Assessment of the effect of the COVID-19 pandemic on UK HbA1c testing: implications for diabetes management and diagnosis

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ABSTRACT

Aims The COVID-19 pandemic, and the focus on mitigating its effects, has disrupted diabetes healthcare services worldwide. We aimed to quantify the effect of the pandemic on diabetes diagnosis/management, using glycated haemoglobin (HbA1c) as surrogate, across six UK centres.

Methods Using routinely collected laboratory data, we estimated the number of missed HbA1c tests for 'diagnostic'/'screening'/'management' purposes during the COVID-19 impact period (CIP; 23 March 2020 to 30 September 2020). We examined potential impact in terms of: (1) diabetes control in people with diabetes and (2) detection of new diabetes and prediabetes cases.

Results In April 2020, HbA1c test numbers fell by ~80%. Overall, across six centres, 369 871 tests were missed during the 6.28 months of the CIP, equivalent to >6.6 million tests nationwide. We identified 79 131 missed 'monitoring' tests in people with diabetes. In those 28 564 people with suboptimal control, this delayed monitoring was associated with a 2–3 mmol/mol HbA1c increase. Overall, 149 455 'screening' and 141 285 'diagnostic' tests were also missed. Across the UK, our findings equate to 1.41 million missed/delayed diabetes monitoring tests (including 0.51 million in people with suboptimal control), 2.67 million screening tests in high-risk groups (0.48 million within the prediabetes range) and 2.52 million tests for diagnosis (0.21 million in the pre-diabetes range; ~70 000 in the diabetes range).

Conclusions Our findings illustrate the widespread collateral impact of implementing measures to mitigate the impact of COVID-19 in people with, or being investigated for, diabetes. For people with diabetes, missed tests will result in further deterioration in diabetes control, especially in those whose HbA1c levels are already high.

INTRODUCTION

The COVID-19 pandemic, and the focus on mitigating its effects, has disrupted healthcare systems across the world,[1 2] including those for the diagnosis and management of people with diabetes.[3 4]

Routine blood testing, a mainstay of diabetes diagnosis and management, became challenging, not least because of the potential risk it posed to facilitating transmission of the virus and associated public concerns regarding attending for tests.[5]

Hence, some healthcare services adopted a pragmatic approach to long-term monitoring, prioritising those at highest risk.[5]

Reflecting this, the demand for blood testing, including for diabetes diagnosis and monitoring, in some countries dropped during lockdowns.[6] Carr *et al*,[7] for example, showed that testing for the key diabetes marker, glycated haemoglobin (HbA1c), for primary care patients with diabetes reduced in the months following the first UK lockdown. However, the scale and impact of these changes across primary and secondary care diabetes services for both monitoring and diagnosis has not been investigated.

We previously showed a link between HbA1c testing frequency and diabetes control expressed as change in HbA1c[8] and likelihood of achieving target,[9] highlighting the importance of regular monitoring in maintaining diabetes control.[10 11] This is particularly important given that those with suboptimally controlled diabetes have poorer outcomes in the event of SARS-CoV-2 infection.[12–16]

HbA1c is also frequently used in diagnosis in symptomatic patients[17] and as a screening tool in high-risk groups (~5 million people in England alone[18]), where annual HbA1c testing is generally recommended.[18–21] HbA1c forms part of the English Health Check programme for people aged 40–74.[22] As in those with diabetes, there is evidence that people with prediabetes, obesity and other causes of dysglycaemia are also at risk of poorer outcomes following SARS-CoV-2 infection.[12 13 23]

We assessed the impact of the pandemic on diabetes diagnosis and management, using HbA1c as a surrogate, across regions covered by six UK laboratories. We estimated the number of missed HbA1c diabetes monitoring and diagnosis tests over a 3-year period and investigated the potential impact of these missed tests in terms of (1) effect on diabetes control in people with diabetes and (2) detection of new diabetes cases.

METHODS

Data on all HbA1c test requests received by the Clinical Biochemistry Departments at the University Hospitals of North Midlands, St. Helens & Knowsley Hospitals, Salford Royal Foundation Trust, Cambridge University Hospitals, Warrington & Halton Hospitals and Mid-Cheshire

Table 1 Characteristics of the study cohort

	UHNM	SRFT	STHK	CUH	WHH	MCFT	Total
Number of tests:							
October 2017 to September 2018	210 081	235 484	225 608	315 075	109 814	155 368	1 251 430
October 2018 to September 2019	232 849	265 087	245 876	324 215	114 675	173 213	1 355 915
October 2019 to September 2020	184 429	193 051	186 906	269 147	85 904	134 240	1 053 677
Total	627 359	693 622	658 390	908 437	310 393	462 821	3 661 022
Mean HbA1c level ±SD							
All tests (mmol/mol)	45.2±15.2	45.2±15.0	44.5±14.6	44.7±14.5	44.6±14.9	43.9±14.4	–
Monitoring tests only (mmol/mol)	60.4±17.2	60.9±18.3	60.8±17.7	60.2±16.5	61.2±17.8	60.2±17.0	–
Total patients tested	281 182	312 121	286 152	445 708	137 590	221 398	1 684 151
Mean tests per patient							
All tests	2.23	2.22	2.3	2.04	2.26	2.09	2.17
Monitoring tests only	4.43	4.1	4.54	4.31	4.78	4.46	–
Proportion of tests from primary care	87.0%	71.9%	89.6%	90.2%	87.1%	93.5%	–
Site-specific data							
Total population covered	667 884	500 381	611 449	1 210 428	276 404	518 634	3 785 140
Proportion aged over 65 years	20.5%	17.3%	20.8%	17.2%	18.3%	21.4%	–
Median GP-associated IMD rank	12 631	10 640	9984	22 331	11 871	16 161	–
Proportion male (%)	50.3%	50.8%	49.4%	50.4%	50.0%	49.8%	–
Overall diabetes prevalence	7.6%	6.9%	7.3%	5.5%	7.2%	6.2%	–

CUH, Cambridge University Hospitals; HbA1c, glycated haemoglobin; IMD, Index of Multiple Deprivation.; MCFT, Mid Cheshire Foundation Trust; SRFT, Salford Royal Foundation Trust; STHK, St. Helens & Knowsley Hospitals; UHNM, University Hospitals of North Midlands; WHH, Warrington & Halton Hospitals.

Foundation Trust from 1 October 2017 to 30 September 2020 were extracted from Laboratory Information and Management Systems (3 661 022 tests in 1 684 154 patients). These sites covered 3 785 140 people; 5.6% of the UK population[24].

Data on the following standardised set of parameters were extracted: unique patient ID (anonymised), test result, date of request, age, sex, source of request (general practitioner or not).

Characteristics of the cohorts are shown in table 1. Data on the areas covered by the laboratories were obtained from National Health Service Digital,[25] based on the GP practices served by each laboratory. The six sites were selected to cover a range of population demographics.

HbA1c analysis

HbA1c was measured using standard laboratory procedures. For all laboratories, the assay was within the scope of the laboratory's ISO 15189 accreditation, as overseen by the United Kingdom Accreditation Service.[26] Throughout the study period, the assay demonstrated acceptable performance on routine Internal Quality Control and External Quality Assurance parameter across all six sites.

All laboratories used a reference range of <48 mmol/mol as a diagnostic cut-off, as recommended by the National Institute for Health and Care Excellence (NICE)[10] and WHO.[17] The use of cut-offs for 'prediabetes' (42–47 mmol/mol) used across the centres was based on NICE guidance.[10] Comments provided on reports varied between centres, from minimal (reference range only), to providing some information on HbA1c targets for different type 1 and type 2 diabetes mellitus groups based on the result. Similarly, local guidance varied across sites but generally referred to NICE guidance.[10]

HbA1c testing trends over time

We examined test volume changes over the course of the pandemic, compared with the prior 2 years. This enabled calculation of the number of missed tests during the COVID-19 impact period (CIP; 23 March 2020 to 30 September 2020). We categorised tests into three groups: 'monitoring' (those in people with diabetes), 'screening' (those in high-risk groups) and 'diagnostic' (testing to see if a person has diabetes) using the algorithm shown in figure 1. This categorisation was used as each of these groups require different intervals for follow-up testing (see below), and this information was critical in the calculations of potential missed tests.

We also stratified tests by HbA1c level into: <30 mmol/mol, 30–41 mmol/mol, 42–47 mmol/mol, 48–53 mmol/mol, 54–58 mmol/mol, 59–75 mmol/mol, 76–86 mmol/mol and >86 mmol/mol.

Monitoring tests

'Monitoring' tests were defined as those in people who had >1 test during the study period, and had at least one HbA1c value of ≥48 mmol/mol (figure 1). Most of these individuals are likely to be those with existing diabetes, even if some of their HbA1c levels dropped below 48 mmol/mol. To calculate whether a 'monitoring' test would have been due during the CIP, we used an expected interval of up to 3 months for those with suboptimal control (≥59 mmol/mol for the test immediately prior to the CIP), and up to 6 months for those with good control (<59 mmol/mol).[8] If a test was due during the CIP, we were able to determine whether this test was actually performed or not.

Screening tests

We assumed that most individuals with multiple HbA1c tests during the study period, but in whom all results were <48 mmol/mol, were most likely to be those people being regularly reviewed as part of screening in high-risk groups, such as those with prediabetes, those in whom health checks were performed, and women with a history of gestational diabetes or polycystic ovaries. As guidance for these individuals generally recommends annual screening,[18–21] we used a 12-month interval to assess if a test was due during the CIP.

Diagnostic tests

'Diagnostic' tests were defined as either: (a) those with only one test during the study period or (b) those whose first test was
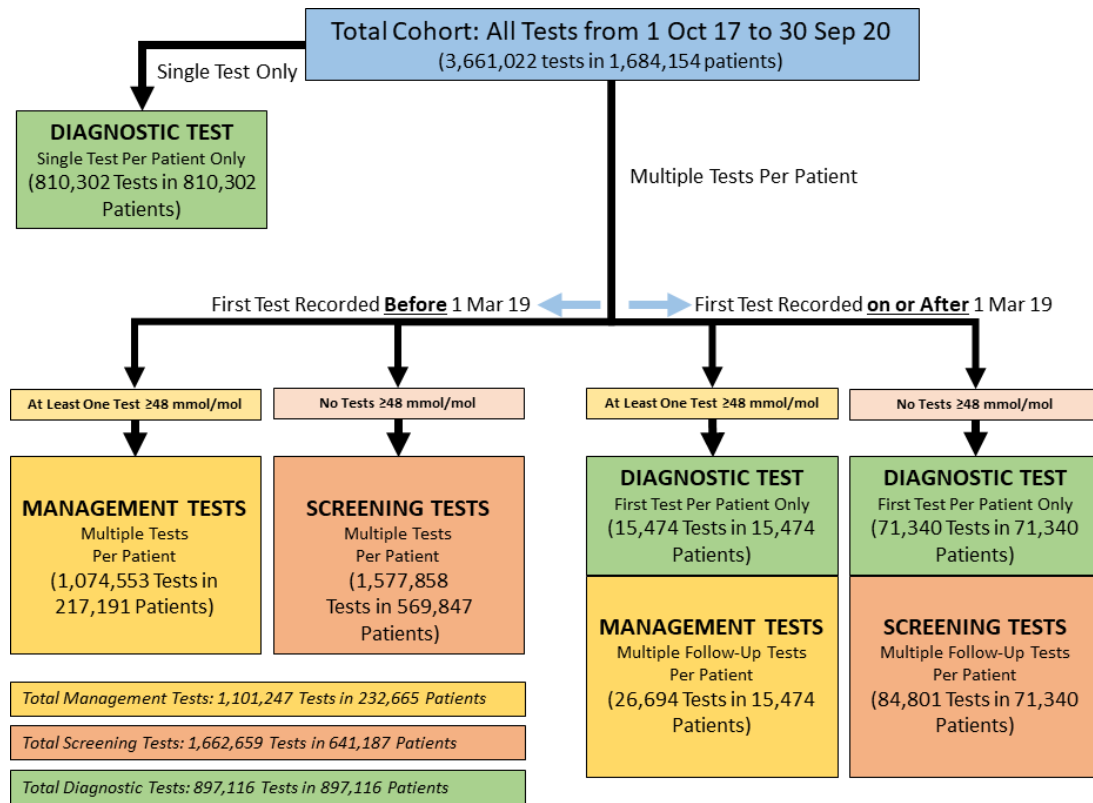
Figure 1 Flow chart showing how the test categories were defined. Some patients will feature in more than one category.

after the first 18 months (figure 1). Within this latter group, we assumed that those who had no tests during the first 18 months were unlikely to be people in either the monitoring or screening groups, at least initially. In these cases, we assumed that the first test was a 'screening' test and all subsequent tests either 'screening' (if all subsequent tests were <48 mmol/mol) or 'monitoring' (figure 1).

Missed 'diagnostic' tests were based on the proportion of all 'diagnostic' tests performed (as a percentage of total tests) during the 12-month period immediately prior to the CIP, using the following formula:

$$\text{Missed DX tests}_{CIP} = \frac{(\text{non} - Dx_{CIP}P + M \times \text{Total}_{Pre - CIP})}{\text{Total}_{Pre - CIP}} - \text{non} - Dx_{CIP}P + M - Dx_{CIP}P$$

where: Dx=diagnostic tests, non-Dx=management+screening tests, Total=diagnostic+management+screening tests, P=Performed tests, M=missed tests.

The rationale for using this approach was, of necessity, different than those used to calculate missed screening and diabetes monitoring tests as they do not have a defined follow-up testing interval. Hence, we used reference to the previous year's data and the data on the monitoring and screening tests to estimate the number of missed diagnostic tests.

Impact of missed monitoring tests

To estimate the impact of missed 'monitoring' tests on change in HbA1c level, we used our previous approach, which assessed the relationship between testing interval and change in HbA1c,[8] for each of the six sites (online supplemental table 1). We then calculated, on a patient-by-patient basis for each HbA1c category, (a) the expected change in HbA1c if the test was done at the recommended interval and (b) the expected change in HbA1c if missed tests were done after the end of the study period (ie, 1 October 2020). We then subtracted (b) from (a) to give the impact of the

delay on the change in HbA1c (online supplemental table 2). This represents the minimum impact as it is not likely that all missed tests would be done on 1 October 2020.

RESULTS

Study population

Table 1 shows that the overall mean HbA1c (43.9–45.2 mmol/mol) and number of tests per patient (2.09–2.30) were similar across the sites. These were also similar when 'monitoring' tests alone were examined (60.2–61.2 mmol/mol and 4.10–4.78, respectively). Site-specific age and gender distributions of general practices covered were similar. Median Index of Multiple Deprivation rank associated with the practices illustrated that the sites encompassed areas of relatively high (eg, STHK) and low deprivation (eg, CUH).

HbA1c test volume trends over time

We observed an overall 8.3% increase in HbA1c testing between the first (October 17 to September 18) and second (October 18 to September 19) 12-month periods (range: +2.9% to +12.6%). This is consistent with the year-on-year trend we observed for HbA1c across UK laboratories (mean annual change from 2017 to 2020: 8.1%), through data collected routinely by The Benchmarking Partnership and available to one of the coauthors (DH). The Benchmarking Partnership[27] collects data on a range of laboratory parameters, including test volumes, as part of a UK-wide pathology benchmarking service. An 8% increase would predict 122 371 tests/month (1 468 456 tests) during October 19 to September 20. However, the actual tests performed during this period averaged 87 806 tests/month (−28.4%); most of the reduction was observed during the 6.28-month CIP.
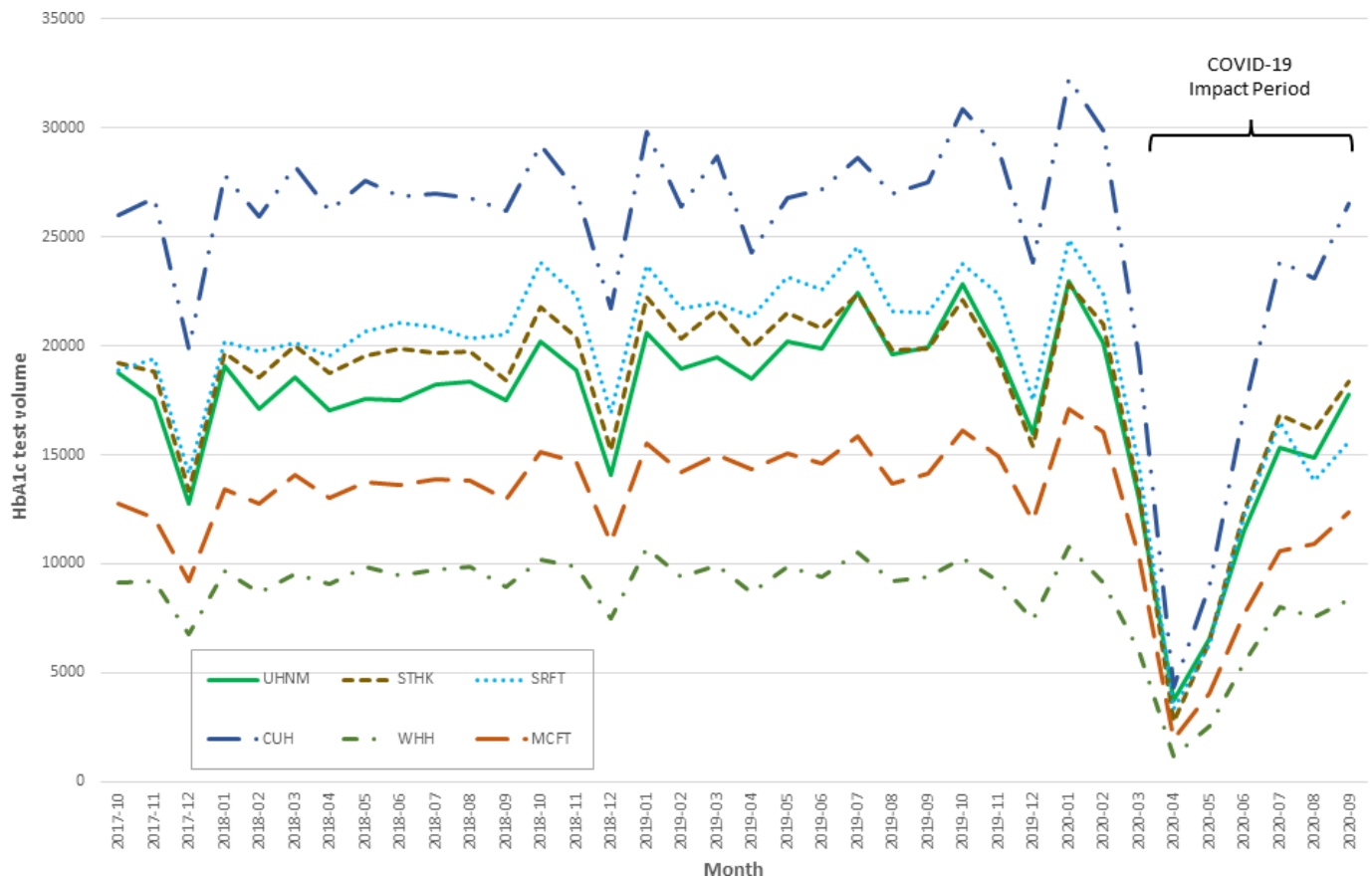
Figure 2 Month-by-month HbA1c test volumes across the six sites. CUH, Cambridge University Hospitals; HbA1c, glycated haemoglobin; MCFT, Mid Cheshire Foundation Trust; SRFT, Salford Royal Foundation Trust; STHK, St. Helens & Knowsley Hospitals; UHNM, University Hospitals of North Midlands; WHH, Warrington & Halton Hospitals.

Figure 2 shows that, across all sites, there was a sharp decline in HbA1c requests immediately after the initial lockdown (from 23 March 2020), dropping by 81.3%–87.8% in April compared with the 2019 mean. This was followed by a gradual rise, reaching 70.6%–96.3% of expected volumes by September 20. HbA1c requests from general practice fell by 84.9%–90.9%, while those from other sources (mostly acute hospitals) fell by 51.8%–75.6%.

Monitoring tests

Overall, there were 32 280 'monitoring' tests/month performed prior to the CIP (table 2). However, the actual number performed during the CIP was 19 138/month, a reduction of 40.7%. When we calculated the missed tests due during the CIP, this equated to 79 131 tests (table 2); 39.7% of those expected (similar to the above 40.7% reduction in testing compared with the pre-CIP period).

Of concern was the observation that 36.1% of the missed tests (4548 tests/month) were in those with suboptimal control (≥59 mmol/mol); 7.3% (920 tests/month) in those with a previous HbA1c of >86 mmol/mol.

Extrapolating this to the UK population we estimated that, during the CIP, 1.41 m 'monitoring' tests would have been missed (>225 000 tests/month). Of these, 0.51 m (81 228/month) would be in those with suboptimal control.

Screening tests

Overall, there were 49 993 'screening' tests/month performed during the pre-CIP period (table 2). However, the number performed during the CIP was 32 212/month; a 35.6% reduction. The tests due during the CIP equated to 149 455 missed screening tests (table 2), representing 42.5% of the expected tests. This was higher than the 35.6% reduction in 'screening' testing compared with the pre-CIP period, perhaps suggesting that a proportion of expected screening tests are not generally carried out (even prior to the pandemic).

As expected, most 'screening' tests (78.4%) performed in the pre-CIP period were within the reference range (<42 mmol/mol). This was similar for those performed during the CIP (79.6%). On average, 4264/month missed 'screening' tests were in the prediabetes range (table 2).

Extrapolating these data to the UK, during the CIP, 2.67 m 'screening' tests would have been missed (>0.42 m/month), including 0.48 m tests (>76 000/month) within the prediabetes range.

Diagnostic tests

During the CIP, an estimated 22 498 test/month were missed, a 60.1% reduction compared with the pre-CIP period (table 2). When missed test were expressed as a percentage of total expected diagnostic tests, this suggested that missed tests represented 64.8% of all 'diagnostic' tests; similar to the 60.1% compared with the pre-CIP period.

Of the 22 498 missed 'diagnostic' tests/month, 8.4% and 2.6% were estimated to be within the prediabetes and diabetes ranges, respectively. An estimated 613 missed tests were in people with an HbA1c>86 mmol/mol (table 2).

Table 2 Number of tests performed/missed, by HbA1c level, compared with those performed in the 12 months prior to the COVID-19 impact period (CIP); (A) 'monitoring', (B) 'screening' and (C) 'diagnostic'

(A) Monitoring tests

Period	Testing	Good Control				Suboptimal Control			Total	Test per month
		<30 mmol/mol	30–41 mmol/mol	42–47 mmol/mol	48–58 mmol/mol	59–75 mmol/mol	76–86 mmol/mol	>86 mmol/mol		
Pre-CIP	Tests performed	361 (0.1%)	16552 (4.3%)	62368 (16.1%)	147279 (38.0%)	101081 (26.1%)	28650 (7.4%)	31074 (8.0%)	387365	32280
CIP	Tests performed	205 (0.2%)	5612 (4.7%)	19200 (16.0%)	44841 (37.3%)	30448 (25.3%)	8950 (7.4%)	10932 (9.1%)	120188	19138
	Missed tests	**65 (0.1%)**	**3635 (4.6%)**	**15235 (19.3%)**	**31632 (40.0%)**	**17724 (22.4%)**	**5066 (6.4%)**	**5774 (7.3%)**	79131	12600

(B) Screening tests

Period	Testing	Within range		Pre-diabetes	Diabetes				Total	Test per month
		<30 mmol/mol	30–41 mmol/mol	42–47 mmol/mol	48–58 mmol/mol	59–75 mmol/mol	76–86 mmol/mol	>86 mmol/mol		
Pre-CIP	Tests performed	11462 (1.9%)	458774 (76.5%)	129682 (21.6%)	–	–	–	–	599918	49993
CIP	Tests performed	5039 (2.5%)	155909 (77.1%)	41342 (20.4%)	–	–	–	–	202290	32212
	Missed tests	**2690 (1.8%)**	**119986 (80.3%)**	**26779 (17.9%)**	–	–	–	–	149455	23799

(C) Diagnostic tests

Period	Testing	Within range		Pre-diabetes	Diabetes				Total	Test per month
		<30 mmol/mol	30–41 mmol/mol	42–47 mmol/mol	48–58 mmol/mol	59–75 mmol/mol	76–86 mmol/mol	>86 mmol/mol		
Pre-CIP	Tests performed	12100 (3.3%)	304514 (82.6%)	35009 (9.5%)	7952 (2.2%)	4184 (1.1%)	1556 (0.4%)	3195 (0.9%)	368510	30709
CIP	Tests performed	4137 (5.4%)	61174 (79.6%)	6816 (8.9%)	2094 (2.7%)	1085 (1.4%)	465 (0.6%)	1105 (1.4%)	76876	12241
	Missed tests	**4050 (2.9%)**	**121501 (86.0%)**	**11880 (8.4%)**	**2035 (1.4%)**	**909 (0.6%)**	**297 (0.2%)**	**613 (0.4%)**	141285	22498

Pre-CIP period defined as 1 March 2019 to 29 February 2020; CIP period defined as 23 March 2020 to 30 September 2020.
HbA1c, glycated haemoglobin.

Across the UK, these equate to 2.52 m missed 'diagnostic' tests during the CIP (0.40 m/month), including ~212 000 in the prediabetes range and 68 800 delayed new diabetes diagnoses (~33 800 and ~11 000/month, respectively).

Impact of missed monitoring tests

We then examined the impact of missed 'monitoring' tests in terms of change in HbA1c caused by the delay in testing. Figure 3A shows the mean testing interval up until the end of the study period, compared with recommended intervals. This showed a mean delay of 2.2–3.4 months in those with good control and ~3.4 months in those with suboptimal control.

Figure 3B shows the difference between the expected HbA1c change based on testing according to recommended interval and that expected if all missed tests were done on 1 October 2020. Our data identified four HbA1c groups; (1)<48 mmol/mol: minimal impact of testing delay (<0.3 mmol/mol), (2) HbA1c 48–58 mmol/mol: small impact (~1 mmol/mol), (3) HbA1c 59–86 mmol/mol: moderate impact (~2 mmol/mol) and (4) HbA1c>86 mmol/mol: large impact (>3 mmol/mol).

UK wide, this suggests that ~565 000 people (40.0% of patients) will see an additional HbA1c increase of ~1 mmol/mol, ~407 000 (28.8%) of ~2 mmol/mol, and ~103 000 (7.3%) of >3 mmol/mol. In contrast, ~338 000 (24.0% of patients) may warrant less frequent testing (9–12 months).

CONCLUSIONS

Using routine clinical laboratory data, we estimate that ~6.6 million UK HbA1c tests were missed during the 6 month CIP: 1.4 m 'monitoring' tests (0.5 million with suboptimal control), 2.7 million 'screening' tests (0.5 million with prediabetes) and 2.5 million 'diagnostic' tests (0.2 million with prediabetes, ~69 000 within the diabetes range). In those with diabetes, we calculated that 76% of patients (~1.1 million) would see their HbA1c rise by >1 mmol/mol more than expected; over 100 000 of these with the worst control (>86 mmol/mol) would

see an additional rise of >3 mmol/mol due to missed tests. These are broadly in keeping with our preliminary analysis.[28]

Impact of pandemic on HbA1c testing and diabetes service provision

Across all sites, the volume of HbA1c test dropped markedly in April 2020 and rose slowly thereafter. This is consistent with Carr et al who showed HbA1c testing in UK people with type 2 diabetes reduced by 77%.[7] Similarly, using South African laboratory data, Kruger et al[6] showed that HbA1c testing overall reduced by ~64% during March to June 2020 compared with the same period the previous year, with the most marked reduction (81%) in April.

In a UK study of the indirect effects of the COVID-19 pandemic on physical and mental health using the UK Clinical Research Practice Datalink, Mansfield et al[29] showed that 'Primary care contacts for almost all conditions dropped considerably after the introduction of population wide restrictions.' A WHO survey conducted in June 2020 showed that treatment for diabetes and associated complications were disrupted in 49% of countries.[30] Similar results have been observed in an international survey of healthcare professionals.[31]

Implications for diabetes management

We showed that HbA1c tests in people with diabetes fell by an average of 40%/month during the CIP. While the majority of missed monitoring tests were in those with lower HbA1c values, 36.1% were in those with suboptimally controlled diabetes, including 7.3% with previous values of >86 mmol/mol. This is particularly concerning as people with diabetes who have higher HbA1c values have increased COVID-19-related mortality[16] and disease severity.[15] Holman et al[16], showed that mortality, and diabetes-related complications, rose with increasing HbA1c. Both HbA1c and blood glucose are risk factors for higher COVID-19-associated mortality.[12 23] Furthermore, studies show that SARS-CoV-2 infection exacerbates the underlying
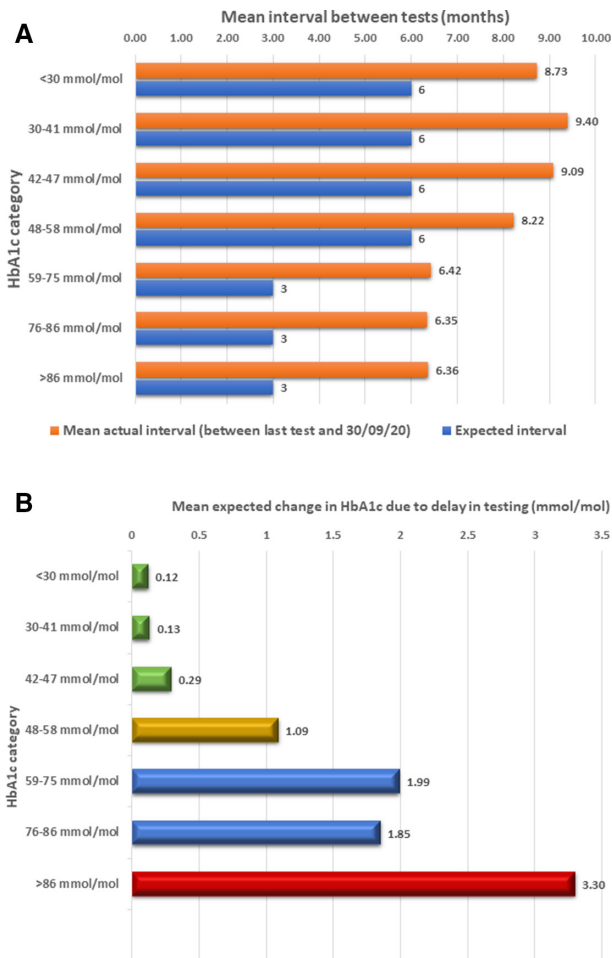
Figure 3 Impact of missed diabetes monitoring tests on (A) mean interval between tests compared with guidance and (B) on change in glycated haemoglobin (HbA1c) due to delay (above that expected if test was performed at recommended interval). Group 1: green, group 2: amber, group 3: blue, group 4: red.

pathophysiology of hyperglycaemic in people with diabetes, leading to further rises in HbA1c.[13 32] In a meta-analysis of 25 studies, Pan *et al*[33] demonstrated that HbA1c is a risk factor for poorer outcome in patients with acute coronary syndrome, illustrating the importance of maintaining stricter glycaemic control in people with diabetes, both outside and within the context of SARS-CoV-2 infection. Hence, lack of engagement with this group of people not only raises their pre-COVID-19-associated risk, but increases the probability of poor outcomes in the event of SARS-CoV-2 infection.

Our data demonstrate that HbA1c testing in over 100 000 people in the UK with HbA1c values of >86 mmol/mol was missed or delayed. In this group, we estimated that this would result, in an average increase of >3 mmol/mol. Smaller delay-associated increases in HbA1c were observed in other groups of patients with HbA1c values of 48–86 mmol/mol who missed tests (estimated at around one third of all people with diabetes).[34] While these increases appear modest, at a population level this represents a significant retrograde step in the management of the most at-risk patients.

We assumed that the change in HbA1c due to the interval between testing would follow a similar pattern to that observed prior to the CIP, and using our previously described methodology.[8 35] However, this may be an underestimate of the impact

of the CIP for two reasons. First, the calculated impact of the delay assumes all missed tests are then performed on the first day following the CIP (ie, 1/10/20). This is highly unlikely to be the case, so the length of the delay in testing, and hence the impact on the HbA1c level, will therefore be greater than our calculations. Second, both discussions with local diabetes patient groups (Diabetes UK local branch) and indications from the literature[36–38] suggest that the significant restrictions imposed throughout the CIP would adversely affect lifestyle factors important for diabetes control.

Screening tests

We estimated that, on average, 23 799 'screening' tests/month (42.5%) were missed during the CIP. While this group may appear less important than the 'monitoring' group, 'screening' tests account for over 40% of missed tests. This equates to 0.4 m tests/month of the 6-month CIP, ~18% of which were in the prediabetes range.

UK NICE guidance recommend use of a risk assessment tool and appropriate tailored lifestyle advice for those with an HbA1c of 42–47 mmol/mol.[18] It suggests that such individuals should be offered a referral to a 'local, evidence-based, quality-assured intensive lifestyle-change programme'. However, in the absence of the test, such advice/referral may have been delayed and hence some may prematurely convert to full diabetes. It is estimated that 5%–10% of patients with prediabetes convert to diabetes each year.[39 40] In this context, during the CIP, we expect that 2.6%–5.2% of the expected 478 196 UK patients with prediabetes in the 'screening' group to convert to diabetes; 12 400–24 800 new diabetes patients in whom treatment would have been delayed. This is particularly important as an estimated 1 in 3 of newly diagnosed patients have complications.[41]

Diagnostic tests

The 'diagnostic' group comprised 141 285 missed tests of whom 11 880 would have been in the prediabetes range. From a national perspective, this equates to a further 212 143 patients with prediabetes of whom 5500–11 000 would be expected to convert to diabetes during the CIP. These people, in addition to the expected 68 521 UK-wide missed tests in the diabetes range, would also have delayed diagnoses and treatment.

Strengths and limitations

Laboratory data generally does not include the reason for HbA1c testing nor the type/duration of diabetes. Hence, it was not possible to definitively differentiate monitoring from diagnostic/screening tests. However, the distribution of tests appears consistent with expectations and the main message of the study remains valid. For example, National Diabetes Audit data indicates that around 34% of patients with type 2 diabetes have an HbA1c≥59 mmol/mol.[34] This is a comparable with our estimates of around 40% for both type 1 and 2 diabetes. Similarly, our estimates for pre-diabetes in the screening and diagnostic tests (~30%) is in keeping with overall estimates for prediabetes prevalence (~35%) in the US[39] and UK.[40]

It is true that HbA1c alone is not the only marker of glucose dysregulation; blood glucose measurement is also important in this regard. Hence, our figures may underestimate the magnitude of the impact of the pandemic on diabetes detection and monitoring. Certainly, derangement in blood glucose has similar negative implications; higher blood glucose levels result in poorer COVID-19 outcomes, irrespective of whether they had

diabetes or not,[12] and severe COVID-19 was associated with higher blood glucose levels.[32]

We recognise that targets for HbA1c monitoring for primary care, as reflected in the Quality and Outcome Framework (QOF) indicators listed within the contract for general practitioners,[42] refer to longer intervals for measuring HbA1c in people with diabetes (12–15 months) than those defined in NICE clinical guidelines.[10] However, QOF, being linked to primary care funding, has a somewhat different remit than NICE clinical guidelines, and we believe that these should be considered a minimum standard rather than a clinically ideal one.

We also acknowledge that, in the data extrapolation to the UK population, there were some differences in the degree of lockdown restrictions between the devolved nations of the UK. However, these differences were more limited during the initial lockdown in March 2020 and hence we do not believe that this would have significant impact on the overall findings of the study.

FINAL CONCLUSION

This study highlights the impact of the pandemic on day-to-day management of people with, and at risk of, diabetes. This will have consequences for their future health that need to be taken account of in the coming years.

Take home messages

► We estimate that ~6.6 million UK glycated haemoglobin (HbA1c) tests were missed during April to September 2020: 1.4 million tests in people with diabetes (0.5 million with suboptimal control) and 5.2 million 'screening'/'diagnostic' tests (0.7 million with prediabetes, ~70 000 within the diabetes range).

► In those with diabetes, >100 000 with HbA1c>86 mmol/mol would see a rise of >3 mmol/mol due to missed tests.

► This highlights the potential impact of the COVID-19 pandemic on day-to-day management of those people with, and at risk of, diabetes. This has major clinical outcome implications.

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