

Issue Date: March 2006

Brief interventions and referral for smoking cessation in primary care and other settings

Foreword

The Department of Health (DH) asked the National Institute for Health and Clinical Excellence (NICE or the Institute) to produce guidance on brief interventions and referrals to specialist services to help people who smoke to stop, in particular, pregnant women and people from disadvantaged groups. It asked the Institute to look at the most effective ways that professionals, both within and outside the NHS in England, can achieve this.

The Public Health Interventions Advisory Committee (PHIAC) considered both a review of the evidence and an economic appraisal before developing these recommendations.

This guidance only examines brief smoking cessation interventions. Although important, these must be seen in the context of a rapidly changing environment.

Publication of the tobacco white paper 'Smoking kills¹' set out a comprehensive tobacco control policy for the UK that has seen increased spending on mass media anti-smoking campaigns, a ban on tobacco advertising and promotion, more prominent health warnings and wider access to stop smoking services and treatments. In addition, the public health white paper, 'Choosing health²' confirmed that all NHS premises and government departments would be smoke-free from the end of 2006. It also paved the way for legislation for a ban on smoking in enclosed public spaces in England by summer 2007.

In light of these changes, the effectiveness of brief interventions should be revisited. In addition, it will be crucial to monitor the impact of this guidance to determine if it is likely to narrow health inequalities or, at least, to ensure that it does not widen them.

The impact of wider policy and practice on smoking cessation is already being examined by the Smoking Cessation Programme Development Group at NICE (www.publichealth.nice.org.uk/page.aspx?o=SmokingCessationPGMain).

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¹ Department of Health (1998) Smoking kills: A white paper on tobacco. London: HMSO.

² Department of Health (2004) *Choosing health: Making healthier choices easier.* London: Department of Health.

Coupled with this guidance on brief interventions, it will provide both practitioners and policy makers with a comprehensive evidence-based approach to delivering smoking cessation services in England.

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1 Recommendations

This document constitutes the Institute's formal guidance on brief interventions and referrals for smoking cessation in primary care and other settings.

The Public Health Interventions Advisory Committee (PHIAC) considered the evidence of effectiveness and cost effectiveness and comments from stakeholders. The original referral from the Department of Health made particular reference to pregnant women and vulnerable groups. However, PHIAC considered that the evidence was insufficient to make specific recommendations for these groups. The resulting recommendations apply to all smokers.

The recommendations in this section are presented without any reference to evidence statements. Appendix A repeats all the recommendations and lists their linked evidence statements.

PHIAC (see appendix C) considered the evidence of effectiveness and cost effectiveness, and comments from stakeholders and service users.

The methods used to develop the guidance are summarised in appendix D. Details of supporting documents are given in appendix E.

1.1 Brief interventions in health and community care

Brief interventions involve opportunistic advice, discussion, negotiation or encouragement. They are commonly used in many areas of health promotion and are delivered by a range of primary and community care professionals.

For smoking cessation, brief interventions typically take between 5 and 10 minutes and may include one or more of the following:

- simple opportunistic advice to stop
- an assessment of the patient's commitment to quit
- an offer of pharmacotherapy and/or behavioural support

 provision of self-help material and referral to more intensive support such as the NHS Stop Smoking Services.

The particular package that is provided will depend on a number of factors, including the individual's willingness to quit, how acceptable they find the intervention on offer and the previous ways they have tried to quit. Diagram 1 below summarises this care pathway.

1.1.1 Practice recommendations

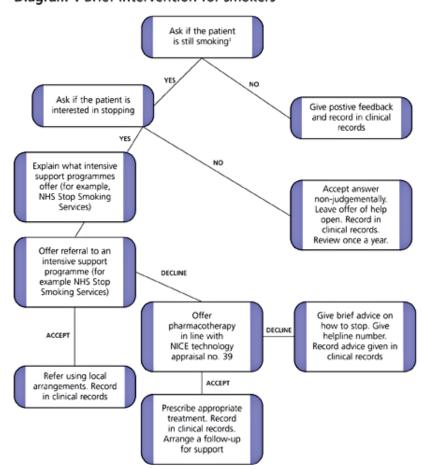


Diagram 1 Brief intervention for smokers

Who should receive advice?

Recommendation 1

Everyone who smokes should be advised to quit, unless there are exceptional circumstances³. People who are not ready to quit should be asked to consider

³ Occasionally it might be inappropriate to advise a patient to quit: for example, because of their presenting condition or personal circumstances.

the possibility and encouraged to seek help in the future. If an individual who smokes presents with a smoking-related disease, the cessation advice may be linked to their medical condition.

Recommendation 2

People who smoke should be asked how interested they are in quitting⁴. Advice to stop smoking should be sensitive to the individual's preferences, needs and circumstances: there is no evidence that the 'stages of change' model⁵ is more effective than any other approach.

Who should advise smokers and how?

Recommendation 3

GPs should take the opportunity to advise all patients⁴ who smoke to quit when they attend a consultation. Those who want to stop should be offered a referral to an intensive support service (for example, NHS Stop Smoking Services). If they are unwilling or unable to accept this referral they should be offered pharmacotherapy in line with NICE technology appraisal guidance no. 39⁶ and additional support. The smoking status of those who are not ready to stop should be recorded and reviewed with the individual once a year, where possible.

Recommendation 4

Nurses in primary and community care should advise everyone who smokes⁴ to stop and refer them to an intensive support service (for example, NHS Stop Smoking Services). If they are unwilling or unable to accept this referral they should be offered pharmacotherapy by practitioners with suitable training, in line with NICE technology appraisal guidance no. 39⁶, and additional support. Nurses who are trained NHS stop smoking counsellors may 'refer' to themselves where appropriate. The smoking status of those who are not ready

⁴ Occasionally it might be inappropriate to advise a patient to quit: for example, because of their presenting condition or personal circumstances.

⁵ DiClemente CC, Prochaska J. et al. (1991) The process of smoking cessation: An analysis of precontemplation, contemplation, and preparation stages of change. *Journal of Consulting and Clinical Psychology*. Vol 59(2) 295-304.

⁶ Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. *NICE technology appraisal* no. 39 (2002). Available from: www.nice.org.uk/TA039

to stop should be recorded and reviewed with the individual once a year, where possible.

Recommendation 5

All other health professionals, such as hospital clinicians, pharmacists and dentists, should refer people who smoke⁷ to an intensive support service (for example, NHS Stop Smoking Services). If the individual is unwilling or unable to accept this referral, practitioners with suitable training should offer a prescription of pharmacotherapy in line with NICE technology appraisal guidance no. 39⁸, and additional support. Those who are trained NHS stop smoking counsellors may 'refer' to themselves. Where possible, the smoking status of those who are not ready to stop should be recorded in clinical records and reviewed with the individual once a year, where possible.

Recommendation 6

Community workers⁹ should refer people who smoke⁷ to an intensive support service (for example, NHS Stop Smoking Services). Those who are trained NHS stop smoking counsellors may 'refer' to themselves.

1.1.2 Strategic recommendations for policy makers, commissioners and managers

Recommendation 7

Strategic health authorities, NHS hospital trusts, primary care trusts (PCTs), community pharmacies, local authorities and local community groups should review smoking cessation policies and practices to take account of the recommendations in this guidance.

Recommendation 8

Smoking cessation advice and support should be available in community, primary and secondary care settings for everyone who smokes. Local policy makers and commissioners should target hard to reach and deprived

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⁷ Occasionally it might be inappropriate to advise a patient to quit: for example, because of their presenting condition or personal circumstances.

⁸ Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. *NICE technology appraisal* no. 39 (2002). Available from: www.nice.org.uk/TA039
⁹ Community workers are practitioners working outside the health sector who have a remit for smoking cessation.

communities including minority ethnic groups, paying particular attention to their needs.

Recommendation 9

Monitoring systems should be set up to ensure health professionals have access to information on the current smoking status of their patients. This should include information on: a) the most recent occasion on which advice to stop was given, b) the nature of advice offered and c) the response to that advice.

2 Public health need and practice

2.1 What is the overall aim of the guidance?

This guidance aims to help local health and social care services as well as the community and voluntary sectors plan and deliver the most effective and most cost-effective services to encourage people who smoke to quit.

2.2 Why is it being produced?

Smoking remains the leading cause of preventable morbidity and premature death in England. It is estimated that between 1998 and 2002, smoking caused an average 86,500 deaths a year.

The prevalence of smoking has declined dramatically since the 1960s, but it still remains alarmingly high in some groups. These include 20–34 year olds (including women who continue to smoke through pregnancy), members of some minority ethnic communities and those from lower socioeconomic groups. Differences in the prevalence of smoking between the higher and lower social classes accounts for over half the difference in the risk of premature death faced by these groups¹⁰.

Chewed tobacco products are widely used by some minority ethnic groups. Although less hazardous than cigarettes, they are still harmful to health and smoking cessation should also be made available for those who want to quit this habit.

Previous UK guidance has emphasised the importance of offering two forms of smoking cessation support to achieve the greatest population health benefit:

- opportunistic, brief advice to encourage all smokers to quit and to point them to effective treatments that can help
- treatment services for those who would like or need help to stop.

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¹⁰ Jarvis M, Wardle J (1999) Social patterning of individual health behaviours: the case of cigarette smoking. In Marmot M, Wilkinson R, editors *Social Determinants of Health*. Oxford: Oxford University Press.

The first option reaches the wider population. The second has a lower reach but higher success rates. It is thought, however, that brief advice could be key in persuading more smokers to try to stop¹¹.

In the 1998 tobacco white paper 'Smoking kills'¹², the government set out a comprehensive strategy to reduce tobacco use in the UK. It led to the establishment of the NHS Stop Smoking Services, the first nationwide stop smoking treatment service in the world, combining psychological support and medication. The latest results (for April 2004 to March 2005) show that 529,520 people who had contact with the service had set a quit date – and 297,828 of them reported that they had stopped smoking 4 weeks after that quit date¹³. There is also evidence that the service is reaching smokers from disadvantaged socioeconomic groups, although they have a lower success rate than other socioeconomic groups¹⁴.

Government policy now states that health professionals should refer patients who need support to the service. This is being reflected in contractual changes:

- since 2004, the General Medical Services contract for general practice (the Quality and Outcomes Framework (QOF)) has awarded points for recording patients' smoking status and providing cessation advice or referrals. The 'Our health, our care, our say'¹⁵ white paper outlines plans for the QOF to include wider public health and well-being measures by 2008
- from spring 2006, nurses and pharmacists who have undergone special training will be able to prescribe any licensed medicine, for any medical condition, within their competence¹⁶

¹¹ West R (2005) Smoking: Prevalence, mortality and cessation in Great Britain www.rjwest.co.uk/smokingcessationgb.pdf accessed January 2006 and last updated October 2005.

Department of Health (1998) *Smoking kills: A white paper on tobacco*. London: The Stationery Office.

¹³ Department of Health (2005) Statistics on NHS stop smoking services in England, April 2004 to March 2005. London: Department of Health.

¹⁴ Chesterman et al. (2005) How effective are the English smoking treatment services in reaching disadvantaged smokers? *Addiction 100.* (Supplement 2):36-45

¹⁵ Department of Health (2006) *Our health, our care, our say: a new direction for community services.* London: The Stationery Office.

¹⁶ See 'Changes to non-medical prescribing' in CMO Update Issue 43, published 11 January 2006.

one of the key tasks of NHS-accredited health trainers¹⁷ is to work in the community to encourage smokers to quit and to refer them to the specialist service¹⁸. This scheme has already been set up in disadvantaged areas and will be rolled out nationally by 2007.

2.3 Who is it for?

This guidance is primarily designed for those who commission or work in local health services – within PCTs, community pharmacies and dental practices – and secondary NHS care, including mental health and hospital trusts. It also has implications for those working in community settings, such as health trainers, youth workers and others who may have a role in advising smokers.

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¹⁷ NHS health trainers are a new workforce to be recruited mainly from the local community, working in the NHS and other local organisations.

¹⁸ Department of Health (2004) *Choosing health: Making healthier choices easier.* London: Department of Health.

3 Implementation

The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the DH in 'Standards for better health' issued in July 2004. The implementation of NICE public health guidance will help organisations meet the standards in the public health (seventh) domain, such as core standards C22 and C23 and developmental standard D13. In addition, it will help meet the health inequalities target as set out in 'The NHS in England: the operating framework for 2006/7¹⁹.

NICE has developed tools to help organisations implement this guidance (listed below). These will be available on our website (www.nice.org.uk/PHI001) in April 2006.

- Costing tools:
 - Costing report to estimate the national savings and costs associated with implementation
 - Costing template to estimate the local costs and savings involved.
- Implementation advice on how to put the guidance into practice and national initiatives which support this locally.
- Audit criteria to monitor local practice.

¹⁹ Department of Health (2006) *The NHS in England: The operating framework for 2006/7*. London: Department of Health.

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4 Background

The processes and methods NICE uses to develop public health guidance are set out in the following documents, which are available from the NICE website at: www.nice.org.uk.

'Methods for development of NICE public health guidance' (NICE 2006)

'The public health guidance development process: An overview for stakeholders including public health practitioners, policy makers and the public' (NICE 2006).

The assessment of evidence used to develop this guidance was based on the following:

• 'Guideline development methods' (NICE 2005)

A quick reference guide (QRG) for professionals whose remit includes public health and for interested members of the public is also available from the NICE website (www.nice.org.uk/PHI001quickrefguide) or from the NHS Response Line (0870 1555 455 – quote reference number N1014).

5 Recommendations for research

PHIAC considered that research funding agencies should ensure that a programme is established to identify the most effective and cost-effective brief interventions for smoking cessation.

The Committee recommended that the following five key research questions be addressed.

- 1. Which brief interventions are most effective (and cost effective) for pregnant women and for people in lower socioeconomic and vulnerable groups – and why?
- 2. What are the key characteristics of an effective brief intervention for smoking cessation?
- 3. How effective (and cost effective) in absolute and relative terms are brief interventions delivered by different professionals in a variety of settings?
- 4. Has the impact of brief interventions changed as a result of increased investment in tobacco control activities, including development of the NHS smoking cessation services?
- 5. Does an individual's previous 'quitting history' affect the success of any subsequent brief intervention?

Ideally all studies should include short (4 week), medium (3 month) and long term (1 year) follow-up and biochemical validation.

More detail on the evidence gaps identified during the development of this guidance is provided in appendix B.

6 Review

In March 2009 this guidance will be reviewed and the state of the evidence base at that time will be reassessed. A decision will then be made about whether it is appropriate to update the guidance. If it is not updated at that time, the situation will be reviewed again in March 2011.

7 Related guidance

Published

 Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. NICE technology appraisal no. 39 (2002). Available from: www.nice.org.uk/TA039

Under development

Guidance on smoking cessation (NICE public health programme guidance).
 Further information can be found at:
 www.nice.org.uk/page.aspx?o=SmokingCessationPGMain

8 Acknowledgements

This guidance was developed by PHIAC supported by the NICE Project Team. For details of PHIAC membership see appendix C.

The NICE Project Team comprised:

Mike Kelly

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Health Economics Adviser.

NICE is grateful for the input of the Academic and Public Health Consortium (APHC)²⁰, which carried out the reviews of the evidence of effectiveness, and the Centre for Health Economics (CHE), University of York, which carried out the cost-effectiveness review. The authors of the reviews of effectiveness were: Lindsay Stead (University of Oxford), Ann McNeill, Lion Shahab and Robert West (University College, London). The economic appraisal was undertaken by Steve Parrott and Christine Godfrey.

NICE would also like to thank the stakeholders who commented on the scope, the evidence base and the draft recommendations, including those who submitted evidence.

 $^{\rm 20}$ APHC is a collaboration between Action on Smoking and Health (ASH) and University College London.

Appendix A: recommendations for policy and practice and supporting evidence statements

This appendix sets out the recommendations and the associated evidence statements taken from the review of effectiveness (see appendix D for the key to study types and quality assessments)

Recommendations are followed by the evidence statement(s) that underpin them. The numbering of the evidence statements reflects the numbering that was used in the brief interventions review. For example, (evidence statement 1) below is numbered 1 in the brief interventions review. Where a recommendation is not directly taken from the evidence statements, but is inferred from the evidence, this is indicated by IDE (inference derived from the evidence).

The review is available on the NICE website at: http://www.nice.org.uk/guidance/index.jsp?action=folder&o=43947

Who should receive advice?

Recommendation 1

Everyone who smokes should be advised to quit, unless there are exceptional circumstances²¹. People who are not ready to quit should be asked to consider the possibility and encouraged to seek help in the future. If an individual who smokes presents with a smoking-related disease, the cessation advice may be linked to their medical condition.

(IDE)

Recommendation 2

People who smoke²¹ should be asked how interested they are in quitting. Advice to stop smoking should be sensitive to the individual's preferences,

²¹ Occasionally it might be inappropriate to advise a patient to quit; for example because of their presenting condition or personal circumstances.

needs and circumstances: there is no evidence that the 'stages of change' model²² is more effective than any other approach.
(Evidence statement 10 and IDE)

Who should advise smokers and how?

Recommendation 3

GPs should take the opportunity to advise all patients²³ who smoke to quit when they attend a consultation. Those who want to stop should be offered a referral to an intensive support service (for example, NHS Stop Smoking Services). If they are unwilling or unable to accept this referral they should be offered pharmacotherapy, in line with NICE technology appraisal guidance no. 39²⁴, and additional support. The smoking status of those who are not ready to stop should be recorded and reviewed with the individual once a year, where possible.

(Evidence statements 1 and 7)

Recommendation 4

Nurses in primary and community care should advise everyone who smokes²³ to stop and refer them to an intensive support service (for example, NHS Stop Smoking Services). If they are unwilling or unable to accept this referral they should be offered pharmacotherapy, in line with NICE technology appraisal guidance no. 39²⁴ and additional support. Nurses who are trained NHS stop smoking counsellors may 'refer' to themselves where appropriate. The smoking status of those who are not ready to stop should be recorded and reviewed with the individual once a year, where possible.

(Evidence statements 2 and 7)

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²² DiClemente CC, Prochaska J. et al. (1991) The process of smoking cessation: An analysis of precontemplation, contemplation, and preparation stages of change. *Journal of Consulting and Clinical Psychology*. Vol 59(2) 295-304.

²³ Occasionally it might be inappropriate to advise a patient to quit, for example, because of

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²⁴ Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. *NICE technology appraisal* no. 39 (2002). Available from: www.nice.org.uk/TA039

Recommendation 5

All other health professionals, such as hospital clinicians, pharmacists and dentists, should refer people who smoke²⁵ to an intensive support service (for example, NHS Stop Smoking Services). If the individual is unwilling or unable to accept this referral, practitioners with suitable training should offer a prescription of pharmacotherapy, in line with NICE technology appraisal guidance no. 39²⁶, and additional support. Those who are trained NHS stop smoking counsellors may 'refer' to themselves. The smoking status of those who are not ready to stop should be recorded in clinical records and reviewed with the individual once a year, where possible.

(Evidence statements 1, 2, 7 and 27 and IDE)

Recommendation 6

Community workers²⁷ should refer people who smoke²⁵ to an intensive support service (for example, NHS Stop Smoking Services). Those who are trained NHS stop smoking counsellors may 'refer' to themselves.

(Evidence statement 27, IDE)

Strategic recommendations for policy makers, commissioners and managers

Recommendation 7

Strategic health authorities, NHS hospital trusts, PCTs, community pharmacies, local authorities and local community groups should review smoking cessation policies and practices to take account of the recommendations in this guidance. (IDE)

Recommendation 8

Smoking cessation advice and support should be available in community, primary and secondary care settings for everyone who smokes. Local policy makers and commissioners should target hard to reach and deprived

²⁵ Occasionally it might be inappropriate to advise a patient to quit, for example, because of their presenting condition or personal circumstances.

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²⁶ Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. *NICE technology appraisal* no. 39 (2002). Available from: www.nice.org.uk/TA039
²⁷ Community workers are practitioners working outside the health sector who have a remit for smoking cessation.

communities including minority ethnic groups, paying particular attention to their needs.

(IDE)

Recommendation 9

Monitoring systems should be set up to ensure health professionals have access to information on the current smoking status of their patients. This should include information on: a) the most recent occasion on which advice to stop was given, b) the nature of advice offered and c) the response to that advice.

(IDE)

Evidence statements

Evidence statement 1

A body of level 1+ evidence directly applicable to UK health care settings supports the efficacy of physician advice as a brief intervention for smoking cessation.

Evidence statement 2

A body of level 1+ evidence directly applicable to the UK supports the efficacy of nurse structured advice as a brief intervention for smoking cessation in primary care and community settings. However, the primary focus of the contact in these studies was smoking, so these interventions are not brief opportunistic interventions made during routine care. In addition, poor uptake of invitations to contact nurses for assistance with smoking cessation was noted in some UK studies. There is insufficient evidence to say whether opportunistic advice increases quit rates. A moderately sized body of evidence failed to detect any effect of advice and interventions delivered by nurses as part of a health check.

Evidence statement 7

A body of level 1+ evidence directly applicable to the UK supports the efficacy of nicotine replacement therapy (NRT) as part of a brief intervention for smokers wishing to make a quit attempt.

Evidence statement 10

A moderately sized body of evidence has not found a benefit of stage-matched over unmatched brief interventions. A moderately sized body of evidence has yielded conflicting results on the efficacy of stage-matched interventions compared with no intervention.

Evidence statement 27

There is insufficient evidence from direct comparisons to draw firm conclusions about the influence of the profession of a provider delivering a brief smoking cessation intervention, or the influence of features of the profession, on intervention effectiveness.

Cost-effectiveness evidence

Overall, brief interventions were found to be cost effective, and would support the above recommendations.

The cost-effectiveness analysis demonstrated that brief interventions conducted by GPs and nurses, in all settings, to all age groups included in the model, and with all adjuncts (NRT, self-help, telephone helpline) can generate quality-adjusted life year (QALY) gains at a low cost. The cost per QALY tends to increase as the patient's age increases, but brief interventions delivered to a 60 year old cohort are still cost effective.

When only comparing the costs of an intervention with no intervention, the estimated incremental cost per QALY gained varied from around £221 to around £9515, depending on the assumptions used (see appendix E – the economic analysis modelling report – for further details).

When the healthcare savings are included (as smokers quit smoking and avoid preventable disease), these are offset by the cost of the intervention. Using this method, the incremental costs per QALY gained vary from £135 to £6472, depending on the assumptions used.

These variations reflect the results from the sensitivity analysis (regarding the assumptions made on background quit rates, length of intervention, age of the individual and their level of dependency).

Appendix B: gaps in the evidence

PHIAC identified a number of gaps in the evidence related to the specific interventions under examination. However, this does not mean these are the only research priorities in relation to smoking cessation activities as a whole. A broader examination of smoking cessation, including research priorities, will be undertaken as part of the development of NICE's programme guidance on smoking cessation. The draft scope for this work was published on the NICE website in March 2006.

Specific gaps in the evidence are set out below. These are based on the full set of evidence statements that can be found in the synopsis and full review.

- 1. Effectiveness of brief cessation advice in relation to age, gender, socioeconomic status and ethnicity.
- Cost effectiveness.
- 3. Patterns of stop smoking attempts, including the use of aids. In particular:
 - a. the effectiveness of brief advice with and without cessation aids
 - b. why brief advice does not work with pregnant smokers
 - the absolute and relative effectiveness of brief advice delivered by different health professionals, and brief advice and NRT offered by nurses and pharmacists from spring 2006
 - d. the influence of previous failures to quit on the effectiveness of subsequent brief advice
 - e. the effectiveness of brief advice delivered via the Internet
 - f. the effectiveness of brief advice with children and adolescents
 - g. the effectiveness of brief advice with smokeless tobacco users
 - the effectiveness of brief advice in a range of settings beyond primary care, including A&E departments, workplaces and community pharmacies
 - i. the effectiveness of brief advice of less than 2 minutes

- j. the effectiveness of a brief, multi-component intervention based on the five 'A's²⁸.
- 4. The effectiveness of brief interventions in light of the wider (and changing) context of tobacco control in England. This includes greater exposure to mass media anti-smoking campaigns, wider access to smoking cessation services and more extensive restrictions on smoking in public places.

The Committee made 5 recommendations for research. These are listed in section 5.

Raw M, McNeill A, West R (1998) Smoking cessation guidelines for health professionals. A guide to effective smoking cessation interventions for the healthcare system. *Thorax* 53: Suppl. S11-S19.

²⁸ National guidelines define a model brief intervention as consisting of the following questions and actions: Ask if the person smokes; Advise them to quit; Assess their willingness to make a quit attempt; Assist them by providing treatment (e.g. behavioural support, NRT or Bupropion) and arranging follow-up or; Arrange referral to an NHS specialist smoking cessation service.

Appendix C: membership of the Public Health Interventions Advisory Committee

NICE has set up a standing committee, the Public Health Interventions Advisory Committee (PHIAC), which reviews the evidence and develops recommendations on public health interventions.

Membership of PHIAC is multidisciplinary, comprising public health practitioners, clinicians (both specialists and generalists), local authority employees, representatives of the public, patients and/or carers, academics and technical experts as follows.

Mrs Cheryll Adams Professional Officer for Research and Practice

Development with the Community Practitioners' and Health Visitors' Association

(CPHVA)

Professor Ron Akehurst Professor of Health Economics and Dean of the School of Health and Related Research (ScHARR), University of Sheffield Professor Sue Atkinson Regional Director of Public Health for London. Health Adviser to Mayor and Greater London Authority

Professor Michael Bury Emeritus Professor of Sociology at the University of London and Honorary Professor of Sociology at the University of Kent

Professor Simon Capewell Chair of Clinical Epidemiology, University of Liverpool

Professor K K Cheng Professor of Epidemiology, University of Birmingham **Mr Philip Cutler** Forums Support Manager, Bradford Alliance on Community Care

Professor Brian Ferguson Director of the Yorkshire and Humber Public Health Observatory

Dr Ruth Hall Director of Public Health for Avon, Gloucestershire and Wiltshire Strategic Health Authority

Ms Amanda Hoey Director, Consumer Health Consulting Limited

Mr Andrew Hopkin Senior Assistant Director for Derby City Council

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Ms Sharon McAteer Health Promotion Manager, Halton PCT

Professor Klim McPherson Visiting Professor of Public Health Epidemiology Department of Obstetrics and Gynaecology, University of Oxford

Professor Susan Michie, Professor of Health Psychology, BPS Centre for Outcomes Research & Effectiveness, University College, London

Ms Jane Putsey Lay Representative. Chair of Trustees of the Breastfeeding Network for Cumbria and Lancashire Strategic Health Authority

Dr Mike Rayner Director of British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

Mr Dale Robinson Chief Environmental Health Officer for South Cambridgeshire District Council

Professor Mark Sculpher Professor of Health Economics at the Centre for Economics (CHE), University of York

Dr David Sloan Director of Health Improvement & Public Health for City & Hackney Teaching PCT

Dr Michael Varnam General Practitioner with the Community of Inner Nottingham

Dr Dagmar Zeuner Consultant in Public Health with Islington PCT

Appendix D: summary of the methods used to develop this guidance

Introduction

The reports of the reviews and economic analysis include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the PHIAC meetings provide further detail about the Committee's interpretation of the evidence and development of the recommendations.

All supporting documents are listed in appendix E and are available from the NICE website at: www.nice.org.uk/PHI001

The guidance development process

The stages of the guidance production process are outlined in the box below:

- 1. Draft scope
- 2. Stakeholder meeting
- 3. Stakeholder comments
- 4. Final scope and responses published on website
- Reviews and cost-effectiveness modelling
- 6. Synopsis report of each review (executive summaries and evidence tables) circulated to stakeholders for comment
- 7. Comments and additional material submitted by stakeholders
- 8. Review of additional material submitted by stakeholders²⁹
- 9. Synopsis, full reviews, supplementary reviews and economic modelling submitted to PHIAC
- 10. PHIAC produces draft recommendations
- 11. Draft recommendations published for comment
- 12. Responses to comments published
- 13. PHIAC amends recommendations
- 14. Final guidance published on website

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²⁹ Submitted material is screened against inclusion criteria used in the reviews.

Key questions

The key questions were established as part of the scope. They formed the starting point for the reviews of evidence and facilitated the development of recommendations by PHIAC.

- 1. Which methods of brief intervention are effective? Which methods are most effective? Which methods are least effective?
- 2. What are the costs and cost effectiveness associated with brief interventions?
- 3. What factors affect the effectiveness of brief interventions? Do they differ for different interventions?
- 4. Increasing the intensity, duration and/or frequency of a brief intervention can increase effectiveness. Is this increase additive or multiplicative?
- 5. To what extent is the effectiveness of a brief intervention influenced by previously received brief interventions?
- 6. To what extent is the effectiveness of a brief intervention influenced by previous quit attempts?
- 7a. Are some interventions more effective than others within population groups e.g. age within gender?
- 7b. Are some interventions more effective than others between population groups for example, with pregnant women and manual workers?
- 8. Are interventions tailored to sub-sets of the smoking population (for example, pregnant women, older smokers) more effective with them than generic interventions?
- 9. Does the setting/site of delivery of the intervention influence effectiveness?

- 10. Does the profession of the practitioner providing the intervention influence effectiveness? What are the significant features?
- 11. How applicable is what we know about the most effective brief interventions to the most disadvantaged smokers and pregnant smokers?
- 12. What are the barriers to delivering smoking cessation interventions?
- 13. What strategies are effective in encouraging primary care professionals and others to undertake smoking cessation interventions?
- 14. What, if any, negative consequences arise from brief interventions?
- 15. What is the impact on inequalities and health? For example, if a brief intervention is targeted at the whole population, will it lead to greater inequalities?

Key questions on referral:

- 1. What factors training, incentives influence the number of referrals?
- 2 What impact, if any, does the PCT have on referrals from primary care to the services?
- 3. What factors mechanisms (e.g. card, fax, telephone, script), role of referrer (e.g. pharmacist, midwife), type and/or location of service influence the likelihood of a patient following up the referral?
- 4. Does the method of promoting the specialist service (e.g. national advertising, referral from GPs and other health professionals, word of mouth) influence the number of referrals?

Reviewing the evidence of effectiveness

One review of effectiveness was conducted.

Identifying the evidence

The following databases were searched for recent systematic reviews (2000–August 2005) and for trials (1985–August 2005): MEDLINE, Cochrane

Database of Systematic Reviews, Cochrane Controlled Trials Register (CENTRAL), Cochrane Tobacco Addiction Group Specialised Register, Reference Manager, DARE, ASSIA, British Nursing Index, Embase, Cinahl, PsycINFO Sociological Abstracts.

Additional searches using the same databases were conducted for information on barriers to implementation and for the question on referrals to NHS smoking services. In addition, a call for information on referrals was put out on Globalink UK, an international network of over 1000 tobacco control activists, smoking cessation workers and researchers. (This includes most smoking cessation coordinators in England.) Regional stop smoking service managers were also asked for referral data. Full details of the databases and search strategies can be found in the full effectiveness review.

Details of the search terms and strategies are included in the rapid review report.

Selection criteria

Reviews were excluded by two reviewers if:

- the title or abstract did not primarily address smoking cessation
- the study was clearly not conducted systematically
- the study did not address any of the scope questions (in such cases lower level evidence was sought).

A similar process was used to exclude trials and other types of research studies. For these studies one reviewer judged the potential relevance of the evidence. Consistency of coding was assessed in a subset of 80 papers and a kappa of >0.6 obtained for inclusion versus exclusion. Papers where there was uncertainty about the intervention's classification were retained.

Quality appraisal

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in the NICE technical manual 'Guideline development methods³⁰'. Each study was described by study type (categorised as types 1-4) and graded (++, +, -) to reflect the risk of potential bias arising from its design and execution:

Study type

- Meta-analyses, systematic reviews of RCTs or RCTs (including cluster RCTs).
- Systematic reviews of, or individual, non-randomised controlled trials, case-control studies, cohort studies, controlled before-and-after (CBA) studies, interrupted time series (ITS) studies, correlation studies.
- 3 Non-analytical studies (for example, case reports, case series).
- 4 Expert opinion, formal consensus.

Study quality

- ++ All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions are thought very unlikely to alter.
- Some criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
- Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

Study type and quality were described together, for example, as (1++) or (2-). The studies were also assessed for their applicability to the UK.

Summarising the evidence and making evidence statements

The review data was summarised in evidence tables (see full reviews and the synopsis). Outcomes of interest included non-validated and validated smoking

³⁰ National Institute for Clinical Excellence (2005) *Guideline development methods.* London: National Institute for Clinical Excellence.

status (such as, self-reported smoking abstinence and bio-chemically validated smoking abstinence such as saliva cotinine).

Trials that included follow-ups of six months or more were the primary focus. Trials of shorter duration were included where necessary.

The findings from the review were synthesised and used as the basis for a number of evidence statements relating to each key question. The evidence statements reflect the strength (quantity, type and quality) of evidence and its applicability to the populations and settings in the scope.

Economic appraisal

The economic appraisal consisted of a review of economic evaluations and a cost-effectiveness analysis.

Review of economic evaluations

A systematic search was carried out on 9 databases from January 1985 to August 2005: CINAHL, Cochrane Library, DARE, EMBASE, NHS HEED, NEED, HMIC, MEDLINE and PSYCINFO.

Where available, abstracts were used to identify papers that might be relevant to the review as appraised by two reviewers. Papers which included, or potentially included, cost-effectiveness results were identified and full copies obtained.

Studies were excluded if they:

- did not contain any original evidence
- did not report the costs (or cost effectiveness) of interventions
- reported on interventions comprising more than one session (other than brief follow-up contacts).

Included studies were assessed for quality using a checklist based on the criteria developed by Drummond et al. (1997)³¹. Inclusion of QALYs as an

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³¹ Drummond MF, et al. (1997) Critical assessment of economic evaluation. In *Methods for the Economic Evaluation of Health Care Programmes*. 2nd edition. Oxford: Oxford Medical Publications.

outcome measure was essential at this stage. As with the review of effectiveness, studies were then given a score (++, +, -) to reflect the risk of potential bias arising from its design and execution. The evidence tables for the cost-effectiveness review are included in the review (see appendix E).

Cost-effectiveness analysis

A cost-effectiveness analysis was carried out for brief interventions in primary care.

An economic model was constructed to incorporate data from the reviews of effectiveness and cost effectiveness. The aim was to estimate the average QALYS gained over the simulation time period. The estimates were based on the estimated 12 month quit rates taken from the review of effectiveness. The estimates were calculated for different ages and gender of the population cohort. Because of the limited nature of the evidence a wide range of sensitivity analyses were performed.

A number of assumptions were made which could underestimate or overestimate the cost per QALY (see modelling report for further details).

How PHIAC formulated the recommendations

At its meeting in January 2006, PHIAC considered the evidence of effectiveness and cost effectiveness and comments from stakeholders to determine:

- whether there was sufficient evidence (in terms of quantity, quality and applicability) to form a judgement
- whether, on balance, the evidence demonstrates that the intervention is effective or ineffective, or whether it is equivocal
- where there is an effect, the typical size of effect.

PHIAC developed draft recommendations through informal consensus, based on the following criteria.

 Strength (quality and quantity) of evidence of effectiveness and its applicability to the populations/settings referred to in the scope.

- Effect size and potential impact on population health and/or reducing inequalities in health.
- Cost effectiveness (for the NHS and other public sector organisations).
- Balance of risks and benefits.
- Ease of implementation and the anticipated extent of change in practice that would be required.

PHIAC noted that the effectiveness of some interventions could vary according to the context in which they were delivered. For example, the social acceptability of smoking in a particular community might affect the way an intervention was received.

PHIAC also considered whether research should be a condition for a recommendation where evidence was lacking.

Where possible, recommendations were linked to an evidence statement(s) – see appendix A for details. Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

The draft guidance, including the recommendations, was released for consultation in January/February 2006. PHIAC met in February 2006 to consider stakeholder comments and to revise the recommendations accordingly. The guidance was signed off by the NICE Guidance Executive in March 2006.

Appendix E: supporting documents

Supporting documents are available from the NICE website (www.nice.org.uk/PHI001). These include the following.

- Review of effectiveness.
- Economic analysis: rapid review and modelling report.