Retrospective Analysis of 55,769 HbA1c EQA Results Obtained From Professional Laboratories and Medical Offices Participating in Surveys Organized by Two European EQA Centers Over a Nine-Year Period

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External Quality Assessment (EQA) is an essential tool for laboratories to monitor the performances of their analyses. It also allows a comparison of methods and types of laboratories (professional laboratories vs. medical offices). We, therefore, compared 55,769 HbA1c EQA results obtained between 1999 and 2008 by laboratories participating in EQA schemes organized by two European centers, Switzerland (center 1) and France (center 2). We used simple, nonparametrical statistics suited to EQA results to calculate the yearly and global precision performances. All the results, including the outliers, were included in the calculations. The best global precision performances were obtained by professional laboratories and medical offices using DCA POCT devices, followed by

professional laboratories with the Integra, Hitachi, Cobas Mira, and HPLC groups of devices, and finally by both types of laboratories with the NycoCard POCT devices. When considering yearly precision performances, an overall improvement over time was observed for almost all diagnostic devices of center 1, whereas the trend was less clear for center 2. The HbA1c EQA results collected and analyzed over a 9-year period showed that the DCA POCT devices used either by professional laboratories or medical offices had better reproducibility than laboratory devices (other than POCT) and that a general improvement of yearly precision performances was observed, especially when frequent EQA schemes were organized. *J. Clin. Lab. Anal.* 25:337–343, 2011. © 2011 Wiley-Liss, Inc.

Key words: EQA statistical procedure; external quality assessment; HbA1c; interlaboratory precision performance; POCT

INTRODUCTION

The increasing incidence of type 2 diabetes in the world population is reaching epidemic proportion, thus rendering the measurement and surveillance of blood glucose and glycohemoglobin (HbA1c) of fundamental importance (1,2). It has been shown that normalizing HbA1c levels in diabetic patients can reduce the incidence and progression of microvascular complications (retinopathy and nephropathy) as well as cardiovascular morbidity and mortality. The tight control of HbA1c is, therefore, of crucial importance for patients, especially when treated with insulin (3), and recently, the American Diabetes Association (ADA) has even

recognized this parameter as a marker to diagnose diabetes (4). In order to compare results obtained with different methods, an IFCC working group made important efforts over the last few years to standardize

Abbreviations: ADA, American Diabetes Association; AFSSAPS, Agence française de sécurité sanitaire des produits de santé; CSCQ, Swiss Center for Quality Control; EQA, external quality assessment; PoCR, Percentage of Correct Results.

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the HbA1c measurement, as summarized by Mosca et al. (5).

Participation in external quality programs is the standard approach for medical laboratories to maintain the quality of the analyses and to compare the performances of diagnostic devices (6).

This study includes 55,769 HbA1c EQA results collected by two European EQA providers, i.e., the Swiss Center for Quality Control (CSCQ, Switzerland; center 1) and the Agence française de sécurité sanitaire des produits de santé (AFSSAPS, France; center 2). All results were collected between 1999 and 2008; the participation in HbA1c EQA surveys has been mandatory since 2000 in Switzerland and 1979 in France.

The data allowed the calculation of the interlaboratory imprecision of results obtained in field conditions with POCT devices or with other laboratory devices, as well as to study the evolution of such imprecision. Because Swiss physicians are authorized to perform a set of analyses in their medical offices, the results also allowed comparing the performances of professional laboratories with medical offices.

MATERIALS AND METHODS

The CSCQ (center 1) has been organizing EQA surveys four times a year since 2000, which is the minimal requirement according to Swiss QUALAB regulations (7). However, since 2003, two additional optional surveys have been organized yearly. Each participant, be it a professional laboratory or a medical office, received on a regular basis a ready-to-use liquid sample manufactured by Consolidated Technologies (Austin, TX)—now part of Thermo Scientific—that guaranteed the samples' stability, homogeneity, and quality. Participants had 2 weeks to measure the HbA1c and send the result to the CSCQ.

The results were first separated by year, survey, type of laboratory (professional laboratories and medical offices), and finally by method/device. The statistical parameters were then calculated when at least ten results were available. All results presented in this study are expressed according to the NGSP standard, the range 4–6% corresponding to the normal level of HbA1c.

Simple, nonparametric (np) statistics were chosen to analyze EQA results because they are well adapted to this type of data. Indeed, some studies (8–10) showed that they are not sensitive to extreme or aberrant results, which are frequently observed in EQA results. Sample conservation, calibration problems, method errors, samples exchange, and typing errors may in fact affect not only patients' (11) but also EQA results (12). Data from laboratories using the same device were considered as (near) normally distributed. Therefore, for each

survey, after separating all the data, we calculated the following four np parameters: (a) the target value of data from laboratories using the same device—the target value is the median here, the mean being too sensitive to extreme results; (b) the np equivalent of standard deviation which derives, for normally distributed data, either from the interquartile range— $\sigma_{np} = [P75-P25]/1.349$, with P being the percentile—or from the median absolute deviation (MAD)— $\sigma_{np} = \text{MAD}/0.6745 = 1.483 \times \text{MAD}$ —(8,13) because the interquartile range corresponds to two MAD; (c) the CV ($\text{CV}_{np}\% = \sigma_{np} \times 100/\text{median}$); and (d) the CV_{np} error, i.e., the 95% confidence interval of the CV (14). Because the Swiss tolerance for HbA1c is 15% during the period under consideration, as defined by the QUALAB, the percentage of results that fell in the range $\text{median} \pm 15\%$ (PoCR, percentage of correct results) was calculated for each survey using the peer group median. For each level and for each diagnostic device, the following weighted global parameters were then obtained: median, CV_{np} , CV_{np} error, and PoCR. We finally calculated the yearly weighted parameters for each level and diagnostic device. The evolution of the yearly weighted CV_{np} and PoCR was determined by linear regressions and the slopes were tested for statistical significance (14).

The two concentration levels available—normal (4.3–6.3%) and abnormal (7.2–13.0%)—were analyzed and all results were included in the calculations, including outliers. The advantage is to avoid eliminating results that are not included in an arbitrary range, e.g., two or three standard deviations. For professional laboratories, there were enough EQA results to be analyzed for four groups of diagnostic devices: Cobas Mira (i.e., Cobas Mira, Mira Plus, and Mira S; Roche Diagnostics, Mannheim, Germany), Integra (400, 700, and 800; Roche Diagnostics, Mannheim, Germany), DCA (i.e., DCA 2000, Plus, and Vantage; Siemens/Bayer, Munich, Germany), and NycoCard (Axis-Shield, Oslo, Norway). The number of HPLC data was insufficient for them to be included in the study. For medical offices, the results obtained with the DCA and the NycoCard groups of diagnostic devices were analyzed.

The DCA and NycoCard diagnostic devices are closed systems with reagents originating from a single manufacturer. Although other devices are open systems, we only considered the results obtained with reagents from a single manufacturer (Roche), which was also by far the most frequent in center 1. We applied the same criteria for center 2.

The AFSSAPS (center 2) has been organizing one survey per year, except in 2005 when there was none. Participants were professional laboratories only, which were sent lyophilized samples manufactured from

human blood with endogenous HbA1c (personal communication) by Biolabo (Maizy, France). The HbA1c results analyzed for center 2 corresponded to the same concentration levels available in center 1, and the same statistical calculations were applied. When available, we also selected the same diagnostic devices among the results provided by center 2, except for the Hitachi diagnostic devices (704, 717, and 912; Roche Diagnostics/Hitachi, Mannheim, Germany) with TinaQuant reagents (Roche). These latter devices were chosen because it was interesting to compare these results with those obtained in a previous study (9). We also studied the results provided by HPLC devices, the Menarini-Arkray HA-8121 and HA-8140 devices (Kyoto, Japan) and the Tosoh A1c 2.2 devices (Tokyo, Japan). Finally, we applied the same criteria to reagents as for center 1.

RESULTS

Table 1 shows the 33,193 EQA results obtained by medical offices (center 1) that used two groups of POCT diagnostic devices, the DCA and the NycoCard. The latter was the most common device used in medical offices. The HbA1c medians were always higher with the NycoCard compared with all the other diagnostic devices (Cobas Mira, DCA, and Integra), which is probably owing to a matrix effect linked to EQA samples. As far as the slopes are concerned for both diagnostic devices and concentration levels, they are all negative for the yearly $CV_{np}\%$ ($CV_{np}\%$ reduction) and all positive for the yearly PoCR (PoCR increase). In all

cases, the slopes had a coherent positive tendency (yearly $CV_{np}\%$ reduction and yearly PoCR increase). All slopes were statistically significant for the NycoCard group of diagnostic devices.

Figure 1 illustrates an example of the yearly $CV_{np}\%$ and medians calculated with the EQA results obtained with the DCA group of diagnostic devices (center 1).

Table 2 shows the 2,852 results obtained by professional laboratories (center 1) using four groups of diagnostic devices. For the normal concentration level, there were four negative slopes out of four for the $CV_{np}\%$ and three positive slopes out of four for the PoCR. Three groups of diagnostic devices had a coherent positive tendency (yearly $CV_{np}\%$ reduction and yearly PoCR increase). For the abnormal level, there were three negative slopes out of four for the $CV_{np}\%$ and two positive slopes out of four for the PoCR. Two groups of diagnostic devices had a coherent positive tendency and the users of the Cobas Mira group of diagnostic devices had a coherent negative tendency ($CV_{np}\%$ increase and PoCR reduction). One slope was statistically significant for the normal level and three slopes for the abnormal level.

Table 3 shows the 12,542 results obtained by professional laboratories (center 2) with the two concentration levels. The EQA samples used by this center did not show any matrix effects with the NycoCard. For the normal concentration level, there was one negative slope out of four for the $CV_{np}\%$ and two positive slopes out of four for the PoCR. The users of the Integra and NycoCard groups of diagnostic

TABLE 1. HbA1c Results ($n = 37,193$) and Precision Performances Obtained From Medical Offices Using Different Diagnostic Devices With EQA Blood Samples From Center 1

Diagnostic system	Normal HbA1c concentrations Center 1		Abnormal HbA1c concentrations Center 1	
	Closed system DCA	Closed system NycoCard	Closed system DCA	Closed system NycoCard
Period	2000–2008	2000–2008	2000–2008	2000–2008
Number of surveys	22	26	20	22
Number of results	3,429	16,475	3,228	14,061
Weighted median HbA1c%	5.6	7.5	9.0	11.4
Range	4.3–6.4	6.3–8.8	7.2–11.4	8.7–17.1
Weighted $CV_{np}\%$	4.1	11.4	3.3	11.1
Range	2.4–6.9	4.8–23.1	1.9–4.8	8.4–17.7
Weighted PoCR	99.0	83.6	99.2	83.5
Range	96.6–100	59.3–94.6	93.3–100	65.3–94.4
Yearly $CV_{np}\%$ –Slope	–0.2192↓	–0.9818↓	–0.1880↓	–0.7931↓
Yearly PoCR–Slope	0.2101↑	2.2853↑	0.1991↑	2.2981↑

Wherever there was an improvement, the background of the arrow was grey (when the slope of the linear regression of the yearly $CV_{np}\%$ was negative [↓ or ↘] and when the slope of the linear regression of the PoCR was positive [↑ or ↗]). When the slope was statistically significant, the arrow was plain [↓ or ↗], when not statistically significant, the arrow was outlined [↘ or ↗]. “Closed system” means that the diagnostic device had to use specific reagents from a given manufacturer.

devices had a coherent negative tendency ($CV_{np}\%$ increase and PoCR decrease) and the users of the DCA group of diagnostic devices had a coherent positive tendency. For the abnormal level, there were three negative slopes out of four for the $CV_{np}\%$ and two positive slopes out of four for the PoCR. Two groups of diagnostic devices had a coherent positive tendency (yearly $CV_{np}\%$ reduction and yearly PoCR increase) and the NycoCard users had a coherent negative tendency. Two slopes were statistically significant for the normal level, and three for the abnormal level.

Fig. 1. Nine-year evolution of yearly weighted $CV_{np}\%$ and median, calculated with 3,228 EQA HbA1c results (abnormal concentrations) obtained by medical offices using the DCA diagnostic devices (center 1). The slope represents the linear regression of the yearly weighted $CV_{np}\%$. Vertical lines represent the 95% confidence interval.

The 3,182 results obtained by professional laboratories (center 2) using HPLC devices for measuring HbA1c are shown in Table 4. As far as the slopes are concerned for both diagnostic devices (Menarini and Tosoh) and concentration levels, they are all negative for the yearly $CV_{np}\%$ ($CV_{np}\%$ reduction) and all positive for the yearly PoCR (PoCR increase). In all cases, the slopes had a coherent positive tendency (yearly $CV_{np}\%$ reduction and yearly PoCR increase). One slope was statistically significant for the Menarini group of diagnostic devices (abnormal level).

If we consider all slopes of center 1, 11 out of 12 were negative for the $CV_{np}\%$ and 9 out of 12 were positive for the PoCR, whereas for center 2, there were 4 negative slopes out of 8 for the $CV_{np}\%$ and 4 positive slopes out of 8 for the PoCR. In addition, if we consider the HPLC slopes, there were 8 negative slopes out of 12 for the $CV_{np}\%$ and 8 positive slopes out of 12 for the PoCR.

DISCUSSION

POCT Precision Performances

The precision performances of medical offices were similar to those of professional laboratories for the two POCT devices (DCA and NycoCard). This is an interesting result, because in previous studies concerning other parameters professional laboratories obtained better results than medical offices (9,15,16).

$CV_{np}\%$ and PoCR

Another important finding of this study is that global precision performances of diagnostic devices are

TABLE 2. HbA1c Results ($n = 2,852$) and Precision Performances Obtained From Professional Laboratories Using Different Diagnostic Devices With EQA Blood Samples From Center 1

Diagnostic system	Normal HbA1c concentrations Center 1				Abnormal HbA1c concentrations Center 1			
	Closed system		Closed system		Closed system		Closed system	
	DCA	Integra	Cobas Mira	NycoCard	DCA	Integra	Cobas Mira	NycoCard
Period	2000–2008	2000–2008	2000–2006	2001–2008	2000–2008	2000–2008	2000–2006	2001–2008
Number of surveys	19	23	14	17	18	21	14	15
Number of results	473	476	264	251	453	450	265	220
Weighted median %	5.5	5.6	5.5	7.5	9.2	9.8	10.6	11.6
Range	4.4–6.4	4.8–6.2	4.9–6.0	6.3–8.8	7.4–11.3	7.7–13.0	7.8–12.8	9.2–18.0
Weighted $CV_{np}\%$	3.8	4.2	7.0	10.8	3.4	5.0	6.9	8.8
Range	1.7–7.3	2.1–7.1	3.2–11.0	2.9–20.0	0.9–5.6	1.5–7.7	4.8–10.1	4.8–18.7
Weighted PoCR	98.1	97.1	91.3	86.9	99.1	96.9	94.7	80.5
Range	80.0–100	86.7–100	79.0–100	54.6–100	94.4–100	86.4–100	81.8–100	61.5–94.4
Yearly $CV_{np}\%$ –Slope	–0.1797↓	–0.1771↓	–0.3920↓	–0.9131↓	–0.1858↓	–0.3505↓	0.2237↑	–0.9545↓
Yearly PoCR–Slope	–0.0538↓	0.2759↑	0.4463↑	3.5650↑	–0.2836↓	0.3734↑	–2.3060↓	0.9387↑

For the legend, see Table 1.

TABLE 3. HbA1c Results ($n = 12,542$) and Precision Performances Obtained From Professional Laboratories Using Different Diagnostic Devices With EQA Blood Samples From Center 2

Diagnostic system	Normal HbA1c concentrations Center 2				Abnormal HbA1c concentrations Center 2			
	Closed system		Closed system		Closed system		Closed system	
	DCA	Integra	Hitachi	NycoCard	DCA	Integra	Hitachi	NycoCard
Period	1999–2007	1999–2007	1999–2007	2001–2007	1999–2007	1999–2007	1999–2007	2001–2007
Number of surveys	7	7	7	5	8	8	8	6
Number of results	3,599	730	1,272	331	4,005	855	1,359	391
Weighted median %	5.5	5.6	5.6	5.8	10.1	10.1	9.5	8.9
Range	5.1–6.0	5.4–6.0	5.3–5.9	5.4–6.5	8.0–12.2	8.2–12.4	7.3–11.4	7.2–10.4
Weighted CV _{np} %	4.3	4.4	4.9	12.0	3.3	4.1	5.1	11.7
Range	3.7–5.7	3.4–5.3	3.9–6.5	9.6–16.8	2.8–3.7	3.5–5.2	4.1–5.7	9.1–14.1
Weighted PoCR	98.8	98.4	95.4	79.8	99.5	98.7	95.9	79.5
Range	98.2–99.7	95.8–100	94.4–96.8	76.6–86.4	98.3–100	97.7–100	93.7–98.0	70.1–89.2
Yearly CV _{np} %–Slope	–0.1860↓	0.0644↑	0.1364↑	1.3255↑	–0.0794↓	–0.1620↓	–0.2214↓	0.9874↑
Yearly PoCR–Slope	0.1919↑	–0.6503↓	0.3742↑	–1.2597↓	0.1184↑	–0.3069↓	0.1921↑	–2.5577↓

For the legend, see Table 1.

TABLE 4. HbA1c Results ($n = 3,182$) and Precision Performances Obtained From Professional Laboratories Using HPLC Diagnostic Devices With EQA Blood Samples From Center 2

Diagnostic system	Normal HbA1c concentrations Center 2		Abnormal HbA1c concentrations Center 2	
	HPLC	HPLC	HPLC	HPLC
	Menarini	Tosoh	Menarini	Tosoh
Period	1999–2007	1999–2007	1999–2007	1999–2007
Number of surveys	7	7	8	8
Number of results	819	625	942	796
Weighted median %	5.5	5.4	9.5	9.9
Range	5.2–5.9	5.0–5.6	7.6–11.8	7.7–12.2
Weighted CV _{np} %	4.3	4.5	3.1	3.5
Range	3.6–5.7	1.3–6.7	2.2–4.7	1.7–4.3
Weighted PoCR	99.1	98.6	99.3	99.6
Range	97.1–100	97.6–100	95.5–100	98.2–100
Yearly CV _{np} %–Slope	–0.0117↓	–0.6286↓	–0.2584↓	–0.0651↓
Yearly PoCR–Slope	0.1887↑	0.2003↑	0.3205↑	0.0275↑

For the legend, see Table 1.

remarkably similar in both centers. Although the surveys' frequencies and the EQA samples were not identical in the two centers (different manufacturers, liquid vs. lyophilized), the DCA ranked first followed by Integra, Hitachi, and HPLC, then by Cobas Mira and finally by NycoCard. This suggests that the precision performances—calculated with our statistical method on EQA results—reflect performances in field conditions. We can also conclude that the imprecision error introduced by the reconstitution step of the lyophilized EQA samples of center 2 was negligible.

Our results are in agreement with other studies which pointed out that DCA diagnostic devices were user

friendly, with few manual steps, and obtained good precision performances (CV) when compared with reference HPLC methods (17,18), whereas NycoCard devices were less user friendly and obtained higher CV in duplicate analysis (17).

Furthermore, it was interesting to compare our CV_{np} % with that of other studies. On the one hand, for professional laboratories, the CV_{np} % obtained in this study with the Cobas Mira, Hitachi, and Integra groups of diagnostic devices are higher when compared with those obtained with the same devices in our previous study on the glucose parameter (9), showing that devices used for measuring glucose are more

reproducible than those for HbA1c. On the other hand, the HbA1c $CV_{np}\%$ calculated for DCA and Integra diagnostic devices are similar to the CV published by the College of American Pathologists in their 2010 GH2-A survey (19).

Even if the HPLC is the reference method for measuring the HbA1c, it did not obtain a better reproducibility in EQA results than immunochemistry devices.

We can also compare our $CV_{np}\%$ results with the HbA1c quality specifications for analytical imprecision defined both by the ADA and C. Ricós. At first, ADA recommendations stated that the analytical coefficient of variation (CV_a , related to within-laboratory imprecision) should be less than 3%. Second, biological variation can be used to define quality specifications as proposed by C. Ricós on the Westgard Website (20). For HbA1c, the within-subject (intraindividual) coefficient of variation, i.e., $CV_w = 3.4\%$, measures the magnitude of concentration fluctuations from the set point of each individual. Therefore, quality specification is defined in terms of analytical imprecision as $CV_a = 0.5CV_w = 1.7\%$ at the desirable level and as $CV_a = 0.75CV_w = 2.6\%$ at the minimum level. Considering our $CV_{np}\%$ results and assuming that the variability observed between the users of the same group of diagnostic devices with reagents of the same manufacturer (interlaboratory performances) is not very different from the within-laboratory imprecision, we can conclude that the majority of diagnostic devices analyzed in this study did not reach even the less stringent analytical imprecision goal. Obviously, the CV calculated in field conditions (EQA schemes) are usually higher than those calculated in well-designed studies (21). However, efforts are to be made to reduce such imprecision.

In 2011, the QUALAB decided to change the tolerance from 15 to 9%, which reduces the PoCR, especially for devices with high CV_{np} . When a laboratory that participates in four surveys per year has two or more results that fall outside the tolerance, its yearly certificate reports an insufficient performance. This can lead to a refusal from the social insurance to reimburse the cost of the HbA1c analyses.

Slopes

We noticed discrepancies between centers 1 and 2. Indeed, even if for center 1 some were not statistically significant, most of them were negative for the $CV_{np}\%$ ($CV_{np}\%$ reduction) and positive for the PoCR (PoCR increase). This suggests that there was a trend toward improved precision performances, as confirmed by findings of other studies (9,22,23). For center 2, with

the same devices as in center 1, the trend was not clear, because only half the slopes indicated improved precision performances. However, if we also consider the performances of HPLC devices, then the trend was toward improved precision performances for center 2 as well.

Such discrepancies are exemplified in the precision performances of NycoCard diagnostic devices from both centers: there were precision performance improvements in center 1 only, which were even statistically significant for medical offices; no improvement was observed in center 2. This could be owing to the frequency of EQA schemes: medical offices and professional laboratories of center 1 participated in more schemes than those of center 2. After each survey, the CSCQ sent EQA reports, including technical recommendations, on how to improve performances and had also the opportunity to give telephone advice when called by participants. This suggests that, for all diagnostic devices, regular and frequent participation in EQA schemes could improve performances. This was quite clear with the users of NycoCard diagnostic devices who had the lowest precision performances but obtained the highest improvements (center 1) for the $CV_{np}\%$ and PoCR, which is very encouraging.

It would be interesting to compare center 2 performances with data collected by other French EQA scheme organizers in order to double check the role of frequent participation.

In Figure 1, the $CV_{np}\%$ corresponding to 2004 is outside the general trend. This is owing to the fact that the $CV_{np}\%$ was related to a single survey, whereas the other $CV_{np}\%$ was weighted being calculated with the results obtained from two or three surveys.

Matrix Effect

The matrix effect (increase of the HbA1c values) was observed in the results provided by the users of the NycoCard devices participating in center 1 surveys. For practical (volume, stability, analytes concentrations) and ethical reasons, it is common to use processed blood during EQA surveys (24–27). The matrix effect observed with many quality control samples—and for which the explanation remains unclear—did not allow us to evaluate the accuracy of HbA1c devices. However, in our experience, the matrix effect does not change the interlaboratory variability. This is confirmed by the results of center 2: no strong matrix effect is observed with the NycoCard series of devices and the performances are similar to that of center 1. Furthermore, a recent publication by Lenters-Westra and Slingerland (28) based on patient samples confirmed our findings: they showed that the NycoCard devices, even if used in

controlled conditions by a single trained technician, did not meet the accepted analytical precision performance criteria, whereas the DCA devices reached them.

Conclusions

In conclusion, when frequent HbA1c EQA schemes were organized, we observed an overall improvement of precision performances for all devices. Furthermore, medical offices and professional laboratories using DCA POCT diagnostic devices clearly reached better precision performances than users of other laboratory devices—Integra, Hitachi, Cobas Mira, and HPLC devices—and all Nycocard users achieved the lowest precision performances. All these performances have to be taken into account because it obviously impacts on patients. Finally, we can underline that even if improvements are observed, efforts should be made to further reduce the interlaboratory variability.

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