Diagnostic radiology using transportable equipment

SUMMARY

Report prepared for AETMIS
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MISSION

The mission of the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) is to contribute to improving the Quebec health care system and to participate in the implementation of the Quebec government's scientific policy. In order to accomplish this, the Agence advises and supports the Minister of Research, Science and Technology as well as the decision-makers in the health care system with respect to the assessment of health services and technologies. The Agence makes recommendations based on scientific reports assessing the introduction, distribution and application of health technologies, including technical aids for disabled persons, as well as the modes of providing and organizing services. The assessments take into account multiple factors, such as the efficacy, safety and efficiency, as well as the ethical, social, organizational and economic implications.

FOREWORD

RADIOLOGICAL EXAMINATIONS USING TRANSPORTABLE EQUIPMENT

At the request of the Minister of Health and Social Services, the *Agence d'évaluation des technologies et des modes d'intervention en santé* studied the possibility of using transportable x-ray equipment in public institutions or private homes. This request from the Minister resulted from the application made by various practitioners working in the medical and dental fields to be authorized to offer diagnostic radiological services using such equipment in places where current laws and regulations do not allow them to do so.

The report explores the needs of the population for such services, determines the relevance of authorizing the use of this equipment, and considers the possible consequences of such an authorization. It also includes indications and contraindications to this effect and describes the current legal framework and the regulations required in order to offer quality and safe radiological services. Four categories of locations are examined: private homes, mobile laboratory units, CLSCs (local community service centres) and CHSLDs (residential and long-term care centres).

The *Agence* concludes that it currently appears to be "inappropriate" to authorize the use of transportable medical x-ray equipment in private homes and in mobile laboratory units. However, the use of such equipment is deemed to be "appropriate under specific conditions" in a dedicated room within a CLSC or CHSLD. With respect to dental diagnostic radiology, it currently appears to be "inappropriate" to authorize the use of transportable equipment in private homes. The use of such equipment is deemed to be "appropriate at all times" in a dedicated room within a CLSC or CHSLD and "appropriate under specific conditions" in mobile laboratory units.

Among the population groups identified by the *Agence* as most likely to benefit from x-ray services through the use of transportable equipment are senior citizens, individuals with a physical or mental impairment, people living in an institution who are confined to bed or experiencing a severe loss of autonomy, as well as residents of remote communities.

The *Agence* hopes that this assessment will assist the policymakers in the health services network concerned by this issue in making an informed decision.

Renaldo N. Battista
President and CEO

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Christian Caron	Dentist, Director, Dental education program specialized in gerodontics, Faculty of dental medicine, Université Laval, Québec, Quebec.
Michel Deschamps	Radiation safety physicist, President of *Radioprotection, Inc.*, Sainte-Julie, Quebec.
Pierre Deschamps	Lawyer, Director of Research, Centre of Private and Comparative Law, Faculty of Law, McGill University, Montreal, Quebec.
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SUMMARY

The aim of this study, carried out by the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) in response to a request made by the Minister of Health and Social Services, was to determine whether medical or dental x-ray services performed with transportable equipment in locations not intended for diagnostic radiology should be authorized in Quebec and if so, to determine under what conditions these services should be offered.

More specifically, its intent was to explore the needs of the population for such services, to rule on the relevance of authorizing these services and to examine the possible consequences of such an authorization. We were also asked to specify the indications, contraindications and regulations that would allow safe and high-quality x-ray services to be offered, if the use of transportable x-ray units were authorized. The request resulted from the application made by various practitioners to be authorized to offer mobile x-ray services using this type of equipment.

It is important to mention that this assessment only deals with general diagnostic radiological transportable equipment. Transportable equipment dedicated either to breast or lung imaging, or to panoramic examinations in dentistry, for example, was not considered, since this equipment presents special characteristics or requirements.

REVIEW OF THE PUBLICATIONS

The relevant publications found in the main bibliographic reference banks and on the Web were located by combining the terms "portable" and "mobile" and "radiograph", "x-rays" and "x-ray" in all fields. This was updated regularly until August 2001.

The review of the existing publications revealed the nearly total absence of scientific information on most of the elements under consideration, which prevented a systematic review of the scientific findings such as is usually performed in the assessment of health technologies from being carried out.

Various health technology evaluation agencies, government authorities and other organizations in the health field were contacted in order to obtain additional information. Formal consultations with experts were also held.

ASSESSMENT APPROACH

The difficulty posed by the nearly total absence of valid scientific data on the subject under consideration was circumvented by resorting to a modified version of the approach developed by Hobbs and his colleagues* to assess the relevance of proceeding with tests outside of hospital laboratories. The method is based on a systematic analysis of the conditions deemed necessary for a test (in the present case, radiodiagnosis using transportable equipment) to be performed in a given place in an appropriate manner.

* Hobbs FDR, Delaney BC, Fitzmaurice DA, Hyde CJ, Thorpe GH et al. A review of near patient testing in primary care. Health Technol Assess 1997;1(5):1-229.

Given the types of potential client groups (senior citizens, individuals with a physical or mental impairment, people who are confined to bed), the use of transportable radiographic units in the following locations was considered:

- in private homes;
- in mobile laboratory units;
- in certain types of health and social services institutions (CLSCs and CHSLDs), other than hospital centres equipped with radiology departments.

The relevance of authorizing the use of transportable units in these locations was assessed based on four main criteria:

1) the influence of the use of these units on patient management;
2) the performance and reliability of these units in the proposed application framework;
3) the cost and effectiveness of services rendered using these units compared to the cost and effectiveness of services offered by laboratories designed for diagnostic radiology;
4) the acceptability of their use, essentially from the perspective of safety for the patient, the staff and the public.

We then identified the conditions required to satisfy each of these criteria, and determined, for various categories of locations where transportable equipment could be used, whether it was possible to meet these conditions. On this basis, the use of transportable x-ray equipment in a given location category could be deemed: 1) appropriate at all times; 2) appropriate under specific conditions; 3) inappropriate. Requirements to be met, established on the basis of the same four criteria, were defined for the first two classifications.

DESCRIPTION AND CURRENT USAGE

X-ray equipment used for diagnostic purposes can be stationary or transportable. The term "transportable" includes mobile and portable equipment. In this case, the adjective "mobile" designates equipment that is essentially autonomous and can be moved over short distances within a single building or that can be installed in a vehicle such as a van or a trailer. The term "portable" applies to equipment that can easily be taken apart and transported to various places in order to offer radiological services.

In Canada, transportable radiological equipment for medical diagnosis, with the exception of equipment used for mobile mammography services, is mainly found in hospital centres. It usually consists in mobile radiological equipment (rather than portable equipment), the use of which is generally reserved for patients who can not be moved to the radiology department. This equipment is therefore used at their bedside, in intensive care units, in surgical units and in traumatology units (emergency rooms). It is primarily used to perform chest x-rays or plain abdominal films, or x-rays of the skeletal system with limited views.
Transportable x-ray equipment is also used in the field of dentistry. It allows for the operation of mobile clinics, which offer care in institutions or in private homes. Such clinics are rare in

Quebec, and are generally operated in association with a university or a health care organization, or by independent dentists.

RESULTS

With regard to the legal framework regulating the use of this equipment

The rules of protection enacted in the field of radiology are based on three fundamental principles: 1) the necessity of **justifying** the practice, with no practice likely to lead to radiation exposure of individuals being adopted unless it produces sufficient benefit to offset potential harm; 2) the necessity of **optimizing** the practice, which consists in balancing the cost of dose reductions and the possible health benefits of such reductions; 3) the obligation to **limit doses**, which means that professional exposure must be subject to a regulatory dose limit, so that it does not cause any risks judged to be unacceptable in normal circumstances.

In Canada, the **fabrication** of transportable x-ray units is subject to the *Radiation Emitting Devices Act* and its related regulations. The **sale**, **advertising** and **labelling** of transportable x-ray units are the object of specific provisions in the *Food and Drugs Act* and the *Radiation Emitting Devices Regulations*. Among other things, these provisions require manufacturers to display warning symbols on x-ray equipment. Quebec authorities have not regulated any of these aspects.

In Quebec, the rules applicable to the functioning and usage of x-ray equipment vary according to the locations in which it is used: locations intended for diagnostic radiology (outside of health and social services institutions), and health and social services institutions. They also vary depending on whether the responsible organizations and employers fall under federal or provincial jurisdiction.

In locations not intended for diagnostic radiology, such as the home of a user, where x-rays could be taken using transportable equipment if this practice was permitted, the only regulations that would apply would be the federal regulations regarding radiation in general. The Quebec *Environment Quality Act* allows for the application of preventive regulations with regard to hazardous materials, but these regulations presently remain general or apply more to storage. More specifically, this law imposes the respect of possible government regulations with regard to sources of radiation and attributes regulatory powers with regard to the installation, exploitation and safe usage of all sources of radiation located outside a health or social services institution. However, no regulations have yet been adopted in this regard

With regard to potential client groups

Certain population groups, such as senior citizens, individuals with a physical or mental impairment, people who are confined to bed or experiencing a severe loss of autonomy, whether living in a private home or in an institution, as well as residents of remote communities, may have a more limited access to diagnostic radiological services, in spite of real needs. For these sub-groups, the possibility of receiving medical or dental general diagnostic radiological services through the use of transportable equipment could present benefits.

With regard to utilization conditions

The use of transportable x-ray equipment will have a favourable influence on patient management if the following conditions are met:

- Complementary diagnostic tests can be performed on site, when necessary.
- Medical or dental treatments can be rendered on site.
- The practitioners have the clinical knowledge to interpret and use the results in an effective manner.
- Professional or technical support is available immediately, if necessary.
- The results are available immediately, or at the time of providing primary care.

The performance and reliability of transportable x-ray equipment will be optimal if the following conditions are met:

- The technical characteristics of the x-ray units allow an adequate image quality for the intended application to be obtained.
- The operating conditions and the physical environment can be adjusted in order to produce optimal diagnostic information.
- The transportation of the x-ray units will not compromise the quality of the results.
- The conditions surrounding the processing of the radiographs will not compromise the quality of the results.
- The radiological examination using a portable or mobile unit will be performed by an operator who has been specifically trained for such purposes.

The use of mobile or portable x-ray equipment could be advantageous from an economic point of view as compared to the services of laboratories designed for diagnostic radiology if the following conditions are met:

- Specific measures (fee limits, services limited to certain groups of patients) allow for the cost control of portable or mobile x-ray services.
- These services will complement those offered by laboratories designed for diagnostic radiography.

Diagnostic radiological services using mobile or portable x-ray equipment could be considered acceptable if the following conditions are met:

- The use of transportable x-ray equipment should be reserved for patients who can not be transported to diagnostic radiology laboratories (with stationary x-ray units).
- The cost of the services should not limit access to them.
- Appropriate radiation protection equipment will be available in the location where the radiographs are taken.
- Quality assurance programs (certification) will ensure the protection of patients, workers and the public.
- The confidentiality of the results and continuity of service delivery will be ensured.

With regard to the legal, administrative and financial implications

In Quebec, the current legal and regulatory provisions do not allow radiography for general diagnostic purposes outside of laboratories designed for diagnostic radiology or outside of health and social services institutions. The authorization to use transportable x-ray equipment in locations not intended for medical or dental diagnostic radiology would therefore have legal, administrative and financial implications.

Among other matters, apart from the necessity of making administrative adjustments, a good number of the sections of the *Regulation respecting the application of the Public Health Protection Act* would have to be reviewed to ensure that they are aligned with the legal and regulatory dispositions already in place. Various professional associations or corporations would have to be consulted in order to oversee the safe and appropriate use of transportable x-ray equipment as a complement to the regulatory requirements, and to modify certain agreements between the Minister of Health and Social Services and certain professional health associations and federations involved.

From a financial perspective, this practice would result in an increase in the cost of general diagnostic radiological services for the State, the level of which can not currently be determined. This increase would especially be imputable to the steps involved in implementing these services and the control measures to be established in order to ensure a quality of service and radiological protection equivalent to those offered with stationary radiographic equipment. Furthermore, if the State authorizes these services of general radiodiagnosis but decides to have the patients pay the cost in whole or in part, this would risk making the access to these services difficult for the client groups usually targeted (senior citizens, mobility impaired persons, etc.), who most often have low incomes.

Moreover, the authorization to use transportable medical diagnostic radiological equipment in private homes could present certain application difficulties, for example, that of limiting this practice to certain groups of professionals (physicians, dentists), to a specific client group (e.g.: mobility impaired persons either living in a private home or in an institution) and even to the field of practice of diagnostic radiology. It also entails the risk of contravening safety principles inherent to the use of ionizing radiation.

With regard to the relevance of authorizing the use of transportable equipment

The analysis of the conditions necessary for the effective and safe use of this equipment in locations not intended for diagnostic radiology led AETMIS to conclude the following with respect to the relevance of authorizing its use[**]. It should be remembered that these conclusions do not apply to transportable equipment used for breast imaging or for dental panoramic examinations, for example, but only to general diagnostic radiological equipment.

For medical radiodiagnosis:

[**] Because of important distinctions between the field of medical radiodiagnosis and that of dental radiodiagnosis, the two types of use were analyzed separately.

- It currently appears to be "**inappropriate**" to authorize the use of transportable medical x-ray equipment in private homes and in mobile laboratory units.

- The use of such equipment can however be deemed "**appropriate under specific conditions**" in a dedicated room within a CLSC or a CHSLD.

For dental radiodiagnosis:

- It currently appears "**inappropriate**" to authorize the use of transportable dental x-ray equipment in private homes.

- The use of transportable dental x-ray equipment is deemed "**appropriate at all times**" in a dedicated room within a CLSC or a CHSLD.

- The use of transportable dental x-ray equipment is deemed "**appropriate under specific conditions**" in mobile laboratory units.

In locations where the use of transportable diagnostic radiological equipment is deemed "***appropriate at all times***", this use should be subject to the following conditions:

- The radiodiagnosis must be restricted to a dedicated location that satisfies certain requirements aimed at ensuring the protection of the patient, the operator as well as the public.
- It should be reserved for patients who can not be easily transported to a hospital or to a diagnostic radiology laboratory (equipped with stationary x-ray units).
- It should be reserved for patients for whom there is a clear clinical indication for a diagnostic radiology examination.
- It must be subject to certification requiring:
    - special training for the operators, physicists and doctors involved;
    - the application of a quality assurance program designed to ensure a degree of image quality and to minimize the radiation exposure of the patient, the staff and the public (must cover the steps involved in the processing of the radiological images).
- It must be the object of standards and guidelines manuals put together by professional organizations in order to ensure its safety and for its implementation to be carried out in an efficient fashion.

In a place where the use of portable or mobile x-ray units is deemed "**appropriate under specific conditions**", this use will be subject to the same requirements as those above. This use must also be restricted to emergency and exceptional situations, in order to respect the identified criteria and the principles adopted in radiation protection.