NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Scope of guidelines

Managing common infections: antimicrobial prescribing guidelines

The Department of Health in England has asked NICE to develop a suite of evidence-based guidelines for managing common infection syndromes, in the context of tackling antimicrobial resistance – specifically in relation to bacterial infection and antibiotic use.

The suite of guidelines will be developed using the interim process guide for antimicrobial prescribing guidelines which is based on Developing NICE guidelines: the manual.

1 Why the guidelines are needed

Resistance to antimicrobials is complex (see the Department of Health's Antimicrobial resistance systems map) and increasing. Combined with a lack of new antimicrobial medicines, there is a growing risk that infections may not be treatable in the future.

The World Health Organization states that 'antimicrobial resistance occurs when microorganisms such as bacteria, viruses, fungi and parasites change in ways that render the medications used to cure the infections they cause ineffective' (Antimicrobial resistance).

The Annual Report of the Chief Medical Officer, volume two, 2011, Infections and the rise of antimicrobial resistance (Department of Health) states that antimicrobial stewardship 'embodies an organisational or healthcare-system-wide approach to promoting and monitoring judicious use of antimicrobials to preserve their future effectiveness'. The report also states that evidence-based guidance is needed for antimicrobial use to help slow development of antimicrobial resistance.

To support this, the Department of Health's UK five year antimicrobial resistance strategy 2013 to 2018 recommends that NICE: 'works with other delivery partners to consider the development of comprehensive evidence-based antimicrobial prescribing guidance for primary and secondary care, supporting work to encourage responsible use of antibiotics, improving professional knowledge and clinical practice with respect to antimicrobial stewardship'.

Several important factors affect how an infection occurs, how is it managed and whether antimicrobials are needed for treatment. NICE has published a guideline on antimicrobial stewardship (systems and processes for effective antimicrobial medicine use) and in January 2017 will publish a complementary guideline on antimicrobial stewardship (changing risk-related behaviours in the general population).

2 Who the guidelines are for

People using services, their families and carers, and the public will be able to use the guidelines to find out more about what NICE recommends and help them make decisions. More specifically, the following groups will find these guidelines useful:

- prescribers (including non-medical prescribers)
- health and social care practitioners working in all care settings
- people receiving care for common infections covered by the guidelines, or those caring for these people
- organisations commissioning or providing care or supporting the provision of care for managing common infections
- organisations regulating or monitoring how services for people receiving care are provided (for example, the Care Quality Commission).

It may also be relevant for:

- people and organisations delivering non-NHS healthcare services
- the devolved administrations.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE has carried out an equality impact assessment during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope, if this was done.

3 What the guidelines will cover

3.1 *Who is the focus?*

Groups that will be covered

- Adults and children (aged 72 hours and over) with common infections.

Specific consideration will be given to people with protected characteristics under the Equality Act 2010, and people:

- taking multiple medicines[1] (polypharmacy)
- with chronic conditions (such as high blood pressure, diabetes, heart or chronic kidney disease)
- with true allergy (see drug allergy: diagnosis and management).

Groups that will not be covered

- Children in the first 72 hours of life.

[1] For these guidelines, the term 'medicine' covers all prescribed and non-prescription (over-the-counter) healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections and wound care products.

3.2 *Settings that will be covered*

All publicly funded health and social care commissioned or provided by NHS organisations, local authorities (in England), independent organisations or independent contractors.

3.3 *Topics that will be addressed*

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

The definition of what a 'common infection' is varies depending on the setting where the infection is being managed, however we will use criteria to try to prioritise those topic areas that require guidelines. Criteria for prioritisation may include infection areas where:

- the likely causative organisms are gram-negative bacteria (where resistance to treatment is more prevalent)
- people present in high numbers to health services
- management in practice is thought to be poor or variable
- there is a lack of existing guidance
- the condition is self-limiting.

Each topic will be reviewed in line with a review protocol agreed by the committee. The initial infection topics that will be reviewed are given in table 1.

Table 1 Initial topics to be reviewed

Area of infection	Infection topic
Upper respiratory tract	• acute sore throat (including tonsillitis or pharyngitis) • acute otitis media • acute rhinosinusitis or sinusitis
Urinary tract	• acute prostatitis • catheter associated urinary tract infections • complicated UTI including acute pyelonephritis • recurrent urinary tract infections • uncomplicated lower urinary tract

Further common infection topics will be identified for the following infection areas and prioritised by the committee using the criteria listed above:

- bone and joint
- central nervous system
- dental
- eye
- genital
- intra-abdominal
- lower respiratory tract
- sepsis
- skin and soft tissue.

Factors that can affect how an infection is managed, taking into account antimicrobial resistance, will be addressed during guideline development and include:

  - antimicrobial resistance, including patterns, trends and levels
  - managing infections in which a definitive diagnosis is difficult
  - avoiding the use of antibiotics for managing infections that are not bacterial, self-limiting or could be managed using other interventions, such as non-pharmacological or non-antimicrobial options
  - prescribing antimicrobials for managing infections that are caused by organisms that have high resistance to that first-line antimicrobial.

3.4 *Key questions*

While writing this scope, we have identified the following key questions relating to the key issues found (see section 3.3):

1 What is the course of the infection with and without antimicrobial treatment? Including:

1.1 What is the expected duration and severity of symptoms with and without antimicrobial treatment?

1.2 What are the known complication rates with and without antimicrobial treatment?

2 What are the most likely causative organisms?

3 What resistance patterns, trends and levels of resistance exist both locally and nationally for the causative organisms of the infection?

4 What is the clinical effectiveness of non-pharmacological strategies in managing the infection or symptoms? (for example, control of the source of infection, watchful waiting, delayed [back-up] prescriptions [as recommended in NICE's guideline on antimicrobial stewardship]).

5 What is the clinical effectiveness for non-antimicrobial, pharmacological strategies for managing the infection or symptoms (for example, analgesics or antihistamines)?

6 What are the indications for prescribing an antimicrobial for each infection?

7 Which antimicrobial should be prescribed if one is indicated?

8 What is the optimal dose, duration and route of administration?

9 For all topics we will take into account:

9.1 'Red flags' indicating the need for immediate treatment.

9.2 Severity of illness and the need for treatment.

9.3 Individual patient factors; for example, age, comorbidity, location of person receiving treatment, pregnancy or breastfeeding.

9.4 Thresholds or indications for antimicrobial treatment, including numbers needed to treat or numbers needed to harm (where this information is available).

9.5 Need for broad or narrow spectrum antimicrobials.

9.6 First, second and third line therapy (including for those with allergic reactions to certain antimicrobials).

9.7 Optimal dose, duration and route of administration (for example, intravenous, oral or topical).

9.8 Single, dual or triple therapy (where indicated).

9.9 Immediate, delayed, no prescribing or other intervention for management of the condition.

9.10 Standby or rescue therapy in line with self-management plans (if agreed by the committee).

9.11 Relative impact of specific antimicrobials on the development of future resistance to that and other antimicrobials.

9.12 Escalation or de-escalation of treatment (for example, admission to hospital, change from oral to intravenous antimicrobials and treatment given before reaching hospital, if appropriate).

The key questions may be used to develop more detailed review questions, which guide the systematic review of the literature.

3.5 *Main outcomes*

The main outcomes that will be considered when searching for and assessing the evidence are:

1 Clinical outcomes such as:
   - mortality
   - infection cure rates or reduction in symptoms (duration or severity)
   - rate of complications in treated or untreated patients
   - safety, tolerability, adherence and adverse effects.
2 Changes in antimicrobial resistance patterns, trends and levels as a result of treatment.
3 Patient reported outcomes such as medicines adherence, patient experience and patient satisfaction.
4 Health and social care-related quality of life, including long-term harm from outcomes affecting quality of life or those leading to disability.
5 Health and social care utilisation, including length of stay, stays in high dependency units, planned and unplanned contacts and reconsultation rates).
6 Ability to carry out activities of daily living.
7 Service user experience.

3.6 *Resource impact*

We will take resource impact into account when making recommendations. For each of the infection topics, the committee will consider whether resource impact considerations are relevant, and if so whether this is an area that should be prioritised for resource impact analysis.

4 Related NICE guidance

- Antimicrobial stewardship – changing risk-related behaviours in the general population NICE guideline in development. Publication expected January 2017.
- Multimorbidity: clinical assessment and management (2016) NICE guideline NG56
- Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures (2016) NICE guideline CG64
- Sepsis: recognition, diagnosis and early management (2016) NICE guideline NG51
- Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use (2015) NICE guideline NG15
- Drug allergy: diagnosis and management (2014) NICE guideline CG183
- Pneumonia in adults: diagnosis and management (2014) NICE guideline CG191
- Fever in under 5s: assessment and initial management (2013) NICE guideline CG160
- Healthcare-associated infections: prevention and control in primary and community care (2012) NICE guideline CG139
- Neonatal infection (early onset): antibiotics for prevention and treatment (2012) NICE guideline CG149
- Neutropenic sepsis: prevention and management in people with cancer (2012) NICE guidelines CG151
- Healthcare-associated infections: prevention and control (2011) NICE guideline PH36
- Meningitis (bacterial) and meningococcal septicaemia in under 16s: recognition, diagnosis and management (2010) NICE guideline CG102
- Respiratory tract infections (self-limiting): prescribing antibiotics (2008) NICE guideline CG69
- Surgical site infections: prevention and treatment (2008) NICE guideline CG74

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues relating to common infections:

- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136
- Medicines adherence (2009) NICE guideline CG76

5 NICE Pathways

When the guidelines are published, the recommendations will be added to NICE Pathways. NICE Pathways bring together everything NICE says on a topic in an interactive flow chart.

6 Context

Key facts and figures

Public Health England's 2014 English surveillance programme antimicrobial utilisation and resistance (ESPAUR) report highlights that 'antibiotic prescribing has increased in England year on year'. It also says that although antimicrobial resistance and antimicrobial prescribing varies across England, 'frequently areas with high prescribing also have high resistance'. Other highlights include:

- Total antibiotic consumption increased by 6.5% from 2011 to 2014 (2.4% rise between 2013 and 2014).
- Antibiotic prescribing mostly occurred in general practice (74%), followed by hospital inpatients (11%) and outpatients (7%) in 2014.
- Primary care data suggest fewer antibiotic prescriptions have been offered in recent years, but that higher doses or longer courses are being used.
- Prescribing of antibiotics in hospital increased significantly both for inpatients (11.7%) and outpatients (8.5%) between 2011 and 2014.

- Use of broad-spectrum antibiotics (antibiotics effective against a wide range of bacteria) in primary care decreased by 8.5% between 2010 and 2014.
- England is the lowest user of cephalosporins and quinolones (broad-spectrum antibiotics likely to lead to more antibiotic resistance) in the European Union.

Current practice

Some guidelines for prescribers exist for specific infection areas when considering antimicrobials. But these do not always take into account resistance patterns.

NICE's guideline on respiratory tract infections (self-limiting): prescribing antibiotics states that around 60% of antibiotics prescribed in primary care are for respiratory tract infection. Rates of prescribing for colds, rhinitis and upper respiratory tract infection declined between 1997 and 2006. However, in 2006 a high proportion of UK primary care consultations led to antibiotic prescribing for tonsillitis, otitis media and acute sinusitis.

Policy, legislation, regulation and commissioning

Antimicrobial stewardship and resistance is high priority for the UK government. The Department of Health's UK five year antimicrobial resistance strategy 2013 to 2018 recommends that NICE, alongside other partners, considers developing comprehensive, evidence-based antimicrobial prescribing guidance for primary and secondary care.

The O'Neill report Review on antimicrobial resistance produced recommendations for the UK government to meet the challenge of antimicrobial resistance to which the Government responded.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires health and care providers to assess the risk of, and prevent, detect and control the spread of infections, including healthcare-associated infections (regulation 12 [h]). The Care Quality Commission has to take into account the Department of Health's The Health and Social Care Act 2008: code of practice

on the prevention and control of infections and related guidance when making decisions about registration. The code applies to NHS bodies and providers of independent healthcare and adult social care in England.

NICE will take account of relevant medicines legislation (such as the Human Medicines Regulations 2012 and the Health and Social Care Act 2012), regulation, policy and guidance when developing the guidelines and recommendations.

Resources

Public Health England:

- Start smart then focus: antimicrobial stewardship toolkit for English hospitals (updated 2015).
- Checklist for antibiotic prescribing in secondary care (This updates the resource published as part of the start smart toolkit.)
- Dental antimicrobial stewardship: toolkit.
- Carbapenemase-producing Enterobacteriaceae: early detection, management and control toolkit for acute trusts.
- Carbapenem resistance: implementation of an enhanced surveillance system.
- English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR): Validation protocol for NHS Acute Trust Antimicrobial Consumption Data.
- Mandatory healthcare associated infection surveillance: data quality statement.
- Primary care guidance: diagnosing and managing infections including managing common infections: guidance for primary care.
- Antimicrobial Resistance: resource handbook.
- Antibiotic guardian and antibiotic awareness: key messages on antibiotic use for patients and Health matters: antimicrobial resistance and Behaviour change and antibiotic prescribing in healthcare settings: literature review and behavioural analysis.

Other organisations:

- The Department of Health and Public Health England have published Antimicrobial prescribing and stewardship competencies.
- The Infection Prevention Society and Royal College of Nursing's Infection prevention and control commissioning toolkit.
- NHS England have published a Quality Premium (2016/17) including 3 measures for reducing Gram Negative Bloodstream Infections (GNBSIs)
- The Royal College of General Practitioners' TARGET toolkit for antibiotic prescribing for clinicians and commissioners
- The Royal College of Paediatrics and Child Health has published the Manual of Childhood Infections (the Blue Book) that summarises the current management of childhood infections in the UK.
- The Scottish Intercollegiate Guidelines Network has produced clinical guidelines on antibiotic prophylaxis in surgery, management of sore throat and indications for tonsillectomy and the management of suspected bacterial urinary tract infection in adults.

7 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 1 November to 28 November 2016.

The final scope will take Public Health England priorities into account to ensure that associated areas of work carried out by the 2 organisations complement each other.

The guidelines are expected to be published between 2017 and 2019 with the first one to be published in July 2017.

Our website has information about how NICE guidelines are developed.