

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## SCOPE

### 1 Guideline title

Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use.

#### 1.1 Short title

Antimicrobial stewardship.

### 2 The remit

The Department of Health and Public Health England have agreed that NICE should develop a guideline on antimicrobial stewardship.<sup>1</sup>

### 3 Need for the guideline

- a) Awareness of antimicrobial resistance is important in ensuring the antimicrobial medicines are used when needed but that use is reduced without an increase in harm when use is not indicated. Resistance to all antimicrobials is increasing and, combined with a lack of new medicines, there is an increasing risk in the future that infections may not be able to be treated.
- b) The [Annual Report of the Chief Medical Officer, Volume Two, 2011, Infections and the rise of antimicrobial resistance](#) 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’. It is not a new concept and several publications have been issued in response to combating antimicrobial resistance and ensuring appropriate use of antimicrobials. For the purpose

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<sup>1</sup> NICE is also developing public health guidance on Antimicrobial resistance: changing risk-related behaviours.

of the guideline the [World Health Organization](#) (WHO) definition will be used to describe antimicrobial resistance.

- c) The [Executive Board of the World Health Organization](#) considers antimicrobial resistance to be the 'loss of effectiveness of any anti-infective medicine, including antiviral, antifungal, antibacterial and antiparasitic medicines'. The WHO states further that 'When the microorganisms become resistant to most antimicrobials they are often referred to as "superbugs". This is a major concern because a resistant infection may kill, can spread to others, and imposes huge costs to individuals and society.' The WHO [Antimicrobial resistance: global report on surveillance 2014](#) provides 'as accurate a picture as is presently possible of the magnitude of [antimicrobial resistance] and the current state of surveillance globally'.
- d) The [Annual Report of the Chief Medical Officer, Volume Two, 2011, Infections and the rise of antimicrobial resistance](#) (Department of Health, 2013) reviews infectious disease in England and the rise of antimicrobial resistance. It discusses the importance of antimicrobial stewardship and preserving the effectiveness of existing antimicrobials. It describes 3 major goals that have been identified for antimicrobial stewardship:
- optimise therapy for individual patients
  - prevent overuse, misuse and abuse
  - minimise development of resistance at patient and community levels.

The report also states that evidence-based guidance is needed for antimicrobial use, with particular consideration given to increasing awareness of heterogeneity of prescribing to help slow the development of antimicrobial resistance.

- e) In 2013, the Department of Health published the [UK five year antimicrobial resistance strategy 2013 to 2018](#), which aims to slow the development and spread of antimicrobial resistance. The strategy states that antimicrobial resistance cannot be eradicated but by using a multidisciplinary approach, the risk of antimicrobial resistance can be

limited and its impact on health now and in the future can be reduced. The report describes 3 strategic aims, to:

- improve the knowledge and understanding of antimicrobial resistance
  - conserve and steward the effectiveness of existing treatments
  - stimulate the development of new antibiotics, diagnostics and novel therapies.
- f) The Department of Health also carried out an impact assessment ([Antimicrobial resistance strategy impact assessment](#)) alongside the 5-year strategy. This supports the introduction of the strategy and highlights issues such as the importance of preserving current effective therapies and focusing on the appropriate use of antimicrobials (including using the correct antimicrobial, dose and duration of treatment for every prescription, and using them wisely and sparingly).
- g) To further support the 5-year antimicrobial strategy, the document [Antimicrobial prescribing and stewardship competencies](#) (Department of Health and Public Health England, 2013) was published. The competencies aim to improve the quality of antimicrobial treatment and stewardship, and so reduce the risks and ill-effects of inadequate and inappropriate treatment.
- h) In 2011 the Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection published [Antimicrobial stewardship: Start smart - then focus](#) providing guidance for antimicrobial stewardship in hospitals in England. However, the principles of this guidance can be applied to all antimicrobial prescribing. The guidance also stresses the importance of clear governance arrangements when managing antimicrobial resistance.
- i) The [TARGET toolkit](#) has been developed by the RCGP, PHE and The Antimicrobial Stewardship in Primary Care (ASPIC) in collaboration with professional societies as a central resource for clinicians and commissioners about safe, effective, appropriate and responsible antibiotic prescribing.

- j) Public Health England in its response to the antimicrobial strategy has established a new national programme, the [English Surveillance Programme for Antimicrobial Utilisation and Resistance \(ESPAUR\)](#). The programme aims to monitor and enhance the use of antimicrobials in the community and in hospitals in England through measuring antimicrobial utilisation, the impact on resistance and patient safety.
- k) For managing infections in the community, the Health Protection Agency<sup>2</sup> first published [Management of infection guidance for primary care](#) for consultation and local adaptation in 2000 (reviewed in 2010). The guidance provides an overview of the treatment options for managing common infections in the community, and aims to lead to more appropriate antibiotic use.
- l) The Health Protection Agency<sup>1</sup> has also published an [Acute trust toolkit for the early detection, management and control of carbapenemase-producing Enterobacteriaceae](#) (2013) provides 'practical advice for frontline clinicians and staff to prevent or reduce spread of these bacteria'.
- m) NICE has issued guidance on [Respiratory tract infections – antibiotic prescribing](#) (CG69) which provides recommendations for the prescribing of antibiotics for self-limiting respiratory tract infections in adult and children in primary care and [Infection](#) (CG139) which provides recommendations for prevention and control of healthcare-associated infections in primary and community care. These guidelines support effective management of these common conditions again aiming to reduce antimicrobial resistance and use antimicrobials appropriately.
- n) As highlighted, several initiatives and guidance have been published to attempt to tackle the growing concern of appropriate use of antimicrobials and antimicrobial resistance; despite these however, prescribing is still variable. This medicines practice guideline is needed to consider the evidence for effective interventions in this area of practice, in particular for

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<sup>2</sup> The Health Protection Agency (HPA) is now part of Public Health England.

changing prescriber and patient behaviour when using antimicrobials and for minimising antimicrobial resistance.

## 4 Data on resistance and antimicrobial use

There are still wide variations in prescribing across primary care organisations. [Limited data](#) on secondary care prescribing also shows variation, but these data are not routinely available.

a) In the NHS in England, as part of the '[Quality, Innovation, Productivity and Prevention](#)' (QIPP) medicines use and procurement work stream several specific topics relating to antimicrobials were identified. These topics are:

- [Antibiotic prescribing – especially quinolones and cephalosporins](#)
- [Three-day courses of trimethoprim for uncomplicated urinary tract infection](#)
- [Minocycline](#)

The topics are based on new guidance and important new evidence, and include prescribing data.

b) NHS Prescription services annual [National Antibiotic Charts](#) show that antibiotic prescribing in general practice in England over the last 5 years has broadly remained constant in relation to breakdown of different antibiotic prescribing. However, the overall use of antibiotics has steadily increased over several years. The most common antibiotic group prescribed is penicillins, followed by tetracyclines and macrolides. Broad-spectrum penicillins comprised 36% of all antibacterial prescribing in 2012-13. However, the prescription and use of cephalosporin antibiotics has declined following initiatives to reduce prescribing.

c) In 2013 the Health and Social Care Information Centre published [Prescriptions dispensed in the community: England 2002-13](#) which provides an overview of the changes in dispensed items between 2012 and 2013. The bulletin states that 'The BNF Section with the largest increase in cost between 2011 and 2012 was Antibacterial Drugs, where

costs rose by £25.1 million (14.8 per cent) to £195.4 million. The number of items dispensed increased by 2.5 million, (6.1 per cent) to 43.3 million.’

- d) Prescribing data collected in hospital and community are not comparable when using items. The common comparator that can be used for comparing data is the cost of prescribing. [Hospital prescribing: England 2012](#) shows that the cost of antimicrobials is greater in the hospital setting compared to primary care. The cost of prescribing antimicrobials in both settings has increased over time. This increased cost may correspond to an increase in usage although this cannot be certain.
- e) Prescribing data for some services, including urgent care (out-of-hours) centres, are not available for England as the supply of medicines is directly to the patient and is funded and monitored locally. These data are not collated nationally and therefore do not appear in national datasets.

## 5 The guideline

The guideline development process is described in detail on the [NICE website](#).

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.<sup>3</sup>

All anti-infective therapies will be considered in the scope (antiviral, antifungal, antibacterial and antiparasitic medicines), additionally all formulations will be considered within the scope (oral, parenteral and topical agents).

The areas that will be addressed by the guideline are described in the following sections.

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<sup>3</sup>NICE is also developing public health guidance on Antimicrobial resistance: changing risk-related behaviours.

## **5.1 Population**

### **5.1.1 Groups that will be covered**

- a) Health and social care practitioners (a term used to define the wider care team including hospital staff [including microbiologists and infection control staff], community matrons and case managers, GPs, pharmacists and community nurses [including those staff working in out-of-hours services], domiciliary care workers and care home staff [registered nurses and social care practitioners working in care homes], social workers and case managers).
- b) Organisations commissioning (for example clinical commissioning groups or local authorities), providing or supporting the provision of care (for example national or professional bodies, Directors of Public Health, Health and Wellbeing Boards, healthcare trusts and locum agencies).
- c) Adults, young people and children (including neonates) using antimicrobials, or those caring for these groups.

### **5.1.2 Groups that will not be covered**

- a) None.

## **5.2 Setting**

- a) All publicly funded health and social care commissioned or provided by NHS organisations, local authorities (in England), independent organisations or independent contractors.
- b) This guideline may also be relevant to individual people and organisations delivering non-NHS healthcare services, and to other devolved administrations.

## **5.3 Key issues**

### **5.3.1 Areas that will be covered**

- a) Supporting antimicrobial use by health and social care practitioners where their use is indicated.
- b) Reducing the use of antimicrobials without increasing harm through changing behaviour of health and social care practitioners and patients or their carers.
- c) Reducing emergence of antimicrobial resistance through effective antimicrobial stewardship.

### **5.3.2 Areas that will not be covered**

- a) The use of specific named medicines (although classes of medicines for example broad spectrum antibiotics will be referred to).
- b) Public health awareness of antimicrobial resistance and self-care as this will be covered by NICE Public Health guidance (see [Antimicrobial resistance: changing risk-related behaviours](#)).
- c) Treatment of specific clinical conditions (such as healthcare-associated infections [see [CG139 – Infection](#)] and respiratory tract infections [see [CG69 – Respiratory tract infection: Antibiotic prescribing](#)]).
- d) Research for new antimicrobials.
- e) Immunisation and vaccination.
- f) Antimicrobial household cleaning products.
- g) Antimicrobials use in animals.
- h) Hand-hygiene, decolonisation and infection prevention and control measures.



- i) Medicines adherence except where there are specific issues for health and social care practitioners to address for antimicrobials. The general principles of medicines adherence are covered by [CG76 – Medicines adherence: Involving patients in decisions about prescribed medicines and supporting adherence](#),
- j) Access to medicines, including local-decision making for drugs not included on local formularies.
- k) Medicines shortages, including supply issues and discontinued medicines.
- l) Prescription charges.
- m) Waste medicines.

#### **5.4 Main outcomes**

- a) Clinical outcomes such as:
  - mortality and morbidity
  - infection cure rates or time to clinical cure
  - surgical infection rates
  - re-infection rates.
- b) Antimicrobial use as measured by change in the variation over time and movement of the mean over time.
- c) Presence, emergence and incidence of organisms resistant to antimicrobials.
- d) Health and social care related quality of life.
- e) Healthcare-associated infections.
- f) Community-associated infections.
- g) Side effects, adverse events and critical incidents.
- h) Hospitalisation and health and social care utilisation.

- i) Planned and unplanned contacts with health professionals or services.
- j) Patient-reported outcomes, such as medicines adherence related specifically to issues of antimicrobial stewardship, patient experience, patient satisfaction with decision-making, patient information and patient expectations.
- k) Professional belief systems and their attitude to the use of antimicrobials.
- l) No harm.

## **5.5 *Review questions***

Review questions guide a systematic review of the literature. They address only the key issues covered in the scope, and usually relate to interventions, diagnosis, prognosis, service delivery or patient experience. Please note that these review questions are draft versions and will be finalised with the Guideline Development Group.

- a) What interventions, systems and processes are effective and cost-effective in changing health and social care practitioners' decision making to ensure appropriate antimicrobial stewardship?
- b) What interventions, systems and processes are effective in overcoming the barriers to decision making by health and social care practitioner's when ensuring appropriate antimicrobial stewardship?
- c) What systems and processes are effective and cost-effective in reducing the emergence of antimicrobial resistance without causing additional harm to patients?

## **5.6 *Economic aspects***

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and

analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods of medicines practice guidelines can be found in interim methods guide and integrated process statement. Economic analyses of antimicrobial stewardship will demonstrate if interventions are cost effective.

## **5.7 Status**

### **5.7.1 Scope**

This is the final scope.

### **5.7.2 Timing**

The development of the guideline recommendations will begin in May 2014.

## **6 Related NICE guidance**

### **6.1 Published guidance and quality standards**

#### **Medicines practice guidelines**

- [Patient group directions](#). NICE medicines practice guideline 2 (2013).
- [Developing and updating local formularies](#). NICE medicines practice guideline 1 (2012).

#### **Clinical guidelines and quality standards**

- [Infection control](#) NICE clinical guideline 139 (2012).
- [Patient experience in adult NHS services](#). NICE clinical guideline 138 (2012).
- [Patient experience in adult NHS services](#). NICE quality standard 15 (2012).
- [Prevention and control of healthcare-associated infections](#) NICE public health guidance 36 (2011).
- [Medicines adherence](#). NICE clinical guideline 76 (2009).
- [Respiratory tract infections \(RTI\) – antibiotic prescribing](#) NICE clinical guideline 69 (2008).

## **Social care guidelines**

- [Managing medicines in care homes](#). NICE social care guideline 1 (2014).

## **6.2 Guidance under development**

NICE is currently developing the following related guidance (details available from the NICE website):

- [Drug allergy](#). NICE clinical guideline. Publication expected October 2014.
- [Medicines optimisation](#). NICE clinical guideline. Publication expected TBC.
- [Antimicrobial resistance: changing risk-related behaviours](#). NICE Public health guidance (in development).
- [Antibiotics for neonatal infection](#). NICE Quality Standard (in development).
- [Infection prevention and control](#). NICE Quality Standard (in development).

## **7 Further information**

Information on the medicines practice guideline development process is provided in the following documents, available from the NICE website:

- [‘Integrated process statement’](#)
- [‘Interim methods guide’](#)

Information on the progress of the guideline will also be available from the [NICE website](#).