Title:	Impact Assessment (IA)
Impact Assessment of a Code of Practice on the prevention and control of infections and related guidance	**IA No:** 3017
Lead department or agency: Department of Health	**Date: 10/11/2010**
Other departments or agencies:	**Stage:** Final
	Source of intervention: Domestic
	Type of measure: Secondary legislation

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

The current Code of Practice coming into force during 2010 applies to NHS bodies, independent healthcare & adult social care providers. Primary dental care & independent ambulance providers then primary medical care providers must be registered with the Care Quality Commission (CQC) by April 2011 and 2012 respectively. All will be registered against the same registration requirements, which includes cleanliness and infection control. This new Code takes account of primary dental, independent ambulances & primary medical care being added by providing additional guidance. Infections can spread and impose costs on other parties, and best practice guidance is a public good which is most efficiently produced once rather than multiple times; this supports a role for government.

What are the policy objectives and the intended effects?

Irrespective of the Code, providers will need to comply with the registration requirement on cleanliness and infection control. The objective of the Code is to exemplify what providers need to do in order to comply with the law - ie the Code itself does not have additional regulatory requirements but it provides guidance on how to meet the regulatory requirement, and the aim is to ensure the application of the Code is proportionate. A further objective is to ensure that best practice is consistently applied in all sectors so that the number of infections can be reduced and benefit service users. Additionally, by providing guidance with the Code, this should save time for providers, who would otherwise need to seek such guidance from multiple alternative sources.

What policy options have been considered, including any "alternatives to regulation". Please justify the preferred option below.

1. Produce a Code of Practice and related guidance emphasising flexibility for all providers of regulated activities. This allows local determination based on risk assessment and proportionality and, will act as a guide to interpretation of legislation and compliance (preferred option).

Will the policy be reviewed? It **will** be reviewed **What is the basis for this review? PIR**	**If applicable, set review date 10/2012**
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	**Yes**

Ministerial Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister: ..... Date: 5.12.10

URN 10/899 Ver. 1.0 04/10

Summary: Analysis and Evidence

Policy Option 1

Description: Produce a CoP and related guidance emphasising flexibility for all providers' of regulated activities.

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £-2.5m	**High:** £42.5m	**Best Estimate: £20m**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	3.3	2		**6.3**
High	9.9			**18.8**
Best Estimate	6.6			**12.5**

Description and scale of key monetised costs by 'main affected groups'

GPs - familiarisation with Code, Dentists - familiarisation with Code; Ambulance providers – familiarisation with Code

Other key non-monetised costs by 'main affected groups'

'None'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	3.3	2	1.2	**16.3**
High	9.9		3.6	**48.8**
Best Estimate	6.6		2.4	**32.5**

Description and scale of key monetised benefits by 'main affected groups'

GPs - savings from not having to assemble own guidance, savings in care from fewer infections; Dentists - savings from not having to assemble own guidance; Ambulance providers - savings from not having to assemble own guidance; NHS - savings from fewer infections.

Other key non-monetised benefits by 'main affected groups'

Patients should experience health benefits from fewer infections, but we have not been able to monetise these owing to lack of data on health status (with and without infections).

Key assumptions/sensitivities/risks **Discount rate (%)**

There are uncertainties around the amount of time needed to review current practices, about the extent of time savings, and about the impact on infections. Hence there is a risk that the overall costs and benefits may diverge from our best estimates by up to, say, 50%. This is reflected in the costs and savings above.

Direct impact on business (Equivalent Annual) £m: The figures here relate to independent ambulances. The other bodies affected are part of the "NHS family" and therefore these other bodies are not classed as "business".			In scope of OIOO?	Measure classified as
Costs: 0.01	**Benefits:** >0.01	**Net:** <0.0	**No**	**IN**

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/04/2011 and 01/04/2012		
Which organisation(s) will enforce the policy?			CQC		
What is the annual change in enforcement cost (£m)?			£0		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	Yes	11
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	15
Small firms Small Firms Impact Test guidance	Yes	15
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	16
Human rights Human Rights Impact Test guidance	No	11

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	

Sustainable development Sustainable Development Impact Test guidance	No	

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

No.	Legislation or publication
1	As above
2	Department of Justice (October 2006), "Human rights: human lives; A handbook for public Authorities"
3	Office for National Statistics (2000) Adult Dental Health Survey - Oral Health in the United Kingdom 1998.
4	Office for National Statistics (2005) Children's Dental Health in England 2003.
5	Department of Health (2008) NHS Next Stage Review: Our Vision for Primary and Community Care
6	Information Centre (2009) Trends in Consultation Rates in General Practice 1995/96 to 2008/2009: Analysis of the QResearch Database
7	Department of Health (2008). Impact Assessment of NHS Next Stage Review proposals for primary and community care.
8	The Health Survey of England 2000 reported that 70% of those aged 65 and over reported a longstanding illness and tat 10% of people aged 65-79 and 25% of those aged 80 and over reported a serious disability.
9	British Society for Disability and Oral Health (2000). Oral health care for people with a physical disability.
10	Department of Health (2007) Valuing People's Oral Health – A good practice guide for improving the oral health of disabled children and adults.
11	England Adult Dental Health Survey 1998 showed that the percentages attending for regular dental check-ups were: 65% for those where head of household is in the highest socio-economic classes; 58% for those where head of household is in the middle socio-economic classes; 50% for those where head of household is in the lowest socio-economic classes.
12	Laura Mitchell, Paul Brunton (2005). Oxford Handbook of Clinical Dentistry.
13	The Health Survey for England 2001 showed that there was a steady increase from Social Class I to Social Class V in the (age-standardised) prevalence of disability, from 8% in Social Class I, to 22% for men and 24% for women in Social Class IV, which then levelled out with the same rates for Social Classes IV and V. Among those with a disability, the proportion categorised as seriously disabled was also lower Social Classes I and II (about one in four) than in Social Classes IIIM, IV and V (one in three).
14	Joint Health Surveys Unit (on behalf of the Department of Health) (2001) Health Survey for England - The Health of Minority Ethnic Groups 1999.
15	2001 Census . Cited in Department of Health (2008) Equality Impact Assessment – World Class Commissioning of Primary Medical Care Guidance.

+ Add another row

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of**

monetised costs and benefits (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Total Transition costs	6.6	6.6								
Total Annual recurring cost	-	-	-	-	-	-	-	-	-	-
Total annual costs	6.6	6.6								
Total Transition benefits	>6.6	>6.6								
Total Annual recurring benefits	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Total annual benefits	8	8	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Business transition costs	0.056	-	-	-	-	-	-	-	-	-
Business annual recurring costs	-	-	-	-	-	-	-	-	-	-
Business annual costs	0.056	-	-	-	-	-	-	-	-	-
Business transition benefits	>0.056	-	-	-	-	-	-	-	-	
Business annual recurring benefits	-	-	-	-	-	-	-	-	-	-
Business total annual benefits	>0.056	-	-	-	-	-	-	-	-	-

* For non-monetised benefits please see summary pages and main evidence base section

Business here means independent ambulance providers.

[Dashes inserted where there are no impacts]

Use the following headings and add or delete as appropriate:

One In One Out

The Code of Practice on the prevention and control of infections and related guidance act purely as guidance to amplify The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, which came into force on 1 April 2010 and are available on the link below. The Code does not introduce any additional regulatory burdens.

www.opsi.gov.uk/si/si2010/uksi_20100781_en_1

Sunset Clause

This is not regulatory and so not subject to a sunset clause.

Evidence Base (for summary sheets)

Introduction

1. The Health and Social Care Act 2008 introduces a new registration framework for all providers of regulated activities in healthcare, including primary care, and adult social care in England. The framework will provide independent assurance of the safety and quality of care and these providers will need to register with the Care Quality Commission (CQC) and meet the same essential levels of safety and quality.

2. The full set of these essential levels, described as 'registration requirements' are set out in Regulations. The 2008 Act enables the Secretary of State for Health to issue a Code of Practice relating to healthcare associated infections ('the Code'), and the CQC will assess compliance with the registration requirement related to infections by reference to the Code.

3. The NHS, independent healthcare and adult social care all comply with the Code of Practice for health and adult social care on the prevention and control of infections and related guidance. The new Code is simply a restructuring of the same information to incorporate registered providers of primary dental care and independent ambulances from April 2011 and primary medical care from April 2012.

4. This final stage impact assessment considers two options for introducing the new Code under the Health and Social Care Act 2008.

    - our preferred approach, where we introduce the ten specific compliance criteria of the Code and provide related guidance to assist the interpretation of these by providers of all healthcare and adult social care, and the CQC; or
    - do nothing; this option acts as the baseline for our assessment of costs and benefits.

Background

5. The Health and Social Care Act 2008 established the CQC in place of the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission to regulate health care and adult social care in England.

Reasons for intervention

6. Under this Act, from 2010, the Government has introduced a new registration framework for all providers of regulated activities in healthcare, including primary care, and adult social care in England. The framework will provide independent assurance of the safety and quality of care and these providers will need to register with the CQC and meet the same essential levels of safety and quality. The full set of these essential levels, described as 'registration requirements' has been set out in Regulations.

7. The Health and Social Care Act 2008 enables the Secretary of State for Health to issue a Code of Practice relating to healthcare associated infections ('the Code'), and the CQC assess compliance with the registration requirement related to infections by reference to the Code.

8. From April 2010, NHS bodies were registered with the CQC against a full range of essential safety and quality requirements, one of which covers 'cleanliness and infection control'. These registration requirements extended to independent healthcare and adult social care providers from October 2010, as outlined in *The Health and Social Care Act 2008 Code of Practice for health and adult social care on the prevention and control of infections and related guidance*.

9. However, the requirements will extend further to include primary dental care and independent ambulance providers from April 2011 and primary medical care providers from April 2012. We are revising the Code in order to make it applicable to all these settings.

10. There are externalities in infection prevention and control (eg practice in one setting may have implications elsewhere, for example for the NHS which may need to deal with the consequences of an avoidable infection), and the provision of guidance has public good attributes and is best produced centrally to avoid duplication of effort, and both of these factors suggest a role for government.

Developing the new Code of Practice

11. A draft illustrative version of the new Code of Practice and its related guidance was produced towards the end of February 2010. This was discussed and initial views sought from a range of stakeholders from primary dental, medical and independent ambulance providers, as well as the CQC and other interested bodies.

12. In addition and in light of comments from a number of specific policy areas within the Department of Health, we made amendments to the draft Code of Practice and its related guidance, with a view to bringing it up to date to reflect current best practice and advice, ready for wider consultation. A consultation-stage impact assessment was also produced.

13. Stakeholders have made clear that they want to see the Code revised so that it can be applied to primary care settings. The Health and Social Care Act 2008 also requires that we consult on any such redraft.

14. A public consultation began on 26 March 2010 and ended on 15 July 2010. The consultation invited comments on the Code and its related guidance and the impact assessment and sought views on content, style, navigation, suitability and usability. In addition, during the consultation period, the Department had meetings with representatives from the primary dental and medical and ambulance professions (30 March); Royal College of Surgeons – Faculty of General Dental Practice (25 May and 11 June); British Medical Association (26 May and 28 July); Care Quality Commission (19 August); and key primary dental care bodies (25 August) to discuss any issues following release of the consultation documents.

15. The consultation did not provide additional quantitative information and, as most respondents were content with the draft, only small changes have been made to the impact assessment.

Policy Objectives

16. Irrespective of the Code, providers will need to comply with the registration requirement on cleanliness and infection control. The objective of the Code is to exemplify what providers need to do in order to comply with

the law - ie the Code itself does not have additional regulatory requirements but it provides guidance on how to meet the regulatory requirement.

17. Our policy objective is to ensure that good practice is consistently and proportionately applied in all sectors so that the number of infections can be reduced and benefit service users. The related guidance supplements the Code by providing practical information to ensure a clear understanding and implementation of the Code by all providers and the CQC, and the aim is to ensure the application of the Code is proportionate.

18. A reduction in infections amongst users of these services will reduce the number of people whose lives are made less comfortable from these conditions. Individuals as well as groups of individuals will benefit as transmission of these diseases between service users and staff will be reduced.

19. A further objective is, by providing guidance with the Code, to save time for providers, who would otherwise need to seek such guidance from multiple alternative sources.

Impacts and Costs

20. The new Code brings together current good practice and exemplifies the standards of care already applying within the other registered providers. Discussions with stakeholders indicate that many primary care providers are already fully compliant. Existing requirements in the primary medical and dental care contract regulations make clear that providers are already expected to have appropriate arrangements for infection control and decontamination.

GPs

21. On average GPs are expected to spend about 2 hours considering the new guidance, and adapting current protocols to make them compliant – for example reviewing their prescribing practices to avoid inappropriate use of broad-spectrum antibiotics which can cause *Clostridium difficile* infections, particularly in elderly people. While 2 hours may be an average, it may well be that some GPs will spend more time than this while others will spend less.

General Practitioners, dentists and opticians, as at 30 September 2006

United Kingdom — Numbers, percentages

	General medical services [1]						General dental services [2]			
	Number of practices	Number of general medical practitioners (GPs) [3]	Percentage who were female	Average list size per GP	Number of practice staff (whole-time equivalents) [4]	Percentage who were direct care practice staff [4,5]	Number of dentists [6]	Percentage of population registered with NHS dentist [6]	Average registrations per dentist	Number of opticians [7]
England	8,325	33,091	*41*	1,610	76,977	*26*	21,111	*49*	1,171	8,946

source: ONS (2008), *United Kingdom Health Statistics*

22. There are now around 34,000 GPs in England. At 2 hours per practitioner at about £90 per hour (source: Unit Costs of Health & Social Care 2009), the cost of their time will come to about £6million. In addition there are about 77,000 general practice staff – 1 hour of their time at £25 per hour (source: Unit Costs of Health & Social Care 2009) will come to nearly £2m, making a total of £8m. These are expected generally to be one-off costs.

23. Irrespective of the Code, providers will need to comply with the registration requirement on cleanliness and infection control. Hence, without the Code and guidance, we expect that GPs and practice staff would have to spend at least as much time as this, and probably more, seeking such guidance from multiple alternative sources – in other words there would be a saving to GPs worth at least £8million

24. In the consultation, the issue of staff immunisations was also raised; however the current Code of Practice does not add new requirements here. Decisions on offering immunisation should be made on the basis of a

local risk assessment as described in *Immunisation against infectious disease* ('The Green Book'). Employers should make vaccines available free of charge to employees if a risk assessment indicates that it is needed (COSHH Regulations 2002).

Dentists

25. Since the consultation earlier this year, our understanding has developed that dentists will very soon have become compliant with the guidance contained in Health Technical Memorandum 01-05: 'Decontamination in primary care dental practices'. The letter of 1st December 2009 from the Chief Dental Officer (England) accompanying HMT 01-05 stated "This guidance aims to progressively raise the quality of decontamination in the primary care environment and, wherever possible, gives options in terms of approach for achieving the requirements. The aim is that all practices will have met the HTM's essential quality requirements within 12 months of receiving this guidance. This will include having a detailed plan showing how practices will work towards achieving best practice." [Source: http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_109367] The current Code of Practice does not add any additional requirements to the guidance in HTM 01-05. Therefore, while there may be costs to dental practitioners from complying with HTM 01-05, there are no significant additional costs over and above those of HTM 01-05 arising from the current Code of Practice that we are aware of, apart from the costs set out in the next paragraph.

26. Dentists are expected to spend, on average, about 2 hours considering the new guidance, and adapting current protocols to make them compliant. Hence we assume that 21,000 dentists will spend about 2 hours each at about £90 per hour, and so the cost of this time will come to about £3.8million. We do not know numbers of dental assistants, but assume that the cost of their time would be in a similar ratio to dentists' time cost as that of GPs and their practice staff – hence we assume that the cost of dental assistants' and practice staff time would be around £1.2m, making a total of about £5m. However, irrespective of the Code, providers will need to comply with the registration requirement on cleanliness and infection control. Hence, without the Code and guidance, we expect that dentists would have to spend at least as much time as this, and probably more, seeking such guidance from multiple alternative sources – in other words there would be a time saving to dentists worth at least £5million.

Ambulances

27. Last year CQC commissioned a market analysis which identified 350 independent ambulance providers in England. Following the model of primary care above, we have assumed that each provider will have to spend, on average, about 4 hours considering the new guidance, and adapting current protocols to make them compliant, at about £40 per hour, and so the cost of this time will come to about £0.056million.

28. However, irrespective of the Code, providers will need to comply with the registration requirement on cleanliness and infection control. Hence, without the Code and guidance, we expect that ambulance providers would have to spend at least as much time as this, and probably more, seeking such guidance from multiple alternative sources – in other words there would be a time saving to them worth at least £0.056million.

Overall costs

29. The above costs for doctors, dentists and ambulance providers therefore sum to around £13.1m, but with offsetting cost savings that are likely to exceed £13.1m, compared with a 'counterfactual' (do nothing option) where the requirements remained the same, but the Code and centrally provided guidance were unavailable.

Benefits

30. Individuals, as well as groups of individuals, will benefit from improved infection control, as transmission of infectious diseases between service users and staff will be reduced. A reduction in infections amongst users

of these services will reduce the numbers of people whose lives are made less comfortable from these conditions: this leads to a potential increase in Q*uality Adjusted Life Years* (QALYs) from preventing illness and death. It can also leads to savings in staff time, for example.

31. To illustrate the potential benefit, we consider reductions in HCAIs such as *Clostridium difficile*. It is difficult to predict the impact of the Code but we anticipate that application of the Code will lead to a reduction in the number of HCAIs because primary care organisations will be taking a systems approach to their infection prevention and control practice.

32. We know that inappropriate prescribing by GPs contributes to the development of *Clostridium difficile* infections (CDIs) and improved prescribing would reduce the number of cases. Fewer individuals would be susceptible to infection as a result of broad spectrum antibiotics killing off the organisms found normally in the human intestine, and thus, hospital admissions. The financial benefits would be to the health system generally rather than the GP practice but their patients would benefit by not having CDI. Any impact on prescribing budgets would be marginal.

33. The number of CDI cases is declining at the moment and we will be setting a CDI objective shortly to ensure a further decrease. However, in 2012 it seems reasonable to assume that there could be 15,000 cases not apportioned to acute trusts ie cases where disease onset was before admission or within 72 hours of admission. Improved prescribing practice could perhaps prevent 1% of these infections – say 150 cases.

34. Cases where CDI is a primary diagnosis have long stays in hospital – latest data show 27 days on average. The Table below suggests that in Scotland the full average cost with a healthcare associated infection was around £3,000 for an added stay of 6.6days – so a cost for 27 days could be about £12,000. This would imply that the benefit of preventing 150 cases should be around £1.8m.

35. CDI is not the only infection that would be prevented but it is the easiest to quantify as we have surveillance data available and we know that CDI has an impact on other services. Reducing the number of minor ie less clinically significant infections such as infected ulcers would have benefits for patients and providers as it would reduce the number of consultations. It is not unreasonable to assume that at least 5,000 minor infections could be prevented in a year and assuming that these need 1 or 2 consultations, prevent 7,500 consultations. According to the Unit Costs of Health and Social Care, GP consultations cost on average about £80 (including average prescriptions). Avoiding such a number of consultations should therefore save about £0.6m.

36. This would suggest a saving from primary medical care of around £2.4million per year.

Table 8-3: *Comparison of economic estimates of cost of HAI estimated by previous studies*

	HAI %	Added stay days	Added cost £	Total cost £ million
Scottish Office 1999 (60)	9	2	314	22
Plowman 1994 (3) (Incidence)	7.8	11	2 917	101
Walker 2001 (13)	9.2	11	2 244	186
This study 2007	9.5	6.6	2 105	183
This study 2007 using the full average cost per stay	9.5	6.6	3 003	262

Source: http://www.documents.hps.scot.nhs.uk/hai/sshaip/publications/national-prevalence-study/report/full-report.pdf

37. There are likely to be further benefits in dentistry, eg arising through prevention of transmission of infections, perhaps including vCJD. Compliance with the Code of Practice will improve infection prevention and control and decrease the risk of transmission.

38. Animal studies indicate that dental tissues can potentially transfer infectivity including vCJD. Where the risks are highest, in dental pulp tissue, HTM 01-05 in line with Departmental policy recommends single use instruments, where effective cleaning of instruments is not possible. Such is the volume of dental procedures undertaken each year in England that even a small reduction in risk could lead to significant benefits for public health. Benefits from such risk reduction were assessed for the Impact Assessment for regulation of primary medical and dental care providers under the Health and Social Care Act 2008 and we have not counted these again here. See http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_107652.pdf

39. Using the standard discount rate of 3.5% pa, over a time period of 10 years, an annual saving of £2.4m produces a present value of £20m.

40. We have not attempted to monetise any further benefits of improved infection control here. However, the benefits to patients of primary care providers are likely to be more wide ranging than has been illustrated here.

Specific Impact Tests

Health Impact Assessment

41. The main impact assessment above is about health and how we expect better regulation to have an improvement in health through reducing the number of adverse incidents to service users of healthcare, including primary care, and adult social care.

Equality Impact Assessment

The evidence base

42. It is anticipated that the new system of regulation and the Code of Practice and its related guidance outlined above will lead to a general improvement in the quality and safety of healthcare, including primary care, and adult social care services. The inclusion of new providers into the registration system will have an impact on the quality of provision of some providers, especially those that are not currently meeting what we consider to be essential levels of quality.

43. The regulations and the Code of Practice and its related guidance will improve the quality of service provision for all users of health care and adult social care services, and the case in support of this is set out in the impact assessment. It is reasonable to assume that this benefit will be felt most strongly by groups who are more frequent users of health and adult social care services.

44. In carrying out the registration system and its other regulatory functions the CQC can consider 'the requirements of any other enactment which appears to the CQC to be relevant'. (Health and Social Care Act 2008). This means that the CQC will be able to consider how registered providers are complying with the requirements of the Human Rights Act 1998 and equality legislation. It will be able to address equality, respect for diversity and other human rights in reaching decisions on registration.

What the evidence shows

Human Rights

45. It is important that including primary medical and dental care within the CQC registration system is compatible with all human rights provisions in accordance with 1998 Human Rights Act[2]. In particular, the new Code of Practice and related guidance reflect two of these human rights provisions in the following way:

• The right to life – the new Code of Practice ensures that the right to life is not compromised by failure to manage hygiene and spread of infection.

• The right to respect for private and family life – the new Code of Practice ensures that the right to privacy is not compromised by healthcare associated infection and attitudes by staff and other people to their consequences.

46. Introducing primary medical and dental care within the CQC registration system and scope of the Code will not infringe on any of the human rights provisions and is compatible with all of the articles in The European Convention on Human Rights.

Equality

Age

47. The physiology of oral disease means that the oral health needs of children and adults are different. The Adult Dental Health Survey 1998[3] found that age was the most significant variable in explaining the variation in the majority of measures of oral health.

48. Fifty-one percent of dentate adults reported having experienced one or more oral problems that had an impact on some aspect of their life occasionally or more often during the year preceding the survey. In contrast, the survey of children's dental health in 2003 found that the parents of most of the children in all age groups did not think their children had been affected by their oral condition in the preceding year[4].

49. Almost everyone, 99 percent of the population, is registered with a family doctor[5]. The overall consultation rate for the general population was 5.5 consultations per person per year. However, GP consultation rates vary markedly by age. In 2008/09 the highest consultation rates were for the very young (7.33 for girls under 5 and 7.83 for boys under 5) and the elderly (13.46 for women aged between 85 and 89 years and 13.96 for men aged between 85 and 89 years)[6].

50. Many risk factors for poor health, such as obesity, hypertension, disability, and poverty increase with age. The prevalence of most acute and chronic diseases increases with age and the proportion of people with a long-term illness or disability that restricts their daily activities also increases with age[7,8]. This helps explain the higher GP consultation rates for those aged over 60.

51. We anticipate that the new Code of Practice and related guidance, will result in overall improvements in healthcare, including primary care, and adult social care services across England. Given the relatively heavier use of dental services by adults they are more likely than children to benefit from improvements. Changes in general practice are most likely to benefit young children and older people.

Disability

52. There is evidence that people with a disability experience poorer oral health, and barriers to achieving good oral health and accessing appropriate dental services[9,10]. Research has also shown that a reduced use of dental services and poorer oral health tend to correlate with lower socio-economic status[11,12]. The Health Survey for England 2001 showed that disabled people are more likely to fall into Social Class IV and V[13]. There is no evidence to suggest that improvements introduced by the Code will impact adversely on disabled groups.

53. Disabled people are likely to be heavier users of both health and social services. Research carried out for the Office for Disability Issues found that fewer than one in five disabled people described their health as good, compared to two in three of the general population. A third of disabled people felt their health had worsened in the last twelve months. More than nine out of ten disabled people had used a health service in the past three months, which is significantly higher than the general population. Thus as a group disabled people are likely to benefit from changes introduced by the Code.

Gender

54. There is evidence that, in line with their use of other parts of the healthcare system, men visit the dentist less often than women. Thus, given their greater use of dental and medical services women are more likely than men to benefit from improved care due to the Code.

Ethnicity

55. We recognise that a disproportionately high number of people from black and minority ethnic (BME) groups live in areas of high social need, which is directly correlated with poor oral health. Dental services are also utilised at different levels across different ethnic communities. A study carried out by the Joint Health Surveys Unit[14] found that men and women in all minority ethnic groups were significantly less likely than the general population to visit a dentist for a regular check-up. Thus, ethnic groups are unlikely to benefit particularly from improvements in dentistry due to the Code.

56. The average proportion of BME patients registered with a GP practice is 19 percent. Practices with the highest proportions of BME patients are performing less well than those practices with lower proportions of BME patients. However, this gap is narrowing over time. Patients from black and ethnic minority backgrounds are more likely to be dissatisfied with the service that they receive from their GPs. Improvements could therefore benefit this group. There is no strong evidence to suggest that the Code of Practice will differentially affect ethnic groups. However, as the prevalence of diabetes is higher in BME populations, especially those with an Asian or Afro-Caribbean background and diabetes is increasing, they may benefit from a reduction of diabetes-related infections in the future. Infections, especially foot ulcers, are a serious medical problem for diabetics.

Religion or Belief

57. There is no direct evidence to suggest that the use of dental services or GP services varies according to people's religion or belief. However, of all faiths, limiting long-term illness or disability rates are reported to be highest among Muslims (24 percent for females, 21 percent for males) and these groups may benefit from change introduced by the Code[15].

Sexual Orientation

58. There is no direct evidence to suggest that the use of dental services or oral health is different according to people's sexual orientation. For primary medical care there is currently limited data available on sexual orientation issues. There is no direct evidence on GP consultation rates or access to GP services.

Overall Impact of Code on Equality

59. An adverse impact is unlikely. On the contrary there is potential to reduce barriers and inequalities that currently exist as, for the first time, all providers of services within the scope of registration will need to register. The registration requirements and the new *Code of Practice on the prevention and control of infections and related guidance* have been designed to produce a fairer playing field across all areas of health, including primary care, and adult social care, reducing any inequalities that exist. None of the proposals are expected to adversely impact on any particular groups or groups of staff working in primary medical care and primary dental care.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. *If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date.* A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)]; Under the Health and Social Care Act 2008, the Department of Health intends to review the impact and likelihood of risk in the regulated activities, and will monitor how proportionate the burden of regulation is to the mitigation of those risks within the next three years. The impact and effectiveness of the Code of Practice on the prevention and control of infections will be part of that review process.
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] Introduction of this Code aims to provide a comprehensive best practice guide to registered providers and the CQC by setting out how providers might meet the registration requirement on cleanliness and infection control as set out in regulations. The Code emphasises that the aim is to ensure the application of the Code is proportionate as clearly the risks differ according to the settings. Assessment of how effective the Code has been in terms of its usefulness as a tool for interpretation of the regulations and how it contributes to reduced infections will be determined by the CQC inspection process, local and national patient satisfaction surveys and infections surveillance data.
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach] Given the purpose of the Code, the above-mentioned methods of assessment are those considered best placed determine its effectiveness. Through our normal working practices we are generally made aware of CQC inspection and patient satisfaction surveys through various reports and infection surveillance data collection is an ongoing process.
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured] There are set dates on which the regulations will come into force for these sectors and although precise attribution of changes in infection rate to the implementation of the Code is not possible, it is possible to form a general idea from detailed feedback through various routes.
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives] Through the processes outlined above, we should be able to determine the effectiveness of the Code and whether a change in approach is required.
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review] Data on infections are collected routinely and trend analysis will show if our approach is effective. Information collected by CQC's risk profiles will enable detailed analysis.
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]

Annex 2: Competition Assessment & Small Firms Impact Test

Introduction
We have estimated the impacts of the Code and Guidance and their costs and benefits in the main part of the Impact Assessment. We believe that the costs are generally going to be one-off costs. This is composed of a small initial time cost to apprise themselves of the new Code and Guidance and checking and ensuring compliance, likely to be more than offset by savings through not having to assemble their own guidance; and over the longer term there are likely to be savings in time costs (and perhaps some material costs) owing to better prevention and control of infections; as well as improvements in the quality of care for vulnerable people.

The time costs are very small in comparison with overall expenditure in this sector.

The above calculations have informed our assessment of competition and small firms impacts.

Competition Assessment

1. The proposal would not be likely directly to limit the number or range of suppliers. Rather it sets a common platform on which suppliers can compete.
2. The proposal would not be likely indirectly to limit the number or range of suppliers. It is not likely to affect costs significantly.
3. The proposal would not be likely to limit the ability of suppliers to compete. In fact the proposal is more likely to increase the ability of suppliers to compete on the basis of a common set of standards applied to all registered suppliers (and there are many thousands of suppliers in the sector).
4. The proposal would not be likely to reduce suppliers' incentives to compete. It is more likely, for example, to enhance consumer and commissioner choice and ability to switch suppliers, based on the knowledge that the same standards apply to all.

Small Firms Impact Test

1. The proposal would affect independent suppliers, many of which could be regarded as small businesses.
2. The proposal sets a common platform on which suppliers can compete on equal terms. The standards deliberately do not favour either small businesses or large businesses.
3. Enforcement by the CQC will be risk-based and take a proportionate approach.
4. We have taken soundings from stakeholders at the British Dental Association; Care Quality Commission; General Dental Council; Royal College of Nursing; British Medical Association; Independent Ambulance organisations and a number of Department of Health officials with policy responsibility in regulatory and primary care specialties. These also included General Practitioners who advise DH on particular matters of policy.
5. The main initial responses were around:
   - the correct use or clarification of specific terms, roles or policy intentions;
   - suggestions of additional text for clarification;
   - matters more appropriate for other bodies, documents or local decision;
   - the Code being very comprehensive but needing to be mindful of equity between providers. However, it offers a helpful and flexible approach;
   - concern about impact of any additional costs/resources, proportionality and the role of commissioning;
   - Appendices are proportionate and helpful for interpreting the Code;
   - concern about how this interacts with other Codes or requirements;
   - a need for longer opportunity to comment in detail.

   This has informed our assessments of impacts.
6. The proposal is not likely to affect suppliers' costs significantly. Given that the cost impacts are relatively small they are unlikely to be appreciably more significant for small businesses than for large ones.

Health Impact Assessment

Executive Summary

This HIA aims to assess the wider and indirect impacts of the new Code of Practice and related guidance, (referred to, from here as the 'Code') on people's health and well-being.

The assessment will be carried out following the Department of Health's HIA screening questions: http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Healthassessment/DH_4093617

Conclusion

There will be no significant impact on people's health through its effect on wider determinants of health.

There will be no significant impact on people's lifestyle related variables.

There will be a significant demand on primary care providers.

Screening Questions

(A) Will your policy have a significant impact on human health by virtue of its effects on the following wider determinants of health?

Income, Crime, Environment, Transport, Housing, Education, Employment, Agriculture, Social Cohesion

The Code has no direct effects on any of the above. Therefore, there are no indirect effects on human health because of these wider determinants of health.

It will have benefits on human health, but these will be through its effect on assuring patients receive primary care that meets essential levels of quality and safety.

The main section of the Impact Assessment gives a detailed analysis of the benefits to human health.

(B) Will there be a significant impact on any of the following lifestyle related variables?

Physical activity; Diet; Smoking, drugs of alcohol misuse; Sexual behaviour; Accidents and stress at home or work

The Code has no direct effects on any of these lifestyle related variables.

(C) Is there likely to be a significant demand on any of the following health and social care services?

Primary care, Community services, Hospital care, Need for medicines, Accident or emergency attendances, Social services, Health protection and preparedness response

The Code will impose demands on primary care providers.

Primary dental and medical care and independent ambulance providers will have to register with the Care Quality Commission. They will be required to comply with the registration requirements and prove compliance; as such, there will be administrative demands. These demands are examined in further detail in the main section of the Impact Assessment.

There will be no significant demand on any of the other health and social care services.