

# The prevalence of hypothyroidism in people living with type 2 diabetes mellitus attending the diabetic clinic at Helen Joseph Hospital

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**Objective:** To determine the prevalence of hypothyroidism in patients with type 2 diabetes mellitus (T2DM).

**Design:** A retrospective clinical audit from 1 January, 2020–30 April, 2020. The SEMDSA/ACE-SA guideline for normal TSH values was used to describe high TSH values and overall control. Descriptive statistics for normally distributed variables were reported in terms of means and standard deviations, and for skewed variables in terms of medians and interquartile ranges.

**Setting:** The diabetic clinic at Helen Joseph Hospital.

**Subjects:** Two hundred and ninety adults aged 45 years or older with T2DM.

**Results:** Of the 290 participants (median age 60 years, 66.6% female), 6.9% had known hypothyroidism, with only 20% achieving TSH targets. No patients were newly diagnosed with overt hypothyroidism; however, 17% had an elevated TSH. Metabolic control was generally poor among the hypothyroid group: none met HbA1c targets, 55% reached blood pressure or total cholesterol goals, and 5% met all lipogram criteria.

**Conclusion:** The prevalence of hypothyroidism was lower than in similar international studies. The low treatment rates and suboptimal levels of control of hypothyroidism highlight the need for clinicians to be more vigilant in screening and correctly managing this population.

## Introduction

Hypothyroidism and diabetes mellitus (DM) are two of the most common endocrine conditions worldwide. Primary hypothyroidism is defined as a disorder whereby the thyroid gland produces insufficient thyroid hormone to meet the requirements of the peripheral tissues.<sup>1</sup> Primary hypothyroidism is diagnosed by an elevated serum thyroid-stimulating hormone (TSH) and a low serum thyroxine (T4). However, the diagnosis cannot solely be based on clinical features, due to the large variety of presentations. The most common aetiologies of primary hypothyroidism include iodine deficiency or excess, autoimmune thyroiditis, iatrogenic (e.g. radioactive iodine therapy or thyroidectomy), drugs (e.g. iodine-containing contrast media, amiodarone, lithium, or anti-thyroid drugs), infiltrative disorders (e.g. sarcoidosis or haemochromatosis), and congenital hypothyroidism.<sup>1</sup>

The prevalence of hypothyroidism globally has been estimated at 5%, with a further 5% of people believed to be undiagnosed.<sup>2</sup> Moreover, the number of patients with hypothyroidism is on the rise, with one retrospective study of two data sets collected in the United States (US) reporting an increase in prevalence from 9.5% in 2012 to 11.7% in 2019.<sup>3</sup> Alarming, the proportion of patients with untreated hypothyroidism also grew from 11.8% to 14.4% over the same period.<sup>3</sup>

Diabetes is defined by persistently elevated serum glucose levels due to insufficient production or utilisation of insulin. Similar to hypothyroidism, there has been a dramatic increase in the worldwide prevalence of diabetes over the past two decades, with a current estimate of 537 million cases in 2021 globally and 24 million cases in Africa.<sup>4</sup> Furthermore, it is projected that 783 million individuals worldwide will have diabetes

by 2045, whilst the number of cases in Africa is estimated to reach 55 million.<sup>1,4</sup> The prevalence of type 2 diabetes mellitus (T2DM) in South Africa is higher in females – 16.78% compared with 12.36% in males; however, diabetes-related mortality rates disproportionately affect men.<sup>5</sup>

Several studies have shown an association between hypothyroidism and T2DM, with an increased prevalence of hypothyroidism amongst diabetic versus non-diabetic patients.<sup>6,7</sup> Factors associated with thyroid dysfunction in patients with T2DM include female sex, smoking, diabetes of more than 5 years' duration, a family history of thyroid disease, elevated glycated haemoglobin (HbA1c) and body mass index (BMI), longstanding dyslipidaemia, anaemia, and diabetic neuropathy and retinopathy.<sup>8,9</sup> The exact cause of elevated TSH levels in individuals with T2DM remains unclear, but is thought to be due to a combination of genetic and physiological factors that contribute to hyperglycaemia via increased hepatic glucose output, enhanced splanchnic glucose reabsorption, and impaired peripheral glucose utilisation.<sup>1</sup> Additionally, a blunted TSH response to thyrotropin-releasing hormone (TRH) has been proposed as a mechanism contributing to the development of hypothyroidism in this population.<sup>7</sup> Moreover, hypothyroidism in T2DM may increase susceptibility to multi-morbidity. A retrospective cross-sectional study in Cape Town, South Africa, reported a twofold increase in cardiovascular risk among T2DM patients treated for hypothyroidism compared with their euthyroid counterparts.<sup>10</sup> Given the relationship between hypothyroidism and T2DM and the consequent increased health risk to patients, as well as the exponentially increasing prevalence of these conditions, it is crucial that more research examines this double burden of disease to enhance clinical management practices.

Individual research studies have reported prevalence rates of thyroid dysfunction in T2DM patients ranging from 12.3% to 17.05%, with a recent meta-analysis of 38 studies (six from Africa) finding a pooled prevalence of thyroid dysfunction in T2DM of 20.24%.<sup>8,11–13</sup> With the exception of those six studies, limited literature exists within Africa on the prevalence of hypothyroidism within T2DM, with only one study in South Africa on the prevalence of subclinical hypothyroidism in T2DM, which found a lower proportion (1.6%) of affected patients than did the international literature.<sup>14</sup> Subclinical hypothyroidism (an elevated TSH with a normal T4) worsens insulin sensitivity and therefore may worsen glycaemic control.<sup>15</sup>

The purpose of this study was thus twofold. First, to describe the prevalence of hypothyroidism within T2DM patients at Helen Joseph Tertiary Hospital (HJH). Second, in those known to have hypothyroidism, to ascertain whether treatment targets were being met as per the 2015 SEMDSA (Society for Endocrinology, Metabolism and Diabetes of South Africa) ACE-SA (Association of Clinical Endocrinologists of South Africa) Guideline for the Management of Hypothyroidism in Adults.<sup>1</sup>

## Methods

### Study design, setting, and sampling

A retrospective, clinical audit for the period 1 January, 2020–30 April, 2020 was conducted at the HJH Diabetic Clinic. As part of standard of care at the HJH Diabetic Clinic, all patients have a screening TSH test done annually. Using convenience sampling, the clinical records of 300 consecutive patients who attended the clinic during this time were assessed. No distinction was made in terms of gender, age, race, socioeconomic status, or ethnicity. Exclusion criteria included patients with type 1 diabetes mellitus (T1DM), pregnant women, individuals younger than 45 years, and those who were acutely ill, to minimise the confounding effects of sick euthyroid syndrome. The study classified those with overt hypothyroidism as a TSH > 10 mIU/l and TSH control was assessed in accordance with the reference ranges specified by the SEMDSA/ACE-SA guidelines.

### Data collection

Two hundred and ninety patient records of the 300 assessed fulfilled the inclusion criteria and were entered into the data collection set. Demographic variables such as age, gender, and ethnicity were collected from the records. Other descriptive data, such as documented pre-existing comorbidities, target organ damage due to diabetes, social habits, including history of smoking and ethanol use, as well as any relevant chronic medication prescribed at the last visit, were also recorded. Data from the patient's first visit during the specified period were utilised for the study, except for clinical data such as blood pressure, heart rate, random blood glucose, and weight, which were recorded from the last clinic visit. The most recent biochemical investigations, such as TSH and T4, thyroid antibodies, and HbA1c were also extracted from the selected participant records.

Data were recorded on data sheets and then transferred to Microsoft Excel spreadsheets (Microsoft Corp, Redmond, WA, USA). Each participant was allocated a unique study number. The participants' hospital folder number and their allocated study number were stored in a password-protected spreadsheet, accessible only to the primary investigator. All other data were stored in a separate, password-protected

spreadsheet that contained only the participants' study numbers and no identifying information.

### Statistical analysis

Data analysis was performed using R v4.5.0 (R Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics for categorical variables were reported in terms of rates/proportions. Shapiro–Wilk testing was performed to assess the normality of continuous variables. Descriptive statistics for normally distributed variables were reported in terms of means and standard deviations, and for skewed variables in terms of medians and interquartile ranges. Appropriate inferential statistical tests were performed. These included Kruskal–Wallis tests, Pearson's and Spearman's correlations, Fisher's exact tests, chi-square tests, t-tests, and ANOVA. Uni- and multivariate logistic regression models were performed. Multivariate regression was performed using an automatic forward stepwise model.

### Treatment targets

The treatment targets used for this study (Table 1) were those set out by the SEMDSA 2017 Guidelines for the Management of Type 2 diabetes mellitus, and the SEMDSA/ACE-SA Guideline for the Management of Hypothyroidism in Adults.<sup>1,16</sup> HbA1c targets are individualised based on a patient's particular clinical scenario; however, for the majority of patients, one should aim to maintain an HbA1c ≤ 7% to mitigate cardiovascular risks. In contrast, patients with risk factors that predispose them to hypoglycaemia, for example, those with multiple comorbidities, severe cardiac or vascular disease, and advanced renal disease, should have less tight control, in which case HbA1c should be targeted between 7.1% and 8.5%.

## Results

### Demographics

The sample size consisted of 290 participants. The median (interquartile range [IQR]) age was 60 years (54–68 years). One hundred and eighty-seven (64.5%) participants were younger than 65, whilst the remaining 103 (35.5%) were aged 65 years or older. One hundred and ninety-three (66.6%) participants were female. There were no significant differences in the proportion of male and female participants between these age groups ( $p = 0.156$ ). One hundred and thirty (44.8%) participants were African, 86 (29.7%) were of mixed race, 42 (14.5%) were Caucasian, and 32 (11.0%) were Indian. There were no significant associations between ethnicity and sex ( $p = 0.554$ );

**Table 1:** Targets for assessment of metabolic parameters in the study population

Parameter	Target
Blood pressure	
Systolic	130–140 mmHg
Diastolic	80–90 mmHg
HbA1c	
Cardiovascular and/or chronic kidney disease	7.1–8.5%
Rest of the study population	≤ 7%
TSH (in hypothyroid patients)	4.0–6.0 mIU/l
> 65 years old	
< 65 years old	0.5–3.0 mIU/l

Note: HbA1c = glycated haemoglobin; TSH = thyroid-stimulating hormone. Adapted from: SEMDSA 2017 Guidelines for the Management of Type 2 diabetes mellitus, and the SEMDSA/ACE-SA Guideline for the Management of Hypothyroidism in Adults.<sup>1,16</sup>

**Table 2:** Distribution of ethnicities among age groups

Ethnicity	Age group, n (%)	
	< 65 years	≥ 65 years
African	35 (34.0%)	95 (50.8%)
Mixed race	45 (43.7%)	41 (21.9%)
Caucasian	11 (10.7%)	31 (16.6%)
Indian	12 (11.7%)	20 (10.7%)

however, proportions of ethnicities differed significantly between participants younger than 65 and those aged 65 years or older ( $p = 0.001$ ; refer to Table 2).

Additionally, 39 (13.4%) participants smoked tobacco and 23 (7.9%) consumed alcohol. There were no significant associations between smoking and age ( $p = 0.258$ ) or sex ( $p = 0.281$ ); however, significantly fewer African participants (4.6%) smoked, when compared with Caucasian (23.8%), mixed race (22.1%), and Indian (12.5%) participants ( $p < 0.001$ ). There were no significant associations between alcohol consumption and age ( $p = 0.150$ ) or ethnicity ( $p = 0.090$ ); however, significantly more male (16.5%) than female (3.6%) participants consumed alcohol ( $p < 0.001$ ).

### Prevalence of hypothyroidism

A total of 20 participants (6.9%) in the study were known to have hypothyroidism. No cases of overt hypothyroidism, as defined by a TSH  $> 10$  mIU/l, were identified among patients without a prior diagnosis of hypothyroidism. The distribution of patients with hypothyroidism according to all categorical variables of interest is presented in Table 3. Gender was the only variable significantly associated with hypothyroidism (see Table 3).

### Treatment targets for patients with known hypothyroidism

Among the 20 participants known to have hypothyroidism, 4 (20.0%) had TSH levels within their age-appropriate SEMDSA target range, whilst 8 (40.0%) patients had TSH levels lower than and higher than their age-appropriate target range. Of the 20 participants known to have hypothyroidism, 19 (95.0%) were using levothyroxine, with a median (IQR) average daily dose of 100.0 mcg (56.3–110.7 mcg) (range = 25.0–200.0 mcg). Only one participant known to have hypothyroidism was not on treatment and had a TSH level lower than their age-appropriate SEMDSA target range.

The proportions of patients known to have hypothyroidism meeting specified SEMDSA guidelines are indicated in Table 4.

### Abnormal TSH

Of the 270 participants not known to have hypothyroidism, a total of 46 (17.0%) were found to have abnormally high TSH levels, but none met the criteria for overt hypothyroidism. The distribution of patients with elevated TSH values according to all categorical variables of interest is presented in Table 5.

The proportions of patients with and without known elevated TSH levels meeting specified SEMDSA guidelines are listed in Table 6.

**Table 3:** Prevalence of hypothyroidism according to all categorical variables

Variable	Prevalence of hypothyroidism, n (%)	p-value
<b>Age</b>		
< 65 years	12 (6.4%)	0.848
≥ 65 years	8 (7.8%)	
<b>Gender</b>		
Female	18 (9.3%)	0.040*
Male	2 (2.1%)	
<b>Ethnicity</b>		
African	9 (6.9%)	0.916
Mixed race	6 (7.0%)	
Caucasian	2 (4.8%)	
Indian	3 (9.4%)	
<b>HbA1c level</b>		
Within SEMDSA target range	0 (0.0%)	0.390
Outside of SEMDSA target range	20 (7.5%)	
<b>Known hypertension</b>		
No	1 (5.0%)	1.000
Yes	19 (7.0%)	
<b>Blood pressure</b>		
Within SEMDSA target range	11 (8.9%)	0.361
Outside of SEMDSA target range	9 (5.4%)	
<b>Known dyslipidaemia</b>		
No	2 (8.3%)	0.675
Yes	18 (6.8%)	
<b>Total cholesterol level</b>		
Within SEMDSA target range	11 (5.6%)	0.318
Outside of SEMDSA target range	9 (9.6%)	
<b>HDL-C level</b>		
Within SEMDSA target range	10 (7.2%)	0.909
Outside of SEMDSA target range	10 (6.6%)	
<b>LDL-C level</b>		
Within SEMDSA target range	5 (4.0%)	0.144
Outside of SEMDSA target range	15 (9.1%)	
<b>Triglyceride level</b>		
Within SEMDSA target range	10 (6.1%)	0.705
Outside of SEMDSA target range	10 (7.9%)	
<b>All lipogram parameters</b>		
Within SEMDSA target ranges	1 (2.9%)	0.458
At least one outside of SEMDSA target range	19 (7.5%)	
<b>Obesity</b>		
No	13 (6.3%)	0.745
Yes	7 (8.2%)	

Note: HbA1c = glycated haemoglobin; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; SEMDSA = Society for Endocrinology, Metabolism and Diabetes of South Africa.

\*p-value significant at 0.05 level or below.

## Discussion

This retrospective clinical audit examined hospital records at a diabetic clinic in South Africa to determine the prevalence of

**Table 4:** Metabolic targets among patients with hypothyroidism

Parameter	Hypothyroid patients within the normal range for parameter, as per SEMDSA guidelines, n (%)
HbA1c	0 (0.0%)
Blood pressure	11 (55.0%)
Total cholesterol	11 (55.0%)
HDL-C	10 (50.0%)
LDL-C	5 (25.0%)
Triglycerides	10 (50.0%)
All lipogram parameters	1 (5.0%)

hypothyroidism in patients with T2DM and compared clinical targets with available guidelines.

Globally, there is disagreement regarding best practice for thyroid disorder screening. In 2000, the American Thyroid Association (ATA) recommended that adults who were 35 years or older should be screened for thyroid disorders by measuring TSH levels every 5 years regardless of their diabetic status.<sup>17</sup> In contrast to this, a statement issued by the US Preventive Services Task Force in 2015 concluded that there was inadequate evidence to recommend screening for thyroid illness in the general population, excluding pregnant or symptomatic adults.<sup>18</sup> Similar to the latter recommendation, several guidelines promote regular TSH screening and other thyroid testing in specific cases only, such as for autoimmune conditions, for example, T1DM, in instances where diabetic patients have positive thyroid autoantibodies or high-normal TSH concentrations and for other metabolic syndrome conditions, such as dyslipidaemia and obesity.<sup>1,17,19</sup> However, there is no clear consensus on the screening of thyroid disorders in T2DM, a crucial gap that the results of this study serve to emphasise.

The prevalence of hypothyroidism (6.9%) was found to be lower than in other international studies.<sup>8,11,12</sup> The low prevalence of overt hypothyroidism observed in this cohort, compared with other literature, may reflect several factors. The study period was limited to four months, and the sample size, although adequate for descriptive analysis, may not have been sufficiently powered to detect rarer outcomes such as overt hypothyroidism. Additionally, differences in genetic, environmental, and dietary factors (including iodine intake), may contribute to variations in disease prevalence. Moreover, access to healthcare and the predominance of women in the study cohort – who are more likely to be screened and treated for hypothyroidism – may have reduced the number of undiagnosed or untreated overt cases. These findings highlight the need for caution in directly comparing prevalence rates across settings, as local demographic and health-system factors likely influence the burden of overt hypothyroidism in patients with type 2 diabetes.

Only 20% of patients with known hypothyroidism had TSH within their target ranges, with 40% being overtreated and the other 40% being undertreated. Of concern was the number of patients with elevated TSH levels, which was more than double (17%) those known to have hypothyroidism. Some of these may represent subclinical hypothyroidism requiring confirmation on repeat testing, but the findings likely also reflect underdiagnosis. The reasons for this within the public

**Table 5:** Prevalence of elevated TSH according to all categorical variables.

Variable	Prevalence of abnormally high TSH value, n (%)	p-value
<b>Age</b>		
< 65 years	42 (24.0%)	< 0.001*
≥ 65 years	4 (4.2%)	
<b>Gender</b>		
Female	26 (14.9%)	0.261
Male	20 (21.1%)	
<b>Ethnicity</b>		
African	23 (19.0%)	0.031*
Mixed race	6 (7.5%)	
Caucasian	11 (27.5%)	
Indian	6 (20.7%)	
<b>HbA1c level</b>		
Within SEMDSA target range	43 (17.5%)	0.776
Outside of SEMDSA target range	3 (12.5%)	
<b>Known hypertension</b>		
No	3 (18.8%)	0.741
Yes	43 (16.9%)	
<b>Blood pressure</b>		
Within SEMDSA target range	16 (14.2%)	0.367
Outside of SEMDSA target range	30 (19.1%)	
<b>Known dyslipidaemia</b>		
No	3 (13.6%)	1.000
Yes	43 (17.3%)	
<b>Total cholesterol level</b>		
Within SEMDSA target range	32 (17.3%)	1.000
Outside of SEMDSA target range	14 (16.5%)	
<b>HDL-C level</b>		
Within SEMDSA target range	21 (16.4%)	0.921
Outside of SEMDSA target range	25 (17.6%)	
<b>LDL-C level</b>		
Within SEMDSA target range	20 (16.7%)	1.000
Outside of SEMDSA target range	26 (17.3%)	
<b>Triglyceride level</b>		
Within SEMDSA target range	23 (14.9%)	0.371
Outside of SEMDSA target range	23 (19.8%)	
<b>All lipogram parameters</b>		
Within SEMDSA target ranges	5 (14.7%)	0.886
At least one outside of SEMDSA target range	41 (17.4%)	
<b>Obesity</b>		
No	29 (15.1%)	0.251
Yes	17 (21.8%)	

Note: HbA1c = glycated haemoglobin; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; SEMDSA = Society for Endocrinology, Metabolism and Diabetes of South Africa.

\*p-value significant at 0.05 level or below.

**Table 6:** Diabetic control among patients with elevated TSH levels

Parameter	Patients within the normal range for parameter, as per SEMDSA guidelines, n (%)		p-value
	Patients with low or normal TSH levels	Patients with elevated TSH levels	
HbA1c	21 (9.4%)	3 (6.5%)	0.776
Blood pressure	97 (43.3%)	16 (34.8%)	0.367
Total cholesterol	153 (68.3%)	32 (69.6%)	1.000
HDL-C	107 (47.8%)	21 (45.7%)	0.921
LDL-C	100 (44.6%)	20 (43.5%)	1.000
Triglycerides	131 (58.5%)	23 (50.0%)	0.371
All lipogram parameters	29 (12.9%)	5 (10.9%)	0.886

health system are multifactorial and may represent a lack of access to specialised care for T2DM patients as well as staff shortages and potentially a lack of knowledge with regard to the importance of hypothyroidism screening within this population.

Importantly, elevated TSH levels have several negative pleiotropic effects, with hypothyroidism being related to recurrent hypoglycaemia in diabetic patients, whilst subclinical hypothyroidism has been shown to be associated with an elevated prevalence of dyslipidaemia and diabetic nephropathy.<sup>19, 20</sup> Undiagnosed hypothyroidism is additionally of concern, as this may lead to increased cardiovascular risk by aggravating dyslipidaemia, insulin resistance, obesity, and vascular endothelial dysfunction.<sup>21</sup> This places further emphasis on the need for screening.

### Demographic and lifestyle factors

Our findings suggest two different patterns regarding gender and age in hypothyroid prevalence. The prevalence of hypothyroidism was significantly higher among women (9.3%) compared with men (2.1%) ( $p=0.040$ ), consistent with global evidence of a female predominance. The prevalence of elevated TSH was higher in the younger age group (24.0%) in comparison with the older age group (4.2%) ( $p < 0.001$ ); however, the prevalence of hypothyroidism was higher in the older age group (7.8%). In terms of lifestyle habits, tobacco smoking was more common in the non-hypothyroid group, whereas alcohol use was more common in the hypothyroid group.

### SEMDSA targets

Patients with hypothyroidism had poor attainment of SEMDSA metabolic targets. None achieved adequate HbA1c control, and only one patient met all lipogram criteria. While blood pressure and total cholesterol targets were reached in just over half, LDL-C control was notably poor, highlighting the difficulty of achieving comprehensive risk factor management in this group.

Although no statically significant associations were observed in the elevated TSH group with HbA1c, blood pressure, or lipid control, international studies have showed subclinical hypothyroidism is associated with an increased risk of diabetic complications including diabetic nephropathy and cardiovascular disease.<sup>22,23</sup> Routine thyroid function screening in patients with T2DM may therefore be warranted to identify subclinical

hypothyroidism early and optimise long-term cardiovascular risk management.

### Strengths and limitations and future research directions

A major strength of this study is that it is the first research of its kind in Johannesburg, South Africa, offering much needed insights into the prevalence of hypothyroidism in T2DM patients in the country. Another strength of this study is the wide variety of racial groups from which data were captured. Mixed-race participants had significantly lower odds of having hypothyroidism than Caucasian participants. This may prompt future research into the contribution of genetic components and ethnicity to hypothyroidism within T2DM.

A limitation of this study was that it was performed at a single centre, thus reducing the external validity of the results. Moreover, it was a retrospective study from patient records, thus no information could be obtained regarding duration of diabetes and family history of thyroid dysfunction, both of which have been associated with increased prevalence of hypothyroidism in T2DM in other studies.<sup>8</sup>

The SEMDSA/ACE-SA guideline recommends screening first-degree relatives with autoimmune thyroid disease.<sup>1</sup> It would therefore have been interesting to note the number of patients with first-degree relatives who had thyroid dysfunction, which may be explored in more detail in further studies.

### Conclusion

The above data set is small in comparison with the growing estimated prevalence of T2DM, highlighting the need for continued research. The prevalence of hypothyroidism was found to be lower than in several international studies. Of concern was the high number of patients with elevated TSH levels, given the increased morbidity and mortality related to untreated hypothyroidism. At present, no guidelines exist within South Africa on the screening of hypothyroidism within T2DM. This study could therefore be used as the foundation for larger studies to make future recommendations in this regard. Of note was that a limited number of patients had TSH values within the SEMDSA/ACE-SA guideline target range, which further strengthens our recommendation to do more routine screening of hypothyroidism within the T2DM population.

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*Ethical approval* – Ethics approval was granted from the Human Research Ethics Committee (Medical) from the University of the Witwatersrand (201009) and was performed in accordance with the ethical standards as laid out in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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