PICNet
PROVINCIAL INFECTION CONTROL NETWORK OF BRITISH COLUMBIA
A program of the Provincial Health Services Authority

Reprocessing of Equipment and Instruments Used in the Provision of Foot Care

Prepared by:
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July 2016

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Document Review

PICNet would like to thank the members of the Foot Care Equipment Reprocessing working group for reviewing and discussing the evidence and various documents, and using their expertise along with the supporting knowledge found, to come to consensus on the recommendations put forward in this document.

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A special thank you to Dr. Victor Leung for his expertise and advice.

Executive Summary

Foot care is a very important service, especially for the older adult population, and is provided in various healthcare settings. As individuals age, changes occur in the musculature and circulation of their feet which can affect comfort and mobility. Some may have compromised mobility and/or sensation that impairs their ability to perform their own foot care. The incidence of diabetes is higher in the elderly and in some at-risk populations. Good foot care is crucial to the health of these individuals in order to prevent infections or injuries which may result in the extensive use of healthcare resources and much human suffering.[1-5]

Significant differences of opinion regarding patient risks associated with foot care and the minimum level of reprocessing required to address these risks (i.e., "sterilization" vs. "high level disinfection") exist across Canada. The lack of evidence supporting a consensus creates difficulty for service providers who seek direction on the level of reprocessing that both protects patient's safety and is achievable within their specific practice setting.

The objective for this working group was to review current evidence associated with foot care equipment and infections, other guidelines and standards in use, and develop recommendations that have fully considered the evidence and risk to patients from reusable equipment used to provide foot care.

In order to address all of the elements associated with the provision of foot care, this multidisciplinary group:

- Developed clear definitions for type of practices the term "foot care" represented
- Reviewed current guidelines and standards and their corresponding supporting evidence
- Reviewed and critically appraised literature related to foot care and infections
- Consulted a physician specialist in infectious disease and medical microbiology

The group reached consensus on the following recommendations:

Recommendations for Reprocessing of Foot Care Instruments

It is recommended that the instruments used by podiatric surgeons be separated from the instruments used by foot care providers for hygienic foot care because the intended use of the instruments used by podiatric surgeons is quite invasive. The intended use of foot care instruments by foot care providers for hygienic foot care is always non-invasive as the care only involves the epidermal layer of the skin.

Key Assumptions

All disinfectants are used according to the manufacturer's instructions.
All instruments used in hygienic foot care are stored in a way that prevents contamination and inadvertent handling by others.

Recommendations for Instruments Used by Foot Care Providers for Hygienic Foot Care

These recommendations received consensus from the group based on the definitions developed, an understanding of actual procedures used and microorganisms of concern, and a review of the literature and appraisal of the evidence. It is acknowledged that these recommendations are not consistent with Accreditation Canada, who has written their required operational practices (ROPs) based on the Canadian Standards Association (CSA) standards.

Semi-critical Instruments

It is recommended that metal files, corn and callus rasps, nail nippers/cutters, scissors, probes, curettes, and rotary tool burr (if not disposable) be reprocessed as though they are semi-critical if they are used for multiple clients. Although the intended use of these instruments brings them in to the non-critical classification, the group agreed that increased prudence was advisable in recognition of the underlying health conditions of many people who require foot care services, and the risk of exposure to non-intact skin should an unintentional nick occur. Semi-critical instruments require cleaning followed by high level disinfection.

Non-critical Instruments

Any instrument that is dedicated for use on the same client (including those in the above paragraph) falls under the "non-critical" classification and requires cleaning and low-level disinfection between uses on the same person.

Recommendations for Instruments used by Podiatric Surgeons:

Critical Instruments:

Instruments require cleaning followed by sterilization in a way that ensures they are kept sterile until the point of use. This is consistent with the College of Podiatric Surgeons' current guidelines, which state that "*all instruments are to be steam autoclaved for sterility after each patient use*".[6]

Introduction

Foot care is a very important service, especially for the older adult population, and is provided in various healthcare settings. As individuals age, changes occur in the musculature and circulation of their feet which can affect comfort and mobility. Some may have compromised mobility and/or sensation that impairs their ability to perform their own foot care. The incidence of diabetes is higher in the elderly and in some at-risk populations. Good foot care is crucial to the health of these individuals in order to prevent infections or injuries which may result in extensive use of health care resources and much human suffering.[1-5]

Significant differences of opinion regarding patient risks associated with foot care and the minimum level of reprocessing required to address these risks (i.e., "sterilization" vs. "high level disinfection") exist across Canada. This lack of evidence supporting consensus creates difficulty for service providers who seek direction on the level of reprocessing that both protects patient's safety and is achievable within their specific setting.

The objective for this working group was to review current evidence associated with foot care equipment and infections, other guidelines and standards in use, and to develop recommendations that have fully considered the evidence and risk to patients from reusable equipment used to provide foot care.

Current Canadian literature makes a recommendation of sterilization for all foot care equipment used in any procedure by any individual. In reality, the definition and procedural details of foot care differs from profession to profession.

Method

The following process was used by the working group to guide discussions, and to fully explore and understand the intricacies of the provision of foot care services:

1. Review of current published guidelines and standards
2. Literature search and critical appraisal of literature related to foot care and infections found
3. Definition of what foot care includes
4. Level of training of healthcare providers who provide foot care services
5. Actual service that is provided under each healthcare provider's professional scope of practice
6. Details of procedures within the foot care spectrum that is provided
    a. Procedures limited to the epidermis versus invasive procedures which penetrate the dermal and subcutaneous layers
7. Details and names of specific instruments used
    a. Intended use of instrument
    b. Whether instruments are considered to be medical devices
    c. Shared versus dedicated to single client
8. Microorganisms of concern
9. Classification under the Spaulding classification system

Documents reviewed for this report were from the Public Health Agency of Canada, Provincial Infectious Disease Advisory Committee of Ontario, Canadian Standards Association, Alberta Health Services, Canadian Agency for Drugs and Technologies in Health, National Collaborating Center for Environmental Health, Ministry of Health of British Columbia, and the United States Centers for Disease Control and Prevention. These documents were chosen for the review because they are the most widely acknowledged and referenced in the various guidelines and recommendations that health care professionals are required to follow.

A request was made to the health librarians of the College of Registered Nurses Association of British Columbia (CRNBC) to search the published literature for any reference to infections of the feet; foot care; and/or podiatry. They completed three separate extensive searches using numerous search terms.

A review of the evidence used by the aforementioned agencies, followed by a literature review of articles found during the literature search by the health librarians of the CRNBC was completed.

Current Published Guidelines and Standards

Many documents reviewed and groups contacted during this process use the Spaulding Classification system as the primary justification for their recommendations. The Spaulding Classification system is widely used to determine the level of reprocessing that reusable medical devices require between uses. It was proposed more than thirty years ago and is based upon on a device's intended use. It groups medical devices into three categories according to the risk of infection that a devices poses to a patient/client when it is reused. Once equipment or instruments are classified according to their intended use, then they are either disinfected (low or high level) or sterilized depending upon the classification category. No examples of specific instruments are provided in early Spaulding Classification documents, only the definitions of the three categories.[7] Examples of specific instruments within Spaulding's classification categories are listed in several Canadian documents published since 1997[8]. They appear on a table entitled "Spaulding's Classifications"; however, no references or rationale is given for why an item is designated to a specific category. These tables are not found in published documents from other countries. It is unclear who developed the table published in some Canadian documents or what evidence, rationale etc. was used to delegate groups of instruments (e.g. dental equipment) to a specific category.

In Health Canada's "*Infection Control Guidelines, Foot Care by Health Care Provider*"[9], it is recognized that foot care is not intentionally invasive. It claims that unsafe nail and foot care practices have been shown to contribute to trauma. The one study that is referenced in this claim was reviewed. This study did not in any way investigate or report any association between nail and foot care, and trauma or negative consequences.[10] This was a small, retrospective, cohort study from 1990 that reviewed the health files of 80 veterans who had lower limb amputations, to try to identify common contributing factors. Common preceding factors identified were trauma to the foot from shoe related pressure sores, thermal traumas, accidental cuts or wounds, and decubitis ulcers combined with neuropathy and faulty healing. No relationship was identified between any of these preceding factors and foot care. Health Canada's guidelines recommend that all instruments used in foot care must be sterile, but offer no supporting evidence or any kind of reference.

In the British Columbia Ministry of Health's 2011 document *"Best Practice Guidelines For Cleaning, Disinfection, and Sterilization of Critical and Semi-critical Medical Devices In BC Health Authorities"*[11], foot care equipment is categorized as "critical", requiring cleaning followed by sterilization. It should be noted that this best practice document was adopted and adapted from the Provincial Infectious Disease Advisory Committees of Ontario (PIDAC) document that is discussed immediately below. The Ministry of Health had relied upon the PIDAC document and the CSA standards for supporting knowledge.

In the Provincial Infectious Disease Advisory Committees of Ontario (PIDAC) 2013 "*Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices*[8]*,* foot care equipment is designated as "critical medical equipment/devices" under the Spaulding

classification system. The document defines this category as "*Medical equipment/devices that enter sterile tissues, including the vascular system …. Critical medical equipment/devices present a high risk of infection if the equipment/device is contaminated with any microorganism, including bacterial spores*." According to this document, foot care equipment requires steam or dry heat sterilization. There are no references provided in the document for these claims, and it is unclear whether the basis for these recommendations is scientific evidence or expert opinion, or a combination of both.

The Canadian Standards Association 2013 document *Medical Device Reprocessing – General Requirements*, *Z314.0-13*[12] states that all foot care equipment shall be sterilized. In this document, the word "shall" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard. The document provides no references for any of its requirements.

In the Accreditation Canada Standards (2012) document, item 12.2 states, "*For each contaminated device and piece of equipment, a trained staff person uses a recognized classification system to determine whether sterilization is required"*.[13] In their 2013 document *Infection Prevention and Control Standards for Community-Based Organizations*,[14] element 9.1, Accreditation Canada asserts that under the Spaulding Classification System, items that contact non-intact skin are critical and require sterilization, and they provide foot care instruments as an example. This assertion is inconsistent with other literature that discusses Spaulding Classifications.

The Alberta Health Services 2013 *Infection Prevention and Control Best Practice Guideline for Foot Care Devices*[15] document states that "*Multi-client reusable FCD* (foot care devices) *must be cleaned and steam sterilized according to the manufacturer's instructions prior to reuse on another client. Sterility must be maintained until use on the next client*." The CSA Standards are provided as a reference for this requirement. The Alberta Health Services document does separate and differentiate cleaning recommendations for equipment that is dedicated to a single client, and recommends it be cleaned according to manufactures instructions after each use. It defines a foot care device as "*device used to perform care on clients feet including, but not limited to, nail nippers, files, rasps, scalpel handles and nail probes."*

In 2009, the Canadian Agency for Drugs and Technologies in Health reviewed the evidence-based guidelines regarding the sterilization of instruments used for foot care. Their literature search identified only one evidence-based guideline on the sterilization of medical equipment including instruments used for foot care. This document was produced by the Provincial Infectious Diseases Advisory Committee for the Ontario Ministry of Health and Long-Term Care (MOHLTC). After reviewing this document, CADTH concluded that the recommendations within it were based on expert opinion rather than on a search of the published literature. Information pertaining specifically to foot care instruments was not reported.[16]

In the National Collaborating Center for Environmental Health's document *Cleaning, Disinfection, and Sterilization at Personal Service Establishments* (2012) foot care

equipment/instruments are either classified as semi-critical or non-critical.[17] They also reference Spaulding Classification as supporting evidence.

The British Columbia Ministry of Health, Public Health Protection document *Guidelines for Personal Service Establishments* also lists foot care equipment/instruments as semi-critical or non-critical.[18]

The US Centers for Disease Control and Prevention (2008) *Guidelines for Disinfection and Sterilization in Healthcare Facilities* does not mention foot care instruments anywhere in the document.[19]

The use of language such as “standards” and “requirements” may imply that the organization who published the document has regulatory authority; however, this is often not the case. For example, the CSA has a disclaimer in their document that states *“CSA Group is a private not-for-profit company that publishes voluntary standards and related documents. CSA Group has no power, nor does it undertake to enforce compliance with the contents of the standards or other documents it publishes.”* The absence of formal or regulatory authority is also true for Accreditation Canada and the Provincial Infectious Disease Advisory Committee of Ontario.

Literature Related to Foot Care and Infections

In 2008, an outbreak of Hepatitis B virus (HBV) was identified in a psychiatric long-term care facility in California. A retrospective cohort study to identify risk factors for the acquisition of acute HBV infection was conducted.[20] The results suggested that the extremely poor infection control practices involving the podiatry instruments were the likely source of transmission. The lack of separation between clean and dirty instruments, which had been covered in blood, was the specific contributing factor rather than the level of disinfection of the instruments. This study had some limitations in that it did not rule out the possibility that the HBV was transmitted through sexual activity or sharing of intravenous (IV) devices.

There have been several outbreaks of mycobacterial infections of the feet and legs of individuals subsequent to pedicures at private spas in the US. Rapidly growing mycobacterium has been cultured in several private spa settings in the tissue and hair found behind the inlet suction screen of whirlpool footbaths, and was considered to be the source of the outbreak.[21-23]

An extensive literature search by the health librarians of CRNBC uncovered no other reports of infections related to foot care procedures in any kind of healthcare setting. Their search covered all countries who publish studies in the English language.

Definitions of "Foot Care"

During working group discussions, it was identified that the term "foot care" had different meanings for different healthcare providers. The group developed the following working definition to move forward with. The group strongly recommends that everyone who provides hygienic foot care completes a foot care course.

Hygienic Foot Care

The filing of corns or calluses, the filing or trimming of nails, skin care, and other routine, hygienic care provided by a healthcare provider educated in foot care processes. These practices are non-sterile in nature. They involve the epidermal layer of the skin only, although it is possible that a nick into the dermal layer may unintentionally occur. Proper foot care processes also include a clinical assessment of the feet, and education for the client.

This definition is consistent with the Scope of Practice Standards and Limitations document from the College of Registered Nurses of BC (CRNBC)[24], and the College of Registered Psychiatric Nurses of BC. These activities are also within the scope of practice for Licensed Practical Nurses of BC[25], with one exception. LPNs may file nails but not trim nails unless they have completed a foot care course. Health Care Aides (HCAs) may provide basic foot care as defined by their education, which includes nail trimming.[26] This task may be limited by agency policy. For foot care beyond the HCA certificate education (washing/applying lotion/trimming nails), a delegation of task must be initiated, and monitored, by a RN after a risk assessment. [27, 28] Delegation of tasks must also be client specific.

Podiatric Surgeons of British Columbia Definitions of Foot Care

A working group from the Podiatric Surgeons of British Columbia was asked to provide a definition for the foot care services they provide. They provided the following definition:

The evaluation, diagnosis and treatment of foot disease, injury, or pathologic condition, and the appropriate treatment required. "Routine" foot care implies the mechanical, electrical, chemical, and medicinal debridement of pathologic epidermal tissue due to underlying disease, injury, or pathology. "Complex" foot care implies the introduction of surgical intervention including the epidermal, dermal, deep fascial, osseous structures, and all other anatomic structures encountered as required by the treatment plan.

Foot Care Provided by Physical Therapists

The type of foot care provided by physical therapists relates to joint and ligamentous injuries or peripheral neuropathies, and involves the recommendation and/or fitting for orthotic devices/braces, and in some cases includes providing wound care assessment and/or treatment. Complex wound care is not an entry level skill, and is provided by physical therapists with additional post-graduate training. The practice consultant of the College of Physical Therapists of BC suggested adding the word "hygienic" to the definition of foot care to

more clearly differentiate the service provided primarily by nurses from that provided by physical therapists.

Microorganisms of Concern Related to Feet

The most common microorganisms reported related to acute infections of the feet are *Staphylococcus aureus*, *Streptococcus* species, *enterococci* and fungi. Chronic wounds develop a more complex colonizing flora, including *enterococci*, various *Enterobacteriaceae*, obligate anaerobes, *Pseudomonas aeruginosa,* and, sometimes, other nonfermentating gram-negative rods.[29]

In contrast to many of the other infections affecting the other organ systems in humans, fungi often cause dermatological conditions that do not involve tissue invasion. The main groups of fungi causing superficial fungal infections are dermatophytes, yeasts, and moulds.[30]

Whenever shared, re-usable instruments are potentially exposed to non-intact skin and blood or other body fluids, there is a potential for exposure to bloodborne pathogens including Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus (HIV).

Details Related to Instruments Used for Hygienic Foot Care

The specific instruments that this document pertains to are metal files, corn and callus rasps, nail nippers/cutters, scissors, probes/curettes, and rotary tool with burr (if not disposable) when these items are used on multiple clients. If an item is dedicated to a single client, the item does not fall into this group. Other items that are used, such as emery boards, are disposable and should never be shared between clients. The burr from the rotary tool may or may not be disposable.

Classification of Foot Care Instruments under the Spaulding Categories

These classifications apply to instruments that were designed and manufactured solely for the purpose of providing hygienic foot care.

Hygienic Foot Care

For instruments that are reprocessed between uses on different people, based solely upon the intended use of the instruments, the group achieved consensus that the instruments are intended to come into contact with intact skin only. This would classify instruments as “non-critical”. However, the group also noted that at times a nick may occur which would constitute exposure to non-intact skin, and that some clients may be at higher risk for a negative outcome (e.g. diabetic). Based on the potential for higher risk of infection and using the precautionary

principle[31] the group felt that increased prudence was warranted, thus recommending these instruments be processed as if they were semi-critical.

Instruments that are dedicated and used only on the same individual fall within the "non-critical" category because their intended use is for contact with intact skin. There is no evidence-based need to increase prudence with instruments dedicated for use on the same individual.

Routine or Complex Foot Care by Podiatric Surgeons of British Columbia

The intended use of instruments for podiatric services most often involves invasive procedures. Even if the initial intention is to provide a non-invasive procedure, the podiatric surgeon may observe or uncover a condition that requires much more invasive activity and, in this case, would proceed to do so. Given the likelihood of a procedure that is invasive much deeper than the epidermal layers of the foot, the group consensus is that these instruments should be classified as critical. This is consistent with the College of Podiatric Surgeons of British Columbia's current position statement.

Reprocessing of Foot Care Instruments

It is recommended that the instruments used by podiatric surgeons be separated from the instruments used by foot care providers for hygienic foot care because the intended use of the instruments used by podiatric surgeons is quite invasive. The intended use of foot care instruments by foot care providers for hygienic foot care is always non-invasive as the care only involves the epidermal layer of the skin.

Key Assumptions

All disinfectants are used according to the manufacturer's instructions.
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Recommendations for Instruments Used by Foot Care Providers for Hygienic Foot Care

Semi-critical Instruments

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Non-critical Instruments

Any instrument that is dedicated for use on the same client (including those in the above paragraph) falls under the "non-critical" classification, and requires cleaning and low-level disinfection between uses on the same person.

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