

Health Service Research

Challenges of audit of care on clinical quality indicators for hypertension and type 2 diabetes across four European countries

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Abstract

Background. The purpose of the study was to measure clinical quality by doing an audit of clinical records and to compare the performance based on clinical quality indicators (CQI) for hypertension and type 2 diabetes across seven European countries: Estonia, Finland, Germany, Hungary, Italy, Lithuania and Spain.

Methods. Two common chronic conditions in primary care (PC), hypertension and type 2 diabetes, were selected for audit. The assessment of CQI started with a literature review of different databases: Organization for Economic Co-operation and Development, World Health Organization, European Commission European Community Health Indicators, US National Library of Medicine. Data were collected from clinical records.

Results. Although it was agreed to obtain the clinical indicators in a similar way from each country, the specific data collection process in every country varied greatly, due to different traditions in collecting and keeping the patients' data, as well as differences in regulation regarding access to clinical information. Also, there was a huge variability across countries in the level of compliance with the indicators.

Conclusions. Measurement of clinical performance in PC by audit is methodologically challenging: different databases provide different information, indicators of quality of care have insufficient scientific proof and there are country-specific regulations. There are large differences not only in quality of health care across Europe but also in how it is measured.

Key words: Diabetes mellitus, type 2, family practice, hypertension, medical records, primary health care, quality indicators.

Introduction

Medical records (MR) contain a huge amount of routinely collected clinical data. This information can be used also to measure different aspects of quality of health care. There is no doubt that quality of health care is important. However, assessment of it is often

complicated. There are valid instruments for assessing the quality of practice management and a large amount of guidelines describing evidence-based treatment recommendations (1,2). Moreover, different countries use varying lists of clinical quality indicators (CQI) to assess the quality of primary care (PC) (3–6). Topics for clinical

process measures are generally defined by conditions [e.g. high blood pressure, type 2 diabetes mellitus (T2DM)], although these may be identified for different age groups, settings or events. One well-known set of indicators is the Quality and Outcomes Framework (QOF) in UK, which uses process measures to assess the performance of PC (7). QOF is a voluntary process for all practices in the UK and awards achievement points for four domains: clinical care, organizational, patient experience and additional services domain. The clinical care domain of QOF includes 87 indicators across different clinical areas and performance of the clinical targets is used to calculate the financial incentives. A similar set of indicators is also found in other countries, e.g. in Canada (8).

Extracting information from MR could provide very detailed clinical data about common disorders in PC but is a complex, costly and time-consuming exercise. However, quality of health care is essential and we should be able to use feasible and objective assessments. To the best of our knowledge, there is no evidence available about what set of CQI derived directly from MR is best for comparisons across countries or different PC systems.

The aim of the study was to measure clinical quality by doing an audit of MRs and to compare the performance based on CQI for hypertension and T2DM across European countries.

Methods

This study is part of the project 'EUprimecare', the objectives of which were to develop a framework aiming to analyse PC across Europe; to assess and compare PC models in terms of quality and identifying costs and to provide recommendations for PC services regarding quality and cost. There were seven countries participating in the project 'EUprimecare': Estonia, Finland, Germany, Hungary, Italy, Lithuania and Spain (9).

In this article we analyse one of the aims of the project, the assessment of the clinical quality.

The process of assessing a set of CQI

The assessment of the CQI started with the literature review. The objective was to identify those indicators, which will allow identifying differences between PC models in terms of clinical performance. Initially, the Organization for Economic Co-operation and Development (OECD), World Health Organization (WHO) and European Commission European Community Health Indicators (ECHI) databases were searched to identify CQI (10–12). An initial list of indicators was identified, describing performance in the field of public health, screening, immunization and management of chronic diseases, and specific tasks of the PC providers.

The next step was to conduct a search of the literature to support the selection of CQI which can identify differences of quality in terms of clinical performance between PC models and which can be derived from MR. The following search strategy was used in order to identify systematic reviews in the US National Library of Medicine (PubMed) database: [(‘quality of health care’[MeSH Terms] AND ‘primary health care’[MeSH Terms]) AND ‘clinical audit’[MeSH Terms]] AND systematic[*sb*].

Altogether 48 systematic reviews were found. None of them directly addressed the question about applicable CQI derived from MR for comparison of quality of PC between countries. There were different sets of indicators, mostly country specific and none of them directly applicable in at least two countries participating in EUprimecare project (3–6). The lack of an international agreed on list of indicators, promoted the necessity to develop a novel set of

CQI for audit within the EUprimecare project. The starting point for the selection of the CQI was the list of CQI developed by the OECD (10). Two common chronic conditions, hypertension and T2DM, were selected for audit. These conditions were selected due to their high prevalence, lower control than needed, the high morbidity and mortality associated with them and the existence of accepted guidelines for the management at PC level (13–16). The precondition for including an indicator into the final set was the direct availability of the values of the indicator from MR for the majority of the participating countries in the EUprimecare project. If the values were not directly available for at least four participating countries, it was not included in the list. The final list of CQI was developed by consensus among the partners.

Data extraction from MR

Data were collected according to the project criteria and possibilities of each participating country.

Each country asked for permission from their local ethics committee to study the clinical data from patients' records. The data collected related only to the objectives of the audit. Staff as well as patient confidentiality was respected.

We used stratified sampling and the number of PC centres allocated from each country was predetermined by sample size calculations. All MR were assessed based on data from 2011 (all entries in 2011 were included) and relevant clinical data were recorded using a uniform template. We included all patients with a diagnosis of T2DM (diagnoses E11 and E11.0–E11.9 according to the ICD-10 classification), patients with diagnosis of hypertension (diagnoses I10, I11, I12, I13 according to the ICD-10 classification) or patients with both T2DM and hypertension.

Process of obtaining CQI from MR varied between partners. Therefore, we report it per country.

Estonia

We used the Estonian Health Insurance Fund database and invited all GP ($N = 804$) to participate in the study; 241 (30%) of them agreed. Then an employee of the Health Insurance Fund randomly selected two patients with T2DM and hypertension from the physician's list of patients. The data of selected patients were forwarded to their physicians, who prepared coded and unidentified patient records and sent them to the investigators. In total, 562 cases were analysed, while 45% of patients had both hypertension and T2DM, 10% of patients had only T2DM and 44% had only hypertension. Analysis was performed on 247 patients with hypertension and 309 with T2DM.

Finland

Most of the PC in Finland is provided by municipal health centres. As the plan was to manually search electronic MR, only those health centres using two of the most common software systems were approached, which cover ~87% of the whole population. For practical travel cost-related purposes, the northernmost very sparsely populated region of Lapland was excluded. Out of the eligible municipalities, 37 were included in the sample after stratification by macro region and size of the health centre catchment population. The sample was set to consist of ~1000 patients with T2DM and 2000 with hypertension. The National Pension Institute is the keeper of the registers of those with special entitlements. It extracted random lists of names and social security numbers for individuals. Out of these lists, individuals with codes for diabetes and hypertension were chosen, up to the target figure set for each municipality. In total, 25 centres from the 37 municipalities were approached for their permission to access the data. All agreed, but two were so late

in their reply that they had to be excluded. In order to compensate for the numbers of individuals lost, target numbers in municipalities in similar regions and communities were increased.

Germany

We used data from the Disease Management Programme (DMP) for T2DM from the North Rhine region. DMP constitute a population-based integrated approach to care management, i.e. it covers the secondary and ambulatory care.

Hungary

The source of data was the Healthcare Episode Database operated by GYEMSZI IRF (Directorate General of Informatics and Health System Analysis). The Healthcare Episode Database processes the data of the National Health Insurance Fund.

Italy

Italian GPs do not use ICD-10 coding. Therefore, no data about patient care with T2DM and hypertension at the individual care cannot be collected.

Lithuania

The study was performed in Kaunas region, which is the most central part of Lithuania, covering urban and rural areas. The economic indicators in this region are equal to the Lithuanian average. There are 49 PC centres in Kaunas region, which provide PC services under the contract with Sickness Funds. In Lithuania, the majority of centres use records in paper form and only one centre had institutional list about the patients with T2DM and hypertension, while in the other PC centres this information was provided personally by each physician. All patients of the same centre were merged and the needed numbers of patients were randomly selected for the audit. As the majority of T2DM patients had both diagnoses (hypertension and diabetes), the final number of patients with hypertension was higher than selected. As in one small urban and one medium urban centre the necessary number of patients with T2DM was not available, two additional centres (which represented the same size and urbanization) were included in the study.

Spain

The information of the study has been provided by the Healthcare Regional Service of Castilla y León. Depending on the indicator, the information was extracted from two different sources. Each source of information represents a specific population. There were a total of 32 of those centres, which were distributed as follows: (i) two rural centres in Avila, (ii) two rural centres in Soria, (iii) two rural centres plus one urban health care centre in Valladolid and (iv) all rural and urban centres in Burgos.

For all the other indicators, PC centres with electronic MR have been selected, which represented ~80% of the Castilla y León population. Electronic MR are implemented in the main PC centres as well as in offices located in towns with a population of 300–500 people.

Results

The final list of CQI is presented in [Table 1](#). The indicators describe the proportion of patients with T2DM and/or hypertension screened for different factors (e.g. cholesterol, blood pressure).

[Table 2](#) presents the results of the assessment of CQI in each country during 1 year. It was not possible to review MR in Italy and

Germany due to data protection reasons; in Hungary, it was not possible to separate PC data from secondary care data. Therefore, we report data only about four countries: Estonia, Finland, Lithuania and Spain.

The proportion of hypertensive patients with a blood pressure level at or below goal (<140/90 mmHg) ranged between 33% and 53% in different countries. Similarly, the proportion of hypertensive patients for whom the lipid profile was measured ranged between 24% and 67%, being the lowest in Lithuania and Spain and the highest in Estonia.

Concerning T2DM, the proportions of patients with diabetes having an average blood pressure at or below goal (<130/80 mmHg) ranged between 8% and 62%. The lipid profile was measured in 23–69% of patients with T2DM. The proportion of patients with diabetes with total cholesterol at or >4.5 mmol/l and statin treatment provided ranged between 15% and 63% and the proportion of patients with T2DM with total cholesterol <4.5 mmol/l was 20–54%. Glycated haemoglobin (HbA1c) was screened for 57–90% of patients with T2DM. The proportion of patients with T2DM with HbA1c <7% was between 49% and 67%. Similarly, the proportion of patients with diabetes with HbA1c ≥7–8.5% under insulin treatment was 43–49%. The proportion of patients with T2DM having an eye examination ranged between 1% and 46%, being the lowest in Spain and the highest in Lithuania.

Most countries used electronic MR, except in Lithuania paper-based MR are used. During the audit we also noticed that there were different ways of recording blood pressure readings for patients who monitor their blood pressure at home. In most cases, the typical record entered into the MR was a generalization, e.g. on the average, or usually on the acceptable levels, or usually <90, or similar. In other words, if the patient has a written card of the readings, the readings are not copied as such, but the doctor or nurse writes a summary or makes conclusion. In such cases the monitoring of blood pressure may look irregular, although it could be very regular in reality.

Discussion

The aim of the study was to measure clinical quality by doing an audit of MRs and to compare the performance based on CQI across different countries.

The first finding is the absence of a previously validated list of CQI. Although different organizations have proposed instruments to measure the quality of PC there is no consensus on how to use the information from MR for this assessment.

As a first step, indicators were agreed for two common chronic conditions in PC, hypertension and T2DM. Although it was required to obtain the CQI in a similar way from each country at the beginning of the study, the specific data collection process in each country varied greatly, due to different traditions in collecting and keeping patients' data, as well as differences in regulation regarding access to clinical information. This is a significant second finding. For example, some countries were not able to collect data at individual patient level (Hungary, Germany, Italy) and in some countries not all proposed indicators were collected. In most of the countries electronic MR were analysed (except Lithuania) and the data were collected in one region of the country. However, in Estonia, data were collected across the whole country and in Finland only the most northern part of the country was excluded due to practical reasons.

The third finding is the variability across countries in the level of compliance with the indicators. Concerning hypertension, the

Table 1. CQI for medical audit agreed by EUprimecare countries

Indicator	Estimate	Source of evidence
Proportion of patients with T2DM screened for HbA1c	Number of patients aged 25–75 years with confirmed T2DM with at least one HbA1c measurement done during 1 year/total number of patients aged 25–75 with T2DM during 1 year	OECD, ADA/EASD
Proportion of patients with T2DM with HbA1c <7%	Number of T2DM patients aged 25–75 years with HbA1c value <7% during 1 year/total number of patients aged 25–75 with T2DM during 1 year	OECD, ADA/EASD
Proportion of patients with T2DM screened for total cholesterol level	Number of T2DM patients aged 25–75 years with at least one cholesterol measurement during 1 year/total number of patients aged 25–75 with T2DM during 1 year	OECD, ESC
Proportion of patients with T2DM with total cholesterol <4.5 mmol/l	Number of T2DM patients aged 25–75 years with at total cholesterol value <4.5 mmol/l during 1 year/total number of patients aged 25–75 with T2DM during 1 year	OECD, ESC
Proportion of patients with T2DM with total cholesterol >4.5 mmol/l and statin treatment provided	Number of T2DM patients aged 25–75 years with total cholesterol at or >4.5 mmol/l and statin treatment provided/total number of patients aged 25–75 with T2DM during 1 year	OECD, ESC
Proportion of patients with T2DM having average blood pressure <130/80 mmHg	Number of patients with T2DM having average blood pressure <130/80 mmHg according to the last measurement during 1 year/total number of patients aged 25–75 with T2DM during 1 year	OECD, ESC
Proportion of patients with T2DM having eye examination (fundus photography or ophthalmologist consultation recorded)	Number of T2DM patients aged 25–75 years having eye examination during 1 year/total number of patients aged 25–75 with T2DM during 1 year	OECD, NICE
Proportion of patients with hypertension with blood pressure <140/90 mmHg	Number of patients aged 25–75 years with hypertension with blood pressure <140/80 mmHg according to the last measurement during 1 year/total number of patients aged 25–75 with hypertension during 1 year	ESC, WHO/ISH
Proportion of patients with hypertension with total cholesterol screened within a year	Number of patients aged 25–75 years with hypertension with blood pressure <140/80 mmHg according to the last measurement during 1 year/total number of patients aged 25–75 with hypertension during 1 year	OECD/ESC

ADA, American Diabetes Association; EASD, European Association for the Study of Diabetes; ESC, European Society of Cardiology; ISH, International Society of Hypertension; NICE, National Institute for Health and Care Excellence.

proportion of hypertensive patients with a blood pressure level at or below goal ranged between 33% and 53% and the proportion of patients with diabetes having average blood pressure at or below goal ranged between 8% and 62% across countries.

One source of variation between countries arises from differences in national recommendations (in comparison to the international standards used to establish the indicator). For example, in Lithuania, according to the Health Ministry Order regarding T2DM care, physicians have to refer patients once a year for an eye fundus checkup, which this explains the highest activity between other countries. In the other words, high activity in the performance of some tests may be explained by country-specific regulations which unfortunately may not always correlate with the good treatment quality results. The other source of variation between results comes from the usual practice doctor–patient based variation, which is the usual focus of attention in comparisons of quality.

Trying to make comparisons of management of T2DM, which is called the epidemic of the 21st century, is complicated. For example, in 2005 the European Core Indicators in Diabetes project report described the process of collecting data about diabetes (17). Nineteen European countries participated, but for most of the countries national data were not available. The indicators were derived from different sources and databases, and primary and secondary care provision were not separable. Also, type 1 diabetes patients were involved in the study. Therefore, these data cannot be used for comparison of diabetes care provision for countries participating in our project. Also, the WHO provides data for most of the countries. However, data from Lithuania and Estonia are incomplete.

Kilpeläinen *et al.* (18) showed that the availability score for ECHI indicators was 74%, ranging from 56% to 84%. However,

important indicators such as health provision, use of health care services and the quality of health care and health care promotion are often missing. Quality of health care, according to ECHI indicators, is defined by survival rates for cancer, surgical wounds infections, equality of access to health care services, diabetes control, cancer treatment delay and waiting time for elective surgeries (19). Criticism of ECHI, WHO and OECD has been discussed and the conclusion was that collaboration is needed between the WHO Europe, the OECD and the European Commission in the work towards an integrated European health information system (20). To sum up, there are large amounts of data and reports of routinely collected data available but the information is often scattered, fragmented, underutilized, incomparable and undervalued. Moreover, the data collection method is also important. According to Green *et al.* (21), the decision about which data collection method is best needs careful consideration regarding its influence on the results. However, the medical chart audit is the most accurate method of data collection.

Strengths and limitations

The most important strength of this study is methodological—we analysed MR in a similar way across countries. Collecting data from MR is laborious and time-consuming. However, this is one of the most accurate methods for measuring actual performance. Limitation of our study is also that some samples were national, some regional, as well as participating GPs were not recruited in the same way in each country, which influences generalizability of our results. During the audit we noticed that needed data were often poorly found/not recorded systematically in MR. In the Canadian Quality Book of Tools there is a special indicator for MR keeping. Criteria for this indicator are that each patient record has to have

Table 2. Results of clinical indicators assessed in EUprimecare countries

Clinical indicator	Estonia	Finland	Lithuania	Spain
	% (n)			
Proportion of hypertensive patients with blood pressure at or <140/90 mmHg	45.5% (112)	35.1% (291)	33.5% (246)	53.4% (240785)
Proportion of hypertensive patients with lipid profile measured	67.6% (167)	44.0% (783)	24.7% (181)	24.7% (111567)
Proportion of patients with diabetes having average blood pressure at or <130/80 mmHg	53.5% (165)	15.1% (76)	8.6% (33)	62.3% (10484)
Proportion of patients with type 2 diabetes with total cholesterol <4.5 mmol/l	20.4% (63)	54.3% (277)	53.8% (205)	–
Proportion of patients with diabetes, with total cholesterol at or above goal and statin treatment provided	40.2% (124)	63.4% (144)	15.0% (57)	42.4% (7129)
Proportion of patients with diabetes for whom lipid profile was measured	69.3% (214)	68.9% (510)	23.8% (91)	51.9% (8734)
Proportion of patients with type 2 diabetes with HbA1c <7%	61.9% (191)	67.6% (342)	49.7% (189)	–
Proportion of patients with diabetes with HbA1c ≥7–8.5%, insulin treatment provided	43.5% (134)	–	49.4% (188)	–
Proportion of patients with diabetes screened for HbA1c	86.2% (266)	68.4% (506)	90.6% (346)	57.7% (9706)
Proportion of patients with type 2 diabetes having eye examination	15.2% (47)	25.9% (192)	46.3% (177)	1.4% (237)

a cumulative patient profile which includes up-to-date list of problems, medications, drug allergies and adverse drug reactions, a list of laboratory test results and of other examinations (8). Having a cumulative patient profile makes the data collection from MR easier.

Conclusions

In conclusion, the assessment of a set of CQI for measurement of clinical performance in PC is methodologically challenging because different databases provide information on different countries, which seriously limits the possibility to make direct cross-country comparisons. Applicability of this developed set of indicators was problematic (four countries out of seven could collect data at individual level). Data sources and data collection principles are not clear and CQI are scattered, with insufficient scientific proof of particular indicator validity and reliability. Differences could also be related to country-specific regulations and unfortunately may not always correlate with the good treatment quality results. As Europe is advancing towards harmonization in health care and as the necessity of maximizing the efficiency of health care spending is higher than ever, it seems necessary to have appropriate instruments that permit comparisons across different models and systems of care. Large differences still exist not only in quality of PC across Europe but also in how it is measured.

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