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SELECTING INDICATORS FOR THE QUALITY OF DIABETES CARE AT THE HEALTH SYSTEMS LEVEL IN OECD COUNTRIES

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SUMMARY

1. This report presents the recommendations of an international expert group on indicators for diabetes care. Based on a review of existing indicators and an assessment of gaps left open by existing indicators, the experts set out to select indicators to cover clinical processes of diabetes care as well as proximal and distal outcomes of care. The review led to a recommendation of nine indicators as follows:

Area	Indicator Name
Processes of diabetes care	Annual HbA1c testing
	Annual LDL cholesterol testing
	Annual screening for nephropathy
	Annual eye exam
Proximal outcomes	HbA1c control
	LDL cholesterol control
Distal outcomes	Lower Extremity Amputation Rates
	Kidney Disease in Persons with Diabetes
	Cardiovascular mortality in patients with diabetes

RESUME

2. Ce rapport présente les recommandations d'un groupe d'experts internationaux sur les indicateurs relatifs au diabète. Les experts se sont basés sur un examen des indicateurs existants et ont répertorié les carences d'informations des indicateurs existants pour sélectionner des indicateurs devant couvrir des processus cliniques pour le diabète ainsi que des résultats de soins proximaux et distaux. L'examen a conduit à une recommandation des neuf indicateurs suivants :

Domaine	Nom de l'indicateur
Soins du diabète	Dosage annuel de l'HbA1c
	Dosage annuel du cholestérol ADL
	Dépistage annuel pour néphropathie
	Examen annuel des yeux
Résultats proximaux	Contrôle de l'HbA1c
	Contrôle du cholestérol LDL (cholestérol basse densité)
Résultats distaux	Taux d'amputations des extrémités inférieures
	Maladie des reins chez des patients diabétiques
	Mortalité cardiovasculaire chez les patients diabétiques

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Background

3. This paper presents proposals for indicators of quality of care in the area of diabetes care. This is one of five areas which have been identified by the OECD as having priority for the development of quality indicators (see Box 1) An Expert Group of academic experts from the participating countries was tasked with identifying a shortlist of potential indicators in close collaboration with the Secretariat. Given resource constraints, this work was limited to reviewing existing indicators in Member countries rather than developing new indicators. This Technical Paper summarizes the indicator recommendations of the Expert Group and incorporates comments from Member countries on an earlier report of the Group. The first section portrays a set of nine indicators for which widespread consensus has emerged and recommends to consider six of them for health systems comparisons. The third section discusses three additional indicators that are not yet well established, but could provide valuable insight into the performance of health care systems.

Box 1. The OECD Quality Indicator Project

The technical quality of medical care, long regarded as a professional responsibility rather than a policy issue, now rivals cost and access as the foremost concern of health policymakers. A growing body of evidence suggests that the daily practice of care does not correspond to the standards that the medical profession itself puts forward. In addition, improving quality of care presents itself as an avenue to restraining the growth of medical expenditures by reducing costly complications and unnecessary procedures. In other words, better organisation and management of medical care would allow countries to spend their health care dollars more wisely. To improve care for their citizens and to realise these potential efficiency gains, policymakers are looking for methods to measure and benchmark the performance of their health care systems as a precondition for evidence-based health policy reforms. As published international health data sets such as OECD Health Data currently lack comparable measures for the technical quality of national health systems, there is, so far, little possibility of such international benchmarking. To fill this gap, the OECD Health Care Quality Indicators Project (HCQI) has brought together 21 countries,[1] the World Health Organization (WHO), the European Commission (EC), the World Bank, and leading research organisations, such as the International Society for Quality in Health Care (ISQua) and the European Society for Quality in Healthcare (ESQH). An expert group representing these countries and organizations has identified five priority areas for initial development of indicators: cardiac care, diabetes mellitus, mental health, patient safety, and prevention/health promotion together with primary care.

1. The participating countries are Austria, Australia, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Japan, Mexico, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

SELECTION OF QUALITY INDICATORS FOR DIABETES CARE

4. A great deal of progress has been made in the development, specification, and field-testing of measures for diabetes in the United States. Parallel efforts in the form of large national and international studies have been carried out in Italy by Nicolucci and colleagues (Pellegrini *et al*., 2003) and by the CODE-2 investigation group across eight European countries (Jonsson, 2002). While the origin of these indicators has been provider-level comparison, they can be aggregated to the regional and national levels and be used for health system comparisons.[2]

5. Thus, diabetes care can be characterised as a field in which there is widespread consensus on good practice patterns and international convergence on measures for processes and outcomes of care. This paper will present two categories of measures that could be used for international comparisons. The first category describes and recommends a set of now widely used provider-level measures that can also be used for benchmarking of healthcare systems by aggregating to the national level. It is argued that this set represents a comprehensive set of scientifically sound and relevant measures, which reflect an international consensus standard. The second category discusses new measures, such as incidence of kidney disease and diabetes-related amputations. Because of attribution problems, those measures are currently not used in provider comparison, but they could reveal valuable insight into the differential performance of health systems.

Box 2. Selection Criteria for Quality Indicators

Following the recommendations for indicator evaluation developed by the US Institutes of Medicine, the Expert Group and all expert panels agreed on the following three selection criteria for indicators (Hurtado, Swift, and Corrigan, 2001). First, it had to capture an important performance aspect. Second, it had to be scientifically sound. And third, it had to be potentially feasible.

The importance of an indicator can be further broken down into three dimensions:

- Impact on health. What is the impact on health associated with this problem? Does the measure address areas in which there is a clear gap between the actual and potential levels of health?
- Policy importance. Are policymakers and consumers concerned about this area?
- Susceptibility to being influenced by the health care system. Can the health care system meaningfully address this aspect or problem? Does the health care system have an impact on the indicator independent of confounders like patient risk? Will changes in the indicator give information about the likely success or failure of policy changes?

2. The concepts embedded in those indicators are also increasingly being used for policy purposes, such as the definition of the National Standards in the National Health Service in England and the criteria for Disease Management Programs in Germany.

The scientific soundness of each indicator can also be broken down into two dimensions:

- Face validity. Does the measure make sense logically and clinically? The face validity of each indicator in this report is based on the basic clinical rationale for the indicator, and on past usage of the indicator in national or other quality reporting activities.
- Content validity. Does the measure capture meaningful aspects of the quality of care?

The feasibility of an indicator reflects the following two dimensions:

- Data availability. Are comparable data to construct an indicator available on the international level?
- Reporting Burden. Does the value of the information contained in an indicator outweigh the cost of data collection and reporting?

As the experts were not able to make a definite statement about data availability for an indicator in all OECD countries, feasibility was given less weight in the decision process. The experts were asked to express their opinion as to whether it was likely, possible or unlikely to find comparable data on the international level for each indicator. If data availability was regarded as unlikely, an indicator was dropped.

ESTABLISHED MEASURES

6. As mentioned above, much of the work on standardised measures for the quality in this area originated in the US: There, the development of measures began with the Diabetes Quality Improvement Program (Fleming *et al.*, 2001), a physician-driven quality improvement program, which has evolved into National Diabetes Quality Improvement Alliance (the Alliance), a voluntary collaboration that now comprises all of the organisations[3] in the US that are concerned about the care of diabetes patients (NDQIA, accessed 2003). This collaboration has converged on a core list of measures that address the most important aspects of good diabetes care. A comprehensive discussion of the importance and scientific soundness of those indicators can be found in a paper by Fleming *et al.* (2001), and in materials produced by the Alliance (NDQIA, accessed 2003). The recently revised list of nine consensus measures, which have also gained widespread acceptance internationally, contains six indicators for care processes and three for outcomes of care.[4]

Process Measures:

- Percentage of patients with one or more HbA1c tests annually;
- Percentage of patients with at least one LDL cholesterol test annually;
- Percentage of patients with at least one test for microalbuminuria during the measurement year; or who had evidence of medical attention for existing nephropathy;
- Percentage of patients who received a dilated eye exam or evaluation of retinal photography by an ophthalmologist or optometrist during the current year or during the prior year if the patient is at low risk for retinopathy;

3. These organizations include: Agency for Healthcare Research and Quality; American Academy of Family Physicians; American Association of Clinical Endocrinologists; American College of Physicians; American Diabetes Association; American Medical Association; Centers for Disease Control and Prevention; Centers for Medicare and Medicaid Services; Joint Commission on Accreditation of Health Care Organizations; National Committee for Quality Assurance; National Institute of Diabetes and Digestive and Kidney Diseases; The Endocrine Society; us Department of Veteran Affairs.

4. Recent research also suggests that combining the measures into a single aggregate measure is possible, which would facilitate the communication and interpretation of performance data (Kaplan, 2003).

- Percentage of patients receiving at least one foot exam annually;
- Percentage of patients whose smoking status was ascertained and documented annually.

Outcome Measures:[5]

- Percentage of patients with most recent HbA1c level >9.0% (poor control);
- Percentage of patient with most recent LDL<130 mg/dl;
- Percentage of patients with most recent blood pressure <140/90 mmHg.

7. All measures use the number of clinically diagnosed diabetics as their denominator, *i.e.* they reflect quality of care contingent upon the patient having been identified as diabetic.[6] For the outcome measures, it is commonly stipulated that the patients who were not tested have failed the standard to avoid creating incentives for undertesting challenging cases.

8. While the importance and scientific soundness of those nine measures goes uncontested and recent studies by Jencks *et al.* (2003) and McGlynn *et al*. (2003) indicate that these measures could be used for health system comparisons, there are some challenges to their feasibility for international comparisons. The first four process measures (HbA1c tests, LDL tests, microalbuminuria tests, and eye exams) stand the best chance of being implementable, as they refer to distinct clinical services and the delivery of those services is usually well documented in administrative records, such as billing data. Recent research by Kaplan and colleagues developed an aggregate measure of the processes obtainable from administrative data that has good measurement properties and performs as well as when those measures are obtained from the medical record (Kaplan, 2003). Those four measures can thus be recommended for use without reservations.

9. Reliably measuring the remaining two process measures on the international level may be challenging, however. A foot exam is not a well-defined clinical test and may not be billed as an individual service in many countries, hampering the ability to extract the necessary information from administrative data. Documentation of smoking status is also not done in administrative data. Thus, both measures are likely to require dedicated data collection, such as medical record review, and substantial efforts would be needed to ascertain that data could be collected in a comparable fashion across countries. A more widespread use of Electronic Medical Records, which can be expected in many OECD countries, may improve the situation in the long run.

10. As to the outcome measures, while administrative records document reliably whether a test has been conducted, they do not record the test result. It is therefore not possible to construct the measures for HbA1c and LDL control form such data sources. However, electronic laboratory data, which are becoming more common, and national reporting requirements could provide the necessary information. For example, the CODE-2 European research project collected data on blood glucose and lipid control (Jonsson, 2002).

5. The concept behind these measures is adequate control of the variables. It has been operationalized as percentage of patients meeting a standard. For international comparisons, an alternative conceptualisation as national average rate is conceivable.

6. Obviously, it would be desirable to combine these measures with information about how well a health system identifies the affected population. Such concerns bout underidentification are commonly voiced when health systems, but are particularly salient in conditions with a long preclinical phase such as diabetes. However, assessing the identification would be very demanding, as it would require testing representative samples of the population for the presence of given disease with standard criteria and determining which percentage of the diagnosed had already been correctly identified as having the disease.

Routine data showing performance levels and change in performance for the US are provided by NCQA, a US organisation for the accreditation of health plans and providers (NCQA, accessed 2003). Thus, there is hope that comparable data would become available for OECD countries.

11. Measuring and reporting blood pressure control in a comparable fashion would be more challenging. The protocols for measuring and reporting of blood pressure would have to be standardized across countries and data collection would require dedicated reporting or Electronic Medical Records, whose implementation lags substantially the implementation of electronic laboratory data systems. In addition, data from the CODE-2 project and the US suggest that blood pressure control may be subject to ceiling effects and therefore not be useful to discriminate sufficiently the performance of health systems. Further research would thus be necessary prior to implementation of this indicator.

12. To summarize, a robust and comprehensive set of indicators for the quality of diabetes care has emerged on the international level that could be used to benchmark health systems. Some operational issues need to be resolved prior to implementation, such as the availability of comparable data for some indicators, and international consensus will have to be found on the periodicity of the process indicators and the threshold levels of the outcome indicators.

NEW MEASURES PROPOSED FOR USE IN HEALTH SYSTEMS COMPARISONS

13. It should be emphasised that the recommended set of measures covers mainly proximal concepts, *i.e.* quality characteristics under the immediate control of providers of medical care For policy purposes, those measures should be combined with indicators that reflect more distal concepts, *i.e.* the long-term outcomes for those chronically ill patients. While such indicators could never be used to compare individual providers, because they represent the end product of numerous little steps that cannot be attributed to a single provider, they are very useful for overall health system comparisons.[7] Several such measures are currently discussed in the literature for possible use at the health system level, such as rates of lower extremity amputations and the incidence of kidney disease. In addition, a novel outcomes measure, cardiovascular disease mortality in patients of certain ages with diabetes, could be considered.

Table 1: Summary table of newly-proposed measures

Indicator Name	Numerator	Denominator
Lower Extremity Amputation Rates	Patients with major (above or below knee) amputations in a given year.	All patients with diagnosed with diabetes.
Kidney Disease in Persons with Diabetes	Patient with End Stage Renal Disease (ESRD).	All patients with diagnosed with diabetes.
Cardiovascular mortality in patients with diabetes	Number of cardiovascular deaths in a given year	All patients with diagnosed with diabetes.

7. A similar reasoning underlies the now commonly reported cancer survival rates. They are the product of the performance of various aspects of the health care system, such as screening, initial diagnosis, initial treatment and aftercare, and thus reflect overall system performance.

Lower Extremity Amputation Rates

Numerator: All patients with major (above or below knee) amputations in a given year.

Denominator: All patients diagnosed with diabetes.

Importance of the indicator

14. Two of the main complications of longstanding inadequate glycemic control or poor diabetes management are peripheral vascular disease, the chronic deprivation of blood supply of the legs due to arteriolosclerosis, and peripheral neuropathy, damage to the peripheral nervous system. The combination of those two complications put diabetics at great risk for lower extremity lesions: The insensate foot makes it more likely that minor trauma occurs and goes unnoticed, the inadequate blood supply results in impaired healing of the trauma. Thus, osteomyelitis (severe infections of the bone) and gangrene (infection-induced tissue necrosis) may result. Foot ulcers and infections can be prevented by careful self foot care behavior, and proper fitting footwear and early treatment of foot lesions can prevent osteomyelitis and gangrene. Amputations also have a large impact on health, particularly on quality of life, and result in substantial follow-on cost in the form of rehabilitation, prostheses and disability.

Scientific soundness of the indicator

15. Although it is widely believed that careful monitoring and intensive treatment of both neuropathic and arterial disease of the extremities can prevent amputations, there are only a few randomised trials to support the conventional wisdom, once it has developed. However, the occurrence of neuropathy and vascular disease is also already suggestive of poor diabetes management. And because of the widely shared belief in the preventability of amputations, and because the data can be collected reliably from administrative data, as is done currently in the US by the CDC (NCQA, accessed 2003), amputations have been proposed as regional, state or national quality measures.

16. This measure is at the moment far from being uncontroversial for several reasons:

1) An amputation is not easily attributable to a provider or a set of providers because the prevention and treatment needed to avert the amputation may have to be performed many years before the amputation itself. This argument would not hold for its use in national comparisons where attributability to given providers is less important, but it does reflect the tension between measures of a nation's population health that are clearly in the public health domain, those that are in the provider quality domain, and those that share both domains.

2) Minor amputations of the toes and feet may be done to prevent major amputations, and could conceivably be the result of improved system and patient surveillance that leads to earlier detection and treatment of foot lesions. Consequently, there are no universally applied criteria for appropriateness. Since major amputations result in large decreases in quality of life (Peters *et al.*, 2001), they may be considered to be a failure of care even, if necessary when performed. Thus, major amputations may be more likely to be linked to antecedent poor quality of care. Rankings of units vary when minor versus major amputations are reported (Tseng *et al.*, in preparation). It should also be noted that major amputations may have low frequencies (5-10 /thousand patients with diabetes or fewer), and statistical comparisons at those levels may not be possible at the provider level, a problem that is resolved with the large sample sizes of health system comparisons.

3) Inadequate self-examination and care of the feet may play a large role in the development of the pathology leading to a major amputation. So the question arises whether and to what degree a health care system can be held accountable for the behaviour of patients.

4) The measure may be distorted by demographic characteristics. In the U.S, minority populations have had the highest rates of amputations and it is thought that socioeconomic status is a major factor leading to amputations. Thus, differences in level and distribution of wealth may be reflected in the measure together with differences in quality of care.

17. Because of the importance of this complications and plausibility of the concept behind the indicators, this measure has great potential. But it needs to be further studied before adopting it for international comparisons. If implemented, the measure should be confined to major amputations, for the reasons mentioned above.

Operational Issues

18. As this indicator is typically derived from hospital discharge information, the ability to construct it reliably for international comparisons depends on the comparability of coding and reporting practices across countries. Amputation rates or the numerator should be ascertainable in a reliable fashion in administrative data, as is done currently in the US by the Centers for Disease Control and Prevention,[8] because such major procedures usually influence hospital payments and are thus reliably reported. But it may be difficult to reliably identify the diabetic population or the denominator, because diabetes may only be recorded as comorbid condition rather than the primary reason for admission and coding of such secondary diagnoses may vary across countries.

Kidney Disease in Persons with Diabetes

Numerator: Patients with End Stage Renal Disease (ESRD).

Denominator: All patients diagnosed with diabetes.

Importance of the indicator

19. Diabetes is the single most frequent cause of ESRD in industrialised countries. Its treatment through chronic dialysis and kidney transplantation has tremendous implications for quality of life and functional status of patients as well as for health care spending.

Scientific soundness of the indicator

20. Research on the prevention and retardation of kidney disease in patients with diabetes has consistently shown that it is possible to prevent or retard kidney disease through blood sugar control, blood pressure control, and certain specific medications such as ACE inhibitors, and angiotension receptor blockers, alone and in various combinations. Thus, the incidence of kidney disease in patients with diabetes would seem to be a good measure of the quality of care for patients with this condition, lending the measure face validity.

Operational Issues

8. NCQA, Available at: http://www.ncqa.org/index.asp. Accessed August 2003.

21. While rates of dialysis initiation and of renal transplantation are readily available in Europe and the US, this information only approximates the true incidence and prevalence of ESRD, because the definition of ESRD and the criteria for dialysis initiation might differ across countries. Ascertainment of the cases could be achieved more precisely by standardized lab tests, such as blood creatinine levels. A creatinine level of 3.0 mg/dL has been a traditional definition of kidney failure, but there has been recent interest in lowering this level in order to initiate treatment at an earlier stage. An even better reflection of the incidence of renal disease could be derived from estimates of the Glomerular Filtration Rate (GFR) (O'Sullivan *et al.*, 2002) rather than creatinine by alone. However, consensus would have to be reached on the threshold level, and creatinine and other variables would have to be universally required and recorded to estimate GFR. In addition, diabetes is not the only cause of kidney disease among patients with diabetes, and one would have to account for differential rates for those diseases across countries.

Cardiovascular mortality in patients with diabetes

Importance of the indicator

22. Macrovascular complications represent the leading cause of morbidity, mortality, and resource consumption in diabetes and their burden is expected to grow in the next years due to the increasing incidence of the disease worldwide. For example, individuals with type 2 diabetes have a two- to fourfold increased risk of cardiovascular disease (CVD) compared with non-diabetic subjects and CVD mortality rates are 1.5-4.5 times higher than in the general population (Haffner, 2000). The increase in the incidence of coronary events is greater for more severe clinical outcomes, such as myocardial infarction and sudden death, than for less serious outcomes, such as angina pectoris (Haffner, 2000). Furthermore, the case fatality rate after a myocardial infarction among subjects with diabetes is higher than that for patients without diabetes; after a first cardiac event, 50% of patients with diabetes die within one year, and half of those who die do so before they reach the hospital (sudden deaths) (Miettinen *et al*., 1998).

23. Diabetes is responsible for premature CVD deaths; the adjusted relative hazard of CVD mortality is in fact 5 times higher in the age range 30-49 and 40-59 years for diabetic individuals as compared to non-diabetic ones (Saydah *et al*., 2002; Roper *et al.*, 2002). Median life expectancy is estimated to be 8 years lower for diabetic adults aged 55-64 years (Gu *et al.*, 1998). Recently, a decline in heart disease mortality in the general US population has been documented, mainly attributable to reduction in cardiovascular risk factors and improvement in treatment of heart disease. Nevertheless, such a positive trend was not documented for diabetic patients, thus suggesting that these changes may have been less effective for persons with diabetes, particularly women (Gu *et al.*, 1999). More aggressive interventions targeted at CVD risk factors have thus been advocated to try to reduce this excess premature mortality.

Scientific soundness of the indicator

24. Monitoring CVD mortality, particularly among in the age band 35-50 years, could thus represent an important indicator of the overall care delivered to diabetic patients, to be used for international comparisons. In fact, using intermediate outcome measures only (*i.e.* blood pressure and cholesterol levels) cannot fully replace the monitoring of the longer-term outcomes they are designed to predict. It is always possible that positive results in the short run fail to be sustained in the long run, even in the presence of scientifically tested indicators that had predicted otherwise (Safran and Vinicor, 1999).

Operational Issues

25. While conceptually appealing, the implementation of this indicator would be challenging. Mortality data, as the numerator for the indicator, are readily available in almost all countries, and causes of death are usually reported using internationally standardised coding systems, such as the ICD-9 or ICD-

10 systems. However, identifying the diabetic population as the denominator for the indicator is difficult. For example, it will depend on national reporting requirements and conventions whether and to what degree underlying diseases that led to the actual cause of death are recorded on death certificates. Alternatively, diabetic patients could be identified from drug prescription databases and mortality data (with specific cause of death) then linked using unique patient identifiers. This method has already been successfully applied (Koskinen *et al.*, 1998), but privacy concerns and operational complexity may stand in the way of widespread adoption. Another data source could be national disease registries, which are now commonly available for cancer diagnoses, that prospectively track all patients or representative samples of patients with chronic diseases.

26. To summarize, all three discussed new outcome measures have great potential to contribute to policymakers' and researchers' understanding of differences in quality of care between health systems, in particular because they represent the long-term outcomes of diabetes care. They would help to gain insight into whether and to what degree differences in the processes and intermediate outcomes that are captured by the established measures translate into better outcomes for patients. However, these measures are not yet universally accepted so that further research remains necessary before they could be recommended for benchmarking the performance of health care systems. A particular challenge will be to assure that the necessary data can be collected in a reliable and comparable fashion across OECD countries.

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