

# Use of thyroid-stimulating hormone tests for identifying primary hypothyroidism in family medicine patients

Elizabeth Birk-Urovitz MD CCFP MPH FRCPC M. Elisabeth Del Giudice MD MSc CCFP  
Christopher Meaney MSc Karan Grewal MD MHS CCFP

## Abstract

**Objective** To assess the use of thyroid-stimulating hormone (TSH) tests for identifying primary hypothyroidism in 2 academic family medicine settings.

**Design** Descriptive study involving a retrospective electronic chart review of family medicine patients who underwent TSH testing.

**Setting** Two academic family practice sites: one site is within a tertiary hospital in Toronto, Ont, and the other is within a community hospital in Newmarket, Ont.

**Participants** A random sample of 205 adult family medicine patients who had 1 or more TSH tests for identifying potential primary hypothyroidism between July 1, 2009, and September 15, 2013. Exclusion criteria included a previous diagnosis of any thyroid condition or abnormality, as well as pregnancy or recent pregnancy within the year preceding the study period.

### EDITOR'S KEY POINTS

- This study investigated the ordering patterns of thyroid-stimulating hormone (TSH) tests at 2 Ontario family medicine sites, assessing the overall use of TSH tests for identifying primary hypothyroidism, including potential overuse. Data relating to overuse of TSH tests might assist with the development of targeted interventions for primary care settings to encourage more prudent test ordering.
- Nearly one-quarter of TSH tests did not appear to conform to test-ordering guidelines according to a protocol devised by the researchers. Moreover, all of these nonconforming test results presented TSH levels within normal limits of the laboratory reference ranges.
- The study found overuse of TSH tests in these family medicine settings. That is, there appears to be a relatively high proportion of TSH tests being ordered for primary hypothyroidism case finding without any clear clinical indication. Some possible methods to help curtail overuse include providing alerts to individuals ordering TSH tests and developing clearer and consistent TSH test-ordering guidelines or algorithms for primary hypothyroidism case finding.

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**Main outcome measures** The proportion of normal TSH test results and the proportion of TSH tests that did not conform to test-ordering guidelines.

**Results** Of the 205 TSH test results, 200 (97.6%, 95% CI 94.4% to 99.2%) showed TSH levels within the normal range. All 5 patients with abnormal TSH test results had TSH levels above the upper reference limits. Nearly one-quarter (22.4%, 95% CI 16.9% to 28.8%) of tests did not conform to test-ordering guidelines. All TSH tests classified as not conforming to test-ordering guidelines showed TSH levels within normal limits. There was a significant difference ( $P < .001$ ) between the proportions of nonconforming TSH tests at the tertiary site (14.3%, 95% CI 8.2% to 22.5%) and the community site (31.0%, 95% CI 22.1% to 41.0%). Preliminary analyses examining which variables might be associated with abnormal TSH levels showed that only muscle cramps or myalgia ( $P = .0286$ ) and a history of an autoimmune disorder ( $P = .0623$ ) met or approached statistical significance.

**Conclusion** In this study, the proportion of normal TSH test results in the context of primary hypothyroidism case finding and screening was high, and the overall proportion of TSH tests that did not conform to test-ordering guidelines was relatively high as well. These results highlight a need for more consistent TSH test-ordering guidelines for primary hypothyroidism and perhaps some educational interventions to help curtail the overuse of TSH tests in the family medicine setting.

# La mesure de l'hormone thyroïdienne pour détecter une hypothyroïdie primaire chez des patients de médecine familiale

Elizabeth Birk-Urovitz MD CCFP MPH FRCPC M. Elisabeth Del Giudice MD MSc CCFP  
Christopher Meany MSc Karan Grewal MD MHS CCFP

## Résumé

**Objectif** Vérifier de quelle façon on prescrit le dosage de l'hormone thyroïdienne (TSH) pour détecter l'hypothyroïdie primaire dans 2 cliniques de médecine familiale universitaires.

**Type d'étude** Étude descriptive à l'aide d'une revue rétrospective des dossiers électroniques de patients en médecine familiale ayant subi un dosage de la TSH.

**Contexte** Deux cliniques universitaires de médecine familiale en Ontario : une située dans un hôpital tertiaire de Toronto et l'autre, dans un hôpital communautaire à Newmarket.

**Participants** Un échantillon aléatoire de 205 patients adultes en médecine familiale qui avaient subi au moins un dosage de la TSH pour éliminer la possibilité d'une hypothyroïdie primaire, entre le 1<sup>er</sup> juillet 2009 et le 15 septembre 2013. Les critères d'exclusion comprenaient un diagnostic antérieur de maladie ou d'anomalie thyroïdienne, de même qu'une grossesse en cours ou survenue dans l'année précédant l'étude.

**Principaux paramètres à l'étude** La proportion des résultats normaux du dosage de la TSH et la proportion des examens non conformes aux lignes directrices relatives à l'ordonnance de ces examens.

**Résultats** Sur les 205 résultats de TSH, 200 (97,6%, IC à 95% 94,4% à 99,2%) étaient dans les limites normales. Les 5 patients avec des résultats anormaux avaient tous des niveaux dépassant la limite supérieure de la normalité. Près du quart des demandes d'examen (22,4%, IC à 95% 16,9% à 28,8%) ne respectaient pas les directives relatives aux ordonnances d'examens. Tous les résultats des examens considérés non conformes aux directives étaient dans les limites normales. Il y avait une différence significative ( $P < .001$ ) entre la proportion des demandes non conformes provenant de l'hôpital tertiaire (14,3% IC à 95% 8,2% à 22,5%) et de celles provenant de l'hôpital communautaire (31,0% IC à 95% 22,1% à 41,0%). Des analyses préliminaires visant à déterminer les variables susceptibles d'être associées aux niveaux de TSH anormaux montraient que seules les crampes musculaires ou les myalgies ( $P = .0286$ ) et des antécédents de maladie auto-immune ( $P = .0623$ ) présentaient une signification statistique ou s'en approchaient.

**Conclusion** Dans cette étude où des dosages de la TSH étaient prescrits comme dépistage d'une éventuelle hypothyroïdie primaire, la proportion des résultats normaux était élevée et celle des demandes d'examen non conformes aux directives était également relativement haute. Ces résultats suggèrent la nécessité de lignes directrices plus précises pour la prescription de ce type de demande et peut-être aussi celle de certaines séances de formation pour réduire le nombre excessif des demandes de dosages de la TSH inutiles dans les cliniques de médecine familiale.

## POINTS DE REPÈRE DU RÉDACTEUR

- Cette étude, effectuée dans 2 cliniques de médecine familiale de l'Ontario, cherchait à examiner les modèles d'ordonnance du dosage de l'hormone thyroïdienne (TSH) pour détecter une hypothyroïdie primaire, en évaluant son utilisation générale, y compris une possible surutilisation. Des résultats suggérant une surutilisation pourraient permettre de concevoir des mesures d'intervention ciblée pour favoriser une utilisation plus prudente de cet examen dans les cliniques de soins primaires.
- Selon un protocole de recherche créé par les chercheurs, près du quart des prescriptions de dosages de la TSH ne semblaient pas conformes aux lignes directrices relatives à la prescription de cet examen. De plus, tous ces résultats d'examens non conformes présentaient des niveaux de TSH dans les limites normales des intervalles de référence des laboratoires.
- L'étude a trouvé qu'il y avait une surutilisation des mesures de la TSH dans ces établissements de médecine familiale. Autrement dit, il semblerait qu'une proportion relativement élevée de ces examens étaient prescrits pour éliminer une éventuelle hypothyroïdie primaire, et ce, malgré l'absence d'une indication claire. Parmi les mesures susceptibles de réduire la surutilisation, mentionnons des avertissements à ceux qui prescrivent des examens du dosage de la TSH et l'élaboration de lignes directrices plus claires et plus cohérentes relatives à l'ordonnance de ces examens ou d'algorithmes pour la détection de l'hypothyroïdie primaire.

Cet article a fait l'objet d'une révision par des pairs.  
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Primary hypothyroidism, both suspected and confirmed, is commonly encountered in family medicine. Thyroid function tests (TFTs), including thyroid-stimulating hormone (TSH) tests, are highly sensitive and specific.<sup>1</sup> Although they are readily available, measures should be taken to ensure their judicious use to help preserve health care resources. Currently, a single TSH test is estimated to cost approximately \$14.

Medical literature that directly or indirectly discusses use of TFTs has been published for at least 30 years.<sup>2</sup> Various international studies<sup>3-7</sup> estimate that the percentage of normal TFT results in the context of hypothyroidism or hyperthyroidism case finding for primary care patients is 80% to 95%. In Canada, according to a 1996 report, TFTs accounted for the second-highest publicly insured laboratory service cost in Ontario, after all microbiology cultures combined.<sup>8</sup> An unpublished retrospective chart review from the mid-2000s suggested that nearly 40% of asymptomatic female patients at an urban family practice in Toronto, Ont, had "screening" TSH tests ordered.<sup>9</sup> In November 2012, owing to claims of overuse and misuse, the standard Ontario Ministry of Health and Long-Term Care laboratory requisition form was amended to remove TSH from the checkbox menu.<sup>10,11</sup> More recent descriptive studies and data regarding the use of TFTs in Ontario and the rest of Canada appear to be lacking.

The nonspecific nature of many signs and symptoms of primary hypothyroidism<sup>12-17</sup> make it difficult to rely on history taking and physical examination to determine which individuals would benefit the most from TFTs. The ongoing variation in guidelines for thyroid dysfunction screening and case finding<sup>13,18-22</sup> is also likely to contribute to clinician uncertainty.

This study investigated the ordering patterns of TSH tests, the most common TFT ordered by clinicians, at 2 Ontario family medicine sites. The objective was to assess the overall use of TSH tests for identifying primary hypothyroidism, including potential overuse. Data relating to overuse of TSH tests could ultimately assist with the development of targeted interventions for primary care settings that encourage more prudent test ordering.

## METHODS

### Study design and setting

This retrospective electronic chart review was conducted by 3 family practice residents (including E.B.U. and K.G.) who practised at 2 family practice sites affiliated with the Department of Family and Community Medicine at the University of Toronto during the time of this study: one site was at a tertiary hospital in Toronto (Sunnybrook Health Sciences Centre) and the other was at a community-based hospital in Newmarket, Ont

(Southlake Regional Health Centre). The study population involved adult patients who had undergone 1 or more TSH tests between July 1, 2009, and September 15, 2013, for identifying potential primary hypothyroidism, had not been previously diagnosed with any thyroid condition or abnormality, and were not pregnant or recently pregnant within the preceding 1-year period.<sup>23</sup>

The study was approved by the Sunnybrook Health Sciences Centre and Southlake Regional Health Centre research ethics boards.

### Data collection

Random sampling without replacement was conducted at each site. Adult patients who had TSH tests ordered during the study period were sorted alphabetically by first name before sampling every 9th chart (at the community-based practice) or 10th chart (at the tertiary practice). The final sample had 205 patients, with 105 from the tertiary site and 100 from the community site. Relevant, anonymized data from the electronic charts were entered into password-protected Microsoft Excel spreadsheets, guided by a data abstraction form. Ninety variables were assessed, including those within the following categories: demographic characteristics, important past medical history and family history, details of patient presentation (history, physical examination findings), reason the TSH test was ordered, results of the TSH test and other investigations, and results of the most recent TSH test or other TFTs before the clinical encounter in question. To assess accuracy, approximately 7.5% of the charts were randomly selected for data re-abstraction and re-entry.

A protocol was developed post hoc to classify TSH use as *not conforming* versus *possibly conforming* versus *conforming* to test-ordering guidelines and was based on the best-available findings from a literature review. The 3 categories were devised from a synthesis of TSH test-ordering recommendations for primary hypothyroidism case finding from 1 American guideline<sup>13</sup> and 5 Canadian guidelines<sup>16,18,19,24,25</sup> that were published or otherwise in effect during the study period. Tests classified as conforming were those ordered for patients who presented with 1 or more primary hypothyroidism signs or symptoms, or who had previously unresolved investigations with results suggestive of primary hypothyroidism. Tests classified as possibly conforming were those ordered for patients who were at increased risk of primary hypothyroidism. All other tests were classified as not conforming. **Table 1** presents additional details of the criteria for each of these TSH test classifications. The intent was to provide best-case scenario estimates of nonconforming tests, taking into account the presence of guideline variability.

**Table 1. Definitions of TSH test classifications**

CLASSIFICATION OF TSH TESTS	DEFINITION
Conforming to test-ordering guidelines*	Test ordered for a patient who presents with ≥ 1 symptoms or signs of primary hypothyroidism or with a previously unresolved investigation with results that might be directly associated with primary hypothyroidism (ie, anemia, hyperlipidemia, prolonged QT interval)
Possibly conforming to test-ordering guidelines*	Test ordered for a patient who does not present with any symptoms or signs of primary hypothyroidism but who is at increased risk of primary hypothyroidism: <ul style="list-style-type: none"> <li>• female patient aged &gt; 50 y</li> <li>• patient with a first-degree relative who has a history of autoimmune thyroid disease</li> <li>• patient with a past medical history of an autoimmune disease</li> <li>• patient with a history of radiation to the thyroid</li> <li>• patient who is taking or who has taken lithium, amiodarone, or an iodine-containing product</li> </ul>
Not conforming to test-ordering guidelines*	Test ordered for the purpose of screening a patient who does not present with any symptoms or signs of primary hypothyroidism and who does not have previously unresolved investigation results that might be directly associated with primary hypothyroidism, and who is not at increased risk of primary hypothyroidism

TSH—thyroid-stimulating hormone.

\*Based on a predetermined list of 37 symptoms and signs of primary hypothyroidism and on the data abstractors' clinical judgment of the patient's presentation and of the clinician's ordering of the TSH test.

### Statistical analyses

Data analyses were conducted using SAS, version 9.4. The main outcome was the proportion of TSH tests with normal results, according to the reference ranges of the laboratories where the tests were completed. The secondary outcome was the proportion of TSH tests that did not conform to test-ordering guidelines. Exact binomial 95% CIs were produced around these estimates, as well as around other relevant point estimates that were obtained through the data collection procedures. Additional variables, including clinicians' reasoning for ordering TSH tests, were also explored. Comparisons of discrete data between the tertiary and community sites (eg, normal TSH test results, TSH tests that did not conform to ordering guidelines) were analyzed using Fisher exact and  $\chi^2$  tests, while comparisons of continuous data were analyzed using Wilcoxon rank sum and *t* tests.

## RESULTS

**Table 2** presents the main patient characteristics. The mean age was 54.5 years (95% CI 52.1 to 57.0 years), with an age range of 18 to 96. Patients at the tertiary site were older (mean age of 58.2 years vs 50.7 years;  $P=.0042$ ) and were more likely to have a reported history of hyperlipidemia (39.0% vs 26.0%;  $P=.0465$ ) or psychiatric disorders (36.2% vs 19.0%;  $P=.0060$ ) than those at the community-based site. For all other patient characteristics, there were no statistically significant differences between sites.

Two hundred of the 205 TSH test results (97.6%, 95% CI 94.4% to 99.2%) had TSH levels within the normal laboratory reference ranges.

All 5 patients (2.4%, 95% CI 0.8% to 5.6%) with abnormal TSH test results had TSH levels above the normal

**Table 2. Main patient characteristics: N = 205.**

CHARACTERISTICS	N (%)
Female sex	128 (62.4)
Female and aged > 50 y	73 (35.6)
Past medical history	
• Hypertension	73 (35.6)
• Hyperlipidemia	67 (32.7)
• Psychiatric disorder	57 (27.8)
• Cardiac arrhythmia	21 (10.2)
• Autoimmune disorder	18 (8.8)
• Congestive heart failure	6 (2.9)
• Dementia	6 (2.9)
Family history	
• Have first-degree relative with history of autoimmune thyroid disease	1 (0.5)

laboratory reference ranges. Only 1 of these 5 patients had a TSH level higher than 10 mIU/L, but this patient had a free thyroxine level within the normal range. Two of the 5 patients had a history of an autoimmune disease, 1 patient presented with obesity, 1 had myalgia, and the remaining patient had various symptoms and signs that were possibly associated with hypothyroidism (weight gain, fatigue, myalgia, and menstrual abnormalities).

For the total sample, TSH tests were most commonly ordered by clinicians as part of an annual screening or because bloodwork for other investigations (eg, fasting glucose, cholesterol) was already ordered simultaneously (42.0%, 95% CI 35.1% to 49.0%). The second most common reason for test ordering was owing to patient reports of fatigue or feeling "unwell" (9.3%, 95% CI 5.7% to 14.1%). All other

reasons for ordering TSH tests (eg, neurologic symptoms or signs; unclear reasons; multiple symptoms or signs associated with hypothyroidism) demonstrated point estimates of less than 8%.

While 22.4% (95% CI 16.9% to 28.8%) of the TSH tests did not conform to test-ordering guidelines, 77.6% (95% CI 71.2% to 83.1%) possibly conformed or did conform to test-ordering guidelines (Table 3). All TSH tests that were classified as nonconforming showed TSH levels in the normal range; thus, all 5 patients with abnormal TSH levels had TSH tests for reasons that conformed to test-ordering guidelines. However, not all TSH tests that had negative results were classified as nonconforming; in fact, 77.0% of negative test results either possibly conformed or conformed to test-ordering guidelines.

There was no statistically significant difference ( $P > .999$ ) in the proportion of normal TSH test results between the tertiary site (97.1%, 95% CI 91.9% to 99.4%) and the community-based site (98.0%, 95% CI 93.0% to 99.8%); however, there was a significant difference ( $P < .001$ ) between the proportions of nonconforming TSH tests at the tertiary site (14.3%, 95% CI 8.2% to 22.5%) and the community site (31.0%, 95% CI 22.1% to 41.0%).

Preliminary bivariate analyses examining which variables might be associated with abnormal TSH levels were also carried out. Only symptoms of muscle cramps or myalgia ( $P = .0286$ ) and past medical history of an autoimmune disorder ( $P = .0623$ ) demonstrated results meeting or approaching statistical significance ( $P < .05$ ).

## DISCUSSION

The proportion of normal TSH test results in the context of primary hypothyroidism case finding and screening was high (97.6%), and even slightly higher than similar estimates (approximately 80% to 95% for hypothyroidism or hyperthyroidism case finding) reported in other, non-Canadian primary care studies.<sup>3-7</sup> Potential explanations for the slightly higher proportion of normal TSH test results found in this study include the following: differences in the

patient populations; how TSH test results are categorized as normal versus abnormal (ie, differences in laboratory reference ranges); and actual test-ordering practices.

The estimate of 22.4% for the overall proportion of nonconforming TSH tests (Table 3) was relatively high, especially considering that our protocol for classifying TSH test use likely produced an underestimated (best-case scenario) result. However, this might not be entirely surprising in the context of highly variable guidelines for thyroid function testing.

It is unclear why the community-based site had a higher proportion of nonconforming tests (31.0% vs 14.3%,  $P < .001$ ). One possibility is average patient age; the community site's mean patient age was lower ( $P = .0042$ ), and TSH tests ordered for older (female) patients (>50 years) were automatically considered to be conforming or possibly conforming using our protocol. Therefore, differences in the average patient age at the 2 sites could have confounded the relationship between site and degree of conformity, as younger (female) patients were more likely to have their test results classified as nonconforming from the outset.

Of importance to Canadian family physicians and other primary care providers, these findings point toward apparent TSH overuse in their patient care settings. That is, there appears to be a relatively high proportion of TSH tests being ordered for primary hypothyroidism case finding without any clear clinical indication.

Some possible methods to help curtail overuse include providing alerts to individuals ordering TSH tests and developing clearer and more consistent TSH test-ordering guidelines or algorithms for primary hypothyroidism case finding.

## Limitations and future directions

Various limitations are inherent to studies involving retrospective (electronic) chart reviews, including reliance on clinicians' documentation and possibilities of missed, misinterpreted, or incorrect data (eg, due to errors in copying data from laboratory reports, although this process was most often automated by computer software). Although there is low probability that a clinician's progress note would reflect all aspects of a patient's history and physical examination, especially in the case of a clinical encounter involving something as broad and vaguely characterized as potential primary hypothyroidism, it seems likely that most pertinent positive and negative results would be documented, and that data pertaining to the main study outcomes would be valid.

Another limitation of this study is that it did not include any data pertaining to patients with suspected secondary or tertiary hypothyroidism. Moreover, although not one of the main outcome measures, this study did not have an adequate sample size to explore fully the potential predictive ability of demographic and clinical factors with respect

**Table 3. Thyroid-stimulating hormone tests classified as conforming, possibly conforming, or not conforming to ordering guidelines:  $N = 205$ .**

CLASSIFICATION OF TSH TESTS	N (%)	95% CI FOR PERCENTAGE
Conforming to test-ordering guidelines	103 (50.2)	43.2-57.3
Possibly conforming to test-ordering guidelines	56 (27.3)	21.3-34.0
Not conforming to test-ordering guidelines	46 (22.4)	16.9-28.8

TSH—thyroid-stimulating hormone.

to abnormal TSH test results. Thus, the preliminary results provided in this respect must be interpreted with caution.

To our knowledge, this is the first published Canadian study to explore in depth TSH test-ordering practices and results across 2 dissimilar family practice sites. Possible future directions include assessing if the 2012 removal of TSH tests from the check-box menu on the standard Ontario Ministry of Health and Long-Term Care laboratory requisition forms affected TSH test-ordering practices or the proportion of normal TSH test results; and performing qualitative research (eg, focus groups, surveys) to explore the reasoning behind TSH test-ordering decisions in greater detail.

## Conclusion

This study's results demonstrate a high overall proportion of TSH test results with levels in the normal range. The results also demonstrate a relatively high proportion of TSH tests not conforming to current test-ordering guidelines and not clearly being clinically indicated. Findings from previous studies that underscore high use of TFTs for detecting hypothyroidism and other thyroid disorders in primary care patients are supported. The results also highlight a need for more consistent TSH test-ordering guidelines in the context of primary hypothyroidism case finding and perhaps some educational interventions to help curtail the overuse of TSH tests in this setting.

When the study was being conducted, **Dr Birk-Urovitz** was completing her family medicine and public health and preventive medicine residencies at the University of Toronto in Ontario. **Dr Del Giudice** is Assistant Professor in the Department of Family and Community Medicine (DFCM) at the University of Toronto and a family physician with the Sunnybrook Academic Family Health Team. **Mr Meaney** is a biostatistician in the DFCM at the University of Toronto. When the study was being conducted, **Dr Grewal** was completing his family medicine residency with the Southlake Academic Family Health Team, Southlake Regional Health Centre, in the DFCM at the University of Toronto.

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## Contributors

**Dr Birk-Urovitz**, **Dr Del Giudice**, and **Mr Meaney** contributed to the concept and design of the study. **Drs Birk-Urovitz** and **Grewal** gathered the data. **Mr Meaney** performed the data analysis. All authors contributed to data interpretation and preparing the manuscript for submission.

## Competing interests

None declared

## Correspondence

**Dr Elizabeth Birk-Urovitz**; e-mail [elizabeth.birk.urovitz@mail.utoronto.ca](mailto:elizabeth.birk.urovitz@mail.utoronto.ca)

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