

# Changes in hyperglycaemia-related testing for prediabetes and type 2 diabetes mellitus management: a prospective, cross-sectional survey of 16 years of general practice data from Australia

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## Research Article

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# Abstract

## Background

The rising prevalence of prediabetes increases the population risk of type 2 diabetes mellitus (T2DM), metabolic syndrome and cardiovascular disease. Early identification by General Practitioners (GPs) provides opportunities for lifestyle modifications that can lower these risks.

## Methods

This study examined 16 years of annual trends (2000/01-2015/16) in hyperglycaemia-related testing for patients in Australia aged 13 years or older with, or at risk of a diagnosis of T2DM. The Bettering the Evaluation and Care of Health (BEACH) study is a national cross-sectional survey, with a single-stage, cluster sampling design. Approximately 1,000 GPs were randomly selected annually (2000/01-2015/16) from across Australia, who each recorded details of 100 consecutive clinical encounters with consenting patients. Means and 95% confidence intervals were adjusted for intracluster correlation and GP characteristics.

## Results

15,679 GPs recorded details of 1,387,190 clinical encounters with patients aged 13+ years. Prediabetes and T2DM were managed at 0.25% (95% CI: 0.24-0.27%) and 3.68% (95% CI: 3.62-3.73%) of encounters respectively. By the end of the study, annual management rates were 2.3 times higher for prediabetes and 1.5 times for T2DM management. The likelihood of ordering at least one hyperglycaemia-related test during prediabetes management occasion was twice the likelihood in management of T2DM. For prediabetes, glucose tolerance tests were most common but from 2014/15, requests for HbA1c tests began to increase. For T2DM, HbA1c tests were most common, and requests for one or more glucose tests gradually declined.

## Conclusion

The observed 16-year annual trends align with the rising incidence of prediabetes and T2DM. GPs appeared to be strongly influenced by changes to the national insurance scheme and clinical guidelines for hyperglycaemia-related pathology testing. However, some GPs may have been pre-empting policy changes as there was also evidence of 'unendorsed' testing, notably for prediabetes that warrants further investigation. The increasing management rates for prediabetes, coupled with higher rates of pathology requesting have substantial resource implication. Calls to lower the risk threshold for prediabetes screening therefore warrant an economic analysis. Ongoing, reliable, up-to-date data is needed to inform clinical practice guidelines and policy in Australia.

## Introduction

The prevalence of Type 2 Diabetes Mellitus (T2DM) continues to rise globally. Current estimates are that around half a billion people worldwide have T2DM and this is projected to increase by at least 50% over the next 30 years [1]. In Australia, well over 1.2 million (4.9%) of the population have a diagnosis of diabetes, mostly T2DM [2, 3]. Another 1 in 6 Australians older than 25 years are likely to have prediabetes [4]. Primary medical care is the cornerstone of T2DM management in Australia. In 2015/16, around 4.0% of general practitioners' (GP) clinical encounters involved T2DM management [5].

The Royal Australian College of General Practitioners (RACGP) in collaboration with Diabetes Australia, provides patient-centered recommendations aimed at optimizing diabetes diagnosis and management [6]. In 2016, glycated haemoglobin (HbA1c) was introduced as an alternative screening pathway to the standard fasting blood glucose (FBG) test that is followed by an oral glucose tolerance test (OGTT) if indicated [6]. In discussion with patients, GPs decide which screening pathway, FBG or HbA1c they will use.

Prediabetes – a state of glucose dysregulation that does not meet the diagnostic criteria of T2DM – is considered part of the continuum of glucose dysregulation culminating in T2DM. However, it is also a recognised clinical entity and is independently associated with an increased risk of the metabolic syndrome and cardiovascular disease [7, 8]. Studies have demonstrated that early identification of prediabetes when accompanied with lifestyle interventions, may reduce the risk of developing T2DM [9].

While T2DM is well defined, there is no agreed, universally recognised screening and diagnostic criteria for prediabetes [10–12]. Notably, the term 'prediabetes' is only used in the RACGP diabetes guidelines in the context of gestational diabetes, and instead 'impaired fasting glucose', 'impaired glucose tolerance', and 'high risk HbA1c' are used when referring to elevated results that do not meet the diagnostic criteria for T2DM [6]. In contrast, leading Australian non-medical primary care professional bodies have continued to use the term 'prediabetes' in their updated 2020 joint position statement on the screening and management of prediabetes in adults in primary care [12]. Along with FBG, HbA1c is now recommended as a first line screening test and a lower risk threshold is applied than that used for screening for T2DM. The addition of HbA1c and their use of the term prediabetes aligns with the American Diabetes Association guidelines [10].

Insulin, either fasting or with an OGTT, is another pathology test that GPs and medical specialists might use when screening and diagnosing prediabetes. Whilst these tests are not widely endorsed, since at least 2010 there have been calls to consider the role of insulin tests [13–15].

Given the current, and potential uses of these hyperglycaemia-related tests (FBG, HbA1c, OGTT and insulin) and their cost implications, it is important to document pathology referral activity by GPs in Australia within the broader picture of T2DM and prediabetes. A secondary analysis of publicly available Medicare Benefits Schedule (MBS) data found that between 2010 and 2019 pathology screening rates for T2DM doubled [16]. Limitations of the data included the MBS item numbers that bundle tests together, no information about who ordered the test, and little, if any information about the clinical circumstances.

Consequently, there remains a need to determine which hyperglycaemia-related pathology tests GPs in Australia use for managing prediabetes and T2DM, and how this may have changed over time relative to changes to Australian diabetes guidelines and MBS funding policies. The aim of this study was to investigate 16 years of GP encounters with patients aged 13 years and over (adolescents and adults) for the management of prediabetes and T2DM, and the rates of requests for hyperglycaemia-related pathology tests.

## Methods

### Study design

Analyses of data from the Bettering the Evaluation and Care of Health (BEACH) study, a national cross-sectional survey of GP clinical activity, with single-stage, cluster sampling of GPs, conducted from April 1998 to March 2016. [5].

### Setting, participants, data source & classification

The BEACH methods are described in detail elsewhere [5]. In brief, each year from April 1998 through to March 2016, the BEACH study involved ever-changing, random samples of approximately 1,000 GPs from across Australia, each of whom recorded details of 100 consecutive clinical encounters with consenting patients. At each encounter, participating GPs recorded, deidentified clinical details including: patient characteristics; up to four problems actively managed at the encounter (free text) and any management actions taken by the GP (directly linked to the problem being managed), including up to 5 pathology tests/batteries of test ordered (free text). The data were then coded by trained clinical coders using the Australian interface terminology ICPC-2 PLUS [17], which is classified according to the International Classification of Primary Care (ICPC-2) [18].

### Data analysis

Data collected in the last 16 years (April 2000 to March 2016) of the BEACH study were selected for the analysis. Only encounters with patients aged 13 years and over (adolescents and adults) were included. The ICPC-2 PLUS terms and codes rubric used to define prediabetes, T2DM, and the hyperglycaemia-related tests is outlined in Box 1. All point estimates were calculated as proportions, if an event could happen more than once (e.g. any glucose test) they were calculated as 'at least one' (e.g. at least one glucose test). The types of patients seen, the problems managed, and treatments provided by the GP can be influenced by the characteristics of the GP. We accounted for the clustering of 100 encounters around each GP in the sample, by using the survey means procedure in SAS v9.4 to calculate the intraclass correlation and adjusting the 95% confidence intervals accordingly. Post-stratification weighting of encounter data was used to adjust for GP activity according to the number of MBS encounters claimed in the previous 12 months and for any minor differences in the age-sex distribution of participating GPs. Statistically significant differences between point estimates were determined by non-overlapping 95% confidence intervals, which is a more conservative approach than the traditional alpha of 0.05 [19].

## Results

Over the 16-year study period (April 2000 to March 2016), 15,679 GPs participated in the BEACH project, recording details of 1,387,190 encounters with patients aged 13 years or older. Substantially more encounters with patients involved T2DM management than prediabetes management (Fig. 1). GPs managed T2DM in 50,979 (3.68%, 95% CI: 3.62-3.73%) of these encounters and prediabetes at 3,530 (0.25%, 95% CI: 0.24-0.27%) encounters. Statistically significant increases in the management rates for both conditions were observed. Compared to 2000-01 (2.89% of encounter (95% CIs 2.67-3.10)), the annual T2DM management rate was 1.46 times higher in 2015-16 (4.22%, 95% CI: 3.93-4.50%). Over the same period, prediabetes management increased 2.33 times (0.14% of encounters (95% CI: 0.10-0.18%) to 0.33% (95% CI: 0.28-0.38%)).

Over the 16-year study period, the proportion of prediabetes and T2DM management occasions where one or more hyperglycaemia-related test(s) were requested was relatively stable (Fig. 2). However, the likelihood of a GP ordering at least one hyperglycaemia-related test in management of prediabetes (55.9%, 95% CI 53.9-57.8%) was significantly higher than when T2DM was managed (27.3%, 95% CI: 26.7-27.9%).

When hyperglycaemia-related tests were considered separately for the management of prediabetes (Fig. 3) and T2DM (Fig. 4), differences were observed in both the annual rates of the different pathology tests that were requested per encounter and the annual trends.

For prediabetes management, requests for any one or more of the glucose-related tests were by far the most common. Requests ranged from 42.2% (95% CI: 35.1-51.3%) of prediabetes management occasions in 2001/02, to a peak of 65.8% (95% CI: 58.0-73.5%) in 2008/09. This trend was attributable to OGTTs that represented the bulk of the glucose-related tests. OGTTs were requested at 24.5% (95% CI: 15.9-33.1%) of prediabetes management occasions in 2001/02, peaking at 46.3% (95% CI: 38.0-54.7%) in 2008/09. Requests for FBG tests were significantly lower each year, ranging from 3.4% (95% CI: 1.1-5.7%) in 2001/02 to 11.9% (95% CI: 6.1-17.7%) in 2007/08. Requests for HbA1c tests ranged between 2.6% (95% CI: 0.3-5.4%) in 2001/02 and 19.7% (95% CI: 13.7-25.7%) in 2015/16. Requests for insulin tests were the lowest. No insulin tests were requested for four of the 16 years of the study, and their highest use was in 2012/13 (3.6%, 95% CI: 2.5-6.9%) (Fig. 3).

For T2DM management, annual requests for HbA1c were significantly more likely than for any of the other hyperglycaemia-related tests. There was a steady, significant increase in HbA1c requests, starting at 18.7% (95% CI: 16.5-21.0%) of T2DM management occasions in 2000/01, increasing to 24.8% (95% CI: 22.7-26.9%) by 2015/16. Over the same timeframe, requests for any glucose-related test fell significantly from 13.5% (95% CI: 11.4-15.6%) to 6.6% (95% CI: 5.3-7.9%). Requests for both FBG (95% CI ranges 1.4-3.7%) and OGTT (95% CI ranges 0.1-1.4%) were substantially lower than in prediabetes management, and the OGTT was the least common glucose test. Pathology requests for insulin were also negligible, with annual rates including the upper limit of the 95% CI remaining below 0.2% (Fig. 4).

## Discussion

This study reports 16 years of hyperglycaemia-related pathology test ordering for the management of prediabetes and T2DM by GPs in Australia. During this time, 3.68% of GP encounters were for the management of T2DM and 0.25% were for prediabetes and the management rates increased by 1.5 and 2.3 times, respectively. For both conditions, the annual requests for hyperglycaemic-related tests per management occasion remained relatively stable. However, significant changes were observed in the types of tests requested for the two conditions and the annual rates. For prediabetes management, glucose tests that mostly reflected high request rates for OGTTs, were most common but from 2014/15, requests for HbA1c tests started to dramatically increase. For T2DM management, HbA1c tests were most often requested, and the annual rate steadily increased as the rates of glucose testing declined. The proportion of prediabetes management occasions where glycaemia-related test were requested was double that of T2DM. Combined, these findings suggest that GP activity was influenced by nationally endorsed clinical practice guidelines for the use of pathology tests [6, 11, 20] and by national health insurance (MBS) funding [21]. However, 'unendorsed' and unfunded pathology tests were also requested.

The appropriate use of pathology tests is important for optimizing patient outcomes and there are substantial cost implications for both insurers and patients. It is reassuring then, that within the BEACH dataset used for this study, hyperglycaemia-related pathology testing for T2DM diagnosis and management generally aligned with the nationally endorsed recommendations [6, 11, 20]. Like other studies, there was also evidence that MBS funding of tests probably influenced GP clinical practice [16]. As such, both appear to be effective policy tools for promoting evidence-based medicine.

Notwithstanding, not all requests for pathology aligned with nationally endorsed guidelines. GPs were requesting HbA1c tests in the context of prediabetes management well before 2009, when some of the first calls were being made in Australia to add HbA1c tests for screening patients with an increased risk of developing T2DM [20], and also before the introduction of MBS funding near the end of 2014 [21]. Similarly, despite no national or international recommendations, insulin tests were requested by GPs, albeit infrequently and mostly for prediabetes management.

It is well recognised that clinical practice guidelines are often not followed for a wide range of reasons, including limited evidence [22–26]. Indeed, only the evidence for HbA1c monitoring of long-term glucose control was graded by the RACGP as high (A), and all other recommendations for pathology testing were graded as moderate (B) or low (C) [6]. Emerging evidence [13–15, 20], along with clinical acumen/wisdom and tailoring pathology screening to the individual patient [22, 24], are also likely to have influenced clinical decisions. Further research is warranted, both in the context of prediabetes and T2DM, and more broadly, to understand the factors that influence clinical decisions.

The findings also raise questions about potential resource implications of the 2020 Australian joint position statement for screening prediabetes in adults in primary care, as a lower risk threshold is applied and HbA1c is included [12]. During the 16-year study period, the management rate of prediabetes more than doubled and hyperglycaemia-related pathology tests were consistently more likely to be ordered

than for T2DM management. Since the end of the BEACH study in 2016, due to the changing demographics of the Australian population and rising rates of obesity the prevalence of prediabetes and T2DM have continued to rise [2, 12]. Additional longitudinal data about the primary care activities and the clinical outcomes of patients at risk of prediabetes and T2DM, would help inform economic modelling of the potential costs and benefits of the proposed policy changes and whether additional MBS funding is indicated.

## **Strengths and limitations of this study**

The BEACH study is unique in the Australian setting. The very large data set, consistently collected over 16 years, coupled with the cluster analysis and weighted stratification approach has generated reliable, representative data to inform Australian healthcare planning and policies. The BEACH dataset allowed exploration of temporal changes in encounter rates and hyperglycaemia-related testing.

Limitations of the BEACH study include its cross-sectional study design which did not allow us to determine how often individual patients consulted the GP or were being tested., nor to explore the reasons GPs ordered tests not endorsed by national guidelines or funded by the MBS. Data were only available up to March 2016. This was the same year that substantial changes to the RACGP diabetes guidelines were made, so the full impact of RACGP endorsement of HbA1c for diagnosing T2DM could not be assessed. A maximum of five pathology tests, or suites of tests (e.g. liver function tests or lipid studies), could be recorded per encounter. Yet, it is common for GPs to order more tests, particularly when there is multimorbidity as is often the case with prediabetes and T2DM [3, 7]. Therefore, when selecting up to five tests, participating GPs might be inclined to first list tests that they perceived as most important and less contentious. As such, it is possible that insulin, and perhaps some prediabetes HbA1c testing, was underreported.

Limitations of this analysis included not investigating the number of tests requested for an individual patient encounter and whether there were any differences in the patient characteristics (e.g. age, gender, ethnicity, multimorbidity) for whom the different hyperglycaemia-related tests were requested. Another limitation was not investigating when hyperglycaemia-related tests were ordered for reasons other than T2DM and prediabetes, such as for metabolic syndrome, polycystic ovarian syndrome, other endocrine disorders, and routine health checks. Such tests for other morbidities were therefore not enumerated in this study.

## **Conclusion**

Annual trends in pathology request rates for hyperglycaemia-related tests suggest that the clinical practice of GPs in Australia is strongly influenced by national guidelines and funding. Changes in Australian diabetes guidelines during the 16-year study corresponded with a significant increase in use of HbA1c and decline in glucose tests for the management of T2DM, and rising rates of HbA1c testing for patients with prediabetes near the end of the study. While it is likely that glucose-related testing will

remain the major mode of testing for prediabetes management, the impact of the recent 2020 joint position statement is uncertain. The BEACH study was completed in 2016, it has proved to be an essential information source for research, health system planning, and policy development. Similar projects are now urgently needed in Australia to ensure there is reliable, up-to-date, primary care data that can be used to inform government, industry, and not-for-profit organisations.

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## Abbreviations

T2DM        type 2 diabetes mellitus

GP         General Practitioner

RACGP     Royal Australian College of General Practitioners

HbA1c     glycated haemoglobin

FBG       fasting blood glucose

OGTT     oral glucose tolerance test

IFG       impaired fasting glucose

MBS       Medicare Benefits Schedule

BEACH    Bettering the Evaluation and Care of Health

ICPC-2    International Classification of Primary Care

ICPC-2 PLUS Australian interface terminology of the International Classification of Primary Care

## Declarations

### Ethics approval and consent to participate

The BEACH program has ethics approval from the Human Research Ethics Committee of the University of Sydney (Reference number 2012/130) for all years of this study and the Australian Institute of Health and Welfare for the years they collaborated on the project (April 1998– March 2011 inclusive). All patient participants gave informed consent to participate in the BEACH study.

### Methods

All methods were performed in accordance to the relevant guidelines.

**Consent for publication** (not applicable)

### **Availability of data and materials**

The dataset analysed during the current study is not publicly available as it contains health data with ethical and privacy restrictions placed on it. However, researchers with reasonable research questions may request analyses of these data if their questions are within the ethical guidelines set for the use of BEACH data. Data for the BEACH dataset can be requested from Dr Chris Harrison (christopher.harrison@sydney.edu.au).

### **Competing interests**

The authors declare no competing interests.

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### **Authors' contributions**

EM conceptualised the research question. CH conducted the data analysis. AL drafted the manuscript and created the figures. JH revised the manuscript. All authors interpreted the data, edited the manuscript, and approved the final manuscript.

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**Authors' information** Not applicable

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# Figures

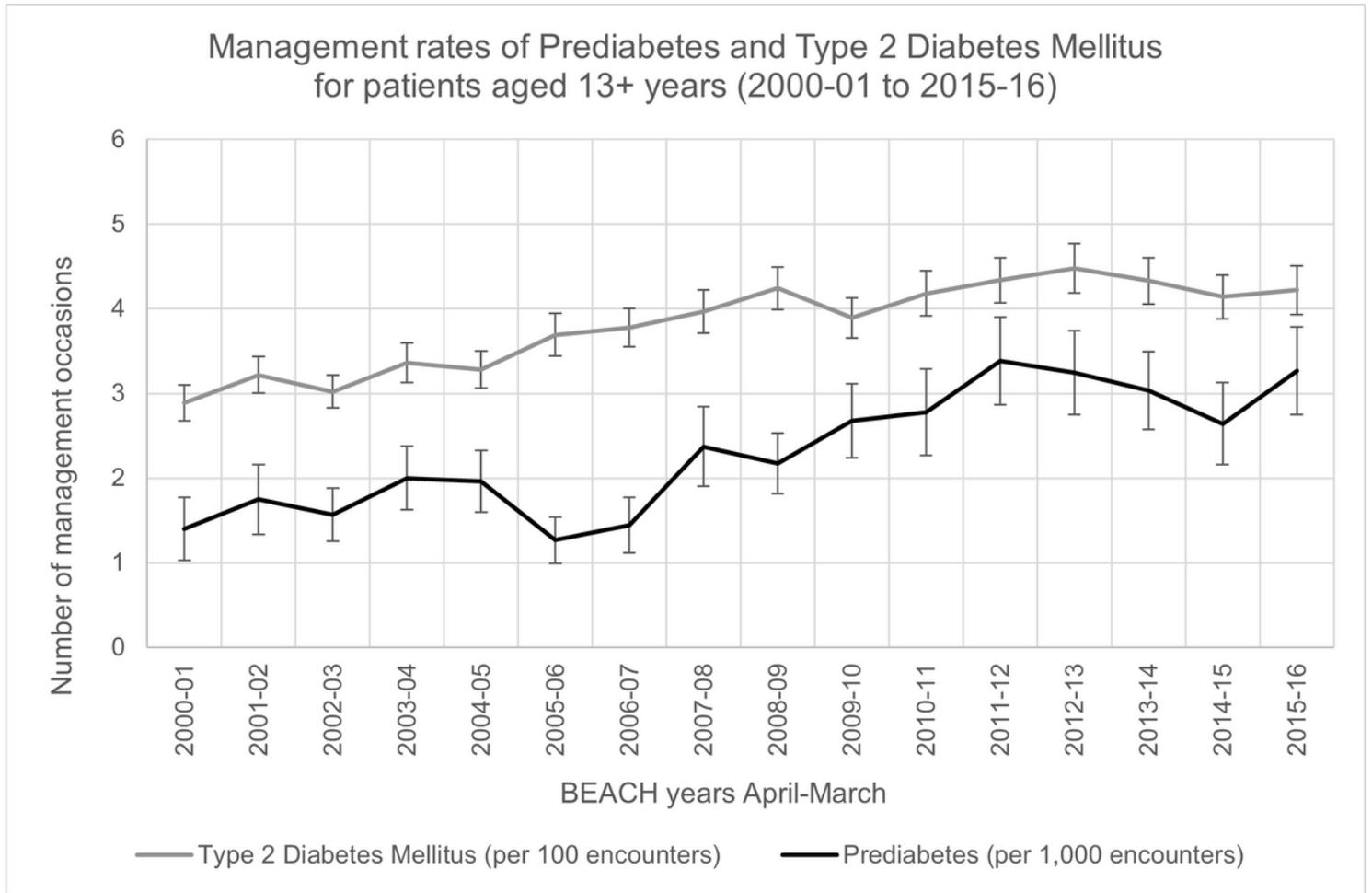
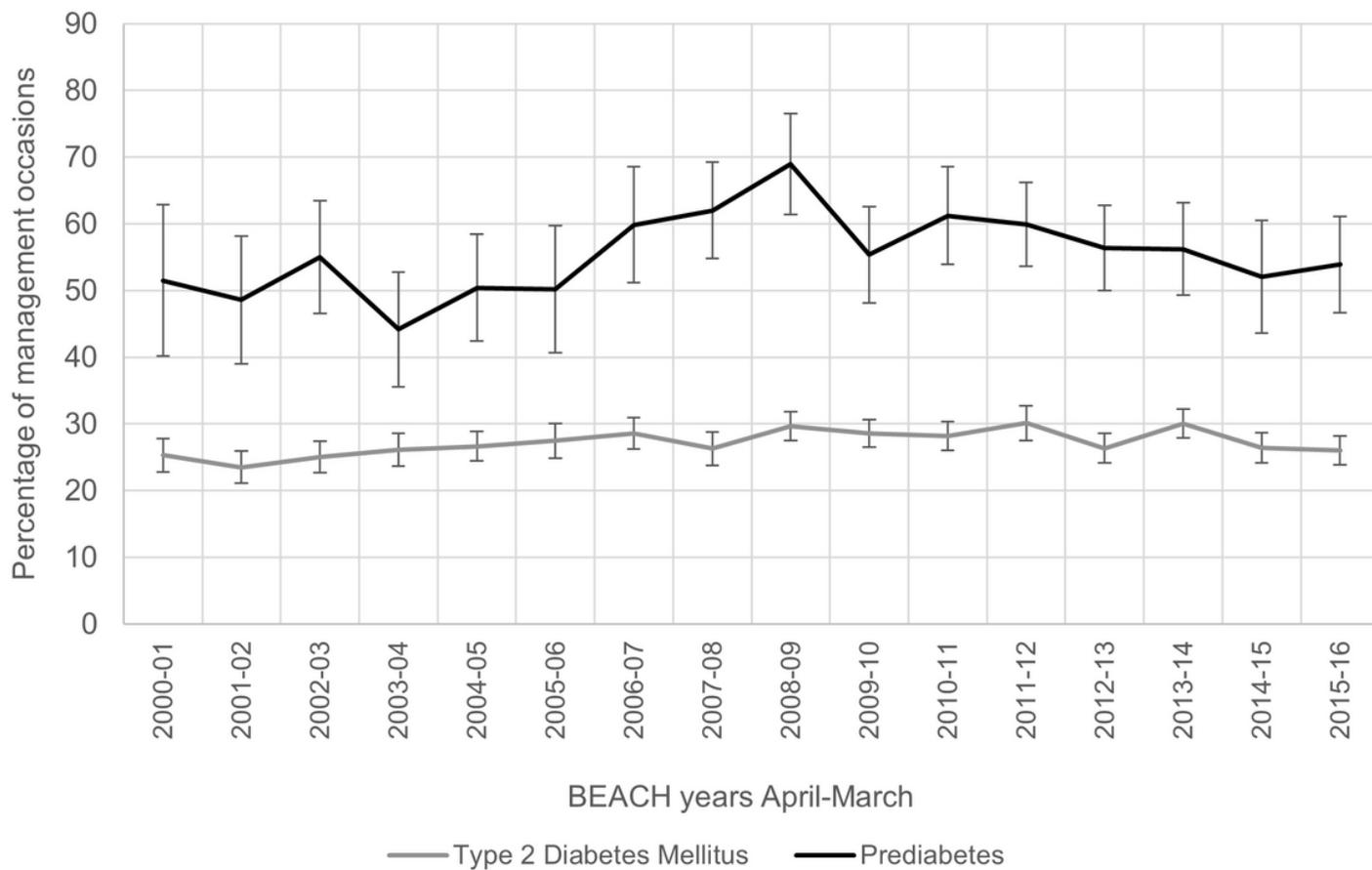


Figure 1

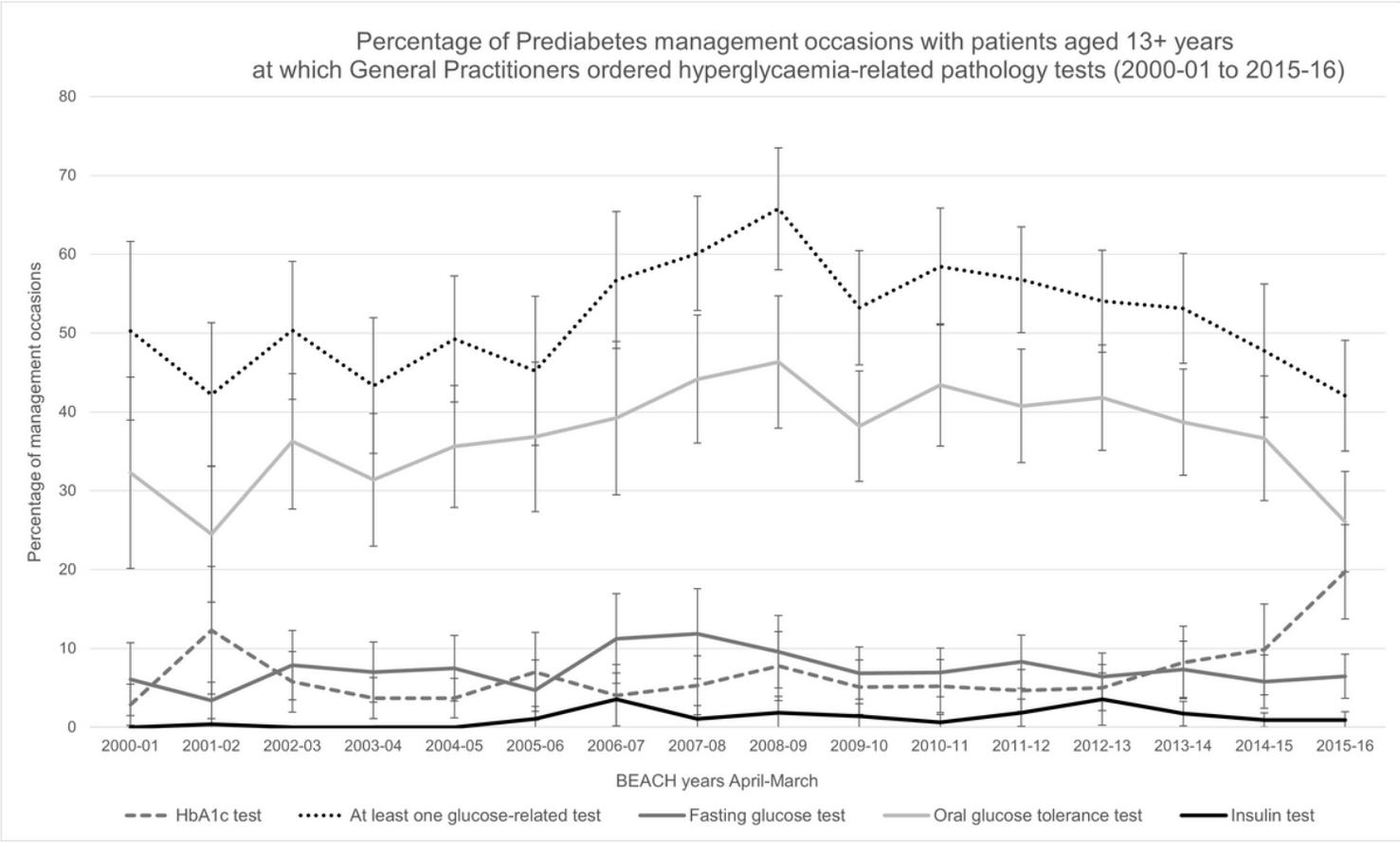
Error bars signify 95% confidence interval.

Percentage of Prediabetes and Type 2 Diabetes Mellitus management occasions with patients aged 13+ years at which General Practitioners ordered hyperglycaemia-related pathology tests (2000-01 to 2015-16)



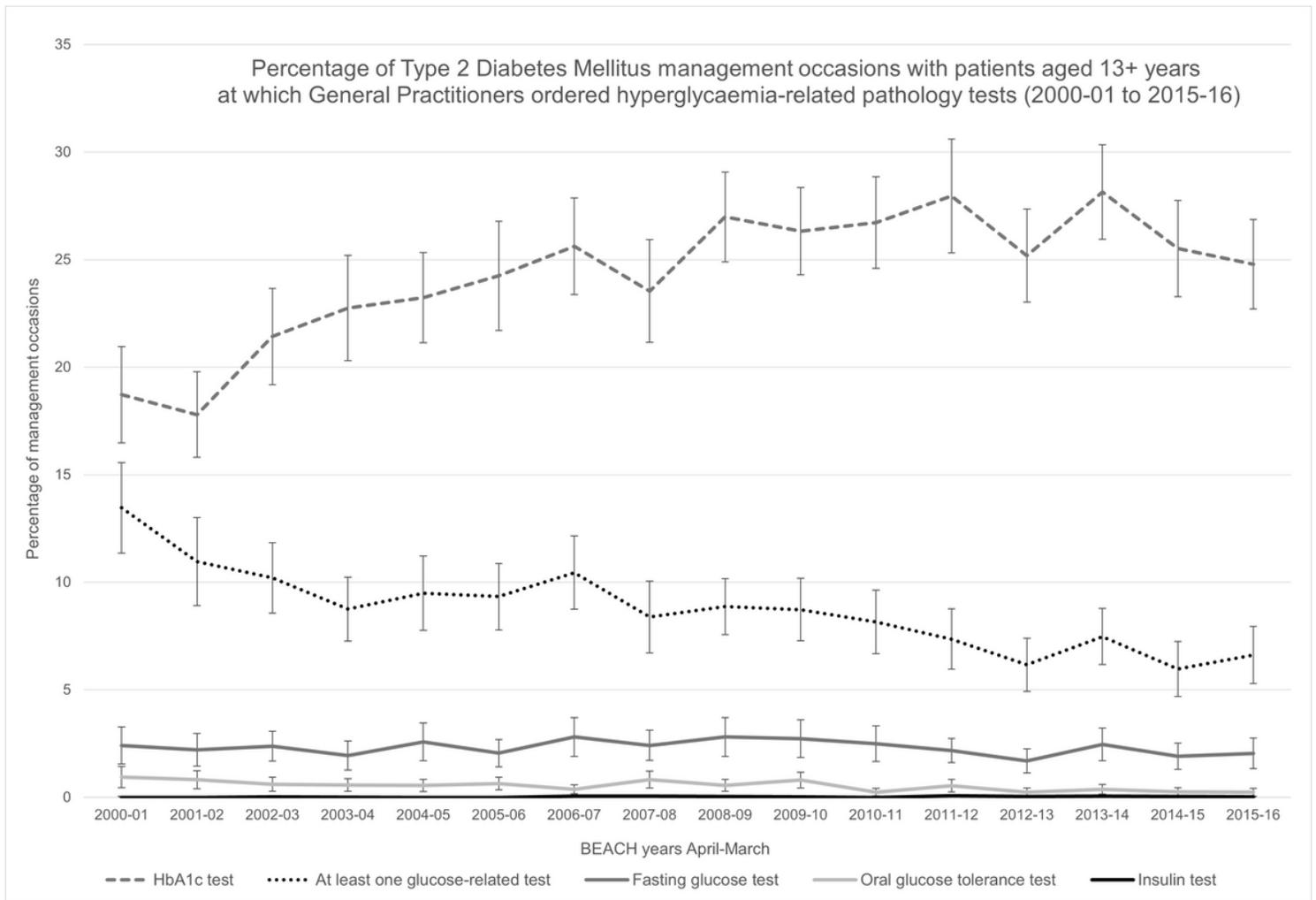
**Figure 2**

Error bars signify 95% confidence interval.



**Figure 3**

Error bars signify 95% confidence interval.



**Figure 4**

Error bars signify 95% confidence interval.

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