Diagnosing Diabetes Mellitus: Performance of Hemoglobin A\textsubscript{1c} Point-of-Care Instruments in General Practice Offices

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BACKGROUND: Hemoglobin A\textsubscript{1c} (Hb A\textsubscript{1c}) measurement by hospital laboratory instruments, but not by point-of-care (POC) instruments, has been recommended for use to diagnose diabetes mellitus. We evaluated results from 13 Hb A\textsubscript{1c} external quality assurance (EQA) surveys over a 6-year period in Norway, from both POC instruments used in general practice (GP) offices and instruments in hospital laboratories, against the analytical quality specifications recommended for use of Hb A\textsubscript{1c} to diagnose diabetes mellitus.

METHODS: All GP offices (n = 1288) and hospital laboratories (n = 52) measuring Hb A\textsubscript{1c} in Norway participated in the EQA survey. The percentage of participants that performed measurements within the quality specifications was calculated. Pooled within-laboratory CVs were estimated for the Afinion, DCA 2000, DCA 2000+, DCA VantageTM, and Nycocard Hb A\textsubscript{1c} Reader instruments and for hospital laboratory instruments.

RESULTS: Between 60% to 90% of Afinion and DCA users and hospital laboratories performed Hb A\textsubscript{1c} measurements within the quality specifications for both trueness (6.0%) and imprecision (CV \leq 2.0%) at 2 levels in each EQA survey. The pooled within-laboratory CVs for the Afinion and DCA instruments and hospital laboratories were below the recommended limits of 2.0% for most of the surveys.

CONCLUSIONS: A large proportion of GP offices using Afinion and DCA POC instruments to measure Hb A\textsubscript{1c} fulfill the analytical quality specifications for diagnosing diabetes mellitus, and these instruments demonstrate analytical quality comparable to that of hospital laboratory instruments. When GP offices participate in a stringent quality assurance program and generate Hb A\textsubscript{1c} measurements that meet analytical quality specifications, these measurements can be recommended for use to diagnose diabetes mellitus.

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measurements or the oral glucose tolerance test (3, 4), and each country should decide what diagnostic criteria they will use to diagnose diabetes (3). In Norway, the Norwegian Directorate of Health recommends that Hb A1c should be the primary diagnostic criterion (7, 8). NACB recommends using hospital laboratory Hb A1c instruments for the diagnosis of diabetes because point-of-care (POC) Hb A1c assays are “currently not sufficiently accurate for this purpose” (5). The quality of evidence for this recommendation is rated moderate, meaning that “further research is likely to have an important impact on the recommendation.” The WHO allows the use of POC Hb A1c assays when this is the “only option available or when a stringent quality assurance program is in place” (3). It would be a great advantage at general practice (GP) offices to use POC instruments for this purpose and have the Hb A1c results during the consultation. All Hb A1c instruments used in Norway are traceable to the IFCC reference method (9). Furthermore, 99% of the Norwegian primary care offices and all hospital laboratories voluntarily participate in the same EQA programs through the Norwegian Quality Improvement of Primary Care Laboratories (Noklus) (www.Noklus.no). To our knowledge, no studies have investigated the performance of Hb A1c POC instruments based on results from EQA surveys (10).

In this study we used data from 13 EQA Hb A1c surveys from 2006 to 2012 and compared the results of POC instruments at GP offices with the analytical performance criteria for the diagnosis of diabetes, which are based on CAP (6), NACB (5) recommendations, and with the performance of hospital laboratory instruments.

Material and Methods

Participants

From 2006 to 2012, Noklus distributed 13 Hb A1c EQA surveys to all GP offices and hospital laboratories in Norway that analyze Hb A1c. In this longitudinal multicenter study, data from these EQA surveys were used. The POC instruments used at the GP offices were the Afinion (Axis-Shield PoC), DCA 2000 Analyzer, DCA 2000+ Analyzer, DCA VantageTM Analyzer (Siemens Healthcare Diagnostics), and Nyocard Hb A1c Reader (Axis-Shield PoC). All participants with the different DCA models were merged to one instrument group. The hospital laboratories participated with the Architect c8200, Architect ci8200 (Abbott), Advia 1200, Advia 1650 (Siemens), Bio-Rad D10 (Bio-Rad), Cobas 6000, Cobas Integra, Cobas Integra 400, Cobas Integra 400 Plus, Cobas Integra 800 (Roche Diagnostics), Dimensions RXL, Dimensions Vista 1500 (Siemens), Hitachi 902, Hitachi 912 (Roche Diagnostics), Modular P (Roche Diagnostics), Tosoh HPLC G7, Tosoh HPLC G8 (Tosoh Bioscience), Variant Classic HPLC, and Variant II HPLC, (Bio-Rad Laboratories). The hospital laboratory instruments were merged into a hospital laboratory group because there were only 1–9 participants with each instrument in each survey. The number of participants in the 13 Hb A1c EQA surveys is shown in Fig. 1. In this report we use the term “laboratory” for both GP offices and hospital laboratories.

EQA Material

Venous blood was collected into tubes containing EDTA. Samples were obtained from healthy volunteers (with Hb A1c levels within reference intervals) and from patients with diabetes (Hb A1c values above the upper limit of the reference interval) and mixed gently. Blood from a minimum of 2 donors with Hb A1c at each level were distributed fresh in cryovials (Sarstedt) within 12 h after sampling. The stability of the EQA material was tested at the Laboratory of Clinical Biochemistry (Haukeland University Hospital, Bergen, Norway) based on ISO 13528 (11). Two cryovials at each Hb A1c level were kept first at room temperature, and then 1 vial was frozen 1 day after the collection of the blood. The remaining vials were kept at 4 °C from day 2 until they were frozen after 4 days. The EQA materials were thawed and the Hb A1c analyzed at the same time on the Variant II HPLC (Bio-Rad Laboratories) in 6 replicates. The Hb A1c concentration was stable in this period. Because the stability of the EQA material can be method dependent, the results from the different POC instruments analyzed the first, second, third, or fourth day after the participants received the EQA material were examined. There were no differences in the median values, indicating that the EQA material was stable for this time period (data not shown). Furthermore, it has been found that Hb A1c values in EDTA whole blood samples were stable at both room temperature and 4°C for more than 4 days for measurement using the Siemens DCA2000+, Tosoh G7 and G8, Bio-Rad Variant II NU, and Trinity Biotech ultra2 (12).

Target Value

The target values for the EQA materials were established at the European Reference Laboratory for Glycohemoglobin (the Netherlands). Values were assigned in triplicate with 2 IFCC secondary reference measurement procedures that were IFCC calibrated (13). Method 1 is HA 8160, HPLC, ionic exchange (Menarini) and method 2 is PDQ, HPLC, boronat affinity Principal (Primus/Trinity Biotech). The results were given in both % Hb A1c (DCCT/NGSP unit) and mmol/mol Hb A1c (IFCC unit). In Norway the DCCT/
NGSP unit is used. The target value is the mean from triplicate measurements from the 2 methods (see Table 1 in the Data Supplement that accompanies the online version of this article at http://www.clinchem.org/content/vol59/issue12). The master equation from Hoelzel et al. (14) was used for calculations from millimoles per mole Hb A1c (IFCC unit) to % Hb A1c (DCCT/NGSP unit).

EQA SURVEY
The GP offices and hospital laboratories received 500 µL of the fresh EQA material in each level, with an Hb A1c level from 5.0% to 5.8% Hb A1c (30.9–39.6 mmol/mol Hb A1c) in the level within the reference interval and from 6.8% to 7.9% Hb A1c (51.3–62.6 mmol/mol Hb A1c) for the level above the upper limit of the reference interval in the 13 surveys (see online Supplemental Table 1). The samples were shipped without temperature control, and the participants kept the EQA materials at 4°C until analysis. Participants analyzed each EQA material on 2 different days (1 × 2) within a 4-day period. In the response forms, the participants were asked to return the analytical results with information about the instrument used and the lot number of the reagent as well as the date of analysis. The scheme was performed twice a year.

STATISTICS
All calculations were performed using the % Hb A1c (DCCT/NGSP) unit. The participant’s performance was evaluated with respect to trueness based on CAP limits for accuracy (6). An estimate of the trueness was defined here as the degree of closeness of the mean of the participant duplicate measurements and the target value. To obtain a measure of the trueness of a method, the mean Hb A1c was calculated from the mean of duplicate measurements from each participant for each instrument group at the 2 Hb A1c levels, and the percentage deviation from the target value was calculated. The deviation of results from the target value was evaluated against the criteria of 5.0%, 6.0%, and 7.0% (6).

Whereas the CAP deals with quality specifications for 1 result from a target value, we used the deviation of the mean of duplicate results for 2 different samples. This makes our quality specifications a little bit wider than the CAP specifications, but it is then an estimate of the trueness.

Because it was not possible to obtain precision measures in the form of CVs from internal QC for all the participants, we used the difference between duplicate measurements as estimates of the precision. To be able to differentiate between the upper limit of the reference interval (6.0% Hb A1c) and the cutoff 6.5% Hb A1c for diagnosis of diabetes, the difference between duplicates must be between 0.2% and 0.3% Hb A1c (15). This corresponds to the NACB limit for imprecision of ±2% (5). These differences between duplicates were therefore evaluated against the quality specifications of 0.2%, 0.3%, and 0.4% Hb A1c (5, 15). In addition, CVs were calculated using duplicate measurements from the last 6 surveys that each GP office and

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**Fig. 1. Number of participants in the 13 Hb A1c EQA surveys from 2006–2012.**
The 4 shadings from top to bottom of each column indicate the following, respectively: hospital laboratory instruments, Nycocard, DCA, and Afinion.
The variation between laboratories based on duplicate measurements (CV inter) was calculated for each Hb A1c EQA survey and each POC instrument group in the 2 Hb A1c levels after exclusion of outliers, using the equation:

$$CV_{inter} \% = \sqrt{\frac{\sum (x_i - \bar{x}_{mean\,dup})^2}{n - 1}} \times 100\%$$

(2)

where $x_i$ is the mean of duplicates from each participant, $\bar{x}_{mean\,dup}$ is the mean of duplicates for all participants, $n$ is the number of participants, and $\bar{x}$ is the median of the means.

Because the participants measured Hb A1c in duplicate, the between-laboratory CV was calculated using the following equation (corresponding to 1 measurement):

$$CV_{between\,laboratory} \% = \sqrt{(CV_{inter})^2 + \frac{(CV_{within})^2}{2}}$$

(3)

Computations were performed using SPSS version 20.0 and Excel version 14.2.4.
Results

The total number of GP participants in the EQA surveys for Hb A1c increased from 1034 (59% of the total of 1758 GP offices in Norway) in the 2006–2 survey to 1288 (75% of the total of 1727 GP offices in Norway) in the 2012–2 survey (Fig. 1). All GPs performing Hb A1c analyses in Norway participated in the EQA survey. The number of participants using the Afinion instrument increased the most, whereas the Nycocard seemed to disappear from the market. In this period Noklus advised GPs to use either the DCA or the Afinion. The number of hospital laboratory participants using laboratory instruments increased from 23 in the 2006–2 survey to 52 in the 2012–2 survey (Fig. 1). In each survey, between 75% and 96% of the participants returned duplicate results for Hb A1c values both within the reference interval and above the upper limit of the reference interval in each survey and are included in the calculations.

SYSTEMATIC DEVIATION FROM TARGET VALUE

Between 72% and 96% of the GPs using the Afinion had a systematic deviation of the results from the target value of ±6.0% for Hb A1c values both within the reference interval and above the upper limit of the reference interval (Fig. 1 and Fig. 2). The corresponding values for DCA users were between 77% and 96%, for Nycocard users between 27% and 59%, and for hospital laboratory participants between 54% and 84% (Ta-

Fig. 2. Boxplots showing percentage deviation of Hb A1c between laboratory results and the target value for Hb A1c values within the reference interval and above the upper limit of the reference interval in the 13 Hb A1c EQA surveys from 2006 to 2012 for Afinion, DCA, Nycocard, and hospital laboratory instruments.

The upper and lower limits of each box are the 75th and 25th percentiles, respectively, and the horizontal line in the middle in the box indicates the median. The bars represent the highest and lowest values that are not outliers. Circles represent outliers between 1.5 and 3 box lengths from the upper or lower quartile, and stars represent outliers more than 3 box lengths from the upper or lower quartile. Horizontal lines indicate ±6.0% deviations from target values. Target values are given in online Supplemental Table 1.

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The mean deviation from target value varied between $-0.29\%$ and $0.23\%$ Hb A1c, $-0.30\%$ and $0.28\%$ Hb A1c, $-0.20\%$ and $0.67\%$ Hb A1c, and $0.03\%$ and $0.63\%$ Hb A1c for the Afinion, DCA, Nycocard, and hospital laboratory instruments, respectively (Fig. 2). The systematic deviation did not change significantly during the observed period (Fig. 2), and the laboratories did not have a systematic high or low bias (data not shown). The percentage of participants that were within $\leq 6.0\%$ in deviation from target value for Hb A1c values both within the reference interval and above the upper limit of the reference interval in 1–6 of the last 6 surveys they participated in is given in Fig. 3A. For Afinion, DCA, and Nycocard users and hospital laboratories, 37%, 58%, 1%, and 27%, respectively, were within $\leq 6.0\%$ in all 6 surveys (Fig. 3A).

**WITHIN- AND BETWEEN-LABORATORY VARIATION**

The percentage of participants for which the absolute difference between duplicate Hb A1c measurements was $\leq 0.3\%$ Hb A1c is given in Table 1. The absolute difference between the duplicate results did not change significantly during the observed period (see online Supplemental Fig. 1). Of the participants with Afinion, DCA, Nycocard, and hospital laboratory instruments, 27%, 36%, 10%, and 78%, respectively, obtained a deviation between duplicate Hb A1c measurements $\leq 0.3\%$ Hb A1c for Hb A1c values both within the reference interval and above the upper limit of the reference interval in the last 6 Hb A1c surveys they participated in (Fig. 3B).

Twenty-four percent, 37%, 9%, and 82% of the Afinion, DCA, and Nycocard users and hospital laboratories, respectively, had a CV $\leq 2.0\%$ for Hb A1c values both within the reference interval and above the upper limit of the reference interval calculated from duplicate measurements from the last 6 surveys they participated in (see online Supplemental Table 2). If the requirement is set to $\leq 2\%$, as given in Sacks et al. (5) (meaning that participants with CV $<2.5\%$ fulfill the recommendation), the corresponding percentages is increased to 51%, 63%, 11%, and 93%, respectively (see online Supplemental Table 2).

The pooled within-laboratory variations of the Afinion, DCA, and hospital laboratory instruments were below the recommended limit of 2% (5) in the majority of the surveys (Fig. 4). Nycocard did not meet...
the requirement for within-laboratory variation in any of the EQA surveys (Fig. 4).

The Afinion and DCA instruments were also below the recommended limit of 3% for within-method between-laboratory variations (5) in the majority of the surveys (see online Supplemental Fig. 2), whereas the Nycocard instrument did not meet the 3% recommendation in any of the surveys (see online Supplemental Fig. 2).

### COMBINED TRUENESS AND IMPRECISION

Thirty-eight percent, 60%, 2%, and 45% of the Afinion, DCA, Nycocard users and hospital laboratories, respectively, were within both the 6.0% limit for trueness and the 0.3% Hb A1c limit for imprecision in the last 5 and 6 surveys they participated in (Fig. 3C). Corresponding numbers for other quality specifications are also given in Table 2. Use of the 7.0% limit for...
trueness from 2012 (6) led to a slight increase in the percentage of participants passing the limits. However, if the limits for trueness and imprecision were reduced to 5.0% and 0.2% Hb A1c, respectively, a very small portion of the participants were able to fulfill the requirements over time (Table 2).

Discussion

The NACB recommends using only hospital laboratory Hb A1c instruments for the diagnosis of diabetes, mainly because there is little information about the analytical quality of POC Hb A1c assays in the clinical setting (5). The main finding in the present study is that about 60%–90% of GPs using Afinion or DCA instruments performed measurements that met the quality specifications for both trueness (≤6.0%) and imprecision (≤0.3% Hb A1c) for diagnosing diabetes mellitus in each EQA survey (Table 1). This performance was similar to that of hospital laboratories (Table 1). Adding the 2 last columns in Fig. 3C shows that 60% of GPs using DCA instruments were within the quality specifications in 5 or 6 of the 6 last surveys they participated in, whereas the corresponding numbers for the Afinion users and hospital laboratories were 38% and 45%, respectively (Fig. 3C). These numbers are close to what can be expected from the numbers given in Table 1, which highlights the finding that the group of GP offices using one type of instrument is rather homogenous and that, for example, DCA users have about 90% probability of passing the quality specifications in each survey. The percentage of laboratories that perform within acceptable quality specifications will of course vary depending on the criteria given (Table 2). For instance, the percentage of laboratories passing the quality specifications for trueness in the last 6 years of participation increased by 5%–10% when the limit for trueness was expanded to 7.0%, which was the CAP limit in 2011 and 2012 (6). Furthermore, DCA and also to some degree Afinion users more often fulfilled the quality specification for trueness than the specification for precision, whereas the opposite was true for hospital laboratories (Fig. 3, A and B, and Tables 1 and 2). It is possible, however, that the overall quality of the trueness of the hospital laboratory methods is not as good as that for most of those laboratories included in the CAP surveys, of which more than 90% had an absolute deviation from the target value of ≤6.0% (16). The within-method between-participant CVs, including those for between-lot variations, were less than the 3% limit recommended by the NACB (5). Our results show that this quality specification was fulfilled for most of the users of Afinion, DCA, and hospital instruments on a group basis in each survey (Fig. 4) and for about 50%–90% of the participants when the precision was calculated from the 6 last surveys of participation for each laboratory (see online Supplemental Table 2).

Fig. 3. Continued.
In addition, we used the difference between the 2 duplicates (≤0.3% Hb A₁c units) as a measure of the precision on a group basis in each survey (Table 1) and for each individual laboratory (Fig. 3B), and these results are in agreement with the results using pooled (Fig. 4) and individual CVs (see online Supplemental Table 2), respectively. Thus, different measures for precision show that at least 70% of Afinion or DCA users or hospital laboratories fulfilled the precision criteria for being able to diagnose diabetes in each survey (Table 1).
Our findings are similar to results with Afinion and DCA instruments in the hands of trained personnel (17, 18). These studies, however, were laboratory experiments following the CLSI EP-5 guidelines (19) and not longitudinal results from clinical practice like the present study.

The strength of the present study is that it includes a large number of GP offices and that it follows their performance in numerous EQA surveys over many years. In addition, in the present study the participants have been evaluated regarding both trueness and imprecision simultaneously, and their performance in clinical practice has been evaluated against criteria based on the current CAP and NACB quality specifications for Hb A1c. The EQA material used is fresh native blood and is similar for all types of instruments. The target values are set by 2 reference methods.

A limitation of the present study is that the estimates of trueness and imprecision might be overly optimistic because they were calculated from duplicates over a short period of time and there is a possibility that the participants might have reanalyzed a “strange” result and removed the results that did not fit. However, we think that the results in general are representative for the practices and that it is not worthwhile to increase the number of replicates in the EQA scheme. Furthermore, the number of hospital laboratories is small and does not permit comparisons of performances between methods. The performance of the overall group of hospital laboratories is therefore dependent on the composition of methods used. However, the aim with the present study was not to compare specifically the performances of different hospital laboratory methods with POC methods in GP offices but to see if the performance of methods used in general practices was as good as the “average” hospital method in Norway. But our findings cannot be generalized to the quality of hospital laboratory instruments in other countries. Nevertheless, the pooled CVwithin results for hospital laboratories (Fig. 4) are similar to those of other studies performed in one laboratory with experienced users (20–24).

The performance of the participants in this study has been evaluated using the quality specifications from CAP (6) and NACB (5), which are given in DCCT units. It is important to underline that the use of

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*a A laboratory may have participated with 2 different instruments during the time period and thus participated 4 and 6 times in 2 different time periods. The total numbers may therefore be higher than those given in Fig. 1.
IFCC units will give different quality specifications when calculated in percentages (25).

A presupposition for high-quality performance of Hb A1c measurements in GP offices is the existence of a stringent quality assurance program (QAP). The WHO has not defined what elements should be included in a stringent QAP. In our opinion, EQAs are an important part of this, and in the Noklus EQA schemes for Hb A1c participants receive EQA materials on a regular basis, the EQA material are commutable (fresh native human blood) at 2 different levels, and a secondary reference laboratory has set the target value. Equally important is that all GP offices should receive regular guidance in the form of visits and courses from laboratory consultants (e.g., biomedical laboratory scientists). When the participants obtain an evaluation of their EQA result outside the “acceptability” limits, the consultants must provide them with advice and instruction regarding their measurement procedures, and they can also recommend what instruments to use. Such recommendations should be based on reports from organizations that perform supplier-independent evaluations of the analytical quality and user friendliness of POC equipment, for example, SKUP (the Scandinavian evaluation of laboratory equipment for primary healthcare) (26).

Noklus runs the EQA surveys for both hospital laboratories and GP offices in Norway, and from the autumn of 2012, the within-laboratory day-to-day variation has been recorded for all participants, and the number of EQA surveys will increase to 4 per year. In the feedback reports it will be stated if the results of the laboratories satisfy the quality specifications to diagnose diabetes mellitus, and help will be offered to GP offices if requested. Participation in the Noklus EQA programs is voluntary, and because 99% of Norwegian GP offices participate, the participants are representative for POC users. We think that our results are generalizable to other countries or areas where GPs analyzing Hb A1c participate in a stringent QAP.

In conclusion, a large proportion of GP offices in Norway using Afinion and DCA for measurements of Hb A1c fulfill the quality specifications based on the CAP and NACB requirements for trueness and precision. Furthermore, their analytical quality is comparable to that of hospital laboratory instruments. About 75% of GP offices in Norway have Hb A1c POC instruments, thus the instruments are easily available. Considering the large number of persons with undiagnosed type 2 diabetes (5), it is a great advantage to have the possibility of using POC instruments at GP offices for this purpose and to have the results during the consultation. Since a national stringent QAP is established that closely monitors the laboratory performance in GP offices in Norway (3), it is therefore recommended that GP offices that participate in this QAP and fulfill the quality specifications can use their POC instruments to diagnose diabetes mellitus.

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