Hypertension (high blood pressure) is a common medical condition that is associated with an increased risk of complications such as heart disease, stroke, kidney and vision problems. It is estimated that 22% of Canadian adults have high blood pressure.\(^1\) Blood pressure (BP) measurement is a routine part of a physical examination. The measurements are repeated over time to diagnose hypertension, but the accuracy of the tests may be affected by various factors, such as: the operator, the equipment, the position of the patient’s arm, the size of the cuff used, the time of day, exercise and diet. Moreover, some people experience a rise in BP due to anxiety when they undergo a medical test, or "white coat hypertension".\(^2\)

BP can be measured directly (intra-arterially), using a catheter, but this method is invasive and not practical for routine screening. Sphygmomanometers are typically used to measure arterial BP indirectly. These devices have a column of mercury or a pressure-registering gauge. The blood flow is temporarily stopped using an inflated cuff wrapped around the upper arm, putting pressure on the main artery. The blood flow resumes gradually as the cuff deflates and the blood pressure measurements are represented in units of millimeters of mercury.\(^3\)

Other non-invasive BP monitoring devices include:

- aneroid sphygmomanometers that use metal as a kind of spring, rather than mercury, to measure BP, and
- electronic or digital devices, that are commonly used in home BP monitoring and pharmacies.\(^3\)

Ambulatory blood pressure monitoring (ABPM), which takes measurements over 24 hours, has been proposed as an alternative method for more accurate measurement. This method can be important both in the accurate diagnosis of hypertension and in monitoring the effect of treatment.\(^4\) ABPM should be distinguished from home BP monitoring, where patients take their own measurements from time to time (self monitoring). In ABPM a technician fits the patient with a portable sphygmomanometer with a recording device. The device measures BP automatically, at set intervals throughout the day and night (continuous waveform analysis is also being developed), as the patient performs normal tasks. The data are collected, uploaded onto a computer, and the results analyzed by a physician. Some patients find the cuff is uncomfortable when inflated and disturbs their sleep.\(^5\) A recent BMJ series, *The ABC of Hypertension*, includes an article on ABPM; this article provides a useful overview of the devices used, the types of data recorded, and the clinical indications for use.\(^6\)
Research Questions

The following questions came to CCOHTA from a provincial ministry of health. The ministry had been asked to fund additional ABPM units (an additional eight units, on top of an existing 31 units). The cost to the ministry of health to purchase and operate the additional devices was estimated at about $2 million per year. Their questions regarding this technology were:

- Is this a medically acceptable (necessary) service?
- Is this a cost-effective service?

A Norwegian assessment of ABPM from 2000 posed further questions:

- Is there an over-diagnosis and over-treatment of hypertension?
- Does ambulatory measurement provide more accurate diagnosis of this condition and thereby reduce the use of antihypertensive drugs?

A 1996 Scottish Health Purchasing Information Centre report defined the questions surrounding this technology as follows:

- Does the use of ABPM provide any advantage over other measurements?
- Does it lead to a reduction in the effects of hypertension or the side effects of hypertension therapies?
- What cost savings for government or patients would result?
- Is ABPM a community health service that offers an option patients prefer?

The report included an analysis of potential costs and cost savings based on a Scottish hospital scenario.

In our preliminary literature search, other controversies concerning the technologies used in BP measurement also became apparent. For example, conventional sphygmomanometers have a mercury-filled column, and environmental concerns have led to pressures to replace this technology with other BP measurement devices. The accuracy of measurements obtained with these devices is a concern. As a recent FDA Consumer article notes:

The two crucial considerations for substituting aneroid and electronic units for mercury instruments are calibration and validation. Calibration is a way to make sure that measurements begin from zero - much like when a scale is balanced before it is stepped on to measure body weight. If the starting mark is above or below zero, the final measurement will be inaccurate. Validation ensures that the instrument can take accurate measurements over a wide range of blood pressures, ages and clinical conditions.
A US working group has been established to investigate the issues surrounding the accurate measurement of BP using non-mercury devices. The European Society of Hypertension Working Group on Blood Pressure Monitoring is also investigating the accuracy of the devices used in blood pressure measurement.

Assessment Process
Preliminary literature searches were run on the PubMed, the Cochrane Library and the HTA databases. The web sites of several major HTA agencies were scanned per the CCOHTA checklist. Research, clinical trials and practice guidelines sources were also searched.

Summary of Findings
The technology for ABPM was developed several decades ago and has received a great deal of attention. It has been assessed by several health technology assessment agencies; for example, an early US government assessment was conducted in 1982. A later assessment, by an Australian agency, reviewed the literature to 1996. However, most assessments conclude that there is still insufficient evidence to properly define the role and value of ABPM. The table below lists assessments, systematic reviews and a selection of practice guidelines, relevant to this topic, published since 1998.

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<th>Type of Report</th>
<th>Title</th>
<th>Reference</th>
<th>Main Findings</th>
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<tr>
<td>HTA</td>
<td>Utility of blood pressure monitoring outside of the clinic setting</td>
<td>Rockville (MD): Agency for Healthcare Research and Quality; 2002. Pub no 03-E003. [Evidence report / technology assessment; no 63]. Summary available: <a href="http://www.ahrq.gov/clinic/epicenters/utilbpm/htm">http://www.ahrq.gov/clinic/epicenters/utilbpm/htm</a> (full text will also be available here soon) or to obtain a print copy e-mail: <a href="mailto:ahrqpubs@ahrq.gov">ahrqpubs@ahrq.gov</a></td>
<td>This report reviews the evidence for both ambulatory blood pressure monitoring (ABP) and self-measurement of blood pressure. - For a number of issues examined by the report, the available literature was deemed insufficient to answer the questions posed. These issues included the comparison of clinic, self and ambulatory blood pressure monitoring measurements, and the effect of treatment guided by ambulatory blood pressure measurement. However, the review did reach the following conclusions: “…ABP levels and ABP patterns were associated with BP-related target organ damage in cross-sectional studies. Likewise, in prospective studies, higher ABP, sustained hypertension, and a nondipping ABP pattern were associated with an increased risk of subsequent CVD</td>
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<tr>
<td>HTA</td>
<td>Ambulatory versus conventional blood pressure monitoring</td>
<td>Bisset AF. <strong>STEER</strong> 2001;1(20).1-8. Available: <a href="http://www.wihrd.soton.ac.uk/projx/signpost/steers/STEER_2001(20).pdf">http://www.wihrd.soton.ac.uk/projx/signpost/steers/STEER_2001(20).pdf</a></td>
<td>The authors found three controlled trials and one cohort study that provided limited evidence that ABPM reduced antihypertensive drug prescriptions, in the short-term, for people with diastolic hypertension. However, they found there was insufficient evidence to evaluate the clinical effectiveness of ambulatory versus conventional BP monitoring. The clinical and long-term effects are not clear and the cost savings of reduced drug therapies may be offset by the increased costs of ABPM.</td>
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<td>HTA</td>
<td>Ambulatory blood pressure monitoring for adults with elevated office blood pressure</td>
<td>Lefevre FV, Aronson N. Chicago: Blue Cross and Blue Shield Association; 2001. Available: <a href="http://www.cms.hhs.gov/coverage/download/8b1%2De3.pdf">http://www.cms.hhs.gov/coverage/download/8b1%2De3.pdf</a> Consumer version of this report, entitled: Is 24-Hour ambulatory blood pressure monitoring useful to diagnose white coat hypertension? Available: <a href="http://www.bluecares.com/consumertec/ctect_whitecoat_hyper.html">http://www.bluecares.com/consumertec/ctect_whitecoat_hyper.html</a></td>
<td>“Existing studies do not provide adequate information to determine whether 24-hour automated ambulatory blood pressure monitoring to diagnose white coat hypertension is useful to decide whether a person will benefit from using medication to control blood pressure.”</td>
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| HTA | Ambulatory blood pressure monitoring | Baltimore: U.S. Centers for Medicare & Medicaid Services; 2001. [Medicare coverage policy ~ NCDs. #CAG-00067N]. Available: http://cms.hhs.gov/coverage/8b3-ff2.asp | This policy paper reviews the findings of Blue Cross Blue Shield's assessments, describes the findings from further controlled trials, and summarizes the main conclusions from recent practice guidelines on the diagnosis of hypertension. It also summarizes their expert committee deliberations on this technology. The Committee identified several questions concerning the use of this technology, but concluded that there was only sufficient good evidence to address the issue of its use for white coat hypertension (WCH): "Although there are other potential uses for ABPM, we will not issue a national coverage decision on such indications at this time, until more data become available as to how it affects patient management.... At this point in time, ABPM will be covered for those patients with suspected WCH. Suspected WCH will be defined as office BP > 140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit...."

| Systematic review | Ambulatory versus conventional methods for monitoring blood pressure during pregnancy [Cochrane review] | Bergel E, Carroli G, Althabe F. Cochrane Database Syst Rev 2002;(2):CD001231. Abstract available: http://www.update-software.com/abstracts/ab001231.htm | The study group found no “randomised controlled trial evidence to support the use of ambulatory blood pressure monitoring during pregnancy.” There is a need for controlled trials with adequate design and sample sizes to assess this technology. It will be important for these trials to assess clinical outcomes and the use of health resources, as well as women’s opinions on the use of this technology.

<p>| HTA | Ambulatory blood pressure measurement. A review of international studies | Oslo: SINTEF Unimed; 2000. English summary available: <a href="http://www.oslo.sintef.no/smm/Publications/Engsmdrag/summary-blood.htm">http://www.oslo.sintef.no/smm/Publications/Engsmdrag/summary-blood.htm</a> | Full report, in Norwegian, available: <a href="http://www.oslo.sintef.no/smm/Rapporter/Rapport%204-00.pdf">http://www.oslo.sintef.no/smm/Rapporter/Rapport%204-00.pdf</a> | ABPM gives information on BP values over 24 hours, but there is not yet a consensus on which measurements should be used to govern clinical decisions to start treatment. Ambulatory BP measurements are “consistently lower and less variable” than measures taken in the doctor's office. However, available evidence does not indicate that ambulatory measurement is necessarily a better method for detecting &quot;clinically relevant hypertension&quot; or for predicting cardiovascular disease risk. In the absence of guidelines, clinical practice may vary from doctor to doctor. |</p>
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<th><strong>HTA</strong></th>
<th><strong>Guidelines</strong></th>
<th><strong>PRE-ASSESSMENT</strong></th>
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<tr>
<td>Management of adults with essential hypertension. Clinical practice recommendations and economic data. <strong>Summary</strong></td>
<td><strong>Ambulatory blood pressure monitoring</strong></td>
<td><strong>24-Hour Ambulatory Blood Pressure Monitoring</strong></td>
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<td>“There is a great deal of research on ABPM, but its role in primary care is still not clear. “Ambulatory devices are increasingly used, but their value is unproven… At present, ambulatory monitoring does not provide a better means of detecting hypertension than conventional sphygmomanometry and repeat measurements over a period of time.”</td>
<td>“ABPM is more closely related to end-organ damage with hypertension. ABPM is a specialized service and quality control is required. -“ABPM is indicated to exclude “white coat” hypertension and has a role in assessing apparent drug-resistant hypertension, the elderly, hypertension in pregnancy, during symptomatic episodes of hypotension or hypertension, and in monitoring adequacy of blood pressure control in patients at high risk of cardiovascular disease.” ”Randomised controlled trials comparing management based on clinic or casual versus ABP measurements are needed.” Evidence on the cost-effectiveness of ABPM is limited. Appropriate use in “selected patient groups to improve diagnosis and reduce unnecessary drug therapy may result in significant cost savings.”</td>
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The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) is a non-profit organization funded by the federal, provincial and territorial governments. (www.ccohta.ca)
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<td>“Self-measurement and 24 hour ambulatory measurement continue to be recommended for consideration in assessing office-induced blood pressure elevation, and the former to improve patient compliance. Only devices meeting international standards should be used.”</td>
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<td>- This recent Australian cost analysis concluded that “the additional costs of 24-hour ABPM in the first year are offset by savings associated with patients with white coat hypertension who would otherwise have been treated.”</td>
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**Conclusion**

There is both an abundance of information on ABPM, and a lack of quality evidence. A recent British study found that self-monitoring, rather than ABPM or office-based monitoring, was preferred by a majority of patients. The study authors comment that “…Ambulatory monitoring performed less well than other methods, largely owing to discomfort and disturbance of life and sleep; there may be a trade-off between the accuracy of ambulatory monitoring and its acceptability…”

In a related study, the same authors found that white coat hypertension has an important effect. Blood pressure readings by physicians or in a clinic were much higher than ambulatory BP measurements. The authors suggest that, if ambulatory or home self-monitoring are not available, serial measurements by a nurse or patient should be used.

Until further evidence becomes available, there may be little that CCOHTA could add to the information that is published in existing assessments.

**References**


