Complete Summary

GUIDELINE TITLE

Managing central venous access devices in cancer patients: a clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Central Venous Access Device Guideline Panel. Managing central venous access devices in cancer patients: a clinical practice guideline. Toronto (ON): Cancer Care Ontario (CCO); 2006 Sep 25. 39 p. (Evidence-based series; no. 16-1). [67 references]

GUIDELINE STATUS

This is the current release of the guideline.

The EVIDENCE-BASED SERIES report, initially the full original Guideline, over time will expand to contain new information emerging from their reviewing and updating activities.

Please visit the Cancer Care Ontario Web site for details on any new evidence that has emerged and implications to the guidelines.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

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SCOPE

DISEASE/CONDITION(S)

Cancer

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Oncology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physicians

GUIDELINE OBJECTIVE(S)

- To prevent catheter-related intraluminal thrombosis and local or systemic catheter-related infection, minimize the need to replace devices, and enhance quality of life among children and adults with cancer by assessing:
    - Whether central venous access devices (CVAD) should be locked with heparin or saline
    - What volume and strength of solution should be used to lock CVADs
    - How frequently CVADs should be locked
    - What type of catheter should be used
- To evaluate, in patients who require systemic therapy for cancer, the indicators (e.g., functional or quantitative neutropenia, age, diagnosis, therapy, immune status, or patient convenience) that have an impact on the decision to insert a central venous access device

TARGET POPULATION

Adult and pediatric patients requiring central venous access devices for cancer treatment

INTERVENTIONS AND PRACTICES CONSIDERED

Consideration of protocols for central venous access devices (CVADs) in cancer patients, including schedule of solutions, volumes, concentrations, and frequencies

MAJOR OUTCOMES CONSIDERED

- Catheter-related thrombosis
- Catheter-related infection
- Rates of removal due to infection or occlusion
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Strategy

A systematic search for clinical practice guidelines, systematic reviews, and clinical trials was conducted in November 2004. The National Guideline Clearinghouse (www.guideline.gov), the Canadian Medical Association (CMA) InfoBase (http://mdm.ca/cpgsnew/cpgs/), MEDLINE (Ovid, 1999-2004), the Joanna Briggs Institute Web site (http://www.joannabriggs.edu.au/), and Web sites for nursing organizations (http://www.ons.org/, http://www.cina.ca/, http://www.rnao.org/, http://www.apon.org/) were searched for recent practice guidelines published in English by other guideline development groups. MEDLINE (Ovid, 1999-2004), EMBASE (Ovid, 1999-2004), the Cochrane Database of Systematic Reviews (3rd quarter, 2004), the Cochrane Database of Abstracts of Reviews of Effects (3rd quarter, 2004), Cumulative Index to Nursing & Allied Health (CINAHL) (Ovid, 1999-2004), and the Joanna Briggs Institute Web site (http://www.joannabriggs.edu.au/) were searched for recent English-language systematic reviews.

When no comprehensive evidence-based guidelines or systematic reviews were found, MEDLINE (1980-November 2004), EMBASE (1980-November 2004), CINAHL (1982-2004), and the Cochrane Central Register of Controlled Trials (3rd quarter, 2004) were searched through Ovid to find reports of relevant clinical trials. Search strategies used are described in Appendix B of the original guideline document. Searches for clinical trials and meta-analyses were not restricted by language. Manufacturers of central venous access devices (CVADs) were contacted by letter and asked to provide information on completed published or unpublished clinical trials and ongoing trials. Abstracts from the 2002, 2003, and 2004 Oncology Nursing Society (ONS) Congress (http://www.ons.org/nursingEd/Conferences/Congress.shtml) and American

Society of Clinical Oncology (ASCO) meeting (http://www.asco.org/) were searched for unpublished studies. Papers cited in literature retrieved by the formal literature search were also assessed for eligibility.

A separate search was conducted to find evidence on the indicators that might have an impact on the decision to insert a CVAD. The subject headings "risk factors/", "thrombophlebitis/pc,et" and "sepsis/pc,et" were added to the terms for cancer and central venous access used for the search above to find English-language papers indexed in MEDLINE (Ovid) between 1980 and January 2005. A PubMed search was also conducted using the phrase "when to insert venous access device."

Study Selection Criteria

Eligibility Criteria

Abstracts or full reports of primary studies were eligible for inclusion in the systematic review. Only studies that used adult and/or pediatric cancer patients were deemed eligible because the cancer population has unique characteristics: in thrombosis development, thrombosis and infection rates, types of catheters, substances administered, and complications due to surgery and chemotherapy. For the set of questions related to the prevention of intraluminal thrombosis and local or systemic catheter-related infection, studies were eligible if they were comparative studies that included either a concurrent or historical control group or if they:

1. Evaluated the effect of solution, strength, volume, or frequency used for locking CVADs or the effect of different types of CVAD on patient outcomes
2. Reported data on intraluminal thrombosis (as a measure of patency), catheter-related sepsis, local site infection, gram-positive bacteremia, line failure or quality of life as outcome variables
3. Included pediatric and/or adult cancer patients

Exclusion Criteria

1. Letters and editorials
2. Studies of short-term, non-tunnelled (percutaneous), open-ended catheters

In addition, narrative reviews were used to provide background and to identify primary studies but not as a source of data.

Evidence Selection

In considering the evidence, most weight was placed on randomized controlled trials, but other types of comparative studies were also reviewed. Meta-analyses conducted as part of systematic reviews by other researchers were considered if they were published after 1994. Where necessary, meta-analyses in other patient populations were used to supplement the evidence from trials in cancer patients; however, that evidence has limited generalizability because cancer patients, especially those with hematologic malignancies, are at higher risk for CVAD-related complications than other types of patients. Only data from those studies

that specifically stated intraluminal thrombosis as the outcome were included in the intraluminal catheter-related thrombosis data tables.

Study results reported only as meeting abstracts were considered in the context of the other available evidence. Although data presented in meeting abstracts may not be as reliable and complete as that from papers published in peer-reviewed journals, abstracts can be an important source of emerging evidence from randomized trials.

Case series that examined the indicators for intraluminal thrombosis or infection related to CVADs in cancer patients who require chemotherapy were reviewed to identify factors (e.g., functional or quantitative neutropenia, age, diagnosis, chemotherapy protocol, or immune status) that might have an impact on the decision to insert a central venous access device.

NUMBER OF SOURCE DOCUMENTS

Six practice guidelines, one report of a pooled analysis, and 41 clinical studies were reviewed

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Published meta-analysis was considered with the other evidence. Where sufficient data from published studies were available, the reviewers pooled events across studies using the MetaView analysis component of the Cochrane Collaboration's Review Manager 4.2 software. Results of the meta-analysis were expressed as risk ratios (RR) with corresponding 95% confidence intervals (CI), where an RR of less than 1 favoured port catheters being removed less due to infection or occlusion and an RR of greater than 1 favoured tunnelled catheters being removed less due to infection or occlusion.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This evidence-based series was developed by the Central Venous Access Devise Guideline Panel of Cancer Care Ontario's (CCO's) Program in Evidence-based Care (PEBC). The series is a convenient and up-to-date source of the best available evidence on managing central venous access devices in cancer patients, developed through systematic review, evidence synthesis, and input from practitioners in Ontario.

The Central Venous Lines Guideline Panel:

1. Formulated a set of guideline questions relevant to cancer care in Ontario
2. Reviewed the available evidence on the effectiveness of locking solutions, volumes, and frequency, and various types of central venous access devices (CVADs)
3. Considered the quantity, quality, consistency, completeness, and relevance of the evidence
4. Drafted recommendations based on the available evidence, panel members' expert opinions, and guidelines from other groups. Patient safety, convenience, and quality of life were considered in formulating recommendations.

Consensus

The Central Venous Access Device Guideline Panel is comprised of nurses from across Ontario specializing in adult and pediatric oncology care and advanced oncology nurses. The recommendations for the adult population were based on a combination of the evidence presented, existing recommendations from institutions across the province and manufacturers' recommendations. Where those lacked, expert opinion and panel consensus were incorporated into the recommendations. As well, the panel used the Practitioner Feedback as further evaluation of the recommendations.

A consensus recommendation to maintain the status quo in pediatric oncology practice was reached based on the lack of evidence for or against any of the protocols currently in use. Although the pediatric representatives on the panel recognized the value of standardized guidelines and practice, the commitment to individual institutional practices remained strong.

Should central venous lines access devices (CVADs) be locked with heparin or saline?

The uses of either saline or heparin in the catheters are based on the manufacturers' recommendations, institutional protocols, and the panel's expertise. Saline is recommended by the manufacturers of closed ended catheters and positive pressure injection/lock adaptors because these valves prevent blood backflow into the lumen of the catheter and therefore would reduce or eliminate the risk of intraluminal thrombus occlusion. The panel would like to emphasize that with the use of saline in these devices, the proper procedure must be followed as outlined by the manufacturers to prevent blood backflow as an

improper flushing procedure and backflow of blood can cause a thrombus or occlusion.

Heparin is used to prevent thrombus development if blood should enter the lumen of the catheter and is therefore used with open ended catheters. Open or closed ended catheters with or without positive pressure devices and external extensions (e.g., Hickman) can become kinked or bent exerting enough pressure to push small amounts of heparin or saline into the vein. This can generate negative pressure when compression is released to draw blood back into the lumen of a catheter, allowing for thrombus development.

Implanted ports are not visible and there is no way of knowing the type of catheter being used or type/size of port unless the patient has some way to verify this. For this reason heparin is used to be safe in reducing the risk of thrombus occlusion.

What volume and strength of solution should be used to lock CVADs?

The volume of solution to be used in a CVAD depends on the catheter length, the internal diameter of the tubing, the reservoirs and extensions, and the need to ensure that all surface areas receive adequate turbulence and flushing. Manufacturer documents state that the volume of the flush solution should be equal to at least twice the volume capacity of the catheter and add-on devices. The panel used the manufacturers' recommendations and expert opinion to arrive at the volume of solution recommendations.

Since there was no evidence to support one concentration of heparin over another, and the manufacturers' recommendation was the use of institutional protocols, the consensus of the group was to recommend a heparin concentration of 100 units/mL since it is the most common concentration of heparin used in most institutions in Ontario.

How frequently should CVADs be locked?

Although patient convenience and costs to patients, families, and institutions may be considered when deciding on the frequency of flushing, the panel used expertise, manufacturers' recommendations and common practice to generate recommendations for the flush frequency for each device. The implanted port does not have any external adaptor that requires changing (i.e., injection caps) unless it is accessed. If a port or catheter is accessed, the recommendations are once weekly, the non-coring needle and extension/injection cap/adaptor are changed and the line flushed. Injection caps require changing a minimum of every week or as needed. For this reason the lines are flushed as a minimum with each cap change since flushing and locking are part of this process with injection cap/adaptor changes.

What type of catheter should be used and what indicators influence the choice?

Consensus was not reached for which indicators had an impact on the decision of inserting a CVAD, due to a lack of evidence and stakeholders. It was determined

that, in the lack of evidence, other considerations would be needed to come to a consensus that are practical and clinical that may dictate if a CVAD be used; such as the attending physicians' and the patients' preference, operating room time, cost, expert availability and resources to support the CVAD.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

External Review

Following the review and discussion of Sections 1 and 2 of this evidence-based series, the Central Venous Access Device Guideline Panel circulated the clinical practice guideline and systematic review to clinicians in Ontario for review and feedback.

Practitioner Feedback was obtained through a mailed survey of 170 practitioners in Ontario. The survey consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a practice guideline. Written comments were invited. The practitioner feedback was mailed out on October 7, 2005. Follow-up reminders were sent at two weeks (post card) and four weeks (complete package mailed again). The Central Venous Access Devices Panel reviewed the results of the survey.

Report Approval Panel

The final evidence-based series report was reviewed and approved by the Program in Evidence-based Care (PEBC) Report Approval Panel in April 2006.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Adults

There is insufficient evidence for or against the choice of a particular protocol in the adult cancer population. Recommendations by the panel regarding the

schedule of solutions, volumes, concentrations, and frequencies are based on a consensus of the expert clinical opinion and the experience of the Central Venous Access Device (CVAD) Panel in their practices and the best available evidence. These recommendations are framed as a consensus schedule and are presented in the Table below.

The purpose of the consensus schedule is to provide clinical institutions and other organizations with a framework on which to build their own institutional protocols, and to encourage standardization of protocols across institutions. While there is dearth of evidence to drive institutional change, standardization of protocols is of value in and of itself as it can increase patient confidence in nursing care, improve the patient experience, and simplify nursing education. Other important considerations include:

- The impact on patients, families, and staff of inconsistent practice, at a time of transition of care between centres.
- The cost to patients and families in both quality of life and dollars of potentially unnecessary increase in frequency of hospital visits for CVAD management that are required by some hospitals.
- The cost to the health care system associated with more frequent flushing with more costly solutions that may not be justified.

Table. Consensus Recommendations for Locking Central Venous Access Devices in Adult Cancer Patients

CVAD	Lock solution	Volume[A]	Concentration	Frequency
Implanted device (e.g., Port-A-Cath™)	Heparin	5 mL	100 units/mL	After each use or four weeks if not in use
Closed end Tunnelled catheter (e.g., Groshong™)	Sterile Saline	10 mL	0.9%	After each use or weekly if not in use
Open ended Tunnelled catheter (e.g., Hickman™)	Heparin	3 mL	100 units/mL	After each use or weekly if not in use
Closed ended peripherally inserted central line (PICC) (e.g., Groshong™)	Sterile Saline	10 mL	0.9%	After each use or weekly if not in use
Open ended PICC (e.g., Cook™, Vaxcel™)	Heparin	3 mL	100 units/mL	After each use or weekly if not in use

[A] Rationale for volumes was based on dead space volume of the catheter plus sufficient volume to ensure positive pressure. The volume of solution should be altered if the volume of the catheter being used is non-standard or unique. The weight of patient is not a consideration when determining the volume of solution; the volume of the catheter is the key parameter.

- Guidelines published by the Oncology Nursing Society (ONS) in 2004 were used as a framework for the consensus schedule.
- Heparin use would be contraindicated in patients with heparin-induced thrombocytopenia (HIT).
- All lines should be flushed with a minimum of 10 mL of normal saline prior to locking to prevent solution incompatibilities.

- Positive pressure apparatus are not included in the recommendations because there is no evidence pertaining to whether they provide a benefit or not.

Pediatric

There is insufficient evidence for or against the choice of a particular protocol in the pediatric population to justify a change in current institutional practices. Although the pediatric representatives on the panel recognized the value of standardized guidelines and practice, a pediatric consensus could not be achieved.

Indicators

There is insufficient evidence to determine specific indicators that may have an impact on the decision to insert a CVAD or for catheter-related intraluminal thrombosis among adults and pediatric cancer patients.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations for the adult population were based on a combination of the evidence presented, existing recommendations from institutions across the province and manufacturers' recommendations. Where those lacked, expert opinion and panel consensus were incorporated into the recommendations. As well, the panel used Practitioner Feedback as further evaluation of the recommendations.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Prevention of central venous access device (CVAD)-related complications, such as catheter-related thrombosis or catheter-related infection

POTENTIAL HARMS

Not stated

CONTRAINDICATIONS

CONTRAINDICATIONS

Heparin use would be contraindicated in patients with heparin-induced thrombocytopenia (HIT).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Care has been taken in the preparation of the information contained in this document. Nonetheless, any person seeking to apply or consult the evidence-based series is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding their content or use or application and disclaims any for their application or use in any way.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Central Venous Access Device Guideline Panel. Managing central venous access devices in cancer patients: a clinical practice guideline. Toronto (ON): Cancer Care Ontario (CCO); 2006 Sep 25. 39 p. (Evidence-based series; no. 16-1). [67 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Sep 25

GUIDELINE DEVELOPER(S)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Program in Evidence-based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario
Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

Central Venous Access Device Guideline Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Esther Green (*Chair*); Melissa Brouwers; Lesley Collins; Lia Kutzscher; Gail Macartney; Patricia Marchand; Linda Robb-Blenderman; Pamela Savage; and Jocelyne Volpe

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The members of the Central Venous Access Device Guideline panel declared no possible conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Managing central venous access devices in cancer patients: a clinical practice guideline summary. Toronto (ON): Cancer Care Ontario (CCO), 2006 Sep 25.

Various p. (Evidence-Based Series 16-1). Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.
- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on December 1, 2006. The information was verified by the guideline developer on January 19, 2007. This summary was updated by ECRI Institute on June 22, 2007 following the U.S. Food and Drug Administration (FDA) advisory on heparin sodium injection. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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