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Comparison of clinical-metabolic monitoring and outcomes and coronary risk status in people with type 2 diabetes from Australia, France and Latin America☆

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ABSTRACT

Aim: To compare clinical-metabolic monitoring and coronary risk status in people with type 2 diabetes from Australia, France and Latin America.
Methods: Retrospective analysis of data collected at primary care (4540 participants from each population) matched for age, gender and disease duration. Measurements included participants' characteristics, performance frequency of clinical-metabolic process indicators, and percentage of clinical-metabolic outcomes at recommended target values.
Results: The weighted mean of the percentage of process performance was within 68 to 81%; that of outcomes at target dropped to 29 to 45%. Although statistically significant, differences among groups were far from those in healthcare budgets, and probably only of marginal clinical impact. The percentage of patients with low, slight or high coronary risk was similar in the three groups, with most people at high or very high risk.
Conclusions: Despite the high difference in health *per capita* investment and system characteristics among countries, the study populations had striking similarities regarding the low percentage of participants who achieved cardiovascular risk factor and diabetes treatment goals. Therefore, differences in health budget and system characteristics would not be the main drivers in care quality. Diabetes education at every level and quality care registries would contribute to improve this situation and assess such improvement.

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1. Introduction

Diabetes mellitus is a prevalent, serious and increasing disease that currently affects approximately 130 million people; this will rise to about 300 million by the year 2025 [1]. Diabetes and its associated cardiovascular risk factors (CVRF) have been repeatedly demonstrated to be undertreated, mainly due to late diagnosis and failure to achieve targeted diabetes and CVRF goals [2–4].

Chronic complications (the main cause of diabetes morbidity, mortality and costs) can be reduced significantly by appropriate control of glycaemia and CVRFs [5–12]. Treatment of cardiovascular complications represents one half of the cost of diabetes care, suggesting that programs to reduce their incidence would be of great economic and social value [13].

Several international initiatives are directed at improving diabetes care. In Europe, the main goals of the *European Action Program of the St. Vincent Declaration* were to improve the clinical and social conditions of people with diabetes. In order to measure progress toward these goals, a system of data collection called DIABCARE has been implemented and data from France are analysed in this report [14]. Also analysed in this report are data from the program of the *Declaration of the Americas* (DOTA) for the collection of data to measure the quality of care of people with diabetes (QUALIDIAB) in Latin America and the Caribbean [3,15]. Finally, ANDIAB (Australian National Diabetes Information Audit and Benchmarking) is a quality audit activity utilizing a standardized diabetes dataset which has considerable data overlap with the two above mentioned datasets. ANDIAB data are collected in diabetes centers throughout Australia [16].

Analysis of the French DIABCARE, the Australian ANDIAB and the Latin American QUALIDIAB databases permitted a comparison of the quality of processes and outcomes of care in three geographic areas with distinct healthcare systems and widely differing healthcare *per capita* expenditures. In an attempt to understand the possible determinants of quality of diabetes care, we currently compared the performance of preventive processes (monitoring of fundus oculi, feet, weight, height, blood pressure, HbA1c, total cholesterol, HDL-cholesterol and triglycerides [TG]) and their outcomes (body mass index [BMI], systolic blood pressure [SBP], HbA1c, total cholesterol, HDL-cholesterol and TG levels) as well as the coronary risk status of people with type 2 diabetes, in a sample of patients from the above mentioned databases paired by gender, age and diabetes duration.

2. Materials and methods

2.1. Common characteristics of the three databases

- Process indicators (e.g., percentage of patients checked for proteinuria or glycemic self-monitoring);
- Acute complication indicators (e.g., ketoacidosis [except ANDIAB] and hypoglycaemia episodes).
- Intermediate indicators (e.g., fasting glycaemia [except ANDIAB] A1C, blood lipid levels, proteinuria); and
- Late indicators (e.g., retinopathy, blindness, neuropathy, amputations and myocardial infarctions).

Data in DIABCARE were collected by general practitioners, in ANDIAB by physicians from diabetes centres and in QUALIDIAB by both.

2.2. Components of the database networks

- Quality of Care Indicators and goals based on values proposed by the International Diabetes Federation (IDF) Guideline [17], the American Diabetes Association (ADA)/European Association for the Study of Diabetes (EASD) Consensus [18], and the American College of Endocrinology/American Association of Clinical Endocrinologists (ACE/AACE) Consensus [19].
- Basic Information Data Sheet, to register clinical, biochemical and therapeutic parameters, and diagnostic and therapeutic actions;
- Software for data loading, error detection and statistical analysis; and
- Providers willing to collect these data.

These three networks make it possible to measure and compare care in the participating healthcare centers. In these networks we looked for patients with type 2 diabetes registered in the period 1999 to 2000, with the same gender, age and diabetes duration. Based on this pairing system we identified a total of 4540 people with type 2 diabetes in each database (Table 1). In this population, we analysed the clinical and biochemical monitoring performance and outcomes (percent of patients with values at target) and the risk score for coronary events.

2.3. Clinical indicators

Clinical indicators were collected by the participating physicians using comparable standard practice procedures. Since we cannot assure compatibility regarding the criteria used to assess the presence of chronic complications in the three datasets, we have not included a comparison of their rates.

2.4. Laboratory tests

Laboratory tests in the three datasets were performed with comparable methods; compatibility of assays was assessed by appropriate statistical techniques [20].

Coronary heart disease risk was estimated using the criteria recommended by the Second Joint Task Force of European and other Societies on Coronary Prevention [21]. This is a multifactorial analysis that estimates the absolute risk of developing a coronary event over the subsequent 10 years considering SBP, total cholesterol, age, gender, and smoking status. The risk is rated as *Very high* (over 40%), *High* (20 to 40%), *Moderate* (10 to 20%), *Mild* (5 to 10%), and *Low* (under 5%).

2.5. Statistical analysis

The data were analysed using the Data Base and Statistical Program for Public Health EpiInfo 6 (version 6.02, CDC and WHO, 1994). Differences between means were tested for statistical significance by one-way ANOVA. Statistical differences

Table 1 – Demographic, clinical and metabolic characteristics of the population sample.

	ANDIAB	DIABCARE	QUALIDIAB	P[a]
n	4541	4540	4539	
Age (years)	62.4 ± 10.8	62.4 ± 10.8	62.4 ± 10.8	1.00
Gender (% female)	49	49	49	1.00[b]
Diabetes duration (years)	9.8 ± 7.9	9.9 ± 8.3	10.2 ± 9.4	0.096
Weight (kg)	84.2 ± 18.7 (4405)	79.8 ± 16.4 (4431)	74.5 ± 16.9 (4463)	0.000
Height (cm)	165.2 ± 9.9 (4041)	164.9 ± 9.2 (4322)	158.9 ± 67.6 (4394)	0.002
BMI (kg/m^2)	30.8 ± 6.1 (4041)	29.3 ± 5.7 (4301)	29.7 ± 7.0 (4388)	0.000
Waist (cm)	NR	102.1 ± 15.9 (2231)	98.7 ± 18.6 (3029)	0.000[c]
Hip (cm)	NR	105.2 ± 13.4 (2178)	106.2 ± 20.4 (2992)	0.042[c]
W/Hip ratio	–	0.97 ± 0.21 (2177)	0.93 ± 0.09 (2986)	0.000[c]
SBP (mmHg)	139.6 ± 19.2 (4178)	140.1 ± 17.5 (4324)	140.4 ± 22.1 (4453)	0.131
DBP (mmHg)	78.3 ± 10.2 (4178)	79.1 ± 10.4 (4282)	83.1 ± 16.3 (4452)	0.000
HbA1c (%)	7.8 ± 1.7 (3905)	8.3 ± 2.1 (3901)	9.02 ± 5.8 (1371)	0.000
T. Cholesterol (mmol/l)	5.1 ± 1.1 (3451)	6.1 ± 1.6 (3836)	5.6 ± 1.3 (3361)	0.000
HDL-Chol (mmol/l)	1.2 ± 0.3 (2452)	1.2 ± 0.4 (2446)	1.1 ± 0.8 (2210)	0.047
TG (mmol/l)	2.2 ± 1.8 (3315)	2.0 ± 1.3 (3827)	2.1 ± 1.4 (3076)	0.000

Values are means ± SD. Between brackets, valid number of patients. NR, not recorded; BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; TG, triglycerides.
[a] Chi-square from one-way ANOVA.
[b] Pearson's chi-square test.
[c] Only between DIABCARE and QUALIDIAB.

between proportions were evaluated by Pearson's chi-square test. A *P*-value <0.05 was considered statistically significant.

3. Results

As mentioned earlier, patients in the three databases were paired by gender, age and diabetes duration (Table 1). Although there were small but significant differences in all the average values of other clinical and biochemical indicators among the three populations, the most striking ones corresponded to HbA1c (ANDIAB, 7.8%; DIABCARE, 8.3%; QUALIDIAB, 9.02%) and total cholesterol (ANDIAB, 5.1%, DIABCARE, 6.1%, QUALIDIAB, 5.6%). The lowest values, however, were not consistently found in any of the three databases.

There are several differences in gross product, health care investments and organization among Australia, France and the countries involved in the Qualidiab database (Table 2). Other differences have been summarized as follows:

Health Care in Australia (http://www.aussiemove.com/aus/hlth.asp): Medicare provides free treatment in public hospitals, free or subsidized treatment by general practice doctors and some treatments by participating specialists, optometrists and dentists. Private health insurance offers ancillary coverage that pays for treatments that Medicare does not, such as dental, optical, podiatry and physiotherapy. Private hospital coverage allows subscribers to choose treatment, timing hospitals and physicians. Medicare covers 75% of the private hospital costs and the health fund the remaining 25%. Charges greater than fee schedule are generally out-of-pocket costs unless the patient's fund provides gap coverage

Health Care in France. National Coalition on Health Care: Every employee and his/her family are covered by a national health insurance plan; those not entitled are required to purchase personal insurance. In 2000, France introduced a mandatory universal health plan, which provides health insurance for all legal residents. Doctors in the Sécurité Sociale system may charge set fees or set their own, but are only reimbursed for the set fee. Doctors outside of Sécurité Sociale are not subsidized. Prescription drugs are reimbursed at a variable rate based on the class of drug. Hospital treatment is reimbursed for 80% for the first month and 100% afterwards.

Private clinics outside *securite*, are reimbursed for about 10% of expenses.

3.1. *Profile of the health services system in countries included in the QUALIDIAB database (http://www.lachsr.org)*

Argentina: The health system is divided into public health, social security and a prepaid system. The public system covers about 50% of the population; it is free and currently provides free insulin and some oral antidiabetic drugs for outpatients,

Table 2 – Macroeconomic characteristics.

Selected indicators	France	Australia	South America[a]
GDP per capita (International USD, 2002)	28094	28277	8063
Total health expenditure per capita (Intl. USD, 2002)	2736	2699	649
Total health expenditure as % GDP (2002)	10	10	8

[a] Average values of Argentina, Brazil, Chile, Colombia, Paraguay and Uruguay. GDP, gross domestic product. Data source: www.who.int/whosis/en/.

Table 3 – Percentage of procedure performance.

	ANDIAB (n = 4540)		DIABCARE (n = 4541)		QUALIDIAB (n = 4539)		P[a]
	% (n)	95% CI[b]	% (n)	95% CI[b]	% (n)	95% CI[b]	
Fundus oculi	69 (3133)	67.3–70.3	73 (3315)	71.7–73.3	19 (879)	18.2–20.5	0.000
Foot control	97 (4405)	96.5–97.5	90 (4100)	89.4–91.2	80 (3615)	78.4–80.8	0.000
Weight	97 (4405)	96.5–97.5	98 (4431)	97.1–98.0	98 (4463)	97.9–98.7	0.000
Height	89 (4041)	88.0–89.9	95 (4322)	94.5–95.8	97 (4394)	96.2–97.3	0.000
Blood pressure	92 (4178)	91.2–92.8	95 (4324)	94.6–95.8	98 (4453)	97.7–98.5	0.000
HbA1c	86 (3905)	84.9–86.9	86 (3901)	84.9–96.9	30 (1371)	28.9–31.6	0.000
Total cholesterol	76 (3451)	74.7–77.2	84 (3836)	83.4–85.5	74 (3361)	72.7–75.3	0.000
HDL-c	54 (2452)	52.5–55.4	54 (2446)	52.4–55.3	49 (2210)	47.2–50.2	0.000
Triglycerides	73 (3315)	71.7–74.3	84 (3827)	83.2–85.3	68 (3076)	66.4–69.1	0.000
Weighted mean	81 (3698)	80.3–82.6	84 (3834)	83.4–85.5	68 (3091)	66.7–69.4	0.000

Data are percent values of performed procedures. Between brackets, number of patients.
[a] Pearson's chi-square test.
[b] The confidence interval (CI) was estimated by simple random sampling.

but not necessarily drugs for cardiovascular risk factor control. The social security system covers about 35% of the population; coverage is usually 100% of the hospital costs (including drugs), but outpatient drug coverage varies considerably. Private insurance coverage and costs (about 15% of the population) vary widely.

Brazil: Brazil provides decentralized universal coverage, offering comprehensive care including free access to essential medicines. Additionally, the Popular Pharmacy Program subsidizes prices for 12 antihypertensive and antidiabetic drugs.

Chile: Sixty-one percent of the population is covered by the public health system through FONASA, 28% by ISAPRE, and the rest by the SNSS. Drugs are provided free of charge to SNSS beneficiaries and in primary care settings affiliated with public system facilities.

Colombia: Social security coverage of 54% was attained in the year 2000. The subsidized system covers every municipality, bringing insurance to the poor.

Paraguay: Ministry pharmacies are subsidized up to 100% for indigent patients; 20% of the population has health insurance; of that percentage, 62.2% corresponds to the Social Security Institute Insurance (IPS), 31.8% to private insurance, and 6.0% to other insurances.

Uruguay: The public sector provides health care to the low-income population and the private sector for groups of average and high income. The State provides services for disease prevention and health care only to the indigent.

Table 3 summarizes the degree of performance of several preventive processes (clinical and laboratory monitoring rates) among the three populations. The data represent the percent of the population in which the processes were performed. The weighted mean performance value was determined with the total number of cases for each parameter measured, and varied significantly among the three populations.

In all three populations, greatest values were observed in foot, body weight, height and blood pressure control, while the lowest corresponded to HDL-cholesterol. Largest differences were recorded in the performance of fundus oculi and HbA1c, without any clear distribution pattern of largest and lowest values associated to one population. The 100% performance was not recorded in any of the populations studied.

Table 4 summarizes data from patients at treatment target goals for different clinical and metabolic parameters. In every database, the weighted mean for patients at target, calculated as mentioned above, was markedly lower than the one recorded in process performance.

Table 4 – Clinical and metabolic outcomes: percentage of patients at goal.

	ANDIAB		DIABCARE		QUALIDIAB		P[a]
	%	95% CI[b]	%	95% CI[b]	%	95% CI[b]	
BMI (kg/m^2) < 25	17 (4041)	15.6–17.9	21 (4301)	19.9–22.4	19 (4388)	18.3–20.7	0.000
SBP < 130 mmHg	27 (4178)	25.8–28.5	19 (4324)	17.5–19.8	23 (4453)	21.9–24.4	0.000
HbA1c < 6.5%	23 (3905)	21.5–24.1	18 (3901)	16.5–18.9	16 (1371)	14.2–18.2	0.000
Cholesterol < 4.7 mmol/l	85 (3451)	83.7–86.1	13 (3836)	11.6–13.8	24 (3361)	22.5–25.4	0.000
HDL-c > 40 mg/dL	84 (2452)	82.4–85.4	65 (2446)	62.6–66.4	57 (2210)	55.3–59.5	0.000
TG < 150 mg/dL	56 (3315)	54.2–57.6	52 (3827)	50.5–53.7	53 (3076)	50.9–54.5	0.000
Weighted mean	45 (3557)	43.0–46.4	29 (3773)	27.1–30.0	31 (3143)	29.2–32.4	0.000

Data represent percentage of patients at goal values for each parameter. BMI, body mass index; SBP, systolic blood pressure; TG, triglycerides. Between brackets, number of patients.
[a] Pearson's chi-square test.
[b] The confidence interval (CI) was estimated by simple random sampling.

Table 5 – Score for risk of coronary event.

Coronary risk	ANDIAB (n = 3650)		DIABCARE (n = 2807)		QUALIDIAB (n = 2593)		P[a]
	%	95% CI[b]	%	95% CI[b]	%	95% CI[b]	
Low	4.0	3.4–4.7	3.2	2.6–3.9	3.9	3.2–4.7	0.213
Mild	10.2	9.2–11.2	9.5	8.4–10.6	9.1	8.90–10.3	0.336
Moderate	46.3	44.7–48.0	40.3	38.5–42.2	38.0	36.2–39.9	0.000
High	38.9	37.3–40.5	46.2	44.3–48.0	48.1	46.1–50.0	0.000
Very high	0.5	0.3–0.8	0.8	0.5–1.2	0.9	0.6–1.3	0.146

Data represent the percentage of the population included in the coronary risk status.
[a] Pearson's chi-square test.
[b] The confidence interval (CI) was estimated by simple random sampling.

In every parameter tested (excepting HbA1c), the percentage of patients at target varied significantly among the three populations, but we did not observe a constant pattern for the highest/lowest values recorded, namely, the percent of people with BMI <25 kg/m^2 was lowest among the Australian population (17%) while the percent of the population with SBP <130 mmHg was significantly lower in the French population (19%); further, the French population had the lowest per cent of patients with total cholesterol values less than 4.7 mmol/l (13%), while the Australian population had the highest (85%). Finally, the percent of patients with A1C less than 6.5% ranged from 16% (QUALIDIAB) to 23% (ANDIAB).

Table 5 summarizes the global coronary risk among the three populations according to the model of Wood et al. [21]. Neither the per cent with low or mild coronary risk nor that with the very high risk differed among the populations. Differences that could be demonstrated were a lower per cent of high risk and a higher per cent of moderate risk in the Australian population. The greatest percentage of participants had either moderate or high risk (85, 87, 86% for ANDIAB, DIABCARE, and QUALIDIAB, respectively).

4. Discussion

Diabetes quality of care has been measured by several organizations [3,4,22]. In our case, the primary goal was to compare the performance of preventive processes (monitoring of clinical and metabolic indicators and of cardiovascular risk factors) and their outcomes in people with type 2 diabetes among three populations (ANDIAB, DIABCARE and QUALIDIAB) with different socioeconomic characteristics, health care organizations and expenditures. We additionally estimated their coronary heart disease risk. We hypothesized that health care expenditures and risk factor monitoring would be related. Secondarily, we verified the relationship between rates of such monitoring and of outcomes at recommended target values recorded in the total number of people with type 2 diabetes belonging to these three databases, matched for age, gender and duration of diabetes (4540 people in each database).

As hypothesized, the average weighted scores of process indicator performance for the DIABCARE population (84%) were significantly higher that those of the QUALIDIB population (68%), while the ANDIAB population occupied an intermediate position (81%). Since the former and the latter databases belong to countries with the highest socioeconomic conditions and investments in health care (while QUALIDIAB has the lowest) these results suggest that such characteristics play a significant role in the performance of risk factor monitoring. Nevertheless, the magnitude of the differences in process performance was far lower than that of health care investment, and in no population did the overall documented compliance with risk factor monitoring approach the accepted 100% standard. Since the importance of such monitoring in the early detection and treatment of diabetes-related complications is well-established, improvement of risk factor monitoring should remain a target for future interventions.

A great difference was recorded between the weighted average values of process performance and those corresponding to patients at target values: while the former were around 80%, the latter dropped down to about 30%.

In all databases, the majority of patients were overweight or obese, suggesting a low adherence to healthy life styles and thus favoring obesity [23]. Despite strong evidence of the beneficial effect of low SBP upon macroangiopathic complications, SBP <130 mmHg was recorded only in 19 to 27% of cases. Similarly, in all three populations most patients had A1c values above those recommended to prevent complications by long-term studies [5–12] and international standards [17–19]. People with values above those recommended were also observed for total cholesterol and TG (Table 4) [24]. The inadequate control of glycaemia and CVRFs as well as the high risk for the development of a coronary events present in each population (Table 5) indicate that the potential benefits to be derived from metabolic control to prevent diabetes complications are not being generally achieved. Such unfavorable trend predicts future increases in the development and progression of diabetes chronic complications, with the consequent rise in the cost of care. Thus, interventions attempting to improve such patterns should result in direct benefits for both patients and health care payers.

Except for measurement and results of BMI and A1C, we found a small but significant difference in intermediate outcomes among the three databases. However, the magnitude of such relationship (around 10% in most cases) closely related to the large size (3 times 4540 patients) and homogeneity of our sample, and would at best be only of marginal clinical significance.

Monitoring of risk factors was related to economic investment, being highest in DIABCARE and lowest in QUALIDIAB, but attainment of treatment target values did

not show the same pattern. This observation suggests that the improvement in the rate of risk factor monitoring (and the economic investment needed to achieve that monitoring) does not automatically translate into a parallel improvement of their respective outcomes sufficient to predicatively reduce chronic complications.

The improvement in quality indicators requires a sequence of events that begins with the measurement itself. Process information must be first correctly interpreted and should trigger the implementation of actions aimed at normalization (e.g., appropriate treatment prescription). Patients will then need to have access to this treatment, should accept it and comply with the new regimen. Finally, there must be a feedback loop for evaluating the effect of treatment and, when necessary, prescription adjustments to optimize results.

We hold that the above mentioned sequence is an educative and system process rather than an economic one. There is clear evidence that education of general practitioners [25,26] and people with diabetes [26,27] is an effective strategy to improve care and the quality of life of people with diabetes and at the same time reduce the socioeconomic cost of diabetes [28]. Intensive glycemic control, intensified hypertension control and serum cholesterol level reduction in people with type 2 diabetes also appear to be cost-effective [4,29].

Even though ANDIAB, DIABCARE and QUALIDIAB used similar indicators and recording systems, they could have populated their registries with differing levels of completeness or accuracy, and as a consequence comparison of their data would not be totally valid. However, it seems unlikely that the striking similarities found in the quality indicators are merely a coincidence. Moreover, the results presented are supported by other studies where quality of care has been measured. We believe that our study provides additional evidence that the care delivered to people with diabetes is generally not achieving the agreed goals.

Our data also suggest that programs like ANDIAB, DIABCARE and QUALIDIAB provide a basis to systematically measure diabetes care processes and outcomes needed to make adjustments and measure their effectiveness. Implementation of such registries provides knowledge about current care and defines the magnitude of deficiencies. Their analysis permits an early detection of care deficiencies, the implementation of strategies for corrective actions, and impact evaluation of the quality of diabetes care. Such an approach would certainly optimize the use of human and economic resources, contribute to decrease the heavy burden of diabetes vascular complications, and improve the quality of life of people with diabetes.

Conflict of interest

The authors declare that they have no conflict of interest.

Addenda

ANDIAB is coordinated by Jeff Flack and Stephen Colagiuri on behalf of the National Association of Diabetes Centers [NADC]; DIABCARE France was coordinated by Line Kleinebreil. Qualidiab is coordinated by Juan José Gagliardino with an International Advisory Committee formed by Pablo Aschner (ALAD); Antonio Chacra (former IDF Vice president); Evelyn Eschwege (Europe); Goyka Roglic (WHO); Gloria López (Latin America); Susana Campanella (IDF-SACA and DOTA); Errol Morrison (IDF-NA and DOTA); and Alberto Barcelo (PAHO). Euro-Lat Link Center Representative: Line Kleinebreil, France. Representatives-by-country Committee: Argentina, Isaac Sinay; Brazil, Adriana Costa e Forti; Chile, M. Cristina Escobar; Colombia, Iván Darío Escobar; Paraguay, Felicia Cañete; Uruguay, Ramiro Draper.

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