 **Table 61: Clinical evidence summary: structured exercise versus usual care**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with physical activity (95% CI)
Resting heart rate	13 (1 study) 12 weeks	⊕⊕⊖⊖ LOW[a, b, c] due to risk of bias, imprecision			The mean resting heart rate in the intervention groups was 19.84 lower (32.06 to 7.62 lower)
Systolic blood pressure mmHg	13 (1 study) 12 weeks	⊕⊖⊖⊖ VERY LOW[a, b, c] due to risk of bias, imprecision			The mean systolic blood pressure - systolic blood pressure in the intervention groups was 2.56 lower (14.72 lower to 9.61 higher)
Diastolic blood pressure - Diastolic blood pressure mmHg	13 (1 study) 12 weeks	⊕⊕⊖⊖ LOW[a, b, c] due to risk of bias, imprecision			The mean diastolic blood pressure - diastolic blood pressure in the intervention groups was 9.29 lower (16.89 to 1.69 lower)
Body mass index - Body mass index	13 (1 study) 12 weeks	⊕⊕⊕⊖ MODERATE[b, c] due to risk of bias			The mean body mass index - body mass index in the intervention groups was 1.66 lower (6.43 lower to 3.1 higher)

[a] Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs.
[b] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias [c] Male inmates with chronic illness, 2 risk factors for chronic illness or aged over 40 years.

2 **Table 62: Clinical evidence summary: exercise and nutrition program versus usual care**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with physical activity (95% CI)
Body mass index	32 (1 study) 6 weeks	⊕⊖⊖⊖ VERY LOW[a] due to indirectness		Mean 27.00 (SD 4.78) pre-test measure	The mean body mass index in the intervention groups was 0.73 lower (3.79 lower to 2.33 higher)

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with physical activity (95% CI)

[a] Downgraded by 1 increment due to indirectness. Noted that this intervention also includes a nutrition component.

Related NICE guidance: Physical activity

The evidence identified for physical activity in the prison population is limited, however the GDG considered other published NICE guidance on exercise and physical activity to be relevant to a prison population and therefore, 4 related NICE guidelines were identified by hand searching the NICE website and considered by the group. These look at a broad population, and as such were discussed by the GDG for applicability and relevance, taking into consideration equity of care for people in prison.

The following guidelines were identified and detailed in Table 63:

- NG7 Maintaining a healthy weight and preventing excess weight gain among adults and children[99]
- PH44 Physical activity: brief advice for adults in primary care[89]
- PH54 Exercise referral schemes to promote physical activity[96]
- CG189 Obesity: identification, assessment and management of overweight and obesity in children, young people and adults[71]

1 **Table 63: Related NICE guidance: Physical activity**

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
NG7	Yes. NG7 includes a broad question, under Evidence review 1, covering modifiable diet and physical activity components, and associated behaviours aimed at maintaining a healthy weight or preventing excess weight gain. (Maintaining a healthy weight and preventing excess weight gain in children and adults – partial update of CG43) Studies (interventions) included are relevant to prison setting.	No. Published 2015	Weak to moderate evidence – majority applicable to UK. Studies are in adults and children, which are separated out. Population is representative of a prison population. Noted that evidence for brisk walking intervention was in a specific population (in overweight or obese participants, or individuals with type 2 diabetes or metabolic syndrome). Similar to evidence we found in those with chronic conditions.	Recommendations for children not applicable. Evidence suggests benefit of brisk walking and aerobic exercise on reduction of weight. We did not identify evidence for brisk walking or comparable aerobic exercise. Evidence on strength training was inconclusive. This is the same finding as identified in our review. Some interventions were deemed not relevant, such as cycle rides and active travel or commuting, see LETR.
PH44	No. Focussed question on effectiveness of 'brief interventions' (less than 30 minutes in duration, or delivered in one session) in addressing physical activity. Interventions were not physical activity, but information, advice and support on how to access or increase physical activity.	No. Published 2013	Very low risk of bias to low risk of bias – majority applicable to UK. Population was adults. Nearly half of the included studies had participants with a mean age that lay between 50 to 69 years. Noted that over half were women, which is higher than in our population.	Although question is not the same as ours the recommendations generated are highly applicable to our population. The evidence identified that brief advice (compared with usual care) increases self-reported physical activity. No significant benefit was found for additional or longer interventions over and above brief advice. GDG stated that sensible interpretation should be applied for recommendations such as allowing access for bicycle rides.

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
				GDG discussed whether the recommended 150 minutes per week is achievable in prison - See LETR.
PH54	Yes. Review 1 of PH54 details exercise referral schemes (ERS) defined as: ERS exercise/physical activity programme that is more intensive than simple advice and needs to include one or a combination of counselling (face-to-face or via telephone); written materials; supervised exercise training.	No. Published 2014	Low to moderate quality - highly applicable to the UK. Population was adults. Review 1 of PH54 states that referral to ERS was in most instances made by the GP, due to an individual's health risk which could be reduced by physical activity, most commonly made referrals are due to increased risk of coronary heart disease, or on the basis of a sedentary lifestyle.	GDG noted detail in reference to those with chronic conditions (List of recommendations: Box 1: The role of structured exercise programmes in the management of, and rehabilitation following, a health condition). This is consistent with evidence found in our original review.
CG189	Yes Focussed question on the role of physical activity in weight loss and/or maintenance, see section 5.8 CG189 (full guideline). Studies (interventions) included are relevant to prison setting. Also covers assessment, diet, pharmacological and surgical management - not relevant for this question.	No. Published 2014. The review on physical activity was conducted in 2006, but not updated.	Evidence from observational studies (low quality). Majority from the USA, but applicable to UK. Population included in studies are also representative of a prison population. All adults, range of ages and some other co-morbidities such as diabetes or pre-existing chronic conditions.	Large amount of evidence identified on physical activity (alone or in combination with diet or behaviour therapy) showing a trend of weight loss. Other benefits also seen included reduction in the risk of developing hypertension and other cardiovascular events and reduction in medication use for comorbidities. Much more evidence identified than in our review, which was hard to draw conclusions from. GDG discussed whether the recommended 30 minutes, 5 times a week is achievable in prison - See LETR.

7.2.1.4 Sexual health

Six studies were included in the review[10,12,35,50,152,159] these are summarised in Table 64. Evidence from these studies is summarised in the clinical evidence summary (Table 65 and Table 66). 2 associated preceding methodological papers,[11,13] were also included. See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, forest plots in Appendix K, GRADE tables in Appendix J and excluded studies list in Appendix L.

Four studies investigating an educational health promotion intervention were included that reported the surrogate outcome knowledge of sexually transmitted infections,[10,12,35,50,159] two of which also reported intention to use condoms in the future.[10,12,35,50,159] Neither the outcomes knowledge nor intention could be combined for meta-analysis due to differences in the intervention methodology and the indexes used to measure the outcomes. Three of these studies were observational whilst the Grinstead 1997 was a quasi-randomised study but did not report standard deviations for the knowledge outcome.

Two studies described self-reported sexual behaviours, which were not able to be pooled. One[152] was a before and after study on the effect on installing a free dispenser, stocked with individually wrapped condoms. The second study was a large cohort study of two comparable prison systems,[12] where prisoners of one system had access to free dispensers, which dispensed small condom kits each containing one condom, a sachet of lubricant, information on the correct use of condoms and a plastic zip-lock bag. Within the other prison system condoms were prohibited.[e] Two associated preceding articles, by Butler 2013 detailed the methodology for data collection from the two prison systems[11,13] Sylla 2010 also reported the percentage of prisoners who self-reported obtaining condoms before installation and after installation of the dispenser.

Table 64: Summary of studies included in the review for intervention: sexual health promotion

Study	Intervention and comparison	Population	Outcomes	Comments
Bryan 2006[10] Multisite before and after	"Beyond Fear" programme (n=196) - structured groups (median size 6) for a weekly 90 minute session during a 6 week period. Group sessions lead by certified HIV/AIDS educator. Participants practiced skills in role-plays and simulated situational exercises while receiving coaching and feedback from the facilitators and other members participants were measured pre-education (n=196)	90% male sample, voluntary self-selection. Programme compulsory in 2 minimum security prisons but- filling in of evaluation form was not. Age range slightly under 18: range: 17–53; mean: 31.61; SD: 7.7 Evidence not downgraded USA (Connecticut) - five level 2, three level 3 and six level 4 facilities Follow-up at 6 weeks	Knowledge - assessed by a 12 true/false test	
Butler 2013[12] Cohort study	New South Wales prisoners (n=1118) who had access to dispensers which dispensed condom	Comparison of two prison systems in Australia – which combined account for 60% of the prison	Self-reported sexual activity	Consensual sex is not banned in Australian

e The original wording in the Butler 2013 article stated that condoms were "not readily available". Following contact with the author it was confirmed that condoms were prohibited items.

Study	Intervention and comparison	Population	Outcomes	Comments
	kits - each containing one condom, a sachet of lubricant, information on the correct use of condoms and a plastic zip-lock bag Queensland prisoners (n=900) who had no "readily available" access to condoms. Following contact with author it has been implied that condoms are prohibited	population. Age New South Wales: median - 33 (19-76) Queensland: median - 31.5 (18-78) Male prisoners randomly selected to target sample size greater than 13% per prison in New South Wales and 18% in Queensland. Australia - New South Wales (23 prisons) and Queensland (11 prisons)		prisons Methodology and baselines presented in two preceding articles: Butler 2010[13] and Butler 2013[11] Missing data for sample that self-reported sex on further question on safe sex New South Wales: 24.3% and Queensland 18.8%
Grinstead 1997[35] quasi-experimental - natural randomisation	Education by Professional Educator at entry to prison (n=648) Peer education (n=1169) and normal entry to prison (n=478) Educators were either HIV+ inmates trained in a four day workshop, mostly African-American or an African-American woman with bachelor's degree and four years of HIV and substance abuse education	Male prisoners entering prison - quasi-randomised by alternating weeks of the intervention Excluded if too ill or judged a security risk (25%) Mean age – 35.1 USA (California) State prison follow-up 60–90 minutes	Knowledge - assessed by 10 questions; Condom intention - assessed by a 5 point Likert scale and screening uptake - assessed by percentage of prisoners who accepted voluntary screening at the end of the intervention (no controls)	Natural randomisation achieved by alternating weeks of intervention. The 5 point Likert was reported on a 3 point scale in the results. No standard deviations were reported for the outcome – Knowledge
Lawrence 1997[50] Before and After	Two Education interventions 'Social cognitive theory' or 'gender and power' (n=90) - Group sessions led by same gender facilitators experience in providing interventions for low-income minority women. pre-intervention - self-administered measures packet (n=90)	Female prisoners randomised to 2 professionally led intervention groups - Selection of initial sample not stated Age range slightly under 18: range: 17–60; mean: 30.4 Evidence not downgraded for indirectness USA (southern urban jail)	Knowledge - assessed with a 27 question test and Intention - assessed by a 5 point Likert scale	n number for individual interventions not reported, only as a total number. Assumed 45 for each as randomisation present.

Study	Intervention and comparison	Population	Outcomes	Comments
		Follow-up 6 weeks		
Sylla 2010[152] before and after	Post intervention have had access to condom dispenser (n=69), lower number of Hispanics and young people surveyed post-intervention Before intervention (n=77) - had access to condoms one at a time via 1-to-1 meeting with the Forensic AIDS project (FAP) of the county health department	88% male prisoners, voluntary self-inclusion - recruited by announcement of voluntary survey in housing units, during recreation periods and during a transgender health class. Age in pre-test/post-test 18-34 - 35%/19% 35-44 - 34%/38% >44 - 31%/44% USA (San Francisco) County Jail Follow-up at 4 months	Self-reported obtaining of condoms and self-reported sexual activity	condom dispenser stocked with individually wrapped condoms
Vaz 1996[159] Before and after	Education by Prisoner-activists (n=300) – 3 educational sessions of AIDS and STD, sessions carried out in groups of 30 and lasted 30 min. Creation of a theatre group comprised of prisoners lead by a semi-professional drama instructor to put on monthly informative shows pre-intervention - measured on entry to prison	Consecutively selected on entry into prison but gender not stated Range of age under 18: (15–70; mean: 26) Evidence downgraded for indirectness Mozambique (Machava prison) Evidence downgraded for indirectness follow-up 6 months	Knowledge - assessed by 23 closed-ended questions administered by interviewers	Knowledge measured as percentage of prisoners achieving 100% on the test.

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1 **Table 65: Clinical evidence summary: sexual health promotion versus usual or no care**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with usual or no care	Risk difference with sexual health promotion (95% CI)
Knowledge 12 True/False Knowledge Questions. Scale from: 0 to 12.	392 (1 study) 6 weeks	⊕⊖⊖⊖ VERY LOW[a,b,c] due to risk of bias, indirectness, imprecision		The mean knowledge with no care was 9.48 points	The mean knowledge in the intervention groups was 1.23 higher (0.86 to 1.6 higher)
Knowledge 10 Knowledge Questions. Scale from: 0 to 10.	1647 (1 study) 60-90 minutes	⊕⊖⊖⊖ VERY LOW[a,b,d] due to risk of bias, indirectness		The mean with usual care was 7.8 points	The mean knowledge in the intervention groups was 0.3 higher
Knowledge 10 Knowledge Questions. Scale from: 0 to 10.	1126 (1 study) 60-90 minutes	⊕⊖⊖⊖ VERY LOW[a,b,d] due to risk of bias, indirectness		The mean knowledge with usual care was 7.8 points	The mean knowledge in the intervention groups was 0.5 higher
Knowledge 27 Knowledge Assessment Questions. Scale from: 0 to 27.	180 (1 study) 6 weeks	⊕⊖⊖⊖ VERY LOW[a,b,c] due to risk of bias, indirectness, imprecision		The mean knowledge with no care was 20.85 points	The mean knowledge in the intervention groups was 0.99 higher (0.09 lower to 2.08 higher)
Knowledge 23 Closed-Ended Knowledge Questions	600 (1 study) 6 months	⊕⊖⊖⊖ VERY LOW[a,b,e,f] due to risk of bias, indirectness	RR 1.77 (1.56 to 2)	561 per 1000	432 more per 1000 (from 314 more to 561 more)
Intention 5 point Likert Scale. Scale from: 1 to 5.	180 (1 study) 6 weeks	⊕⊖⊖⊖ VERY LOW[a,b,c] due to risk of bias, indirectness,		The mean intention with no care was 4.35 points	The mean intention in the intervention groups was 0.34 higher (0.04 to 0.63 higher)

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with usual or no care	Risk difference with sexual health promotion (95% CI)
		imprecision			
Intention 5 Point Likert Scale[6]. Scale from: 1 to 3.	2295 (1 study) 60-90 minutes	⊕⊖⊖⊖ VERY LOW[a,b] due to risk of bias, indirectness		The mean intention with usual care was 2.28 points	The mean intention in the intervention groups was 0.23 higher (0.14 to 0.31 higher)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[b] Downgraded by 1 or 2 increments because: The majority of the evidence had indirect outcomes
[c] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
[d] Imprecision was undetectable as study did not report standard deviations
[e] Downgraded by 1 because the majority of the evidence included an indirect population
[f] Downgraded by 1 because the majority of the evidence included an indirect setting

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1 **Table 66: Clinical evidence summary: access to condom dispensing machines versus no readily available access**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with no readily available access to condoms	Risk difference with access to condom dispensing machine (95% CI)
Practise Safe Anal Sex - Of prisoners who have sex Self-reporting	69 (1 study) 10 years	⊕⊖⊖⊖ VERY LOW[a] due to risk of bias	Peto OR 11.4 (4.16 to 31.24)	31 per 1000	322 more per 1000 (from 98 more to 937 more)
Practise Safe Anal Sex - Of prisoners who have sex Self-reporting	9 (1 study) 4 months	⊕⊖⊖⊖ VERY LOW[a,b] due to risk of bias, imprecision	RR 2.5 (0.49 to 12.89)	333 per 1000	500 more per 1000 (from 170 fewer to 1000 more)
Practise Safe Anal Sex - Total prisoner sample Self-reporting	2018 (1 study) 10 years	⊕⊖⊖⊖ VERY LOW[a] due to risk of bias	Peto OR 5.15 (2.21 to 11.98)	1 per 1000	4 more per 1000 (from 1 more to 11 more)
Practise Safe Anal Sex - Total prisoner sample Self-reporting	146 (1 study) 4 months	⊕⊖⊖⊖ VERY LOW[a,b] due to risk of bias, imprecision	RR 5.58 (0.67 to 46.59)	13 per 1000	60 more per 1000 (from 4 fewer to 593 more)
Obtaining Condoms Self-Reported behaviour	146 (1 study) 4 months	⊕⊖⊖⊖ VERY LOW[a] due to risk of bias	RR 3.81 (1.35 to 10.77)	58 per 1000	163 more per 1000 (from 20 more to 567 more)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[b] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

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Related NICE guidance: Sexual health

No related NICE guidance was identified as applicable to cross refer to for sexual health.

7.2.1.5 Smoking cessation

Four studies (3 RCTs and 1 crossover trial) were included in the review;[19,46,68,138] these are summarised in Table 67. It is noted that 1 study is in women only[19] and the other 2 include men only.[68,138] Evidence from these studies is summarised in the clinical evidence summary in Table 68 to Table 72.

See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, forest plots in Appendix K, GRADE tables in Appendix J and excluded studies list in Appendix L.

Table 67: Summary of studies included in the review for intervention: smoking cessation

Study	Intervention and comparison	Population	Outcomes	Comments
Cropsey 2008[19] RCT - crossover	Behavioural intervention (mood management training to prevent smoking relapse, 10 sessions over 10 weeks) plus nicotine patch versus control. n=539	Women prisoners Adult smokers who smoked at least 5 cigarettes a day, housed in general population (e.g. not in segregated housing or in acute mental health wing), and with at least 1 year left to serve. USA Follow up 6 months	Smoking abstinence, sessions attended and medication compliance	Note rate of attrition. Crossover RCT.
Jalali 2012[46] RCT	Motivational interviewing-based (MI-based) treatment with or without combination with nicotine replacement therapy (NRT) versus control. n = 213	Male prisoners. Adults imprisoned for more than 6 months, who smoke more than 10 cigarettes per day, with at least 6 months left to serve and are not taking other medication. Iran Follow up 90 days	Expired CO concentrations (to determine smoking abstinence) Number of cigarettes smoked per day.	Smoking ban in some sections of the prison, other sections permit smoking outdoors.
Naik 2014[68] RCT	Behavioural intervention (introduction to tobacco, prevalence of tobacco use, effects of tobacco use on general health and dental health, psychosocial factors influencing tobacco use, healthy diet and behavioural	Male prisoners Adult smokers who used any tobacco product either daily or occasionally at the time of the study, with at least 1 year left to serve. India	Smoking abstinence, attempt to quit and willingness to quit	Includes both chewing and smoking tobacco

Study	Intervention and comparison	Population	Outcomes	Comments
	intervention for prevention of tobacco use) versus control. n=600	Follow up 6 months		
Richmond 2013[138] RCT	Multicomponent intervention (cognitive behavioural therapy, nicotine patch, information booklet, access to telephone helpline) plus nortriptyline versus multicomponent intervention alone. n=425	Male prisoners Adults, incarcerated for 1 or more months, with at least 6 months of current sentence remaining, English speaking, score of 5 or more on the Fagerström Test for Nicotine dependence. Australia Follow up 12 months	Smoking abstinence and smoking reduction (50%)	

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1 **Table 68: Clinical evidence summary: behavioural intervention versus usual care in male prisoners**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Smoking status (95% CI)
Mean change in CO-oximetry - MI - Pre-test and post-test	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean CO-oximetry in expired air with control was 18.21	The mean reduction in co-oximetry in the intervention groups was 7.44 higher (6.29 to 8.59 higher)
Mean change in CO-oximetry - MI - Pre-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean CO-oximetry in expired air with control was 18.21	The mean reduction in co-oximetry in the intervention groups was 7.44 higher (6.25 to 8.63 higher)
Mean change in CO-oximetry - MI - Post-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean CO-oximetry in expired air with control was 18.21	The mean reduction in co-oximetry in the intervention groups was 0 higher (0.87 lower to 0.87 higher)
Mean change in cigarettes per day - MI - Pre-test and post-test	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean number of cigarettes per day in the control was 23.32	The mean reduction in cigarettes per in the intervention groups was 8.98 higher (6.78 to 11.18 higher)
Mean change in cigarettes per day - MI - Pre-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean number of cigarettes per day in the control was 23.32	The mean reduction in cigarettes per day in the intervention groups was 5.81 higher (3.45 to 8.17 higher)
Mean change in cigarettes per day - MI - Post-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean number of cigarettes per day in control was 23.32	The mean reduction in cigarettes per in the intervention groups was 3.78 higher (2.56 to 5 higher)
Mean change in Fagerström test score - MI - Pre-test and post-	142 (1 study)	⊕⊕⊖⊖ LOW[a]		The mean Fagerström test score in the control was 5.01	The mean reduction in Fagerström test score in the intervention groups was 2.67 higher (1.92

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Smoking status (95% CI)
test	90 days	due to risk of bias			to 3.42 higher)
Mean change in Fagerström test score - MI - Pre-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean Fagerström test score in the control was 5.01	The mean reduction in Fagerström test in the intervention groups was 4.32 higher (3.53 to 5.11 higher)
Mean change in Fagerström test score - MI - Post-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean Fagerström test score in the control was 5.01	The mean reduction in Fagerström test in the intervention groups was 1.64 higher (0.96 to 2.32 higher)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.

1 **Table 69: Clinical evidence summary: behavioural intervention plus NRT versus usual care in male prisoners**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Smoking status (95% CI)
Mean change in CO-oximetry - MI + NRT - Pre-test and post-test	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean CO-oximetry in expired air with control was 18.21	The mean reduction in co-oximetry in the intervention groups was 10.51 higher (9.32 to 11.7 higher)
Mean change in CO-oximetry - MI + NRT - Pre-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean CO-oximetry in expired air with control was 18.21	The mean reduction in co-oximetry in the intervention groups was 10.87 higher (9.89 to 11.85 higher)
Mean change in CO-oximetry - MI + NRT - Post-test and follow-	142 (1 study)	⊕⊕⊖⊖ LOW[a]		The mean CO-oximetry in expired air with control was 18.21	The mean reduction in co-oximetry in the intervention groups was 0.36 higher (0.39

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Smoking status (95% CI)
up	90 days	due to risk of bias			lower to 1.11 higher)
Mean change in cigarettes per day - MI + NRT - Pre-test and post-test	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean number of cigarettes per day in the control was 23.32	The mean reduction in cigarettes per day in the intervention groups was 9.41 higher (7.78 to 11.04 higher)
Mean change in cigarettes per day - MI + NRT - Pre-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean number of cigarettes per day in the control was 23.32	The mean reduction in cigarettes per day in the intervention groups was 10.06 higher (8.97 to 11.15 higher)
Mean change in cigarettes per day - MI + NRT - Post-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean number of cigarettes per day in control was 23.32	The mean reduction in cigarettes per in the intervention groups was 0.64 higher (0.99 lower to 2.27 higher)
Mean change in Fagerström test score - MI + NRT - Pre-test and post-test	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean Fagerström test score in the control was 5.01	The mean reduction in Fagerström test score in the intervention groups was 6.29 higher (5.55 to 7.03 higher)
Mean change in Fagerström test score - MI + NRT - Pre-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean Fagerström test score in the control was 5.01	The mean reduction in Fagerström test score in the intervention groups was 8.51 higher (7.8 to 9.22 higher)
Mean change in Fagerström test score - MI + NRT - Post-test and follow-up	142 (1 study) 90 days	⊕⊕⊖⊖ LOW[a] due to risk of bias		The mean Fagerström test score in the control was 5.01	The mean reduction in Fagerström test score in the intervention groups was 2.22 higher (1.57 to 2.87 higher)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.

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2 **Table 70: Clinical evidence summary: behavioural intervention plus nicotine patch versus usual care in women prisoners**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with smoking status (95% CI)
Smoking abstinence - 10 weeks	539 (1 study) 10 weeks	⊕⊕⊖⊖ LOW[a,b] due to risk of bias	RR 0 (5.58 to 56.29)	10 per 1000	10 fewer per 1000 (from 46 more to 553 more)
Smoking abstinence - 3 months	539 (1 study) 3 months	⊕⊕⊖⊖ LOW[a,b] due to risk of bias	RR 6.94 (3.17 to 15.16)	24 per 1000	143 more per 1000 (from 52 more to 340 more)
Smoking abstinence - 6 months	539 (1 study) 6 months	⊕⊕⊖⊖ LOW[a,b] due to risk of bias	RR 5.06 (2.39 to 10.7)	28 per 1000	114 more per 1000 (from 39 more to 272 more)
Subgroup of intervention (smoking abstinence versus smoking at end of treatment)					
Sessions attended - End of treatment (mean sessions attended)	500 (1 study) 10 weeks	⊕⊕⊖⊖ LOW[a,b] due to risk of bias			The mean sessions attended - end of treatment in the intervention groups was 2.7 higher (2.27 to 3.13 higher)[d]
Sessions attended - 6 months (mean sessions attended)	500 (1 study) 6 months	⊕⊕⊖⊖ LOW[a,b] due to risk of bias			The mean sessions attended - 6 months in the intervention groups was 1.4 higher (0.9 to 1.9 higher)[d]
Medication compliance - End of treatment (mean medication compliance)	250 (1 study) 6 months	⊕⊕⊖⊖ LOW[a,b] due to risk of bias			The mean medication compliance - end of treatment in the smoking abstinence group was 21.6 higher (12.04 to 31.16 higher)[d]
Medication compliance - 6 months	250	⊕⊖⊖⊖			The mean medication compliance - 6 months in the

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with smoking status (95% CI)
(mean medication compliance)	(1 study) 6 months	VERY LOW[a,b, c] due to risk of bias, imprecision			smoking abstinence group was 5.8 higher (5.26 lower to 16.86 higher)[d]

[a] *Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.* [b] *Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.* [c] *Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs*
[d] *Outcome given for subgroup of intervention, smoking versus smoking abstinence at end of treatment. Clinical benefit or harm not appropriate.*

1 **Table 71: Clinical evidence summary: behavioural intervention versus usual care in male prisoners**

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with smoking status (95% CI)
Smoking abstinence	600 (1 study) 6 months	⊕⊖⊖⊖ VERY LOW[a, b] due to risk of bias, indirectness	RR 8 (3.48 to 18.41)	20 per 1000	140 more per 1000 (from 50 more to 348 more)
Attempt to quit (yes/no)	600 (1 study) 6 months	⊕⊖⊖⊖ VERY LOW[a, b] due to risk of bias, indirectness	RR 2.55 (2.13 to 3.06)	307 per 1000	476 more per 1000 (from 347 more to 632 more)
Willing to quit (yes/no)	600 (1 study) 6 months	⊕⊖⊖⊖ VERY LOW[a, b] due to risk of bias, indirectness	RR 1.12 (0.99 to 1.26)	613 per 1000	74 more per 1000 (from 6 fewer to 159 more)

[a] *Downgraded by 1 increment for risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias*
[b] *Downgraded for indirectness. Participants used both chewable and smoking tobacco. 5.3% chewing tobacco and 2.1% chewable and smoking tobacco.*

Table 72: Clinical evidence summary: behavioural intervention plus nicotine patch plus nortriptyline versus behavioural intervention plus nicotine patch in male prisoners

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with smoking status (95% CI)
Continuous smoking abstinence - 3 months	425 (1 study)	⊕⊕⊖⊖ LOW[a, b] due to risk of bias, imprecision	RR 1.45 (0.98 to 2.13)	164 per 1000	74 more per 1000 (from 3 fewer to 185 more)
Continuous smoking abstinence - 6 months	425 (1 study)	⊕⊕⊖⊖ LOW[a, b] due to risk of bias, imprecision	RR 1.42 (0.89 to 2.25)	123 per 1000	52 more per 1000 (from 14 fewer to 154 more)
Continuous smoking abstinence - 12 months	425 (1 study)	⊕⊖⊖⊖ VERY LOW[a, b] due to risk of bias, imprecision	RR 0.98 (0.58 to 1.65)	119 per 1000	2 fewer per 1000 (from 50 fewer to 77 more)
Point prevalence abstinence - 3 months	425 (1 study)	⊕⊕⊖⊖ LOW[b] due to risk of bias, imprecision	RR 1.41 (1 to 1.99)	196 per 1000	80 more per 1000 (from 0 more to 194 more)
Point prevalence abstinence - 6 months	425 (1 study)	⊕⊕⊖⊖ LOW[b] due to risk of bias, imprecision	RR 1.37 (0.89 to 2.11)	142 per 1000	53 more per 1000 (from 16 fewer to 158 more)
Point prevalence abstinence - 12 months	425 (1 study)	⊕⊖⊖⊖ VERY LOW[a, b] due to risk of bias, imprecision	RR 0.83 (0.51 to 1.35)	146 per 1000	25 fewer per 1000 (from 72 fewer to 51 more)
Smoking reduction 50% - 3 months	425 (1 study)	⊕⊕⊕⊖ MODERATE[b]	RR 1.01 (0.95 to	886 per 1000	9 more per 1000 (from 44 fewer to 71 more)

Outcomes	No of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with smoking status (95% CI)
		due to risk of bias	1.08)		
Smoking reduction 50% - 6 months	425 (1 study)	⊕⊕⊕⊖ MODERATE[b] due to risk of bias	RR 1.05 (0.95 to 1.16)	776 per 1000	39 more per 1000 (from 39 fewer to 124 more)
Smoking reduction 50% - 12 months	425 (1 study)	⊕⊕⊕⊖ MODERATE[b] due to risk of bias	RR 0.93 (0.83 to 1.03)	776 per 1000	54 fewer per 1000 (from 132 fewer to 23 more)

[a] *Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs.*
[b] *Downgraded by 1 increment for risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias*

1

Related NICE guidance: Smoking cessation

The evidence identified for smoking cessation in the prison population is limited, however the GDG considered other published NICE guidance on smoking cessation to be relevant to a prison population and therefore, 4 related NICE guidelines were identified by hand searching the NICE website and considered by the group. These look at a broad population, and as such were discussed by the GDG for applicability and relevance, taking into consideration equity of care for people in prison.

The following guidelines were identified and detailed in Table 73:

- PH45 Tobacco: harm reduction approaches to smoking (NICE public health guideline 45)[90]
- PH26 Quitting smoking in pregnancy and following childbirth (NICE public health guideline 26)[90]
- PH1 Brief interventions and referral for smoking cessation (NICE public health guideline 1)[78]

1 **Table 73: Related NICE guidance: Smoking cessation**

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
PH45	Yes. See review 2 of PH45, which includes questions on the effectiveness of different combinations of nicotine replacement therapy (NRT) products and behavioural support, counselling, advice or self-help (with or without pharmacotherapy) in helping people cut down smoking before quitting.	No. Published 2013	Moderate evidence – majority applicable to UK. Population was adults. Population is representative of a prison population. Although the studies do not include people in prison PH45 makes recommendations for people in closed institutions (including custodial sites such as prisons and police stations) - see recommendation 9. For further detail see LETR.	Evidence reported in PH45 is in agreement with our evidence review, which suggests reduced number of cigarettes per day prior to quitting, and in quitting itself with both NRT and behavioural therapy. PH45 makes specific recommendations for people in prison (see recommendation 9) such as: • • Provide the support required for their circumstances. This includes prescribing or supplying licensed nicotine-containing products. • Ensure staff understand that, if someone reduces the amount they smoke (or stops completely), this can impact on their need for psychotropic and some other medications. Ensure arrangements are in place to adjust their medication accordingly.
PH26	Yes. Review 1 of PH26 looks at the effectiveness of behavioural interventions alone (including motivational interviewing, stop smoking counselling, professional education,	No. Published 2010	Review 1 of PH36 includes studies of low to moderate quality - majority were from the USA, but considered to be highly applicable to the UK. Population included in studies are also representative of a prison population. This evidence shows very weak associations between the counselling interventions and smoke free related outcomes (such as	Our review did not identify any evidence in pregnant women, but this is an equality consideration relevant for this guideline and therefore PH26 is highly applicable. Findings were consistent with our review, that the health promotion intervention showed an increase in smoking cessation.

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
	comprehensive and individualised smoke free home policy), in encouraging the establishment of smoke free homes. The briefing paper in PH26 on smoking cessation during pregnancy details effectiveness of NRT in pregnancy.		cotinine measures or self reported smoking). The briefing paper in PH26 identifies that a Cochrane review of NRT in pregnancy was effective; however it included a large trial from which the independent effect of NRT for cessation cannot be isolated. It also did not include one large negative trial. The briefing paper in PH26 concludes that there is still insufficient evidence for the effectiveness of NRT for smoking cessation in pregnancy.	
PH1	Yes. Review question 1 in PH1 has a focussed question on the effect of NRT delivered with minimal additional support from physicians or purchased over the counter. Main focus of PH1 is on which methods of brief intervention are effective.	No. Published 2006.	Evidence from moderate to high quality studies, directly applicable to the UK. Population included in studies are also representative of a prison population. Evidence supports the efficacy of physician advice giving routine brief intervention for smoking cessation and nurse advice as a brief structured intervention only. With respect to the type of brief interventions, evidence supports the efficacy of NRT as part of a brief intervention for smokers wishing to make a quit attempt. Evidence also supports the limited efficacy of standard self-help materials as a brief intervention, and the efficacy of individually (but not population) tailored materials.	Evidence in PH1 agrees with evidence identified in our evidence review, that there is a benefit of behavioural intervention plus NRT. Difference in 'brief intervention' as described in PH1 compared to more time intensive, multi-session behaviour interventions as identified in our review. However, brief single interventions were included within our protocol and would have been included if identified in the prison population.

1

7.2.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

7.2.3 Evidence statements

Clinical

Nutrition

- One non randomised controlled trial was included comparing a reduced calorie diet in women diagnosed with diabetes (n=63) compared to usual care. Very low quality evidence onBMI was reported to be lowered in the reduced calorie diet group, however the effect was imprecise.

Hygiene

- One observational study was included in the review reporting very low quality evidence for two validated indexes to measure the periodontal and oral hygiene of prisoners before and after an educational intervention (n=52), however standard deviations were not reported and the clinical difference could not be ascertained.

Physical activity

- One RCT reportedcardiovascular resistance training versus usual care in 75 men. No clinical difference was identified for the low to moderate quality evidence presented forthe outcomes of body mass index and coronary heart disease risk. Cardiovascular resistance training suggests a decrease in systolic and diastolic blood pressure, but the results are imprecise and therefore of uncertain clinical benefit. The same study also reports high intensity strength training versus usual care and shows no clinical difference in the reported outcomes.
- Structured exercise versus usual care was reported in 1 RCT (n=13)and showed a clinical benefit favouring exercise for the outcomes of resting heart rate and diastolic blood pressure (imprecise)(very low to moderate quality). The population was men with a chronic illness, 2 or more risk factors for developing a chronic illness or who were over the age of 40 years.
- An observational before-and-after study in 18 women showed no difference in body mass index for the intervention of an exercise and nutrition program versus usual care.

Sexual health

- Three observational before and after studies (n=196, n=90 and n=300) and 1 quasi-randomised study (n=648) compared sexual health education versus no education. Studies were not meta-analysed due to differences in education programs. Very low quality evidence from 2 unpooled studies showed a clinical benefit of sexual health education in increasing sexual health knowledge. Very low quality evidence from 2 unpooled studies showed no clinical effect of sexual health education in increasing condom use intention.
- Two studies (1 cohort, n=69, and 1 before and after study, n=300) compared providing access to a condom dispensing machine versus less readily available access to condom. Very low quality evidence from 2 unpooled studies showed a clinical benefit of access to condom dispensing machines for increasing the practice of safe anal sex of prisoners who self-report having sex in prison (one study is imprecise). Very low quality evidence from 2 unpooled studies showed a clinical benefit of access to condom dispensing machines for increasing the practice of safe anal sex of prisoners. Very low quality evidence from 1 study showed a clinical benefit of access to

condom dispensing machines for increasing the self-reported uptake of condoms. However all the results are imprecise and have large confidence intervals.

Smoking cessation

- Behavioural intervention with or without NRT versus usual care was identified in 1 low quality RCT in men (n=213) and showed clinical benefit of health promotion for the outcomes of mean change in expired CO-oximetry, number of cigarettes per day and Fagerström test score, at both Pre-test versus post-test and per-test and follow up. Smaller effects in outcomes were seen from post-test to follow-up.
- Behavioural intervention plus nicotine patch versus usual care was identified in 1 low quality RCT crossover in women (n=539) and showed clinical benefit of health promotion for the outcomes of smoking abstinence at 10 weeks, 3 months and 6 months.
- No clinical benefit was identified for the addition of nortriptyline to a behavioural intervention plus nicotine path for the outcomes of continuous smoking abstinence up to 12 months, point prevalence smoking abstinence or smoking reduction of 50% (1 RCT, n - 425, very low to moderate quality).
- One RCT of 600 men showed that a behavioural intervention versus control had a clinical benefit of increasing smoking abstinence at 6 months and attempting to quit smoking at 6 months, but no difference in willingness to quit at 6 months.

Economic

- No relevant economic evaluations were identified.

7.2.4 Recommendations and link to evidence.

See section 7.6 below.

7.3 Review question: What are the most clinically and cost-effective methods of delivering health promotion activities in prison?

For full details see review protocol in Appendix C.

Table 74: PICO characteristics of review question

Population	Adults (18 years and over) in prisons or young offender institutions (YOIs)
Interventions	Validated health assessment tools/triage/policies/protocols • Group work • 1-2-1s • Wing-based vs. central • Radio • Audio-visual • Posters • Leaflets • Internet/intranet • Self-help/workbook • Prisoner newspapers • Newsletters • Events (Wellbeing days) • Mentoring • Peers • Motivational/incentivising • Teaching through learning English • Educational classes around life skills • Welcome pack • Induction
Comparisons	Against each other or usual care
Outcomes	**Critical** Nutrition – healthy BMI Personal hygiene/self-care/oral health – patient-reported satisfaction Physical activity – healthy BMI Sexual health – decrease in sexually transmitted disease (STD) diagnosis from in-prison, accessing barrier methods and sexual health clinics Smoking cessation – quit for at least 4 weeks **Important** Uptake of screening programmes Morbidity Mortality Health-related quality of life
Study design	Randomised controlled trials Systematic reviews and meta-analyses of the above Observational studies if no RCTs are identified

7.3.1 Clinical evidence

Randomised controlled trials and observational studies comparing the effectiveness of different methods in delivering health promotion interventions in prison were searched for. The search was split into the five groups of health promotion interventions under investigation: nutrition, hygiene, physical activity, sexual health, and smoking cessation. Relevant indirect comparisons presented in previous review questions were highlighted to the GDG and any direct comparisons are presented in this review.

No relevant studies were identified which compared the delivery methods of health promotion interventions in prison. For further information see the study selection flow chart in Appendix E and excluded studies list in Appendix L.

7.3.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

7.3.3 Evidence statements

Clinical

- No evidence was identified comparing delivery methods of health promotion interventions in prison.

Economic

- No relevant economic evaluations were identified.

7.3.4 Recommendations and link to evidence

See section 7.6 below.

7.4 Review question: Who should deliver health promotion activities in prison?

For full details see review protocol in Appendix C.

Table 75: PICO characteristics of review question

Population	Adults (18 years and over) in prisons or young offender institutions (YOIs)
Interventions	Validated health assessment tools/triage/policies/protocols Who delivers the activities • healthcare staff (including external organisations, prison officers/nurses/doctors) • custody staff (escorting staff/contracting staff/PE officers) • educational staff • Probation staff • Health trainers/health champions • IMB • Social care assistants • CARAT workers/RAPT workers/PASRO/Clinks • UKBA officers • Positively UK • Peer-led (serving prisoners/external organisations) and professionally led approaches
Comparisons	Against each other or usual care.
Outcomes	**Critical** Nutrition: • healthy BMI Personal hygiene, self-care, oral health: • patient-reported satisfaction Physical activity: • healthy BMI Sexual health: • decrease in sexually transmitted disease (STD) diagnosis from in-prison, accessing contraception and sexual health clinics Smoking cessation: • quit for at least 4 weeks **Important** • Uptake of screening programmes • Morbidity • Mortality • Health-related quality of life
Study design	Randomised controlled trials Systematic reviews and meta-analyses of the above Observational studies if no RCTs are identified

17.4.1 Clinical evidence

Randomised controlled trials and observational studies comparing the effectiveness of different entities who undertook health promoting interventions in prison were searched. The search was split into the five groups of health promotion interventions under investigation: nutrition, hygiene, physical activity, sexual health, and smoking cessation. Relevant indirect comparisons presented in previous review questions were highlighted to the GDG and any direct comparisons are presented in this review.

One study was included in the review[35] which is summarised in Table 64. Evidence from this study is summarised in the clinical evidence summary (Table 65). See also the study selection flow chart in Appendix E, study evidence table in Appendix H, forest plots in Appendix K, GRADE table in Appendix J and excluded studies list in Appendix L.

Grinstead 1997 was a quasi-randomised trial conducted in the USA which investigated the effectiveness of a sexual health educational programme on entry to prison conducted by either peer educators or a professional educator. This study reported the surrogate outcome knowledge of sexual transmitted infections (for which standard deviations were not reported) and intention to use condoms in the future. One important outcome reported was uptake of HIV screening which recorded the numbers of prisoners who accepted voluntary HIV testing immediately following the education intervention.

Table 76: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Grinstead 1997[35] quasi-experimental - natural randomisation	Education by Professional Educator at entry to prison (n=648) Peer education (n=1169) and normal entry to prison (n=478) Educators were either HIV+ inmates trained in a four day workshop, mostly African-American or an African-American woman with bachelor's degree and four years of HIV and substance abuse education	Male prisoners entering prison - quasi-randomised by alternating weeks of the intervention Excluded if too ill or judged a security risk (25%) Mean age – 35.1 USA (California) State prison follow-up 60–90 minutes	Knowledge - assessed by 10 questions; Condom intention - assessed by a 5 point Likert scale and screening uptake - assessed by percentage of prisoners who accepted voluntary screening at the end of the intervention (no controls)	Natural randomisation achieved by alternating weeks of intervention. The 5 point Likert was reported on a 3 point scale in the results. No standard deviations were reported for the outcome – Knowledge

1 **Table 77: Clinical evidence summary: professional educator versus peer educator**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with peer education	Risk difference with professional sexual health education (95% CI)
Knowledge 10 Knowledge Questions. Scale from: 0 to 10	1817 (1 study) 60-90 minutes	⊕⊖⊖⊖ VERY LOW[a,b,d] due to risk of bias, indirectness		The mean knowledge in the peer group was 8.1 points	The mean knowledge in the professional groups was 0.2 higher
Intention 5 Point Likert Scale. Scale from: 1 to 3[c]	1817 (1 study) 60-90 minutes	⊕⊖⊖⊖ VERY LOW[a,b] due to risk of bias, indirectness		The mean condom use intention in the peer group was 2.53 points	The mean intention in the professional group was 0.05 lower (0.15 lower to 0.05 higher)
HIV Testing Percentage volunteered for HIV test	1817 (1 study) 60-90 minutes	⊕⊕⊖⊖ LOW[a] due to risk of bias	RR 1.06 (0.95 to 1.18)	425 per 1000	25 more per 1000 (from 21 fewer to 76 more)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[b] Downgraded by 1 or 2 increments because: The majority of the evidence had indirect outcomes
[c] A 3 Point Likert Scale was reported in the results
[d] Imprecision and confidence intervals were undeterminable as standard deviations were not reported

2

17.4.2 Economic evidence

Published literature

One economic evaluation was identified that compared a peer-led educational intervention with professionally-led and 'do nothing' approaches to prevent future HIV infections and has been included in this review.[148] This is summarised in the economic evidence profile below (Table 78) and the economic evidence table in Appendix I.

See also the economic article selection flow chart in Appendix F.

Unit costs

See Table 59 in Appendix O.

Table 78: Economic evidence profile: peer-led interventions versus professionally-led and 'do nothing' approaches

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects (QALY loss averted)	Cost-effectiveness	Uncertainty
South 2014 [148] (UK)	Partially applicable[(a)]	Potentially serious limitations[(b)]	• Cost-utility analysis • Static probabilistic Bernoulli model used within a cost-effectiveness framework • Evidence from a prison and a non-prison setting are combined in the analysis. • Inputs were sourced from a systematic literature review	Professionally-led versus doing nothing: £71,961 favouring professionally led (95% CI: NR; p=NR) Peer-led versus professionally led: £119,912 favouring peer led (95% CI: NR; p=NR)	Professionally-led versus doing nothing: 1.26 favouring professionally led (95% CI: NR; p=NR) Peer-led versus professionally led: 2.08 favouring peer led (95% CI: NR; p=NR)	• Intervention 1 is dominated by both Interventions 2 & 3 (more expensive and less effective) • Intervention 2 is dominated by intervention 3 (more expensive and less effective)	The peer-led intervention always dominates the professionally led for all parameters of the Bernoulli model and the follow up cost and QALY inputs in the one way sensitivity analysis. In the probabilistic sensitivity analysis the "do nothing" intervention is clearly dominated. Point estimates for the other two interventions are partly overlapping; however the mean estimates are clearly distinct.

Abbreviations: QALY: quality-adjusted life years; NR: not reported

(a) Quality of life values are derived from studies conducted on a non-prisons population.

(b) Health outcomes sourced from a non-prison setting. Resource use was extracted from a US prison setting.

7.4.3 Evidence statements

Clinical

- One quasi-randomised trial (n=1,817) investigated the effectiveness of a sexual health educational programme on entry to prison conducted by either peer educators or a professional educator. There were no clinical differences found between the interventions for all reported outcomes: HIV screening uptake, condom intention, or HIV-related knowledge.

Economic

- One cost-utility analysis that compared 2 HIV prevention interventions (1 professionally led, 1 peer-led) versus no intervention found that:
  - The "no intervention" strategy was dominated by both prevention interventions (more expensive and less effective).
  - The professionally led prevention intervention was dominated by the peer-led prevention intervention (more expensive and less effective).

7.4.4 Recommendations and link to evidence

See section 7.6 below.

7.5 Review question: What are the barriers and facilitators to information provision, support and mentoring for prisoners to promote health and wellbeing?

For full details see review protocol in Appendix C.

Table 79: Characteristics of review question

Objective	Identification of barriers and facilitators around information provision, support and mentoring that could be addressed to improve the health and wellbeing of people in prison.
Population and setting	Adults (18 and over) in prisons or young offender institutions. Indirect settings: Immigrant Removal Centres (IRCs), secure environments, forensic units, low/medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Review strategy	Study designs to be considered: Qualitative studies (for example, structured interviews, focus groups, observations). A thematic analysis of the data will be conducted and findings presented in the studies will be reported.

7.5.1 Clinical evidence

7.5.1.1 Methods

Twenty one qualitative studies were included in the review[2,17,18,23,38,41,49,52,53,55,56,132,133,137,140,145-147,154,158,165] these are summarised in Table 101 below. Key findings from these studies are summarised in the clinical evidence summary below (Table 103, Table 83, Table 84 and Table 85). See

also the study selection flow chart in Appendix E, study evidence tables in Appendix H, forest plots in Appendix K and excluded studies list in Appendix L.

7.15.1.2 Summary of included studies

Table 80: Summary of studies included in the review

Study	Methods used	Population	Research aim	Comments
Qualitative studies				
Alves 2015[2]	Focus groups	n=14 Female adult (mean age 39±12.91 years) prisoners 1 women's prison, Portugal	To investigate the health of detained women and the influence of incarceration from their perspective	
Condon 2007[18] Condon 2008[17]	Semi-structured interviews	n=111 Male (91%) and female (9%) prisoners and young offenders (aged 16-20 years)(18%) 12 prisons (men's prisons, young offenders institutions and a women's prison), England, UK	To explore the views of prisoners about health services provided in prisons To explore the views of prisoners of making healthy choices in prison	Includes participants <18 years
Douglas 2009[23]	1:1 semi-structured interviews Focus groups	n=49 (1:1 interview n=12; focus groups n=37) Female adult (aged 17-50 years) prisoners 2 closed prisons, England, UK	To explore the views of women prisoners of the impact of imprisonment on their health	Includes participants <18 years
Harner 2013[38]	Focus groups	n=65 Female adult (aged 23-46) prisoners 1 maximum security prison, USA	To explore barriers to good physical health in incarcerated women	
Hatton 2006[41]	Focus groups	n=78 Female adult (aged 19-61) prisoners (n=60) and ex-prisoners (n=18) 1 county jail, USA	To explore healthcare from the perspective of incarcerated women	
Loeb 2011[52]	Focus groups	n=42 Male, older adult (aged 50-68) prisoners 2 prisons, USA	To identify perceived barriers to the health of older inmates	
MacDonald	Focus groups	n=223	To investigate	Includes

2013[55]		Male and female, prisoners and young offenders Prisons and young offenders institutions (YOIs) Bulgaria Czech Republic England and Wales Estonia Germany Latvia Romania	availability of existing health promotion practises	participants <18 years
Pulford 2011[132] Pulford 2013[133]	1:1 interview, open and closed questions	n=79 Male adult (under 25, 30%; 25-44 years 52%; 45+ years 18%) prisoners 1 high security prison, Scotland, UK	To explore prisoners' views on their own health and health promotion	
Richmond 2009[137]	Focus groups	n=40 Male (70%) and female (30%), adults (age range mid-20s to mid-40s), prisoners (n=9) and ex-prisoners (n=31) Prisoners all current smokers Australia	To explore role of tobacco use in prison and influence of prison environment on smoking in context of developing smoking cessation programmes	
Russell 2006[140]	Focus group	Number of participants not reported Male young offenders 1 YOI, England, UK	To explore young offenders' perception and expectations of dental health services	Includes participants <18 years
Sifunda 2006[146]	Focus groups	Number of participants not reported Male adult prisoners (aged 18-35) 4 prisons, South Africa	To explore inmates perception of the state of healthcare services	
Smoyer 2014B[147]	Semi-structured interviews	n=30 Female adult (mean age 37.7±10.5 years) ex-prisoners	To explore women prisoners' food practises and perception of health	

		1 prison, USA		
Thibodeau 2012[154]	1:1, semi-structured interviews	n=49 Male adult (aged 19-60 years) prisoners All current smokers 1 minimum security prison, USA	To explore the views of prisoners on the smoking ban	Prison smoking ban
Valera 2014[158]	Semi-structured interviews	n=30 Male adults (Mean age 47, range 35-60) under parole or probation Smoking habits not reported 1 prison, USA	To investigate smoking behaviours in prison	Prison smoking ban
Woodall 2010[165]	1:1 interviews Focus groups	n=36 Male adult (aged 22-70) prisoners 3 category-C prisons, England, UK	To explore concepts of health and wellbeing with male prisoners	
Surveys (questionnaire design: open-ended or closed)				
Lawn 2014[49]	Closed questions	n=45 Male (93.3%) and female adult (age <30, 11.1%; 30-39, 40%; 40-49%, 37.8%; >50, 11.1%) psychiatric in-patients 80% smoked prior to admission 4.4% ex-smokers 1 forensic psychiatry in-patient facility, Australia	To investigate views on smoking ban in forensic psychiatry in-patient facility	Smoking ban Forensic psychiatry in-patient facility
Loeb 2007[53]	Open-ended questions	n= 51 Male, older adult (aged 50-80) prisoners 1 minimum security state correctional facility, USA	To explore health beliefs and concerns of older male inmates	Principle investigator or their trained assistant read survey aloud to each participant (1:1) and participant responses were immediately

				logged onto the questionnaire booklet
Makris 2012[56]	Closed questions	n=204 Male adult (mean age 33.6±12.5) prisoners 75.5% smokers 7.35% ex-smokers 1 detention centre, Greece	To investigate what helps prisoners quit smoking	
Sieminksa 2006[145]	Closed questions	n=907 Male, young adult and adult (aged 17-62 years) prisoners 81% smokers 12% ex-smokers Poland	To investigate prisoner's attitudes to smoking and smoking cessation	Includes participants <18 years

7.5.1.3 Evidence

7.5.1.3.1 Themes and sub-themes derived from the evidence

Table 81: Themes and sub-themes

Main theme	Sub-themes
Environmental factors	Movement around prison
	Access to outdoors/fresh air
	Sharing cell/environment with smoker
	Unclean facilities
	Lack of privacy/confidentiality
Psychosocial factors	Prisoner stress
	Prisoner boredom
	Prisoner motivation
	Social stigma
	Smoking as a social norm
Resources	Lack of/accessibility of health promotion information
	Lack of health promotion education/programmes
	Lack of physical exercise opportunities
	Lack of places available on health promotion programmes
	Lack of healthy food choices/lack of variety of food choices
	Poor quality of food
	Lack of frequent access to washing facilities
	Lack of access to self-care equipment
	Prisoner's financial resources
Support	Peer support

Main theme	Sub-themes
	Family/friend support
	Lack of staff support/negative staff attitudes towards prisoners

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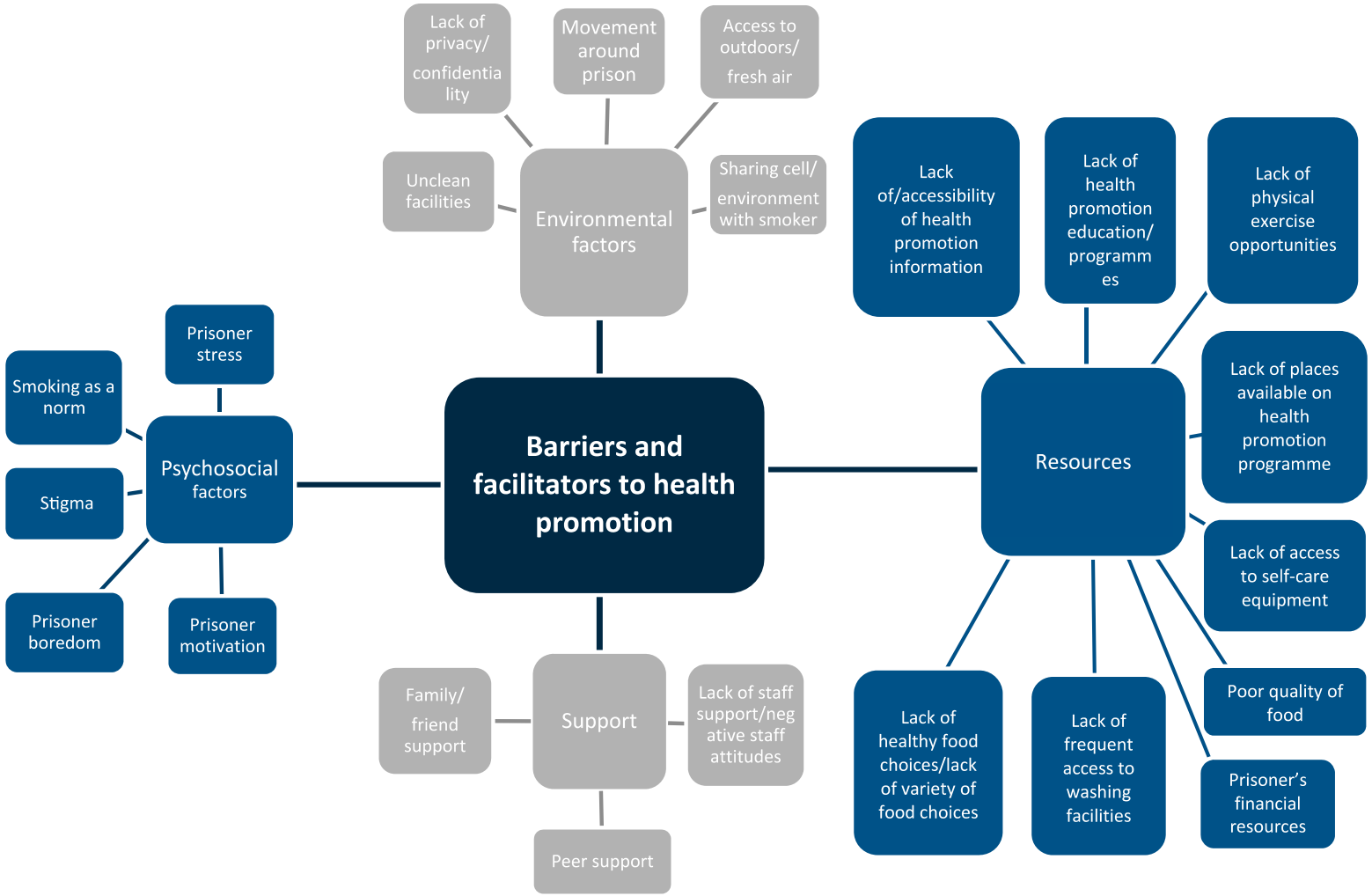
Figure 4: Themes and sub-themes



7.5.1.4 1 Evidence summary

2 **Table 82: Summary of evidence: Theme 1 – Environmental factors**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Movement around prison					
2	1 interview 1 focus group (UK; South Africa)	• Access to health education programmes and exercise facility constrained by prison environment, often due to security concerns	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Access to outdoors/fresh air					
3	1 interview 1 focus group 1 interview and/or focus group (2 UK; Europe)	• Lack of time outside cell, in fresh air • "not enough chance to exercise outside"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	
Sub-theme 3: Sharing cell/environment with smoker					
7	2 interviews 3 focus groups 2 surveys (2 UK; 2 Australia; Europe; Greece; USA)	• Sharing cell and wider environment with smoker was seen as barrier to quitting smoking • Concern about passive smoking • "I am not a smoker until now I stay in a smokers' room" • "there aren't enough non-smoking areas as prisoners can really just smoke anywhere"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	
Sub-theme 4: Unclean facilities					
4	1 interview 2 focus groups	• Vermin • Unclean washing facilities	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
	1 interview and/or focus group (2 UK; Europe; USA)	• Unclean bedding and clothes • "got head lice and scabies in here"	Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 5: Lack of privacy/confidentiality					
5	1 interviews 3 focus groups 1 survey (2 UK; 2 USA; South Africa)	• Lack of privacy being escorted to health services, e.g. sexual health services • Lack of confidentiality during appointments due to prison guard being present • "what I can say is they don't take them [condoms] if there is somebody looking, but they check if there is nobody watching and take them"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	

1 **Table 83: Summary of evidence: Theme 2 – Psychosocial factors**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Prisoner stress					
10	3 interviews 4 focus groups 1 interview and/or focus group 2 survey (2 UK; Australian; Europe; Greece;	• Prison as a stressful environment • Smoking as a coping method of dealing with stress • "it's too stressful in jail to give up cigarettes"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
	Poland; USA; South Africa)				
Sub-theme 2: Prisoner boredom					
6	1 interview 2 focus groups 1 interview and/or focus group 2 survey (UK; Australia; Europe; Greece; Poland; USA)	• Boredom in prison due to lack of constructive activities e.g. exercise activities • Boredom as a barrier to cessing unhealthy activities e.g. smoking, overeating • "now it's boredom, and boredom is where you eat a lot… there's nothing constructive in prison" • "in here I smoke just because it's something to do… but on the street, I didn't smoke at all"	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Coherent Applicable Saturated	VERY LOW
Sub-theme 3: Prisoner motivation					
4	2 interviews 1 focus group 1 interview and/or focus group (UK; 3 USA)	• Participants cited their own motivation, or lack thereof, as a facilitator or barrier to health promotion • "I tried to stay healthy while I was in there. That was like something that kept me motivated, was, going to the gym, trying to eat healthy" • "I do not have the will power to quit cigarettes right. I think it's got me. It's very addictive"	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Coherent Applicable Saturated	VERY LOW
Sub-theme 4: Social stigma					
3	2 interviews 1 focus groups (2 UK; South Africa)	• Participant were concerned about social stigma around accessing sexual health services, e.g. condoms, STD testing and treatments • "people could be bullied for accessing this [sexual health] service"	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Coherent Applicable Saturated	VERY LOW
Sub-theme 5: Smoking as a social norm					
2	1 interview	• Smoking as part of daily routine	Limitations of evidence	Major limitations	VERY LOW

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
	1 focus groups (Australia; USA)	• Tobacco as currency • • "tobacco is like cash to use in trade as long as the pouch of tobacco is unopened" • "I smoke when I wake up. When I wake up I want a cigarette"	Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	

1 **Table 84: Summary of evidence: Theme 3 – Resources**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Lack of/accessibility of health promotion information					
2	2 focus groups (Australia; USA)	• Lack of literature/hand outs • Health promotion information in written form inaccessible to those without relevant education • Difficulty in obtaining health promotion information from staff due to time restrictions • "if you can't educate yourself you are in trouble"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Lack of health promotion education/programmes					
3	1 focus group 2 survey (UK; USA; South Africa)	• Lack of education programmes, e.g. healthy eating and sexual health • Infrequency of health education programmes • "more teaching on cholesterol and healthy food groups [would be helpful]"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 3: Lack of physical exercise opportunities					

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
3	2 focus groups 1 survey (UK; Europe; USA)	• Lack of availability of physical exercise/sports opportunities	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 4: Lack of places available on health promotion programme					
2	1 interviews 1 focus group (UK; USA)	• Health promotion programmes described as full with long waiting lists • "the [physical exercise] classes are always full or during work"	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 5: Lack of healthy food choices/lack of variety of food choices					
7	2 interviews 3 focus group 2 survey (3 UK; Portugal; 3 USA)	• Lack of healthy food choices for prison meals • Lack of healthy food choices from canteen • Lack of variety in food options • "our diet consists of processed meats, no fresh vegetables, and low-dairy products with no iron-enhanced food… the diet is poor and there aren't good items on commissary" • "everything's got sugar in that's on the canteen list"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	
Sub-theme 6: Poor quality of food					
3	3 focus group (Europe; 2 USA)	• Spoiled, undercooked or overcooked food • Unhygienic food preparation • "the food itself coming in is not bad but they cook out the goodness"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 7: Lack of frequent access to washing facilities					

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
1	1 focus group (Europe)	• Lack of access to frequent showers/baths	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 8: Lack of access to self-care equipment					
4	2 focus groups 1 interview and/or focus group (2 UK; Portugal; USA)	• Poor access to soap, shampoo, good quality toothbrush and toothpaste, sanitary products • Poor access to self-administered treatments • "there's no Derbec or Lyclear. You know, if I was at home and I thought the kids have nits, I'd just give myself a treatment just to make sure that I didn't have them"	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	
Sub-theme 9: Prisoners' financial resources					
4	1 interviews 2 focus group 1 interview and/or focus group (2 UK; Portugal; USA)	• Choice between working and going to gym/educational programmes • "if you have to work or take education classes you cannot go to the gym"	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	

1 **Table 85: Summary of evidence: Theme 4 – Support**

Study design and sample	Descriptors of themes	Quality assessment

No of studies	Design		Criteria	Rating	Overall
Sub-theme 1: Peer support					
2	2 focus groups (2 USA)	• Participants noted that both trained and non-trained peers gave support, e.g. through providing information	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Family/friend support					
6	1 interview 2 focus groups 1 interview and/or focus group 2 surveys (UK; Australia; Europe; Greece; Poland)	• Participants noted that family/friends were a source of support in their attempts to quit smoking in prison	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	
Sub-theme 3: Lack of staff support/negative staff attitudes towards prisoners					
6	5 focus groups 1 survey (Australia; 5 USA)	• Participants noted that they lack support in undertaking health promotion activities e.g. exercise, smoking cessation plan • Participants that staff were not listening to them, did not care about their needs and/or were unresponsive to their needs • "I have complaints but they don't hear all my complaints" • "they have attitudes like I don't give a damn"	Limitations of evidence	Major limitations	VERY LOW

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17.5.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

17.5.3 Evidence statements

Clinical

Environmental factors

- Environmental factors were identified as a theme by 11 qualitative studies in over 900 people in interviews, focus groups and surveys of prisoners. Five subthemes were identified: movement around prison; access to outdoors/fresh air; sharing cell/environment with smoker; unclean facilities; and lack of privacy/confidentiality. The evidence was of very low quality. All of the subthemes had major limitations. The majority of subthemes showed limited applicability due to the inclusion of studies from outside the UK. Three of the subthemes were saturated (access to outdoors/fresh air, sharing cell/environment with smoker, lack of privacy/confidentiality) and two of the subthemes showed no theme saturation (movement around prison and unclean facilities).

Psychosocial factors

- Psychosocial factors were identified as a theme by 14 qualitative studies in over 1800 people in interviews, focus groups and surveys of prisoners. Five subthemes were identified: prisoner stress; prisoner boredom; prisoner motivation; social stigma; and smoking as a social norm. The evidence was of very low quality. All of the subthemes had major limitations and were of limited applicability due to the inclusion of studies from outside the UK.

Resources

- Resources were identified as a theme by 12 qualitative studies over 750 people in interviews, focus groups and surveys of prisoners. Nine subthemes were identified: lack of/accessibility of health promotion information; lack of health promotion education/programmes; lack of physical exercise opportunities; lack of places available on health promotion programmes; lack of healthy food choices/lack of variety of food choices; poor quality of food; lack of frequent access to washing facilities; lack of access to self-care equipment; prisoner's financial resources. The evidence was of very low quality. The majority of the evidence had major limitations. The evidence showed limited applicability due to the inclusion of studies from outside the UK. One subtheme was saturated (lack of healthy food choices/lack of variety of food choices) but the other subthemes showed limited or no theme saturation.

Support

- Support was identified as a theme by 10 qualitative studies in over 1600 people in interviews, focus groups and surveys of prisoners. Three subthemes were identified: peer support; family/friend support; lack of staff support/negative staff attitudes towards prisoners. The evidence was of very low quality. The evidence has minor to major limitations and was applicable (due to the inclusion of non-UK studies). Two subthemes were saturated (family/friend support and lack of staff support/negative staff attitudes towards prisoners) and one showed no theme saturation (peer support).

Economic

- No relevant economic evaluations were identified.

7.5.4 Recommendations and link to evidence

See section 7.6 below.

7.6 Recommendations and link to evidence

7.6.1 Interventions (see section 7.2)

Recommendations	**Promoting health and wellbeing**
	
	Exercise
	
	38. Encourage people to be physically active. Offer them information about:
	• **the benefits of exercise**
	• **what exercise facilities are provided, where they are and how they can use them, for example:**
	  ○ **going to the gym**
	  ○ **using the exercise yard**
	  ○ **exercises that can be done in the cell.**
	
	39. Offer people information and advice in line with recommendations in the NICE guidelines on:
	• **physical activity: brief advice for adults in primary care**
	• **physical activity: exercise referral schemes**
	• **preventing excess weight gain**
	• **obesity: identification, assessment and management (see the section on physical activity).**
	
	Diet
	
	40.Offer people information about:
	• **the benefits of a healthy diet**
	• **healthier food options available in the prison.**
	
	See the section on diet in NICE's guideline on obesity: identification, assessment and management

Relative values of different outcomes	The GDG prioritised healthy Body Mass Index (BMI) as the critical outcome for this review, with important outcomes being morbidity, mortality and health related quality of life. A healthy BMI was defined as 18.5–24.9, as stated in the NICE obesity guideline CG189.[71]
Trade-off between	The interventions included for this review include time in the open air, mobilisation

clinical benefits and harms	and any structured or unstructured physical fitness/exercise plan compared to usual care or alternative interventions. The benefits of physical activity on physical health were limited within the evidence identified from this review, including uncertain reductions in BMI and blood pressure due to wide confidence intervals. The GDG expected wider health gains, and also noted other benefits linked to mood, anxiety, depression and stress, which are outside the scope of this guideline. Harms were not identified in the review, but may include injury from inappropriate exercise or over exertion.
Trade-off between net clinical effects and costs	No relevant economic evaluations were identified. The GDG noted that NICE guidelines NG7, PH44, PH54 and CG189 considered the cost-effectiveness of interventions to maintain healthy weight, and made recommendations that were cost-effective for the general public. Where NICE guidelines consider a general population with a certain condition it is recognised that some members of that population will require fewer resources and some more resources to treat. However, due to its strong commitment to principles of equality, and obligations under the Equalities Act 2010, NICE makes decisions for the whole population group with a condition, unless there are clinical differences between subpopulations justifying different treatments.[105] A prisoner with a health condition is part of the broader population group with that condition, therefore if the cost-effectiveness of treating the group as a whole has been established in previous NICE recommendations, the GDG agrees that the prisoner should receive equivalent treatment, regardless of whether the cost to the NHS of treating the prisoner is higher or lower than the average cost to the NHS of treating an individual with the same condition. The GDG recognised that prisons differ greatly in size, age, design and layout, and provision of exercise facilities varies between prisons. The GDG was hence unable to make general recommendations regarding the likely cost-effectiveness of providing specific exercise facilities in prisons, as the costs of changing current facilities would be highly context-specific, although low-cost changes allowing and encouraging prisoners to undertake more exercise would be very likely to be cost saving or cost-effective. The GDG did however agree that ensuring that all prisoners are provided with full information on what facilities are available and how to access them would provide additional benefit at very low cost and so would be cost-effective compared with not systematically providing such information.
Quality of evidence	Very low to moderate quality evidence was identified for this review, consisting of 2 RCTs in male prisoners and 1 observational before-and-after study in women. The studies in men were both structured exercise programs, including a cardiovascular plus resistance training, high intensity strength training and cardiorespiratory endurance, strength and flexibility training. Quality was downgraded for selection bias as there was variation in baseline outcome data across the study arms. There was no clinical benefit of BMI identified for cardiovascular plus resistance training or high intensity strength training versus usual care. The relatively low numbers of participants give wide confidence intervals around the estimate of effect for systolic blood pressure, making it difficult to know the true effect size for this outcome. The study in women included both an exercise and nutrition component, with limited details given about each and only outcome data given related to the exercise program. This study also showed no clinical benefit in BMI. The evidence could not be combined in meta-analysis due to very different physical activity interventions. The GDG considered the evidence to be applicable, but that the number of participants was low within each study and that the length of follow up reported may not have been long enough to detect a change in BMI. In particular the study in female prisoners had a follow up of 6 weeks. No data were reported for mortality or health-related quality of life. For the nutrition review, 1 very low quality non-randomised controlled trial was included comparing a reduced calorie diet in women diagnosed with diabetes

	compared to usual care. The study reported that BMI was lowered in the reduced calorie diet group, however the effect was imprecise and therefore uncertain.
Other considerations	The GDG discussed that equivalence should be aimed for and that there is a vast amount of existing NICE guidance in this area. The GDG discussed that related NICE guideline recommendations made for non-prisoners are also valid for prisoners. The NICE guideline on Maintaining a healthy weight and preventing excess weight gain among adults and children (2015), was considered particularly relevant, with recommendations on topics such as encouraging physical activity habits to avoid low energy expenditure, encouraging self-monitoring, communicating the benefits of maintaining a healthy weight and the benefits of gradual improvements to physical activity and dietary habits. The following NICE guidance is available: • NG7 Maintaining a healthy weight and preventing excess weight gain among adults and children, 2015 • PH54 Exercise referral schemes to promote physical activity, 2014 • CG189 Obesity: identification, assessment and management of overweight and obesity in children, young people and adults, 2014 • PH44 Physical activity: brief advice for adults in primary care, 2013 The GDG considered the related NICE guidance to be applicable for the prison setting (with some considerations for setting and populations, for example the recommendations for children are not relevant and sensible interpretation should be applied for recommendations such as allowing access for bicycle rides) and the evidence review is relevant and appropriate. The evidence reviews underpinning these recommendations are not likely to have changed significantly since their publication. The group did not wish to make any formal adaptations to the recommendations. Related NICE guidance did comment on the amount of exercise recommended per week, for example CG189 states 30 minutes 5 times a week and PH44 states 150 minutes per week. The GDG discussed whether this is achievable and although it would be challenging to provide as time in open air, or as exercise classes, this would not preclude exercises that could be done in cells. The GDG discussed the variation in access to physical activity (for example limitations in being able to access the gym or number of places on an exercise class) and recommended that information should be provided about available exercise facilities and how to access them. Time spent in the open air was also discussed and it was noted that the minimum requirement is now 30 minutes per day, as stated in PSI 10/2011. Residential Services.[114] This document defines 'time in open air' as time spent in a situation where the prisoner is able to benefit from fresh air and natural light. The GDG were also aware of the PSI 58/2011[113] on Physical education (PE) for prisoners. This document details the statutory requirements including rule 21 (for prisoners aged 21 and over), stating prisoners are given the opportunity to participate in PE for at least one hour a week. In addition appropriate facilities are to be provided for prisoners with a need for remedial physical activity. For those under 21 arrangements should be made to participate in PE for two hours a week on average. The group made sensible specific recommendations on encouraging people to be more physically active, such as using the exercise yard or accessing exercise classes. In addition the GDG discussed other exercises that could be done in cells and was not dependant on equipment or limited to a specific time of day. Examples of exercises that could be done in cells includes jogging on the spot, press-ups, sit-ups and stretches. The GDG discussed that provision of tailored exercise for people with existing comorbidities is variable across the prison estate, but that existing NICE guidance should be followed for specific conditions in which certain physical exercise is recommended, e.g. chronic heart failure (CG108).

	Nutrition Very little evidence was identified on nutrition and so no specific recommendations were made. Reference to CG189 obesity guideline and NG7 preventing excess weight gain is made, which both include evidence on nutrition and exercise and make recommendations on a balanced diet, which are applicable to a prison population. The GDG recognised that many interventions to increase physical activity may have an element of education about healthy eating, including reduction in sugary and fatty foods, which are available from the canteen list. Special diets for prisoners, such as those with coeliac disease were discussed and it was agreed that they should be provided, if clinically indicated, in line with the relevant NICE guidance. Please also see recommendations on the second part of physical health assessment (Section 0), which include questions on general health, weight, smoking and other lifestyle choices.

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Recommendations	**Sexual health** **41. Offer people in prison information about sexually transmitted infections and available sexual health services.** **42. Ensure that people in prison have discreet access to condoms, dental dams and water-based lubricants without the need to ask for them.**
Relative values of different outcomes	The GDG considered 3 critical outcomes for this review: STI diagnosis in prisons, access to barrier methods, and access to sexual health clinics; of these one was identified for inclusion: access to condoms. One surrogate outcome was identified for inclusion in this recommendation: prisoner's self-reported condom usage during anal sex. The GDG considered condom usage an important outcome as increased use of condoms would correlate to decreased STI transmission within prison.
Trade-off between clinical benefits and harms	Evidence suggests that providing a condom dispenser or condom kit dispenser increased the uptake of condoms, and increased the use of condoms when sex occurred within prison, compared to condoms being available on request or no readily available supply The GDG agreed that the benefit of providing condoms, without the need to request, would increase condom uptake and minimise the harm of sexual activity in prison. The GDG considered any potential clinical harms of providing free access to condoms and thought these would be minimal. The GDG noted that there was a lack of evidence on the clinical effect of providing greater access to lubricants and dental dams. A consensus was reached that these should be provided at the same level of access as condoms due to equivalence of care for men and women. The GDG noted that dental dams provide equivocal protection against transmittion of sexually transmitted diseases as a barrier method of protection, similar to condom use for men, and therefore women should be offered the same level of protection. The GDG considered the correct use of condoms minimises the risk associated with anal sex related STI transmission. Using a lubricant reduces the probability of condom breakage and/or rectal tearing, both of which contribute to the risk of STI transmission. Although no evidence was identified, the GDG were aware that dental dams minimise the risk associated with oral-vaginal or oral-anal STI transmission and

	recommended these for equality reasons.
Trade-off between net clinical effects and costs	No relevant economic evaluations were identified. In the absence of applicable published economic evidence the GDG discussed the potential cost-effectiveness of providing condoms, dental dams and lubricant without the need to request, compared with the current policy of providing these items on request only. It was noted that in both cases the items would be provided by healthcare services within prisons, and thus the costs would fall upon the NHS, not upon the prisoners or the prison provider, in line with an NHS perspective. The GDG noted that a change in guidance would be expected to lead to an increase in the quantity used, but since the current quantity provided in prisons is not known it is hard to quantify the increase. However, the low unit cost of condoms, dental dams and lubricants was also noted. Since condoms are currently available to those who are willing to ask for them, the most likely estimate would be a moderate increase, such as a doubling of the quantity of materials needed. This would lead to some increased cost, although this may be partially mitigated by a reduction of the staff time currently required to process a request. The potential cost savings of preventing transmission of infectious diseases such as HIV and hepatitis C are very high, and so the prevention of a single case of these diseases by the increased availability of condoms would offset the costs of providing tens of thousands of condoms. Given the prevalence of blood-borne viruses in UK prisons, an increase in condom use would be expected to prevent additional infections. Therefore the GDG considered that improved accessibility of free condoms, dental dams and lubricants, leading to increased use, would be quite likely to be cost saving, and very likely to be cost-effective at a threshold of £20,000 per QALY gained. The GDG were unable to judge the cost-effectiveness of particular methods of making condoms available – such as dispensing machines – and felt that implementation was a matter for local decision, but noted that low technology methods of implementing this recommendation, such as bowls of condom kits at the entrance to the health clinic or the gym, would be very low cost to implement.
Quality of evidence	One observational study was identified for the outcome uptake of condoms. This reported the outcome sexual activity of prisoners; outcome quality for both was very low due to study design and very serious risk of bias. One further observational study was identified which reported sexual activity of prisoners. The reported outcome was of very low quality due to study design and very serious risk of bias. This study compared freely accessible condoms versus no condom availability but the GDG considered that the study was applicable to this recommendation. The GDG agreed that these 2 studies were not comparable due to the differences in settings, population, and comparators used and therefore the studies were not pooled for meta-analysis. The GDG noted that it would be unlikely that RCTs would ever be conducted in this area given the difficulty in data collection for this outcome and ethical considerations. The GDG noted the quality of evidence for these outcomes and assessed the evidence's applicability to the UK prison system. They agreed with the findings of the evidence that providing readily accessible condoms would increase condom uptake and minimise the harm of sexual activity in prison.
Other considerations	The GDG noted that in other high-risk populations condoms are provided without charge. The GDG's consensus was that the prison population should be treated with equivalence and have free access to condoms. The group considered that prevention of blood borne viruses by using condoms would have a benefit within the prison population and for public health post release. In addition this is not a change in practice as these are already available. The GDG considered it important for people in prison to have free and discreet

	access to barrier methods as supported by the qualitative review findings, (see section 7.5) which found that lack of privacy or confidentiality was a barrier to people accessing barriers methods: "what I can say is they don't take them [condoms] if there is somebody looking, but they check if there is nobody watching and take them". Current policy in the prison system is to provide condoms, dental dams and lubricant on request.[124] The GDG noted anecdotal reports that suggest implementation of this policy varies significantly around the prison system. The GDG noted that the World Health Organisation currently recommends condom provision "should be made easily and discreetly accessible to prisoners so that they can pick them up at various locations in the prison, without having to ask for them and without being seen by others".[25] The World Health Organisation currently recommends that "Water-based lubricant should also be provided since it reduces the probability of condom breakage and/or rectal tearing, both of which contribute to the risk of HIV transmission." The GDG noted that current Prison Health Performance and Quality Indicators for sexual health require that prisoners "are aware of means of accessing condoms in prisons" and "have access to barrier protection and lubricants". The GDG discussed existing NICE guidance in this area. It noted that the majority is focused on HIV testing and information provision to high-risk populations, and is therefore more applicable to other areas of this guideline.

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Recommendations	**Stopping smoking** **43. Offer people in prison information about:** • **the risks of smoking** • **support available to stop (for example nicotine patches or motivational support)** **See the NICE pathway on smoking.**
Relative values of different outcomes	The GDG prioritised the outcome of smoking cessation (quitting for at least 4 weeks) as the critical outcome for this review. Other important outcomes that were looked for in the literature included morbidity, mortality and health-related quality of life.
Trade-off between clinical benefits and harms	The GDG discussed any potential harms of the interventions (nicotine replacement therapy [NRT, nicotine patches], information provision/cognitive behaviour therapy/mood management and antidepressants such as nortriptyline). The evidence did not report any adverse effects, however the GDG acknowledged many potential side effects of anti-depressants. Potential harms for NRT were not identified in the review, but were thought to be minimal. The GDG noted that any prescribed medication would be monitored and regularly reviewed by the prescribing GP and any adverse effects managed. The GDG noted that the course of treatment for NRT should be within current NICE guideline recommendations for length of time, and that long-term treatment could be harmful. The included evidence showed benefit of a behavioural intervention and NRT compared to usual care in smoking cessation. The included studies noted that participants should not have any contraindications for NRT, such as having had a myocardial infarction in the last 6 months. It was considered that any harms would be outweighed by the long-term health benefits gained by quitting smoking.

Trade-off between net clinical effects and costs	No relevant economic evaluations were identified. The GDG noted that the existing NICE public health guidance listed in the recommendation has considered the cost-effectiveness of smoking cessation interventions and made recommendations that were cost-effective for the general public. The GDG noted that the exact costs of offering counselling-based interventions may vary slightly in prisons due to different use of staff time and space, but not significantly, while nicotine replacement therapy on prescription will be at the same cost as throughout the NHS. The GDG reviewed economic modelling conducted for existing NICE guidance for the general public, and found it to be equally applicable to a prison setting. Therefore the GDG judges that the existing NICE recommendations should be equally cost-effective as in the general population.
Quality of evidence	Low-quality RCT evidence showed increased smoking abstinence using a behavioural intervention plus nicotine patches compared to usual care. Very low quality RCT evidence showed benefit of a behavioural intervention in increasing abstinence from smoking compared to usual care. No difference was found from adding nortriptyline to a behavioural intervention and nicotine patches (very low to moderate quality evidence). It was noted that none of the evidence was from UK settings, but the GDG considered the findings to be applicable. Limitations of the studies included large numbers of drop outs from the intervention arm with the papers noting intention-to-treat analysis and assuming that any loss to follow-up was counted as smoking. One study included those using chewing tobacco as well as smoking tobacco, which was downgraded for indirectness to our population. The GDG noted that some prisons do have a large population of Asian populations where chewing tobacco is used as a preference, but that this is not representative of the majority of the prison population. As there are several relevant existing NICE guidelines detailing smoking and health promotion the GDG was presented related recommendations and a summary of the quality of the evidence underpinning them. The most relevant recommendations were from the NICE public health guidance PH45 Tobacco: harm reduction approaches to smoking (2012). The full guideline described the evidence as limited and that it consisted of some non UK evidence of limited applicability. However, the technical team noted that there was more evidence than identified in our review.
Other considerations	The GDG noted that any appropriate NRT should be recommended, with the emphasis on those that are available, for example gum and sprays are banned in the prison setting (listed as a prohibited item). Other forms of NRT include skin patches, inhalators, lozenges or tablets. In current practice prescription of different forms of NRT in prison may differ due to security level of the prison and individual access. The group discussed that NRT offered to prisoners need to be licenced and approved and that currently electronic cigarettes are not licenced, but may be available on the canteen list. Quit smoking telephone lines were also discussed and were considered feasible, pending security level of the prison and if facilities are available e.g. some prisons may only have older styles of phone that do not allow multi-layered phone menu systems. The dose of NRT was discussed and that other NICE guidance gives advice on appropriate dose and length of time it can effectively and safely be used for – typically 8–12 weeks. NRT is not to be used long-term, and is typically reduced in the later part of the treatment course, and then stopped. The GDG discussed No Smoking policies in closed institutions and the potential for future total bans in all such accommodation. The group noted that prison and health services would need strategies and resources in place to respond quickly and effectively to any reduction in smoking in establishments for the adult prison population (18 upwards). In addition the GDG agreed that a smoking ban is a harm

reduction measure in itself given the known negative impact on health from smoking and second-hand smoking. The group also noted that any ban would be on smoking and not on nicotine, which would still be available via the canteen list e.g. nicotine patches and/or e-cigarettes.

The GDG agreed that prisoners should be treated as any other person when stopping smoking and that equivalence to non-prison settings should be the aim. As such it agreed that existing NICE guidance is applicable, and thus appropriate to refer to, as it is also consistent with the findings of this review (offering a behavioural intervention and NRT).

The NICE guideline PH45 Tobacco: harm reduction approaches lists several recommendations that are highly relevant and applicable to the prison population including covering the following topics:

1. Raising awareness of licensed nicotine-containing products
2. Self-help materials
3. Choosing a harm-reduction approach
4. Behavioural support
5. Advising on licensed nicotine-containing products
6. Supplying licensed nicotine-containing products
7. Follow-up appointments
8. Supporting temporary abstinence
9. People in closed institutions

Recommendation 9 does have a specific recommendation for those in closed institutions, which details the following:

- Incorporate management of smoking in the care plan of people in closed institutions who smoke.
- Ensure those giving harm-reduction advice in situations where smoking is not permitted are trained to the same standard as the level required for the National Centre for Smoking Cessation and Training stage 2 assessment (or the equivalent). This includes people working in mental health and prison health services.
- Ensure staff recognise that some people perceive smoking as an integral part of their lives. Also ensure staff recognise the issues arising from enforced, as opposed to voluntary, abstinence.
- Ensure staff recognise how the closed environment may restrict the techniques and coping mechanisms that people would normally use to stop smoking or reduce the amount they smoke. Provide the support required for their circumstances.
- This includes prescribing or supplying licensed nicotine-containing products. Ensure staff understand that, if someone reduces the amount they smoke (or stops completely), this can impact on their need for psychotropic and some other medications (see UK Medicines information for further details). Ensure arrangements are in place to adjust their medication accordingly.

The GDG considered that this guidance is applicable for the prison setting (with some considerations for setting and populations, for example the use of nicotine gum is prohibited in prison) and that the evidence review is relevant and appropriate and that the evidence review underpinning these recommendations is not likely to have changed significantly since their publication. The GDG did not make any formal adaptations to the recommendations.

The GDG noted that existing NICE guidance is available:

- PH49 Behaviour change: individual approaches (2014)
- PH45 Tobacco: harm reduction approaches to smoking (2012)
- PH26 Quitting smoking in pregnancy and following childbirth (2010)
- PH1 Brief interventions and referral for smoking cessation (2006)

	The GDG was also aware of the Public Health England report Reducing Smoking in Prisons: management of tobacco use and nicotine withdrawal.[131]

Hygiene

Very little evidence was identified on hygiene and therefore no specific recommendations were able to be made. No relevant existing NICE guidance on personal hygiene was identified to provide any further information.

7.6.2 Who should deliver health promotion activities (see sections 7.4 and 7.5)

Recommendations	**General health advice** **44. Consider using peer support and mentoring to help promote a healthy lifestyle while in prison.**
Research recommendation	**4. What is most effective method for delivering health promotion activities and who should lead them (peers or professionals)?**
Relative values of different outcomes	Healthy BMI, patient-reported satisfaction, in-prison sexually transmitted infection (STI) diagnosis, accessing contraception and sexual health clinics, and quitting smoking for at least 4 weeks were considered by the GDG to be critical outcomes Uptake of screening programmes, morbidity, mortality, and health-related quality of life were considered by the GDG to be important outcomes. Two surrogate outcomes were identified for inclusion in this recommendation: prisoners' self-reported condom use intention and prisoners' HIV-related knowledge. The GDG considered both as important outcomes as increased use of condoms and awareness of the modes of STI transmission should correlate to decreased STI transmission within prison.
Trade-off between clinical benefits and harms	One quasi-randomised study was included which directly compared a peer-led education intervention against an intervention led by a professional HIV educator. There were no clinical differences found between the interventions for all reported outcomes: HIV screening uptake, condom intention, or HIV-related knowledge. The GDG noted that the only evidence identified was in a sexual health promotion intervention, but believed that the results were likely to be applicable to a wide range of health promotion activities. There was general consensus and anecdotal evidence that prisoners prefer peer-led interventions compared to professionally-led, and that peer-led interventions have greater attendance.
Trade-off between net clinical effects and costs	One economic evaluation was identified that modelled the cost-effectiveness of a peer-led educational intervention to prevent HIV infections with a professionally led educational intervention and no intervention.[148] It was based on the prevalence of HIV in people in UK prisons, and assumed that the effectiveness of both interventions at increasing condom use in heterosexual relationships for 1 year after leaving prison would be equal to the self-reported intention to always use condoms reported by Grinstead in the quasi-randomised US study described above, and that the attendance at education sessions (greater for peer-led sessions) would be as in that study. Given these assumptions the economic model found that professionally led education dominated (was cheaper and more effective) than no intervention, and that peer-led education dominated both no intervention and professionally led education. Peer-led education was therefore found to be more effective and cost saving in this model. The GDG noted that self-reported intention to use condoms is a much weaker

	surrogate outcome than actual condom use, and that the results relied upon a single US study. The GDG therefore could not be sure that the results would necessarily apply to a UK setting. However, the GDG noted that for any area of health promotion, if peer-led interventions did lead to higher attendance at high promotion sessions and higher adherence to healthy behaviours by those attending, then they would be very likely to be cost saving or highly cost-effective given the generally low cost of providing peer-led interventions compared to professionally led sessions. Current practice is that few prisons have peer-led trainers, but where they are used they receive NVQ level training. In some cases funding for this training may be provided by charitable organisations, in others it may come from local healthcare providers. This is an initial cost for training the peer-led trainers, there will not be any ongoing payment costs as for professional trainers. However, given the turnover and movement of prisoners, it should be expected that new peer-led trainers will need to be trained regularly to replace previous trainers.
Quality of evidence	One quasi-randomised study was identified that reported the outcomes of HIV screening uptake, condom intention, and HIV-related knowledge. This study was set in the USA and outcome quality for both surrogate outcomes was very low due to very serious risk of bias and indirectness, whilst HIV screening uptake outcome was of low quality due to very serious risk of bias.
Other considerations	The single study identified for clinical evidence also included economic data that was included in the economic evaluation identified within this review. This study reported the outcome condom use intention, which was reported as a 5 point Likert scale and extracted as a continuous outcome for the clinical evidence. However within the economic evaluation this outcome was dichotomised, with only the results reported from the top result on the Likert scale extracted ("Always intend to use condoms from now on"). Furthermore this result was then treated within the analysis as future condom use (that is prisoners who reported that they intend to always use condoms they all achieved this goal). The GDG noted that there are many well-received peer-led health promotion schemes across the prison service. These would not have been identified for inclusion as evaluations are often not published, have no comparator, or were of interventions and outcomes not specified for inclusion in this review. This study was also included with similar sexual education health promotion activities in the review to assess what are the most clinically and cost-effective interventions that can be implemented to promote health and wellbeing. Here it was found that there was only a slight benefit to conducting these interventions compared to no intervention, however qualitative evidence also identified that people in prisons are concerned about the lack of health promotion information available. The GDG discussed the implementation of peer-led training in different categories of prisons. There was consensus that it was possible to implement within category A prisons, but that it may require different management or methods to implement compared to lower-security prisons. It was noted that the included paper was a state prison in the USA (equivalent to a category B or C) and that the training consisted of video feedback exercises to learn presentation skills. The GDG agreed further research conducted in the UK prison system on the most effective methods for delivering health promotion activities would be beneficial and a research recommendation in this area was drafted. The GDG noted anecdotal evidence of the benefit of peer-led interventions compared to professional-led interventions for health promotion in prison, therefore the GDG decided to make a research recommendation in this area. For more details please see Appendix P.

	Research recommendation The evidence review on health promotion identified little data on how health promotion interventions should be delivered and who is best to deliver them. This is considered to still be an important question as it is known that prisoners find it difficult at times to gain access to services which require an interaction with those they perceive to be in authority, including prison officers but also health professionals, as acknowledged within the qualitative review in this area. Many examples of how to deliver health promotion exist, ranging from information leaflets, one-to-one sessions or group-based learning. If it can be established which methodology of health promotion delivery is more effective then both the NHS and prisons would be able to better target the resources it has to better inform, educate and develop independence around health offering equivalence of service, a 'real world' experience and more confidence in overall health provision.

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7.6.3 Barriers and facilitators to health promotion (see section 7.5)

Recommendations	**45. Offer people in prison tailored health information in a variety of formats, including face-to-face. Include advice about:** • **exercise** • **diet** • **stopping smoking** • **sexual health** • **personal hygiene.**
Relative values of different outcomes	The GDG agreed with the themes identified from the qualitative review on barriers and facilitators to information provision, support and mentoring for prisoners to promote health and wellbeing. An important theme identified from the review was the provision of accessible health promotion information.
Trade-off between clinical benefits and harms	The evidence from the qualitative review suggests that people in prisons were concerned about the lack of health promotion information available, including information on how to access health promoting activities in prison, for example which smoking cessation services are available and how to access these. There were two primary concerns about accessibility: firstly information is often written in English and so is inaccessible to those who are unable to read, or unable to read English; secondly they reported difficulties in obtaining health promotion information one-to-one from health professionals due unwillingness of the health provision to provide this information and due to time constraints. The provision of accessible health promotion information would benefit people in prison by addressing these concerns and enabling easier access to health-promoting activities. There were no harms noted for the provision of information.
Trade-off between net clinical effects and costs	No relevant economic evaluations were identified through the qualitative review. The GDG considered the cost-effectiveness of providing appropriate health promotion information. Following modest initial development costs, the physical provision of such information should be very cheap, and if effective could lead to small health benefits and savings to future healthcare costs in many different aspects of health. The GDG hence expects the provision of such materials to be cost-effective, in line with the recommendations in NICE clinical guideline 138 Patient experience.

Quality of evidence	The evidence identified in the review covered health promotion in general and only made specific reference to the provision of information on smoking cessation services. The quality of the evidence for the lack of or accessibility of health promotion information subtheme was very low. The evidence had major limitations due to sampling and data collection methods. Although the findings were coherent. The GDG considered that the evidence was applicable to a UK prison setting; evidence came from 2 focus groups, one conducted in Australia and the other in the USA. There was no theme saturation.
Other considerations	The GDG noted that the provision of health promotion information was best practice in the community and should be given equivalency in the prison environment. The GDG agreed that health promotion information should be provided in the following areas: sexual health, smoking, nutrition, physical activity and hygiene. The GDG noted that it was also important to provide specific information on oral hygiene. The GDG suggested the following examples for the subject matter of health promotion information: • Sexual health, for example sexually transmitted diseases; how to use condom/dental dams; available sexual health services (see section 7.2.1.4). • Smoking, for example harms of smoking; how to quit; available stopping smoking services • Nutrition, for example benefits/harms of healthy/unhealthy diet; • Physical activity, for example benefits of exercise; exercises that can be done in cell; available exercise programmes • Hygiene, for example self-care such as personal hygiene/washing • Oral hygiene, for example how to brush teeth and take care of gums The GDG noted existing NICE guidance on health promotion information: • Prevention of sexually transmitted infections and under 18 conceptions 2007 (PH3) .[79] This recommends one to one structured discussions with individuals at high risk of STIs. Ideally, each session should last at least 15–20 minutes. The number of sessions will depend on individual need. • Increasing the uptake of HIV testing among men who have sex with men 2011 (PH34),[84] Recommendation 3: Promote HIV testing when delivering sexual health promotion and HIV prevention interventions to men who have sex with men. This can be carried out in person (using printed publications such as leaflets, booklets and posters) or via electronic media. • Brief interventions and referral for smoking cessation 2006 (PH1)[77] Recommendation 2: People who smoke should be asked how interested they are in quitting. Advice to stop smoking should be sensitive to the individual's preferences, needs and circumstances: there is no evidence that the 'stages of change' model is more effective than any other approach. • Workplace interventions to promote smoking cessation .2007 (PH5)[80] Recommendation 4 Offer one or more interventions that have been proven to be effective • Managing overweight and obesity in adults – lifestyle weight management services 2014 (PH53),[93] Recommendations 6 Refer people to a group rather than an individual programme if they express no preference because, on average, group programmes tend to be more cost-effective. The GDG noted that written information (for example leaflets) was inaccessible to people who could not read or could not read English and, accordingly, agreed that health promotion information should be provided in a range of accessible formats within the prison environment. The GDG agreed that health promotion information and directions on how to access this information in the future should be provided face-to-face in a non-written format during the second stage of the reception health

	assessment. The GDG noted that health promotion information could be provided in different languages and could be provided in a variety of formats: face-to-face; media formats such as video or radio; leaflets; Easy Read. The GDG was aware of existing recommendations in the NICE guideline on Patient Experience[69] that detail requirements for the provision of information, this includes: giving both oral and written information; giving information in an accessible format, for example: written information, pictures, symbols, large print Braille and different languages. This guideline also has a section on patient concerns, which details that: • 1.2.3 Be prepared to raise and discuss sensitive issues (such as sexual activity, continence or end-of-life care), as these are unlikely to be raised by some patients. • 1.2.4 Listen to and discuss any fears or concerns the patient has in a non-judgemental and sensitive manner. The patient experience guideline also mentions that patients should be made aware of whom to contact, how to contact them and when to make contact about their ongoing healthcare needs (QS14). The GDG also discussed other themes identified in the qualitative review. The GDG noted that lack of privacy or confidentiality in accessing health promotion services or activities was a barrier to health promotion, particularly with regards to sexual health. The GDG agreed that some health promotion information should be available in a discrete manner which enables the prisoner to access the information privately, for example information around sexual health may require discretion and sensitivity. For example, health promotion information (both face-to-face and leaflet/booklet) should be given on reception to prison in the confidential meeting with the prisoner and healthcare professional, as well as the provision of advice on how to access health promotion information (for example, how to book GP appointments, where written information is available in prison) and how to attend any health promotion activities in the future. The GDG noted that lack of education, lack of health promotion programmes and places on the available programmes and lack of physical exercise opportunities can be barriers to health promotion in prisons. The GDG agreed that having more opportunities like these may help improve health in prisons. The GDG also noted that prisoners can provide support for each other and also from their family, friends and from the people working in the prison. The GDG agreed that support can be an important factor in facilitating health promotion in prison.

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8 Medication management

8.1 Introduction

Medicines optimisation for people in prison presents some unique challenges and therefore the GDG prioritised review questions on access to medications. Ensuring continuity of medicines is important when a person comes into prison, is transferred between prisons or released into the community as medicines may not be made available to the person (or the escorting staff) on admission before transfer or release and, as a result, doses can be delayed or missed.

Some people in prison misuse prescribed medication and many of these people will have a previous history of substance misuse. Medications may be traded within prisons, willingly or under duress, presenting a risk to the person misusing it and others who may acquire it. If a person misuses multiple medications the potential harm is increased through the additional risk of drug interactions.

These risks have resulted in additional safeguards being used that restrict some medicines from being prescribed routinely or being held in the possession of prisoners.[120] Each dose of non in-possession medicines is administered under the supervision of a healthcare professional. This practice creates significant operational challenges that impact on the timeliness of medicines access and safety.

Choices of medicines for people in prison may also be different to those choices used by clinicians in the community due to the risk of harm due to misuse or diversion. People in prison may not be aware of these reasons for changing their medicines, which compromises shared decision-making and affects the quality of the person's experience of care.

8.2 Review question: What are the most clinically and cost-effective methods for people to access medicines in prisons to maximise adherence and good health outcomes and reduce inappropriate use?

For full details see review protocol in Appendix C.

Table 86: PICO characteristics of review question

Population	Adults (18 and over) in prisons or young offender institutions (YOIs) Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low-medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres
Interventions	In possession medication (self-administration) versus non in possession (directly observed administration) Formulary adaptation Monitoring adherence (random checks of in possession medication to support clinical review) Mandatory drug testing (tests for specific drugs - NOMS function) Stock medicines (supply held by ward for use when required) versus non-stock (named patient medicine) In possession risk assessment Minimising diversion

	Minimising bullying Minimising abuse of medicines Electronic versus manual prescription
Comparison	Compared to each other
Outcomes	Critical outcomes Drug adherence Morbidity Important outcomes Measures of drug diversion/trading Overdose Mortality Health-related quality of life
Study design	Randomised controlled trials Systematic reviews and meta-analyses of the above If no RCTs are identified, observational studies

18.2.1 Clinical evidence

Studies were searched for that compared interventions that aimed to maximise adherence to medications, reduce inappropriate medication use and improve health outcomes of people in prisons. Two RCTs were identified and included in the review[143,161] which investigated the effectiveness of directly observed therapy (DOT) for hepatitis C and HIV medications; these are summarised in Table 101 below. We also looked for observational studies in the areas where no randomised controlled trials were identified; studies which looked at interventions for medications other than the ones already identified, such as pain medications. However no observational studies were found in this area.

Evidence from the included studies is summarised in the clinical evidence summary in Table 87. See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, forest plots in Appendix K, GRADE tables in Appendix J and excluded studies list in Appendix L.

Table 87: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes
Saiz de la hoya 2014[143]	Intervention (n=122): Directly observed therapy (DOT) of hepatitis C treatments ribavirin and pegylated interferon alpha-2a Comparison (n=130): Self-administered therapy (SAT) of ribavirin. DOT of pegylated interferon alpha-2a	Adults (aged 18 or older; mean age DOT 36.07±6.66, SAT 35.72±6.46) Gender (M:F): DOT 95:5; SAT 93:7 25 prisons Spain	Sustained virological response at 24 weeks Mild adverse events (anaemia, thrombocytopenia, neutropenia, leucopenia) at 48 weeks Serious adverse events at 48 weeks (not defined)
White 2015[161]	Intervention (n=20): DOT of antiretroviral therapy (ART) Comparison (n=23): SAT of ART	Adults (aged 18 or older; median age DOT 38, SAT 39) Gender (M:F): DOT 85:15; SAT 87:13	Adherence at 24 weeks and 48 weeks, measured using: • Medication Event Monitoring System pill caps (MEMS) • Pill count

Study	Intervention and comparison	Population	Outcomes
		11 prisons USA	

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Table 88: Clinical evidence summary: Directly Observed Therapy versus Self Administered Therapy

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with SAT	Risk difference with DOT (95% CI)
Sustained virological response	252 (1 study) 24 weeks	⊕⊕⊖⊖ LOW[a,b] due to risk of bias, imprecision	RR 0.918 (0.746 to 1.125)	662 per 1000	53 fewer per 1000 (from 165 fewer to 86 more)
Mild adverse events anaemia, thrombocytopenia, neutropenia, leucopenia	252 (1 study) 48 weeks	⊕⊕⊕⊖ MODERATE[a] due to risk of bias	RR 1.1 (1.03 to 1.18)	892 per 1000	89 more per 1000 (from 27 more to 161 more)
Serious adverse events not defined	252 (1 study) 48 weeks	⊕⊖⊖⊖ VERY LOW[a,b] due to risk of bias, imprecision	RR 1.07 (0.46 to 2.47)	77 per 1000	5 more per 1000 (from 42 fewer to 113 more)

[a] Downgraded by one increment if the majority of the evidence was at a high risk of bias and downgraded by two increments if the majority of the evidence was at a very high risk of bias
[b] Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs

Narrative findings

One study (White 2015[161]) compared DOT with SAT on drug adherence for antiretroviral therapy (ART). They measured adherence at 24 weeks and at 48 weeks. Drug adherence was measured using a Medication Event Monitoring System pill caps (MEMS) and by a pill count. The data for these outcomes are displayed in Table 89 and Table 90. The evidence at 24 weeks was at high risk of bias and showed no significant difference between DOT and SAT on drug adherence when measured using MEMS or using pill count. The evidence at 48 weeks was at very high risk of bias and showed no significant difference between DOT and SAT on drug adherence when measured using MEMS or pill count.

Table 89: Drug adherence at 24 weeks: results from White 2015[161]

Median (IQR) at 24 weeks	DOT (n=16)	SAT (n=21)	p
MEMS	99 (93.9, 100)	98.3 (96, 100)	0.82
Pill count	97.1 (95.1, 99.3)	98.5 (98.5, 100)	0.40

Table 90: Drug adherence at 48 weeks: results from White 2015[161]

Outcome at 48 weeks	DOT (n=11)	SAT (n=11)	p
MEMS	99.8 (96.3, 100)	99.9 (85.2, 100)	0.79
Pill count	100 (94.8, 100)	99.5 (IQR 97, 100)	0.84

Related NICE guidance

The evidence identified for access to medication in the prison population is limited, however the GDG considered other published NICE guidance in this area to be relevant to a prison population and therefore, 3 related NICE guidelines were identified by hand searching the NICE website and considered by the group. These look at a broad population, and as such were discussed by the GDG for applicability and relevance, taking into consideration equity of care for people in prison.

The following guidelines were identified and detailed in Table 91:

- NG46 The safe use and management of controlled drugs,[102] April 2016
- CG76 Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence,[106] January 2009

NG33 Tuberculosis,[100] published in January 2016, contains a section on adherence and treatment completion (section 9.2 of the full guideline). This section includes a specific heading of "Strategies in prisons or immigration removal centres" and makes several recommendations including that all prisoners having treatment for active TB should have directly observed therapy.

Table 91: Related NICE guidance: Access to medication

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
NG46	Yes. The full version of the guideline contains review questions split into chapters: Chapter 5, prescribing controlled drugs; Chapter 6 obtaining and supplying controlled drugs; Chapter 7 administering controlled drugs. The review questions focus on interventions, systems and processes.	No. Published 2016	Limited evidence across the questions (1 low quality RCT in Australia, 1 qualitative study in the UK and 1 audit from UK). Majority of evidence from national guidance and policies - UK. Population was adults. Population is representative of a prison population.	As with our review, the guideline identified limited evidence. Evidence that was identified was similar to our review (no significant difference between observed and unobserved dosing groups for treating heroin users in retention to treatment and heroin use). The guideline makes a series of recommendations around risk assessment, record keeping, local policy development and communication. The GDG considered these recommendations to be highly applicable to the prison population, and noted that the Scope highlights the relevance of recommendations to secure environments
CG76	Yes, The full guideline of CG76 details review questions on: Chapter 6 Information for inpatients and practitioners when patients are transferred between services, Chapter 8, interventions to increase adherence to prescribed medication	No. Published 2009	A wide variety of evidence from qualitative, systematic reviews and RCTs. Some studies based in the UK, others deemed applicable to UK. Population was adults. Population is representative of a prison population.	CG76 identified inconclusive evidence for interventions to increase adherence, similar to findings from our review. CG76 makes recommendations on offering and discussing information, supporting adherence, including listening to concerns and information provision, which the GDG agree apply to the prison population.

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
	and Chapter 9 reviewing medicines.			

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18.2.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

Unit costs

See Table 60 in Appendix O.

8.2.3 Evidence statements

Clinical

Adherence

- One RCT comprising of 252 participants demonstrated no clinical difference between DOT and SAT with regards to virological response (surrogate outcome for adherence). The evidence was of low quality as it was at high risk of bias and demonstrated serious imprecision. Another RCT of 27 participants (high risk of bias; GRADE quality assessment not possible due to findings reported narratively) also showed no significant difference between DOT and SAT with regards to drug adherence at 24 weeks measuring using MEMS. Additionally, the study demonstrated no significant difference between DOT and SAT with regards to drug adherence at 48 weeks measuring using MEMS for 22 participants. The evidence was at very high risk of bias.

Adverse events

- One RCT comprising of 252 participants demonstrated no clinical difference between DOT and SAT with regards to mild and serious adverse events. The evidence was of moderate and very low quality, respectively. The evidence for mild adverse events was at high risk of bias. The evidence for serious adverse events was at very high risk of bias and demonstrated very serious imprecision. A second RCT (high and very high risk of bias; GRADE quality assessment not possible due to findings reported narratively) in 27 participants also showed no clinical difference between DOT and SAT with regards to drug adherence at 24 and at 48 weeks, measured using pill count.
- No evidence was identified reporting mortality, health-related quality of life, overdose or measures of drug diversion.

Economic

- No relevant economic evaluations were identified.

18.2.4 Recommendations and link to evidence

See section 8.5 below.

8.3 Review question: What are the most clinically and cost-effective methods for continuity of care for people to access medicines to maximise adherence and good health outcomes and reduce inappropriate use when:

- coming into prison?
- being transferred between prisons?
- discharged from prison?

For full details see review protocol in Appendix C.

Table 92: PICO characteristics of review question

Population	Adults (18 and over) in prisons or young offender institutions (YOIs) Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low-medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres
Interventions	In possession medication (self-administration) versus non in possession (directly observed administration) Formulary adaptation Monitoring adherence (random checks of in possession medication to support clinical review) Mandatory drug testing Stock medicines (supply held by ward for use when required) versus non-stock (named patient medicine) Medicine reconciliation
Comparison	Compared to each other Usual care
Outcomes	<u>Critical outcomes</u> Drug adherence Morbidity <u>Important outcomes</u> Mortality Health-related quality of life Overdose
Study design	Randomised controlled trials (RCTs) Systematic reviews and meta-analyses of RCTs

8.3.1 Clinical evidence

RCTs were searched for investigating the effectiveness of interventions to improve the continuity of medication. Four randomised controlled trials were included in the review;[136,162-164] these are summarised in Table 101 below. The populations of the included studies varied in terms of both setting and in medication use. One study[164] was set in prison and another[136] included both prison and jail populations. These two studies both included participants who were on antiretroviral therapy

(ART) for HIV. There were also two studies that were set in jail[162,163] which included participants who were undertaking isoniazid prophylaxis for tuberculosis (TB). The studies looked at a wide range of interventions including: education, incentives, counselling, case management and discharge planning. We also looked for observational studies in the areas where no randomised controlled trials were identified; studies which looked at interventions for medications other than the ones already identified, such as pain medications. However no observational studies were found in these areas.

Evidence from the included studies is summarised in the GRADE clinical evidence profile in Table 93. See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, forest plots in Appendix K, GRADE tables in Appendix J and excluded studies list in Appendix L.

Table 93: Summary of studies included in the review

Study	Intervention and comparison	Population	Outcomes	Comments
Reznick 2013[136]	Intervention 1 (n=81): Ecosystem-based intervention (2 x 1:1 sessions pre-release; 16 x 1:1 and group sessions with members of participant's 'ecosystem' post-release). Participants' ecosystems refers to the following: family, friends, sexual and drug use partners, and service providers. The membership, functional patterns and roles in the participant's ecosystems were assessed, and. interactions and roles were restructured through direct interventions Control (n=81): Individual counselling (2 x 1:1 sessions pre-release; 16 x 1:1 sessions post release). Focused on the participant's own goals and objectives. Provided information and support on: (1) reduction of sexual and drug-related HIV transmission risk; (2) promotion of HIV related medication adherence	Adults (aged 18 years or older; mean age - intervention 42±7.9, control 41.4±7.8) Male/female ratio 90:10 2 prisons and 1 jail USA	Drug adherence post-release (12 months)	64.4% participants taking ART for HIV pre-release
White 1998[163]	Intervention 1 (n=30): Incentive and TB education. Incentive - $5 cash on first visit to TB clinic. TB education - research assistants met with each inmate individually and provided standard education about TB and the importance of continuing isoniazid prophylaxis treatment to prevent disease at a later date, and answered any questions about TB and/or TB medication Control (n=31): TB education	Adults (mean age 32) Male/female ratio 98.4: 1.6 2 jails USA	Drug adherence post-release -completed first visit to TB clinic (12 months)	All participants taking isoniazid prophylaxis for TB
White 2002[162]	Intervention 1 (n=185): TB education - education provided every 2 weeks whilst in jail Intervention 2(n=185): Incentive - $25 of food or transportation vouchers provided at first visit to TB clinic Control (n=188): Usual care	Adults (mean age 29) Male/female ratio 89:11 2 jails	Drug adherence post-release -completed first visit to TB clinic (6 months)	All participants taking isoniazid prophylaxis for TB

Study	Intervention and comparison	Population	Outcomes	Comments
		USA	Drug adherence post-release -completed isoniazid therapy (6 months)	
Wohl 2011[164]	Intervention 1 (n=52): Bridging case management. • Case managers met with the study participants 1:1 prior to and after release to identify medical and non-medical needs, and to develop plans to meet those needs including: housing, employment, medical care, substance abuse counselling and family reconciliation. • Bridging case management is largely directed by the person rather than the case manager. • Focuses on the identification of talents, resources and goals of the person in an open, non-judgemental environment. • Case managers attempted to meet with participants a minimum of every 2 weeks prior to release, weekly for the first 2 weeks post-release and then at approximately 2 week intervals up to 6 months after release. Control (n=52): Discharge planning. • Conducted by dedicated HIV outreach nurse. • Each nurse worked with participants approximately 3-6 months prior to their release to make referrals to community clinics and social services, identify sources for coverage of medication expenses, and attempt to locate housing. • Nurses met with participants approximately 3 times prior to release.	Adults (aged 18 years or older) Male/female ratio 73:27 Multiple prisons USA	Unplanned admissions post-release – hospitalisation (12 months) Unplanned admissions post-release – emergency department presentations (12 months)	All participants taking ART for HIV

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1 **Table 94: Clinical evidence summary: TB education versus usual care**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with Education (95% CI)
Drug adherence Completed first visit to TB clinic	211 (1 study) 6 months	⊕⊕⊕⊖ MODERATE[a] due to imprecision	RR 1.56 (1.02 to 2.37)	240 per 1000	135 more per 1000 (from 5 more to 329 more)
Drug adherence Completed isoniazid therapy	221 (1 study) 6 months	⊕⊕⊕⊖ MODERATE[a] due to imprecision	OR 2.21 (1.03 to 4.72)[b]	105 per 1000	101 more per 1000 (from 3 more to 252 more)

[a] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

[b] Adjusted for stable housing before jail; time in United states; statement that they would "definitely" complete isoniazid therapy

2 **Table 95: Clinical evidence summary: incentive (payment) versus usual care**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with Incentive (95% CI)
Drug adherence Completed first visit to TB clinic	218 (1 study) 6 months	⊕⊕⊕⊖ MODERATE[a] due to imprecision	RR 1.53 (1.01 to 2.33)	240 per 1000	127 more per 1000 (from 2 more to 320 more)
Drug adherence Completed isoniazid therapy	218 (1 study) 6 months	⊕⊕⊖⊖ LOW[a] due to imprecision	OR 1.07 (0.47 to 2.41)[b]	115 per 1000	7 more per 1000 (from 58 fewer to 124 more)

[a] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

[b] Adjusted for stable housing before jail; time in United states; statement that they would "definitely" complete isoniazid therapy

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1 **Table 96: Clinical evidence summary: incentive plus education versus education**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Education	Risk difference with Incentive and education (95% CI)
Drug adherence Completed first visit to TB clinic	61 (1 study) 12 months	⊕⊕⊖⊖ LOW[a] due to imprecision	RR 1.18 (0.49 to 2.85)	226 per 1000	41 more per 1000 (from 115 fewer to 418 more)

[a] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

2 **Table 97: Clinical evidence summary: ecosystemic intervention versus individual counselling**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with individual counselling	Risk difference with Ecosystemic intervention (95% CI)
Drug adherence Self-reported	151 (1 study) 12 months	⊕⊕⊖⊖ LOW[a, b] due to risk of bias, imprecision	OR 0.35 (0.13 to 0.95)[c]	d	d

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[b] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
[c] Unadjusted
[d] Raw data not reported

3 **Table 98: Clinical evidence summary: bridging case management versus discharge planning**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Discharge planning	Risk difference with Bridging case management (95% CI)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Discharge planning	Risk difference with Bridging case management (95% CI)
Unplanned admission Hospitalisation	89 (1 study)	⊕⊕⊖⊖ LOW[a,b] due to risk of bias, imprecision	RR 2.14 (0.96 to 4.79)	152 per 1000	173 more per 1000 (from 6 fewer to 577 more)
Unplanned admission Emergency department presentation	89 (1 study) 12 months	⊕⊕⊖⊖ LOW[b] due to imprecision	RR 1.01 (0.6 to 1.69)	391 per 1000	4 more per 1000 (from 157 fewer to 270 more)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[b] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

1

Related NICE guidance

The evidence identified for continuity of medication in the prison population is limited, however the GDG considered other published NICE guidance in this area to be relevant to a prison population and therefore, 2 related NICE guidelines were identified by hand searching the NICE website and considered by the group. These look at a broad population, and as such were discussed by the GDG for applicability and relevance, taking into consideration equity of care for people in prison. NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes,[98] published in 2015 is detailed in Table 99.

1 **Table 99: Related NICE guidance: Continuity of medication**

NICE guideline	Is the review question similar?	Is the evidence review underpinning the recommendations likely to have changed?	Is evidence review for the review question relevant and appropriate?	GDG comment on areas of agreement and difference
NG5	Yes. The most applicable is Chapter 7, medicines reconciliation, which has a focussed question on interventions to reduce suboptimal use of medicines and medicines-related patient safety incidents.	No. Published 2015	RCTs and systematic reviews of very low to moderate quality, based in the USA, Canada and Northern Ireland. The GDG note that these studies are in hospital settings, but noted the same barriers would be applicable here as in a prison population. Population was adults (including one paper in those aged over 55 and another with acute heart conditions). Population is representative of a prison population.	NG5 reported that medicines reconciliation improved medicines-related outcomes over usual care in 2 studies that involved pharmacist-led medicines reconciliation at discharge or multidisciplinary team led medicines reconciliation at discharge. One study showed no significant difference in medicines-related outcomes between medicines reconciliation (at admission and discharge) and usual care, but did result in fewer clinically important medication prescribing errors and potential adverse drug reactions compared with usual care. Our guideline did not identify any interventions on medicine reconciliation. The GDG considered the evidence and recommendations in NG5 to be applicable for to a prison population.

2

18.3.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

8.3.3 Evidence statements

Clinical

Adherence

- One three-armed RCT demonstrated a clinical benefit of education compared to usual care with regards to drug adherence, when measured both by the completion of first visit to TB clinic and by the completion of isoniazid therapy. This study arm had 211 participants at follow-up. The evidence was of moderate quality, due to demonstrating serious imprecision. The study also demonstrated a clinical benefit of incentives compared to usual care with regards to drug adherence, when measured by completion of the first visit to TB clinic. The evidence was of moderate quality due to demonstrating serious imprecision. Although the study demonstrated no clinical difference when drug adherence was measured by the completion of isoniazid therapy. This evidence was of low quality due to demonstrating very serious imprecision. The study arm had 218 participants at follow-up
- One RCT comprising of 61 participants demonstrated no clinical difference between incentives plus education and education with regards to drug adherence, when measured by completion of the first visit to TB clinic. The evidence was of low quality due to demonstrating very serious imprecision.
- One RCT comprising of 151 participants demonstrated a clinical benefit of individual counselling compared to an ecosystemic intervention with regards to self-reported drug adherence. The evidence was of low quality as it was at serious risk of bias and demonstrated serious imprecision.

Adverse events

- One RCT comprising of 89 participants demonstrated a clinical benefit of discharge planning compared to bridging case management with regards to hospitalisation. The evidence was of low quality as it was at serious risk of bias and demonstrated serious imprecision. Additionally the study demonstrated no clinical difference between bridging case management and discharge planning with regards to emergency department presentations. This evidence was of low quality as it demonstrated very serious imprecision.
- No evidence was identified reporting measures of mortality, health-related quality of life or overdose.

Economic

- No relevant economic evaluations were identified.

8.3.4 Recommendations and link to evidence

See section 8.5 below.

8.4 Review question: What are the barriers and facilitators to ensuring access to medicines to maximise adherence and good health outcomes and reduce inappropriate use when:

- coming into prison?
- in prison?
- being transferred between prisons?
- discharged from prison?

For full details see review protocol in Appendix C.

Table 100: Characteristics of review question

Objective	Identification of themes around barriers and facilitators for access to, management of, and continuity of medications within a prison environment. To provide details of areas for improvement in adherence to medication and minimising inappropriate use.
Population and setting	Adults (18 and over) in prisons or young offender institutions. Indirect settings: Immigrant Removal Centres (IRCs), secure environments, forensic units, low/medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Review strategy	Study designs to be considered: Qualitative studies (for example, structured interviews, focus groups, observations) and surveys to support themes from qualitative studies. A thematic analysis of the data will be conducted and findings presented in the studies will be reported.

8.4.1 Clinical evidence

8.4.1.1 Methods

Eight studies[1,8,9,40,62,128,149,155] were identified for inclusion. The majority of included studies are based in the UK with 3 study based in USA. Three of the studies include young offender institutions and 3 have a focus on medication for mental health problems. The included studies utilised various methods including focus groups, semi structured interviews and mixed methods (incorporating semi structured interviews). These are summarised Table 101. Key findings from these studies are summarised in the clinical evidence summaries in Table 103 to Table 106.

See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, and excluded studies list in Appendix L.

8.4.1.2 Summary of included studies

Table 101: Summary of studies included in the review

Study	Methods used	Population	Research aim	Comments
Qualitative studies				
Adams 2011[1]	Semi-structured interviews	n=29 Former prisoners (length of time since release, mean (range): 42 (5 - 82)	To understand how former inmates perceive barriers to accessing health. Also looked at themes around	Non-UK (USA)

		days. Male:female 20:9 Age in years, mean (range): 39 (22 - 57) USA Prison category not reported.	risk of HIV and HCV after release - not included.	
Binswanger 2011[8]	Semi-structured interviews	n=29 Former prisoners, 2 months post-release Adults (mean age 39, range 22-57) Male: female ratio: 69:31 USA	To understand the health-seeking experiences, perceptions of risk, and medical and mental health needs of former prisoners in the first two months after release from prison	
Bowen 2009[9]	Mixed methods (semi-structured interviews supported by participant observation)	n = 39 people in prison and n=71 prison staff in 4 prisons. People in prison Male:female 27:12 Age: – <25 years = 13, <35 years = 17, <45 years = 7, <55 years = 2 Prison staff Male:female 43:28 UK - Includes 1 female prison, 1 male young offender and juvenile facility, 1 male category B prison and 1 prison from the High Security Estate	To explore prescribing and taking of medication related to the management of mental health problems in prison.	Ethnicity not reported Focus on mental health. Includes young offenders.
Hassan 2012[40]	Mixed methods (semi-structured interviews supported by a questionnaire)	n = 92 (24 people in prison and 68 staff) across 12 prisons People in prison Male:female 21:3 Age - not reported UK – Adult male local = 5, Adult male sentenced = 1, Male youth Offender Institution = 3 and Female = 3	To explore staff and people-in-prison's views on in-possession medication.	Age and ethnicity not reported Includes young offenders.
Mills 2011[62]	Semi-structured interviews	n = 44 people in prison in 3 local prisons Male:female 36:8	To investigate people-in-prison's experiences of antipsychotic medication and exploring the impact	Focus on mental health.

		Age - 19 - 61 years. Mean age 37 years UK - 2 male category B prisons and 1 female prison	of the prison environment and regime on adherence and satisfaction.	
Prison reform trust[128]	Interviews, focus groups and letters directly received by researchers,	n = unclear Interviews with 78 men in prison, 18 ex-prisoners, 2 focus groups with women prisoners and letters received by researchers and prison reform trust's advice and information service. UK	To investigate views of older people in prison.	Unclear methodology and poorly defined population.
Sowell 2001[149]	Focus groups	n=16 Former prisoners/in jail diagnosed with HIV Adults (mean 38.7±7.9; range 23-51) Male/female ratio 11:5 USA	To identify social service needs of HIV-infected persons at the time of release from prison/jail and to describe their case management experiences after release from jail	Some themes omitted around cost of medication (USA setting)
Tompkins 2009[155]	Semi-structured interviews	n = 30 Men with history of injecting drug use. Age = 20 - 50 years. Mean age 34 (SD 6.99) UK. Men had served in over 35 different adult and young offender establishments throughout England.	To explore prison buprenorphine (Subutex) misuse, including diversion of prescriptions	Includes young offenders. Ex-offenders with history of injecting drug use.

1

8.4.1.3 Clinical evidence

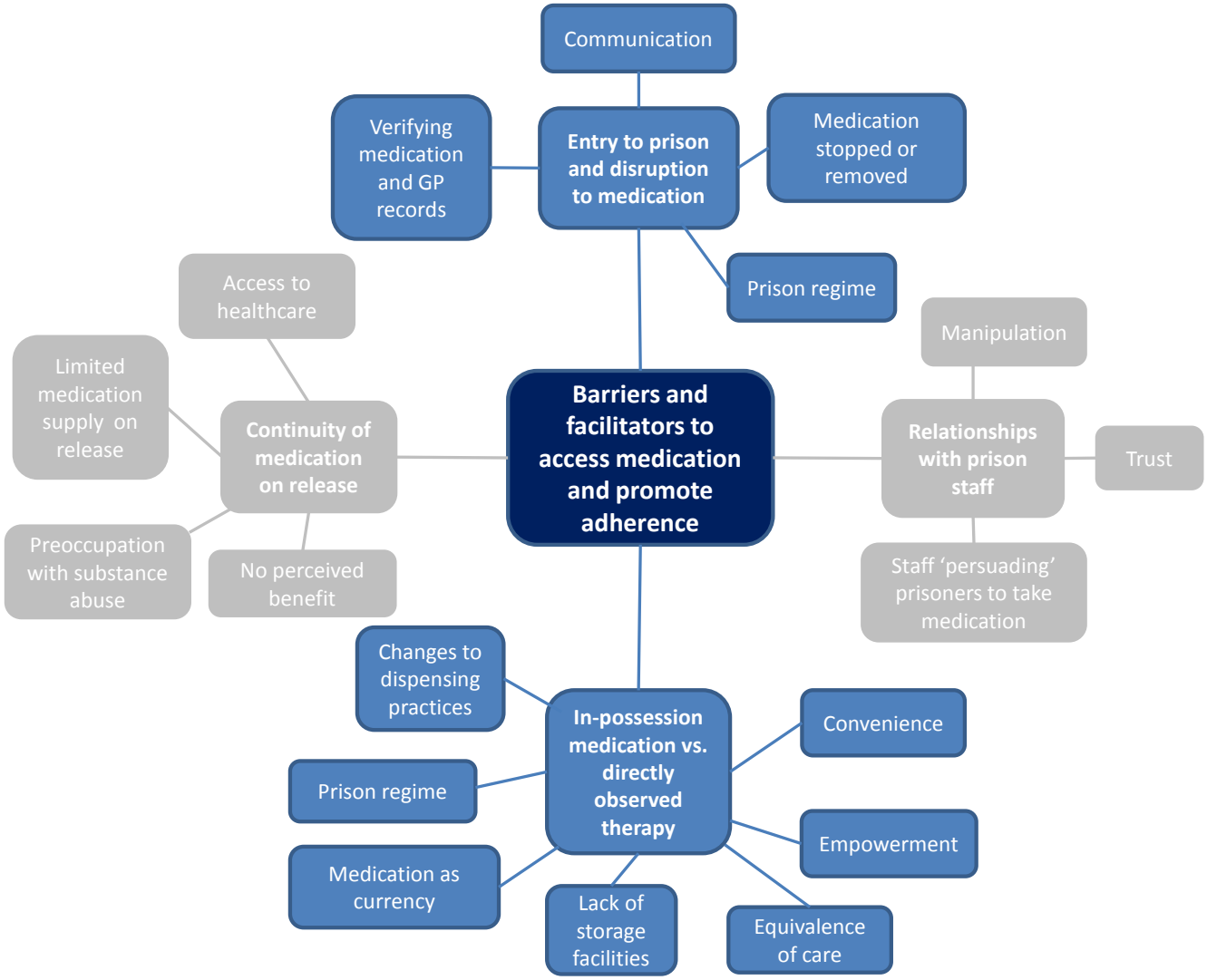
8.4.1.3.1 Themes and sub-themes derived from the evidence

Please note subthemes are listed alphabetically within themes.

Table 102: Themes

Main theme	Subthemes
Entry to prison and disruption to medication	Communication
	Medication stopped or removed
	Prison regime
	Verifying medication and GP records
In-possession medication vs. directly observed therapy in prison	Changes to dispensing practises (crushing drugs or prescribing other drugs)
	Convenience
	Empowerment
	Equivalence of care
	Lack of storage facilities
	Medication as currency (trading, diversion, misuse)
	Prison regime
Relationships with staff in prison	Manipulation
	Staff 'persuading' prisoners to take medication
	Trust
Continuity of medication on release	Access of healthcare
	Limited medication supply on release
	No perceived benefit
	Preoccupation with substance misuse

Figure 5: Themes and sub-themes



1 **Evidence summary**

2 **Table 103: Summary of evidence: Theme 1 – Entry to prison and disruption of medication**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Communication					
1	Semi-structured interviews (UK)	• Misunderstood when frustrated about medication *"The doctor told me he wasn't going to give me anti-depressant .....So I said, all I said was ' it's no wonder people hang their selves'. It was taken the wrong way and I was taken to hospital and put in a 'strip cell' because they thought I'd said that I was going to hang meself.... I tried to explain that I'd only said it out of frustration because I mean, it is a worry." Prisoner BOWEN*	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No saturation	
Sub-theme 2: Medication stopped or removed					
2	Semi-structured interviews, focus groups and letters. (UK)	• Disruption to medication management on arrival to prison *"I was on tablets for depression running back over the past 10 years, and when I came here, they refused to give me any..... so for just short of a month of being here, I didn't get any... And when I first came in and I explained it, I explained what medication I was on the outside, and the doctor says 'well we don't give that out in here'. "….prisoner BOWEN* *"I came in and they took the HRT off me – I was suicidal anyway – it was terrible." prisoner- Prison Reform Trust*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturation	
Sub-theme 3: Prison regime					
1	Semi-structured interviews (UK)	• Staff say certain drugs are not available in prison *"[healthcare say] 'I'm sorry, these drugs are just not available in this prison', which is not always correct... Valium is the obvious one. We can use Valium in the prison but it is*	Limitations of evidence	Minor limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		extremely rare that we use it and it is a 'no-no'. Technically, in here, [it's] a non-formulary item, so you have to fill out another form. You have to get another doctor to agree with you so as to prescribe it, which is time consuming. So 99.9% of the time, they'll just tell you 'it's not available'..." - member of in-reach team BOWEN • Staff say that the prison system leads to delays in medication *""The only way really around it is that you need to revamp the system of people being reviewed [on arrival in prison]. If you can imagine, the courts sit 'til 5 o'clock. If someone is remanded, they mightn't get to the prison 'til 8 o'clock, 9 o'clock that night. They're [the nursing staff on duty] not going to start ringing GPs at that time of night." Prison staff BOWEN*	Theme saturation/sufficiency	Saturation	
Sub-theme 4: Verifying medication and GP records					
1	Semi-structured interviews (UK)	• Prison, healthcare staff and people in prison acknowledge difficulty in accessing GP records and verifying medication *"...If they come in with drugs that are in their name, have pharmacy labels on them, then they get prescribed you see. But because they don't turn up with any evidence of what they've been taking, it is the problem of checking out with the GP surgeries, who are extremely reluctant I have to say, to give us information of what these guys are taking, so that we can continue that. Nursing staff BOWEN* *"I would say that General Practice in here [in prison] is at about 1980 in terms of comparison with the outside world. The biggest deficit now is the lack of an IT system, an integrated IT system, which means we work entirely off paper notes, and have all the problems of paper notes which are that they are a mess, they are difficult to get information*	Limitations of evidence	Major limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturation	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		from them quickly...Doctor BOWEN			

1

Table 104: Summary of evidence: Theme 2 – In-possession medication versus directly observed therapy in prison

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Changes to dispensing practices					
1	Semi-structured interviews (UK)	• Healthcare response to medication trading and diversion *"They're crushing it (Subutex) up and giving it to you like that now. And all the lads (male prisoners) are getting round it." Prisoner, TOMPKINS* *"Prescribing other drugs "It has changed now in (prison 1) because they've got to go on methadone because too much people grafting (stealing from) healthcare right and spitting them out and just snorting them or just selling them." Prisoner, TOMPKINS*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Convenience					
2	Semi-structured interviews (UK)	• Prisoners discussed a reluctance to queue for medication "Having it is better than coming down for it every day, it would be a pain coming then." -Prisoner HASSAN *"They call you for your medication, I will make (sic) my best to go and get it, but if there's … people queuing up, I might miss… a dose. Just because of the aggro of it. It's only a tablet for God's sake…" Prisoner MILLS*	Limitations of evidence	Major limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturation	
Sub-theme 3: Empowerment					
1	Semi-structured interviews (UK)	• Empowerment of prisoners through having their medication in-possession *"Prisoners should have their own medication in-possession… that's coming from my core beliefs that we've got to enhance their autonomy and independence and get them to take charge of their care treatment." Mental health manager HASSAN* *"It actually gives the prisoner a certain amount of control over their*	Limitations of evidence	Major limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		illness or their treatment… they are taking the responsibility on for themselves. Healthcare is supposed to reflect inside the prison what happens outside the prison. " Mental health nurse- HASSAN • Also empowering for staff: "*Nurses spend far too much time giving out medication rather than being nurses." Pharmacist HASSAN*	Theme saturation/sufficiency	Saturation	
Sub-theme 4: Equivalence of care					
1	Semi-structured interviews (UK)	• Prisoners noted that their healthcare needs should be separate from their offending. *"It makes you feel normal. I'm not a monster, so I should get my inhaler." Patient. - HASSAN* • Noted it was common to hear staff frustration over in-possession, and may have an overly cautious approach: *"Some people do get rather upset and agitated about it but the incident of death by overdose is very low. Plus, if they were in the community they would have a cupboard full of tablets anyway." Healthcare manager HASSAN*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No saturation	
Sub-theme 5: Lack of storage facilities					
1	Semi-structured interviews (UK)	• Concerns over storage "I don't think there is any benefit of anyone having their own medication… unless there was a safe place to keep them in your pad [cell]. (Patient, Prison A)" HASSAN	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No saturation	
Sub-theme 6: Medication as currency					
2	Semi-structured interviews (UK)	• Staff suspicious of prisoner motives - *"[In possession medication] can only be a good thing if they can be trusted to have it, but a lot of these would sell their granny for a few extra cigarettes." Prison officer HASSAN*	Limitations of evidence	Major limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		• Subutex was identified as a major currency in prison. *"The doctors were prescribing it (Subutex) in (prison 2) at one point to the adults. And a lot of people, a lot of people wasn't taking it; they were bringing it back onto the wing to sell to other drug users, and that's how it was getting brought back and everybody was buying it and I brought it myself and just use it…" Prisoner TOMPKINS*	Theme saturation/sufficiency	Saturation	
Sub-theme 7: Prison regime					
3	Semi-structured interviews (UK)	• Prisoners and healthcare staff noted that the inflexible prison regime and limited in-possession medication had a negative impact on medication adherence *"I only had been taking the Trazodone of a night time [i.e. prior to coming into prison]. I had problems for quite a few weeks [i.e. after entering prison]. I used to get the tablet at 4 o'clock before tea at 5 o'clock, and if I took the tablet at 4 [o'clock], by the time I come to 5 [o'clock] I couldn't even get myself off the bed because I was that drugged up on it.... But I've manage to get that moved to 7 o'clock now after a lot of negotiation." Prisoner BOWEN* *"Some establishments had a more flexible approach to in-possession medication and ruled out fewer drugs and were more likely to adapt or 'calibrate' approaches individually. Inflexibility invoked frustration among some patients "It's the drug, not me! They'd be better off assessing individual cases rather than having a blanket ban. (Patient, Prison F)" HASSAN* *"I've had appointments elsewhere, because I was on the detox wing, they only give it out at certain times so I actually missed it." Prisoner MILLS*	Limitations of evidence	Major limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturation	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		"First time I was on the house block and I got my dinner and then had to have medication so I went to get medication, but then I wanted to have my dinner. So I missed the medication and went back for my dinner." Prisoner MILLS			

Table 105: Summary of evidence: Theme 3 – Relationships with staff in prison

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Manipulation					
1	Semi-structured interviews (UK)	• Prisoners "lying" and saying they are on certain medications or doses *"Like there's one guy at the moment who is convinced that he's on certain doses of certain things and I've got the GP to read me his psychiatrist's letter that came in January, so I know that the doses we've prescribed are correct. Do you know what I mean? 'Cos I've seen him three times with the same issue... So there's a bit of that, and a bit of manipulation..." nursing staff BOWEN*	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Staff "persuading" prisoners to take medication					
1	Semi-structured interviews (UK)	• Use of incentives to take medication *"I think they'd offer me incentives like 'we'll lend you a kettle if you take your medicine' or 'come on, you'll never get back to your own prison if you don't take your medicine', so I think they'd use social underhand measures to try and coax me." Prisoner, MILLS* *"Some of the staff bribe me…[saying for example] 'I'll give you proper cigarettes if you take your medication'." Prisoner MILLS*	Limitations of evidence	Minor limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturation	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		• Strong coercion to take medication *"They told me if I didn't take it, I'd go to healthcare which is like punishment because,…[you are] banged up [for ages] down there. They were like 'we can make you take it'. And I was just like 'oh stuff that then, I'll take it over here'." Prisoner MILLS*			
Sub-theme 3: Trust					
1	Semi-structured interviews (UK)	• Alienation and mutual distrust: anti-therapeutic relationships between staff and inmates over medication prescribing *"Yeah… with prison and the 'out' [outside community], it's different. Like, on the out, your doctor knows who you are, what you are, what medication you're on and what your problem is. In here, it doesn't matter what medication you're on out there, you don't get it in here. Do you know what I mean?" Prisoner BOWEN*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

1

Table 106: Summary of evidence: Theme 4 – Continuity of medication on release

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Access of healthcare					
2	Semi-structured interviews (USA, UK)	• Difficulty in accessing healthcare and medication on release *"I've spent quite a bit of time down there learning the ropes on what you have to do to get this free health care because you know how it's free health care, but by golly you're going to wait quite a long time and you gotta kind of know, you know, the ins and outs." Ex offender ADAMS* • Forgot to take it/did not wish to attend appointments at depot clinics *"It's just remembering to take it. That's the difficult part."* *"To begin with my CPN used to come and…give me an injection at my house. But then they changed it and said I had to go to the Bridge Centre…And it made it hard for me to get there because I didn't like going out." Ex offender MILLS*	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Minor limitations Coherent Applicable Saturation	LOW
Sub-theme 2: Limited medication supply on release					
4	Semi-structured interviews (USA)	• Difficulty obtaining needed medications after being released without them or with only a short-term supply. *"They gave me a [30 day] supply of medication, but I'm not able to take the medication because the medication knock me out and I might not hear the page…If I don't make these calls, that can be taken for escape for me not calling back…so I just don't take my medication." Ex-offender ADAMS* • Participants being released from the state prison system frequently reported receiving enough medication to last until they could see a doctor. "Well, when I was released, the Department of Corrections gave me a month's supply of medication to take with me."	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Coherent Applicable Saturation	LOW
Sub-theme 3: No perceived benefit					

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
1	Semi-structured interviews (UK)	• Did not feel the benefit "*When I feel it's not working and I'm in a bad mood about it…I think 'well, it's not working, there's no point in taking it', so that's stopped me from taking it."* *"I sometimes get to that stage where I feel I think I feel better so I don't need it." Ex-offender, MILLS*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 4: Preoccupation with substance misuse					
1	Semi-structured interviews (UK)	• Preoccupation with substance misuse. *"The drink had usually been my number one priority…Yes, I forgot [when drinking]. I don't like the symptoms I suffer when I'm not on the medication so it wouldn't make sense for me not to take it on purpose. " prisoner MILLS* *"I forget. Maybe it's because of the drugs I used to take." prisoner MILLS*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

1

8.4.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

8.4.3 Evidence statements

Clinical

- Eight studies were identified for incorporating views of over 400 prisoners and staff. The majority of included studies are based in the UK with 3 studies based in USA. Three of the studies include young offender institutions and 3 have a focus on medication for mental health problems. Four main themes were identified: entry to prison and disruption to medication, in-possession medication versus directly observed therapy in prison, relationships with staff in prison and continuity of medication on release.

Economic

- No relevant economic evaluations were identified.

8.4.4 Recommendations and link to evidence

See section 8.5 below.

8.5 Recommendations and link to evidence

8.5.1 Methods to access medicines (see section 8.2)

Recommendations	**Managing medicines** **Access to medicines** **46. Carry out an individual risk assessment to determine if the person can hold their medicines in-possession. Allow people in prison to hold all medicine in-possession unless the person does not pass the risk assessment.** **47. Directly observe the administration of all schedule 2 and 3 medicines (see NICE's guideline on controlled drugs) and medicines for tuberculosis (see NICE's guideline on tuberculosis).** **48. Directly observe the administration of any medicine that is not in-possession.** **49. Work with prison staff to ensure a system is in place to:** • **supervise the administering of medicines not held in-possession to maximise adherence** • **reduce diversion (passing medicines on to other people)**

	• **protect confidentiality.** **See the section on supporting adherence in NICE's guideline on medicines adherence.** **50. Review and (if necessary) repeat a person's risk assessment for in-possession medicine if the person's circumstances change. Involve a multidisciplinary team if needed, including prison staff. Examples of when the risk assessment should be repeated include:** • **when carrying out a medicines review** • **if a person is considered able to manage their own medicines after a period of having medicines not in-possession** • **if there is a medicine safety incident, including evidence of self-harm** • **if someone has raised security concerns (for example, about bullying, diversion or hoarding)** • **if the person has not been taking their prescribed medicines** • **if there is concern about the person's ability to self-medicate** • **following the Assessment Care in Custody and Teamwork care planning approach** • **if the person is transferred to a segregation unit.** **51. Consider providing storage for in-possession medicine in prison cells, for example, a lockable cupboard.** **52. Give people in prison information and education about medicines adherence (see the section on patient involvement in decisions about medicines in NICE's guideline on medicines adherence).**
Research recommendation	
Relative values of different outcomes	The GDG considered drug adherence and morbidity to be critical outcomes. The GDG considered mortality, measures of drug diversion or trading, overdose and health-related quality of life as important outcomes.
Trade-off between clinical benefits and harms	The GDG noted that the evidence showed that there was no clinical difference between directly observed therapy (DOT) and self-administered therapy (SAT) for hepatitis C treatments in terms of sustained virological response (which was used as a surrogate outcome for adherence) and the number of adverse events. Additionally the evidence showed that there was no significant difference between DOT and SAT for antiretroviral therapy (ART) in terms of adherence, measured by medication event monitoring system (MEMS) pill caps or by pill count. The GDG noted the potential harms of holding medicines in-possession included poor adherence, overdose and the diversion or trading of drugs.
Trade-off between net clinical effects and costs	No published economic evaluations were identified for this review question. The GDG considered evidence from NICE guidelines CG76, NG33 and NG46 . The GDG noted that the mentioned guidelines already took into account the cost-effectiveness of its recommendations for the general public and due to principles of equality these should also apply to a prison population. Relevant justification can also be found in section 7.6.1 (Trade-off between net clinical effects and costs).Acknowledging there were no differences in the clinical outcomes between DOT and SAT, the GDG discussed potential cost implications of the 2 strategies,

	taking also into account patient safety. DOT requires additional time, most likely of a nurse's time, to administer the medicine safely. The amount of time needed for each patient receiving a DOT medicine is 1-2 minutes. This is due to the need to identify the patient, locate and retrieve the medicine (s), measure out the dose and administer the medicines to the patient, closely monitoring the patient to minimise the risk of diversion. The ease of accessing DOT would depend on the configuration of the prison: some prisons may be able to dispense from a treatment room on each wing; in some prisons the prisoner will be able to move freely to the a central point (usually the healthcare wing) to receive the medication; while in other prisons the prisoner may need to be escorted to access their medicines on each occasion – this means DOT uses much more human resources, and is more expensive for the prison service and for the NHS. For SAT the costs incurred relate to conducting an initial risk assessment, dispensing medication once a month or once a week, and possibly an increased frequency of routine or random validation checking to see if the prisoner is taking their medication. As a result, in situations where SAT is considered safe (following the individual risk assessment) then a modest decrease in costs is an additional factor in favour of SAT, suggesting it would be cost saving compared to DOT. The GDG also considered the provision of secure lockers in cells to keep in-possession medication safe. There is clearly a cost to installing and maintaining such lockers. It was noted that these are installed in cells in some prisons, but not in most, and they can be used for storing non-health related valuables as well as medication. The GDG however noted that the provision of secure storage for medication and valuables is standard in hospitals, and that equivalent treatment would require secure storage to be available to those prisoners who required it. The GDG agreed that a recommendation should be made for prisons to consider provision of secure storage.
Quality of evidence	The evidence was based on 2 RCTs. The quality of the evidence for DOT compared with SAT for hepatitis C treatments ranged from moderate to very low. This was predominately due to a high rate of missing data. The evidence for serious adverse events was also at a serious risk of bias, as 'serious adverse event' was not defined and the data showed very serious inconsistency. The quality of the evidence for DOT compared with SAT for ART was of moderate to low quality. This was due to a high rate of missing data and the use of inadequate analysis. The GDG discussed the applicability of surrogate outcome measures for adherence: virological response, MEMS and pill count. However, the GDG noted that these were adequate outcome measures for adherence as accurate measures of adherence were extremely difficult, so they were not downgraded for indirectness. The evidence was directly relevant as studies were conducted within a prison setting. Although the studies were conducted in non-UK settings (Spain and USA), the evidence is applicable to UK settings as the differences between health systems were not deemed to have a substantial effect on the comparison of DOT and SAT.
Other considerations	The GDG was reassured that there was no clinical difference between DOT and SAT for treatment of people with hepatitis C and HIV, which supports their view that holding medication in possession should be standard practice, unless otherwise indicated. The GDG noted that in-possession medication was the norm for people in the community and that equivalent management should be given in prison. Although the GDG noted the lack of evidence comparing DOT and SAT for prescribed named high risk medicines, the GDG decided to make a research recommendation in this area (for more details please see Appendix P). The GDG agreed that the majority of people in prison can safely be in-possession of

their medication with no difference to medication adherence, and agreed that in possession should be standard for low risk medication (for example medication for hepatitis C, HIV) as defined by the 'Safer Prescribing in Prisons' 2011 guidance[7] published by the Royal College of General Practitioners and Royal Pharmaceutical Society. There is existing guidance from the National Prescribing Centre[119,120] and in pharmacy service for prisoners[22] which states that people in prison should be given the responsibility of holding their medications in-possession where possible. The GDG discussed the need to standardise practice by using the same tool to assess individual risk for in-possession medication and noted the National Prescribing Centre 2005 risk assessment tool[120].

The GDG noted the NICE guidance on the safe use and management of controlled drugs, NG46 ,[102] which details recommendations on prescribing controlled drugs, obtaining and supplying controlled drugs and administering controlled drugs. The guideline makes a series of recommendations around risk assessment, record keeping, local policy development and communication. The GDG considered these recommendations to be highly applicable to the prison population.

The GDG chose to cross refer to the existing NICE guidance on Tuberculosis, NG33,[100] which makes a specific recommendation on directly observing TB medication in prisons (see section 9.2 of the full guidance on adherence and treatment completion: the recommendation states: All prisoners having treatment for active TB should have directly observed therapy).

The GDG noted that before people can have their medication in possession an individual risk assessment is undertaken to determine whether this is appropriate. This includes an assessment of their, ability to self-medicate, risk of suicide, self-harm and misuse and/or diversion. The GDG emphasised that medicines in use should normally be held in-possession as the default position and that a risk assessment should be used to screen people out rather than in. However, the GDG noted that in practice there is evidence of variation across prisons in the percentage of drugs held in possession compared with DOT.

Medication is usually taken away when the person enters prison for the first time and re-prescribed, which can occasionally occur in missing doses or delays in completing treatments resulting in adverse health outcomes for individuals. Continuity of medication needs to be considered when there is the potential for a prolonged delay (for example over a weekend, bank holiday or on transfer to prison that does not have 24 hour healthcare) in obtaining confirmation of medication from the prisoner's GP or it is difficult to obtain medication. The majority of people are serving short sentences and there is regular movement of prisoners within and between establishments. The GDG highlighted that allowing prisoners to hold their own medication would improve continuity of care. See review question on continuity of medication for further information (section 8.3).

The GDG also discussed that some people in prison do not want their medication in-possession because it may be stolen, or when medication is in held on their person they may be subject to bullying or misuse and/or diversion. The GDG agreed that this could be avoided by having storage facilities for medication, for example a lockable storage cupboard. The GDG noted that it was current policy to provide safe storage for in-possession medications: the HM Inspectorate of Prisons 'Expectations: Criteria for assessing the treatment of prisoners and condition of prisons'[42] document states that an indicator for prisoners living in a safe, clean and decent environment which is in a good state of repair and fit for purpose is that prisoners have a 'lockable cupboard and [that] provision for the storage of personal belongings is adequate'. The GDG noted that storage for medication was variable in UK prisons however in UK hospital settings patients do have lockers for their medication. The draft NICE guidance on controlled drugs[102] supports the need for storage of controlled drugs (such as, discussing storage options and detailing storage requirements as part of a risk assessment).
The GDG also discussed access to medications such as those required as part of end

	of life care, in particular anticipatory prescribing. NICE has existing guidance in this area in the Care of the dying adult guideline[72], which states that: "Prison settings were discussed from an equalities perspective as not all prisons include full hospitals and access to pharmacists. The Committee discussed whether separate recommendations for this group should be made. They concluded that all recommendations were applicable in this setting, as people in the last days of life in prison settings were likely to have access to medical care which should provide an individualised assessment, including risk assessment for any appropriate anticipatory prescribing". The GDG also chose to make a recommendation to provide information and education to support medicines adherence and to cross refer to related NICE guidance on medicines adherence [CG76][106], in particular the sections on patient involvement, providing information, assessing adherence and interventions to increase adherence. The GDG considered the evidence and recommendations to be applicable to a prison population.

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28.5.2 Continuity of care in access to medicines (see sections 8.3 and 8.4)

Recommendations	**<u>Continuity of medicine</u>** **53. Ensure the person can keep taking their medicines after coming into prison. Use the examples of critical medicines in Table 107 in conjunction with clinical judgement and any safety alerts.** **54. Hold a one-to-one discussion with the person to agree a plan for how they will take their medicine after their release from prison. This should include education about taking prescribed medicines.** **55. Consider carrying out a medicines review for people who are assessed as needing extra support to manage their medicines on release or transfer from prison. For example:** • **people with tuberculosis, HIV, diabetes, substance misuse or mental health problems** • **people with neurodevelopmental disorders or learning disabilities** • **people receiving end of life care** • **older people** • **people serving long-term sentences.** **56. When a person is discharged or transferred from prison give them a minimum of 7 days' prescribed medicines or an FP10 prescription.** **57. Set up a process to ensure that people being discharged or transferred at short notice from prison are given a supply of their medicines or are given an FP10 prescription.** **58. For recommendations on care for people moving from one care setting to another see the section on medicines-related communication systems in NICE's guideline on medicines optimisation.**

Research recommendation	5. Does the use of directly observed supply of named high-risk medicines (that is, not supplying medicines to prisoners to hold 'in possession') reduce diversion, abuse and non-adherence?
Relative values of different outcomes	The GDG considered drug adherence and morbidity to be critical outcomes. The GDG considered mortality, overdose and health-related quality of life as important outcomes.
Trade-off between clinical benefits and harms	The GDG noted that the evidence showed a clinical benefit of TB education in improving TB treatment adherence. The GDG also noted that the evidence showed a clinical benefit of individual counselling and of discharge planning with a HIV outreach nurse, in improving antiretroviral therapy (ART) adherence and reducing hospitalisation. In accordance with the evidence the GDG decided that one-to-one discharge planning with an educational component would benefit people who are leaving prison. The GDG noted the potential harms of being in-possession of controlled drugs on release from prison were similar to the harms in prison, such as potential drug abuse and diversion.
Trade-off between net clinical effects and costs	No published economic evaluations were identified. The GDG considered evidence from NICE guidelines NG5, CG51. The GDG noted that the mentioned guidelines already took into account the cost-effectiveness of its recommendations for the general public and due to principles of equality these should also apply to a prison population. Relevant justification can also be found in section 7.6.1 (Trade-off between net clinical effects and costs). The GDG noted the clinical benefit of medication continuity planning and holding a consultation with the individual prior to release. The cost of these steps would be the time spent by the relevant healthcare professionals in compiling the discharge plan and holding the discharge meeting. Assuming that the person's notes are correct and up to date), it is anticipated that discharge planning for medication will take a short amount of time (this may be done as part of a wider process of discharge planning, see Chapter 11). The consultation meeting would be expected to take around 15 minutes and could be conducted by a nurse or registered pharmacy staff. The GDG noted that provision of a pre-discharge interview is already current policy, though this is inconsistently applied. The GDG agreed that, in addition to a positive clinical impact, the implementation of these recommendations would also be likely to reduce later costs to the NHS, both by reducing the need for subsequent follow-up contacts with healthcare staff in the community and by reducing health spending on the results of adverse events and complications related to non-adherence or misuse of medication by people who have not received adequate education and support at discharge. The GDG therefore considered that such upfront planning and support would be likely to be cost saving and highly likely to be cost-effective for the NHS as a whole at the NICE cost-effectiveness threshold compared to no provision of discharge support.
Quality of evidence	The evidence was based on 4 RCTs. The overall quality of the evidence was of low to very low quality. This was predominantly due to imprecision. The evidence for the clinical benefit of individual counselling on improving adherence was also at risk of outcome reporting bias because the outcome was self-reported. The studies were conducted in both prison and jails in the USA. The GDG considered jail settings to be directly relevant as USA jails are similar to UK remand prisons. The GDG agreed that although conducted in the USA, the studies were applicable to a UK prison setting as provision for discharge is similar. The GDG thought that the

	individual counselling, bridging case management and discharge planning interventions were similar to the UK hospital model of discharge planning. Although the GDG expressed concern about the use of financial incentives to improve adherence. The qualitative review identified themes to support this recommendation including providing in-possession medication as a default (subject to risk assessment) and storage facilities. Other themes included the importance of continuity of medication on release and communication.
Other considerations	The GDG noted that there is current prison policy on ensuring continuity of healthcare for prisoners (HM Prison Service 2006, Prison Service Order 3050[45]). **Entry to prison** The GDG discussed what commonly happens to medication on reception into prison from the community. The GDG noted that medication is usually taken away at reception, and confirmation of the prescription is then acquired from the community GP before the medication is re-prescribed and given to the patient. The GDG chose to cross refer to the NICE guideline on Medicines Optimisation[98], in particular the section on medicines reconciliation, as the recommendations are applicable to a prison population. The GDG agreed that medicines reconciliation should be completed by the second stage of the reception assessment (see section 0). The GDG also discussed potential barriers to medicines reconciliation. For example, people may lack knowledge about which medicines they take; people who have survived (sexual) violence may be reluctant to disclose information about medication. The GDG noted that when entering prison from police custody, people should have already had their medication verified and should be able to keep it when entering prison subject to verification checks (for example in original packaging and no evidence of tampering). The GDG noted that in certain cases clinical judgement can be used to assess whether medication can be kept and administered on a short-term basis whilst awaiting a formal, named supply. For example, where missed doses can cause severe harm and new medication cannot be re-prescribed over the weekend. The GDG noted that there was variation in the time taken to re-prescribe medicines between prisons. The National Patient Safety Agency 2010 rapid response report on reducing harm from omitted and delayed medicines in hospital[118] showed that medications are often omitted or delayed in hospital and cites patient safety incidents as a result of this. The report goes on to give immediate actions including: • identifying a list of critical medicines where timeliness of administration is crucial; • ensuring medicine management procedures include guidance on the importance of prescribing, supplying and administering critical medicines, and what to do when a medicine has been omitted or delayed; • review and, where necessary, make changes to systems for the supply of critical medicines within and out-of-hours to minimise risks. The GDG discussed the similarity of medicines omitted or delayed in hospital and prison and felt that the report is applicable across settings. The UK medicines information (UKMi) have issued a tool to support local implementation of the NPSA rapid response report[156,157]. This tool is not designed to replace individual local medicines lists, but rather to assist in their generation , as well as with subsequent actions suggested by the NPSA. The risks of delay or omission for each drug or drug class in the BNF are categorised using a traffic light system. The GDG used this list to provide some examples of critical medicines, relevant to a prison population, as shown in Table 107, that are crucial to prevent omitted and delayed doses. The group included substance misuse medicines for alcohol and opioid dependence, as continuity of these medicines forms an important

part of maintaining safety in substance misuse care pathways in prisons

The group discussed the inclusion of vitamins, and noted that Pabrinex is in prisons (parenteral vitamins B and C for rapid correction of severe depletion or malabsorption [e.g. in alcoholism, after acute infections, postoperatively, or in psychiatric states]), as supported by the NICE guidance on alcohol.

The GDG highlighted that the table contains examples only and should be used in conjunction with clinical judgement. It is important to assess each person on an individual case basis.

The GDG noted that people entering prison were often anxious when their medication was taken away on reception and it would be beneficial if staff could provide reassurance that either minimal harm would be caused by not taking the medication whilst further information was obtained or that medication would be re-prescribed and provided if necessary, before or as part of their second health assessment.

The GDG discussed the consequences of missing doses if medication is taken away and not replaced within a reasonable time frame (for example, transmission of communicable disease, breaks in antibiotics can lead to an increase in resistance, security risks following a break in antipsychotic use, delayed doses of eye medicines may lead to deterioration).

Discharge from prison

The GDG discussed the importance of discharge planning before leaving prison and before being transferred. A HMIP standard already exists for pre-release planning of prisoners, and although all people should have a discharge interview there is no consistent practice.[45] The high turnover of prisoners in some prisons was noted as one of the reasons for variation in managing a planned release. The GDG thought that the length of discharge planning should be proportional to length of stay in prison and that people who are at higher risk of harm(for example, people with TB, HIV, diabetes, substance misuse, mental health, learning disabilities) may require having multiple discharge planning sessions. An important part of discharge planning is facilitation of sourcing a GP. Discharge planning may also include, sending a pre-release letter to the patient's GP and communication with secondary care.

The GDG also noted that it is current practice to provide a 7-day supply of medication on release or when a person is going to court in case of unexpected discharge. Seven days supply ensures that the person has an adequate supply until they are able to seek a healthcare appointment to obtain more. The GDG also state that an FP10 prescription can be given instead of 7 days supply which may be more appropriate for controlled drugs that need to be given under supervision post release. It was also discussed that in future FP10s should be transferred electronically.

See also the chapter 11 on continuity of care.

Research recommendation

Since 2003, a principle of self- administration (in-possession medicines) by prisoners has been encouraged with directly observed administration reserved for high risk medicines and vulnerable patients. However, this has led to a variable and inconsistent application of this principle as different medicines are categorised as high risk by different prisons. This is influenced by local factors including the capacity for delivering directly observed medicines which is labour intensive and difficult to include within prisoners' daily schedules. There is no evidence base underpinning the choice of medicines that should be administered under observation. This research will provide the evidence to inform the development of a more consistent list of high risk medicines that require direct observation to improve safety. In addition the research will inform commissioners of health and offender management services

	about the need to provide the workforce and operational capacity to administer high risk medicines safely.

Table 107: Examples of critical medicines where timeliness of administration is crucial to prevent omitted and delayed doses

This table contains examples only and should be used in conjunction with clinical judgement. It is important to assess each person on an individual case basis.

Area	Drugs
Cardiovascular system	Anticoagulants Nitrates
Respiratory system	Adrenoceptor agonists Antimuscarinic bronchodilators
Central nervous system	Anti-epileptic drugs Drugs used in psychoses and related disorders Drugs used in parkinsonism and related disorders Drugs used to treat substance misuse
Infections	As clinically indicated, such as anti-infectives or anti-retrovirals
Endocrine system	Corticosteroids Drugs used in diabetes
Obstetrics, gynaecology and urinary tract disorders	Emergency contraceptives
Malignant disease and immunosuppression	Drugs affecting the immune response Sex hormones and hormone antagonists in malignant disease – depot preparations
Nutrition and blood	Parenteral vitamin B and C
Eye	Corticosteroids and other anti-inflammatory preparations Local anaethetics Mydriatics and cycloplegics Treatment of glaucoma

Based on NPSA Rapid Response Report: Reducing Harm from omitted and delayed medicines in hospital. Revised January 2016.[156,157]

9 Monitoring chronic conditions

9.1 Introduction

People in prison are considered to have a higher burden of infectious diseases, substance use disorders and psychiatric illness than the general population, but it is also thought that their health in general is poorer due to existing or undiagnosed chronic medical conditions, such as hypertension, diabetes, and asthma. The GDG have prioritised a review question on how such chronic conditions should be monitored in prison, as when poorly monitored these conditions may be exacerbated and lead to rapidly deteriorating health and/or emergency situations. As chronic conditions cover a wide spectrum of disorders the main areas considered within this review were chosen based on those presented in the Prisons and Probation Ombudsman report detailing natural causes of death in prison[129]: chronic heart disease, chronic respiratory conditions, chronic kidney disease, diabetes and epilepsy.

9.2 Review question: How should chronic conditions be monitored in prison? – review of NICE guidance

For full details see review protocol in Appendix C.

Table 108: PICO characteristics of review question

Population	Adults (18 and over) in prisons or young offender institutions. Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low/medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Intervention(s)	Methods for monitoring chronic conditions as listed in current NICE guidelines (diabetes, chronic respiratory conditions, epilepsy, chronic heart disease, chronic kidney disease)
Comparison(s)	Not applicable
Outcomes	Adoption of health-promoting behaviours. Uptake of screening programmes. Morbidity. Mortality. Health-related quality of life
Study design	Review of existing NICE guidelines and cross referral or adaptation of recommendations.

9.3 Clinical evidence

It was decided that the most appropriate method for monitoring chronic conditions in prisons would be to review existing NICE guidance and so no full systematic reviews have been conducted for this question in each specialist area. It was considered that as existing NICE guidelines have already been developed for many chronic conditions that sought expertise and knowledge from specialist health professionals this would be duplication of work. Published NICE clinical guidelines were checked for recommendations regarding monitoring of chronic conditions. The GDG prioritised chronic conditions in the protocol to include diabetes, chronic respiratory conditions, epilepsy, chronic heart disease, chronic kidney disease. The NICE catalogue of guidelines is extensive and it is noted that many other conditions could be included within the list of chronic conditions; however the GDG prioritised based on the major conditions commonly seen in prisons and where poor management

has a significant impact on health outcomes. The GDG acknowledged that other NICE guidelines would still be appropriate and may also be cross-referred in other chapters of this guideline. No literature search was conducted; recommendations were identified based on hand searching the clinical guidelines on the NICE website.

The guidelines reviewed are summarised in Table 101 below (listed alphabetically). Relevant recommendations and the evidence underpinning them are summarised by guideline in the clinical evidence profiles in Table 110 to Table 120. Appendix Q contains the list of relevant recommendations from each guideline.

Table 109: Summary of published NICE clinical guideline review questions included in the review

NICE Guideline	Review question	Comments
Anaemia management in people with chronic kidney disease (update). NG8. Published June 2015.[97]	In patients with ACKD treated with ESAs, how frequently should iron status be checked? In patients with ACKD treated with ESAs, how frequently should haemoglobin levels be checked a) during Hb correction and b) during Hb maintenance?	
Chronic heart failure: Management of chronic heart failure in adults in primary and secondary care. CG108. Published August 2010[81]	How should the initial management plan be determined? In what circumstances should a previous diagnosis of heart failure be reassessed?	Currently being updated. Due to publish March 2018.
Chronic kidney disease: early identification and management of chronic kidney disease in adults in primary and secondary care. CG182. Published July 2014[91]	How frequently should eGFR, ACR or PCR be monitored in people with CKD? In people with CKD, what constitutes a clinically significant decline in eGFR?	
Chronic obstructive pulmonary disease: Management of chronic obstructive pulmonary disease in adults in primary and secondary care (partial update). CG101 Published June 2010[82]	How often should the long term care of patients with stable COPD be reviewed in order to maximise patient outcomes? What are the most appropriate tests in a patient with suspected exacerbation of COPD? In patients with an exacerbation of COPD, what are the most appropriate tests to monitor recovery?	
Hepatitis B (chronic): Diagnosis and management of chronic hepatitis B in children, young people and adults CG 165 Published June 2013[88]	How frequently should monitoring tests be done to ascertain virological, serological, biochemical response and resolution of fibrosis (HBeAg and antibody, HBsAg and antibody, ALT and transient elastography) and resistance (HBV DNA increase or virological breakthrough) in people with chronic hepatitis b? When and how frequently should surveillance testing be offered to detect early hepatocellular carcinoma in people with chronic hepatitis B?	

NICE Guideline	Review question	Comments
Hypertension: Clinical management of primary hypertension in adults. CG 127 Published August 2007[83]	In adults with treated primary hypertension, what is the best method to measure blood pressure (home vs. ambulatory vs. office) for response to treatment?	
Management of stable angina. CG 126 Published July 2011[86]	None.	No review question or recommendations made on monitoring.
MI – secondary prevention: Secondary prevention in primary and secondary care for patients following a myocardial infarction CG172 Published November 2013[95]	None	No review question. Recommendations were based upon informal consensus of the GDG
Rheumatoid arthritis in adults: management CG79 Published February 2009[75]	In adults with a recent onset of rheumatoid arthritis, and in established disease, what are the most effective methods to monitor the ongoing activity of the disease in order to minimise the impact of the disease on symptoms, joint damage, function and quality of life?	Currently being updated. Due to publish August 2018.
The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care. CG137. Published January 2012[87]	What features of the care process in primary care/shared care lead to improved health outcomes for adults and children with epilepsy?	
Type 1 diabetes in adults: diagnosis and management NG 17. Published August 2015[101]	In adults with type 1 diabetes, what is the optimum timing and frequency to self-monitor blood glucose for effective diabetic control? In adults with type 1 diabetes, what is the optimum glucose target or profile for self-monitoring of blood glucose for effective diabetic control? In adults with type 1 diabetes, what are the benefits of technologies (bolus calculators and downloads) for self-monitoring of blood glucose?	
Type 2 diabetes in adults: management NG 28. Published December 2015[73]	Should self-monitoring be used to manage blood glucose levels in people with type 2 diabetes?	
Asthma. QS25, published February 2013 Based on BTS/SIGN (2014) British guideline on the management of asthma SIGN clinical guideline 141.	In adults (>12 years) with asthma, what is the best method for monitoring their condition? Monitoring treatment. What is the evidence for the value of PEF, Sa02 FEV1?	Note this is a quality standard. The NICE clinical guideline on Asthma - diagnosis and monitoring is in progress.

1 **Table 110: Clinical evidence summary: Anaemia management in people with chronic kidney disease**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Anaemia management in people with chronic kidney disease (update). NG8. Published June 2015. Recs 1.4.1 - 1.4.12 (2006 and 2015) - see Appendix D	Protocol not given for this review.	1 cohort study n = 16 Country – not stated (no evidence table for this study) No GRADE ratings – quality rating level 2. (Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal)	In patients with ACKD treated with ESAs, how frequently should iron status be checked? It is clear from the evidence that monitoring soon after intravenous iron is not helpful, and the GDG felt that a minimum time elapsed of 1 week would be appropriate. In patients with ACKD treated with ESAs, how frequently should haemoglobin levels be checked a) during Hb correction and b) during Hb maintenance? A comprehensive literature search did not identify any studies that were suitable to address the clinical or economic aspects of this section, therefore no evidence statements are given.

2 *Abbreviations: Anaemia of chronic kidney disease (ACKD), Erythropoiesis stimulating agent (ESA), Hb (Haemoglobin)*

3

1 **Table 111: Clinical evidence summary: Chronic heart failure**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Chronic heart failure: Management of chronic heart failure in adults in primary and secondary care. CG108. Published August 2010 Recs 1.4.1.1 - 1.4.1.5 (2003 and 2010)	Population: All hospitalised patients included irrespective of age gender of clinical condition Intervention / Comparisons: A programme of discharge planning entailing initial assessment, planning, implementation and monitoring in each study compared to usual care Outcomes: Quality of life [MLHFQ (Minnesota Living with Heart Failure questionnaire) and SF-36 scores (Short Form 36)], mortality and hospital readmission	4 studies, comprising of: 1 systematic review n=8 trials n=4837 patients (USA, Canada, Denmark) 1 RCT n=192 transitional care (Canada) 1 RCT n = 70 Multidisciplinary intervention (Ireland) 1 RCT n = 200 Multidisciplinary intervention (USA) No GRADE ratings, described as level I (Evidence obtained from systematic review of meta-analysis of randomised controlled trials) and IV (Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.)	How should the initial management plan be determined? In what circumstances should a previous diagnosis of heart failure be reassessed? Addressed by an expert discussion paper There have been few direct comparisons of the impact of different intensities and frequencies of monitoring of patients with chronic heart failure – although almost all published studies comparing closer, more frequent contact with a healthcare professional who has experience in managing heart failure with 'routine' care report an improvement in quality of life for patients, and a reduction in the need for urgent hospitalisation. (I) It is not clear which components of these programmes are responsible for the benefit. Authors of trials have commented that more frequent contact with health professionals in itself may have a beneficial clinical effect. Monitoring of patients with chronic heart failure is necessary for a variety of reasons, and the guideline development group agreed a pragmatic approach. (IV)

2

1 **Table 112: Clinical evidence summary: Chronic kidney disease**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Chronic kidney disease: early identification and management of chronic kidney disease in adults in primary and secondary care. CG182. Published July 2014. Recs 1.3.1 - 1.3.2 (2014)	Adults (aged 18 and over) with CKD Prognostic factor: eGFR measure, ACR measure, PCR measure Outcomes: • CKD progression: change in eGFR, • CKD progression: occurrence of end stage kidney disease (ESRD or ESKD as reported by the study) • All-cause mortality • Cardiovascular mortality • [1Classification of chronic kidney disease using GFR and ACR categories given in Appendix D]	Eleven retrospective cohort studies were identified (4 Canada, 2 UK, 2 USA, 1 Belgium, 1 Netherlands, 1 Spain) Meta-analysis was not carried out due to differences in reference groups for hazard ratios and covariates included in the multivariate analyses. Quality assessed by GRADE per outcome. Frequency of monitoring eGFR, ACR or PCR in people with CKD by change in serum creatinine and eGFR subgroups - majority of outcomes rated as high quality. Frequency of monitoring eGFR, ACR or PCR in people with CKD - majority of outcomes rated as moderate quality.	How frequently should eGFR, ACR or PCR be monitored in people with CKD? <u>Mortality</u> High quality evidence from one study showed an increased risk of mortality for people with a certain drop in eGFR at one year for all baseline eGFR categories compared to those whose eGFR remained stable. This was also true for a certain rise in eGFR for those with a baseline eGFR 45-89 ml/min/1.73 m^2. There was a two-fold increase in mortality with a drop in eGFR compared to those with a stable eGFR. Other studies showed an increasing risk of mortality with lower baseline eGFR and with higher baseline ACR. <u>Progression of CKD</u> Moderate to high quality evidence from one study403 showed a 4-5 times increased risk ESRD (by one-year change in kidney function) for people with a certain drop in eGFR at one year for all baseline eGFR categories compared to those whose eGFR remained stable. An uncertain drop in eGFR also conferred a 2-3 times increased risk of ESRD. Any rise in eGFR was protective against progression to ESRD at all baseline eGFR levels. Other studies showed an increasing risk of ESRD with lower baseline eGFR and with higher baseline ACR. One study provided moderate to low quality evidence that increasing proteinuria was associated with an increased risk of progression defined by either a sustained drop in eGFR by 15 or to 10ml/min/1.73 m2 or defined as a sustained 25% reduction in eGFR and CKD stage change. The same study found a 5 times increased risk of progression to RRT with CKD stage 4 compared to stage 3 and with ACR >30 compared to no proteinuria. There was an increased risk, over a period of 7.8 years, of ESRD in older people (aged 65-79 and over 80 years) with baseline eGFR 45-60 or >60 ml/min/1.73 m^2 compared to people aged 50-64 ml/min/1.73 m^2 in the

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			same eGFR categories. The opposite was true with lower baseline eGFR values.
Recs 1.3.3 to 1.3.6 (2008, updated 2014)	Adults (aged 18 and over) with CKD Prognostic review (prognostic factors): CKD and acute kidney injury Outcomes: Critical: • Incident CKD; • CKD progression: change in eGFR • CKD progression: occurrence of end stage kidney disease (ESRD or ESKD as reported by the study) Study design Prospective cohort Important: Hospitalisation	8 included studies. This includes large cohorts (n=8592 and n = 3732) as well as smaller studies of n=20 - 100. Includes subgroups: • those with macroalbuminuria or impaired kidney function • healthy men and women • men and women with comorbid conditions • healthy younger subjects (mean age 26 years) compared with healthy older people (mean age 68 years), • hypertensive older people (mean age 70 years) or • older people with heart failure (mean age 69 years). • GFR decline over time in older (> 66 years old) males and females stratified by GFR. The decline in GFR in diabetics was compared with non-diabetics. Quality - Level 2 and 3. Level 3: non-analytic studies (for example, case reports, case series).	In people with CKD, what constitutes a clinically significant decline in eGFR? <u>Kidney function decline in adults with kidney disease</u> For men with kidney disease or urinary tract disease, there was NS difference in the decline in creatinine clearance compared with healthy. (Level 3) In the PREVEND cohort study, the decline in GFR was significantly greater in people with macroalbuminuria compared with the general population (–7.2 versus –2.3 ml/min/1.73 m^2, p<0.01) Interestingly, the decline in GFR was significantly less in those with impaired kidney function compared with the general population (–0.2 versus –2.3 ml/min/1.73 m^2, p<0.01). This data suggests that macroalbuminuria is a better predictor of GFR decline than low baseline GFR. (Level 2+) <u>Kidney function decline in adults with hypertension</u> There was NS difference in the decline in creatinine clearance in men taking antihypertensive drugs compared with healthy men. Kidney function decreased more rapidly as mean arterial pressure (MAP) increased. (Level 3) Mean inulin clearance was significantly lower in older hypertensive people compared with young healthy people. Mean GFR was NS different between older healthy and older hypertensive people. (Level 3) <u>Kidney function decline in adults with diabetes</u> In adults >66 years of age (n=10,184), the rate of GFR decline was greater in people with diabetic CKD compared with people nondiabetic CKD. Few participants in this older cohort experienced a rapid progression of CKD (decline in GFR >15 ml/min/1.73 m^2/year): 14% of mild, 13% of moderate,

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
		Level 2+: Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal. Canada, Germany, Netherlands (2) and USA (4).	and 9% of severe CKD subjects. (Level 3) <u>GFR in adults with heart failure</u> Mean GFR (inulin clearance) was significantly lower in older people with heart failure (92 ml/min/1.73 m^2, n=14, mean age 69 years) compared with young healthy people (121 ml/min/1.73 m^2 n=24, mean age 26 years, p <0.05). Mean GFR (inulin clearance) was significantly lower in older people with heart failure (92 ml/min/1.73 m^2, n=14, mean age 69 years) compared with older healthy (103 ml/min/1.73 m^2, n=29, mean age 68 years) or older hypertensive (103 ml/min/1.73 m^2, n=25, mean age 70 years) people (p<0.05). (Level 3)

1 *Abbreviations: Chronic Kidney disease (CKD), Estimated glomerular filtration rate (eGFR), albumin:creatinine ratio (ACR), protein:creatinine ratio (PCR)*

2 **Table 113: Clinical evidence summary: Chronic obstructive pulmonary disease**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
CG101 Management of chronic obstructive pulmonary disease in adults in primary and secondary care (partial update). Published June 2010 Recs 1.2.14.1 - 1.2.14.4 and 1.3.2.1 (2004)	No evidence.	No evidence. Grade D (based on GDG consensus)	Q84 How often should the long term care of patients with stable COPD be reviewed in order to maximise patient outcomes? Q96 What are the most appropriate tests in a patient with suspected exacerbation of COPD? Q100 In patients with an exacerbation of COPD, what are the most appropriate tests to monitor recovery? There are no data to guide decisions on how frequently patients should be reviewed but clearly this will vary according to individual circumstances and the severity of the patient's disease. Some patients with COPD deteriorate faster than others and it is important to identify these individuals as they need specialist input. Many of the recommendations in this section of the guideline are based on expert opinion rather than on the result of research studies, due to the

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			paucity of evidence and difficulty of conducting studies in this area.

1 *Abbreviations:* *Chronic obstructive pulmonary disease (COPD)*

2 **Table 114: Clinical evidence summary: Hepatitis B**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
CG 165 Hepatitis B (chronic): Diagnosis and management of chronic hepatitis B in children, young people and adults Published June 2013 Recs 1.2.14.1 - 1.2.14.4 and 1.3.2.1 (2004)	Population: Children, young people and adults with chronic hepatitis B virus infection (CHB). Predictive factors: HBV DNA levels at different points in treatment • HBeAg loss, seroconversion at different points in treatment • ALT normalization at different points in treatment • HBsAg seroconversion at different points in treatment • Incidence of resistance (HBV DNA increase or virological breakthrough) Outcomes: • virological response (undetectable HBV DNA,	33 included studies (majority prospective cohorts). Four studies included multivariable analyses. Study sizes range from n = 29 to n = 461. Countries include: Canada, China, India, Japan, Netherlands, Taiwan, South Korea and Switzerland. Overall the evidence was highly consistent which overcame some of the limitations of individual studies. Quality reported as “generally low” One large study based on an RCT carried out serial measurements to identify patterns, but the analysis was unadjusted for confounders and	How frequently should monitoring tests be done to ascertain virological, serological, biochemical response and resolution of fibrosis (HBeAg and antibody, HBsAg and antibody, ALT and transient elastography) and resistance (HBV DNA increase or virological breakthrough) in people with chronic hepatitis b? For people in the immune tolerant phase of hepatitis B (detectable HBV DNA levels and normal ALT), there were two studies examining monitoring to predict future reactivation. One showed in multivariable analysis that ALT levels above 5 x ULN during that phase was predictive of future reactivation but gave no indication of frequency of monitoring (low quality evidence). Multivariable analysis in the other small study found no significant predictors for the time to future ALT elevation, but showed an increase in absolute ALT levels of about 8% at 3 months follow up (low quality evidence). In people who are inactive carriers (HBeAg negative and normal ALT), two studies investigated monitoring ALT levels to predict future ALT flares or elevation. One study suggested a minimum period of monitoring of 3 months would identify about 90% of people with flares, but the evidence did not take into account censored patients (very low quality). Another small study suggested in univariate analyses that HBV DNA levels above 10,000 copies/ml at 12 months could predict future ALT elevation; this threshold was not significant at 6 months (low quality). Other higher DNA thresholds predicted ALT elevations at earlier monitoring times, but at the expense of missing some people at risk (low quality evidence).

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
	viral breakthrough) • serological response (HBeAg loss/seroconversion, HBsAg loss/seroconversion) • biochemical response (ALT normalization, ALT flare) • resolution of fibrosis (histological improvement) • side effects • resistance	the comparative analysis had to be considered to be low quality.	Eight studies examined monitoring in people with CHB who were receiving pegylated (or non-pegylated) interferon alfa (2a or 2b) treatment. There was variability across studies in the measures of response reported, in the interventions, in the predictors and thresholds used, and in the times of monitoring. • Four studies reported multivariable analyses: one small study indicating that a 12 week decline in HBsAg was a predictor of sustained response, but this measure was not significant at 8 weeks (peg); another study (non-peg) that a change in DNA level was not a significant predictor of response at 8 weeks but a change in HBeAg at 8 weeks was significant; and another small study (non-peg) showed that a HBV DNA level of more than 5 log10 copies/ml at 12 weeks was an independent predictor of relapse, (all low quality evidence). The final small study (peg) reported a significant effect for HBV DNA decline at 4, 8 and 12 weeks and for HBsAg decline at 12 weeks, but no odds ratios or even p-values were given (very low quality evidence). • Unadjusted analyses comparing predictions for values above versus below the thresholds allowed examination of trends: the body of evidence was consistent and suggested that monitoring after 8 weeks was the shortest time at which a significant predictive effect was found. Predictors included: a decrease of at least 90% in HBeAg levels at 8 and 12 weeks (non-peg); HBeAg levels of less than 10 IU/ml at 24 weeks (peg); HBV DNA levels of less than 5 log10 copies/ml at 24 weeks (peg); a decline and HBsAg levels above 0.5 log IU/ml (peg) (all low quality evidence). • One large study identified patterns of response to peg interferon treatment and determined (in unadjusted analysis) that an early (0-4 weeks) decline of more than 1 log copies/ml or a delayed (4-32 weeks) decline of 2 log copies/ml HBV DNA predicted HBeAg loss at 24 weeks follow up post treatment (low quality).

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			Nine studies examined monitoring in people with CHB who were receiving lamivudine treatment. There was variability across studies in the measures of response reported, in the predictors and thresholds used, and in the times of monitoring. • For response to treatment (HBeAg seroconversion and HBV DNA undetectable), one large retrospective study identified three HBeAg patterns based on monitoring at 2-monthly intervals and used multivariable analysis to examine the usefulness of these patterns in predicting response. A pattern of continuously decreasing HBeAg to more than 90% of pretreatment values was a strong independent predictor of response, in comparison with the group having a continuous decrease to 90% levels followed by a progressive increase or the group with no change/fluctuation in HBeAg levels (moderate quality evidence). • In unadjusted analyses, comparing predictions for values above versus below various thresholds allowed examination of trends on response: the body of evidence was consistent and suggested that monitoring after 6 months was the shortest time at which a significant predictive effect was found. Predictors included: undetectable HBV DNA (< 2.83 x 10^5 copies/ml) at 6 months (low quality); HBsAg > 3 log IU/ml at 6 months (very low quality) • For viral breakthrough, unadjusted analyses compared predictions for values above versus below various thresholds allowed examination of trends on breakthrough: the body of evidence was consistent and all studies investigated monitoring after 6 months. Predictors included: decline of HBsAg < 0.7 log IU/ml at 6 months, (very low quality); persistently detectable HBV DNA > 2.83 x 10^5 copies/ml at 6 months (low quality) but detectable HBV DNA > 6 IU/ml at 6 months was not a significant predictor (very low quality). • For viral breakthrough, one large retrospective study identified three HBeAg patterns based on monitoring at 2-monthly intervals and used multivariable analysis to examine the usefulness of these patterns in predicting virological breakthrough. A pattern of a continuous decrease to 90% levels followed by a progressive increase was a strong

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			independent predictor, as was a pattern of no change or fluctuation in HBeAg levels, both in comparison with a pattern of continuously decreasing HBeAg levels to more than 90% of pretreatment values (moderate quality evidence). In people having virological breakthrough in the breakthrough group, the change in HBeAg levels started to occur around 32 weeks of therapy. • For resistance(YMDD mutation on sequencing), one small study used multivariable analysis to show that detectable HBV DNA (> 10^5 copies/ml) at 6 months of treatment was an independent predictor (low quality). One small, retrospective study examined monitoring HBV DNA levels in people receiving adefovir. Univariate analysis suggested that a decrease of 1 log copies/ml at 12 and 24 weeks, but not at 4 weeks, was a significant predictor of virological response (very low quality evidence). Two prospective studies investigated monitoring in people receiving entecavir treatment, but only one gave comparative results: • One small study conducted multivariable analyses and showed that, in patients who were HBeAg positive, significant predictors of virological response at the end of 12 months were: undetectable HBV DNA below 50 copies/ml at 3 months, but not 6 months (p-value only) and HBsAg levels below 3000 IU/ml at 3 months. At 24 months treatment, the only significant independent predictor was HBsAg level below 3000 IU/ml at 3 months; undetectable HBV DNA was not a significant predictor. In patients who were HBeAg negative, HBV DNA was a significant predictor at 6 months but not 12 months (low quality) for virological response at 12 months (low quality evidence) and there were no significant predictors for the outcome at 24 months. • For the outcome, serological response at 12 months, undetectable DNA levels below 2000 copies/ml were significant at 3 months, but not at 6 months, and so were HBsAg levels below 3000 at 3 months. For the outcome at 24 months, HBV DNA levels and HBsAg levels were not independent predictors at any time during treatment (very low quality evidence).

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			Three studies investigated people off-treatment, investigating monitoring to predict virological relapse at 6 and 12 months following discontinuation of lamivudine treatment in people who had achieved seroconversion /loss: one small study conducted a multivariable analysis and showed that 'higher' HBV DNA levels at the time of discontinuing treatment and the time to seroconversion/loss were significant independent predictors of virological relapse at 6 and 12 months post treatment (low quality). A univariate analysis in a small retrospective study suggested that HBV DNA level above 4.7 x 10_3 copies/ml at the time of seroconversion was a significant predictor of relapse (very low quality). One very small, retrospective study in children showed in unadjusted analysis that detectable levels of HBV DNA at 16-24 weeks was a significant predictor of response to interferon alfa treatment , but measurements at 4-15 weeks were not significant (very low quality evidence)
	Population: Children, young people and adults with CHB infection (particularly those with cirrhosis) Intervention/comparison: Ultrasound and/or serum alpha feto-protein assay at: - 12 monthly - 6 monthly - 3 monthly Outcomes: • Lesion or hepatocellular carcinoma ≤1, 2 and 3cm in diameter • Survival rate • All-cause mortality	4 studies (two are abstracts), of which 2 are randomised studies and 2 are retrospective cohort studies. n = 3071 Country: Belgium, France, Italy, Korea, Taiwan GRADE - Very low quality	When and how frequently should surveillance testing be offered to detect early hepatocellular carcinoma in people with chronic hepatitis B? 6 monthly versus 12 monthly intervals of HCC surveillance One observational study of 400 patients (72% hepatitis B; unclear cirrhotic status) suggested that 6 monthly intervals of HCC surveillance (ultrasound and alpha-fetoprotein) maybe beneficial for identifying a greater proportion of patients with solitary HCC ≤3cm compared to 12 monthly intervals of HCC surveillance (VERY LOW QUALITY). One observational study of 634 patients (9.1% hepatitis B; 42% patients with cirrhosis) showed that 6 monthly intervals of HCC surveillance (ultrasound +/- alpha-fetoprotein) is beneficial for identifying a greater proportion of patients with solitary HCC ≤3cm compared to 12 monthly intervals of HCC surveillance (VERY LOW QUALITY). 3 monthly versus 6 monthly intervals of HCC surveillance One randomised study of 1278 patients with compensated cirrhosis (12.5% hepatitis B) suggested that 3 monthly intervals of HCC surveillance (ultrasound +/- alpha-fetoprotein) may be neither beneficial nor harmful

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
	• Liver cancer staging • Hepatocellular carcinoma • Morbidity (end stage liver failure)		on the following outcomes, compared to 6 monthly intervals of HCC surveillance at a median follow up of 47 months: • Proportion of patients with hepatocellular carcinoma (VERY LOW QUALITY) • Mortality (VERY LOW QUALITY) • Mortality from liver failure (VERY LOW QUALITY) • Mortality from HCC (VERY LOW QUALITY) 4 monthly versus 12 monthly intervals of HCC surveillance One cluster randomised study of 744 patients (mixed population of hepatitis B and C, proportions unclear; unclear cirrhotic status) suggested that 4 monthly intervals of HCC surveillance (ultrasound and alpha-fetoprotein) may be neither beneficial nor harmful in reducing the proportion of patients with hepatocellular carcinoma, compared to 12 monthly intervals of HCC surveillance at 4 years of follow up (VERY LOW QUALITY).

Abbreviations: *Hepatocellular carcinoma (HBeAg), Hepatitis B surface antigen (HBsAg), Hepatitis B virus (HBV), Hepatocellular carcinoma (HCC)*

1 **Table 115: Clinical evidence summary: Hypertension**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Hypertension: Clinical management of primary hypertension in adults CG 124. August 2007 Recs 1.5.4 - 1.5.8 and 1.7.3	Population: Intervention / Comparisons: Blood pressure (BP) measurement method for monitoring treatment in order to reach target BPs (home monitoring vs. office or usual care Outcomes: Blood pressure and reaching blood pressure targets	Two systematic reviews/meta-analysis (n=6038 and n = 6322) and 3 RCTs All studies were of moderate to good quality. NOTE: all RCTs were underpowered to detect a difference in BP. In order to detect a 5mm difference, a sample size of N≥500 is needed. Countries not stated for systematic reviews/meta-analysis. RCTs are in Canada, Belgium, Finland and Switzerland.	In adults with treated primary hypertension, what is the best method to measure blood pressure (home vs. ambulatory vs. office) for response to treatment? One well-conducted meta-analysis found that: • Self-monitoring was significantly better than usual care for reducing clinic SBP and DBP [very low and low quality evidence] and the proportion of patients achieving target clinic blood pressure [very low quality evidence] • There was NS difference between self-monitoring and usual care for reduction in mean daytime SBP and DBP ABPM. [low quality evidence] • When self-monitoring was accompanied by an additional co-intervention, participants were more likely to meet target blood pressure compared to when there was none. One meta-analysis found that: • with anti-hypertensive treatment (regardless of drug class used for treatment) clinic SBP and DBP fell significantly more than home blood pressure [very low quality evidence] – home blood pressure fell approximately 20% less than clinic blood pressure – changes in clinic blood pressure were linearly related to those of home blood pressure – the difference between clinic blood pressure and home blood pressure was attributable to the difference in baseline blood pressure levels • home blood pressure fell significantly more than daytime ambulatory SBP and night-time ambulatory SBP and DBP [low quality evidence] – daytime ambulatory SBP fell 15% less and night-time ambulatory SBP fell 30% less than home blood pressure • the reduction in daytime ambulatory DBP was NS different than the

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			reduction in home blood pressure [low quality evidence] • changes in home SBP were intermediate between clinic and ambulatory SBPs (for 24h, daytime and night-time measurements) One RCT found that there was NS difference between treatment targeted to home DBP vs. targeted to ABPM DBP for home, 24h ABPM SBP and clinic SBP and DBP blood pressure measurements (end of trial) [very low quality evidence] One RCT found that: • treatment managed with ABPM measurements was significantly better than treatment managed with CBPM for: ○ reductions in mean 24h ABPM SBP [very low quality evidence] ○ number of patients with controlled 24-hour blood pressure [very low quality evidence] • there was NS difference between treatment managed with CBPM measurements versus measured with ABPM for: ○ reductions in mean clinic SBP and DBP [low and very low quality evidence] ○ reductions in mean 24h ABPM DBP [low quality evidence] ○ number of patients with controlled clinic blood pressure measurements [very low quality evidence] ○ number of antihypertensive drugs used [very low quality evidence] One RCT found that: • treatment managed with home blood pressure was significantly better than treatment managed with clinic blood pressure measurements for: ○ number of patients who could permanently stop a-HT treatment [moderate quality evidence] • treatment managed with clinic blood pressure was significantly better than treatment managed with home blood pressure measurements for : ○ reduction in clinic SBP and DBP blood pressure [low quality evidence] ○ reduction in home SBP and DBP blood pressure [low and moderate

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			quality evidence] ○ reduction in 24h

Abbreviations: Diastolic blood pressure (DBP), systolic blood pressure (SBP), Ambulatory blood pressure measurement (ABPM), Clinic blood pressure measurement (CBPM), Hypertensive / hypertension (HT)

Table 116: Clinical evidence summary: Rheumatoid arthritis

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Rheumatoid arthritis in adults: management. CG 79 February 2009 Recs 1.5.1.1 - 1.5.1.4	Population: People with recent onset or established RA Outcomes: symptoms, joint damage, function and quality of life	Recent-onset RA: Two RCTs (n = 111 and 299) and one case-series (n = 110) were found. Established RA: One cluster RCT (n = 205), 1 pooled analysis of 3 RCTs (n = 1839), and 4 case-series' (n = 71 - 233)were found Study quality ranged from 1++ to level 3. Countries: UK, South Africa, The Netherlands and 1 multinational study.	In adults with a recent onset of rheumatoid arthritis, and in established disease, what are the most effective methods to monitor the ongoing activity of the disease in order to minimise the impact of the disease on symptoms, joint damage, function and quality of life? In recent-onset RA time-integrated CRP predicts radiological progression and mean CRP correlates with articular index In two studies of recent-onset RA, intensive treatment strategies with the aim of keeping the Disease Activity Score to low levels of activity resulted in substantially better outcomes when compared with usual care for most measures of disease activity, remission, function and radiological progression. A similar approach in established disease also resulted in improved disease control. In established disease, studies show high correlations between indices of disease activity. In established disease changes in disease activity correlate with changes in function and indices that amalgamate several measures of disease activity show greater validity than out-perform single measures of disease activity. In established disease that disease activity index performs better than the Riel Index and Mallya index for correlations with clinical status and joint damage, and the ability to differentiate between low and high disease activity

Abbreviations: *Rheumatoid arthritis (RA)*

Table 117: Clinical evidence summary: Secondary prevention of myocardial Infarction

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Secondary prevention of myocardial infarction. CG48 2013 Recs 1.3.2 (2013) Rec 1.3.9 (2007)	Population: People who have had an MI No specific review protocol.	No evidence identified.	No specific review question included. These recommendations were based upon informal consensus of the GDG, whilst discussing the evidence presented in the drug therapy chapter. Linking evidence to recommendation sections states: The GDG discussed the importance and relevance of various outcomes in assessing treatments in the context of secondary prevention of MI. For heart disease, mortality is clearly of greatest concern. The GDG focussed on total mortality, but also considered sudden death and cardiac mortality. However, quality of life was considered of critical importance as well, given that many people receive treatment to prevent relatively few deaths. Other events of concern in people after an MI, of lesser importance to mortality, but clearly important outcomes for the patient and society, were stroke, reinfarction and revascularisation. Rehospitalisation was considered a relevant outcome by the GDG. It was clearly undesirable and in addition had significant economic impact. The adverse effects of treatment (including renal dysfunction, hypotension and dizziness/fainting), which impact on quality of life (which was not always measured) were also considered relevant. The GDG considered that it was important for people who have had an MI to undergo assessment of their left ventricular function. It was agreed that this was important for those on drug therapy following an MI, given that the effectiveness of treatment with ACE inhibitors, ARBs and beta-blockers was dependent upon left ventricular function. It was noted that the outcome of assessment could impact upon the type, titration and duration of therapy given to a person who has had an MI.

Abbreviations: *Myocardial Infarction (MI), angiotensin converting enzyme (ACE), Angiotensin receptor blockers (ARB)*

1 **Table 118: Clinical evidence summary: Epilepsy**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
CG137 The Epilepsies: The diagnosis and management of the epilepsies in adults and children in primary and secondary care Published January 2012 Recs 1.20.1 - 1.20.4 (2004)	Populations: Adults and children with epilepsy Intervention and comparison: N/A audit data and surveys included. Outcomes: Mortality, seizures (or seizure-free)	Audit of GP case notes n = 285 Two survey of survey of users' views on epilepsy services n = 2394 and n = 135. Both UK No GRADE ratings. Described as "lack of good evidence" and goes on to describe "some" and "limited evidence"	What features of the care process in primary care/shared care lead to improved health outcomes for adults and children with epilepsy? There is a lack of good quality evidence of effectiveness for structured annual review in primary care. A high proportion of adults who died of epilepsy in the National Sentinel Clinical Audit of Epilepsy related Death had not had a structured review. Audits in primary care can improve the process of care for people with epilepsy. (IV) [Audit]After a first seizure most individuals (84%) were referred to secondary care. There was a low level of clinical information recording in relation to all those who died. Documented evidence of individual, written care plans was lacking. In the year prior to death, there had been no recorded review of 67% of people receiving all their care in general practice. 78% of those who were receiving combined care had been reviewed by either the specialist or the GP. Around 29% of individuals had been seen by their GP for non-epilepsy related problems in the month before death. Four individuals receiving only primary care had a change in seizure frequency, but were not referred. Of those receiving combined primary/secondary care, 68 individuals were considered to fulfil the criteria for reassessment, but only 6 (9%) were re-referred. [Postal survey]The CSAG postal survey of users' views on epilepsy services was conducted across the UK and involved people recruited from both general practice (community sample) and secondary care (hospital sample). A response rate of 52% (2394/4620) was achieved. Overall 91% were satisfied or fairly satisfied with GP care. There were no major differences between adults and children, between community-based and hospital-based samples, or between those who suffer from new-onset continuing epilepsy and those who have controlled epilepsy. Many people did not consult their GP regularly about their epilepsy and did not expect their GP to have a detailed knowledge of epilepsy. In the 12 months before the survey, 58% of the community sample had not visited a GP to consult about their epilepsy. The majority of adults in the community sample, most

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			of whom had controlled epilepsy and were not attending hospital, considered their GP to be the main provider of care (70%) and expressed a preference for GP care (61%). The majority of adults in the hospital sample regarded their hospital doctor as the main provider of care (55%). Only 17% of the overall sample considered their care to be shared between the GP and hospital doctor.
Recs 1.20.6 - 1.20.9 (2004)	Populations: Adults and children with epilepsy Intervention and comparison: N/A audit data and surveys included. Outcomes: Mortality, seizures (or seizure-free)	Audit n = 180 (includes 22 children). UK Postal survey of survey of users' views on epilepsy services n = 2394	There is a lack of good quality evidence of effectiveness of dedicated epilepsy clinics in secondary and tertiary care. (Ia) [Audit] Clinical review of these deaths suggested that 60% of epilepsy-related deaths were SUDEP and a further 7% were possible SUDEP [Sudden Unexpected Death in Epilepsy]. However, these numbers were estimates because of concerns about information available to the audit on the circumstances of death, the events leading up to the death and the adequacy of post-mortem investigations. Only 3% of people who died were recorded as seizure-free at their last hospital appointment. Although most adults (93%) were not recorded as seizure-free for at least a year before death, at least 37% of these people were not seen in the year before they died. The reasons for this were unclear in 50% of cases. Three individuals with learning disabilities had been 'lost' in the handover from paediatric to adult care. Around 15% of adults missed at least one appointment. [postal survey] There was little difference in overall experience between adults and children, or between those who had new-onset continuing epilepsy and those who had controlled epilepsy. In the community-based sample, only 30% of all people had attended as an outpatient at a hospital in the preceding 12 months. For those attending hospital clinics, the levels of satisfaction were reasonably high: 87% found communication with their hospital doctors satisfactory or fairly satisfactory (85% adults and 93% children), and 80% felt that their hospital doctors took their views into account. However, 73% of respondents attending the

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			hospital clinics reported seeing the same doctor repeatedly. Most individuals (90% of the community-based sample and all of the hospital based sample) had been referred to a hospital doctor at the onset of symptoms. Approximately a third were waiting for six weeks or more before being seen. Individuals with established epilepsy had far longer waiting times for re-referral and longer intervals between follow-up appointments.

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1 **Table 119: Clinical evidence summary: Type 1 diabetes**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Type 1 diabetes CG 15 - updated August 2015 Recs 1.2.5 (2004, amended 2015)	Populations: Adults with type 1 diabetes Intervention and comparison: Self-monitoring of blood glucose (SMBG - finger pricks) – blood glucose target/profile values/glucose variability. Other target values (RCTs and comparative observational studies). No targets (prognostic studies Outcomes: HbA1c value Quality of life, risk of complications, risk of hypoglycaemia, risk of nocturnal hypoglycaemia, risk of severe hypoglycaemia	Study design - No RCTs. 1 descriptive review and 1 guideline. No evidence tables provided. Quality rating of IV: evidence from expert committee reports or opinions and/or clinical experience of respected authorities.	No specific review question. <u>Annual review</u> No RCTs address the concept of integrated annual review. Newly-implemented structured annual review has been subject to a descriptive review, suggesting improved satisfaction with care and improved patient motivation. Few full-length descriptions of the review process are available, most references being editorials and letters (IV). The current guideline suggests annual surveillance of a number of potentially developing late complications (as do all other guidelines for the most complications). The International Diabetes Federation's European guideline recommends integration of these activities into one patient visit. Annual review also is the basis of many quality control structures proposed for diabetes care, including (implicitly) that of the UK Audit Commission (IV).
Recs 1.6.10 - 1.6.19 (2015)	Population: Adults with type 1 diabetes Intervention: SMBG - (finger pricks) Comparison: SMBG (finger pricks) – the same as the intervention but at a different frequency or delivery time Outcomes: Adherence, adverse events, diabetic	a) 35 relevant studies on frequency. These included 2 RCTs, 31 observational studies, and 2 post-hoc analysis of RCTs. 4 relevant studies on timing. These included 3 observational studies and one post-hoc analysis of an RCT. b) 7 relevant studies all of which were observational	a) In adults with type 1 diabetes, what is the optimum timing and frequency to self-monitor blood glucose for effective diabetic control? b) In adults with type 1 diabetes, what is the optimum glucose target or profile for self-monitoring of blood glucose for effective diabetic control? **<u>Frequency of self-monitoring of blood glucose</u>** Low quality evidence from 35 studies (two RCTs, two cross-over studies, and 31 observational studies) showed the following: •Evidence mostly from large studies showed that self-monitoring of blood

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
	ketoacidosis (DKA), HbA1c, hypoglycaemia, nocturnal hypoglycaemia, quality of life, severe hypoglycaemia, time within range (blood glucose), unscheduled care use	GRADE rating: low quality	glucose was associated with lower HbA1c levels (glycated haemoglobin) than those who do not self-monitor blood glucose. •Evidence mostly from large studies showed that more frequent self-monitoring of blood glucose levels up to 3 or 4 times a day is associated with lower HbA1c levels and with fewer complications such as hypoglycaemia, DKA, retinopathy, low-level (micro) albuminuria, physical complaints, psychological distress, leisure restrictions, conscious experience and management of hypoglycaemia, diet, and difficulties at work. Evidence from large studies also showed it was associated with lower mortality rates. •Evidence mostly from large studies showed that self-monitoring of blood glucose at least 4 times a day and up to ten times a day is associated with lower HbA1c levels. •Evidence mostly from small studies showed generally that increased frequency of self-monitoring of blood glucose is not associated with lower HbA1c levels, incidence of severe hypoglycaemia or other adverse events. **Timing of measuring blood glucose** Low quality evidence from 4 observational studies showed the following: •In terms of HbA1c, evidence from large studies showed that the strongest correlation with HbA1c is the mean blood glucose reading taken after breakfast, before and after lunch and before and after dinner. And the best predictor of HbA1c level is blood glucose measured before and after breakfast, and before dinner. However, evidence from a single small showed that HbA1c did not correlate with post-prandial levels •In terms of taking measurements at variable times of day, evidence from a single small study showed that measuring blood glucose four times a day was no better than at a variable time. **Optimal target of blood glucose** Low quality evidence from 7 observational studies showed the following: • terms of HbA1c, evidence from two large studies showed that higher blood glucose readings are associated with higher HbA1c values, and every

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
			1% rise in HbA1c results in an increase in night-time as well as pre-and post-prandial blood glucose levels. At an HbA1c between 6.5 and 6.99, mean blood glucose values were 144 mg/dl (fasting), 140 mg/dl (preprandial), 161 mg/dl (postprandial) and 154 mg/dl (bedtime). At an HbA1c between 5.5 and 6.49, mean blood glucose values were: 122 mg/dl (fasting), 119 mg/dl (preprandial), 139 mg/dl (postprandial) and 140 mg/dl (bedtime). Evidence from a small study showed that intensively measured blood glucose levels at home achieved 'excellent' glycaemic control with preprandial blood glucose values mostly under 200 mg/dl and complete absence of glycosuria. • In terms of hypoglycaemia, evidence from a small study showed that fewer hypoglycaemic events were associated with blood glucose readings of less than 2.75 mmol/litre. However, evidence from a large study showed that more severe hypoglycaemic events were associated with blood glucose readings of less than 3.3 mmol/litre, and hypoglycaemia symptoms were first felt by most people at more than or equal to 2.8 mmol/litre. Evidence from a small study also showed that fasting blood glucose of more than or equal to 5.5 mmol/litre is never preceded by early morning hypoglycaemia. However, less than 5.5 mmol/litre are associated with early morning hypoglycaemia in 6/12 patient-nights. •In terms of retinopathy, evidence from a large study showed an increased risk of retinopathy with blood glucose readings of more than 8.3mmol/litre.
Rec 1.6.22		No specific review question.	No specific question on education and review. Linked to review question: In adults with type 1 diabetes, what are the benefits of technologies (bolus calculators and downloads) for self-monitoring of blood glucose?

1 *Abbreviations:* *Self-monitoring of blood glucose (SMBG)*

2

1 **Table 120: Clinical evidence summary: Type 2 diabetes**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Type 1 diabetes NG 28 - updated December 2015 Recs 1.4.1 to 1.4.6 and 1.4.14 (2009)	Populations: Adults with type 2 diabetes Intervention and comparison: No specific review question or protocol on monitoring.	No evidence identified. Recommendations based on consensus.	No specific review question, but indirect evidence from: What are the serious adverse effects of long-term use of pharmacological interventions to control blood glucose in people with type 2 diabetes? No evidence identified regarding frequency of monitoring.
Recs 1.6.1,	Populations: Adults with type 2 diabetes Intervention and comparison: No specific review question or protocol on when to measure HbA1c	No evidence identified. Recommendations based on consensus.	No specific review question, but indirect evidence from : What are the optimal target values for HbA1c, fasting blood glucose and post prandial blood glucose in people with type 2 diabetes? No evidence identified regarding when to measure HbA1c.
1.6.12 to 1.6.16 and 1.6.36 to 1.6.37	Populations: Adults with type 2 diabetes Intervention and comparison: Self-monitoring of blood glucose using lancets No self-monitoring of blood glucose, standard or usual care, self-monitoring of urine glucose, other types of self-monitoring of blood glucose Outcomes: Changes in blood glucose levels (HbA1c, fasting and postprandial blood glucose)	19 unique trials were included Countries: UK, Netherlands, Germany, Italy, USA, Korea, Malaysia, plus multinational studies. Very low to moderate quality.	Should self-monitoring be used to manage blood glucose levels in people with type 2 diabetes? SMBG versus no SMBG A total of 4710 people (study size ranged from 23 to 1024) were included from 17 RCTs, carried out in the UK. The mean age ranged from 48.9 to 67.5 years. The mean duration of diabetes in 15 studies ranged from 2.7 to 15.4 years. Mean HbA1c at baseline ranged from 56 to 108 mmol/mol (7.3% to 12.0%). Mean BMI ranged from 25 to 34.2 kg/m2, with 7 studies not reporting this information. People taking insulin were included in 5 studies, 1 study included people managed on diet alone, while the participants in the remaining trials were managed on diet and/or oral antidiabetic medicines. Follow-up periods ranged from 24 to 208 weeks. Frequency of SMBG testing

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
	Hypoglycaemic events Development of microvascular and macrovascular complications		A total of 475 people (study sizes 202 and 273) were included from 2 RCTs. The mean ages were 61 and 64 years. The mean duration of diabetes was 8 and 10.6 years. Mean HbA1c levels at baseline were 55 mmol/mol (7.2%) and 64 mmol/mol (8.0%). Mean BMI was reported in 1 study as 29 kg/m2. Both studies included people managed on diet and/or oral antidiabetic medicines. Follow-up periods were 26 and 52 weeks.
1.7.13, 1.7.17 and 1.7.22	Populations: Adults with type 2 diabetes Intervention and comparison: No specific review question or protocol on monitoring.	No evidence identified. Recommendations based on consensus.	No specific review question on annual review of erectile dysfunction or eye screening. No evidence identified.

1 *Abbreviations: Self-monitoring of blood glucose (SMBG)*

2 **Table 121: Clinical evidence summary: Asthma**

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
Asthma QS25, published February 2013 Quality standards 5, 6, 7 and 10 - see Appendix Q	Protocol not given for this review Outcomes stated as: • symptom scores • lung function tests • exhaled nitric oxide • sputum eosinophilia • endobronchial biopsy.	32 studies across 9 different tools (Spirometry, Peak expiratory flow (PEF), Royal College of Physicians (RCP) 3 Questions, Asthma Control Questionnaire (ACQ), Asthma Control Test (ACT), Mini Asthma Quality of Life Questionnaire (AQLQ), Airway responsiveness, Exhaled nitric oxide (FE_{NO}), Eosinophil differential count in induced sputum). Country – not stated (no	In adults (>12 years) with asthma, what is the best method for monitoring their condition? Monitoring treatment. What is the evidence for the value of PEF, Sa02 FEV1? Symptomatic asthma control is best assessed using directive questions such as the Royal College of Physicians 3 questions, or the Asthma Control Questionnaire or Asthma Control Test, since broad non-specific questions may underestimate symptoms. Reduced lung function compared to previously recorded values may indicate current bronchoconstriction or a long term decline in lung function and should prompt detailed assessment.

Link to recommendation	Population / Intervention / Comparisons / Outcomes	Studies, setting and quality	Review question and evidence statement (as reported in the published guidance)
		evidence table for this study) No GRADE or quality ratings	

1

9.4 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

9.5 Evidence statements

Clinical

- Anaemia of chronic kidney disease (2006 and updated in 2015) – Recommendations made based on two review questions, one based on a small cohort study and the second with no evidence identified. Quality rating described as level 2 (low risk of bias).
- Chronic heart failure - Recommendations (2003 and updated in 2010) made based on evidence from 1 systematic review of meta-analysis of 3 RCTs and an expert discussion paper. No GRADE ratings given.
- Chronic kidney disease - Recommendations (2014) based on low to high quality evidence (11 retrospective cohort studies). Further recommendations were made in 2008 and updated in 2014, based on 8 studies described as well-conducted.
- Chronic obstructive pulmonary disease - Recommendations (2004) made based on GDG consensus as no evidence was identified.
- Hepatitis B - Two review questions were asked and recommendations (2013) made for both. The first question on monitoring was based on 33 included studies, which are mainly prospective observational studies, described as of "generally low" quality. The second question on surveillance identified 4 studies, including 2 abstracts, and were assessed as very low quality.
- Hypertension - Very low to moderate quality evidence (2 systematic reviews and 3 RCTs) used to make recommendations (2007).
- Secondary prevention of MI - No evidence identified and no separate review question. Recommendations made based upon informal consensus of the GDG during discussion of the drug therapy evidence (2007, updated in 2013).
- Epilepsy - Recommendations (2003) made based on audit data and 2 surveys of users views. No GRADE ratings, described as a "lack of good quality evidence" and "some" and "limited evidence".
- Rheumatoid arthritis - RCT evidence and case series from recent onset and established rheumatoid arthritis, with quality ratings from 1++ to level 3, were used to inform recommendations.
- Stable angina - No review question or recommendations were made on monitoring.
- Type 1 diabetes - No specific recommendations on annual review, but recommendations (2004, amended 2015) made based on 1 descriptive review and 1 guideline (no evidence tables provided), quality described as from expert committee reports or opinions and/or clinical experience of respected authorities. Frequency of self-monitoring of blood glucose. Recommendations made on frequency based on low quality evidence from 35 studies (two RCTs, two cross-over studies, and 31 observational studies).
- Type 2 diabetes - No specific review question on frequency of monitoring or when to measure HbA1c, but recommendations (2009 and 2015) made on consensus and indirect evidence from other review questions. Recommendations were made on self-monitoring to manage blood glucose levels in people with type 2 diabetes based on 19 RCTs of very low to moderate quality

evidence. No specific review questions on annual review of erectile dysfunction or eye screening, but recommendations were made based on consensus.

- Asthma quality standard (2013) - Recommendations based on two review questions in the BTS/SIGN guideline on the management of asthma. Further details not given.

Economic

- No relevant economic evaluations were identified.

9.6 Recommendations and link to evidence

Recommendations	**Monitoring chronic conditions** **59. Monitor people with chronic conditions in accordance with the following NICE guidelines (see appendix Q in the supporting evidence for this guideline for specific recommendations):** • **chronic heart failure** • **chronic kidney disease** • **chronic obstructive pulmonary disease** • **epilepsies** • **hypertension** • **myocardial infarction** • **type 1 diabetes and type 2 diabetes** **See also the NICE quality standard on asthma.** **60. Monitor people with chronic conditions that need specialist management in line with relevant NICE guidelines[f] (for example on hepatitis B).** **61. Consider more frequent monitoring for older people and people with chronic conditions (such as diabetes) who are serving longer prison sentences.**
Relative values of different outcomes	This review identified how chronic conditions should be monitored and was a review of existing NICE guidance. Prioritised outcomes included adoption of health-promoting behaviours, uptake of screening programmes, morbidity, mortality and health-related quality of life. When evidence from existing NICE guidelines was summarised for the GDG, evidence statements were reported as originally written with no changes to text. Therefore all outcomes were reported as per original guidelines for any questions relating to monitoring. Any prioritisation of outcomes was as per existing NICE guidelines. The GDG considered the appropriateness and applicability of the review question, evidence statements and recommendations as a whole when deciding whether to cross-refer to or adapt existing recommendations, or to write new

[f] NICE guidance is expected to be taken into account. However, decisions should always be based on the person or population being worked with.

	recommendations.
Trade-off between clinical benefits and harms	This review identified existing reviews and associated recommendations on monitoring across a range of chronic conditions. The evidence underpinning the recommendations from existing NICE guidance was variable; however the group considered that as these evidence reviews had been conducted with expert opinion and experience from healthcare professionals in the relevant specialty the recommendations were appropriate. In addition the GDG agreed that there should be equivalence of care for people in prison compared to any other setting where adults access primary care services, as such recommendations made in existing guidelines were deemed applicable (with consideration for security and environmental factors within prisons). The benefit of recommending monitoring chronic conditions according to existing NICE guidance would be a general improvement in health status and a decrease in health deterioration and preventing emergency situations. The GDG discussed that there is variation in practice and concerns over mortality in prison from chronic conditions, as detailed in the Prisons and Probation Ombudsman report.[129] The GDG noted that prison environments differ, such as the category of prison and levels of security required, or the age of prison buildings, and this would affect how NICE guidance could be implemented in practice. The GDG discussed whether the same equipment or resources would be available in prison compared to other settings to carry our monitoring of chronic conditions, for example, blood pressure monitoring at home for hypertension; GDG consensus was that equipment is likely to be available, with the caveat that this may be subject to risk assessment on a case by case basis due to any security concerns.The GDG discussed the need for some of the guidance to be conducted in hospital via referral (for example, some recommendations for secondary care such as those for hepatitis B monitoring, unless there is a specialist hepatitis B GP clinic available). The GDG made a consensus recommendation based on their expert knowledge and opinion that older people (over 50 years) with chronic conditions serving longer sentances require more frequent monitoring. This is thought to be due to the impact of incarceration on health (linked to poor diet or lack of exercise), and that this may exacerbate chronic ill health and cause early onset of conditions associated with old age. Although no evidence was identified, the GDG considered the health benefit of monitoring older people with chronic conditions serving longer sentences to outweigh the negative impact of uncontrolled symptoms relating to their chronic conditions being undiagnosed, for example someone with diabetes related complications being identified early rather than late.
Trade-off between net clinical effects and costs	The GDG recognised that the cost-effectiveness of each of the recommendations in each of the existing NICE guidelines has been considered in the relevant NICE guidance, and so all of these recommendations have therefore already been considered to be cost-effective for a general population compared with NICE's threshold. Where NICE guidelines consider a general population with a certain condition it is recognised that some members of that population will require fewer resources and some more resources to treat: for example, people with more comorbidities may be more complex to treat; while hospitals serving a small, dispersed rural population may have greater costs per person to deliver the same treatment. However, due to its strong commitment to principles of equality, and obligations under the Equalities Act 2010, NICE makes decisions for the whole population group with a condition, unless there are clinical differences between subpopulations justifying different treatments.[105] A prisoner with a health condition is part of the broader population group with that condition, therefore if the cost-effectiveness of treating the group as a whole has been established in previous NICE recommendations, the GDG agrees that the prisoner should receive equivalent treatment, regardless of whether the cost to the NHS of treating the prisoner is higher or lower than the average cost to

	the NHS of treating an individual with the same condition. For the monitoring of the majority of chronic conditions, the GDG judges that costs of providing primary care in prisons is in fact similar to the cost of providing primary care in the community, as approximately the same number of appointments of approximately the same length will be required. The GDG recognises that in some prisons prison officers are required to escort prisons to the healthcare department, but this is related to security considerations within the prison, and differs between prisons. The NHS healthcare service within the prison cannot control and is not responsible for the cost of this security, but should work with the prison to consider the location and timing of services that would enable access by prisoners to be maximised and prison service resources to be minimised. It is possible that for a few conditions or individuals the monitoring of their condition could be more expensive in a prison setting (perhaps, for example, if very regular monitoring is required), but this is not sufficient reason for not providing that service to the prisoner, as it has been recommended for all people with the condition, as discussed above, in the same way that some patients in the community are more expensive to treat than others, but must still receive treatment. However, it is clearly appropriate and cost-effective that services should be organised so as to minimise the cost to the NHS of providing the equivalent standard of care to people in prison. It is not necessary that primary care services should always be provided in the same way in prisons as in the community, so long as the same standard of care is provided. It is up to prison healthcare services, working with the rest of the prison, to determine how, where and when services are supplied, so long as they can be accessed without undue delay. The GDG also considered more frequent monitoring as appropriate for older people with chronic conditions. The GDG acknowledged that since there is a great likelihood that chronic ill health is exacerbated by older age it may be more cost-effective to monitor these individuals more frequently. In addition to the general cost-effectiveness of the recommendations in these guidelines as established by the specific guidelines, the GDG noted additional benefits in the prison setting. One of the major benefits to health of good monitoring is to reduce the likelihood of emergency situations, by picking up deteriorating health at an earlier stage. As noted in Chapter 10, emergency incidents are both very complex to deal with and very expensive for both the health service and the prison service. By decreasing such events, not only will the individual benefit from better health and avoid the distressing as well as dangerous aspects of a health emergency, but the NHS is likely to make slightly larger cost savings than for an average person in the community in an equivalent situation, and so this outcome of care would be even more cost-effective in a prison population than in a general population, whilst there would be additional cost savings to the prison service. For people requiring elements of specialist care as well as primary care, the GDG discussed opportunities for shared care models where patient management can be assigned to a prison primary care health service which is in contact with a relevant specialist. This can reduce the number of visits needed by prisoners to external secondary care facilities, by providing certain services, particularly consultations, within the prison. Where such services are coordinated efficiently, they can reduce costs for both the NHS and the prisons service and reduce safety and security concerns due a reduction in transportation of prisoners to external services, whilst providing at least the same quality of healthcare to the patient. As long as such services are managed efficiently to ensure that the volumes of demand and supply are well matched, such arrangements are likely to be cost-effective or cost saving for the NHS whilst saving additional prisons service resources.
Quality of evidence	The GDG was presented with recommendations on monitoring chronic conditions from a range of published NICE guidelines. The GDG considered the applicability and appropriateness of each guideline to the prison population. The GDG determined that the review questions asked by other related guidelines around monitoring were

	similar to the review question asked in this chapter: 'How should chronic conditions be monitored?' The evidence reviews presented were considered relevant and appropriate. The quality of the evidence underpinning these recommendation varied from low to very high quality with some guidelines citing large numbers of included studies (33 in Hepatitis B) to others basing recommendations on limited evidence (Epilepsy: audit data, surveys) or basing recommendations on GDG consensus (COPD) due to no evidence identified.
Other considerations	The GDG has cross-referred to recommendations rather than made any formal adaptations. The GDG considered the guidelines on specific chronic conditions highly relevant to a prison population and feasible within this setting. Areas were discussed such as glucose self-monitoring or continuous blood pressure monitoring and whether there were any security concerns, however it was considered that both are feasible and are currently achieved in prisons. The GDG noted the high prevalence of asthma in the prisons population, likely to be attributed to the high proportion of smokers. The NICE guideline on asthma diagnosis and monitoring is currently in development (publication date to be confirmed). Other relevant guidance is published, but does not focus on monitoring, such as the BNF section on asthma management [47]. The NICE quality standard on asthma[111] has been cross referred to, which contains standards such as: • QS 5 People with asthma receive a structured review at least annually. • QS 6 People with asthma who present with respiratory symptoms receive an assessment of their asthma control. The GDG agreed that these quality statements are both achievable and applicable to a prison population. The current guidance on chronic heart failure is currently undergoing update, due to publish in 2018. It was noted that the NICE catalogue of guidelines does not cover allconditions; notably, there are no guidelines on Hep C or HIV. NICE guidelines on HIV only cover diagnosis, however the British HIV Association (BHIVA) publishes a range of clinical guidelines, including guidance on management of HIV, which are NICE accredited.http://www.bhiva.org/documents/Guidelines/Monitoring/hiv_971_EV.pdf[3,21] The GDG discussed end of life care in prison and noted the existing NICE guidance in this area.[72] This guidance states that "It is aimed at all health and care professionals who might be involved in the care of a person who is dying in any NHS setting…" and that "For those dying at home or in prison it is likely that care will be provided at end of life by NHS providers and so recommendations contained in this guideline apply." People in prison who have learning disabilities were discussed and it was noted that this group may have complex physical and mental health needs. The GDG discussed whether this group would require more frequent monitoring or any specific recommendation, but considered that the recommendations apply equally to them. The group noted that social care assessments would be routinely undertaken for this population. As this is a particular equalities consideration the group felt additional resources may be required to implement these recommendations. The group considered discussed the health needs of older prisoners and that a separate recommendation was needed for more frequent monitoring. In addition the group made a research recommendation to support this further, stating "When should subsequent health assessments be undertaken in prison for people serving long-term sentences?". This is intended to capture information on when people should be assessed during incarceration and notes the increasing numbers of older people serving longer prison sentances and that opportunities for self care are limited.

	The GDG discussed the potential impact of the subsequent reception assessment (see recommendations in section 5.8.4) and that this recommendation would be more robust than current practise in identifying people in prison with a chronic condition. Therefore it is hoped that more people would be identified at an early stage and therefore mechanisms put in place to monitor via existing NICE guidance. The group noted that these guidelines could only be used when it is known that someone has the condition and that if not identified during reception or the within the first week, unless the person self-identifies there is a risk of any undiagnosed condition deteriorating and leading to an emergency situation (see Chapter 10). The GDG noted that the current prevalence of a wide range of health conditions in people in prison in the UK are largely unknown compared to the general population. The GDG noted evidence of the prevalence of health conditions in the UK prison population would be useful to inform recommendations for people in prison in the future, therefore the GDG decided to make a research recommendation in this area (for more details please see Appendix P).

10 Deteriorating health and emergency management

10.1 Introduction

Urgent and emergency care in prison is important for a wide range of reasons, including self-harm, seizure, assault, restraint, deteriorating health due to chronic disease, accidental injury and overdose. People in prison are reliant on prison and health care staff to identify and act on deteriorating health, and to ensure they receive care that is delivered in a timely fashion; this is particularly important overnight. Ensuring access and delivery of urgent and emergency care therefore becomes the responsibility of both prison staff and prison healthcare staff. Most prisons have trained first aiders (usually prison staff) and prison healthcare professionals available to respond to any emergency call. Care providers must ensure they have a competently trained member of staff with the correct equipment attending in a timely manner.

The Prisons and Probation Ombudsman (PPO) has reported[129] on a number of challenges to urgent and emergency care in prison, which include poor monitoring of chronic conditions, poor care planning for those identified with deteriorating health, delays in summoning external emergency services, delays in healthcare staff and paramedics reaching the scene, lack of access to emergency equipment and lack of first aid-trained staff. Therefore, it is important for staff to identify and manage long-term and deteriorating conditions to proactively avoid the point of emergency where possible.

Given the secure context within which emergency and urgent care is provided, other challenges are presented to those caring for prisoners that centre on the need to ensure staff safety and prison security. Whilst emergencies do arise, prison staff must be alert to the possibility of illness presentations as a means for secondary gain and this only reinforces the need for care providers to ensure that there are competent, well-trained healthcare staff available to assess, interpret and support prison staff when dealing with these circumstances.

The GDG chose to prioritise review questions in this area to explore further these challenges facing healthcare and prison staff and people in prison and to identify ways to improve care.

10.2 Review question: What are the barriers and facilitators to prison staff, healthcare workers and prisoners for recognising deteriorating health?

For full details see review protocol in Appendix C.

Table 122: Characteristics of review question

Objective	Identification of themes around delays in responding to deterioration in health. To provide details of areas for improvement to prevent and respond appropriately to deteriorating health.
Population and setting	Adults (18 and over) in prisons or young offender institutions. Indirect settings: Immigrant Removal Centres (IRCs), secure environments, forensic units, low/medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Review strategy	Study designs to be considered: Qualitative studies (for example, structured

	interviews, focus groups, observations) and surveys to support themes from qualitative studies. A thematic analysis of the data will be conducted and findings presented in the studies will be reported.

10.2.1 Clinical evidence

10.2.1.1 Methods

Six studies were included in the review.[18,31,57,126,127,160] Five studies utilised either focus groups, interviews or a combination of these methodologies whilst one study used a quantitative and qualitative questionnaire for which the results were used to inform the structure of focus groups. These are summarised in Table 101 below. Key findings from these studies are summarised in the clinical evidence summary below (Table 103 to Table 129). See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, and excluded studies list in Appendix L.

Themes and sub-themes were generated from focus groups and interviews and results of questionnaires used to support findings; with the exception for the theme Medication access – medication trading, which was generated from the findings of an open-ended questionnaire.

10 12.1.2 Summary of included studies

2 **Table 123: Summary of studies included in the review**

Study	Methods used	Population	Research aim	Comments
Qualitative studies				
Condon 2006[18]	Semi-structured interviews	n=111 in 12 prisons Male:female – 101:10 Age – Median (range): 34 (16-78) UK - Cat A = 1, cat B = 5, cat C = 2, YOI = 2, women = 1	To explore prisoners' views of health care within the prison setting.	Included juveniles
Gately 2006[31]	Semi-structured interviews	Prisoners with chronic conditions n= 11 pre-course and 8 post-course at 'prison X' 2 post course interviews at 'prison Y' Male Age NR UK - Two category C training prisons	To explore the barriers and opportunities for managing long term conditions in a prison setting. To uncover individuals' experiences of the Expert Patients Programme (EPP), a policy aimed at mainstreaming patient experience in the NHS operationalised through the introduction of a lay-led self-management course for people suffering from long-term conditions.	Different recruitment methods at each prison (X - selection by prison officer, Y - self-selection response to poster)
Marks 2006 [57]	Interviews (Structure not reported)	n=10 doctors, 5 healthcare managers Gender NR Age NR UK - Closed male YOI, Category B mixed local prison, high security female prison, high security male prison, category B male local prison, closed female prison and YOI	Identify views on the training needs of doctors and health care managers working in prisons.	
Plugge 2008[126]	Focus groups and semi-structured interviews	n= 37 (focus groups), 12 (interviews) Female Age= 18-21 (focus groups), 19-46 (interviews) UK –2 closed local prisons	To explore women prisoners' experiences of primary healthcare provision in prison.	Themes from both methodologies reported together.
Powell 2010 [127]	Focus groups and semi-structured interviews	Nurses and healthcare staff n= 68 (12 focus groups) Nurse managers n= 12	Study the views and experiences of nurses and other prison healthcare staff about their roles and	Healthcare managers split after first focus group, as staff

		(interviews) Male:female - 21:59 Age - mean (range): 44.59 (24-58) UK – 12 prisons; purposive sampling in order to "capture all categories of prison"	the nursing care they provide to prisoners	deferred to their managers. Participation possibly compulsory
Walsh 2014[160]	Focus groups and questionnaire	n=23 (questionnaire), 5 (focus group) Gender NR Age NR UK – 1 category B prison	To explore the attitudes and perceptions of prison staff towards pain management in prison.	Focus group recruited from questionnaire sample. One manager verbally requested to be included

NR = not reported.

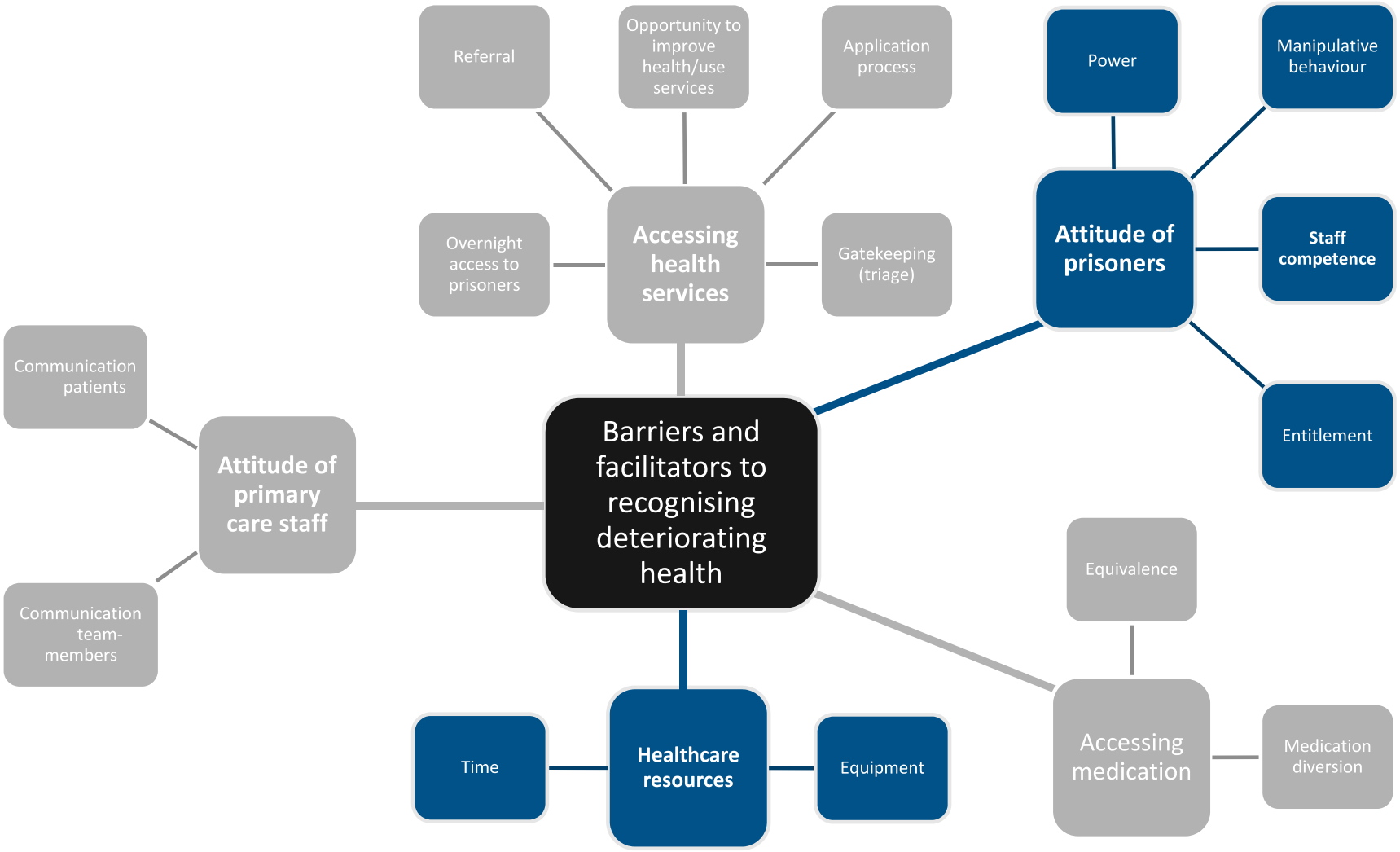
10.2.1.3 Evidence

10.2.1.3.1 Themes and sub-themes derived from the evidence

Table 124: Themes and sub-themes

Main theme	sub-themes
Accessing health services	Application process
	Gatekeeping (triage)
	Opportunity to improve health/use services
	Overnight access to prisoners
	Referral
Attitude of primary care staff	Communication with patients
	Communication with team-members
Attitude of prisoners	Entitlement
	Manipulative behaviour
	Power
	Staff competence
Medication access	Equivalence
	Medication diversion
Healthcare resources	Equipment
	Time

Figure 6: Themes and sub-themes



10.211.3.2 Evidence summary

2 **Table 125: Summary of evidence: Theme 1 – Accessing health services**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Application process					
3	2 Semi-structured interviews 1 focus group (UK)	• Mixed views from both prisoners and healthcare professionals. • Positive views due to its prevalence across the prison system and when it worked efficiently. • Majority felt that the system was inefficient and led to long waiting times. • Variation across prisons, particularly between types. *"This app business - do you know how long it takes to see a doctor here? I would have damned killed myself if I wanted to do that."* *"If you say it's an emergency - 'I think my tooth's broke on me' - then you'll probably go the next day."*	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Not coherent Applicable Saturated	VERY LOW
Sub-theme 2: Gatekeeping (triage)					
4	2 Semi-structured interviews 2 focus group + semi-structured interviews (UK)	• Discordant views from patients compared to healthcare staff • Staff viewed gatekeeping as a necessity, with some concerns about training • Some patients had positive views, as it decreased initial waiting time but majority viewed it as a delaying step to seeing a doctor *"I mean, I once ended up with nearly having pneumonia. Because, you know, the triage nurse kept fobbing me off with, telling me it were just a cold and I had a, bit of a, you know, a chest infection and it'll wear off, you know what I mean. And then when eventually I did get to see the doctor, the doctor told me off for not, you know, seeing him earlier, you know what I mean…"*	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Not coherent Applicable Saturated	VERY LOW
Sub-theme 3: Opportunity to improve health/use services					
2	2 interviews	• Prison was an opportunity to catch up on healthcare and get	Limitations of evidence	Minor limitations	VERY LOW

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
	(UK)	regular check-ups for chronic conditions. *"It's time to get healthy… get back to normal, it's just a thing with prisoners - come to jail and get yourself sorted. I had better things to do when I was out, but in here you've got all the time in the world, so you might as well get everything done."*	Coherence of findings Applicability of evidence Theme saturation/sufficiency	Coherent Applicable No theme saturation	
Sub-theme 4: Overnight access to prisoners					
2	1 Semi-structured interviews 1 Interviews (UK)	• Concerns from both staff and prisoners over access to prisoners at night. • Some prisoners described a near ban on pressing buzzers for help at night, even in the case of illness. Additionally cell doors would not be opened except in the most serious of circumstances.	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Coherent Applicable No theme saturation	VERY LOW
Sub-theme 5: Referral					
2	1 focus groups + semi-structured interviews 1 Interviews (UK)	• Difficulty in either referring patients to external services or having visits to the prison for non-emergency cases. • External referrals often cancelled due to lack of prison staff for escort *"It's not neglect – if the officers aren't there to do it, we can't do it."*	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Minor limitations Coherent Applicable No theme saturation	VERY LOW

1 **Table 126: Summary of evidence: Theme 2 – Attitude of primary care staff**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Communication with patients					

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
1	Focus groups and semi-structured interviews (UK)	• Patients felt staff could be disrespectful and uncaring *"They make you feel - oh… I can only speak for myself, but I - they make you feel like that you - you're [sighs]. They look beneath you. Erm, down at you, if you know what I mean? Because you're a prisoner.*	Limitations of evidence	No limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Communication with team-members					
1	1 Interviews (UK)	• Lack of team-work with the healthcare team compared to the community *"We don't all meet together and discuss common problems, like we do in the practice"*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

1 **Table 127: Summary of evidence: Theme 3 – Attitude of prisoners**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Entitlement					
2	2 Focus groups and semi-structured interviews (UK)	• Belief that some patients feel entitled to certain drugs or painkillers *"Most of the people that come in 'clucking' or withdrawing, they want their drugs and they want whatever is going to make them feel better now"* *"there is a strong sense of victim, a strong sense of entitlement, you know, if you come in and say "look, the police have beaten me up, look at my arm, dog bite, therefore I should have"*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 2: Manipulative behaviour					
4	2 Semi-structured interviews 1 interview 1 Focus groups and semi-structured interviews (UK)	• Both staff and prisoners felt that a lot of manipulative behaviour occurred. • 'hardened' staff were felt to be less likely to believe the 'legitimate patient' *"They're so used to girls blagging them, trying to get any sort of drugs… they think that everybody's the same - we're all trying to blag them. But that's not the case for everybody"*	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Coherent Applicable Saturated	VERY LOW
Sub-theme 3: Power					
1	1 Focus groups and semi-structured interviews (UK)	• Using complaint of pain as way of exerting power over the health care professional *" 'I've tried that, that doesn't work' so you come up with another drug, ' I had that years ago and that didn't work'…It feels combative really quite often"*	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	Major limitations Coherent Applicable No theme saturation	VERY LOW
Sub-theme 4: Staff competence					
1	1 Focus groups and semi-structured interviews (UK)	• Healthcare staff not considered competent *"I don't rate them that they're qualified doctors. I reckon they just [expletive] got them off the street yeah."*	Limitations of evidence Coherence of findings Applicability of evidence Theme saturation/sufficiency	No limitations Coherent Applicable No theme saturation	LOW

1 **Table 128: Summary of evidence: Theme 4 – Medication access**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Equivalence					
3	2 Semi-structured interviews 1 interview (UK)	• dissatisfaction at the range of analgesics available • Considered that they were treated as prisoners first and foremost and only secondly as patients. • Staff reported differences in prescribing in prisons compared to the community *"it shouldn't be that 'cos you're in prison you're not allowed to have certain medication. It should be (that) if you're ill, then you should be treated"*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	
Sub-theme 2: Medication diversion[g]					
1	1 Focus groups and questionnaire (UK)	• majority of respondents had witnessed or heard about trading • All believed that prisoners accessed health care services to obtain pain medication that they do not need *"It's very easy for prisoners to 'blag' pain relief. They even crush up pain killers and sell them as illicit drugs"*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

1 **Table 129: Summary of evidence: Theme 5 – Healthcare resources**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Equipment					
1	1 Interviews	• Lack of computers created difficulties for managing long-term conditions	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	

g The sub-theme 'Medication diversion' was generated from the findings of an open-ended questionnaire rather than a focus group or interview.

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
	(UK)		Applicability of evidence	Not applicable[h]	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Time					
2	1 Focus groups and semi-structured interviews 1 Focus groups and questionnaire (UK)	• Managing pain took a significant amount of time • Healthcare workers had to work around the 'prison regime'	Limitations of evidence	Major limitations	VERY LOW

1

h The Guideline development group noted that all the evidence identified for this theme preceded the introduction of SystmOne, a central clinical computer system used in all prisons.

10.2.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

10.2.3 Evidence statements

Clinical

- Five main themes were identified from the evidence: accessing health services, attitude of primary care staff, attitude of prisoners, medication access and healthcare resources. Very low quality evidence was identified from 6 UK qualitative studies conducted in the UK, ranging from 15 to 111 participants.

Economic

- No relevant economic evaluations were identified.

10.2.4 Recommendations and link to evidence

See section 10.4 below.

10.3 Review question: What are the barriers and facilitators for prison staff, healthcare workers and prisoners in managing emergency situations including first person on the scene?

For full details see review protocol in Appendix C.

Table 130: Characteristics of review question

Objective	Identification of themes around managing emergency situations. To provide details of areas for improvement in responding appropriately to emergency situations.
Population and setting	Adults (18 and over) in prisons or young offender institutions. Indirect settings: Immigrant Removal Centres (IRCs), secure environments, forensic units, low/medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Review strategy	Study designs to be considered: Qualitative studies (for example, structured interviews, focus groups, observations) and surveys to support themes from qualitative studies. A thematic analysis of the data will be conducted and findings presented in the studies will be reported.

10.3.1 Clinical evidence

10.3.1.1 Methods

Two studies were included in the review.[18,127] One study utilised semi-structured interviews of prisoners to develop the findings, whilst the other utilised focus groups of healthcare staff combined with semi-structured interviews of healthcare managers. These studies are summarised in Table 101

below. Key findings from these studies are summarised in the clinical evidence summary (Table 103 and Table 126). See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, and excluded studies list in Appendix L.

10.3.1.2 Summary of included studies

Table 131: Summary of studies included in the review

Study	Methods used	Population	Research aim	Comments
Qualitative studies				
Condon 2006[18]	Semi-structured interviews	n=111 in 12 prisons Male:female – 101:10 Age – Median (range): 34 (16-78) UK - Cat A = 1, cat B = 5, cat C = 2, YOI = 2, women = 1	To explore prisoners' views of health care within the prison setting.	Included juveniles
Powell 2010 [127]	Focus groups and semi-structured interviews	Nurses and healthcare staff n= 68 (12 focus groups) Nurse managers n= 12 (interviews) Male:female - 21:59 Age - mean (range): 44.59 (24-58) UK – 12 prisons; purposive sampling in order to "capture all categories of prison"	Study the views and experiences of nurses and other prison healthcare staff about their roles and the nursing care they provide to prisoners	Healthcare managers split after first focus group, as staff deferred to their managers. Participation possibly compulsory

10.3.1.3 Evidence

10.3.1.3.1 Themes and sub-themes derived from the evidence

Table 132: Themes

Main theme
Access to prisoners
Emergency referrals

Figure 7: Themes and sub-themes

1

10.3.1.4 2 Evidence summary

3 **Table 133: Summary of evidence: Theme 1 – Access to prisoners**

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
1	Interviews (UK)	• Prisoners felt confident an emergency during the day would be dealt with promptly • Prisoners were particularly worried about an emergency occurring at night within the cells *"How about if anybody gets a heart attack, you know, in their cell – what do you do? You just leave him until the next morning or something"*	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

Table 134: Summary of evidence: Theme 2 – Emergency referrals

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
1	Focus groups and semi-structured interviews (UK)	• Staff felt emergency referrals of prisoners to hospital were easier to organise compared to routine appointments *"Emergency care is probably the easiest, because the prison has to find staff – there's no option."*	Limitations of evidence	Major limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

10.3.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

10.3.3 Evidence statements

Clinical

- Very low to low quality evidence was identified from 2 qualitative studies, with 2 themes identified: access to prisoners and emergency referrals. Both studies were conducted in the UK, n=111 and n=68.

Economic

- No relevant economic evaluations were identified.

10.3.4 Recommendations and link to evidence

See section 10.4 below.

10.4 Recommendations and link to evidence

10.4.1 Deteriorating health and emergency management (see sections 10.2 and 10.3)

Recommendations	**<u>Managing deteriorating health and health emergencies</u>** **62. Ensure a local protocol is available for responding to and managing situations in which a person's health quickly deteriorates, or in a health emergency. This could include, for example:** • **essential training for front-line prison staff, including the first person likely to be on the scene in an emergency** • **processes to enable healthcare staff to reach a person in prison quickly, such as how to gain access to their cell** • **processes to ensure a person can be quickly seen by a healthcare professional if their health deteriorates quickly** • **availability of emergency equipment, such as emergency 'grab bags'** • **recording the actions and observations taken by prison and healthcare staff when assessing people with rapidly deteriorating health or in an emergency situation, such as:** o **updating a person's care plan or** o **recommendations for immediate follow-up** • **a clear care plan for supporting people with rapidly deteriorating health** • **guidance on sharing information between prison staff and healthcare staff, such as details on standardised clinical handovers and follow-up.**

	63. Ensure prison and healthcare staff are made aware of people who have underlying chronic conditions and allergies: • **if the person agrees (in line with the local information-sharing policies)** • **in emergencies, in line with the duty of healthcare staff to share relevant confidential patient data.**
Relative values of different outcomes	The GDG agreed with the themes identified from the 2 qualitative reviews on the barriers and facilitators to identifying and managing both deteriorating health and emergency situations. The majority of evidence identified was within the identifying deteriorating health review on 2 themes: access to healthcare and the attitude of prisoners.
Trade-off between clinical benefits and harms	The evidence from the qualitative reviews suggests that people in prisons were concerned about their access to healthcare and increasing the ease of a prisoner's access to healthcare could provide a benefit in identifying deteriorating health before an emergency arose. Both prisoners and healthcare staff identified the attitude of prisoners, in particular potential manipulative behaviour, as a barrier to identifying deteriorating health in a prisoner. It was recognised that although some prisoners may have a hidden agenda, many may be labelled as such unnecessarily and that caution should be used when examining this theme. The GDG discussed these findings but agreed that prison healthcare staff should still treat prisoners equivalently to how they would be treated in the community, use their clinical judgement in their assessment, and should not presume all people in prison have an ulterior motive. Mixed evidence was identified for gatekeeping (triage system of seeing a nurse or healthcare assistant prior to a doctor) as a theme. The majority of evidence identified gatekeeping as a possible barrier to identification of deteriorating health; however this view was discordant with prison staff members who often supported gatekeeping. The GDG discussed that when managed well gatekeeping can work well, but understood the concerns of those in prison and considered that this needs to be handled sensitively and that communication between health staff is key here. During management of emergency situations the review suggests that possible difficulties and delays in accessing a prisoner's cell are significant barriers to healthcare access. Increasing the ease of access to a prisoner during an emergency is critical in ensuring an emergency is managed appropriately. Potential harms identified during these reviews were that prison healthcare staff identified increasing access to healthcare by reducing gatekeeping by non-clinical staff would make the workload of the prison healthcare service unmanageable. The GDG considered that the current practice of gatekeeping was required in some form, but that there were often difficulties in implementing it effectively, due to lack of training and communication. The evidence stated that nurses felt pressured to protect the GP's time and others mentioned that it was purely a paper sorting task, suggesting that there may be incidences in which people in prison do not see a GP and have a poorer health outcome due to undiagnosed conditions or incorrect medication reviews etc. The recommendations were based mainly on GDG consensus, however the GDG considered that the components of the protocol were based on established best practice and would often already be current policy in many prisons. As the GDG felt these recommendations reflected current best practice the GDG considered the clinical benefits were well understood and outweighed any potential clinical harm.
Trade-off between net clinical effects and costs	No published economic evaluations were identified relating to these questions. The GDG discussed the economic implications of the various recommended protocol components. It was highlighted that no major amendments would be required to the

	existing service arrangements since many of the elements were already considered best practice and therefore implemented in some prisons or are part of the existing prison service instructions and should be followed by all prisons. It is noted that these recommendations are not prescriptive and leave to prisons the responsibility for determining the detail of how each element would be best implemented in their particular environment, which should include doing so in the most cost-effective way. Insofar as any prisons do not currently have adequate local protocols for responding to emergencies in place or do not currently have adequate procedures in place for ensure information is shared appropriately for the safeguarding of prisoners with health conditions, the GDG consider that it is a matter of safety (as well as of compliance with existing NOMS policies and healthcare principles[14,32,33]) that minimum standards are in place, and so these are not primarily economic questions. Notwithstanding the essential nature of these recommendations, the GDG did note that in practice most elements of these recommendations are likely to be cost saving or highly cost-effective for both the NHS and the prisons service. Those elements requiring the establishment of procedures will have small one-off costs, but should lead to better care and fewer expensive emergency events. The most expensive element could be the training of prison and healthcare staff, but the GDG is not recommending a level of training above that which is already considered essential to be prepared for situations that staff may expect to encounter as part of their respective jobs. The GDG agreed that there should be no major economic implications associated with the encouragement of more comprehensive information sharing protocols. More specifically, any additional staff time required for medical information to be shared between prison and healthcare staff would be offset by the benefits of a more accurate response when deteriorating health is indeed recognised. Therefore, there is a lower likelihood of a costly adverse event when both prison and healthcare staff are aware of people in prison who have underlying chronic conditions. A streamlined system could even save staff time from multiple informal conversations required in a less organised system.
Quality of evidence	The evidence covered the identification and management of both deteriorating health and emergency situation. Themes on deteriorating health were identified from 1 set of focus groups, 3 sets of semi-structured interviews, and 2 sets of semi-structured interviews combined with focus groups. Themes on emergency situations were identified from 1 set of semi-structured interviews and 1 set of semi-structured interviews combined with focus groups. The quality of the evidence for themes within both deteriorating health and emergency situations was generally very low, with the majority of evidence having major limitations due to sampling and data collection methods as well as a general lack of theme saturation. The findings were generally coherent but within some themes, such as access to healthcare, prison staff and prisoners held discordant views. The GDG considered that the evidence was applicable to a current UK prison setting with the exception of a theme that identified a lack of computer equipment available, as the evidence was produced before the introduction of the NHS prison health IT system.
Other considerations	<u>Essential training and first person on the scene</u> The GDG considered that for management of emergency situations best practice would be for prison officers to have adequate training to begin treatment, for example having up-to-date first aid and CPR training. This is because non-healthcare staff are most likely to be the first on the scene in an emergency. The GDG noted that essential training for prison officers is given in prison service instructions, Safer Custody PSI.[64] Additionally the GDG considered that in order to identify deteriorating health best practice would be for prison officers to have training on recognising the signs of deterioration and to support custodial staff to raise concerns. The rationale

being that prison officers have the most contact with prisoners, and would be able to identify changes from baseline level of health that may go unnoticed by healthcare professionals in a single appointment.

Access to people in prison

The GDG considered that particular elements of a structured response were critical in acting effectively in an emergency. These were ensuring that staff members are aware of how to access a prisoner's cell quickly during an emergency and communicating with the emergency services on how to access the prison, for example making sure there is a protocol for allowing paramedics or ambulance staff into the prison estate if necessary. The GDG noted that a structured response is necessary so that a prisoner receives access to the appropriate emergency treatment as quickly as possible. The GDG also noted the National Offender Management Service report on Emergency access to establishments for ambulance services[116]

Triage and quickly recognising deteriorating health

Rapid health deterioration was seen as a big concern within the prison population and although the gatekeeping or triage systems within prison were identified as both a barrier and facilitator for this question the GDG felt it was an important area for a recommendation. In the absence of evidence the GDG have made a consensus recommendation to ensure a process is in place to ensure a person is quickly seen by a healthcare professional if their health is deteriorating. The GDG were aware of early warning systems or track and trigger systems used to identify deteriorating health in secondary care settings, which have been adapted for use by the police and border forces. The GDG discussed these tools but whilst it was noted that assessment tools in general would be supportive for frontline prison staff, the ones currently identified would not be applicable within a prison healthcare setting due to the physiological observations required.

The GDG noted that an increase in essential training for prison officers could improve identification of deteriorating health, as prison officers will often be the first point of contact for a prisoner. Furthermore prison officers will be first on the scene in an emergency, and an increase in training levels will lead emergency situations being appropriately managed and offer greater support to non-health staff managing complex emergency situations.

Availability of equipment

The GDG noted PPO inquiries[129,130], as well as anecdotal evidence, where mix-ups with emergency equipment may lead to delays in prisoners receiving emergency care. The GDG noted that best practice would be for standardised equipment within a 'grab bag' to be readily available so that when staff members respond to an emergency they can do so without the need to check what equipment is present. Locations for these bags should be chosen that allow rapid access to a prisoner's cell, so, for example, the bags should not be all kept at a central location away from prisoners. The GDG noted that the specific equipment required would depend on the local services available, but may include a defibrillator and bandages etc. Access to other emergency equipment may also be relevant, for example oxygen canisters. The GDG noted the information from the RESUS council - Minimum equipment and drug lists for cardiopulmonary resuscitation within mental health in-patient care.[134]

Documenting information and care plans

The GDG discussed that all actions and observations taken by prison staff and healthcare staff related to rapidly deteriorating health or an emergency situation should be documented. This is to enable a clear record of what has happened and aid communication and continuity of care for the person in prison. Changes in staff or different shift patterns can mean that rapid deterioration could go unnoticed or unchecked by subsequent staff members, which may lead to emergency situations.

If a person has been recognised to have deteriorating health, the GDG considered that a clear plan of care is necessary to support that person and detail any further actions or monitoring required. This plan could also be shared and updated following

an assessment or any further action taken including any follow up required by staff at handover.

Information sharing between prison staff

During emergency situations current policy is that staff members have a duty to share appropriate and justified information when in the patient's best interest but the GDG noted anecdotal cases in which people incorrectly thought that this would contravene patient confidentiality or that there was a legal obligation preventing the sharing of information'. The GDG considered that greater sharing of information amongst staff would enable more effective monitoring of deteriorating health and management of emergency conditions. Further information is detailed in The Information Governance Review.[14]

The GDG noted that information sharing can be poor amongst healthcare staff or prison officers, as well as between prison officers and healthcare staff. The GDG considered that a lack of communication between staff was a key factor in not recognising deteriorating health before it became an emergency situation. The GDG considered that best practice would be a standardised clinical handover between healthcare staff when a prisoner was being monitored for deteriorating health. For example it is important that all staff are aware of people who have underlying chronic condition and allergies to ensure there is not a delay in care if there is health deterioration or a situation where there is an allergic reaction and, for example an epi pen is required. The GDG discussed patient consent and confidentiality at length and noted the duty of healthcare staff to share relevant confidential patient data[14] and other existing guidance on consent (http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp).

The GDG also considered information sharing between healthcare staff and prison officers, and considered best practice to be when prison officers are notified of relevant medical information by healthcare staff so that they are aware and can respond effectively to signs of deteriorating health. The GDG acknowledged the publication on Information sharing between prison staff: Learning from PPO investigations: Making recommendations.[130] Equally, the GDG considered it best practice that prison officers notify healthcare staff of prisoners where deteriorating health or health concerns (early warning signs) are suspected. This is also supported by recommendations on continuity of care (see chapter 11) and communication (see chapter 6).

These recommendations are supported by qualitative evidence, but are largely consensus of the GDG based on expert opinion and knowledge of current practice.

11 Continuity of healthcare

11.1 Introduction

At any given point, the prison estate comprises approximately 80,000 places for sentenced and remand prisoners.[66] However, the estimates of people going in and out of prison over the course of a year is considerably greater than this. Every person will have some interaction with the healthcare team within the prison, whether this is to provide initial assessment at reception, signposting to services, prescribing of medication, disease management or referral on to hospital.

Healthcare staff are reliant on the person to provide information on their healthcare and to then obtain information from community services (GP, drug service, hospital etc.). This results in potential delays and disruption to treatment plans for the patients.

Historically, there has been reluctance in sharing of information owing to concerns about patient confidentiality. This in itself has adverse consequences. Current guidelines from the Caldicott review[14] support the sharing of information between appropriate care providers where the benefit of the patient is being considered. These same principles need to be considered and applied at the end of a person's stay in custody.

Having effective systems in place to manage and share records between multi-professional staff is readily acknowledged, but is currently poorly implemented. There is a strategic objective from the Health and Justice Information Service to connect the clinical systems of all places of detention within the Health and Justice pathway in order to improve continuity of care, support clinical decision-making and enable equivalent care.

11.2 Review question: What are the barriers and facilitators to ensuring continuity of healthcare, including management of patient records, of people moving from:

- **community to prison?**
- **prison to prison?**
- **prison to court?**
- **court to prison?**
- **prison to hospital?**
- **hospital to prison?**
- **prison to community?**
- **transport to or from other detention centres?**

For full details see review protocol in Appendix C.

Table 135: Characteristics of review question

Objective	To identify the most effective systems, including management of patient records, to ensure continuity of healthcare of people moving from one prison to another, or between prison and the community, court or hospital.
Population and	Adults (18 and over) in prisons or young offender institutions.

setting	Health professionals and other staff working in prisons or young offender institutions Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low or medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Review strategy	Study designs to be considered: qualitative studies (for example, structured interviews, focus groups, observations). A thematic analysis of the data will be conducted and findings presented in the studies will be reported.

11.2.1 Clinical evidence

12.2.1.1 Methods

Studies were searched for exploring the continuity of healthcare of people from community to prison, from one prison to another or to another detention centre, from prison to court and vice versa, from prison to hospital and vice versa, and from prison to the community. Twelve qualitative studies were included in the review;[8,24,27,31,37,43,48,51,125,127,144,149] these are summarised in Table 101. These studies focus on the continuity of healthcare when entering and when being released from prison. Key findings from these studies are summarised in the evidence summary (Table 138). See also the study selection flow chart in Appendix E, study evidence tables in Appendix H, and excluded studies list in Appendix L.

1112.2.1.2 Summary of included studies

Table 136: Summary of studies included in the review

Study	Design	Population	Research aim	Comments
Binswanger 2011[8]	Semi-structured interviews	n=29 Former prisoners, 2 months post-release Adults (mean age 39, range 22-57) Male: female ratio: 69:31 USA	To understand the health-seeking experiences, perceptions of risk, and medical and mental health needs of former prisoners in the first two months after release from prison	
Bracken 2015[27]	Focus groups	n=27 Former prisoners, up to 24 months post-released, with HIV Adults (aged 18 years or over; 72% aged over 40 years) Male: female: transgender ratio 96:0:4 USA	To increase understanding of what contributes to HIV medical care engagement in former prisoners	Focus on people with HIV
Dyer 2013[24]	Semi-structured interviews and	n=17	To explore prison health discharge planning in 4	

Study	Design	Population	Research aim	Comments
	focus groups	Prison staff members including GPs, nurses, nursing assistants and healthcare support workers, members of the Mental Health In- Reach Teams, pharmacy and CARATs (Counselling, Assessment, Referral, Advice and Throughcare) staff. UK	prisons in North East England	
Gately 2006[31]	Semi-structured interviews and focus groups	n= 21 Prisoners with chronic conditions Male Age: not stated UK	To explore the barriers and opportunities for managing long term conditions in a prison setting. To uncover individuals' experiences of the Expert Patients Programme (EPP), a policy aimed at mainstreaming patient experience in the NHS operationalised through the introduction of a lay-led self-management course for people suffering from long-term conditions.	
Hammett 2015[37]	Semi-structured interviews and focus groups	n=65 (27 correctional staff, 13 community HIV providers, 25 other community providers) USA	To investigate facilitators and challenges of in-prison care, transitional interventions, and access to and continuity of care in the community in Rhode Island and North Carolina	Focus on people with HIV
HM Inspectorate of Prisons 2012[43]	Semi-structured interviews	n= 69 (19 prisoners, 18 prison officers or managers, 32 prison healthcare staff) Prisoners: Mainly adults, 15% young offenders aged 17 or younger Male/female ratio 14:5 UK	To explore: the extent to which information contained in person escort records (PERs) is helpful to staff in prisons and young offender institutions (YOIs) when assessing risk of self-harm and devising care plans identifying common gaps in information contained in PERs how PERs and their associated processes can be made more effective and enable the protection of vulnerable detainees to be	Limited applicability due to focus on mental health. Additionally, the study includes 15% young offenders

Study	Design	Population	Research aim	Comments
			improved	
Joanna 2008[48]	Semi-structured interviews and focus groups	n= 70 (45 former prisoners; 25 professionals in prisons and community services) Former prisoners: Mainly adults (aged 17 years or older) Male/female ratio 18:27 UK	To explore the continuity of care experienced by prisoners before and after release	Includes n=1 young offender
Lloyd 2015[51]	Semi-structured interviews	n=30 (12 former prisoners, 12 family members, 8 community service providers) Former prisoners: Adults (aged 18 years or over) Male/female ratio 7:5 Aboriginal Australia	To explore how primary health care can better meet the health care and social support needs of Aboriginal Australians transitioning from prison to the community	Aboriginal
Plugge 2014[125]	Focus groups	n=41 (22 people on probation, 10 probation officers, 9 professionals who work for partner organisations) People on probation: Adults (aged 19-60) Male/female ratio 15:7 UK	To explore issues around health and access to health services for those on probation	
Powell 2010[127]	Semi-structured interviews and focus groups	n=80 (67 nurses working in prison healthcare centres including nurse managers, community psychiatric nurses/mental health nurses, substance misuse nurses and in-patient nurses; 13 healthcare assistants/healthcare workers/nursing auxiliaries) Age: not stated Gender: not stated UK	To explore views and experiences of nurses and other prison healthcare staff about their roles and the nursing care they provide to prisoners	
Sidibe 2015[144]	Semi-structured interviews	n=38 Community-based health care and service professionals, including nurses, physicians,	To assess health care workers' experiences with and perceptions of the health care needs of HIV-infected, formerly	Focus on people with HIV

Study	Design	Population	Research aim	Comments
		case managers, and counsellors/therapists Mental health professional n=12 Health care provider n=6 Case manager/outreach worker/social worker n=20 USA	incarcerated individuals	
Sowell 2001[149]	Focus groups	n=16 Former prisoners/in jail diagnosed with HIV Adults (mean 38.7±7.9; range 23-51) Male/female ratio 11:5 USA	To identify social service needs of HIV-infected persons at the time of release from prison/jail and to describe their case management experiences after release from jail	

11 12.1.3 Evidence synthesis

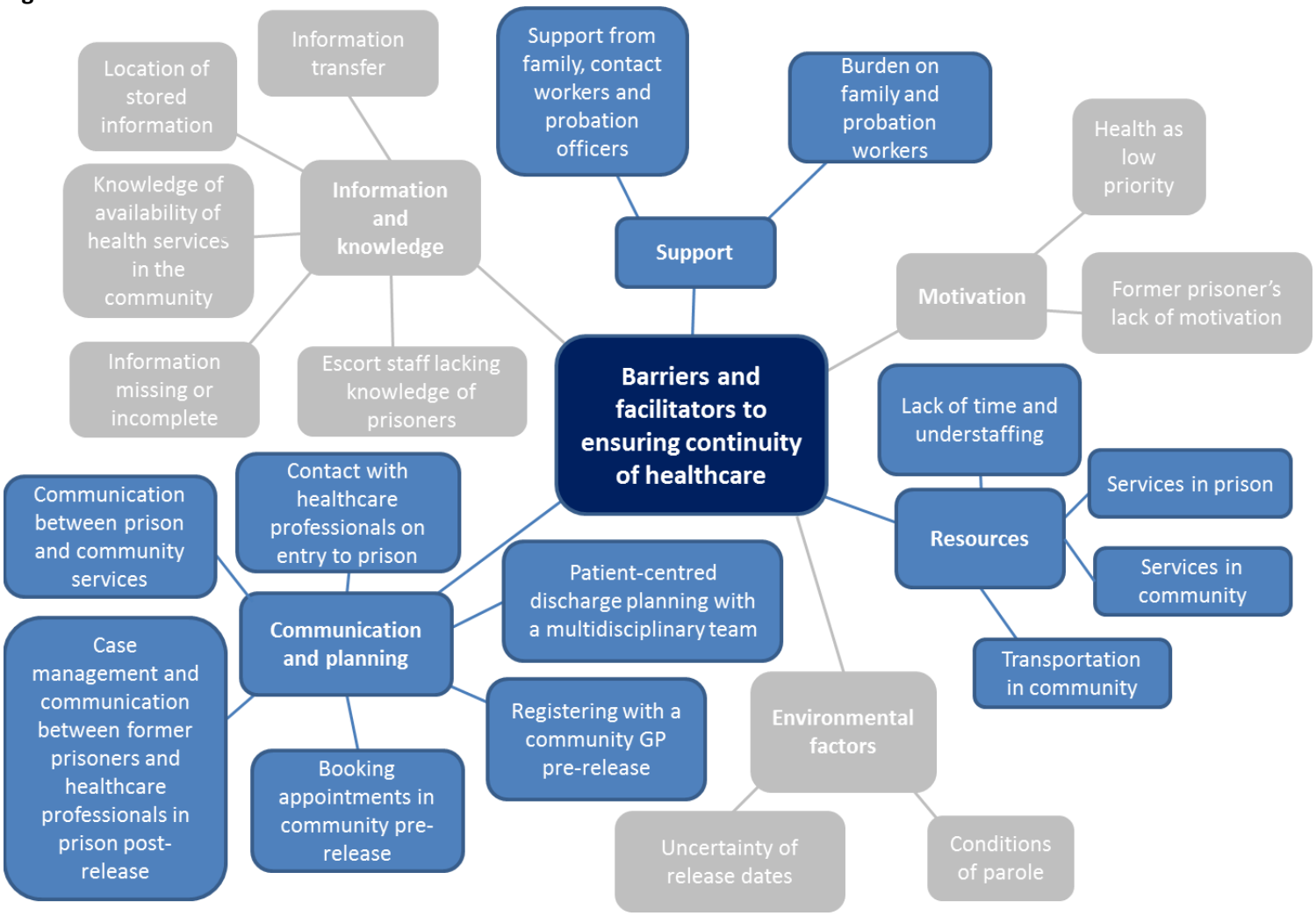
12 12.1.4 Themes and sub-themes derived from the evidence

3 **Table 137: Themes and sub-themes**

Main theme	Sub-themes
Information and knowledge	Information transfer Location of stored information Information missing or incomplete Escort staff lacking knowledge of prisoners Knowledge of availability of health services in the community
Communication and planning	Contact with healthcare professionals on entry to prison Patient-centred discharge planning with a multidisciplinary team Registering with a community GP pre-release Booking appointments in community pre-release Case management and communication between former prisoners and healthcare professionals in prison post-release Communication between prison and community services Confidentiality
Motivation	Former prisoner's lack of motivation Health as a low priority
Environmental factors	Uncertainty of release dates Conditions of parole
Support	Support from family, contact workers, mentors and probation officers Burden on family and probation workers
Resources	Lack of time and understaffing Services in prison Services in community Transportation in community

4

Figure 8: Themes and sub-themes



12.1.5 Evidence summary

Table 138: Summary of evidence: Theme 1: Information and knowledge

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Information transfer					
3	3 semi-structured interviews and focus groups UK, USA	Prisoners reported problems with records not accompanying them on transfers between prisons: "my medical records were not transferred with me and this caused real problems… they wouldn't believe what I said was prescribed" (prisoner, UK). Professionals reported that sometimes information, such as discharge summaries, medical records, details of release dates, was not transferred between prison and community services: "we've seen it with those who've got drug issues, suddenly now their 'script information hasn't followed them out to the community and the next worker who's less likely to provide them with the right sort of drugs." (Resettlement agency, UK) Not transferring information to a GP was reported to affect access to other services; "I've found at the health care unit at [name of prison] that if a person's going to be released they don't pass on the medical information to the GP; they're not allowed to pass it on to their GP or any other local mental health team" (Resettlement agency, UK).	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	
Sub-theme 2: Location of stored information					
1	1 semi-structured interviews UK	Prison reception staff reported that self-harm warning forms were not always attached to personal escort records (PERs)	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme	No theme saturation	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
			saturation/sufficiency		
Sub-theme 3: Information missing or incomplete					
4	2 semi-structured interviews 2 semi-structured interviews and focus groups UK	Information was reported missing or incomplete on reception (n=2), for example: self-harm warning forms missing; inadequate information provided in PERs Medical records were reported incomplete at discharge (n=2) despite the introduction of SystmOne, for example discharge summaries not written.	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	
Sub-theme 4: Escort staff lacking knowledge of prisoners					
1	1 semi-structured interviews UK	Escort staff lacking knowledge of prisoners	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 5: Knowledge of availability of health services in the community					
5	2 semi-structured interviews 1 semi-structured interviews and focus groups 2 focus groups Australia, USA	Service providers reported that former prisoners did not know what health services were available in the community and former prisons reported that they were unaware of how to access these services. Former prisoners reported that discharge planning needed to provide information about the services available in the community and how to access these, including providing the contact details and addresses of service providers. "I think the more that they can be set up with while they're here with very clear instructions on this is where you go, this is who you talk to, and actually have an appointment made for them would be the most helpful." (correctional	Limitations of evidence	Minor limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		administrator, USA)			

Table 139: Summary of evidence: Theme 2: Communication

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Contact with healthcare professionals on entry to prison					
2	2 semi-structured interviews and focus groups UK	Prisoners reported the loss of contact with services in the community on entry to prison	Limitations of evidence	Minor limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	Limited theme saturation	
Sub-theme 2: Patient-centred discharge planning with a multidisciplinary team					
3	1 semi-structured interviews 2 semi-structured interviews and focus groups UK, Australia, USA	Participants highlighted the importance of writing a discharge plan which focused on the person's preferences and circumstances, and that had the input of a multidisciplinary team, covering all aspects of the person's health and social care needs. "The person that you're writing the plan for has to be invested in it. They have to take ownership. It's their plan. I routinely tell inmates, "I'm not going home with you. I'm not driving you to an appointment. I'm going to do the best I can do give you the best plan that I can when you leave, but it's your plan" (correctional administrator, USA). "I think what needs to happen, everyone needs to sit down	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		and say, alright, well, this is what's going to go on [before release]. This is the plan … By a strong team, I'm talking about you have someone from Probation and Parole. You have somebody from the HASI1 program … You have somebody from mental health. You have somebody from drug and alcohol. They don't have to be from the same service, but they have to know what role they're actually planning." (service provider - Aboriginal mental health worker, Australia)			
Sub-theme 3: Registering with a community GP pre-release					
3	2 semi-structured interviews 1 semi-structured interview and focus groups UK, Australia	Prisoners reported not being assisted to register with a GP in the community before release from prison. Difficulties in registering with a GP were reported when the person had no fixed address in the community.	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	
Sub-theme 4: Booking appointments in community pre-release					
4	3 semi-structured interviews 1 semi-structured interviews and focus groups Australia, USA	Participants noted that booking appointments in the community before people are released would facilitate continuity of care when transitioning to the community. "It should be an extension from the prison system to the hospitals, doctors that they could refer them to before getting out. Making appointments…instead of having to get out and try to get all this started themselves. If it was started for them at release it is … probably easier for them to go ahead on and accomplish those things" (former prisoner, USA).	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Saturated	
Sub-theme 5: Case management and communication between former prisoners and healthcare professionals in prison post-release					

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
2	2 semi-structured interviews and focus groups UK, USA	Participants noted the benefits of having a case manager and of continuing contact with healthcare professionals after release from prison. However prisoners reported that their relationships with healthcare professionals in prison were often ended on release. "[W]e're trying to have discharge planners…work with probation and parole and be able to follow up with people for 60 days while they're out… I think we know those initial months if they're successful give them a better chance. And we're… making those … initial appointments for them here as part of their discharge plan and not putting that burden on the probation-parole officer" (correctional administrator, USA)	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	
Sub-theme 6: Communication between prison and community services					
3	3 semi-structured interviews and focus groups UK, USA	Professionals reported poor communication between prison and community-based serviced. It was noted that staff in prisons did not always know who to contact in the community to establish the transfer of care. This was complicated by prisoners being release into a different area than the prison they resided in: "If you are in a prison away from your home, when you're released you're not going to be linked in with the services you need in your home area" (Employment agency, UK). The quality of communication between services was reported to depend on established networks, the development of good working relationships and on individual good practice: "When it's a legal formal record, like prison, like probation, then sharing that information is restricted for security reasons. You might be able to access that but it's driven by individual good practice … rather than a system's	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
		basis" (Resettlement agency, UK).			
Sub-theme 7: Confidentiality					
1	1 semi-structured interviews USA	Participants reported that concerns about confidentiality, such as about HIV status, prevented people from accessing social support (for example friends/family helping with transportation to healthcare) and services in the community (for example not providing contact details to service providers to prevent family/friends finding out about their status). "A lot of times, they don't want to put a phone number on the ADAP (AIDS Drug Assistance Program) application. They won't give adequate or correct addresses on the application because family members and friends are not aware of their diagnosis. And they are fearful of being treated differently or put out of the house and not having a place to stay because of their diagnosis" (Outreach Worker, USA) "I know a lot of [clients] don't wanna tell anybody. They usually have to figure out a way to get transportation, and if they're coming to a place that is specifically related to HIV, they may not go" (Case Manager, USA).	Limitations of evidence	No limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

Table 140: Summary of evidence: Theme 3: Motivation

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Former prisoners' lack of motivation					
1	1 semi-structured	Healthcare staff and former prisoners reported that some	Limitations of evidence	Major limitations	LOW

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
	interviews and focus groups UK	former prisoners lack the interest or motivation to engage with healthcare in the community. This can often be linked to a perception that they have no alternative to a life characterised by re-offending and imprisonment	Coherence of findings	Coherent	
			Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Health as a low priority					
3	2 semi-structured interviews 1 focus groups UK, USA	Former prisoners, people on probation and partner organisations identified that health was not a priority. More pressing concerns included finding employment, appropriate housing, dealing with alcohol/drug problems, adjusting to life in the community and reconnecting with family and friends. "[health is at the] bottom of the pile. It's the last thing they want to do… get yourself a balanced diet and a goodnight's sleep!" (partner organisation, UK).	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	

Table 141: Summary of evidence: Theme 4: Environmental factors

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Uncertainty of release dates					
2	1 semi-structured interviews 1 semi-structured interviews and focus groups UK, Australia	Uncertainty regarding release dates was reported as a barrier to effective discharge planning: "That's [End of Custody Policy] crazy because if you get 18-day early release, you see the doctor two weeks before you go … so if you get your 18-day early, you're out before you've seen the flipping [doctor]" (prisoner, UK).	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 2: Conditions of parole					
1	1 semi-structured interviews USA	Conditions of parole were also viewed as a barrier to establishing healthcare in the community: "… if you are a parolee… they have… mandatory things that they have to do to survive, it's just a daunting task for somebody who doesn't have any resources or any family or friends to support and help them. And it's just… like for myself the success rate for me succeeding out here this time and not going back to the DOC [Department of Corrections] is like 1%" (former prisoner, USA).	Limitations of evidence	No limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

Table 142: Summary of evidence: Theme 5: Support

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Support from family, case workers and probation officers					
5	2 semi-structured interviews 3 focus groups UK, Australia, USA	Former prisons identified the need for professional support when moving from prison to the community. Participants reported that family, case workers and probation officers provided support post-release, for example to identify and access services, check patients attending appointments: "oh, they're good, Probation and Parole. Like she's been really good to me. She helped me when I went to a refuge and she helped me ring around a few places" (Aboriginal women, former prisoner, Australia).	Limitations of evidence	No limitations	LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	
Sub-theme 2: Burden on family and probation workers					
2	1 semi-structured interviews	Both family members and probation officers felt unsupported when trying to help former prisoners adjust to	Limitations of evidence	No limitations	VERY LOW
			Coherence of findings	Coherent	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
	1 focus groups UK, Australia	living in the community and to deal with mental health/drug/alcohol issues: "the crisis team has services, but it is very much about, we get an offender phone up and say they are going to kill themselves, if they [crisis team] have been working with them for a while, they are just like 'look the guy has personality disorder, and they do this all the time'. But, we are dealing with someone who goes in crying for help, and even if they have no intention of killing themselves, it is pretty desperate to be even saying that, and it needs a health assessment at that stage" (probation officer, UK).	Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

Table 143: Summary of evidence: Theme 6: Resources

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
Sub-theme 1: Lack of time and understaffing					
2	1 semi-structured interviews 1 semi-structured interviews and focus groups UK	Reception staff reported that staff lacked time to fully process prisoners on reception, for example to go through PER forms thoroughly. Staff also reported often having little time to plan for discharge or transfer; this was reported to be particularly the case for security-related transfers. Low staff numbers was also reported as a barrier to effective reception assessment and to discharge planning.	Limitations of evidence	Major limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 2: Services in prison					
1	1 semi-structured interviews and focus groups	Differences in services between prisons mean that prisoners may not be able to continue on programme when transferred between prisons	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	

Study design and sample		Descriptors of themes	Quality assessment		
No of studies	**Design**		**Criteria**	**Rating**	**Overall**
	UK		Applicability of evidence	Very applicable	
			Theme saturation/sufficiency	No theme saturation	
Sub-theme 3: Services in community					
4	1 semi-structured interview 2 semi-structured interviews and focus groups 1 focus groups UK, USA	Participants reported difficulty accessing healthcare services in the community, including those for: mental health issues, drug/alcohol issues and learning disabilities. This was particularly problematic for people with no fixed address: "Prisoners that are of no fixed address, NFA, homeless, find it the most difficult to access services because there is no local authority that will take responsibility for them" (Substance misuse worker, UK).	Limitations of evidence	Minor limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	Limited theme saturation	
Sub-theme 4: Transportation in community					
1	1 semi-structured interviews USA	Participants reported that poor access to transportation was a barrier to recently released people accessing healthcare. Participants described a number of factors that influenced a person's ability to access transportation. For example, lack of family and friends to give them rides, lack of accessible and convenient public transportation. "[lack of transportation is a barrier to] getting to treatment, getting to their medical provider, making their appointments" (HCP, USA).	Limitations of evidence	No limitations	VERY LOW
			Coherence of findings	Coherent	
			Applicability of evidence	Applicable	
			Theme saturation/sufficiency	No theme saturation	

11.2.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

11.2.3 Evidence statements

Clinical

- Twelve qualitative studies were identified which generated 6 main themes; information and knowledge, communication and planning, environmental factors, motivation, support and resources.
- Information and knowledge was identified as a theme by 9 qualitative studies (n=403) of interviews and focus groups with prisoners, former prisoners, family members, healthcare professionals, prison staff and community services. Five subthemes were included: information transfer, location of stored information, information missing or incomplete, escort staff lacking knowledge of prisoners, knowledge of availability of health services in the community. The evidence was of low to very low quality.
- Communication and planning was identified as a theme by 8 qualitative studies (n=334) of interviews and focus groups with prisoners, former prisoners, family members, healthcare professionals, prison staff and community services. Seven subthemes were included: contact with healthcare professionals on entry to prison; patient-centred discharge planning with a multidisciplinary team; registering with a community GP pre-release; booking appointments in community pre-release; case management and communication between former prisoners and healthcare professionals in prison post-release; communication between prison and community services; confidentiality. The evidence was of low to very low quality.
- Motivation was identified as a theme by 4 qualitative studies (n=125) of interviews and focus groups with former prisoners, healthcare professionals, prison staff and community services. Two subthemes were included: former prisoners' lack of motivation and health as a low priority. The evidence was of low to very low quality.
- Environmental factors was identified as a theme by 4 qualitative studies (n=167) of interviews and focus groups with former prisoners, family members, healthcare professionals, prison staff and community services. Two subthemes were identified: uncertainty of release dates and conditions of parole. The release dates subtheme showed minor limitations, limited applicability (included one study conducted in Australia) and no theme saturation. The evidence was very low quality.
- Support was identified as a theme by 5 qualitative studies (n=152) of interviews and focus groups with former prisoners, family members and community services**.** Two subthemes were identified: support from family, contact workers, mentors and probation officers; burden on family and probation workers. The quality of the evidence was low to very low.
- Resources was identified as a theme by 6 qualitative studies (n=300) of interviews and focus groups with prisoners, former prisoners, healthcare professionals, prison staff and community services**.** Four subthemes were identified: lack of time and understaffing; services in prison; services in community; transportation in community. The quality of the evidence was very low.

Economic

- No relevant economic evaluations were identified.

11.2.4 Recommendations and link to evidence

See section 11.4 below.

11.3 Review question: What are the most clinically and cost-effective systems to manage patient records, to ensure continuity of healthcare of people moving from one prison to another, or between prison and the community or hospital?

For full details see review protocol in Appendix C.

Table 144: PICO characteristics of review question

Population	Adults (18 and over) in prisons or young offender institutions. Indirect settings: Immigration removal centres (IRCs), secure environments, forensic units, low or medium secure units, regional secure units, high secure units, places of detention, secure training centres (STCs), police custody and detention centres.
Interventions	Any generic IT system, email system, telephone, record keeping or other named method of communication SystmOne Social care record systems
Comparisons	Compared to any other system Before-and-after data for non-randomised studies
Outcomes	Omitted and delayed medication Cancelled hospital appointments Medication errors Adverse events Patient safety incidents
Study design	Systematic reviews and meta-analyses Randomised controlled trials (RCTs) If no RCTs then comparative cohort studies (prospective and retrospective)

11.3.1 Clinical evidence

No relevant clinical studies comparing systems to manage the medical or other health records of people in prison were identified. See also the study selection flow chart in Appendix E, and excluded studies list in Appendix L.

11.3.2 Economic evidence

Published literature

No relevant economic evaluations were identified.

See also the economic article selection flow chart in Appendix F.

11.3.3 Evidence statements

Clinical

- No relevant clinical evidence was identified.

Economic

- No relevant economic evaluations were identified.

11.3.4 Recommendations and link to evidence

See section 11.4 below.

11.4 Recommendations and link to evidence

11.4.1 Continuity of healthcare (see section 10.2)

Recommendations	**Continuity of healthcare** **On entry into prison** **64. Arrange for the person's medical records to be transferred from primary and secondary care to the prison healthcare team on the person's entry to prison (see recommendation 5).** **65. Primary and secondary care services should provide information from the person's medical records to the prison healthcare team that is:** • **relevant** • **in the person's best interests.** **Transit between custodial settings** **66. Ensure continuity of care between custodial settings including court, the receiving prison or during escort periods by, for example:** • **providing access to relevant information from the patient record** • **providing any medicines (including controlled drugs) – see also recommendations 53-58 on continuity of medicines** • **issuing an FP10 prescription.** **Before release from prison** **67. Carry out a pre-release health assessment. This should be led by primary healthcare and involve multidisciplinary team members and the person. It should take place at least 1 month before the date the person is expected to be released.** **68. For people who may be in prison for less than 1 month, plan pre-**

	release health assessments during the second-stage health assessment (see recommendation 31 for details of this assessment).
	
	69. Include the following in the person's care summary and post-release action plan:
	• **any significant health events that affected the person while they were in prison, for example:**
	  o **new diagnoses**
	  o **hospital admissions**
	  o **instances of self-harm**
	• **any health or social care provided in prison**
	• **details of any ongoing health and social care needs, including:**
	  o **medicines they are taking (see recommendations 53-55)**
	  o **mental health or substance misuse**
	• **future health and social care appointments, including appointments with:**
	  o **secondary and tertiary care**
	  o **mental health services**
	  o **substance misuse services**
	  o **social services.**
	
	70. Give the person a copy of the care summary and post-release plan and also send a copy to the person's GP (if they are registered with one).
	
	71. Help people who are being released from prison to find and register with a community GP if they are not already registered with one.
	
	72. Before the person is released, liaise with services that will be providing care and support to them after they leave prison. This should include (as needed):
	• **secondary and tertiary specialist services (for example HIV, TB, oncology)**
	• **mental health or learning disability services**
	• **substance misuse services**
	• **social services**
	• **external agencies such as home care.**

Barriers and facilitators	The GDG noted that the evidence identified barriers and facilitators to ensuring the continuity of healthcare in the following setting transitions: from community to prison, prison to prison and prison to community. The GDG agreed with the identified themes as barriers and facilitators in these settings. The following barriers were identified in this review: records not being transferred between settings; information being stored in an incorrect location; missing or incomplete information in records; escort staff lacking information about prisoners; prisoners lacking knowledge about services provided in the community; loss of contact with healthcare professionals in the community on entry to prison; poor communication between prison and community services; perceived barriers to sharing appropriate information; former prisoners' lack of motivation; former prisoners viewing health as a low priority; uncertainty regarding release dates; conditions of parole; burden on family and probation workers; lack of time and understaffing; differences in services between prisons; difficulty accessing services in community; difficulties accessing transportation in the community. The following facilitators were identified: patient-centred discharge planning with a multi-disciplinary team; supporting registering with or identifying a GP pre-release; booking appointments with community services pre-release; case management and communication between former prisoners and healthcare professionals in prison post-release; support from family, case workers and probation officers.
Trade-off between net clinical effects and costs	No published economic evaluations were identified. The GDG noted the clinical benefits of continuity of care at the point of entry and release from prisons. Costs related to these recommendations would include the time spent on administrative tasks (request of medical records from community primary care on reception, sending a care summary before release) and the face to face pre-release health assessment. It was highlighted that there is already existing prisons policy (PSO 3050) regarding continuity of care, though this is inconsistently applied, therefore no major changes in clinical practice would be expected as a result of these recommendations. The GDG noted that consistently sharing people in prisons' medical records for their own best interest would probably lead to the avoidance of duplication of healthcare activities in and out of prisons (for example, the equivalent of the comprehensive health assessment conducted in prisons would not need to be repeated upon release). It was also highlighted that there is a health information system currently under development for the prison service will better facilitate the sharing of medical records between prisons and community healthcare practices. The GDG noted that pre-release health assessments may not currently be conducted consistently across prisons and therefore relevant recommendations may bring a shift to practice. However, it was highlighted that people in prisons with no/few health issues may not need to be present during their assessment and therefore most of these are expected to be brief. The GDG therefore considered that any additional administrative tasks and upfront planning are likely to be cost saving and highly likely to be cost-effective for the NHS as a whole at the NICE cost-effectiveness threshold of £20,000 per QALY gained when compared to no support on release from prison.
Quality of evidence	The overall quality of the evidence was low to very low. The majority of studies were conducted in the UK and were very applicable. A few studies were conducted in Australia or in the USA; these were downgraded for applicability due to variations in the prison and healthcare systems compared to the UK. The GDG noted that one study was based in Australia and had an aboriginal population – the GDG agreed that although the aboriginal population is segregated from the rest of the population in Australian prisons, the themes identified in the study were still applicable to the UK prison setting. The GDG also mentioned that the availability of transport subtheme,

	even though based on USA data, was still applicable to the UK. Some themes showed theme saturation: information missing or incomplete; knowledge of healthcare services available in the community; registering with a community GP pre-release; booking appointments in community pre-release. However many of the themes showed limited theme saturation as the theme was only identified in a couple of studies and the data was not rich, or no saturation where the theme was identified in one study. The GDG noted that barriers and facilitators to continuity of care in the following circumstances were not identified: prison to court; court to prison; prison to hospital; hospital to prison; transport to or from other detention centres
Other considerations	The GDG noted that there is current prison policy on ensuring continuity of healthcare for prisoners (HM Prison Service 2006, Prison Service Order 3050[45]). The GDG also noted that the NICE 2012 'Patient experience in adult NHS services: improving the experience of care for people using adult NHS services' [CG138][69] guideline provides guidance on ensuring continuity of care. **On entry to prison** The GDG noted that on reception to prison, prison healthcare would contact primary healthcare in the community to attain the person's medical record. The GDG noted that primary community healthcare should provide prison healthcare with relevant information from the person's medical records, where consent has been obtained[32] or that it is in the persons best interest, in line with the Caldicott 2013[14] principles. The group also discussed that there will be provision for temporary registration of those who wish to remain registered with their community GP, such as those serving very short sentences. In addition it was also recommended that any relevant medical records from secondary care also be transferred on entry to prison. **Transit between custodial settings** The GDG recommended ensuring continuity of care between custodial settings, including court and discussed patient records, medicines (see continuity of medications section) or FP10 prescriptions. The group discussed that relevant information from patient records (for example if the person is a diabetic) should be shared with staff responsible for the person being transferred from prison, which includes escort staff. It was acknowledged that any medicine being transferred with the person leaving prison would be held with the escort staff until arrival at the new location. An FP10 may be appropriate to be issued to ensure continued supply of medication, if for example the person is attending court and there is the possibility that they will be released that day. Although there was no evidence for transfer between custodial settings the GDG felt the evidence identified from entry and exit from prison were also applicable to these circumstances (themes around information and knowledge, and communication and planning continuity as barriers to continuity of care) and made a consensus recommendation based on their expert opinion. The GDG noted that for people who are on remand and are going to court, a health discharge summary would be written using the electronic clinical records system before the court date to send on to GP if they are released. **Before release from prison** The GDG discussed when the pre-release health assessment should occur. The GDG noted that the 'End of custody' license mentioned in the uncertainty regarding release dates subtheme, which allowed release of prisoners up to 18 days early, was abolished in 2010. PSI 13/2013,[115] an update to the 2002 PSO on sentence calculation, states that there are 2 opportunities for health to be informed, firstly that release dates must be calculated within 5 working days of reception following sentencing and at reception on transfer to another establishment. Secondly, that

calculations must be checked 14 calendar days and 2 working days prior to release.

The GDG agreed that in order to maximise the number of people to have a pre-release health assessment this should occur at least 1 month before the person's expected release date. This was noted to accommodate the re-prescription of medicines on release, which are given on a 28 day cycle. However the GDG noted people may still not receive this assessment, for example who are released unexpectedly.

The GDG noted that the evidence identified in the review suggested that discharge planning might be improved by the input of members of different teams (for example primary care, mental health, substance misuse, social services). The GDG also thought that discharge planning should be led by primary care and involve the input of multidisciplinary team members involved in the person's care. The GDG agreed that discharge planning should always include the person who is being discharged and agree it should be centred around their circumstances and preferences in accordance with the NICE 2012 Patient experience guidance.[69]

The GDG thought that details of the person's care summary and action plan should be given to the person as well as being sent to the person's GP. The GDG agreed that it was important to give a summary to the person, as people with no fixed address may find it difficult to register with a GP in the community before release and to access services in the community - the provision of this summary would help to ensure continuity of care in these cases.

If the person does not have a GP, registration should be supported, for example by identifying local GPs via NHS choices website. The GDG noted that people in prison not having a registered GP in the community was a common barrier to continuity of care between prison and the community. The GDG acknowledged current guidance from NHS England[121] which states that people released from prison should have equitable access to primary services. The GDG agreed that healthcare staff should encourage and assist people in prison to register with a GP in the community before release. The GDG also agreed that usual practice is for a care summary and post-release action plan to be sent to GPs in the community before release, subject to consent being given.

The GDG noted that primary healthcare could liaise with any other people who are involved in the person's care (for example secondary and tertiary specialists, external agencies) to provide them with relevant information about the person, their care plan and the person's expected release dates. The GDG also noted that, when necessary, primary care should liaise with external agencies to arrange the provision of health and social care needs before release, such as any assessments needed or , appointments with community services.

The GDG discussed the current practice with regards to discharge planning and noted that many prisons use a discharge checklist to assess the status of people before leaving prison. The GDG noted that the use and content of discharge checklists varied throughout the UK. The GDG agreed that discharge planning should involve providing a summary of any significant events that occurred in prison (for example new diagnoses, hospital admissions, instances of self-harm), the care provided in prison and a care plan for the person's health care, including any future appointments.

The GDG noted that the 'Transfer Rehabilitation' strategy,[65] in which prisoners are transferred to a local prison before release, may be a barrier to providing a health assessment before release due to unclear division of responsibility.

The GDG noted that some people in prison may not give consent for transfer of information regarding health or social care due to concerns about confidentiality and privacy. The GDG discussed this and noted that some people may not want their community GP to know that they have been in prison. The GDG highlighted the

	importance of gaining consent before the transfer of records back to the community. The GDG noted the evidence highlighted that having no fixed address was a barrier to continuity of care. In such cases they agreed it would be beneficial to give people a care summary and post-release action plan on release, which they could hand to the relevant health professional when needed. The GDG discussed access to transportation as a barrier to care after leaving prison and noted that limited financial resources can act as a barrier to getting public transport to healthcare appointments.

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12 Reference list

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13 Acronyms and abbreviations

Term	Definition
AAA	Abdominal aortic aneurysm
ACCT	Assessment care in custody and teamwork
ART	Antiretroviral therapy
BBV	Blood-borne virus
BMI	Body mass index
BNF	British National Formulary
BP	Blood pressure
CARAT	Counselling, assessment, referral, advice and throughcare
CHAT	Comprehensive health assessment tool
CJS	Criminal justice system
CPR	Cardiopulmonary resuscitation
DNA	Did not attend
DOT	Directly observed therapy
EPP	Expert patients programme
HIV	Human immunodeficiency virus
HMPS	Her Majesty's prison service
HMIP	Her Majesty’s inspectorate of probation
IMB	Independent monitoring board
IRC	Immigration removal centre
MEMS	Medication event monitoring system
NFA	No fixed address
NOMS	National offender management service
NPSA	National Patient Safety Agency
NRT	Nortriptyline
P-ASRO	Prison- addressing substance related offending
PER form	Person escort record form
PPO	Prisons and Probation Ombudsman
Prison-NOMIS	Prison national offender management information system
PSI	Prison service instructions
PSO	Prison service orders
RAPt	Rehabilitation for addicted prisoners trust
RGN	Registered general nurse
RMN	Registered mental health nurse
SAT	Self-administered therapy
STC	Secure training centre
STD	Sexually transmitted disease
TB	Tuberculosis

Term	Definition
TTO	'To take out'
UKBA	United Kingdom border agency
UKMI	UK Medicines Information
YOI	Young offender institution

14 Glossary

The NICE Glossary can be found at www.nice.org.uk/glossary.

14.1 Guideline-specific terms

Term	Definition
Abdominal aortic aneurysm (AAA)	An abdominal aortic aneurysm (AAA) is a swelling (aneurysm) of the aorta – the main blood vessel that leads away from the heart, down through the abdomen to the rest of the body. Aneurysms can be very serious. If a large aneurysm bursts, it causes massive internal bleeding and is usually fatal.
Assessment care in custody and teamwork (ACCT)	When a member of staff receives information, including that from family members or external agencies, or observes behaviour which may indicate a risk of suicide and self-harm of a person in prison, they must open an ACCT by completing the Concern and Keep Safe form. Once an ACCT is opened a care-planning system which aims to reduce risk of or suicide and self-harm is initiated, which includes: talking to the person and completing an Immediate Action Plan (IAP); ensuring that they have been offered, where available, the opportunity to talk to a Listener and/or Samaritans; informing relevant staff members (for example healthcare); recording the opening of ACCT in prison and healthcare records; and regular assessments of the person's risk of self-harm.
Adrenoceptor agonist	A class of drugs that is particularly used to manage cardiac arrhythmias, and to protect the heart from a second heart attack (myocardial infarction) after a first heart attack.
Anticoagulant	An anticoagulant is a medicine that helps prevent blood clots.
Antiretroviral therapy (ART)	Antiretroviral therapy (ART) consists of taking a combination of a number of different antiretroviral (ARV) drugs together, which function to maximally suppress the HIV virus, as HIV can quickly adapt and become resistant to one single ARV, and stop the progression of HIV disease.
Barrier methods	Devices such as condoms and dental dams which may be used during sexual intercourse to reduce the probability of spreading sexually transmitted diseases (STDs).
Blood-borne virus (BBV)	A blood-borne virus (sometimes referred to as a blood-borne disease) is one that can be spread through contamination by blood and other body fluids. The most common examples are HIV, hepatitis B, and viral haemorrhagic fevers.
Blag	In the prison jargon, to feign illness to get additional medication or to miss work.
Blagger	One who blags (see 'blag').
Body mass index (BMI)	BMI is a measure of body fat based on height and weight that applies to adult men and women.
British National Formulary (BNF)	The British National Formulary is a pharmaceutical reference book that contains a wide spectrum of information and advice on prescribing and pharmacology, along with specific facts and details about many medicines available on the National Health Service (NHS).
Blood pressure (BP)	Blood pressure is the pressure exerted by circulating blood upon the walls of

Term	Definition
	blood vessels. When used without further specification, "blood pressure" usually refers to the arterial pressure in the systemic circulation.
Braille	Braille is a tactile writing system used by people who are blind or visually impaired.
Bronchodilator	Bronchodilator medicines, or bronchodilators, make breathing easier by relaxing the muscles in the lungs and widening the airways (bronchi).
Counseling, assessment, referral, advice and throughcare (CARAT)	Drug treatment service available in prisons in England and Wales as part of the Prison service drug strategy.
Comprehensive Health Assessment Tool (CHAT)	. CHAT is a validated assessment tool that is used to assess the health needs of younger people in the youth justice system.
Clinks	Organisation supporting voluntary organisations working within the Criminal Justice System in England and Wales.
Criminal justice system (CJS)	Public service covering England and Wales which includes police, the Crown prosecution service, the courts, prisons and probation work.
Cardiopulmonary resuscitation (CPR)	CPR is a lifesaving technique useful in many emergencies, including heart attack or near drowning, in which someone's breathing or heartbeat has stopped.
Coeliac disease	A disease in which the small intestine is hypersensitive to gluten, leading to difficulty in digesting food.
Corticosteroid	Corticosteroids, often known as steroids, are an anti-inflammatory medicine prescribed for a wide range of conditions.
Cycloplegic	A cycloplegic eye drop is an eye drop that temporarily paralyzes the ciliary body, allowing a doctor to fully measure a patient’s vision problem.
Detention	The process of keeping a person held in custody.
Diversion (medication)	The transfer of any prescription medicines from the individual for whom they were prescribed to another person for misuse.
Did not attend (DNA)	Term used for a patient who missed a healthcare appointment.
Directly observed therapy (DOT)	Term referring to a treatment method in which patients are directly observed when receiving treatment or taking their medication. See ‘SAT’.
Expert patients programme (EPP)	NHS self-management programme for people living with a long-term (chronic) condition.
FP10 (prison-issued)	A prescription form. People who are released from prison unexpectedly can take an FP10 to a community pharmacy to obtain their medicines free of charge until they can arrange to see their GP or register with a new GP.
Grab bag	Medical emergency bags containing equipment and medication for dealing with common medical emergencies. The equipment may include dressings, automatic external defibrillator (AED), and oxygen. It may also include medication, for example for treating allergic reactions (anaphylaxis).”
GMS1 form	NHS family doctor services registration form. Form completed at registration with a GP practice. When the GP signs the form they assume responsibility for the patient and can retrieve the patient’s records.
Human immunodeficiency	HIV is a virus that attacks the immune system and weakens the ability to fight

Term	Definition
virus (HIV)	infections and disease. It is most commonly caught by unprotected sexual contact (i.e., without a condom).
Her Majesty's prison service (HMPS)	HMPS is a part of the National offender management service of Her Majesty's government, which is responsible for managing most of the prisons in England and Wales.
Her Majesty's Inspectorate of Prisons for England and Wales. (HMIP)	Independent inspectorate which reports on conditions and treatment of those in prison, young offender institutions, secure training centres, immigration detention facilities, police and court custody suites, customs detention facilities and military detention. The role of HM Inspectorate of Prisons is to provide independent scrutiny of the conditions for and treatment of prisoners and other detainees, promoting the concept of 'healthy establishments' in which staff work effectively to support prisoners and detainees to reduce reoffending and achieve positive outcomes for those detained and for the public.
Independent monitoring boards (IMB)	Boards of independent members of the public monitoring the day-to-day life in their local prison or removal centre and ensuring that proper standards of care and decency are maintained.
In-possession	Medication is held in-possession when a person is responsible for holding and administering their own medication.
Immigration removal centre (IRC)	Holding centres for foreign nationals who are awaiting decisions on their asylum claims, or who are awaiting deportation due to their application for asylum being rejected, having their visa expiring or not having complied with their visa terms, or lacking the required documentation to live in the UK .
Mammogram	A mammogram is an X-ray of the breast. It can help to detect breast cancer early as part of a breast cancer screening programme.
Medicines reconciliation	The process of identifying the most accurate list of a person’s current medicines (including the name, dosage, frequency and route) and comparing them to the current list in use, recognising discrepancies and documenting any changes.
Medication event monitoring system (MEMS)	A device used to monitor medication adherence. MEMS consists of a medicine container fitted with a special closure that records the time and date each time the container is opened and closed.
Mental Health In-Reach Teams	Mental health in-reach teams have been established in prisons across England and Wales to provide an equivalent service to a Community mental health team in the identification and treatment of mental disorders.
Multidisciplinary team	A specialist team made up of different types of experts who meet and discuss how to address the needs of people requiring the intervention of more than one kind of professional. In prisons settings, a multidisciplinary team may include medical staff, including mental and physical health professionals, prison staff, chaplains and other agency staff, such as UK Border Agency.
Mydriatic	A mydriatic is an agent that induces dilation of the pupil. It is used in medicine to permit examination of the retina and other deep structures of the eye, and also to reduce painful ciliary muscle spasm (see cycloplegic).
No fixed address (NFA)	Term referring to a person without a home.
Nitrate	Nitrates are medicines that help easing and preventing angina pain.
National offender management service	Executive agency of the Ministry of Justice tasked with managing the correctional services in England and Wales.

Term	Definition
(NOMS)	
National Patient Safety Agency (NPSA)	Special health authority of the National Health Service in England whose mandate was to identify and address patient safety issues. In 2012 the key functions of the NPSA were transferred to the NHS Commissioning Board Special Health Authority.
Nortriptyline	Nortriptyline is a tricyclic antidepressant.
Nicotine replacement therapy (NRT)	A type of treatment that uses special products to give small, steady doses of nicotine to help stop cravings and relieve symptoms that occur when a person is trying to quit smoking. These products include nicotine patch, nicotine inhaler, nicotine nasal spray and nicotine lozenges.
Parole	The provisional release of a person in prison who is subject to continued monitoring and agrees to certain conditions prior to the maximum sentence period. If an individual breaks the terms of the condition they can be recalled to prison to complete their sentence.
Prison- addressing substance related offending (P-ASRO)	A cognitive-behavioural intervention that was offered by prisons in England and Wales intended to address offending related to substance misuse.
Person escort record form (PER form)	Document provided when a person is being transferred or moved from an establishment (such as court, hospital, prison) to prison. It is addressed to the relevant prison staff which includes the necessary information to enable safe transfer and reception of detainees, including any risks or vulnerabilities that the person may present.
Prisons and Probation Ombudsman (PPO)	The Prisons and Probation Ombudsman for England and Wales is an independent body appointed by the Secretary of State for Justice to investigate complaints made by people in prison, young people in detention (prisons and secure training centres), offenders under probation supervision and immigration detainees. The organisation is also responsible to investigate all deaths of people in prison, young people in detention, approved premises' residents and immigration detainees due to any cause.
Prison-NOMIS	'Prison national offender management information system'. Operational database issued on the authority of the NOMS Agency Board used in prisons for the management of offenders.
Probation	Where a person serves a sentence in the community.
Parole	Where a person who has been sentenced is allowed to be released from custody before the end of their sentence or to be transferred to an open prison. A person on parole may be kept under supervision ('on licence') or on probation.
Prison service instructions (PSI)	A published body of regulations by which the HMPS is run. All Prison Service operating instructions are published as PSIs. PSIs have a fixed expiry date. See 'PSO'.
Prison service orders (PSO)	A published body of regulations by which the HMPS is run. More specifically, Prison service orders are long-term mandatory instructions which are intended to remain in force until cancelled. See 'PSI'.
Remand	The process of keeping a person who has been arrested in custody, normally in a remand prison, prior to a hearing to a magistrates' court. Depending on

Term	Definition
	the nature of the offence, the person may be remanded to prison again until their case is heard in a crown court.
Registered general nurse (RGN)	In the UK, a nurse who has taken a degree course and received training in all aspects of nursing care to enable him or her to be registered with the nursing and midwifery council (NMC) as an RGN.
Registered mental health nurse (RMN)	In the UK, a nurse who has taken a degree course and received training in mental health aspects of nursing care to enable him or her to be registered with the nursing and midwifery council (NMC) as an RMN.
Self-administered therapy (SAT)	Where people administer their own medication without being directly observed by a healthcare professional or prison staff. See 'DOT'.
Smear cervical screening test	A smear cervical screening test is a method of detecting abnormal cells on the cervix. Detecting and removing abnormal cervical cells can prevent cervical cancer.
Secure training centre(STC)	In the UK, centres for children aged 12 to 17 who have been remanded or sentenced to periods of detention that are ran by private companies.
Sexually transmitted infection (STI)	See 'STD'.
Sexually transmitted disease (STD)	An STD (also referred to as STI, sexually transmitted infection) is an infection that is spread by sexual contact, especially vaginal intercourse, anal sex and oral sex.
SystmOne	Clinical computer system used by healthcare professionals in England and Wales for a variety of care settings. The system is being deployed as one of the accredited systems in the modernisation of IT in the NHS.
Tuberculosis (TB)	Tuberculosis is a bacterial infection spread through inhaling droplets from the coughs or sneezes of an infected person. TB mainly affects the lungs. However, it can affect any part of the body, including the glands, bones and nervous system.
To take out (TTO)	Medicines that are given to a person on discharge from prison or transfer between prisons.
Urinalysis	A urinalysis, also known as routine and microscopy (R&M), is an array of tests performed on urine, and one of the most common methods of medical diagnosis.
United Kingdom border agency (UKBA)	UKBA was the border control agency of the Government of the United Kingdom until April 2013, when its functions returned to the Home Office.
United Kingdom Medicines Information (UKMi)	UKMi is an NHS pharmacy based service.
Young offender institution (YOI)	An HMPS correctional establishment for offenders under 21 years of age.

1

14.2 General terms

Term	Definition
Abstract	Summary of a study, which may be published alone or as an introduction to a full scientific paper.

Term	Definition
Algorithm (in guidelines)	A flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.
Allocation concealment	The process used to prevent advance knowledge of group assignment in an RCT. The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone who is not responsible for recruiting participants.
Applicability	How well the results of a study or NICE evidence review can answer a clinical question or be applied to the population being considered.
Arm (of a clinical study)	Subsection of individuals within a study who receive one particular intervention, for example placebo arm.
Association	Statistical relationship between 2 or more events, characteristics or other variables. The relationship may or may not be causal.
Base case analysis	In an economic evaluation, this is the main analysis based on the most plausible estimate of each input. In contrast, see Sensitivity analysis.
Baseline	The initial set of measurements at the beginning of a study (after run-in period where applicable), with which subsequent results are compared.
Bayesian analysis	A method of statistics, where a statistic is estimated by combining established information or belief (the 'prior') with new evidence (the 'likelihood') to give a revised estimate (the 'posterior').
Before-and-after study	A study that investigates the effects of an intervention by measuring particular characteristics of a population both before and after taking the intervention, and assessing any change that occurs.
Bias	Influences on a study that can make the results look better or worse than they really are. (Bias can even make it look as if a treatment works when it does not.) Bias can occur by chance, deliberately or as a result of systematic errors in the design and execution of a study. It can also occur at different stages in the research process, for example, during the collection, analysis, interpretation, publication or review of research data. For examples see selection bias, performance bias, information bias, confounding factor, and publication bias.
Blinding	A way to prevent researchers, doctors and patients in a clinical trial from knowing which study group each patient is in so they cannot influence the results. The best way to do this is by sorting patients into study groups randomly. The purpose of 'blinding' or 'masking' is to protect against bias. A single-blinded study is one in which patients do not know which study group they are in (for example whether they are taking the experimental drug or a placebo). A double-blinded study is one in which neither patients nor the researchers and doctors know which study group the patients are in. A triple blind study is one in which neither the patients, clinicians or the people carrying out the statistical analysis know which treatment patients received.
Carer (caregiver)	Someone who looks after family, partners or friends in need of help because they are ill, frail or have a disability.
Case–control study	A study to find out the cause(s) of a disease or condition. This is done by comparing a group of patients who have the disease or condition (cases) with a group of people who do not have it (controls) but who are otherwise as similar as possible (in characteristics thought to be unrelated to the causes of the disease or condition). This means the researcher can look for aspects of their lives that differ to see if they may cause the condition. For example, a group of people with lung cancer might be compared with a group of people the same age that do not have lung cancer. The researcher could compare how long both groups had been exposed to tobacco smoke.

Term	Definition
	Such studies are retrospective because they look back in time from the outcome to the possible causes of a disease or condition.
Case series	Report of a number of cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (control) group of patients.
Clinical efficacy	The extent to which an intervention is active when studied under controlled research conditions.
Clinical effectiveness	How well a specific test or treatment works when used in the 'real world' (for example, when used by a doctor with a patient at home), rather than in a carefully controlled clinical trial. Trials that assess clinical effectiveness are sometimes called management trials. Clinical effectiveness is not the same as efficacy.
Clinician	A healthcare professional who provides patient care. For example, a doctor, nurse or physiotherapist.
Cochrane Review	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration).
Cohort study	A study with 2 or more groups of people – cohorts – with similar characteristics. One group receives a treatment, is exposed to a risk factor or has a particular symptom and the other group does not. The study follows their progress over time and records what happens. See also observational study.
Comorbidity	A disease or condition that someone has in addition to the health problem being studied or treated.
Comparability	Similarity of the groups in characteristics likely to affect the study results (such as health status or age).
Concordance	This is a recent term whose meaning has changed. It was initially applied to the consultation process in which doctor and patient agree therapeutic decisions that incorporate their respective views, but now includes patient support in medicine taking as well as prescribing communication. Concordance reflects social values but does not address medicine-taking and may not lead to improved adherence.
Confidence interval (CI)	There is always some uncertainty in research. This is because a small group of patients is studied to predict the effects of a treatment on the wider population. The confidence interval is a way of expressing how certain we are about the findings from a study, using statistics. It gives a range of results that is likely to include the 'true' value for the population. The CI is usually stated as '95% CI', which means that the range of values has a 95 in a 100 chance of including the 'true' value. For example, a study may state that "based on our sample findings, we are 95% certain that the 'true' population blood pressure is not higher than 150 and not lower than 110". In such a case the 95% CI would be 110 to 150. A wide confidence interval indicates a lack of certainty about the true effect of the test or treatment – often because a small group of patients has been studied. A narrow confidence interval indicates a more precise estimate (for example, if a large number of patients have been studied).
Confounding factor	Something that influences a study and can result in misleading findings if it is not understood or appropriately dealt with. For example, a study of heart disease may look at a group of people that exercises regularly and a group that does not exercise. If the ages of the people in the 2 groups are different, then any difference in heart disease rates between the 2 groups could be because of age rather than exercise.

Term	Definition
	Therefore age is a confounding factor.
Consensus methods	Techniques used to reach agreement on a particular issue. Consensus methods may be used to develop NICE guidance if there is not enough good quality research evidence to give a clear answer to a question. Formal consensus methods include Delphi and nominal group techniques.
Control group	A group of people in a study who do not receive the treatment or test being studied. Instead, they may receive the standard treatment (sometimes called 'usual care') or a dummy treatment (placebo). The results for the control group are compared with those for a group receiving the treatment being tested. The aim is to check for any differences. Ideally, the people in the control group should be as similar as possible to those in the treatment group, to make it as easy as possible to detect any effects due to the treatment.
Cost-benefit analysis (CBA)	Cost-benefit analysis is one of the tools used to carry out an economic evaluation. The costs and benefits are measured using the same monetary units (for example, pounds sterling) to see whether the benefits exceed the costs.
Cost-consequences analysis (CCA)	Cost-consequences analysis is one of the tools used to carry out an economic evaluation. This compares the costs (such as treatment and hospital care) and the consequences (such as health outcomes) of a test or treatment with a suitable alternative. Unlike cost-benefit analysis or cost-effectiveness analysis, it does not attempt to summarise outcomes in a single measure (like the quality-adjusted life year) or in financial terms. Instead, outcomes are shown in their natural units (some of which may be monetary) and it is left to decision-makers to determine whether, overall, the treatment is worth carrying out.
Cost-effectiveness analysis (CEA)	Cost-effectiveness analysis is one of the tools used to carry out an economic evaluation. The benefits are expressed in non-monetary terms related to health, such as symptom-free days, heart attacks avoided, deaths avoided or life years gained (that is, the number of years by which life is extended as a result of the intervention).
Cost-effectiveness model	An explicit mathematical framework, which is used to represent clinical decision problems and incorporate evidence from a variety of sources in order to estimate the costs and health outcomes.
Cost-utility analysis (CUA)	Cost-utility analysis is one of the tools used to carry out an economic evaluation. The benefits are assessed in terms of both quality and duration of life, and expressed as quality-adjusted life years (QALYs). See also utility.
Credible interval (CrI)	The Bayesian equivalent of a confidence interval.
Decision analysis	An explicit quantitative approach to decision-making under uncertainty, based on evidence from research. This evidence is translated into probabilities, and then into diagrams or decision trees which direct the clinician through a succession of possible scenarios, actions and outcomes.
Deterministic analysis	In economic evaluation, this is an analysis that uses a point estimate for each input. In contrast, see Probabilistic analysis
Diagnostic odds ratio	The diagnostic odds ratio is a measure of the effectiveness of a diagnostic test. It is defined as the ratio of the odds of the test being positive if the subject has a disease relative to the odds of the test being positive if the subject does not have the disease.
Discounting	Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.

Term	Definition
Disutility	The loss of quality of life associated with having a disease or condition. See Utility
Dominance	A health economics term. When comparing tests or treatments, an option that is both less effective and costs more is said to be 'dominated' by the alternative.
Drop-out	A participant who withdraws from a trial before the end.
Economic evaluation	An economic evaluation is used to assess the cost-effectiveness of healthcare interventions (that is, to compare the costs and benefits of a healthcare intervention to assess whether it is worth doing). The aim of an economic evaluation is to maximise the level of benefits – health effects – relative to the resources available. It should be used to inform and support the decision-making process; it is not supposed to replace the judgement of healthcare professionals. There are several types of economic evaluation: cost-benefit analysis, cost-consequences analysis, cost-effectiveness analysis, cost-minimisation analysis and cost-utility analysis. They use similar methods to define and evaluate costs, but differ in the way they estimate the benefits of a particular drug, programme or intervention.
Effect (as in effect measure, treatment effect, estimate of effect, effect size)	A measure that shows the magnitude of the outcome in one group compared with that in a control group. For example, if the absolute risk reduction is shown to be 5% and it is the outcome of interest, the effect size is 5%. The effect size is usually tested, using statistics, to find out how likely it is that the effect is a result of the treatment and has not just happened by chance (that is, to see if it is statistically significant).
Effectiveness	How beneficial a test or treatment is under usual or everyday conditions, compared with doing nothing or opting for another type of care.
Efficacy	How beneficial a test, treatment or public health intervention is under ideal conditions (for example, in a laboratory), compared with doing nothing or opting for another type of care.
Epidemiological study	The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences (for example, infection, diet) and interventions.
EQ-5D (EuroQol 5 dimensions)	A standardised instrument used to measure health-related quality of life. It provides a single index value for health status.
Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals or patients).
Exclusion criteria (literature review)	Explicit standards used to decide which studies should be excluded from consideration as potential sources of evidence.
Exclusion criteria (clinical study)	Criteria that define who is not eligible to participate in a clinical study.
Extended dominance	If Option A is both more clinically effective than Option B and has a lower cost per unit of effect, when both are compared with a do-nothing alternative then Option A is said to have extended dominance over Option B. Option A is therefore cost-effective and should be preferred, other things remaining equal.
Extrapolation	An assumption that the results of studies of a specific population will also hold true for another population with similar characteristics.
Follow-up	Observation over a period of time of an individual, group or initially defined population whose appropriate characteristics have been assessed in order to observe changes in health status or health-related variables.

Term	Definition
Generalisability	The extent to which the results of a study hold true for groups that did not participate in the research. See also external validity.
Gold standard	A method, procedure or measurement that is widely accepted as being the best available to test for or treat a disease.
GRADE, GRADE profile	A system developed by the GRADE Working Group to address the shortcomings of present grading systems in healthcare. The GRADE system uses a common, sensible and transparent approach to grading the quality of evidence. The results of applying the GRADE system to clinical trial data are displayed in a table known as a GRADE profile.
Harms	Adverse effects of an intervention.
Health economics	Study or analysis of the cost of using and distributing healthcare resources.
Health-related quality of life (HRQoL)	A measure of the effects of an illness to see how it affects someone's day-to-day life.
Heterogeneity or Lack of homogeneity	The term is used in meta-analyses and systematic reviews to describe when the results of a test or treatment (or estimates of its effect) differ significantly in different studies. Such differences may occur as a result of differences in the populations studied, the outcome measures used or because of different definitions of the variables involved. It is the opposite of homogeneity.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of effect.
Inclusion criteria (literature review)	Explicit criteria used to decide which studies should be considered as potential sources of evidence.
Incremental analysis	The analysis of additional costs and additional clinical outcomes with different interventions.
Incremental cost	The extra cost linked to using one test or treatment rather than another. Or the additional cost of doing a test or providing a treatment more frequently.
Incremental cost-effectiveness ratio (ICER)	The difference in the mean costs in the population of interest divided by the differences in the mean outcomes in the population of interest for one treatment compared with another.
Incremental net benefit (INB)	The value (usually in monetary terms) of an intervention net of its cost compared with a comparator intervention. The INB can be calculated for a given cost-effectiveness (willingness to pay) threshold. If the threshold is £20,000 per QALY gained then the INB is calculated as: (£20,000 × QALYs gained) − Incremental cost.
Indirectness	The available evidence is different to the review question being addressed, in terms of PICO (population, intervention, comparison and outcome).
Intention-to-treat analysis (ITT)	An assessment of the people taking part in a clinical trial, based on the group they were initially (and randomly) allocated to. This is regardless of whether or not they dropped out, fully complied with the treatment or switched to an alternative treatment. Intention-to-treat analyses are often used to assess clinical effectiveness because they mirror actual practice: that is, not everyone complies with treatment and the treatment people receive may be changed according to how they respond to it.
Intervention	In medical terms this could be a drug treatment, surgical procedure, diagnostic or psychological therapy. Examples of public health interventions could include action to help someone to be physically active or to eat a more healthy diet.
Intraoperative	The period of time during a surgical procedure.

Term	Definition
Kappa statistic	A statistical measure of inter-rater agreement that takes into account the agreement occurring by chance.
Length of stay	The total number of days a participant stays in hospital.
Licence	See 'Product licence'.
Life years gained	Mean average years of life gained per person as a result of the intervention compared with an alternative intervention.
Likelihood ratio	The likelihood ratio combines information about the sensitivity and specificity. It tells you how much a positive or negative result changes the likelihood that a patient would have the disease. The likelihood ratio of a positive test result (LR+) is sensitivity divided by (1 minus specificity).
Long-term care	Residential care in a home that may include skilled nursing care and help with everyday activities. This includes nursing homes and residential homes.
Logistic regression or Logit model	In statistics, logistic regression is a type of analysis used for predicting the outcome of a binary dependent variable based on one or more predictor variables. It can be used to estimate the log of the odds (known as the 'logit').
Loss to follow-up	A patient, or the proportion of patients, actively participating in a clinical trial at the beginning, but whom the researchers were unable to trace or contact by the point of follow-up in the trial
Markov model	A method for estimating long-term costs and effects for recurrent or chronic conditions, based on health states and the probability of transition between them within a given time period (cycle).
Meta-analysis	A method often used in systematic reviews. Results from several studies of the same test or treatment are combined to estimate the overall effect of the treatment.
Multivariate model	A statistical model for analysis of the relationship between 2 or more predictor (independent) variables and the outcome (dependent) variable.
Negative predictive value (NPV)	In screening or diagnostic tests: A measure of the usefulness of a screening or diagnostic test. It is the proportion of those with a negative test result who do not have the disease, and can be interpreted as the probability that a negative test result is correct. It is calculated as follows: TN/(TN+FN)
Net monetary benefit (NMB)	The value in monetary terms of an intervention net of its cost. The NMB can be calculated for a given cost-effectiveness threshold. If the threshold is £20,000 per QALY gained then the NMB for an intervention is calculated as: (£20,000 × mean QALYs) − mean cost. The most preferable option (that is, the most clinically effective option to have an ICER below the threshold selected) will be the treatment with the highest NMB.
Number needed to treat (NNT)	The average number of patients who need to be treated to get a positive outcome. For example, if the NNT is 4, then 4 patients would have to be treated to ensure 1 of them gets better. The closer the NNT is to 1, the better the treatment. For example, if you give a stroke prevention drug to 20 people before 1 stroke is prevented, the number needed to treat is 20. See also number needed to harm, absolute risk reduction.
Observational study	Individuals or groups are observed or certain factors are measured. No attempt is made to affect the outcome. For example, an observational study of a disease or treatment would allow 'nature' or usual medical care to take its course. Changes or differences in one characteristic (for example, whether or not people received a specific treatment or intervention) are studied without intervening.

Term	Definition
	There is a greater risk of selection bias than in experimental studies.
Odds ratio	Odds are a way to represent how likely it is that something will happen (the probability). An odds ratio compares the probability of something in one group with the probability of the same thing in another. An odds ratio of 1 between 2 groups would show that the probability of the event (for example a person developing a disease, or a treatment working) is the same for both. An odds ratio greater than 1 means the event is more likely in the first group. An odds ratio less than 1 means that the event is less likely in the first group. Sometimes probability can be compared across more than 2 groups – in this case, one of the groups is chosen as the 'reference category', and the odds ratio is calculated for each group compared with the reference category. For example, to compare the risk of dying from lung cancer for non-smokers, occasional smokers and regular smokers, non-smokers could be used as the reference category. Odds ratios would be worked out for occasional smokers compared with non-smokers and for regular smokers compared with non-smokers. See also confidence interval, risk ratio.
Opportunity cost	The loss of other healthcare programmes displaced by investment in or introduction of another intervention. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.
Outcome	The impact that a test, treatment, policy, programme or other intervention has on a person, group or population. Outcomes from interventions to improve the public's health could include changes in knowledge and behaviour related to health, societal changes (for example, a reduction in crime rates) and a change in people's health and wellbeing or health status. In clinical terms, outcomes could include the number of patients who fully recover from an illness or the number of hospital admissions, and an improvement or deterioration in someone's health, functional ability, symptoms or situation. Researchers should decide what outcomes to measure before a study begins.
P value	The p value is a statistical measure that indicates whether or not an effect is statistically significant. For example, if a study comparing 2 treatments found that one seems more effective than the other, the p value is the probability of obtaining these results by chance. By convention, if the p value is below 0.05 (that is, there is less than a 5% probability that the results occurred by chance) it is considered that there probably is a real difference between treatments. If the p value is 0.001 or less (less than a 1% probability that the results occurred by chance), the result is seen as highly significant. If the p value shows that there is likely to be a difference between treatments, the confidence interval describes how big the difference in effect might be.
Placebo	A fake (or dummy) treatment given to participants in the control group of a clinical trial. It is indistinguishable from the actual treatment (which is given to participants in the experimental group). The aim is to determine what effect the experimental treatment has had – over and above any placebo effect caused because someone has received (or thinks they have received) care or attention.
Posterior distribution	In Bayesian statistics this is the probability distribution for a statistic based after combining established information or belief (the prior) with new

Term	Definition
	evidence (the likelihood).
Positive predictive value (PPV)	In screening or diagnostic tests: A measure of the usefulness of a screening or diagnostic test. It is the proportion of those with a positive test result who have the disease, and can be interpreted as the probability that a positive test result is correct. It is calculated as follows: TP/(TP+FP)
Post-test probability	In diagnostic tests: The proportion of patients with that particular test result who have the target disorder (post-test odds/[1 plus post-test odds]).
Power (statistical)	The ability to demonstrate an association when one exists. Power is related to sample size; the larger the sample size, the greater the power and the lower the risk that a possible association could be missed.
Pre-test probability	In diagnostic tests: The proportion of people with the target disorder in the population at risk at a specific time point or time interval. Prevalence may depend on how a disorder is diagnosed.
Prevalence	See Pre-test probability.
Prior distribution	In Bayesian statistics this is the probability distribution for a statistic based on previous evidence or belief.
Primary care	Healthcare delivered outside hospitals. It includes a range of services provided by GPs, nurses, health visitors, midwives and other healthcare professionals and allied health professionals such as dentists, pharmacists and opticians.
Primary outcome	The outcome of greatest importance, usually the one in a study that the power calculation is based on.
Probabilistic analysis	In economic evaluation, this is an analysis that uses a probability distribution for each input. In contrast, see Deterministic analysis.
Product licence	An authorisation from the MHRA to market a medicinal product.
Prognosis	A probable course or outcome of a disease. Prognostic factors are patient or disease characteristics that influence the course. Good prognosis is associated with low rate of undesirable outcomes; poor prognosis is associated with a high rate of undesirable outcomes.
Prospective study	A research study in which the health or other characteristic of participants is monitored (or 'followed up') for a period of time, with events recorded as they happen. This contrasts with retrospective studies.
Publication bias	Publication bias occurs when researchers publish the results of studies showing that a treatment works well and don't publish those showing it did not have any effect. If this happens, analysis of the published results will not give an accurate idea of how well the treatment works. This type of bias can be assessed by a funnel plot.
Quality of life	See 'Health-related quality of life'.
Quality-adjusted life year (QALY)	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality of life score (on a scale of 0 to 1). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.
Randomisation	Assigning participants in a research study to different groups without taking any similarities or differences between them into account. For

Term	Definition
	example, it could involve using a random numbers table or a computer-generated random sequence. It means that each individual (or each group in the case of cluster randomisation) has the same chance of receiving each intervention.
Randomised controlled trial (RCT)	A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug or treatment. One group (the experimental group) receives the treatment being tested, the other (the comparison or control group) receives an alternative treatment, a dummy treatment (placebo) or no treatment at all. The groups are followed up to see how effective the experimental treatment was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.
RCT	See 'Randomised controlled trial'.
Reference standard	The test that is considered to be the best available method to establish the presence or absence of the outcome – this may not be the one that is routinely used in practice.
Reporting bias	See 'Publication bias'.
Resource implication	The likely impact in terms of finance, workforce or other NHS resources.
Retrospective study	A research study that focuses on the past and present. The study examines past exposure to suspected risk factors for the disease or condition. Unlike prospective studies, it does not cover events that occur after the study group is selected.
Review question	In guideline development, this term refers to the questions about treatment and care that are formulated to guide the development of evidence-based recommendations.
Risk ratio (RR)	The ratio of the risk of disease or death among those exposed to certain conditions compared with the risk for those who are not exposed to the same conditions (for example, the risk of people who smoke getting lung cancer compared with the risk for people who do not smoke). If both groups face the same level of risk, the risk ratio is 1. If the first group had a risk ratio of 2, subjects in that group would be twice as likely to have the event happen. A risk ratio of less than 1 means the outcome is less likely in the first group. The risk ratio is sometimes referred to as relative risk.
Secondary outcome	An outcome used to evaluate additional effects of the intervention deemed a priori as being less important than the primary outcomes.
Selection bias	Selection bias occurs if: a) The characteristics of the people selected for a study differ from the wider population from which they have been drawn, or b) There are differences between groups of participants in a study in terms of how likely they are to get better.
Sensitivity	How well a test detects the thing it is testing for. If a diagnostic test for a disease has high sensitivity, it is likely to pick up all cases of the disease in people who have it (that is, give a 'true positive' result). But if a test is too sensitive it will sometimes also give a positive result in people who don't have the disease (that is, give a 'false positive'). For example, if a test were developed to detect if a woman is 6 months pregnant, a very sensitive test would detect everyone who was 6 months pregnant, but would probably also include those who are 5 and 7 months pregnant. If the same test were more specific (sometimes referred to as having

Term	Definition
	higher specificity), it would detect only those who are 6 months pregnant, and someone who was 5 months pregnant would get a negative result (a 'true negative'). But it would probably also miss some people who were 6 months pregnant (that is, give a 'false negative'). Breast screening is a 'real-life' example. The number of women who are recalled for a second breast screening test is relatively high because the test is very sensitive. If it were made more specific, people who don't have the disease would be less likely to be called back for a second test but more women who have the disease would be missed.
Sensitivity analysis	A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring the generalisability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results. One-way simple sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study. Multi-way simple sensitivity analysis (scenario analysis): 2 or more parameters are varied at the same time and the overall effect on the results is evaluated. Threshold sensitivity analysis: the critical value of parameters above or below which the conclusions of the study will change are identified. Probabilistic sensitivity analysis: probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analytical techniques (for example, Monte Carlo simulation).
Significance (statistical)	A result is deemed statistically significant if the probability of the result occurring by chance is less than 1 in 20 ($p<0.05$).
Specificity	The proportion of true negatives that are correctly identified as such. For example in diagnostic testing the specificity is the proportion of non-cases correctly diagnosed as non-cases. See related term 'Sensitivity'. In terms of literature searching a highly specific search is generally narrow and aimed at picking up the key papers in a field and avoiding a wide range of papers.
Stakeholder	An organisation with an interest in a topic that NICE is developing a guideline or piece of public health guidance on. Organisations that register as stakeholders can comment on the draft scope and the draft guidance. Stakeholders may be: • manufacturers of drugs or equipment • national patient and carer organisations • NHS organisations • organisations representing healthcare professionals.
State transition model	See Markov model
Systematic review	A review in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. It may include a meta-analysis.
Time horizon	The time span over which costs and health outcomes are considered in a decision analysis or economic evaluation.
Transition probability	In a state transition model (Markov model), this is the probability of moving from one health state to another over a specific period of time.
Treatment allocation	Assigning a participant to a particular arm of a trial.

Term	Definition
Univariate	Analysis which separately explores each variable in a data set.
Utility	In health economics, a 'utility' is the measure of the preference or value that an individual or society places upon a particular health state. It is generally a number between 0 (representing death) and 1 (perfect health). The most widely used measure of benefit in cost–utility analysis is the quality-adjusted life year, but other measures include disability-adjusted life years (DALYs) and healthy year equivalents (HYEs).

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