

# SUMMARY

## POPULATION ULTRASOUND SCREENING FOR ABDOMINAL AORTIC ANEURYSMS

### Introduction

Abdominal aortic aneurysm (AAA) is a serious and potentially fatal vascular disease. It is from three to eleven times more frequent in men than in women. Studies conducted in various European countries and the United States estimate that the prevalence of AAA is roughly 6.5% (between 4.2% and 8.8%) in men and roughly 1% (between 0.6% and 1.4%) in women older than 50 years. Many clinical and economic studies, along with systematic reviews, have addressed the efficacy of ultrasound screening for AAA and its cost effectiveness. AETMIS was asked to assess the organizational aspects involved in implementing an AAA screening program in Québec. This report analyzes available evidence to assess the appropriateness and feasibility of such a program.

### Assessment methods

This document is primarily a systematic literature review of population screening for AAA, its acceptability and cost effectiveness, and its potential organizational requirements in the Québec context. Relevant health technology assessment reports and systematic reviews were first identified. Various search strategies were used in Medline and the Cochrane Library, among other databases, to retrieve primary studies in order to update existing literature reviews. The articles were selected according to predefined inclusion and exclusion criteria. Data were extracted by a single researcher. The appropriateness of AAA screening was analyzed against the criteria set by the U.K. National Screening Committee by pooling the evidence extracted from the literature review with data pertaining to the Québec context. The contextual data were obtained through semi-structured interviews with medical and administrative stakeholders in Québec's public health system. Finally, a modelling exercise, including a sensitivity analysis, was conducted to estimate the potential yield of an AAA screening program if one were to be implemented in Québec.

### Disease and diagnosis

Abdominal aortic aneurysm is defined as a permanent localized dilatation of the abdominal aorta exceeding 3 cm in diameter. It can sometimes be detected during physical examination. One of the most sensitive and specific methods for diagnosing AAA is abdominal ultrasound (focused on the aorta). Known risk factors are age, male sex, positive first-degree family history of AAA or history of popliteal aneurysms, history of regular smoking and atherosclerosis. The natural history of AAA, its growth rate, especially in men, and the risk of rupture based on aneurysm size are known.

### Available treatments

Two types of AAA treatment exist: conventional open surgical repair and endograft treatment, or endovascular aortic repair (EVAR). These treatments are recommended for AAA greater than 5.5 cm in diameter. Medical treatments to slow the growth of AAA are currently under trial. An evidence synthesis of AAA treatment shows that, for patients suitable for open surgery, both surgery and endovascular repair reduce AAA-related mortality in the mid term (three years). Open surgery requires longer hospital stays, and its associated short-term mortality is higher. The major risk is post-operative death,<sup>1</sup> which ranges from 3% to 9.5%. Vascular endograft is associated with more mid-term complications and requires more frequent reinterventions. Systematic reviews also indicate that vascular endograft treatment is not efficient, since it is more expensive and does not provide additional benefits over conventional treatment. A very recent field evaluation in Ontario showed that endovascular repair can be cost-effective, especially in patients at high risk for open surgery. Improved endografts, implantation techniques and surgical expertise partly explain this new situation. Given the reduced morbidity and mortality risks reported in recent years, endovascular repair has

1. "Post-operative death" refers to deaths occurring during surgery, within 30 days of surgery or during the hospital stay for surgery.

become a treatment option for patients at high risk for open surgery who require periodic follow-up. Several systematic reviews also reveal that hospital and surgeon procedure volumes affect clinical outcomes, and certain minimum volumes are documented in the literature.

### Screening and its implications

Several health technology assessment reports have presented the outcomes of four large randomized controlled trials. These reports confirm the clinical efficacy of screening for reducing AAA-related mortality. According to the RCTs, screening is effective for men aged 65 to 74 years, but not for women, who have a lower prevalence for AAA. In women who have a family history of AAA combined with several other risk factors (age, known cardiovascular disease and history of smoking), the prevalence of AAA reaches 6.4%, but no study has examined screening efficacy in this particular group.

Many modelling studies and a few cost-effectiveness analyses for AAA screening in Europe have been published. These show that a strategy targeting men aged 65 years or from 65 to 75 years for AAA screening is cost-effective, according to generally accepted threshold values for determining the economic viability of a public health program.

Screening acceptability varied with the randomized trial situations or screening initiatives, which raises the issue of effectiveness, which likely differs from clinical efficacy. Several ethical and legal issues were highlighted and these should be resolved to optimize screening, especially the need for a preliminary assessment of the patient's general status and mortality risk in undergoing major surgery, along with counselling to explore the patient's acceptance of screening consequences before an ultrasound scan is prescribed.

### Québec context

Ultrasound screening for AAA is recommended in a Canadian clinical practice guideline. There is no known information on the current level of opportunistic screening provided by clinicians, compared with the cases detected by chance during examinations performed for other diagnostic purposes (i.e., X-rays or ultrasounds).

If a screening program were in place today, it is estimated that elective surgeries would total 2400 per year for men aged 65 to 74 years. A review of Québec 2004–2007 data on AAA surgeries revealed that annual volumes totalled about 1200 elective procedures and 220 emergency procedures, of which roughly 430 elective procedures and 65 emergency procedures were in the target age group. This means that only about 18% of the population targeted by a potential program is currently being treated. These numbers of procedures likely correspond to the number of people currently being screened for AAA (based on a status quo scenario) without a program. If screening were offered to men reaching the age of 65 years, nearly 36,000 ultrasounds would need to be performed. This activity would detect 2200 AAAs (5.5%), of which 344 would require surgery. In other countries or regions, the family physician's role in screening is clearly defined, but this presents several challenges for Québec. First, regular access to a family physician is not guaranteed for all the people in Québec. Furthermore, many guidelines advocating various types of screening recommend that screening be performed by family physicians; yet their practice situations do not make that recommendation easy to follow. Physicians' lack of availability to provide pre-screening counselling, prescribe ultrasound scans or conduct post-screening follow-up for their patients limits any possible scenarios for implementing it.

Second, ultrasound imaging is generally not widely accessible in Québec at this time because this procedure is not covered by the public health insurance plan unless it is performed in a hospital. Wait times of six months for an ultrasound have been reported. A focused scan of the abdominal aorta, recommended for screening, is not listed as one of the procedures that radiologists are paid for under Québec's health insurance plan. Moreover, negotiations are still underway regarding the division of responsibilities between radiology technologists and radiologists for this type of procedure. On the one hand, technologists would need additional training to develop the skills to perform these examinations if they were called to do so. On the other hand, the small number of experienced technologists means that access to screening examinations could remain limited.

With respect to geographic access to AAA treatments, a look at the distribution of hospitals across Québec shows that at least one provider exists in each administrative region (except for the regions Côte-Nord, Nord-du-Québec and Gaspésie–Îles-de-la-Madeleine) and that elective surgery is concentrated in a small number of hospitals. As for the distribution of elective procedures, according to the minimum procedure volumes documented in the literature (40–50 surgeries per year), hospital statistics indicate that, in 2006, twelve hospitals with threshold volumes of 40 procedures per year performed 80% of them, and seven hospitals with thresholds of 50 per year performed 45% of them. In 2007, Québec had 42 vascular surgery specialists. According to the medical professionals interviewed, it would be feasible to perform the additional number of surgeries arising from a population screening program. The data available on the quality of care and short-term outcomes of elective surgery indicate that the post-operative mortality risks fall within the range of published scientific standards.

What would the potential yield of a screening program be for a cohort of Québec men aged 65 to 74 years? This question was initially answered through a modelling exercise based on a similar one carried out in 2007 for all of Canada but using parameters specific to Québec's experience. To start, this exercise needed to take into account the fact that several of the randomized controlled trials on AAA screening defined mortality as including deaths from ruptured aortic aneurysms in unspecified sites, given that some of them may occur in the abdominal aorta. The estimated yield included that possibility, which added roughly 26% to AAA-related mortality. The selected parameters for Québec were chiefly the rates of emergency and elective surgeries and their associated operative mortality. The exercise also took into consideration the fact that deaths due to ruptured AAAs occur before patients arrive at the hospital or receive surgery and that these deaths are not classified as such in official mortality statistics. These rupture cases outside the hospital would account for 66% of total ruptures, the others effectively being treated through emergency surgery. Lastly, since the rate of attendance is a key variable in any screening program, two assumptions were used: 74.3% (in the Canadian modelling exercise) and 50% (to reflect Québec's experience).

According to this modelling exercise, the number of actual preventable AAA-related deaths over a 41-month period could vary between 155 and 480 (including AAAs in unspecified sites), or between 45 and 141 annually, which is a modest yield for a population screening program. The overall mortality benefit would be small, an outcome consistent with the fact that studies on AAA screening have not demonstrated a statistically significant impact on overall mortality.

## Conclusions

In light of this analysis, AETMIS is of the opinion that a good number of the criteria for appraising the appropriateness of a screening program are met in the case of AAA, especially those concerning the disease, its detection through abdominal ultrasound and its treatment, although that finding differs in men and women. However, these criteria are only partially or poorly met with respect to the program itself.

For men, the aspects that favour implementing a screening program are the following:

- The natural history, risk factors and course of the disease are relatively well known.
- The examination to detect AAA, focused abdominal aortic ultrasound, is sensitive and specific.
- The effectiveness of the treatment has been demonstrated, especially for men aged between 65 and 74 years who qualify for surgery.
- The clinical efficacy of an AAA screening program for that target population has been demonstrated.
- Its cost effectiveness is acceptable to society, according to generally accepted threshold values.

For women aged 65 years and older, even if ultrasound has the same sensitivity and specificity, there are insufficient data to clearly demonstrate the benefits of population screening for AAA. Nevertheless, women who present with multiple risk factors could be included in a potential program, as recommended in the Canadian guideline. Targeting patients most likely to benefit from screening, including men, is the approach to favour in order to increase the cost effectiveness

of the screening program and to better address the ethical issues raised by screening, surveillance and surgery.

The aspects that do not favour implementing a population screening program relate to its effectiveness, in general, and to the state of the required organizational conditions, in particular.

In terms of its effectiveness:

- Despite the positive recommendations for population AAA screening programs issued by several health technology assessment agencies (Ontario, Spain, Netherlands and Sweden) or preventive task forces (United States), the authorities concerned have decided not to follow through on them, or else to do so only in a limited way (the U.S. Medicare program offers it only to newly enrolled men).
- To date, only the United Kingdom has decided to implement this type of program. It is open to men who reach 65 years of age and, on request, to older men wanting to take part in it.
- No assessment of the operation or actual effectiveness of such a program is available at this time.

In terms of its required organizational conditions:

- The randomized trials conducted thus far have conferred an important role on family physicians. These physicians perform preliminary clinical examinations, prescribe tests, ensure surveillance of screened AAAs and refer patients to the right specialists, while counselling them so that they can make an informed decision before agreeing to the tests and procedures that might follow. In Québec, however, approximately one in four people have difficulty accessing a family physician. Apart from the need to improve access to organized care, physicians will have to be in a position to add new treatment modalities to their daily practices (besides being asked to ensure specific follow-up for other diseases). They will also need proper training and access to relevant clinical practice guidelines and patient decision-support tools. These improvements are major challenges for Québec's health-care system.
- Providing ready access to abdominal ultrasound, in terms of both its technical and its professional

aspects, is a key factor for the success of an AAA screening program. In Québec, the increase in the number of abdominal ultrasounds that would result from such a program would likely very quickly exceed the actual capacity to perform them, given that this procedure is not covered by the public system unless it is performed in a hospital and that the resources needed to run this program are scarce. Different measures could help solve this problem: creating a service category for abdominal aortic ultrasounds, widening public health insurance to cover ultrasounds in private radiology clinics, drafting guidelines for the legal and professional framework governing the staff concerned, especially radiology technologists, and putting in place the human and material resources required for ultrasound procedures.

- Implementing an AAA screening program would lead to a rise in the demand for elective surgical procedures. In Québec, although the vascular surgery specialists are capable of meeting that demand, organized surgery services would need to be reviewed to ensure an appropriate overall response. That review should strive to solve both the challenge of ensuring equitable and timely access to this service in all the regions and the challenge of quality assurance by meeting the minimum volume thresholds for surgical and hospital procedures. Solutions could start with recognizing (or designating) surgery centres by the Ministère de la Santé et des Services sociaux (MSSS), according to quality and efficiency criteria, and with establishing service corridors.
- The success of any population screening program is based on a minimum attendance level. Québec has only limited experience in this area, however, and studies or pilot tests will need to be conducted to properly assess what the participation rate would likely be.
- Lastly, the decision to implement a screening program depends on its relative value to society, which has a direct impact on budget choices. The contextual analysis of Québec's situation reveals many constraints on its human and technical resources and organized health services, which may be difficult to overcome in the short or mid term. According to a

preliminary estimate in Québec's context, the yield of a screening program targeting men aged 65 to 74 years would be rather modest, that is, approximately 100 additional preventable deaths per year. Furthermore, both the MSSS and other health-system stakeholders are dealing with a number of other health problems demanding more immediate and greater attention.

**In conclusion:**

- According to available scientific evidence, an AAA screening program would theoretically be effective, given that the criteria regarding the disease, screening test, treatment and cost effectiveness are met, especially among men aged 65 to 74 years.
- To date, the effectiveness of such a program, which depends on epidemiological and organizational conditions in actual contexts, has not been demonstrated.
- If this population screening program were implemented in Québec with a cohort of men aged 65 to 74 years followed up for 41 months, it would yield approximately 100 preventable deaths per year.
- The current state of Québec's epidemiological and organizational conditions, while scarcely favourable to the immediate implementation of such a program, does reveal several possible avenues for improvement.
- The MSSS and directly concerned professional organizations are invited to jointly set priorities and develop an action plan to improve the clinical and organizational aspects surrounding the management of people who present with an abdominal aortic aneurysm or its associated risk factors, and to fully evaluate the real potential of a population screening program.