

# An audit of people admitted to hospital with diabetes and coronavirus (SARS-CoV-2): data collection methods. The Association of British Clinical Diabetologists (ABCD) Nationwide Audit

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## Abstract

We describe the rationale, aims and objectives and the methodology of data collection for the ABCD nationwide audit of individuals admitted to hospital with coronavirus (SARS-CoV-2; COVID-19) and diabetes. The audit was inspired and undertaken by the urgent need to understand the clinical course of COVID-19 in patients with diabetes admitted to hospital in the UK during the pandemic. We wished to understand the clinical behaviour of diabetes per se, post hos-

pital admission and the factors which may be associated with admission to the Intensive Care Unit (ICU) and death due to COVID-19. This was a clinically-led audit. We used existing infrastructure and expertise to collect data using an electronic tool specifically designed and piloted by the steering group members. The clinical variables were chosen to fulfil the main aim of this audit as stated above, and factors influencing the clinical course of COVID-19 in individuals with both type 1 and type 2 diabetes at the time of admission to hospital and during the whole length of stay, until discharge or death from COVID-19. The data collected so far represent a large, multicentre audit with more than 3,500 admissions during the pandemic. We plan to continue collecting additional data and publish ongoing reports of interest to diabetes clinicians with the aim of enhancing knowledge and understanding and thereby improving clinical care of, and outcomes for, people with diabetes who are admitted to hospital with COVID-19 in the UK.

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**Key words:** COVID-19, diabetes, pandemic, COVID-Audit, risk factors and mortality, ABCD nationwide Audit

## Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; COVID-19) was first reported in Wuhan, China in December 2019 and has since been responsible for over 2.5 million deaths from COVID-19 infection globally by February 2021.<sup>1</sup> Several publications have reported that chronic co-morbidities such as hypertension, diabetes, cardiovascular disease, chronic kidney disease and chronic obstructive pulmonary disease are associated with an increased risk of severe COVID-19 and mortality.<sup>2</sup> A population-based study from England (UK) reported that, up to 11 May 2020, 23,698 in-hospital COVID-19-related deaths had occurred, of which 1.5% were people with type 1 diabetes and 31.4% were people with type 2 diabetes.<sup>3</sup> The study reported that, after adjustment for age, sex, deprivation, ethnicity and

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geographical region, the risk of in-hospital COVID-19-related death was 3.51 times greater for people with type 1 diabetes and 2.03 times greater for those with type 2 diabetes compared with people without diabetes.<sup>3</sup>

Other studies have reported associations between admission hyperglycaemia and in-hospital mortality in people with diabetes.<sup>4-6</sup> However, sample sizes have typically been small, derived from single centres or single cities, which precludes differential reporting of outcomes by diabetes subtype. Few studies, except those drawing on large quantities of routinely-collected data, have had sufficient power to describe factors associated with poor outcomes among people with diabetes.<sup>7-9</sup> One notable exception is the CORONADO study, based on data collected in centres across France, which has reported characteristics and outcomes for people with diabetes hospitalised for COVID-19 since 10 March 2020. The group's latest report describes 2,796 patients, 88.2% of whom had type 2 diabetes, with 50.2% being discharged from hospital within 28 days of admission and 20.6% dying.<sup>10</sup> In an age-adjusted regression analysis, male sex and history of either microvascular or macrovascular complications were among the baseline factors associated with a poor outcome.<sup>10</sup>

The impetus and rationale for the Association of British Clinical Diabetologists (ABCD) nationwide audit was the urgent requirement to learn and understand more about the clinical course of COVID-19 in the UK in individuals with diabetes. Early reports indicated a high risk of severe outcome for individuals with diabetes admitted to hospital. In addition, there were indications that the clinical course of diabetes itself was different from patients who were admitted to hospital with acute diabetes decompensation in the absence of a COVID-19 diagnosis. The audit was therefore developed to collect clinical data rapidly on the severity of diabetes at presentation, and the clinical course of diabetes and of COVID-19 during hospital care.

The ABCD has a longstanding, well-established infrastructure for nationwide audit.<sup>11</sup> This infrastructure was originally created to allow diabetes specialist teams across the UK to collate real-world experience of new therapies for diabetes.<sup>11</sup> More recently, this modus operandi has been extended to other clinical issues including newer glucose monitoring and insulin delivery technologies.<sup>11</sup> The dissemination of results from the ABCD audit programme has added to knowledge and understanding of new therapies and technologies, beyond the scope of randomised clinical trials.<sup>12</sup>

### **ABCD COVID-19 diabetes audit tool development**

A steering group was formed to include individuals with a variety of interests and expertise in clinical audit. The group adopted a pragmatic design, facilitating rapid collection of retrospective data from hospital records, with minimum burden on hard-pressed clinical teams and, through several rounds of iterative discussion, a pilot data collection tool was created. Parameters for data collection were selected for their relevance to diabetes clinical practice and to the emerging science of SARS-CoV-2 and COVID-19. The accessibility and likely reliability of these data within paper and electronic clinical records was assessed through

testing by members of the steering group. A finalised set of variables was included in a bespoke tool created in Microsoft Excel. This allowed collection of data in a standardised format for submission to the NIHR Health Informatics Collaborative (NIHR HIC) coordinating centre, based in Oxford University Hospitals NHS Foundation Trust (OUH).<sup>13</sup>

At each participating centre, diabetes specialist teams assume responsibility for identifying patients with diabetes who have been admitted to hospital with COVID-19 since the beginning of the pandemic, and for collecting and reporting their clinical data in pseudonymised form. Only patients with a positive SARS-CoV-2 test are included in the audit. In practice, this means that identification of patients has occurred in most centres through systematic assessment of the clinical records of all people admitted with a positive SARS-CoV-2 test. In other centres, data have been reported only for patients with diabetes and COVID-19 who required clinical input from the diabetes specialist team. The audit therefore provides an augmented record of clinical experience of diabetes specialist teams across the UK, whilst recognising that it will not be a comprehensive record of all patients with diabetes admitted to hospital with COVID-19.

As of 10 February 2021, data collected from 3,542 patients with type 1 or type 2 diabetes and COVID-19 have been submitted by a total of 42 NHS centres around the UK. For the purpose of this audit, severe COVID-19 was defined as death in hospital and/or admission to the adult intensive care unit (AICU). The database comprises complete data on 212 inpatients with type 1 diabetes and 3,201 with type 2 diabetes hospitalised between March and December 2020. The data include outcomes to discharge or death, for up to 70 days from admission, reflecting the prolonged hospital course of many patients with severe COVID-19.

### **Data collection, storage and handling**

Clinical teams based at UK hospitals were invited to contribute to the audit by word of mouth, by email and by announcement on the ABCD website.<sup>14</sup> A centre-specific audit data collection tool was provided to each registered centre. At each centre the tool was maintained behind the NHS firewall in secure servers. As a final step before transfer of data to the NIHR HIC coordinating centre at OUH, pseudonymisation was achieved through replacement of all personal identifiers by a centre-specific code. Transfer of pseudonymised data occurred via secure NHS email. Submissions were checked by the NIHR HIC team and additional information sought from participating centres if necessary. Data were cleaned by the NIHR HIC team to standardise formats – for example, dates, units removed where only results were expected, invalid entries removed or corrected with additional information from the participating centre. The cleaned data were loaded into an MS SQL Server database, hosted on a secure server within OUH, and made available to the analysis team through a LabKey portal. The data analysis has taken place within the secure OUH information governance environment.

### **Ethical approval**

The audit was registered with OUH and a Data Protection Impact

Assessment carried out by the steering group was reviewed for use in England and Wales by the OUH Caldicott Guardian and for use in Scotland by the Public Benefit and Privacy Panel (reference 2021-0111). The NHS supports clinical audits, with clear guidance for all NHS trusts and health boards<sup>15</sup> on the use of routinely collected clinical data, including submission in pseudonymised form via the secure NHS network. As this is an audit of clinical data gathered routinely during clinical care, there is no requirement for approval by a Research Ethics Committee.<sup>15</sup>

### Variables

Inpatients' demographic information, clinical characteristics, medication history and laboratory measurements are collected from electronic and paper medical record systems. Demographic data comprise age in years, sex, ethnicity and census-derived Index of Multiple Deprivation decile. Clinical characteristics include weight and height, or BMI; type of diabetes (see Table 1 for details of classification); duration of diabetes; presence or absence of diabetes complications including diabetic ketoacidosis, diabetic foot ulcer, diabetic nephropathy, diabetic peripheral neuropathy, diabetic retinopathy, peripheral vascular disease, ischemic heart disease, myocardial infarction and/or heart failure, cerebrovascular disease (stroke/transient ischemic attack) and other significant co-morbidities (hypertension, dementia, asthma, chronic obstructive pulmonary disease, malignant neoplasm, smoking status). Medication history includes antidiabetic medications and other selected classes (angiotensin converting enzyme inhibitor or angiotensin receptor antagonist, oral corticosteroid, statin, antiplatelet, anticoagulant and regular non-steroidal anti-inflammatory drug).

Laboratory data include latest pre-admission HbA<sub>1c</sub> and serum creatinine, and the COVID-19 admission blood glucose, pH, bicarbonate, lactate and capillary blood ketone concentration. Dates of the start and finish (if applicable) of each hospital admission are collected in individuals who had diabetes and a positive test for COVID-19, along with the date of the first positive SARS-CoV-2 test (a positive result is a prerequisite for inclusion in the audit). Recorded outcomes include vital status and admission to an AICU. The ABCD audit remains open with information on how to join and new centres can request the data collection sheet from the ABCD secretariat with details of the audit readily available online.<sup>16</sup>

### Discussion

To the best of our knowledge, this audit comprises the largest cohort yet assembled of people with diabetes admitted to NHS hospitals in the UK with COVID-19 infection for whom detailed clinical information is available. We believe that this audit has several strengths, in particular the detailed biochemical data and long-term outcomes of people admitted to hospital with COVID-19 and diabetes (Table 2). The steering group has started to analyse the data to explore a number of unanswered questions regarding the clinical characteristics and outcomes of the pandemic and its effect on people with diabetes. A summary of the analyses of interest is shown in Box 1. We would encourage hospitals across the UK to submit their data in order to ensure

**Table 1** Methodology of classification of type of diabetes

	T1 Diabetes	T2 Diabetes
<b>Entry in data collection</b>	"1", "IDDM", "T1DDM", "T1DM", "type 1", "Type 1", "Type 1", "type1"	"2", "T2", "t2ddm", "t2DDM", "T2DDM", "T2DM", "typ2", "type 2", "Type 2", "TYPE 2", "type2", "Type2", "type 2"
<b>Checked against other data</b>	Removed if no insulin use reported in columns: Basal insulin/Rapid insulin/Insulin pump/Premixed or biphasic insulin	Assumed if no insulin use reported AND Patient on Sulfonylurea/DPP-IV inhibitor/GLP-1 agonist

**Table 2** Unique features of the ABCD Nationwide Audit of COVID-19 and Diabetes

<b>1</b>	An audit which is clinically led and designed
<b>2</b>	Large number of participating centres, allowing general applicability of the results
<b>3</b>	Data collected in a standardised form and handled by a single coordinating centre
<b>4</b>	Data collected on a large cohort of population through UK centres (>3,000 submissions so far)
<b>5</b>	A hospital-based audit
<b>6</b>	Data collected on both type 1 and type 2 diabetes
<b>7</b>	Data available throughout the clinical course of the disease from admission until discharge or death  Data collected during first and subsequent waves of the pandemic, allowing comparison of changes in the clinical course of COVID-19
<b>8</b>	Data quality checked by the coordinating centre and issues of completeness and accuracy actively followed up and addressed with participating centres

**Box 1** Summary of the initial proposed analysis of the ABCD Nationwide Audit of COVID-19 and Diabetes dataset

- Analysis of clinical characteristics and outcomes for people with type 1 diabetes and COVID-19 (submitted to Diabetologia)
- Description of audit methodology
- Detailed comparison of characteristics and outcomes of people with type 1 and type 2 diabetes
- Paper on type 2 diabetes with focus on ethnicity and outcomes and also the relationship of micro- and macrovascular complications of diabetes and outcome
- Detailed understanding of relative protection or harm of angiotensin-converting enzyme inhibitors and angiotensin II receptor blocking medication
- Detailed clinical characteristics and outcomes of people presenting with diabetic ketoacidosis

that these analyses are as robust and detailed as possible. Authorship of any publications will follow the usual ABCD guidelines, with all submitting centres referenced as collaborators and larger centres providing titled authorship.

There has been a large number of studies in relation to COVID-19 and diabetes. However, the majority of these have been under-



## Key messages

- We have shown that, a rapid assimilation of a team of researchers to response to COVID-19 pandemic and its impact of acute diabetes admissions to hospital was vital to this project
- The data collection contains comprehensive information on a large unselected cases admitted to UK hospitals during COVID-19 Pandemic
- This clinically led nationwide COVID-19 and diabetes audit hope to provide with insights, different from the previous published data
- Knowledge of COVID-19 and diabetes from this audit will help better clinical care of cases admitted to hospital with COVID- and diabetes (both type 1 and type 2)

taken using non-contemporaneous data. Few studies have collected data within hospital settings and these have, for the most part, been limited by coming from single centres, with small numbers of patients, limited ethnic diversity, short time frames for determination of outcomes, and a lack of differentiation by type of diabetes. The ABCD nationwide audit will therefore make a significant contribution to the literature on diabetes and COVID-19 as a result of its size, the systematic approach to in-hospital data collection, the multi-ethnic nature of the UK population and the collection of data through to discharge alive or to in-hospital death, reflecting the prolonged hospital course of some patients with severe COVID-19.

The audit is limited by incomplete case ascertainment and reporting of patients with diabetes and COVID-19 in some participating centres, by the absence of a comparator group of people suffering COVID-19 but not diabetes, and by rapid changes in prevalence and inpatient management of COVID-19 that have occurred throughout the pandemic. However, it will provide evidence on patterns of outcomes that are representative of the experience of people with diabetes admitted to hospital with COVID-19 in the UK. We envisage the findings will help to target diabetes-specific advice and interventions for people admitted with COVID-19.

**This audit has been conducted using NIHR Health Informatics Collaborative (HIC) data resources at Oxford University Hospitals NHS Foundation Trust.**

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