

# Working with Guidelines

Welcome to a new series of articles looking at the latest major guidelines that have been published and the implications for you as a pharmaceutical company representative. This month, MGP's Ivor Eisenstadt defines guidelines and looks at the opportunities they provide for pharma.

NICE defines clinical guidelines as: "Recommendations on the appropriate treatment and care of people with specific diseases and conditions. They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills."

The major organisations that produce evidence-based clinical guidance are NICE (for England and Wales – [www.nice.org.uk](http://www.nice.org.uk)), SIGN (Scottish Intercollegiate Guidelines Network – [www.sign.ac.uk](http://www.sign.ac.uk)) and professional bodies such as the British Hypertension Society, the National Obesity Forum and Diabetes UK.

NICE produces guidance in three areas of health:

- Clinical practice – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS
- Health technologies – guidance on the use of new and existing

medicines, treatments and procedures within the NHS

- Public health – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector.

The most important of these for the industry are the health technologies (technology appraisals) and the clinical practice guidelines. NICE lists a number of aims for clinical guidelines (see below). As an industry representative these aims are very much in line with what you are trying to do. As such, a positive clinical guideline for your product should be seen as a significant opportunity supporting you in changing clinical practice. Some of the most notable recent guidelines are summarised opposite.

These high-profile pieces of guidance are good examples of the significant opportunity that

such publications can present in helping you to change clinical practice in line with the high-quality management of patients.

## The opportunity for representatives

So how do you go about making the most of this opportunity? To begin with, the most important thing is to recognise that guidance will not be implemented just because it has been published. Healthcare professionals have many conflicting priorities on their time and only those that relate most closely to their personal or locality aims will reach the top of the pile.

Clearly a guideline that relates to the quality and outcomes framework (QOF) of the GMS contract will take precedence over a guideline relating to an area that does not. Equally a guideline that involves a condition that is seen frequently is likely to be taken up ahead of one where few patients present.

However, even those guidelines outside of the QOF or the major disease areas will be addressed if you can make it easy and painless for healthcare professionals to do so. So what are the barriers that you need to overcome to ensure the successful implementation of a guideline?

The 2005 Audit Commission report 'Managing the financial

## Perceived barriers to implementing clinical guidelines and appraisals

- Lack of money
- Lack of access to necessary resources – staff, equipment or space
- Too much change already occurring
- Too busy
- Resistance to change
- Apathy – lack of interest in implementing guidance
- Lack of knowledge – staff do not know that the guidance exists

Source: Audit Commission 2005

implications of NICE guidance' found a number of perceived barriers to implementing clinical guidelines and appraisals (see above). So what can you do to help overcome these barriers? This theme will be explored next month.

## Aims of Clinical Guidelines

Good clinical guidelines aim to improve the quality of healthcare. They can change the process of healthcare and improve people's chances of getting as well as possible. Clinical 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

Source: National Institute for Health and Clinical Excellence (NICE)

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## Diabetes – type 2

**Guidance type:** NICE Clinical Guideline

**Date issued:** May 2008

**Expected review date:** May 2012

Web address: <http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11983>

### Summary

This guidance is about the care and treatment of people with type 2 diabetes in the NHS in England and Wales. It covers:

- The monitoring of glucose, lipid (blood cholesterol and fat)

and blood pressure levels.

- Diabetes education programmes.
- Dietary advice.
- The use of medications to:
  - control blood glucose
  - prevent vascular (blood vessel) disease
  - reduce blood pressure
  - improve lipid levels.
- The detection and ongoing management (with referral to a specialist if necessary) of:
  - eye disease
  - kidney disease
  - nerve damage and nerve pain
  - depression.

## 'British Guideline on the Management of Asthma' (substantially updated SIGN in conjunction with the British Thoracic Society (BTS) guideline)

**Guidance type:** Clinical guideline

**Date issued:** May 2008

**Expected review date:** Annual updates

Web address: <http://www.sign.ac.uk/guidelines/fulltext/101/index.html>

### Summary

This updated guideline contains:

- A new section on 'difficult asthma' emphasising the importance of accurate diagnosis in this group of patients where it is often necessary to separate out several co-morbidities.
- A section stressing that the current practice of using nebulisers to deliver high doses of airway-opening medicines in emergency departments to those with out-of-control

asthma is very often not necessary - the guideline emphasises that there is clear evidence that using a spacer to administer much lower doses is at least as effective as a nebuliser in treating most such exacerbations.

- A call for greater use of written personalised action plans when giving control to the person with asthma as part of self-management education.
- A completely rewritten section on diagnosis for both adults and children.
- Updated sections on pharmacological and non-pharmacological management.
- A section on diagnosing and treating occupational asthma – it is estimated that 1 in 8 asthma patients has contracted the condition through their occupation.

## Lipid modification

Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease.

**Guidance type:** NICE Clinical Guideline

**Date issued:** May 2008

**Expected review date:** TBC

Web address: <http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11982>

### Summary

This guideline covers:

- Adults at higher risk of heart disease, stroke or peripheral arterial disease (cardiovascular disease). Risk of cardiovascular disease is higher with age, as well as in people who smoke or who have high blood pressure or high cholesterol.

People with heart disease in the family or men with a South Asian (for example, Indian, Pakistani or Bangladeshi) background are also at higher risk.

- People who have already had a heart attack, stroke or 'mini-stroke' (transient ischaemic attack or TIA).
- People who have angina or some other forms of cardiovascular disease.

The guideline does not cover everyone who is at increased risk of cardiovascular disease.

The guideline does not include people with diabetes, with major genetic causes of high cholesterol (familial hypercholesterolaemia) or with chronic kidney disease, who are also at higher risk.

## Erythropoietin (alpha and beta) and darbepoietin for the treatment of cancer-treatment induced anaemia

**Guidance type:**

Technology Appraisal

**Date issued:** May 2008

**Expected review date:** TBC

Web address: <http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11990>

### Summary

Erythropoietin analogues with iron injections are recommended as a possible treatment for anaemia caused by cancer treatment only in:

- women receiving platinum-based chemotherapy for cancer of the ovaries who

have a blood haemoglobin level of 8g/100ml or lower

- people who have very severe anaemia and cannot receive blood transfusions.

Healthcare professionals should not stop prescribing erythropoietin analogues for people who were already taking them when the guidance was issued. These people should be able to carry on taking erythropoietin analogues until they and their healthcare professionals decide it is the right time to stop treatment.



**Would your brand campaign benefit from the educational support of a clinical guideline?**

**If so, please contact Ed Senior or Ben Mansfield at MGP**  
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