

health

# Outcomes

indicators

## DIABETES MELLITUS

Report of a working group  
to the Department of Health



## FOREWORD

The Government consultation document "A First Class Service - Quality in the new NHS", published in 1998, emphasised three essential aspects of ensuring delivery of high quality of care by the National Health Service: setting, delivering and monitoring standards. It also discussed the importance of partnership between the Government and the clinical professions and patients in achieving such quality.

This series of 10 reports concerns the third aspect - monitoring standards. It represents the culmination of work that was started several years ago under the auspices of the Clinical Outcomes Group, chaired jointly by the then Chief Medical Officer, Sir Kenneth Calman, and the Chief Nursing Officer, Dame Yvonne Moores. The work was commissioned by the former Central Health Outcomes Unit of the Department of Health. The Unit has since moved and is now called the National Centre for Health Outcomes Development (NCHOD), based jointly at the Institute of Health Sciences, University of Oxford and the London School of Hygiene and Tropical Medicine, University of London.

The background to the work was the need to ensure that the NHS is driven by considerations of quality and outcome. The Department wanted to build on an earlier set of Population Health Outcome indicators, which had been limited by the constraints of existing routine data. It therefore commissioned systematic work on ten clinical topics, to be undertaken by a Working Group on each, tasked to make recommendations on 'ideal indicators' for each condition. 'Ideal indicators' were defined as statistical measures of what should be known, and realistically could be known, about the outcomes of the condition in routine clinical practice. The Groups were asked to consider a wide spectrum of possible uses of outcome indicators, from national monitoring of NHS performance by government to the periodic assessment of local services by clinicians and users.

The work of the Working Groups was coordinated by Michael Goldacre, University of Oxford. A particular feature of the work is that the Groups have recommended definitions and technical specifications for each indicator. It is hoped that people interested in monitoring the topic covered by each indicator will use the same definitions so that comparisons can be facilitated. Moreover, the methodology adopted by the Working Groups is applicable to developing health outcome indicators for many other conditions.

The publication of these reports, however, is only one further step on a long road of quality assessment in health care. The reports present 'menus' of suggestions for ways in which outcomes might be monitored in a variety of settings, by a variety of organisations and people. It goes without saying that NCHOD will welcome feedback on the reports and on the development and use of outcome indicators.

I believe that the work described here shows the value and potential of partnerships between various parties. Each working group had members who brought together perspectives of all the relevant clinical professions plus patients, NHS managers, policy makers, researchers and others as appropriate. The recommendations of the Working groups show quite clearly how these various perspectives may contribute to a broader and more balanced monitoring of standards. I would personally like to congratulate and thank everyone who has worked so hard and well to bring this initiative to fruition.

Azim Lakhani (Director - National Centre for Health Outcomes Development)

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# SUMMARY OF RECOMMENDATIONS

Using a variety of check lists including a health outcome model, the Group identified outcome indicators which were fully specified in a standard format and are included in this Report. Outcome indicators, whose numbers correspond to the specifications in Section 4, were grouped under three headings relating to the aim of the intervention.

Recommendations for implementation were made for each indicator using the following categories:

- A.** To be implemented generally on a routine basis.
- B.** To be implemented generally by periodic survey.
- C.** To be implemented where local circumstances allow on a routine basis.
- D.** To be implemented where local circumstances allow by periodic survey.
- E.** To be implemented following IT developments on a routine basis.
- F.** To be further developed either because the link with effectiveness is not clear or the indicator specification is incomplete.

| Category | Page      |  |
|----------|-----------|--|
|          |           | <b><i>Indicators related to reducing or avoiding risk of diabetes and appropriate detection of diabetes</i></b>  |
| <b>A</b> | <b>22</b> | <b>1.</b> Prevalence of clinically diagnosed diabetes.   |
| <b>E</b> | <b>24</b> | <b>2.</b> Percentage prevalence of retinopathy and maculopathy at the time of diagnosis of diabetes.   |
| <b>B</b> | <b>26</b> | <b>3A.</b> Prevalence of obesity in persons aged 16-64 (defined as BMI > 30 kg/m <sup>2</sup> ).   |
| <b>F</b> | <b>26</b> | <b>3B.</b> Proportion of people undertaking rigorous physical activity in the previous 28 days.  |
| <b>F</b> | <b>26</b> | <b>3C.</b> Proportion of people who, on average, consume fruit or vegetables or salad each day, within the general population.   |
|          |           | <b><i>Indicators related to reducing risk of complications</i></b>   |
| <b>C</b> | <b>28</b> | <b>4.</b> Percentage of patients, aged 16 and over and known to have diabetes, who smoke.  |
| <b>C</b> | <b>30</b> | <b>5.</b> Percentage of patients, aged 16-64 and known to have diabetes, who have a BMI >30 kg/m <sup>2</sup> .  |
| <b>C</b> | <b>32</b> | <b>6.</b> Percentage of patients known to have diabetes with elevated blood pressure: Type 1 >140/90 mm Hg Type 2 >160/90mm Hg.  |
| <b>C</b> | <b>34</b> | <b>7.</b> Percentage of patients known to have diabetes with HbA <sub>1c</sub> that was > 7.5% on a DCCT standardised assay, at time of last recording within the previous year. |
| <b>C</b> | <b>36</b> | <b>8.</b> Percentage prevalence of retinopathy and maculopathy within a population known to have diabetes.   |
| <b>C</b> | <b>38</b> | <b>9.</b> Percentage prevalence of microalbuminuria within a population known to have Type 1 diabetes.   |

- |   |    |  |
|---|----|--|
| C | 40 | 10. Percentage prevalence of protective sensation loss within a population known to have diabetes.   |
| C | 42 | 11. Percentage prevalence of absence of both pulses in at least one foot within a population known to have diabetes.   |
| C | 44 | 12. Percentage of patients known to have diabetes where there is no record of blood pressure, the retinae or the feet having been assessed within the previous year. |
| C | 46 | 13. Percentage prevalence of symptomatic angina within a population known to have diabetes.  |
| C | 48 | 14. Percentage prevalence of claudication within a population known to have diabetes.  |

***Indicators related to reducing impact of diabetes***

- |   |    |  |
|---|----|--|
| A | 50 | 15. Number of patients who have had at least one hypoglycaemic emergency, within the last year, that required therapeutic intervention by a health professional, expressed as a proportion of a population of patients known to have diabetes.   |
| A | 52 | 16. Number of patients who have had at least one hyperglycaemic emergency, within the last year, that required hospital admission expressed as a proportion of a population of patients known to have diabetes.                                  |
| C | 54 | 17. Case fatality rate associated with acute diabetic episodes treated in hospital.  |
| A | 56 | 18A. SMR for death due to diabetes mellitus.   |
| A | 56 | 18B. Years of life lost per 10,000 resident population by death due to diabetes mellitus.  |
| A | 56 | 18C. Years of life lost by death due to diabetes mellitus.   |
| C | 58 | 19. Annual incidence of severe visual impairment (visual acuity < 6/60 in the better eye) within a population of patients known to have diabetes.  |
| C | 60 | 20. Annual incidence of leg amputation above the ankle within a population of patients known to have diabetes.   |
| C | 62 | 21. Annual incidence of amputation below the ankle within a population of patients known to have diabetes.   |
| C | 64 | 22. Annual incidence of myocardial infarction within a population of patients known to have diabetes.  |
| C | 66 | 23. Annual incidence of stroke within a population of patients known to have diabetes.   |
| D | 68 | 24. Number of patients who have started renal replacement therapy or have had a creatinine level > 500 mol/litre recorded for the first time within the last year, expressed as a proportion of a population of patients known to have diabetes. |
| C | 70 | 25. Rates of late stillbirth and perinatal mortality in deliveries from a population of patients known to have diabetes and who become pregnant.   |
| C | 73 | 26. The rate of delivery by caesarean section, in deliveries from a population of patients known to have diabetes and who become pregnant.   |

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|----------|-----------|---|
| <b>C</b> | <b>75</b> | <b>27.</b> The incidence of delivered babies with birthweight greater than the 90th centile (allowing for gestational age) from within a population of patients known to have diabetes and who become pregnant.                     |
| <b>C</b> | <b>77</b> | <b>28.</b> The incidence of occurrence of specific congenital malformations (i.e. neural tube defects, cardiac and renal malformations) in deliveries from a population of patients known to have diabetes and who become pregnant. |
| <b>C</b> | <b>79</b> | <b>29.</b> The rate of admission to special care baby units (and nurseries) of babies delivered from a population of patients known to have diabetes and who become pregnant.   |
| <b>F</b> | <b>81</b> | <b>30.</b> Summary of a measure of psychological well-being within a population of patients known to have diabetes.   |
| <b>F</b> | <b>83</b> | <b>31.</b> Summary of a measure of health status / health related quality of life within a population of patients known to have diabetes.   |
| <b>F</b> | <b>85</b> | <b>32.</b> Summary of a measure of satisfaction with service within a population of patients known to have diabetes.  |

# 1. INTRODUCTION TO THE REPORT

## **Health outcome indicators**

- 1.1** This Report is one of a series containing the recommendations of working groups set up to develop 'ideal' indicators of the health outcomes of specific conditions. The background to the work, commissioned by the Department of Health, is summarised in Appendix A.
- 1.2** Health outcomes have been defined as changes in health, health related status or risk factors affecting health, or lack of change when change is expected. They may be the result of the natural history of the condition or may be the effect of interventions to prevent or treat it. The particular concern of the working groups has been to make recommendations about outcomes which may be attributable to interventions or the lack of them.
- 1.3** The term 'indicator' has been defined as an aggregated statistical measure, describing a group of patients or a whole population, compiled from measures or assessments made on people in the group or the population. An indicator may not necessarily provide answers to whether care has been 'good' or 'bad'; but well chosen indicators, as the term implies, should at least provide pointers to circumstances which may be worth further investigation.
- 1.4** An 'ideal' indicator has been taken to mean what should be known, and realistically could be known, about the outcomes of the prevention and care of specific conditions. The development of the recommendations has, of course, been tempered by considerations of the likely cost and availability of information. However, the working groups have tried to be reasonably far-sighted in their views about future advances in information systems.
- 1.5** For each condition the working group has developed a menu of indicators which can be used by different groups of people for a variety of purposes. In particular, an attempt has been made to recommend, within each set, indicators which reflect a population, clinical, patient, and in relevant cases, a carer perspective.

## **Diabetes Working Group**

- 1.6** The terms of reference and membership of the Group are shown in Appendix B. The Group included representatives of professional, managerial and patient groups involved with the prevention and treatment of diabetes.

**1.7** The work of the Group had three main components:

- development of check lists including a health outcome model for diabetes to assist members choose candidate indicators by which is meant potential indicators worth detailed consideration
- specification of candidate indicators
- recommendations about implementation and further development.

**1.8** In this Report:

- the health outcome model is described in Section 2
- check lists for choosing candidate indicators are outlined in Appendix C
- guidelines for specifying candidate indicators are described in Appendix D
- candidate indicators chosen for specification are listed in Section 3
- candidate indicator specifications are included in Section 4
- recommendations about implementation and development are made in Section 5
- references to all sections and appendices are in Appendix E.

### **Recommendations**

**1.9** The recommendations made by the Group were categorised as those which:

- can be implemented generally throughout the NHS as there are systems available which can provide the requisite data
- could be implemented now where local circumstances allow and more generally in the near future once expected developments are in place
- will not be possible to implement in the near future but, because of their desirability, they should be considered in the future development of clinical and management information systems
- require further work before a recommendation can be made.

**1.10** The recommendations have been further categorised as to whether the requisite indicators should be available:

- routinely on a universal and continuous basis
- from periodic surveys and/or sampling, either at different points in time nationally or in geographical areas when there is a particular need or interest.

## 2. HEALTH OUTCOME MODEL FOR DIABETES

### **Definitions and scope of the work**

**2.1** Diabetes is a group of disorders with a number of features in common, of which raised blood glucose is the most evident. The three disorders in this group which make the most impact on the health of people in this country are:

- Insulin dependent diabetes mellitus (IDDM or Type 1)
- Non-insulin dependent diabetes mellitus (NIDDM or Type 2)
- Gestational diabetes (or diabetes of pregnancy).

A further group of individuals may be identified who, whilst not meeting the biochemically defined criteria recommended for the diagnosis of diabetes, nonetheless do have impaired glucose tolerance.

**2.2** The Group decided to exclude from its remit the specific consideration of children and impaired glucose tolerance and pregnancy associated diabetes. However, outcomes of pregnancy in women who had diabetes before becoming pregnant are within the scope of the work.

**2.3** The Group recognise that the aetiology and natural history of Type 1 and Type 2 diabetes are very different. However, many of the serious adverse health impacts and in particular those arising from damage to the eyes, feet, kidneys, and heart are eventually common to both types of diabetes, as is the importance of self management and the impact of this on lifestyle. Accordingly, despite the differences, the Group felt able to recommend a common set of indicators, albeit with analysis for the two types of diabetes always being separate.

### **Developing a health outcome model**

**2.4** The greater part of the input to the development of the diabetes outcome model came from already published national work including:

- *Diabetes mellitus: an epidemiologically based needs assessment review* (Williams 1994).
- *Standards of clinical care for people with diabetes* (Clinical Standards Advisory Group 1994).
- *Chapter on diabetes in the Oxford Textbook of Medicine* (Bell and Hockaday 1996).
- *The recommendations of the St. Vincent UK Workgroup* (1996).

**2.5** The health outcome model for diabetes was developed as an aid to help Group members identify potential indicators. The model contains four elements:

- an overview of the epidemiology of the disorder
- a review of causes and risk factors
- a review of the course, complications and impact of the disorder
- a review of relevant interventions.

### **Overview of epidemiology**

**2.6** The prevalence of clinically diagnosed diabetes of all types in England was once thought to be around 2%, but the recent studies suggest much higher values, depending to some extent on the racial mix of the particular population under study. The figure of 2% is likely to be an underestimate of the true prevalence as many patients with diabetes, particularly Type 2, will be undiagnosed. The ratio of undiagnosed to diagnosed diabetes will vary with geographical location. The prevalence of diabetes is higher in the lower socio-economic groups. The prevalence of Type 2, may be at least twice as high amongst people of Asian and Afro-Caribbean than European origin.

**2.7** The incidence of diabetes in children and adolescents (those aged 0-19 years) in England is between 10 and 15 new cases per 100,000 population per year. It is likely that all of these people will present to medical services because they will nearly all require insulin treatment.

**2.8** Care of people with diabetes is costly, consuming around 5-8% of the UK NHS budget or around £1.25 to 2 billion in the UK (Marks 1996). Most of the healthcare costs of diabetes result from complications requiring hospital admission and treatment (Clinical Standards Advisory Group 1994). Foot problems and cardiovascular disease account for a high proportion of hospital admissions, considerable disability and, in the case of cardiovascular disease, considerable premature mortality.

### **Causes and risk factors**

**2.9** Type 1, insulin dependent, diabetes often has an onset in childhood or adolescence, with genetic susceptibility in association mainly with certain HLA antigen markers and to a much lesser extent with genes on other chromosomes.

**2.10** For clinical diabetes to develop, those with a genetic predisposition must encounter environmental influences that precipitate diabetes. The precise factors are unknown.

- 2.11** Type 2, non-insulin dependent, diabetes tends to develop during later adult life and it appears to have a strong genetic component demonstrated by the frequent finding of a family history of diabetes in patients with the condition. Obesity and diabetes are often seen in association, and control of blood sugar and lipid levels may frequently be achieved by attention to weight reduction, dietary control and increased physical activity.
- 2.12** Diabetes may sometimes be secondary to other conditions such as pancreatic and liver disease, hormonal abnormalities, genetically determined syndromes or drug treatment. Pregnancy may be associated with impaired glucose tolerance or diabetes in 3% of women generally, but this is considerably greater in some ethnic groups. Though many of them will not be diabetic after childbirth, some do continue to have a problem and many develop diabetes in later life.

#### **Course, complications and impact**

- 2.13** Having diabetes may have a profound impact on social and psychological well-being as well as physical ill health. As with any chronic disease, a person's employment, home life and position in society may come under pressure, often with implications for the life and health of carers. If the late complications develop then day to day living may be severely impaired.
- 2.14** There is a close association between glucose intolerance, obesity, hypertension, dyslipidaemia, peripheral vascular disease and ischaemic heart disease. These conditions frequently occur together in the same individual and cause considerable mortality and morbidity.
- 2.15** In patients whose diabetes is untreated, including those who have newly developed the disease, glucose metabolism may be sufficiently disturbed to cause symptoms. The classic symptoms of high blood sugar are polyuria, thirst, weight loss and fatigue. Left untreated, patients may become dehydrated and suffer profound metabolic disturbance, especially if they have Type 1 diabetes, leading to coma and death.
- 2.16** The main complications of diabetes are eye disease, kidney disease, peripheral neuropathy, peripheral vascular disease and cardiovascular disease. Estimates of the prevalence of these complications are shown in Exhibit 1. The occurrence of all of these complications is lowest in younger people and rises quite markedly with increasing age.

**Relevant interventions**

**2.17** The Group reviewed the relevant interventions for diabetes using the following classification of aims of interventions:

- reduce or avoid risk of diabetes
- detect diabetes early
- reduce risk of complications of diabetes
- reduce the impact of diabetes and its complications once developed.

**EXHIBIT 1: BIOMEDICAL IMPACT OF LATE COMPLICATIONS IN THE UK  
(St. Vincent UK Workgroup 1996)**

|   |                    |
|---|--------------------|
| Diabetic patients newly requiring renal replacement therapy | 600 per annum      |
| Incidence of sight-threatening retinopathy                  | 1.5% per annum     |
| Prevalence of foot ulceration                               | 3.3% per annum     |
| Incidence of lower extremity amputation                     | 0.6-1.0% per annum |
| Incidence of new ischaemic heart disease in Type 2          | 3.2% per annum     |
| Cardiovascular disease as cause of death                    | 55%                |
| Number of people with diabetes in UK                        | 1,210,000          |

**2.18** For practical purposes it is not possible at present to **prevent the onset** of Type 1 diabetes. It is probable that the volume of Type 2 diabetes in the population would be reduced by measures aimed at reducing obesity and increasing physical activity in the population.

**2.19** Those developing insulin dependent diabetes at a younger age are likely to present to the medical services as they become acutely symptomatic. The people who may go for years without being diagnosed as diabetic, and who are therefore exposed to an increased risk of complications, are those with late onset Type 2 diabetes. These undiagnosed people constitute a significant proportion of the total population with diabetes. It is possible to **screen for glycosuria** in primary care and a small study in the UK has shown that it is feasible to do this by using urine testing sticks sent by post. Although the testing is cheap, the logistics of maintaining a continuing surveillance programme are currently not attractive. However, there are also problems associated with such an approach which revolve around the sensitivity, specificity and predictive value of testing in these circumstances, the postal response rate, the adverse social and psychological consequences of a new diagnosis in an asymptomatic individual and the size of any benefit to such patients.

- 2.20** With respect to **avoiding complications**, control of hyperglycaemia is important in avoiding acute deterioration into metabolic acidosis or hyperosmolar state and in reducing the risks of acute infections and serious thrombotic events. Hypoglycaemia is an unpleasant and often feared problem, and not infrequently results in acute cognitive impairment or even coma.
- 2.21** It has been accepted for some time by those who care for people with diabetes that the achievement of as normal a blood glucose concentration as possible is advantageous in that it will contribute to the reduction or postponement of long term complications of diabetes. The direct evidence to support this in Type 1 diabetes has been slow in accumulating but is now available particularly for diabetic retinopathy and renal disease.
- 2.22** The risk of long term complications may be reduced by attention to cardiovascular risk factors such as smoking, hypertension, obesity and dyslipidaemia.
- 2.23** There is a large degree of agreement on the aims of diabetes care and how these might be achieved. These should include:
- maintenance of quality of life
  - identification of all those with diabetes
  - involvement of all those identified in planned programmes of care
  - ensuring that all those with diabetes have access to appropriate education
  - maintenance of metabolic control
  - control of arterial factors
  - elimination of the acute problems of hypo- and hyperglycaemia
  - ensuring the early identification and treatment of complications
  - improvement of metabolic control pre-conception and in pregnancy.
- 2.24** Achieving control of diabetes relies heavily on the motivation and understanding of the condition by people with diabetes and their carers. This is facilitated and supported by a health care team which has expertise and the time available to enable patients to manage their diabetes (Clinical Standards Advisory Group 1994).

**2.25** The routine care of people with diabetes is often undertaken by a team of health care staff working in primary and secondary care settings. Specialised treatment and investigation of diabetes and its complications will usually be undertaken by a hospital-based or diabetes centre-based team, while more routine care and regular monitoring of patients is often undertaken by primary care teams as well as by specialists in hospital out-patient clinics. The relative effectiveness of diabetes care delivered in different settings has been the subject of a large number of UK based studies. Such studies suggest that where practices are enthusiastic and interested in the care of patients with diabetes there is no detectable difference between general practice and hospital care for the variables measured. The same is probably not true for the less interested or less motivated practices or hospitals.

**2.26** The Clinical Standards Advisory Group Report (1994) states that high quality care is most likely to take place, wherever the setting, when the following are available:

- well defined liaison between hospital and community teams
- trained and motivated personnel
- practice-based register of patients with diabetes, linking to a population-based register where possible
- protected time for the initiation of treatment, education and follow-up
- clinical and educational audit of activities
- recognition of a protocol for diabetes care
- regular recall of the patients for clinical review
- curriculum for patients' education.

**2.27** Major long term complications of diabetes affecting the eye are retinopathy and cataract. Small blood vessel disease in the back of the eye may lead to poor blood supply, haemorrhages, exudate formation and proliferation of small blood vessels. Laser treatment to the back of the eye is effective in modifying the course of diabetic retinopathy. Cataracts may be removed and replaced with an artificial lens, where appropriate, to restore sight and visual access to the back of the eye by clinicians.

**2.28** Coronary artery disease is at least twice as common in patients with diabetes as in the normal population. Painless ischaemia appears to be more common with diabetes, making angina an unreliable indicator of myocardial ischaemia. Congestive cardiac failure is more common following myocardial infarction in patients with diabetes than those without the condition.

**2.29** Modifiable pathogenetic factors in Type 2 diabetes include hyperglycaemia, dyslipidaemia, hypertension and hypercoagulability, but other factors such as smoking and ethnic group can also be significant. In people with Type 1 diabetes premature vessel disease is often associated with diabetic renal disease, when a similar spectrum of pathogenetic factors are often present.

- 2.30** Renal impairment may be caused by small vessel disease and made worse by hypertension. Detection and treatment of renal disease, reduction of blood pressure and dietary measures are effective at reducing the impact of renal disease. Effective services are available for the treatment of people with renal failure, a large proportion of whom have diabetes.
- 2.31** Peripheral vascular disease may be severe causing poor blood supply to the feet and legs and a higher incidence of stroke. Impaired blood supply to the legs makes ulcers and infections particularly problematic and may require amputation as the only form of treatment in some cases.
- 2.32** To **reduce the impact** of the condition, people with diabetes should be helped to manage the condition themselves as far as possible by improving patient education and information provision, knowledge of services, professional support and participation in social networks. Self management may also have an impact on the physical progression of the disease and its complications.
- 2.33** Whilst medical care may be aimed at reducing the risk and impact of complications, people with diabetes may nonetheless be left with profound impairments. At the severe end of the spectrum a patient may be blind or have suffered a stroke or be without the use of a limb or suffer some other major complication. These physical impairments may result in disability and handicap and also impact on a person's social functioning and emotional well-being.
- 2.34** Carers, usually the unpaid family and friends, often share much of the burden of living with diabetes. They cope with the administration of insulin therapy and self monitoring, share the continuing sufferings of painful neuropathy and angina and adopt nursing roles for those on dialysis or after a stroke.

### 3. CHOICE OF CANDIDATE INDICATORS

**3.1** In choosing candidate indicators the Group took into account work from:

- Audit Working Group of the British Diabetic Association and Royal College of Physicians funded on a grant from the Department of Health to the Royal College of Physicians.
- DiabCare Initiative of the World Health Organisation/International Diabetes Federation (Europe) St Vincent Declaration Initiative.
- CASPE/Freeman Hospital Outcome Project.
- Diabetes Information Management and Audit Group of the British Diabetic Association.
- Diabetes Optimisation through Information Technology (DOIT) Study Group of the European Association for the Study of Diabetes.

**3.2** To ensure that all potentially useful aspects of outcomes were considered the matrix in Exhibit 2 was drawn up using the following dimensions:

- aim of interventions (see paragraph 2.17)
- perspectives of measurement (see paragraph C.6).

**EXHIBIT 2 : MATRIX FOR DIABETES OUTCOME INDICATORS**

| <b>Aim of health intervention</b>                                 | <b>Primary Population</b>        | <b>measurement Clinical</b>   | <b>perspective Patient</b> |
|---|----------------------------------|-------------------------------|----------------------------|
| <b>Reduce or avoid risk of diabetes and appropriate detection</b> | <b>1, 2, 3A, 3B, 3C</b>          |                               |                            |
| <b>Reduce risk of complications:</b>                              |                                  |                               |                            |
| <i>Risk factors</i>   |                                  | <b>4, 5, 6, 7</b>             |                            |
| <i>Metabolic control</i>  |                                  |                               |                            |
| <i>Markers for late complications</i>                             |                                  | <b>8, 9, 10, 11, 12</b>       |                            |
| <i>Symptoms</i>   |                                  | <b>13,14</b>                  |                            |
| <b>Reduce impact of diabetes:</b>                                 |                                  |                               |                            |
| <i>Incidence of acute complications</i>                           | <b>15, 16, 17, 18A, 18B, 18C</b> |                               |                            |
| <i>Incidence of late complications</i>                            |                                  | <b>19, 20, 21, 22, 23, 24</b> |                            |
| <i>Complications of pregnancy</i>                                 |                                  | <b>25, 26, 27, 28, 29</b>     |                            |
| <i>Impact on quality of life</i>                                  |                                  |                               | <b>30, 31, 32</b>          |

**3.3** For each part of the matrix consideration was given to possible indicators. The following paragraphs describe which indicators were chosen, grouped together by the aim of the health intervention. The numbers in the text relate to Exhibit 2 and to the indicator specifications in Section 4.

**3.4** With respect to **reducing the risk of diabetes development and detecting the condition early** the following indicators were chosen:

- 1:** prevalence of clinically diagnosed diabetes
- 2:** percentage prevalence of retinopathy and maculopathy at the time of diagnosis of diabetes.

It was agreed that no indicators related to screening the general population for diabetes should be specified.

**3.5** Information about diabetes risk factors are already being collected in national and other surveys and this includes:

- 3A:** prevalence of obesity in persons aged 16-64 (defined as BMI > 30 kg/m<sup>2</sup>)
- 3B:** proportion of people undertaking rigorous physical activity in the previous 28 days
- 3C:** proportion of people who, on average consume fruit or vegetables or salad each day, within the general population.

**3.6** With respect to the **reduction of the risk of complications** candidate indicators have been classified as related to:

- risk factors associated with the development of complications
- metabolic control
- markers for late complications
- symptoms.

**3.7** Three candidate indicators were specified with respect to *risk factors* associated with the development of complications:

- 4:** percentage of patients, aged 16 and over and known to have diabetes, who smoke
- 5:** percentage of patients, aged 16-64 and known to have diabetes, who have a BMI > 30 kg/m<sup>2</sup>
- 6:** percentage of patients known to have diabetes with elevated blood pressure: Type 1 > 140/90 mm Hg; Type 2 > 160/90mm Hg.

**3.8** One candidate indicator related to *metabolic control* was specified:

**7:** percentage of patients known to have diabetes with HbA that was > 7.5% on a DCCT standardised assay, at time of last recording within the previous year.

**3.9** As *markers of late complications*, the following candidate indicators were specified:

**8:** percentage prevalence of retinopathy and maculopathy within a population known to have diabetes

**9:** percentage prevalence of microalbuminuria within a population known to have Type 1 diabetes

**10:** percentage prevalence of protective sensation loss within a population known to have diabetes

**11:** percentage prevalence of absence of both pulses in at least one foot within a population known to have diabetes

**12:** percentage of patients known to have diabetes where there is no record of blood pressure, the retinae or the feet having been assessed within the previous year.

**3.10** Two candidate indicators were specified which were related to the onset of *symptoms associated with late complications*:

**13:** percentage prevalence of symptomatic angina within a population known to have diabetes

**14:** percentage prevalence of claudication within a population known to have diabetes.

**3.11** With respect to **reducing the impact of diabetes** candidate indicators have been classified as related to:

- incidence of acute complications
- incidence of late complications
- complications of pregnancy
- impact on quality of life.

**3.12** The candidate indicators associated with the incidence of *acute complications* which have been specified were:

- 15:** number of patients who have had at least one hypoglycaemic emergency, within the last year, that required therapeutic intervention by a health professional, expressed as a proportion of a population of patients known to have diabetes
- 16:** number of patients who have had at least one hyperglycaemic emergency, within the last year, that required hospital admission expressed as a proportion of a population of patients known to have diabetes
- 17:** case fatality rate associated with acute diabetic episodes treated in hospital
- 18A:** SMR for death due to diabetes mellitus
- 18B:** years of life lost per 10,000 resident population by death due to diabetes mellitus
- 18C:** years of life lost by death due to diabetes mellitus.

**3.13** Candidate indicators related to the occurrence of *chronic complications* were specified as follows:

- 19:** annual incidence of severe visual impairment (visual acuity < 6/60 in the better eye) within a population of patients known to have diabetes
- 20:** annual incidence of leg amputation above the ankle within a population of patients known to have diabetes
- 21:** annual incidence of amputation below the ankle within a population of patients known to have diabetes
- 22:** annual incidence of myocardial infarction within a population of patients known to have diabetes
- 23:** annual incidence of stroke within a population of patients known to have diabetes
- 24:** number of patients who have started renal replacement therapy or have had a creatinine level > 500 umol/litre recorded for the first time within the last year, expressed as a proportion of a population of patients known to have diabetes.

**3.14** For women with *pre-existing diabetes who become pregnant*, indicators related to the outcome of pregnancy were specified as follows:

- 25:** rates of late stillbirth and perinatal mortality in deliveries from a population of patients known to have diabetes and who become pregnant
- 26:** the rate of delivery by caesarean section, in deliveries from a population of patients known to have diabetes and who become pregnant

- 27:** the incidence of delivered babies with birthweight greater than the 90th centile (allowing for gestational age) from within a population of patients known to have diabetes and who become pregnant
- 28:** the incidence of occurrence of specific congenital malformations (i.e. neural tube defects, cardiac and renal malformations) in deliveries from a population of patients known to have diabetes and who become pregnant
- 29:** the rate of admission to special care baby units (and nurseries) of babies delivered from a population of patients known to have diabetes and who become pregnant.

**3.15** Apart from the development of complications, diabetes may affect a variety of aspects of a patient's life. Candidate indicators related to the *impact on quality of life* were specified as follows:

- 30:** summary of a measure of psychological well-being within a population of patients known to have diabetes
- 31:** summary of a measure of health status/health related quality of life within a population of patients known to have diabetes
- 32:** summary of a measure of satisfaction with service within a population of patients known to have diabetes.

**3.16** It was decided not to develop indicators associated with male erectile impotence or symptomatic neuropathy. There is an absence of accepted and commonly used definitions of these problems and clinical ascertainment is highly variable.

**3.17** It was not felt possible to make a recommendation about an indicator with regard to control of blood lipids. Total serum cholesterol and LDL cholesterol appear from statin trials to have the same predictive value in people with diabetes as in any other high risk group, but epidemiological evidence points to low HDL cholesterol and serum triglycerides as being more important. However, the uncertainty and variability that surround measurement of these entities post-prandially currently preclude any definite recommendation as regards their use as indicators.

**3.18** Although it was recognised that carers may have an important role to play in the care of people with diabetes, no candidate indicators were chosen. However, the Group reviewing outcome indicators for stroke has developed indicators with a carer perspective and these may be appropriate for carers of patients with other disorders (Working Group on Outcome Indicators for Stroke 1997).



## 4. CANDIDATE INDICATOR SPECIFICATIONS

- 4.1** This section contains the detailed specifications of the candidate indicators chosen by the Group. To facilitate ease of reference indicators derived from broadly similar data have been grouped together.
- 4.2** Guidance notes which explain the attributes used in the specifications are included in Appendix D.
- 4.3** The detailed work on the specifications was carried out by James Coles and Robert Cleary of CASPE Research.
- 4.4** People with Type 1 (insulin dependent) and Type 2 (non-insulin dependent) diabetes have a different clinical course. Data from these two groups should never be analysed together as the proportions within the group will effect the calculated results. Each indicator should be calculated and reported separately for Type 1 and Type 2 diabetes.
- 4.5** In general, clinicians do not follow a single standard in defining people as having either Type 1 or Type 2 diabetes, resulting in non-comparability between samples. Accordingly both UK national and international recommendations are that an epidemiological definition be used, albeit with the recognition that this might result in the misclassification of a small number of people with diabetes in either direction. This definition specifies that those diagnosed before age 35 and requiring insulin treatment be allocated to Type 1 diabetes, while those diagnosed aged 35 or later and requiring any form of treatment (dietary, with tablets, or with insulin) are classed as having Type 2 diabetes. The Group recognises that the chance of misclassification is higher in populations with a higher prevalence of diabetes, particularly in some ethnic groups, where Type 2 diabetes may be quite commonly diagnosed before the age of 35 years.

## Candidate indicator 1

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Prevalence of clinically diagnosed diabetes</b>  |
| <b>Intervention aim</b>     | Reduce or avoid risk of diabetes and encourage appropriate detection of diabetes.   |
| <b>Definition</b>           | For a given population, and by sex and age band: <i>the proportion of patients who have been clinically diagnosed as having diabetes</i> . In addition to the proportion, the numerator and denominator should also be reported, and the indicator should be calculated locally for different ethnic groups.  |
| <b>Rationale</b>            | <p>Estimates of the age adjusted prevalence of clinically diagnosed diabetes in England range between 1.5% and 2.0%, although the elderly and people of Asian and Afro-Caribbean origin have considerably higher prevalences. It is also considered that, at any point in time, up to 50% of patients with diabetes may remain undiagnosed. Diabetes can lead to both major acute and chronic complications and planned programmes of care seek to reduce or delay the onset of such complications.</p> <p>Monitoring the prevalence will provide background information as to the burden of this illness within the population and can provide an indication of under-diagnosis overall or in particular sub-groups.</p>   |
| <b>Potential uses</b>       | Monitoring national trends over time. Clinical audit. Provide comparisons at a health authority level.  |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers, policy makers.   |
| <b>Possible confounders</b> | <p>The indicator seeks to identify the prevalence of clinically diagnosed diabetes, and is therefore influenced by the actual prevalence within a population and the level of its clinical diagnosis. In turn, actual prevalence will be affected by the level of social deprivation in the population concerned. The interpretation of the indicator would benefit from knowledge about the separate contribution of each of these factors.</p> <p>Comparisons between general practices may be affected by the frequency with which patients visit their general practitioner. This is determined by a number of variables, other than an episode of illness, such as access, appointment times and availability, transport, and the doctor-patient relationships. Deprivation and social status also affect consultation rates.</p> <p>The rationale of the indicator identifies the need to look separately at different ethnic groups, since prevalence across groups is known to vary widely (McColl and Gulliford 1993).</p> <p>Practice in the enumeration and inappropriate inclusion of patients with impaired glucose tolerance within a diagnosis of diabetes (and within the Chronic Disease Management Programme) varies and may act as a further confounder.</p> |

|                                  |   |
|----------------------------------|---|
| <b>Data sources</b>              | The Chronic Disease Management Programme (Dawson 1996) requires that a register of patients suffering from diabetes should be kept and that annually a report covering the number of Tgm I and II diabetes patients should be reported. Although the programme does not stipulate that the register should be electronically stored, many practices are moving in this direction and data collation would be made easier. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11). Comparable Read codes are IDDM - X40J4, NIDDM - X40J5. The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. Prevalence, although imperfectly defined by number on the register, would be straightforward to collect and to compare to practice size. |
| <b>Data quality</b>              | GPs with an active Chronic Disease Management Programme could be expected to produce data of an acceptable quality, although the threshold at which diabetes is 'clinically diagnosed' might vary somewhat. Where GPs are not participating in such a programme (it has been estimated that 93% of GPs are participating), it might be expected that the quality of these data would be lower. The validity of aggregations above GP practice and/or comparisons would depend therefore on the consistency of recording and coding.   |
| <b>Comments</b>                  | No specific points.   |
| <b>Further work required</b>     | More work is probably needed to examine the confounding factors identified, in order to interpret the indicator better.   |
| <b>Conclusion &amp; priority</b> | <b>A - To be implemented generally on a routine basis.</b>  |
| <b>References</b>                | <p>Dawson, A. (1996). <i>Chronic disease management registers: proceedings of a workshop</i>. HMSO, London.</p> <p>McColl, A. J., and Gulliford, M. C. (1993). <i>Population health outcome indicators for the NHS : a feasibility study for the Department of Health</i>. Faculty of Public Health Medicine of the Royal College of Physicians, London.</p>  |

## Candidate indicator 2

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Percentage prevalence of retinopathy and maculopathy at the time of diagnosis of diabetes</b>   |
| <b>Intervention aim</b>     | Reduce or avoid risk of diabetes and encourage appropriate detection of diabetes.  |
| <b>Definition</b>           | For a given population, and by sex and age band: <i>the proportion of patients who, at the time diabetes is clinically diagnosed, are examined for retinopathy (and separately for maculopathy) and in whom it is found to be present.</i> The indicator implies collation at a given point in time, probably annually, and that separate figures are obtained for the rate of examination for retinopathy/maculopathy and for their prevalence. In each case, numerator and denominator figures should be reported with the overall proportion.   |
| <b>Rationale</b>            | Retinopathy and maculopathy are known to be markers for adverse visual outcomes of diabetes and, within a diabetic population, have prevalences of about 8% and 3% (Houston 1982; Neil et al. 1989). Early detection will facilitate early treatment and reduce their impact by up to 70-80%. Higher prevalences of retinopathy and maculopathy at the time of diagnosis of diabetes should indicate delayed diagnosis. The indicator recognises that detection requires both screening of appropriate patients and the identification of the condition(s).  |
| <b>Potential uses</b>       | Clinical audit. Trends over time. Provide comparisons at a health authority level.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.   |
| <b>Possible confounders</b> | As mentioned in the definition, the indicator implies that at the time of diagnosis, a routine examination for retinopathy and maculopathy is made. If this does not occur, the prevalence of these two conditions will be understated.  |
| <b>Data sources</b>         | This indicator requires a diagnosis of diabetes to be made, and the presence (or otherwise) of retinopathy (ICD9 code: 250.4, with 362; ICD10 codes: E10.3 to E14.3, with H36.0; Read code: F4200 - Background diabetic retinopathy, F4201 - Proliferative diabetic retinopathy, F4202 - Preproliferative diabetic retinopathy) to be recorded at that time. Maculopathy can be coded in Read codes by X00dG or by F4203 (Advanced diabetic maculopathy). The indicator can also be derived from the UK Diabetes Dataset (Vaughan & Home 1995) and from the DIABCARE Dataset (Piwernetz et al. 1995). The particular fields required are BACKGND, PREPRO, PROLIF, MACULA and ADV-RET each with a suffix of -R or -L to identify the particular eye (UKDD) and r_path, r_nonpro, r_prepro, r_prolif and r_adv_di again with _l and _r suffices (DIABCARE). The denominator is defined by patients diagnosed with diabetes and the prevalence figure includes patients diagnosed in earlier years. |

|                                  |  |
|----------------------------------|--|
| <b>Data quality</b>              | GPs with an active Chronic Disease Management Programme could be expected to produce data of an acceptable quality although, as with Indicator 1, the threshold at which diabetes is 'clinically diagnosed' might vary somewhat. Where GPs are not participating in such a programme (it has been estimated that 93% of GPs are participating), it might be expected that the quality of these data would be lower. A similar comment might be made about the examination for, and identification of diabetic retinopathy and maculopathy. The validity of aggregations above GP practice and/or comparisons would depend therefore on the consistency of recording and coding.  |
| <b>Comments</b>                  | Prevalence figures smooth the data over time and therefore may lack sensitivity to change. In this respect, incidence figures may be preferable but they also have problems related to identification, collection and interpretation.  |
| <b>Further work required</b>     | A continuing need for the standardisation of recording of eye examination findings according to published standards.   |
| <b>Conclusion &amp; priority</b> | <b>E - To be implemented following IT development on a routine basis</b>   |
| <b>References</b>                | <p>Houston, A. (1982). Retinopathy in the Poole area: an epidemiological inquiry. In <i>Advances in diabetes epidemiology</i> (ed. E Eschwege). Elsevier Biomedical Press.</p> <p>Neil, H. A. W., Thomson, A. V., Thorogood, M., Fowler, G. H., and Mann, J. I. (1989). Diabetes in the elderly: the Oxford community diabetes study. <i>Diabetic Medicine</i>, <b>6</b>, 608-613.</p> <p>Piwernetz, K., Bruckmeier, A., Home, P. D., Kleinbreil, L., van Combrugge, P., Sando, S.H., Brundobler, M., Azzopardi, J., Massi Benedetti, M., Tamas, G., and Kerenyi, S. (1995). Diabetes Data Set: a key element of the DIABCARE quality network. In <i>The St Vincent Declaration Newsletter, Supplement 1</i>. World Health Organisation, Copenhagen.</p> <p>Vaughan, N. J. A., and Home, P. D. for the Diabetes Audit Working Group of the Research Unit of the Royal College of Physicians and the British Diabetic Association (1995). The UK Diabetes Dataset: a standard for information exchange. <i>Diabetic Medicine</i>, <b>12</b>, 717-722.</p> |

## Candidate indicator 3

### Characteristics

*Specificity:* Generic

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Indirect

### Title

**Life style risk factors:**

- 3A. prevalence of obesity in persons aged 16-64 (defined as BMI > 30 kg/m<sup>2</sup>)**
- 3B. proportion of people undertaking rigorous physical activity in the previous 28 days**
- 3C. proportion of people who, on average, consume fruit or vegetables or salad each day, within the general population**

### Intervention aim

Reduce or avoid risk of diabetes and encourage appropriate detection of diabetes.

### Definition

For a given population, identified separately by sex, age band and time period:

- A. *Indicator HON A7 from the Public Health Common Data Set - proportion of persons aged 16 - 64 defined to be obese, having a body mass index (weight (kg) / height (m<sup>2</sup>) greater than 30*
- B. *proportion of people aged 16-64 who had undertaken moderate or vigorous physical activity on four or more occasions within the previous twenty eight days.*
- C. *proportion of people aged 16-64 who report eating fruit, or vegetables or salad at least once a day, on average.*

Indicator definitions B and C are as used in the periodic Health Survey for England.

Information could be collected at the time of an annual review, and reported by the following age bands:

- i) Aged 16-64
- ii) Aged 16-24 and by ten year age bands to 64
- iii) Aged 16-44 and 45-64.

### Rationale

- A. The obesity indicator is a Health of the Nation indicator (Institute of Public Health 1995) used to monitor the nation's movement to targets associated with coronary heart disease and stroke. Diabetes can increase the likelihood of coronary heart disease, but obesity is also a risk factor for diabetes itself.
- B. Vigorous physical activity will reduce the likelihood of obesity, contributes to maintaining a healthy circulation and reduces the incidence of diabetes.
- C. A healthy diet, including frequent eating of fruit and vegetables, is also likely to maintain body systems. The indicator, as defined, refers separately to fruit and vegetables or salad and, to some extent, is constrained by the wording of the current survey question.

Monitoring these risk factors should reduce the incidence of diabetes in the long term and can help in the evaluation of educational and health promotion programmes.

|                                  |   |
|----------------------------------|---|
| <b>Potential uses</b>            | Monitoring impact of preventive measures. Trends over time. HA and other population based comparisons.  |
| <b>Potential users</b>           | Local and national policy makers, commissioners, clinicians, the public.  |
| <b>Possible confounders</b>      | Indicator B requires consistent definition and interpretation of terms such as ‘moderate’ and ‘vigorous physical activity’. Interpretation of results could be inhibited should other clinical conditions indicate conflicting activity or dietary requirements.  |
| <b>Data sources</b>              | Data to be collected at least annually, at a review of the patient’s health, through measurement and the application of questions as used in the Health Survey for England, 1994 (Questions 73-80 re: exercise; 91 re: eating of fruit, vegetables etc.) (Colhoun and Prescott-Clarke 1996). Denominator data to be obtained from mid-year population estimates at HA or similar level. Read codes permit the recording of BMI against code 22K.. , or can be calculated from body weight (X76C7) and body height (X76Bs). Indicator A can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are ‘BMI’ (UKDD) and ‘weight’ and ‘height’ (DIABCARE). Indicator B can be obtained from Read codes (138J. through to 138N.) which refer to FITT activity levels in excess of one occasion of ‘moderate/vigorous activity’ in previous four week period. |
| <b>Data quality</b>              | Data are obtained through self-reporting, which might cause concern about data quality, although some clinical validation is possible. The Health Survey has found data quality acceptable at the macro-level. The validity of aggregation to HA level or above requires a consistency of recording and coding across practices.  |
| <b>Comments</b>                  | No specific points.   |
| <b>Further work required</b>     | Population studies in respect of indicators B and C to determine their relationship with the incidence of diabetes.   |
| <b>Conclusion &amp; priority</b> | <b>3A: B - To be implemented generally by periodic survey.</b><br><b>3B &amp; C: F - To be further developed because link with effectiveness is not clear.</b>  |
| <b>References</b>                | Colhoun, H., and Prescott-Clarke, P. (1996). <i>Health Survey for England 1994</i> . Joint Health Surveys Unit, SCPR and Dept of Epidemiology and Public Health, University College, London.<br><br>Institute of Public Health (1995). <i>Public Health Common Data Set</i> . University of Surrey.   |

## Candidate indicator 4

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Percentage of patients, aged 16 and over and known to have diabetes, who smoke</b>   |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Risk factors</i> .  |
| <b>Definition</b>           | For a given population and year: <i>the number of patients aged 16 years and over and previously diagnosed with diabetes mellitus, who report currently smoking cigarettes, cigars or pipe divided by the number of patients, in the same age range, previously diagnosed with diabetes mellitus</i> . The resulting fraction should be expressed as a percentage and reported together with its denominator, by patient age-group and sex.   |
| <b>Rationale</b>            | <p>Cessation of cigarette smoking in people with diabetes is an important contributory factor in the prevention of long term complications e.g. peripheral vascular disease and cardiovascular disease. People with diabetes are much more susceptible to such vascular problems, which are exacerbated by smoking.</p> <p>Monitoring and addressing such risk factors should reduce the incidence of complications in the long term and can help in the evaluation of educational and health promotion programmes.</p>   |
| <b>Potential uses</b>       | Monitoring impact of preventive measures. Trends over time. HA and other population based comparisons.  |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | Self-reporting of smoking habits is unreliable. However, unless known biases exist, unreliable responses are likely to occur at random through the population. Biochemical measurements could be used to validate patient responses, but these are likely to be considered too intrusive.   |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Data on smoking should be collected at least annually, on reviewing the patient's health, through the application of questions as used in the Health Survey for England 1994 (Questions 93b for aged 18+; and self completion booklet for 16 and 17 year olds) (Colhoun & Prescott-Clarke 1996). The Read coding system codes 'Current smoker' as Va28x. The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'SMOKING' (UKDD) and 'nicot_yn' (DIABCARE). |

|                                  |   |
|----------------------------------|---|
| <b>Data quality</b>              | As mentioned above self-reporting of smoking habits can vary in its reliability. The correct interpretation of trends and/or comparative data will depend on the validity of the assumption that the degree of reliability is consistent. |
| <b>Comments</b>                  | No specific points.   |
| <b>Further work required</b>     | Validation of changes in self reporting bias in people within the general population.   |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b><br>(compiling the indicator annually).  |
| <b>References</b>                | Colhoun, H., and Prescott-Clarke, P. (1996). <i>Health Survey for England 1994</i> . Joint Health Surveys Unit, SCPR and Dept of Epidemiology and Public Health, University College, London.  |

## Candidate indicator 5

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Percentage of patients, aged 16-64 and known to have diabetes, who have a BMI &gt; 30 kg/m<sup>2</sup></b>  |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Risk factors</i> .   |
| <b>Definition</b>           | For a given population and year: <i>the number of patients, aged 16 - 64 and previously diagnosed with diabetes mellitus, who are defined to be obese, having a body mass index (weight (kg) / height (m<sup>2</sup>) greater than 30 divided by the number of patients in the same age range previously diagnosed with diabetes mellitus</i> . The resulting fraction should be expressed as a percentage and reported together with its denominator, by patient age-group and sex.   |
| <b>Rationale</b>            | <p>The obesity indicator is a Health of the Nation indicator (Institute of Public Health 1995) used to monitor the nation's movement to targets associated with coronary heart disease and stroke. Diabetes can increase the likelihood of coronary heart disease, but obesity is also a risk factor for diabetes itself and is an important marker of future problems in diabetic care.</p> <p>Monitoring and addressing such risk factors should reduce the incidence of diabetes in the long term and can help in the evaluation of educational and health promotion programmes.</p>  |
| <b>Potential uses</b>       | Monitoring impact of preventive measures. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.   |
| <b>Possible confounders</b> | Existing co-morbidities may affect the interpretation of the indicator, although obesity, however caused, is an important marker of future problems in diabetic care.  |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Data concerning obesity should be collected at least annually, at a review of the patient's health, through measurement as made in the Health Survey for England 1994 (Colhoun & Prescott-Clarke 1996). Read codes BMI as 22K.. which is accompanied by the recording of the specific value. Alternatively it can be derived from codes X76Bs (height) and X76C7 (weight). The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'BMI' (UKDD) and 'weight' and 'height' (DIABCARE). |

|                                  |   |
|----------------------------------|---|
| <b>Data quality</b>              | <p>Quality will be dependent on the completeness of the annual review process within an individual practice i.e. identification of patients with diabetes, and appropriate monitoring systems.</p> <p>The validity of aggregations above GP practice and/or comparisons would depend on the consistency of recording.</p> |
| <b>Comments</b>                  | <p>No specific points.</p>  |
| <b>Further work required</b>     | <p>None recommended.</p>  |
| <b>Conclusion &amp; priority</b> | <p><b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).</p>  |
| <b>References</b>                | <p>Colhoun, H., and Prescott-Clarke, P. (1996). <i>Health Survey for England 1994</i>. Joint Health Surveys Unit, SCPR and Dept of Epidemiology and Public Health, University College, London.</p> <p>Institute of Public Health (1995). <i>Public Health Common Data Set</i>. University of Surrey.</p>                  |

## Candidate indicator 6

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Percentage of patients known to have diabetes with elevated blood pressure: Type 1 &gt; 140/90 mm Hg.; Type 2 &gt; 160/90 mm Hg</b>   |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Risk factors.</i>  |
| <b>Definition</b>           | <p>For a given population and year: <i>the number of patients previously diagnosed with diabetes mellitus, whose resting, sitting blood pressure was found to be elevated ( as defined by being greater than 140/90 mm Hg. for Type 1 diabetes and greater than 160/90 mm Hg. for Type 2 diabetes and independent of whether they are being treated by anti-hypertensive therapy), divided by the number of patients previously diagnosed with the particular Type of diabetes.</i> The resulting fractions should be expressed as percentages and reported separately, each with its denominator, and by patient age-group and sex. While assessment of prevalence of hypertension in the population should be measured independently whether people are treated or not, recording of the percentage treated with therapy in addition is helpful to the interpretation of the data.</p> |
| <b>Rationale</b>            | <p>Long-term blood pressure control in hypertensive patients with Type 2 diabetes results in a significant reduction in all diabetes related endpoints (UK Prospective Diabetes Study Group 1998a).</p> <p>Monitoring and addressing blood pressure should reduce the incidence of complications in the long term and can help in the evaluation of educational and health promotion programmes.</p>   |
| <b>Potential uses</b>       | Monitoring impact of preventive measures. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.   |
| <b>Possible confounders</b> | <p>Existing co-morbidities may affect the interpretation of the indicator, although an elevated blood pressure, however caused, is an important marker of future problems in diabetic care.</p> <p>Consistent measurement of blood pressure can also present problems. Care should be taken to check the calibration of the instrument periodically. Blood pressure, like other physical and biochemical measures can be influenced by co-morbidities, or by short-term factors operating at the time of measurement. Interpretation of results requires the significance of such factors to be assessed alongside the progress of the underlying condition.</p>   |

|                                  |   |
|----------------------------------|---|
| <b>Data sources</b>              | <p>The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Data concerning blood pressure should be collected at least annually, at a review of the patient's health, using the same instrument and ensuring appropriate calibration. The Read code for systolic blood pressure is XM02X and for diastolic blood pressure is XM02Y, each with the recording of the numeric finding. The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'SBP' and 'DBP' (UKDD) and 'bp_sys' and 'bp_dia' (DIABCARE).</p> |
| <b>Data quality</b>              | <p>Quality will be dependent on the completeness of the annual review process within an individual practice i.e. identification of patients with diabetes, and appropriate monitoring systems.</p> <p>The validity of aggregations above GP practice and/or comparisons would depend on the consistency of recording.</p>   |
| <b>Comments</b>                  | <p>A reduced blood pressure in some groups may be contraindicated and this may affect the interpretation of this indicator.</p>   |
| <b>Further work required</b>     | <p>Understanding of the comparability of data collected in different health care settings, by different people, and using different procedures.</p>   |
| <b>Conclusion &amp; priority</b> | <p><b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).</p>  |
| <b>References</b>                | <p>UK Prospective Diabetes Study Group (1998a). Tight blood pressure control and risk of macrovascular and microvascular complications in Type 2 diabetes: UKPDS 38. <i>British Medical Journal</i>, <b>317</b>, 703-713.</p>   |

## Candidate indicator 7

### Characteristics

*Specificity:* Condition-specific  
*Perspective:* Clinical  
*Timeframe:* Cross-sectional  
*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Percentage of patients known to have diabetes with HbA that was &gt; 7.5% on a DCCT standardised assay, at time of last recording within the previous year</b>   |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Metabolic control.</i>  |
| <b>Definition</b>           | <p>For a given population and year: <i>the number of patients previously diagnosed with diabetes mellitus, whose HbA was, at time of last recording within the previous year, either greater than</i></p> <ul style="list-style-type: none"><li><i>i) 7.5% on a DCCT standardised assay, or (if standardised assay not available)</i></li><li><i>ii) five S.D. above the local laboratory mean for the normal population, divided by the number of patients previously diagnosed with diabetes mellitus.</i></li></ul> <p>The resulting fraction should be expressed as a percentage and reported together with its denominator, by patient age-group and sex.</p>  |
| <b>Rationale</b>            | <p>Improved glucose control reduces the incidence of microvascular complications in Type 2 diabetes in the long term (UK Prospective Diabetes Study Group 1998b) and can help in the evaluation of educational and health promotion programmes.</p> <p>Better control of blood glucose levels has been shown to lessen exposure to hyperglycaemia and the risk of ketoacidosis. Admission rate for diabetics with ketoacidotic coma (ICD9 250.2) varied, in a six year period, between 26 and 44 per million inhabitants per year, and for hypoglycaemic coma (ICD9 251.0) from 11 to 66 (Williams 1989). The rate of progression of retinopathy in patients receiving intensive therapy has been shown to be less than 2 per 100 patient-years when mean glycosylated haemoglobin is maintained below 7.5% (The Diabetes Control and Complications Trial Research Group 1993).</p> |
| <b>Potential uses</b>       | Monitoring impact of preventive measures. Trends over time. HA and other population based comparisons.  |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | It should be noted that the five SD alternative is less reliable because estimates of the normal population distribution depend on the precision (variability) of the assay as well as the actual distribution. As a result, low precision assays will have a wider normal distribution and underestimate people with poor blood glucose control. Additionally, because the distribution of HbA in the population is highly skewed, this effect is magnified. HbA, like other physical and biochemical measures can be influenced by comorbidities, or by short-term factors operating at the time of measurement. Interpretation of results requires the significance of such factors to be assessed alongside the progress of the underlying condition.   |

|                                  |  |
|----------------------------------|--|
| <b>Data sources</b>              | The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Data concerning blood glucose levels should be collected when patients are reviewed, on an annual basis, and require high quality measurement and assay control. The indicator also allows for data to be collected opportunistically at other times throughout the year. The Read code for measurement of HbA is X772q and is accompanied by the numerical finding. The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'GHB' (UKDD) and 'hba1c' (DIABCARE). |
| <b>Data quality</b>              | Quality will be dependent on the completeness of the annual review process within an individual practice. As described in the 'Possible confounders' section, the measure assumes the validity and accuracy of the normal ranges used. This is important at individual practice level but its importance is increased at aggregations above GP practice where collation or comparisons requires consistency of recording and analysis.   |
| <b>Comments</b>                  | No specific points.  |
| <b>Further work required</b>     | Continuing efforts to standardise HbA assays are needed in accordance with WHO policy.   |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).  |
| <b>References</b>                | <p>Diabetes Control and Complications Trial Research Group (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. <i>New England Journal of Medicine</i>, <b>329</b>, 977-986.</p> <p>UK Prospective Diabetes Study Group (1998b). Intensive blood sugar control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with Type 2 diabetes: UKPDS 33. <i>Lancet</i>, <b>352</b>, 837-853.</p> <p>Williams, D. R. R. (1989). Outcome indicators for diabetes services: what do we have and what do we need? <i>Community Medicine</i>, <b>11</b>, 57-64.</p>  |

## Candidate indicator 8

### Characteristics

*Specificity:* Condition-specific  
*Perspective:* Clinical  
*Timeframe:* Cross-sectional  
*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Percentage prevalence of retinopathy and maculopathy within a population known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Markers of late complications.</i>  |
| <b>Definition</b>           | For a given population, and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, at the time of compilation, are known to have retinopathy (or maculopathy), divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The condition of the worst eye should be considered and the resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group, sex and where possible, by severity level of the retinopathy.  |
| <b>Rationale</b>            | <p>Diabetic retinopathy is the single, most common cause of visual disability and blindness in the middle years of life in most industrialised nations (Kohner et al. 1982) and is preventable by good metabolic control. Prevalence of visual acuity &lt; 6/60 has been estimated at 2% within the diabetic population. ‘Complex’ retinopathy (retinal neovascularisation, fibrosis retinitis proliferous, more than two cotton wool spots plus more than two large haemorrhages in either eye) is thought to have a prevalence of about 8% amongst patients with diabetes, while maculopathy’s prevalence in this group is about 3% (Williams 1994).</p> <p>Early detection and effective photocoagulation reduces the risk of blindness by 70 - 80% (Cheng et al. 1975; Diabetic Retinopathy Study Research Group 1981).</p> |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | As with other prevalence measures, this indicator can be confounded by a lack of an effective surveillance programme for the condition and /or failure to recognise the condition in the patient. With the introduction of severity, there will be an increased likelihood of disagreement on coding at the boundaries between levels.  |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Diabetic retinopathy is coded by 362 with 250.4 diabetes with ophthalmic manifestations (ICD9); H36.0A with E10.3 to E14.3 diabetes with ophthalmic complications (ICD10) and by F420. (Read) and data should be collected at least annually, at a review of the patient’s health. Only Read codes different severity levels - (F4202) pre-proliferative retinopathy and (F4201) proliferative retinopathy. The indicator can also be derived   |

from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are EYESTATUS (which provides a summary of the status of the retina) or detailed fields such as BACKGND, PREPRO, PROLIF, MACULA and ADV-RET each with a suffix of -R or -L to identify the particular eye (UKDD) and r\_path, r\_nonpro, r\_prepro, r\_prolif and r\_adv\_di again with \_l and \_r suffices (DIABCARE).

|                                  |   |
|----------------------------------|---|
| <b>Data quality</b>              | Quality will be dependent on the completeness of the annual review process within an individual practice i.e. identification of patients with diabetes and with retinopathy, and the appropriateness of monitoring and recording systems. As indicated above, recording severity requires the use of the Read codes and it might be expected that data quality will increase where computerised patient record systems, that capture such data easily, are in use.  |
| <b>Comments</b>                  | Prevalence figures smooth the data over time and therefore may lack sensitivity to change. In this respect, incidence figures may be preferable but they also have problems related to identification, collection and interpretation.   |
| <b>Further work required</b>     | None recommended.   |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).   |
| <b>References</b>                | <p>Cheng, H., Kohner, E. M., Keen, H., Blach, R. H., and Hill, D. W. (1975). Photocoagulation in the treatment of diabetic maculopathy. <i>Lancet</i>, <b>306</b>, 1110-1111.</p> <p>Diabetic Retinopathy Study Research Group (1981). Photocoagulation treatment of proliferative retinopathy: clinical application. <i>Ophthalmology</i>, <b>88</b>, 583.</p> <p>Kohner, E. M., McLeod, D., and Marshall, J. (1982). Diabetes and the eye. In <i>Complications of diabetes</i> (ed. H. Keen and J. Jarrett). Edward Arnold, London.</p> <p>Williams, R. (1994). Diabetes mellitus. In <i>Health care needs assessment</i> (ed. A. Stevens and J. Raftery). Radcliffe Medical Press, Oxford.</p> |

## Candidate indicator 9

### Characteristics

*Specificity:* Condition-specific  
*Perspective:* Clinical  
*Timeframe:* Cross-sectional  
*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Percentage prevalence of microalbuminuria within a population known to have Type 1 diabetes</b>  |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Markers of late complications.</i>  |
| <b>Definition</b>           | For a given population, and year: <i>the number of patients previously diagnosed with Type 1 diabetes mellitus and who, at the year end, are known to have microalbuminuria (albumin excretion level &gt;20 (µg/min. in a resting overnight sample), divided by the number of patients previously diagnosed with Type 1 diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.   |
| <b>Rationale</b>            | <p>Microalbuminuria is thought to be an early sign of possible renal failure. Urinary albumin losses in non-diabetic individuals are small but are greater in the majority of diabetic patients and can rise markedly after exercise. After only a few years of diabetes, albumin excretion in a resting overnight sample can rise to over 20 (µg/min, and it is these patients who may be at risk of developing frank albuminuria and eventual renal failure (Tunbridge and Home 1991).</p> <p>Initial screening for microalbuminuria is most easily performed on an early morning sample where an albumin: creatinine ratio of &gt; 2.5 mg/mmol in men and &gt; 3.5 mg/mmol in women would suggest the need for overnight monitoring (Viberti et al. 1996). Such screening should be performed annually for patients with Type 1 diabetes mellitus.</p> |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | As with other prevalence measures, this indicator can be confounded by a lack of effort in screening for the condition and/or failure to recognise the condition in the patient. This indicator can also be confounded by the misclassification of people with Type 2 diabetes as Type 1, because of the high prevalence of microalbuminuria in the Type 2 diabetic population, and the problem that screening methods are often based on albumin concentrations or albumin:creatinine ratios rather than the albumin excretion rate.   |

|                                  |  |
|----------------------------------|--|
| <b>Data sources</b>              | The denominator is defined by patients already diagnosed with Type 1 (primarily insulin dependent, but see detailed definition in Section 2) diabetes who should be monitored annually. Insulin dependent diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 in ICD10 with the comparable Read codes being X40J4. Presence of microalbuminuria is not recorded within ICD9 or 10 which only recognise 'Diabetes with renal manifestations or complications' (250.3 in ICD9), (E10.2 to E14.2 in ICD10). The Read code for microalbumin excretion rate is X773D against which the level should be recorded with data being collected at least annually, at a review of the patient's health. The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'MICROALB' (UKDD) and 'albuminuri' (DIABCARE). |
| <b>Data quality</b>              | Quality will be dependent on the completeness of the annual review process within an individual practice i.e. identification of patients with diabetes and with microalbuminuria, and the appropriateness of monitoring and recording systems. As indicated above, recording of this condition requires the use of the Read codes and it might be expected that data quality will increase where computerised patient record systems, that capture such data easily, are in use.   |
| <b>Comments</b>                  | Prevalence figures smooth the data over time and therefore may lack sensitivity to change. In this respect, incidence figures may be preferable but they also have problems related to identification, collection and interpretation.  |
| <b>Further work required</b>     | None recommended.  |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).  |
| <b>References</b>                | Tunbridge, W. M., and Home, P. D. (1991). <i>Diabetes and endocrinology in clinical practice</i> . Edward Arnold, London.<br><br>Viberti, G-C., Marshall, S., Beech, R., Brown, V., Derben, P., Higson, N., Home, P., Keen, H., Plant, M., and Wallis, J. (1996). Report on renal disease in diabetes. <i>Diabetic Medicine</i> , <b>13</b> , S6-S12.  |

## Candidate indicator 10

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Percentage prevalence of protective sensation loss within a population known to have diabetes</b>   |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Markers of late complications.</i>   |
| <b>Definition</b>           | For a given population, and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, at the year end, are known to have developed loss of protective sensation, in both feet, as defined by the inability to detect a 5.07 nylon monofilament when it is pressed on the foot until it buckles (a linear pressure of 10g), divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.  |
| <b>Rationale</b>            | Distal sensory neuropathy is a major risk factor for foot ulceration in people with diabetes and should be monitored at least annually (Edmonds et al. 1996). The prevalence of diabetic neuropathy increases with age and has been reported to be 5% in the age group 20-29 years, rising to 44.2% in the age group 70-79 (Young et al. 1993). Neuropathy may be detected using pin prick, vibration (using a tuning fork), temperature sense and objective testing of vibration using a biothesiometer. Testing cutaneous sensation with a 5.07 nylon monofilament is thought by many to be the easiest and most discriminating method of detecting loss of protective sensation in the practice setting (McNeely et al. 1995). If the patient does not detect the filament when it is pressed on the foot until it buckles some degree of protective sensation in the foot has been lost (Sosenko et al. 1990). |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.  |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.   |
| <b>Possible confounders</b> | As with other prevalence measures, this indicator can be confounded by a lack of effort in screening for the condition and/or failure to recognise the condition in the patient.   |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Diabetic polyneuropathy is coded 250.5 with 357.2* in ICD9 and E10.4 to E14.4 with G63.2 in ICD10. The Read code for distal sensorimotor polyneuropathy is X00Ah against which the level should be recorded with data being collected at least annually, at a review of the patient's health. Neuropathy can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset although these only identify pin prick and vibratory sensitivity, the particular fields being 'PIN-R', 'PIN-L', 'VIBR-R'   |

and 'VIBR-L' (UKDD) and 'f\_nor\_pi\_r', 'f\_nor\_pi\_l', 'f\_nor\_vi\_r' and 'f\_nor\_vi\_l' (DIABCARE) with each being assessed as normal or abnormal. Cut-off points for people using a biothesiometer or Reidal-Siffert tuning fork would be 25v and Scale 4 respectively.

|                                  |  |
|----------------------------------|--|
| <b>Data quality</b>              | Quality will be dependent on the completeness of the annual review process within an individual practice i.e. identification of patients with diabetes and protective pain sensation loss, and the appropriateness of monitoring and recording systems. The use of the filament in measuring diabetic polyneuropathy is strongly recommended, since the use of other methods is likely to result in a gross underestimate.   |
| <b>Comments</b>                  | Prevalence figures smooth the data over time and therefore may lack sensitivity to change. In this respect, incidence figures may be preferable but they also have problems related to identification, collection and interpretation.  |
| <b>Further work required</b>     | Further standardisation on the use of monofilaments in surveillance for diabetic neuropathy.   |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).  |
| <b>References</b>                | <p>Edmonds, M., Boulton, A., Buckenham, T., Every, N., Foster, A., Freeman, D., Gadsby, R., Gibby, O., Knowles, A., Pooke, M., Tovey, F., Unwin, N., and Wolfe, J. (1996). Report of Diabetic Foot and Amputation Group. <i>Diabetic Medicine</i>, <b>13</b>, S27-S43.</p> <p>McNeely, M. J., Boyko, E. J., Ahroni, J. H., Stensel, V. L., Reiber, G.E., Smith, D. G., and Pecoraro, R. E. (1995). The independent contributions of diabetic neuropathy and vasculopathy in foot ulceration: how great are the risks? <i>Diabetes Care</i>, <b>18</b>, 216-219.</p> <p>Sosenko, J., Kato, M., Soto, R., and Bild, D. E. (1990). Comparison of quantitative sensory threshold measures for their association with foot ulceration in diabetic patients. <i>Diabetes Care</i>, <b>13</b>, 1057-1061.</p> <p>Young, M. J., Boulton, A. J. M., Macleod, A. F., Williams, D. R. R., and Sonksen, P.H. (1993). A multicentre study of the prevalence of diabetic neuropathy in the UK hospital clinic population. <i>Diabetologia</i>, <b>36</b>, 150-154.</p> |

## Candidate indicator 11

| Characteristics                        |
|--|
| <i>Specificity:</i> Condition-specific |
| <i>Perspective:</i> Clinical           |
| <i>Timeframe:</i> Cross-sectional      |
| <i>Outcome relationship:</i> Direct    |

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Percentage prevalence of absence of both foot pulses in at least one foot within a population known to have diabetes</b>   |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Markers of late complications.</i>  |
| <b>Definition</b>           | For a given population, and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, at the year end, are identified as having both foot pulses absent in at least one foot, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex. Additionally, the proportion of known patients, examined within the year, should be reported.  |
| <b>Rationale</b>            | Peripheral vascular disease in the diabetic patient is more diffuse and distal than in non-diabetic individuals (Edmonds et al. 1996). Absent peripheral pulses may indicate that the feet are threatened by ischaemia which can lead to ulcers, necrosis and eventual amputation. Pecoraro et al. (1990) and Stebbings and Wood (1991) have shown that early and effective intervention can reduce the need for major limb amputations.  |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | As with other prevalence measures, this indicator can be confounded by a lack of effort in screening for the condition and/or failure to recognise the condition in the patient.  |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Diabetes with peripheral circulatory disorders is coded 250.6 with 443.8* in ICD9 and E10.5 to E14.5 with I79.2* in ICD10. Within the Read codes, a code exists for absent peripheral pulse - Xa7sp, while more specificity could be gained by recording absence of posterior tibial pulse (Xa7sx with 24E7 for right foot, and 24F7for left foot) and absence of dorsalis pedis pulse (Xa7sy with 24E9 for right foot, and 24F9 for left foot). The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'PULSES-R' and 'PULSES-L' (UKDD) and 'f_p_prs_r' and 'f_p_prs_l' (DIABCARE). Data should be collected at least annually, at a review of the patient's health. |

|                                  |   |
|----------------------------------|---|
| <b>Data quality</b>              | Quality will be dependent on the completeness of the annual review process within an individual practice i.e. identification of patients with diabetes and protective pain sensation loss, and the appropriateness of monitoring and recording systems.   |
| <b>Comments</b>                  | Prevalence figures smooth the data over time and therefore may lack sensitivity to change. In this respect, incidence figures may be preferable but they also have problems related to identification, collection and interpretation.   |
| <b>Further work required</b>     | None recommended.   |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b><br>(compiling the indicator annually).  |
| <b>References</b>                | <p>Edmonds, M., Boulton, A., Buckenham, T., Every, N., Foster, A., Freeman, D., Gadsby, R., Gibby, O., Knowles, A., Pooke, M., Tovey, F., Unwin, N., and Wolfe, J. (1996). Report of Diabetic Foot and Amputation Group. <i>Diabetic Medicine</i>, <b>13</b>, S27-S43.</p> <p>Pecoraro, R. E., Geiber, G. E., and Burgess, E. M. (1990). Pathways to diabetic limb amputation. <i>Diabetes Care</i>, <b>13</b>, 513-521.</p> <p>Stebbing, W. S. L., and Wood, R. F. M. (1991). Amputations in diabetics. <i>Annals of Royal College of Surgeons of England</i>, <b>73</b>, 170-175.</p> |

## Candidate indicator 12

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Indirect

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Percentage of patients known to have diabetes where there is no record of blood pressure, the retinae or the feet having been assessed within the previous year</b>  |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Markers of late complications.</i>  |
| <b>Definition</b>           | <p>For a given population, and year: <i>the number of patients previously diagnosed with diabetes mellitus and whose medical notes, at the year end, contain no record of their:</i></p> <ul style="list-style-type: none"><li><i>i) blood pressure</i></li><li><i>ii) retinae, or</i></li><li><i>iii) feet</i></li></ul> <p><i>being assessed in the previous year, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.</p>  |
| <b>Rationale</b>            | <p>Previous indicators identify the potential benefits, in terms of risk reduction, that might be occasioned by the early detection of high blood pressure, retinopathy and foot problems (including ulceration). Conversely, this indicator identifies the proportion of patients that have been diagnosed with diabetes, yet appear not to have received at least one of the three monitoring checks outlined, recognised as minimum aspects of good practice (British Diabetic Association 1993). As such, it measures the proportion of this population (possibly through migration or through non-attendance) that have not received basic care.</p> |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | This indicator requires the reporting of a departure from recommended good practice and an apparent failure of health services. As such it might be expected that there will be a level of under-reporting. Unlike other measures where unreliable responses are likely to occur at random through the population, under reporting of this indicator is more likely to occur where difficulties have been experienced. Validation of this indicator is likely to be needed to ensure its value.   |

**Data sources**

The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Data on the monitoring of the three features noted should be collected at least annually, at a review of the patient's health.

The appropriate Read codes are as follows:

- measurement of blood pressure: systolic BP reading XM02X  
diastolic BP reading XM02Y (both  
with scope to add numeric finding)
- degree of retinopathy: F4202 and F4201
- examination of the foot: Xa2hv (non-disease specific) or Xa1J5  
(observations on the diabetic foot & laterality attributes).

The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'SBP', 'DBP', 'EYECHECK' and 'CHIROPODY' (UKDD) and 'bp\_sys', 'bp\_dia', 'r\_12' and 'f\_12' (DIABCARE), although results of eye and foot examinations entered in other fields would also imply a review had taken place.

**Data quality**

As mentioned above the reporting of adverse events i.e. omission to carry out checks could be expected to vary in its reliability, therefore it is recommended that the data are collected in terms of where such checks have been recorded and their complement then calculated. The strength of this intermediate outcome measure lies in its expected correlation to future complications. The correct interpretation of trends across time and/or through the use of comparative data depends on the reliability of the measure which may require validation.

**Comments**

No specific points.

**Further work required**

Develop means of validating and assuring the quality of the indicator.

**Conclusion & priority**

**C - To be implemented where local circumstances allow on a routine basis**  
(compiling the indicator annually).

**References**

British Diabetic Association (1993). *What diabetic care to expect: the British Diabetic Association's Patients' Charter*. British Diabetic Association, London.

## Candidate indicator 13

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Percentage prevalence of symptomatic angina within a population known to have diabetes</b>   |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Symptoms</i> .  |
| <b>Definition</b>           | For a given population, and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, at the year end, have been identified as having symptomatic angina, divided by the number of patients previously diagnosed with diabetes mellitus within the given population</i> . The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.   |
| <b>Rationale</b>            | Ischaemic heart disease is very common in people with diabetes, the relative risk of myocardial infarction possibly being four in middle aged men, and rather higher in women (Tunbridge and Home 1991). The incidence of all macrovascular disease is greater in diabetic patients with the prevalence of angina, in a group aged over 60, having been estimated at 11% (Neil et al. 1989). Good control of diabetes should be important in preventing, or limiting, the gradual development of arterial disease. Blood glucose control and dietary attention are important features in preventing this and other complications. Education efforts focusing on risk factors including diet and smoking can also influence the indicator (Yudkin et al. 1996).  |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | As with other prevalence measures, this indicator is often confounded by a failure to diagnose the co-morbid condition in the patient.  |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes who may well be on a chronic disease management register. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Angina should be coded 413 in ICD9 and I20 in ICD10. The Read code for angina is G33.. . The angina code should fall in the primary diagnosis position with diabetes defined as a secondary condition, <i>although the combination of both codes being present at the time of an annual review is probably sufficient</i> . The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'ANGINA' (UKDD) and 'd_ang_p' (DIABCARE). Data should be collected at least annually, at a review of the patient's health. |

|                                  |  |
|----------------------------------|--|
| <b>Data quality</b>              | Quality will be dependent on the completeness of diagnosis at annual review within the individual practice i.e. identification of patients with diabetes who have also presented with angina where both conditions are present contemporaneously, and the quality of monitoring and recording systems.   |
| <b>Comments</b>                  | Prevalence figures smooth the data over time and therefore may lack sensitivity to change. In this respect, incidence figures may be preferable but they also have problems related to identification, collection and interpretation.  |
| <b>Further work required</b>     | None recommended.  |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b><br>(compiling the indicator annually).   |
| <b>References</b>                | <p>Neil, H. A. W., Thomson, A. V., Thorogood, M., Fowler, G. H., and Mann, J. I. (1989). Diabetes in the elderly: the Oxford community diabetes study. <i>Diabetic Medicine</i>, <b>6</b>, 608-613.</p> <p>Tunbridge, W. M., and Home, P. D. (1991). <i>Diabetes and endocrinology in clinical practice</i>. Edward Arnold, London.</p> <p>Yudkin, J. S., Blauth, C., Drury, P., Fuller, J., Henley, J., Lancaster, T., Lankester, J., Lean, M., Pentecost, B., Press, V., and Rothman, D. (1996). Prevention and management of cardiovascular disease in patients with diabetes mellitus: an evidence base. <i>Diabetic Medicine</i>, <b>13</b>, S101-S121.</p> |

## Candidate indicator 14

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Percentage prevalence of claudication within a population known to have diabetes</b>   |
| <b>Intervention aim</b>     | Reduce risk of complications - <i>Symptoms.</i>   |
| <b>Definition</b>           | For a given population, and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, at the year end, have been identified as having claudication, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.  |
| <b>Rationale</b>            | Intermittent claudication predisposes the feet of diabetic patients to gangrene. The condition can be improved through patient education (encouraging him/her to walk for one hour per day; avoiding tobacco products). The prevalence of intermittent claudication in a group of people with diabetes over 60 years old has been reported at 11%, or 9% across the whole age range over 20 (Neil et al. 1989).   |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | As with other prevalence measures, this indicator can be confounded by a lack of effort in screening for the condition and/or failure to recognise the condition in the patient.  |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes who should be monitored annually. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Diabetes with peripheral circulatory disorders or complications is coded 250.6 with 443.8* in ICD9 (although intermittent claudication can be coded as 443.9) and E10.5 to E14.5 with I79.2* (peripheral angiopathy) in ICD10. The corresponding Read code for intermittent claudication is G73z0. The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'CLAUD' (UKDD) and 'd_claud' (DIABCARE). Data should be collected at least annually, at a review of the patient's health. |
| <b>Data quality</b>         | Quality will be dependent on the completeness of the annual review process within an individual practice i.e. identification of patients with diabetes and claudication, and the appropriateness of monitoring and recording systems.   |

|                                  |   |
|----------------------------------|---|
| <b>Comments</b>                  | Prevalence figures smooth the data over time and therefore may lack sensitivity to change. In this respect, incidence figures may be preferable but they also have problems related to identification, collection and interpretation. |
| <b>Further work required</b>     | None recommended.   |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b><br>(compiling the indicator annually).  |
| <b>References</b>                | Neil, H. A. W., Thomson, A. V., Thorogood, M., Fowler, G. H., and Mann, J. I. (1989). Diabetes in the elderly: the Oxford community diabetes study. <i>Diabetic Medicine</i> , <b>6</b> , 608-613.                                    |

## Candidate indicator 15

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Number of patients who have had at least one hypoglycaemic emergency, within the last year, that required therapeutic intervention by a health professional, expressed as a proportion of a population of patients known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of acute complications or death.</i>   |
| <b>Definition</b>           | For a given population, and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, during the year, suffered at least one hypoglycaemic emergency that required therapeutic intervention by a health professional, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group, sex and treatment modality (i.e. diet alone, diet plus oral agents and insulin).   |
| <b>Rationale</b>            | Hypoglycaemic emergencies are life threatening events to patients and are potentially avoidable. Twenty-seven per cent of attendances at A&E departments, by those people with diabetes, are attributable to hypoglycaemia (Holmwood et al. 1992) although this is considered to be only the 'tip of the iceberg' of all diabetic hypoglycaemic occurrences in the population. As well as measuring admission or attendance at hospital for hypoglycaemia, the indicator includes any emergency that requires a therapeutic intervention such as an injection of glucose or glucagon.   |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.   |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.  |
| <b>Possible confounders</b> | Failure to recognise hypo- and hyperglycaemic events within hospital episode data might underestimate the occurrence by up to 30%. Multiple re-admissions of the same individual can also confuse the picture, while hypoglycaemia can be a part cause of the admission, particularly in the elderly, leading to recording and coding anomalies. Treatment in A&E departments need to be included in the numerator. Finally, as noted in other indicators, the ethnic composition of the population is likely to affect the indicator.  |
| <b>Data sources</b>         | The numerator can imply a hospital admission, with the data being obtained from HES data where the primary diagnosis of diabetes mellitus (ICD9 - 250; ICD10 - E10 - E14) is recorded and diabetic hypoglycaemia is coded. This should be coded by a suffix of .0 in ICD10, which should probably occur in the primary position, and is non-specific being used also for hyperglycaemic coma. However, it also includes attendance at A&E or treatment by a GP or paramedic that would require alternative data collection methods via the A&E minimum data set, through the use of appropriate Read codes and within the paramedical services. The Read code for |

a hypoglycaemic event in diabetes is X40Jq, although this might be used without reference to the definition as used above i.e. 'requiring therapeutic intervention by health professional'. The denominator requires identification of patients having been diagnosed with diabetes, including those outside hospital. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Compilation of the indicator may prove complex requiring linkage between hospital and GP records and with paramedical or other sources in primary care.

The indicator can be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'HYPO-HSP' and 'HYPO-GP' (UKDD) the latter being defined as an intervention by a GP or paramedic while 'hypo' (DIABCARE) is defined as 'requiring help from a third party'.

**Data quality**

Quality will be dependent on the completeness and validity of the recording of relevant hospital admissions (see 'Possible confounders') and of recording GP interventions. The denominator requires a valid and up to date register of patients with diabetes within an individual practice.

**Comments**

No specific points.

**Further work required**

Further work may be needed to assure the mechanics of data collection, particularly with respect to paramedic systems, and the collation and compilation of the indicator. Further national/international standardisation of recording of hypoglycaemia episodes is desirable.

**Conclusion & priority**

**A - To be implemented generally on a routine basis.**

**References**

Holmwood, K. I., Williams, D. R. R., and Roland, J. M. (1992). Accident and emergency. *Diabetic Medicine*, **9**, 379-385.

## Candidate indicator 16

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Number of patients who have had at least one hyperglycaemic emergency, within the last year, that required hospital admission expressed as a proportion of a population of patients known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of acute complications or death.</i>  |
| <b>Definition</b>           | <p>For a given population, and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, during the year, suffered at least one hyperglycaemic emergency that required a hospital admission, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.</p> <p>(A similar indicator could be produced that considers the number of such emergencies across the whole GP population, i.e. to take into account where diabetes had not been diagnosed prior to the emergency occurring).</p> |
| <b>Rationale</b>            | Hyperglycaemic emergencies, which carry a significant risk of mortality are mostly avoidable with careful and experienced management (Tunbridge and Home 1991). Better control of blood glucose lessens exposure to hyperglycaemia and the risk of ketoacidosis. Since these emergencies are potentially avoidable, the objective should be to reduce the rate to as low as possible, recognising that it is not realistic to eliminate these admissions completely.   |
| <b>Potential uses</b>       | Clinical management of patients; clinical audit. Trends over time. HA and other population based comparisons.  |
| <b>Potential users</b>      | Clinicians, health care commissioners and providers.   |
| <b>Possible confounders</b> | Failure to recognise the hypo- and hyperglycaemic events within hospital episode data might underestimate occurrence by up to 30%. Deaths due to diabetic coma and ketoacidosis occurring in the community or before admission to hospital will affect the indicator and should be considered for inclusion in the numerator. Finally, as noted in other indicators, the ethnic composition of the population is likely to affect the indicator.   |
| <b>Data sources</b>         | Since the numerator requires a hospital admission (although see caveat with respect to treatment in A&E), these data may be obtained from contract minimum data set (CMDS) data where the primary diagnosis of diabetes mellitus (ICD9 - 250; ICD10 - E10-E14) is recorded. Coma with ketoacidosis, or hyperosmolar coma is coded 250.2 in ICD9, and by a suffix of .0 in ICD10, and might occur in the primary position, although the latter suffix is also used for hypoglycaemic coma, and hence differentiation would be needed. The Read codes have a code for hyperglycaemia   |

(X40J2) which could be attached to the diagnosis of diabetes to ensure its appropriate collection. The use of the word 'emergency' should imply a particular mode of admission, also readily available from CMDS. The denominator requires identification of patients having been diagnosed with diabetes, including those outside hospital. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. The construction of the indicator requires linkage between hospital and GP records, the numerator being based on hospital admissions while the denominator is defined by primary care populations.

The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'ADM-DKA' (UKDD) and 'hyper' (DIABCARE) although the latter is defined as 'requiring professional help' rather than requiring a hospital admission.

|                                  |   |
|----------------------------------|---|
| <b>Data quality</b>              | Quality will be dependent on the completeness and validity of the recording of relevant hospital admissions (see 'Possible confounders'). The denominator requires a valid and up to date register of patients with diabetes within an individual practice. |
| <b>Comments</b>                  | This indicator is known to be sensitive to effective patient education.   |
| <b>Further work required</b>     | No specific points.   |
| <b>Conclusion &amp; priority</b> | <b>A - To be implemented generally on a routine basis.</b>  |
| <b>References</b>                | Tunbridge, W. M., and Home, P. D. (1991). <i>Diabetes and endocrinology in clinical practice</i> . Edward Arnold, London.   |

## Candidate indicator 17

### Characteristics

*Specificity:* Generic  
*Perspective:* Population  
*Timeframe:* Longitudinal  
*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Case fatality rate associated with acute diabetic episodes treated in hospital</b>   |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of acute complications or death.</i>   |
| <b>Definition</b>           | For a given provider unit, or group thereof, and time period: <i>the proportion of in-patients with a primary diagnosis of diabetes mellitus (or manifestation thereof, including hypoglycaemia) who die within 30 days of their admission.</i> The numerator and denominator are to be reported as well as the derived rate.   |
| <b>Rationale</b>            | Mortality in hospital, or within 30 days of admission, may in part represent an adverse outcome of antecedent health care. Comparisons of mortality, with suitable case mix controls, across providers may reflect the effectiveness of care within individual provider units. In particular, comparisons in large populations over time may indicate whether care is resulting in improved outcomes.   |
| <b>Potential uses</b>       | Provider based comparisons of the effectiveness of secondary care provision. Clinical audit of individual fatal cases within the provider unit. Trends over time. (N.B. The validity of comparisons between providers will be affected by many factors including the rarity of the event, the accuracy of source data and the presence of confounding factors. With small numbers, it may be more appropriate to monitor over time, at national or regional level.)   |
| <b>Potential users</b>      | Provider management, purchasers, clinicians.  |
| <b>Possible confounders</b> | The attribution of deaths is often confounded by an incomplete recording of deaths due to diabetes where ketoacidosis, hyperglycaemia or hypoglycaemia is the acute admitting reason, but death itself occurs from cardiological, respiratory, renal or other complications of the management of that episode. Additionally there are problems through interactions between co-morbidities precipitating the hyperglycaemic emergency (such as infections, myocardial infarction) or the inappropriate use of alcohol or non-therapeutic drugs. Furthermore, comparisons should be made in the context of information on the relative severity of diabetes within the patient populations. This might be described by the type of diabetes, the level of current complications and the propensity of the population to diabetic trauma. |
| <b>Data sources</b>         | For in-hospital mortality, the numerator and denominator data may be obtained from CMDS data with a primary diagnosis of diabetes mellitus and discharge method coded as death (code 4). Identification of all deaths, including those outside hospital, within a defined time-period such as 30 days would require linkage between hospital records and death certificates. Severity data could require linkage to GP information about the presence of complications.   |

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|----------------------------------|---|
| <b>Data quality</b>              | <p>The indicator proposed requires diabetes to be coded as the primary diagnosis. Data quality could be compromised, in individual cases, by incorrect coding of diabetes as a secondary diagnosis when it is the major cause of death. Problems with accuracy of items in CMDS and availability of data from GP systems might be overcome by review and abstraction from clinical notes, where considered necessary, in view of the small number of deaths in any one locality.</p>                                |
| <b>Comments</b>                  | <p>Deaths among people with diabetes under the age of 50 has been variously estimated at between 5 and 19 per million (McColl and Gulliford 1993). In the population aged over 50 the number of deaths will be greater but only a proportion of these will occur during or soon after an in-patient episode. This indicator should provide useful information, particularly comparing trends in large populations over time when used in conjunction with hospital admission rates (From Indicators 15 and 16).</p> |
| <b>Further work required</b>     | <p>The data are already available, although linkage of data elements outside the hospital setting may continue to produce problems in the short-term. However, the indicator is probably of limited local use due to the relative rarity of its occurrence. Its value in monitoring long-term trends over time in a large population (e.g. nationally) is worth exploring, as is its value for study as a sentinel event.</p>   |
| <b>Conclusion &amp; priority</b> | <p><b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).</p>  |
| <b>References</b>                | <p>McColl, A. J., and Gulliford, M. C. (1993). <i>Population health outcome indicators for the NHS: a feasibility study for the Department of Health</i>. Faculty of Public Health Medicine of the Royal College of Physicians, London.</p>   |

## Candidate indicator 18

### Characteristics

*Specificity:* Generic

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <p><b>Mortality indicators from the Public Health Common Data Set:</b></p> <p><b>18A. SMR for death due to diabetes mellitus (similar to CDS C5)</b></p> <p><b>18B. Years of life lost per 10,000 resident population by death due to diabetes mellitus (CDS C6)</b></p> <p><b>18C. Years of life lost by death due to diabetes mellitus (CDS C7)</b></p>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of acute complications or death.</i>  |
| <b>Definition</b>           | <p>For a given population, identified separately by sex, and time period:</p> <p>18A. SMR for death due to diabetes mellitus: <i>the ratio of observed to expected deaths in a population, multiplied by 100</i>, where the expected deaths are derived by applying the age-specific death rates for England &amp; Wales (in similar age bands) to the population under consideration.</p> <p>18B. <i>YLL rate</i> = <math>YLL * 10,000 / P</math>, where P is the resident population.</p> <p>18C. <i>Years of life lost (YLL) up to the age of 75 due to diabetes mellitus (ICD E10 to E14)</i>, calculated as: <math>YLL = (74.5 - y) * N_y</math>, summed over ages 0 to 74, where y is age at death and <math>N_y</math> is the number of deaths due to diabetes mellitus at age y.</p> |
| <b>Rationale</b>            | <p>Variations in mortality due to diabetes mellitus may be partly explained by variations in the prevalence of clinically diagnosed diabetes or in its severity. Given that these variables are currently unmeasured across the whole population, geographical differences cannot easily be interpreted as reflecting differences in health service provision. A substantial proportion of deaths due to diabetes are recognised as avoidable (Borch-Johnsen et al. 1987) and, within a region, the effectiveness of interventions aimed at preventing them should be reflected by changes in the indicator over time.</p>   |
| <b>Potential uses</b>       | Measuring impact of disease on premature death; population based comparisons; trends over time.  |
| <b>Potential users</b>      | Local and national policy makers, purchasers, clinicians, the public.  |
| <b>Possible confounders</b> | <p>Apart from the effect of patient variables other than age and sex, this indicator will reflect diabetes-related mortality caused by both immediate and longer term factors. Earlier studies (Gulliford and Burney 1991) have recommended trying to separate these influences.</p>   |
| <b>Data sources</b>         | <p>For 18A and 18C, the indicator is already being produced within the Public Health Common Data Set. SMR indicators are also being compiled for selected conditions. Although diabetes mellitus is not one of these, this indicator can be easily compiled using data collected by the Office for National Statistics.</p>  |

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| <b>Data quality</b>              | The indicator depends on the reliability of recording the underlying cause of death by the death certificate, and considerable under-reporting has been recorded in a number of studies. The quality of these data are thought to be improved in patients under the age of 45. The recording of deaths caused by other conditions, which are more prevalent in patients with diabetes, need to be treated consistently across regions and over time.                                    |
| <b>Comments</b>                  | This indicator is particularly useful in monitoring trends over time and for comparing across large populations. The data on which the indicator is based are collected routinely, and although improvements in data quality are urgently needed, it is proposed that the indicator should be used now.   |
| <b>Further work required</b>     | Ongoing work to assure the reliability of recording cause of death; separation of deaths due to acute exacerbations of the condition from longer term factors.  |
| <b>Conclusion &amp; priority</b> | <b>A - To be implemented generally on a routine basis.</b>  |
| <b>References</b>                | <p>Borch-Johnsen, K., Nissen, H., Salling, N., Henriksen, E., Kreiner, S., Deckert, T., and Nerup, J. (1987). The natural history of insulin-dependent diabetes in Denmark: long-term survival - who and why. <i>Diabetic Medicine</i>, <b>4</b>, 211-216.</p> <p>Gulliford, M. C., and Burney, P. G. J. (1991). Year of birth and mortality caused by diabetes mellitus under 45 years: England and Wales 1927-1986. <i>Journal of Public Health Medicine</i>, <b>13</b>, 204-208.</p> |

## Candidate indicator 19

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Longitudinal

*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Annual incidence of severe visual impairment (visual acuity &lt; 6/60 in the better eye) within a population of patients known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of late complications.</i>   |
| <b>Definition</b>           | For a given population and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, during the year, are newly identified as having a visual acuity &lt; 6/60 in the better eye, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported overall and by age-group and sex.   |
| <b>Rationale</b>            | <p>The St Vincent Declaration (Krans et al. 1992) called for a reduction of one third or more in new blindness due to diabetes. For the purposes of this indicator, blindness has been defined to be visual acuity of less than 6/60 in the better eye. Hence, if the patient was already blind in one eye, the incidence of blindness in the second eye would be counted.</p> <p>Comparison of incidence rates are therefore proposed and reflect the effect of prevention policies if suitable adjustment is made for differences in the risk status of patients considered.</p>  |
| <b>Potential uses</b>       | Measuring impact of disease; population and provider based comparisons (although small numbers may limit the value of comparisons at the provider level); trends over time.   |
| <b>Potential users</b>      | Local and national policy makers, purchasers, clinicians, provider management.  |
| <b>Possible confounders</b> | <p>The incidence of blindness within a diabetic population might be expected to increase with the average time from onset within that population. To remove this effect, the indicator could be standardised and reported together with the time element. It may, however, be difficult to estimate accurately the time from onset in any particular case since visual acuity often fluctuates around 6/60 in patients with severe impairment. Longitudinal data are needed to ensure that identification of a deterioration is genuinely new.</p> <p>Co-existing ocular pathology, e.g. cataracts, may influence the level of acuity and hence the recording of the incidence of blindness attributable to diabetes.</p> |

|                                  |  |
|----------------------------------|--|
| <b>Data sources</b>              | The denominator is defined by patients already diagnosed with diabetes as on a particular day (probably 31st December). Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Although visual acuity is almost uniformly recorded by means of a Snellen chart, there is no standard system, which is widely applied, for the routine collection of these data in a form that can be readily aggregated. ICD10 supports the coding of acuity in terms of the 'better eye' (H54.0) as do the Read codes (e.g. Visual acuity, right eye, 6/60: 2B68; Visual acuity, left eye, 6/60: 2B78). The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'VA-R' and 'VA-L' (UKDD) and 'vis_acu_r' and 'vis_acu_l' (DIABCARE). The other fields 'sv_blind' and 'sv_blind12' (DIABCARE) measure incidence of blindness in one eye, rather than in the 'better' eye as defined here. Numerator data require the collection of newly identified cases of severe visual impairment within each year (probably a calendar year), across a period of at least three to five years. |
| <b>Data quality</b>              | Measurements of visual acuity made in a specialist setting are likely to be more valid and reliable, although it is within primary care that the majority of acuity checks will be initiated. However, all measurements should be made as 'best corrected'. The quality of the data will also be dependent on the completeness of the recording within individual practices i.e. of the identification of patients with diabetes, and of the incidence of blindness.   |
| <b>Comments</b>                  | No specific points.  |
| <b>Further work required</b>     | It is suggested that a sample survey be undertaken to ascertain current practice in respect of the recording of visual acuity in patients with diabetes, its retrieval and collation.  |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).  |
| <b>References</b>                | Krans, H. M. J., Porta, M., and Keen, H. (1992). <i>Diabetes care and research in Europe; the St Vincent Declaration action programme</i> . World Health Organisation, Copenhagen.   |

## Candidate indicator 20

### Characteristics

*Specificity:* Condition-specific  
*Perspective:* Clinical  
*Timeframe:* Longitudinal  
*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Annual incidence of leg amputation above the ankle within a population of patients known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of late complications.</i>   |
| <b>Definition</b>           | For a given population and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, during the year, have a leg amputated above the ankle, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.  |
| <b>Rationale</b>            | <p>There is a substantial literature (Davidson 1983; Edmonds et al. 1986; Pecoraro et al. 1990; Stebbings and Wood 1991) that has shown that the appropriate management of diabetes, including the identification and provision of appropriate care for the diabetic foot which leads to early and effective intervention where needed, can be effective in reducing the incidence of major amputations. The prevalence of lower limb amputation in a population with diabetes has been recorded at 3% (Neil et al. 1989). The amputation is counted even if the person had a previous below ankle amputation on the same side.</p> <p>Comparisons of incidence rates are proposed and reflect the effect of preventive policies and practice if suitable adjustment is made for differences in the risk status of the patients considered. In this respect, comparisons with the annual incidence of amputations in similar non-diabetic populations would be particularly useful.</p> |
| <b>Potential uses</b>       | Measuring impact of disease; population and provider based comparisons; trends over time.   |
| <b>Potential users</b>      | Local and national policy makers, purchasers, clinicians, provider management.  |
| <b>Possible confounders</b> | Co-existing pathologies may influence the level of amputation and thereby confound the recording of the incidence of diabetes related amputations.  |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes as on a particular day (probably 31st December). Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. OPCS codes for a leg amputation above the ankle are X09.1 to X09.9, with diabetes coded diagnostically within the same episode/spell. The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'AMPUTLEG-R' and 'AMPUTLEG-L' (UKDD) and 'sv_a_ank' and 'sv_a_ank12' (DIABCARE) with the latter being particularly relevant as it indicates occurrence within the last 12 months. Numerator data require the collection of newly undertaken procedures of above-ankle leg amputation within a one year period, probably a calendar year.  |

|                                  |  |
|----------------------------------|--|
| <b>Data quality</b>              | Some studies have found variation in lower limb amputation rates (Williams 1989) and have reported up to 40% under reporting of diabetes as a co-morbidity in such cases (Macleod et al. 1988).  |
| <b>Comments</b>                  | No specific points.  |
| <b>Further work required</b>     | None recommended.  |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).  |
| <b>References</b>                | <p>Davidson, J. K. (1983). The Grady Memorial Hospital diabetes programme. In <i>Diabetes in epidemiological perspective</i>. (ed. J. Mann, K. Pyorala, and A. Teuscher.). Churchill Livingstone, Edinburgh.</p> <p>Edmonds, M. E., Blundell, M. P., Morris, M. E., Thomas, E. M., Cotton, L. T., and Watkins, P. J. (1986). Improved survival of the diabetic foot: the role of a specialised foot clinic. <i>Quarterly Journal of Medicine</i>, <b>60</b>, 763-771.</p> <p>Macleod, C. A., Murchison, L. E., Russell, E. M., and Dingwall-Fordyce, I. (1988). Measuring outcome of diabetes: a retrospective survey. <i>Diabetic Medicine</i>, <b>6</b>, 59-63.</p> <p>Neil, H. A. W., Thomson, A. V., Thorogood, M., Fowler, G. H., and Mann, J. I. (1989). Diabetes in the elderly: the Oxford community diabetes study. <i>Diabetic Medicine</i>, <b>6</b>, 608-613.</p> <p>Pecoraro, R. E., Geiber, G. E., and Burgess, E. M. (1990). Pathways to diabetic limb amputation. <i>Diabetes Care</i>, <b>13</b>, 513-521.</p> <p>Stebbins, W. S. L., and Wood, R. F. M. (1991). Amputations in diabetics. <i>Annals of Royal College of Surgeons of England</i>, <b>73</b>, 170-175.</p> <p>Williams, D. D. R. (1989). Outcome indicators for diabetes services: what do we have and what do we need? <i>Community Medicine</i>, <b>11</b>, 57-64.</p> |

## Candidate indicator 21

### Characteristics

*Specificity:* Condition-specific  
*Perspective:* Clinical  
*Timeframe:* Longitudinal  
*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Annual incidence of amputation below the ankle within a population of patients known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of late complications.</i>   |
| <b>Definition</b>           | For a given population and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, during the year, have an amputation below the ankle, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.  |
| <b>Rationale</b>            | <p>There is a substantial literature (Davidson 1983; Edmonds et al. 1986; Pecoraro et al. 1990; Stebbings and Wood 1991) that has shown that the appropriate management of diabetes, including the identification and provision of appropriate care for the diabetic foot which leads to early and effective intervention where needed, can be effective in reducing the incidence of amputations. The prevalence of lower limb amputation in a population with diabetes has been recorded at 3% (Neil et al. 1989). The amputation is counted even if the person had a previous below ankle amputation on the same side.</p> <p>Comparisons of incidence rates are proposed and reflect the effect of preventive policies and practice if suitable adjustment is made for differences in the risk status of the patients considered. In this respect, comparisons with the annual incidence of amputations in similar non-diabetic populations would be particularly useful.</p> |
| <b>Potential uses</b>       | Measuring impact of disease; population and provider based comparisons; trends over time.   |
| <b>Potential users</b>      | Local and national policy makers, purchasers, clinicians, provider management.  |
| <b>Possible confounders</b> | Co-existing pathologies may influence the level of amputation and thereby confound the recording of the incidence of diabetes related amputations.  |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes as on a particular day (probably 31st December). Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. OPCS codes for an amputation below the ankle are X10.1 to X10.9 (foot) and X11.1 to X11.9 (toe), with diabetes coded diagnostically within the same episode/spell. The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'AMPUTOFT-R' and 'AMPUTOFT-L' (UKDD) and 'sv_b_ank' and 'sv_b_ank12' (DIABCARE) with the latter being particularly relevant as it indicates occurrence within the last 12 months. Numerator data require the collection of newly undertaken procedures of below-ankle amputation within a one year period, probably a calendar year.                           |

|                                  |  |
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| <b>Data quality</b>              | Some studies have found variation in lower limb amputation rates (Williams 1989) and have reported up to 40% under-reporting of diabetes in such cases (Macleod et al. 1988).  |
| <b>Comments</b>                  | No specific points.  |
| <b>Further work required</b>     | None recommended.  |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).  |
| <b>References</b>                | <p>Davidson, J. K. (1983). The Grady Memorial Hospital diabetes programme. <i>In Diabetes in epidemiological perspective</i>. (ed. J. Mann, K. Pyorala, and A. Teuscher.). Churchill Livingstone, Edinburgh.</p> <p>Edmonds, M. E., Blundell, M. P., Morris, M. E., Thomas, E. M., Cotton, L. T., and Watkins, P. J. (1986). Improved survival of the diabetic foot: the role of a specialised foot clinic. <i>Quarterly Journal of Medicine</i>, <b>60</b>, 763-771.</p> <p>Macleod, C. A., Murchison, L. E., Russell, E. M., and Dingwall-Fordyce, I. (1988). Measuring outcome of diabetes: a retrospective survey. <i>Diabetic Medicine</i>, <b>6</b>, 59-63.</p> <p>Neil, H. A. W., Thomson, A. V., Thorogood, M., Fowler, G. H., and Mann, J. I. (1989). Diabetes in the elderly: the Oxford community diabetes study. <i>Diabetic Medicine</i>, <b>6</b>, 608-613.</p> <p>Pecoraro, R. E., Geiber, G. E., and Burgess, E. M. (1990). Pathways to diabetic limb amputation. <i>Diabetes Care</i>, <b>13</b>, 513-521.</p> <p>Stebbins, W. S. L., and Wood, R. F. M. (1991). Amputations in diabetics. <i>Annals of Royal College of Surgeons of England</i>, <b>73</b>, 170-175.</p> <p>Williams, D. D. R. (1989). Outcome indicators for diabetes services: what do we have and what do we need? <i>Community Medicine</i>, <b>11</b>, 57-64.</p> |

## Candidate indicator 22

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Longitudinal

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Annual incidence of myocardial infarction within a population of patients known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of late complications.</i>  |
| <b>Definition</b>           | For a given population and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, during the year, are diagnosed as having suffered a myocardial infarction (MI), divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.  |
| <b>Rationale</b>            | <p>The diagnosis is based on clinical findings and history, namely of a prodrome and typical laboratory test results e.g. enzyme levels or ECG changes.</p> <p>Myocardial infarction and strokes resulting from macrovascular disease are the commonest causes of death in people with diabetes over the age of 50 (Macleod et al. 1987). The prevalence of 'possible' myocardial infarction in a group of people with diabetes over 60 years old has been estimated at 9% (Neil et al. 1989). People with diabetes are also more prone to myocardial infarction and strokes at an earlier age than other patients (Yudkin et al. 1996).</p> <p>Comparisons of incidence rates are proposed and reflect the effect of preventive policies and practice if suitable adjustment is made for differences in the risk status of the patients considered.</p> |
| <b>Potential uses</b>       | Measuring impact of disease; population and provider based comparisons; trends over time.  |
| <b>Potential users</b>      | Local and national policy makers, purchasers, clinicians, provider management.   |
| <b>Possible confounders</b> | <p>Co-existing pathology may affect the incidence of myocardial infarction and thereby confound the recording of the incidence of diabetes related MI.</p> <p>'Silent' MIs may lead to an understated incidence, while data on the occurrence of infarcts outside of hospital need a comprehensive and reliable recording system.</p>  |

|                                  |  |
|----------------------------------|--|
| <b>Data sources</b>              | <p>The denominator is defined by patients already diagnosed with diabetes as on a particular day (probably 31st December). Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Coding for the occurrence of a MI are 410 &amp; 412 (ICD9), and I21 &amp; I22 (ICD10) with diabetes coded diagnostically within the same episode/spell. The corresponding Read codes are G30.. . Diagnosis of MI requires a prodrome, and rise in enzyme levels or appropriate change in ECG trace.</p> <p>The indicator might also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset, although UKDD's definition excludes the requirement of a prodrome, while DIABCARE's definition includes the incidence of CABG or PTCA with that of an MI. The particular fields within these datasets are 'MI' (UKDD) and 'sv_m_inf' and 'sv_m_inf12' (DIABCARE) with the UKDD and the latter DIABCARE variables indicating occurrence within the last 12 months. Numerator data require the collection of newly identified (although not necessarily first) occurrence of myocardial infarction within the diabetic population, within a one year period, probably collected over a calendar year.</p> |
| <b>Data quality</b>              | <p>The quality of the data will be dependent on the completeness of the recording within individual practices i.e. of the identification of patients with diabetes, and recognition of the incidence of myocardial infarction, which in turn requires good communication between hospitals and primary care. As mentioned above, the recording of MI can be ambiguous, particularly in those MIs that are never admitted to hospital. This may lead to an understated incidence.</p>   |
| <b>Comments</b>                  | <p>No specific points.</p>   |
| <b>Further work required</b>     | <p>None recommended.</p>   |
| <b>Conclusion &amp; priority</b> | <p><b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).</p>   |
| <b>References</b>                | <p>Macleod, J., Edwards, C., and Bouchier, I. (1987). Diabetes mellitus. In <i>Davidson's principles of medicine</i>. Churchill Livingstone, Edinburgh.</p> <p>Neil, H. A. W., Thomson, A. V., Thorogood, M., Fowler, G. H., and Mann, J. I. (1989). Diabetes in the elderly: the Oxford community diabetes study. <i>Diabetic Medicine</i>, <b>6</b>, 608-613.</p> <p>Yudkin, J. S., Blauth, C., Drury, P., Fuller, J., Henley, J., Lancaster, T., Lankester, J., Lean, M., Pentecost, B., Press, V., and Rothman, D. (1996). Prevention and management of cardiovascular disease in patients with diabetes mellitus: an evidence base. <i>Diabetic Medicine</i>, <b>13</b>, S101-S121.</p>   |

## Candidate indicator 23

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Longitudinal

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Annual incidence of stroke within a population of patients known to have diabetes</b>   |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of late complications.</i>  |
| <b>Definition</b>           | For a given population and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, during the year, are diagnosed as having suffered a stroke, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i> The resulting fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.  |
| <b>Rationale</b>            | <p>Myocardial infarction and strokes resulting from macrovascular disease are the commonest cause of death in people with diabetes over the age of 50 (Macleod et al. 1987). The prevalence of stroke in a group of people with diabetes over 60 years old has been estimated at 5% (Neil et al. 1989). People with diabetes are also more prone to myocardial infarction and strokes at an earlier age than other patients.</p> <p>Comparisons of incidence rates are proposed and reflect the effect of preventive policies and practice if suitable adjustment is made for differences in the risk status of patients considered.</p>   |
| <b>Potential uses</b>       | Measuring impact of disease; population and provider based comparisons; trends over time.  |
| <b>Potential users</b>      | Local and national policy makers, purchasers, clinicians, provider management.   |
| <b>Possible confounders</b> | Co-existing pathology may affect the incidence of stroke or, at time of occurrence, diabetes may not be identified or recorded, thus affecting the accurate reporting of the incidence of the diabetes related condition. The threshold for the recording of 'stroke', particularly those where admission to hospital does not take place may lead to an understated incidence.  |
| <b>Data sources</b>         | The denominator is defined by patients already diagnosed with diabetes as on a particular day (probably 31st December). Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Coding for the occurrence of a stroke is 431, 432, 434 and 436 (ICD9) and I61 to I64 (ICD10) with diabetes coded diagnostically within the same episode/spell. The corresponding Read codes are stroke (X00D1), or cerebral infarction unspecified (Xa0kZ). The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'CVA' (UKDD) and 'sv_strok' and 'sv_strok12' (DIABCARE) with the UKDD and the latter DIABCARE variables being particularly relevant as they indicate occurrence within the last 12 |

months. Numerator data require the collection of newly identified (although not necessarily first) occurrence of stroke within the diabetic population, within a one year period, probably collected over a calendar year.

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| <b>Data quality</b>              | The quality of the data will be dependent on the completeness of the recording within individual practices i.e. on the identification of patients with diabetes, and recognition of the incidence of stroke. As mentioned above, the recording of stroke can be ambiguous, particularly in those cases that are never admitted to hospital. This may lead to an understated incidence. As with many indicators, the completeness and accuracy of data capture also depends on good communications between hospitals and primary care. |
| <b>Comments</b>                  | No specific point.  |
| <b>Further work required</b>     | None recommended.   |
| <b>Conclusion &amp; priority</b> | <b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).   |
| <b>References</b>                | <p>Macleod, J., Edwards, C., and Bouchier, I. (1987). Diabetes mellitus. In <i>Davidson's principles of medicine</i>. Churchill Livingstone, Edinburgh.</p> <p>Neil, H. A. W., Thomson, A. V., Thorogood, M., Fowler, G. H., and Mann, J. I. (1989). Diabetes in the elderly: the Oxford community diabetes study. <i>Diabetic Medicine</i>, <b>6</b>, 608-613.</p>   |

## Candidate indicator 24

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Number of patients who have started renal replacement therapy or have had a creatinine level &gt; 500 µmol/litre recorded for the first time within the last year, expressed as a proportion of a population of patients known to have diabetes</b>   |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Incidence of late complications.</i>  |
| <b>Definition</b>           | <p>For a given population and year: <i>the number of patients previously diagnosed with diabetes mellitus and who, during the year, have either:</i></p> <ul style="list-style-type: none"><li><i>i) started renal replacement therapy i.e. started on dialysis or have received a transplant, or</i></li><li><i>ii) had a creatinine level &gt; 500 µmol/litre recorded for the first time, divided by the number of patients previously diagnosed with diabetes mellitus within the given population.</i></li></ul> <p>The resulting single fraction should be expressed as a percentage and reported as an overall figure and by age-group and sex.</p>   |
| <b>Rationale</b>            | <p>A significant percentage of all Type I patients develop diabetic nephropathy (Viberti et al. 1996) and will go into end-stage renal failure (ESRF) after an average diabetes duration of 20-25 years. Mortality associated with diabetic nephropathy is up to 100 times that of a matched background population (Borch-Johnsen et al. 1985). Good metabolic control from the time of diagnosis is probably the most important feature in the good management of diabetic renal disease. However, it is also important for the diabetic patient to enter renal replacement therapy early and possibly receive transplantation at relatively low creatinine levels (below 500 (µmol/litre). The indicator measures, therefore, the proportion of patients with diabetes who are considered appropriate for transplantation and therefore identifies the impact of this complication. Knowledge of those receiving a transplant might also indicate the shortfall in the level of donor organs or service provision.</p> |
| <b>Potential uses</b>       | Measuring impact of disease; population and provider based comparisons; trends over time.  |
| <b>Potential users</b>      | Local and national policy makers, purchasers, clinicians, provider management.   |
| <b>Possible confounders</b> | <p>Co-existing pathologies may affect the incidence of end stage renal disease and hence the start of renal replacement therapy, thus making the interpretation of the indicator, and its relationship to diabetes care, difficult.</p> <p>End stage renal disease is time related from onset of diabetes. To remove this effect, the indicator could be standardised and reported with the time element. It may, however, be difficult to estimate accurately the time from onset in any particular case.</p>   |

|                                  |  |
|----------------------------------|--|
| <b>Data sources</b>              | The denominator is defined by patients already diagnosed with diabetes as on a particular day (probably 31st December). Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Renal transplant and dialysis have been variously coded as V42.0 and V56.0 respectively in ICD9, and M01.- and X40.1 (OPCS). End stage renal disease has been coded 585 (ICD9) and N18.0 (ICD10). Comparable Read codes are renal transplant (7B00.), renal dialysis (7L1A0), ESRF (X30J0). The indicator can also be derived from the UK Diabetes Dataset and from the DIABCARE Dataset. The particular fields required are 'DIALYSIS' and 'CREAT' (UKDD) and 'sv_dialy12' and 'crea' (DIABCARE). In the case of the creatinine variables, there is a need to identify the level going above 500( $\mu\text{mol/litre}$ for the first time in the year under consideration. Numerator data require the identification of the number of patients with diabetes who have started renal replacement therapy in the last year or who clinically require it, probably collected over a calendar year. |
| <b>Data quality</b>              | The quality of the data will be dependent on the completeness of the recording within individual practices i.e. on the identification of patients with diabetes, and knowledge of creatinine level (or status of renal replacement therapy), which in turn requires good communication between hospitals and primary care.   |
| <b>Comments</b>                  | No specific points.  |
| <b>Further work required</b>     | None recommended.  |
| <b>Conclusion &amp; priority</b> | <b>D - To be implemented where local circumstances allow by periodic survey.</b>   |
| <b>References</b>                | <p>Borch-Johnsen, K., Anderson, P. K., and Deckert, T. (1985). The effect of proteinuria on relative mortality in Type 1 (insulin dependent) diabetes mellitus. <i>Diabetologia</i>, <b>28</b>, 590.</p> <p>Viberti, G-C., Marshall, S., Beech, R., Brown, V., Derben, P., Higson, N., Home, P., Keen, H., Plant, M., and Wallis, J. (1996). Report on renal disease in diabetes. <i>Diabetic Medicine</i>, <b>13</b>, S6-S12.</p>   |

## Candidate indicator 25

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Rates of late stillbirth and perinatal mortality in deliveries from a population of patients known to have diabetes and who become pregnant</b>   |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Complications of pregnancy.</i>   |
| <b>Definition</b>           | <p>For a given population of patients previously diagnosed with diabetes mellitus, by age group, and for a given year: <i>the number of pregnancies that result in:</i></p> <ul style="list-style-type: none"><li><i>i) the delivery of a fetus, after the 24th week of gestation, which did not at any time after delivery breathe or show any other signs of life,</i><br/>and separately,</li><li><i>ii) the death of the infant between 24 completed weeks gestation and one week after birth, divided by the number of completed pregnancies in the population of interest and in the given year.</i></li></ul> <p>The resulting rates, expressed as percentages, should be reported separately and with their numerators.</p>  |
| <b>Rationale</b>            | <p>Diabetes during pregnancy carries risks to both the mother and the developing fetus. Indicators 25 to 29 focus mainly on outcomes associated with the fetus, but the sub-population of mothers who are known to have diabetes before becoming pregnant is likely to suffer greater problems from hypertension, ketoacidosis, retinopathy and nephropathy than a similar non-pregnant population (Tunbridge and Home 1991; Jardine Brown et al. 1996) and it may be appropriate to examine this sub-group of patients separately when considering other relevant indicators.</p> <p>Early metabolic disturbance can lead to abnormal development, which may lead to fetal death or congenital malformations, and hence close monitoring and control during the ante-natal period is to be desired. The rate of late stillbirths and perinatal mortality within this subgroup is known to be significantly higher than in the normal population. (Hawthorne et al. 1997).</p> |
| <b>Potential uses</b>       | Clinical audit, trends over time and as a basis for provider comparisons, although small numbers may require special consideration.  |
| <b>Potential users</b>      | Clinicians, provider management and commissioners. Local and national policy makers.   |
| <b>Possible confounders</b> | Adverse outcomes of pregnancy in this patient group need to be considered in the context of information about maternity outcomes in the general and local population, and those associated with other maternity risk factors and other co-morbidities.   |

|                                  |   |
|----------------------------------|---|
| <b>Data sources</b>              | <p>Generally, the indicator will result from an in-patient episode with data being captured via diagnostic coding within the contract minimum data set or through other routine data capture systems. However, should the delivery (or deliveries, in the case of the denominator figure) have taken place at home, or should the death occur post discharge, data will need to be collected from GP systems. As with other indicators collation from the two separate systems will be required which would be facilitated by use of a diabetic register.</p> <p>The denominator is defined by patients already diagnosed with diabetes before booking as pregnant and who have completed a pregnancy. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5, with details of the outcome of the delivery being collected on the mother's record in the delivery episode. The UK Diabetes Dataset does not identify outcomes of pregnancy in patients with diabetes. However, the DIABCARE Dataset includes fields which would allow some of these indicators to be derived. The particular fields required to derive this indicator are 'p_yes_12', 'p_mis_12' and 'p_peri_12' (DIABCARE) with each relating to occurrences within the last 12 months. However, these fields (p_mis_12 and p_peri_12) define stillbirths as occurring at up to 28 weeks, with perinatal deaths occurring after that point.</p> |
| <b>Data quality</b>              | <p>The validity of the data will depend on the accuracy and completeness of clinical coding for both numerator and denominator. In particular, the indicator is dependent on the identification of diabetes as a secondary diagnosis in the coded record, and the separation of gestational diabetes from the pre-existing condition. With many provider units having fewer than ten cases per year, this indicator is likely to be best reported at a sub-region level, the indicator being calculated annually.</p>   |
| <b>Comments</b>                  | <p>An indicator recording stillbirths and perinatal deaths in mothers with diabetes has been introduced into the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) since 1998.</p>  |
| <b>Further work required</b>     | <p>None recommended.</p>  |
| <b>Conclusion &amp; priority</b> | <p><b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).</p>  |

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## Candidate indicator 26

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>The rate of delivery by caesarean section in deliveries from a population of patients known to have diabetes and who become pregnant</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Complications of pregnancy.</i>   |
| <b>Definition</b>           | For a given population of patients previously diagnosed with diabetes mellitus, by age group, and for a given year: <i>the number of pregnancies that result in the delivery of an infant by means of caesarean section, divided by the number of completed pregnancies in the population of interest and in the given year.</i> The resulting rates should be reported as percentages and with their numerators.  |
| <b>Rationale</b>            | <p>Diabetes during pregnancy carries risks to both the mother and the developing fetus. Indicators 25 to 29 focus mainly on outcomes associated with the fetus, but the sub-population of mothers known to have diabetes before becoming pregnant is likely to suffer greater problems from hypertension, ketoacidosis, retinopathy and nephropathy than a similar non-pregnant population (Tunbridge and Home 1991; Jardine Brown et al. 1996) and it may be appropriate to examine this sub-group of patients when considering other relevant indicators.</p> <p>Such risks may require a greater level of intervention than in the non-pregnant population, but such interventions also carry their own level of risk. The degree of variability across units is probably not clinically justifiable, but determining 'appropriate' rates is fraught with difficulties.</p> |
| <b>Potential uses</b>       | Clinical audit, trends over time and as a basis for provider comparisons although small numbers may require special consideration.   |
| <b>Potential users</b>      | Clinicians, provider management and commissioners. Local and national policy makers.   |
| <b>Possible confounders</b> | Adverse outcomes of pregnancy in this patient group need to be considered in the context of information about maternity outcomes in the general and local population, and those associated with other maternity risk factors, and other co-morbidities. Caesarean section rates vary as a matter of policy between obstetric units and localities and therefore the indicator may need reporting as a ratio of the local general population rate. However, the rate may also be confounded by the use of other interventions e.g. early induction and might benefit by being linked to gestational age.  |

|                                  |   |
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| <b>Data sources</b>              | <p>Generally, the indicator will result from an in-patient episode with data being captured via diagnostic coding within the contract minimum data set or through other routine data capture systems. However, where the delivery (in the case of the denominator figure) has taken place at home data will need to be collected from GP systems. As with other indicators collation from the two separate systems will be required which would be facilitated by use of a diabetic register.</p> <p>The denominator is defined by patients already diagnosed with diabetes before booking as pregnant and who have completed a pregnancy. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Delivery by caesarean section is recorded as 669.7 (ICD9) and by O82 (ICD10) as well as via other fields in the delivery episode on the mother's record. Neither the UK Diabetes Dataset nor the DIABCARE Dataset includes fields that would enable this indicator to be derived from them.</p> |
| <b>Data quality</b>              | <p>The validity of the data will depend on the accuracy and completeness of clinical coding for both numerator and denominator. In particular, the indicator is dependent on the identification of diabetes as a secondary diagnosis in the coded record, and the separation of gestational diabetes from the pre-existing condition. With many provider units having fewer than ten cases per year, this indicator is likely to be best reported at a sub-region level, the indicator being calculated annually.</p>   |
| <b>Comments</b>                  | <p>No specific points.</p>  |
| <b>Further work required</b>     | <p>None recommended.</p>  |
| <b>Conclusion &amp; priority</b> | <p><b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).</p>  |
| <b>References</b>                | <p>Jardine Brown, C., Dawson, A., Dodds, R., Gamsu, H., Gillmer, M., Hall, M., Hounsome, B., Knopfler, A., Ostler, J., Peacock, I., Rothman, D., and Steel, J. (1996). Report of the Pregnancy and Neonatal Care Group. <i>Diabetic Medicine</i>, <b>13</b>, S43-S53.</p> <p>Tunbridge, W. M., and Home, P. D. (1991). <i>Diabetes and endocrinology in clinical practice</i>. Edward Arnold, London.</p>   |

## Candidate indicator 27

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>The incidence of delivered babies with birthweight greater than the 90th centile (allowing for gestational age) from within a population of patients known to have diabetes and who become pregnant</b>   |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Complications of pregnancy.</i>   |
| <b>Definition</b>           | For a given population of patients previously diagnosed with diabetes mellitus, by age group, and for a given year: <i>the number of delivered babies whose birthweight is greater than the 90th centile (allowing for gestational age), divided by the number of babies born to mothers from the population of interest and in the given year.</i> The resulting rates should be reported as percentages and with their numerators.   |
| <b>Rationale</b>            | <p>Diabetes during pregnancy carries risks to both the mother and the developing fetus. Indicators 25 to 29 focus mainly on outcomes associated with the fetus, but the sub-population of mothers known to have diabetes before becoming pregnant is likely to suffer greater problems from hypertension, ketoacidosis, retinopathy and nephropathy than a similar non-pregnant population (Tunbridge and Home 1991; Jardine Brown et al. 1996) and it may be appropriate to examine this sub-group of patients when considering other relevant indicators.</p> <p>Late metabolic disturbances, especially around the third trimester, can lead to the development of a large but immature infant, probably resulting from the over-stimulation of the fetal pancreas.</p> |
| <b>Potential uses</b>       | Clinical audit, trends over time and as a basis for provider comparisons although small numbers may require special consideration.   |
| <b>Potential users</b>      | Clinicians, provider management and commissioners. Local and national policy makers.   |
| <b>Possible confounders</b> | <p>Adverse outcomes of pregnancy in this patient group need to be considered in the context of information about maternity outcomes in the general and local population, and those associated with other maternity risk factors and co-morbidities.</p> <p>The use of the 90th centile as a standard requires that this figure is kept up to date, in respect of both normal deliveries and those from diabetic mothers, and that the standard is relevant locally for the particular population being considered. A number of commonly used standards have been used e.g. from Aberdeen &amp; Oxford, although users should ensure their relevance locally. The application of inappropriate standards will confound the interpretation of this indicator.</p>            |

|                                  |   |
|----------------------------------|---|
| <b>Data sources</b>              | <p>Generally, the indicator will result from an in-patient episode with data being captured via the contract minimum data set or through other routine data capture systems. However, should the delivery (or deliveries, in the case of the denominator figure) have taken place at home data will need to be collected from GP systems. As with other indicators collation from the two separate systems will be required which would be facilitated by use of a diabetic register.</p> <p>The denominator is defined by babies born to patients already diagnosed with diabetes before booking as pregnant and who have completed a pregnancy. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Birthweight is recorded within the delivery episode of the mother's record as is gestational age. Neither the UK Diabetes Dataset nor the DIABCARE Dataset includes fields that would enable this indicator to be derived from them.</p> |
| <b>Data quality</b>              | <p>The validity of the data will depend on the accuracy and completeness of clinical coding for both numerator and denominator. In particular, the indicator is dependent on the identification of diabetes as a secondary diagnosis in the coded record, and the separation of gestational diabetes from the pre-existing condition. With many provider units having fewer than ten cases per year, this indicator is likely to be best reported at a sub-region level, the indicator being calculated annually.</p>   |
| <b>Comments</b>                  | <p>No specific points.</p>  |
| <b>Further work required</b>     | <p>To validate the standard distributions of birthweight by gestational age, and to examine their relationship to ethnic group and other variables.</p>   |
| <b>Conclusion &amp; priority</b> | <p><b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).</p>  |
| <b>References</b>                | <p>Jardine Brown, C., Dawson, A., Dodds, R., Gamsu, H., Gillmer, M., Hall, M., Hounsome, B., Knopfler, A., Ostler, J., Peacock, I., Rothman, D., and Steel, J. (1996). Report of the Pregnancy and Neonatal Care Group. <i>Diabetic Medicine</i>, <b>13</b>, S43-S53.</p> <p>Tunbridge, W. M., and Home, P. D. (1991). <i>Diabetes and endocrinology in clinical practice</i>. Edward Arnold, London.</p>   |

## Candidate indicator 28

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>The incidence of occurrence of specific congenital malformations (i.e. neural tube defects, cardiac and renal malformations) in deliveries from a population of patients known to have diabetes and who become pregnant</b>   |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Complications of pregnancy.</i>   |
| <b>Definition</b>           | For a given population of patients previously diagnosed with diabetes mellitus, by age group, and for a given year: <i>the number of delivered babies who are identified with specific congenital malformations (i.e. neural tube defects, cardiac and renal malformations), divided by the number of babies born to mothers from the population of interest and in the given year.</i> The resulting rates should be reported as percentages and with their numerators.   |
| <b>Rationale</b>            | <p>Diabetes during pregnancy carries risks to both the mother and the developing fetus. Indicators 25 to 29 focus mainly on outcomes associated with the fetus, but the sub-population of mothers known to have diabetes before becoming pregnant is likely to suffer greater problems from hypertension, ketoacidosis, retinopathy and nephropathy than a similar non-pregnant population (Tunbridge and Home 1991; Jardine Brown et al. 1996) and it may be appropriate to examine this sub-group of patients when considering other relevant indicators.</p> <p>Early metabolic disturbance can lead to abnormal development which may lead to fetal death or congenital malformations (Hawthorne et al. 1997).</p> |
| <b>Potential uses</b>       | Clinical audit, trends over time and as a basis for provider comparisons although small numbers may require special consideration.   |
| <b>Potential users</b>      | Clinicians, provider management and commissioners. Local and national policy makers.   |
| <b>Possible confounders</b> | Adverse outcomes of pregnancy in this patient group need to be considered in the context of information about maternity outcomes in the general and local population, and those associated with other maternity risk factors and co-morbidities.   |
| <b>Data sources</b>         | Generally, the indicator will result from an in-patient episode (in this case the birth episode, which relates to the baby) with data being captured via the contract minimum data set or through other routine data capture systems. However, should the delivery (or deliveries, in the case of the denominator figure) have taken place at home, data will need to be collected from GP systems. As with other indicators collation from the two separate systems will be required which would be facilitated by use of a diabetic register.  |

The denominator is defined by babies born to patients already diagnosed with diabetes before booking as pregnant and who have completed a pregnancy. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. The particular congenital malformations included are coded as Q00-Q07, Q20-Q26 and Q60, Q61, Q63 (ICD10). Within the Read codes there are many abnormalities listed, some examples being given by X77q9 (neural tube defect), X785S (congenital abnormality of kidney) and X77tV (congenital abnormality of heart). The UK Diabetes Dataset does not identify outcomes of pregnancy in patients with diabetes. However, the DIABCARE Dataset includes fields which would allow some of these indicators to be derived. The particular fields required to derive this indicator are 'p\_yes\_12' and 'p\_alf\_12' (DIABCARE) although the latter variable, relating to the specific nature of the malformation is defined as only including cardiovascular and neuroskeletal abnormalities.

**Data quality**

The validity of the data will depend on the accuracy and completeness of clinical coding for both numerator and denominator. In particular, the indicator is dependent on the identification of diabetes as a secondary diagnosis in the coded record, and the separation of gestational diabetes from the pre-existing condition. With many provider units having fewer than ten cases per year, this indicator is likely to be best reported at a sub-region level, the indicator being calculated annually.

**Comments**

No specific points.

**Further work required**

To specify particular congenital abnormalities of interest.

**Conclusion & priority**

**C - To be implemented where local circumstances allow on a routine basis** (compiling the indicator annually).

**References**

Jardine Brown, C., Dawson, A., Dodds, R., Gamsu, H., Gillmer, M., Hall, M., Hounsome, B., Knopfler, A., Ostler, J., Peacock, I., Rothman, D., and Steel, J. (1996). Report of the Pregnancy and Neonatal Care Group. *Diabetic Medicine*, **13**, S43-S53.

Hawthorne, G., Robson, S., Ryall, E.A., Sen, D., Roberts, S.H., and Ward Platt, M.P. on behalf of the Northern Diabetic Pregnancy Audit, 1994 (1997). Prospective population based survey of outcome of pregnancy in diabetic women: results of the Northern Diabetic Pregnancy Audit, 1994. *British Medical Journal*, **315**, 279-281.

Tunbridge, W. M., and Home, P. D. (1991). *Diabetes and endocrinology in clinical practice*. Edward Arnold, London.

## Candidate indicator 29

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>The rate of admission to special care baby units (and nurseries) of babies delivered from a population of patients known to have diabetes and who become pregnant</b>   |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Complications of pregnancy.</i>   |
| <b>Definition</b>           | For a given population of patients previously diagnosed with diabetes mellitus, by age group, and for a given year: <i>the number of delivered babies who are admitted to a special care baby unit (and/or nursery) immediately following the birth episode, divided by the number of babies born to mothers from the population of interest and in the given year.</i> The resulting rates should be reported as percentages and with their numerators.   |
| <b>Rationale</b>            | <p>Diabetes during pregnancy carries risks to both the mother and the developing fetus. Indicators 25 to 29 focus mainly on outcomes associated with the fetus, but the sub-population of mothers who are known to have diabetes before becoming pregnant is likely to suffer greater problems from hypertension, ketoacidosis, retinopathy and nephropathy than a similar non-pregnant population (Tunbridge and Home 1991; Jardine Brown et al. 1996) and it may be appropriate to examine this sub-group of patients when considering other relevant indicators.</p> <p>Admission to Special Care Baby Unit (SCBU) immediately following the birth is likely to be attributable to an adverse outcome of the pregnancy, other than where SCBU admission protocols are based on other criteria e.g. birthweight.</p> |
| <b>Potential uses</b>       | Clinical audit, trends over time and as a basis for provider comparisons although small numbers may require special consideration.   |
| <b>Potential users</b>      | Clinicians, provider management and commissioners. Local and national policy makers.   |
| <b>Possible confounders</b> | <p>Adverse outcomes of pregnancy in this patient group need to be considered in the context of information about maternity outcomes in the general and local population, and those associated with other maternity risk factors and co-morbidities.</p> <p>As mentioned above, some SCBUs have a range of admission criteria which are not necessarily directly related to clinical need. This, together with the effect of the variability of available resources, may confound the interpretation of this indicator as an outcome measure of antecedent care.</p>  |

|                                  |   |
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| <b>Data sources</b>              | <p>By definition, this indicator will result from an in-patient episode (in this case, the episode immediately following the birth episode) with data being captured via the contract minimum data set or through other routine data capture systems.</p> <p>The denominator is defined by babies born to patients already diagnosed with diabetes before booking as pregnant and who have completed a pregnancy. Diabetes mellitus is diagnostically coded as 250 (ICD9) and E10 to E14 in ICD10 (IDDM being coded E10 and NIDDM E11) with the comparable Read codes being IDDM - X40J4, NIDDM - X40J5. Admission to SCBU will be recorded through the standard hospital systems and should produce a separate episode from the birth episode. Neither the UK Diabetes Dataset nor the DIABCARE Dataset include fields that would enable this indicator to be derived from them.</p> |
| <b>Data quality</b>              | <p>The validity of the data will depend on the accuracy and completeness of clinical coding for both numerator and denominator. In particular, the indicator is dependent on the identification of diabetes as a secondary diagnosis in the coded record, and the separation of gestational diabetes from the pre-existing condition. With many provider units having fewer than ten cases per year, this indicator is likely to be best reported at a sub-region level, the indicator being calculated annually.</p>   |
| <b>Comments</b>                  | <p>No specific points.</p>  |
| <b>Further work required</b>     | <p>None recommended.</p>  |
| <b>Conclusion &amp; priority</b> | <p><b>C - To be implemented where local circumstances allow on a routine basis</b> (compiling the indicator annually).</p>  |
| <b>References</b>                | <p>Jardine Brown, C., Dawson, A., Dodds, R., Gamsu, H., Gillmer, M., Hall, M., Hounsome, B., Knopfler, A., Ostler, J., Peacock, I., Rothman, D., and Steel, J. (1996). Report of the Pregnancy and Neonatal Care Group. <i>Diabetic Medicine</i>, <b>13</b>, S43-S53.</p> <p>Tunbridge, W. M., and Home, P. D. (1991). <i>Diabetes and endocrinology in clinical practice</i>. Edward Arnold, London.</p>   |

## Candidate indicator 30

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Patient

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Summary of a measure of psychological well-being within a population of patients known to have diabetes</b>   |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Impact on quality of life.</i>  |
| <b>Definition</b>           | For a GP population of patients previously diagnosed with diabetes mellitus, and for a given year: <i>a summary of patients' responses to a questionnaire measuring psychological well-being (to be specified), administered at an annual review.</i> The summary statistics (which have not been specified), will describe the distribution of scores from the instrument, broken down by patient age-group and sex.  |
| <b>Rationale</b>            | <p>Psychological influences within diabetes are well recognised (Tunbridge and Home 1991). Patient's psychological states will have a significant influence on what they gain from a consultation or an educational session, or whether they feel capable of altering their lifestyle in a desirable way.</p> <p>Psychological states are also affected by patient's underlying personalities which can also interact with the disease and with their treatment. A particular example lies in whether the patient's see the disease as external to themselves and therefore to be managed by others, or something in need of self management.</p> <p>An assessment of psychological well-being should be made at least annually, at a review of the patient's health, and at other times if necessary and will provide information for the ongoing management of the individual patient. Aggregated longitudinal measures can indicate the appropriateness, or otherwise, of the care programme in meeting patients' psychological needs.</p> <p>At present there is no validated instrument in routine use to assess the psychological well-being of the diabetic patient, although a number (Hutchinson et al. 1995; Bradley 1994) have been used in diabetic populations with encouraging results. The issues that need to be addressed when considering assessing this aspect of diabetic care have been well documented by Bradley.</p> |
| <b>Potential uses</b>       | Clinical audit; trends over time.  |
| <b>Potential users</b>      | Clinicians, provider management, commissioners, public.  |
| <b>Possible confounders</b> | It is recognised that different configurations of services are available in different places and that this may have a direct effect on the results obtained through the use of such indicators. While this may be considered to be an important assessment of 'outcome' e.g. a particular configuration is preferred by patients, it is important to understand how such effects impact on the benefits to be obtained in respect of the clinical and other dimensions of care.  |

|                                  |   |
|----------------------------------|---|
| <b>Data sources</b>              | <p>No specific measure to support this indicator has so far been identified. A selected instrument might be applied at the time of an annual review of a patient's health either through personal interview or through the administration of a questionnaire.</p> <p>As with some other indicators, specification of a suitable data collection method may have to consider the role of carers as informants, in those cases where direct data collection from the patient is impractical.</p> <p>The indicator might also be derived from the UK Diabetes Dataset but the DIABCARE Dataset does not contain fields to address this indicator. The particular fields required are 'G-DEPR-WB' and 'D-DEPR-WB' (UKDD) which refer to scores obtained from the Depressed Well-being Scale which that dataset has proposed (Wilson et al. 1993).</p> |
| <b>Data quality</b>              | <p>As indicated above, the chosen instrument should have been previously tested and validated within a diabetic population. The quality of the data will also be dependent on the completeness of its application within individual practices i.e. requiring the identification of patients with diabetes and the instrument's application, an adequate response rate from patients and appropriate recording and interpretation of results.</p>  |
| <b>Comments</b>                  | <p>No specific points.</p>  |
| <b>Further work required</b>     | <p>Development and testing of appropriate data collection methods.</p>  |
| <b>Conclusion &amp; priority</b> | <p><b>F - To be further developed either because the indicator specification is incomplete.</b></p>   |
| <b>References</b>                | <p>Bradley, C. (1994). <i>Handbook of psychology and diabetes</i>. Harwood Academic Publishers.</p> <p>Hutchinson, A., McColl, E., Meadows, K., Riccalton, K., and Fowler, P. (1995). <i>A health status measures guide for asthma &amp; diabetes</i>. Universities of Hull and Newcastle.</p> <p>Tunbridge, W. M., and Home, P. D. (1991). <i>Diabetes and endocrinology in clinical practice</i>. Edward Arnold, London.</p> <p>Wilson, A. E., and Home, P. D. for a Working Group of the Research Unit of the Royal College of Physicians and the British Diabetic Association (1993). A dataset to allow exchange of information for monitoring continuing diabetes care. <i>Diabetic Medicine</i>, <b>10</b>, 378-390.</p>   |

## Candidate indicator 31

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Patient

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |   |
|-----------------------------|---|
| <b>Title</b>                | <b>Summary of a measure of health status/health related quality of life within a population of patients known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Impact on quality of life.</i>   |
| <b>Definition</b>           | For a GP population of patients previously diagnosed with diabetes mellitus, and for a given year: <i>a summary of patients' responses to a questionnaire measuring health status or health related quality of life (to be specified), administered at an annual review.</i> The summary statistics (which have not been specified), will describe the distribution of scores from the instrument, broken down by patient age-group and sex.  |
| <b>Rationale</b>            | <p>The case for employing health status (alternatively 'health related quality of life') measures in assessments of the effectiveness of clinical interventions has been argued both in general (Bowling 1991) and for diabetes in particular (Hutchinson et al. 1995). A number of instruments are available in the case of diabetes, but often require validation or sensitivity testing, particularly with a UK population.</p> <p>For present purposes, the required health status instrument should meet a number of criteria. Firstly, the measure should be broadly based in terms of the components of health status it measures - to reduce the chances that aspects of the outcome that are of importance to patients are excluded from consideration. Furthermore, the results relating to these different dimensions of health status should be reported separately so that important aspects of the outcome are not obscured by aggregation (Yudkin et al. 1996). Secondly, the metrical properties of the instrument (in terms of validity, reliability and sensitivity to clinical intervention) should have been demonstrated in the population of interest. Thirdly, the design of the instrument should meet practical considerations relating to its administration.</p> <p>Assessments of general health status should be made at least annually, at a review of the patient's health, and can give, once suitably standardised, a cross sectional view of the health of the diabetic population. Longitudinal measurement on an individual basis will show improvements in the overall level of health or the rate of deterioration in health status over time. The selection of summary statistics used to describe the aggregate changes in patients' responses should be informed by an examination of typical pre- and post-intervention distributions and pilot testing of alternative report contents and formats.</p> |
| <b>Potential uses</b>       | Clinical audit; trends over time.   |
| <b>Potential users</b>      | Clinicians, provider management, commissioners, public.   |
| <b>Possible confounders</b> | Co-morbidity, and life events affecting health (but possibly of little relevance to the patient's diabetic condition) will influence levels of general health status.   |

|                                  |  |
|----------------------------------|--|
| <b>Data sources</b>              | No existing measures to support this indicator have so far been identified. A selected instrument might be applied at the time of an annual review either through personal interview or through the administration of a questionnaire. As with some other indicators, specification of a suitable data collection method may have to consider the role of carers as informants, in those cases where direct data collection from the patient is impractical. Neither the UK Diabetes Dataset nor the DIABCARE Dataset include fields that would enable this indicator to be derived from them.   |
| <b>Data quality</b>              | As indicated above, the chosen instrument should have been previously tested and validated within a diabetic population. The quality of the data will also be dependent on the completeness of its application within individual practices i.e. requiring the identification of patients with diabetes and the instrument's application, an adequate response rate from patients and appropriate recording and interpretation of results. Use of such health status questionnaires within the UK has generally shown acceptable response rates and good validity and reliability, although the latter requires attention to training if interviewers are to be used. Biases can be introduced, when using particular forms of administration, by excluding or limiting access from e.g. non-English speakers, those who do not own telephones etc. |
| <b>Comments</b>                  | No specific points.  |
| <b>Further work required</b>     | Development and testing of appropriate data collection methods.  |
| <b>Conclusion &amp; priority</b> | <b>F - To be further developed because the indicator specification is incomplete.</b>  |
| <b>References</b>                | <p>Bowling, A. (1991). <i>Measuring health: review of quality of life measurement scales</i>. Open University Press, Milton Keynes.</p> <p>Hutchinson, A., Hewison, J., and Eccles, M. (1996). Assessing health outcomes in chronic disease. In <i>Health outcome measures in primary and out-patient care</i> (ed. A. Hutchinson, E. McColl, M. Christie, C. Riccalton). Harwood Academic Publishers, Amsterdam.</p> <p>Yudkin, J. S., Blauth, C., Drury, P., Fuller, J., Henley, J., Lancaster, T., Lankester, J., Lean, M., Pentecost, B., Press, V., and Rothman, D. (1996). Prevention and management of cardiovascular disease in patients with diabetes mellitus: an evidence base. <i>Diabetic Medicine</i>, <b>13</b>, S101-S121.</p>   |

## Candidate indicator 32

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Patient

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

|                             |  |
|-----------------------------|--|
| <b>Title</b>                | <b>Summary of a measure of satisfaction with service within a population of patients known to have diabetes</b>  |
| <b>Intervention aim</b>     | Reduce impact of diabetes - <i>Impact on quality of life.</i>  |
| <b>Definition</b>           | For a GP population of patients previously diagnosed with diabetes mellitus, and for a given year: <i>a summary of patients' responses to a questionnaire measuring satisfaction with in-patient care and/or community care (to be specified) administered at the time of an annual review.</i> The summary statistics (which have not been specified), will describe the distribution of scores from the instrument, broken down by patient age-group and sex.  |
| <b>Rationale</b>            | While patient satisfaction is itself a desirable outcome, there is also evidence that care which is less satisfactory to the patient is also less effective (Kaplan et al. 1989). It has also been shown that patients' reported levels of satisfaction can reflect doctors' technical competence as judged by independent, professional assessors (Dimatteo and Hays 1980).   |
| <b>Potential uses</b>       | Clinical audit; provider based comparisons. Trends over time.  |
| <b>Potential users</b>      | Clinicians, provider management, commissioners, public.  |
| <b>Possible confounders</b> | A range of social and demographic variables have been shown to influence patient satisfaction (Fitzpatrick 1990). As a minimum, comparative analyses of satisfaction would be informed by knowledge of the age/sex of patients within different populations.   |
| <b>Data sources</b>         | There are a number of generic measures that have been widely used to assess patient satisfaction (Thompson 1988; Smith 1992; Wilkin et al. 1992) within the NHS although these have been designed for different purposes and for different modes of application. Before selecting a specific instrument, it is necessary to decide on the focus of the indicator e.g. acute episode, general management of the patient etc., and the mode of application, as well as understanding the need to ensure the appropriateness of the particular instrument to the survey's purpose (Bradley 1994). The indicator might also be derived from the UK Diabetes Dataset but the DIABCARE Dataset does not contain the relevant fields. The particular field required is 'SATIS-SERV' (UKDD). |
| <b>Data quality</b>         | One criticism of patient satisfaction surveys is that the results are insensitive suggesting that the majority of patients are highly satisfied with their care. Concerns have also been expressed as to the potential bias resulting from selecting out certain patients unable to participate in the survey and the lack of a well established, valid and reliable measure of satisfaction.  |

|                                  |   |
|----------------------------------|---|
| <b>Comments</b>                  | Needs validation against objective measures of quality.   |
| <b>Further work required</b>     | Selection of a generic measure or development of condition specific questionnaire, on the basis of pilot data collection experience with patients under care for diabetes.  |
| <b>Conclusion &amp; priority</b> | <b>F - To be further developed because the indicator specification is incomplete.</b>   |
| <b>References</b>                | <p>Bradley, C. (1994). <i>Handbook of psychology and diabetes</i>. Harwood Academic Publishers.</p> <p>Dimatteo, M. R., and Hays, R. (1980). The significance of patients' perceptions of physician conduct: a study of patient satisfaction in a family practice centre. <i>Journal of Community Health</i>, <b>6</b>, 18-34.</p> <p>Fitzpatrick, R. (1990). Measurement of patient satisfaction. In <i>Measuring the outcomes of medical care</i> (ed. A. Hopkins and D. Costain). Royal College of Physicians, London.</p> <p>Kaplan, S., Greenfield, S., and Ware, J. (1989). Assessing the effects of physician-patient interactions on the outcomes of chronic disease. <i>Medical Care</i>, <b>27</b>, S110-S127.</p> <p>Smith, C. (1992). Validation of a patient satisfaction system in the United Kingdom. <i>Quality Assurance in Health Care</i>, <b>4</b>, 171-177.</p> <p>Thompson, A. G. H. (1988). <i>The measurement of patient's perceptions of the quality of hospital care</i>. Doctoral thesis, University of Manchester.</p> <p>Wilkin, D., Hallam, L., and Doggett, M. (1992). <i>Measures of need and outcome for primary health care</i>. Oxford University Press.</p> |

## 5. RECOMMENDATIONS

### To be implemented generally on a routine basis

**5.1** It is **recommended** that the following indicators be implemented generally on a routine basis (the numbers refer to the indicator specifications in Section 4) :

- 1:** prevalence of clinically diagnosed diabetes
- 15:** number of patients who have had at least one hypoglycaemic emergency, within the last year, that required therapeutic intervention by a health professional expressed as a proportion of a population of patients known to have diabetes
- 16:** number of patients who have had at least one hyperglycaemic emergency, within the last year, that required hospital admission expressed as a proportion of a population of patients known to have diabetes
- 18A:** SMR for death due to diabetes mellitus
- 18B:** years of life lost per 10,000 resident population by death due to diabetes mellitus
- 18C:** years of life lost by death due to diabetes mellitus.

Indicators 18A-C are currently included in the Public Health Common Data Set.

**5.2** The **prevalence of clinically diagnosed diabetes** defines the denominator population for many of the other indicators and also gives a basis for the planning of services. The number of people with undiagnosed diabetes is unknown, except where it has been ascertained in local population-based prevalence surveys. However, this group needs to be borne in mind as they are also in need of services.

**5.3** The proportion of people known to have diabetes who have **at least one hypoglycaemic emergency** reflects the quality of self care undertaken by people with diabetes and this may be related to the standard of diabetic care provided for them by health professionals. This indicator will allow monitoring of trends over time, but its validity will be dependent on the completeness of the data available. Many such episodes are treated in primary care or A&E departments where the data are not readily available.

**5.4** **Hyperglycaemic episodes requiring admission to hospital** carry a high risk to the patient and the data quality is good as the indicator is derived from in-patient data. This indicator will facilitate monitoring of trends over time and the identification of populations with higher than average rates of admission.

- 5.5** Three **mortality indicators** are already calculated for the Public Health Common Data Set. The information can be used to monitor trends over time and identify populations with higher than expected mortality related to diabetes. It is important that due emphasis is given to accurate death certification as the underlying cause of death is not always completed correctly.

**To be implemented generally by periodic survey**

- 5.6** It is **recommended** that the following indicator be implemented generally by periodic survey:

**3A: prevalence of obesity in persons aged 16-64 (defined as BMI > 30 kg/m<sup>2</sup>).**

- 5.7** **Obesity** is a known risk factor for diabetes. The data are currently collected nationally but they could also be collected locally by periodic survey.

**To be implemented where local circumstances allow on a routine basis**

- 5.8** It is **recommended** that the following indicators be implemented where local circumstances allow on a routine basis:

*Risk factors*

- 4: percentage of patients, aged 16 and over and known to have diabetes, who smoke**  
**5: percentage of patients, aged 16-64 and known to have diabetes, who have a BMI > 30 kg/m<sup>2</sup>**  
**6: percentage of patients known to have diabetes with elevated blood pressure: Type 1 > 140/90 mm Hg.; Type 2 > 160/90 mm Hg.**

*Metabolic control*

- 7: percentage of patients known to have diabetes with HbA<sub>1c</sub> that was > 7.5% on a DCCT standardised assay, at time of last recording within the previous year.**

*Markers for late complications*

- 8: percentage prevalences of retinopathy and maculopathy within a population known to have diabetes**
- 9: percentage prevalence of microalbuminuria within a population known to have Type 1 diabetes**
- 10: percentage prevalence of protective sensation loss within a population known to have diabetes**
- 11: percentage prevalence of absence of both foot pulses in at least one foot within a population known to have diabetes**
- 12: percentage of patients known to have diabetes where there is no record of blood pressure, the retinae or the feet having been assessed within the previous year.**

*Symptoms*

- 13: percentage prevalence of symptomatic angina within a population known to have diabetes**
- 14: percentage prevalence of claudication within a population known to have diabetes.**

*Incidence of acute complications*

- 17: case fatality rate associated with acute diabetic episodes treated in hospital.**

*Incidence of long term complications*

- 19: annual incidence of severe visual impairment (visual acuity < 6/60 in the better eye) within a population of patients known to have diabetes**
- 20: annual incidence of leg amputation above the ankle within a population of patients known to have diabetes**
- 21: annual incidence of amputation below the ankle within a population of patients known to have diabetes**
- 22: annual incidence of myocardial infarction within a population of patients known to have diabetes**
- 23: annual incidence of stroke within a population of patients known to have diabetes.**

*Complications of pregnancy*

- 25: rates of late stillbirth and perinatal mortality in deliveries from a population of patients known to have diabetes and who become pregnant**
- 26: the rate of delivery by caesarean section, in deliveries from a population of patients known to have diabetes and who become pregnant**
- 27: the incidence of delivered babies with birthweight greater than the 90th centile (allowing for gestational age) from within a population of patients known to have diabetes and who become pregnant**
- 28: the incidence of occurrence of specific congenital malformations (i.e. neural tube defects, cardiac and renal malformation) in deliveries from a population of patients known to have diabetes and who become pregnant**
- 29: the rate of admission to special care baby units (and nurseries) of babies delivered from a population of patients known to have diabetes and who become pregnant.**

- 5.9** Monitoring the prevalence of risk factors for complications of diabetes including **smoking, obesity and elevated blood pressure** will facilitate the assessment of the impact of health promotion measures in people with diabetes in areas where the information can be collected.
- 5.10** Good glucose control reduces the incidence of complications of diabetes and **HbA<sub>1c</sub>** is the best way of assessing glucose control. This indicator will show the proportion of patients whose diabetes is well controlled.
- 5.11** The indicators relating to the prevalence of the late complications of diabetes are **retinopathy and maculopathy, microalbuminuria, loss of protective sensation, absence of the foot pulses**. Some complications may be avoided by good glucose control. When present, they require monitoring or appropriate treatment to minimise the sequelae. These indicators demonstrate the outcome of earlier diabetic care and that the complications have been identified. Indicator 12 highlights people who are not recorded as having the recommended assessments within the past year. This group is unlikely to be receiving adequate care.
- 5.12** Vascular disease is a common complication of diabetes. The symptomatic indicators, the prevalence of **angina and intermittent claudication**, may reflect the patients' chosen lifestyles but also the advice and care they have received.

- 5.13 Fatalities** associated with acute diabetic episodes treated in hospital will be relatively rare but they are important as they may be avoidable and may reflect the standard of care the individual has received previously. The small numbers will require careful interpretation.
- 5.14** The specified indicators relating to the incidence of late complications of diabetes are the **annual incidence of severe visual impairment, amputation above the ankle, amputation below the ankle, myocardial infarction, and stroke**. Comparison of age-adjusted incidence rates may allow monitoring of trends over time and comparison between geographical areas. The effectiveness of preventive strategies may be assessed.
- 5.15** Diabetes in pregnancy increases the risk to the mother and infant. We have therefore specified indicators relating to **mortality, the rate of intervention in delivery and the size of the infant**. The specific effect that diabetes may have on the development of the fetus is reflected by the **incidence of specific congenital malformations**. The rate of admission to a **special care baby unit** is an indirect indicator relating to the infants' condition at birth. Together these indicators will give some reflection of the outcome of care in pregnancy, although they will have to be interpreted with care as none of them occurs only in relation to diabetes.

**To be implemented where local circumstances allow by periodic survey**

- 5.16** It is **recommended** that the following indicator be implemented where local circumstances allow by periodic survey:
- 24: number of patients who have started renal replacement therapy or have had a creatinine level > 500 µmol/litre recorded for the first time within the last year, expressed as a proportion of a population of patients known to have diabetes.**
- 5.17** Recording those who **have started renal replacement therapy or have a creatinine level > 500 µmol/litre** identifies those who may benefit from a renal transplant and also those whose care may have been less than ideal in the past as the incidence of renal failure in diabetes is thought to be reduced with good metabolic control. Trends over time and comparisons of geographical areas may highlight areas where diabetic care may need to be reviewed to reduce the incidence of renal disease.

**To be implemented following IT developments on a routine basis**

**5.18** It is **recommended** that the following indicator be implemented following IT developments on a routine basis:

**2: percentage prevalence of retinopathy and maculopathy at time of diagnosis of diabetes.**

**5.19** The presence of **retinopathy or maculopathy at the time of diagnosis** suggests the late diagnosis of diabetes, but only some general practitioners may code the result of examination, particularly if it is negative. This indicator can be implemented where the findings are routinely coded on computer and the data can be aggregated. Small numbers may make the interpretation of this indicator difficult in practices gathering the data.

**To be further developed**

**5.20** It is **recommended** that the following indicators require further development either because the link with effectiveness is not clear or the indicator specification is incomplete:

**3B: proportion of people undertaking vigorous physical activity in the previous 28 days**

**3C: proportion of people who, on average, consume fruit or vegetables or salad each day, within the general population**

**30: summary of a measure of psychological well-being within a population of patients known to have diabetes**

**31: summary of a measure of health status / health related quality of life within a population of patients known to have diabetes**

**32: summary of a measure of satisfaction with service within a population of patients known to have diabetes.**

**5.21** Indicators 3B and C are currently collected by the Office of National Statistics as part of the Health Survey of England. The results should be reviewed in the context of diabetes to see if **vigorous physical activity and consumption of fruit or vegetables** are directly related to diabetes. They are important generally in the promotion of better health.

**5.22** Measures of the impact of diabetes on individuals' lives are relevant in order to identify areas that could be improved, as there is some evidence that such improvements may lead to better metabolic control as well. However, indicators of **psychological well-being, health status / health related quality of life, and satisfaction with service** are still being developed and no one measurement instrument can currently be recommended as being superior for use in this context.

## **Conclusions**

**5.23** As has been described in the indicator specifications, indicators collected routinely may be used to highlight differences:

- over time
- between providers
- between groups of patients.

**5.24** The main use of such indicators is to make broad comparisons to identify significant differences or anomalies that require further detailed examination. Small differences in routine indicators may be attributable to a wide range of factors, many of which will probably not reflect differences in health outcomes which can be attributed to the process of care.

**5.25** Some indicators may best be used in combination to aid interpretation. For example:

- The indicators relating to pregnancy (paragraph 5.15) should be considered as a group as individually they give little interpretable information.
- It would suggest that there are problems with a local diabetic service if, there is generally poor metabolic control as shown by HbA<sub>1c</sub> (Indicator 7) with a high incidence of hypoglycaemic or hyperglycaemic emergencies (Indicators 15 & 16), and an increased number of people with diabetes with no record of routine assessment in the past years (Indicator 12) compared to other providers.
- If the incidence of late complications (Indicators 19-24) including severe visual impairment, amputation above and below the ankle, myocardial infarction, stroke and end stage renal failure is raised compared with other providers or the population, the prevalence of markers for late complications (Indicators 8-10) such as retinopathy, microalbuminuria and loss of sensation should be reviewed to see if they are also raised.

# APPENDIX A: BACKGROUND TO THE WORK

## Summary

**A.1** Over the last few years a major component of the Department of Health's and NHS Executive's strategy has been to promote the development and use of measures of health outcome. In July 1993 the Central Health Outcome Unit (CHOU) was set up within the Department of Health (DoH). Commissioned by the DoH, in 1993 a feasibility study of potential outcome indicators was published by the Faculty of Public Health Medicine and a package of indicators was published by the University of Surrey for consultation. Following these two phases of development, a third phase of work was initiated by the CHOU. Its remit is to report on 'ideal' health outcome indicators.

## Central Health Outcome Unit

**A.2** The CHOU is an internal DoH unit whose goal is 'to help secure continuing improvement in the health of the people of England through cost-effective and efficient use of resources' (Lakhani 1994). The objectives of the Unit are to:

- encourage and co-ordinate the development of health outcome assessment, particularly in respect of the development of appropriate methods, appropriate data collection systems, expertise, analytical skills, and interpretation
- encourage and support the use of health outcome assessment and information in making policy about health interventions and in the planning, delivery and monitoring of services.

**A.3** Several national committees have a special interest in outcomes and have been kept informed of progress:

- Clinical Outcomes Group
- Public Health Network
- CMO Working Group on Information Management and Technology.

## **Phases 1 and 2**

**A.4** The Faculty of Public Health Medicine was commissioned to undertake a feasibility study of potential indicators which reflect health end-points for health services and which cover topics in which health care has an important contribution to make. This work (McColl and Gulliford 1993) was constrained in that the set of indicators were to:

- be based on reliable routinely collected data
- reflect health service interventions rather than the wider influences on health.

**A.5** The University of Surrey was commissioned to produce a package of comparative statistics based on the outcome measures recommended in the feasibility study. Forty indicators were chosen, 18 for maternal and child health, three for mental health and the rest for other topics in adult health. The publication (Department of Health 1993) contained indicator definitions, maps and scatter plots showing geographical variations, and tables presenting the rates, with corresponding observed numbers and confidence intervals when appropriate.

## **The Phase 3 work : ideal indicators of health outcomes**

**A.6** In the third and current phase of the work on health outcomes a number of research institutions were commissioned to assist in developing a structured approach to identify indicators to cover a number of clinical topics. The prime contractor is the Unit of Health-Care Epidemiology, Department of Public Health and Primary Care, University of Oxford.

**A.7** The respective roles of the supporting organisations were as follows:

- Unit of Health-Care Epidemiology, University of Oxford, to provide epidemiological and managerial support to the Group and co-ordinate the input of the other agencies.
- CASPE Research, in London, to provide technical advice with regard to the indicators and their data sources, and prepare the detailed indicator specifications.
- Royal College of Physicians' Research Unit, in London, to co-ordinate the clinical input.

- A.8** In the previous work a key criterion for selection of indicators was the requirement for the work to be based on routinely available data. This practical constraint has meant that the recommended indicators selected were an opportunistic rather than an ideal set. This inevitably led, as the DoH acknowledged, to a bias towards outcomes which may be measurable now but which may not necessarily be those which are most appropriate and most needed. The aim of the third phase is to advise on and develop 'ideal' outcome indicators without confining recommendations to data which have been routinely available in the past.
- A.9** The initial task of the third phase of the work was to select clinical topics for detailed study. In order to ensure that the work would be manageable, and that the NHS would have the capacity to absorb the output, the CHOU decided to limit the activity to five clinical topics a year.
- A.10** A workshop to initiate the work which was attended by over 70 individuals representing a wide range of interests was held in January 1995. A report of the proceedings has been published (Goldacre and Ferguson 1995). The main aims were:
- to identify the criteria which should be used to choose clinical topics for the Phase 3 work
  - to suggest a list of potential clinical topics which workshop participants would like to be included in the Phase 3 work.
- A.11** Following further consultation within and outside the DoH, the CHOU decided in June 1995 to include the following topics in the first two years of Phase 3 work:
- Asthma
  - Breast cancer
  - Cataract
  - Diabetes mellitus
  - Fracture of neck of femur
  - Incontinence
  - Myocardial infarction
  - Pregnancy and childbirth
  - Severe mental illness
  - Stroke.

**A.12** The Group was influenced in its work by considering the potential uses of outcome information, as follows:

- for clinical decision-making and audit of clinical work, including:
  - audit and management of health professionals' practice
  - research
- for informing decisions about the strategic and operational development of services
- for comparisons of organisations in the delivery of services which may be:
  - provider based
  - population based
- for assessing progress towards agreed standards or targets for health outcomes, agreed nationally or locally, which may be:
  - identified from the research literature
  - set by clinical and managerial decisions.

**A.13** Current managerial interests which are relevant to the use of health outcome information include:

- The NHS goal 'to secure, through the resources available, the greatest improvement in the physical and mental health of people in England'
- clinical audit
- evidence-based commissioning.

**A.14** An important purpose of this work has been to recommend indicators which, if possible, would allow 'health gain' to be assessed alongside information used to measure health service input. Our particular focus has been to make recommendations about aggregated statistical information about people with diabetes which can be used to:

- enable providers of care to review outcomes of the care of their patients
- make comparisons, where appropriate, of health outcomes against locally agreed targets and/or between different places and/or over time.

**A.15** Information for outcome indicators may be obtained from systems which collect data routinely as part of clinical care, but when such information is not routinely necessary, or when the cost or complexity of this is high, use should be made of sample survey techniques or periodic surveys.

**A.16** Health indicators are more likely to be successful if they fit naturally into the everyday work of health care professionals than when they have to be collected as a separate activity. The aim is to have indicators that are:

- *Relevant* because professionals use them everyday in clinical management and will record them accurately.
- *Reliable* because they can be validated or cross checked from other sources.
- *Responsive* because they readily identify changes in the patient's state of health.
- *Research-based* because there is a likely link between processes of care and outcome.

**A.17** In common with the approach taken to other types of indicators by the NHS, the Group recognises that useful outcome indicators should be capable of identifying circumstances worthy of investigation but that, in themselves, they may not necessarily provide answers to whether care has been optimal or sub-optimal. In particular it is recognised that there may be difficulties in drawing causal conclusions - say, that a particular aspect of care caused a particular outcome - from indicators derived from non-experimental clinical settings. Nonetheless the vast majority of clinical care is delivered in routine rather than experimental practice. The assessment of its outcomes entails, by definition, the use of observational rather than experimental data.

**A.18** To be useful, work on 'ideal' outcome aspects needs to incorporate considerations of practicability. It is a time of rapid change in information technology. What may be feasible now in some places may not be feasible everywhere. What may not be practical today may become so in a year or two.

## APPENDIX B: DIABETES WORKING GROUP

**B.1** The Diabetes Working Group was formally constituted in April 1996 and met three times, completing its work in February 1997. The Report was completed in September 1997. The terms of reference were:

- To advise on indicators of health outcomes of the prevention and treatment of diabetes and its complications.
- To make recommendations about the practicalities of the compilation and interpretation of the indicators, and to advise if further work is needed to refine the indicators and/or make them more useful.

**B.2** The membership of the Working Group and the staff of the supporting organisations are shown below. The composition of the Group included the major professional and managerial groups and representatives of patients and carers involved with the prevention, management and care of diabetes.

### Chairman and members

|                |   |                   |                               |
|----------------|---|-------------------|-------------------------------|
| Physicians     | : | Philip Home       | Newcastle ( <b>Chairman</b> ) |
|                |   | Nick Vaughan      | Brighton                      |
|                |   | Ken Paterson      | Glasgow                       |
| GPs            | : | Michael Hall      | Exeter                        |
|                |   | Roger Gadsby      | Nuneaton                      |
|                |   | Colin Bradshaw    | South Shields                 |
| Nurse          | : | Susan Higgins     | Manchester                    |
| Chiropodist    | : | Ali Foster        | London                        |
| Dietitian      | : | Norma McGough     | London                        |
| Researchers    | : | Rhys Williams     | Leeds                         |
|                |   | Michael O'Brien   | Northumberland                |
| CEOs           | : | Mark Common       | Wrexham                       |
|                |   | Chris Newton      | South Yorkshire               |
| Voluntary body | : | Robert Snowden    | British Diabetic Association  |
| DoH            | : | Ann Dawson        | -                             |
|                |   | Netta Lloyd-Jones | -                             |

### Academic support and secretariat

Michael Goldacre, Alastair Mason, Ewan Wilkinson & John Fletcher, University of Oxford

James Coles & Robert Cleary, CASPE Research

## APPENDIX C: METHODS FOR CHOOSING INDICATORS

**C.1** Candidate outcome indicators were identified by the Group with the help of the following:

- the health outcome model for diabetes (see Section 2)
- various classifications of the characteristics of outcome indicators.

**C.2** The Group noted that indicators may be related to:

- i. causal factors in the general population or relating to the individual
- ii. knowledge, attitudes, behaviour in the general population
- iii. knowledge, attitudes including satisfaction with service delivery and behaviour of individual patients with diabetes
- iv. patients' symptoms, function, health status and well-being
- v. patients' clinical state
- vi. patients' pathological/physiological state
- vii. events occurring to patients as endpoints of the earlier occurrence of disease and/or interventions such as contacts with general practitioners, issuing of prescriptions, out-patients visits, in-patient admissions, death
- viii. knowledge, satisfaction with service delivery, emotional and physical well-being of carers.

**C.3** The data sources for the indicator entities noted in paragraph C.2 will differ. It is likely that:

- indicators for (i) and (ii) would come from population surveys
- indicators for (iii), (iv) and (viii) would come from patients either opportunistically or when specifically called
- indicators for (v) and (vi) would come from doctors and other health professionals
- indicators for (vii) would come from administrative information systems.

**C.4** The Group recognised the cost and complexity of obtaining information from continuous data collection systems. Particular consideration was given to obtaining outcome indicator data from sample survey techniques such as a periodic survey when it is not essential to have continuously collected information.

**C.5** Four characteristics of an outcome indicator have been identified and each has been classified. They are:

- measurement perspective, relating to whose perspective the indicator is most relevant (see paragraph C.6)
- specificity (see paragraph C.7)
- measurement timeframe (see paragraph C.8)
- outcome relationship, in that the indicator is either a direct or an indirect, proxy measurement of outcome (see paragraph C.9)

**C.6** For the Group's purposes measurement perspective was classified as that from the patient's, the carer's, the clinical, or the population's viewpoint. In the treatment of diabetes, for example, a measure of quality of life may be most relevant to the patient's perspective while clinical concerns may properly focus on biochemical measures. The population perspective has a broader view, best addressed by measures able to assess the burden of the condition as a whole. Of course, these perspectives are not necessarily in opposition and will often be associated with shared goals. Where possible, a set of indicators should be developed which satisfies all three measurement perspectives.

**C.7** The specificity of an indicator relates to whether it is specific or generic in application. For example, the measurement of blood glucose is specific to carbohydrate metabolism. The measurement of general health status is much less specific and would be influenced by a number of conditions. Condition-specific indicators have the advantage that their relative insensitivity to other conditions is likely to increase their sensitivity to changes in the condition of interest. Generic measures provide outcomes relevant to a wide range of conditions. A comprehensive indicator set might contain examples of both generic and specific indicators.

**C.8** The measurement timeframe relates to whether the indicator is:

- cross-sectional and thus an indicator at a single point in time for any one individual
- a longitudinal measure of progression over time for any one individual.

**C.9** The Group's main task has been to develop direct indicators of health outcome although in many areas it may be difficult to identify or obtain such information. However, it is recognised that some care processes are so closely related to the production of benefits that the successful completion of the intervention might be used as a proxy measure of the actual outcome. In the absence of direct outcomes, proxy indicators have therefore been developed.

**C.10** There is increasing recognition of the importance of outcome measures derived from data generated by patients and carers. For the purposes of our work, three main areas of interest have been identified:

- impact of the condition on the patient and/or carer
- satisfaction of the patient and/or carer with the care provided
- awareness of the patient and/or carer of the management of the condition.

**C.11** The condition may impact on the patient in terms of:

- general health
- specific impairments associated with the condition
- disabilities
- handicaps.

**C.12** The condition may impact on carers in terms of their:

- physical health
- psychological health
- social functioning.

**C.13** With the assistance of the check-lists and a knowledge of the condition the Group addressed the following key questions:

- What are health professionals trying to achieve for each patient?
- What can each patient realistically expect will be achieved for him/herself?
- What should be achieved for the population as a whole in respect of the prevention, care or cure of the condition?

## APPENDIX D: GUIDANCE NOTES FOR INDICATOR SPECIFICATIONS

|                             |  |
|-----------------------------|--|
| <b>Indicator title</b>      | <b>A short title to identify the indicator</b>   |
| <b>Intervention aim</b>     | <p>Distinguishes the level of intervention for which the indicator is primarily developed. It is assumed that, for a given condition, an ideal set of indicators would be reasonably balanced across the spectrum of health intervention stages. For diabetes these stages are:</p> <ul style="list-style-type: none"><li>- reduce or avoid risk of diabetes.</li><li>- detect diabetes early.</li><li>- reduce risk of complications of diabetes.</li><li>- reduce the impact of diabetes and its complications once developed.</li></ul>                     |
| <b>Characteristics</b>      | <p>Classifies the indicator on four dimensions:</p> <ul style="list-style-type: none"><li>- Specificity: <i>condition specific or generic</i>.</li><li>- Perspective: <i>population, clinical, patient or carer</i>.</li><li>- Timeframe: <i>cross-sectional</i> measure or <i>longitudinal</i> assessment of change.</li><li>- Outcome relationship: whether it is a <i>direct</i> measure of outcome or an <i>indirect</i> measure of structure or process, used as a proxy for outcome.</li></ul>   |
| <b>Indicator definition</b> | <p>In addition to a definition of the variable of interest, the description specifies:</p> <ul style="list-style-type: none"><li>- how the variable is to be aggregated across cases, e.g. definitions of both a numerator and a denominator</li><li>- if a variable is to be reported with respect to a set of denominators, e.g. mortality broken down by age and sex</li><li>- if appropriate, how longitudinal change in the variable is to be represented, e.g. over what time interval and whether absolute difference or proportional change.</li></ul> |
| <b>Rationale</b>            | <p>A brief statement of the reasons and objectives behind the indicator, both in terms of the issues it addresses and it's selection from a range of potential alternatives.</p>   |
| <b>Diabetes definition</b>  | <p>A single definition of diabetes will be used as identified in paragraph 2.1. Its application is affected by the rationale, location of incidence and data sources used and these factors are addressed in each indicator definition.</p>  |
| <b>Potential uses</b>       | <p>The following classification has been used:</p> <ul style="list-style-type: none"><li>- local clinical practice</li><li>- clinical audit</li><li>- provider based comparisons</li><li>- population based comparisons</li><li>- assessment of regional/national trends or progress towards targets.</li></ul>  |

It is recognised that a given indicator may serve several purposes. Indicators that

are valuable for the management of individual patients are likely to have practical advantages with respect to data collection in a clinical setting. However, in order for such indicators to be useful for other purposes, a method of aggregation across cases must be specified for the variable of interest.

**Potential users**

The following classification has been used:

- clinicians
- provider management
- commissioners
- national/regional policy makers
- consumers/public.

**Possible confounders**

This section has attempted to identify the population risk factors likely to influence the outcome indicator, and therefore useful in its interpretation. Where such factors are well defined and have a clear or potential association with the outcome of interest, they may be used to specify denominators to be included in the indicator definition itself.

**Data sources**

Where possible, existing sources of data have been identified for deriving the indicator and the degree to which complete coverage of the population of interest would be obtained has been noted. Where data are not widely available from existing systems, suggestions for new methods of data collection, capable of wide implementation have been made.

**Data quality**

While the theoretical capabilities of existing and proposed information systems are outlined above, the actual or expected limitations of those systems - in terms of their completeness and accuracy etc. - are noted in this section.

**Comments**

General comments regarding the indicator's definition, validity, practicality etc.

**Further work required**

Suggestions about the additional research and development work required to complete the indicator's specification to a level appropriate for large scale piloting.

**Conclusions & priority**

A statement indicating the Working Group's assessment of the priority for implementation.

**References**

Appropriate references used in the construction of the indicators.

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