

UETMIS

*Unité d'évaluation des technologies
et des modes d'intervention en santé*



Intravenous contrast medium administration in computerized axial tomography at the CHUQ Medical Imaging Department

Summary



CENTRE HOSPITALIER
UNIVERSITAIRE DE QUÉBEC



L'UNITÉ D'ÉVALUATION DES TECHNOLOGIES ET DES MODES D'INTERVENTION EN SANTÉ

Centre hospitalier universitaire de Québec

Intravenous contrast medium administration in computerized axial tomography at the CHUQ Medical Imaging Department

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**Direction de l'évaluation, de l'ingénierie, de la qualité
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NOTE TO READER

The Unité d'évaluation des technologies et des modes d'intervention en santé (UETMIS) of the CHUQ has a mission to support and advise policymakers (managers, clinicians and professionals) in decisions related to the efficient allocation of resources for the implementation of technologies, new practices or the revision of existing practices in light of new problems.

This evaluation report consists in a summary and analysis of knowledge based on an extensive review of various documents available, leading to the development of recommendations. It has been approved by the Scientific Council of UETMIS.

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This paper presents the information available as at May 14, 2007, according to the documentary research methodology selected. The recommendations describe experiments that were conducted with equipment and materials owned by the CHUQ, which may differ in many respects from those used by other healthcare facilities. The recommendations are not a substitute for the judgment of a clinician in a more specific context. This document in no way legally binds the CHUQ, its employees or its professionals with respect to the recommendations.

Accordingly, the CHUQ, the members of the multidisciplinary work group as well as the members of the UETMIS Scientific Council shall in no case be held liable for any damages of any kind whatsoever stemming from the use or the interpretation of the information in this document

DISCLOSURE OF CONFLICT OF INTEREST

No conflict of interest to report

SUMMARY

Introduction

The growing concern over the past few years about nosocomial infection prevention highlights the importance of patient and staff safety for healthcare institutions. The CHUQ shares this vision and, as such, has officially decided not to reuse single-use devices (SUD), by approving recommendations to this effect made by its Risk Management Committee.

However, questions have been raised concerning the safety of the technique used for intravenous contrast medium administration in computerized axial tomography at the CHUQ Medical Imaging Department. According to current practice, a single container of contrast medium, set up on an injection system, is used for consecutive intravenous injections in multiple patients (only part of the injection system—tubing with two check valves connecting the patient to the injector—is changed for each patient). As a result, medical devices (contrast medium container, tubing with perforated ends and three-way stopcock, and injector syringe) are shared by several patients. Due to the potential risk of this practice to patients' safety, the CHUQ Infection Control Committee (ICC) has issued a recommendation to the CHUQ authorities not to reuse medical devices for the administration of intravenous contrast medium.

Due to the conflicting views regarding the application of this recommendation and the anticipated costs of implementing this change at the CHUQ, the Risk Management Committee has requested an opinion from the CHUQ's Unité d'évaluation des technologies et des modes d'intervention en santé (UETMIS) to assist in the decision-making.

Objective

To assess the risk of contamination and infection associated with the technique used for intravenous contrast medium administration in computerized axial tomography at the CHUQ Medical Imaging Department and, if applicable, to suggest one or several alternatives in order to decrease the risk and assess the financial and organizational impacts.

Evaluation methodology

The literature search comprised a review of the scientific documentation on the risk of contamination and infection associated with the current technique used for intravenous contrast medium administration at the CHUQ Medical Imaging Department, according to the hazards identified:

1. multiple punctures of single-dose contrast medium containers, or of multidose containers intended for single punctures only;
2. sharing of medical devices (tubing connecting the contrast medium container to the injector, and injector syringe) by several patients;
3. malfunction of one-way check valves.

The literature review was performed in established Health Technology Assessment databases, web sites of professional associations or government agencies, as well as web sites of contrast medium and medical devices manufacturers. The literature review comprised documents published between 1980 and 2006. The methods used for quality assessment and data extraction are described in the UETMIS - CHUQ methodology guide.

A multidisciplinary work group was established comprising representatives from the Medical Imaging Department, the Infection Control Committee and CHUQ microbiologists-infectious disease specialists. Direct observation was applied to describe the technique used for intravenous contrast medium administration in computerized axial tomography at the CHUQ. The technique used in seven other Quebec university hospital centers was also documented with a questionnaire. A cost-analysis of various alternatives was performed in conjunction with administrators in the CHUQ Medical Imaging and Finance Departments.

Results

Risks of contamination associated with intravenous contrast medium administration

Three out of six studies evaluating the risk of contamination associated with contrast medium administration were included in this evaluation. They revealed a 0-2% prevalence of contrast medium contamination by skin microorganisms in routine conditions of use. In unsterile conditions, the prevalence of contamination was as high as 50%.

Risks of microorganism proliferation in contrast medium

The majority of the studies reviewed (5/6) showed little or no proliferation of microorganisms in contrast medium. The growth of certain microorganisms (*Candida albicans*, *Pseudomonas aeruginosa* and *Enterococcus gallinarum*) was reported after more than 8 hours of incubation in contrast medium at room temperature or 37° Celsius.

Risks of contamination associated with one-way check valve malfunction

Three studies evaluated the integrity of one-way check valves. The results show that spring valves can withstand back-pressures equivalent to normal arterial pressure with no leakage. In an experiment on ten check valves (from 10 different batches), only one valve failed at a back-pressure equivalent to ten times the blood pressure of a hypertensive patient. The number of valves tested in each of these studies was relatively small (ten or less).

Risks of infection associated with contrast medium administration

Four out of the seven studies available were of adequate quality and were included in this evaluation. Cases of infection by different microorganisms (bacteria, parasites, viruses) have been documented in patients following intravenous contrast medium administration. Breaches in aseptic techniques by Medical Imaging staff members were the main presumed cause of patient-to-patient transmission of infectious agents. Only one study reported patient-to-patient transmission by reverse blood flow from a malaria-infected patient. Presumably, the subsequent reuse of the same injection system for the next patients resulted in their contamination. However, the system used in that case did not feature one-way check valves.

Context-specific results

The technique used for intravenous contrast medium administration at the CHUQ

The system used for intravenous contrast medium administration in computerized axial tomography (CAT) at the CHUQ Medical Imaging Department includes the following components:

- multidose contrast medium container (200 ml or 500 ml);
- tubing with three-way stopcock connecting the contrast medium container to the injector;
- syringe inserted in an automatic injector;
- tubing with two spring check valves connecting the syringe to the patient.

Only the tubing with two check valves is changed with every patient. The syringe and tubing with three-way stopcock are changed every 3-4 hours. The multidose contrast medium container is used for multiple patients and is discarded a maximum of 8 hours after opening. The multidose container may be perforated more than once if a different contrast medium is medically required. At the CHUQ, there is no written procedure describing the technique for intravenous contrast medium administration nor any formal process for staff training or quality assurance.

The technique used at other Quebec university hospital centers

The technique used for intravenous contrast medium administration at seven other Quebec university hospital centers is similar to that used at the CHUQ. However, a written procedure is available at most of these hospitals, and some centers also have training and quality assurance mechanisms in place.

Recommendations and guidelines of established organizations and manufacturers

Various established organizations have issued guidelines concerning the intravenous administration of contrast medium. These include hand hygiene (for example, hand washing or disinfection), disinfection of the container membrane with 70% alcohol, and the use of a sterile device to access the container. According to USP <797>, considered to be the gold standard for the preparation of sterile products, multidose containers should be divided in the utmost sterile conditions, namely in the pharmacy under a laminar flow hood. For its part, Health Canada recommends that healthcare facilities using tubing fitted with check valves institute continuous surveillance procedures to monitor the efficacy of this practice. Contrast medium manufacturers have also established guidelines stating that multidose containers are intended for multiple dispensing for intravenous use and must be spiked only once. They add that this format is restricted to hospitals with a recognized intravenous admixture program.

Discussion

The analysis of available data on the risk of patient contamination in computerized axial tomography by reverse blood flow in the tubing leads to the presumption that the risk is virtually nonexistent. There is, however, a risk of contamination of the injection system due to staff members handling the device. According to the literature, the main cause of contamination and infection transmission is the breach of asepsis by personnel. Given all these elements and their possible impacts on patient safety, changes are required to the current technique used for intravenous contrast medium administration in computerized axial tomography at the CHUQ. There are two possible scenarios.

The first scenario is to use single-dose contrast medium containers and to change the syringe and the tubing connecting the container to the injector after every patient. This scenario represents the gold standard for patient safety. Three different options are available: the use of prefilled syringes, the use of single-dose containers, and the preparation in the pharmacy of single doses

from multidose containers. The estimated additional costs of these options range from \$108,000 or more for the preparation of single doses in the pharmacy to \$286,000 for the use of single-dose containers.

A second scenario is to use single-dose or multidose containers with an injection system (syringe and tubing connecting the container to the injector) for multiple patients. This scenario is considered acceptable because of the practically nonexistent risk of patient-to-patient contamination and because it is possible to make the technique safer by making the following adjustments:

- 1) reinforce the rules of asepsis for intravenous contrast medium administration at the Medical Imaging Department by writing a formal procedure, and by training and evaluating personnel on this procedure;
- 2) comply with the guideline to puncture contrast medium containers only once;
- 3) change the syringe and the tubing connecting the container to the injector every 4 hours;
- 4) use new tubing with two spring check valves for every patient;
- 5) dispose of any unused contrast medium within a maximum of 8 hours after opening the container;
- 6) institute continuous surveillance of fever and chills in patients receiving an intravenous contrast medium injection.

Two options that meet these conditions have been evaluated. The first option is to add, in every computerized axial tomography room, a second injector reserved exclusively for a single type of contrast medium. The second option is to change the syringe and the tubing connecting the container to the injector whenever it is medically necessary to change the contrast medium. The estimated costs of these respective options range from \$35,000 to \$54,000 or more.

Conclusion and recommendations

In a context of risk management, where patient safety is of the utmost importance, the administration of intravenous contrast medium from single-dose containers using single-use syringes and tubing for each patient represents the gold standard. However, the tight financial situation at the CHUQ, like that at other Quebec hospitals, requires a certain balance between acceptable risk and capacity to pay. The large amounts of money associated with implementing the gold standard could be allocated to other activity sectors at the CHUQ with more pressing needs.

Considering,

- the importance given by the CHUQ to safe healthcare services;
- the presumption that the risk of patient-to-patient infection transmission is virtually nonexistent during intravenous contrast medium administration using tubing with two spring check valves, according to the analysis of currently available scientific data;
- the guidelines for injection systems and from contrast medium manufacturers as well as recommendations on the prevention of infections associated with intravascular access devices;
- the additional costs associated with the different options available for intravenous contrast medium administration using single-dose containers;

it is recommended that the CHUQ Medical Imaging Department be allowed to continue the intravenous administration of contrast medium using multidose or single-dose containers for multiple patients using a common injection system (syringe and tubing) with automatic injector **if all of the following conditions are met:**

- 1) reinforce the rules of asepsis for intravenous contrast medium administration;
- 2) comply with the guideline to puncture contrast medium containers only once;
- 3) change the syringe and the tubing connecting the container to the injector every 4 hours;
- 4) maintain the use of tubing with two spring check valves connecting the injector to the patient, and change the tubing for every patient;
- 5) dispose of any unused contrast medium within a maximum of 8 hours after opening the container;
- 6) include all of the above conditions in a formal written policy; train and evaluate personnel on this procedure.
- 7) institute continuous surveillance of fever and chills in patients receiving an intravenous contrast medium injection.

It is recommended that the above conditions be implemented within a maximum of 12 months following the deposit of this report.

It is also recommended to implement these conditions in other sectors of the CHUQ where intravenous administration of contrast medium from multidose containers for multiple patients takes place, using a common injection system (syringe and tubing connecting the container to the injector).

Regarding other techniques used for the intravascular administration of contrast medium from a single container for multiple patients or multiple doses, it is recommended that they be evaluated in light of the infection prevention standards and practices recognized at the CHUQ. The principles of asepsis and the importance of a single perforation of contrast medium containers must be taken into consideration.

These recommendations are based on information currently available. They will need to be revised should new information from the scientific literature or from process analyses at the CHUQ suggest that patient safety may be jeopardized.

GLOSSARY

- CONTRAST MEDIUM** Radiopaque substance injected orally, intravenously or intra-arterially and used during certain radiology examinations to create a contrast in the images of various tissues and organs.
- SPRING VALVE** A valve is a mechanical device used to open and close a chamber or conduit. A spring valve must be subjected to considerable pressure to open in the direction of flow.
- COMPUTERIZED AXIAL TOMOGRAPHY** Computerized axial tomography is a medical imaging technique in which the patient is scanned with an x-ray beam.