CLP 016
JUNE 1998

Guidelines for the Use of Serum Testing in the Management of Primary Hypothyroidism

1. Background

The Ontario government's Task Force on the Use and Provision of Medical Services (Scott Task Force) recommended the testing of serum TSH as the most accurate method to diagnose **primary hypothyroidism** in ambulatory patients.

The current guideline is intended to provide physicians practising in the community with information to support their decision-making and guidance as to when serum TSH testing is appropriate in the management of patients with **identified primary hypothyroidism** A companion guideline, *Guidelines for the Use of Serum Tests to Detect Thyroid Dysfunction* (CLP 015) is available from the OAML. Guidelines are generally applicable but will not apply in every clinical situation, nor can they serve as a substitute for sound clinical judgement.

The members of the Guideline Panel strongly encourage open lines of communication between specialists and general practitioners to ensure that current test results are readily available to both. Physicians may request on the laboratory requisition that duplicate copies of test results be forwarded to other physicians.

2. Limitations

- The measurement of serum TSH levels in the management of primary hypothyroidism can be a useful procedure. Before initiating treatment, however, a definitive diagnosis of persistent primary hypothyroidism must be established. Refer to OAML Guideline CLP 015, *Guidelines for the Use of Serum Tests to Detect Thyroid Dysfunction*
- Abnormalities in serum TSH levels may be the result of conditions other than thyroid dysfunction such as inflammatory thyroiditis or medications (e.g., lithium carbonate or amiodarone).
- This guideline may not apply in certain cases (e.g., pregnant women or the elderly); in such cases the assistance of a specialist may be useful.
- This test will not reliably identify patients with central (secondary) hypothyroidism. If pituitary or hypothalmic disease is suspected, the free T4 level should be measured along with the TSH level.

3. Indications:

The objective of thyroxine replacement therapy in cases of primary hypothyroidism is to restore serum TSH to normal levels. Monitoring of serum TSH levels through laboratory testing is an important aspect

of therapy. To be a useful measure of therapeutic efficacy, however, the test should only be performed after an appropriate interval following dose adjustment. This should generally be no sooner than six to eight weeks after starting therapy and no sooner than three to four months after the subsequent dose adjustment.

4. Recommendations

- It is recommended that, in relatively asymptomatic patients without marked elevation in TSH, testing be repeated three to four months later to confirm a diagnosis of primary hypothyroidism, before initiating therapy.
- Once a diagnosis of hypothyroidism is definitively established and treatment has begun, it is recommended that the physician managing therapy allow sufficient time for TSH levels to stabilize after dose adjustment. The physician would generally appropriately test no sooner than six to eight weeks after establishment of the provisional optimal replacement dosage and no sooner than three to four months after subsequent dose adjustment.

5. References

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The Ontario Association of Medical Laboratories

The Ontario Association of Medical Laboratories (OAML) represents the community-based laboratory sector in Ontario.

Its mission is to promote excellence in the provision of laboratory services and, as an essential component of the health care system, to contribute to shaping the future of health care in Ontario.

The OAML encourages the highest level of professional and ethical integrity and technical excellence among laboratory owners, operators and staff in the provision of laboratory services for the benefit of the people of Ontario.

Guidelines for Clinical Laboratory Practice

The OAML, through its Quality Assurance and Clinical Laboratory Practice Committee, co-ordinates the development and dissemination, implementation and evaluation of Guidelines for Clinical Laboratory Practice.

A proposed Guideline is developed by a working group of the Committee with the participation of outside experts. The proposed guideline is then submitted to the Committee as a whole and to a Professional Advisory Group who provide an overall review of the document. The comments of the Committee and the Professional Advisory Group are incorporated into a revision of the guideline and this draft is submitted to laboratory Medical Directors, professional associations and other representatives of end users for additional comment. The document is revised in light of these comments and submitted to the OAML Board of Directors for approval.

Approved guidelines are distributed to Community-based Laboratories and by them to their client physicians.

There may be additional educational materials produced, if it is thought that they might be useful, and these are distributed with the guideline.

The comments of end users are essential to the development of guidelines and will encourage adherence. You are strongly encouraged to submit your comments on this or on any other OAML Guideline to:

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