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DIABETIC Medicine

Remote capillary blood collection for HbA_{1c} measurement during the COVID-19 pandemic: A laboratory and patient perspective

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Abstract

Aims: The purpose of this study was to assess the clinical performance and user acceptance of capillary blood samples prepared remotely using the MiniCollect® capillary blood collection device as an alternative to blood collection by venepuncture for glycated haemoglobin (HbA_{1c}) analysis.

Methods: Following written informed consent, a cross-sectional study was conducted in individuals aged ≥18 years with any type of diabetes who routinely self-monitor their blood glucose. Eligible participants recruited whilst attending their routine clinical appointments were required to provide a venous blood sample, prepare a capillary blood sample at home (remotely) and complete a bespoke questionnaire. HbA_{1c} in whole blood collected in ethylenediaminetetraacetic acid was determined by capillary electrophoresis on the Sebia Capillary's 3 Tera analyser following standard operating procedure.

Results: HbA_{1c} results from both venous and capillary collection demonstrated good agreement. Passing-Bablok regression: $y = 0 + 1x$ ($p = 0.18$), Spearman correlation $r = 0.986$, $p < 0.0001$. The Bland–Altman difference plot provided a mean difference of 0.3 mmol/mol (2.2%). Over half of the participants found the MiniCollect device easy to use. The majority of participants were in favour of the remote capillary blood collection service and would use it if routinely available.

Conclusion: The home collection of capillary blood for HbA_{1c} determination is a valuable and convenient alternative to standard venous blood collection as it provides an opportunity to support routine HbA_{1c} monitoring, whilst mitigating the transmission of SARS-CoV-2. This service would additionally allow individuals to attend clinic visits with a HbA_{1c} value, ensuring optimal continuance of patient care for individuals with diabetes.

KEYWORDS
capillary sampling, delivery of care, glycaemic control, HbA_{1c}, remote monitoring

Prior presentation: An abstract of this study was accepted for the 45th Irish Endocrine Society Annual Meeting hosted virtually on the 19/20 November 2021.

1 | INTRODUCTION

Diabetes is a chronic disease in which individuals require ongoing support from diabetes services. The severity of the current COVID-19 pandemic has disrupted this provision of support; to minimize the spread of SARS-CoV-2 infection and to support social distancing measures, many phlebotomy appointments have been stopped and face-to-face consultations replaced by remote virtual or telephone appointments.[1] Consequently, people with diabetes have had reduced access to routine appointments and regular monitoring of glycated haemoglobin (HbA_{1c}). HbA_{1c} is the product of in vivo non-enzymatic glycation of haemoglobin, a process which is proportional to the plasma glucose concentration and occurs throughout the lifespan of a red blood cell (RBC).[2] The average lifespan of an RBC is 120 days. HbA_{1c} is a time-weighted average of blood glucose concentrations, meaning that of the 120-day RBC lifespan, the average plasma glucose for the 30 days preceding blood sampling contributes to 50% of the HbA_{1c} value, whilst glucose levels from the previous 90–120 days contribute only 10%.[3]

HbA_{1c} is currently the gold standard test for monitoring glycaemic control in individuals with diabetes[4] and predicts the risk of developing chronic microvascular complications. The Diabetes Control and Complications Trial (DCCT) and the UK Prospective Diabetes Study (UKPDS) demonstrated a clear correlation between glycaemic control and microvascular complications[5,6] and the results of these trials subsequently led to the recommendations for glycaemic targets based on HbA_{1c} concentrations.[7]

The COVID-19 pandemic has resulted in a significant reduction in HbA_{1c} testing.[8] This has led to difficulties in monitoring glycaemic control and identifying people whose glycaemic control is not to target. Delayed detection of diabetes and prolonged suboptimal control increase the risk of individuals developing serious long-term complications of diabetes, which, in turn, place an economic burden on health services and significantly reduce the quality of life of people with diabetes.

An alternative way to increase accessibility to HbA_{1c} laboratory testing is required in order to support routine HbA_{1c} testing whilst mitigating the risk of SARS-CoV-2 infection and transmission.[1,9] The self-collection of capillary blood samples provides a feasible alternative approach that can support remote provision of care for individuals with diabetes.

The primary aim of this study was to determine whether HbA_{1c} analysis of blood obtained by fingerprick, collected remotely, agrees with HbA_{1c} analysis of blood collected by the standard method of venous blood collection. The secondary aim was to assess the user acceptance of the remote HbA_{1c} service as a potential alternative to venous blood collection.

What's new

- The COVID-19 pandemic has challenged the traditional way health services are delivered. Consequently, there has been a significant reduction in face-to-face consultations and routine phlebotomy. For people with diabetes, the inability to have blood collected for glycated haemoglobin (HbA_{1c}) measurement has resulted in suboptimal assessment of glycaemic control.
- This study demonstrates that HbA_{1c} levels measured from remotely prepared capillary samples are clinically concordant with HbA_{1c} measured from blood collected by venepuncture.
- Remote capillary blood collection can enable people with diabetes to take control of their own HbA_{1c} blood sampling and provide an opportunity to support HbA_{1c} monitoring during the COVID-19 pandemic.

2 | METHODS

2.1 | Study design

A cross-sectional study of individuals with diabetes was conducted between June and July 2021. Eligible participants were recruited whilst attending their routine clinical appointments at the Galway University Hospital and Roscommon University Hospital. The purpose of the study was outlined to eligible participants using a specifically designed patient information leaflet. During their routine appointment, each participant had a venous sample collected for routine measurement of HbA_{1c}. Following informed written consent, participants were asked to provide an additional blood sample (capillary) which was to be collected remotely. They were provided with a home-pack for the collection and return of the home-prepared capillary sample. The home-pack included a stamped addressed envelope, a labelled MiniCollect® capillary blood collection device, a leakproof container, an instruction leaflet, a five-level questionnaire and a labelled laboratory request form. The postal HbA_{1c} service instruction leaflet which included a link to a pre-existing YouTube video was created to aid participants in capillary sample collection.

2.2 | Reference population

The inclusion criteria were written informed consent, individuals aged ≥18 years with any type of diabetes who routinely self-monitor their blood glucose. Individuals without diabetes, age <18 years, pregnant women and persons receiving renal replacement therapy were excluded.

2.3 | Sample collection

2.3.1 | Venous blood collection

During their routine clinic appointment, each participant had a venous whole blood sample collected into a potassium ethylenediaminetetraacetic acid (EDTA) collection tube (Greiner Bio-One Vacuette® 3 ml K3E K3EDTA) for routine measurement of HbA_{1c}.

2.3.2 | Capillary blood collection

Each participant was asked to provide a capillary blood sample which was to be collected into the Greiner Bio-One 0.25/0.5 ml K3E K3EDTA MiniCollect device (Figure 1) at home.

Participants were shown by the clinical team how to use the MiniCollect device and a home-pack was provided to each participant. Participants were asked to collect 250 μl of capillary blood into the MiniCollect device within 24 h of venous blood collection and to post the capillary sample within 24 h of its preparation to the laboratory for HbA_{1c} analysis.

FIGURE 1 A MiniCollect capillary blood collection with and without capillary blood (Adapted from Ref. [10]).

2.4 | Laboratory HbA_{1c} analysis

HbA_{1c} in venous and capillary whole blood collected into EDTA was determined by capillary electrophoresis on the Sebia Capillary's 3 Tera automated platform using the Sebia HbA_{1c} kit. This assay is accredited to ISO:15189:2012 standards.

The 0.25/0.5 ml gradation markings on MiniCollect tube facilitated an approximate visual assessment of the capillary blood volume for each sample. For low-volume whole blood samples, in accordance with the instruction for use, prior to analysis 20 μl of capillary/venous blood was transferred into a low-volume collection tube containing 100 μl haemolysing solution.

2.5 | Capillary HbA_{1c} stability

Stability studies were carried out over a period of 7 days to reflect expected real-world maximum length of time between sample collection and laboratory analysis. Capillary samples were selected from 12 participants, analysed on receipt and after storage at 4°C[11] for 3, 4, 5, 6 or 7 days. HbA_{1c} was not measured on a fresh capillary sample.

2.6 | Statistical analysis

Statistical analyses were performed using Analyze-it® (Version 17) and MedCalc® Statistical Software (Version 20.027). Tests for normality were performed on all variables using the Shapiro–Wilk normality test. Gaussian data were represented as the mean (±standard deviation) and non-Gaussian data as the median (range). Descriptive statistics were performed on the baseline characteristics. A histogram and box and whisker plot were used to illustrate the distribution of the data. The statistical differences in the median HbA_{1c} values from the two collection methods were analysed using the Mann–Whitney *U* test. A *p*-value of <0.05 was deemed statistically significant. The relationship between the venous and capillary whole blood sample for HbA_{1c} was assessed using the Spearman's rank coefficient. Passing-Bablok regression analysis and the Bland-Altman difference plot were used to assess the agreement and bias between the results for HbA_{1c} using the two collection methods in accordance with the Clinical Laboratory and Standards Institute (CLSI) guidance EP09-A3.[12]

The questionnaire was used to assess participant's experience with the MiniCollect device and acceptance of the postal HbA_{1c} service.

3 | RESULTS

3.1 | Participant characteristics

A total of 84 participants were recruited to this study. The reference population comprised of more men ($n = 49$) than women ($n = 35$); the median age was 44 (19–85) years.

3.2 | Returned capillary samples

Of the 84 participants recruited to this study, 22 did not complete the study and return their capillary sample to the laboratory. Possible reasons for this include: the sample was not received in the laboratory, the participant was unable to collect the capillary sample or the participant no longer wished to participate.

Of the 62 capillary samples received in the laboratory, 16 did not have a concomitant venous sample (collected within 24 h) and 5 were of insufficient volume (<20 µl) to permit HbA_{1c} analysis. In total, there were 41 capillary samples that met the study inclusion criteria with a paired venous sample collected within 24 h of the capillary sample collection (Figure 2).

Furthermore, it was determined that six participants, who had prepared a capillary sample for HbA_{1c} analysis remotely but omitted to undergo venepuncture for HbA_{1c}, had a venous sample collected and analysed for HbA_{1c} in the month prior to their capillary sample collection.

The average volume of capillary blood collected by the 62 participants was 175 µl. Sample volume appeared to vary with age: individuals aged >50 years ($n = 27$) had an approximate blood volume of 146 µl whilst participants >70 years ($n = 7$) collected the smallest amount of blood with an average volume of 75 µl. Regression analysis revealed no correlation between the age of the participant and the volume of capillary blood collected ($R = 0.12$, $p = 0.0053$).

3.3 | Study population

Baseline characteristics of the 41 participants who met the inclusion criteria are shown in Table 1.

3.4 | HbA_{1c} analysis

The HbA_{1c} results determined in venous blood were designated the reference comparator result for this study. The HbA_{1c} results from venous and capillary samples were almost identical ($p = 0.849$). A wide range of HbA_{1c} concentrations were used to compare HbA_{1c} results collected by venepuncture and fingerprick (capillary whole blood): the minimum HbA_{1c} concentration

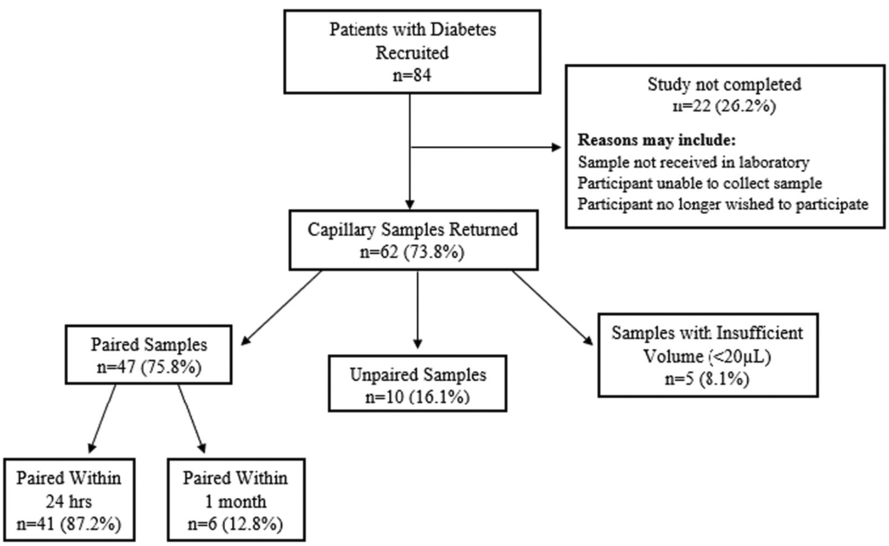

FIGURE 2 Schematic representation showing the recruitment of participants and the returned capillary samples.

TABLE 1 Participant characteristics of the study population as represented by gender, age, type and duration of diabetes

Type of diabetes	Men (*n*)	Women (*n*)	Age (years) Median (range)	Duration of diabetes (years) Median (range)
T1DM	15	9	37.5 (19–69)	17 (0–37)
T2DM	9	6	36 (36–81)	8 (0–39)
Other	0	2	67.5 (67–68)	24.5 (1–48)
Total ($n = 41$)	24	17	47 (19–81)	13 (0–48)

Note: Other: 1× MODY (maturity-onset diabetes of the young) type 3 and 1× secondary diabetes mellitus.

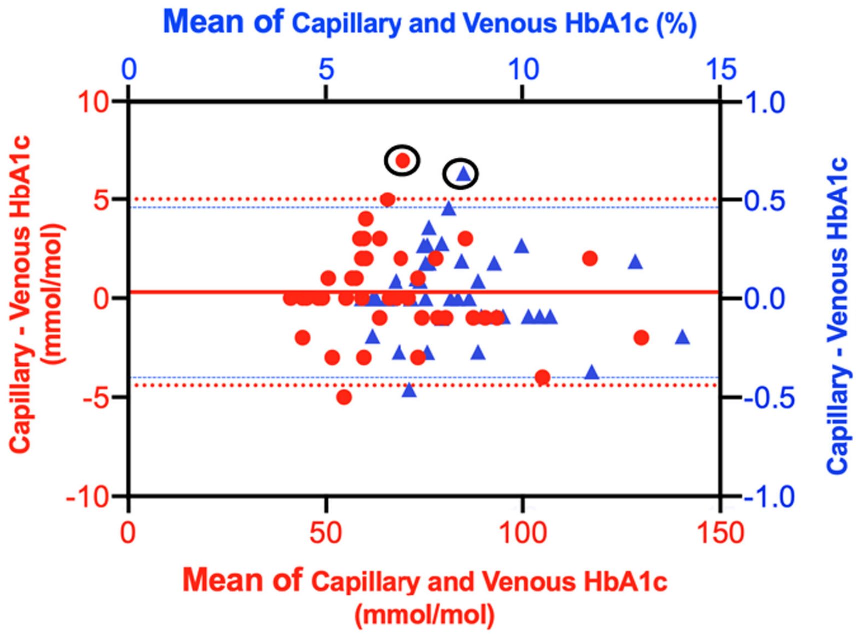

FIGURE 3 Method agreement statistical evaluation: Bland-Altman difference plot in mmol/mol and %. The single outlier is depicted by the value (in mmol/mol and %) circled in black.

for both capillary and venous samples was 41 mmol/mol (5.9%) and the maximum concentrations for venous and capillary samples were 131 and 129 mmol/mol (14.1% and 14%), respectively. The median HbA_{1c} results were 62 mmol/mol (7.8%) and 63 mmol/mol (7.9%) for the venous and capillary samples, respectively. HbA_{1c} results from capillary samples exhibited a strong positive correlation with the routine venous HbA_{1c} collection method results ($r = 0.986$, $p < 0.0001$).

The Passing-Bablok regression line of $y = 0 + 1x$ revealed a slope of 1 (95% confidence interval [CI]: 0.9697–1.0400) and an intercept of 0 (95% CI: −2.2000 to 1.8485). The Cusum test for linearity revealed no significant deviation from linearity ($p = 0.18$). The Bland-Altman difference plot (Figure 3) showed a mean difference of 0.3 mmol/mol (2.2%) (95% CI: −0.44 to 1.07) between the two collection methods. The limits of agreement ranged from 4.4 mmol/mol (2.6%) (95% CI: −5.67 to −3.07) to 5 mmol/mol (2.6%) (95% CI: 3.70–6.31). The majority of HbA_{1c} values (95%) fell within the limits of agreement. All HbA_{1c} results except one fell within the maximum acceptable difference of 5 mmol/mol (2.6%), a difference which was selected a priori. This value, 5 mmol/mol (2.6%), was chosen as the maximum allowable difference as it is based on the smallest difference in HbA_{1c} concentrations in consecutive HbA_{1c} tests that guide physicians to change therapy.[13,14]

All HbA_{1c} results for the six participants who had a venous sample collected a month prior to capillary sample collection were within 5 mmol/mol (2.6%) of that obtained from the home-prepared capillary sample.

3.5 | Questionnaire

Of the 62 participants who returned capillary samples, 60 returned with a questionnaire of which 57 were completed.

The first section of the questionnaire was used to assess participants' experience with the MiniCollect device (Table 2). The majority (92.3% [48/52]) of the respondents found the written instructions-for-use very easy (73.1% [38/52]) or easy to use (19.2% [10/52]). Of those respondents who followed the instructions-for-use video on YouTube ($n = 30$), the majority found the video very easy (60.0% [18/30]) or easy to use (26.7% [8/30]). In total, 57.1% (32/56) of respondents found the MiniCollect device very easy or easy to use, whilst 25.0% (14/56) found the device difficult or very difficult to use. Participants appeared to have the most difficulty obtaining enough blood

TABLE 2 Analysis of questionnaire responses used to assess participants' experience with the MiniCollect collection device and the overall postal glycated haemoglobin (HbA_{1c}) service

I found...	Number of responses to each question (*n*)	Very easy to use % (*n*)	Easy % (*n*)	Neither easy nor difficult % (*n*)	Difficult % (*n*)	Very difficult % (*n*)
Following the written instructions-for use	52	73.1 (38)	19.2 (10)	3.8 (2)	3.8 (2)	0.0 (0)
Following the instruction-for-use video on YouTube	30	60.0 (18)	26.7 (8)	6.7 (2)	6.7 (2)	0.0 (0)
The MiniCollect capillary blood collection device easy to use	56	33.9 (19)	23.2 (13)	17.9 (10)	19.6 (11)	5.4 (3)
Getting enough blood was	57	8.8 (5)	12.3 (7)	15.8 (9)	38.6 (22)	24.6 (14)
Deciding when I had enough blood	57	21.1 (12)	31.6 (18)	19.3 (11)	17.5 (10)	10.5 (6)
Securing the cap on the collection device	56	66.1 (37)	25.0 (14)	7.1 (4)	0.0 (0)	1.8 (1)
Posting sample on the day of preparation	52	51.9 (27)	34.6 (18)	9.6 (5)	3.8 (2)	0.0 (0)
Posting the sample within 24 h of preparation	51	62.7 (32)	33.3 (17)	3.9 (2)	0.0 (0)	0.0 (0)
I would...	**Number of responses to each question (*n*)**	**Strongly agree % (*n*)**	**Agree % (*n*)**	**Neither agree nor disagree % (*n*)**	**Disagree % (*n*)**	**Strongly disagree % (*n*)**
This service made me feel more in control of my diabetes	55	27.3 (15)	25.5 (14)	40.0 (22)	5.5 (3)	1.8 (1)
Use this service routinely if available	57	47.4 (27)	28.1 (16)	12.3 (7)	10.5 (6)	1.8 (1)
Prefer to use this service over attending Clinics/GP surgeries	56	42.9 (24)	25.0 (14)	16.1 (9)	10.7 (6)	5.4 (3)
Be more likely to test for HbA_{1c} if this service was available	57	43.9 (25)	24.6 (14)	22.8 (13)	7.0 (4)	1.8 (1)
Be happy to collect testing pack from my local GP surgery	55	32.7 (18)	38.2 (21)	16.4 (9)	9.1 (5)	3.6 (2)
Prefer to have the testing pack posted to my address	55	50.9 (28)	20.0 (11)	25.5 (14)	3.6 (2)	0.0 (0)

and deciding when enough blood was collected into the device. Overall participants had no difficulty posting their capillary sample on the same day of preparation or within 24 h of its preparation (Table 2). The second section of the questionnaire was used to assess user acceptance of the postal HbA_{1c} service (Table 2). When asked if this service made them feel more in control of their diabetes management, half of the participants reported that it did, whilst a quarter of participants remained undecided. In total, 75.4% (43/57) of respondents reported that they would use this service routinely if it was available. A further 67.9% (38/56) respondents agreed that they would prefer to use this service over attending clinics or general practitioner's surgeries for phlebotomy whilst 16.1% (9/56) reported that they would still prefer to attend appointments. In total, 68.4% (39/57) of respondents agreed that they would be more likely to test for HbA_{1c} if this service was available.

3.6 | Assay performance characteristics

Over the period of the study, the analytical variation (%CVA) at a mean HbA_{1c} concentration of 36 mmol/mol (5.4%) and 67 mmol/mol (8.3%) was <2% and the assay bias ranged from 0% to 2.4%.

3.7 | Capillary HbA_{1c} stability

Capillary HbA_{1c} was found to be stable up to 7 days at 4°C (Figure 4).

4 | DISCUSSION

This was a pilot study to examine the potential use of a remote blood collection service for routine HbA_{1c} testing.

The HbA_{1c} results from the two collection methods correlated well with each other. Regression analysis demonstrated no bias, indicating that the capillary blood collection method can be used for HbA_{1c} measurement. The Bland–Altman difference plot indicated excellent concordance between the two methods across the wide range of HbA_{1c} (41–131 mmol/mol [5.9%–14.1%]) concentrations assessed. One HbA_{1c} result fell outside 5 mmol/mol (2.6%) as the difference between the venous and capillary sample was 7 mmol/mol (2.8%). The venous sample was repeated and produced the same result (66 mmol/mol [8.2%]). However, there was insufficient capillary sample to allow for a repeat analysis. Ordinarily, a repeat test result with this magnitude of difference would not be acceptable, however, for the purpose of this study, the result was included. The cause of this outlier is unknown, it may potentially be the result of an analytical or a human error.

All comparisons of HbA_{1c} results for the six participants who had a venous sample collected a month prior to capillary sample collection were within the maximum acceptable difference of 5 mmol/mol (2.6%). These results may be considered to be as expected, given that HbA_{1c} is a time-weighted average of blood glucose levels in the previous 30 days.[15]

Although many of the participants found the written instructions and YouTube video easy to follow, the largest difficulty encountered by the participants was in deciding that they had collected enough blood. This difficulty was evident in the blood volumes returned; younger participants were able to collect larger volumes of capillary blood in comparison to the more elderly participants. A further study on remote capillary collection may include an additional free-text section in the questionnaire for participants to document any specific difficulties that they may have had with sample collection. A follow-up discussion with participants particularly elderly participants may also be considered. Feedback provided by participants can provide insights into how to further develop the remote capillary collection idea.

Of note, no correlation was observed between the age of participants and the volume of capillary blood collected. However, we acknowledge that further studies with larger numbers of participants are required to verify these findings.

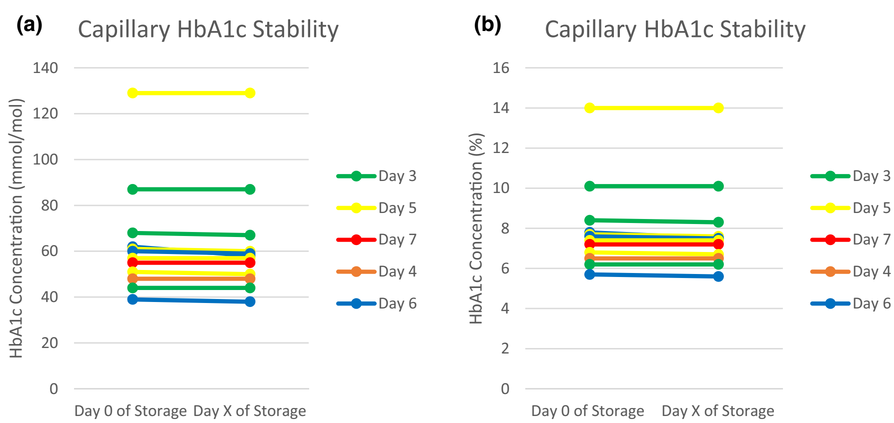

FIGURE 4 The stability of glycated haemoglobin (HbA_{1c}) in capillary whole blood samples in (a) mmol/mol and (b) %.

Overall, participants had a positive experience with the MiniCollect device. Although, a quarter of participants found the device difficult to use, this difficulty was not reflected in the blood volumes returned where 11 of these participants provided sufficient blood volume for HbA_{1c} analysis.

A small number of participants felt that they would still prefer to attend the clinic or their general practitioner (GP) for a consultation. This may be because they require other tests to be carried out in addition to HbA_{1c} or perhaps participants may feel that remote testing will result in a missed opportunity for discussion with their healthcare professional about their diabetes management.[16] Whilst a remote blood collection service has many benefits, its value in certain cohorts of patients i.e., those with multiple co-morbidities, must be considered.

Good concordance has been reported in the literature for HbA_{1c} measured in capillary and venous blood samples using both dried blood spot devices and collection tubes.[9,16–19] Two previous studies reported that 69.2% and 70% of participants, respectively, would use a remote HbA_{1c} service if available or recommend this service.[1,16] Our study gave similar results with over three quarters of respondents (75.4% [43/57]) reporting that they would use the remote HbA_{1c} service routinely if available.

Involvement of patients in clinical decision making has been reported to improve health outcomes and adherence to treatment/medication.[20] Nwankwo et al. reported that participants ($n = 8$) involved in a pilot study for remote capillary sampling agreed that the remote capillary collection process resulted in better decision making and planning of care.[20] Our study findings support those of Nwanko et al., with our participants supporting a greater uptake of this remote collection approach.

There are several strengths of the study. The wide range of HbA_{1c} concentrations obtained covered the medical decision thresholds, common glycaemic treatment targets and values indicative of high blood glucose levels. While we acknowledge that the study sample size is relatively small, the HbA_{1c} concentration range and number of results meet the CLSI requirements to evaluate method agreement.[12]

A significant strength of the study is public and patient involvement; people with diabetes were involved in this study through the completion of the participant questionnaire. The information provided by participants in the questionnaire gives a valuable insight into what people with diabetes want in terms of their diabetic care.

A challenge encountered during the study was the incompatibility of the MiniCollect device with the Capillary's 3 Tera analyser. To analyse patient samples, a specified volume of capillary blood was transferred from the MiniCollect device into a low-volume tube and put onto the instrument. These additional work-steps disrupt the normal running of the laboratory and thus if this service was used routinely, this device would not be suitable for the collection and analysis of capillary blood. In addition, the transfer of sample from one tube to another increases the potential for laboratory error to occur. If this service were to be progressed, an alternative capillary blood collection device which could be analysed directly on the laboratory instrumentation would be required. In addition, the mechanism by which results would be conveyed to people is another crucial consideration. Future work may focus on the development of a reliable communication service for remote testing.

In this study, we have shown that HbA_{1c} results from capillary samples prepared at home and subsequently posted to the laboratory compared well and were clinically concordant with HbA_{1c} results measured from venous samples. The collection of a fingerprick blood sample at home by individuals is an inexpensive, feasible and convenient alternative to standard venous blood collection for HbA_{1c} testing. This service provides an opportunity to support routine HbA_{1c} monitoring, whilst mitigating the transmission of SARS-CoV-2 and adhering to public health recommendations.

AUTHOR CONTRIBUTIONS

Paula M. O'Shea, Wendy N. Groenendijk and Tomás P. Griffin were responsible for study concept and design. Wendy N. Groenendijk was responsible for patient recruitment, the analytical measurements and quality of analyses. Paula M. O'Shea/Wendy N. Groenendijk was responsible for data collation and Deirdre Wall statistical analysis. Wendy N. Groenendijk drafted the initial manuscript. All authors (Wendy N. Groenendijk, Tomás P. Griffin, Md N. Islam, Liam Blake, Marcia Bell, Deirdre Wall, Paula M. O'Shea) made substantial contributions to the interpretation of data, critically reviewed the manuscript for important intellectual content and approved the final version of the manuscript. Paula M. O'Shea is responsible for the integrity of the work as a whole.

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CONFLICT OF INTEREST

The author(s) declare no potential conflict of interest that could be perceived as prejudicing the impartiality of the research, authorship and/or publication of this article.

ETHICS STATEMENT

Ethical approval was granted by the Clinical Research Ethics Committee, Galway University Hospitals (Ref: C.A. 2507) and the National University of Ireland, Galway Research Ethics Committee (Ref: 17-July-05).

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